BIOMECHANICAL ASPECTS OF THE INITIAL STABILITY OF INSTRUMENTAL FIXATION IN THE TREATMENT OF SUBAXIAL CERVICAL DISLOCATIONS: AN EXPERIMENTAL STUDY

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Objective. To study the influence of thoracic inlet angle (TIA) and the fracture of the articular process on the initial strength of the fixation of the spinal segment during its anterior and circular instrumental surgical stabilization in an experiment on a model of the lower cervical spinal segment.
Material and Methods. The material of the study was assembled models of C6–C7 spinal segments made using addictive technologies by 3D printing. After preliminary instrumentation, spinal segments were installed on the stand testing machine using specially manufactured equipment. A metered axial load simulating the native one was applied along the axis of the parameters SVA COG–C7 and C2–C7 SVA, which values were close to the value of 20 mm, at a rate of 1 mm/min until the shear strain was reached. The system's resistance to displacement was measured, and the resulting load was evaluated. Four study groups were formed depending on the modeling of the T1 slope parameter, the integrity of the facets, and the type of instrumentation. Three tests were conducted in each group. The graphical curves were analyzed, and the values of the parameters of the neutral and elastic zones, the yield point, time to yield point, and the value of the applied load for the implementation of shear displacement were recorded. The data were subjected to comparative analysis.
Results. In Group 1, anterior shear displacement of the C6 vertebra could not be induced in all series. In groups 2, 3, and 4 a shear displacement of ≥4 mm was noted in all series. In Group 3 where a fracture of the articular process was additionally modeled, the average value of the yield point was 423.5 ± 46.8 N. Elastic zone, the time to the onset of the yield point, the time at the end point or at a shear of C6 ≥4 mm did not differ significantly. In Group 4, a translational displacement of ≥4 mm was observed, though the average yield point was 1536.0 ± 40.0 N.
Conclusion. The direction of the load applied to the fixed spinal segment, as well as the presence of damage to the articular processes, play a crucial role in maintaining resistance to shear deformation of the spinal segment during its instrumental stabilization. At high values of TIA (T1 slope) and the presence of fractures of the articular processes, the isolated anterior stabilization is less effective, circular fixation of 360° under these conditions gives a high initial stability to the spinal segment.
Key Words: anterior cervical discectomy and stabilization, anterior spinal fusion, cervical sagittal balance, cervical vertebra dislocation, recurrent dislocation, redislocation, loss of correction, flexion-distraction injury.
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A surgical treatment of subaxial cervical dislocations is one of the unsolved challenges at the current stage of spinal surgery development. The variety of surgical treatment tactics presented in the specialized literature, the uncertainty with the choice of surgical approach, the type of surgical stabilization imposes further research. The defenders of isolated anterior stabilization [1] argue for its reliability and effectiveness in the treatment of three column injuries of type C (AO Spine subaxial classification system), including gradations FD3 and higher according to the Allen classification [2]. They are manifested by a high frequency of injury to the spinal cord and its roots. A significant frequency of loss of correction and redislocation of vertebrae after surgery was a consequence of the ineffectiveness of the surgical techniques applied in the first half of the 20th century for the treatment of traumatic dislocations at the lower cervical spinal segment. This resulted in the search for alternative stabilization methods [3]. The concept of external osteosynthesis, in particular the application of anterior neckplates, has enabled to change horses in this direction. A considerable reduction in the frequency of postoperative complications, despite the manifestation of complications specific to each neckplate's generation, related to the design and biomechanics of stabilization. Based on literature data [1, 3, 5], the effectiveness of isolated anterior cervical plate stabilization in fractures is 75–100 %. Since the first papers on the effectiveness of anterior neckplates in traumatic dislocations at the subaxial level, the authors of publications

[1, 6, 7] have begun to notice cases of reluxation, vertebral dislocation in a number of patients under instrumental stabilization. The analysis of the literature demonstrated the causes of loss of intraoperatively achieved correction. They are the following: a low height of the interbody graft [1], fracture of the subjacent vertebral body [6, 8], fracture of the articular process [6], bilateral pattern of dislocation [9], osteoporosis [7], high risk at the level of C6–C7 [3], injury degree to the posterior support complex [4, 7], listhesis degree [10], lack of surgical technique [1], features of the cervical sagittal balance and a fracture of articular processes [11]. The design of most studies is retrospective. It means that the research is based on small samples. A retrospective clinical study performed by a team of authors [11] demonstrated that the parameter of the sagittal cervical balance "thoracic inlet angle" (TIA), as well as an articular process fracture at the level of injury, are statistically significant factors. They determine initial stability during isolated anterior surgical reconstruction and spinal stabilization at the lower cervical level with flexion-distraction injuries of type 3 according to Allen. Therefore, we have conducted a concurrent experimental study aimed at data confirmation obtained within clinical material.

The objective is to study the influence of thoracic inlet angle (TIA) and the fracture of the articular process on the initial strength of the fixation of the spinal segment during its anterior and circular instrumental surgical stabilization in an experiment on a model of the lower cervical spinal segment.

Study design: an experimental cross-sectional study.

Material and Methods

The material of the study was assembled models of C6–C7 spinal segments. They consisted of polymer models of C6 and C7 cervical vertebrae (Fig. 1). They were manufactured using 3D printing of PA 2200 polyamide. In vitro instrumentation was done by advanced neckplates of generation 3 Atlantis Element Express (Medtronic) and interbody spacer device made of trabecular titanium nickelide (Russia). The posterior stabilization was performed by Conmet screw mounting system (Russia) according to the transpedicular fixation technique.

For ensuring the transformation of the translational motion of the MTS-machine platform into an axial load, a metal equipment in the form of two supports for the caudal and cranial vertebrae was previously developed (Fig. 2).

In the center of the upper support, at the points relevant to the assumed load axis, spherical grooves were formed, into which a metal ball (d = 15 mm) was placed to equally distribute the load from the platform during testing (Fig. 3). The point was defined by drawing a vertical line from the cranioventral angle of the C7 body perpendicular to the horizon. It was done until it intersected with the surface of the upper metal platform. This modeled the value of the indicators SVA COG–C7 and C2–C7 SVA, equal to 20 mm. The T1 slope values (20° and 35°) were modeled using inclined platforms with the appropriate surface slope (Fig. 4), on which the assembled structure was laid and securely fixed with a screwed joint. The equipment allowed the polymer vertebrae to be fixed symmetrically in the frontal and axial projections with the forming of segmental lordotic angle of 6° between the adjacent endplates of the C6 and C7 vertebral body models.. The sample was prepared in the following manner: polymer vertebral models were securely fixed to metal supports by screws (Fig. 3). After that, with the help of a specially made metal device (Fig. 5), the required segmental angle of 6° and a translation of 0 mm were set. A cellular titanium nickelide implant with a height of 6 mm and a diameter of 14 mm was placed in the interbody space. Four screws with a diameter of 4 mm and the length of 14 mm anteriorly fixed the Element Express Atlantis front plate (Medtronic) to the vertebral bodies. The canals with a diameter of 3.5 mm were previously formed in the vertebral bodies by drilling. After that a 4.0 mm tap was used. The fixation stability during the application of the implant was provided by the built-in feature of the screws and holes of the plates. A posterior stabilization was performed transpedicularly. When the facets were fractured, a typical technique was used: Conmet screws (3.5 x 24.0 mm).

The assembled structure was installed on the stand of the Instron 3369 testing machine. Following that, its top traverse was moved down through a movable platform consisting of a polished steel plate and roller supports, until the apposition to a metal ball with a diameter of 15 mm (Fig. 6). The ball was placed in the center of a spherical slot formed in the cranial support. The centers of the slots were formed at the intersection point of the cranial platform with the perpendicular restored upwards from a point on the horizontal plane located 20 mm in front of the craniodorsal angle of the 3D model of the C7 vertebra. The caudal platforms had a slope angle to the horizon of 20° and 35° (Fig. 5). This corresponded to the average and extremely high value of the "slope of the first thoracic vertebra" (T1 slope). The spherical slots in the cranial platform are formed in such a way that both when modeling the T1 slope of 20° and 35°, the application point of the axial load will conform to the axis of the parameters SVA COG–C7 and C2–C7 SVA, which are close to the value of 20 mm. We consider that this allows to simulate the native axial load falling on C6 vertebra under certain conditions of sagittal balance defined by the study design. Its main part consists in the axial movement of the top traverse at a speed of 1 mm/min until the translational displacement of the upper vertebra relative to the lower one is ⩾4 mm [6, 12–14]. The displacement was registered by moving the injection needle point relative to a millimeter-graded strip of paper fixed to the caudal surface (Fig. 6).

The testing machine recorded the load values applied at each time (N). Meanwhile, a typical "stress-strain" dependence curve was recorded on the graph (Fig. 7).

The curves were analyzed. The following values were recorded: NZ, EZ, yield point (YP), time to yield point (tYP), the value of the applied load for the implementation of shear displacement (Sstress.) (Fig. 7). Accordingly, the data of each group was subjected to a comparative analysis.

The study design was formed under the assumption that the biomechanical values of the sagittal cervical balance of asymptomatic volunteers correspond to the following: T1 slope = 25.7 ± 6.4, but not more than 40; C2–C7 SVA = 20 mm, but not more than 40 mm; NT = 43.7 ± 6.1; TIA = 69.5 ± 8.6 [15]. The experiment simulates anterior and circular (360°) surgical stabilization after a three-column DF3 type injury at C6–C7 level, according to Allen classification. As a rule, static elements of the stabilizing complex (capsular ligaments, yellow ligament, posterior longitudinal ligament, anterior longitudinal ligament) are torn or extremely frayed. Additionally, the segmental muscles are significantly injured. Therefore, it was decided to neglect the ligamentous structures of the spine and segmental muscles during modeling. For modeling facet fractures on both sides, we have done a resection of articular processes of C6 and C7 vertebrae on both sides before the start of the tests. These actions were performed to confirm the scientific hypothesis formed on the basis of a retrospective clinical study in groups 2, 3, 4. Table 1 presents 4 groups of the study.

A visual assessment of the translation value of the inker along the calibration strip was performed. The test performance was stopped when either a forward displacement of 5 mm, or a load of more than 150 kg, or a displacement of the main head of the Instron equipment of more than 3 mm was reached. The values of the applied stress (S) and the distance traversed by the main head of the Instron device (displacement during compression, mm) were evaluated.

Results

In Group 1, anterior shear displacement of the C6 vertebra could not be induced

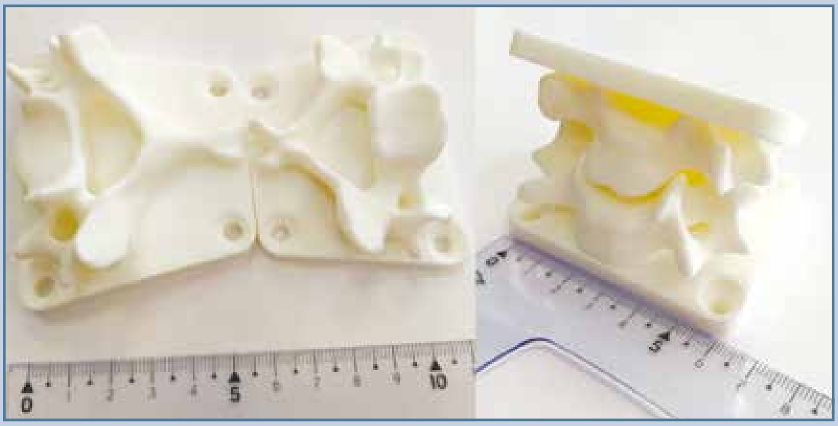

Fig. 1
Prefabricated models of C6–C7 vertebral segments

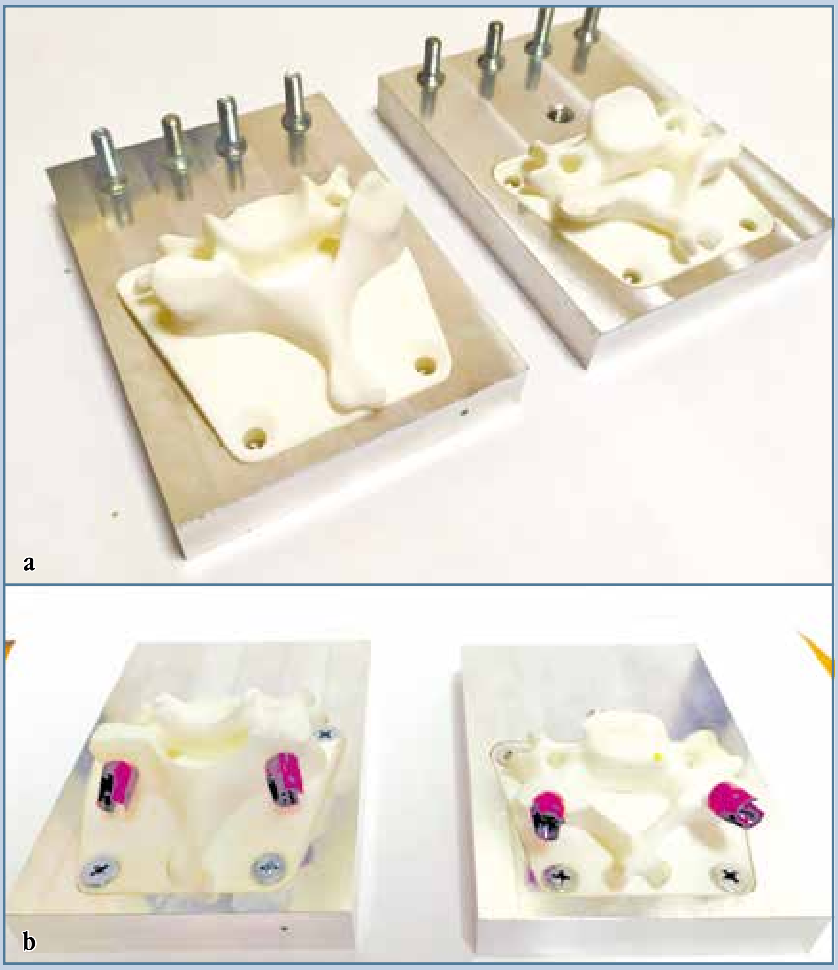

Fig. 2
A caudal (left) and a cranial (right) metal supports with 3D vertebrae models **(a)** and models with transpedicular mounted screws **(b)**

Fig. 3
A cranial metal support (plane view)

in all series. Meanwhile, the average stress at the end point (S_{stress}) reached 1857.0 ± 210.3 N (Fig. 8a). In groups 2, 3, and 4 a shear displacement of ⩾4 mm was noted in all series. The profile of the graphical curves was identical in groups 2, 3, 4. The values were different. In Group 2, the average yield point (YP) was 728.7 ± 50.6 N (Fig. 8b). In Group 3 where a fracture of the articular process was additionally modeled, the average value of the yield point was 423.5 ± 46.8 N. This suggests a significant decrease in the initial strength of the fixation of the vertebral segment under T1 slope = 35 ° and with an articular process fracture (Fig. 8c). In Group 4, a translational displacement of ⩾4 mm was observed, though the average yield point was 1536.0 ± 40.0 N (Fig. 8d). This corresponds to the effect on the cervical vertebral segment of 153 kg, which impossible in physiological conditions.

The curves in the groups had an identical profile, but differed in values. We associate this with the co-called free-hand technique (plates fixation to the vertebrae).

The following indicators: an elastic zone (EZ), the time to the onset of the yield point (tYP), the time at the end point or at a shear of C6 ⩾4 mm did not differ significantly (Table 2).

The value NZ = 0 in the experiment demonstrated that the instrumental stabilization of the vertebrae was performed identically in all groups.

Discussion

Despite the introduction and widespread clinical use of anterior neckplates and posterior cervical screw systems, the challenge of optimal stabilization techniques for subaxial dislocations remains open. Some authors [16, 17] consider anterior stabilization in three-column subaxial injuries optimal. Others [18], referring to the pronounced instability in such injuries, highlight the combined (anterior and posterior) stabilization. The discussion concerning when circular stabilization is unnecessary in three-column injuries, and in which cases it is justified, is still open and relevant. Most experts concur that the main objectives of the instrumentation of the vertebral segment in the surgical treatment of unstable spinal injuries are to maintain the relationship between the vertebrae during the formation of the bone block, as well as early and safe mobilization of the patient [19, 20].

The fixation failure in spinal implant application is formed by simultaneous overload or cyclic loading with subsequent fatigue failure. For bone fusion to be achieved, a sufficient segmental stability and an appropriate load sharing on the segment are required. The absolute stability of fixation can prevent the implementation of the processes of reparative osteogenesis due to the stress shielding on the interbody spacer device or the bone graft. The formed artifactual bone block withdraws the implant from the stress load. Thus, fatigue destruction of the implant does not manifest [3].

As of biomechanical point of view, the cervical spine is a load-bearing mechanical structure with six degrees of mobility: flexion/extension, lateral inclination to the left and to the right, rotation to the right and to the left [21, 22]. The traumatic powers affecting the surgically stabilized spine can be described as vectors of forces having a clear spatial direction. The force vectors are divided into rotational (flexion, extension, lateral inclination, torsion) and linear (compression, distraction, translation). When a force is applied in any direction, the stabilized structures of the vertebral motor seg-

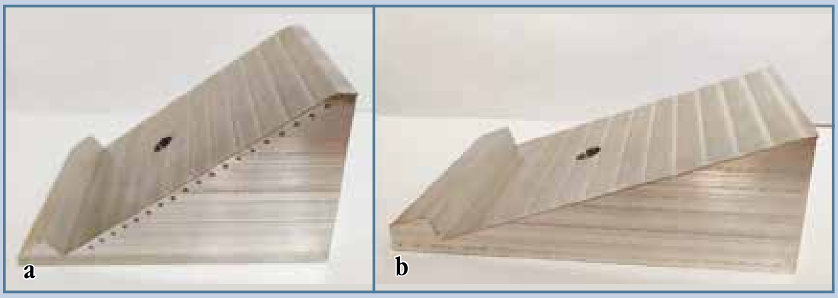

Fig. 4
The platforms modeling the T1 slope: **a** – 35°; **b** – 20°

Fig. 5
A device for generating an identical segmental lordosis in a segment with interbody stabilization and plate fixation

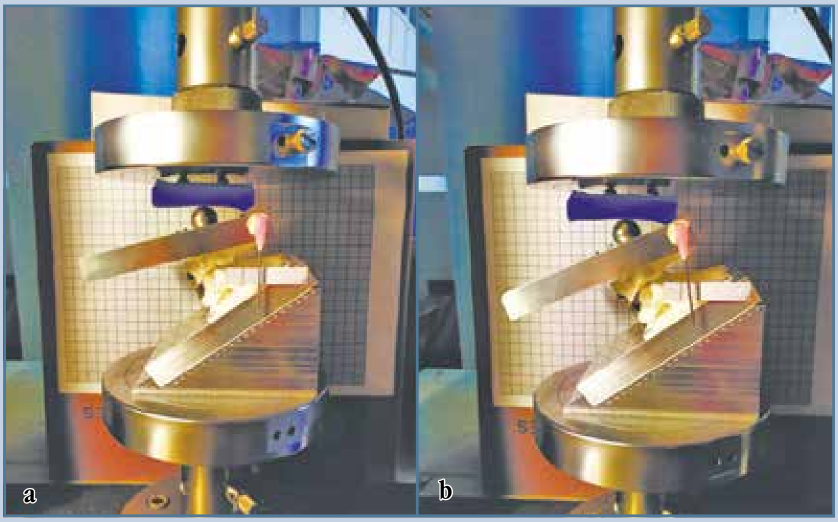

Fig. 6
The beginning **(a)** and the end **(b)** of testing: a translational displacement of the vertebra ⩾4 mm has been reached

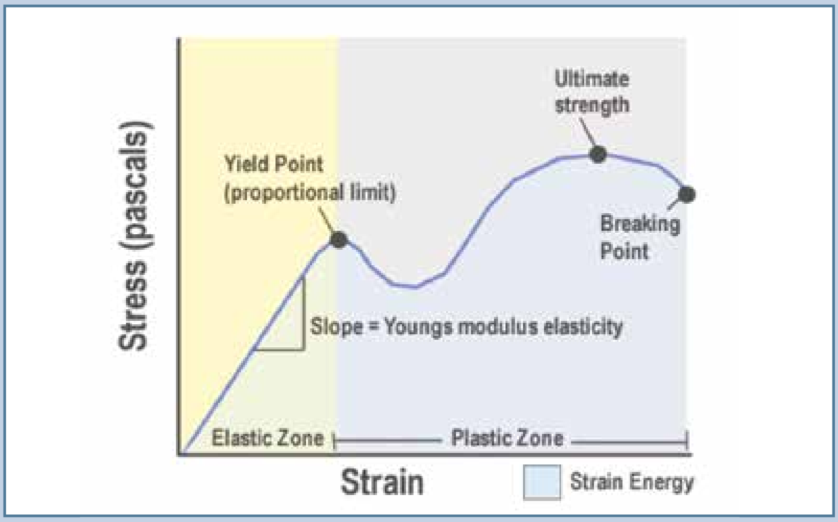

Fig. 7
An ordinary "stress – strain" curve

ment undergo the typical deformity stages given in Fig. 9.

The usual load curve consists of several zones [23–25].

The neutral zone (NZ) is a part of the physiological range of the intervertebral range of motion measured from a neutral position. In this case, the movement is produced with minimal internal resistance (stress). The higher the fixation stability of the spinal motor segment, the smaller the neutral zone.

An elastic zone (EZ) is a part of the range of motion measured from the end of the neutral zone and ending with YP (Fig. 7). An intervertebral movement is generated in the elastic zone under conditions of significant internal resistance of the system. The magnitude of this zone is determined by the modulus of elasticity of the materials representing the system. This is a zone of high rigidity.

Next, the zone of irreversible deformity of the system is the plastic zone (PZ). EZ ends with the yield point (YP), the value of which defines the beginning of PZ. Being in the plastic zone, the test material does not take its original shape and position after the load is removed.

The extreme end of PZ is the break point of the system (Break point), followed by the failure zone FZ (Failure zone).

The following types of spinal implant function assessment are described in the literature [25]:

1) implant strength testing: it is performed before the implant is being broken or the «material – implant» system is destroyed;

2) fatigue failure testing: a cyclic loading is performed; the implant–bone system's resistance to destruction under conditions of physiological stress is assessed;

3) instability testing:

a) flexion tests: flexural resistance is evaluated; a controlled load is applied; the resulting displacement is evaluated;

b) fixation strength assessment: a controlled displacement is applied; the system's resistance to displacement is evaluated; the resulting load is assessed.

Our study belongs to the last group – the assessment of the fixation strength. It assessed the resistance of the vertebra – implant – vertebra system to deformation (shear displacement) under the axial load in various biomechanical conditions.

In the 80s of the XX century, the doctors were interested in the fixation stability in flexion-distraction injuries, particularly dislocation-fractures of the DF3 type according to Allen. From this time the anterior neckplates have taken their place among the implants used in the treatment of unstable injuries at the lower cervical spinal segment.

In a biomechanical experiment conducted on bovine cervical vertebrae, Coe et al. [26] modeled a DF3-type injury. Then they have studied the effectiveness of anterior, posterior and circular stabilizations. A posterior wire fixation according to Bohlmans, a posterior fixation with Roy-Camille plates, a posterior fixation with hook-shaped plates according to AO, and an anterior Caspar neck plate were used. The cyclic flexion tests were performed using the MTS machine. The study demonstrated the inefficiency of isolated fixation with Caspar plates in comparison with all posterior and combined stabilization methods.

In a biomechanical cadaveric study, Oberkircher et al. [27] have analyzed the primary stability of anterior fixation by a plate in a three-column injury and the effect of an articular process fracture on it.

The authors observed a significant decrease in strength under shear load on the segment in conditions of fracture of the articular process compared with intact facets. The destruction of the segment happened if the load was 73.42 ± 32.51 N and 174.60 ± 46.93 N, respectively [27].

In the cadaveric study using cyclic loads, a group of researchers led by Kim [28], compared the fixation stability in bilateral dislocations. Three types of it were studied at the C5–C6 level: isolated anterior plate stabilization, anterior plate stabilization plus posterior interosseous stabilization, anterior plate stabilization and posterior transpedicular fixation. A force moment of 2 Nm was applied in six different directions (flexion, extension, lateral inclination to the right and left, axial rotation to the right and left). The range of motion and the size of the neutral zone were calculated. The authors have demonstrated that the combined technique has the maximum primary stability: anterior and posterior screw fixation [28].

Henriques et al. [[18] performed biomechanical cadaveric tests *in vitro*, applying cyclical loads and comparing the fixing qualities of spinal implants for injuries of type DF3 according to Allen [2]. Using the MTS machine, 3 ranges of movements were simulated: flexion -

Table 1

A characterization of the study groups

Group	T1 slope, deg.	Facets	C2–C7 SVA, mm	Stabilization type
1	20	Intact	20	Anterior
2	35	Intact	20	Anterior
3	35	Fracture	20	Anterior
4	35	Fracture	20	360°

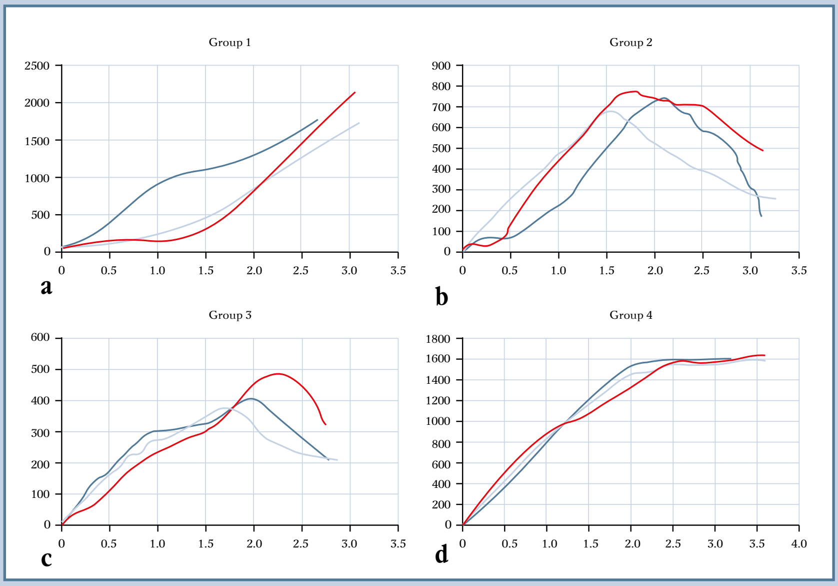

Fig. 8
“Stress – strain” graphical curves: **a** – Group 1; **b** – Group 2; **c** – Group 3; **d** – Group 4

Table 2

Parameter values in the study groups (M ± SD)

Parameters	Group 1	Group 2	Group 3	Group 4
Neutral zone, mm	0	0	0	0
Elastic zone, mm	2.90 ± 0.20	1.78 ± 0.30	1.90 ± 0.30	2.20 ± 0.25
Time to the yield point, sec	None	107.70 ± 13.50	120.00 ± 13.00	135.30 ± 14.30
Time at the end point or at a shift of C6 ≥4 mm, sec	175.00 ± 13.40	191.30 ± 5.00	172.00 ± 12.80	197.00 ± 15.10
Yield point, N	None	728.70 ± 50.60	423.50 ± 46.80	1536.00 ± 40.00
Stress at the end point or at a shift of 4 mm, S_{stress}	1857.00 ± 210.30	304.30 ± 168.24	244.80 ± 54.00	1591.00 ± 28.80
Main head displacement, mm	2.90 ± 0.20	3.10 ± 0.08	3.00 ± 0.20	3.50 ± 0.50

extension, lateral inclinations, and axial rotation. A force moment of ±1.5 Nm was applied. The range of movements was assessed. The study proved the insufficiency of isolated anterior fixation in DF3. The circular stabilization provides the recovery of the posterior tension band mechanism and is most efficient in case of three-column injuries.

In all of the above types of testing, as a rule, animal or human cadaver material was used, MTS machines were applied, the direction of load application was selected based on existing guidelines and protocols [29, 30].

We performed our study using additive technologies. Instead of cadaveric ones, physical 3D models of C6 and C7 cervical vertebrae were used. This enabled us not to be limited in the number of models and to create identical fixation conditions in all experimental series. The impact of the average and extreme values of the T1 slope parameter, as well as the articular process fracture on the implementation of the cranial vertebra shear displacement in the experiment was considered.

The experiment demonstrated that in the case of the average values of the T1 slope parameter 20° (and, consequently, TIA), it is not feasible to simulate the vertebral dislocation, the yield point cannot be reached, even with supraphysiological loads of 1857 N (about 187 kg). At a value of 35° in T1 slope, the dislocation is modeled. This necessitated a load of about 728 N. Following additional resection of the articular processes, the yield point is found at a load of 423 N. An additional posterior screw stabilization under these conditions significantly restores the stability of the segment. The yield point occurs at a load of 1591 N.

The issue of determining the volume of stabilization in extremely unstable three-column injuries remains controversial in the current papers [17, 20]. Today, an isolated and circular stabilization for tree-column injuries at the subaxial cervical level are relevant therapeutic options used at the discretion of the surgeon [15, 20, 31]. We have tried to substantiate the expediency of this or that type of stabilization based on a fundamentally new approach. It consists in an assessment of the injury morphology and the characteristics of the cervical sagittal balance.

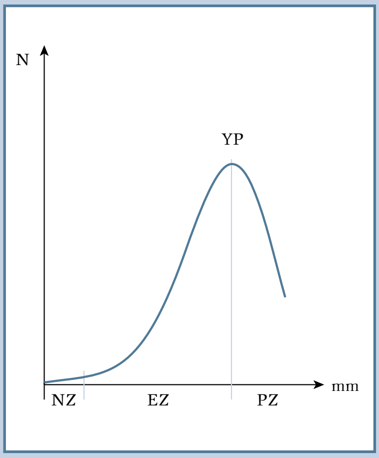

Fig. 9
"Stress – strain" dependency graph

Conclusions

The direction of the load applied to the fixed spinal segment, as well as the presence of damage to the articular processes, play a crucial role in maintaining resistance to shear deformation of the spinal segment during its instrumental stabilization. The sagittal balance parameter T1 vertebra slope and TIA, highly correlating with it, as well as the articular process fracture, are significant factors affecting the primary fixation strength of the lower cervical vertebral segment during isolated anterior surgical fixation due to the three-column injury (stage 3 and more according to the Allen classification). At high values of TIA (T1 slope) and the presence of fractures of the articular processes, the isolated anterior stabilization is less effective, circular fixation of 360° under these conditions gives a high initial stability to the spinal segment.

The study had no sponsors. The authors declare that they have no conflict of interest.

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