

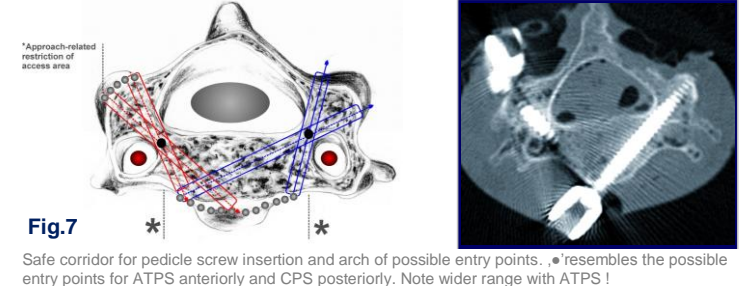
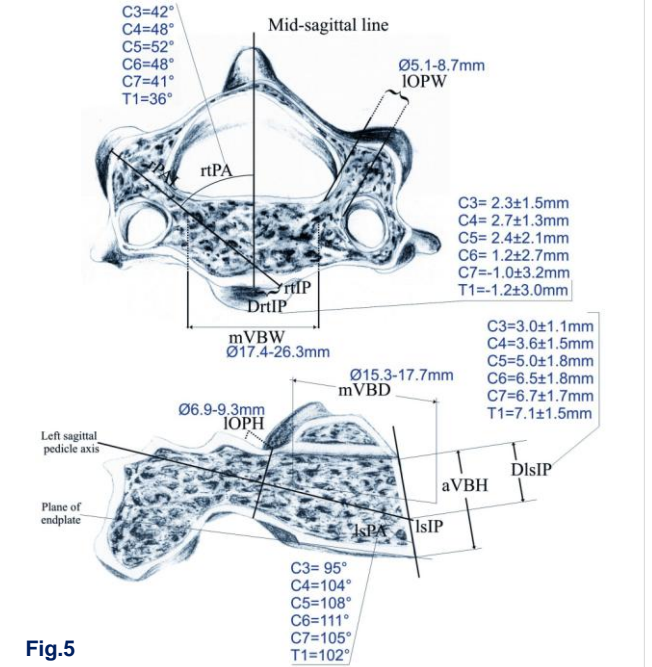
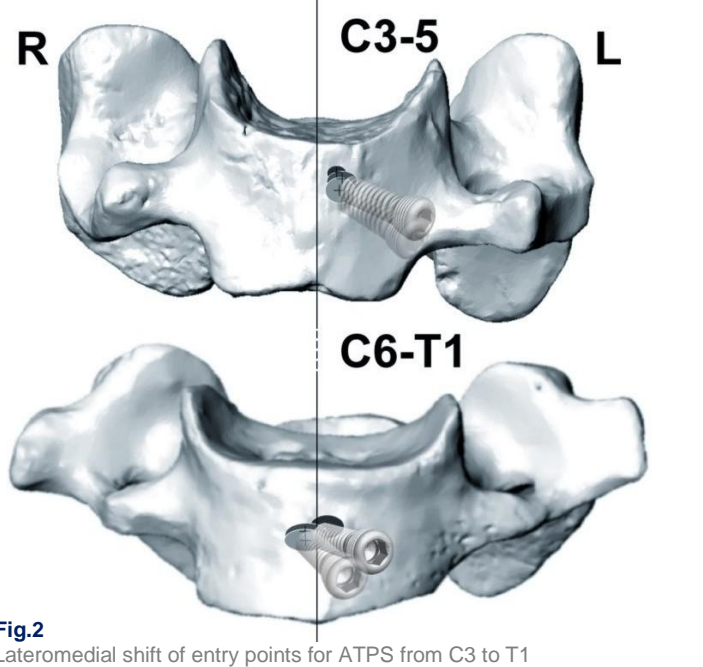
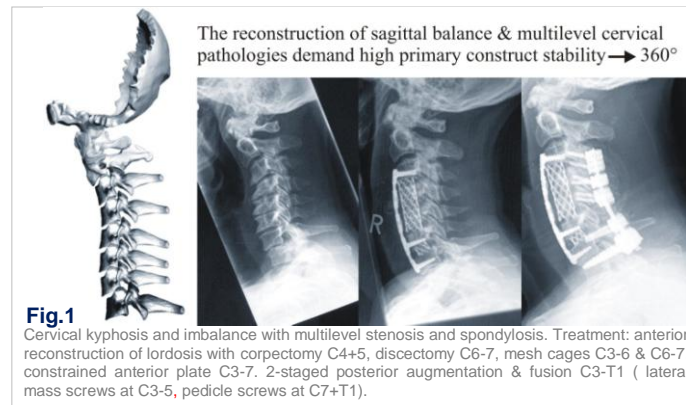
Development of the Anterior Transpedicular Screw (ATPS) fixation technique: A three-part study project on the clinical preparation for ATPS.

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Introduction

The number of patients with cervical pathologies indicating multilevel decompressive and reconstructive surgery is increasing [1-3,8]. Most cases are addressed by an anterior approach first. Nevertheless, the highly unstable decompressed cervical spine frequently demands not only rigid anterior instrumentation but also posterior augmentation and stabilization (fig.1). Indications include >2 level corpectomies, cases where posterior column insufficiency accompanies 2-level and even 1-level corpectomies, neoplastic instability with affection of both the anterior and posterior column as well as extensive tumor mass resections challenging current instrumentations; cervical trauma in patients with ankylosing spondylitis or DISH, 1- or 2-level corpectomies or hybrid constructs in the setting of fragile osteopenic and osteoporotic bone, long fusions (≥4 discs) crossing the cervicothoracic junction, advanced fracture and discoligamentous cervical instabilities including 3-column failure, reconstructions in cervical osteomyelitis and revision surgery for cervical nonunion following long fusions. Hence, several of the challenging pathologies indicate circumferential stabilization and fusion. The posterior approach causes significant morbidity for the patient, it has the potential for inherent complication and utilizes extra costs. To avoid secondary posterior surgery, particularly in the elderly population, while increasing primary construct rigidity of anterior-only reconstructions, the authors introduced the concept of anterior transpedicular screw (ATPS) fixation and plating. In the setting of increasing safety and comfort with cervical pedicle screw (CPS) fixation the authors initiated a project yielding for the evaluation of ATPS fixation and plating as a concept for advanced rigid cervical spine instrumentation in biomechanically challenging situations. The project is divided into 4 parts. The first 3 parts with results are presented.



ATPS I - Morphological study of feasibility

We performed an in-vivo CT-based study exploring the feasibility of ATPS. The study was conducted on 29 cervical CT-scans. Measurements were performed including standard parameters for the assessment of the pedicle morphometry at C2-T1. New parameters for the ATPS-technique included sagittal and transverse intersection points of the pedicle axis with the anterior vertebral body (distance in sagittal plane=DlsIP/DrIP; in transverse plane=DltIP/DrtIP, fig.5) and distances between sagittal intersection points C2-T1 (fig.3). With the obtained data, standard spine models were reconstructed (fig.3) demonstrating the feasibility of ATPS. For an ATPS-plate to accommodate all possible pedicle axis and screw positions in the axial and sagittal plane, it will have to allow versatile features in craniocaudal and mediolateral direction.

ATPS II - Biomechanical performance & accuracy

The objectives of part II were to assess the ex-vivo accuracy of placing ATPS into the cervical vertebra and the biomechanical performance of ATPS in comparison to vertebral body screws (VBS) in terms of pull-out strength (POS). We inserted 1 ATPS alternately to 2 vertebral body screws (VBS) into six cadaveric specimens from C3-T1. For insertion of ATPS, the measurements of DlsIP/DrIP and DltIP/DrtIP were used for determining the entrance points for ATPS. For insertion we used a manual, fluoroscopically-assisted technique (fig.3) that utilizes 'fluoroscopic pedicle axis views'. This means visualizing a 'true-ap view' and 'true-lateral view' of the pedicle (fig.6). Pre- and post insertional CT-scans were used to assess anatomy and accuracy. A new grading system and accuracy score were used to delineate accuracy (fig.4). After screw insertion, 23 ATPS and 22 VBS were subjected to pull-out testing (POT). The bone mineral density (BMD) of each specimen was assessed prior to POT. Statistical analysis showed that the incidence of correctly placed screws and non-critical pedicle breaches in axial plane was 78.3%, and 95.7% in sagittal plane. Hence, according to our definition of 'critical' pedicle breaches exposing neurovascular structures at risk, 21% (n=5) of all ATPS inserted showed a critical pedicle breach in axial plane. No critical pedicle perforation occurred at C6 to T1 levels. The percentage of pedicles instrumented with an outer pedicle width <5mm was 22% and accuracy was correlative with outer pedicle width (p<.001) and product of [OPWxOPH] (p=0.03). Mean accuracy score in axial plane was 1.96pts (1-3.3) and 1.52 (1-5) in sagittal plane. Accuracy sum score was 03.48 (2-10). Pull-out testing of ATPS and VBS revealed that POS of ATPS was 2.5 fold that of VBS. Mean POS of 23 ATPS with a BMD of 0.566g/cm² and osseous screw purchase of Ø27.2mm was 467.8N. In comparison, POS of 22 VBS screws with BMD of 0.533g/cm² and osseous screw purchase of Ø16.0mm was 181.6N. The difference in ultimate POS between the ATPS and VBS group was significant (p<.000001). Additionally, the POS was shown to be significantly correlated to the accuracy sum score of the ATPS placed (p=0.01). In contrast, there was no correlation between screw-length, BMD, or level of insertion and the POS of ATPS or VBS.

ATPS III - Increasing accuracy of ATPS

Part III yielded for an increase of accuracy. Hence, we analyzed the impact of an electronic conductivity device (ECD, Pediguard) on the accuracy of ATPS (and pCPS) insertion. 30 ATPS & 30 pCPS were inserted alternately into the C3-T1 vertebrae of 5 fresh-frozen specimen. Fluoroscopic assistance was only used for entry point selection, pedicle tract preparation was done using the ECD. Preoperative CT-scans were assessed for sclerosis at the pedicle entrance or core. Vertebrae with dense pedicles were excluded from analysis. Postop CT-scans were analysed for screw positions according to the above-mentioned grading system (fig.4). With ATPS insertion, the CT-based preop calculations of pedicle axis projection on the anterior vertebral body surface (data of DlsIP/DrIP in sagittal and DltIP/DrtIP in transverse plane, fig.5) eased templating the approximated entry points. Following real-time fluoroscopic entry point determination using 'true-ap' and 'true-lateral' pedicle axis views, the anterior vertebral cortex was opened using a small awl. The awl was advanced stepwise for 5mm without fluoroscopic control. The ECD was then introduced and advanced to the pedicle base. According to signal changes, the entrance to the pedicle was identified and the ECD was advanced through the lateral mass and beyond its cortex, afterwards 3.5mm screws were inserted (fig.8). Results: Concerning ATPS, the analysis of CT-measurements revealed an accuracy score for the axial plane of 1.2 pts (1-2) and 1.1pts (1-2) in the sagittal plane. The accuracy sum score was 02.3 pts (2-4). Non-critical screw positions were identified in 100% in the ATPS-group using an ECD, there was no critical breach. Increasing accuracy in the axial plane was reflected by an increased accuracy in sagittal plane (p=0.02). Concerning the pCPS, accuracy in axial plane scored 01.4 pts (1-4) and 01.2 (1-4) in sagittal plane. The accuracy sum score was 02.6 pts (2-4). Non-critical breaches in axial plane occurred in 88.9%, critical in 11.1%. In the sagittal plane, non-critical breaches were detected in 96.3% and critical in 3.7%. In 52% of pedicle screws, changes of ECD signals indicated redirection of the ECD during the pedicle tract preparation.

Standard Spine models ±1 and 2 SD calculated from distances of sagittal intersection points C2-T1 (in mm)

Level	C2	C3	C4	C5	C6	C7	T1
C2	13.41 14.98 16.55 18.12 19.69 (1.57)						
C3	29.38 33.11 36.84 40.57 44.30 (3.73)	15.97 18.13 20.29 22.45 24.61 (2.16)					
C4	43.48 50.44 57.40 64.36 71.32 (6.96)	30.07 35.46 40.85 46.24 51.63 (5.39)	14.10 17.33 20.56 23.79 27.02 (3.23)				
C5	58.09 67.61 77.13 86.65 96.17 (9.52)	44.68 52.63 60.58 68.53 76.48 (7.95)	28.71 34.50 40.29 46.08 51.87 (5.79)	17.61 17.17 19.73 22.29 24.85 (2.66)			
C6	72.75 84.84 96.93 109.02 121.11 (12.09)	59.34 69.86 80.38 90.90 101.42 (10.52)	43.37 51.73 60.09 68.45 76.81 (8.36)	29.27 34.40 39.53 44.66 49.79 (5.13)	14.14 11.11 11.11 11.11 11.11 (2.5)		
C7	88.91 103.42 117.93 132.44 146.95 (14.51)	75.55 88.44 101.38 114.32 127.26 (12.94)	59.53 70.31 81.09 91.87 102.65 (10.78)	45.43 53.88 60.53 68.08 75.63 (7.55)	30.41 35.8 40.80 45.79 50.78 (4.99)	16 18.58 21.00 23.42 25.84 (2.42)	

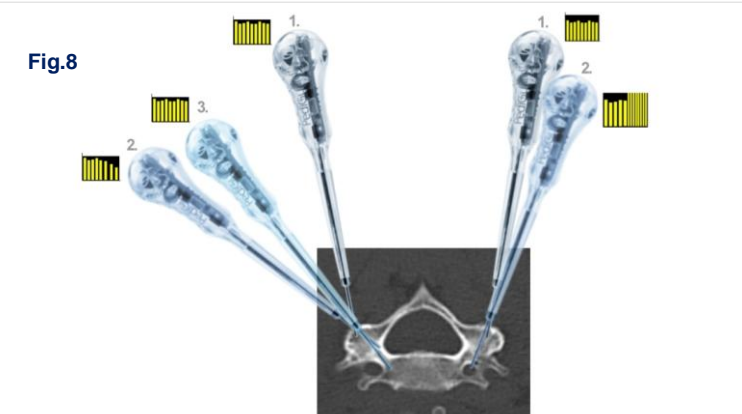
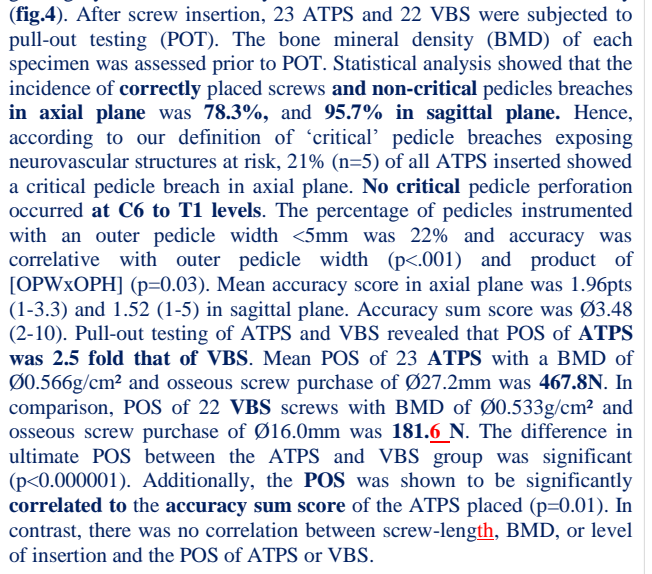
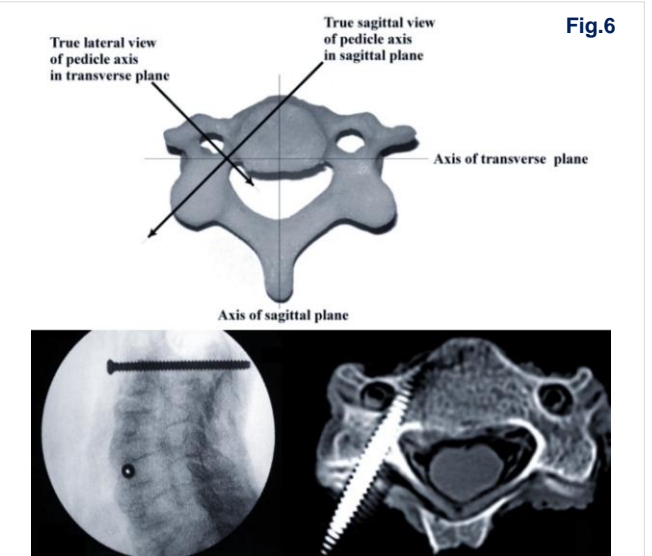


Fig.4. Grading of screw positions:

Grade 1: Screw centred in the pedicle, at most causing only minor plastic deformation of the pedicle cortex. **Grade 2:** Screw threads less than one third of the screw cross section (≈1.2mm with a 3.5mm screw) penetrating the cortex. **Grade 3:** Between one-third and one-half of the screw cross section penetrating the cortex (or <2mm). **Grade 4:** More than one-half of the screw cross section penetrating the cortex (or deviation ≥2mm). **Grade 5:** Deviation ≥ the screw diameter. Grading based on previous CPS-studies and data by Tomasino&Koller (see Poster#5) who calculated a safe zone based on the pedicle-to vertebral artery distance (Ø 1.2mm at C3 to 2.0 mm at C6). Non-critical pedicle breaches are determined as Grade 1 and critical pedicle breaches as Grade 3-5 posing potential risk to the vertebral artery and nerves. With this scoring system, assessment of screw position can be performed in the axial and sagittal plane. 1 point is assigned to each of the five grades of screw position. The accuracy score in axial plane (1-5 pts) and the accuracy score in sagittal plane (1-5 pts) is summed up and described as the accuracy sum score with its maximum being 10 points (worst) and the minimum being 2 (best).



Right pedicle: After radiographic entry point selection & cortex perforation with the ECD (position 1), the ECD is inclined medially in direction of the pedicle axis (pos. 1 to 2). If there is, e.g., too much medial inclination, the tip of the ECD will face cortical bone. Thus, while progressing towards the cortical wall, the ECD will emit sounds with decreased frequency signalling that the ECD is facing a cortex (pos. 2). As illustrated, the ECD is only 14mm inside the vertebra and therefore the surgeon has to redirect the ECD (pos. 2 to 3). After redirection the ECD will protrude again in cancellous bone and emit homogenous signals indicating correct pedicle protrusion. Left pedicle: Example of perforation: As on the right side, the ECD is driven into the cancellous bone of the lateral mass (pos. 1). If the surgeon does not address the medial inclination of the pedicle axis he will breach the transverse foramen (TF) with the ECD (pos. 2). But, if approaching the foramen is done slowly, the surgeon will face signal changes emitted by the ECD with high pitching & high frequenced signals indicating a need of redirection or abortion of pCPS fixation and change to lateral mass screws. The same principle applies to ATPS insertion. The main difference is the larger corridor towards the pedicle and work space with the ATPS.

Discussion & Conclusion

We showed the morphological feasibility of ATPS, its superior biomechanical characteristics compared to VBS and the accuracy of ATPS insertions using a fluoroscopically-assisted technique. It was high in the biomechanically challenged end-vertebrae (C6-T1, 100%). The use of an ECD for pCPS and ATPS tract preparation with exclusion of dense cortical pedicles was shown to be a successful concept with even higher accuracy rates. In concert with fluoroscopy & pedicle axis views, application of an ECD with exclusion of dense cortical pedicles will increase safety of insertion. Usage of ATPS has the potential to increase construct rigidity in biomechanically challenging environments through transpedicular 3-column fixation. First successful clinical applications of ATPS are presented (poster#x) and biomechanical tests of ATPS-plates finish in 2009. Successful application of pCPS & ATPS founds on selection of indications [1-6] and vertebra and pedicles, resp. ATPS & pCPS should not inserted into pedicles with diameter <4.5mm or sclerotic closure. Biomechanical studies indicated [7] that pedicle screw instrumentation of the end-vertebrae in long constructs is superior to lateral mass constructs. Likewise, unilateral pedicle screw fixation at C3-C6 decreases the likelihood of neurovascular sequelae from potential vertebral artery injury while still providing increased - and clinically sufficient - construct rigidity compared to common anterior screw-plate systems or posterior lateral mass constructs.