SpineAssist - Miniature Robotic Guidance for Spinal Surgery – Cadaveric Efficacy Study for Time, Accuracy and Radiation Exposure

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BACKGROUND CONTEXT: Accurate positioning of pedicle screws is important in the avoidance of neurovascular injury and to ensure adequate spinal fixation. Currently, most pedicle screw placements are performed using a freehand technique. Fluoroscopy assists with the accurate placement of pedicle screws; however, use of fluoro exposes patient, surgeon and operating room staff to potentially detrimental radiation. Miniature, bone-mounted robotic technology may prove useful in guiding surgical tools based on a pre-planned image-based trajectory for pedicle screws placement in both open and minimally invasive procedures, while significantly reducing the need for fluoro.

PURPOSE: To evaluate the efficacy of the SpineAssist system in planning and placing pedicle screws during minimally invasive, percutaneous spinal stabilization procedures, and to evaluate the system's efficacy in reducing fluoro radiation exposure during these procedures.

STUDY SETTING: Prospective, controlled, multi-center, cadaveric.

PATIENT SAMPLE: Eleven human cadavers were instrumented with a total of 217 pedicle screws by 16 surgeons.

OUTCOME MEASURES: (1) Accuracy of pedicle screw placements was evaluated using post-procedural CT scans. Implantation time and accuracy with bone-mounted robotic guidance was measured and compared to a control arm using the standard surgical approach. (2) Total radiation exposure for the surgeon was measured by a badge on surgeon's chest over lead apron, and a dosimeter ring on dominant hand. These readings, along with total fluoro time, were recorded and compared to a control arm.

METHODS: Fifteen surgeons using the miniature robotic device implanted pedicle screws percutaneously from T9 to S1. A control surgeon, experienced in MIS percutaneous techniques, instrumented the same spinal levels using a combination of fluoroscopic and mini-open techniques. Pedicle screw placement accuracy was evaluated using post-procedural CT scans, upon which was measured the planned versus executed screw placement. Procedure time was measured from initiation of screw placement to final implantation for both the robotic guidance technique and the conventional control arm technique. Screw placement accuracy, procedure time and radiation exposure data for the SpineAssist users were compared to the control surgeon.

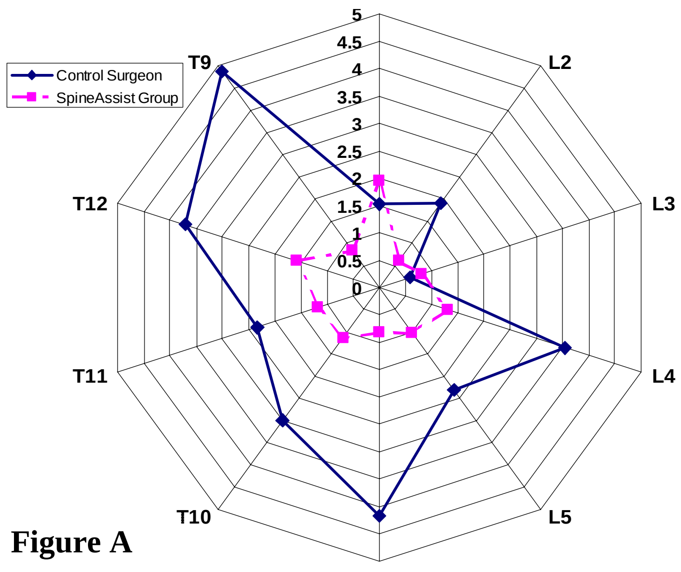

Figure A

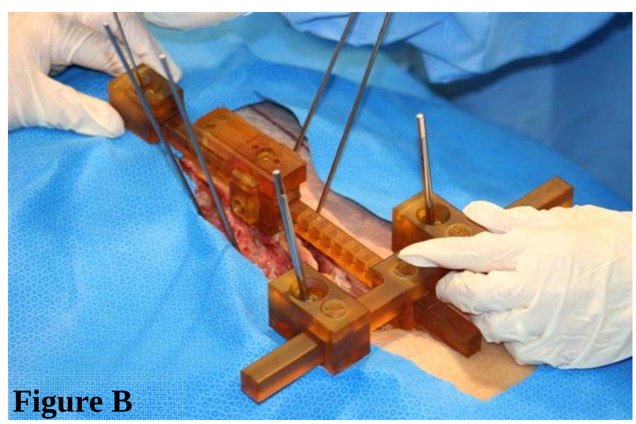

Figure B

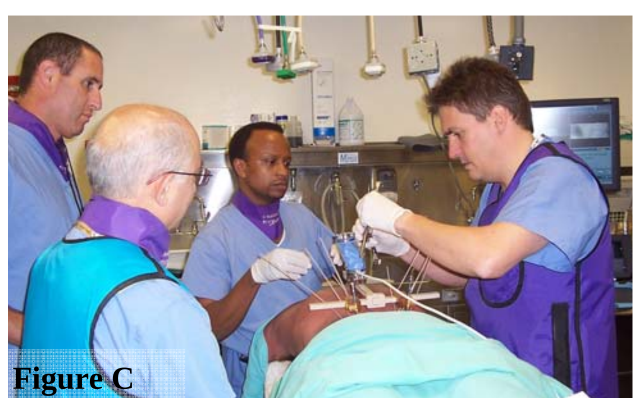

Figure C

See reverse for results and conclusions

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RESULTS: Two hundred and seventeen screws were initially implanted. Fifteen screws were omitted from the statistical analysis due to technical difficulties with the study design and equipment (6.9%).

Accuracy: the mean deviation of pedicle screw placement from the preoperative plan in the control group, which used the freehand technique, was 2.8 mm (std 1.3mm). In contrast, the mean deviation for users of robotic guidance was 1.1 mm (std 0.4mm) – Figure 1. Pedicle screw placement accuracy was consistent regardless of the vertebra level. In addition, screw placement accuracy was independent of surgeon experience.

Time: the procedure time for SpineAssist users and the control arm was similar, averaging at 76 and 89 minutes respectively for 10-level instrumentation (T9-S1). The effect of the learning curve was clear, as an experienced user of miniature robotic guidance completed the procedure in 49.5 minutes for the same levels.

Radiation exposure: the control surgeon, using the percutaneous approach for L2-S1 (5 levels) and a traditional open approach without fluoroscopy on T9-L1 (5 levels), was exposed to 103 mrem. In contrast, surgeons using robotic guidance for percutaneous placements in all 10 levels were exposed to 4.2 mrem in average; 13 out of 15 surgeons in this group were exposed to radiation levels below the minimal detectable level – **Figure 2**. Average radiation dose per screw in the control group was 10.3 mrem, while the robotic guidance group averaged a significantly lower 0.2 mrem. The control group used 4:36 minutes of fluoro for 5 levels. Use of the robotic device, in contrast, was associated with an average of 24 seconds of fluoro for 10 levels. Radiation exposure and fluoroscopy times in the robotic group were consistent regardless of surgeon experience in spinal surgery.

CONCLUSIONS: Use of the SpineAssist resulted in consistent pedicle screw placement averaged 1.1 mm of the pre-operatively planned trajectory, regardless of the vertebra level. Use of the system did not lengthen the procedure, and pedicle screw placement accuracy was not dependent on surgeon experience. Radiation levels using miniature robotic guidance for pedicle instrumentation were 51 times lower than the control group (average of 0.2 and 10.3 mrem/screw, respectively); most readings in the group of robotic guidance users were below measurable levels (13 out of 15 surgeons). This is a significant finding as the study was performed using a minimally invasive, percutaneous approach, which typically requires a large number of fluoroscopic images.

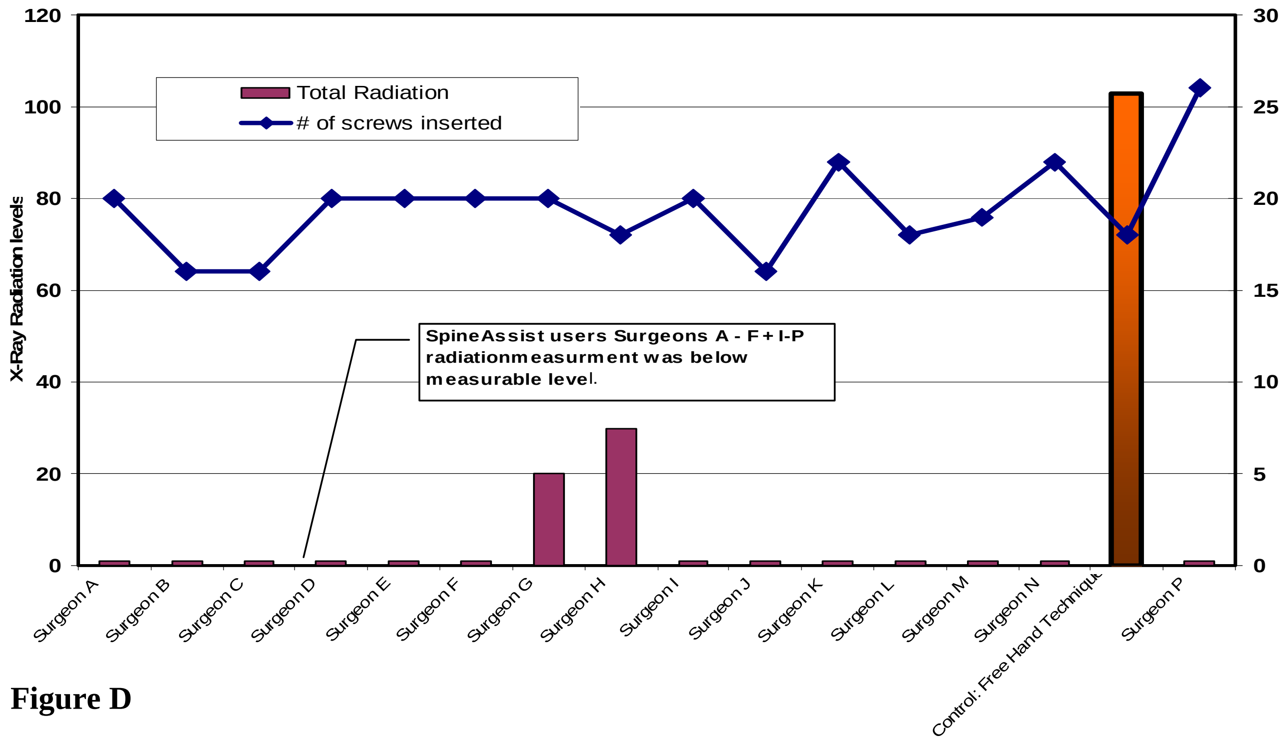

Figure D

Figure: (A) Average accuracy (mm) per level. **(B)** Hover T platform mounted on cadaver and K-wires placed with the guidance of the SpineAssist device **(C)** At one of the cadaver labs – surgeon and Mazor personel around a cadaver with the SpineAssit mounted on the Hover-T platform. **(D)** Radiation exposure & number of screws per surgeon.