

# Miniature robotic guidance for spine surgery – introduction of a novel system and analysis of challenges encountered during the clinical development phase at two spine centres<sup>†</sup>

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## Abstract

**Background** Instrumented spinal fusion surgery is increasingly performed. Breaching of the pedicle occurs in 3–55% of screws; clinically significant screw misplacements occur in 0–7% of all transpedicular screw placements. Several techniques have reduced this incidence but none gained popularity due to cost as well as staff issues. Surgical robots offer distinct added value in accuracy and minimal invasiveness. The aim of this study is to introduce the SpineAssist<sup>®</sup> - a novel spine surgery miniature robot, to discuss the various reasons that had prevented full success with its use, to identify patients related, technical related, and surgeon related issues, and to offer ways to avoid them.

**Methods** The SpineAssist miniature robotic system is presented, including a short description of the system, its mode of action and a short summary of the surgical procedure.

15 patients had undergone lumbar fusion procedures using the robotic system as part of clinical trials in two Israeli spine centres. A group of 9 procedures was identified within this prospective cohort. This group represents a wide array of technical challenges and human errors which were encountered during the clinical development phase of the SpineAssist. These 9 cases were conducted in two different sites by different surgical teams, over a period of 9 months, with an average interval of 7 weeks between consecutive cases.

The cases were analysed for patient, system, surgeon and technical issues causing the difficulty. Conclusions were drawn as to how to avoid these hurdles in the future.

**Results** In six cases the system operated smoothly, resulting in accurate screws placement according to the pre-operative plan, this was confirmed by a post-operative CT scan. Technical and surgical challenges which are associated with the system early development stage were encountered during 9 procedures. On the technical side, the following phenomena were evident: 1) failure of the software to automatically achieve satisfying CT-to-fluoro image registration and 2) failure of the hospital's peripheral equipment/logistics preventing registration. On the clinical side of things, the following issues were encountered: 1) failure to avoid excessive pressure on the guiding arm caused by surrounding soft tissues, leading to a shift in the entry point and trajectory of the tool guide. 2) a surgeon applying too much force on the tool guide at the tip of the robotic arm, causing deviation from plan. 3) pre-operative plan out of the reach of the robot

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arm and 4) attachment of the clamp to the spinous process in a suboptimal orientation.

**Conclusions** It is expected that following a steep learning curve in the range of 5–10 cases, recommended to take place within 2–3 weeks time, the surgical team will gain sufficient experience in operating the SpineAssist miniature robotic device in order to achieve excellent surgical results. The system may be used for wide range of applications including but not limited to pedicle screws, trans-facet and trans-laminar screws, biopsy needles, vertebroplasty or kyphoplasty tools and more. The preoperative plan has to be logical, intraoperative fluoro images taken with care, gentle surgical technique must be kept – maintaining the integrity of the posterior elements, and avoiding pressure between the robot arms and the soft tissues. During the clinical development phase discussed in this study, both teams used an early version of the system. Based on the results of this study several significant software and hardware improvements have already been implemented. It is our hope that describing and analysing our findings will help in planning and preparing for the clinical utilization of the SpineAssist system in future sites and will shorten their learning curve. By the time this article is published wider clinical experience will have been gathered and we expect to soon follow up with an analysis of clinical utilization of this system in a larger study group. Copyright © 2006 John Wiley & Sons, Ltd.

**Keywords** miniature surgical robotics; spine surgery; pedicle screw misplacement; learning curve; pitfalls

## Introduction

Instrumented spinal fusion surgery is increasingly performed in the treatment of mechanical back pain due to degenerative disc disease, spondylolytic spondylolisthesis, trauma and tumours affecting the spine (1,2). *In vitro* and *in vivo* studies using free-hand or fluoroscopically-assisted techniques documented breaching of the pedicle in 3–55% (3–21). Clinically significant screw misplacements, however, occur in 0–7% (3–15,21–22). Neuro-monitoring, neuro-stimulation and computer-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 (23–42,44–45).

Surgical robots emerged during the 1990s and offer distinct added value in terms of accuracy and minimal invasiveness of the surgical procedure. However, current systems are extremely expensive and large in size, and typically require immobilization of the patient (43).

The SpineAssist® (SA) (46) (Mazor Surgical Technologies, Caesarea, Israel) is a bone-mounted miniature robotic guidance system, clinically tested for spinal surgery. It facilitates image-based semi-active guidance for providing high accuracy in the insertion of implants, e.g. pedicle screws. To the best knowledge of the authors, no other robotic system is available today for spinal surgery.

In this paper we present only the cases in which we have encountered difficulties with the utilization of the SA. We

focus on identifying technical issues as well as patient-related and surgeon-related issues that we encountered during the early learning curve, and we offer ways to avoid them in the future, when new users are introduced to this system.

## The system, methods and patients

### The system

The SpineAssist® (SA) is a miniature bone-mounted robot (2.5 in diameter; 250 g) featuring a six degrees of freedom parallel design. The miniature robot is connected to the SA workstation (Figure 1), which controls its motion and

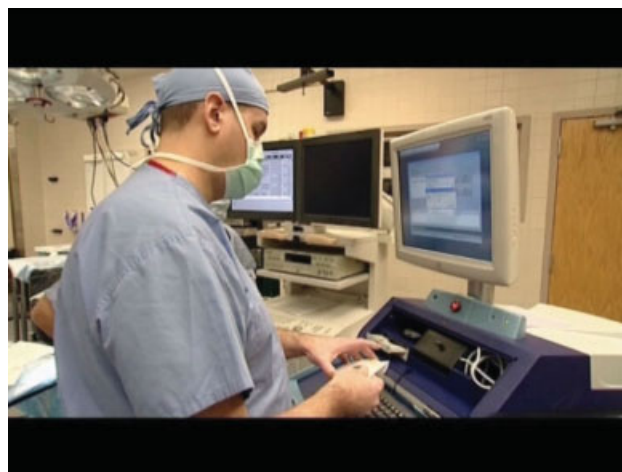


Figure 1. The Mazor SpineAssist workstation

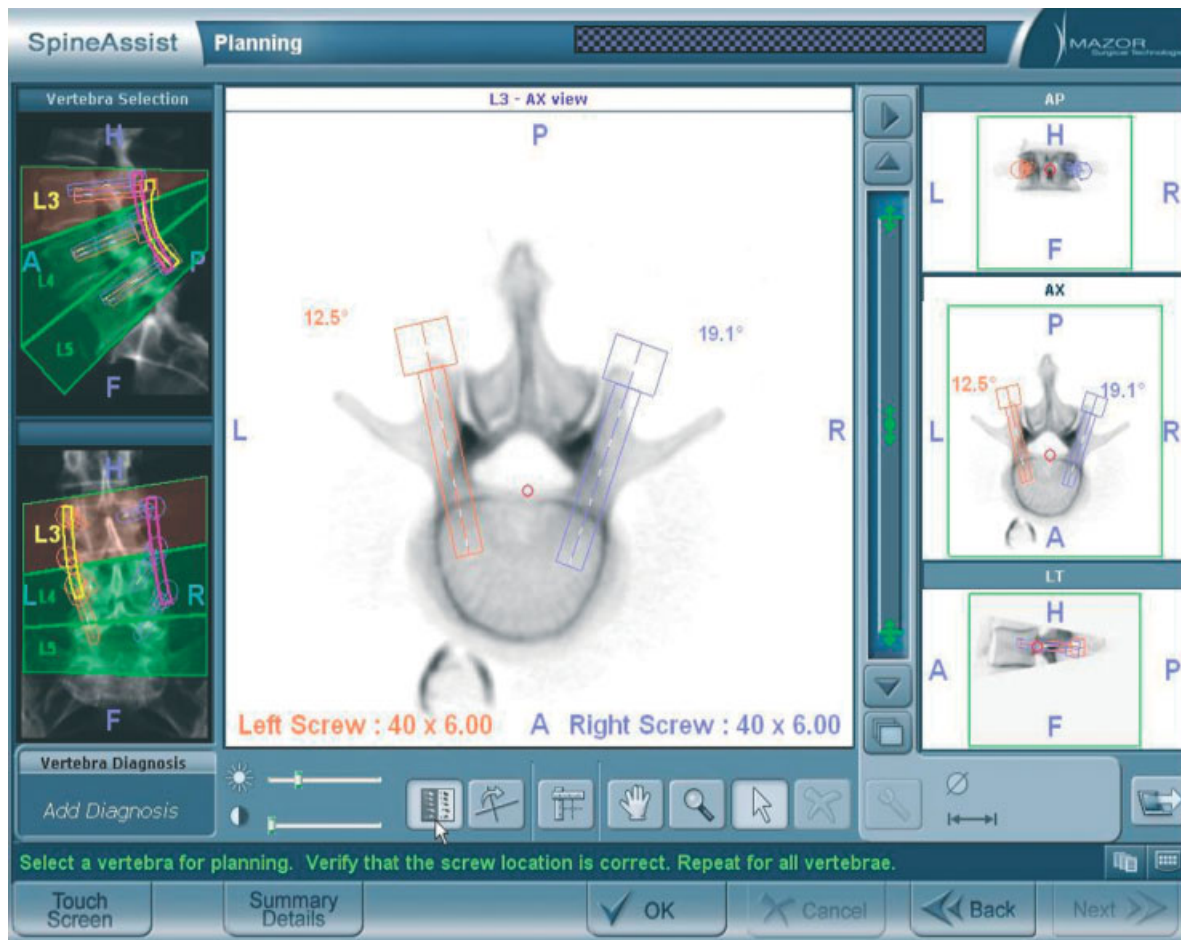


Figure 2. 3D planning of pedicle screws to be introduced into L3 vertebra

runs specially designed graphic user interface software. 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 preoperative planning and intraoperative execution. The planning is done on a three-dimensional (3D) model of the patient's spine generated by the system, based on a CT scan (Figure 2). The plan includes implant 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.

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 lateral (LAT), are taken using 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, using a specially designed jig with three marker holes at positions that are known to the software. The entire process of image and robot calibration takes about 10 min and is performed by

the radiology technician during the set-up of the operating room for surgery, in parallel to other preparations and prior to bringing in the patient.

As the operation begins, a minimally invasive Hover-T<sup>®</sup> frame or a less invasive spinous process clamp are attached to the patient's bony anatomy. Four fluoroscopic images are taken, 2 AP and 2 LAT, with and without targeting devices attached to the Hover-T/clamp. The system performs automatic, per vertebra merging of these intraoperative fluoroscopic images with the preoperative CT. The accuracy of the image registration process is visually verified by the surgeon and the first level to be operated on is chosen. 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 preoperative plan. Based on the known kinematic 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, medium or long) 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 (Figure 3) or percutaneous (Figure 4) approach may be used.



Figure 3. Intraoperative open approach: notice the tool guide through which the surgical tools are inserted

Table 1. Clinical details of the 'difficulties' group of patients

Patient No.	Age	Sex	Indication	Procedure	Special remarks
1	61	F	Stenosis/instability L2–5	PLIF L2–5	Obesity
2	48	M	Mechanical LBP, DDD L4–5	PLIF L4–5	
3	19	M	LBP, spondylolysis L3	PLIF L3–4	Morbid obesity
4	26	F	Re-Re HNP L5–S1	PLIF L5–S1	Morbid obesity
5	81	F	Spinal stenosis L4–5	PDPLF L4–5	
6	70	F	Degenerative spondylolisthesis L4–5	PLIF L4–5	
7	27	M	Burst fracture L2	PSF L1–3	
8	62	F	Degenerative scoliosis post-decompression	Revision PSF T12–S1	Deformed spine
9	55	M	Not available	Revision PLF L4–5	

## Methods

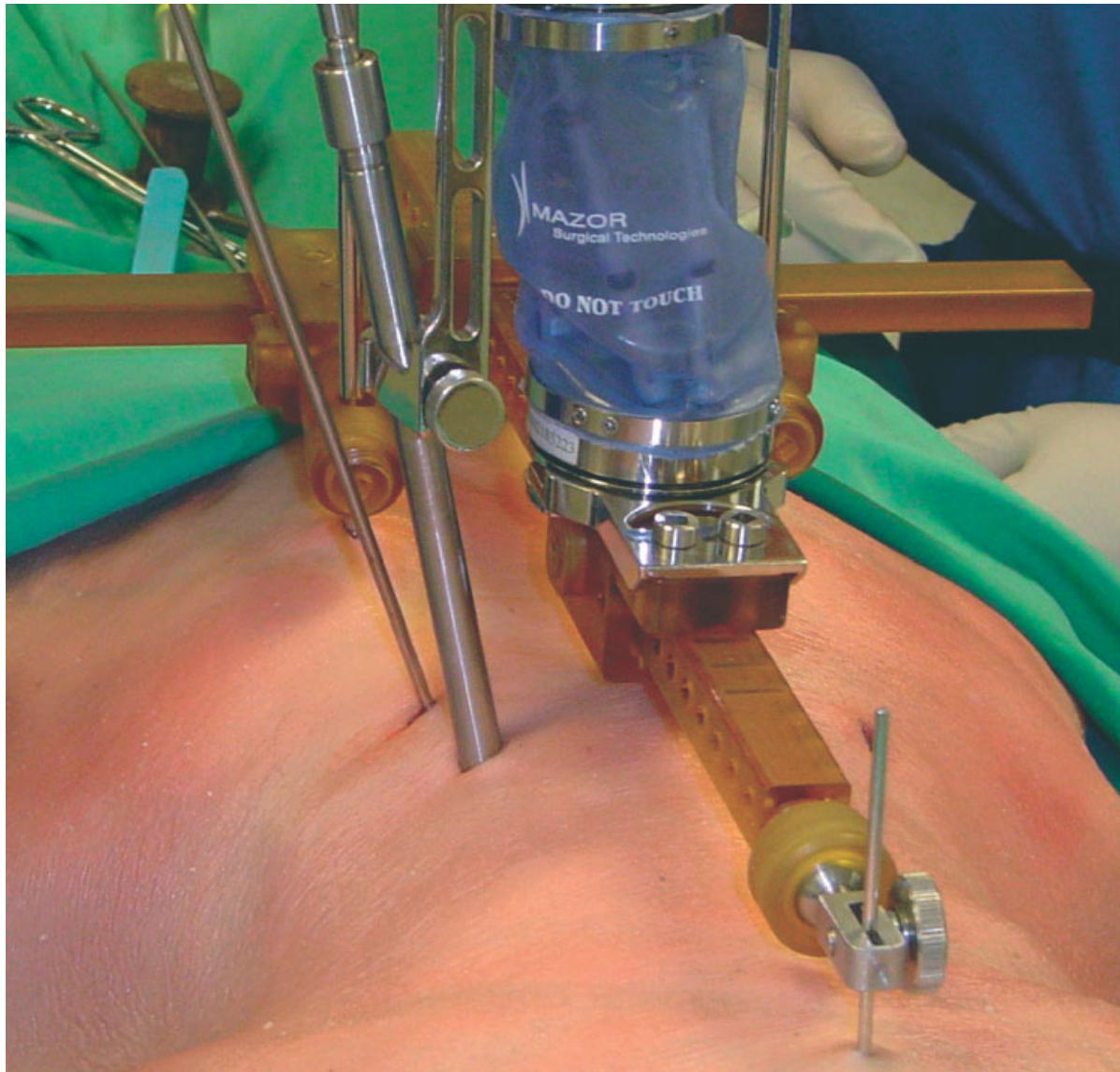
This prospective cohort study was approved by the national as well as regional ethics committees and by the Israeli Ministry of Health. Informed consent was obtained from all patients undergoing fusion procedures under the SA guidance. Demographic, clinical and technical data were prospectively collected. Postoperative CT scans compared screw position with preoperative planning. The study group for this paper comprised all the cases in which difficulties were encountered during the operative procedure – typically the first few cases in each medical centre. These difficulties were analysed for cause, identifying issues related to the patient, software, surgical accessories or operative technique. Surgical tips and

recommended modifications to software and hardware were drawn up and are detailed.

## Patients

During March–November 2005, 15 patients underwent spinal fusion procedures using the SA guidance system in Tel Hashomer (9) and Hadassah medical centres (6). In six of 15 cases (40%), the SA performed smoothly and successfully. In these cases a postoperative CT scan confirmed screw position to be as planned and they were taken out of this study group.

In others, success was only partial, due to various technical reasons as well as improper surgical techniques (6/15, 40%; cases 2, 4, 6–9; Tables 1, 2) and in yet



**Figure 4.** Intraoperative percutaneous approach

other cases the usage of the system was unsuccessful or had to be altogether aborted (3/15, 20%; cases 1, 3, 5; Tables 1, 2). The demographic data, indications for surgery and operative procedures of the study group are summarized in Table 1.

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 the patient's CT, planning, C-arm and robot calibration, fluoro-acquisition, CT-to-fluoro registration, finding the appropriate kinematic solution for guidance, and overall accuracy of placements. Failures were analysed off-line and technical improvements were made accordingly (see Discussion). The ability of the surgical team to appropriately utilize the system with its various software and especially hardware components was also evaluated, together with the appropriate utilization of

supporting systems, such as the C-arm fluoroscopy machine. Human errors and faulty surgical techniques were analysed as well, and lessons were learned from one case to the next, separately among the team of each medical centre.

## Results

In six cases the system operated smoothly, resulting in accurate screw placement according to the preoperative plan; this was confirmed by a postoperative CT scan. Technical and surgical challenges associated with the system's early development stage were encountered during nine procedures and are summarized in Table 2. At Hadassah medical centre, two fully successful cases followed the first four cases, which were challenging, with partial or no success. At Tel-Hashomer medical centre four successful cases were slightly interspersed within the

Table 2. Analysis of issues encountered during the surgical development phase of the SpineAssist system

Patient No.	Intraoperative difficulties	Cause	Solutions
1	Registration failed	C-arm failure	C-arm fixed
2	Operative field too small for planned trajectory; percutaneous approach used	Percutaneous kit was not available in the OR	Percutaneous screw insertion is possible only with proper kit, which is now part of the system's accessories
	Spinous process broke	Too much force applied on the SA device	Surgical protocol has been modified; clamp design has been improved
3	Registration failed	Registration algorithm not robust enough	The registration algorithm has been improved significantly and now yields reliable, repeatable results
4	Registration problems	Marked surgical gauze left in field	Clear surgical field of all radio-opaque objects prior to registration (pads, retractors, etc.)
	Difficulties in connecting bridge to clamp	Clamp was attached to bone at wrong angle	Clinical protocol has been modified: position clamp according to alignment of the region of interest
	Pins on cannulated tool guide twisted beyond repair	Excessive force was used in tapping the tip of the tool guide into the bone	Tapping should be performed gently, seating the pins at the tip of the tool guide, 1–2 mm into the bone, without losing the entry points or damaging the pins
5	Registration failed	Registration algorithm not robust enough	The registration algorithm has been improved significantly and now yields reliable, repeatable results
6	'L5 Unreachable' message	Preoperative plan beyond system's work volume	Plan revised
	Two K-wires inaccurate	Soft tissue pressure on tool guide	Avoid soft tissue pressure on the tool guide and arm
7	One K-wire inaccurate	Soft tissue pressure on tool guide	Avoid soft tissue pressure on the tool guide and arm
8	L2 registration failed	Old screws present on CT but removed before registration	In revision cases – do not remove old instrumentation prior to completing the registration process
	T12 Right out of range	Unknown	
	L1 Right inaccurate	Soft tissue pressure pushed tool guide off the desired trajectory; in a second attempt, accurate placement was achieved	Avoid soft tissue pressure on the tool guide and arm
9	L4 Right inaccurate	Soft tissue pressure on tool guide	Avoid soft tissue pressure on the tool guide and arm

initial challenging cases, but mostly concentrated towards the end of the series. It is also worth mentioning that the cases at each centre were far apart from each other time-wise, which made it harder for the surgical teams to learn and improve from one case to the next.

On the technical side, the following phenomena were evident:

1. In three cases the software failed to automatically achieve satisfying CT-to-fluoro-image registration. In these events the fluoro segmentation step was usually repeated, in order to give the software a better 'first guess' as the basis for the automatic image registration algorithm. If that did not help, acquisition of fluoroscopic images was repeated for the AP or LAT images, or both. In cases where this also did not suffice, the SA procedure would have to be aborted and the surgery continued without it.
2. Failure of the hospital's peripheral equipment/logistics: in one case, a C-arm technical failure led to inadequate, low-quality fluoroscopic images, which prevented proper registration and caused the SA procedure to be aborted.
3. The predominant cause for inaccurate placements was our failure to avoid excessive pressure on the guiding arm of the SA miniature robot caused by surrounding soft tissues. In four cases this led to a shift in the entry point and trajectory of the tool guide. In one other case deviation was caused by the surgeon himself applying too much force on the tool guide at the tip of the robotic arm. In all instances the misalignment was detected by the surgeon prior to screw insertion, by means of either visual observation or intraoperative fluoroscopic image. All misalignments were corrected by the surgeon; no clinical implications were incurred.
4. In one case the system could not reach the preoperative plan – the angle of insertion on the axial plane was too wide, outside of the system's work volume. In most instances, the plan can be modified instantaneously during the operation and a new trajectory can be planned which will satisfy the clinician and, at the same time, be executed by the miniature robot.
5. In yet another case the robot could not reach the desired trajectory due to the angle of attachment of the clamp to the spinous process. The angle of attachment has to be with respect to the anticipated angle and trajectory of the screws. This is especially true for L5–S1 fusions, where the clamp is attached to L5 and

On the clinical side of things, the following issues were encountered:

**Table 3. Retrospective analysis of technical failures – comparing old and new software versions**

Patient No.	Reason for failure during the study	Results based on the SpineAssist 2006 version	Explanation
3	Registration failed	Successful	Improved registration technology
4	Registration failed	Successful L5, S1 failed	Poor fluoro-image quality
5	Registration failed	Successful	Improved registration technology
6	'L5 Unreachable' message	Reachable	Guidance arms were redesigned and optimized
8–L2	L2 registration failed	Failed	Old metal implanted instrumentation was removed prior to fluoro-shots
8–T12	T12 Right side out of range	In range	Guidance arms were redesigned and optimized

screws have to be inserted into S1, which often displays a sharp angle to L5.

4. In one case the surgeon left gauze in the wound during fluoro-acquisition. As all gauze pads are embedded with radio-opaque markers, the markers prevented good registration.
5. In one revision case, old screws were present in vertebra L2 when the patient underwent his preoperative CT scan. However, intraoperatively these screws were removed by the surgeon prior to acquisition of fluoros for the SA. The discrepancy between the CT and the fluoros, once they were taken, was such that achieving registration on this specific level was prevented. Metallic objects are very prominent in fluoroscopic images; their existence in one imaging modality and lack thereof in the other significantly reduces the system's ability to match the images.
6. In one case the surgeon carried out a percutaneous approach although the necessary SA surgical accessories were not available. This resulted in significant forces exerted on the guiding arm and robot, which resulted in a broken spinous process and hence abortion of the SA procedure.

Following the recent software and hardware improvements, we went back to check whether the system's performance would have been different using the latest version. The original data for all the cases in the study group (CT, fluoroscopic images and preoperative plan) was run through the latest software release; the registration and reach ability results are summarized in Table 3.

## Discussion

This study does not represent a recommended learning curve process for medical devices. Several studies prove that an effective learning curve is a condensed process, accumulating a critical mass of cases in a short period of time. The nine cases presented in this study were conducted at two different spine centres over a 9 month period, utilizing an early version of the SpineAssist system. The long time interval, the limited number of cases per centre and the fact that several different surgeons and operating room teams were involved in

few of these cases is assumed to have a significant effect on performance. Having said that, the main difficulties seem to be clearly divisible into technical challenges, stemming from the system being in clinical development stages, and challenges related to inappropriate surgical technique, stemming from an immature surgical protocol and unfamiliarity of the surgical team with the system's requirements. The latter improved significantly over time and cases; we estimate the learning curve in the range of five cases for surgeon–system familiarity and another 10 cases for developing a surgeon's independence in operating the SpineAssist technology. These cases should ideally be concentrated in 2–4 weeks of intensive utilization of the system. Beyond the learning curve – four cases in one medical centre and five in the other, as we experienced it – the system performed as expected and yielded accurate screw placements.

In light of the technological difficulties, significant software and hardware improvements were implemented, viz. improving the robustness of the image registration algorithm and redesigning the three arms for increased work volume and decreased sensitivity to soft-tissue pressure. The surgical accessories have also been redesigned; they now provide enhanced ability to perform percutaneous procedures and are less affected by soft tissue pressure or any other cause. These changes led to a substantial improvement in system performance.

A large prospective cohort detailing the clinical and radiological outcomes and quantifying the consequences of the progress made in both categories will be presented in the near future.

In conclusion, the SpineAssist is a highly accurate surgical guidance system, incorporating a bone-mounted miniature robot and unique image registration software. 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 preoperative plan, which becomes an integral part of the surgery, and to intraoperatively acquiring high-quality fluoroscopic images. When these simple rules are followed, very good results should be expected. Looking 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; this will facilitate the utilization of the system for patients with extreme deformities, in which we believe it will have a significant added value.

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