

## Case Series: SpineAssist - Assessment of Clinical Advantages and Reduction in Fluoro Utilization - in Four Centers in Germany, Sep-Nov 2006

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**GENERAL:** 41 patients with various lumbar spine pathologies were treated with fusion and trans-pedicular instrumentation, using the SpineAssist guidance for pedicle screw placements. Indications for surgery included Spondylolisthesis, Spinal stenosis, degenerative disk disease, iatrogenic Spinal instability, segmental instability, Spondylolysis, Osteochondrosis, persistent low back pain, and disc inflammation (6 revisions).

**PURPOSE:** To evaluate the feasibility, accuracy and implications of a bone-mounted miniature robotic guidance system for placement of lumbar pedicle screws in open spinal fusion surgery.

**PATIENT SAMPLE:** 41 patients (20 male, 21 female), average age 57.4 years (37-80), average weight 86.3kg (51-210) and average height 170.8cm (157-187) underwent one-level (26) or two-level (15) fusion with posterior pedicle screw fixation for the treatment of the above mentioned condition. 6 were revision surgeries.

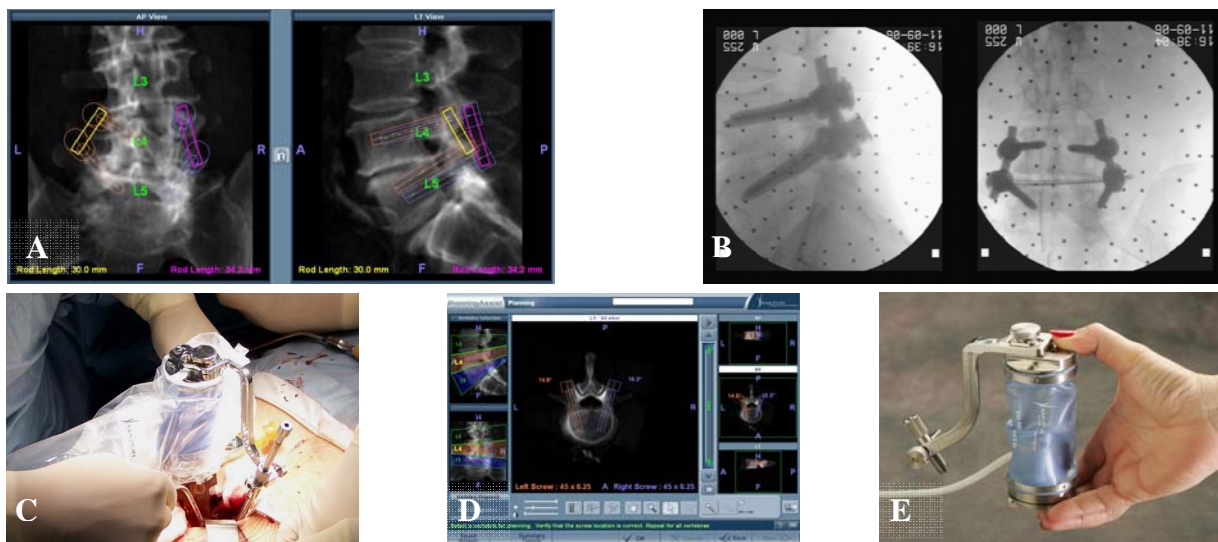
**METHODS:** A pre-operative CT scan was obtained for all patients; optimal screw sizing and positions were planned on a 3D computer model of the patient's spine created by the system software. Intra-operatively, a clamp was attached to the exposed spinous process, and a special target was mounted on it. Two fluoroscopic images (anterior-posterior and 60-degrees-oblique) were taken and automatically coupled with the CT data per vertebra. The target was removed and a special bridge was mounted onto the clamp, onto which the miniature robotic device was then attached. The robotic device directed the surgeons in accurately introducing the implants at the designated entry points and trajectories according to the preoperative plan. Accuracy of placements was assessed by means of post-operative CT scans (17 patients) and by means of anterior-

posterior and lateral fluoroscopic images during and at the conclusion of instrumentation (all patients). Actual placements were compared to the pre-operative plan.

**RESULTS:** 74 screws placed accurately for the 17 patients who were post operatively scanned. During these surgeries only 56 seconds of fluoro (90 shots taken) was used for registration – less than 1 second of fluoro usage per screw. Moreover, the images were taken while the surgeon and team are several feet away from the operating table, thus reducing their exposure to a negligible bare minimum.

77 screws were planned, 74 were executed (96.1%). Three screws were placed manually; one due to the surgeon's suspicion of a deviation, and two due to mechanical failure. All placements were clinically acceptable - screws completely contained within the pedicle boundaries; no pedicle wall breaches were observed, unless planned so preoperatively (in-out-in approach – 3 screws). 100% of the screws were accurately placed in perfect alignment with the preoperative plan. Average deviation between Planning and Acquisition (based on post Op CT): Axial - 0.58 mm, LT – 0.85 mm. Average deviation from Pre Op plan in 2D: 1.12 mm. Variance direction: Lateral - 51% of variances were caudal; Axial - 90% of variances from plan were lateral. Data from the other sites supports this trend.

**CONCLUSIONS:** This study suggests that the SpineAssist provides highly accurate, reliable guiding for trans-pedicular instrumentation. Moreover, it does so while reducing the exposure of surgeon and team to harmful x-ray radiation by several magnitudes. Our findings support it's applicability for a large range of conditions and surgical approaches, including single- and multi-level fusions, as well as revision surgeries.



**Figure:** A+B. Plan and Execution of L4-L5 fusion at Bochum; Spinal instability due to previous discectomy & vertebral rotation. C. SpineAssist Device mounted on Clamp for spinal fusion surgery. D. SpineAssist software Planning screen. E. SpineAssist Device is smaller than a soda can and weighs less than 250 grams.