Clinical Experience with Miniature Robot for Spinal Surgery: 89 Clinical Cases

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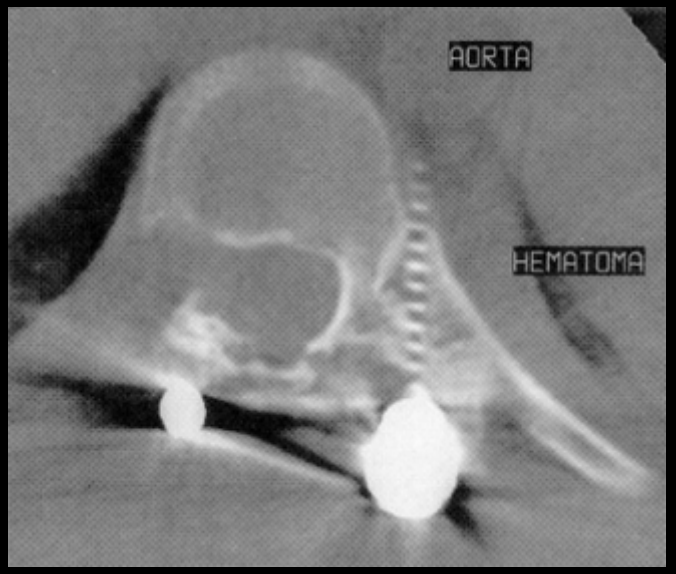
MAZOR Surgical Technologies

Accuracy, Safety & Radiation

- Accurate positioning of pedicle screws
  - Minimized risk of vascular and neurological injury
  - Optimal mechanical stabilization
  - Increased chances of proper fusion.

- Freehand techniques
  - Risk of malpositioned screw placements
  - Increased fluoroscopy exposes surgeon/staff to potentially dangerous levels of radiation



SpineAssist® : Miniature, Bone-Mounted Robotic Guidance

Miniature robotic guidance technology may assist in achieving highly accurate screw placements, while significantly reducing the need for fluoroscopy

- Miniature, bone-mounted, robotic guidance technology
- Pedicle screw placement is preplanned
- Minimum utilization of fluoroscopy – only two images needed for up to 12 pedicle screws

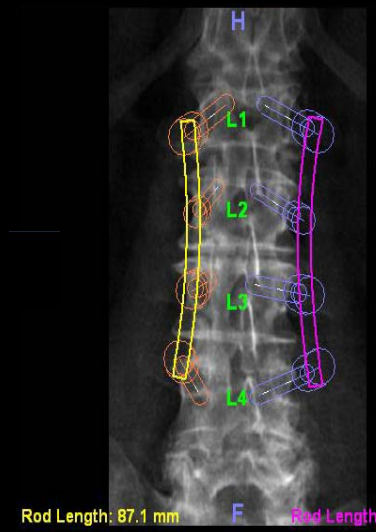
Study Design

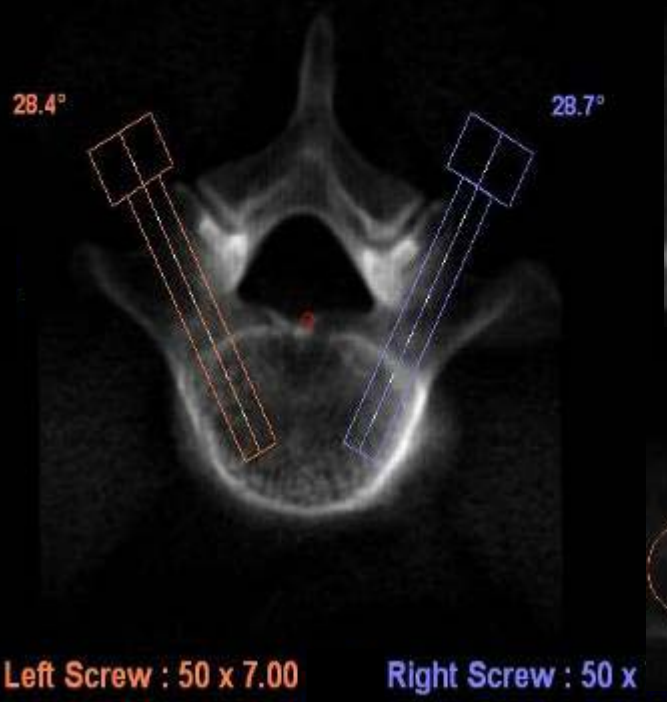
- Retrospective, multi-center

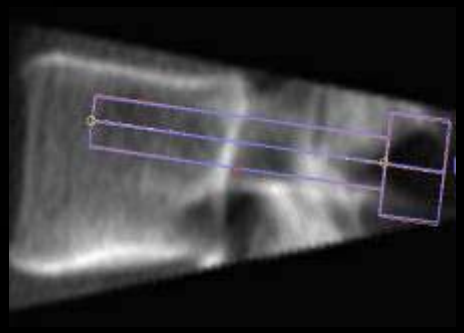
- Between June 2006 and January 2007, the SpineAssist was used in 89 clinical cases in the US, Germany and Israel.
- Indications included several types of degenerative disc disease and various spinal deformities as well as revision surgeries on the lumbar, thoracic and sacral spine.
- 37% of the procedures were performed percutaneously in a minimally invasive manner.
- Overall 365 screws were inserted using the system.
- Accuracy was assessed by means of post-operative CT scans in 28 patients, and X-Rays in all patients.
- Intra operative fluoro time was measured as an indicator of radiation exposure to the surgeon.

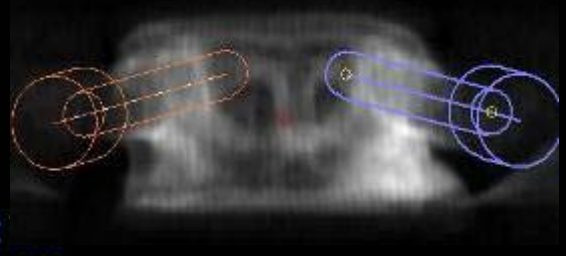
Pre-operative planning

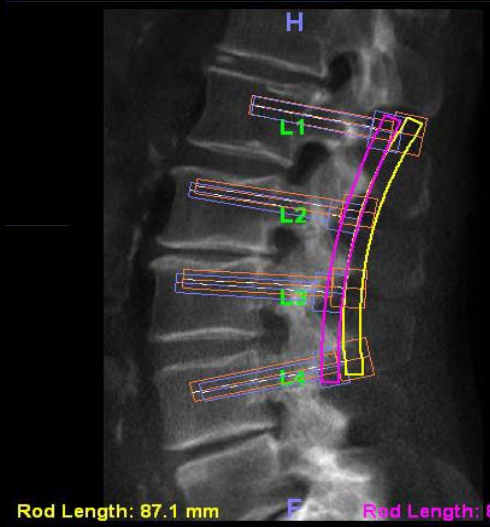
- Pre-operative 3D planning, based on a CT scan.





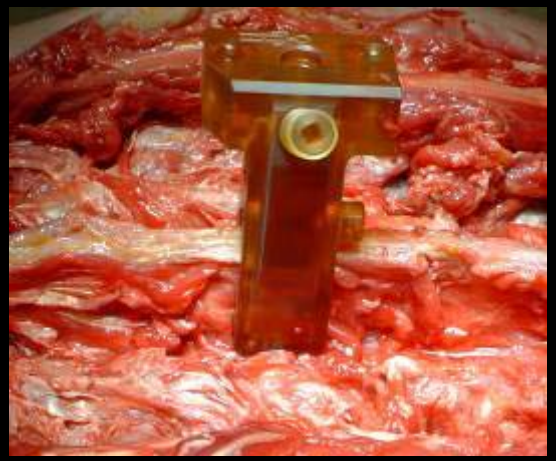






SpineAssist Skeletally Mounted

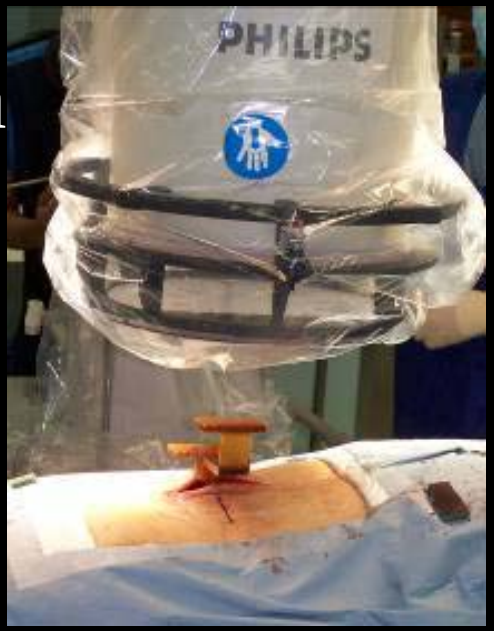
– Spinous Process Clamp, for single- / two-level open procedures

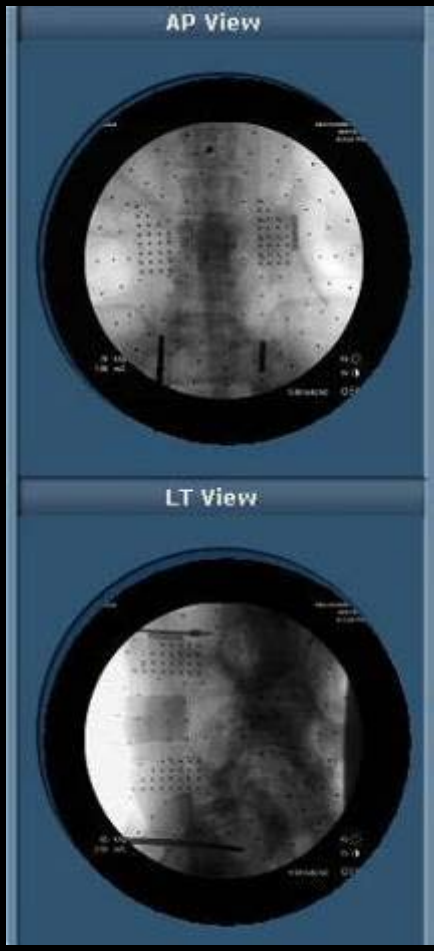


–Hover-T Frame, for MIS approaches and long fusions

Two fluoroscopic images

- Fluoro acquisition
- CT-to-Fluoro Registration
- Guided instrumentation

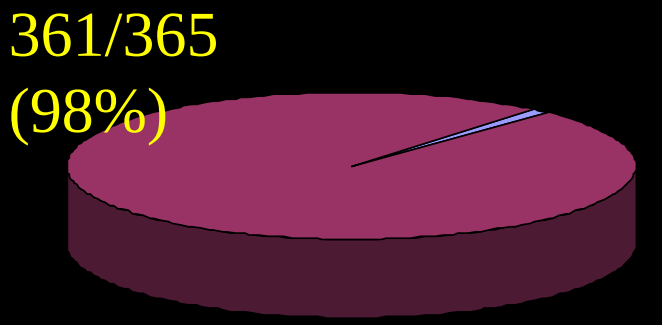




Results –

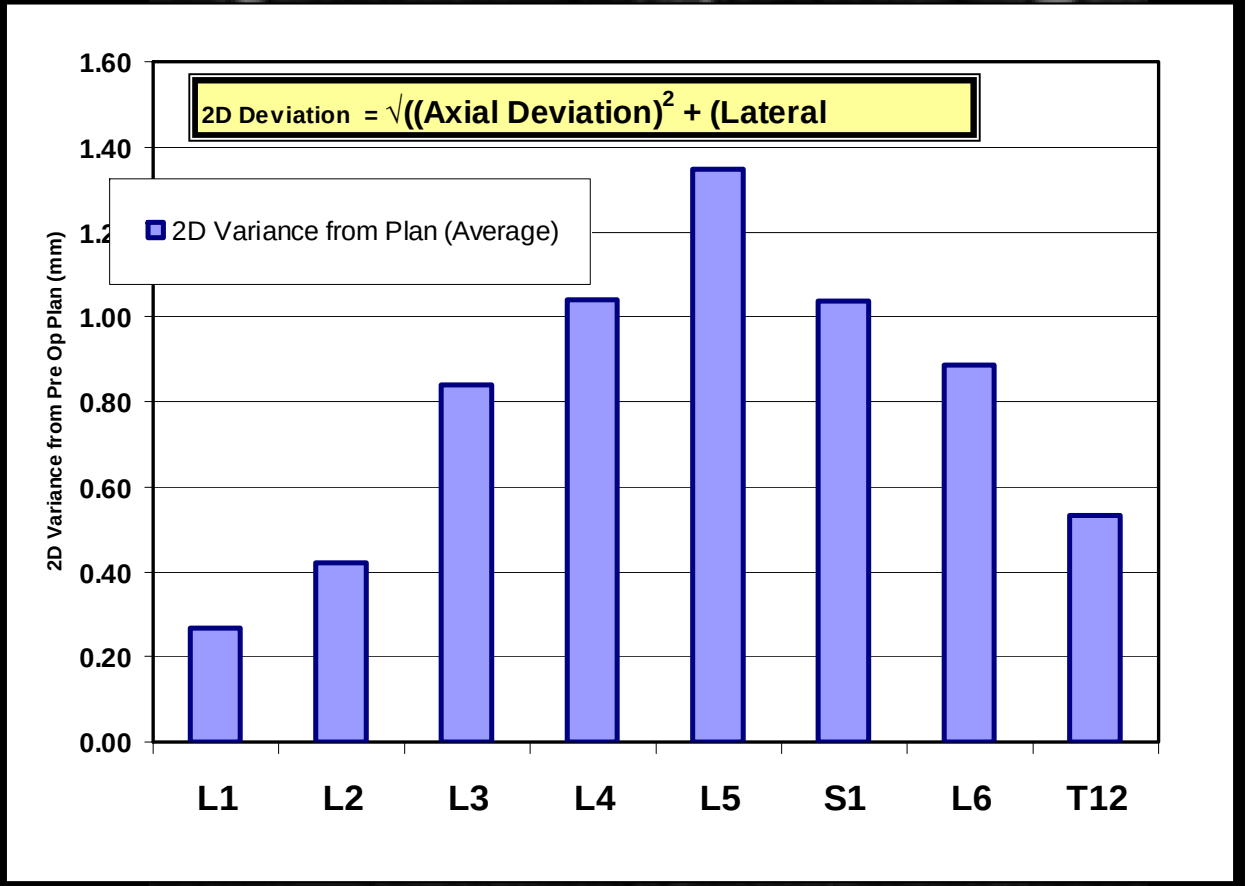
431 screws were planned; 365 were inserted with the guidance of the SpineAssist system (85%). Non-execution was due to mechanical failure of the robot (4%), suboptimal CT-to-Fluoro image registration (7%) and other clinical reasons (4%).

- 361 of 365 (98.9%) implanted screws were accurately positioned within the pedicle.
- Four malpositioned screws
  - The surgeon decided to override the plan and insert the screws manually in two
  - Guide-wires were accurately placed with the SpineAssist, but the cannulated screws breached the pedicles and required revision in two



Results – Accuracy Cont'd

- 23 patients underwent a Post-Op CT scan. Screw placements were compared to preoperative plan
- Deviations were measured in the Axial and Lateral views
- Average deviation was 0.79mm (0-1.7mm)



Results – Fluoro Utilization

- During the first 5 months of utilizing the system, we averaged 1.95 fluoro images per implanted screw (≈ 1.4 sec/screw)
- In the last 2 months the average went down to 1.3 shots per screw (≈ 0.9 sec/screw)

Conclusions

- This study demonstrates the feasibility of robotically assisted pedicle screw insertion accurately with minimal fluoroscopic utilization and radiation exposure
- Effective in percutaneous/minimally-invasive screw placement, deformity and revisions



References

1. **Pedicle Screw Placement Accuracy: A Meta-analysis;** Kosmopoulos, Victor PhD; Schizas, Constantin MD, PD, FRCS; Spine 32(3): pp E111-E120, February 1, 2007.
2. **Radiation Exposure to the Spine Surgeon During Fluoroscopically Assisted Pedicle Screw Insertion ;** Rampersaud, Y. Raja *et al*; Spine 25(20):2637-2645, October 15, 2000.