Case Series: SpineAssist Miniature Robotic Guidance in Thoracic Fusion

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GENERAL: 41 patients with different thoracic spine pathologies - including extradural tumor, vertebral fracture, scoliosis, spinal stenosis, and kyphosis - were treated with various thoracic fusion procedures, using pedicle screw instrumentation. Screws were inserted utilizing minimally invasive (MIS) as well as open approaches, using Mazor SpineAssist – an advanced, bone-mounted, miniature semi-active robotic guidance system, mounted on the Hover-T (MIS) or on the Multi-Level Bridge (LIS).

BACKGROUND CONTEXT: Placement of thoracic pedicle screws allows for segmental stabilization of the thoracic spine. Bone-mounted robotic guidance can facilitate accurate placement of pedicle screws thereby reducing the risk of mal-positioning and associated morbidity, while minimizing the need for fluoroscopy.

PURPOSE: To evaluate the feasibility and accuracy of a bone-mounted miniature robotic guidance system for placement of thoracic pedicle screws utilizing a minimally invasive or less invasive approach.

STUDY DESIGN: Retrospective, multi-center, case series.

PATIENT SAMPLE: 41 patients (10 male, 31 female, ages 11-76) underwent one-level to nine-level thoracic fusion with posterior pedicle screw fixation utilizing the SpineAssist system for the treatment of scoliosis (19 cases), vertebral fracture (12 cases), segmental instability (4 cases), spinal stenosis (3 cases), kyphosis (1 case), osteomyelitis and extradural tumor (2 cases)

METHODS Pre-operatively, the desired positions of the screws were mapped on a 3-D computer model of the patient's spine created by the robotic-system software using a CT scan of the thoracic spine. Intra-operatively, two fluoroscopic images (anterior-posterior and oblique) with targeting devices were taken and automatically coupled with the CT data per vertebra. The miniature robotic device was then attached to a proprietary platform mounted onto the patient's bony anatomy (the Hover-T platform for MIS/percutaneous approaches, or the Multi-Level Bridge for open approaches). The device then directed the surgeon in accurately introducing the implants at the designated entry points and trajectories according to the surgeon's preoperative plan. Accuracy of placements was assessed by means of anterior-posterior and lateral fluoroscopic images during and at the conclusion of instrumentation and compared to the pre-operative plan. In four patients a post-operative CT scan was performed as well and detailed analysis of actual placements relative to planned position was carried out.

RESULTS: 301 screws were planned, 230 were executed (76.41%). The screws which were not executed were aborted due to unmatched Fluoro-to-CT images or poor CT quality (41 screws), operator mistake (12 screws), clinical difficulties (11 screws), mechanical failure or were out of reach of the robotic device (7 screws). Of the 230 executed screws, 226 were accurately placed in perfect alignment with the preoperative plan (98.26%). Four screws deviated more than 1mm from the pre-operative plan. All four deviations occurred due to suboptimal surgical technique. Deviations were identified during surgery with control C-Arm image. All screws remained in place since no pedicle breaching or neurological compromise were detected.

CONCLUSIONS: Robotic-assisted thoracic pedicle screw insertion is feasible and beneficial. The SpineAssist yielded highly accurate placements with minimal use of fluoroscopic imaging, hence improving clinical outcomes while reducing radiation exposure to the surgeon and team. Moreover, the pre-operative planning software allowed us to measure pedicle size and match and optimal screws size to each pedicle; it also facilitated easy identification of hypoplastic pedicles that could not support screws - especially in scoliosis patients - and avoid the struggle and damage of trying to instrument them. Lastly, the system made easy the planning and accurate execution of in-out-in approaches at various thoracic levels.

These results verify the system's accuracy and support its use for thoracic pedicle screw instrumentation in a wide range of indications.

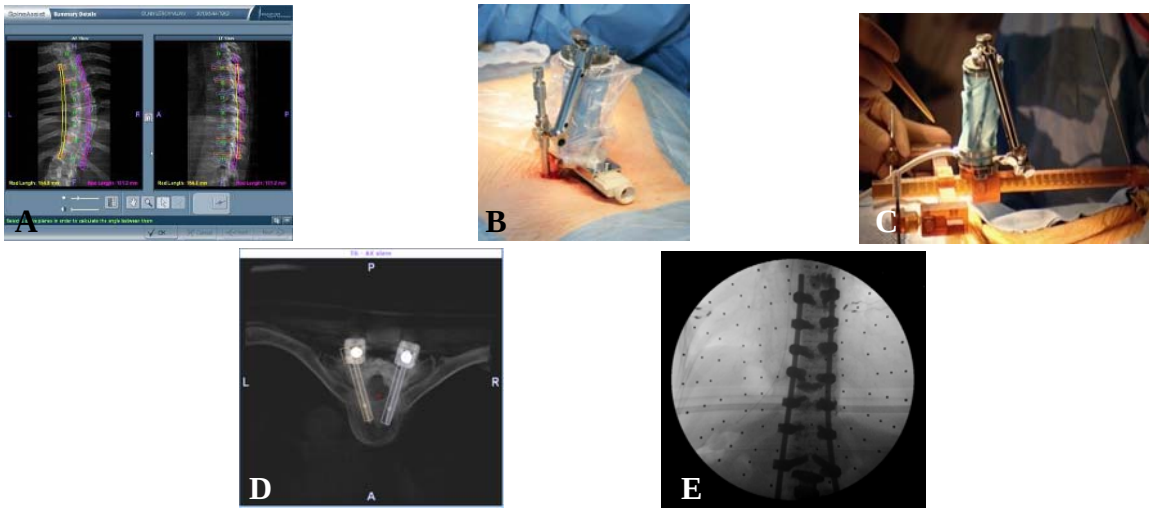

Figure: (A) Planning summary of a multi level thoracic fixation case. (B) The Multi-Level Bridge anchored to the patient's bony anatomy via Clamp. (C) The Hover-T frame anchored to the patient's bony anatomy via three small incisions. (D) Post-op CT analysis showing perfect alignment of plan to execution in a percutaneous case. (E) Fluoroscopic images of multi level thoracic fixation case.

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