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Biomechanical Evaluation of the Modular Anterior Construct System (MACS^{TL}) Internal Fixator for Thoracic Spinal Stabilisation

R. VESELÝ[1], Z. FLORIÁN[2], P. WENDSCHE[1], J. TOŠOVSKÝ[2]

[1]Clinic of Traumatology, Faculty of Medicine, Masaryk University in Brno, Czech Republic
[2]Institute of Mechatronics and Biomechanics, Faculty of Mechanical Engineering in Brno, Czech Republic

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Abstract

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Unstable fractures of the thoracic spine in humans represent a serious social and economic issue. They may lead to persistent consequences and chronic disease. The anatomical and biomechanical characteristics of the thoracic spine are different from all the other spinal parts due to its higher mobility. The vertebrae of the chest area are less mobile, conferring a higher degree of rigidity to the spine. To destabilize this relatively rigid system, a considerable force is necessary.

The treatment of unstable spinal fractures is solely surgical. The decompression of the spinal canal with reposition and stabilisation of the fracture is indicated urgently. This intervention is performed mostly from the posterior approach in the first phase. However, the anterior spinal column is the structure responsible for the stability of the spine. Therefore, the recent advances in spine surgery focus on this area of expertise. For this reason, we carried out a bio-mechanical study aimed at assessing the effectiveness of two surgical tactics used. The study consisted of comparative experiments performed by computer-aided device on segments of pig cadavers (n = 5). The experiment involved a comparison of segments of the thoracic spine under the following conditions: an anatomically intact segment, a spine segment with an artificially created anterior instability, and a segment with an applied internal fixator. The experiment compared the mechanical characteristics of these segments.

The experiment has demonstrated that after application of the internal fixator used for stabilisation of the injured anterior spinal column at defined pre-loading of 200 N, the stability of damaged spinal segment in torsion increased twofold. It was also verified that sufficient stability can be ensured using the Modular Anterior Construct System (MACS^{TL}) implant for ventral stabilisation of thoracic spine unstable injuries. Endoscopic application of this implant represents an additional advantage of this surgical procedure.

Thoracic spine, unstable fractures, anterior approach, biomechanical study, swine, model

Unstable fractures of the thoracic spine represent a serious social and economic issue in human medicine. On one hand, these injuries involving damage to the spinal cord can result in irreversible persistent consequences; on the other hand, such traumas with minimal force without radiographic signs develop into a chronic condition that can result in permanent disability.

The thoracic spine is the longest section of the spine with a prevalence of trauma exposure, especially in its lower area. Anatomical and biomechanical characteristics of the thoracic spine differ from other, more flexible, sections of the spine. The chest limits motion and contributes greatly to spinal rigidity. This is obvious especially in extension movements. Flexion and lateral rotation in the thoracic area are, however, limited in comparison to other parts of the spine. Apart from the skeleton, the ligament apparatus is also important for spinal stability. In bio-mechanical terms, the main contribution of the chest is to alleviate the impact of a violent trauma. It increases spinal resistance to compression. Additionally, the costovertebral joints play an important role. In the event of damage to them, the spinal stability is decreased.

Address for correspondence:
MUDr. Radek Veselý, PhD.
Traumatological Hospital Brno
Ponávka 6
662 50 Brno, Czech Republic

Phone: +420 545 538 111
E-mail: r.vesely@unbr.cz
http://www.vfu.cz/acta-vet/actavet.htm

Until 1960s, unstable fractures of the thoracolumbal spine were treated only by decompression of nerve structures, regardless of the fact that the procedure would aggravate this instability even further. The first person to use transpedicular screws to stabilise the fracture was Boucher (1959). Magerl (1980) applied the external fixator to perform the reposition in various directions and levels. Based on Magerl's principles, Dick used the internal fixator in 1987. CT imaging brought significant progress not only for the treatment, but also for the diagnostics in the early 1980s. A new classification of fractures was created reflecting advanced anatomical and biomechanical knowledge. It was demonstrated that the anterior spinal column is a critical factor affecting spinal stability. Although surgical stabilisation cannot repair the neurological lesion, a correctly indicated and performed surgery will prevent secondary changes and speed up recovery. With the development of new surgical methods, emphasis has been placed on treatment of the anterior spinal column in recent years. This fact motivated us to conduct a biomechanical study focused on comparative experiments on segments of the thoracic spine of pig cadavers (n = 5), performed using a computer-aided device. Mechanical characteristics of the thoracic spine segments were compared in the following conditions: anatomically undamaged segment, thoracic segment with an artificially created anterior instability, and a segment with an applied internal fixator.

Materials and Methods

The experiment was performed in laboratories of the Institute of Mechatronics and Bio-mechanics of the Faculty of Mechanical Engineering in Brno. The computer-aided mechanical experimental device ZWICK (Plate VIII, Fig. 1) allows the researcher to load the experimental component with a combination of traction force, pressure and distortion. Spinal segments of the thoracic spine of pigs were used in the experiment. The specific segments were removed from male pigs of the same age (3 years). All experiments were performed according to recommendations of the Ethicas Committee (No. 46613/2003-1020). The actual spinal segment was formed by two adjacent vertebrae with intravertebral disc and ligaments.

The segment was anchored to a clamping fixture, after which the measurements were carried out. The device applied the predefined pressure or traction force to the sample, followed by torsion. The torsion loading had deforming characteristics, and the distortion angle was used as the command variable. For the duration of our experiment, the angle was set to the constant value of 10º.

From the technical point of view, the experimental scheme was identical (Plate IX, Fig. 2):

a) The segment was anchored to the device, initial parameters were adjusted and the first measurement was performed using the undamaged spinal segment.

b) The complete anterior instability was created artificially in the same spinal segment and the second measurement was performed. The anterior instability was realised by an incision into the anterior ligament apparatus and intervertebral disc.

c) The damaged spinal segment was stabilised by a $MACS^{TL}$ internal fixator and the third measurement was performed.

The $MACS^{TL}$ internal fixator used in the experiment is applied solely in instabilities of the anterior spinal column. The predominant area of application is the thoracic spine. The fixator comprises two polyaxial and two stabilising screws that anchor a bridging plate to the injured vertebrae. To eliminate a possible measurement error, all applications in experiment were performed by the author, using the original instrumentarium and $MACS^{TL}$ implant (Plate X, Fig. 3).

Results

The first run of the experiment was performed on a sample loaded with a compressive axial force of 50 N. The constant value of the torsion angle was 10º. The correlation between the value of the force couple and angular displacement was delineated in the graph. Only the combinations regarded as essential are included in the results. Some measurements were repeated to exclude potential errors and to record changes of mechanical features during the loading sequence.

The surprising results of the first measurement are shown in Table 1. The value of the force couple necessary to distort the damaged sample with the fixator is lower than the necessary value for the damaged sample without a fixator (14.32 vs. 13.13 Nm). It may be due to the fact that all spinal junctions are functional during an axial loading. Its function is limited and excluded only under a traction force load, which basically corresponds to flexion loading. For this reason, our maximal attention was paid to the effects of axial loading during the second run of the experiment. A new sample was used for the second experiment, as shown in Table 2. There is no substantial difference in the value of the force couple for the axial traction force loading of 50 N, 100 N and 200 N in the undamaged sample. There is a substantial difference in the value of the force couple necessary for 10º torsion of the spinal sample under the axial traction force loading of 200 N between the damaged and undamaged sample (4.44 vs. 11.92 Nm). Given the results we inferred that the axial traction force loading of 200 Nm does not exceed the spinal loading under typical loading circumstances. That value, however, substantially affects the mechanical characteristics of the damaged segment. That is why we decided to perform the next experiment under the axial traction force loading of 200 N.

Based on the above mentioned conclusions, the third experiment was carried out on three spinal segments. Table 3 demonstrates that the maximum value of the force couple in a loaded undamaged sample under the axial traction force of 200 N does not change substantially (16.25 - 16.96 - 17.62 Nm). At the same time, the essential difference in the mechanical behaviour of the damaged sample without and with the fixator is evident (5.27 and 19.02 Nm, respectively).

Based on our measurements, it is possible to state that torsion rigidity of the damaged sample with the fixator exceeded more than twofold the value obtained without the fixator.

Table 1. The first experiment under the compressive axial force of 50 N

Sample 1	Maximal strength of couple forces (Nm)
Undamaged	20.59
Damaged	14.32
With fixator	13.13

Table 2. The second experiment with an undamaged segment

Sample 2	Maximal strength of couple forces (Nm)
Undamaged axial traction force loading 50 A	11.98
Undamaged axial traction force loading 100 N	11.87
Undamaged axial traction force loading 200 N	11.92

Table 3. The third experiment on three spinal segments

Sample 3	Maximal strength of couple forces (Nm)
Undamaged axial traction force loading 200 A	16.25
Damaged axial traction force loading 200 A	5.27
With fixator 200 A	19.02
Sample 4	Maximal strength of couple forces (Nm)
Undamaged axial traction force loading 200 A	18.96
Damaged axial traction force loading 200 A	6.06
With fixator 200 A	21.42
Sample 5	Maximal strength of couple forces (Nm)
Undamaged axial traction force loading 200 A	19.62
Damaged axial traction force loading 200 A	9.05
With fixator 200 A	22.05

Discussion

The results evaluated in previous experiments were distorted due to the high diversity of biological states of the cadaver spine segments used (Florián et al. 2002). To minimise such distortion, we enforced strict selection based on the criteria described above. As this was the first time this experiment was performed, the optimal initial settings (pressure, traction force) needed to be determined before the start. Following a number of tests, the traction force of 200 N was chosen as the initial loading because it was recorded that choosing lower values or a pressure force would distort the measured values due to the function of spinal junctions.

During the experiment, spinal segments were used under physiological conditions. Tests were performed on an undamaged and damaged segment. In practice, physiological loading changes over the time. In studies, static model loading is used rather than cyclic, because it is very difficult to simulate cyclic loading experimentally (Cunningham et al. 1993; Kotani et al. 1999). Moreover, *in vitro* degradation processes only occur, as opposed to reparative processes in the injured spine under usual conditions.

Taking into account the above mentioned facts, static loading was chosen as the standard in our experiment, although we understand that cyclic loading is more realistic (Valenta 1985). Cyclic loading, however, does not describe all effective biomechanical factors *in vivo*, either. For example, the replacement of an injured disc by a bone graft is not considered; as another example, the treatment of a damaged spinal segment using two implants and combining the ventral and dorsal approach, where the resulting properties are also completely different (Panjabi et al. 1995; Wilke et al. 1998).

The upper thoracic spine differs from other spinal parts with its rigidity and higher stability against compression force. Considerable force is required to destabilise this rather rigid system (El-Khoury and Whitten 1993; Schweighofer et al. 1997). Unstable spinal fractures are only treated surgically (McLain and Benson 1999; Veselý et al. 2003). It is urgently indicated in the event of decompression of the spinal column with reposition and stabilisation of the fracture. Typically, the stabilisation is initially performed from the posterior approach (Stanislas et al. 1998). However, the structure responsible for spinal stability is the anterior spinal column, and this is where the attention of spine surgery is currently focused (Rosenthal 2000). While major development effort of implants for posterior stabilisation has been completed, it is still underway for anterior access implants. The goal of our study was to express our opinion on mechanical features of the compared segments of the thoracic spine, namely an undamaged segment, a segment with damaged intervertebral disc and anterior ligament apparatus and a segment stabilised with an internal fixator. The experiment has demonstrated that the stability of the damaged spinal segment in torsion enhances twofold after the application of an internal fixator to stabilise the injured anterior spinal column, under the defined primary loading of 200 N.

The higher stability of the implant compared to an injured spinal segment or with the dorsal stabilisation is presented also by Schultheiss et al. (2002). Those mechanical tests were, however, focused on flexion/extension movements. The experiment of Grupp et al. (2002) was based on the synthetic model of Kotani (Kotani et al. 1999) and compared the MACS^{TL} implant with plate osteosynthesis in dynamic testing of the model after a corpectomy. Conclusions of that experiment are the same, in that the ventral stabilisation is sufficient in unstable injuries of the anterior spinal column (Florián et al. 2002; Tošovský et al. 2002; Veselý 2003).

In conclusion, it is possible to state that the experiment was technically rather demanding. During its progress and assessment of the results, many new problems and intriguing phenomena occurred, requiring further study in the future. This was the first experiment to use a mechanical computer-aided device, which was designed for biomechanical experiments and is able to perform tests applying compression, traction and torsion loading. The obtained results will be used in further experiments. The experiment has demonstrated that after application of the internal fixator used for stabilisation of the injured anterior spinal column at defined pre-loading of 200 N, the stability of the damaged spinal segment in torsion increased twofold. It was also verified that sufficient stability can be achieved using the MACS^{TL} implant for ventral stabilisation of unstable injuries of the thoracic spine. Endoscopic application of this implant represents an additional advantage of this surgical procedure.

Nestabilní zlomeniny hrudní páteře - experimentální studie

Nestabilní zlomeniny hrudní páteře jsou vážným sociálním i ekonomickým problémem. Mohou vést k nevratným trvalým následkům nebo k chronickým potížím. Oblast hrudní páteře má odlišné anatomické a biomechanické vlastnosti ve srovnání s ostatními více pohyblivými částmi páteře. Hrudní koš omezuje pohyb a přidává páteři na pevnosti.

K destabilizaci tohoto poměrně rigidního systému je zapotřebí značného násilí. Léčba nestabilních zlomenin páteře je výhradně operační. Urgentně je indikována dekomprese páteřního kanálu s repozicí a stabilizací zlomeniny. Ta je v první fázi většinou provedena ze zadního přístupu. Přední sloupec páteře je však strukturou, která je zodpovědná za většinovou stabilitu páteře a sem se zaměřuje v poslední době pozornost spondylochirurgie. Tato skutečnost nás vedla k provedení biomechanické studie, kdy na segmentech hrudní páteře kadaverů prasete domácího byly pomocí počítačem řízeného přístroje realizovány srovnávací experimenty. Porovnávány byly segmenty hrudní páteře v podmínkách anatomicky neporušeného segmentu, páteřního segmentu s arteficiálně provedenou přední nestabilitou a segmenty s aplikovaným vnitřním fixatérem s cílem srovnání jejich mechanických vlastností.

Experiment prokázal, že po aplikaci vnitřního fixatéru používaného ke stabilizaci poraněného předního sloupce páteře při definovaném předzatížení 200 N se dvojnásobně zvýší stabilita porušeného páteřního segmentu v torzi. Současně bylo ověřeno, že implantát pro ventrální stabilizaci nestabilních poranění hrudní páteře MACS^{TL} zajišťuje dostatečnou stabilitu. Výhodou tohoto implantátu je i možnost endoskopického použití.

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Fig. 1. Computer-aided mechanical experimental device ZWICK

Plate IX

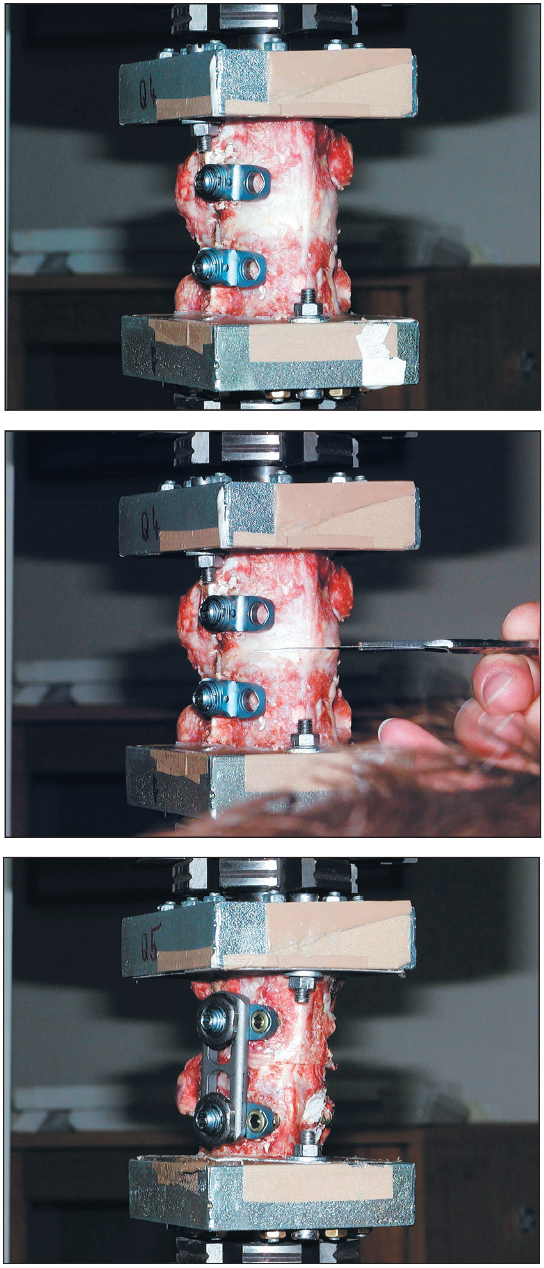

Fig. 2. Experimental measurement: undamaged, damaged and stabilised spinal segments

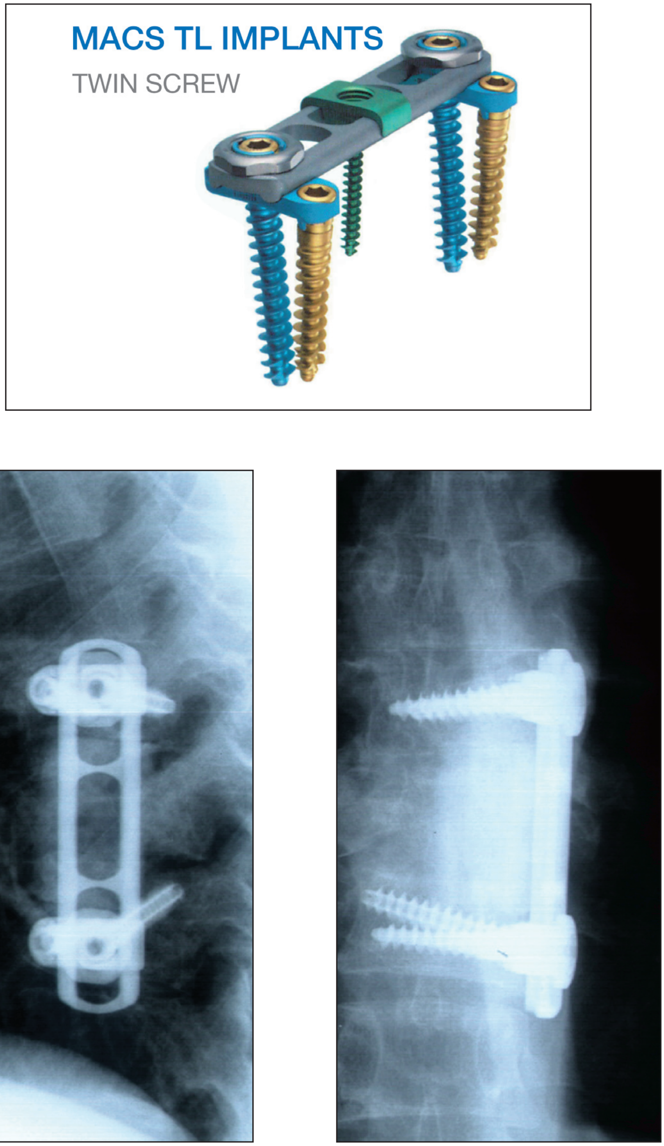

Fig. 3. Original MACS^{TL} implant and pictures after the stabilisation of Th8 fracture