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Miniature robotic guidance for spine surgery

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1. Introduction

Instrumented spinal fusion surgery is increasingly performed in the treatment of degenerative disorders, Spondylolisthesis, deformity, trauma and tumors affecting the spine (Davis, 1994; Katz, 1995). In-vitro and In-vivo studies using the free hand or fluoroscopically assisted techniques documented breaching of the pedicle in 3-55% (Amiot et al., 2000; Belmont et al., 2001; Belmont et al., 2002; Boachie-Adjei et al., 2000; Carbone et al., 2003; Castro et al., 1996; Esses et al., 1993; Farber et al., 1995; Gertzbein & Robbins, 1990; Laine et al., 1997a; Laine et al., 1997b; Laine et al., 2000; Liljenqvist et al., 1997; Lonstein et al., 1999; Odgers et al., 1996; Schulze et al., 1998; Suk et al., 1995; Vaccaro et al., 1995a; Vaccaro et al. 1995b; Weinstein et al., 1998; Xu et al., 1998)

Clinically significant screw misplacements however occur in 0-7% (Amiot et al. 2000; Belmont et al.2002; Belmont et al. 2001; Boachie-Adjei et al. 2000; Carbone et al. 2003; Castro et al. 1996; Esses et al. 1993; Farber et al. 1995; Gertzbein & Robbins, 1990; Laine et al. 2000; Laine et al. 1997a; Liljenqvist et al. 1997; Lonstein et al. 1999; Odgers et al. 1996; Schulze et al. 1998). Neuro-monitoring, neuro-stimulation, and computed assisted navigation systems reduce the incidence of screw misplacement, however none of them has gained significant popularity in spine surgery, mainly due to logistical and cost-effectiveness issues such as the need for dynamic referencing and a line-of sight, extra staff, expensive tools and cumbersome procedures, longer operation time and the high cost of the capital equipment (Berlermann et al. 1997; Bolger & Wigfield, 2000; Carl et al. 1997; Choi et al. 2000; Digioia et al. 1998; Ebmeier et al. 2003; Foley & Smith, 1996; Girardi et al. 1999; Glossop et al. 1996; Kalfas et al. 1995; Kim et al. 2001; Laine et al. 1997b; Merloz et al. 1998; Mirza et al. 2003; Rampersaud et al. 2001; Rampersaud and Foley, 2000; Raynor et al. 2002; Reidy et al. 2001; Schlenzka et al. 2000; Schwarzenbach et al. 1997; Simon and Lavallee, 1998; Welch et al. 1997).

Surgical robots have emerged during the 1990's and offer distinct added value in terms of accuracy and minimally-invasiveness of the surgical procedure. However, current systems are extremely expensive and large in size, and typically require immobilization of the patient (Taylor & Stoianovici, 2003). The SpineAssist® (Shoham et al. 2003) (Mazor Surgical Technologies, Caesarea, Israel) is a bone-mounted miniature robotic guidance system, clinically and experimentally validated for spinal surgery (Barzilay et al. 2006, Lieberamn et al 2006; Togawa et al. 2007). It facilitates image-based semi-active guidance for providing high accuracy in the positioning of surgical tools and implantable devices such as Pedicle

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screws, Kyphoplasty needles, tumor evacuators and more. To the best knowledge of the authors, no other clinically validated robotic system is available today for spine surgery. In a recent publication (Barzilay et al. 2006) technical issues as well as patient-related and surgeon-related issues encountered during the clinical development phase were analyzed and lead to improvements in software and in robotic tools. Ways were offered to reduce errors and shorten the learning curve when new users are introduced to this system. In this chapter, a short summary of the clinical development phase and an overview of the early routine clinical use of the SpineAssist in procedures involving pedicle screws insertion, kyphoplasty, vertebroplasty and biopsy of the spine are presented. Also describes is the very early usage of the system in deformity surgery.
The SpineAssist® (SA) (Fig. 1) is a miniature bone-mounted robot - 2.5 inch diameter, 250 gram - featuring a six-degree-of-freedom parallel design.

Figure 1. The SpineAssist miniature robot

The miniature robot is connected to the SA workstation (Fig. 2), which controls its motion and runs specially designed graphic user-interface software.

Figure 2. The SpineAssist Workstation

The system is semi-active, in that it guides the surgeon to the desired implant positions according to his/her preoperative plan, while leaving the actual surgical act in the physician's hands. The concept is of pre-operative planning and intra-operative execution. The planning is done on a 3-D model of the patient's spine generated by the system based

on a CT scan (Fig. 3). The plan includes implant sizing and placements for all the levels of the spine to be operated on, and can be done on the workstation itself or on the physician's laptop or desktop computer.

Figure 3. 3D planning of pedicle screws to be introduced into L3 vertebra and a summary of a plan for L3-4-5 fusion

In preparation for the intraoperative execution of the plan, the SA workstation is connected by means of a BNC video cable to a C-Arm fluoroscopy imaging machine and two blank images – anterior-posterior (AP) and 60º Oblique – are taken with a special Image Calibrator attached to the image intensifier of the C-Arm. These two "blank" images are used by the system to automatically compensate for distortions due to ambient magnetic fields and other sources of distortion to the intraoperative fluoroscopy images. The miniature robotic device is also verified for calibration prior to every case by using a specially designed jig with 3 marker holes at positions that are known to the software. The entire process of image and robot calibration takes about 10 minutes and is performed by the radiology technician during the setup of the OR for surgery – parallel to other preparations and prior to bringing the patient in. As the operation begins, a minimally-invasive Hover-T® frame or a less-invasive spinous-process clamp (Fig. 4) is attached to the patient's bony anatomy.

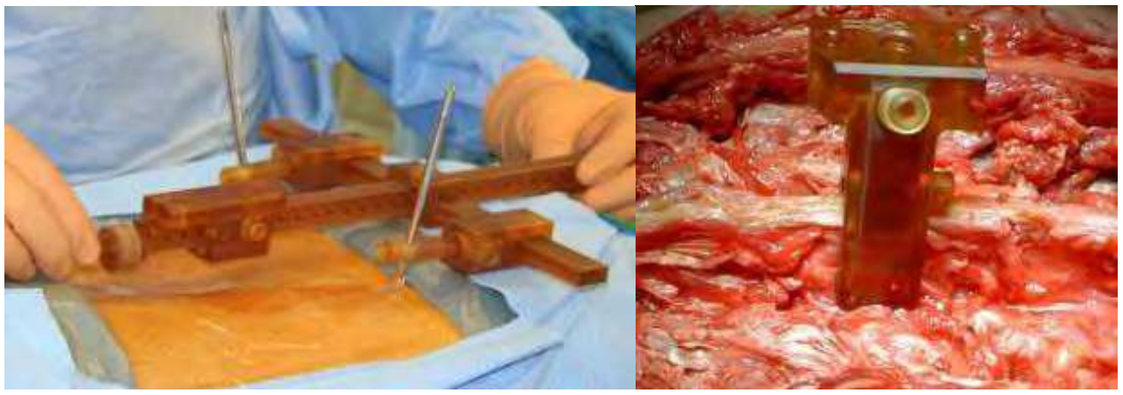

Figure 4. The clamp (right) and the Hover-T frame (left) firmly connect the robot to the patient's body

Two fluoroscopic images are taken - AP and 60º oblique – with a targeting device attached to the Hover-T / Clamp. The system performs automatic, per-vertebra, matching of these

intra-operative fluoroscopic images with the pre-operative CT. The accuracy of this process, also referred to as the image registration process, is visually verified by the surgeon; the first level to be operated on is then selected. The target is removed, the SA device is mounted onto the clamp/frame and the system controls its motion so that it points to the exact entry point and trajectory according to the surgeon's pre-operative plan. Based on the known kinematical properties of the system and the desired entry point relative to the robot base the system instructs the surgeon to attach one of three guiding arms (short-1 medium-2 or long-3) to the top plate of the robotic platform, through which surgical tools are inserted by the surgeon to facilitate introduction of the implant. The three arms cover the entire workspace necessary for a variety of spinal procedures. An open approach may be used (Fig. 5), as well as MIS (minimally invasive) and percutaneous approaches (Fig. 6).

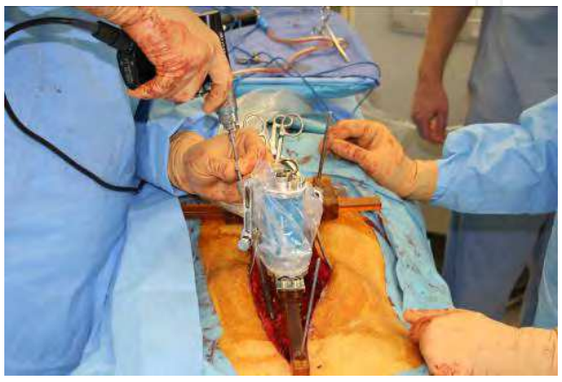

Figure 5. Intraoperative open approach, notice the tool guide through which the surgical tools are inserted

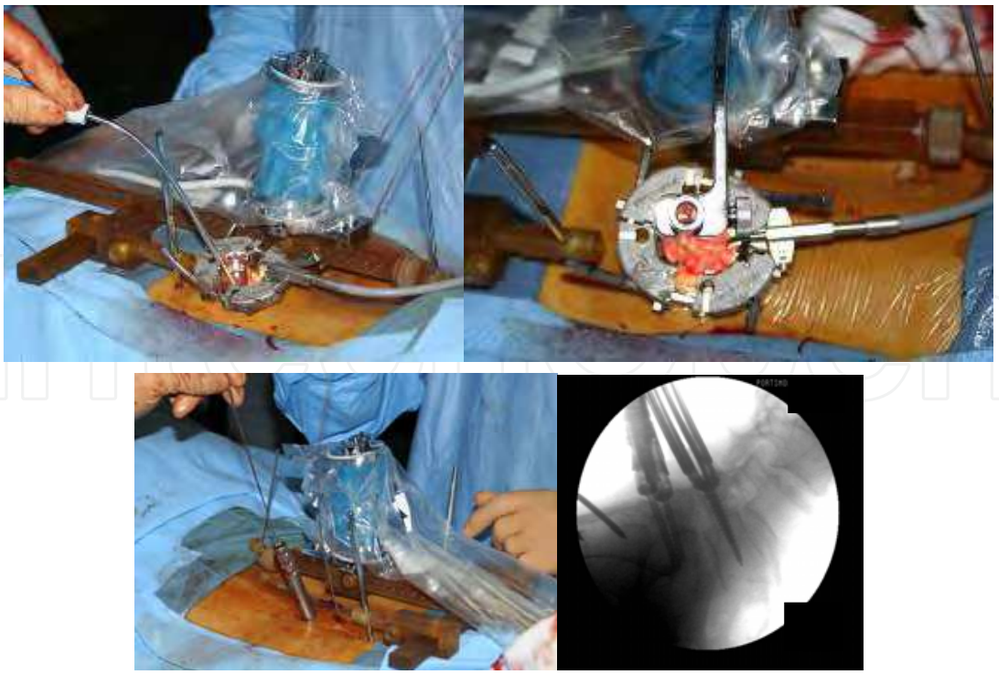

Figure 6. Intraoperative minimally invasive surgery (MIS, upper left and right) and percutaneous (lower left and right) approaches

Fifteen patients were operated on during the clinical development phase of the Spine Assist in two spine centers (March to November 2005) with obstacles occurring in 9 cases (Barzilay et al. 2006). These obstacles were defined as related to surgeon, technique, software or equipment. Conclusions drawn during this period led to improvements in all aspects mentioned. The software was improved, making it more robust, easier to use and better in terms of pre-operative planning. Improvement in the robot's tools made them more user friendly and less prone to skiving by soft tissues. As for surgeon related errors – The clamp must be secured tightly to the spinous process in order to avoid unwanted mobility leading to errors in entry point and trajectory. Minimal force should be used when using the SA and no foreign bodies (i.e. surgical gauze) should be left in the surgical field during acquisition of fluoroscopy images or during operation of the robot. Routine clinical usage of the SA in the authors institution commenced in September 2006. The SA guidance was used by the authors in 24 procedures including 19 spinal fusions, 4 kyphoplasy/vertebroplasty and 1 biopsy. The demographic data and indications for surgery of the study group are summarized in table 1.

Number of patients	24	18 F 6 M
Age (Years)	61 (24-75)	
Indications	Related to degenerative disorders	19
	Vertebral compression fractures	Osteoporotic 3 Metastatic 1
	Infection	Spondylodiscitis 1

Table 1. Demographic data and indications for surgery

Total	**Primary**	**Revisions**		
24	21	3		
Procedure	**1-Level**	**2-Level**	**3-Level**	**4-Level**
TLIF + Posterior fixation	8	7		1
PDPLF	2			
Vertebroplasty	2			
Kyphoplasty	2			
Craig needle biopsy	1			

Table 2. SpineAssist guided surgical procedures

A detailed account of each surgery was taken during the procedure, with attention being paid to system and team performance during all preoperative and intraoperative stages. The ability of the system to successfully accomplish each stage of the procedure was recorded, including importing patient's CT, planning, C-Arm and robot calibration, fluoro acquisition, CT-to-fluoro registration, finding the appropriate kinematical solution for guidance, utility of the surgical accessories and overall accuracy of placements. Surgical data included time measurements of total procedure, time from attachment of clamp/hover-t to detachment, time of fluoro utilization, number of planned screw/needles and the number of executed screws/needles. Parallel to the routine use of the SA in "simple" fusion cases, Kyphoplasty and biopsy, the system was used in three deformity cases, one Scheuermann's kyphosis (80 degrees Cobb T3-T12), one Juvenile idiopathic scoliosis of 78 degrees with pedicle diameter ranging from 3 to 4.5 mm and one case of congenital scoliosis with a hemi vertebra of L2-3

partially segmented from L2. Data from these cases were excluded from results as they were not considered routine. These cases will be further discussed later in this chapter. Table 2 summarizes the surgical procedure performed with SA guidance.

Three cases are presented in figures 10 to 12; these cases demonstrate the abilities of the SA to accurately guide implants or needles. In the first case (Fig. 10) the vertebroplasty needle was aimed at a void in the lower end plate of L3 caused by an osteoporotic fracture.

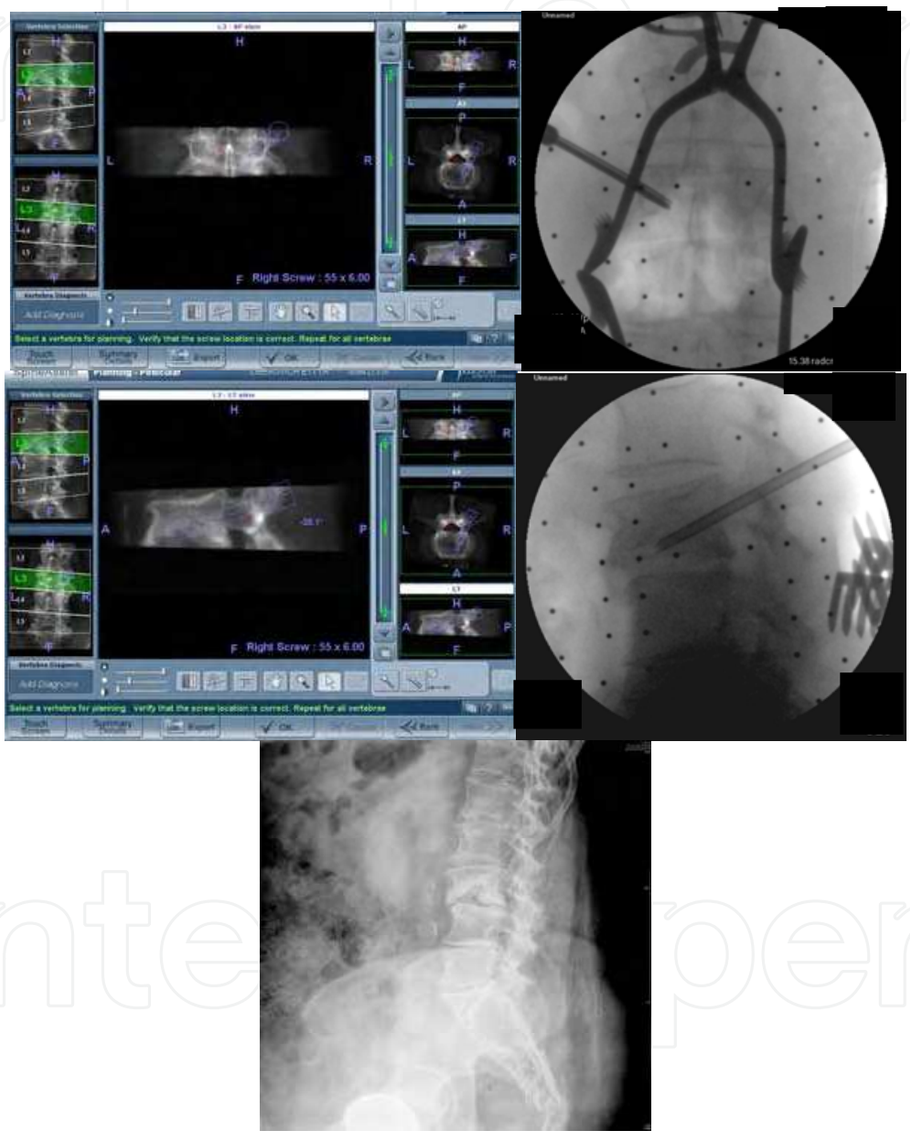

Figure 10 a-f. A 60 years old lady with corticosteroid induced osteoporotic fracture of the inferior endplate of L3 and recess stenosis of L4 presented with intractable low back pain and rt L4 radicular pain unresponsive to non operative treatment. She underwent SA guided L3 Vertebroplasty followed by bilateral L3-4 decompression. The vertebroplasty needle was aimed at a void in the inferior endplate of L3. Axial planning and AP fluoro are reversed in directions, but represent same anatomical sides

In the second case (Fig. 11), 4 cannulated pedicular screws were implanted with SA guidance, again according to the preoperative plan.

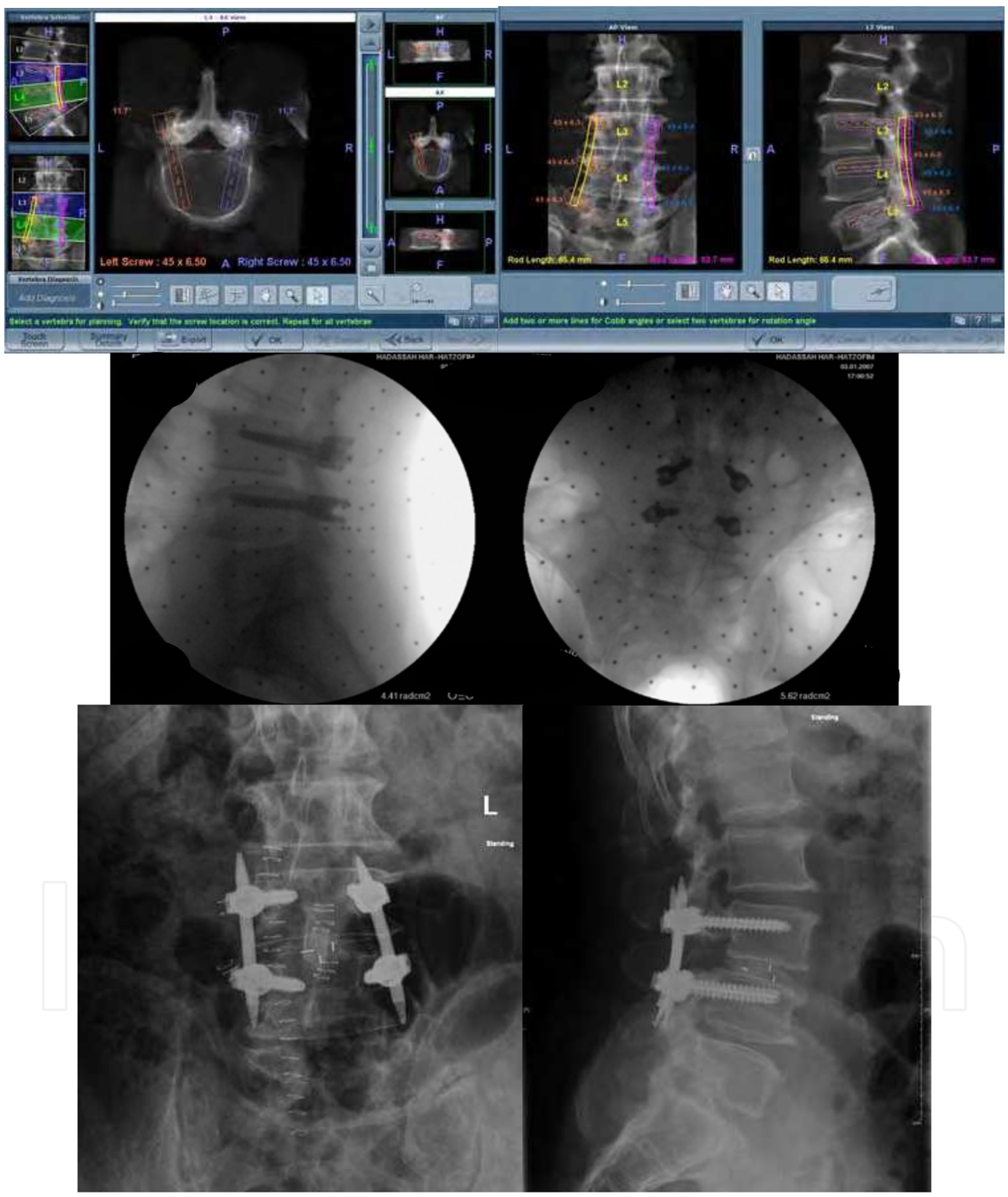

Figure 11 a-f. Preplanning and execution of L3-4 fusion, using cannulated screws. The L5 screws were planned in order to improve the segmentation process of the SA work station

In the third case (figure 12), pedicular screws were used in a lady with lumbar scoliosis de-novo. The intra-operative fluoroscopy images document how close the execution is to the plan.

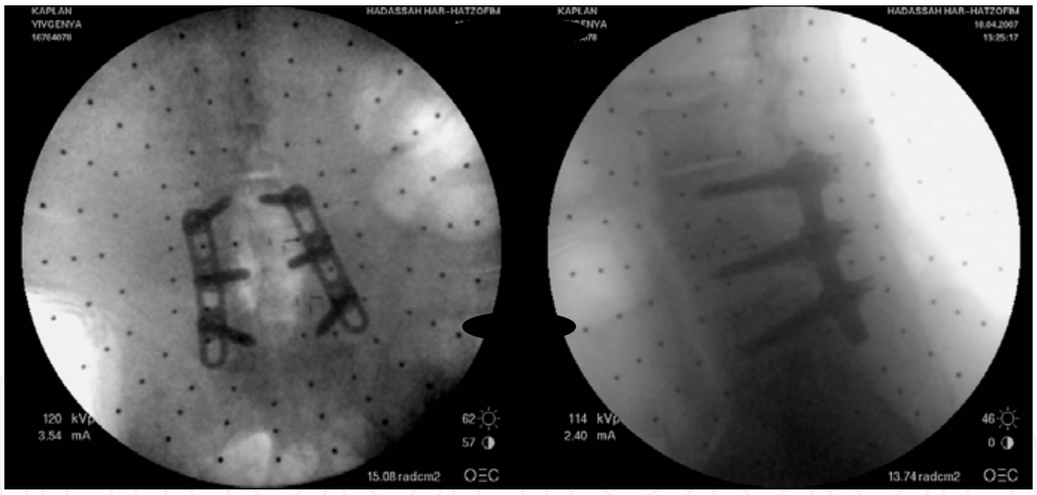

Figure 12 a-c. Planning summary and execution on a 70 years old lady with back pain and spinal intermittent claudication with lumbar scoliosis de-novo and spinal stenosis of L3-5. The surgical procedure included TLIF of L3-4 L4-5, bilateral decompression and SA guided posterior fixation of L3-4-5. The fluoroscopy images represent true AP and Lateral views of the operated levels

Data summarizing the SA usage is shown in tables 3 and 4. Table 3 contains data regarding time measurement in the use of the SA, including time from clamp attachment to detachment (instrumentation time without plates) and total procedure. Table 4 details clinical success (defines as screw in acceptable clinical position and according to plan).

	Average	Range
Screws per case	3.7	1-6
Total case time (Min)	186	47-298
SpineAssist time per case = instrumentation time without plates (Min)	39	17-95
SpineAssist Time per screw (Min)	10.2	4.25-38

Table 3. SA usage compared to whole procedure, instrumentation time in total and per-screw

	Total	Range
Entry points	89	1-6 (3.7 average per-case)
Success rate	85%	0-100%**
Success rate excluding technical failures*	95%	66-100%***

* Technical failures leading to abandonment of SA procedure
** 0% and 25 success rates in 2 cases where technical failures prevented robot usage
***66% in a case where gauze was left in the field, blocking the robot's arm from attaching to the bone, deviating two entry points

Table 4. Clinical success rates

The SA was first used in one level, "simple" fusion cases. Each step was carried out with great care, paying attention to every technical detail, which led to prolonged procedures. A strategic decision was taken to drill the entry point under fluoro guidance (AP and Lateral) in a similar manner to needle insertion in vertebroplasty, and then to verify the drill hole using probes and finders. In the first few cases entry point were found to be higher and lateral relative to the accessory process. Comparing the planning screen to the entry point position, it was found that the robot executed the plan accurately. These early planning errors led to further software improvements – the planning screen now enables a "film" in axial, coronal and sagittal planes, improving surgeon's 3-D understanding of planned implant position. Implementation of the lessons learned in the first few cases led to higher success rates, quicker procedures and minimized fluoroscopy usage (range of SA procedure time and success rates - tables 3 and 4). Later on in the series the SA was used in more levels and in cases with degenerative deformities such as Spondylolisthesis and lumbar scoliosis

de-novo. After gaining enough confidence and experience, percutaneous cannulated pedicular screws were inserted, leading to a smaller surgical exposure, easier recovery and a better cosmetic result. Of the 24 procedures in the series, technical failures were encountered in two, and surgeon related errors occurred in two. These failures and possible solutions for future users are summarized in table 5.

Case #	Failure	Solution
1	Technical failure of robot arm	Production process modified
16	Gauze left in field	Check before mounting clamp Gauze seen on fluoroscopy
17	Faulty cable	Have extra set of equipment
24	Clamp moved	Check clamp stability If wrong entry point reassess Re-position and repeat fluoro acquisition

Table 5. Failure analysis and solutions for future users

As mentioned above, the system was used in 3 cases of spinal deformity. In the first case of a teenaged male with painful Scheuermann's kyphosis measuring 80 degrees the Hover-T frame was used, the system passed all stages successfully but, being attached to a rigid frame, relatively far away from the patient's body, the robot was unable to reach the desired angles and the procedure was aborted. In the second case- a teenaged boy with progressive lumbar congenital scoliosis (Hemi vertebra L2-3 RT) the clamp was used. The system guided excellent entry points into the pedicles above the hemi vertebra, but failed to recognize entry points distal to the hemi vertebra. This case is being studied at the R&D department. In the 3rd case of a teenage patient with idiopathic scoliosis measuring 80 degrees and with tiny pedicles (3-4.5mm) registration failed using the Hover-T frame. However, when the clamp replaced the Hover-T the system performed well leading to perfect entry points and trajectories. At this stage the authors consider the usage of the SA in cases with deformity as early learning curve. A new Hover-T frame with more flexibility in positioning and an improved range of motion may enable percutaneous screw insertion in deformity cases and will upgrade these difficult procedures substantially. Another technical difficulty encountered during this series was the acquisition of high quality AP fluoroscopy images in the transition area between the chest support of the Jackson frame and air surrounding the abdomen, especially in patients with osteoporosis. In short procedures such as vertebroplasty, involving T7-10, the authors prefer to use the OSI plate, having a uniform "background", leading to easier fluoroscopy acquisition.

In conclusion, the SpineAssist is a highly accurate surgical guidance system, incorporating a bone-mounted miniature robot and unique image registration software. The system has been validated, is routinely used in the author's institution and is undergoing further evolution, expanding its work volume and the indication for its use. At the same time, it is a delicate system, especially sensitive to mechanical overload. While excess forces exerted to

different parts of the robot and its attachments will generally not damage it, they may well affect the system's accuracy in guiding the surgeon to the desired position. Special care should be taken to follow the recommended, gentle, surgical technique and to utilizing the appropriate tools and surgical accessories. Careful attention should also be given to the pre-operative plan – which becomes an integral part of the surgery – and to intra-operatively acquiring high-quality fluoroscopic images. When these simple rules are followed, and simple errors mentioned earlier are avoided, excellent results should be expected. Looking forward into the future we recommend that the working volume of the robot be increased, for example by means of modified designs of the guiding arms and robot attachments to the body; this will facilitate the utilization of the system for patients with extreme deformities or with tiny tumors (i.e. osteoid osteoma) in "unreachable" locations, in which we believe it will have a significant added value.

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Medical Robotics

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The first generation of surgical robots are already being installed in a number of operating rooms around the world. Robotics is being introduced to medicine because it allows for unprecedented control and precision of surgical instruments in minimally invasive procedures. So far, robots have been used to position an endoscope, perform gallbladder surgery and correct gastroesophogeal reflux and heartburn. The ultimate goal of the robotic surgery field is to design a robot that can be used to perform closed-chest, beating-heart surgery. The use of robotics in surgery will expand over the next decades without any doubt. Minimally Invasive Surgery (MIS) is a revolutionary approach in surgery. In MIS, the operation is performed with instruments and viewing equipment inserted into the body through small incisions created by the surgeon, in contrast to open surgery with large incisions. This minimizes surgical trauma and damage to healthy tissue, resulting in shorter patient recovery time. The aim of this book is to provide an overview of the state-of-art, to present new ideas, original results and practical experiences in this expanding area. Nevertheless, many chapters in the book concern advanced research on this growing area. The book provides critical analysis of clinical trials, assessment of the benefits and risks of the application of these technologies. This book is certainly a small sample of the research activity on Medical Robotics going on around the globe as you read it, but it surely covers a good deal of what has been done in the field recently, and as such it works as a valuable source for researchers interested in the involved subjects, whether they are currently “medical roboticists” or not.

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