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Cage Subsidence after Surgery on the Anterior Part of the Subaxial Cervical Spine: a Monocentric Prospective Clinical Study with a 3-Year Follow-Up

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Abstract

Background. The choice of an implant for vertebra body defect replacement in corpectomy for traumatic lesions remains a point of discussion among spinal surgeons. Nanostructured carbon cages are promising for use in spinal surgery. ***The purpose*** of this study was to determine the rate and degree of cage subsidence in the patients with traumatic lesions of the cervical spine undergone a single-level anterior corpectomy in the subaxial part of the cervical spine with reconstruction using a carbon or titanium cage. ***Materials and Methods.*** A prospective study included 47 patients undergone a single-level corpectomy of the cervical spine due to traumatic injury. Two groups were formed by adaptive randomization: group I with the patients with carbon cages (n = 23), and group II with the patients with titanium cages (n = 24). The evaluation of cages subsidence and stability was carried by X-rays and CT before and after surgery. The quality of life before and after the surgery was evaluated using NDI and VAS questionnaires. ***Results.*** According to the questionnaires, the absolute majority of the patients in both groups showed a statistically significant improvement of quality of life in the postoperative period (p<0.01). The first signs of implant subsidence were noted 3 months after surgery in group II. There were none of such cases in group I. The final result of the subsidence at the end of the follow-up comprised: for group I 0.6±0.4 mm, for group II 3.1±1.4 mm (p = 0.023). In group II, the bone block between bone tissue and the cage was recorded in 30% of patients (p = 0.037), in group I, the bone block was not formed. At the same time, according to the functional X-ray data, there were no signs of carbon cages instability in group I. None of the patients in groups I and II required revision surgery due to complications associated with cages placement. ***Conclusion.*** The outcomes of carbon nanostructure cages placement as body-replacing implants in the cervical spine were not inferior to the outcomes of titanium mesh cages using. In group I, the carbon cages subsidence was significantly lower than in group II with titanium cages. The bone block was not formed in the case of carbon cages. It is worth noting that the carbon structure of the cages allowed the radiological diagnostics of the operated segment without artifacts formation.

Keywords: cervical spine injury, carbon cage, titanium mesh cages.

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Introduction

The main approach in the treatment of unstable injuries of the cervical spine is the surgical stabilization of the affected spine segment with additional decompression of the neural structures, if necessary [1]. Ventral cervical corpectomy with reconstruction of the anterior spine is a common and effective method for treating diseases of the cervical spine, including trauma [2, 3]. One of the main indications for ventral cervical corpectomy employment is compression lesion of the vertebral bodies. Ventral cervical corpectomy makes it possible the direct decompression of the spinal cord and subsequent the spine stabilization with one or another type of an implant. The anterior approach is low-traumatic. It not only provides the decompression, but also ensures the reduction of the facet joints in the event of their dislocation, as well as restoration of the cervical spine lordosis [4, 5]. At the same time, the problem of maintaining the structural integrity of the cervical spine after corpectomy remains unsolved [6].

Most often, bone grafts or interbody cages are used to form a bone block. Both iliac crest autografts and allografts are used as bone grafts. The use of autografts is associated with a large number of complications in the postoperative period, such as pain and fractures in the area of the donor bed, infection of the graft collection area, pseudoarthrosis, displacement of the graft, its fracture or deformation [7]. However, the literature shows a significantly higher degree of bone block formation and a lower rate of the collapse in the patients with an autograft than in the patients with an allograft [8, 9]. In order to reduce the risk of postoperative complications, various interbody cages have been developed to improve the stability of the anterior column, avoid complications in the area of donor sites, improve biocompatibility, and reduce the number of complications associated with the implants used [10]. However, all the proposed implants have one or another disadvantage. This determines the need to continue the search in this area [11, 12].

Since the late 1980s repeated attempts were made to use carbon implants in spinal surgery, including for the replacement of vertebral bodies [13, 14, 15]. Since 2012, a new impetus to the use of carbon-based implants has been given by the launch of a plant for the production of nanostructured carbon (NSC) cages in Russia. Since 2015 to the present, a multi-center study on the use of NSC implants in clinical practice has been carrying out on the basis of several large Russian clinics [2].

*The purpose o*f this study was to determine the rate and degree of cage subsidence in patients with traumatic injuries of the cervical spine undergone a single-level anterior corpectomy and reconstruction with a carbon or titanium cage in the subaxial part of the cervical spine.

Materials and Methods

The study design

A monocentric prospective randomized study of the patients undergone the single-level corpectomy of the cervical spine for traumatic injury from 2014 to 2016 was conducted. For all patients, the surgery was performed by two leading surgeons of the department. The study was approved by the local ethics committee. In total, the study included 47 patients divided into two groups: group I included the patients undergone the NSC cages placement, group II — the patients undergone the standard mesh titanium cages placement. Distribution into the groups was carried out by adaptive randomization.

Inclusion criteria:

– injury type A according to AOSpine classification;

– injury at the level of C3 to C7 vertebrae;

– isolated lesion of one vertebra body.

Traumatic lesions of the subaxial part of the cervical spine were assessed in accordance with the AOSpine classification. The study included patients with type A injury (Fig. 1).

Most of the patients had no neurological deficits in the preoperative period. This corresponded to the E value according to the Frankel classification (Fig. 2).

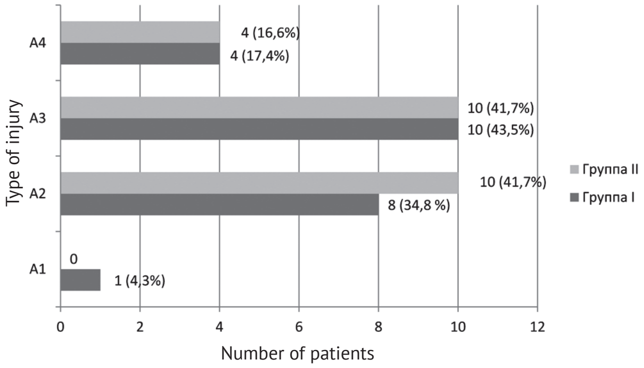

Fig. 1. Patient distribution by AOSpine classification.

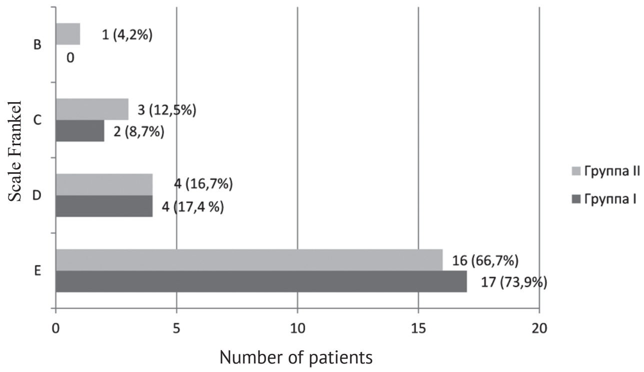

Fig. 2. Frankel scale patient distribution.

One or another degree of neurological deficit was recorded in 6 patients in group I and in 8 patients in group II.

Outcomes assessment

Quality of life was evaluated before and after surgery using the NDI and VAS questionnaires. Cage subsidence and stability were evaluated at the control time based on X-ray and CT data before and after surgery. Subsidence was recorded if the decrease in the height of the operated segment during the last radiological examination was 2 mm or more compared with the results on the day of the surgery, or when the penetration of the cage into the endplate of the vertebral body was evident.

Surgical technique

In all cases, the autografts from the resected vertebral body were placed inside the cage before placement. In case of NSC autografts employment, the autografts were laid along the cage. All patients underwent additional stabilization of the spine with titanium plates.

Statistical analysis

The statistical data are presented as arithmetic mean ± standard deviation for continuous data and as a percentage for categorical variables. The threshold of statistical significance corresponded to $p<0.05$. The independent t-test, paired t-test and χ^2, and Statistica 12 software (StatSoft, USA) were used. The equality of dispersions was checked using the Fisher test. The normal distribution was checked by Kolmogorov-Smirnov test.

Results

Of the 47 patients included in the study, the majority were males (31 men, 16 women). The NSC cages were placed in 23 patients (group I), the mesh titanium cages — in 24 (group II). The study design is shown in Figure 3.

The comparative analysis of the groups did not reveal any statistically significant differences in gender, age, body mass index, and bone mineral density (Table 1). The most common cause of injury was road traffic accidents (83% in group I and 79% in group II). Moreover, in both groups of the patients, the lower cervical vertebrae C6 and C7 were most often affected (74% in group I and 75% in group II) (Fig. 4).

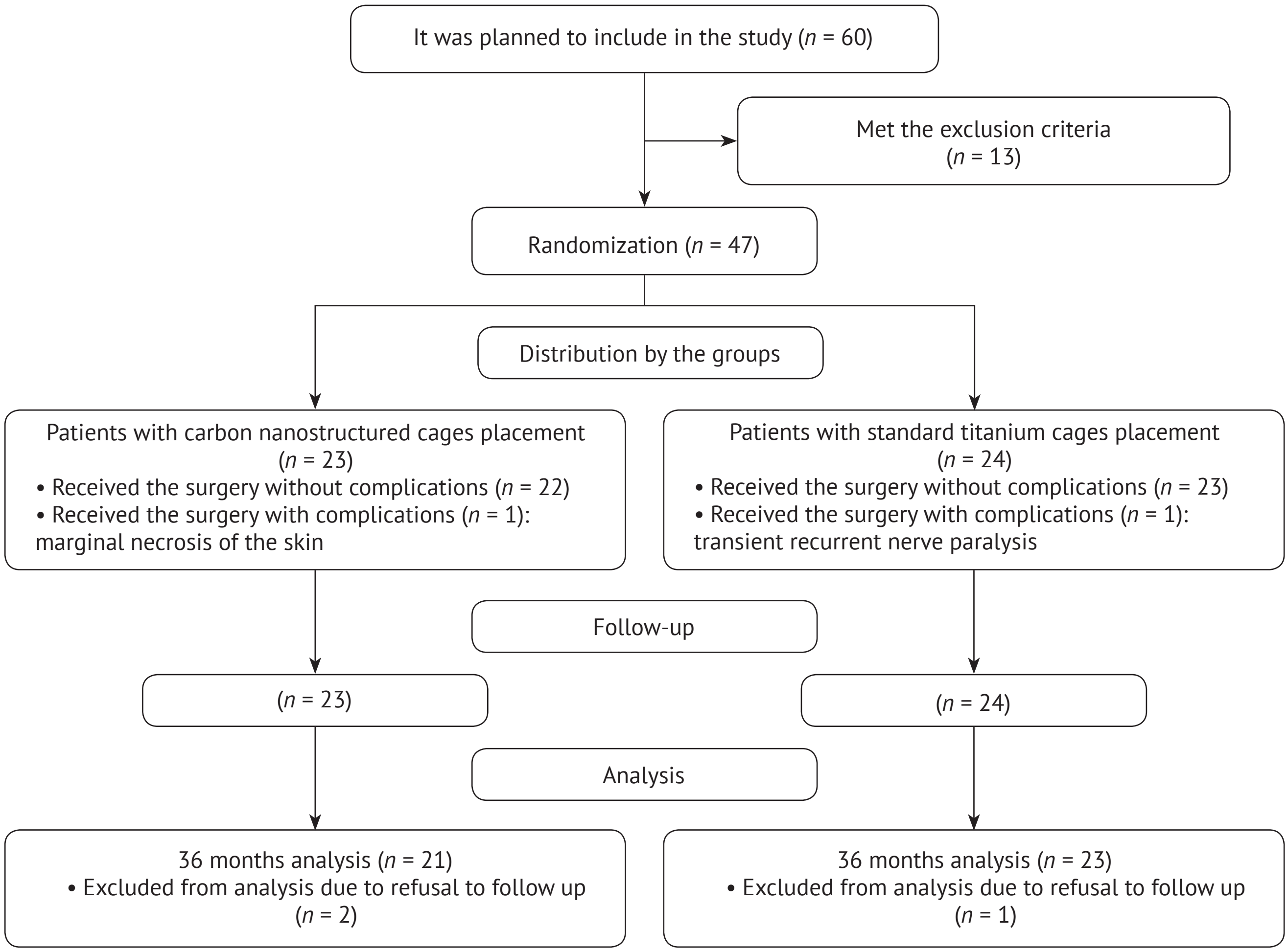

Fig. 3. Flowchart of the study.

Table 1

Characteristics of the patients in both groups

Indicator	Group I	Group II	p
Mean age, years	45.5±10.7	41.5±8.7	0.976
Gender:			
M	14	17	0.324
F	9	7	–
Body mass index, kg/m^2	24.7±8.9	26.1±7.5	0.577
Bone mineral density, g/cm^2	0.853±0.119	0.879±0.132	0.634
Follow-up period, months	42.4±8.3	44.7±10.8	0.412

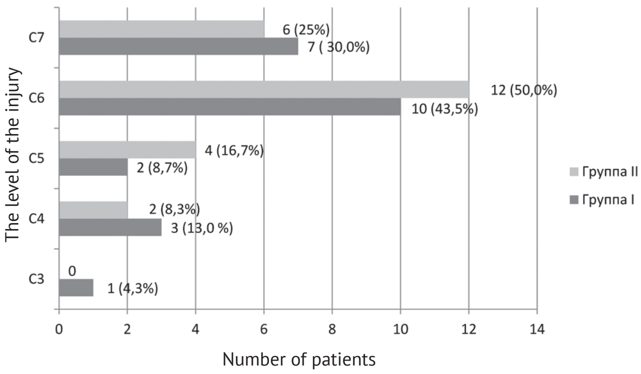

Fig. 4. Levels of vertebrae lesions in the groups.

Fig. 5. Patient, 34 y. o., group II, CT scan after 3.5 months after the surgery surgery, the first signs of implant subsidence.

According to questionnaires, the absolute majority of patients in both groups in the postoperative period showed a statistically significant improvement of their quality of life (p<0.01) (Table 2).

The first signs of implant subsidence were noted in 3 months after surgery in group II (Fig. 5).

The final result of subsidence at 3 years follow-up after the surgery was 0.6±0.4 mm in group I, and 3.1±1.4 mm in group II (p = 0.023). 43.5% of patients of group I had no signs of subsidence, while in group II this percentage was 79.3% (p = 0.008) (Fig. 6).

In group I, the formation of a bone block between the bone tissue and the NSC cage was recorded only in 2 patients, which is significantly less than in group II, where a reliable bone block was formed in 7 patients (p = 0.037) (Fig. 7).

Fig. 6. Patient, 39 y. o., group I, 12 months after the surgery. The position of the carbon cage is stable, there are no signs of resorption and subsidence.

Table 2

Quality of life of the patients in groups I and II according to the results of questionnaires before and after surgery

Group	Questionnaire	Before the surgery	In 3 years after the surgery
I	NDI	55.6±21.3%	24.5±14.7%
	VAS	8.1±1.1	3.2±1.3
II	NDI	57.7±31.1%	26.5±15.3%
	VAS	7.9±1.6	3.3±1.5

p<0,001.

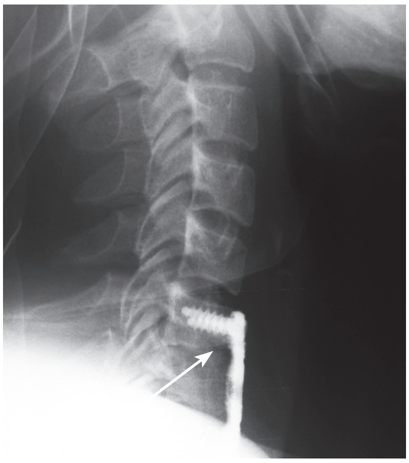

Fig. 7. Patient, 39 y.o., group I, 1.5 years after surgery. The position of the carbon cage is stable without the signs of resorption and subsidence. Also there are no signs of bone block formation, a gap can be traced between the vertebral body and the carbon rod (marked by arrow).

In the patients with NSC cages, the functional X-rays showed no instability of the cage, which can be interpreted as the development of a fibrous block between the patient's tissues and the cage.

Complications

None of the patients in groups I and II required revision surgery due to complications associated with cage placement. One patient from group I developed marginal necrosis of the skin in the postoperative period. But this complication did not require any additional interventions. One patient from group II had the transient recurrent nerve paralysis, manifested by a hoarse voice, followed by complete recovery.

Discussion

The number of cervical spine injuries requiring surgical intervention has not decreased. So, the issue of choosing an implant to replace the vertebral body defects remains important [16, 17]. Most of the of the cervical spine injuries in adults occur in the subaxial spine, with more than 50% — in the C5 to C7 segments [18]. The same trend can be traced in our study. Despite the ongoing debate about surgical approaches, the anterior approach is often the main in the treatment of subaxial injuries of the cervical spine [19, 20, 21] due to its low-traumatic nature, the ability to restore lordosis, reposition the facet joints, and the possibility of adequate decompression.

Despite the fact that the autograft provides the maximum rate of bone block formation and a lower frequency of subsidence, most surgeons prefer not to use this option for defect replacement due to the high risk of potential complications from both the donor site and the graft itself [22]. In this regard, the use of autologous grafts has largely been replaced by polyetheretherketone and titanium cages.

Back in 2005, it was suggested that the overall cage subsidence of more than 4 mm was clinically significant [23]. However, there is no convincing evidence in the literature on the correlation between the degree of subsidence and clinical manifestations. Studying this issue for new implants is important for understanding the risks of complications of employment in the long-term follow-up.

In our study, the NSC cages showed significantly less subsidence compared with titanium cages. The mean subsidence in the NSC implant group (0.6 mm) was comparable to the results of the study published in 2010 that reported the similar data [24]. We also observed a tendency to an increase in subsidence in elderly patients, which was consistent with literature data and correlated with a decrease in the quality and density of the spinal bone in the elderly [25].

The results of our study demonstrated the absence of a correlation between the degree of subsidence and the risk of complications requiring revision. And this was despite the fact that for the most cases the cause of revision was clinically manifested pseudarthrosis [10].

Study limitations

First of all, it is the sample size, which is relatively small for each group. Also, an increase in fixation levels rises the risk of subsidence and pseudarthrosis with an increase in the number of revision surgeries [25, 26, 27], while our study included the patients with one level of fixation.

NSC cages subsidence occurs statistically less frequently than titanium implants. The same is true for the degree of subsidence in the patients with NSC cages which is also significantly less than in the patients with titanium cages (p = 0.023). No bone block is formed with the employment of NSC implants. The carbon nature of the cages makes it possible to conduct the radiological diagnostics of the operated segment without artifacts. The use of NSC cages as body replacement implants in the cervical spine has shown outcomes that are not inferior to those of titanium mesh cages.

To assess the long-term results for more than five years, further research is needed, including multicenter, which will allow a more detailed study of the possibilities of using NSC cages.

Publication Ethics

The patients gave a voluntary informed consent for the participation in this clinical study and publication of its results.

Conflict of interest: The authors declare no conflict of interest.

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Authors' contribution

S.V. Kolesov — research concept and design, data interpretation and analysis, editing.

A.I. Kazmin — coordination of the study participants, data interpretation and analysis, data statistical processing, text preparation.

I.V. Skorina — collection and processing of the material, research conduction, text preparation.

V.V. Shvets — research concept and design, data interpretation and analysis, editing.

M.L. Sazhnev — collection and processing of the material, research conduction, text preparation.

A.A. Panteleev — collection and processing of the material, research conduction, text preparation.

V.S. Pereverzev — collection and processing of the material, research conduction, text preparation.

D.A. Kolbovski — data statistical processing and analysis, text preparation.

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