ANTERIOR LOWER CERVICAL INTERBODY FUSION WITH POROUS BIOCERAMIC IMPLANT*

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Objective. To analyze the results of the anterior spinal fusion with an interbody implant made of nanostructured porous alumina ceramic in patients with degenerative diseases of the spine.

Material and Methods. Clinical trial included surgical treatment of three patients aged 28—46 years with cervical intervertebral disc disease and severe pain in the neck and upper extremity. The developed porous bioceramic implant was installed into the lower cervical spine through classical anterior approach. The follow-up examination was carried out 3, 6 and 12 months after operation.

Results. Patients had a regression of pain in the early postoperative period due to adequate decompression and stabilization at the level of affected spinal segment. Sagittal size of the spinal canal at this level increased from 9.2 ± 0.3 mm to 10.1 ± 0.8 mm. Pain in the neck and arm disappeared completely in two patients after three months and in one patient after six months. The final follow-up showed the full motion recovery and the absence of sensitivity disorders.

Conclusion. The use of porous ceramic interbody fixator allows maintaining relationships in the spinal segment for the entire period of bone block formation. It is advisable to use fixing devices made of this material, which does not produce MRI artifacts, for adequate assessment of spinal cord structures.

Key Words: bioceramics, nanostructure, spinal fusion, osseointegration.

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Anterior approach to the spinal cord decompression and stabilization of the cervical spine was first proposed by Leroy and Abott (USA) and the first operation was performed by surgeons Bailey and Badgley in 1952 [7]. In the 1960s, the anterior approach to the treatment of traumatic, degenerative, neoplastic, and infectious lesions of the cervical spine became widely used in North America and Western Europe owing to the works by Smith and Robinson [32], Cloward [9], and Verbeist [36]. In our country, this approach was promoted and developed by A.A. Lutsik [1], Ya.L. Tsivyan [4], and G.S. Yumashev [6]. In patients with degenerative diseases of the spine with replacement of one intervertebral disc, the share of successful operations is quite high and amounts to 74–98%. Despite this fact, transplant migration and development of pseudarthrosis is observed in 2.1–4.6% of cases [17]. Moreover, longer fusion in associated with increased probability of nonunion [39]. Therefore, the search for materials that are approved for medical use, inert, sufficiently porous, strong, and demonstrate significant osseointegration properties and production of implants made of these materials to perform the anterior fusion is still relevant.

The objective of this study is to analyze the results of the use of an interbody implant made of nanostructured porous alumina ceramic after the anterior spinal fusion in patients with degenerative diseases of the spine.

Materials and methods

In 2013–2014, 3 patients (2 males and 1 female) aged 28–46 years (37.4 ± 10.5) suffering from intervertebral cervical osteochondrosis with severe pain in the neck and upper limb underwent surgical treatment at Novosibirsk Research Institute of Traumatology and Orthopedics (RITO) as a part of clinical trial. All patients had varying degrees of reduction of strength and sensitivity due to unilateral compression of spinal roots caused by a herniated disc and spinal canal stenosis. C5–C6 segment was involved in two cases, and C6–C7 segment was involved in in one case. There were pronounced manifestations of unilateral compression-ischemic radiculopathy.

The functional capacity of patients was assessed using NDI questionnaire [37]. In the preoperative period, patients underwent complex clinical and X-ray examination, MRI, and MSCT. Interbody distance, sagittal diameter of the vertebral canal (mm), and Cobb's angle at the level of the spinal segment in degrees were measured. Bone tissue of adjacent vertebral bodies, condition of intervertebral discs, epidural, subdural, and cerebrospinal fluid spaces, dura mater and tissue of the spinal cord, and spinal roots were qualitatively assessed by MRI. MSCT provided assessment of the presence or absence of osseointegration between the implant and the bone bed. Radiographs of the cervical spine performed in flexion and extension positions were used to measure angular relationship at the level of fusion. We used the in-house developed porous bioceramic implant. [5]

This new material has been obtained by solid-phase synthesis of the alumina ceramics. This technology enabled producing interbody fixator made of this material with continuous porosity of the structure (porous permeability) in the range of 15–25%. Pore size distribution was as follows: below 100 μm – not more than 10%; 100 to 300 μm – 75%; higher than 300 μm – not more than 15%. Compression strength of the interbody fixator along the longitudinal axis without fracture and residual strain is not less than 50 MPa. Interbody fixator design provides resistance to shock loads, such as single strike of 0.05–0.15 kJ. We obtained new results related to producing ceramic non-resorbable matrix of interbody fixator, whose porous structure is adaptive to osseogenesis processes and mechanical properties reach the level sufficient for intraoperative manipulations and withstanding the load during formation of bone-ceramic block [2, 3]. The material is non-toxic under application conditions in accordance with the Russian State Standard (RSS, GOST) R ISO 10993. The design of the interbody fixator for the effective spinal fusion includes appropriate dimension, shape, and wedge. There is notching on the side surface to eliminate migration. In the central part, there is a hole used to place biological or synthetic bone-plastic material, which facilitates formation of the vertebral segment blocking.

Operations were performed using the conventional anterior approach to the lower cervical spine. The level of affected disk was determined and the disk was then incised along with hyaline plates. The posterior portion of the fibrous ring and the intervertebral hernia, which was in all cases represented by a sequestered fragment of the fibrotic portion of the nucleus pulposus, was removed in the traction position. Endplates of adjacent vertebrae were removed with bone file until the pinpoint bleeding, and the optimal size of interbody fixator was chosen using templates. In extension and traction position, interbody fixator with bone substitute Chronos, which was the same in all cases, was inserted into the formed bed. Distraction and extension were eliminated and interbody fixator was tightly fixed in the interbody space. The wound was closed. Control examination was conducted 3, 6, and 12 months after the surgery.

Results

Clinical outcomes of the treatment were evaluated 13.2 ± 1.8 months after operations along with interim control examinations in 3 and 6 months. It should be noted that significant regressed of pain syndrome was observed in all patients in the early postoperative period due adequate decompression and stabilization at the affected spinal segment. Sagittal diameter of the spinal canal at this level increased from 9.2 ± 0.3 mm (before surgery) to 10.1 ± 0.8 mm (end of follow-up), the average increase was 2.0 ± 0.52 mm. Pain in the neck and arm completely disappeared after 3 months in 2 patients and after 6 months in 1 patient, and complete recovery of mobility with no sensory disorders was observed. Quality of imaging of the spinal cord, spinal roots, dura matter, and the spinal cord itself was high due to the absence of artifacts (Fig. 1). The height of the interbody space, where interbody fixator was inserted, increased from 3.8 ± 0.5 to 7.8 ± 0.9 mm after surgery and amounted to 5.1 ± 1.5 mm in one year. Before the surgery, all patients had kyphosis at the level of the affected vertebral segment of 0.3 ± 0.3 mm, which was eliminated to -6.0 ± 2.0 mm in the postoperative period, and -2.0 ± 1.4 lordosis by the end of follow-up. According to CT, in 2 cases, there was somewhat greater subsidence of interbody fixator into the inferior bodies, and minor subsidence into the superior adjacent vertebral bodies by 1.2 ± 0.3 mm. Bone condensation at the contact points of the ceramic implant with the vertebral body was observed in all patients without instability signs, but with osseointegration signs (Fig. 2). Functional radiographs of the cervical spine showed no instability at the level of the operation on the spine. In 1 patient, MRI showed increased intensity of signal from the

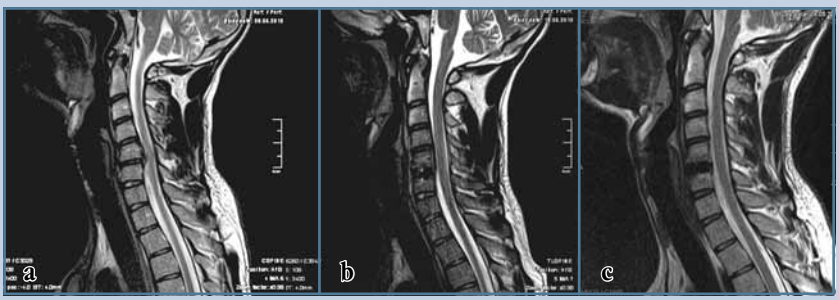

Fig. 1
MRI of the cervical spine of patient K., 28 years old, with C5–C6 herniated disc before surgery **(a)**, two days **(b)**, and 1 year **(c)** after surgery

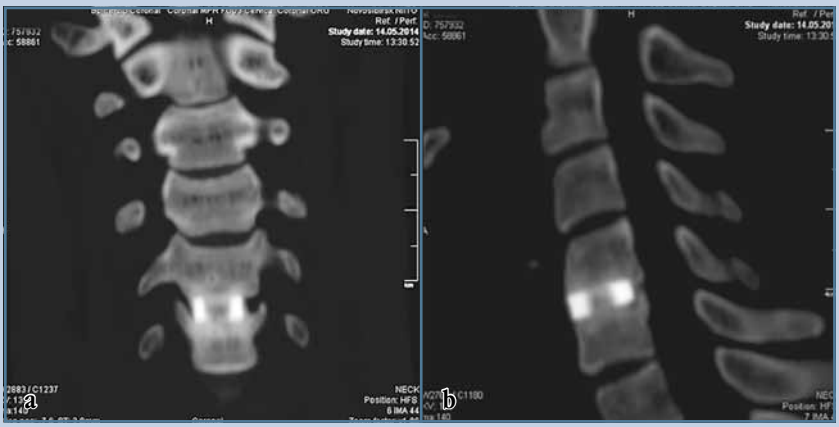

Fig. 2
MSCT of patient K., 28 years old, 1 year after surgery: **a** – frontal reconstruction, **b** – sagittal reconstruction

bodies adjacent to the interbody fixator in the early postoperative period and for up to 6 months with a tendency to decrease. This patient demonstrated complete clinical recovery. In all cases, Neck Disability Index (NDI) indicated recovery and reached the value of 22.0 ± 12.7 (initial value was 65.3 ± 19.2).

Discussion

Intraoperative disc removal eventually leads to instability. Decompression with excision of the posterior longitudinal ligament leads to increased instability of the spinal segment. Furthermore, the latter increases exponentially with the number of removed disks. This determines the need for stabilization by spinal fusion, which includes replenishment of the interbody space and firm fixation of the ventral column using interbody implants (grafts) and plates [23, 30, 31, 33]. Researchers believe that stabilization reaches its full strength only 6 months after the interbody fusion. The first month is the most important period. When only bone is used as a graft, postoperative immobilization with a firm collar is required [25, 29, 39]. Despite the reliability of the internal fixation, external immobilization is required [39]. Duration of immobilization are related to the consolidation of the graft with bed. Notably, quite reliable bone block is formed in 3 months, although it is believed that 8–12 months are required for full consolidation. [38]. When plates are used, normal duration of wearing firm collar is 8–12 weeks. Later on, wearing of soft collar is recommended during 1 month. Six months after the surgery, complete physical activity can be allowed. Of course, particular surgical situation, the nature of the operation, X-ray data, and activity of the patient should be taken into account [28, 31].

In the literature, there are reports that breaking of screws fixing the plate were detected by X-ray examination of patients, but there were no clinical manifestations. However, the notable fact is that bone autografts, allografts, or synthetic bone substitutes were used as a material for plastic repair of defects of a body or interbody space [13, 14]. This is primarily due to the fact that structural adjustments reduce the strength of bone grafts, thereby reducing their ability to withstand the vertical load [11, 15, 16, 19, 25-27, 34]. It is also important that immunological incompatibility of biological tissues with recipient's body is possible [24, 35]. As a result, the need to increase the support ability after the anterior spinal fusion has been solved owing to the development and use of hollow implants made of metal (mainly titanium alloys), porous metal implants (tantalic and titanous), and plastic derivatives allowed for medical use [10, 18] . Many of them have low osseointegrative properties and fracture ability [8, 21, 22]. Hollow implants must always be used with bone grafts or synthetic bone substitutes, otherwise there is resorption at the contact with the bed, loss in the height of interbody space and instability. The use of autologous bone is believed to be the gold standard [12, 18, 39].

In most cases, the observed failure of the anterior fixation is due to initial technical errors in the anterior spinal fusion and misunderstanding of the extent and type of fixation from the standpoint of biomechanics and bone strength. The development of bioceramic implants having high osseointegrative properties and high strength is a particular focus in surgery of diseases and injuries of the cervical spine [3, 4, 20]. Porous bioceramics, in particular aluminum oxide one, is a material having required properties for the manufacture of implants that can be used in stabilizing operations of the cervical spine. The strength characteristics of such material are due to its nanostructure, while the shape of implants, matching the anatomy of interbody intervals, ensures tight contact with the bone during installation and thereafter, allowing high axial loads at this point. The desired through-porosity of 30% with a pore size of 100-700 nm, as well as the properties of the material itself, contribute to high implant osseointegration with the bone bed [2, 3].

The use of implants made of porous nanostructured ceramics in patients with degenerative diseases of the spine, who underwent the removal of disc herniation and anterior spinal fusion, led to complete clinical recovery during the postoperative period and one-year-long follow-up, restoration of social activity and work capacity. Radiodiagnosis methods (x-ray radiography, MRI, and MSCT) showed stability of the spinal segments that underwent surgery with osseointegration of bioceramic implant and bone bed with no signs of instability. Radiation survey methods also provided reliable assessment of the CSF and epidural

space, dura mater, and spinal cord itself. This is possible due to the properties of the material constituting the implant: it does not cause interference distorting the obtained images, which allows one to study the implant itself, bone tissue, liquid media, as well as soft and nervous tissue.

Conclusion

In the context of evaluation of long-term results, the use of porous ceramic interbody fixator preserves the relationships in the segment for the entire period of block formation. Furthermore, it is advisable to use fixing structure made of this material, which does not cause artifacts on MRI, for adequate assessment of the spinal cord structures. It should be kept in mind that the best results of surgical treatment of degenerative diseases of cervical spinal segments can be obtained based on not only the use of some design and correct installation of interbody implant, but also an adequate decompression, elimination of all kinds of displacement and instability, and restoring the axis of the segment.

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