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Research Article

Application of Biologically Integrated Titanium Cages of Unique Design for Transforaminal Fusion in Patients with Degenerative Diseases of the Spine

Renat Nurmukhametov*

Head of Spinal Department at Scientific Clinical Center #2 of Russian scientific center of surgery named after B.V. Petrovskiy, Head of spinal clinical base at Neurosurgery Department RUDN, Russia

***Corresponding Author:** Renat Nurmukhametov, Head of Spinal Department at Scientific Clinical Center #2 of Russian scientific center of surgery named after B.V. Petrovskiy, Head of spinal clinical base at Neurosurgery Department RUDN, Russia.

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Abstract

This publication discusses aspects of the possibilities of improving technologies and materials for transforaminal spinal fusion in patients with degenerative diseases of the spine. The technology of surgical treatment of patients with degenerative diseases of the spine's intervertebral discs using biologically integrated titanium cages of unique design based on computer 3D modeling has been proposed and experimentally tested.

Objective: To compare the radiological and clinical results of posterior interbody fusion of the lumbar spine using a porous 3D titanium alloy cage and a titanium-coated PEEK cage. Study characteristics: a randomized, prospective, interventional, double-blind, single-blind, single-center, post-marketing study conducted to assess the difference infusion rate and the difference compared to PEEK cages. The experiment involved 80 patients, 40 in the Study Group and 40 in the Control Group with degenerative-dystrophic diseases of the lumbar spine, who underwent surgery using the technique of posterior transforaminal fusion with transpedicular fixation at the operating levels. Research methods: assessment by computed tomography (CT), Oswestry questionnaire (every 3, 6 months), and evaluation by visual analog scales (VAS), if necessary - clinical neurological examination. Results of the study: patients of two groups show comparable late (from 6 months - 1 year after surgery) results of fusion and the degree of cage subsidence. In the Study Group: migrations, screw instability - 0; the number of reoperations for adjacent segment syndrome - 2; back pain at a minimal level. According to CT data from 3-6 months after the operation - the screws are stable, the incisors of the cages are cut into the endplates, sclerosis of the endplates around the cage. In the control group: migration of the cage into the spinal canal with screw instability - 1; instability of screws without migration, but with the formation of pseudoarthrosis - 1; adjacent segment syndrome - 2; a number of revisions - 4. Conclusions: the effectiveness of the technology for treating patients with degenerative diseases of the spine/or instability of the spinal motion segments with elements of neural compression using biologically integrated titanium cages of unique design based on computer 3D has been confirmed, which makes it possible to use a new method of spinal fusion in practice, allowing restore the local sagittal balance of the spinal motion segment, reduce the incidence of pseudarthrosis and, as a consequence, the frequency of revision surgery.

Keywords: Degenerative Diseases of the Spine; Titanium Cages; Transforaminal Fusion; Custom Design Cages; Biologically Integrable Titanium Cages; Custom Design of Computer 3D Modeling

Introduction

The heterogeneity of degenerative lesions of the spine and the polymorphism of clinical and pathomorphological manifestations predetermine the need to develop and test promising methods and tools aimed at ensuring early and long-term results based on the principles of reliable fusion and complex clinical and morphological compliance.

In current conditions, to eliminate pathological conditions of the spine, the technique of transforaminal fusion is actively used using structures made of various materials, including titanium alloys [1-3], many of these materials belong to the class of materials with a shape memory effect [4,5].

Inter-body fusion is performed using a structural-holistic graft. The main task is to bear the load on the spine, the distribution of axial stresses that fall on the operated segment of the spine. The solution to such problems can be provided with the use of special implants called cages (from the English. cage-cell). The cages are installed from the anterior or posterior surgical access to the operating segment of the spine. The use of fusion technologies using cages provides good results in restoring and maintaining the standard height of the intervertebral disc, or close to it [6], thereby contributing to the patient's normal functioning. The implant at the optimum should form a mechanical support and grow into the surrounding tissues, thereby demonstrating a significant level of integrative qualities. Such qualities are provided through the use of unique materials for the manufacture of cages - namely, porous and plastic compounds that can build up an intermediate layer of tissue between the bone and cartilage structures and, in fact, the implant.

The main problem in applying the methodology for eliminating pathological spine conditions using various fixation structures, including cages, is implant migration, which in clinical spine surgery ranges from 1 to 5% [7]. The use of cages in practice is often combined with other difficulties, including the problem of fusion with body tissues, biomechanical conflict between the cage and the adjacent vertebra.

To prevent cage migration, it is necessary to develop the geometry of the fixation elements and improve the case's design, which is functionally oriented towards facilitating the formation of spinal fusion and maintaining the axial load.

As a result, the task of surgical treatment of degenerative diseases of the spine is localized both in terms of the choice of cage material and the correct design of their design. Based on the synthesis of advanced domestic and foreign experience, it seems appropriate to expand the range of research on the possibilities of using biologically integrated titanium cages of individual design for the stated purposes, with the development of the latter based on the results of 3D modeling, including with competing technologies, including PEEK (polyether ether ketone)., Russian poly ether ether ketone.

This publication presents the results of an empirical study of a promising technology for transforaminal fusion in patients with degenerative diseases of the spine using biologically integrated titanium cages of an unique design based on 3D computer modeling.

Literature Review

In modern medical practice, interbody fusion using a titanium cage in combination with transpedicular fixation is recognized as an effective solution for eliminating spinal instability [8, 9, 10]. Technologically, cages are special closable structures consisting of an upper and lower aperture and an internal cavity (to be filled with bone chips or a replacement material) forming a titanium frame.

For the treatment of spinal injuries, as well as for stabilization during operations for fractures of the vertebral bodies, subsidence of the condyles in case of periarticular fractures, or degenerative-dystrophic diseases, the usual procedure is the replacement of bone and cartilage structures, which, as a rule, is performed using implants (cages) made of various materials [11].

The choice of material for the manufacture of the cage is an important scientific task; this material should promote effective germination, not cause biomechanical conflicts with human tissues, and meet the needs for load and shock absorption. The options for choosing materials for the manufacture of cages for the interbody fusion of the spine are metal, ceramic products, as well as products made of polymer materials [12].

In connection with the complex clinical tasks and the context of the development of medical materials technologies, cages made of composite materials and special alloys, including those with a

shape memory effect, such as titanium and titanium alloys, as well as titanium-coated PEEK, are the most common [13].

These technologies and materials are more consistent with the stated requirements for interbody fusion but may also have disadvantages. In particular, PEEK technologies used in practice still do not fully provide protection against migration, and not in all cases the use of PEEK cages leads to proper indications of integration with tissues [14]. Biointegration performance may be better for porous titanium materials than PEEK [15]. The need to conduct comparative studies of the two technologies is associated with the significantly high cost of PEEK-titanium cages manufactured and imported from foreign countries, limiting the mass practical application in Russian medicine.

The titanium cage design alone does not provide tissue integration; the material used to fill the apertures is often localized and does not form adhesions, which leads to pseudarthrosis [16]. Due to the difference in elastic moduli between the cage (the elastic modulus of titanium is 120 GPa) and the vertebral body (0.75-10 GPa), biomechanical conflicts may occur [17].

The combination of these problems can be successfully solved by biologically integrating the implantable titanium cage and bone, which is ensured by using a porous material made of titanium fibers. This technology provides reliable results in the penetration of the cage into the bone and the formation of shock absorption when the structure is pressed against the bone.

It seems necessary to improve existing technologies to improve the geometry of the structures used and increase their elasticity and shock absorption capacity.

Modern information technologies and related industrial solutions can provide individualization of implant design, thereby eliminating existing shortcomings. Such solutions include 3D modeling and 3D printing technologies [18-20].

As a result, it can be stated that the use of biologically integrated titanium cages of unique design for transforaminal fusion can provide better results in the elimination of pathological conditions of the spine, which, meanwhile, requires additional empirical verification.

Materials and Methods of Research

The author has improved the previously patented edition Implant (a frame made of a metal wire connected by diffusion welding and made in the form of a cylindrical sleeve formed by a spirally wound wire with the subsequent laying of turns along the axis of the sleeve, having a rigidity of 1000 to 5000 N/mm with an average size of open pores from 150 to 600 μm, porosity coefficient 50-60%) [21]. Biologically integrable titanium cages of unique design were developed based on 3D computer modeling with the following technical parameters.

The cages are designed to replace the lost bone and cartilage fragments of the spine, restore the height of the interbody space, and, at the same time, eliminate the instability of the anterior support of the spinal column. They are selfmade titanium implants created based on a unique 3D model of cage placement in the interbody space (Figure 1).

Figure 1: 3D modeling of the implant.

Source: Author's development.

Implants are made from a monolithic titanium frame and an internal porous base (pressed titanium thread) (Figure 2). The rigid part of the cage is a titanium frame, has a bullet-shaped geometric shape. Technological holes for fixing the installation tool are located on the back of the cage and are grooves or threaded holes. The height of the anti-migration teeth on the body of the rigid frame is 1.2-1.5 mm, the thickness of the sidewalls of the rigid frame is 1.2 mm.

Implantation method: posterior interbody fusion (Russian ZMTS, English PLIF/TLIF - posterior/transformational interbody fusion).

Product name: TLIF-cage «Biodynamics.»

Figure 2: Block diagram of the simulated cage.
Source: Author´s development.

The purpose of this empirical study is to compare the radiographic and clinical outcomes of lumbar posterior interbody fusion using a 3D porous titanium alloy cage, and a titanium-coated PEEK cage, including:

- The quality of fusion
- Time of fusion
- Preoperative and postoperative assessments of patients
- The presence, severity, and other characteristics of side effects.

Descriptive (classification) characteristics: a randomized, prospective, interventional, double, single-blind, single-center, post-marketing study conducted to evaluate the difference in the rate of formation of fusion and the difference in comparison with PEEK cages.

The object for comparison: PEEK cages is developed by Stryker (here in after referred to as PEEK cages).

The experiment involved 80 patients, 40 in the study group and 40 in the control group. Both groups included patients with degenerative-dystrophic diseases of the lumbar spine who underwent surgery using the technique of posterior transforaminal fusion with transpedicular fixation at the operating levels (Table 1).

Age, years	Number of patients	%	sex			
			Female	%	Male	%
< 30	6	8%	2	3%	4	18%
30-39	6	8%	4	7%	2	9%
40-49	12	15%	5	9%	7	32%
50-59	19	24%	16	28%	3	14%
60-70	37	46%	31	53%	6	27%
Total	80	100%	58	100%	22	100%

Table 1: Characteristics of study participants.
Source: Compiled by the author.

Men predominate in the able-bodied age groups, except for the older ones, which heavier physical and static loads can explain on the spinal column. In the group represented by patients aged 51-60 years, the ratio of women is significantly higher than that of men (Table 1), and with further aging, the number of female patients increases significantly.

The main part of patients with degenerative-dystrophic diseases of the spine, who underwent surgical intervention, falls on the able-bodied part of society, which undoubtedly emphasizes the relevance of research in the subject area.

According to the above technique, the study group included patients operated on using biologically integrated titanium cages of unique design based on 3D computer modeling.

Inclusion criteria for participants: mature skeleton, compliance with the requirements for the disease, age from 21 to 75 years, absence of complications in the form of obesity (BMI > 40), sensitivity to titanium materials, absence of objective contraindications to surgery, and/or anomalies were affecting the normal bone regeneration process.

The control group included patients who had previously, from 1 to 1.5 years old, undergone surgery with the installation of a cage made of medical plastic (PEEK) of a standardized non-individual design.

The observation period is from 3-6 months after the operation.

Research methods: evaluation by computed tomography (CT), Oswestry questionnaire (every 3, 6 months), and evaluation by visual analog scales (VAS), if necessary, clinical and neurological examination.

The complex of preoperative radiation diagnostics included: survey and functional radiography, multislice computed tomography (MSCT), magnetic resonance imaging (MRI). Multislice computed tomography (MSCT) was performed for all patients of the Study Group to calculate the necessary parameters and manufacture an individual cage.

Recommendations [22] were used to assess bone block. A full-fledged bone block was recognized if there was at least one continuous bone bridge between the vertebral bodies, both through the interbody implant and around it, otherwise the presence of failure of the bone block formation was recognized. In parallel, the state of the fixation system was assessed, in the presence of a bilateral fracture of the longitudinal rods at the same level or a fracture of both screws in at least one vertebra and/or the presence of osteolysis around both screws in at least one vertebra, the presence of instability of the fixation system was recognized.

CT interpretation was used to estimate the time of fusion formation during postoperative follow-up and to identify side changes and migrations in the long term.

The Oswestry questionnaire was used to assess patients' functional activity and quality of life. The version of questionnaire 2.1a (Russian Version of the Oswestry Disability Index) adapted into Russian was used [23]. Interpretation of the results: with an ODI indicator of 0-20%, disability is considered as minimal, with an indicator of 20-40% - as moderate, with an indicator of 40-60% - as pronounced, with an indicator of 60-80% as individualizing and with an indicator of 80-100% as extremely pronounced or exaggerated.

VAS was used to assess the intensity of the pain syndrome. The indicator was considered significant if the score was less than 2 points.

Clinical and neurological examination was additionally performed in the presence of chronic back pain syndrome (provided VAS > 4 points and/or ODI > 30% for at least the last three months); syndrome of intermittent neurogenic claudication; the presence of radicular pain syndrome and sensitivity disorders (any options) in the absence of the effect of conservative therapy; violation of the motor sphere (with muscle strength of 4 or less points).

Research Results

As a result of the study, six months after surgery, the signs of fusion and the degree of cage subsidence were significantly lower in the group using the porous titanium 3D cage than in the group using the PEEK cage (spinal fusion sign, $p = 0.044$; cage subsidence, $p = 0.043$). However, the effectiveness of the operation both 6 months and 1 year after the operation did not differ between the two groups.

Up to one year after surgery, the clinical outcomes discussed with patients were similar between the porous 3D titanium alloy cage and titanium-coated PEEK cage groups. However, the higher incidence and extent of postoperative endplate fusion.

In patients with custom-designed bio integrable titanium cages based on 3D computer, modeling was a remarkable radiological finding.

During the observation period (from 3-6 months after the operation), no cases of migration or instability of screws were detected in the Study Group, while in the control group 1 case of cage migration into the spinal canal with screw instability, 1 case of screw instability without migration was detected, but with the formation of pseudarthrosis (Figure 3).

Figure 3: Proportion of patients with screw instability and cage migration, % of the total number of group participants.
Source: Compiled by the author.

The number of reoperations in patients of the study group for the syndrome of the adjacent segment - 2 units. In patients of the Control Group, 2 cases of the adjacent segment were identified, the number of revisions was 4 units. (Figure 4).

Figure 4: The proportion of patients with reoperations, % of the total number of group participants.
Source: Compiled by the author.

In patients of the Study Group, according to the results of examinations, back pain is identified at a minimum level, in patients of the Control Group for back pain at a minimum level (36 people, 90% of the number of participants in the Group), with the exception of 4 patients who required a second operation.

In patients of both Groups, according to CT data from 3-6 months after surgery, the screws are stable, the cage incisors are cut into the endplates, there is sclerosis of the endplates around the cage.

The results of assessment according to the Oswestry questionnaire (Figure 5) and on the VAS scale (Figure 6) are slightly better in patients of the Study Group, however, statistically significant differences with the indicators for patients from the Control Group were not identified, which indicates the similarity of the results obtained.

The Discussion of the Results

In general, studies indicate a slight improvement in controlled parameters in patients of the Study Group, which allows us to state that the method of eliminating pathological conditions of the spine using biologically integrated titanium cages of unique design based on computer 3D modeling is not inferior and, generally outperforms the standardized non-custom design medical-grade plastic (PEEK) cage technique. Taking into account the high cost and the associated limited use of PEEK technologies, as well as the objective need for import substitution in Russian medicine, based on the results obtained, it can be recommended to actively use a promising technology for eliminating pathological conditions of the spine using biologically integrated titanium cages of unique design based on computer 3D modeling.

Figure 5: The results of the assessment according to the Oswestry questionnaire (average ODI by group), %.
Source: Compiled by the author.

Figure 6: Average group values of the VAS indicator, points.
Source: Compiled by the author.

The technology allows you to control the modulus of elasticity and the integration of implants and maintains the highest degree of biological inertness. In addition, the use of this technology allows you to build up your own newly formed tissue over the implant and simulate the properties of a lost intervertebral disc or vertebral body.

It seems possible to state that the technology of surgical treatment of patients with degenerative diseases of the intervertebral discs of the spine using biologically integrated titanium cages of unique design based on 3D computer modeling will provide scientific and technical results that are the basis for the innovative development of the domestic market of products and services, and the transition to personalized medicine. And health-saving technologies.

Figure 7

Figure 8

Conclusion

Based on the results of the study, the effectiveness of the technology for treating patients with degenerative diseases of the spine/or instability of the spinal motion segments with elements of neural compression using biologically integrated titanium cages of unique design based on computer 3D is confirmed, which allows the use in practice of a new technique of spinal fusion, which allows restoring local sagittal balance spinal motion segment, reduce the incidence of pseudarthrosis and, as a result, the frequency of revision surgery.

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