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ORIGINAL ARTICLE

Disc replacement using Pro-Disc C versus fusion: a prospective randomised and controlled radiographic and clinical study

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Abstract Anterior cervical discectomy and fusion (ACDF) may be considered to be the gold standard for treatment of symptomatic degenerative disc disease within the cervical spine. However, fusion of the segment may result in progressive degeneration of the adjacent segments. Therefore, dynamic stabilization procedures have been introduced. Among these, artificial disc replacement by disc prosthesis seems to be promising. However, to be so, segmental motion must be preserved. This, again, is very difficult to judge and has not yet been proven. The aim of the current study was to first analyse the segmental motion following artificial disc replacement using a disc prosthesis. A second aim was to compare both segmental motion as well as clinical result to the current gold standard (ACDF). This is a prospective controlled study. Twenty-five patients with cervical disc herniation were enrolled and assigned to either study group (receiving a disc prosthesis) or control group (receiving ACDF, using a cage with bone graft and an anterior plate.) Radiostereometric analysis was used to quantify intervertebral motion immediately as well as 3, 6, 12 and 24 weeks postoperatively. Further, clinical results were judged using visual analogue scale and neuro-examination. Cervical spine segmental motion decreased over time in the presence of disc prosthesis or ACDF. However, the loss of segmental motion is significantly higher in the ACDF group, when looked at 3, 6, 12 and 24 weeks after surgery. We observed significant pain reduction in neck and arm postoperatively, without significant difference between both groups ($P > 0.05$). Cervical spine disc prosthesis preserves cervical spine segmental motion within the first 6 months after surgery. The clinical results are the same when compared to the early results following ACDF.

Keywords Spine · Bone · Fusion · Implants · Disc replacement · Clinical study

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Introduction

To date, anterior cervical discectomy and fusion (ACDF) may be considered to be the standard procedure for treatment of degenerative disc disease of the cervical spine [4–6, 39, 42]. However, there are clues that ACDF may result in progressive degeneration of the adjacent segments [15–17, 24, 33, 38, 44]. To avoid this, there have been numerous attempts to develop, test and use artificial cervical discs [1, 9, 10, 13, 14, 25, 31, 40]. Recently, first clinical experiences with cervical spine disc prosthesis are available, and most of them seem to be encouraging [1, 3, 7, 9, 10, 12–14, 23, 29, 35]. However, it is to early to judge if the clinical long-term results are favourable [3, 7, 12–14, 28]. These will be influenced by the function of such an implant that has been designed to preserve segmental motion. If this is true, the implant should preserve segmental motion for

a long time. However, there is, to the authors' knowledge, no study to show that such an implant works as it has been considered to work. One of the reasons for the lack of such a study is the difficulty to measure segmental motion precisely. Therefore we performed this radiostereometric analysis (RSA) to get information concerning long-term results of segmental motion.

Radiostereometric analysis has been developed by Selvik et al. [36, 37]. It is a radiographic technique, used to measure micro-motion in spine and its principles are explained elsewhere especially in orthopaedic fields [18–21, 32, 36, 37]. Pape et al. [26] showed that RSA is a useful tool to exclude segmental motion and to document a sold fusion in the lumbar spine. RSA is also used by Zoegea et al. [45] to measure the additional effect of plate fixation in cervical spine fusion. In our study, RSA has been used to measure motion in patients who received cervical disc prosthesis or ACDF.

The objective of the current study was to investigate segmental motion following implantation of a cervical spine disc prosthesis (Synthesis Spine, Im Kirchenhürstle 4–6, 79224 Umkirch, Germany) versus segmental motion of a segment having received ACDF using a cage polyether–ether–ketone ''PEEK'' (Stryker Howmedica GmbH, Gewerbeallee 18, 45478 Mülheim, Germany) with bone graft and an anterior titanium alloy plate (Aesculap AG + CoKG, Am Aesculap-Platz, Tuttlingen, Germany), 6 months after surgery.

Methods

Study design

This is a prospective randomised and controlled study, approved by the local ethical committee of Saarland (Germany), n 119/04.

Thirty-three patients [19 male, 14 female, mean age 45 years, standard deviation (SD) 11 years] suffering from symptomatic soft disc herniation, not responding to a trial of conservative treatment and or progressive radicular deficits were included between April and December 2004. Inclusion as well as exclusion criteria are listed in Table 2. All patients had confirmatory imaging studies consistent with clinical findings. All patients were informed about the purpose of the study giving a written informed consent that was signed at least 24 h before surgery.

Next, patients were assigned to the study group (prosthesis) or control group (ACDF) by randomisation. Sixteen patients received disc replacement, whereas 17 patients were treated with ACDF. Eight patients were excluded during first RSA measurement due to some markers being obscured (three patients with prosthesis and five with ACDF).

Surgery was performed by two surgeons from the author board (A. N., T. P.). A standard left-sided anterior approach was performed, the symptomatic disc was removed, the lateral parts of the annulus were preserved; however, the posterior longitudinal ligament (PLL) was removed. The disc or cage and plate were inserted according to the manufacturer's 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 adjacent vertebrae.

Clinical symptoms as neck and arm pain were investigated preoperatively and immediately, 3, 6, 12 and 24 weeks postoperatively. Visual analogue scale (VAS) was used for grading of neck and arm pain [11, 22, 30].

Implants used in the study

The cage used for ACDF named Solis consists of polyether–ether–ketone (PEEK). It has one large central perforation to allow bony ingrowths.

The plate used here is a nonconstrained plate which we used in combination with mono-cortical screws, both made from titanium alloy. The screw for mono-cortical fixation is a titanium alloy, self-tapping, conical screw of 14, 15, 16, 17 or 19 mm length with an outer diameter of 4.0 mm and an inner diameter of 2.2 mm at the tip, increasing to 2.7 mm at its head. This is a nonconstrained plate–screw system for anterior cervical fixation.

The prosthesis implant is a metal polyethylene ball-in-socket design with two metal fins; the material used is an interface ultra-high-molecular-weight polyethylene inlay; the superior and inferior plate are made of cobalt-chrome alloy with titanium surface facing the bony side.

Radiostereometric analysis (RSA)

Patients were followed by RSA postoperatively. The insertion of 4–6 radio-opaque tantalum markers in each vertebra is required to determine the geometric characteristics of the vertebral anatomy. Radiostereometric examinations were carried out uniformly in all patients in the supine position using a uniplanar technique. All patients were positioned above the combined reference plate and calibration device with 0.8 mm tantalum indicators, placed at known positions in front of the film plane. The cage markers defined the laboratory coordinate system and were used to calcu-

late the position of the X-ray foci. RSA radiographs were taken directly after surgery and 3, 6, 12 and 24 weeks after the procedure in two positions to induce intervertebral mobility. Mobility provocation was obtained by examining the patient in two different positions of the head versus cervical spine (neutral position of the head and extension with rotation of the head to the right side, Fig. 1a, b). The patient's head was passively moved to the different end points by the examiner. At subsequent evaluations, the three-dimensional coordinates of the patient marker were determined at each examination. Intervertebral motion occurring between neutral and extended with right-rotated head was computed. For mathematical evaluation of the radiographs, we used a software package (UmRSA, RSA Biomedical Innovations, Umea, Sweden), mainly based on RSA measurement techniques according to Selvik [36, 37]. The calculated intervertebral motion allowed visualisation of persisting translation and rotation between the vertebrae. The most distal cervical vertebrae were used as a fixed reference segment. All motion were related to the laboratory co-ordinate system defined by the cage. Raw data were expressed as translation (Table 4). The relative translation of the centre of gravity of the markers in the most proximal vertebra was recorded in all cases. Translations were measured as:

1. Medial–lateral translations (left–right, *x*-axis)
2. Proximal–distal translations (distraction–compression, *y*-axis)
3. Anterior–posterior translations (sagittal direction, *z*-axis)

The data were used to evaluate motion. Rotations were calculated in the order:

1. Extension (deg) (rotations along the transverse axis)
2. Right-sided axial rotation (deg) (rotation along the longitudinal axis)
3. Right-sided lateral bending (deg)(rotation along the sagittal axis)

The precision (= reproducibility) of the measurement was calculated by double examinations on the same day in six patients at different times during the follow-up period. We calculated the 99% confidence limits for significant translations and rotations as the absolute mean value ± 2.8 SD based on a normal distribution (Table 1). The precision of our RSA set-up was determined similar to the method used by Zoegea et al. [45], who published comparable values for the three axis of motion. (Tables 2, 3, 4)

The accuracy of the RSA method depends most importantly on stability, spacing and number of tantalum markers inserted into the bony region of interest [19]. The degree of marker instability is expressed in millimetres as the mean error of rigid body fitting. In this study only values below 0.4 mm were accepted.

Statistics

Mann–Whitney test for unpaired values were used to determine a statistical difference of residual intervertebral translations before and after prosthesis as well as ACDF in the three axis of motion ($P < 0.05$). The segmental motion was additionally calculated using a vector of X, Y, and Z axes.

Results

Patients excluded from study

Out of 33 patients 8 were excluded during first RSA measurement due to some markers being obscured.

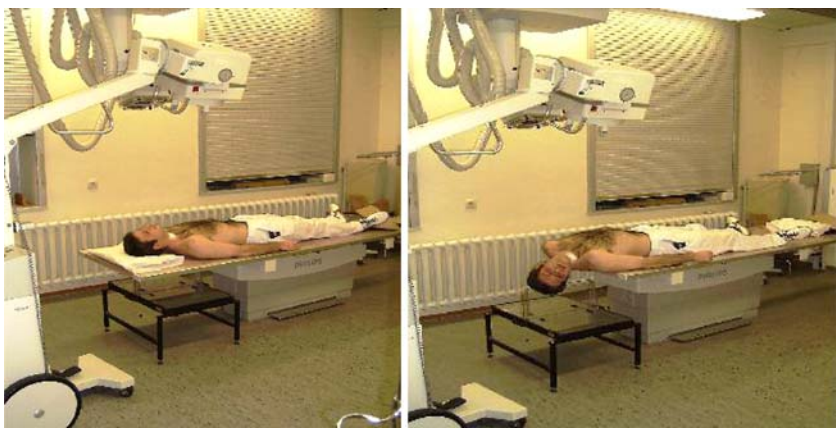

Fig. 1 Positioning of the patient and X-ray projection in neutral position (**a**) as well as extension combined with right-sided lateral bending (**b**) for RSA examination

Table 1 The 99% confidence limits of radiostereometry in the cervical spine in six double examinations

	Translations (mm)
Anterior–posterior (*X*-axis)	0.45
Proximal–distal (*Y*-axis)	0.30
Medial–lateral (*Z*-axis)	0.65
	Rotations (deg)
Transverse axis	4.2
Longitudinal axis	3.9
Sagittal axis	1.5

Results from radiographic study

Study group (prosthesis)

Segmental rotation between 3 weeks and immediately postoperative significantly decreased in extension ($P = 0.024$), right-sided axial rotation ($P = 0.005$) and right-sided bending ($P < 0.01$).

Six weeks postoperative there was no further decreased segmental motion in extension ($P = 0.32$), right-sided axial rotation ($P = 0.20$) and right-sided bending ($P = 0.42$) (Table 5; Figs. 2, 3, 4, 5, 6).

Data for each motion plane (extension, right-sided axial rotation and right-sided bending) are shown in Table 5 and Figs. 4, 5, and 6.

Control group (ACDF)

Segmental rotation between 3 weeks and immediately postoperative significantly decreased in right-sided axial rotation ($P = 0.016$). However, there was no significant decrease in motion in extension ($P = 0.06$) and right-sided bending ($P = 0.48$). Segmental rotation between 24 and 3 weeks shows further decreased motion significantly only in extension ($P = 0.001$). Six weeks postoperative there was no further decreased segmental motion in extension ($P = 0.32$), right-sided axial rotation ($P = 0.20$) and right-sided bending ($P = 0.42$) (Table 5, Figs. 4, 5, 6).

Six weeks after surgery there was no significant decreased motion compared to 24 weeks ($P > 0.05$). Data for each axis (extension, right-sided axial rotation and right-sided bending) are shown in Table 5 and Figs. 4, 5, and 6.

Table 2 Criteria for patients with Pro-Disc C and RSA study

Inclusion criterIa	Exclusion criteria
Mono-segmental cervical disc disease between C3 and C7	Marked cervical instability on resting or flexion/extension radiographs
	Greater than 11 of angulations
	Translation greater than 3 mm
Unresponsive to conservative treatment or presence of signs of nerve root compression with paresis	More than one level pathology
Soft disc herniation	Myelopathy
Age between 20 and 60 years	Radiographic confirmation of severe facet joint degeneration
Signed informed consent	Hard disc disease
	Osteoporosis, infection, rheumatoid arthritis
	Spondylodiscitis and active infection
	Malignant disease
	System disease, e.g. Hepatitis, HIV, AIDS
	Known allergy to cobalt, chromium, molybdenum, titanium, or polyethlene
	Traumatic injury of spine
	Pregnant or possible pregnancy in the next 3 years

Table 3 Visual analogue scale (VAS) for neck and arm pain

	Preoperatively		1 week		3 weeks		6 weeks		12 weeks		24 weeks	
	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF
Neck pain	6.2 (1.2)	6.4 (0.9)	3.3 (0.6)	2.9 (0.7)	3.4 (0.6)	2.2 (0.7)	2.4 (0.5)	1.8 (0.5)	2.5 (0.6)	1.9 (0.5)	2.8 (0.4)	2.0 (0.5)
Arm pain	7.6 (1.4)	7.2 (1.7)	1.6 (0.4)	1.5 (0.4)	1.5 (0.4)	1.7 (0.4)	1.3 (0.3)	1.5 (0.3)	1.6 (0.3)	1.7 (0.3)	1.4 (0.2)	1.7 (0.3)

Mean value and standard deviation (SD) are given for each time

Table 4 Translation in (mm) at postop, 3, 6, 12, and 24 weeks

Translation (mm)	Postop		3 weeks		6 weeks		12 weeks		24 weeks	
	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF
Medio-lateral	0.69 (0.9)	0.25 (0.30)	0.39 (0.16)	0.11 (0.06)	0.29 (0.16)	0.07 (0.06)	0.39 (0.18)	0.06 (0.05)	0.33 (0.17)	0.06(0.09)
Cranio-caudal	0.48 (0.27)	0.28 (0.4)	0.21 (0.10)	0.14 (0.07)	0.22 (0.12)	0.11(0.07)	0.17 (0.1)	0.06(0.06)	0.23 (0.13)	0.05(0.06)
Anterior–posterior	1.67 (0.93)	0.42 (0.5)	1.08 (0.4)	0.16 (0.05)	0.71 (0,38)	0.18 (0.07)	0.53 (0.3)	0.13 (0.09)	0.67 (0.42)	0.05(0.05)

Mean value and standard deviation (SD) are given for each time

Table 5 Rotations in (deg) postoperatively and 3, 6, 12, and 24 weeks

Rotation (deg)	Postop		3 weeks		6 weeks		12 weeks		24 weeks	
	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF	Prosthesis	ACDF
Extension (deg)	5.77 (1.6)	2.1 (1.73)	3.79 (2,0)	2.06 (0.89)	2.67 (1.4)	0.92 (0.83)	2.79 (1.7)	0.94 (0.90)	2.36 (1.0)	0.95 (0.80)
Right-sided motion (deg)	2.5 (1,5)	2.20 (1.80)	4.83 (0.9)	1.53 (1.20)	2.13 (1.2)	1.35 (0.81)	3.07 (1.5)	0.82 (0.72)	2.56 (0.7)	0.79 (0.64)
Right-sided bending (deg)	3.15 (2.1)	1.22 (1.14)	3.24 (1.0)	0.91 (0.72)	2.06 (0.6)	0.76 (0.57)	2.24 (1.0)	0.72 (0.39)	2.24 (1.3)	0.74 (0.44)

Mean value and standard deviation (SD) are given for each time

Study group versus control group

Segmental motion was significantly different between both groups for extension (deg): ($P = 0.0001$ immediately postoperative, $P = 0.025$ after 3 weeks, $P = 0.001$ after 6 weeks, $P < 0.01$ after 12 weeks and $P = 0.0001$ after 24 weeks).

Segmental motion was not significantly different between both groups for right-sided axial rotation (deg): ($P = 0.0001$ immediately postoperative, $P = 0.61$

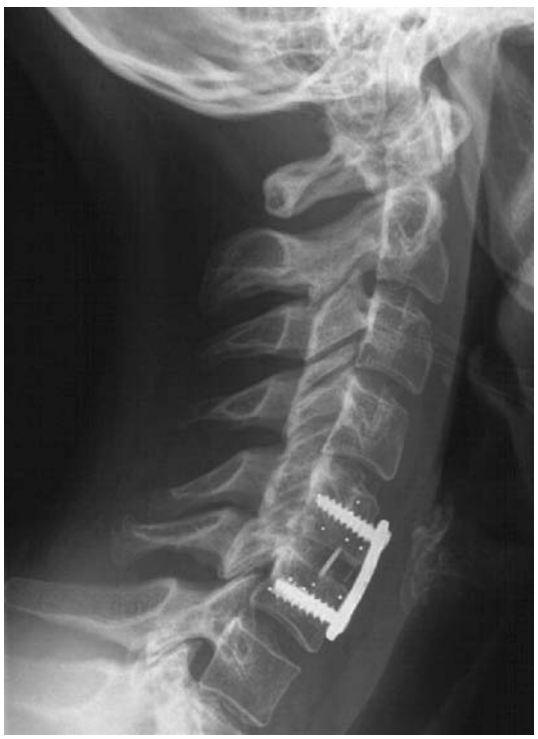

Fig. 2 Lateral X-ray of a cervical spine. ACDF was performed within C5/6. Please note the tantal markers of C5 and C6, some of the markers are obscured by the screws

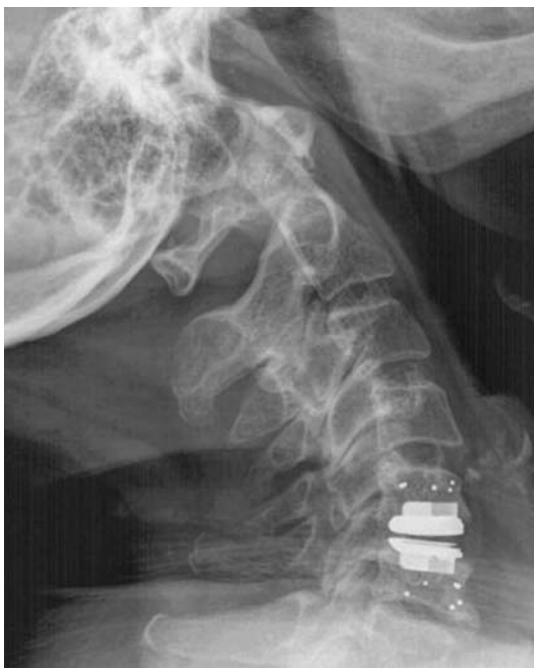

Fig. 3 Lateral X-ray of a cervical spine. Disc prosthesis was implanted in C5/6. Please note the tantal markers in the adjacent vertebra

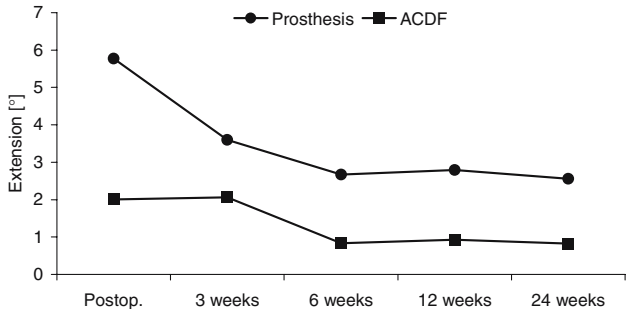

Fig. 4 Graph illustrating segmental motion in extension (deg) (mean value) for each follow-up examination. For each follow-up examination, the micro-motion of a segment receiving prosthesis is more pronounced when compared to fusion group. However, segmental motion decreases in both groups over time

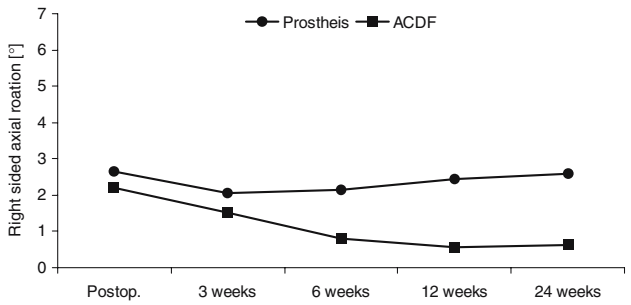

Fig. 5 Graph illustrating segmental motion in right-sided axial rotation (deg) (mean value) for each follow-up examination. For each follow-up examination, the micro-motion of a segment receiving prosthesis is more pronounced when compared to fusion group. However, segmental motion decreases in both groups over the time

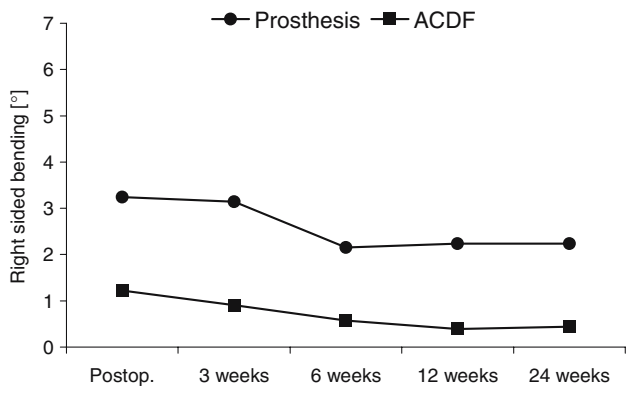

Fig. 6 Graph illustrating segmental motion in right sided lateral bending (°) (mean value) for each follow-up examination. For each follow-up examination, the micro-motion of a segment receiving prosthesis is more pronounced when compared to fusion group. However, segmental motion decreases in both groups over the time

after 3 weeks, $P = 0.23$ after 6 weeks, whereas there was significant difference 6 weeks after surgery, $P = 0.012$, 12 weeks after surgery $P = 0.01$ and after 24 weeks, $P > 0.01$).

Segmental motion was significantly different between both groups for right-sided bending (deg): ($P = 0.0001$ immediately postoperative, $P = 0.015$ after 3 weeks, $P = 0.01$ after 6 weeks, $P < 0.01$ after 12 weeks, $P < 0.01$ and $P = 0.001$ after 24 weeks).

Results from clinical study

Study group (prosthesis)

Mean value and standard deviation for neck pain measured using VAS decreased from 6.2 (1.2) preoperatively to 2.8 (0.4) after 24 weeks postoperatively. Mean value and standard deviation for arm pain measured using VAS decreased from 7.6 (1.4) preoperatively to 1.4 (0.2) after 24 weeks postoperatively.

Control group (ACDF)

Mean value and standard deviation for neck pain measured using VAS decreased from 6.4 (0.9) preoperatively to 2.0 (0.5) after 24 weeks postoperatively. Mean value and standard deviation for arm pain measured using VAS decreased from 7.2 (1.7) preoperatively to 1.7 (0.3) after 24 weeks postoperatively.

Study group versus control group

Statistical comparison between the two groups showed nonsignificant differences in pain relief ($P > 0.05$; Table 3).

Discussion

Results of the current study

Within the current study, we found, that cervical spine segmental motion decreases over time in the presence of disc prosthesis or ACDF. However, the loss of segmental motion is significantly higher in the ACDF group.

Advantages and disadvantages of the study

To the authors' knowledge, the current study is unique in its design. First, a group of patients having received an prosthesis (Pro-Disc C) were compared to a control group with ACDF. Next, the design of the study is

randomised. Finally, RSA has been used to document persisting motion of a cervical spine segment treated with an artificial disc device or ACDF. Persisting motion is a desired goal in cervical spine surgery that also has been transformed into an industrial philosophy. However, up to now there is no evidence that this goal has been achieved over a long time period. The current data, however, given by an accepted technique for both the lumbar and cervical spine region, give some evidence that this goal may be achieved by this implant [8–10, 12, 17, 34, 41]. This, however, is due to our data, just true for the observed postoperative follow-up period. Furthermore, it should be considered that our patient population is small and results may change if more data from more patients will be available. Nevertheless, our data give insight into the motion of a surgically treated cervical spine segment under physiological loads. Finally, it should be mentioned that these results are just true for both, the time period given here, and the implants used here.

Former experiences with artificial disc replacement

The results of the current study support the results of some former in vitro investigations. Puttlitz et al. [31] found that cervical spine disc replacement replicates both segmental motion in the treated and the adjacent levels of a human cervical spine. The value of this finding supports the increased clinical application of disc prosthesis. This again has been found in some clinical studies [3, 7, 12, 14, 34, 43]. Again, it must be pointed out that (especially facing these former results) the value of our study lies in the information of a measured motion under physiological loads within the treated segment. Nevertheless, there is still the possibility of reduced segmental motion within the further follow-up period by calcification or scar formation as observed by Parkinson and Sekhon [27] and Bartels and Donk [2].

Clinical results

Within this study, both treatment concepts resulted in [3, 7, 13, 14, 34] significant reduction of neck and arm pain without statistical difference between groups. This is not surprising, especially not if arm pain is illuminated: this result is much more if it is not only an effect of decompression. Decrease in neck pain may be due to stabilisation, which is given by disc replacement, being considered to be a dynamic stabilisation. Moreover, treatment of neck pain may be effect of discectomy. Finally, long-term results will show, if cervical arthroplasty could prevent or reduce the incidence of adjacent segment disease.

Conclusion

Cervical spine segmental motion decreases over time in the presence of both disc replacement with Pro-Disc C or ACDF. However, the loss of segmental motion is significantly higher in the ACDF group, when checked 3, 6, 12, and 24 weeks after surgery.

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