In vitro comparison of the pullout strength of 3 anterior double-screw fixation techniques with different screw angulations

Laboratory investigation

Sebastian Fuerderer, M.D., Ph.D., Jan Vonhoegen, M.D., Oliver Coenen, M.D., Joern Michael, M.D., Juergen Koebke, Ph.D., and Peer Eysel, M.D., Ph.D.

1Department for Orthopaedic and Spine Surgery, Klinikum Matterhaus der Borromäerinnen, Trier; 2Orthopaedic Department, Cologne University Hospitals, Cologne; 3Praxis für Orthopädie, Cologne; and 4Institut für Anatomie II, Cologne University, Cologne, Germany

Object. The pullout resistance of double-screw fixation systems in anterior spine surgery has been shown to be dependent on screw length as well as on screw angulation. The objective of the study was to evaluate the pullout strength of anterior double-screw systems with different angulations.

Methods. The authors conducted a comparative pullout test of converging, parallel, and diverging angulations of double-screw systems in human cadavers. Twenty-four human vertebral bodies from T-11 to L-1 were harvested from 8 donors, dissected from surrounding tissue, and matched to 3 different fixation groups. Three systems were tested: VentroFix, with near parallel screw direction; the Hopf Anterior Fixation System (HAFS), with converging screw angulation; and the ART anterior system, with diverging screw angulation.

Results. The mean (±SD) pullout strength of the VentroFix system was 699 ± 214 N, whereas the HAFS resisted to 591 ± 372 N. The ART anterior system with diverging screws demonstrated a pullout resistance of 810 ± 273 N. There was no significant difference amongst the pullout forces of the 3 groups (p > 0.05). In the HAFS and the ART anterior group, a weak correlation of pullout strength and bone mineral density measured by quantitative CT was found (r = 0.59 and r = 0.62, respectively), whereas the pullout force of the VentroFix system was not correlated with bone mineral density (r = 0.33).

Conclusions. The in vitro pullout resistance of anterior double-screw systems does not appear to depend on screw angulation. (DOI: 10.3171/2010.9.SPINE09495)

Key Words • stability • anterior spinal fixation • VentroFix • double-screw fixation system • Hopf Anterior Fixation System • ART anterior system

Abbreviations used in this paper: BMD = bone mineral density; HAFS = Hopf Anterior Fixation System; VB = vertebral body.
cadavers ranged from 60 to 96 years. The vertebrae were dissected from surrounding tissue, the discs were excised, and the ribs were cut at 4 cm lateral to the costotransverse joints to preserve the posterior and lateral osteoligamentous elements. Bone mineral density was measured (range 20–179 mg/cm³) using the quantitative CT hydroxyapatite method. A spiral CT scanner (MX 8000 IDT, Phillips) was used for both imaging and measurement. The VBs were assigned to the 3 fixation technique groups and distributed from each spine equally between the 3 groups. The VBs were marked, sealed in plastic bags, and stored frozen at –20°C. They were thawed for 24 hours before testing at room temperature.

For testing, the anterior fixators were mounted following the official recommendations of the manufacturers of the systems used. According to the testing protocol, 3 different anterior fixators were tested in a left-sided assembly. The VentroFix system (Synthes) is designed for short-segment instrumentation, consisting of an anterior connector in which 2 screws can be attached at a fixed angle. The connectors are available for 1- or 2-rod assembly (Fig. 1); in our testing, the single-rod system was used. The HAFS (Medtronic Sofamor Danek) is also available with a 1- or 2-rod connection. The VB screws are inserted in a 35° convergent angulation (Fig. 2). The ART anterior system (Advanced Medical Technologies) exists only as a single-rod connector. The screws are inserted craniocaudal to each other with a 15° open angle in the transverse plane (Fig. 3). All systems were tested in the single-rod assembly. Group 1 consisted of the VentroFix double-screw single-rod system. In Groups 2 and 3, the HAFS and the ART anterior system, respectively, were tested.

For the testing, the VB was attached to a specimen holder allowing the VB to adjust to the pullout direction perpendicular to the VB axis. Using a steel fiber cable attached to a short rod, the fixator was fixed to the testing machine, and the testing was performed with a pullout speed of 50 mm/minute. This condition was chosen because it was estimated as a possible pullout failure condition during a reduction maneuver. Axial pullout strength was measured using a Zwick Z50 servoelectric testing machine.

Due to the small number of specimens tested, no power analysis was performed. Statistical analysis was limited to descriptive parameters. The Student t-test was used for matched samples with an assumed error of α = 0.05. Significance was assumed with p < 0.05.

Results

Bone Mineral Density

Average BMD was 59.91 mg/cm³ (range 23–102 mg/cm³) for T-11, 66 mg/cm³ (range 28.4–178.4 mg/cm³) for T-12, and 61.7 mg/cm³ (range 19.1–102.4 mg/cm³) for L-1. Eighteen of 24 VBs had a BMD < 80 mg/cm³ so these samples were considered osteoporotic. The BMD was not statistically different in the tested groups, but differed among the specimens before matching the vertebrae. The mean BMD of the vertebrae was 62.58 ± 52.3 mg/cm³ in Group 1 (VentroFix), 60.45 ± 30.5 mg/cm³ in Group 2 (HAFS), and 64.59 ± 31 mg/cm³ in Group 3 (ART anterior).

Pullout Resistance Force

Pullout force was defined as the maximum force followed by a loss of resistance of at least 20% of the maximum force. The VentroFix system resisted to a mean (± SD) pullout force of 698.75 ± 214 N (range 260–910 N). The HAFS system registered a mean pullout force of 591.25 ± 372 N (range 200–1480 N), and in the ART anterior group the mean pullout force was 810 ± 273 N (range 390–1130 N) (Fig. 4). The Student t-test showed no significant differences between the VentroFix and HAFS (p = 0.353), VentroFix and ART anterior (p = 0.148), and HAFS and ART anterior systems (p = 0.079).

Correlation of Pullout Force and BMD

The VBs used in this test were taken from donors over the age of 60 (range 60–96 years). Eighteen of 24 VBs met the criteria of osteoporosis, meaning a BMD < 80 mg/cm³. To evaluate the influence of reduced bone quality, the pullout force was correlated to the BMD of each tested vertebra using the Pearson correlation coefficient. The stability of the VentroFix system was not correlated with BMD (r = 0.33). The HAFS (r = 0.59) and the ART anterior system (r = 0.62) showed a weak correlation with BMD (Fig. 5).

Discussion

Anterior instrumented spinal fixation began with the Dwyer system in 1969.8 At first, single screws were connected by cables to exert compression between the VBs.79 In 1975, Zielke and colleague30,31 changed the cables to threaded rods because of frequent cable failures. From this period forward, screw fixation at the VB appeared to be one critical point in anterior stabilization. The maximum pullout forces of an anterior fixation system are known to appear at the cephalad end during correction maneuvers.21,22 As a consequence, most of the studies investigat-
ing the stability of anterior fixation refer to the pullout resistance. Bicortical insertion of the screws was shown to increase the pullout stability of anterior fixation systems. The concept of a pullout nut at the screw tip was abandoned due to possible damage of neurovascular structures at the opposite side, which is also hard to visualize. In 12%–15% of screws inserted bicortically, the tips are found to be in contact with the aorta. As one of the first systems, the Dunn fixator addressed this problem by using double-screw fixation at 1 VB. There is consensus that double-screw systems nearly double the force needed for destructive pullout compared with a single screw. With the increasing volume of the systems, special problems arose concerning the paraspinal structures, such as greater vessels and nerve plexus. After reports of aortic laceration due to the system in 1986, the Dunn fixator was abolished. In 1984 Kaneda et al. introduced a smaller double-screw system in which 2 parallel Tulip screws were inserted into a spiked plate. The first systems with angulating screws were the Texas Scottish Rite Hospital system (Medtronic) developed in 1990, which allows a free screw direction, and the Cotrel-Dubousset-Hopf system (Medtronic), in which the screws are inserted convergently. In biomechanical testing, Eysel demonstrated the positive effect of screw angulation. In his human cadaver study, the systems with angulating screws (TSRH, CDH) had a significantly better pullout resistance than the parallel double-screw Kaneda Anterior Spine System (KASS). However, Shimamoto and colleagues found a higher stability of the KASS compared with the CDH system using bovine VBs. In a recent study, the effect of twin screws was confirmed, but no influence of different converging screw angulation was found. The influence of BMD on pullout resistance found by Wittenberg et al. in posterior instrumented fusion could not be confirmed in this study with anterior fixation techniques.

In all of these double-screw systems, the insertion points are located at the anterior and posterior edge of the VB, occupying a considerable area at the lateral aspect of the vertebra. Especially in the lower lumbar spine, this might lead to a compromise of neural and vascular structures. Besides the life-threatening aortic or venous laceration, venous thrombosis, aneurysms, and arteriovenous fistulae are described as resulting from implant-related complications. Eysel investigated different anterior systems regarding the risk of contact to these structures and found that in one-third of the cases at L-5, placement was not possible without contacting the iliac artery or vein. The placement of single screws, however, was possible without potential damage in half of the cases in which a double-screw system would have come into contact with the vessels.

The 3 systems tested in this study differ considerably in the volume of the connector. The 3 dimensions of the fixator mounted onto the vertebra consist of an anteroposterior length, a craniocaudal length, and a height. The anteroposterior length of the VentroFix is 30 mm and of the HAFS is 29 mm, whereas the ART anterior system is only 16 mm in the anteroposterior direction. The craniocaudal diameter among the 3 systems varies between 15 mm (HAFS), 18 mm (ART), and 26 mm (VentroFix). The longer connector of the VentroFix and HAFS allows for a smaller height (10.5 and 10 mm, respectively), whereas
the short ART anterior system requires 16 mm for rod connection. As the zone at risk is always the anterior part of the paravertebral space, the shorter construct of the diverging system may be an advantage.

In this study, the stability regarding the pullout resistance did not differ significantly between double-screw systems with different screw angulation. However, there was a considerable variation with the high range of pullout forces in all of the groups tested. The BMD was shown to have only minor influence on the stability of the different fixation systems. A critical factor of this study is the small sample size due to the availability of human donors. The number of specimens tested in each group, however, corresponds to other cadaveric testing in the literature. The high range of the absolute values as well as the SDs emphasizes the nonsignificant differences of the systems used in this test. As a consequence, due to an exploratory character of the study, the statistical data should be regarded as descriptive. The indication of a statistical power number does not appear to be justified.

Conclusions

Screw direction does not appear to influence the pullout resistance of anterior spinal double-screw fixators. Based on the results of this study, no recommendation concerning the screw direction in double-screw systems can be made. Systems with diverging screw direction, which may have the advantage of smaller implants, do provide the same stability as systems with converging screws and larger connectors.

Disclosure

Dr. Fuerderer works as an adviser in the development of spinal implants when consulted by the AMT company without receiving any financial benefit. He received working fees as course director for Synthes Inc. No financial benefit was received for the study nor was it initiated by any of the companies involved.

Author contributions to the study and manuscript preparation include the following: Conception and design: Fuerderer. Acquisition of data: Vonhoegen. Analysis and interpretation of data: Fuerderer. Critically revising the article: Michael. Statistical analysis: Vonhoegen. Administrative/technical/material support: Koebke. Study supervision: Fuerderer, Coenen, Eysel.

References


Fig. 5. Scatterplots of the correlation between BMD and pullout force in each group.
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