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ORIGINAL ARTICLE

Evaluation of a new monocortical screw for anterior cervical fusion and plating by a combined biomechanical and clinical study

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Abstract The purpose of this combined study was to evaluate the stability and safety of a new monocortical screw-plate system for anterior cervical fusion and plating (ACFP) according to Caspar in comparison with classical bicortical fixation. In the biomechanical part of the study two groups, each comprising six fresh human cadaveric spines (C4–C7), matched for bone mineral density, additionally resulting in almost the same mean age, were used. Range of motion and neutral zone were analyzed in flexion-extension, rotation (left, right) and lateral bending (left, right) using pure moments of ± 2.5 Nm for each specimen in the intact state, after discectomy at C5/6 and after discectomy at C 5/6 followed by bone grafting plus plating (Caspar plates), with either monocortical or bicortical screws. For all three motion planes, no significant difference could be found between the new monocortical and the bicortical fixation techniques. The clinical part of the study was performed as a prospective study on 30 patients suffering from symptomatic degenerative cervical disc disease in one segment. At the latest follow-up, no hardware- or graft-related complications were seen in any of the patients. Following these findings monocortical screw fixation can be recommended for the majority of anterior cervical fusion and plating procedures in degenerative disease, making the procedure quicker, easier, and safer. Bicortical screw fixation still has specific indications for multilevel stabilization, poor bone quality (osteoporosis, rheumatoid disease – as bicortical oversized rescue screw), unstable spines (trauma, tumour) and in particular for the realignment of kyphotic deformities (restoration of the normal lordotic curve). Due to the design of the study the results apply only to surgical treatment of monosegmental degenerative disc disease at the time.

Key words Spine · Spine, bone plates · Spine, screws · Spine, biomechanics · Spine, implant testing · Spine, stability

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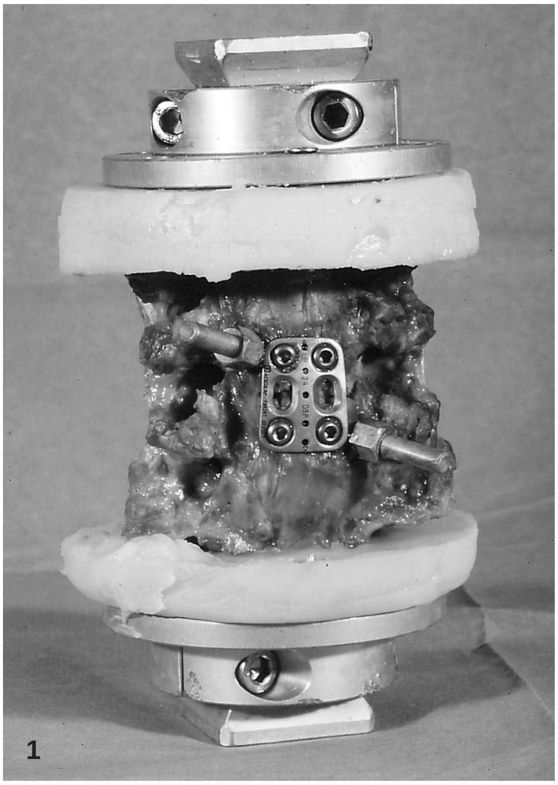
Introduction

Following the experiences of Cloward [6] and Smith and Robinson [14], Orozco and Llovet [10] were the first to describe additional anterior cervical plating, in 1971. Today anterior cervical fusion and plating (ACFP) has become a widely accepted technique in cervical spine stabi-

Fig. 1 Specimen prepared for biomechanical testing after anterior cervical fusion and plating (ACFP): end plates of C4 and C7 fixed by polymethylmethacrylate (PMMA), modified Schanz screws fixed in C5 and C6 for the motion analysis system ▶

Fig. 2 The two types of screw: monocortical (*upper*) and bicortical



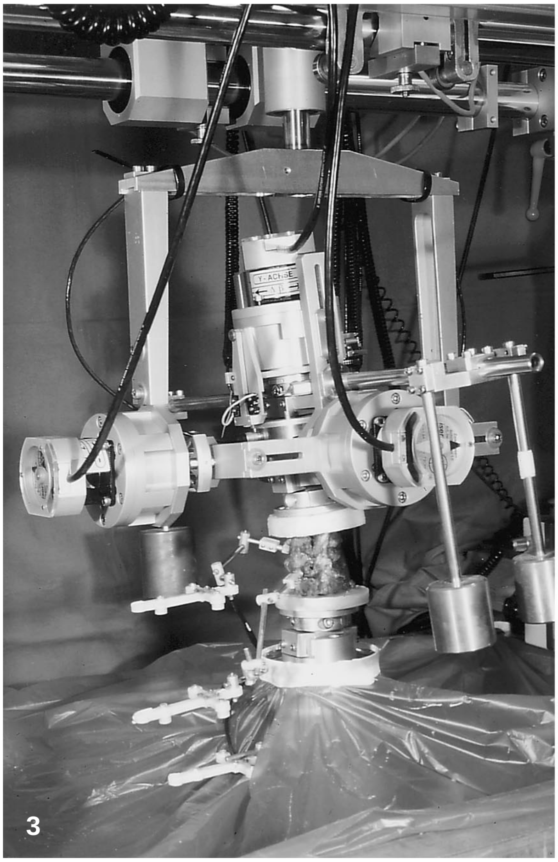


Fig. 3 Custom spine tester with specimen. The specimen has been fixed by PMMA plates and screws to the spine tester. Note the Zebris system fixed by screws in C5 and C6 and at the bottom of the spine tester

Fig. 4 Anterior cervical autologous bone graft fusion and plating with monocortical screws C5/6 in a 35-year-old woman: anteroposterior and lateral radiograph of the cervical spine **A** preoperatively and at **B** 6 weeks, and **C** 6 months postoperatively. Note that the screws are as long as possible, but do not perforate the posterior cortical shell

lization for a variety of indications [1, 2, 12, 15]. The stabilization system, the special instruments and the technical steps developed by Caspar [1] can be described as a classical cervical plating procedure. One of the main points in the development of this technique has been the bicortical fixation of the plate. By anchoring the screws in the posterior cortex, excellent stability is provided. This has been shown in three earlier studies [4, 5, 13], where monocortical screw fixation in ACFP failed to achieve the stability of bicortical fixation. However, there is a risk of perforating the dura and damaging the spinal cord with bicortical screw fixation – even if intraoperative fluoroscopy is used [9, 12]. Therefore, the most logical step for further evolution of ACFP had to be the development of a monocortical screw providing the same stability as fixation with the bicortical Caspar screw. The purpose of this biomechanical study was to evaluate the stability of such a new screw for monocortical use by a combined study.

Table 1 Matched-pair analysis: the two groups of C4–C7 specimens for monocortical (MC) and bicortical (BC) instrumentation were matched in bone densityy

Pair	MC specimen		BC specimen	
	Mineral bone density (mg/cm^3)	Age (yrs)	Mineral bone density (mg/cm^3)	Age (yrs)
1	261	35	211	67
2	243	63	264	39
3	208	86	232	65
4	241	54	230	49
5	209	35	161	66
6	135	60	173	51
Mean	216.2	55.5	211.8	56.2

Materials and methods

The classic Caspar plate for anterior osteosynthesis of the cervical spine is a trapezoidal, titanium plate that can be bent to the patient's individual lordosis (Fig. 1). Thus far it has been fixed onto the anterior aspect of the cervical spine by titanium, non-self-tapping screws placed also into the posterior cortex of the vertebral body. The new screw for monocortical fixation is a self-tapping, conical screw 14, 15, 16, 17 or 19 mm in length, with an outer diameter of 4.0 mm and an inner diameter of 2.2 mm at the tip, increasing to 2.7 mm at the head (Fig. 2). The classic bicortical screw is a non-self-tapping screw, available in 16 different lengths, between 10 and 28 mm, with a constant outer diameter of 3.5 mm and an inner diameter of 2.2 mm. Both screws are made of titanium alloy with a corrundum-blasted surface over one-third of the length at the tip.

Twelve fresh human cadaveric spinal segments (C4–C7) were removed, frozen, and prepared for biomechanical testing. Great care was taken to avoid damaging any of the bony structures or the joint complexes, including the ligaments. The end plates of C4 and C7 were cleaned of fibrous material and between three and five screws were inserted through the upper end plate of C4 and the lower end plate of C7. Lateral and anteroposterior X-rays were performed to detect fractures, tumorous destruction, or spondylodiscitis. Bone mineral density (BMD) was determined to document bone quality (Stratec XCT-9600 A, Birkenfeld, Germany). For matched-pair analysis (Table 1) specimens were selected according to the criterion of bone mineral density (as the main factor influencing the strength of fixation of the screws [18]). The mean BMD was 216.2 mg/cm^3 in the monocortical group and 211.8 mg/cm^3 in the bicortical group, resulting in almost the same mean age in both groups (55.5 years in the monocortical group, 56.2 years in the bicortical group). Mean BMD was 214 mg/cm^3, range 135–264 mg/cm^3. The upper end plate of C4 and the lower end plate of C7 were anchored in polymethylmethacrylate (PMMA) (Fig. 1) for mounting in the spine tester [17].

Testing of each specimen was performed without preload in flexion-extension, axial rotation (left, right) and lateral bending (left, right) in three cycles with pure moments of ± 2.5 Nm [15, 16]. The range of motion (ROM) and neutral zone (NZ) of the instrumented segment was documented by a motion analysis system (Zebris, cmstrao V. 1.0, Isny, Germany), fixed by screws in the anterior aspect of C5, C6, and C7 at the bottom of the spine tester (Fig. 3). This is an ultrasound-based motion analysis system. A single element of the system looks like a cross. Each cross carries three ultrasound sources at its surface and three microphones at its lower surface. Thus, two crosses are able to communicate for measuring the distance between them. From the data recorded by the three crosses fixed in the vertebral bodies of C5, C6 and C7, computer calculates rotation and translation in each segment. The accuracy of the system is as high as 0.2° without time-dependent drift. The specimens were tested first intact, then again after complete discectomy with removal of the posterior longitudinal ligament, and again after stabilization of this segment with bone graft and plating with either monocortical or bicortical screws. The bicortical screws were fixed in the posterior cortex, whereas the monocortical screws were choosen to be as long as possible without perforating the posterior cortex. All specimens were tested three times at each stage and for each loading mode of the analysis, but only the third cycle was evaluated. Statistical analyses were performed using the Mann-Whitney-Rank, with a significance level set at $P < 0.05$.

The clinical study was performed as a prospective study on 30 patients (15 males, 15 female, mean age 46 years, mean follow-up 14.6 months) suffering from cervical myelopathy (5 patients), radiculopathy (24 patients) or myelo-radiculopathy (1 patient) caused by degenerative pathology in one cervical motion segment (Table 2). None of them had severe instability. Surgical procedure was discectomy and removal of the posterior longitudinal ligament, autologous bone graft fusion and plating (Fig. 4A–C). Intraoperative fluoroscopy was used to select the optimal screw length – the screw should be as long as possible without penetrating the posterior cortical shell (Fig. 4B,C). A total of 120 screws were used; 118 of them were the new monocortical screws as described above, two screws were so-called "oversize rescue" screws, designed by Caspar. The rescue screws, as well as eight monocortical screws that had to be anchored by bone cement, had to be used because sufficient screw torque of at least 40 Ncm could not be obtained in these cases. All patients were given a soft collar for 6 weeks after the operation. Clinical and radiological (anteroposterior, lateral X-ray) examinations were performed immediately after surgery, and at 10 days, 3 weeks, 6 weeks, 3 months, 6 months, 12 months and 18 months after surgery. Fusion was assessed (AP and lateral X-ray) by the criteria of bony bridging between the graft and the adjacent vertebral bodies and the absence of implant and/or graft dislocation. Lateral X-ray in flexion and extension was performed when solid bony fusion was documented to show stability of the construct. The radiological follow-up was performed by an independent radiologist, whereas the clinical follow-up was performed by the author.

Table 2 Cinical data of the patients (*n* = 30)

Male	Female	Mean age (yrs)	Location of levels	Levels fused	Disease
n = 15	*n* = 15	46	C4/5: *n* = 4 C5/6: *n* = 13 C6/7: *n* = 12 C7/D1: *n* = 1	One: *n* = 30	Radiculopathy: *n* = 24 Myelopathy: *n* = 5 Radiculomyelopathy: *n* = 1

Results

Biomechanical study

Anterior cervical fusion and plating (ACFP) led statistically to the same stabilization in both groups (Fig. 5). Mean ROM in the monocortical (MC) group was 9.8° (± 2.7°) for flexion-extension, 10.3° (± 4.0°) for rotation, and 8.1° (± 2.9°) for lateral bending. In the bicortical (BC) group mean ROM was 10.6° (± 2.0°) for flexion-extension, 9.9° (± 3.5°) for rotation, and 10.6° (± 2.9°) for bending in the intact specimen. ROM increased in both group after discectomy and resection of the posterior longitudinal ligament in C5/6. In the MC group the increase was 18.3° (± 4.3°) for flexion-extension, 12.9° (± 5.5°) for rotation, and 10° (± 4.1° for bending. In the BC group it was 16.1° (± 4.3°) for flexion-extension, 12.4° (± 3.4°) for rotation, and 13.6° (± 4.2°) for bending. ACFP made the segment stiffer than it was in the intact specimen, with slightly better results in the MC group of 1.2° (± 1.0°) for flexion-extension, 2.3° (± 1.2°) for rotation, and 1.4° (± 1.0°) for bending, compared with 3.2° (± 3.8°) for flexion-extension, 3.6° (± 3.2°) for rotation and 2.6° (± 2.7°) for bending in the BC group.

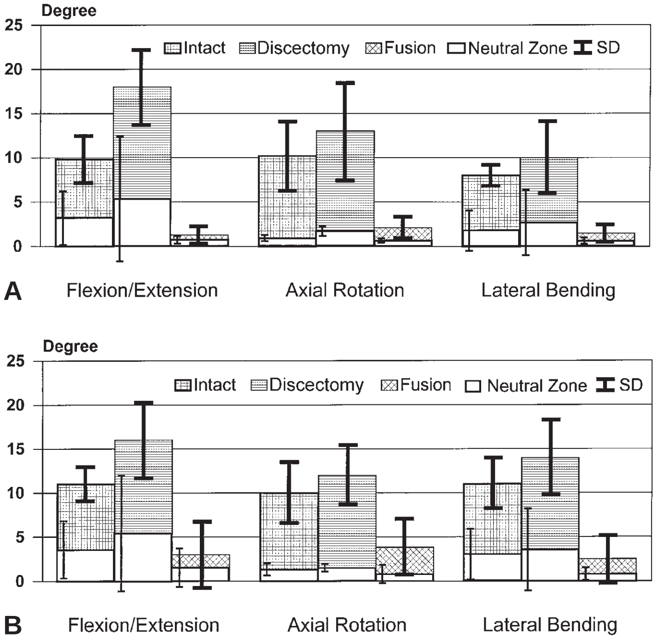


Fig. 5 Mean range of motion and neutral zone (standard deviation) in **A** the monocortical (MC) and **B** bicortical (BC) group. The values represent the sum of flexion plus extension, axial rotation left plus right, and lateral bending left plus right

Clinical study

Fusion had occurred in all patients at latest 12 months after surgery. No graft- or hardware-related complication such as graft height reduction, graft collapse, graft extrusion, graft compression fracture, screw breakage or screw back-out occurred in any of the patients.

Discussion

This biomechanical matched-pair analysis and clinical study demonstrates that the new screw for monocortical fixation of Caspar-plates provides the same stability as the classical bicortical screw, with the additional advantage of avoiding the risks of bicortical fixation (dural perforation, spinal cord damage, epidural hematoma). The biomechanical test was performed using 12 cadaveric human spinal specimen C4-C7 with a mean BMD of 214 mg/cm^3, range 135–264 mg/cm^3, which is in the range of normal quality reported by another study [19]. Pure moments without preload and neglecting muscle forces, thus not representing the real physiological loading of the cervical spine, were used. However, as this physiological load is not known, the loading conditions used in this test are widely accepted and even recommended, allowing standardized testing [8, 11, 16]. The clinical part of the study was performed after biomechanical results had shown no significant difference concerning the initial stability of both constructs.

Three earlier studies dealing with the evaluation of monocortical screw fixation in ACFP failed to show a stability that was comparable to bicortical screw fixation: Clausen [5] and colleagues compared the Caspar system, using bicortical screws, with the cervical spine locking plate system, using unicortical locking screws. In this study, which used a model of complete C5/6 instability, the Caspar system with bicortical screws was superior to the system with the unicortical screws. Chen [4] compared stability of ACFP using a porcine model with an H-plate fixed uni- and bicortically. The results showed comparable stability in both groups before cyclic loading; however, after cyclic loading bicortically fixed screws rendered additional stability. Ryken et al. [13] fixed Caspar's plate with unicortical and bicortical screws to compare the stabilizing potential: the unicortical screw placement resulted in inadeqate stabilization in half of the specimens. The results of the present study are in contrast to the results of Chen [4], Clausen [5], and Ryken [13]. This may be due to the different shape of the implants used in the studies. The new implant we used has a special design – a self-threading screw with a conical inner diameter by which the cancellous bone is compressed when the screw is inserted. This may result in higher screw torque. Furthermore, we chose in every case, the longest screw possible without perforating the posterior cortical shell, to achieve maximal contact area between the screw and bone. The present study also differed from the studies to which it has been compared. We did not use cyclic loading [4] for biomechanical testing of the implants. Repeated cyclic loading may be useful in biomechanical testing to simulate the situation of the "worst case". On the other hand, cyclic loading can not simulate the biological process of bony fusion in a segment, and the influence of an external orthesis is neglected completely. Whether cyclic loading is appropriate to mimic a stress situation is not clear, either: a constant load is applied to the construct in conditions of cyclic loading, whereas it tends to be a sudden increase of complex moments and forces that leads to the failure of the construct in a stress situation. Thus, clinical data seem to be more important for analysis of a stress situation.

Because the results of the biomechanical part of the study demonstrated no significant difference concerning the initial stability of both constructs, a prospective clinical study on 30 patients was performed. At the latest follow-up, by the time fusion had occurred, no hardware- or graft-related complication had been observed. These clinical data underline the importance of initial stability in biomechanical testing, which seems to be a sufficient predictor for stability of osteosynthetic spinal constructs. Thus, additional clinical data – as reported here – seem to be useful only to emphasize the results of the biomechanical part of the study.

Since its first description by Orozco [10] and development by Caspar [1], ACFP has become a widely accepted technique in cervical spine surgery for a variety of indications: trauma, tumor, spondylodiscitis, rheumatoid arthritis, leading to segmental instability, of the cervical spine were all thought to be indications for anterior decompression, fusion, and plating [1, 2, 12, 15]. But for degenerative pathology additional plating is still thought to be an overtreatment, although the rate of reoperations is significantly reduced by plating [3, 7]. There are some arguments against the use of additional plating: longer operation times, need for intensive X-ray monitoring and, when bicortical screws are used for plate fixation, the need for penetrating the posterior cortex and the increased risk of dural perforation, epidural hematoma, and damage of the spinal cord [9, 12]. Conversely, three studies have demonstrated that the use of monocortical screws for ACFP leads to a drastic reduction of stability within the fused segment when compared to ACFP with bicortical screws, so that bicortical fixation had to be favored in ACFP [3, 4, 13]. The new device can be recommended for ACFP in degenerative disease of the cervical spine. However, due to the design of the study the results apply only to surgical treatment of monosegmental degenerative disc disease at the time.

Conclusion

ACFP provides an immediate stabilization, leading to a significant reduction of graft-related complications (i.e. pseudarthrosis, graft collapse and/or dislocation). Bicortical fixation has been favored in the past, because all former studies documented a significantly better stabilization when bicortical screws were used for plate fixation. But the use of bicortical screws calls for penetration of the posterior cortex, thus risking dural perforation, epidural hematoma, or spinal cord damage. Although the use of intraoperative X-ray monitoring is also recommended in monocortical screw fixation, X-ray time will be much shorter.

This study demonstrates that there is no statistically significant difference in stability within the fused segment between monocortical and bicortical Caspar screws when used for ACFP. Monocortical screw fixation with these special screws can therefore be recommended on the basis of this biomechanical study.

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