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Thoracolumbar fracture stabilization: comparative biomechanical evaluation of a new video-assisted implantable system

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Abstract Minimally invasive techniques for spinal surgery are becoming more widespread as improved technologies are developed. Stabilization plays an important role in fracture treatment, but appropriate instrumentation systems for endoscopic circumstances are lacking. Therefore a new thoracoscopically implantable stabilization system for thoracolumbar fracture treatment was developed and its biomechanical in vitro properties were compared. In a biomechanical in vitro study, burst fracture stabilization was simulated and anterior short fixation devices were tested under load with pure moments to evaluate the biomechanical stabilizing characteristics of the new system in comparison with a currently available system. With inter-

body graft and fixation the new system demonstrated higher stabilizing effects in flexion/extension and lateral bending and restored axial stability beyond the intact spine, as well as having comparable or improved effects compared with the current system. Because of this biomechanical characterization a clinical trial is warranted; the usefulness of the new system has already been demonstrated in 45 patients in our department and more than 300 cases in a multicenter study which is currently under way.

Keywords Biomechanics · Thoracolumbar burst fractures · Spinal stabilization · Spinal decompression]

Introduction

Several instrumentation systems and operative techniques for the surgical treatment of fractures of the thoracolumbar junction have been developed and marketed. The surgical goals are decompression of the spinal canal, reduction of spinal deformities and maintenance of stable fixation of the spine to permit early mobilization.

After laminectomy and dorsal instrumentation, a second anterior intervention is often necessary and is associated with significant approach-related trauma, increased blood loss, a higher risk of infection and the problem of screw-hold in the ventral vertebral body. Additionally anterior surgery is technically demanding and is not a generally familiar procedure to orthopedic surgeons, especially under emergency conditions [10, 18, 36, 37]. On the other

hand, a direct anterior approach provides optimal visibility for recovery of neural tissue and allows reconstruction, alignment and immediate stabilization of the anterior load-bearing column through strut grafting [1, 10, 18, 33, 36, 37].

The optimal intervention seems to be an initial or second-stage dorsal assisted thoracoscopic ventral decompression, reduction and stabilization to minimize the approach and to maximize visibility for optical equipment for decompression of the neural tissue. Previous investigations on endoscopic or video-assisted intervention have focused on degenerative diseases of the spine, and have shown that endoscopic techniques are superior in terms of safety and costs [2, 3, 4, 7, 8, 11, 14, 15, 16, 17, 27, 28, 29, 30].

Especially in fracture treatment, with the necessity of spinal decompression which may extend over several segments, long-distance overbridging by strut graft and stabi-

lization is an important factor, but there is a lack of available instrumentation systems for endoscopy and biomechanical studies [4, 22, 28]. Therefore a new system specially adapted for endoscopically or video-assisted instrumentation was developed to satisfy the following requirements [31]:

- small dimensions
- rigid anchorage system with individual adaptability
- safe endoscopic implantation technique; easy transfer to open procedure
- single anterior or combined procedure with mono- or bisegmental fusion.

The purpose of this study was to characterize the biomechanical in vitro properties of the new system, specially adapted for thoracoscopic procedures, in comparison with a currently used system.

The study was designed to investigate the following hypothesis: The novel endoscopic anterior stabilization system improves primary stability compared with an established conventional system and offers the advantages of an improved implantation procedure.

Materials and methods

The study consisted of a biomechanical in vitro study to evaluate the biomechanical stabilizing characteristics of the new system in comparison with a currently available system in an anterior defect model simulating burst fracture stabilization with anterior short fixation.

Implant description: MACS TL twin-screw system

A new totally endoscopic video-assisted implantable system for the treatment of fractures from T4 to L3 was developed and tested in static and dynamic tests according to the ASTM (Fig. 1) [31]. This modular anterior construct system (MacS TL: Modular Anterior Construct System Thoracic Lumbar; Aesculap, Tuttlingen, Germany) allows an endoscopic approach and instrumentation from T4 to L1 thoracoscopically, to L2 thoracoscopically with endoscopic diaphragm splitting, and to L3/4 with a minimally invasive retroperitoneal approach. As a twin-screw concept it consists of a rigid-angle stable monocortical anchorage by means of two convergent polyaxial screws in each vertebral body and a low-profile plate (<10 mm) or rods. The system is connected for mono- and multisegmental stabilization.

The self-cutting, unicortical screws are connected to the fracture overbridging plate by means of a polyaxial clamping element (Fig. 1). The cannulated posterior polyaxial screw can be inserted over a K-wire. Its length ranges from 25 to 50 mm, the diameter is 7.0 mm and the angle of rotation is 15°. The direction of the anterior stabilization screw is determined by the clamping element. Its length ranges from 25 to 50 mm and the diameter is 6.5 mm. A locking mechanism in the clamp prevents the anterior screw from backing out.

Plates are available in lengths from 45 to 100 mm. Locking nuts and screws guarantee a rigid fixation between overbridging plate, clamping elements and screws. Additionally a bone graft clamp can be used to fixate the bone graft with a screw.

The whole operative endoscopic procedure is performed in a stable lateral position through three intercostal working channels and one optical channel using general anesthesia with one-lung

Fig. 1 MACS TL System: implant description

ventilation. A short description of the instrumentation technique, but not the operative handling and endoscopic technique of the implant, is given below; further description is outside the scope of this technical report [31].

The polyaxial clamping element and the posterior, pre-assembled cannulated screw have to be inserted endoscopically under fluoroscopic control with the help of a centralizer over a positioned K-wire. This centralizer guarantees easy application of all implant parts and instruments needed for an endoscopic procedure. The clamping element has to be orientated to position the hole for the anterior stabilization screw anteriorly. After K-wire removal through a cannulated instrument this procedure has to be repeated in the adjacent vertebral body. Then discectomy or corpectomy and decompression of the spinal cord can be achieved and proper preparation of the graft bed and graft placement will be done. If necessary, distraction and restoration of spinal alignment can be achieved with the help of a distraction ratchet placed over the centralizers using a holding forceps. Afterwards a fitting plate can be placed in the clamping elements, and fixated by the fixation nut. Now the assembly has to be brought into the final position directly onto the surface of the vertebral bodies by tightening the polyaxial screws. Finally the anterior screw is fixed to the clamping element and the locking screw guarantees rigid four-point stabilization. Locking nuts have to be tightened with a torque of 15 Nm, locking screws with 10 Nm using an appropriate torque wrench.

Comparative biomechanical in vitro testing

The biomechanical in vitro tests were performed with 12 human T10–L2 specimens in two groups of six specimens each (Fig. 2). Group 1 was stabilized with the MACS TL system (Aesculap, Tuttlingen, Germany), group 2 with the Ventrofix system (Stratec, Oberdorf, Switzerland). The mean age of group 1 was 77 ± 18 years and the mean age of group 2 was 68 ± 4 years. The specimens were wrapped in triple-sealed plastic bags and kept frozen at -28°C prior to preparation and testing. Trabecular bone mineral density of the anterior vertebral body was measured by peripheral quanti-

Fig. 2 Thoracolumbar human specimen T10–L2 fixed in the three-dimensional spinal loading simulator and stabilized with the MACS TL System and strut graft. Segmental motions were measured using a non-contacting ultrasound motion analysis system

tative computed tomography at each level in a horizontal plane (XCT-9600A pQCT, Stratec, Birkenfeld, Germany). The CT was calibrated using a hydroxyapatite phantom. Before testing, the fresh-frozen specimens were thawed at room temperature. In preparation, surrounding soft tissue and muscle were dissected with care to preserve bone, discs and spinal ligaments, and during testing the specimens were kept moist with saline. T10 and L2 were potted in polymethylmethacrylate (Technovit 3040, Heraeus Kulzer, Wehrheim/Ts, Germany) for fixation in the spine tester [34]. To achieve a better anchorage of the vertebra in this embedding material, short screws were partially driven into the embedded bony structures. L2 was fixed rigidly in the testing device. T10 was fixed to a cardan device containing integrated stepper motors that could introduce pure moments separately around three axes. The remaining five of six degrees of freedom were free, enabling the specimen to move without constraints. Testing in flexion/extension, lateral bending and rotation was first performed on the intact specimens.

Stabilization was performed after creating the corpectomy and strut grafting between the vertebral bodies proximally and distally on the left side. In both groups decompression of the spinal canal and corpectomy was performed by resecting the anterior vertebral body including the anterior and posterior longitudinal ligaments. For strut grafting of the corpectomy defect an adapted wooden block was made, representing the strut graft. The dorsal USS sys-

tem (Stratec, Oberdorf, Switzerland) was tested in both groups together with the anterior wooden block as reference implant for numeric comparison alone without anterior instrumentation.

Each device was implanted according to the insertion instructions provided by the manufacturer and maximal axial preload created by the overbridging implant was performed on the strut graft. The length of the monocortical MACS TL screws was 40 mm for the posterior polyaxial screw and 30 mm for the anterior screw, and plate length varied between 80 and 100 mm. Length of the Ventrofix screws was 40 mm for the posterior screw and 35 mm for the anterior screw (diameter 7 mm) and rod length was 90 mm. Proper placement was verified radiologically.

Stabilization between the vertebral bodies proximal and distal to the wooden block was achieved using the following combinations of the various hardware components in groups 1 and 2 according to the testing criteria for standardization of in vitro stability testing of spinal implants [35]:

Group 1

- (1) intact spine
- (2) corpectomy: MACS TL (Aesculap, Tuttlingen, Germany)
- (3) corpectomy: USS dorsal (Stratec, Oberdorf, Switzerland)

Group 2

- (1) intact spine
- (2) corpectomy: Ventrofix (Stratec, Oberdorf, Switzerland)
- (3) corpectomy: USS dorsal (Stratec, Oberdorf, Switzerland)

Following current recommendations pure moments of 3.75 Nm and no preload in flexion/extension ($\pm My$), right/left lateral bending ($\pm Mx$) and left/right axial rotation ($\pm Mz$) were first applied at a constant rate of 1.7°/s [35]. Two precycles were applied to precondition the construct so as to minimize the viscoelastic effect, and data of the third cycle were recorded. Resulting three-dimensional rotations were measured between all adjacent segments with an non-contacting ultrasound motion measurement system (Cmtrao 1.0, Zebris, Isny, Germany). From the load-deformation curves, T11–L1 range of motion (ROM) and neutral zone (NZ) [24, 25] were determined for the three principal motion planes.

ROM was defined as the angular deformation at maximum load. NZ is a measure of the laxity and was defined as the difference at zero load between the angular positions corresponding to the loading and unloading phases of the test cycle, which corresponds to the range in which only very small moments are needed to flex, rotate and bend the specimen.

Data are reported as means and standard deviations of the observed ROM and NZ. Nonparametric tests were used because sample sizes were small and our data were not distributed normally. We performed the Friedman test to determine whether there were significant differences between the tested conditions. Afterwards a Wilcoxon signed rank test was used. Although we tested many conditions and several parameters, we did not adjust the calculated *P* value for multiple parameters. This would have resulted in a great loss of information. Since a Bonferroni-Holm correction for multiple comparisons would have raised all *P* values above 0.05, only non-corrected *P* values are presented and no level of significance has been determined. The *P* values listed in this paper are considered to indicate tendencies and to underline the descriptive statistics, not to reveal statistically significant differences.

Results

Comparative biomechanical in vitro testing

Trabecular bone mineral density was $145 \pm 40 \text{ mg/cm}^3$ in group 1 and $219 \pm 12 \text{ mg/cm}^3$ in group 2, as measured by peripheral quantitative QCT.

Fig. 3 Mean values and standard deviations for ROM (total of *black + gray bars*) and NZ (*black bar*) of T11–L1 for all loading directions with applied maximum moments of 3.75 Nm of group 1: MACS TL, USS, intact

Group 1

When corpectomy was performed and stabilized with strut grafting and the MACS TL system, total ROM in flexion/extension was reduced in group 1 from 6.2° (intact) to 3.2°, and total NZ from 1.2° to 0.9°; in axial rotation, total ROM was reduced from 4.2° (intact) to 3.5°, and total NZ increased from 0.5° to 1.0°; and in lateral bending total ROM was reduced from 7.3° (intact) to 2.1°, and total NZ from 1.0° to 0.3°. In flexion/extension with the dorsal USS system, total ROM was reduced from 6.2° (intact) to 3.0°, and total NZ from 1.2° to 0.8°; in axial rotation total ROM was increased from 4.2° (intact) to 4.3°, and total NZ increased from 0.5° to 2.0°; and in lateral bending total ROM was reduced from 7.3° (intact) to 3.3°, and total NZ from 1.0° to 0.7° (Fig. 3).

Group 2

When corpectomy was performed and stabilized with Ventrofix system while strut grafting, total ROM in flexion/extension was reduced in group 2 from 10.0° (intact) to 4.2°, and total NZ from 1.7° to 1.6°; in axial rotation total ROM was reduced from 5.3° (intact) to 3.1°, and total NZ increased from 0.5° to 0.7°; and in lateral bending total ROM was reduced from 11.2° (intact) to 4.8°, and total NZ increased from 1.3° to 1.5°. In flexion/extension with the dorsal USS system, total ROM was reduced from 10.0° (intact) to 3.4°, and total NZ from 1.7° to 0.7°; in axial rotation total ROM was reduced from 5.3° (intact) to 3.5°, and total NZ increased from 0.5° to 0.6°; and in lateral bending total ROM was reduced from 11.3° (intact) to 2.5°, and total NZ from 1.3° to 0.7° (Fig. 4).

Fig. 4 Mean values and standard deviations for ROM (total of *black + gray bars*) and NZ (*black bar*) of T11–L1 for all loading directions with applied maximum moments of 3.75 Nm of Group 2: Ventrofix, USS, intact

Statistics

P values concerning differences in ROM and NZ of the instrumented segments for all loading conditions were determined by the Friedman test and the Wilcoxon signed rank test for all instrumentations, and are listed in Table 1.

Discussion

In this study static and fatigue mechanical properties of a newly developed thoracoscopically implantable thoracolumbar instrumentation system have been considered; additionally, comparative testing was performed to evaluate its biomechanical in vitro characterization. We confirmed the ini-

tial hypothesis that the new endoscopically anterior stabilization system improves primary stability compared with an established conventional system and has the advantages of an improved endoscopic implantation procedure.

Several investigators have looked at anterior thoracolumbar fixation devices. Anterior instrumentation for the thoracolumbar spine has evolved rapidly in recent years. Modern designs such as the Kaneda device, TSRH system, Z-plate and Universal plate are becoming more popular because of the biomechanical stability of the constructs and their user-friendliness [1, 9, 13, 19, 37]. The challenge of endoscopic implants is to provide the same measure of mechanical stability provided by conventional systems while working within a smaller scale. In the beginning of thoracolumbar fracture treatment, the established

Table 1 *P* values concerning differences in range of motion (ROM) and neutral zone (NZ) of the instrumented segments T11–L1 for all loading conditions, determined by the Friedman test and the Wilcoxon signed rank test for all implants

	Flexion/extension			Lateral bending			Axial rotation		
	ROM+	ROM–	NZ	ROM+	ROM–	NZ	ROM+	ROM–	NZ
<i>Group 1</i>									
Friedman test	0.04	0.01	0.07	0.03	0.01	0.11	0.31	0.60	0.51
Ventrofix vs intact	0.60	0.04	0.89	0.04	0.04	0.90	0.24	0.17	0.34
Ventrofix vs USS	0.02	0.34	0.07	0.01	0.02	0.07	0.46	0.91	0.34
<i>Group 2</i>									
Friedman test	0.01	0.01	0.08	0.01	0.01	0.01	0.20	0.61	0.04
MACS vs intact	0.04	0.07	0.34	0.04	0.02	0.02	0.24	0.75	0.04
MACS vs USS	0.02	0.24	0.34	0.02	0.68	0.04	0.17	0.91	0.41
MACS vs Ventrofix	0.11	0.91	0.11	0.02	0.04	0.02	0.17	0.34	0.02

standard intervention is performed after initial or intermittent transcutaneous dorsal intervention and reduction and secondary mono- or bisegmental ventral strut grafting with overbridging by four-point stabilization with the Z-plate [4]. But the Z-plate normally is intended for an open implantation technique. Only time-consuming improvisation such as screw fixation with twine to prevent loosening allows its applicability in such cases [4]. Furthermore reduction through a single anterior approach in combination with this implant is not possible without an initial or intermittent posterior intervention. This adds to complication rates and sacrifices the posterior spinal musculature directly or through longer-term atrophy.

McAfee et al. [22], Regan et al. [28] and Bühren et al. [4] concluded that the limiting factor in the wide application of the endoscopic technique is the absence of a commercially available internal fixation system for this endoscopic approach. This agrees with the results of Connolly et al. [6] who compared the VATS technique with the open procedure in a comparative biomechanical test performed with a porcine corpectomy model. Therefore the new totally thoracoscopically implantable MACS TL stabilization system was developed.

Comparative biomechanical in vitro testing

According to the recommendations for standardization of in vitro stability testing of spinal implants using human specimens the biomechanical in vitro testing was performed to compare the MACS TL system with the Ventrofix system. To eliminate factors such as differences in screw core diameter and screw convergence, a series of six specimens was tested for each stabilization system to guarantee a rigid fixation and screw-hold. Although the initial ROM of the intact specimens differed in the two groups, it did not affect the final numeric comparison of the results, because in both groups nearly total stiffening of the overbridged segments should be achieved by the implant. Only this stabilizing effect of the instrumentation

was in the field of interest. In addition in both groups the dorsal USS system was tested alone as a reference implant and demonstrated nearly identical values for the stabilized spine during flexion/extension and rotation. To eliminate the differences in the inherent material characteristics of bone a wooden plug was used for the bone graft.

In the present study within the interbody graft and fixation devices, the MACS TL and Ventrofix system showed stabilizing effects in the three primary directions in comparison with the intact spine, especially in flexion/extension and lateral bending. In flexion both systems achieved nearly the same ROM and NZ; however, in extension the ROM of the Ventrofix was clearly higher. In left and right rotation there was no real difference in either ROM or NZ at maximal load. In left and right lateral bending the MACS TL system possibly achieved a better high primary stability in comparison with the Ventrofix. Overall, the primary stability of the MACS TL system is equal to or better than that of the clinically well-established Ventrofix system with respect to the NZ and ROM following corpectomy with overbridging implant and strut grafting. This result was confirmed by an older mean age and worse bone mineral density in the MACS TL system group in comparison with the Ventrofix group. These results demonstrate equivalent or improved primary stability between conventional open and new, endoscopically implantable systems mechanically as well as biomechanically. Therefore, the widely held reservation that an appropriately smaller device for endoscopic use would necessarily fail to meet stability requirements or fall short of the stability provided by established systems was shown to be unjustified.

We have to note some limitations of the study. One limitation of this type of testing in general is that the in vivo environment differs from the in vitro environment both biologically and mechanically. Also, comparison of results from the present study with those of previous in vitro reports is complicated by differences in test methods and specimen selection [1, 13, 21, 32, 37].

The use of pure bending moments in this study provided constant and equal loading conditions in all motion seg-

ments, following the currently most accepted method for simulating the in vivo environment. [5, 23, 24, 25, 26, 35]. ROM and NZ of the intact specimens were comparable to values reported in the literature. No preload was used, because it is well known that in the absence of muscles the in vitro ligamentous spine buckles under a very small axial load [12].

While the behavior of the various implant systems under high loads and extended cycles – such as those experienced in vivo – cannot necessarily be extrapolated from these data, it is reasoned that their relative performance in vitro provides a basis for estimating their prospects for successful clinical use. It has been shown furthermore that bone mineral density varies significantly in humans, and this variability may affect the results of construct testing. In this study, specimens were selected to be within a rela-

tively small range of bone mineral density in order to minimize this effect [20].

In summary, the new MACS TL system combined with the previously mentioned results fulfills the initial requirement of a rigid anchorage system, individual adaptability with no compromise on primary stability and fatigue properties, and includes all the advantages of conventional open implantable stabilization systems (rigid-angle, stable, polyaxial, four-point stabilization device, low profile, etc.) The clinical utility of the new video-assisted implantable MACS TL system has already been demonstrated in 45 patients in our department and more than 300 cases in a multicenter study which is currently under way [31]. No implant- or approach-related failure occurred. The results of this clinical multicenter study will be reported in detail elsewhere.

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