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Original Paper

Influence of loading history on the cervical screw pullout strength value

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The problem of the loosening and pullout of bone screws in cervical spine stabilisation is a significant factor in failed implantations of that spine region. Therefore, studies were undertaken to determine the impact of the loading history of bone screws of the cervical spine, inserted from the anterior approach, on the stability of the screw–bone interface. The research was conducted on vertebrae obtained from cadaver specimens of the cervical spine. Two screws were inserted into each vertebra and then pulled out with a force acting along the screw axis.

The mean pullout force for the screws subjected to cyclic preloading was 355.2 ± 74.4 N, and for the screws subjected to direct pullout it was 411.0 ± 78 N ($p < 0.05$).

The research results show a significant impact of bone tissue preloading with a cyclic variable force on the pullout force obtained. For the preloaded bone screws the recorded rupture strength of the implant–vertebral body interface was by 16% lower compared to the screws pulled out without preloading. The values presented also show a strong correlation between the bone density and the pullout force obtained after cyclic loading with the strength normal to the screw axis.

Key words: *cervical spine, cyclic loading, pullout strength, experimental investigations, experimental investigation*

1. Introduction

The cervical spine is especially exposed to various types of overload caused by the wide range and the high frequency of the motions performed. An additional factor contributing to its high susceptibility to injury is the lack of spatial stabilising elements characteristic of the lower spine segments, such as: thorax at the thoracic spine or abdominal press at the lumbar spine.

In most cases, cervical spine injuries require surgical treatment using technical measures in the form of implants. Throughout the world spinal fusion procedures are growing in popularity, including operations of the cervical spine and operations with the use of fixators [1], [2]. This is caused by a growing public demand for surgical treatment of the spine as a result of processes associated with lifespan lengthening and increasing number of spinal injuries.

Cervical spine surgery has been developing since the beginning of the twentieth century. Dynamic progress in this field is connected with the development of the technique of anterior surgical stabilisation, thanks to the work of BAILLEY and BEDGLEY [3] as well as the work of CLOWARD [4]. On the other hand, the first trial applications of a plate for anterior osteosynthesis date back to the 1950s [5]–[9].

At present anterior stabilisation is commonly used in the treatment of cervical spine injuries. However, as clinical practice shows, this method is not free of complications, which appear both during the implantation and the use of fixator. One of the major problems is the loosening of bone screws fastening the plate to the vertebral body. This ulti-

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mately leads to secondary destabilisation of the spinal column. In extreme cases, the oesophagus may even be penetrated by some implant elements [10]. The most popular causes of bone screw loosening include: a pathological condition of the bone tissue (e.g. osteoporosis); the application of excessive force during the implantation of the screws (excessive torque on screw during screwing leads to stripping of the threaded connection between screw and bone); an incorrect fastening of the bone screws (at the vertebral body–intervertebral disk border); premature and too intensive loading of the stabilised segment, or infections.

From the biomechanical point of view, the stability of bone screw embedment in the cervical vertebral body is expressed as the force leading to destabilisation of the interface and, consequently, to the screw pullout from the vertebra.

The studies on the stability of the screw–cervical bone fixation concern mainly the impact of various geometrical and mechanical parameters of the screws on the force resulting in the loss of the interface stability and screw pullout from the bone tissue of the vertebra [11]–[16]. Another important factor analysed in the research is the impact of the method of screw support in the vertebral body (on the anterior or the anterior and posterior cortex) on changes in the strength of such interface [17]–[19].

The analysis also covers the correlations between the force leading to loss of the screw–bone contact and the density of the bone itself [18], [20], [21].

However, most of those studies are carried out under the conditions of "pure" pullout, where the force leading to screw pullout from bone acts in line with the screw axis. The analysis of how cyclic bending load acting on bone screws affects their pullout force (and, consequently, changes the screw–bone fixation stability) is only rarely undertaken in biomechanical research of the cervical spine [22].

There is a strong rationale for the research with the use of cyclic loading because of the physiological work of the spine, which is subjected to high-cyclic dynamic loading during normal life functions.

This paper presents the results of research analysing how the history of screw loading (anterior access) affects the stability of the screw–vertebral body interface of the cervical spine. The research covered the analysis and comparison of the interface strength in the pullout test and the pullout strength after preloading the screw with cyclically variable force normal to its axis. Additionally, the radiological bone density was analysed to assess the impact of that parameter on the value of the pullout force.

2. Material and method

The research was carried out on 19 vertebrae obtained from cadaver specimens (individuals aged 24–68). Sixteen specimens were obtained from the cervical spine (C3÷C7) and three specimens were obtained from the thoracic spine (Th1). The specimens were stored in double plastic packaging at a temperature of 20 °C. Before starting tests, the research material was defrosted at room temperature and then segmented into separate vertebrae and cleaned of soft tissue.

In order to exclude possible degenerative and traumatic changes, all preparations were subjected to X-ray analysis (radiographs). CAT analysis (using a CT/e Dual scanner by General Electric) was also carried out to determine the radiological density (RD) of the spongy tissue of the vertebrae examined. The RD value for each of the vertebral bodies under examination was determined as a mean of six measuring points, located according to the diagram presented in figure 1.

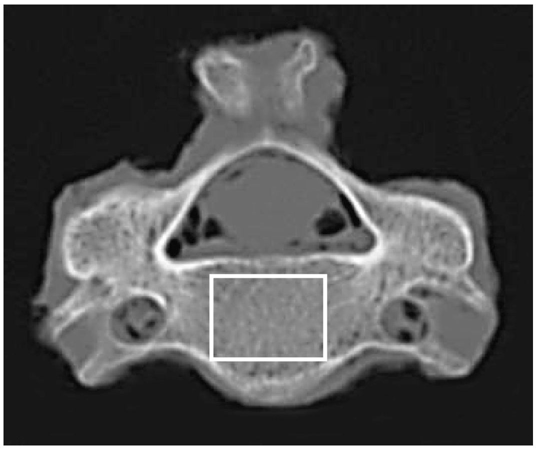


Fig. 1. Inner square placed within the vertebral body around the planned screw entrance point for determining radiological bone density

Screws, made of the Ti6Al4V alloy, 5-mm outer diameter d, 18 mm in length l and a conical core, were placed into the prepared vertebrae bone. The screws were placed into a depth ensuring an effective plate–bone interface during an actual clinical procedure. As a result, bone screws implanted in the examined vertebrae were supported on the anterior cortex of the vertebral body without being anchored in the dense tissue of the posterior wall of the vertebral body. Each vertebra was implanted with the same type of screw (figure 2), in accordance with the implantation procedure for such elements.

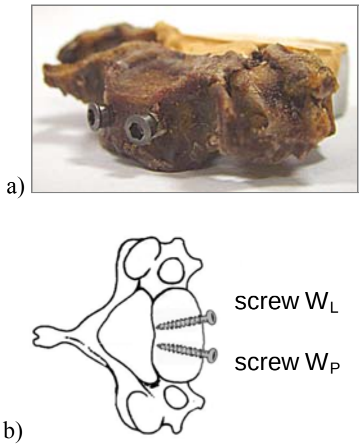


Fig. 2. Vertebra with anterior screw (a), schema of inserting screws into vertebra (b)

The vertebrae together with the implanted screws were fastened to a custom-made grip provided with a joint giving three degrees of freedom (figure 3) [23], [24]. Construction of the grip enabled alignment of the screw axis in accordance with the direction of the set pullout force P_{PO} (figure 3b). When the screw tested was subjected to cyclic preloading P_{CL} the direction of that force was perpendicular to the screw axis (figure 3a). The tests were carried out on the MTS MiniBionix 858 strength tester.

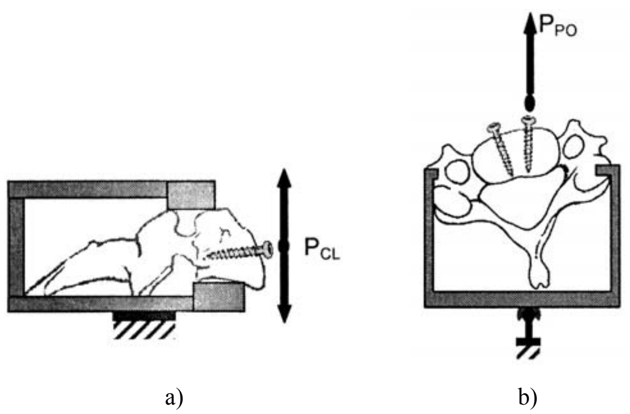


Fig. 3. Schema of setup for extraction of cervical anterior screw in a jig for realization: a) cyclic preloading P_{CL}, b) axial pullout loading P_{PO}

During the first stage bone screws were subjected to cyclic loading with the force P_{CL} applied perpendicularly to the screw axis. Each of the cases examined consisted of 10,000 loading cycles with the 1 Hz frequency in the ±60-N range.The adopted range of the force P_{CL} corresponds to the loading in the cervical spine [25]. The preloading, executed in accordance with the procedure described above, involved only one of the two screws that were screwed into each of the vertebral bodies examined. The second screw was subjected only to the pullout force without cyclic preloading with normal force.

The performance of the planned number of preloading cycles was followed by the second stage of the research, involving application of the force P_{PO} to the screw head, resulting in its gradual pullout from the point of embedment in the vertebral body.

The pullout test involved loading the implanted bone screw with the force P_{PO} acting in the direction aligned with the screw axis. The screw was pulled out at a constant speed of 2 mm/min. In all cases, the test was carried out until the moment of rupture of the screw interface between the screw and the bone structure of the vertebral body.

During the tests changes were recorded in the force P_{PO} (N) in relation to the displacement d (mm) of the screw towards the direction of the pullout force. The experimental data obtained were used to determine the mean values of the screw pullout force and the standard deviation.

3. Results

The research results provided characteristics of the changes in the pullout force necessary for screw displacement in relation to the bodies of the examined vertebrae $P_{PO} = f(d)$, depending on the bone screw loading history. A sample progress of the pullout characteristics for a screw preloaded with the cyclic force P_{CL} and without cyclic loading is presented in figure 4.

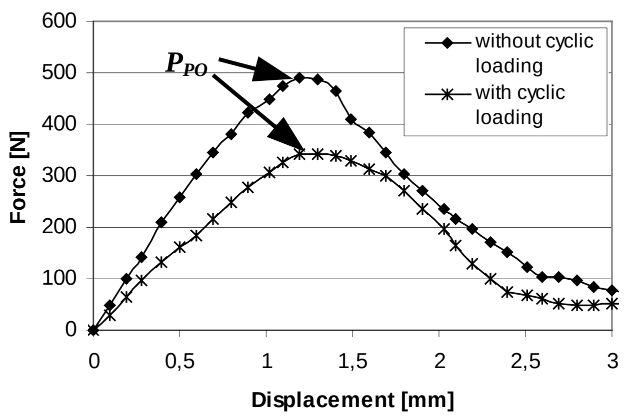


Fig. 4. Example of characteristic load–displacement curve representing a sample progress for a screw preloaded with the cyclic force P_{CL} and without cyclic loading (P_{PO} is a maximum force registered during the test)

The graphs $P_{PO} = f(d)$ received for the cases under examination were used to determine the pullout force

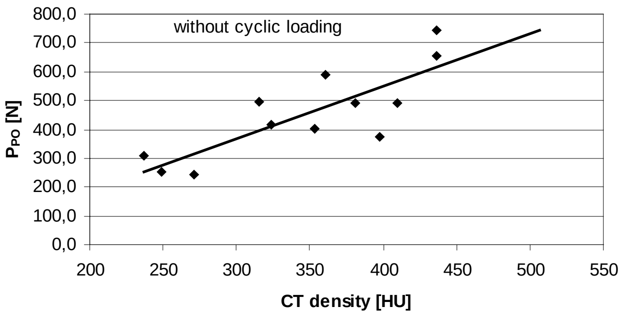
P_{PO}. This force was defined as the maximum force after which there is a significant drop in force. The table shows the value of the pullout force P_{PO}, depending on the loading method and the level from which the vertebra examined was taken. The mean pullout force for the screws subjected to cyclic preloading was P_{PO} = 355.2 ± 74.4 N, and for the screws not subjected to cyclic loading with a variable normal force, the corresponding value was P_{PO} = 411.0 ± 78 N (statistically significant differences $p < 0.05$). There are also visible differences in the pullout forces between the respective vertebrae. The greatest force P_{PO} was recorded for the C3 vertebrae, i.e. 394.4 ± 158.0 N with cyclic loading and 458.7 ± 146.6 N without cyclic loading.

Table. Average values of pullout strength P_{PO}

	Pullout force P_{PO} (N)		Changes (%)
	With cyclic loading	Without cyclic loading	
C3 (n = 4)	394.4±158.0*	458.7±146.6*	14.0
C5 (n = 4)	388.4±143.5	455.2±134.8	14.7
C6 (n = 4)	376.0±139.5	454.9±185.0	17.4
C7 (n = 4)	222.7±131.0	275.9±131.4	19.3
Th1 (n = 3)	394.3±137.5	410.3±155.6	
Average value	**355.2±74.4**	**411.0±78.1**	**16.4**

* Standard deviation.

a)



b)

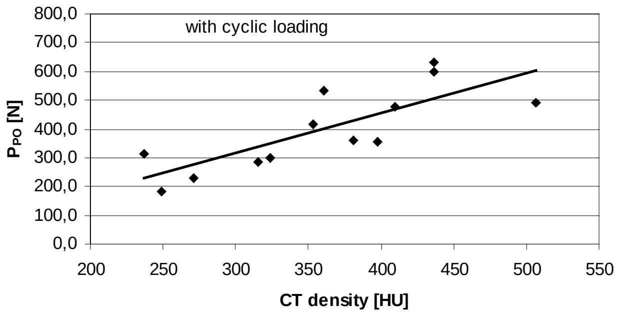


Fig. 5. Correlation between pullout strength value and radiological bone density (HU) for: a) test without cyclic preloading, b) test with cyclic loading

The greatest force P_{PO} was recorded for the C3 vertebrae, i.e. 394.4 ± 158.0 N with cyclic loading and 458.7 ± 146.6 N without cyclic loading.

The lowest force P_{PO} was recorded for the C7 vertebrae and it concerns both screws with cyclic loading (222.7 ± 131.0 N) and screws without cyclic loading (275.9 ± 131.4 N).

The radiological bone density (HU) was calculated for vertebra body trabecular bone before its mechanical testing. The recorded values of mineral density for individual vertebrae ranged from 280.1 HU to 439.5 HU with average value equal to 359.8 ± 79.7 HU.

The radiological bone density was correlated with the pullout force value (R^2 = 0.8 for the tests without cyclic loading and R^2 = 0.7 for the tests with cyclic loading, figure 5).

4. Discussion

The research demonstrated a significant impact of the preloading of the bone screw with a cyclically variable normal force on the obtained force causing pullout of the screw from a vertebral body of the cervical spine. For the preloaded bone screws the rupture strength of the implant–vertebral body interface was by 16% lower compared to the screws pulled out without such preloading.

Cyclically variable loading, aligned perpendicularly to the screw axis, generates a certain kinematic state requiring displacement (in the loading plane) of the threaded part of the screw embedded in the spongy substance of the vertebral body. In such a situation, reactive forces appear inside the spongy bone tissue being in contact with the screw surface that prevents such screw displacement. Because under experimental conditions the loading set at the nominal force of P_{CL} = 60 N is cyclic and repeats 10,000 times, the bone tissue in direct contact with the screw surface gradually becomes permanently deformed. As a result, some microloosening starts to appear at the screw–bone tissue border, which consequently leads to a weakening of the initial stability of the implant–tissue interface. This weakening of the screw–bone tissue interface manifests itself as a decrease in the force required for a change of its position in the axial direction, which consequently leads to its pullout. In clinical practice, when in extreme cases the limits of loads placed on the spongy bone tissue are exceeded, the tissue undergoes osteolysis, and the screw–bone interface is ruptured, which results in screw migration outside the vertebral body [26], [27].

The analysis of the interface strength of the implant–bone, conducted on the basis of the pullout test without taking into account the preloading in the form of cyclically changing forces, provides an incomplete image of the processes leading to the loss of interface stability. Experimental research presented by MAIMAN et al. [13] demonstrated unequivocally that there were no differences in the pullout force between bicortical screws and unicortical screws in the "pure" pullout test. However, for the same research configuration the use of a dynamic cyclic load, preceding the actual test and directed perpendicularly to the screw axis, demonstrated a statistically important difference in the behaviour of those two types of screws and their impact on the interface stability [25].

An important role in the pullout process is played by the density of the bone tissue in which the bone screws are embedded. Many researchers conducting static tests documented in their studies the correlation between the pullout strength and the bone density [18], [28], [29]. Also, the results presented in this paper confirm of such a relationship and additionally point to a strong correlation between the bone density and the value of the pullout force obtained after cyclic loading with a force normal to the screw axis. On the other hand, a weaker correlation between cyclic loading and bone density was demonstrated by LOTZ et al. [30].

These studies have several limitations. Under in vivo conditions the bone tissue is subjected to the process of reconstruction connected with the impact of loads put on the spine during the performance of typical life functions. Consequently, after the first phase of treatment and bone reconstruction, the pullout force would probably undergo radical changes. Therefore, the studies performed can only have their counterparts in the first period after the implantation procedure, when there are still no changes around the implant. Another limitation is the performance of studies on a single, isolated vertebra, unsupported and not influenced by the adjoining vertebrae and the soft tissue. It should be emphasized that the same vertebra was used in the analysis of the pullout strength for statically loaded screws ("pure" pullout) as well as dynamically loaded screws. This could possibly do microdamage to the bone tissue, and consequently affect the results obtained. Therefore, the bone screws were pulled out in alternating fashion – in a given sample first a statically loaded screw and then a dynamically loaded screw were pulled out.

The stability of the bone screw–vertebral body interface is affected, among others, by: screw geometry (diameter, length, shape) [24], [31]; the density and quality of the bone tissue in which the screw is embedded; and bone reaction to the implant insertion (resorption, remodelling).

The results of the research and reports available in the literature show the equal importance of the loading "history", which models the functional state of loading of the elements stabilising the treated spine region.

In everyday functioning, the human spine is subjected to cyclic loading repeated hundreds of thousands times. That is why it is very important to carry out research with simulated loads, approximating those existing in the physiological system. The simulations of cyclic loads in biomechanical tests analysing the stability of interfaces between fixator elements and bone have an important cognitive significance. The inclusion of cyclic loading effects in the experimental research on bone screw strength in vertebrae not only expands the scope of the acquired knowledge, but also approximates the test system to a real-life system.

5. Conclusion

1. Statistically important differences were obtained between the pullout forces, depending on the loading history of bone tissue.

2. The pullout force (both with and without the application of cyclic preloading) depends to a significant degree on the biomechanical quality of the bone tissue, which in our research was represented by radiological bone density.

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