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INTERBODY CERVICAL CAGE IMPLANTATION INTO CADAVERIC MODEL OF THE RAM SPINE: BIOMECHANICAL TESTS

O.A. Spirin[1], A.G. Aganesov[1], M.M. Aleksanyan[1], S.A. Makarov[1], N.G. Sedush[2], A.E. Krupnin[2], V.V. Pobezhimov[2]
[1]Russian Scientific Center of Surgery n.a. acad. B.V. Petrovsky, Moscow, Russia;
[2]National Research Center "Kurchatov Institute", Moscow, Russia

Objective. To evaluate the biomechanical properties of biodegradable poly-L-lactide cages on a cadaveric model of the cattle cervical spine.

Material and Methods. Prototypes of interbody cervical implants were developed on the Ender 3v2 3D printer. The mechanical characteristics of experimental cage specimens were evaluated, and the orientation of the specimens during 3D-printing was investigated. Single-level cervical discectomy with fixation by a cage made of poly-L-lactide was performed in 12 cadaveric models. Biomechanical tests of the operated vertebral segment were carried out under cyclic loading conditions.

Results. In this type of testing, the developed cervical cage models demonstrated high deformation stability under compression load, and the absence of deformation and migration in static and cyclic tests.

Conclusion. The development of biocompatible biodegradable cervical cages is a promising direction in medicine. Given the high rate of postoperative complications associated with migration and subsidence of cages made of non-resorbable materials, biodegradable implants may become a competitive analog for cervical segment fixation.

Keywords: cervical discectomy; cervical cage; cadaveric model; biomechanical testing.

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The choice of material for subsequent fixation of the cervical cage after anterior cervical discectomy is a topical issue in the global medical community. Bone autografts, rigid cervical plates with screw fixation, and interbody cages have become the most widely used devices in surgical practice. The main complications associated with this fixation technique are plate migration, screw migration, plate fractures, autograft dislocation, hematomas, and suppuration at the graft area [1–4]. Instrumentation (screws, plates) migrates in 1.3%–15.0% of patients, and bone grafts become displaced in 0.2%–21.0% [5]. According to a meta-analysis of studies on cervical segment fixation with cages made of non-biodegradable materials (titanium, PEEK), the frequency of bone block formation was 46%–100% for titanium cages and 76%–100% for PEEK cages, and the incidence of cage subsidence was 16%–35% and 0%–28%, respectively [6]. According to other authors, interbody bone block was found in 94.3%–100% of patients, and interbody cage subsidence was found in 0%–10% of patients [7]. The inconsistency of the obtained results and the high complications rate have been a driving force behind the development of technology for the production of bioresorbable materials [8, 9]. Thus, for example, biocompatible porous composite scaffolds made of polylactide/β-tricalcium phosphate (PLA/β-TCP) can be used to repair osteochondral defects [10]. In the study by Laubach et al. [11], the results of tests on biodegradable cages made from different lactide polymers are reported. The materials chosen for fabrication were poly-L-lactide and a copolymer, poly(L-lactide-co-D, L-lactide). The cages were implanted in large artiodactyls *in vivo.* The authors report complete bioresorption of the implanted cage after 2 years and bone block formation after 4 years following surgery. The issue of evaluating the stability of cages *ex vivo* remains topical. Laboratory practice using universal testing machines provides an opportunity to simulate various types of mechanical stress on the spine segment of a cadaver spine model. The study by Teunissen et al. [12] presented the placement of titanium cages in the lumbar spine after discectomy. Cadaveric dog models were used as research material. Spinal segments before and after discectomy were placed in a four-point bending device (flexion–extension, lateral flexion, and torsion). According to the authors, implantation of titanium cages without plates (stand-alone cages) recovers the stability of the spinal segment to a condition similar to a non-operated spinal segment. Currently, there are no articles in the literature on ex vivo biomechanical testing of biodegradable cervical cages.

Material and Methods

Twelve cadaver models of the sheep cervical spine were collected for the study. All models underwent preoperative CT imaging (Fig. 1) to evaluate the intervertebral space. The distance was evaluated in the frontal and sagittal planes, with dimensions ranging from 2.5 to 5.0 mm.

Prototypes of neck cages were produced on an Ender 3v2 3D printer based on preliminary templates and pre-calculated settings. The dimensional

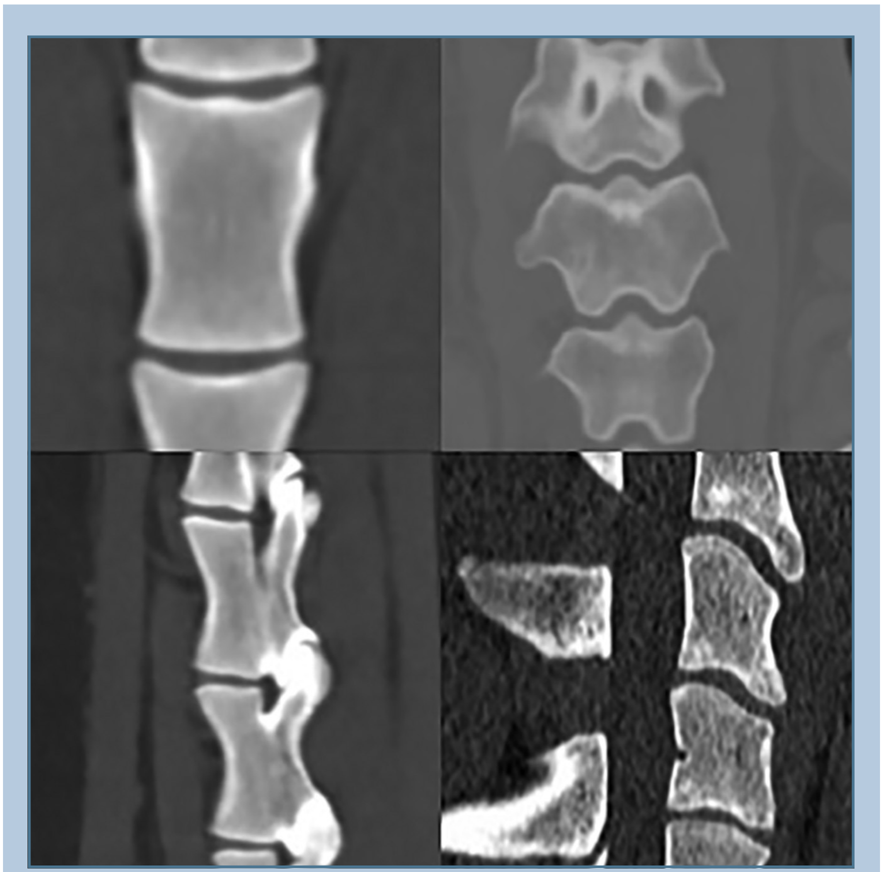

Fig. 1
Preoperative CT scan

range of cervical cage prototypes varied as follows: 2.0–5.5 mm in height, 5.24–14.4 mm in width, and 4.93–13.57 mm in length (Fig. 2, Table).

The prototypes of the cages were cut using PrusaSlicer 2.7.1 software. The samples were produced from polylactide-L-lactide filament (Fig. 3).

The mechanical properties of the experimental cage samples were assessed on an INSTRON5982 testing machine at a temperature of 37 °C.

Compression tests were performed between parallel plates at a constant deformation rate of 50% per minute. Additionally, the effect of sample positioning during 3D printing on mechanical properties was studied (Fig. 4).

After production of the device, subtotal resection of the intervertebral disc was performed on 12 models (Fig. 5a). Disc curettage was performed using conchotomes and Kerrison forceps, then the disc space was measured, and experimental samples of cervical cages were placed (Fig. 5b, c).

The mechanical properties of the experimental cage samples were assessed on an INSTRON5965 testing machine at a temperature of 23°C and a constant deformation rate of 5 mm/min (Fig. 6a). Static and cyclic tests (10 cycles) were done under a compression force of 300 N.

Results

No matter how the items were placed on the printing table, the samples showed plastic properties under compression without breaking within the specified deformation range. For samples with layers oriented parallel to the printing table, the yield strength FT was 4.5 kN, after which hardening was noted. Samples with layers oriented perpendicular to the printing table revealed lower rigidity (slope of the straight section on the curve) but higher yield strength: *Ft* = 5.5 kN. Moreover, the section of softening induced by the bending of

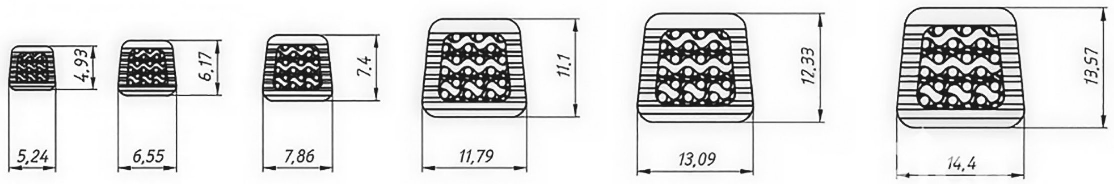

Fig. 2
Size rage of cervical cage prototypes

Table

3D printing parameters for experimental cage samples

Parameters	Cages with a height of 2.0; 2.5; 3.0 mm	Cages with a height of 4.5; 5.0; 5.5 mm
Nozzle temperature, °C	200	200
Temperature of the printing table, °C	70	70
Filling density, %	100	100
Print speed, mm/s	40	60
Layer height, mm	0.15	0.2

Fig. 3
Cervical cage prototype

individual layers and the loss of their stability was registered on the diagram (Fig. 7). The compression load settings for each series of prototypes are established at the point at which undesirable plastic deformation develops.

The obtained readings were greater than the physiological compression load acting on the human cervical spine, equal to 736 N [13–15].

Fig. 6b illustrates the load-deformation curves obtained from the test results. Hysteresis in cyclic tests is related to the viscoelastic characteristics of intervertebral discs and is not associated with the material qualities of the product. If a force of 300 N was reached, there were significant dislocations of up to 10 mm in the spinal segment, unusual for real biomechanical movement systems. The developed cage models exhibited high resistance to deformation under compression loads and showed no deformation or migration in static and cyclic tests. As natural limitations of the used biomechanical system included low force values associated with significant dislocation and deformation of intervertebral discs, as well as changes in the properties of living tissues *ex vivo*, cyclic (10 cycles) tests were performed in accordance with ASTMF2077 standard on an INSTRON 5965 universal testing machine at a temperature of 23 °C and a constant deformation rate of 1 mm/min (Fig. 8). The loading was done up to a force of 5000 N (500 kg) with preliminary cycling for each sample in the range from 1000 to 2000 N, from 2000 to 3000 N, and from 3000 to 4000 N, respectively.

The samples with layers perpendicular to the printing table showed lower rigidity but higher yield strength (Ft = 5.5 kN). Therefore, compression load values are determined for the devices produced in each series, once undesirable plastic deformation develops in the test sample. The obtained readings are several times higher than the physiological compression load on the human cervical spine. The cages, which are 5 mm high, 7.86 mm wide, and 7.4 mm long, showed optimal rigidity and stability in the spinal segment. There is almost no hysteresis at the assigned amplitude load values, indicating high resistance to deformation of the developed cervical items (Fig. 8).

Conclusion

The items demonstrate plastic properties and no destruction irrespective of their positioning on the printing table. The compressive load parameters used in this test are not typical for biomechanical systems and substantially surpass the compressive load encountered by the human cervical spine. This illustrates the cages' exceptional resistance to migration and deformation in both static and cyclic testing conditions.

The designed and tested *ex vivo* cervical cage models can possibly be used as alternatives to non-biodegradable metal fixators and cages, which would presumably reduce the number of postoperative complications outlined above owing to the plastic properties and biodegradable component of poly-L-lactide cag-

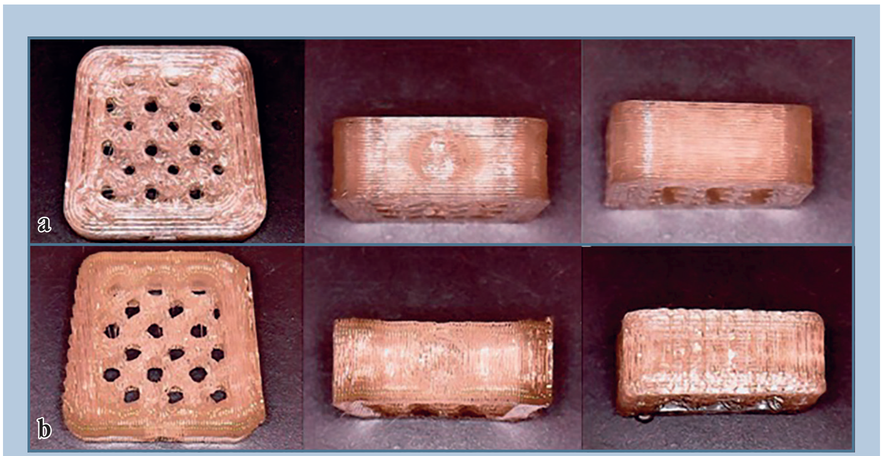

Fig. 4
Experimental cage samples: **a** – with layer orientation parallel to the printing table (as built); **b** – with layer orientation perpendicular to the printing table (transverse)

Fig. 5
Segment after subtotal discectomy **(a)**, placed cage, lateral view **(b)**, placed cage, front view **(c)**

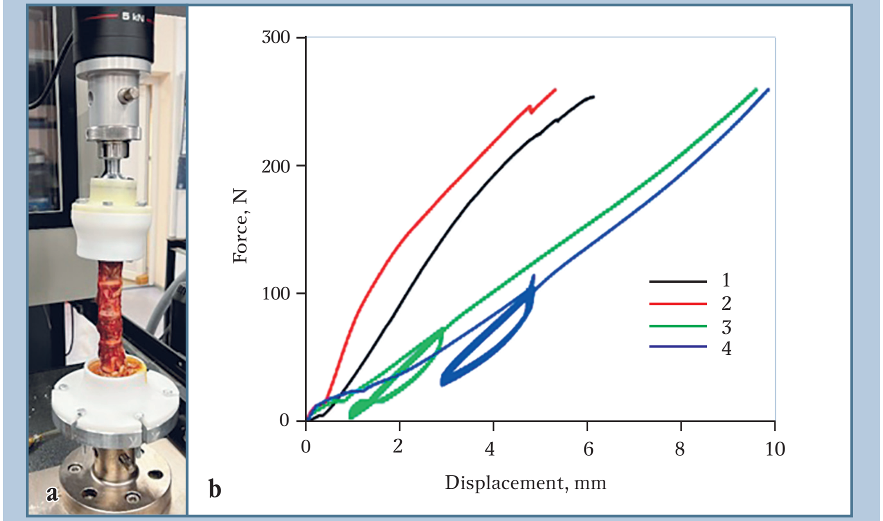

Fig. 6
Biomechanical tests of a 5 mm thick cage: a – spinal segment with an implanted cage and assembled equipment; b – deformation curves: *1* – spinal segment without a cage, *2* – static loading of a spinal segment with an implanted cage, *3* – cyclic (in the range of 20–80 N) tests of a spinal segment with an implanted cage, *4* – cyclic (in the range of 40–120 N) tests of a spinal segment with an implanted cage

es. Subsequently, it is planned to assess the mechanical, biocompatible, and bioresorbable properties of the placed implants.

The study was conducted partly within the framework of a state assignment for the National Research Center "Kurchatov Institute" (involving the design and 3D printing of the cage prototypes) and partly under an agreement between the National Research Center "Kurchatov Institute" and the Russian Scientific Center of Surgery n.a. acad. B.V. Petrovsky (involving the preparation of cadaveric models and testing).
The authors declare that they have no conflict of interest. The study was approved by the local ethics committee of the institution.
All authors contributed significantly to the research and preparation of the article, read and approved the final version before publication.

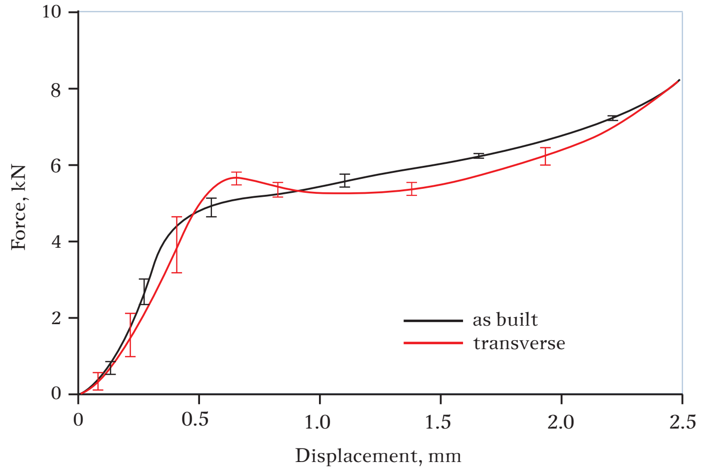

Fig. 7
Deformation curves of experimental cage samples

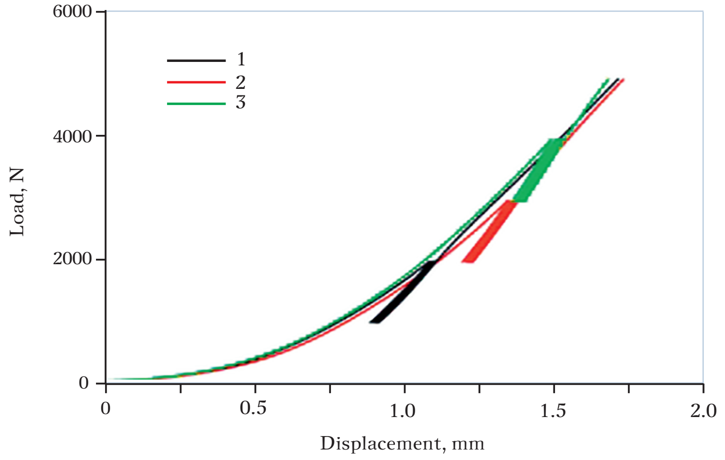

Fig. 8
Results of mechanical tests with preliminary cycling of cage structures

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Address correspondence to:

Spirin Oleg Artyomovich,
Russian Scientific Center of Surgery n.a. Acad. B.V. Petrovsky,
2 Abrikosovsky Pereulok, Moscow, 119991, Russia,
spirinoleg94@gmail.com

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Oleg Artemovich Spirin, junior researcher of the Spine Surgery Department, Russian Scientific Center of Surgery n.a. Acad. B.V. Petrovsky, 2 Abrikosovsky Pereulok, Moscow, 119991, Russia, eLibrary SPIN: 2168-6039, ORCID: 0000-0002-3243-4327, spirinoleg94@gmail.com;
Alexander Georgyevich Aganesov, DMSc, Prof., Chief of the Spine Surgery Department, Russian Scientific Center of Surgery n.a. Acad. B.V. Petrovsky, 2 Abrikosovsky Pereulok, Moscow, 119991, Russia, eLibrary SPIN: 1805-5790, ORCID: 0000-0001-8823-5004, aaganesov@gmail.com;
Mark Mikaelovich Aleksanyan, MD, PhD, senior researcher of the Spine Surgery Department, Russian Scientific Center of Surgery n.a. Acad. B.V. Petrovsky, 2 Abrikosovsky Pereulok, Moscow, 119991, Russia, eLibrary SPIN: 3477-2860, ORCID: 0000-0003-1321-086X, Alexanyanmm@gmail.com;
Sergei Aleksandrovich Makarov, researcher of the Spine Surgery Department, Russian Scientific Center of Surgery n.a. Acad. B.V. Petrovsky, 2 Abrikosovsky Pereulok, Moscow, 119991, Russia, eLibrary SPIN: 2010-9879, ORCID: 0000-0001-7237-240X, makarov.spine@gmail.com;
Nikita Gennadyevich Sedush, PhD in Physics and Mathematics, Head of the Laboratory of Polymeric Materials, National Research Center "Kurchatov Institute", 1 Akademika Kurchatova Square, Moscow, 123182, Russia, ORCID: 0000-0002-6744-7662, Sedush_NG@nrcki.ru;
Arthur Evgenyevich Krupnin, junior researcher of the Laboratory of Polymeric Materials, Acting Head of the Resource Center for Additive and Virtual Technologies, National Research Center "Kurchatov Institute", 1 Akademika Kurchatova Square, Moscow, 123182, Russia, ORCID: 0000-0002-5674-4143, artkrupnin@gmail.com;
Vsevolod Vasilyevich Pobezhimov, research assistant of the Resource Center for Additive and Virtual Technologies, National Research Center "Kurchatov Institute", 1 Akademika Kurchatova Square, Moscow, 123182, Russia, eLibrary SPIN: 9760-4662, ORCID: 0009-0003-6326-2382, usemvladeyu@mail.ru.