

# Bone-Mounted Miniature Robotic System for Spine Surgery

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## Introduction

The use of instrumentation is a common practice for the stabilization of spinal fusions. Pedicle screws, facet screws or translaminar facet screws, all require accurate insertion into a specific entry point and trajectory. Achieving the desired accuracy involves significant exposure in open procedures or, alternatively, a significant amount of X-Ray radiation in Minimally-Invasive Surgeries (MIS). Implant misplacement is common (misplacement rates range from 4.2% to 39.9% [1]) and may result in neural and vascular complications, as well as suboptimal biomechanical stabilization of the spine.

Image-guided navigation systems, although shown to reduce the rate of misplacements [1,2], are not in wide use for this application.

The SpineAssist device is a miniature (80 mm height, 50 mm diameter and 250 grams weight) semi-active robotic system (figure 1), [3] which is in clinical use for the accurate guidance of spinal implant placements, such as pedicle screws and translaminar facet screws.

## Operation

**Pre-operatively**, a standard CT scan is displayed in a 3-D model of each vertebra in the range of interest (figure 2). The surgeon "places" the screws on the model, choosing the ideal screw size with appropriate length and diameter for each pedicle and vertebral body [4].

**Intra-Operatively**, a spinous-process clamp (figure 3) or a T-Shaped minimally-invasive frame (Hover-T) (figure 4) is attached to the patient's bony anatomy; two fluoroscopic X-ray images with targeting devices are taken and automatically matched to the reconstructed CT images. The miniature robot is then attached to the clamp/frame and the software controls the robot's motion to the designated entry point and trajectory according to the surgeon's preoperative plan. The robot locks in position and enables the surgeon to work with various tools through a set of guiding tubes. Validation studies have included animal and human cadaveric trials. Clinical database, at the time of submitting this paper, consists of 31 surgeries worldwide.

## Results

The system's accuracy was evaluated in a series of cadaveric [5] and clinical trials. The SpineAssist was used for the introduction of fifty-four implants in thirty-six vertebrae of ten human cadavers. Instrumentation included K-wires as replacements for pedicle screws and trans-laminar facet screws; open and MIS approaches were implemented; the spinous process clamp and the Hover-T frame were used interchangeably. All implants were left inside the specimens and the cadavers were sent for a post-procedural CT scan. Accuracy was evaluated by comparing the pre-operative plan with the actual position of each K-wire in all three planes. The system proved to be accurate in 97.9% of the cases, with an average deviation of less than 1mm from the preoperative plan and a maximal deviation of 1.5mm. These results verified the system's accuracy and supported its use for clinical cases [4].

The SpineAssist is CE marked and FDA approved for all spinal procedures and has been used in various sites around the world since early 2005. Clinical use has included pedicle screws placements in the lumbar spine during open surgeries (figure 5, 6), less invasive approaches and MIS cases, as well as trans-laminar facet screw placements utilizing a percutaneous less-invasive technique. Among the performed procedures there were PSF (Posterior Spinal Fusion), PLIF (Posterior Lumbar Inter-body Fusion), lower thoracic (T12), revision surgeries, spondylolisthesis grade I and extreme scoliosis.

Out of all planned procedures - over one hundred screws in over 30 cases - 72% were executed, and out of all executed procedures 98% yielded accurate, highly satisfactory results. Non-executions stemmed, by and large, from human errors and from failure of the software to match the fluoroscopic images to the CT data. Both factors have been address and improved recently.

## Conclusions

This investigation focuses on the performance of the semi-active, bone-mounted, SpineAssist miniature surgical robot, used in spinal fusion procedures. Cadaver and clinical tests show that this system offers improvement in implant placement accuracy, relative to the surgeon's free hand. Based on pre-operative CT images the surgeons were able to place 98% of the screws within 1.5 mm from the planned location with less exposure to X-Ray radiation. It was also found that using the Hover-T frame, the same placement accuracy can be achieved not only in open surgery but also in a minimally invasive approach.

### References:

1. Togawa D, Lieberman IH, Benzel EC, Kayanja MM, Reinhardt MK, Friedlander A, Knoller N: Bone-mounted miniature robot for pedicle screw and translaminar facet screw placement - Part I. Technical development and test case result. Neurosurgery: submitted.
2. Austin MS, Vaccaro AR, Brislin B, Nachwalter R, Hillibrand AS, and Albert TJ: Image-guided spine surgery: a cadaver study comparing conventional open laminoforaminotomy and two image-guided techniques for pedicle screw placement in posterolateral fusion and nonfusion models. Spine 27:2503-2508, 2002.
3. Shoham, M., Burman, M., Zehavi, E., Joskowicz, L., Batkalin, E., and Kunicher Y.: "Bone-Mounted Miniature Robot for Surgical Procedures: Concept and Clinical Applications." IEEE Transactions on Robotics and Automation, Vol. 19, No. 5, pp. 893-901, 2003.
4. Togawa D, Kayanja MM, Lieberman IH, Benzel EC, Reinhardt MK, Friedlander A, Knoller N: Bone-mounted miniature robot for pedicle screw and translaminar facet screw placement -Part II. Evaluation of Systems accuracy Neurosurgery: submitted.
5. Togawa D, Lieberman IH, Benzel EC, Kayanja MM, Reinhardt MK, Zehavi E: Bone-Mounted Miniature Robotic Guidance for Pedicle and Translaminar Facet Screw Placement. International Meeting on Advanced Spine Techniques (IMAST), 12th annual meeting: E-Poster presentation, 2005.



Figure 1: The SpineAssist Device

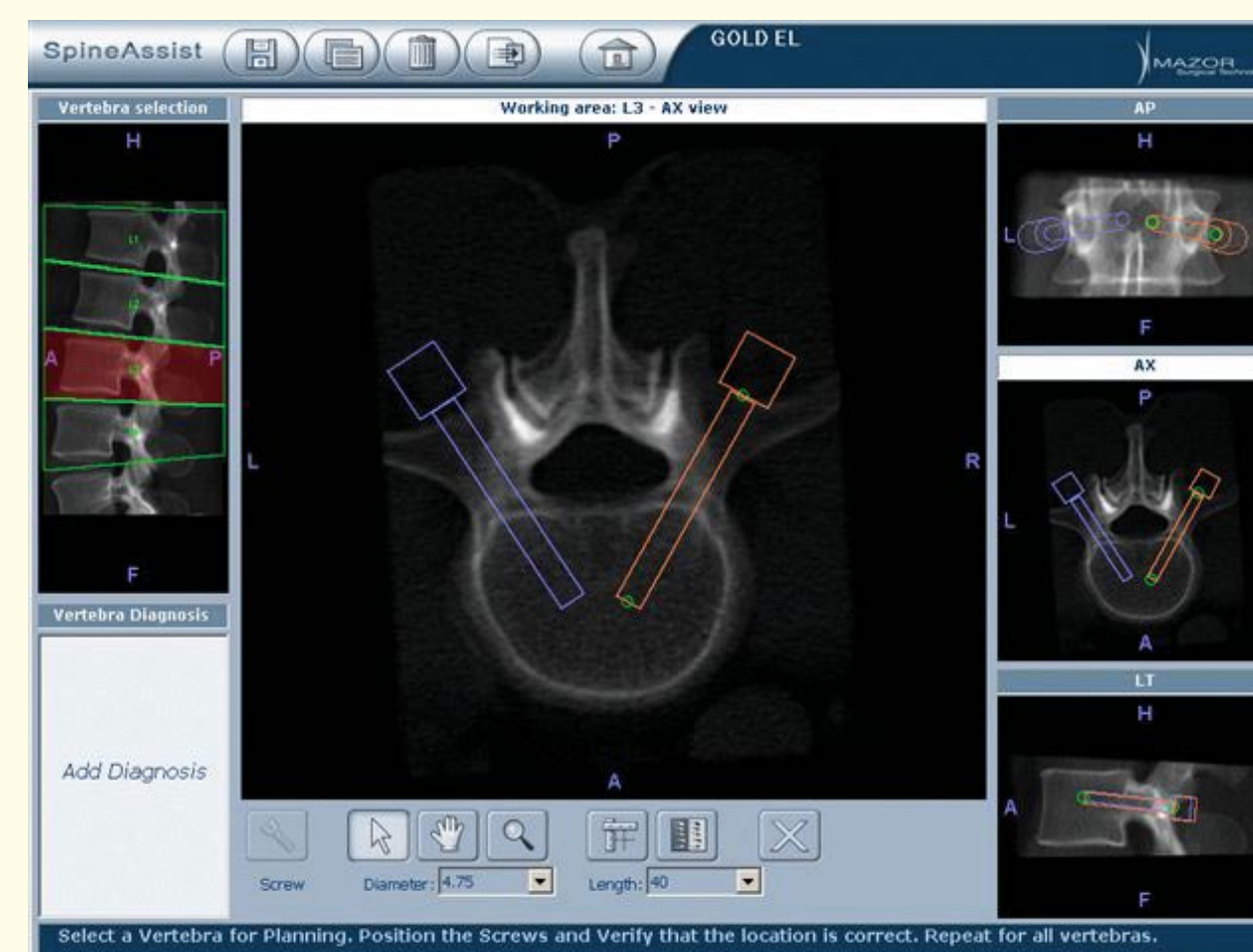


Figure 2: Planning screen; the three planes (AP, Axial and Lateral) are shown in small panes on the right; the axial view is also enlarged in the center pane; each view can be displayed in the center pane by touching the touch screen



Figure 3: The SpineAssist Device mounted on a model of the lumbar spine with the spinous process clamp and multi-level bridge



Figure 5: Single-level operation performed with SpineAssist Clamp & Bridge post-procedural AP

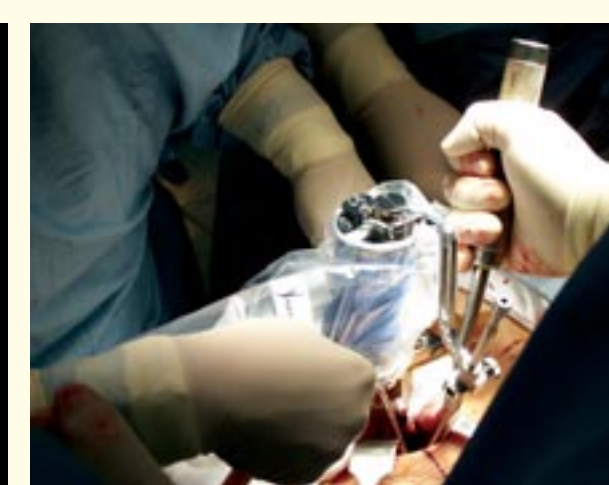


Figure 6: The SpineAssist in use with the Clamp and Bridge