ASSESSMENT SYSTEM OF DESIGN PARAMETERS AND FUNCTIONALITY OF METAL VERTEBRAL BODY ENDOPROSTHESIS FOR ANTERIOR INTERBODY FUSION

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The article presents the estimates of the parameters of endoprosthesis, which allows to determine the advantages and disadvantages of various implants as systems for reconstruction and stabilization of the spinal motion segment, and creating conditions for bone fusion of vertebrae adjacent to the resected one. The results obtained in studying characteristics of the cages allow their division into 4 groups depending on the combination of features necessary for performing surgeries on the anterior and middle columns of the spine. Based on these data, the authors developed a design of vertical cylindrical telescopic endoprosthesis LAS. The above information increases the possibility of an objective evaluation of the mechanisms of probable postoperative complications and may facilitate the selection of the optimal design, taking into account characteristics of the clinical situation in each particular case.
Key Words: assessment system, anterior arthrodesis, telescopic vertebral body endoprosthesis, structural features, functional characteristics.

Please cite this paper as: *Nekhlopochin AS, Nekhlopochin SN, Shvets AI. Assessment system of design parameters and functionality of metal vertebral body endoprosthesis for anterior interbody fusion. Hir. Pozvonoc. 2016;13(1):13–19. In Russian.*
DOI: http://dx.doi.org/10.14531/ss2016.1.13-19.

At the modern stage of the spinal surgery development, the operations performed using various implantable structures made of bioinert metals or synthetic materials are the most effective method of decompressive, stabilizing, and reconstructive surgery of the anterior and middle weight-bearing columns of the spine [4, 26].

Despite the adequate pathomorphological, biomechanical, and mathematical research aimed at studying the processes occurring in the “implant – vertebral body” system and the determining the impact of the implants on the bone structure of the vertebral bodies, many national and foreign authors give the data concerning the problems associated with implant migration and fragmentation of structures or their components [2, 6]. These complications result in a loss of the achieved intraoperative correction, destabilization of the operated segment, and worsening of neurological deficits caused by compression of the spinal cord, its roots and meninges [8, 10].

The study was aimed at developing the assessment system for design parameters and functionality of the vertebral body implants (VBI) in order to select optimal design of the endoprosthesis during reconstructive surgeries on the spine.

Material and Methods

We analyzed the information available in brochures, abstracts, and reports and describing the design features of 25 types of vertebral implants. Classification of the structural features and functionality of VBIs was suggested.

Results and Discussion

Based on the current literature analysis, we have developed a system of parameters that enables assessing the impact of the design parameters of the functionality of the implants for the reconstruction of the spinal motion segment (SMS).

I. Adaptation and reclination capabilities.

1. Vertical dimension changes.

2. Slope angle of the abutment surfaces (lordotic angles).

II. Stabilizing properties.

1. Construction type.

2. Construction design.

3. Type of cage response to compression load.

III. Creating conditions for bone regenerate formation

1. The volume of the cavity in the construction to be filled:

a) construction design;

b) location of the telescopic mechanism.

2. The structural characteristics of cavity filler:

a) contact area between the filler in cage and vertebral endplates;

б) contact density in the “cage filler – vertebral endplates” system:

– type of cavity filling with the filler;

– variants of location of the functional opening used to add the material after cage installation into the bone defect.

IV. Cage functionality.

V. Weight of the fusion system.

1. Cage weight.

2. Weight of additional stabilizing system (ventral plate or transpedicular system).

Each of these parameters determines the characteristic features of the implant as a whole or its individual components, as well as their constructive, biomechanical, or functional distinctive features.

Notion of adaptive properties of the vertebral body implants (VBI) assumes a possibility of changing the implant`s vertical size. Based on this characteristic, VBIs can be classified as follows: fixed-height monoblock, monoblock with vertical size adjusted during the operation, and telescopic systems.

The disadvantages of fixed-height monoblock include the need for a large set of standard sizes of the implants for adequate repair of the defect between the vertebral bodies adjacent to the resected one [24].

When using the monoblock capable of vertical size adjustment during the operation, it can be difficult of the implant, in case of inaccurate selection of the implant height, the following two situations can occur:

a) the length of the VBI is more than the required size. In this case, there is high strain induced by compression load in the system “metal – vertebral body”, which will accelerate bone resorption processes and increase the risk of implant prolapse (migration) into the vertebral body [4]. In addition, hyperextension of the intervertebral joint capsules at the level subject to stabilization will cause the local pain syndrome [6];

b) the length of the VBI is less than the required size. In this case, an attempt to restore sagittal balance will be ineffective, that is required reclination in this segment will not be reached. The lack of stability in the operated segment will lead to instability of the VBI.

Load distribution imbalance in certain parts of the «cage – vertebral body” system in various functional positions of the operated segment will be intermittent, and this will also cause the destruction of the vertebral endplates and increase the risk of implant migration.

The telescopic systems. Currently, the telescopic systems can be considered as the most effective and sophisticated structures used to restore the anteriorcolumn. They optimize the process of sagittal balance correction, providing metered recovery of the distance between the vertebrae adjacent to the resected one.

Reclination properties are determined by the slope angle of the abutment surfaces (lordotic angles). Bearing surfaces of the side plates are positioned at a certain angle with respect to the implant axis in order to improve adaptation of the VBI edges to the configuration of the vertebral endplates and to achieve the uniform distribution of compressive stress [5]. In the case of anterior fusion at the cervical spine, structures with bearing surface angle from 0 to 7° are required; for the thoracic and lumbar fusion, three slope angle of 0°, 4°, and 6° are required [22, 27]. When choosing the implant, attention should be paid to the presence or absence of lordotic angles.

Stabilizing properties of VBI are determined by the degree of fusion stability achieved using these implants. These characteristics are determined by the type of the structure, configuration of the implant and its end faces, since their structural features determine the magnitude of stress-induced strain in the “metal — bone” system. Moreover, the structure and locations of the telescopic mechanism have a net effect on this characteristic in telescopic systems.

It is known that stabilizing properties of VBI during SMS reconstruction suggest that these structures can be divided into two types.

Type A – the structures designed for reclination at the SMS. Stabilizing properties of these systems are not sufficient to preserve the intraoperative correction of sagittal balance. Additional fixation of the segment with ventral plates or transpedicular systems is required, when using these systems [26].

Type B – the structures that enable SMS stabilization without additional fixation. The advantages of these implants include less traumatic surgery; lower metal content compared to a combination of type A structures with additional stabilizing systems, lower weight, reduced operation time, and reduced cost of the tools required for the operation. These features provide enhanced stabilizing capabilities, using a single approach and a single structure by following the two-in-one principle [20, 29].

Configuration of the structures is of great importance to reduce the magnitude of stress load on the contact area between the implant and vertebral endplates, which is achieved due to increased contact area between the end face of the implant and the bone (Sk) [17]. Not cylindrical but parallelepiped-shaped structures are characterized by larger area [15, 27]. This shape of the implant reduces the likelihood of stress-induced strain in the “implant – bone” system and reduces the risk of structure migration during the postoperative period.

For the same purpose, the end faces of the implants are made plane, with spiked side plates, perforated with holes of different diameters and having additional elements (bridges) [30, 31].

Variant of the implant’s perception of compression load. In terms of response to compression loads, axisymmetric structures (VBR) are more effective and reliable compared to TPS-type systems due to uniform strain distribution. Compression loads in these structures are distributed over the entire cross section of the implant, so that relatively thin-walled structures may withstand rather large compression loads. The thickness of the walls at the structures enables appropriate thread cutting and only depends on its depth. In systems with rack-type load accommodation, deeper notches are required to achieve similar strength and, therefore, the thickness of the implant wall sat the rack zone is higher than in its other areas, which increases amount of metal per VBI. This dependence is more pronounced in case of screw-type load accommodation (TeCorp), that is in the case of local concentrations of stress caused by compression load. E.g., the smaller the area of the load-accommodating element, the greater loads it should withstand to preserve the required length of the telescopic implant in the operating condition.

Thus, there are the following types of compression strain accommodation by the cage structures: using locking screw, rack-type, axisymmetric.

The conditions for bone regenerate formation are among the qualitative criteria of telescopic VBI performance. This feature determines the possibility of creating conditions for bone fusion of the vertebrae and it is determined by the amount of filler placed inside the implant.

The cavity for filler. The amount of filler is determined by the volume of the internal cavity of the VBI [3]. This feature is somewhat affected by the design of the structure and location of its telescopic mechanism. Thus, in parallelepiped-shaped implants (BodyVertEx, TPS, X-tens, X-Mesh), the volume of the inner cavity (Vc) is larger than in cylindrical systems. This configuration increases the contact area between end faces of the implant (Sc) and its filler (Sf) and the vertebral body.

In the telescopic systems for SMS reconstruction, Vc is significantly affected by location and volume of telescopic mechanism, particular parameters determine the internal volume of the limited-size structures. In order to facilitate the analysis of these characteristics, all VBIs were compared to the Mesh construction without extension-type mechanism and Vc having maximum value. The systems with internal extensible mechanism are characterized by the lowest Vc value. Evaluation of VBIs based on the increase it in Vc depending on the location of telescopic mechanism results in the following classification of the structures: Group I – telescopic mechanism is located within the VBI cavity [37]; Group II – telescopic mechanism is located on the outer surface of the body and consists of threaded system, telescopic mechanism is an extra tool – distractor [14, 33]; Group III – VBI body itself is a telescopic mechanism [32]; Group IV – there is no telescopic mechanism [8, 28].

Design characteristics of a cavity being filled. We believe that, when assessing the qualitative characteristics of the vertebral body fusion in the operated segment formed due to implant filler, the following parameters of the structures should be considered: the area and the density of the contact between cage filler and vertebral endplates.

These characteristics of the structures are important as the contact area in the "cage filler –vertebral endplates" system in a certain way affects the supporting ability of the bone regenerate. It is known that formation of bone regenerate within the cage is only possible in the case of dense filling of its internal cavity with filler, and bone fusion between the filler and endplates of adjacent vertebral bodies is possible provided that there is close contact between the filler and endplates. Failure to observe this condition results in formation of bone-fibrous fusion of the vertebrae adjacent to the resected one [19].

The contact area between the cage filler and the vertebral endplates. The optimum configuration of the end faces of the structures should include a rational combination of Sc and Sf with the vertebral bodies, which significantly affects the functionality of the implants [13, 15].

For example, an increasing Sc in VBI with vertebral body enhances the support ability and prevents its migration. However, this results in decreased Sf in the "filler — vertebral body" system, thereby reducing the likelihood of formation of an appropriate bone block and to some extent decreases the VC of the structure.

According to some authors [11, 21], in VBI system of the type I, the contact area between the filler and the vertebral body should account for about 54–59 % of the total end face area of the implant, type II – not less than 80 %.

Contact density in the "cage filler — vertebral endplates" system depends on the type of VBI cavity filling and type of positioning of the functional openings for superinjection of the filler after implant installation into the bone defect.

Various options can be used for cage filling with material, depending on the design of the implant. Type I – no filling is required [18], II – filling prior to installation into the bone defect [16], III – after installation into the bone defect [35, 36], IV – adding the material after installation into the bone defect.

The internal cavity of the cage should contain sufficient amount of material having required density in order to achieve bone fusion between the vertebrae adjacent to the resected one.

The small holes on the side surface of the VBI (Mesh) are to provide vascularization of the filling and initiation of the osteogenesis processes. Their size should enable formation of a certain uniform density of the material, when filling the internal cavity of the structure.

Extension of telescopic VBIs pre-filled with material and installed into the bone defect results in formation of free space between the filler and the vertebral body – a filling defect. Absence of a wall of the implant or its part may be used to add material into the cage [9]. However, location of these openings and their size hinder uniform compaction of the material in the VBI, which is especially pronounced at its poles [25]. Furthermore, some implants have specially designed structural defects on the opposite walls of the body. This configuration of the cage also hinders, and in some cases prohibits dense filling of the structural cavity with the filler.

Depending on the effectiveness of additional filling of the VBI, there are several structural options.

Options of the location of the functional openings for material adding: 1) no openings for additional filling; 2) large openings located on the opposite walls of the carcass; 3) designed functional openings are located at one pole, in the middle third of the structure, or on the two poles.

It is advisable to arrange the openings for adding and compacting the material at the "filler – vertebral body" area after extension of the structure on its two poles.

Design characteristics of both monolithic and telescopic systems define their functionality, which determines classification of the structures into the following groups.

1. Structures with "reconstruction" function. Characteristic features of ADD, Obelisc®,TeCorp, Tellur, X-Mesh, XRL, Xpand, XPAND-R, GIZA, VBR-Actipore, ECD, Hydrolift, Synex System structures limit their effectiveness in creating conditions for bone fusion of the vertebrae due to the small volume of the filler cavity [23, 31, 32, 38]. This can be exemplified by ADD endoprosthesis (Fig. 1b). The cage is convenient to use, requires no additional tools (retractors), however, its telescopic mechanism is located inside the structure, which reduces the volume of the cavity for filling with biomaterial or composite material.

In our view, this group of implants is quite effective as the systems for SMS reconstruction. When using these systems, additional stabilization of the segment with ventral plates or transpedicular systems is required.

2. Structures with "reconstruction + stabilization" function. ADDplus, BodyVertEx, Monolit (Fig. 1c), and Fortify-I implants have a wide range of functional characteristics, because along with reclination functions they also provide additional stabilization of the SMS, i.e. they function both as 1st group structures and ventral plates [7].

3. Structures with "reconstruction + creating conditions for bone block formation". The size of the cavity for filler in the monoblock structures (Mesh) is definitely higher than that in telescopic systems. From this viewpoint, telescopic implants X-tens, Verte-Span (Fig. 1d), VBR, VLIFT are the most close to the mesh structure (Fig. 1a). They function as reconstructor and in certain degree provide the conditions for bone fusion of the vertebrae [9, 34]. These VBIs are used in combination with additional stabilizing systems (ventral plates or transpedicular systems).

4. Structures with "reconstruction of + stabilization + creating conditions for bone block formation". This group of implants efficiently combines technical features that maximize the clinical effectiveness of the anterior interbody fusion. These implants enable reconstruction and stabilization of the operated SMS and formation of supporting bone block owing to significant volumes of filling cavities. It is noteworthy that TPS implant (Fig. 2) provides maximum contact area in the "metal – bone" and "material – bone" systems [12]. Its configuration enables compaction of the material in the area of the contact with the vertebral body after insertion into the bone defect and SMS reconstruction. However, large size of the openings on the side surfaces can complicate the compact filling of the internal cavity with material. It belongs to the systems with rack-type accommodation of compression load.

Based on the analysis of characteristics of cage structures used in the anterior interbody fusion at the cervical spine, the structure of the vertical, cylindrical, telescopic, mesh-type vertebral body endoprosthesis was designed [5] (Fig. 3).

This implant belongs to type B structures (hybrid cages) and it does not require additional SMS stabilization with ventral plates. It has a large volume of the internal cavity for the filler, which makes it similar to the hollow cylindrical mesh-type cages in terms of this characteristic. It is classified as a structure with axisymmetric load accommodation and therefore it has low weight. For the first time, the method of deformational lock-

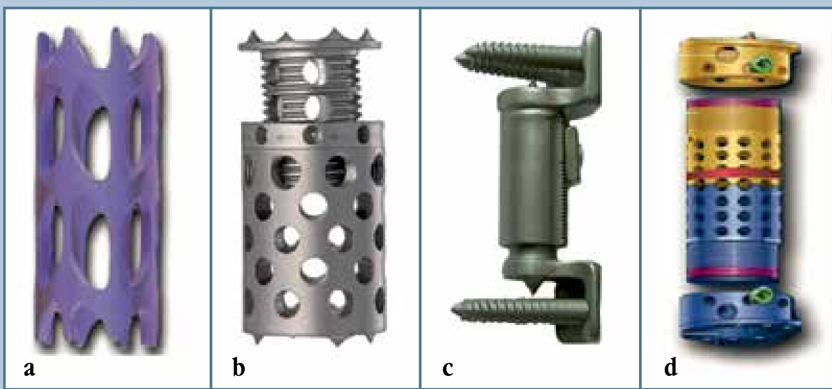

Fig. 1
Structures of the vertebral body implants for anterior fusion: **a** – «Xenos Cage Mesh System For Spine» (Biotec®); **b** – «ADD™» (Ulrich medical® spinal systems); **c** – Monolit; **d** – «Verte-SpanTM» (Medtronic Sofamor Danek)

Fig. 2
Telescopic Plate Spacer. TPS™ (Interpore Cross International®)

Fig. 3
Cylindrical, telescopic, mesh-type vertebral body implant "LAS"

ing of the working position thread of metal implants for anterior interbody fusion was used instead of a screw lock in order to reduce the number of constituent elements and weight and improve the adaptability.

Low weight of the implants for anterior fusion is an important characteristic. This is due to the fact that excessive weight of the implant in combination with higher compression elasticity modulus and lower shear elasticity modulus compared to the resected vertebral body will cause an imbalance in distribution of these forces. These forces are higher in magnitude and have different distribution compared to those in the natural vertebral segment, which can lead to destructive changes in the superjacent and subjacent segments of the spine [1].

Telescopic flanged implants used in the anterior spinal fusion should have the same metal content as the systems consisting of the interbody cage and the ventral plate. This fact must be considered, when assessing the structural characteristics of the implants.

The weight and cost of the structure influence the choice of the implant. These parameters are rather variable due to a number of objective and subjective reasons (technology used by the manufacturer, the number of manufactured and purchased copies, market pricing, etc.) [21].

Conclusions

Classification of the implants basically gives an idea about their reconstruction and stabilization capabilities and the need to combine some cages with additional fixation systems (ventral plates or posterior stabilizing structures) and provides guidance on the use of the implants or their combinations in certain spine pathologies. At the same time, we believe that insufficient attention is paid to characteristics of these structures as systems facilitating bone fusion of the vertebrae, which seems to be one of the key objectives of the anterior interbody fusion and is essential for preservation of intraoperative correction of the SMS.

The issues related to the investigation of the adequate combination of the internal volume of the cage, the contact area in the “metal – bone” and “filler – bone” systems, and required contact density in the “cage filler – vertebral body” system are still relevant.

In our view, the present system of characteristics used to assess structural parameters and functionality of metal vertebral body implants for anterior interbody fusion enables determining the advantages and disadvantages of various implants and provides an objective assessment of the possible mechanisms of postoperative complications.

We are grateful to Valentin D. Shapovalov, Cand. Sc. {Engineering}, Associate Professor of Automation and Computer Technology Department of V. Dal’ Luhansk University, for their help in preparing this manuscript.

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Received 15.09.2015

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