Robotic-based guidance for pedicle screw instrumentation of the scoliotic spine

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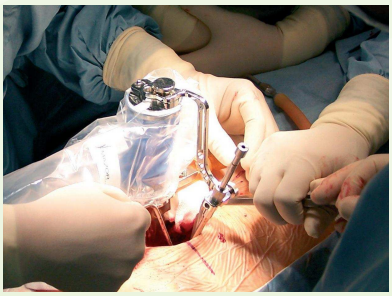
Introduction:

Precise implant placement in the deformed spine of patients with scoliosis is vital in order to avoid neurovascular damage while providing a platform for the safe application of forces required for optimal curve correction.

The purpose of this study is to retrospectively review the accuracy of robotically guided spinal implant insertions and to examine the added value of image-based guidance with regard to pre-operative planning and reproducible operative results.

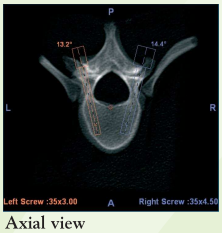
Methods:

SpineAssist is a bone mounted miniature robot that serves as a computerized mechanical positioning tool that guides the surgeon in the insertion of pedicle screws along a pre-operatively planned ideal trajectory. The system consists of a cylindrical 250 gram robot, a work station that runs software integrating image acquisition and registration with pre-operative plans, bone mounting mechanism, and real-time robot motion control. IRB study consists of a single center review of 80 patients (14 male, 66 female) with an average age of 14.4 years, all with adolescent idiopathic scoliosis, who underwent open posterior spinal instrumentation and fusion. Pre-operative CT scans were obtained for all patients and the system software was used to evaluate the variable size and shape of each vertebra, planning specific screw dimensions and preferred trajectory for ideal placement.



SpineAssist® Robot

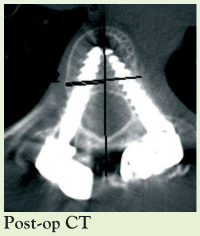
Intra-operatively, two fluoroscopic images of the spine (AP and oblique) with targeting devices were coupled with the CT data per vertebra to register the robot's position relative to the planning; accuracy within 1.2 mm per segment. Precision of implant placements was assessed by intra-operative biplanar fluoro, post-operative radiographs, and by occasional CT scan. Screws were categorized as clearly within the pedicle (A), equivocal, but not significant breach (B); or aberrant placement (C).



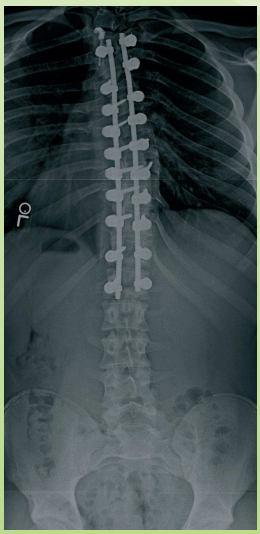
Axial view

SpineAssist planning software

SpineAssist summary details



Post-op CT



Full body X-ray

Results:

Pre-operative spine curvature averaged 66.5 degrees (46-95 degrees); 647 spinal levels instrumented from T3-L5. 1163 screws were robotically placed (1400 planned insertions) with an average 14-15 per patient. The most common reasons for not executing a planned insertion were unsatisfactory registration of a spinal level (102/237), hypoplastic pedicle anatomy (63/237), robot unable to reach (41/237), and surgeon decision to change instrumented levels (31/237). Average instrumentation time was 5 minutes per screw, registration time 21 minutes per case, and total fluoro time 2.4 seconds per screw.

Executed screws were precise in 95.9% of insertions (A), with 4% deemed equivocal, but adequate (B). One screw was lateral to the pedicle at L2 but was attributed to an error of insertion rather than guidance (C). 13 screws were placed in a transmuscular fashion without direct visualization of the drill site, all rated precise. Accuracy rates remained equal in spite of a large number of 'in-out-in' trajectories planned due to small pedicle anatomy (<4mm). No device or implant related complications; no screw revisions.

Conclusions:

Image-based guidance provided safe and accurate screw placements, graded as precise in 95.9% (99.9% including otherwise acceptable placements), overcoming the complexity of scoliosis related deformities. A high correlation can be expected between planned screw positions and executed robotic guidance. Pre-operative planning capabilities resulted in better preparedness in the OR, providing the surgeon the ability to strategically plan and review ideal screw placements especially in the case of hypoplastic or deformed pedicles where screw trajectories needed to be modified from 'standard' technique. Accumulated experience with improved surgical workflow contributed to reduced operative time and minimized the need for fluoroscopic imaging.