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M. Richter
H.-J. Wilke
P. Kluger
S. Neller
L. Claes
W. Puhl

Biomechanical evaluation of a new modular rod-screw implant system for posterior instrumentation of the occipito-cervical spine: in-vitro comparison with two established implant systems

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M. Richter (✉) · P. Kluger · W. Puhl
Department of Orthopaedics and SCI,
University of Ulm,
Ulm, Germany
e-mail: marcus.richter@medizin.uni-ulm.de,
Tel.: +49-7308-919325,
Fax: +49-731-1103

H.-J. Wilke · S. Neller · L. Claes
Department of Orthopaedic Research
and Biomechanics,
University of Ulm,
Ulm, Germany

M. Richter
RKU, Orthopädische Klinik
mit Querschnittgelähmtenzentrum
der Universität Ulm,
Oberer Eselsberg 45,
89081 Ulm, Germany

Abstract Posterior instrumentation of the occipito-cervical spine has become an established procedure in a variety of indications. The use of rod-screw systems improved posterior instrumentation as it allows optimal screw positioning adapted to the individual anatomic situation. However, there are still some drawbacks concerning the different implant designs. Therefore, a new modular rod-screw implant system has been developed to overcome some of the drawbacks of established systems. The aim of this study was to evaluate whether posterior internal fixation of the occipito-cervical spine with the new implant system improves primary biomechanical stability. Three different internal fixation systems were compared in this study: the CerviFix System, the Olerud Cervical Rod Spinal System and the newly developed Neon Occipito Cervical System. Eight human cervical spine C0/C5 specimens were instrumented from C0 to C4 with occipital fixation, transarticular screws in C1/C2 and lateral mass or pedicle screws in C3 and C4. The specimens were tested in flexion/extension, axial rotation, and lateral bending using pure moments of ± 2.5 Nm without axial preload. After testing the intact spine, the different instrumentations were tested after destabilising C0/C2 and C3/C4. Primary stability was significantly increased, in all load cases, with the new modular implant system compared to the other implant systems. Pedicle screw instrumentation tended to be more stable compared to lateral mass screws; nevertheless, significant differences were observed only for lateral bending. As the experimental design precluded any cyclic testing, the data represent only the primary stability of the implants. In summary, this study showed that posterior instrumentation of the cervical spine using the new Neon Occipito Cervical System improves primary biomechanical stability compared to the CerviFix System and the Olerud Cervical Rod Spinal System.

Key words Posterior instrumentation · Occipito-cervical spine · Biomechanical testing, in vitro

Introduction

Posterior instrumentation and fusion of the occipito-cervical spine is a well-established procedure in a variety of indications. It may be indicated for patients with instability of the occipito-cervical junction or upper cervical spine due to congenital, iatrogenic, traumatic, degenerative, infectious or neoplastic processes [11, 16, 39].

Traditional techniques of obtaining occipitocervical fusion have used simple onlay grafts or onlay grafting supplemented by spinous process wiring, facet wiring, and sublaminar wiring [5, 7, 11, 13, 16, 25, 26, 29, 31, 34, 35, 39, 43]. However, these techniques provide no immediate

stability and require the prolonged postoperative use of traction or immobilization in a halo vest or Minerva brace. Therefore, posterior plate-screw instrumentation techniques were introduced by several groups and better clinical results and improved biomechanical properties compared to the traditional techniques were reported [10, 12, 14, 15, 24, 36, 37, 40, 41]. Nevertheless, all plate-screw implant systems have some disadvantages in common. The position of the plate holes is fixed and not always adaptable to the actual anatomic situation. The insertion angle of the screws is restricted to a certain angle, depending on the geometry of the screws and holes. Rod-screw implant systems were developed to overcome these disadvantages, and showed good clinical results [3, 20, 32].

However, there are still some drawbacks concerning the different implant designs, i.e. they are not angle-stable or have no variable rod-screw connection or a high fiddling factor. Therefore, one of the authors of this paper (M.R.) developed, together with Ulrich GmbH (Ulm, Germany), a new modular rod-screw system for posterior instrumentation of the occipito-cervical spine with the aim of allowing a combination of different instrumentation techniques and of improving the biomechanical stability compared to established systems.

Besides the type of implant system, optimal screw position with respect to the instrumented segment is still a matter of debate. The C1/C2 transarticular instrumentation established by Magerl and Seemann [27] improved occipito-cervical instrumentation due to improved biomechanical stability and significantly increased fusion rates. More recently (1994), pedicle screw fixation in the cervical spine, and especially in C2, was introduced, and improved biomechanical properties and good clinical results have been reported [1, 2, 3, 21, 24]. Abumi reported a better correction of the cranial settling in rheumatoid arthritis when using C2 pedicle screws instead of C1/C2 transarticular screws [3]. Due to improved pull-out strength of pedicle screws compared to lateral mass screws, they may be also beneficial in the subaxial cervical spine in patients with poor bone quality, multilevel or three-column instabilities or those in need of significant reduction [22]. Reports on lateral-mass screw fixation procedures have shown several cases of screw loosening that resulted in pseudarthrosis and loss of correction [8,18] indicating that in some situations pedicle screw fixation may be beneficial.

The objectives of this in-vitro study were to evaluate the biomechanical stability of this newly developed implant system in comparison with established implant systems for posterior instrumentation of the occipito-cervical spine. Furthermore, we wanted to evaluate the influence of pedicle screws compared to lateral mass screws in an instability model adapted to rheumatoid arthritis.

The study was designed to investigate the following hypotheses:

1. The new Neon Occipito Cervical System with increased rod diameter and angle-stable rod-screw fixation improves the primary stability compared with an established implant system with subaxial lateral mass screw fixation.
2. Subaxial pedicle screw fixation improves the primary stability compared with subaxial lateral mass screw fixation.
3. The new Neon Occipito Cervical System with increased rod diameter improves the primary stability compared with an established implant system with subaxial pedicle screw fixation.

Materials and methods

Three different modular rod-screw implant systems for posterior instrumentation of the cervical spine were tested in this study.

Neon Occipito Cervical System

The Neon Occipito Cervical System (OCS; Ulrich GmbH, Ulm, Germany) is a newly developed titanium-alloy (Ti Al4 V6) modular system consisting of 4.5-mm rods, closed connectors with four different lengths and 4.0-mm cannulated self-tapping and self-drilling screws for C1/C2 transarticular instrumentation and 4.0-mm cannulated self-tapping screws for C2-C7 pedicle instrumentation, as well as 4.0-mm screws for lateral mass and transarticular instrumentation from C3 to C7. For pedicles smaller than 5 mm, non-cannulated 3.0-mm screws are available. The head of the screws is spherical, with an angulation of 45° between screw-axis and the connector fixation area. This angulation itself, according to Kluger (patent pending) preserves variable screw-rod stability without toothing the ball's surface, thereby avoiding tooth-related angular steps. For fixation to the occiput a prebent omega-shaped occiput rod fixed at the occiput with up to five 3.5-mm occiput screws or toggles is available. The toggles are used if the thickness of the occipital bone is below 6 mm, because of their improved fixation strength compared to screws. The toggles (Fig. 1) are T-shaped, they are inserted through a rectangular bony hole which is pre-

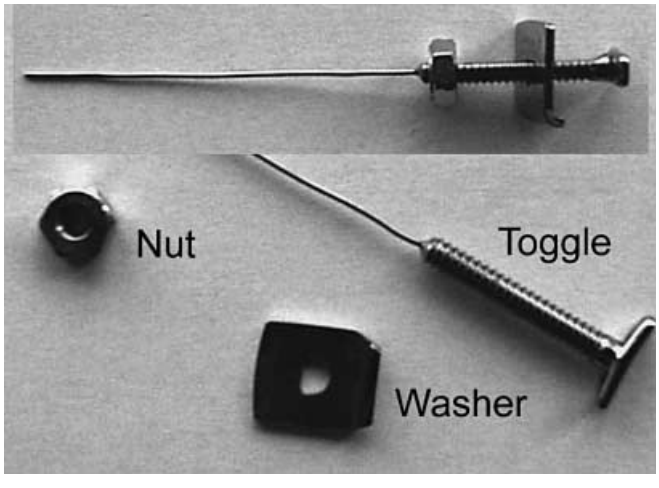

Fig. 1 Toggle for occipital fixation

pared with Kerrison punches after drilling an initial 2.5-mm hole. After insertion, the toggle is turned 90° and then fixed to the occiput rod with a nut and a special washer that prevents turning back of the toggle to the insertion position. After tightening of the nut, the toggle is shortened with a pincer. Cervical fixation is possible with transarticular screws in C1/C2, lateral mass screws or transarticular screws from C3 to C7 or pedicle screws from C2 to C7. Hooks for sublaminar anchoring, connectors to other rods and a cross-linking device are also available.

CerviFix

CerviFix (Stratec GmbH, Oberdorf, Switzerland), the second system tested in the study, is a pure titanium/titanium alloy modular system consisting of 3.5-mm rods (pure titanium), clamps and 3.5-mm self-tapping screws. For fixation to the occiput, the 3.5-mm titanium rod goes over into a 3.5-mm AO-reconstruction plate, two occiput rods are needed for occipito-cervical instrumentation. The occiput rod is fixed lateral to the midline with up to four screws at the occiput on each side. Three types of clamps with different angulations of the screw hole with respect to the rod allow cervical fixation with transarticular screws in C1/C2, lateral mass screws from C3 to C7 and pedicle screws in C7. Hooks for sublaminar anchoring, connectors to other rods and a cross-linking device are also available.

Olerud Cervical Rod Spinal System

The third system was the Olerud Cervical Rod Spinal System (CROSS, Norpaedic, Uppsala, Sweden). It is a titanium-alloy modular system consisting of 3.5-mm rods, double loop couplers with links at different angulations and 4.0-mm self-tapping screws. For fixation to the occiput, a prebent occiput rod fixed at the occiput with up to three occiput screws in the midline and two foramen magnum screws is available. Cervical fixation is possible with transarticular screws in C1/C2, lateral mass screws or transarticular screws from C3 to C7 or pedicle screws from C2 to C7. Hooks for sublaminar anchoring, connectors to other rods and a cross-linking device are also available.

We tested eight human cadaveric cervical spine segments (C0-C5) with a mean age of 76.2 ± 12.8 years. The specimens were wrapped in triple-sealed plastic bags and kept frozen at –28 °C prior to preparation and testing. Before testing, the specimens were thawed at room temperature and all musculature was removed while carefully preserving ligamentous and bony structures.

Bone quality was assessed by measuring the bone mineral density (BMD) of the vertebra C3 using peripheral quantitative computed tomography (CT) (XCT 960A, Stratec, Pforzheim, Germany). The CT was calibrated using a hydroxylapatite phantom. An attenuation coefficient of 0.45 cm^{-1} was used for data analysis.

The cranial vertebra (C0) and the caudal vertebra (C5) were potted in polymethylmethacrylate (Technovit 3040, Heraeus Kulzer GmbH, Wehrheim, Germany). To achieve a better anchorage of the vertebrae in the plastic material, short screws were partially driven into the embedded bony structures. The specimens were mounted in a previously described spinal loading simulator (Fig. 2) [44]. C5 was fixed rigidly in the testing device. C0 was fixed in a coupling device containing integrated stepper motors that could introduce pure moments separately around three axes. The other five out of six degrees of freedom were free, enabling the specimen to move unconstrained. Segmental motions of C0-C2, C2-C3, C3-C4 and C4-C5 were measured using a non-contacting ultrasound motion analysis system (Zebris 50/4, Isny, Germany). The motion of the instrumented cervical spine C0-C4 segment was calculated from the mono- or bisegmental motions. Alternating sequences of flexion/extension (± M*y*), left/right axial rotation (± Mz), right/left lateral bending (± M*x*) moments of 2.5 Nm in each direction were applied at a constant rate of 1°/s. Two precycles were applied to precondition the construct so as to minimise the viscoelastic effects, and data of the third cycle were recorded.

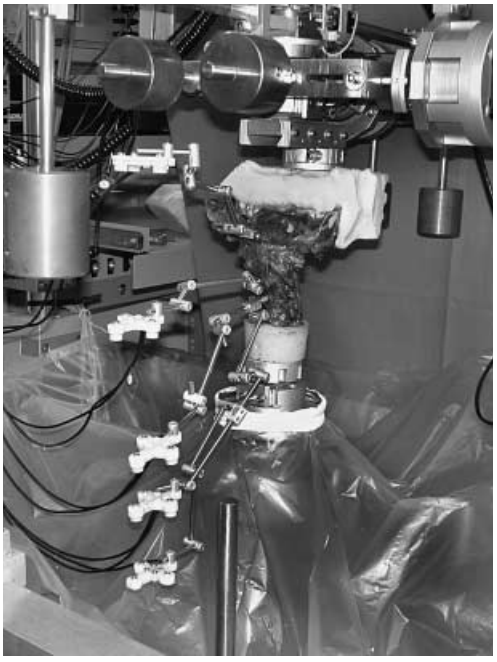

Fig. 2 Cervical human C0–C5 specimen fixed in the three-dimensional spinal loading simulator. Monosegmental motion of the segments C0-C2, C2-C3, C3-C4 and C4-C5 was measured using a non-contacting ultrasound motion analysis system

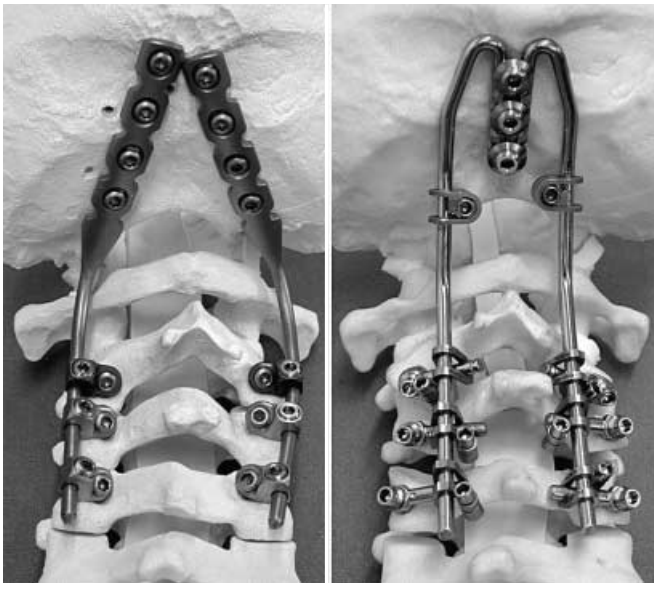

Fig. 3 Sawbone models instrumented with the CerviFix system (*left*) and the Olerud Cervical System (*right*) in the tested configuration

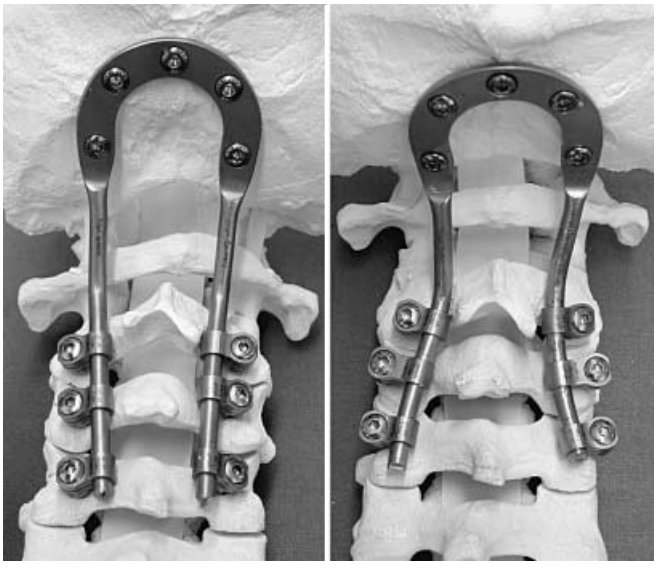

Fig. 4 Sawbone models instrumented with the new Occipito Cervical System with lateral mass screws (*left*) and pedicle screws (*right*) in C3 and C4 in the tested configuration

The range of motion (ROM) and the neutral zone (NZ) of the segments C0-C2, C2-C3, C3-C4 and C4-C5 were determined for each direction of loading. ROM was defined as the angular deformation at maximum load. NZ 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.

Six different types of instrumentation from C0 to C4 were tested according to the testing criteria for spinal implants specified in the recommendations for the standardisation of in vitro stability testing of spinal implants created by the study group for pre-clinical testing formed by the German Society for Spinal Surgery [45]:

CerviFix CerviFix system: two single occiput rods fixed with three or four screws on each side of the occiput, cervical fixation with transarticular screws in C1/C2 and lateral mass screws in C3 and C4 (Fig. 3)

OCS1 Neon Occipito Cervical System: omega-shaped occiput rod fixed at the occiput with five occiput screws or rather toggles, cervical fixation with transarticular screws in C1/C2 and lateral mass screws in C3 and C4 (Fig. 4)

CROSS1 Olerud Cervical Rod Spinal System: occiput rod fixed at the occiput with three occiput screws in the midline and two foramen magnum screws, cervical fixation with transarticular screws in C1/C2 and pedicle screws in C3 and C4 (Fig. 3)

OCS2 Neon Occipito Cervical System: omega-shaped occiput rod fixed at the occiput with five occiput-screws or rather toggles, cervical fixation with transarticular screws in C1/C2 and pedicle screws in C3 and C4 (Fig. 4)

CROSS2 Olerud Cervical Rod Spinal System: occiput rod fixed at the occiput with three occiput screws in the midline and two foramen magnum screws, cervical fixation with transarticular screws in C1/C2 and pedicle screws in C4

OCS3 Neon Occipito Cervical System: omega-shaped occiput rod fixed at the occiput with five occiput-screws or rather toggles, cervical fixation with transarticular screws in C1/C2 and pedicle screws in C4

Before testing of the instrumentations, the intact specimens were tested. The segments C0-C2 and C3-C4 were then destabilised with sectioning of the ligamentum transversum and both ligamenta alaria, capsulotomy of the intervertebral joints C1/C2, C3/C4, sectioning of the anterior longitudinal ligament C3/C4 and incision of the annulus fibrosus C3/C4. Due to the screw diameter of 3.5 mm, CerviFix was always tested first. Then OCS1 was tested, as this also used lateral mass screws. The instrumentations with pedicle screws, CROSS1+2 and OCS2+3, were tested in alternating sequence. Thus the following two sequences were tested alternating:

1. Intact – CerviFix – OCS1 – CROSS1 – CROSS2 – OCS2 – OCS3
2. Intact – CerviFix – OCS1 – OCS2 – OCS3 – CROSS1 – CROSS2

Radiographs were taken of the intact specimen to detect serious degenerative disease as well as neoplastic disease. The drill holes in C1/C2 and the pedicle holes in C3 and C4 were placed using a computer-assisted surgery (CAS) system (Navitrack, Sulzer Orthopedics Ltd., Switzerland) to ensure the correct positioning of the implants.

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 used the Friedman test to determine whether there were significant differences between the four test conditions CerviFix – OCS1 – CROSS1 – OCS2. The Wilcoxon signed rank test was used to prove our three main hypotheses. Although we tested many conditions and several parameters, we did not adjust the calculated *P*-values for multiple parameters. This would have resulted in a great loss of information. Therefore, we used the word “distinct” instead of “significant” for $P < 0.05$.

Results

Intact versus instrumented

The intact C0-C5 specimens could only be tested in lateral bending with moments of ± 2.5 Nm, due to the restricted ROM of the spine testing device of 33° in each testing di-

Table 1 Values for range of motion (ROM) and neutral zone (NZ) of intact human cervical spine segments from the literature (mean and standard deviation)

	Flexion/extension		Axial rotation		Lateral bending	
	ROM (°)	NZ (°)	ROM (°)	NZ (°)	ROM (°)	NZ (°)
C0/C2 [33]	52.0 ± 6.3	36.4 ± 5.8	80.7 ± 10.1	54.9 ± 10.1	32.3 ± 5.9	22.8 ± 5.3
C2/C3 [42]	11.1 ± 3.0	6.8 ± 2.7	11.1 ± 2.9	6.7 ± 2.9	11.6 ± 2.2	9.0 ± 1.7
C3/C4 [42]	12.0 ± 4.0	6.7 ± 3.2	12.2 ± 4.4	8.4 ± 3.5	10.8 ± 3.4	7.8 ± 3.2

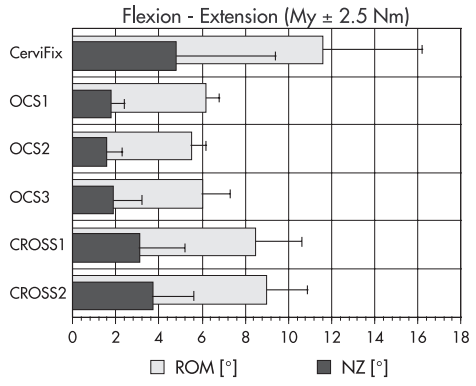

Fig. 5 Mean values and standard deviations for range of motion (ROM) and neutral zone (NZ) of C0–C4 for flexion/extension with applied flexion/extension moments of ± 2.5 Nm

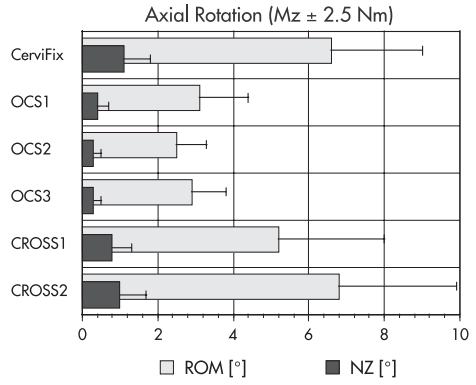

Fig. 6 Mean values and standard deviations for ROM and NZ of C0–C4 for left/right axial rotation with applied left/right axial rotation moments of ± 2.5 Nm

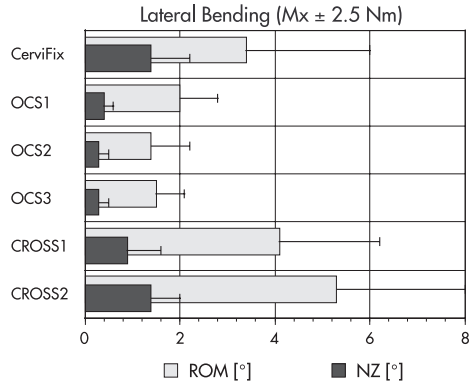

Fig. 7 Mean values and standard deviations for ROM and NZ of C0–C4 for right/left lateral bending with applied right/left lateral bending moments of ± 2.5 Nm

rection. In the other testing directions, only moments clearly below ± 2.5 Nm could be achieved, due to the restricted ROM of the spine testing device, so that extrapolation of the data was not possible. Therefore, we used data from the literature [33, 42] to compare the intact with the instrumented spines (Table 1). The instrumented specimens had for all loading conditions distinctly reduced ROM and NZ compared to the intact specimens.

CerviFix versus OCS with subaxial lateral mass screws

With OCS1 instrumentation, ROM and NZ were distinctly reduced compared to the CerviFix instrumentation for all loading conditions (Fig. 5, Fig. 6, Fig. 7, Table 2, Table 3, Table 4).

OCS with subaxial lateral mass screws versus pedicle screws

ROM and NZ were reduced for all loading conditions when using subaxial pedicle screws. The greatest influence was seen in lateral bending, while flexion/extension was influenced least. The differences were distinct only for ROM in lateral bending (Fig. 5, Fig. 6, Fig. 7, Table 2, Table 3, Table 4).

CROSS versus OCS with subaxial pedicle screws

Instrumentation with the OCS with subaxial pedicle screws reduced ROM and NZ distinctly compared to the instrumentation with the CROSS for all loading conditions. Axial rotation and lateral bending were more influenced than flexion/extension (Fig. 5, Fig. 6, Fig. 7, Table 2, Table 3, Table 4).

Influence of number of instrumented vertebrae when using pedicle screws

With the OCS, no distinct impact on ROM and NZ was observed with the use of pedicle screws in C3. When using the CROSS, ROM was distinctly increased without pedicle screws in C3 compared to the instrumentation with pedicle screws in C3 in lateral bending and axial rotation (Fig. 5, Fig. 6, Fig. 7, Table 2, Table 3, Table 4).

Table 2 ROM and NZ of the instrumented C0–C4 segment for all loading conditions tested with pure moments of ± 2.5 Nm: mean values and standard deviations are presented (*OCS* Neon Occipito Cervical System, *CROSS* Olerud Cervical Rod Spinal System)[a]

[a] Details of the instrumentations are given in the Material and methods section

	Flexion/extension		Axial rotation		Lateral bending	
	ROM (°)	NZ (°)	ROM (°)	NZ (°)	ROM (°)	NZ (°)
CerviFix	11.6 ± 3.9	4.8 ± 4.6	6.6 ± 2.4	1.1 ± 0.7	3.4 ± 2.6	1.4 ± 0.8
OCS1	6.2 ± 1.9	1.8 ± 0.6	3.1 ± 1.3	0.4 ± 0.3	2.0 ± 0.8	0.4 ± 0.2
OCS2	5.5 ± 1.4	1.6 ± 0.7	2.5 ± 0.8	0.3 ± 0.2	1.4 ± 0.8	0.3 ± 0.2
OCS3	6.0 ± 1.4	1.9 ± 1.3	2.9 ± 0.9	0.3 ± 0.2	1.5 ± 0.6	0.3 ± 0.2
CROSS1	8.5 ± 3.8	3.1 ± 2.1	5.2 ± 2.8	0.8 ± 0.5	4.1 ± 2.1	0.9 ± 0.7
CROSS2	9.0 ± 3.3	3.7 ± 1.9	6.8 ± 3.1	1.0 ± 0.7	5.3 ± 2.7	1.4 ± 0.6

Table 3 Significance levels concerning differences in ROM and NZ of the instrumented C0–C4 segment for all loading conditions, determined by the Friedman test and the Wilcoxon signed rank test for the following instrumentations: CerviFix vs OCS1, CROSS1 vs OCS2, and OCS1 vs OCS2

	Flexion/extension		Axial rotation		Lateral bending	
	ROM	NZ	ROM	NZ	ROM	NZ
Friedman test	0.002	0.002	0.002	0.034	0.001	0.034
CerviFix vs OCS1	0.011	0.011	0.011	0.017	0.044	0.091
CROSS1 vs OCS2	0.028	0.044	0.018	0.018	0.018	0.035
OCS1 vs OCS2	0.327	0.482	0.093	0.726	0.011	0.091

Table 4 Significance levels concerning differences in ROM and NZ of the instrumented C0–C4 segment for all loading conditions, determined by the Wilcoxon signed rank test for the following instrumentations: OCS2 vs OCS3 and CROSS1 vs CROSS2

	Flexion/extension		Axial rotation		Lateral bending	
	ROM	NZ	ROM	NZ	ROM	NZ
OCS2 vs OCS3	0.735	0.398	0.128	0.612	0.345	0.600
CROSS1 vs CROSS2	0.917	0.346	0.028	0.345	0.027	0.091

Bone mineral density

The mean BMD of the vertebra C3 was 0.19±0.03 g/cm^3. Negative correlations between the BMD and the ROM after instrumentation with all of the three implants were observed for all loading cases.

Discussion

The indications for posterior cervical spine stabilisation vary and include traumatic, degenerative, infectious, and neoplastic instabilities, as well as iatrogenic instability [23]. The appropriate stabilisation technique depends on the type and nature of the instability. In instabilities or dislocations due to rheumatoid arthritis, posterior instrumentation is indicated when the occipito-cervical junction is involved. For traumatic instabilities, posterior stabilisation is indicated when there is significant disruption of the posterior ligamentous structures including the posterior longitudinal ligament [23, 30, 41]. A combined anterior-posterior approach may be indicated for a combined anterior and posterior instability including the posterior longitudinal ligament, especially in severe cervical spine fracture, e.g. flexion teardrop fracture, vertical compression burst fracture with significant posterior ligamentous injury, or bilateral facet dislocation with associated compression of the ventral cord [23, 30, 41]. In neoplastic diseases, posterior instrumentation may also be indicated when the occipito-cervical region is involved. In these cases, a high biomechanical stability of the instrumentation with the possibility of a brace-free postoperative mobilisation is beneficial for the patient. Furthermore, depending on the prognosis of the neoplastic disease, an additional anterior approach may not be necessary due to high biomechanical stability in some cases. Following multisegmental posterior decompression of the cervical spine with laminoplasty or laminotomy, postoperative kyphotic deformity may occur, especially after laminectomy [28]. This means that in these cases a posterior instrumentation may be indicated, especially following decompression with laminectomy.

Implant design: Neon Occipito Cervical System

The goals for the development of the new implant system were:

1. Improved biomechanical stability compared to established systems
2. Occipital fixation that combines good fixation strength, while leaving enough bony area free for fusion
3. Possible combination of cervical fixation techniques, i.e. transarticular screws C1/C2, pedicle screws C2 and below and lateral mass as well as transarticular screws from C3 to C7

The occiput fixation is based on the Madeira plate (Endotec, Burscheid, Germany), developed by Kluger, and the combination of cortical screws and toggles for fixation introduced by Buchholz, Kluger, Staudte [4]. The Madeira plate was developed some years ago, based on the design of the Griss plate [12]. The toggles provide improved occipital fixation strength in bone thickness below 6 mm. Therefore, this fixation principle allows the use of an omega-shaped occiput rod, part of which is fixed lateral to the midline where the bone is thinner than in the midline. The omega shape has the advantage of leaving a free bony area at the occiput near the midline for fusion. The rod diameter was increased compared to established systems to provide an improved biomechanical stability. The ball-shaped screw design, together with the fixation to the rod, allows an angle-stable rod-screw connection with a high degree of angle variability between rod and

screws. To reduce the necessity of bending the rod, the closed connectors are available in four different lengths. The cannulated C1/C2 transarticular screws are self-drilling and self-tapping. This allows screw insertion C1/C2 after placing a 1.5-mm K-wire, and has the advantage, compared to other systems, that no C1/C2 dislocation can occur between drilling and screw insertion. The 4.0-mm pedicle screws are cannulated and self-tapping. The possibility of inserting the pedicle screws over a K-wire reduces the risk of screw misplacement. For pedicles with a width below 5.0 mm, non-cannulated 3.0-mm pedicle screws are available. The 4.0-mm lateral mass screws are not self-tapping, as the pull-out force of self-tapping screws in the lateral mass is significantly reduced compared to normal screws [19]. The system can be used for occipito-cervical fixation, cervical fixation and cervico-thoracal fixation. Furthermore, it can be connected to 6.0-mm or 6.25-mm rods in order to extend the instrumentation to the thoracic and lumbar spine with other rod-screw systems.

Study protocol

Our study protocol was defined according to the testing criteria for spinal implants specified in the recommendations for the standardisation of in vitro stability testing of spinal implants created by the study group for pre-clinical testing formed by the German Society for Spinal Surgery [45]. The purpose was to allow comparisons of our data with future results from various research groups. So far it has been very difficult to compare in vitro data of research groups because of variations in the study protocols.

Intact versus instrumented specimens

Due to the restricted ROM of the spine tester of 33° in each testing direction, the intact specimens could not be tested with pure moments of ± 2.5 Nm. We therefore used data from the literature to compare the intact with the instrumented spines. This may be a source of error, nevertheless the differences were highly significant, with $P < 0.0001$ for all instrumentations and all loading conditions.

CerviFix versus OCS with subaxial lateral mass screws

The primary biomechanical stability with OCS instrumentation was distinctly better than the CerviFix instrumentation for all loading conditions. This result can be explained by the implant design of the OCS, with a larger rod diameter (3.5 mm vs 4.5 mm), different rod materials (titanium alloy vs pure titanium), the closed occiput rod and the angle-stable rod-screw connection. As with the CerviFix system, good clinical results are reported [20]. Clinical assessment of the new implant system will be necessary to determine whether the biomechanical differences observed in this study are clinically significant.

OCS with subaxial lateral mass screws versus pedicle screws

More recently, pedicle screw fixation in the cervical spine has been introduced and improved biomechanical properties and good clinical results have been published [1, 2, 3, 21, 24]. Due to their improved pull-out strength compared to lateral mass screws [22], pedicle screws may be beneficial in the subaxial cervical spine in patients with poor bone quality, multilevel or three-column instabilities or in those in need of significant reduction. Reports of lateral mass screw fixation procedures have shown several instances of screw loosening that resulted in pseudarthrosis and loss of correction [8, 17, 18], indicating that in some situations pedicle screw fixation may be beneficial. Therefore, one of the hypotheses of this study was that subaxial pedicle screw instrumentation improves fixation strength. Our data showed reduced ROM and NZ for all loading conditions, but the differences were only distinct for lateral bending. Our data seem to be partially in contrast to the results of Kotani et al. [24], who showed improved biomechanical stability with pedicle screws compared to lateral mass screws. In our study the results for the pedicle screw instrumentation may have been negatively affected by the fact that it was always tested after the instrumentations with lateral mass screws. As the pedicle screws crossed the path of the lateral mass screws, the bony purchase of the pedicle screws may have been reduced. Additionally, age-related changes in our specimens led to an increase in bone density in the joint processes compared to the vertebral bodies.

CROSS versus OCS with subaxial pedicle screws

Primary biomechanical stability with OCS instrumentation was distinctly better than with the CROSS instrumentation for all loading conditions. This result may be explained by the implant design of the OCS, with the greater rod diameter (3.5-mm vs 4.5-mm). As with the CROSS, good clinical results are reported [32]. Clinical assessment of the new implant system will be necessary to determine whether the biomechanical differences observed in this study are clinically significant.

Influence of the number of instrumented vertebrae when using pedicle screws

With the OCS, no distinct difference in ROM or NZ was observed according to the presence or absence of pedicle screws in C3. This may allow for a reduced number of in-

strumented segments in long instrumentations when using the OCS, thereby reducing operation time and instrumentation costs compared to implant systems with lower primary biomechanical stability, like the CROSS for example.

Bone mineral density and biomechanical stability

The BMD of our specimens was low compared to values reported by other authors [6, 9, 38], but this can be explained by the high mean age of the human specimen donors of 76.2 years. As the positive correlations between the BMDs and the ROMs showed, primary stability is strongly dependent on the BMD. Accordingly, in specimens with a higher BMD we found a better primary stability with all implants and perhaps smaller or not significant differences between the implants. However, it is the patients with a low BMD who often show problems with the stability of implants, especially with implant loosening, and thus the data with low-BMD patients are of particular interest for the clinical application of the implants.

Limitations of the study

Several limitations in our study should be noted. The method of applying pure moments does not truly represent physiological loads, as compressive and shear forces are neglected. However, in vivo motion patterns are well reproduced and loading is consistent and thus known at every point in the specimen. This has the advantage of reproducible loading from one specimen or from one study to the next.

The testing sequences were determined following the screw diameters and in order to evaluate our hypotheses, as mentioned in the Introduction. Therefore, the results should not be taken to represent a valid comparison of the CerviFix with the CROSS system, as the CROSS system was always tested after the CerviFix system.

The study design, with all implants tested with the same specimens, precluded any cyclic testing. That is why the data only represent the primary stability of the implants.

Conclusions

In posterior instrumentation of the cervical spine, the new modular Neon Occipito Cervical System provides better biomechanical stability than both the CerviFix system and the Olerud Cervical Rod Spinal System (CROSS).

Clinical assessment of the new implant system will be necessary to determine whether the biomechanical differences observed in this study are clinically significant.

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