



TELESCOPIC VERTEBRAL BODY REPLACEMENT IMPLANT FOR SUBAXIAL CERVICAL FUSION

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Objective. To assess the outcomes in patients with disorders of the cervical spine treated by anterior subaxial cervical fusion with telescopic vertebral body replacement implant.

Material and Methods. The developed design of a telescopic vertebral body replacement implant for anterior interbody fusion at the subaxial level is described in details. The effectiveness of the implant was analyzed basing on the outcomes in patients of two groups. In patients of Group 1 (n = 21) the stabilization was carried out with the Mesh implant in conjunction with anterior plate fixation, and in patients of Group 2 (n = 12) – with the vertebral body replacement implant of the telescopic design.

Results. The obtained evidence showed the absence of postoperative complications associated with the violation of the operated segment stability and the loss of intraoperative correction of the sagittal profile of the cervical spine in patients of Group 2. The achieved correction of the spinal motion segment persisted throughout the entire period of observation. The recurrence of deformation of the anterior wall of the spinal canal causing compression of the epidural space and the spinal cord was not observed.

Conclusion. Telescopic systems can be considered the most effective and perfect in restoring the anterior spinal support. They optimize the process of sagittal profile correction by metered changing the distance between the vertebrae adjacent to the rejected one, which is the main advantage of the telescopic systems.

Key Words: anterior fusion, telescopic vertebral body replacement implant, design features.

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Traumatic injuries cause various osteo-ligamentous lesions of the spine, that differ in their nature and incidence. Most often, they involve the anterior spinal column, that is determined by its anatomical, physiological, and biomechanical characteristics. This is caused by the fact that about 90 % of the contact area between the adjacent vertebrae falls at their bodies, which bear up to 80 % of the spinal motion segment (SMS) load [24].

It is proved that in more than 90 % of cases the spinal cord, roots, and dura mater compression occur in the anterior spinal canal. This specificity of traumatic spinal injuries have been reported in the studies of Ya.L. Tsivyan, A.A. Lutsyk, A.A. Korzh [2, 8, 13]. Metastatic and inflam-

matory processes are often localized at the vertebral bodies and can cause ventral compression of the dural sac. Herniations of the intervertebral discs and osteophytes of the vertebral bodies caused by spondylosis also often result in the compression effect on the anterior portions of the neural structures [20].

When choosing tactics of surgical treatment for this pathology with allowance for the nature and location of the compressing factor, in most cases, decompression and stabilization intervention through the anterior surgical approach is the method of choice, since it is the most radical and pathogenetically approved one [1, 12, 14]. The effectiveness of the anterior interbody fusion is equally determined by anatomical and

physiological characteristics of the spine structure. In 96 % of cases, proper supporting bone regenerate forms at the area of resected vertebral body due to extensive vascularization of the cancellous bone of the vertebral bodies, as opposed to surgical interventions through the posterior approach [22].

Increased number of interventions through the anterior approach is due to the increased level of research capabilities of scientists, which enabled the development and implementation of evidence-based methods of computer and mathematical modeling to support the benefits of anterior fusion, as well as the expansion of the range of indications for surgical procedures on the spine [28].

Currently, various vertebral body replacement implants made of metal or synthetic bioinert materials are being designed and widely used in clinical medicine to perform the anterior fusion with subaxial prosthetic replacement of the vertebral body [2, 23]. Meanwhile, the anterior fusion using metal implants has certain specificity, which is due to the difference between the elastic moduli of bone structures of the vertebral bodies and metal [21]. This can cause bone resorption and mechanical damage to the endplates in the “implant – vertebral body” system, since only bone tissue is deformed upon spine loading. This results in increased risk of implant migration (subsidence of the structure into the vertebral bodies) accompanied by loss of achieved intraoperative correction of the SMS and fusion failure [15].

In this regard, the effectiveness of anterior fusion with metal structures is directly proportional to the strength characteristics of bone regenerate at the area of resected vertebral body, which, in turn, depend on the volume of cavity for the filler [25].

Optimization of configuration of the implants used during subaxial surgery is a topical issue due to the small size of bone defect wherein they are accommodated, on the one hand, and the large range of motions of the cervical spine (CS), on the other hand, which determines more stringent requirements to technical and functional characteristics of implantable systems. The objective of this study is to evaluate the results of treatment of patients with CS pathology using telescopic vertebral body replacement implant (VBRI) for the anterior subaxial cervical fusion.

Material and Methods

We analyzed design of various implants. We selected 25 types of VBRI having design solutions for their basic units characteristic of vertebral body replacement systems [9, 10]. We performed static testing of mechanical features of the structures for the anterior vertebral body replacement fusion and mathematical modeling using the finite

element method in order to assess the characteristics of the stress-strain state during the replacement of the vertebral bodies with artificial VBRI.

When designing the implant, we proceeded from the assumption that telescopic VBRI can be considered the most effective and perfect structure in restoring the anterior support. They optimize the process of sagittal profile correction due to the capability of metered changing the distance between the vertebrae adjacent to the resected one, which is the main advantage of these systems, maximizing surgeon's capabilities when dealing with the problem [19, 27].

Stabilizing capabilities of the VBRI are determined by the degree of fusion stability resulting from their application. It is attributable to the structure type, configuration of the implant and its end surfaces, which interact with the endplates of the vertebrae adjacent to the resected one, since the magnitude of stress strains in the “metal – bone” system depends on their design features. Furthermore, this characteristic is in a certain way affected by the effectiveness of the compression load accommodation by the VBRI, which differ in their magnitude and direction and is determined by the structure and location of the telescopic mechanism in telescopic systems.

In view of the aforementioned data, when designing the implant, we tried to develop the structure with improved technical and functional characteristics in order to improve the effectiveness of the anterior subaxial cervical vertebral body replacement fusion along with reducing traumatization of the vertebrae adjacent to the resected one during surgery by making appropriate structural changes to all elements of the VBRI.

We found a correlation between the structural characteristics and functionalities of the VBRI, that is, even minor changes in the implant design can have a significant impact on its functional characteristics [11].

The following characteristics were concluded to be the most rational ones:

- type of the structure – plate-integrated, i.e. not requiring additional stabi-

lization of the operated SMS with anterior plates or transpedicular systems;

- parallelepiped-shaped implants are superior to the cylinder-shaped ones, since they have larger internal cavity for filler and larger contact area in the “VBRI – vertebral body” system; however cylindrical shape is more rational for telescopic systems, which in a certain way implies an optimal type of positioning of the telescopic mechanism, compression load accommodation, and structure fixation in operating position;

- lateral surfaces of the implants must be perforated for the purpose of osteogenesis process initiation, vascularization of the implant filler and its fusion with the surrounding tissues; the hole size should allow for formation of certain uniform density of the material when filling the internal cavity of the structure; large holes and complete or partial absence of implant walls make it difficult to achieve the required density of the material in the VBRI in the “filler – vertebral body” system [29];

- the number of components of the structure should be minimal; ideally, the components should have the same configuration to be interchangeable;

- we believe that the situation when the shell of the implant plays a role of telescopic mechanism of the VBRI is the best option, it is possible in the case of threaded connection of components; these structures are characterized by the most effective axisymmetric compressive load accommodation; with this type of connection, the compressive load is uniformly distributed over the entire diameter of the VBRI, and the wall thickness is determined only by the need for adequate threading; these systems can bear considerable compressive load with minimum wall thickness and they are lightweight due to low metal consumption;

- it is advisable to use the deformational thread lock to maintain the required implant height in the operating position in order to reduce the components of the structure;

- in the case of the anterior cervical fusion, the implants with abutment surface slope angle of 0 to 7° should be used; configuration of the end surfaces of the

structure should provide a rational combination of the contact area of the structure (SS) and filler (SFIL) with the vertebral bodies, which have significant impact on their functionality [16].

Thus, increase in SS of the implant with the vertebral body improves its supporting ability and prevents it from migration; at the same time this results in reduced SFIL in “filler – vertebral body” system and relative decrease in filler volume, which together reduce the likelihood of formation of bone block with required supporting ability;

- in our view, it is enough to place 3–5 spikes at the end surface of the VBRI equidistant from each other, and their should be higher than spikes in Mesh structure [3];

- the volume of the internal cavity of the VBRI is one of the qualitative criteria of the effectiveness of telescopic systems when creating conditions for vertebral bone fusion; its magnitude must be as close as possible to that of the Mesh structure, having a maximum volume; this determines the amount of filler placed inside the implant [26], and directly affects the quality characteristics of bone fusion of the vertebrae adjacent to the resected one;

- we believe that rationally designed structure should enable filling its inner cavity with the filler prior to installation to the bone defect, adding and compacting the material after placing the implant in the operating position; this is due to the fact that after extension of the structure prefilled with filler, filling defect occurs on its poles, while bone fusion between the filler and vertebral body occurs only provided they are in tight contact; non-compliance with this requirement causes the formation of osteofibrous fusion;

- it is advisable to place holes for adding and compacting the material at the “filler – vertebral body” area after extension of the structure on both its poles.

Results

We suggest VBRI for subaxial cervical fusion (Fig. 1, 2) that comprises a central cylindrical hollow rod 1 with

an oppositely directed (left and right) thread from its center [5]. The rod 1 is provided with holes 2 in its center for the instrument (not shown) for its rotation. Transverse through holes in the rod 1 are made in the form of longitudinal grooves 3. Half-shells 4 with the appropriate internal oppositely directed thread are screwed on the rod 1, and the former are fixedly attached to the L-shaped plates 5 with twin screw holes 6 (not shown). Cylindrical half-shells 4 have radial transverse through holes 7, arranged in tiers. There are spikes 8 on the outer ends of the half-shells 4, preventing displacement of the half-shells 4 from their initially selected spatial orientation in the bone defect formed after resection of the vertebral body due to penetration of the spikes 8 into the adjacent vertebral bodies. In the half-shells 4, there are windows 9 from the side of L-shaped plates 5. Windows 9 enable free approach to the internal cavity of the VBRI after its extension (elongation), and therefore the implant can be completely filled with an additional portion of the filler to compensate for the missing volume followed by its compacting by reducing the overall length of the VBRI, thus creating favorable conditions for formation of adequate bone regenerate in the middle of the structure, maximizing fusion effectiveness.

Bridge 10 in the half-shell 4 between the window 9 and its internal end face has minimum thickness with a slot in the middle. Predetermined height of the endoprosthesis is maintained due to thread locking by means of bending the edges of the slot in the bridges 10 inside the longitudinal groove 3 of the rod 1 [4].

The holes 3 in the form of longitudinal grooves in the rod 1 extremely simplify the procedure of matching bridges 10 in the half-shells 4 to the specified grooves 3 when blocking the length of the implant.

When developing the structure of the VBRI, we conducted static testing of mechanical characteristics of the implants for the anterior interbody fusion using special equipment (test device calibration certificate P-0.5 No 21/1701) and mathematical model-

ing using the finite element method in order to determine the characteristics of the stress-strain state during replacement of the vertebral bodies with artificial implants.

Surgical Technique. Surgery was performed through the anterolateral approach with partial or complete resection of the damaged vertebral body, removal of adjacent intervertebral discs and, if necessary, posterior longitudinal ligament followed by revision of the epidural space.

Prefilled implant is placed in the bone defect formed after resection of the vertebral body or corporectomy. At this stage, the adjacent vertebrae may come in contact with the end faces of the VBRI rod. This contact can be minimized, depending on the chosen original length of the implant (Fig. 3).

Next, the rod is rotated, while holding the implant with a special key. During this process, half-shells are moved along the rod in the opposite directions due to oppositely directed thread; the structure extends (the overall length of the implant increases). Spikes located on the end surfaces of the half-shells rest against the bone tissue of adjacent vertebrae. Further rotation of the rod causes separation of adjacent vertebrae. Increased length of the internal cavity of the VBRI results in formation of filling defect in the “implant filler – vertebral body” system, so that the initial filling volume will be insufficient (Fig. 4).

This insufficiency can be eliminated by adding filler into the implant cavity to the contact area between the vertebral body and half-shell through the hole at the bottom of the half-plates until complete filling of the VBRI cavity (Fig. 5).

Further, the overall length of the structure is somewhat reduced (up to a certain optimum level) by rotating the rod 1 in the opposite direction, which leads to compaction of the filler in its internal cavity (Fig. 6).

This results in both press-fit installation of the VBRI in the interbody space and close contact between the filler and adjacent vertebral bodies, which facilitates further formation of proper sup-

porting bone block. Then bridge edges should be bend by pressing on the slots.

When this happens, bridge edges enter the longitudinal groove of the rod, which precludes and makes impossible rotation of the rod with respect to the half-shells. Fixation of the VBRI to the vertebral bodies adjacent to resected one is carried out using monocortical screws, which are passed through the paired holes in the L-shaped plates of the half-shells of the implant (Fig.7).

Postoperatively, the cervical spine is fixed using headholder.

Clinical examples of the bisegmental and multisegmental interbody fusion using telescopic VBRI are shown in Fig. 8, 9.

We conducted a comparative analysis of the results of the subaxial anterior interbody fusion in two groups of patients in order to assess the effectiveness of VBRI. In Group I (n = 21), the stabilizing stage of the surgery was per-

formed using vertical cylindrical Mesh implants in combination with anterior plate. In Group II (n = 12), using the newly developed original type II implant (which does not require further stabilization of the segment with anterior plates or transpedicular systems).

We studied the dynamics of the following radiometric indices: average value of the segmental kyphosis, axis angle, and the average shear displacement. Calculations were carried out based on radiographs or CT scans before and immediately after the surgery, as well as 3, 6, and 12–24 months after the surgery. All possible complications, such as implant migration and fragmentation (breakage) of its constituent elements were subject to analysis. Injuries were classified depending on the nature of damage to the spine according to classification suggested by Argenson et al. [15] (Table).

The present data characterizing telescopic VBRI demonstrated that there

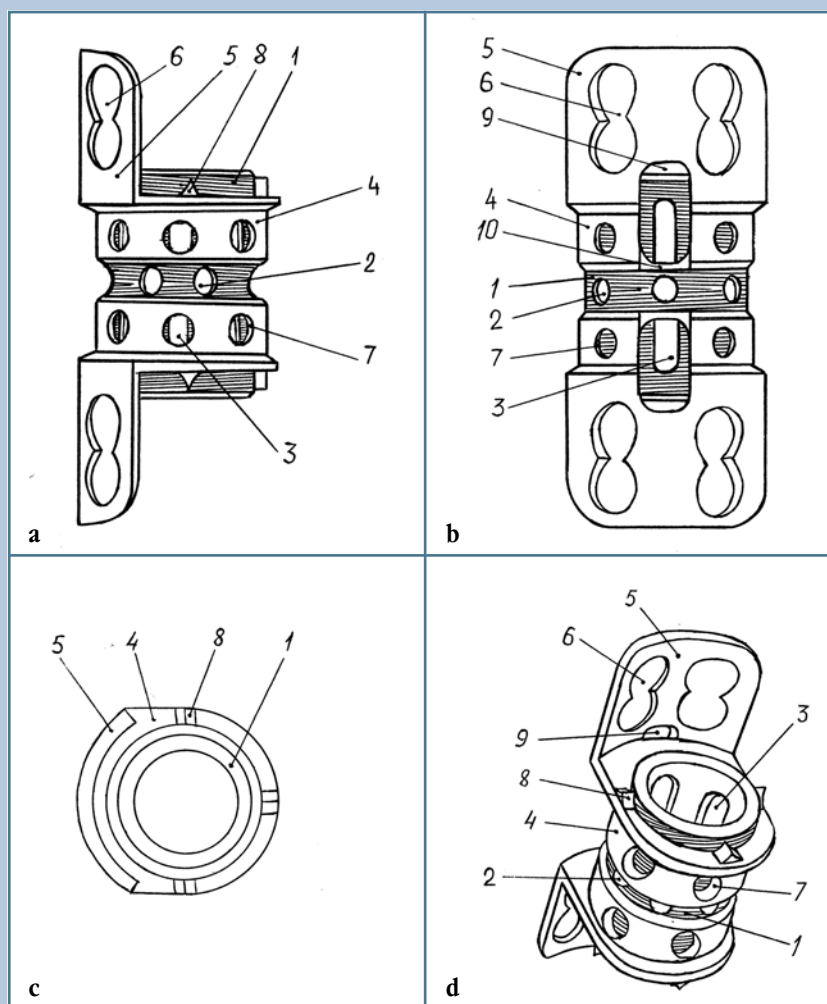


Fig. 1

Telescopic vertebral body replacement implant (1 – rod; 2 – holes for instrument; 3 – longitudinal grooves; 4 – half-shells; 5 – L-shaped plates; 6 – paired screw holes; 7 – radial lateral through holes; 8 – spikes; 9 – windows; 10 – bridge): **a** – structure of the suggested telescopic vertebral body replacement implant, side view; **b** – rear view; **c** – end view; **d** – plan view



Fig. 2

Telescopic vertebral body replacement implant

were no postoperative complications related to the destabilization of the operated segment and no loss of intraoperative correction of sagittal profile of the CS associated with failure of stabilization, broken implant or its components, as well as migration of the implant.

Achieved correction of the SMS was maintained throughout the whole follow-up period (Fig. 10, 11). There were no recurrences of deformation of the anterior wall of the spinal canal, causing compression of the epidural space and spinal cord.

Discussion

Currently, cervical anterior fusion is usually carried out using Mesh structures and telescopic implants such as ADD, ADDplus, BodyVertEx, TeCorp, Monolit, ECD, TPS.

Each of these systems has certain structural and functional features. For example, Mesh implant has large cavity for filler suitable for bone block formation and performs reconstructive function. It is used in combination with the anterior plate [19].

ADD and TeCorp implants are successfully used as reconstructors. When using these systems, SMS stabilization is achieved by additional fixation with the anterior plate [24].

Furthermore, the volume of the filler cavity is limited, since telescopic mechanism is located inside the structure and is insufficient to form the supporting bone block [7].

New generation stabilizing systems ADDplus, BodyVertEx, and Monolith are effective for retraction and stabilization of the SMS and enable sagittal profile correction and SMS stabilization without anterior plates. However, they usually do not provide conditions for effective bone block formation, which is essential for preservation of intraoperative correction of the SMS in the late postoperative period [6].

It is noteworthy that parallelepiped-shaped TPS implant has rational combination of the maximum contact area in the “metal – bone” and “material – bone” systems. However, the problematic struc-

tural features of these systems make these implants unaffordable to patients due to their high cost [18].

Telescopic systems can be considered the most effective and perfect in restoring the anterior support. They optimize the process of sagittal profile correction since they enable metered variation of the distance between the vertebrae adjacent to the resected one, which is the main advantage of these systems. In this way, they maximize surgeon’s capabilities when dealing with the problem [20, 28].

Thus, the aforementioned functional features and problematic characteristics of the VBRI for the anterior cervical subaxial fusion suggest that further studies aimed at improving and optimizing these structures are required.

Conclusion

We developed the method of the anterior vertebral body replacement fusion and the original structure for its implementation, which is superior to other analogues since this VBRI has the following benefits:

- has minimum size required for subaxial anterior fusion;
- maximizes filling of the large cavity with biomaterial or other fillers, which provides large contact area in the “filler – vertebral body” system in order to create conditions for adequate bone block formation;
- it is strong enough and has low metal content and low weight due to the



Fig. 4
Filling defect in the “filler – vertebral body” system



Fig. 5
Adding filler into the cavity of the implant



Fig. 6
Compacting the material in the “filler – vertebral body” system



Fig. 3
Initial position of the implant prior to placement to the bone defect



Fig. 7
Operating position of the vertebral body replacement implant in the bone defect

**Fig. 8**

Compression-comminuted fracture of C5 vertebral body: **a** — preoperative MRI; **b** — preoperative spiral CT; **c** — radiographs after C5 corpectomy and C4—C6 fusion using telescopic implant

axisymmetric compression load accommodation;

- prevents from injury of the end-plates by the spikes of the end surfaces when placing them in the operating position;
- technological manufacture and easy to operate.

The studies have demonstrated the effectiveness of the structure in sagittal profile recovery, stabilization of the operated SMS, and creating conditions for the formation of an adequate supporting bone block.

**Fig. 9**

Comminuted fractures of C5—C6 vertebral bodies (**a**) condition after C5—C6 corpectomy and C4—C7 fusion using the telescopic implant (**b**)

Table

The results of surgical correction of deformities caused by lower cervical spine injuries, depending on the type of the original deformity, according to classification of Argenson et al. [15], $M \pm m$

Type of deformity	Follow-up period	Average value of the segmental kyphosis, deg.	Axis angle, deg.	Average shear displacement, mm	Migration of the structure, n	Design fragmentation, n
Group I						
A (n = 9)	Preoperative	10.889 ± 1.596	4.333 ± 1.714	0	—	—
	3–5 days after surgery	-2.889 ± 2.434	23.222 ± 2.489	0	—	—
	3 months after surgery	-2.500 ± 2.046	19.111 ± 2.713	0	—	—
	6 months after surgery	-1.722 ± 1.253	15.444 ± 2.480	0	1	—
	12–24 months after surgery	-1.389 ± 0.928	12.833 ± 2.693	0	1	—
B (n = 12)	Preoperative	11.833 ± 1.875	8.667 ± 1.174	3.60 ± 0.25	—	—
	3–5 days after surgery	-2.708 ± 0.916	23.458 ± 1.738	0	—	—
	3 months after surgery	-1.917 ± 0.900	19.583 ± 2.120	0	1	—
	6 months after surgery	-1.125 ± 0.678	14.833 ± 1.850	0	2	1
	12–24 months after surgery	-1.042 ± 0.542	11.875 ± 1.908	0	2	1
Group II						
A (n = 6)	Preoperative	11.333 ± 1.080	2.833 ± 1.366	0	—	—
	3–5 days after surgery	-3.083 ± 0.665	20.833 ± 2.582	0	—	—
	3 months after surgery	-2.833 ± 0.408	19.833 ± 2.483	0	—	—
	6 months after surgery	-2.667 ± 0.408	$18.667 \pm 2.183^*$	0	—	—
	12–24 months after surgery	$-2.583 \pm 0.492^*$	$18.083 \pm 2.154^*$	0	—	—
B (n = 6)	Preoperative	12.500 ± 1.673	8.583 ± 1.201	5.70 ± 1.27	—	—
	3–5 days after surgery	-3.083 ± 0.736	$20.167 \pm 2.620^*$	0	—	—
	3 months after surgery	-2.750 ± 0.524	20.083 ± 2.746	0	—	—
	6 months after surgery	$-2.583 \pm 0.376^*$	$18.583 \pm 2.538^*$	0	—	—
	12–24 months after surgery	$-2.500 \pm 0.447^*$	$18.417 \pm 2.333^*$	0	—	—

* $P < 0.005$.

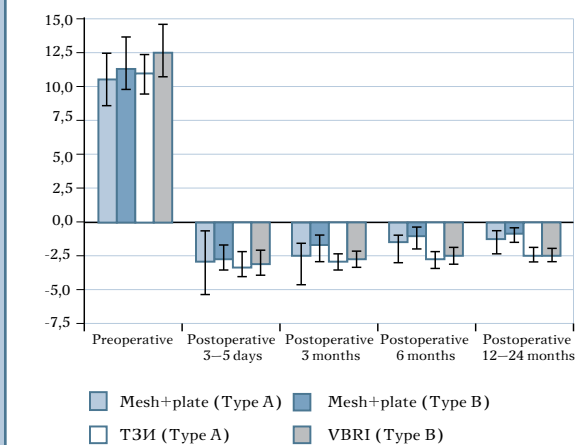


Fig. 10

Changes in the average value of segmental kyphosis over time depending on the stabilizing structure and the type of injury; VBRI – telescopic vertebral body replacement implant

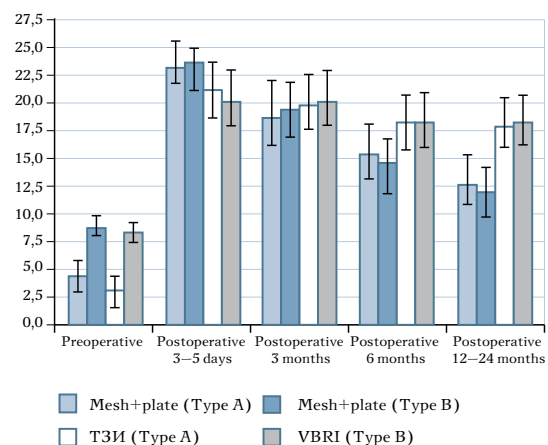


Fig. 11

Changes in the average value of axis angle over time depending on the stabilizing structure and the type of injury; VBRI – telescopic vertebral body replacement implant

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