A NOVEL FATIGUE TESTING MACHINE FOR SPINAL FIXATION SYSTEMS UNDER VARIOUS CONDITIONS OF LOADING

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ABSTRACT

For recent years, a new technologies of treatment of spinal disease and injuries received underwent rapid development. Many of them use different types of artificial implants and fixation systems. At the same time the most widely a transpedicular and ventral systems are used.
If the spinal surgical operation is performed by the modern technology, patients quickly acquire the ability to lead an active life, during which the elements of the fixation systems (screws, longitudinal and transverse rods) are subjected to intensive loading and for various reasons may lose its functionality. One such reason is the fatigue of design elements.

Efficiency of fixation system components is determined by the quality of their surgical implantation, taking into account the mechanical characteristics of materials and the design features. It is rather difficult to take into consideration the influence of all factors and to quantify the resource of the known and newly designed structures. The most accurate estimates can be obtained through the testing only.
In this work is presented a new design of the machine for fatigue tests of spinal fixation systems, which allow to obtain reliable estimates of the resource under different loading conditions.

Keywords: spine, spinal fixation systems, transpedicular fixation system, fatique testing machine

1. INTRODUCTION

The spine is one of the most complex biomechanical systems in the human body, which is capable of providing movement of interconnected elements (vertebrae) in six degrees of freedom. Relative linear and angular displacement of the vertebrae are small, but functionally or pathologically curved spine as a whole can be greatly differing forms, with high reliability providing a support function [1].

Biomechanics of the spine is the basis for the development of new technologies for its treatment methods and devices for the rehabilitation of patients in the postoperative period, at the design of implants, surgical instruments, etc. In particular, modern surgical techniques treatment of diseases and spinal injuries involve the use of interbody implants and fixation systems developed based on its biomechanical characteristics. This allows patients in the postoperative period to quickly restore the capacity for active living [2].

At damaged the thoracic and lumbar spine is widely used method of transpedicular fixation of elements. Transpedicle fixing system consists of the rods which forming the design of frame type, which attached by pedicle screws to the vertebral bodies (Fig.1).

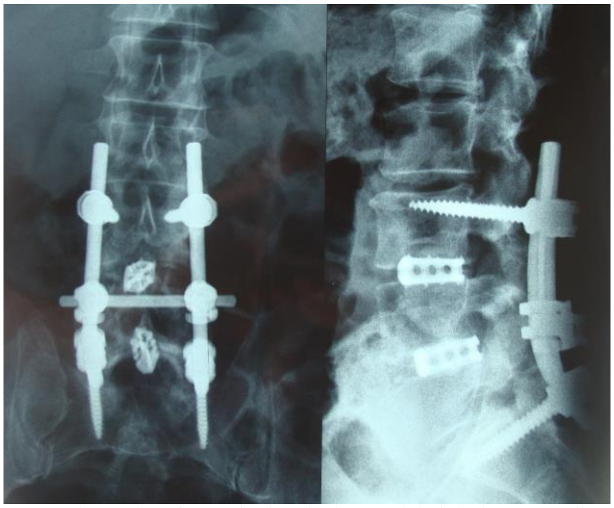
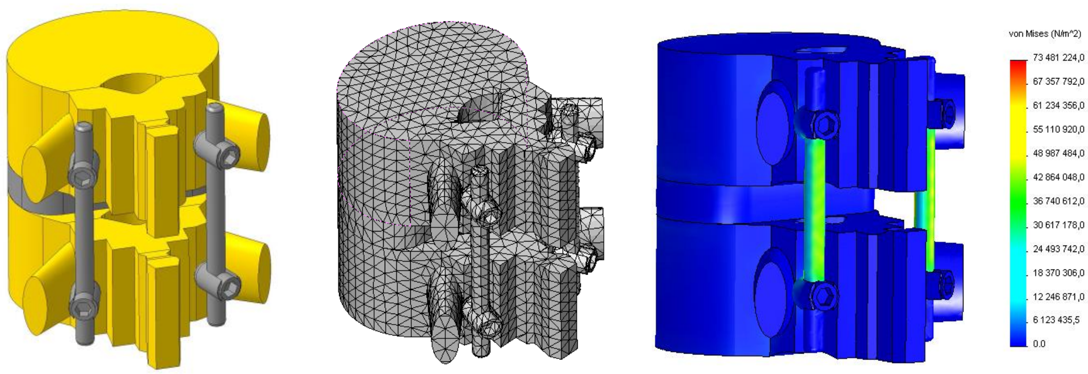


Fig. 1. The results of posterior interbody spondylodesis by transpedicular system “Bridge” at patient N in 5 years after implantation (Dr. O. Bryekhov, Crimean State Medical University, Ukraine)

Typically, these structures rigid enough and take the spine current workloads without significant deformation, but arising from this stresses can lead to loss of strength of the support elements. The static stresses in the elements of fastening systems can be assessed by finite element analysis models of structures under the action of various load on magnitude and type and taken into account in the design of new structures (Fig.2) [3].



a) b) c)

Fig.2. The model of the vertebral-motion segment of transpedicular system: a) 3D model; b) finite-element model; c) distribution of the equivalent Mises stresses in the elements of model

Despite on the fact that the clinical effectiveness of transpedicular fixation in the treatment of the spine is not in doubt, the use of this method can lead to a number of complications. The most common of these is the destabilization of the fixing system [4]. There are the next to lead to destabilization: fatigue fractures of the structural elements, the unwinding of fixing nodes, migration of pedicle screws in the vertebral bodies, the destruction of the cortical bone of the roots arc in contact with pedicle screws, bone resorption around the pedicle screws, etc. It should be noted that the destruction or destabilization of the transpedicular systems occurs most often as a result of alternating dynamic forces. Performed by us in the laboratory of biomechanics of SevNTU the preliminary experimental study of vertebra-movement segments models stability showed that the local fracture of transpedicular systems elements of various types occur under the influence of alternating vertical loads of the order of 1500 N and bending moments in the sagittal plane of the order of 65 Nm. Full or partial destabilization of structures was observed, respectively, at the vertical load about 2500 N and the bending moment about 75 Nm.

The problem of determining the number of cycles of the stresses change until the transpedicle systems failure in these experiments is not intended as with the required accuracy it can be solved only by using specialized equipment certified in compliance with the standards governing this type of testing. In this regard, actual task is to design and create a universal fatigue testing machine for spinal fixation systems under various conditions of loading. Such a machine will allow carry out tests to assess on the required confidence level the resource of the existing and newly developed fixation systems of the spine (including dynamic) under various loading conditions corresponding to the most probable nature of everyday human activity.

2. MATERIALS AND METHODS

There are many designs of devices for both static and dynamic tests of spinal elements, its models and the implants used in the treatment of diseases and injuries of the spine [5 - 20, etc.]. Most of them in the process of testing can provide a compression/decompression, shear, flexion/extension and torsion test sample and, in general, can be divided into the following groups: systems containing rotating blocks, single-axis system (servo-hydraulic and pneumatic); robotic systems. The most advanced device complies with international standards (ISO/DIS 18192-1, ASTM F2077-03, ASTM F2267, ASTM F2624, ASTM F1798-97, ASTM F1717-04, ISO/DIS 18192-2, ISO / DIS 12189-1, ISO / DIS 12189-2, ISO/DIS 12189-3 etc.), regulating the requirements for static and dynamic testing of implants used in spinal surgery.

The requirements of these standards generally apply to tests of the fixation systems. In particular, when testing the transpedicular systems of various type the angular displacement of one of the blocks of the vertebral-motion segment can meet the requirements of ISO / DIS 18192-1 (Fig.3). However, during systems fatigue testing that fix multiple segments, these requirements need to be modified for practical reasons.

For example, the life and activity of the majority of the patients depends on gender, age, temperament, the kind of every day work and many other factors. In this regard, the character of the loading of the same type fixing systems in the postoperative period, and, therefore, their lifespan may be significantly different. In addition, the quality of surgery and the state of vertebrae bone tissue can have a significant impact on the lifespan of the fixing systems. Therefore, a reliable evaluation of the fixing systems resource with preservation of stability can be obtained only from the tests that take into account the whole set of design and operational factors. The information about reliable resource of the fixing systems specified with many factors noted above, is not only important for design engineers of such systems, but also for surgeons, both at the planning of the operation and in the postoperative period.

The multifactorial fatigue tests of the fixing systems must be carried out on the devices that can rapidly reconfigurable, provide a sufficiently large number of loading cycles ($(1.0 \div 5.0) \cdot 10^6$) and should be commercially available. Analysis of modern testing machines showed that the most fully satisfy to these requirements the design with rotating independently blocks that allow to implement the loading of the test object by twisting and bending moments acting on different planes, the amplitude values of which vary widely. In addition, such structures should have nodes, allowing to provide the effect of the constant component of the compressive load and, where appropriate, its periodic change.

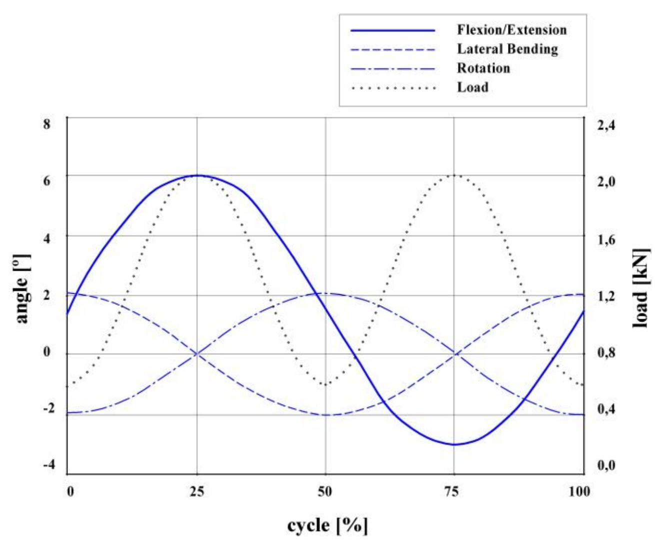


Fig.3. Lumbar intervertebral implants displacement and load test diagrams according to ISO/DIS 18192-1 – three degrees of freedom

As a prototype of the developed machine for the fatigue testing was chosen the wear testing machine for total hip joint prostheses developed at the laboratory of biomechanics of SevNTU, that performs the testing in accordance with standards, and in accordance with customers' requirements, which can vary over a wide range. General view of the wear testing machine for total hip joint prostheses is shown in Fig.4.

Fig.4. General view of the wear testing machine for total hip joint prostheses

A distinctive feature of this machine is to use in it as a drive the mechatronic modules of a new generation, made by FESTO Company, that can produce quite complicated laws of movement of working bodies in a wide range of parameters.

The design elaboration of machine for transpedicular systems fatigue testing was performed in SolidWorks based on 3D-modules, previously used in the design of wear testing machine. In order to determine the optimal kinematic and dynamic parameters of the drive mechanism for each of the degrees of freedom were solved problems of multicriteria optimization of structures with a view of minimizing pressure angles in the kinematic pairs and to maximize the power transmission coefficient. Besides taken into account the characteristics of the electromechanical axes EGC-120-50-TB-KF-50H-GK-ZUB-2MY2X, EGC-185-100-TB-KF-50H-GK-ZUB-2MY2X and stepper motor EMMS-ST-87-M-SEB made by FESTO Company.

3. THE RESULTS OF WORK

Developed testing machine is an electromechanical device with a mechatronic drives, allowing to implement a rotation in transverse plane, bend at the coronal and sagittal panes and vertical axial loading of the test object, by applying to it periodically changing effort.

The test object is a one or more vertebra-motion segments, assembled under the scheme: the vertebra - the intervertebral disc (cage) - the vertebra - the intervertebral disc (cage) - ..., fixed together by transpedicular system. Vertebrae models according to ASTM F1717-04 in most cases are made of ultra high molecular weight polyethylene, and where necessary, from the materials with similar properties to the bone (for example, in a case of lifespan assessment of the transpedicular system, fixing the vertebrae affected by osteoporosis).

The lower vertebra of the test object is rigidly attached to the holder, which in the process of testing is rotated in three dimensions (transverse (Inward-Outward Rotation - IOR), coronal (Adduction-Abduction - AA) and sagittal (Flexion-Extension - FE)), and the upper vertebra is attached to the rod of mechanism of the loading device, so that has the ability to move with ability of small movement in a vertical direction. Horizontal displacements and rotations of the upper vertebrae are locked.

The fragment of SolidWorks model of the testing machine is shown in Fig.5.

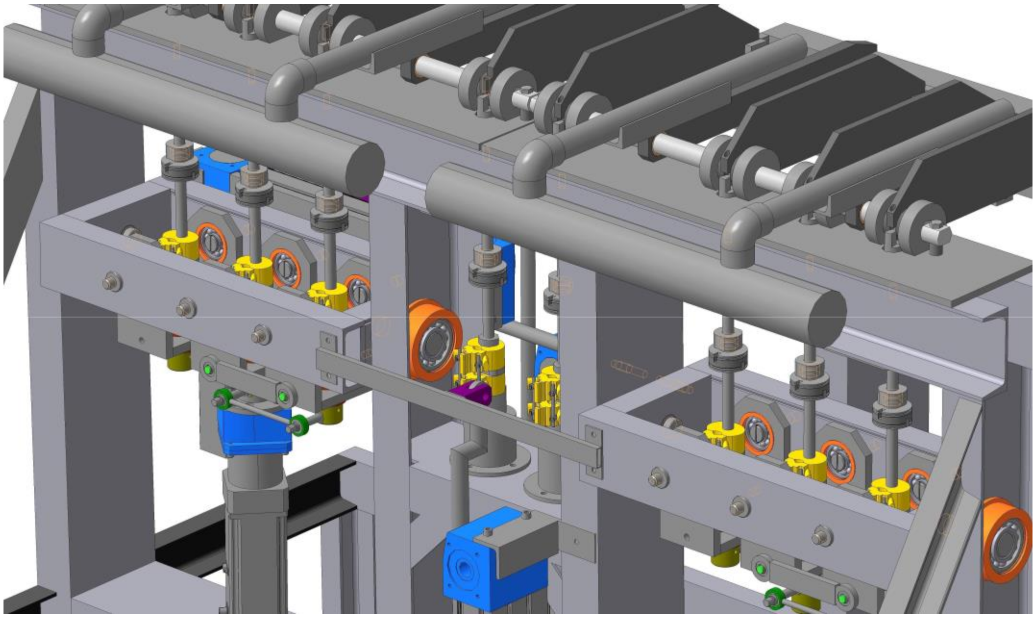


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Fig.5. SolidWorks model of the fatigue testing machine for spinal fixation systems (fragment)

The rotation of the lower vertebrae holders about their own axes (IOR) is carried out directly by a stepper motor EMMS-ST-87-M-SEB with a gear unit. The engine control system allows for the motion of the output shaft of the gear unit, satisfying a wide range of requirements. Considering the total moment of inertia of the masses reduced to the output shaft, the maximum torque at the implementation of the rotation according to the harmonic law (Fig.3) does not exceed $0.05\ Nm$, and the maximum instantaneous power no more $0.02\ W$. Thus, the motor EMMS-ST-87-M-SEB allows to produce more complex laws of motion, including those in which the peak of angular acceleration is much higher.

For the rotations AA and FE are used the actuators with electromechanical axes EGC-120-50-TB-KF-50H-GK-ZUB-2MY2X, EGC-185-100-TB-KF-50H-GK-ZUB-2MY2X and the mechanisms, kinematic scheme of which is shown in Fig.6.

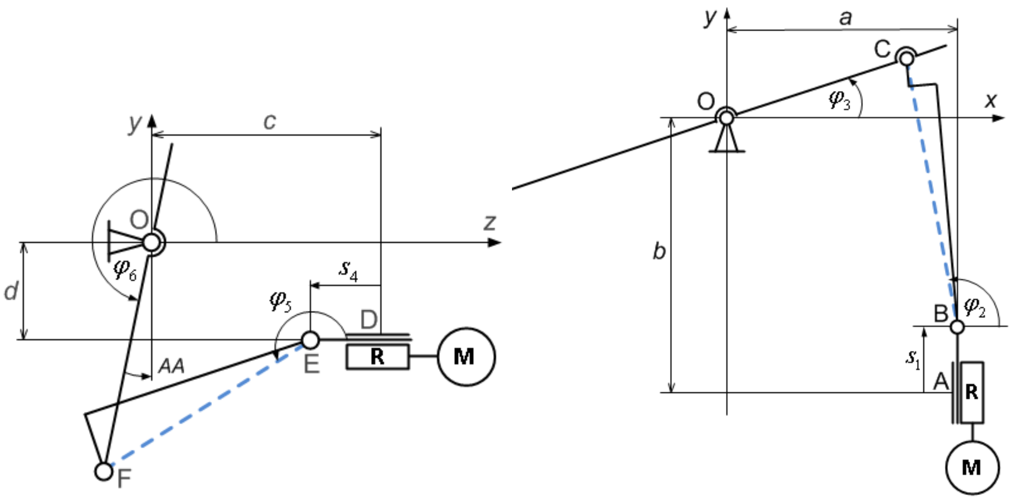
Solving for the mechanisms the inverse kinematics problem, we obtain the motion laws of the electromechanical axes sliders:

$$s_4 = -c + l_{OF}\cos\varphi_6 - \sqrt{l_{EF}^2 - d^2 - 2dl_{OF}\sin\varphi_6 - l_{OF}^2\sin^2\varphi_6}\ , \qquad (1)$$

$$s_1 = b + l_{OC}\sin\varphi_3 + \sqrt{l_{BC}^2 - a^2 + 2al_{OC}\cos\varphi_3 - l_{OC}^2\cos^2\varphi_3}\ . \qquad (2)$$

Thus, the control system generates the laws of motion (1) and (2) required for compliance testing rotation angles $\varphi_6 = \varphi_6(t)$ - AA and $\varphi_3 = \varphi_3(t)$ - FE. A preliminary dynamic analysis of mechanisms has shown that electromechanical axes EGC-120-50-TB-KF-50H-GK-ZUB-2MY2X and EGC-185-100-TB-KF-50H-GK-ZUB-2MY2X have sufficient reserve capacity to implement holder turns into a wide range of functions $\varphi_6 = \varphi_6(t)$ и $\varphi_3 = \varphi_3(t)$.

The vertical load is applied to the test object through the mechanism of loading device, which is provided by electromechanical axes EGC-185-100-TB-KF-50H-GK-ZUB-2MY2X. The force created by the deformation of the spring connected to the rod which is attached to the upper vertebra. At the maximum deformation of spring $\delta = 0.0036\ m$ device provides a compressive (vertical) load $F = 3000\ N$.



a) b)

Fig.6. Kinematic schemes of the rotation mechanisms of a holder device: a) rotating mechanism of a U-shaped bracket (AA); b) rotating mechanism of a rectangular frame (FE)

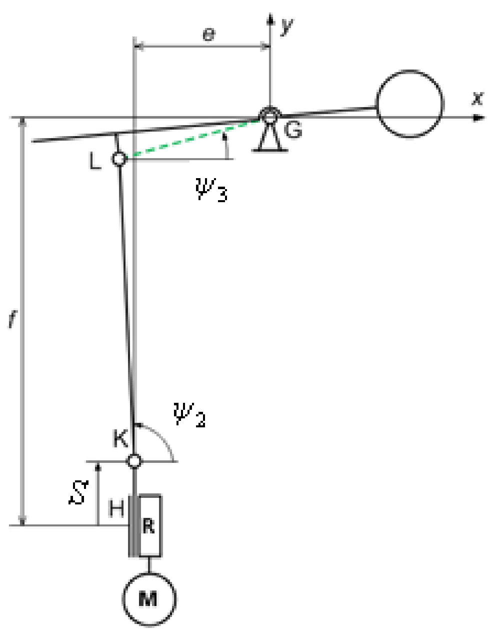


Fig.7. Kinematic scheme of the mechanism of loading device

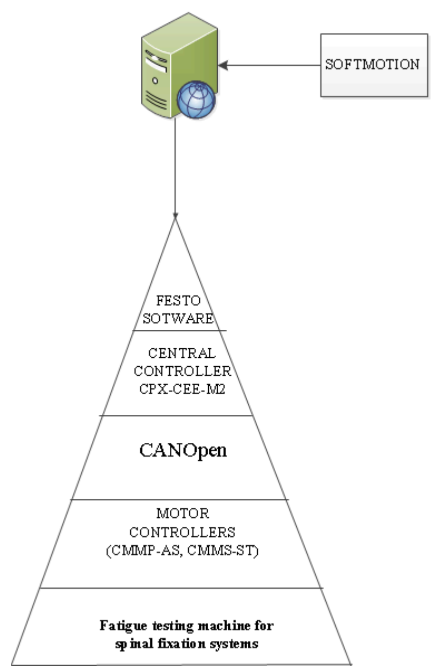


Fig.8. Control scheme of the fatigue testing machine for spinal fixation systems

It should be noted that as a result of optimization were derived the kinematic parameters of mechanisms (Fig.6, Fig.7) under which on possible areas of definition φ_6, φ_3 и ψ_3 the inverse position function is almost linear, and can be approximately represented as linear functions: $s_4 = K_1\varphi_6 + C_1$, $s_1 = K_2\varphi_3 + C_2$, $S = K_3\psi_3 + C_3$, where K_i, C_i, $i = 1,2,3$ - dimensional constants determined from the tables of the function $s_4 = s_4(t)$, $s_1 = s_1(t)$ и $S = S(t)$. Thus, the extra accelerations of the output links connected with the related features of the kinematic schemes, practically equal zero.

The control of testing machine performed by means of FESTO software according to the scheme shown in Fig.8

4. CONCLUSION

The control system of modules allows to implement complex laws of the periodic deformation of object subjected to testing, including those that are required by standards or specific to different types of human activity. If necessary, the extrema of the laws of motion for different degrees of freedom can be shifted in phase. While designing the fatigue testing machine the design of simulator for testing hip joints on wear was accepted as the basis. According to the requirements of ISO 14242-1, this simulator is operating at much higher loads than it needs for fixation systems of the spine and will have a much greater resource.

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