DECOMPRESSION AND STABILIZATION SURGERY USING CUSTOM-MADE 3D PRINTED CAGES

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The paper describes a method for three-dimensional printing of custom-made interbody cages accounting for biomechanical parameters of the intervertebral disc (anteroposterior size, anterior and posterior disc heights), which provides the implant with unique characteristics. An example of using custom-made cages providing optimal conditions for the formation of interbody bone-metal block due to the extra tight fit of the combined implant is given. It is shown that custom-made cages have a beneficial effect on the spine support recovery time, significantly reduce the surgical injury, and shorten the time of surgery. The manufacturing of each developed implant which has its own form and architecture is not a serial but a piece production not requiring additional registration procedure. The use of custom-made spinal cages allows optimizing the process of surgical treatment and improving short- and medium-term results.
Key Words: interbody fusion, bone-metal block, custom-made cage.

Please cite this paper as: *Peleganchuk AV, Bazlov VA, Krutko AV. Decompression and stabilization surgery using custom-made 3D printed cages. Hir. Pozvonoc. 2018;15(1):65–70. In Russian.*
DOI: http://dx.doi.org/10.14531/ss2018.1.65-70.

The main objective of surgical treatment of patients with degenerative diseases of the spine is to reduce back pain and arrest radicular symptoms by performing decompression and eliminating the instability of the vertebral segments. Simultaneous transpedicular and interbody fixation enables correction of displacement and fast and high-quality formation of bone-metal block, which leads to significantly better clinical outcomes. Titanium implants (cages) used for interbody fusion serve also as a container for bone-plastic material. In the daily practice, various types and sizes of the cages are used to match the required parameters. The large range of these products allows us to address various issues. However, the required size is not always available to a surgeon, and the standard cage cannot fully match individual parameters of an individual patient [13].

The problem is resolved by the use of custom-made cages, manufactured in full adherence to the unique parameters of a particular patient using a 3D printing technology.

In 1986, Carl Deckard invented a method of selective laser sintering. The essence of the method lies in the layer-by-layer sintering of the powder material by a laser beam. The powder is heated up almost to the melting point in the build chamber. After that, the material is leveled, and the laser beam draws the necessary contour on its surface. When the beam touches the powder, it heats up to the melting point and is sintered. After this, a new layer of powder is poured into the chamber, and the sintering process is repeated. Cycles of adding material, its leveling and sintering are carried out according to a predetermined scheme until a finished model with a rough porous structure is formed on the chamber's working table. The finished product is taken out of the printer, and the excess powder is removed.

In medicine, this technique has found application in manufacture of custom-made implants, the first of which were installed in Germany in 2000. The technology has been available on the Russian market since 2007 but become widespread only in 2014 with the manufacture of customized plates for cranioplasty. At the moment, the modeling and printing of customized implants have become almost routine practice for large medical centers.

This technology is successfully used in Novosibirsk RITO for endoprosthetics of the hip, knee joints, cranioplasty and surgical interventions to close the defects of the scapula. The use of custom-made cages for interbody fusion enable early restoration of the support capacity of the spinal column, the best possible stable fixation, and creation of optimal conditions for formation of an interbody bone-metal fusion. All this is achieved through the extremely tight fit of the custom-made combined implant. It is important to note that this method can reduce the traumatic nature of surgical intervention and shorten the surgery time.

The aim of the study was to demonstrate the advantages of a custom-made

cage made using the 3D-printing method by a clinical example.

Material and Methods

Custom-made interbody cages were created using three-dimensional printing in several stages. This was caused by the need to take into account the biomechanical parameters of the intervertebral disc (anteroposterior size, anterior and posterior disc height), which provide the implant with the unique characteristics.

The first stage included MSCT carried out with a layer thickness of 0.5 mm (2.0 ± 0.9 mSv). The data obtained in the form of a series of DICOM files was converted into a 3D model of the spinal motion segments using specialized software. Then, the length of the future product and the anterior and posterior height of the intervertebral disc were determined. The result is a 3D model of the implant with specific dimensions in millimeters. The resulting virtual model was used to adapt the implant attachment points to the cortical layer of the vertebral body, to modify its shape, and to correct the congruence of the implant components and bone surfaces. After the completion of 3D modeling of the implant, the model was saved in the format required for CAD/CAM production.

The next step was the manufacturing of the implant on the 3D printer «EOS M 290» using the SLS-printing method (selective laser sintering; Fig. 1) [2]. The particles of powdery material (EMI titanium, authorized for implantation by an ISO certification system) were sintered by carbon dioxide laser beam by layer-by-layer tracing of the digital model. After completion of the sintering of a layer, the working platform was lowered, and a new layer of material was applied. The process was repeated until a volumetric model of the given object was produced [1].

After the manufacture of the cages (Fig. 2), they were implanted into a patient.

Clinical example

Patient O., 60 years old, was admitted with complains of pain in the lumbar spine with irradiation into her left leg. She was forced to make frequent stops while walking due to the growing weakness in her legs and pain in her right leg along the outer surface, up to the foot. In patient word, the pain in the lumbar spine first appeared three years ago, the condition worsened 6 months ago. A week before the admission, she started to experience pain in the leg. Conservative treatment was ineffective.

Orthopedic status at admission.

Smoothed lumbar lordosis, symmetrical tension of paravertebral muscles, tenderness in the lower lumbar spine during palpation of interstitial spaces and paravertebral points. Tendon reflexes from the hands of average vivacity, D = S, from the legs of low vivacity. Abdominal reflexes are sluggish. No pathological reflexes were identified. Muscle tone is unchanged. There are no pareses. There are no sensory disorders. Slight disequilibrium in Romberg's test. Lacega symptom on the left is 60°. The function of the pelvic organs is normal.

Data of examinations (interpreted).

MRI of the lumbar spine reveals multiple degenerative changes in the lumbar region, posterior-medial hernia of L4–L5 disc, posterior medial hernia of L5-S1 disc with right-side lateralization, causing right-side lateral stenosis of the spinal canal; circular protrusions of L1–L2, L2–L3, L3–L4 discs; degenerative polysegmentary stenosis of the spinal canal; 2nd degree spondylarthrosis; foraminal stenosis of L2–L3, L3–L4, L4–L5, L5–S1 on both sides (Fig. 3).

The following results were obtained for assessment of the intensity of pain syndrome according to VAS: back pain – 8 points, leg pain – 7 points. Oswestry questionnaire ability score – 78 points.

Diagnosis: extensive degenerative changes in the lumbar spine, degenerative stenosis at L4–L5, L5–S1 levels; disruption of the sagittal balance; syndrome of neurogenic intermittent claudication.

The patient underwent L4, L5 laminectomy, microsurgical decompression of the spinal cord roots, transpedicular fixation with the Legacy system at L4–L5, L5-S1 levels, transforaminal interbody fusion with custom-made implants at L4–L5, L5–S1 levels.

Surgery technique. A linear dissection of soft tissues was made along the line of spinous processes at L3-S1 level. The arches and the interarches spaces at L4–L5–S1 levels were isolated on both sides. Transpedicular «Legacy» screws with a length of 50 mm and a diameter of 6.5 mm were inserted into the bodies of L4, L5, S1 vertebrae through the corresponding pedicles under the control of the image intensifier. Control using the image intensifier showed the correct position of screws.

Bilateral laminectomy at L4, L5 level and total facetectomy at L4–L5, L5–S1 levels were conducted under magnification of 2.2–4.4.

It was discovered that the roots and dural sac were compressed by hypertrophied yellow ligament and the articular couple. Bilateral decompression of the roots of the spinal cord was performed. The compression was eliminated, the roots were straightened and lied down freely, a distinct pulsation of the dural sac appeared.

The L5 root on the right was displaced medially, and L4–L5 discectomy was performed on the left. Following the discectomy, the bilateral transforaminal L4–L5 interbody fusion was performed with implants of 11 x 25 mm in size with a lordosis angle of 8°; on the left with ReproBone, on the right with autologous bone. The free interbody space was filled with fragments of autologous bone.

The S1 root on the right was displaced medially, and L5–S1 discectomy was performed on the left. Following the discectomy, the bilateral transforaminal interbody fusion was performed with implants of 8 x 25 mm in size with a lordosis angle of 8°; on the left with ReproBone, on the right with autologous bone. The free interbody space was filled with fragments of autologous bone.

With the help of flexion of the surgical table and contraction of the screws, lordosis of the operated segment was set up and a transpedicular fixation system was mounted. Image-intensifier control estimated the position of implants as correct (Fig. 4).

Fig. 1
3D printer «EOS M 290» (Germany)

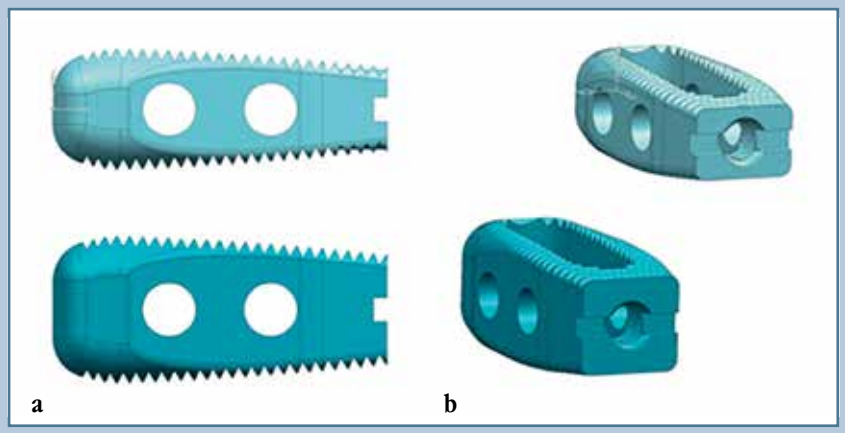

Fig. 2
Interbody implants: **a** – side view; **b** – 3/4 view

The wound was washed with 1 liter of saline solution, tubular drainage was installed and connected to a system for active drainage of the wound, the wound was sutured layerwise and an aseptic bandage was applied. The blood loss was 100 ml.

Post-surgery diagnosis: extensive degenerative changes in the lumbar spine, degenerative stenosis at L4–L5, L5–S1 levels; disruption of the sagittal balance; syndrome of neurogenic intermittent claudication.

As a result of the operation, the radicular symptoms were reversed. The patient was discharged under the supervision of a neurologist at the place of residence for further treatment. The following results were obtained for assessment of the intensity of pain syndrome according to VAS at the time of discharge: back pain – 4 points, leg pain – 0 points. The follow-up visit is scheduled 3.6 months after the surgery and the patient will be evaluated using the Oswestry questionnaire.

Results and Discussion

Indications for interbody fusion include spondylolisthesis, degenerative disease of the lumbar spine with discogenic pain syndrome, recurrences of herniated disc, secondary stenosis of the spinal canal, deformity of the spine, etc. [3]. Currently, the choice of more or less effective methods of surgical correction of these pathologies of the spine is quite wide. It includes decompression, stabilization, decompression and stabilization, and decompression and plasty surgeries [4, 9, 10]. Interbody fusion is most effective in combination with transpedicular fixation [11]. Titanium implants used for interbody fusion serve also as a container for bone-plastic material.

According to the literature [3, 7], the proportion of successful bone adhesions for interbody fusion reaches 96 %. The high percentage of successful bone adhesions is due to the fact that grafts are placed in an area that takes 80 % of the vertebral segment load and occupies 90% of the bone surface between the vertebrae, has the best blood supply and contains a large number of cellular elements with osteogenic potential. The bone graft located in the zone with optimal conditions and under load is rebuilt faster, which leads to good clinical outcomes [3, 8, 12].

Sufficient area of contact with the plastic material and sufficient volume of the material of the graft ensure a successful fusion. That is, the implants should be the best possible fit for all parameters of the vertebrae of the operated segment, as well as for the intervertebral height [3, 5, 6]. However, it is not always possible to achieve full matching, moreover, at present there is a shortage of serial interbody implants with a height of more than 14 mm.

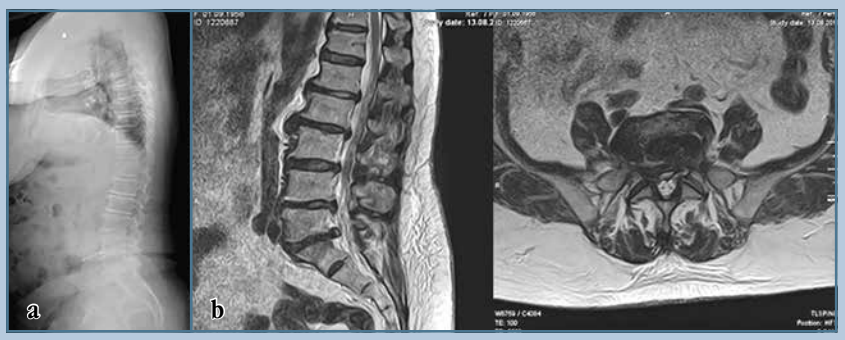

Fig. 3
X-Rays **(a)** and MRI **(b)** of the lumbar spine of patient O., 60 years, prior to surgical treatment

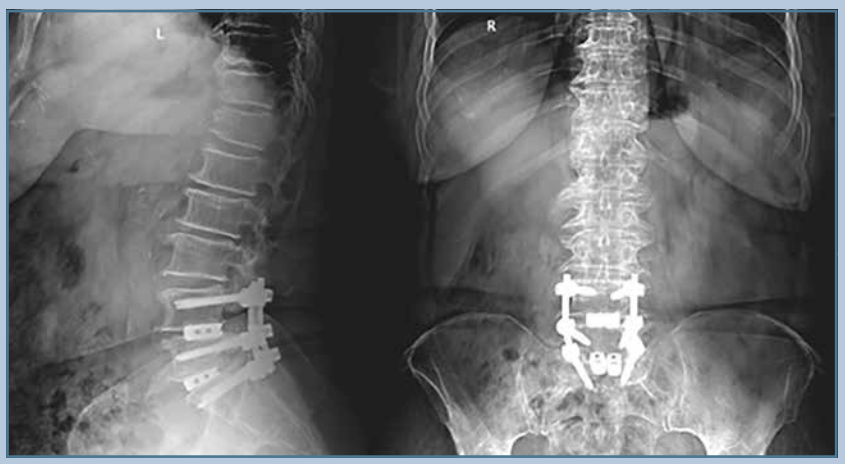

Fig. 4
Interbody fusion with custom-made cages and transpedicular system

The main advantage of 3D-printed cages is their ability to account for individual patient parameters. All necessary biomechanical parameters are calculated during the modeling of implants at the preoperative stage with a minimum error. Taking into account the individual anatomical parameters of a patient makes it possible to create optimal conditions for the formation of the interbody bone-metal block due to the particularly tight fit of the combined implant, which shortens the time for recovery of supportive capacity and formation of the bone-metal block.

In other words, metal construct is customized individually for a patient. The interbody implant is manufactured with the required height (including more than 14 mm), width, and the angle of the lordotic inclination. The use of 3D-printing technology removes the need to model an implant bed during the surgery, and therefore, it provides better supporting ability and a bone-metal block is formed more quickly. Thus, this method significantly reduces the traumatic nature of surgical intervention, shortens the surgery time, reduces the proportion of failed bone-metal blocks and the likelihood of repeated revision surgery due to poor fit of the implants to the geometric parameters of the intervertebral disc.

The prompt restoration of the supporting capacity of the anterior and posterior columns of the spine in the operated segments provides an opportunity for early activation of the patient and initiation of rehabilitation measures. The cost of the implant itself also decreases. In addition, the manufacturing of each developed implant which has its own form and architecture is not a serial but a piece production not requiring additional registration procedure.

The early outcomes achieved in the clinical case can be considered good, since the performed decompression and stabilization surgery on the spine relieved the patient from radicular pain in the legs by significantly reducing the pain syndrome in the lumbar spine. The patient is socially adapted, does not require additional care. Further outpatient rehabilitation treatment is planned.

Conclusion

The use of custom-made cages allows to optimize the process of surgical treatment and improve the short-term outcomes. The availability of equipment and technologies for 3D printing is currently insufficient but given the present pace of development of the medical equipment industry, the situation is likely to change in the nearest future. The practice of selecting the appropriate type of implants will be replaced by an individual approach to each patient. However, further observations are required to obtain reliable long-term results of treatment with custom-made cages.

The study did not have sponsorship. The authors declare no conflict of interest.

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Received 07.12.2017
Review completed 24.01.2018
Passed for printing 25.01.2018

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