

International Multi-Center Case Series: **SpineAssist Adds Value in Scoliosis Surgery**

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ABSTRACT:

40 patients with scoliosis of various types and degrees were treated with posterior spinal fusion. Mazor SpineAssist – a bone-mounted, miniature robotic guidance system - was used for pre-operative planning (CT-based) and intra-operative guidance of surgical tools and implants.

BACKGROUND CONTEXT:

Placement of pedicle screws in patients with adolescent and adult scoliosis, where normal bony landmarks are distorted and sometimes absent due to previous surgery, presents a considerable challenge. In a study by Belmont in 2002, the rate of screw perforation was 27% in patients without coronal deformity and 41% when there was a coronal deformity. Precise placements are desired to avoid possible nerve and vascular damage, achieve adequate correction of the deformity and ensure proper stabilization and fusion.

PURPOSE:

To evaluate the added value of miniature robotic guidance for placement of pedicle screws in the treatment of adult and adolescent scoliosis, specifically in regards with operative time savings, reduction of radiation exposure, accuracy of placements, and the value of pre-operative planning.

STUDY DESIGN/ SETTING:

Prospective, multi-center, non-controlled consecutive case series.

PATIENT SAMPLE:

40 consecutive scoliosis patients (8 male, 32 female), average age 18.2 years old (11 - 71) and average Body Mass Index (BMI) 22.6 (15 - 38). Thirty-six patients were diagnosed with adolescent idiopathic scoliosis, three adult patients had idiopathic scoliosis with degenerative disc and joint disease, and one adult patient had iatrogenic scoliosis post uninstrumented lumbar fusion. All patients underwent open posterior spinal fusion. Instrumentation included various commercially-available pedicle-screw-based systems; in some instances hooks were used to supplement the structure, especially in the presence of Hypoplastic pedicles that could not support screws.

METHODS Pre-operative CT scans were obtained for all patients. SpineAssist software was used to determine optimal screw sizes and placements. The software also enabled global evaluation of the nature and degree of the deformity, allowing for strategic planning of the necessary correction. Locally, use of the software enabled detection of Hypoplastic pedicles that would not support screws, allowing for early understanding of the necessary constructs combining screws and hooks.

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 clamped to the spinous process of a selected vertebra and directed the surgeon in accurately introducing each screw at the precise designated entry point and trajectory according to the preoperative plan. In longer fusions with smaller-diameter C-Arm, the process of fluoro acquisition and robot attachment repeated itself one or two more times, to cover the entire range of levels. 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. Three patients had post-operative CT scans for confirmation of screw placements. Fluoro time, instrumentation time and total surgery time were recorded.

RESULTS:

A total of 289 spinal levels were instrumented during this study (average 7 levels per patient, min 2-level, max 10-level); levels of instrumentation included T3 to S1. A total of 585 screws were implanted (average 14 screws per patient, min 6, max 19). There were no device-related or implant-related complications; no mal occurrences or harmful screw placements were observed.

Average instrumentation time per level was 13.8 minutes, or 6.7 minutes per screw (min 2.7 minutes, max 24.5 minutes). Once the learning curve was crossed (5 cases) significant time savings were observed – average instrumentation time per level was 10.3 minutes (down 26%), or 5.0 minutes per screw (down 24%), min 2.7 minutes and max 10.8 (down 66%).

Total fluoroscopy time per case averaged 42.4 seconds (min 13 sec, max 106 sec), or 6.4 seconds per level (min 2.5 sec, max 25.3 sec), or average 3 sec per screw (min 1.1 sec, max 13.3 sec).

CONCLUSIONS:

SpineAssist provided safe and accurate screw placements, overcoming the complexity of scoliosis-related deformities and the absence of anatomical landmarks in revision surgeries. SpineAssist has also contributed to reduced operative time and minimized the need for fluoroscopic imaging. Time savings become even more dramatic once the learning curve is crossed (5 cases). In addition, pre-operative planning capabilities resulted in better preparedness in the OR. Ability to avoid instrumentation of hypoplastic or deformed pedicles and to modify screw trajectories from 'standard' technique in order to safely place the screw - resulted in overall improved patient care.



Challenging adolescent idiopathic scoliosis case due to severity of the rotation: 67 over a 70 degrees curve. Figure: (A) Pre-operative CT. (B) Pre-operative planning.

Revision of adult iatrogenic scoliosis post uninstrumented fusion and laminectomy. Challenging deformity and lack of anatomical landmarks. Figure: (C) Pre-operative CT. (D) Post-operative – excellent correction and screw placements.