OUTCOMES OF INTERBODY FUSION AND ARTHROPLASTY FOR CERVICAL SPINE DEGENERATIVE DISEASE*

D.L. Glukhikh
District Clinical Hospital "Traumatology Center", Surgut, Russia

Objective. To compare the results of interbody fusion and arthroplasty in patients with cervical spine degenerative disease.
Material and Methods. Thirty-seven Bryan cervical disc prostheses were implanted in 31 patients after discectomy (Group 1). Interbody fusion was performed in 47 patients (Group 2). Comprehensive survey of all patients was performed preoperatively and immediately postoperatively, 3, 6, 9, 12, and 24 months after surgery. A visual analogue scale (VAS), the scale of disability assessment, radiography, MSCT, and MRI were used.
Results. VAS assessment showed that in patients from Group 1 the pain relieved in the arm by 62.37 %, in the neck — by 38.75 %, and in Group 2 in the arm — by 38.75 % and in the neck — by 35.59 %. Quality of life improved by 53.18 % in Group 1 and by 30.34 % in Group 2. Adjacent segment degeneration within 24 months after surgery was observed in 5.30 % of patients from Group 1 and in 55.00 % of patients from Group 2. Neither subsidence nor displacement of prostheses was observed in the Bryan Group. In the Group of interbody fusion, 35.00 % of patients showed subsidence and nonunion between implants and vertebrae of the operated segment.
Conclusion. Arthroplasty provided better clinical and radiographic results in early and long-term postoperative periods.
Key Words: cervical arthroplasty, interbody fusion, clinical and radiographic results, comparison.

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Degenerative lesion of the intervertebral disc is the most frequently occurring spinal pathology [2–12, 44]. Isolated discectomy or discectomy followed by interbody fusion is a common surgical approach for treatment of degenerative changes in intervertebral discs [2–7, 9, 12, 31, 35]. Over the past 50 years, interbody fusion has become the conventional type of intervention for a number of pathological conditions, including cervical osteochondrosis [2–9, 12, 19, 21, 25]. The hypothesis that pain in the spinal column is attributed to the motion in the affected disk is obviously close to being valid: immobilization of this segment significantly reduces the pain [15, 20, 40]. The accumulated experience allowed the researchers to detect and examine the negative manifestations that are more or less prevalent during the application of any of these techniques.

Discectomy without subsequent interbody fusion was found to result in full-fledged bone block only in 80% of cases [28, 31, 34], while monosegmental isolated fusion using auto- or allograft without additional plate fixation caused the development of pseudarthrosis in up to 20% of cases. When interbody fusion was performed at two or more levels, the failure of the bone block increased to 68% (in particular, when allografts were used) [31, 35, 40].

Another argument against fusion is that it accelerates the development of degenerative changes in the adjacent segment [16, 17, 20, 22, 24, 30, 34, 42]. The most thorough description of this phenomenon has been provided by Hilibrand et al. [26, 27], who observed 374 patients subjected to a total of 409 cervical fusions during the course of treatment of cervical spondylolysis using radiculopathy and/or myelopathy. During the period of 10 years, Hilibrand et al. have annually observed the emergence of symptoms of degenerative changes in the adjacent levels in 2.9 % of patients after surgery. Therefore, the authors established that degeneration of adjacent segments requiring reoperation occurred in 25.6 % of patients during a 10-year period.

Surgical techniques enabling one to maintain the mobility of the segments subjected to surgery have been proposed in order to prevent pseudarthrosis and accelerated degeneration of the adjacent levels [1, 10, 11, 15, 16, 25—27, 34, 35, 40].

A number of publications suggested that prospective randomized trials characterized by external strict or even rigorous requirements have a number of drawbacks. Blinded or double-blinded control cannot be achieved during surgical manipulations, since both the surgeon and the patient must be aware of the procedures being performed [18]. It is believed that this fact renders it possible to demonstrate the advantage of the novel device for the investigation. Certain objects that were regarded as atypical can be included in the study groups or be excluded during the analysis (so-called post-randomization). A select group of patients who fit extremely rigorous (occasionally relatively atypical) eligibility criteria and agree to submit to randomization is often formed [13,

14, 28, 29]. These factors along with the complexity of the project of the randomized trials [29] indicate that the results of the randomized controlled studies require further confirmation via thoroughly conducted clinical research in a daily practice.

The purpose of this study was to analyze outcomes results of arthroplasty and interbody fusion in the treatment of cervical spine osteochondrosis.

Material and Methods

The trial included two groups of patients undergoing surgery for treatment of degenerative lesions of the cervical intervertebral discs. The selection was made from 78 patients who suffered from herniated discs and/or osteophytic overgrowth at one, two or three levels causing symptoms of compressive lesion of the cerebral spine. Patients with manifestations of myelopathy were excluded from the study, since the application of arthroplasty to manage cervical myelopathy is disputable. Arthroplasty using a Bryan prosthesis (Medtronic) was performed in Group 1 (31 patients) following the conventional discectomy procedure and decompression: at one level – 25; at two levels – 6 (a total of 37 prostheses). Group 2 consisted of 47 patients with a similar clinical presentation, whose treatment included interbody fusion (Tables 1 and 2).

We investigated the demographic, clinical, instrumental and intraoperative data for all patients. Clinical examination included a neurological examination, assessment of abnormalities in vital functions using the Neck Disability Index (NDI) scale, assessment of neck and arm pain using the visual analogue scale (VAS). The following instrumental methods were used: MRI, CT, radiography in standard positions, as well as during flexion/extension bending in the sagittal plane and flexions in the frontal plane.

The results were evaluated prior to surgery, during the early postoperative period, and then after 3—6 months, 6—12 months, and 12—24 months. In group 2, the results were evaluated after 24—36 and 36—132 months in order to assess the dynamics of the degenerative processes occurring in the cervical spine subjected to surgery. The complications in the form of degenerative lesions of the adjacent level (osteophyte expansion attributed to the plate protruding into the interbody space, osteophyte expansion in patients with correctly positioned plate, osteophyte expansion of both the anterior and the posterior edges of the adjacent vertebral body attributed to abnormal mobility), as well as subsidence and fusion failure, which have led or could have led to reoperations were thoroughly selected and analyzed. The changes in the interbody space of the prosthetic vertebrae, the range of motion at flexion/extension bending and lateral flexions, as well as signs of efficiency of the prosthesis were evaluated. The presence or absence of heterotopic ossification in the periprosthetic space was evaluated in accordance with the Mehren/Suchomel modification of the McAfee classification [36, 37].

Surgical technique. All surgeries were performed at the same neurosurgery department using identical surgical techniques. The patient was lying on the operating table in the supine position with the shoulder girdle fixed; the neck was in neutral or slightly unbent position. Preoperative lateral radiographic control was mandatory in order to optimize the trajectory of the surgical approach and to control the sagittal axis of the spinal column. The conventional anterior cervical approach was performed by a right-sided transverse incision for all cases. Maximally complete discectomy with extensive foraminal and central decompression was performed. A needle distractor was used in all cases to increase the interbody space. The posterior longitudinal ligament was removed; the anterior and posterior osteophytes were thoroughly resected. The anatomical center of the disk was identified after the discectomy. A special device for installing the prosthesis was fixed to the anterior regions of the vertebral bodies in order to precisely control the position and movements of

Table 1
Main characteristics of patients from the groups under study

Characteristics	Group 1	Group 2
Number of patients, n	31	47
Males	14	15
Females	17	32
Median age, years	44.39	46.49
Mean surgery duration, min	116	115
Average blood loss, ml	141	249
1 level involved	25	21
2 levels involved	6	17
3 levels involved	–	8
4 levels involved	–	1

Table 2
Distribution of patients from the groups under study with respect to length of follow-up, n

Length of follow-up	Group 1	Group 2
Prior to surgery	31	47
After 3—6 months	22	32
After 6—12 months	10	26
After 12—24 months	19	20
After 24—36 months	–	16
After 36—132 months	–	10

the equipment that prepared the end plates of the vertebral bodies for exact matching to the contour of the convex outer surface of the prosthesis. At the end of sawing out, the contour of the end plate must most congruently capture the shell frame of the prosthesis to ensure primary stability. One should seek to maximize the preservation of the end plates in order to reduce the risk of prosthesis subsidence and loosening. Lateral radiography was carried out at all stages of preparing and installing the prosthesis to assess its correct position. External immobilization after surgery was not used. Mobilization of the patient was initiated the next day after the surgery. An implant made of porous titanium nickelide was installed into the interbody space in group 2 patients after similar decompression procedures; additional internal fixation using Atlantis, CSLP, and Cervi Lok plates was applied in 36 (76 %) cases.

Results

The cervical arthroplasty using Bryan Cervical Disc prosthesis has been performed at the clinics since November 2007. The success of the conventional surgery through the anterior approach is attributed to the decompression of the contents of the spinal canal and provision of conditions for interbody fusion. Excellent clinical results during the early postoperative period are specifically associated with the abovementioned factor. However, the aim of the surgery is to maintain the achieved result over the longest possible period of time. Negative consequences of rigid interbody fusion manifesting themselves as subsidence, fusion failure, and accelerated degeneration of the levels adjacent to the immobilized ones lead to a loss of the result. Devices preserving the motions in the operated segment have been designed to prevent these phenomena.

The clinical and X-ray findings were analyzed at fixed intervals. Complications during the approach, discectomy, and decompression were identified in none of the cases. The initial and early postoperative data were identical. Arm

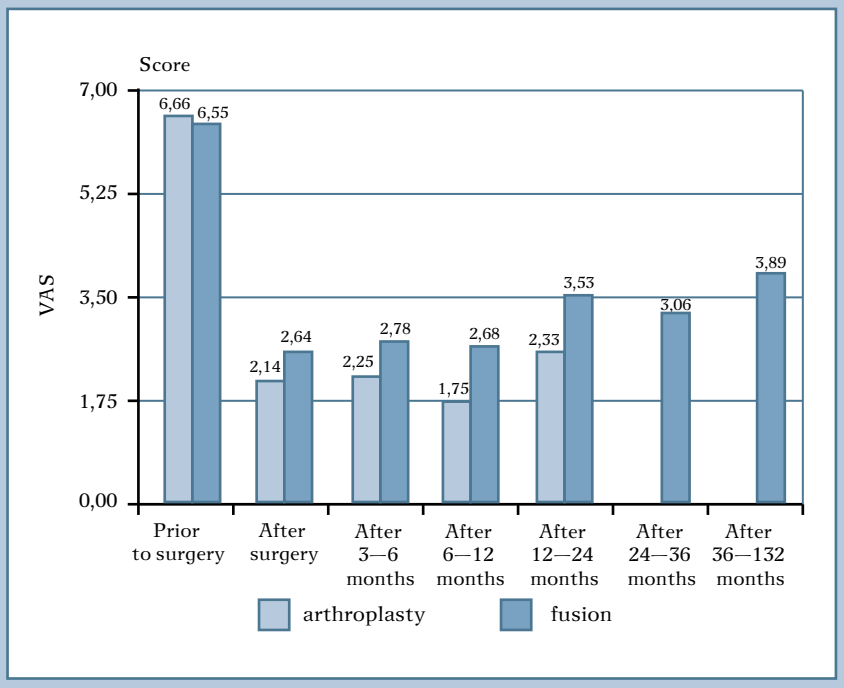

Fig. 1
Assessment of the arm pain using visual analog scale (VAS) in patients from the study groups

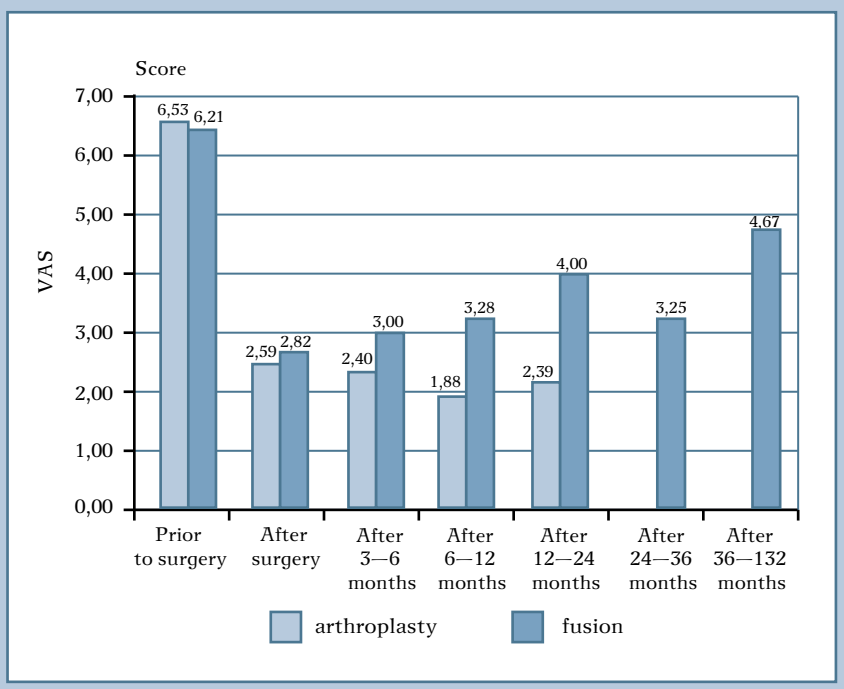

Fig. 2
Assessment of neck pain using visual analog scale (VAS) in patients from the study groups

pain evaluated using the VAS decreased from score 6.66 to 2.14 for group 1 and from score 6.55 to 2.00 for group 2; neck pain decreased from score 6.53 to 2.29 (group 1) and from score 6.21 to 2.82 (group 2). The index of vital function impairment improved from 46.24 to 24.79 % (group 1) and from 45.84 to 27.18 % (group 2). Three to six months after the surgery, 46.9% of fusion failures were identified in group 2, which can be interpreted as delayed consolidation; manifestations of the adjacent level degeneration in the form of hypermobility, ossification of the anterior longitudinal ligament, and formation of osteophyte were identified in 21.9 % of cases. In group 1, neither degeneration of the adjacent level, nor prosthesis subsidence/displacement was identified; prosthetic mobility was ~5.86°.

Over the entire observation period, group 1 demonstrated the most acceptable clinical outcome according to all the scales: after 24 months, the arm pain regressed from VAS score of 6.66 to 2.33 (by 62.37 %); in group 2, pain reduced from score of 6.55 to 3.53 (by 38.75 %; Fig. 1). After 24 months, neck pain decreased from score of 6.53 to 2.39 in group 1 (by 65.00 %) and from score of 6.21 to 4.00 in group 2 (by 35.59 %, Fig. 2). The index of vital function impairment decreased from 46.24 to 21.65 % for group 1 (an improvement by 53.18 %) and from 45.84 to 31.93 % for group 2 (an improvement by 30.40 %, Fig. 3).

During the study period, degeneration of adjacent levels was observed in 55.0 % of group 2 patients (Fig. 4), pseudarthrosis was observed in 37.5 % group 2 patients (Fig. 5). Reoperations for the identified complications were performed in 6 (12.8 %) patients. Neither prosthesis subsidence nor displacement was observed in group 1 patients. Heterotopic ossification at the initial stage [36, 37] was observed in 2 (11.6 %) of 19 patients examined postoperatively 24 months after the surgery. The average range of motion in the sagittal plane in the prosthetic segment within 24 months was 13.9° (Fig. 6).

Discussion

Interbody fusion performed to immobilize the degenerative segment at the cervical level of the spinal column has been for a long time regarded as the golden standard. Good overall results with a relatively low level of long-term complications have been mentioned by many researchers [4–6, 9–12, 22]. Taking

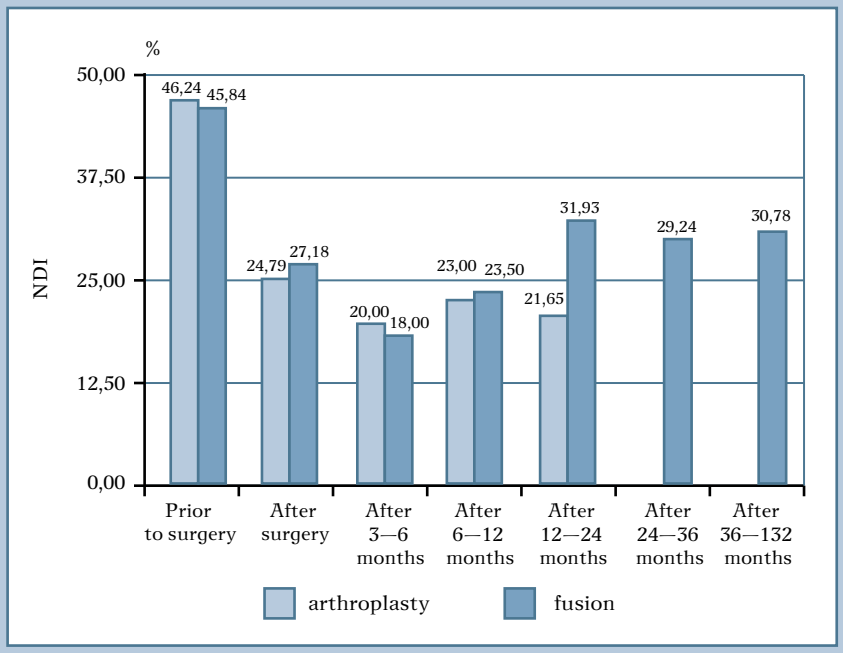

Fig. 3
Assessment of abnormalities in the vital functions using Neck Disability Index (NDI)

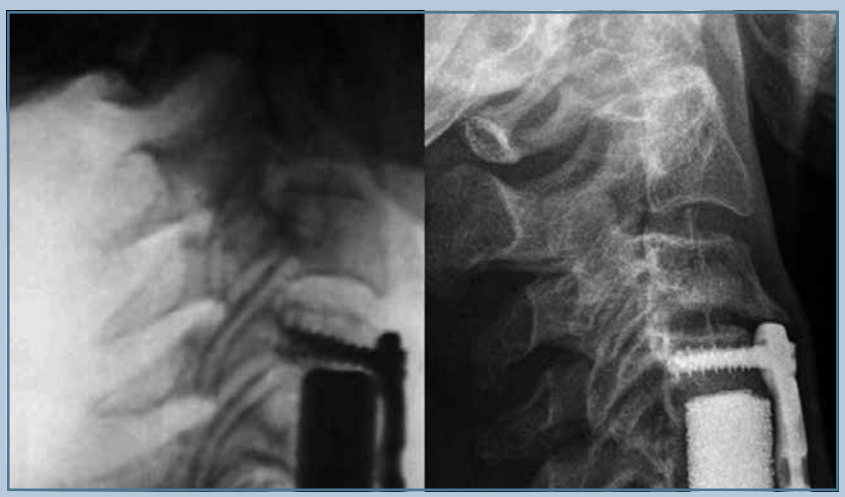

Fig. 4
Degeneration of the upper layer manifested as a reduction in the interbody space, emergence of osteophytes both on the anterior surface of the caudal edge of the vertebra and on the posterior edge 12 months after the surgery; correct position of the plate immediately after the surgery: the plate does not protrude in the projection of the disc

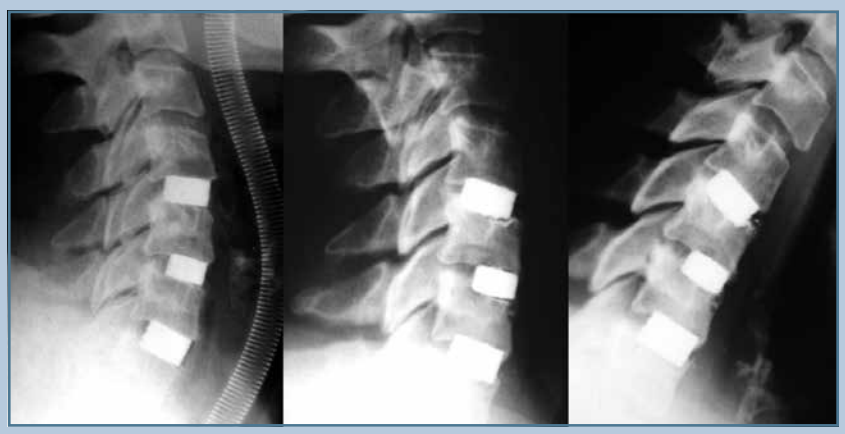

Fig. 5
Subsidence and fusion failure (pseudoarthrosis): intraoperative image (endotracheal tube can be seen) and images 16 months after the surgery (flexion/extension bending); subsidence and pseudarthrosis at all levels subjected to surgical intervention as an area of clearing and osteosclerosis

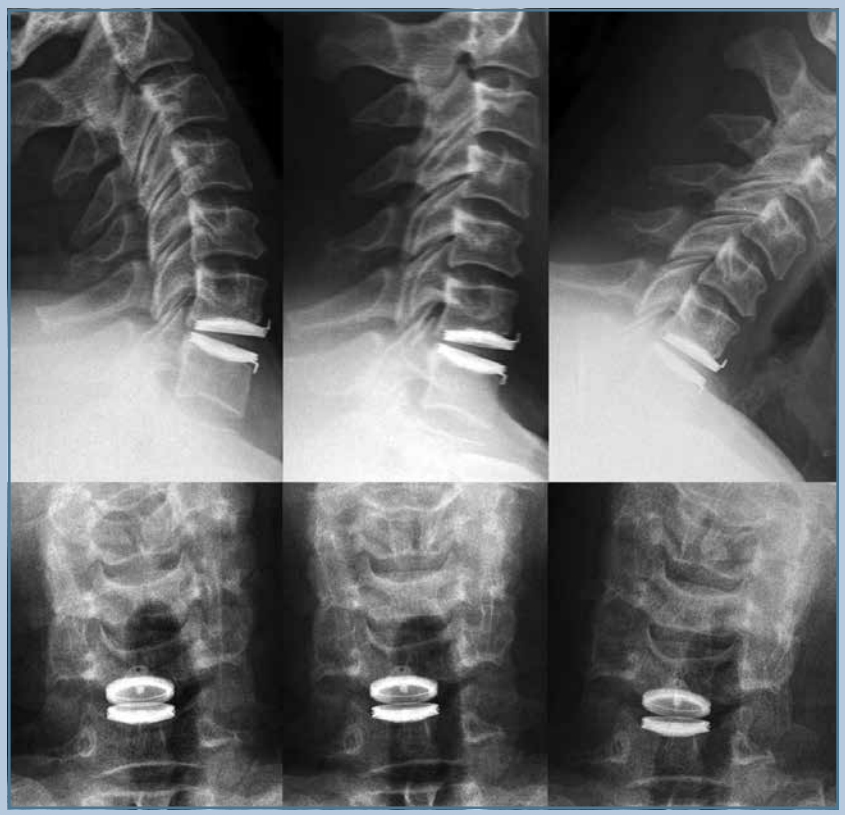

Fig. 6
Twenty-four months after the surgery: the amplitude of flexion/extension bending in the prosthesis was 8°, in the adjacent upper level – 9°; lateral flexions – 5°; segmental sagittal balance at the level of arthroplasty – 1°, lordosis; segmental sagittal balance of the adjacent upper level – 2°, lordosis

these facts into account, the invention and application of the novel device seem controversial. The degree of importance of rigid fusion complications (manifesting as accelerated degeneration of the adjacent levels, subsidence and fusion failure) remains a subject of debate. However, the recent publications have consistently indicated that arthroplasty during surgical treatment of cervical osteochondrosis is not worse and sometimes even better than the rigid fusion technique, in particular if the long-term outcomes are analyzed [1, 10, 14, 16, 23, 25, 32, 38, 39, 41, 42].

The present study does not allow one to draw any definitive conclusions because of the relatively small number of patients. However, clinical results and comparative analysis enable one to present the advantages of arthroplasty.

The re-examination of the patients subjected to surgery has confirmed that the problems of degeneration of the upper adjacent level do exist. Along with the natural degeneration as a manifestation of aging, the abovementioned degeneration develops more rapidly in the segment adjacent to the fixated segment. While the emergence of osteophytes in the anterior segments of the vertebral bodies associated with improper positioning of the plate can be attributed to irritant action of the plate with respect to the interbody space, how can one explain the decrease in height of the adjacent space and osteophyte formation on the posterior surface of the adjacent vertebral bodies, as well as the formation of osteophytes in cases when a plate was not applied? Sometimes these phenomena are asymptomatic. However, if a patient reports the recurrence of cervical pain, the X-rays and CT reveal changes in the adjacent segments, and discography with subsequent intradiscal manipulation (introduction of anesthetics) temporarily relieves patient's condition. This becomes a problem. In the long-term period, the clinical outcomes become worse (to a significant extent in some cases).

We have seen that the problem associated with subsidence and fusion failure in the operated segments does exist.

The best results for the formation of a full-fledged bone fusion were obtained with single-level fixation combined with a plate. The greater the number of fixed segments, the greater the likelihood of fracture healing is. The plate does not always guarantee the success of the surgery. Subsidence, fusion failure, and loss of operative correction in the sagittal and frontal planes were observed in patients with a combined fusion. The criteria for full-fledged fusion have not been fully determined. The accepted standard of permissibility of segment swinging by 2–4° and divergence of the interspinous gap on the functional X-rays by 2–4 mm are controversial. We support the view that at the present level of development of imaging techniques, only a reliable bone bridge in CT images and the lack of any discrepancy in the interspinous gap in functional X-rays approve the full-fledged fusion in the operated segment. The instrumentally determined fusion failure does not always manifest itself clinically; however, sometimes this phenomenon significantly worsens the clinical outcome and additional fixation is required. The decision on performing reoperation is an very challenging task: there are no absolute indications. The desire to improve the lost result by extending the fusion is controversial. Additional fixation of the unfused segment in our series of cases yielded good results.

A relatively short period of application of arthroplasty by spinal surgeons revealed certain negative manifestations, such as heterotopic ossification and prosthetic dysfunction [36, 37]. In our series of clinical cases, the initial effects were observed in 2 (11.6 %) patients examined 24 months after the surgery. Further observations will allow one to clarify the incidence and clinical significance of these manifestations. It can be assumed that the gradual immobilization of the prosthetic segment is identical to natural degeneration.

Periprosthetic changes observed and described by orthopedic surgeons dealing with prosthetics of the major joints of the extremities are the next serious concerns associated with arthroplasty. Revision surgeries on the ventral spinal column structures are potentially dangerous [10, 11, 26, 27, 33, 39, 41, 43]. We have not encountered any of these complications. This problem most likely will be addressed by manufacturing companies in their search for the most reliable and safe design of the prosthesis.

Conclusions

Analysis of the results revealed more favorable clinical and radiological outcomes of treatment using total cervical disc prosthesis procedure as compared to the method of interbody fusion formation. No serious intraoperative complications were observed. No cases of prosthesis fracture or periprosthetic reactions were identified. The physiological range of motion in the operated segment was not preserved. No accelerated degeneration of the levels adjacent to the prosthesis was observed. None of the patients in the arthroplasty group demanded reoperation. The best results can obviously be attributed to the high level of correspondence between the intervertebral disc prostheses and the anatomical and physiological characteristics of the spinal column. Thorough follow-up of the two groups of patients using the modern universally recognized imaging techniques and clinical tests will be continued, and the results will probably be corrected to some extent.

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Corresponding author:
Dmitry Glukhikh
Nefteyuganskoe sh. 20, Surgut, 628406
Russia
District Clinical Hospital "Traumatology Center"
E-mail: Glukhikhdl@mail.ru

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Commentary

Vertebrologists are concerned with accelerated degeneration of adjacent discs after anterior decompressive-stabilizing and stabilizing surgeries (especially in cases of polysegmental rigid fusion). Six months after the surgery, the clinical manifestations of the degenerated intervertebral discs and/or facet joints adjacent to the blocks often emerge and after several years many patients need reoperation. Initially, reflex algesic syndromes emerge, which can be followed by formation of compressive syndromes requiring reoperation. The number of publications devoted to the emergence of a cascade of degenerative lesions of the adjacent spinal segments after stabilizing surgeries is growing like a snowball.

Searching for a solution to this problem can proceed in two ways: 1) minimally invasive microsurgical decompressive surgeries (without fusion), 2) decompressive-plastic interventions preserving the mobility in the operated spinal motion segments. Therefore, this article devoted to arthroplasty associated with surgical treatment of radicular compression syndrome caused by cervical osteochondrosis is highly relevant and published in a timely manner. However, it also casts certain doubts.

The authors have thoroughly justified the objections against prospective randomized controlled trials in surgery. Whereas the most efficient and advanced treatment techniques are used in the test and control groups of patients (as in this case), the randomization, as the most objective tool of the evidence-based medicine, is not a hindrance. It is difficult to agree with the authors' idea that blind or double-blind control cannot be achieved when carrying out surgical manipulations, since the surgeon and the patient must be aware of the procedures being performed. Both the surgeon and the patient should be aware of the fact that one of the most up-to-date and effective treatment techniques will be used and that the benefits of the procedure under study have not been confirmed yet. Misinterpretation of the results of an insufficiently controlled trial may cause harmful and unethical actions with respect to the present and future patients. Hence, the opinion that a well-designed randomized trial is more ethical than less reliable non-randomized studies is justified.

Groups of patients being compared in a controlled prospective randomized trial must differ only with respect to the treatment method under investigation; patients from the control group receive the best treatment (diagnosis) according to the modern concepts and in no way should be adversely affected. Of course, from the ethical point of view, the clinical experiment is permissible if there is a strong justification that the proposed treatment method is at least no worse than the ones that have been used so far If it is found during the experiment that regardless of all preconditions, the novel method is worse than the conventional one, the trial should be immediately terminated. Legal, social and ethical issues that arise during randomized trials cast doubt on the permissibility of such experiments, in particular in the surgical field. Indeed, some patients always suffer during a randomized trial: if the novel method is highly effective, it is the control group of patients that suffers; if it is not effective or causes serious complications, it is the test group that suffers. Two questions arise: 1) whether deprivation of even a single patient of treatment that may be more effective is justified and 2) whether there is a contradiction in such case between the physician's duty to a patient and the demands of science.

The best method for randomization is blind selection (i.e., a method in which the physician responsible for inclusion of a patient into the study does not know in advance which treatment option the patient will receive). This is achieved either through the centralized distribution of treatment options or using envelopes. In the latter case, the center (leader) of the controlled trial provides researchers with a series of numbered and sealed envelopes, each of them containing information regarding one of the treatment options being compared. The envelope with the next sequential number is opened after a patient was included in the trial. Only then the surgeon can tell the patient about the planned intervention.

The negative aspects of cervical disc arthroplasty have not been sufficiently studied yet. Hence, this method can be recommended for widespread use only from the standpoint of evidence-based medicine, with a larger body of observations and the use of profound and more objective criteria. The authors have reasonably indicated that the relatively short application of arthroplasty enabled vertebrologists to identify certain negative manifestations: heterotopic ossification and termination of prosthesis function.

Evidence-based medicine is a conscious, well-defined and unbiased application of the best available proven data using mathematical assessment of the probability and risk for decision making regarding individual patient care. Negative attitude or even resistance to the introduction of evidence-based medicine techniques is often attributed to unacceptable timelines of conducting prospective controlled trials at a single institution, especially for rare forms of pathology.

Attempts are being made to remove this obstacle in the following ways: 1) summarizing the materials published by various authors regarding the results of treatment; 2) parallel studies involving the same type of tests being carried out simultaneously at several institutions and the analysis of results performed separately in each study; and 3) integrated studies in which the institutions of different expertise perform their specific parts of a syndicated research. However, all of them are untenable, since they do not meet the requirements of evidence-based medicine. A solution to this problem was found in combining the efforts of several institutions through organization of cooperative research. This is a coherent system of research, organizational, and practical activities carried out simultaneously within the framework of a single program and using identical methodology (protocol) at several research and practical institutions in order to collect reliable data within a reasonable time required to obtain statistically significant results. All data regarding patients during co-operative research is transferred to the institution organizing the study as special forms adapted for automatic processing. In order to obtain comparable results of the controlled studies conducted by various institutions, the methods of organizing and conducting the study, terminology, and methods for assessing the effects of treatment are to be standardized. Cooperative research is the only available advanced and objective approach for developing the methodology of clinical trials.

Two factors are doubtful: 1) poor results of decompressive-stabilizing surgeries in the control group (e.g., pseudarthrosis in 37.5 % patients); 2) frequent residual radicular pain in the arm in both the first and the second groups of patients.

The application of porous NiTi graft for spinal fusion typically ensures full-fledged vertebral fusion, especially with the additional use of internal fixation with a plate. The use of polysegmental fusion at the cervical spine level should be avoided if possible. Fusion of several motion segments is most often associated with overestimation of the data obtained using instrumental method of research and underestimation of reflex algesic pseudoradicular brachialgias that are diagnosed more often than radicular pain.

Reflex (referred, myosclerotomic, myodistonic, dyscirculatory) pseudoradicular brachialgias are typically mistakenly interpreted as signs of spinal root compression. It is known that in 40.0% of cases, herniated discs identified using MRI have

no compressing value. Overestimation of the MRI data leads to wasted surgeries when pseudoradicular brachialgias can be eliminated by puncture treatment methods. It is hard to imagine that none of 76 patients with degenerative lesions of the cervical spine operated on by the authors was diagnosed with reflex algesic syndromes. Clinical characteristics of patients subjected to surgery should not be limited to the statement "mainly manifested as radiculopathy".

Radicular pain in the arm must subside completely after the surgery. Its persistence in most cases is indicative of inadequate root decompression (or of reflex brachialgia). In order to evaluate the postoperative residual radicular pain it is inappropriate to use the word "regression" (decrease). It is obvious that even partial decompression of the root reduces the radicular pain. Repeated MRI should be performed to find the cause of residual radicular pain. It is better to open the wound and eliminate the compressing substrate than to subsequently reoperate a patient with postoperative scars.

A.A. Lutsyk – Professor, Head of the Neurosurgery Department of the Novokuznetsk State Institute of Postgraduate Medical Studies