



TOTAL ARTHROPLASTY AND ANTERIOR CERVICAL DISCECTOMY WITH FIXATION: LONG-TERM RESULTS OF A RANDOMIZED CLINICAL TRIAL

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Objective. To perform comparative analysis of the long-term results of using the methods of total cervical disc arthroplasty (CDA) and anterior cervical discectomy and fusion (ACDF) in the surgical treatment of patients with single-level degenerative diseases of cervical intervertebral discs.

Material and Methods. The study included 186 patients aged 21–60 years. Independent sequential randomization (1:1) of 173 patients was performed using software. The following parameters were used to evaluate patients: the VAS score of pain syndrome severity in the cervical spine and upper extremities, the Neck Disability Index (NDI) score of the quality of life, the amplitude of movements of the operated segment, the frequency of adjacent discs degeneration and of repeated surgical interventions and adverse events.

Results. In the long-term follow-up, the best clinical outcomes according to VAS and NDI data were recorded in patients from the CDA group. Their amplitude of movements in the segment remained in the physiological volume. In the ACDF group, a complete fusion was verified in 83 (93.3 %) cases. A significantly higher degree of degenerative disease of superjacent intervertebral discs was revealed in ACDF group ($p < 0.01$), while no significant degenerative changes were recorded in the subjacent discs ($p > 0.05$). The number of intraoperative and early postoperative complications did not have a statistically significant intergroup difference ($p > 0.05$). Symptomatic degeneration of adjacent segments was verified in 2 (2.4 %) respondents from the CDA group and in 8 (9.0 %) from the ACDF group ($p < 0.001$). Symptomatic adverse effects were found in 3 (3.6 %) CDA patients in the form of heterotopic ossification and in 6 (6.7 %) ACDF patients in the form of pseudoarthrosis.

Conclusions. The operations of total disc arthroplasty (CDA) and anterior cervical discectomy and fusion (ACDF) are safe and effective methods of surgical treatment of patients with single-level degenerative diseases of cervical intervertebral discs. In CDA patients, significantly better clinical results were noted, as compared with the ACDF group. The CDA method allowed preserving the normal biomechanics of the cervical spine and preventing the development of degenerative disease of adjacent segments.

Key Words: degenerative disease of cervical intervertebral discs, long-term results, prospective randomized study, total arthroplasty, anterior cervical discectomy and fusion.

Please cite this paper as: Byvaltsev VA, Stepanov IA, Kalinin AA, Aliyev MA, Aglakov BM, Yusupov BR, Shepelev VV. Total arthroplasty and anterior cervical discectomy with fixation: long-term results of a randomized clinical trial. *Hir. Pozvonoc.* 2019;16(1):48–56. In Russian.

DOI: <http://dx.doi.org/10.14531/ss2019.1.48-56>.

Anterior cervical discectomy and fusion (ACDF) is the gold standard of surgical treatment of patients with degenerative diseases of cervical intervertebral discs [1, 2]. In most patients, ACDF allows one to achieve regression of clinical neurological symptoms and improve quality of life [3]. There is currently no evidence that the long-term outcomes of surgical treatment of patients with degeneration of cervical intervertebral discs are superior to patients who had undergone conservative treatment. Meanwhile, the short-term outcomes of surgical treatment of this cohort of patients are

much better than those achieved using conservative treatment procedures [4].

ACDF is known to limit the range of motion in the operated spinal motion segment, thus imposing biomechanical stress on the adjacent segments and causing degeneration of the adjacent spinal motion segments [5, 6]. These factors inspired the development of total arthroplasty of intervertebral discs and launching it into clinical practice. This procedure allows one to preserve normal cervical spine biomechanics and prevent degeneration of adjacent segments [7]. Studies have demonstrated that it shows reliably better clinical outcomes when

used for surgical treatment of patients with degenerative diseases of cervical intervertebral discs [8–10]. It should be mentioned that some of these studies have methodological drawbacks, focus on application of only a certain type of artificial disc and/or have received financial support from implant manufacturers. These features of study design undoubtedly increase the risk of a conflict of interest.

The objective of the present study was to perform a comparative analysis of the long-term outcomes of total cervical disc arthroplasty (CDA) and anterior cervical discectomy and fusion in surgical treat-

ment of patients with single-level degenerative diseases of cervical intervertebral discs.

Materials and Methods

This was a prospective randomized single-center cohort study.

The study involved patients with single-level degenerative diseases of intervertebral discs at the level between C3–C4 and C6–C7.

The exclusion criteria were as follows: single-level degenerative disease of intervertebral discs at the C2–C3 or C7–T1 level, osteoporosis, a history of spinal injuries, signs of segmental instability, decompensated diabetes mellitus, chronic heart failure or chronic kidney failure, and administration of medications impeding bone block formation.

Study subjects were 186 patients (89 males and 97 females) aged 21–60 years. They were allocated into two groups: patients who had undergone total CDA or ACDF. A total of 173 patients were independently sequentially allocated into groups (1:1) using software. The patient selection diagram is shown in Fig. 1.

The study was carried out at the Center of Neurosurgery of the Road Clinical Hospital at Irkutsk-Passazhirskiy Station.

Duration of the postoperative follow-up period was at least 48 months.

Surgical approach. After the operative field was disinfected thrice with an antiseptic solution, the retropharyngeal approach in the projection of degenerated vertebral disc was performed using the Cloward technique in a mechanically ventilated patient lying in a supine position under intravenous anesthesia. Blunt dissection of skin and subcutaneous tissue provided an access to the anterolateral surface of the cervical spine. A distractor was placed, and total microdiscectomy involving bilateral foraminotomy for spinal nerve roots and resection of the posterior longitudinal ligament was performed under 12×–16× magnification (OPMI Pentero 900 operating microscope). A specialized set of tools was used to form the bed for placing implants (M6-C and Activ C intervertebral disc prostheses, HRC Cervical and Concorde

cages; Fig. 2). Positioning of the placed implants was controlled by intraoperative fluoroscopy.

The following clinical and instrumental parameters were evaluated in patients: the VAS score for pain intensity in the cervical spine and upper extremities, patients' quality of life related to the Neck Disability Index (NDI), the motion amplitude of the operated spinal motion segment, frequency of developing adjacent segment degeneration, and frequency of reoperations and adverse events.

The VAS score for pain intensity in the cervical spine and upper extremities, as well as patients' quality of life related to the NDI, was evaluated using a questionnaire. The motion amplitude of the operated spinal motion segment was evaluated according to the data of functional spondylograms of the cervical spine. Degeneration of the adjacent segments was verified by MRI and MSCT of the cervical spine. The degree of degeneration of the adjacent intervertebral discs was assessed using the original classification proposed by Pfirrmann et al. [11]. The clinical and instrumental parameters were evaluated preoperatively and 6, 12, 24, 36, and 48 months after the surgery. Any surgical interventions at the operated level and the adjacent segments were classified as reoperations. The term 'adverse events' was used to refer to any complications related to the surgical intervention.

The study was approved by the Ethics Committee of the Irkutsk State Medical University (protocol no. 51/3 dated February 8, 2012) and conducted in full compliance with the Good Clinical Practice regulations and the Declaration of Helsinki [12]. Written informed consent was obtained from all patients prior to study initiation.

Statistical data analysis was performed using the Microsoft 2010 and Statistica 8.0 software. The results are presented as the median values (Me) and interquartile range (25 %; 75 %). The categorical variables in the total CDA and ACDF groups were compared using the Fisher's exact test. Continuous variables in these respondent groups were compared using the t-test or the Mann–Whitney–Wilcoxon

on test. The t-test was utilized for intra-group comparison of the results. The differences with $p < 0.05$ were considered significant.

Results

The overall characteristics of the analyzed patient cohort are summarized in Table 1. There were no statistically significant intergroup differences in gender, anthropometric data, or the somatic status of the respondents according to the ASA (American Society of Anesthesiologists) scale, as well as in the clinical parameters at baseline ($p > 0.05$).

In both groups, the preoperative clinical parameters did not differ significantly ($p > 0.05$). Smaller VAS scores for pain intensity in the cervical spine (Fig. 3) and upper extremities (Fig. 4), as well as improved patients' quality of life according to the NDI (Fig. 5, $p < 0.01$) were observed in all the cases. No intergroup difference ($p > 0.05$) was revealed for these parameters in the early postoperative period, while the best long-term clinical outcomes were observed in the group of patients who had undergone total CDA.

Table 2 shows the dynamics of motion amplitude for the operated spinal motion segment. An analysis demonstrated that the motion amplitudes for the operated segment after 6-month follow-up were comparable in both patient groups ($p = 0.18$). However, the motion amplitude for the operated segment in the CDA group in the late postoperative period remained within the physiological range. In the ACDF group, complete fusion was verified in 83 (93.3 %) cases.

Changes in the segments adjacent to the operated one are summarized in Table 3. A significantly higher degeneration degree of superjacent intervertebral discs was revealed in the ACDF group ($p < 0.01$), while no significant degenerative changes were recorded in subjacent discs during the follow-up period ($p > 0.05$).

Table 4 summarizes the data on the type and area affected by perioperative adverse events. No statistically significant

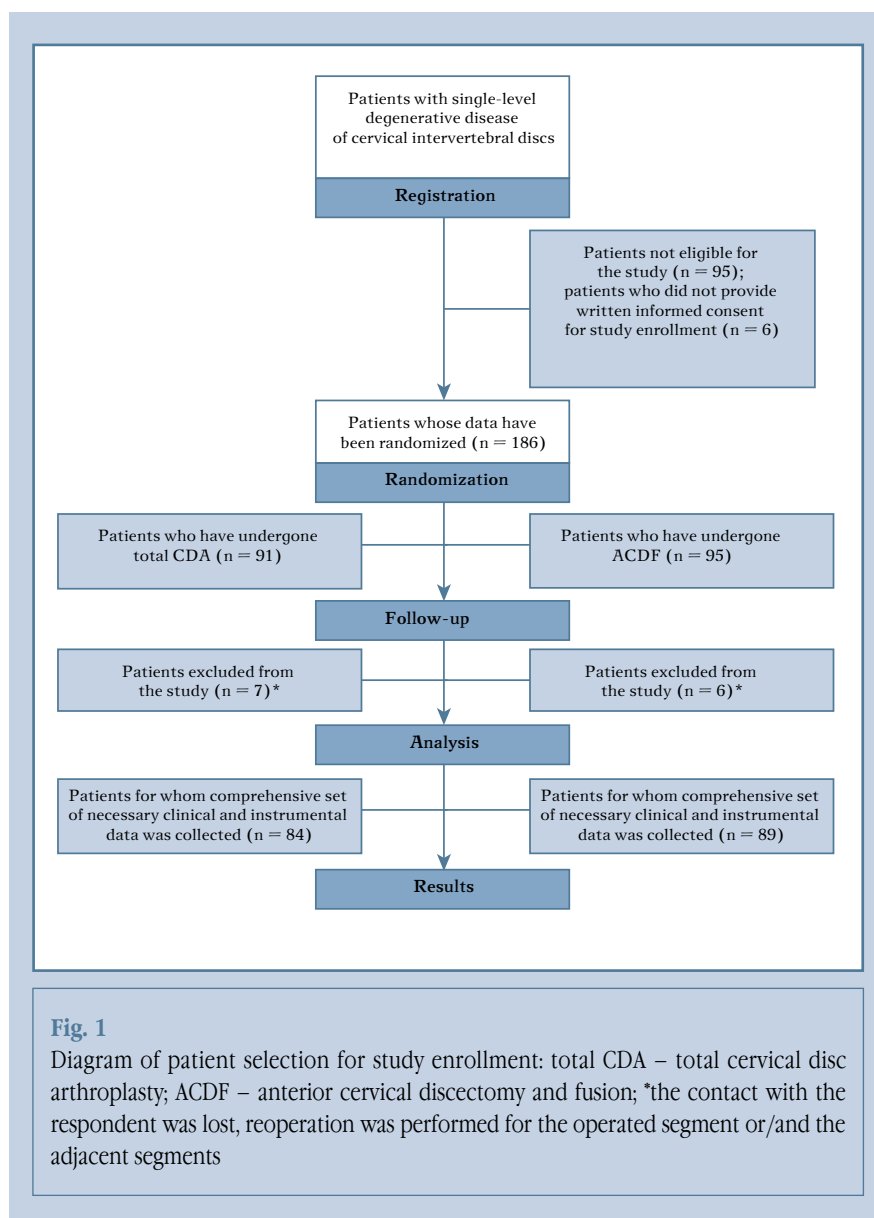
intergroup difference was detected for the number of intraoperative and early postoperative adverse events ($p > 0.05$). Symptomatic degeneration of adjacent spinal motion segments was verified in two (2.4 %) patients in the CDA group and in nine (9 %) patients in the ACDF group ($p < 0.001$). It should be mentioned that reoperations were performed for all patients with symptomatic degeneration of the adjacent segments. Furthermore, symptomatic adverse events in the form of heterotopic ossification were verified in three (3.6 %) patients in the CDA group; the adverse events in the form of pseudoarthrosis were verified in six (6.7 %) patients in the ACDF group.

Discussion

Although the total CDA technique has been actively used at many neurosurgical clinics worldwide for the past decade, the ACDF surgery still remains the preferred option of surgical treatment for patients with degeneration of cervical intervertebral discs [13]. Some authors [5, 14] believe that spinal surgeons are suspicious about wide application of total CDA in patients with degenerative disorders of cerebral intervertebral discs because no convincing data proving the long-term effectiveness of this surgical treatment method are available yet.

The results of this study clearly demonstrate that patients after total CDA showed statistically significantly better long-term clinical outcomes compared to the respondents who had undergone ACDF. Furthermore, the total CDA procedure made it possible to preserve the physiological range of motion in the operated spinal motion segment and prevent degeneration of adjacent segments. In addition, there was a statistically significantly smaller tendency to be reoperated or have long-term adverse events among patients in the CDA group.

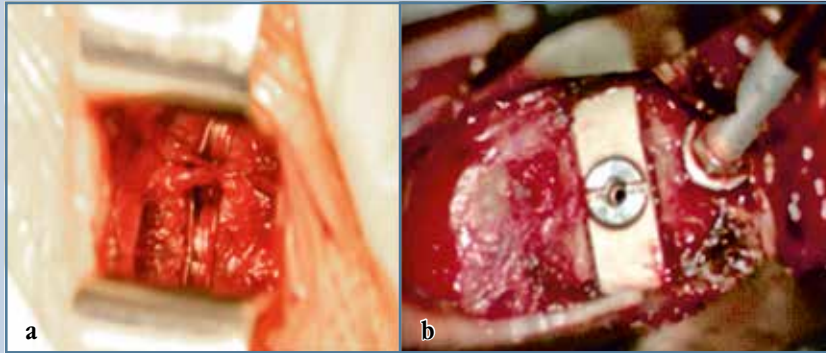
Our findings are largely consistent with the results of some studies. Thus, in their prospective randomized clinical trial, Phillips et al. [15] proved that patients after total CDA showed statistically significantly better clinical outcomes after the postoperative follow-up for 60 months.



Burkus et al. [16] demonstrated that total CDA preserved the normal biomechanics of the cervical spine, prevented degeneration of adjacent segments, and reduced the number of reoperations (the mean postoperative period being no shorter than 84 months). These randomized clinical trials have certain methodological limitations, which increase the risk of bias in these studies and the validity of their results. The authors of the present prospective randomized trial did their best to take into account all the features and shortcomings of previous reports in order to eliminate the risk of bias and provide reliable interpretation of the

results. According to the scale proposed by Jadad et al. [17] to assess methodological quality of clinical trials, the present prospective randomized clinical trial was given score 4.

It is beyond argument that total arthroplasty is indicated not for all patients having degenerative diseases of cervical intervertebral discs. The main indications for this procedure include degenerative disorders of cervical intervertebral discs at the level between C3–C4 and C6–C7 (grade I–II according to the Pfirrmann's classification), minimal degenerative changes in zygapophysial joints (grade I–II according to the Fuji-

**Fig. 2**

Intraoperative images: **a** – appearance of the inserted M6-C prosthetic intervertebral disc; **b** – appearance of the inserted HRC Cervical cage

wara's classification [18]), persistent pain syndrome resistant to conservative treatment (4–6 weeks), preserved height of the intervertebral disc space (>50 % of the height of the superjacent one), and no signs of segmental instability in the spinal motion segment. Total arthroplasty of spinal intervertebral discs is not indicated for patients having signs of osteoporosis, segmental instability, spondyloarthrosis with compensatory changes in the zygapophysial joints and limited range of motion, congenital spinal stenosis, as well as for patients who had earlier undergone surgical interventions for the spinal motion segment [19]. A number of authors [20–24] believe that

total arthroplasty of cervical intervertebral discs is also not recommended for patients older than 50 years because of the pronounced degeneration of structures of the vertebral column. Nonetheless, in our opinion, this surgical technique can be used in patients of this age group if they do not have severe degenerative changes in zygapophysial joints or other contraindications.

We would like to outline a number of shortcomings of the present study. First, it focuses on the effectiveness of application of only several types of prosthetic intervertebral discs and cages, preventing extrapolation of the results into other types of implants. Second, this study

was carried out at a single neurosurgical center and involved patients who strictly met the eligibility (inclusion and exclusion) criteria, which could have interfered with the results. Third, total cervical disc arthroplasty was performed for the better preserved structures of the cervical spine in the overwhelming majority of cases, which may be the reason why this surgical procedure showed better clinical effectiveness in the long-term follow-up period.

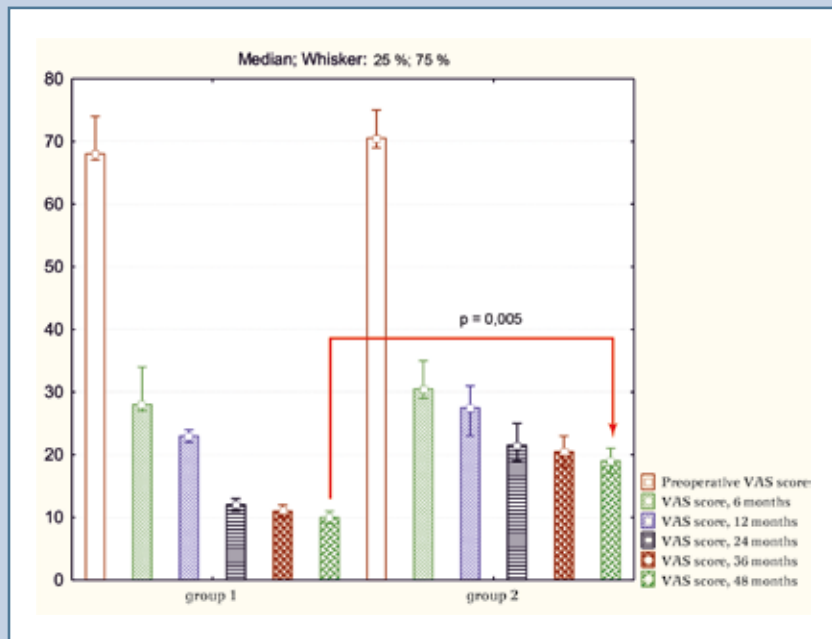
Conclusions

This study has illustratively demonstrated that total CDA and ACDF are safe and efficient methods for surgical treatment of patients with single-level degenerative diseases of cervical intervertebral discs. Patients who had undergone total CDA showed significantly better clinical results as compared to the ACDF group. The total CDA method allowed preserving the normal biomechanics of the cervical spine and preventing the development of degeneration of the adjacent segments. A prospective cohort study involving a greater patient sample (with the data from several neurosurgical centers included) should be performed for the unbiased comparison of the effectiveness of these surgical procedures.

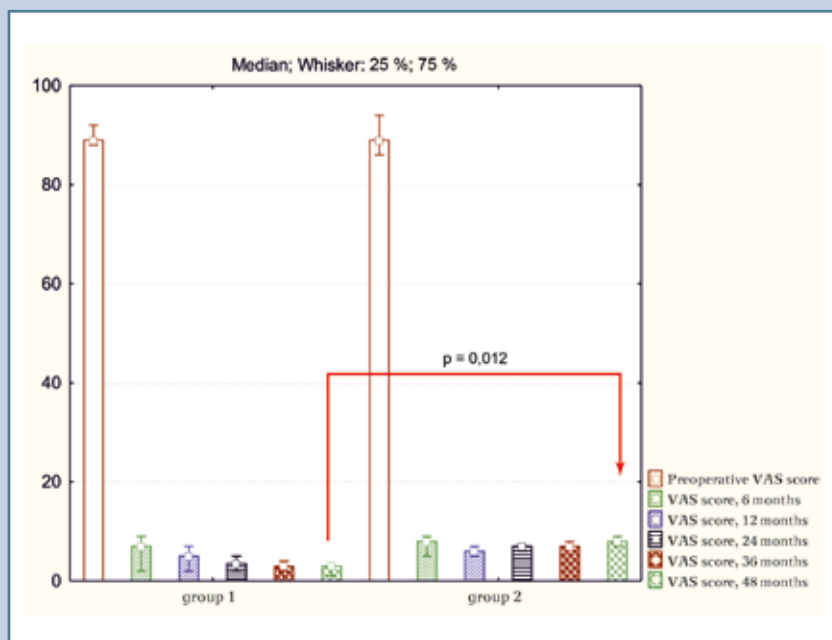
Table 1

The overall characteristics of the analyzed patient cohort

Sign	Total cervical disc arthroplasty (n = 84)	Anterior cervical discectomy and fusion (n = 89)	p
Age, years, Me (25 %; 75 %)	42 (26; 58)	45 (29; 60)	0.26
Sex, n (%)	male	51 (60.7)	0.12
	female	33 (39.3)	
Body weight index, kg/m ² , Me (25 %; 75 %)	23.4 (22.1; 24.2)	23.5 (22.4; 24.4)	0.68
ASA, Me (25 %; 75 %)	II (I; II)	II (I; II)	0.76
VAS: cervical spine, mm, Me (25 %; 75 %)	68 (62; 74)	70 (65; 75)	0.51
VAS: upper extremities, mm, Me (25 %; 75 %)	89 (76; 93)	90 (79; 95)	0.47
NDI, score, Me (25 %; 75 %)	39 (32; 46)	40 (34; 46)	0.69

**Fig. 3**

Comparison of pain intensity in the cervical spine evaluated using the VAS in patients who had undergone total cervical disc arthroplasty (group 1) and anterior cervical discectomy and fusion (group 2) at different follow-up points

**Fig. 4**

Comparison of the intensity of upper limb pain evaluated using the VAS in patients who had undergone total cervical disc arthroplasty (group 1) and anterior cervical discectomy and fusion (group 2) at different follow-up points

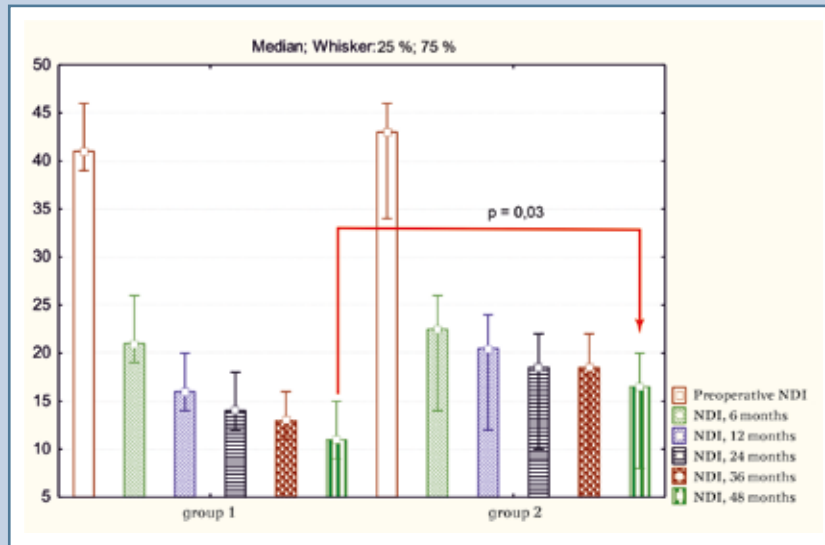


Fig. 5

Comparison of patients' quality of life evaluated using the NDI in patients who had undergone total cervical disc arthroplasty (group 1) and anterior cervical discectomy and fusion (group 2) at different follow-up points

Table 2

The motion amplitudes of the operated segments in the analyzed patient cohort, degrees

Group	Preoperatively	After 6 months	After 48 months
Total cervical disc arthroplasty (n = 84)	6.8 (5.9; 7.3)	7.9 (6.8; 7.6)	8.1 (7.5; 8.7) *
Anterior cervical discectomy and fusion (n = 89)	6.3 (5.1; 7.0)	7.4 (6.2; 7.4)	0.5 (0; 0.7)

*statistically significant values.

Table 3

The area affected by the degenerative disease of the adjacent spinal motion segments

Sign (preoperatively)	Total cervical disc arthroplasty (n = 84)		Anterior cervical discectomy and fusion (n = 89)	
	after 48 months	preoperatively	after 48 months	preoperatively
Degree of degeneration of intervertebral discs in the superjacent segment, n (%)	I	7 (8.3)	7 (8.3)	6 (6.7)
	II	30 (35.7)	26 (30.9)	42 (47.2)
	III	28 (33.3)	31 (36.9)	22 (24.7)
	IV	19 (22.7)	20 (23.9)	19 (21.4)
	V	—	—	—
Degree of degeneration of intervertebral discs in the subjacent segment, n (%)	I	9 (10.7)	8 (9.5)	6 (6.7)
	II	39 (46.4)	37 (44.0)	35 (39.3)
	III	23 (27.4)	25 (29.8)	29 (32.6)
	IV	13 (15.5)	14 (16.7)	19 (21.4)
	V	—	—	—

Table 4

Types and frequency of adverse events in the analyzed patient cohort

Sign	Total cervical disc arthroplasty (n = 84)	Anterior cervical discectomy and fusion (n = 89)	p
Intraoperative complications, n (%)	3 (3.6)	3 (3.4)	0.780
injury to <i>a. vertebralis</i>	1	—	
injury to <i>n. laryngeusrecurrens</i>	2	1	
esophageal injury	—	1	
injury to the dura mater	—	1	
Early postoperative complications, n (%)	1 (1.2)	2 (2.2)	0.130
surgical site infection	1	1	
lower extremity deep vein thrombosis, pulmonary embolism	—	1	
Late postoperative complications, n (%)	5 (5.9)	14 (15.7)	0.002
degeneration of adjacent spinal motion segments	2	8	
heterotopic ossification	3	—	
pseudoarthrosis	—	6	

This study received no support from any sponsors. The authors declare that there is no conflict of interest.

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Received 09.10.2018

Review completed 19.11.2018

Passed for printing 27.11.2018

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