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Characteristics of an extended internal fixation system for polysegmental transpedicular reduction and stabilization of the thoracic, lumbar, and lumbosacral spine

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Abstract The Kluger internal fixator, with its artificial fulcrum outside the operative site, had to be extended for multisegmental use. Three different prototypes, called Central Bar (CB), Double Bar I (DB I) and Double Bar II (DB II) were designed, which were fully compatible with the existing reduction system. To evaluate the ability of these newly developed systems to provide primary stability in a destabilized spine, their stiffness characteristics and stabilizing effects were investigated in multidirectional biomechanical stability tests and compared with those of the clinically well-known Cotrel-Dubousset (CD) system. The investigations were performed on a spine tester using freshly prepared calf spines. The model tested was that of an intact straight spine followed by a defined three-column lesion simulating the most destabilizing type of injury. Pure moments of up to 7.5 Nm were continuously applied to the top of each specimen in flexion/extension, left/right axial rotation, and left/right lateral bending. Segmental motion was measured using a three-dimensional goniometric linkage system. Range of motion and stiffness within the neutral zone were calculated from obtained load-displacement curves. The DB II attained 112.5% ($P = 0.26$) of the absolute stiffness of the CD system in flexion and enhanced its stability in extension by up to 144.3% ($P = 0.004$). In axial rotation of the completely destabilized spine, this system achieved 183.3% of the stiffness of the CD system ($P < 0.001$), and in lateral bending no motion was measured in the most injured specimens stabilized by the DB II. The DB I, which was the first to be designed and was considered to provide high biomechanical stability, did not attain the stiffness standard set by the CD system in either flexion/extension or axial rotation of the most injured spine. The study confirms that it is worthwhile to evaluate in vitro the biomechanical properties of a newly developed implant before its use in patients, in order to refine weak construction points and help to reduce device-related complications and to better evaluate its efficacy in stabilizing the spine.

Key words Biomechanics · Stability · Calf spine · Spinal implants · Transpedicular fixation

Introduction

In the past 10 years, rigid internal fixation systems, based on transpedicular anchoring screws, have been widely accepted in spine surgery. The progressive development of stable-angle devices for short-distance stabilization that could be expanded for polysegmental use, extended their field of application to include surgical treatment of multisegmental degenerative instability and spinal stenosis or multifocal metastatic spine disease [2, 7, 16, 25, 26, 36].

Compared to all other analogous internal fixation systems of the spine, the Kluger internal fixator offers the advantage of transposing the artificial fulcrum for reposition outside the operative site, enabling three-dimensional reduction and stabilization [18, 19]. Access to the spine is thus maintained during and after reduction. The longitudinal bars used for reduction in all other fixation systems block such access, and are used in the procedure developed by Kluger only for permanent internal stabilization. They are mounted on the pedicle screws only at the end of the operation, just before the reduction instrument is removed.

Since this system was conceived based on two-point anchoring only for short-distance stabilization, its field of application is limited.

To extend the system for multisegmental use, three different prototypes were developed, which are fully compatible with the existing reduction instruments. The prototypes share the basic principles of the Kluger fixator, which enables the separation of reduction from stabilization procedure.

For an optimized application of the new implant in patients, it is mandatory to examine its biomechanical properties in in vitro tests, to refine weak construction points and to better evaluate its efficacy in stabilizing the spine.

The purpose of the present in vitro study was to investigate the primary stability of the prototypes in multidirectional biomechanical stability tests and to compare their stiffness characteristics and stabilizing effects with that of the clinically approved CD system [7, 11, 26]. We propose that the new device must provide at least as high stability as the CD system in order to maintain surgically achieved reduction and to gain a high fusion rate.

The new device would also take into account results from previous studies, which imply that an increase in stability of an implant can increase the fusion rate [21, 27, 29, 45].

Materials and methods

Compact CD (CCD)

Two tempered rods with diamond-shaped asperities on the entire surface are attached to open pedicle screws. From this system, open-back vertebral screws (length: 45 mm; diameter: 6 mm) were used. The rods had an outer diameter of 7 mm and were 260 mm long. A cross-linkage system (CLS) consisting of two hooks and a transverse bar was attached cranially and caudally (Fig. 1).

Central Bar (CB)

One longitudinal rod, 8 mm in diameter, with a smooth surface and a circular cross-section, is connected to the pedicle screws by transverse links. Each transverse link consists of a connecting screw and a clamping shoe, which completely encloses the rod, locking it securely against rotation. The connecting screws are available in variable lengths, so that the rod can be attached to the pedicle screws without tension or loss of achieved reduction (Figs. 2, 5).

Double Bar I (DB I)

Two longitudinal rods with an entirely threaded surface and an outer diameter of 7 mm are attached to the pedicle screws by small connecting plates. These plates have a recession to accept a threaded bar, and their thread differs slightly from that of the rod. A screw with a conical head secures the rod in the recession, and anchors the connecting plate and the rod at the pedicle screw; thus the two different threads interlock, providing rotational stability. The reverse of the connecting plates has a star-shaped grid that corresponds to the surface of the screw head. This configuration enables a rigid connection between the pedicle screws and the plates.

DB I is equipped with a CLS that consists of two hooks and an H-shaped plate. The thread on the inner side of the hooks differs slightly from the thread of the rod. As in the CCD instrumentation, the CLS was attached cranially and caudally (Figs. 3, 5).

Double Bar II (DB II)

Two rods with a smooth surface and a diameter of 6.2 mm are anchored at the pedicle screws by connecting clamps, which completely enclose the rod. By attaching the clamps to the pedicle screw, the rod is fixed within elastic deformity and is rigidly held stable against rotational deformity. Again, the reverse of the connecting clamps contains a star-shaped grid that corresponds to the surface of the screw head and provides rigid fixation between the pedicle screws and the connecting clamps (Figs. 4, 5). A CLS, like the one described above, with a smooth surface on the inner side of the hooks, was designed but not used in this study.

The design of the initially used Kluger pedicle screws [19] was revised by Kluger in 1993, slanting the surface of the screw head 30° to the screw axis, and has remained unchanged for the new devices. In this study, revised Kluger pedicle screws with an outer diameter of 6 mm were used in all new constructions (CB, DB I, DB II). The depth of screw penetration into the vertebra was chosen to be 100%, so that the screw tip was placed just underneath the surface of the anterior cortex of the vertebra [10, 22, 24]. Therefore the screw length varied between 50 mm and 60 mm. In all CB montages, 265-mm-long rods were used; in the DB I and DB II constructions the bars were 260 mm long. In these systems the longitudinal rods have to be modeled on the alignment of the pedicle screws. Rubber-coated aluminum rods form a suitable, easily modeled stencil for this purpose, largely facilitating the montage of the rods.

Twenty-eight spine specimens from T_{13} to L_6 were extracted from the spines of 10- to 12-week-old calves weighing approximately 130 kg ± 10 kg. All specimens were dissected immediately after slaughter and stripped of soft tissue. The discs, ligaments, and joint capsules were left intact and the spines were stored frozen at –20 °C in double plastic bags until used. Before testing, the specimens were gently thawed in a cold-storage room at +4 °C. T_{13} and L_6 were embedded in polymethylmethacrylate (Technovit 3040, Heraeus Kulzer, Wehrheim/Ts., Germany).

The investigations were performed on a spine tester, which enables loading the specimen in all physiological directions with pure moments and without any further manipulation. Thus the specimen can be loaded in one controlled direction and can move unconstrained in the remaining degrees of freedom [38]. The embedded L_6 of the specimen was screwed tight to the frame of the spine tester; T_{13} was fixed in a gimbal joint. Pure moments of up to 7.5 Nm were continuously applied by stepper motors to the top of the specimen at a constant rate of 1.33 Nm/s in flexion/extension (+/– M*y*), left and right axial rotation (+/– Mz), and right and left lateral bending (+/– M*x*). To simulate repetitive in vivo physiologic loads and reduce viscoelastic properties of the spine, each moment was applied three times, and measurements obtained from the third cycle were analyzed [30]. As representative segmental

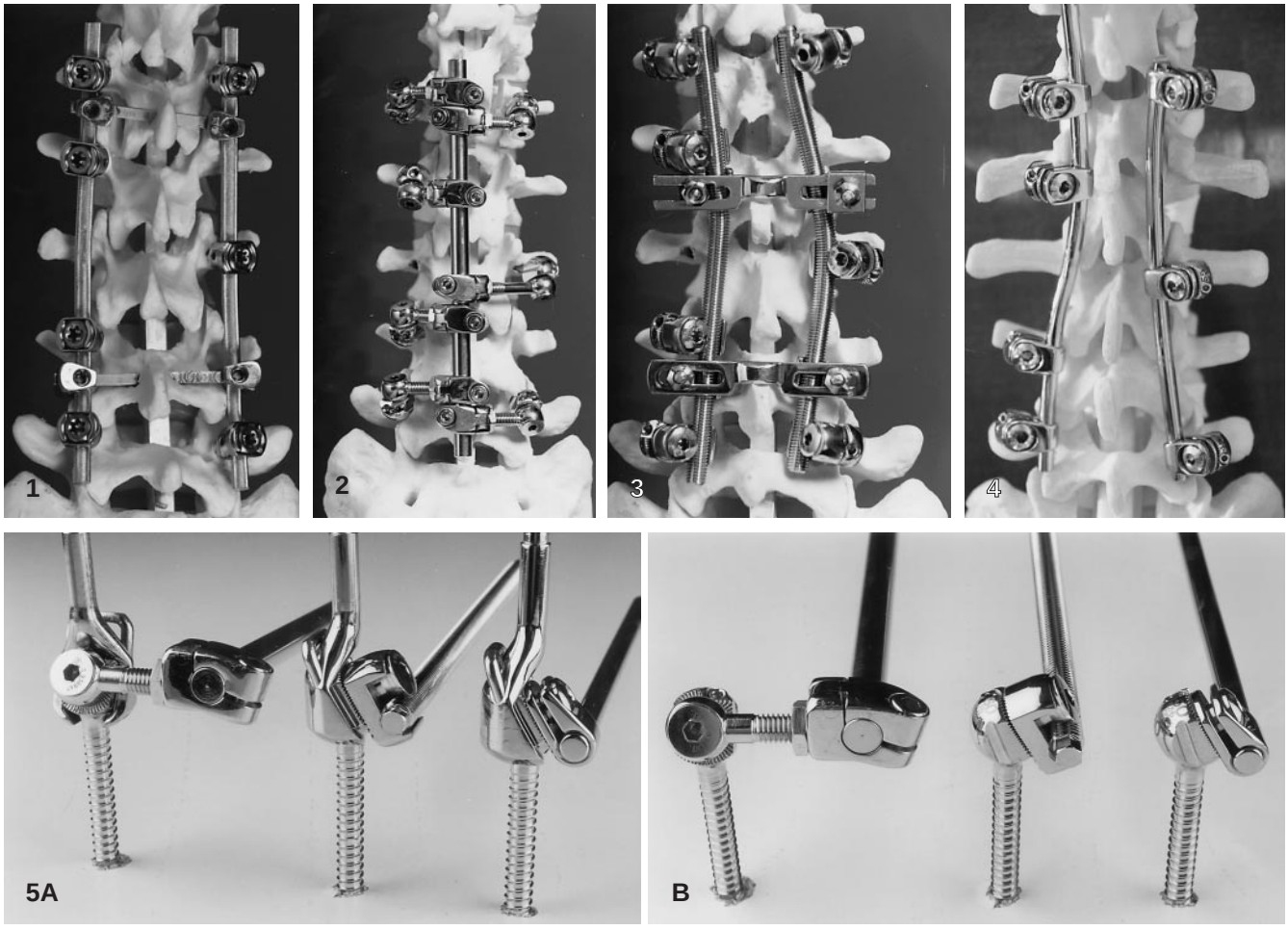


Fig. 1 Posterior view of the Compact CD (CCD) with assembled cross-linkage system (CLS) instrumented at a spine model. The rods have diamond-shaped asperities covering the entire surface. A set screw secures a little plate and attaches the rod to the open pedicle screw

Fig. 2 Posterior view of the Central bar (CB) instrumented at a spine model. The rod is connected to the pedicle screws by transverse links consisting of a clamping shoe and a connecting screw

Fig. 3 Posterior view of the Double bar I (DB I)with attached CLS instrumented at a spine model. The surface of the rod is entirely threaded. A screw with a tapered head secures the rod in the recession and anchors the connecting plate and the rod to the pedicle screw

Fig. 4 Posterior view of the Double bar II (DB II) instrumented at a spine model. The rods have a smooth surface and are attached to the pedicle screws by connecting clamps, which completely enclose the rod

Fig. 5 A, B Attachment of the rod of the newly developed systems to the pedicle screw. *Left*: CB, *middle*: DB I, *right*: DB II. **A** The extension rod, used as a manipulation lever, is clamped to the screw. **B** Permanent implants after removal of the reduction instrument

motion, the rotation of L_3/L_4 was measured using a three-dimensional goniometric linkage system [39] fixed at L_3 and L_4 with modified Schanz screws. This system had a resolution of 0.1 mm for translation and 0.1° for rotation. To help align the goniometer system and to exclude anatomical deformities, anteroposterior and lateral radiographs were obtained before the specimen was fixed in the spine tester.

First, the biomechanical characteristics of the intact spine were investigated. In a second step, the specimen was instrumented with one of the implants. In L_1 and L_5 pedicle screws were anchored bilaterally; in L_2-L_4 only one pedicle screw was used. The screw in L_3 lay contralateral to L_2 and L_4 (Figs. 1–4). All pedicle screws were directed with a convergence of 10° - 15° towards the sagittal plane through the pedicles into the vertebral body [10, 23]. Again anteroposterior and lateral radiographs were taken to document the correct position of the pedicle screws. In a third step, a reproducible injury was created in the measured segment L_3/L_4 by complete removal of the disc, laminectomy, and bilateral facetectomy.

The CCD, CB, DB II and DB I + CLS were tested on six different calf spines, and the DB I without CLS on four. As each specimen was used only once, the pedicle screws remained tightly anchored in the vertebrae.

Range of motion (ROM) and stiffness within the neutral zone were determined from obtained hysteresis curves. Stiffness was defined as the inverse of the slope within the neutral zone, and ROM describes the angular deformation at maximum load [30]. Neutral zone (NZ) was defined as the displacement from neutral position to the start of the third load cycle [30, 40] (Fig. 6).

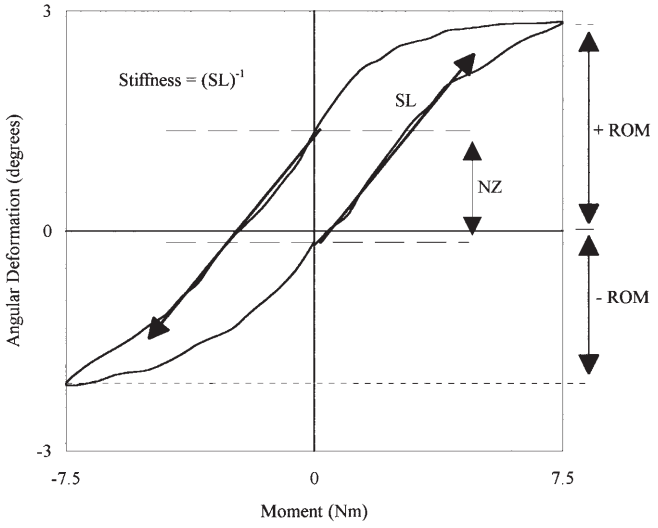


Fig. 6 Characteristic hysteresis curve with the definition of range of motion (ROM), neutral zone (NZ), and stiffness. The slope (SL) of the curve within the NZ was determined as indicated by the *arrows*

Statistical analysis was performed using statistical analysis software (Sigma Stat, Jandel Scientific Software). Data from CB, CCD, DB I+CLS, and DB II were first evaluated with the Kruskal-Wallis analysis of variance on ranks with a significance level of $P = 0.05$. Differences among the constructs were pairwise further assessed using the Mann-Whitney rank sum test, with a P value for normality and equal variance of $P = 0.05$ [33]. The data from the DB I without CLS were not included in the statistical analysis and are presented descriptively only.

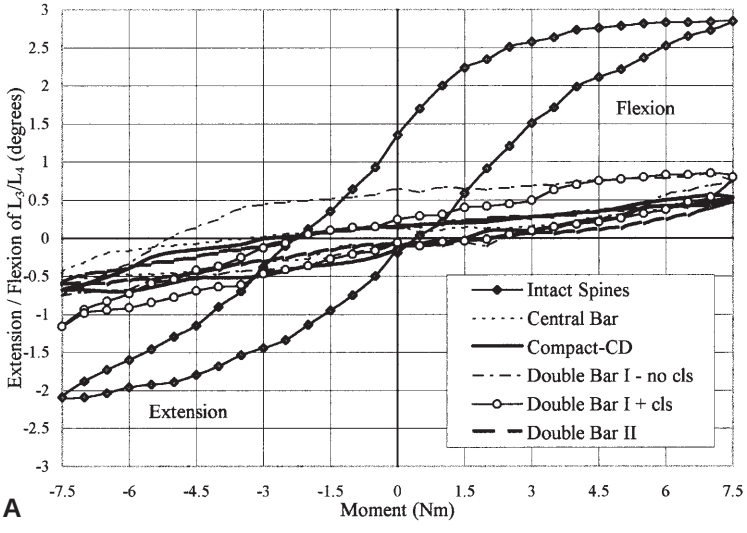
Fig. 7 A, B Flexion/extension of L_3/L_4 of intact ($n = 28$) and instrumented, injured calf spines ($n = 4$ from "DB I no CLS" group, $n = 6$ from each other group). **A** Hysteresis curves obtained from third loading cycle. **B** Average ROM ± SD

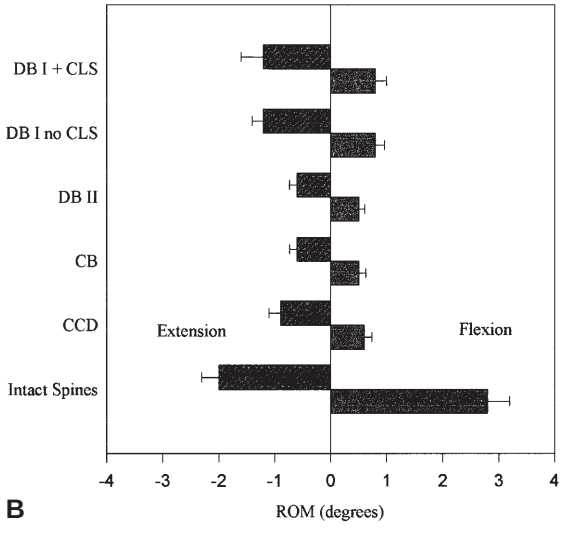
Results

With all implants, sufficiently rigid constructions could be obtained for no translation or rotation to be measurable in intact instrumented spines either in flexion/extension or left/right lateral bending. The first tests with the DB I (DB I no CLS) on four calf spines demonstrated that this system, initially designed without CLS, showed a lack of stability against axial rotational loads. Once a suitable CLS was developed, the DB I was re-tested (DB I + CLS).

In flexion of injured instrumented spines, no statistically significant difference was found between the DB II, CB, and CCD. The CB achieved 108% ($P = 0.619$) and the DB II attained 112.5% ($P = 0.26$) of the absolute stiffness of the CCD. In comparison with these devices the DB I provided less stability and achieved, with attached CLS, 71.8% of the stiffness of the CCD ($P = 0.041$). In extension no difference was observed between the CB and DB II. Compared with the CCD the CB increased the stiffness to 154.4% ($P = 0.015$) and the DB II to 144.3% ($P = 0.004$). The DB I with attached CLS achieved 73.0% ($P = 0.12$) of the stiffness of the CCD (Figs. 7, 10).

In axial rotation of intact instrumented specimens no significant differences between the CB, CCD, and DB I with attached CLS were found. The CLS was found to increase the rotational stability of the DB I by 33%. The DB II exceeded the rigidity of the compared implants and reached 215% ($P = 0.004$) of the stiffness of the CCD (Figs. 8B, 10). In axial rotation of injured instrumented specimens the DB II attained more rigidity than the other implants. This system achieved the stability of intact spines (intact spines vs DB II: $P = 0.14$) and enhanced the absolute stiffness of the CCD by up to 183.5% ($P < 0.001$) (Figs. 8, 10). In the completely destabilized spine the ROM of CB-instrumented spines was 1.8 times and of CCD-instrumented specimens 2.1 times that of intact spines (CCD vs CB: $P = 0.31$) (Fig.





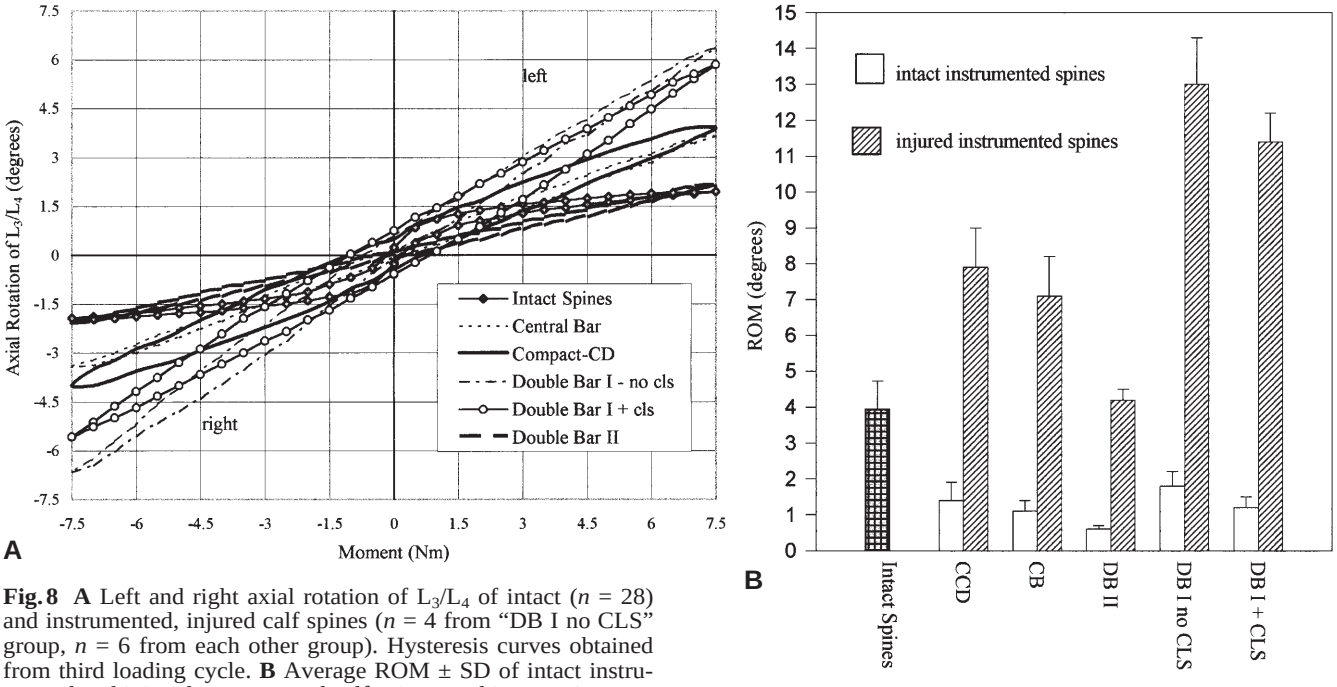


Fig. 8 **A** Left and right axial rotation of L_3/L_4 of intact (n = 28) and instrumented, injured calf spines (n = 4 from "DB I no CLS" group, n = 6 from each other group). Hysteresis curves obtained from third loading cycle. **B** Average ROM ± SD of intact instrumented and injured instrumented calf spines, and intact spines

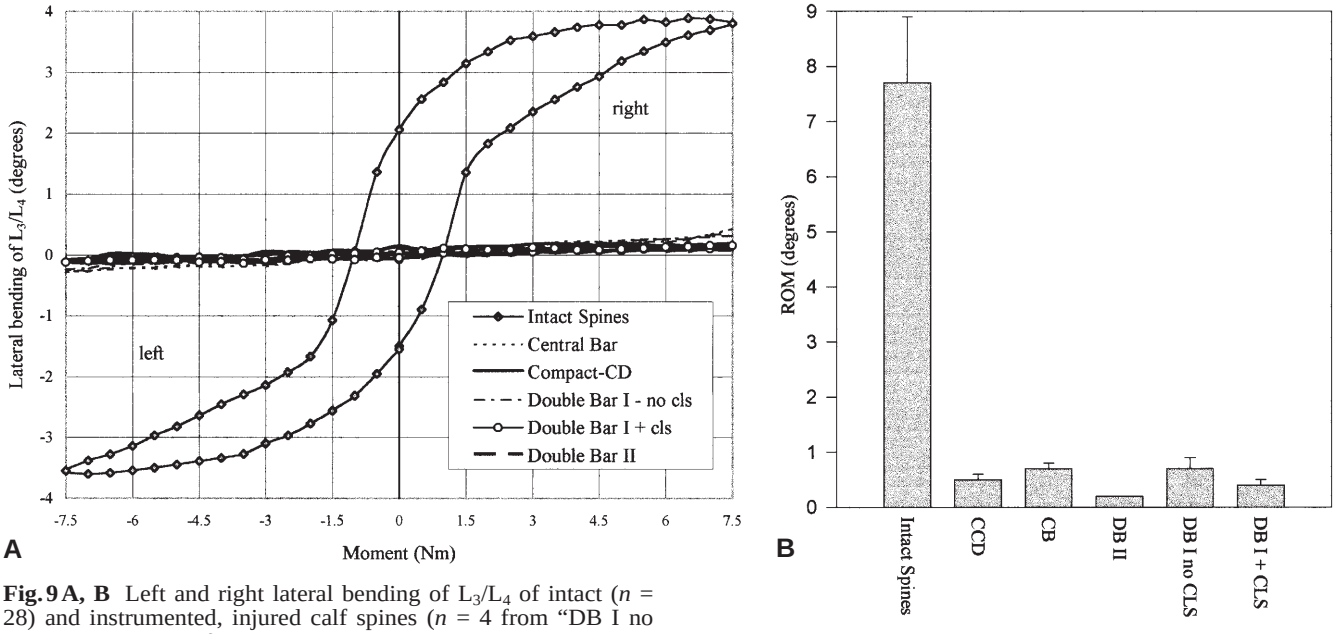


Fig. 9 A, B Left and right lateral bending of L_3/L_4 of intact (n = 28) and instrumented, injured calf spines (n = 4 from "DB I no CLS" group, n = 6 from each other group). **A** Hysteresis curves obtained from third loading cycle. **B** Average ROM ± SD

8 A). The DB I was the most unstable. Though its stiffness could be increased using the CLS by 12.6%, this still represented 2.9 times the motion of the intact spines ($P < 0.002$ for pairwise comparison of DB I + CLS vs CCD, CB, DB II).

In lateral bending all devices provided high stability (Fig. 9). With DB II instrumentation no motion could be measured with the available goniometric linkage system even in the most injured spine. With the systems resolution of ± 0.1°, ROM of the DB II was less than 0.2°.

Discussion

The objective of this in vitro study was to evaluate the stiffness characteristics of the newly developed implants

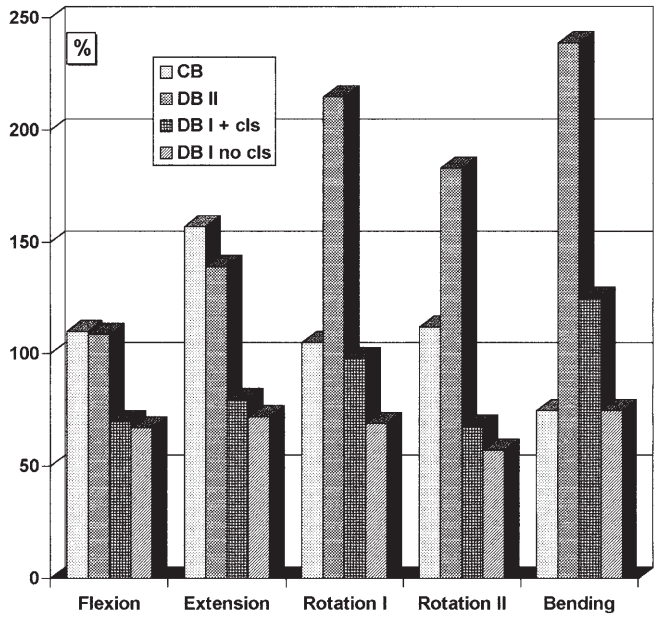


Fig. 10 Comparison of the absolute stiffness at 7.5 Nm of the newly developed systems to the CCD system. The stiffness of the CCD system was defined as 100%. (*Rotation I* left and right axial rotation of the intact, instrumented spines, *Rotation II* left and right axial rotation of the injured, instrumented spines, *Bending* left and right lateral bending)

in multidirectional biomechanical stability tests and to compare their stiffness characteristics and stabilizing effects to that of the already clinically approved CD system.

As a system, the CB exceeds the stiffness of the compact CD (CCD) in flexion by 8% and in extension by 54.5%. The implants were comparable in axial rotation. Due to the variable transverse links the system enables tension-free attachment of the bar to the pedicle screws without changing the reduction achieved. However, this system is hard to assemble, bulges when used on the upper thoracic spine, and impedes reinsertion of the paravertebral musculature. In response to these disadvantages, the DB I was developed. Prototype I, initially designed without CLS, did not provide the required primary stability either in flexion/extension or in axial rotation. A CLS had to be developed to improve the stability of the device against axial rotational loads. Yet even with the CLS, the stiffness standard set by the CCD could not fully be attained. Constructive analysis revealed that the threaded longitudinal rods are often bent near the open connection plates. This apparently prevents the differentially threaded rods and plates described above from gripping to prevent rotation, and could explain the weakness of this system, especially in terms of rotational stress.

DB II was therefore conceived to address this disadvantage. This system provided similar stability to the CCD in flexion and exceeded its stiffness in extension by 44.3%. It enhanced stiffness of the CCD in axial rotation in intact spines by up to 215% and in injured spines by up to 183%. In the most destabilizing injury, the implant provided stability approaching that of intact spines. In lateral bending, no motion was measurable even in the three-column lesion. The high stiffness of the construct was probably achieved by the connecting clamps, which completely enclose the rod and fix it within elastic deformity. The smooth surfaces of the rod and the clamps provide a larger corresponding surface and friction than the components of the CD system. In this device the rod fits loosely in the open pedicle screw head. Asperities of the rod interact with a smooth surface of the screw head, and the rod is secured by a set screw providing a two-point anchoring only. Enclosing the rod within connecting clamps and attaching it within elastic deformity was a design feature already present in the CB, and proved able to provide high stability, particularly against torsional loads. As an improvement to the CB, the rods in the DB II are attached to the anchoring screws without transverse links, avoiding further lever arms increasing the torsional stress within the system. Because the DB II achieves high rotational stability when the pedicle screws are anchored with a convergence of 10°–15° towards the sagittal plane, it requires no CLS. The extra-osseous component of the construction, and with it the amount of metal that can irritate the soft tissues, can be reduced.

The study was subject to several limitations. As in previous biomechanical investigations of spinal implants [5, 6, 12, 14, 15, 28, 35, 42, 43], the tests were performed using calf spines. Calf spines are in general

Table 1 Range of motion (mean ± SD) of L_3/L_4 at 7.5 Nm of the intact spines and the devices tested. (*Rotation I* left and right axial rotation of the intact, instrumented spines, *Rotation II* left and right axial rotation of the injured, instrumented spines, *Bending* left and right lateral bending, *CCD* Compact Cotrel-Dubousset, *CB* Central bar, *DB II* Double bar II, *DB I* Double bar I, *CLS* cross-linage system)

	Intact spines	CCD	CB	DB II	DB I no CLS	DB I + CLS
Flexion	2.8 ± 0.4	0.6 ± 0.1	0.5 ± 0.1	0.5 ± 0.1	0.8 ± 0.1	0.8 ± 0.2
Extension	2.0 ± 0.3	0.9 ± 0.2	0.6 ± 0.1	0.6 ± 0.1	1.2 ± 0.2	1.2 ± 0.4
Rotation I	3.9 ± 0.8	1.4 ± 0.5	1.1 ± 0.3	0.6 ± 0.1	1.8 ± 0.4	1.2 ± 0.3
Rotation II	3.9 ± 0.8	7.9 ± 1.1	7.1 ± 1.1	4.2 ± 0.3	13.0 ± 1.3	11.4 ± 0.8
Bending	7.7 ± 1.2	0.5 ± 0.1	0.7 ± 0.1	< 0.2	0.7 ± 0.2	0.4 ± 0.1

anatomically and geometrically similar to human spines [9]. It has been reported that high loads have to be applied to cause failure in their cartilaginous vertebral endplates [3]. They have similar physical and mechanical properties to human spines [37], and show homogeneous bone mineral density and a uniform size [42]. In biomechanical tests of spinal implants, the bone mineral density of the specimens is of immense importance. The strength of screw fixation in the pedicle is more dependent on bone mineral density than on screw design [8, 42, 44]. However, calf spines differ from human spines in the orientation of the articular facets in the two axes measured and in intervertebral disc height, which have important implications for biomechanical behavior [9]. A previous investigation of the segmental motion pattern of spines from 12- to 16-week-old calves verified that calf and human spines behave in a similar manner in axial rotation and lateral bending. This study demonstrated that calf spines are stiffer in flexion/extension than human specimens [41]. Even if calf spines are considered to meet the requirements of an appropriate model and can be used as a substitute for human spines for in vitro evaluation of spinal implants [37, 41, 42], the differences between calf and human spines can influence the experimental results [9] and limit direct comparison of data from previous biomechanical studies in which different models were used.

In line with Eggli et al. [12], we decided to create a "most destabilizing injury" model, destroying all three columns of the spine, in order to eliminate the different stiffness characteristics of calf and human spines, to clearly demonstrate the differences between the systems and to meet the demand for multidirectional three-column stabilization of an internal fixation system. The range of load applied in previous studies was 7.5–15 Nm [1, 4, 12–15, 31, 35, 41]. Rohlmann et al. measured in vivo a maximum bending moment of 5–8 Nm after resection of intervertebral discs at L_2/L_3 and L_3/L_4 and transpedicular internal fixation from L_2 to L_4 [32]. Schläpfer et al. evaluated in vivo loads up to 7.3 Nm on a spinal external fixation device [34]. In screw-vertebra pullout tests the mean failure load of self-tapping pedicle screws with a penetration into the vertebra of 100% was 10.6 Nm for flexion and 7.1 Nm for torsion moments [22]. The maximum moment of 7.5 Nm applied in this study was close to the loads measured in vivo and managed to produce segmental displacement of the native specimens until the plateau phase of the hysteresis curves was reached.

At the time when the CB and DB I were tested, a system to measure multisegmental motion that was compatible with the software of the spine tester was not available. Based on the assumption that pure bending moments result in uniform loading of the construct along its entire length, producing similar motion in each segment [30], we decided to create a monosegmental defect only and measure representatively segmental motion in this segment. Since then, a system has been developed that enables the spine tester to measure three-dimensional multisegmental motion. It would be worthwhile to test the implants in a further study with a multilevel injury model and measure segmental motion over the entire specimen, in order to examine the influence of additional defects on the stability of the construct and to investigate the behavior of adjacent instrumented segments to the created injuries.

At present the ideal stiffness for spinal implants is not known. Clinical and experimental investigations imply that an increase in biomechanical stability of a construction accelerates the union of a fusion mass and increases fusion rates. Stiffer implants reduce the rate of pseudoarthrosis and loss of achieved reduction [2, 7, 11, 17, 21, 27, 29]. In all known systems for stable-angle stabilization of the spine, the fusion rate is always more favorable for the thoracic and thoraco-lumbar regions, for patients with normal or low body weight, and for less physically active patients. This contradicts the hypothesis that the "stress-protection" mechanism of shaft bone osteosynthesis might also be applied to cases involving the spine, or that so-called semirigid or dynamic systems could therefore have a positive effect on the process of bone fusion. Moreover, the dynamics of such systems must be properly adapted to meet the stress differentials across spinal regions, across individuals, and movement amplitudes, in order to provide adequate rigidity in each case [20].

Based on the performed measurements it can be assumed that the DB II provides enough stability to keep a destabilized spine under various loading conditions in a reduced position, and stiffens the spine sufficiently to show good fusion results and a low pseudoarthrosis rate. For a more extensive evaluation of the biomechanical properties and a better estimation of the in vivo efficiency of an implant, both its stabilizing capabilities as well as its fatigue characteristics have to be known. Fatigue tests of the DB II have been recently performed. A clinical multicenter study is planned in order to examine the in vivo properties of the device.

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