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REVIEW

Evaluation of the ROSA™ Spine robot for minimally invasive surgical procedures

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Abstract:

The ROSA® robot (Medtech, Montpellier, France) is a new medical device designed to assist the surgeon during minimally invasive spine procedures. The device comprises a patient-side cart (bearing the robotic arm and a workstation) and an optical navigation camera. The ROSA® Spine robot enables accurate pedicle screw placement. Thanks to its robotic arm and navigation abilities, the robot monitors movements of the spine throughout the entire surgical procedure and thus enables accurate, safe arthrodesis for the treatment of degenerative lumbar disc diseases, exactly as planned by the surgeon. Development perspectives include (i) assistance at all levels of the spine, (ii) improved planning abilities (virtualization of the entire surgical procedure) and (iii) use for almost any percutaneous spinal procedures not limited in screw positioning such as percutaneous endoscopic lumbar discectomy, intracorporeal implant positioning, over te top laminectomy or radiofrequency ablation.

Key words

Robotic , Spine, Minimally invasive, Rosa®

Introduction

The new ROSA® robot (Medtech, Montpellier, France) has been designed to assist the surgeon during minimally invasive spine procedures. The ROSA® Spine version of the robot was cleared by the US Food & Drug Administration (FDA) in January 2016, and received the CE Mark in 2014. The ROSA™ Spine was derived from Medtech's ROSA™ Brain robot, which received FDA clearance in 2012 and is currently being used in 29 US facilities.

In the ROSA® Spine device, a robotic arm with tracking abilities is combined with a navigation system. The device comprises a patient-side cart and an optical navigation camera. The main platform includes a robotic arm (with six degrees of freedom) coupled with a haptic sensor and a surgical workstation with a touch screen. The device's software is used to

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perform robot's registration, plan the surgery and provide image guidance during surgery. The second component is the optical camera, which is linked to another monitor that shows exactly the same information as the main monitor (Figure 1).

At the time of writing (May 2016), the ROSA® Spine robot has been used for more than 100 spine operations worldwide (including more than 65 in our department). The device presented here is part of a new generation of image-guided devices that combine robotics and navigation within the same platform. The objective is to perform minimally invasive procedures with greater accuracy, reproducibility and safety.

In the present review, we describe our surgical technique, the main indications for use, the advantages associated with use of this new technology in spine disorders, current limitations, and development perspectives.

FDA- and CE-approved indications

The device has been approved by the authorities for minimally invasive lumbar fusion in general and percutaneous transpedicular screw insertion for the L1-S1vertebra in particular. Hence, the main indication is minimally invasive circumferential lumbar arthrodesis.

Over the last two decades, there has been a notable surgical trend towards minimizing injury to healthy tissues while nevertheless obtaining an acceptable or even excellent technical outcome. Percutaneous transpedicular instrumentation is now a widely used, well-accepted technique in thoracic and lumbar spine procedures[1–5]. The advantages of percutaneous pedicle screw instrumentation are clear: significantly less blood loss, a lower postoperative infection rate and faster recovery (due to minimal injury to the tissues around the spine). Accurate pedicle screw placement is mandatory during these procedures [2]. In order to provide high levels of accuracy and limit exposure to radiation, robotic devices and intraoperative image-guided navigation systems have been developed [6,7]. It has been demonstrated that the combination of navigation and peroperative computed tomography (CT) has helped to improve the accuracy of screw position [8,9] and greatly reduce the surgical team's exposure to ionizing radiation [10–13].

The main indication for the ROSA® Spine is minimally invasive circumferential arthrodesis, which is commonly used to treat degenerative lumbar diseases such as spondylolisthesis or recurrent herniated disc. The ROSA® Spine has been designed to help the surgeon decrease the frequency of poor arthrodesis screw positioning, limit the surgical team's

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exposure to ionizing radiation, and diminish surgery-associated morbidities (such as infections and pain) by reducing normal tissue injury.

Surgical technique

We present the surgical technique for circumferential lumbar arthrodesis with a minimally invasive transforaminal approach, as described elsewhere [14]. Transforaminal lumbar interbody fusion (TLIF) is a treatment option for degenerative lumbar diseases, such as spondylolisthesis and recurrent herniated disc. The technique was first described in 1998 by Harms and Jeszenszky [15], and has since been adopted widely because the low incidence of peroperative complications [16–18].

The operation is carried out using the ROSA® Spine with intraoperative flat-panel CT guidance (using the O-arm® from Medtronic, Minneapolis, MN, USA). The patient is placed in the prone position on a radiotransparent spinal operating table. The lumbar spine is prepared and draped under sterile conditions. A percutaneous reference pin is placed in the right iliac wing. This is the only part of the surgery without robotic assistance. The O-arm® device is placed opposite the surgeon and slightly to his/her left. The anesthesiologists are situated near the patient's head. The typical layout of the operating theater is shown in Figure 2. Installation of the patient, robot and O-arm® takes around 10 to 15 minutes. Firstly, the robot's position is co-registered with the patient reference by using the optical camera. Secondly, image registration (with the patient in the operating position) is performed. The robotic arm holds a fiducial box, which the surgeon places by using the robotic arm's haptic properties. The robotized arm has a haptic sensor, allowing the surgeon to move the robotic arm freely. The fiducial box is placed just over the skin, as close as possible to the operating site. Three-dimensional (3D) images are acquired with the O-arm® CT scanner in breath-hold mode (so that the robot can track the movement of the spine induce by breathing) and transferred to the ROSA® Spine's workstation. Registration is performed by automatic recognition of the fiducial box. The registration procedure takes around 7 to 10 minutes.

After completion of the registration procedure, the surgical procedure per se begins. Firstly, the surgeon plans the 3D trajectory for bilateral transpedicular screw placement from L1 to S1. Most fusions involve L4-L5, L5-S1 or L4-L5-S1. The surgeon can choose the screws' length and diameter. The trajectory is based on an entry point (which is usually facing the posterior part of the pedicle) and a target point (above the body of the vertebra). The

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surgeon has access to axial, sagittal and coronal views but can also look along the planned trajectory and perpendicular to the trajectory. The surgeon can place the screw exactly where he/she wants and can plan to avoid (for example) cortical breaches, articular facets, etc. In our experience, the planning takes around 5 minutes - depending on the patient's anatomy and the numbers of screws, etc.

Secondly, the robotic arm is placed along the trajectory, and the movement tracking function is activated. With a reducer hold by the robot, a dilator is placed through the skin and muscle, in order to access the entry point over the bone and to place the latter along the planned trajectory. The drill is placed inside the dilator, which is held by the robot. The robot is able to track the movements of the patient's body in real time, which means that the drill is always aligned with the planned trajectorya hole is drilled percutaneously (with a 3 mm bit) through each pedicle by using real-time, robotized navigation and tracking guidance..

In order to avoid a "ripping" effect between the drill and the bone (the planned trajectory is rarely perpendicular to the entry point), we recommend drilling 20 mm through the bone and performing back-and-forth drill movements until no resistance is met. The objective (as in open surgery) is to widen the entry point with back-and-forth movements.

A guide tube needle is placed through the dilator and then through the pedicle into the posterior part of the vertebral body. Next, a guide wire is placed through the guide-tube needle using real-time, computer-aided navigation. The guide tube needle and the first dilator are then removed. The guide wire and all the instruments are monitored by the robot via real-time, computer-aided navigation; this provides the surgeon with the instruments' exact spatial positions throughout the procedure and enables placement at the required depth.

A Sextant®, Longitude® (Medtronic®, Minneapolis, MN, USA) or Socore® (Novaspine®, Amiens, France) percutaneous ancillary system is used for this procedure in our department. In theory, ROSA™ Spine is compatible with all types of percutaneous ancillary system. All instruments inside the ancillary system are monitored by the robot in real time. It is important to monitor not only for the instruments' depth but also a potential "ripping" effect. If the position of an instrument given by the navigation system differs from the planned trajectory, we recommend using intraoperative fluoroscopy to check the instrument's actual position. The entire surgical procedure is describe in Figure 3. As in conventional percutaneous procedures, dilators are placed, pedicles are threaded and screws are inserted via the guide wire under real-time robotic guidance. The use of K wire allows the

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device to be compatible with all percutaneous instrumentations in the market. There is no need to additional investment. In addition, using drill allow to limit the ripping risk.

One of the advantage of the robotic arm is that it holds the instruments gently. This exerts less pressure on the guide wire and thus lowers the risk of moving the latter during the screw positioning procedure. The size of each screw is based on the pedicle size measurements made during the initial 3D planning. Furthermore, the two left percutaneous incisions are combined, in order to position the retractor (ILLICO® MIS, Alphatec Spine, Carlsbad, CA, USA). The latter has now been replaced by a dedicated Socore® retractor (Novaspine®, Amiens, France) placed on the screw extenders – thus allowing optimal access to the articular facet.

Exposure of the articular facet enables the foraminotomy to be initiated. The nerve root is progressively released. The surgeon is free to use a navigated pointer to recognize anatomic features more easily. Appropriate discectomy then enables placement of the TLIF cage. The surgeon can also navigate the rotating cutter, interbody dilator and cage insertion into the interbody segment, which reduces the use of fluoroscopy and optimizes the implant's position.

Lastly, arthrodesis is completed by introducing and clamping the rods. Another 3D acquisition is then performed with the O-arm®, in order to check the mounting's final position (and especially the cage and screw positions). Finally, all the wounds are closed.

To check the mounting's position, a lumbar X-ray is acquired under weight-bearing conditions two days after surgery.

Uses not approved by the FDA or CE marking

We use the robot for three additional indications.

Firstly, we use the system to position intracorporeal implants for vertebral fractures (coupled with percutaneous posterior osteosynthesis in some cases) throughout the dorsal and lumbar regions of the spine. The surgical technique is very similar to that used for pedicle screw placement, except that we position an implant instead of a screw. The procedure is completed under fluoroscopic guidance with the O-arm® (placement of the implant and injection of poly(methyl methacrylate)). For dorsal spine procedures, we place a reference pin above the spinous process. The biggest advantage of robotic guidance is its optimization of implant positioning and thus fracture reduction.

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Secondly, we use robotic assistance during percutaneous endoscopic lumbar discectomy (PELD). In fact, we performed the world's first ever robot-assisted PELD (Figure 4). The robot is used to optimize the endoscope's position relative to the disc. It decreases the risk of poor targeting (too far from the diseased area, or too close to a nerve). The working cannula is also navigated, providing 3D information on the endoscopic placement throughout the procedure.

Thirdly, we use the ROSA® Spine and the Easy-go® ancillary (Karl Stortz®, Tuttlingen, Germany) for minimally invasive over-the-top laminectomy. The robot is use to optimize retractor placement and as a navigator system during surgery.

Results

As with every new tool, there are very few data on the system's accuracy. To the best of our knowledge, most of the literature data on this device has been published by our department.

In our department, We first published a cadaver study of the device's accuracy. We evaluated the positioning of 38 percutaneous transpedicular screws (between D8 and S1) implanted in two separate cadaver sessions by coupling the ROSA® Spine robot with the flat-panel CT device [19]. Thirty-seven screws (97.4%) were fully contained within the pedicle (grade A on the Ravi scale [20]). One screw breached the lateral cortical of one pedicle by less than 1 mm (grade B on the Ravi scale). We were also able to compare each screw's planned and actual positions. The mean ± standard deviation (SD) accuracy (relative to the surgical plan) was 2.05 ± 1.2 mm for the head of the screw, 1.65 ± 1.11 mm for the middle of the pedicle and 1.57 ± 1.01 mm for the tip of the screw. We observed a significantly greater accuracy in the second session (in which we used our method to limit a mechanical "ripping" effect), with a mean accuracy of 1.59 mm for the head of the screw, 1.16 mm for the middle of the pedicle and 0.89 mm for the tip of the screw. This level of accuracy is very similar to that observed in stereotactic brain surgery [21].

Lonjon et al presented pre market evaluation of the robot in open approaches. They have compared 10 patients operated using robotic assistance (Rosa®spine) with 10 other patients using freehand conventional technique. Accurate placement of the implant was achieved in 97.3 % of patients in the robotic group and in 92 % of those in the freehand technique. Four implants in the RG were placed manually following failed robotic assistance.

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In clinic, with percutaneous mini invasive approache, our team have also reported very preliminary results on the device's accuracy for our first seven patients with lumbar arthrodesis [14]. Three senior neurosurgeons performed minimally invasive TLIF using the robot. No pedicle breaches were seen on the O-arm® CT scan during the procedure. A follow-up consultation two months after surgery confirmed that the patients' clinical status had improved. The mean ± SD operating time was 244 ± 38 min minutes. Five of the seven operations concerned the L4L5 disc. In this study, we compared the first seven patients in a "robotic surgery" group with seven age-matched "neuronavigation" patients (i.e. patients having undergone minimally invasive TLIF using a neuronavigation system and O-arm® CT). The mean ± SD cumulative dose for fluoroscopy was 1802 ± 719mGycm^2 per patient and the mean cumulative ± SD dose for O-arm® 3D CT was 509 ± 281 mGycm^2 per patient. There was no significant difference between robotic surgery and neuronavigation surgery in terms of the mean dose for O-arm® 3D CT ($p=0.6$ in a paired Student's test). Similarly, there was no significant inter-technique difference in the mean fluoroscopy dose ($p=0.28$ in a paired Student's test) [14].

For this review, we have reviewed the first 100 trajectories planned with the robot (96 screw placements and 4 transpedicular implantations of the Spinejack® device from Vexim®, Paris, France) in our department. This represents 24 patients with TLIF indications. We did not face any significant per-operative nor post-operative complications, in particular no nerve injury or infection. All the patients presented a significant improvement of their pre-operative status with at least a minimal post operative follow-up of 6 months. There were 93 grade A screws, 2 grade B screws and 1 grade C screw. Hence, 98.9% of the screw placements with robotic assistance were classified as grade A or B. For the two grade B cases, the screw breached the lateral cortical of one pedicle by less than 1 mm. The grade C case occurred during intracorporeal expandation with a Spinejack® implant. The trajectory enabled us to place the implant inside the vertebral body without damaging the nerve. We therefore continued the surgery and positioned the implant. The vertebral body was successfully repaired, and the patient was discharged from hospital two days after surgery. We consider that this grade C incident was caused by movement of the patient's fiducial during surgery. It must be noted that for four trajectories, the screw was implanted without robotic assistance. In the first two of these cases, the surgical team noted movement of the patient's fiducial and thus a loss of accuracy. Although we had the option of re-registration and using 3D images, the lead surgeon decided to finish the operation with fluoroscopy (in order to avoid another

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3D CT acquisition). This happened with two different surgeons, at the start of their learning curve for this technique. Furthermore, both cases concerned the last screw to be implanted. In the third of the four cases, the surgeon did not feel confident with the robot-assisted placement of the K-wire. After a fluoroscopic check failed to provide conclusive information on accuracy, the surgeon chose to remove the K-wire and place it again under fluoroscopic guidance. In the fourth case, a technical problem prevented the robot from monitoring spine movement. Although we could have rebooted the robot, the surgeon chose to implant the last screw was under fluoroscopy guidance. It is important to note that these four trajectory failures occurred at the start of our learning curve. We have not encountered this type of problem in our last 30 operations.

Current limitations and future developments : Five-Year view

The robot's main advantage is that it tracks the patient's movements in general and respiratory motion in particular. Once the fiducial marker has been placed, the O-arm® CT device performs a 30-second 3D breath-hold acquisition. Subsequently, the robot arm monitors all of the patient's movements. This is of significant value because the spine is a dynamic system that can move slightly during surgery as a result of respiration motion or the surgical procedures [22].

However, the current device presents several clear limitations. Firstly, it is only FDA- and CE- approved for lumbar screw positioning. In our department, we have decided to use it for dorsal surgery with spinous reference. The results are as good as those for lumbar surgery, so there is clearly a need to obtain approval for all types of percutaneous spinal surgery (such as PELD, intracorporeal implant, radiofrequency ablation, etc.) and not just for screw positioning.

The robot's other limitations are very similar to those of navigation systems. For example, no information can be provided if the patient's fiducial moves abnormally. In such an event, the robot's movements will be erroneous throughout the surgery. The robot follows the anatomic layout measured at the start of the operation; if the spine moves significantly during surgery, the robot will be precise but inaccurate. Great care must be taken during spine trauma surgery, and screw insertion must be avoided after interbody implants have been positioned. In our opinion, great care must be taken during image-guided surgery. The surgeon must have a perfect understanding of how the device works, in order to remain in control of the operation

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and not have “blind faith” in the device. As with navigation systems, we recommend that all the surgical team members should have received specific training in the use of this kind of system. Lastly the use of Robotic assistance plus cone beam CT (O-arm® in our department) increases the cost of each procedure. It is obvious that this technology has substantial acquisition and maintenance costs. However robotic assistance has the potential to reduce hospital stay, re-operation rate, infection rate… and so to increase safety for the patient with almost no overall cost for the society. A specific economic evaluation of cost effectiveness has to be realized such as with intra operative cone beam CT navigation [23] and to be adapted country by country function of the heath policy of the state.

In our opinion, the device also needs to be improved in several respects. The installation and registration procedures are (despite ongoing improvements) are too long. We believe that the process can be shortened without any loss of accuracy. We also consider that the software interface should provide a segmented 3D view and show virtual images of cages, rods and vertebral body implants as well as planned trajectories; this would enable the surgeon to improve the planning process. Lastly, we think that the device needs to increase the number of devices and tools that can be faithfully modelled.

In the future, we hope to see the following improvements at different levels:

(i) robot assistance for surgery on the dorsal and cervical spine and not just the lumbar spine.

(ii) optimized planning, with virtual images of the surgical outcome (for example, being able to estimate the degree of fracture reduction as a function of the implant’s placement within the vertebra, or being able to calculate the impact on sagittal balance when planning circumferential arthrodesis).

(iii) greater haptic functionality in spine surgery (in order to improve interlaminar approaches in PELD or adapt the position of tubular retractors in over-the-top laminectomy with more than two levels of decompression).

Expert commentary

The recent combination of neuronavigation techniques and robotics [6,24–28] [29] has led to further progress in spine surgery– notably in terms of reducing the morbidity specifically associated with poor screw positioning. When compared with free hand open with

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lateral conventional fluoroscopy techniques, neuronavigation provides more accurate pedicle screw placement (in 68.1% vs. 95% of cases, respectively [30,31]). In addition, if an accurate positioning can be obtained with double fluoroscopy during mini-invasive approaches [32], navigation and or robotic assistance offer significant lower exposure to ionizing irradiation to the surgical team[10,25,33]. The ROSA® Spine device used in the present study is a development of the ROSA® Brain robot used in brain surgery [34,35]. The robot has been designed to have the same precision in spinal surgery as in stereotactic brain surgery. Trajectories are planned in the same way as in the brain system, with specification of the screw's entry point, direction, and final position. This feature enables the surgeon to optimize screw placement by (for example) avoiding articular facets and by optimizing the position of potentially any percutaneously introduced tool. In our opinion, the ROSA® robot is an advanced neuronavigation tool with some of the features of other image-guided tools. However, the addition of a robotic arm and tracking abilities opens up a whole new field in spine surgery because it allows the surgeon to execute the planned surgery with millimeter-level accuracy. This enables the surgeon to design a personalized disease-specific surgical plan for each patient. In its currently authorized indications, thus the robot's greatest advantage is its ability to place the screws exactly as planned. In our department, the device helps surgeons to optimize not only screw positioning but also the placement of intracorporeal implants and endoscope positioning during PELD . In turn, the robot will facilitate all mini – invasive percutaneous spine procedures, such as radiofrequency ablation, PELD and minimally invasive over-the-top laminectomy. Finally, the biggest interest of such device is to allow the surgeon to achieve exactly the planned surgery.

Conclusion

When coupled with intraoperative flat-panel CT, the ROSA® Spine robot can performed highly accurate pedicle screw placement. Along with its navigation abilities, this ability enables accurate, safe arthrodesis in the treatment of degenerative lumbar disc diseases. The device's level of accuracy and its ability to allow the surgeon to perform the planned surgery should lead to greater safety and biomechanical strength when the technique is applied to larger numbers of patients. The preliminary data described here must be confirmed in long-term studies of large patient populations. Lastly, the robot is able to assisted spine surgeons with almost all minimally invasive percutaneous surgical procedures. The device's value in indications other than screw placement requires further investigation.

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Declaration of Interest

M. Lefranc has provided consultancy services to Medtech (Montpellier, France). The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Figure 1:

The ROSA® robot (Medtech, Montpellier, France). The robot comprises a patient-side cart (bearing the robotic arm and a workstation) and an optical navigation camera.

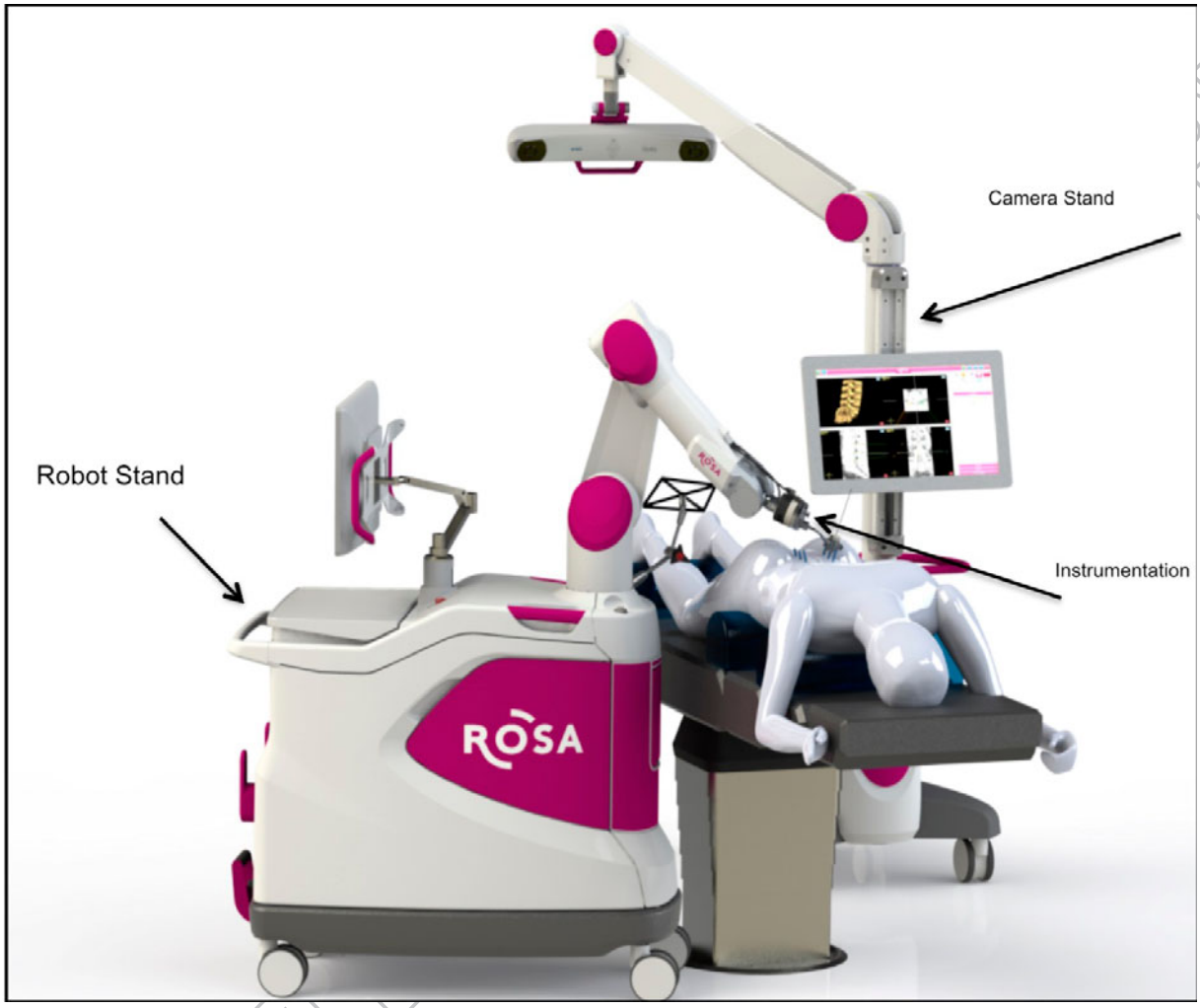

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Figure 2:

Typical organization of the operating theater. The patient is in the prone position. The O-arm® device is placed opposite the surgeon and slightly to his left. The anesthesiologists are situated near the patient's head. The robot is placed opposite the surgeon. The optical camera is placed near the patient's feet (right of the surgeon).

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Figure 3:

Typical flow chart of the surgical procedure.

(1) installation, (2) robot registration, (3) image registration, (4) planning, (5) screw positioning (muscle dilator – pedicle drilling – insertion of the guide tube needle– guide wire insertion – muscle dilators of the ancillary system – rotate cutter – screw insertion)

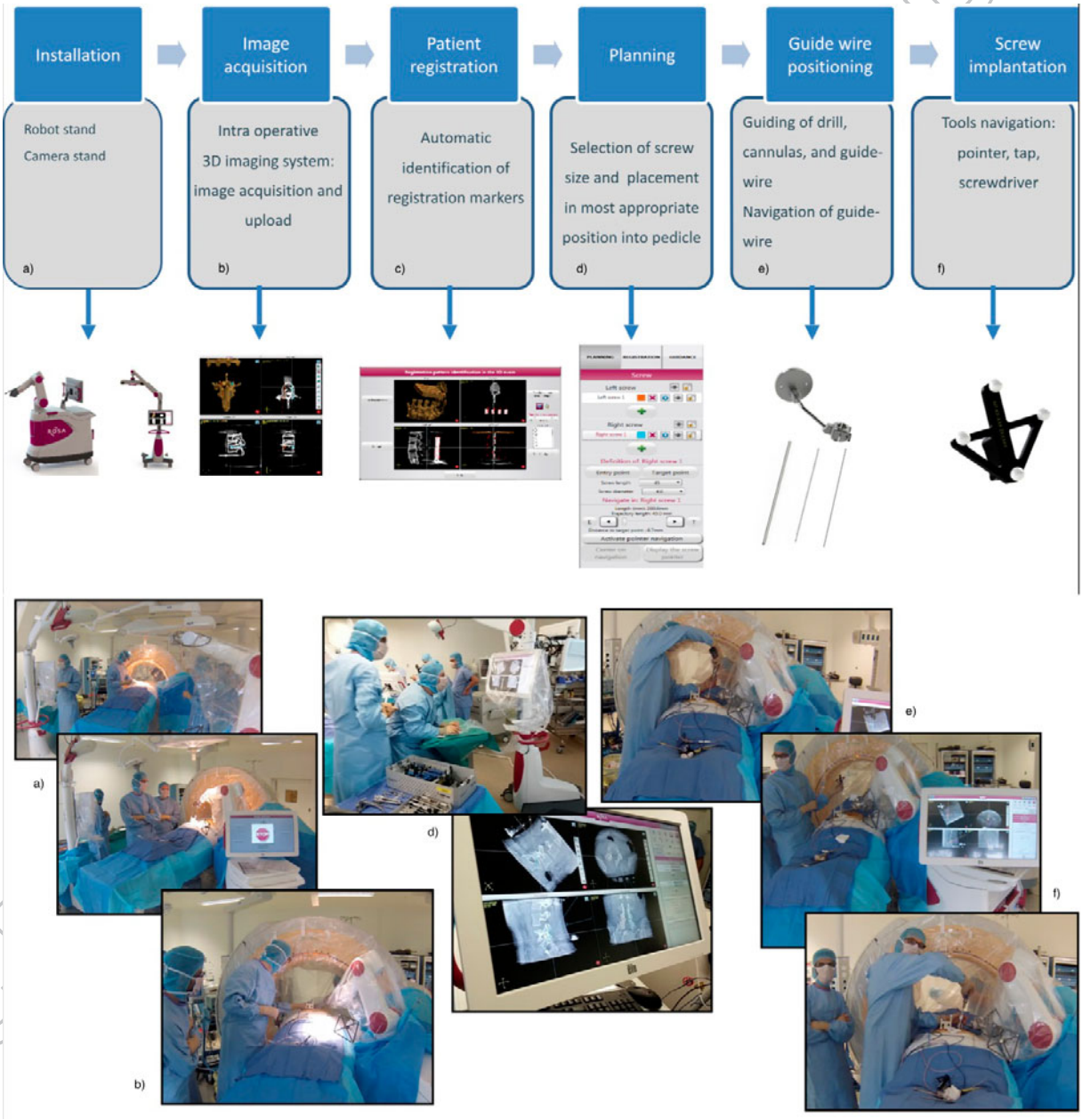
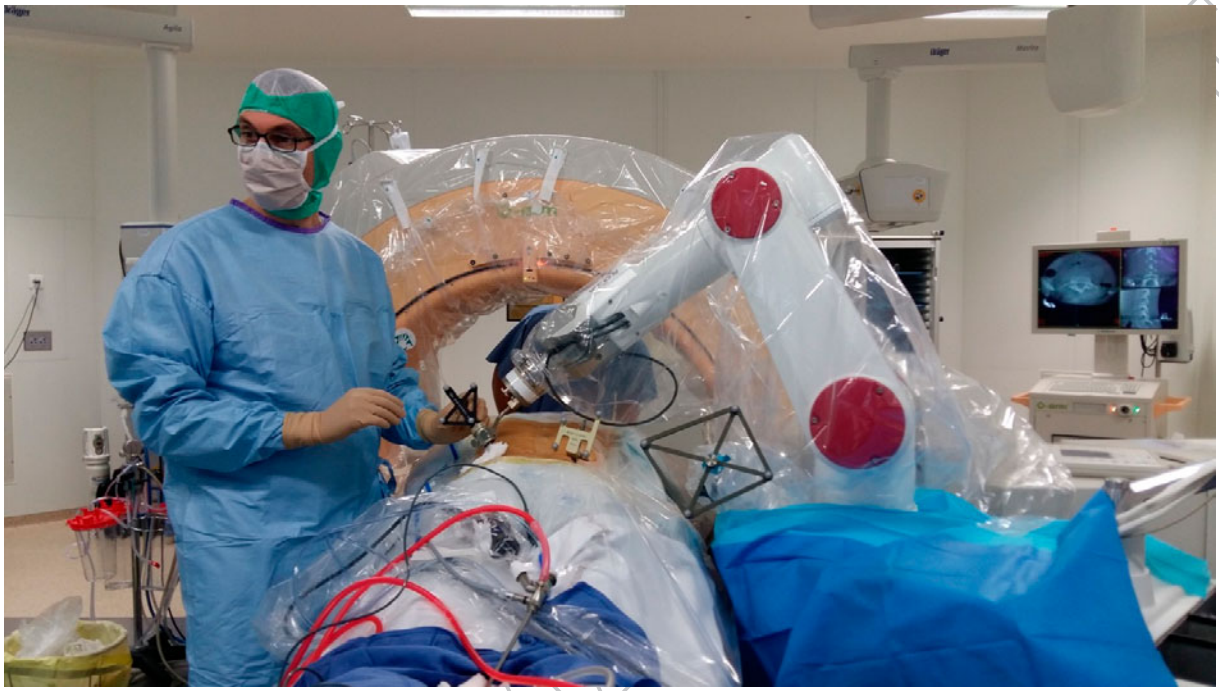


Figure 4:

Image from the world's first robot-assisted percutaneous endoscopic lumbar discectomy. The robot helps to improve positioning of the working cannula.



Video 1:

The ROSA® Spine robot is able to track any movement of the spine in real time.

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