ACCURACY AND SAFETY ASSESSMENT OF SPINAL IMPLANTS ASSISTED BY THE ROBOTIC SPINAL SURGERY SYSTEM: ANIMAL STUDY

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INTRODUCTION

Pedicle screw insertion is a daily clinical task in spine surgical procedures; it is an advanced posterior fixation technic which could get the patients great biomechanical benefits[1-3]. The spine pedicle width for Asian is only about 8mm[4], it is very difficult to insert screws into the spine pedicel without penetrate the cortex. There are many important tissue beside the spine pedicel such as the never root, dural and vascular systems, screw malposition may cause serious complications. The rate of screw dislocation ranges form 4.9% to 37.5%[5-11].

Image based computer assisted navigation system has been applied into spine surgery to improve the screw insertion accuracy[12]. Recent studies suggested the improvement in lower thoracic and lumbar pedicle screw placement[5, 13-16]. However, there are still some disadvantages of this navigation method, such as the navigation system will distract the surgeon's attention during the drilling process and it is not easy to judge the penetration all based on surgeon's sense of the feedback from the drilling device. One way to overcome all these drawbacks is to use a robot, and such studies have been introduced in several reports[17-21]. However, most of their methods were only applied in vitro, although the results of cadaveric tests are remarkable[19, 21].

We have also proposed the Robotic Spinal Surgery System (RSSS), which fuse the CT images for navigation and sense trust force signals to prevent penetration in the pedicel screw inserting process[22, 23]. In this article, we evaluated the accuracy and safety of pedicle screw placement using RSSS in vivo.

MATERIALS AND METHODS

The RSSS:

Briefly, the RSSS consisted of four different systems, which are the navigation and tracking system, the planning system, the robotic system and the state recognition system.

Navigation and Tracking system

The image data were acquired by ARCADIS Orbic 3D (Siemens Medical Solution, Erlangen, German), and the image data was transferred to the navigation system. After reconstruction the image data into sagittal, coronal and axial view, we registered the animal with the reconstructed images into the navigation system by using the optical tracking system. The driller on the robot arm has also been registered into the navigation system.

The optical tracking system consists of an infrared camera (NDI brand: Polaris) and homogeneous markers. The homogeneous markers that attached to animal vertebral and robot driller can reflect the infrared ray. So, the tracking system will get both the animal and the driller's position in real-time by capturing the reflected infrared ray, the position information was integrated into the reconstructed image and showed on the navigation screen.

Planning system

As we integrated the animal's image data into the navigation system, we can use it for precise trajectory planning. For the safety reason, we can plan as much as 6 trajectories at one time. After designing all the surgical paths, the trajectories information was transferred to the robot.

Robotic system

The mechanical system of RSSS composed of a 5-DOF robotic arm and a 2-DOF pedicle-drilling device. The robot arm was used for position adjustment and orientation of the drilling device. The drilling device's speed was 12,000rpm, and the feed speed was 0.5mm/s.

There was a 6-DOF-force/torque sensor equipped at the end of the drilling device which can track the generalized force by the drilling device and send the force/torque information to the data acquisition card (DAQmx card). The sampling rate of the acquisition card is 1,000Hz. After acquired the force/torque profiles, the data was buffer with a length of 50 and showed in the monitor.

State Recognition system

By analysis the force/torque profiles, state recognition system guarantees the safety for RSSS during the surgery. The automatic drilling was achieved by identifying the five different stages of the force signal corresponding to the anatomical structures. They are initial state, outer cortical state, cancellous state, inner cortical state and pull out state. We have set up a force signals model for state recognition system[23], and this system can stop the driller before the spinal canal being penetrated. And its sensitivity and specificity has been test before[22].

Surgical Outflow:

The surgery workflow was mainly divided into three major parts as showed in Fig. 1.

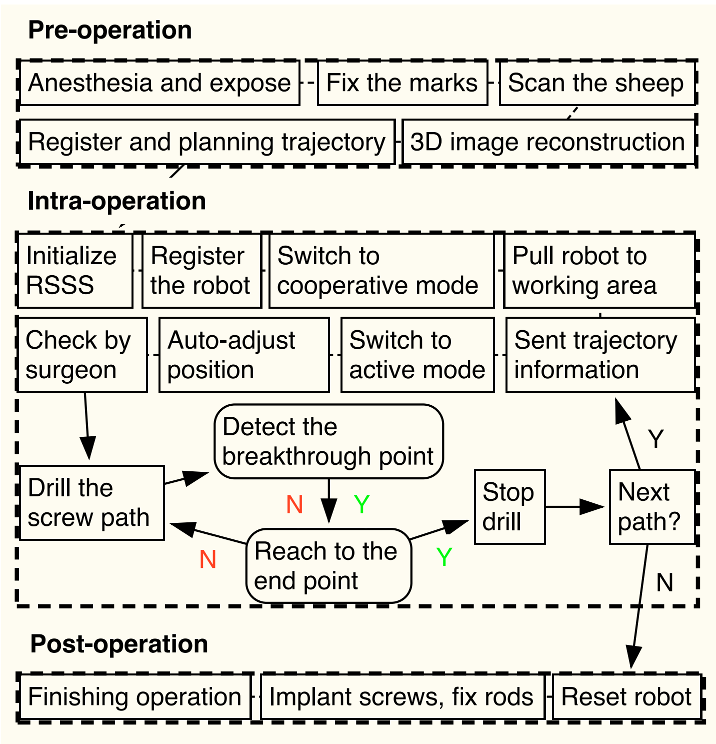


Figure 1: The procedure of screw insertion operation during surgery with the RSSS.

The in vivo animal model and special instruments:

The in vivo animal model is sheep. The pedicle width of the sheep is even narrower than the human[24], which makes it the appropriate in vivo model for pedicle screw insertion. The sheep are brought from qualified suppliers by the animal experiment center, with the approval of the Institutional Animal Care and Use Committee of Peking University. The Animal Experimental Ethics Committee in our hospital has approved the animal experiment (No. 201306-02). All the surgeons involved in the animal experiment have the animal experiment license that issued by Beijing Association on Laboratory Animal Care.

The pedicle screws and rods that we used in the animal experiment were provided by the Fule company (Fule Science & Technology). The type of the screw that we used is 4.0mm in diameter and 25mm long.

Evaluation after surgery:

We evaluated the surgery time, blood loses and the radiation explosion time during the operation. A postoperative CT scan was also being performed after the operation. The CT image data was reconstructed to sagittal, coronal and axial views by the mimics 14.0 software, a blind evaluation of the position of the screws was performed by two spine surgeons who are not related with the surgery. Any penetration of the cortex in the lateral, medial, cranial or caudal directions was measured according to the Gertzbein-Robbins classification (A: no cortical violation; B: cortical breach <2 mm; C: ⩾2 mm to <4 mm; D: ⩾4 mm to <6 mm; E: ⩾6 mm)[25]. We also measured the discrepancies between the actual path and the planned trajectory in entry point deviation and angles deviation[19].

RESULTS

To conduct the animal experiment, there were two sheep involved in. Bilateral pedicle screw insertion in the lumber spine (L2-5 and L3-4) was performed with the assistance of the RSSS. The sheep's weights are 65Kg and 74kg, the surgery time for each sheep were 140min and 110min, and the blood lose are 100ml and 80ml.

According to the post-operation CT image data (Fig. 2), all 12 pedicle screw's insertion were relatively well located in the spine, there was no cortical breaches in the lateral, medial, cranial or caudal directions. All 12 screws fell into group A according to the Gertzbein-Robbins classification.

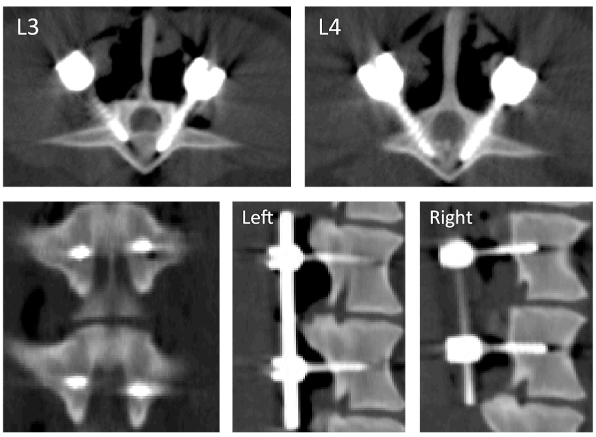


Figure 2: Post-operation computer tomography scans indicating the results of the animal study for the safety analysis.

Further evaluation of the pedicle screw placements use the method that we mentioned before was also conducted (Fig. 3). As we merged the post-operation image with the trajectory planning image together, we found that the mean entry point deviation of the screws in lateral view is 1.07±0.56mm, in axial view is 1.25±0.42mm. The mean screw deviation angles in later and axial view are 1.78±0.98°and 2.52±1.03°.

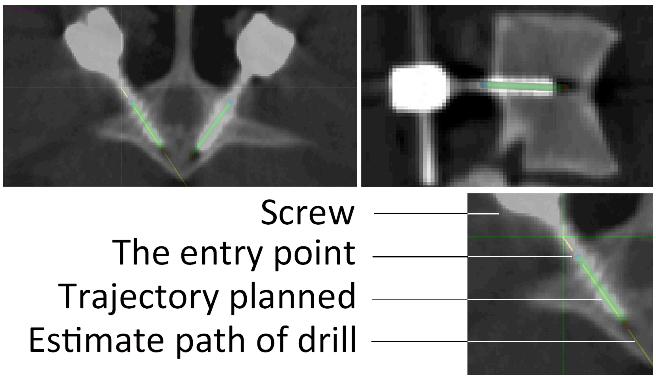
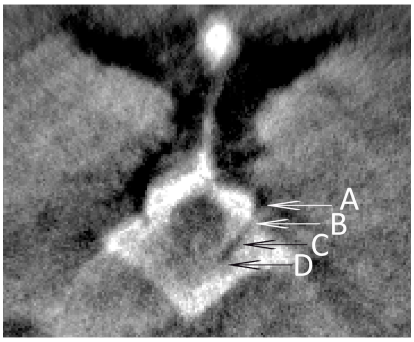


Figure 3: Screw position accuracy measurements on post-operation CT scan by merging methods.

DISCUSSION

In recent years, various methods have been introduced for improve the accuracy of pedicle screw placements in the spine. Traditional methods and navigation methods of intraoperative spinal localization both played an important role in spine surgery. However, all these methods have some disadvantages[5-11, 26], which have led to the use of robot-assist surgery.

The RSSS realized the automatically drilling by recognize the drilling states of the robot and provide vital safety and stability for the whole system. Safety and stability is the most priority issue for a medical robot, especially for an automatically drilling robot. There have been lots of solutions for safety control[27]. However, the most successful method to prevent penetration is force–based safety control[28, 29]. We set up the stage recognition system based on analysis of the force profiles; the stage recognition system can automatically stop drilling based on the thrust force threshold information (Fig. 4 and Fig. 5)[22]. The state recognition system recognized each state of the drilling device during the process successfully. In addition, although the robot can do the drilling process automatically, it also enables the surgeons to do interventions that the procedure remains under the surgeon's supervision and the surgeon cloud stop the robot in case of unexpected occasions.



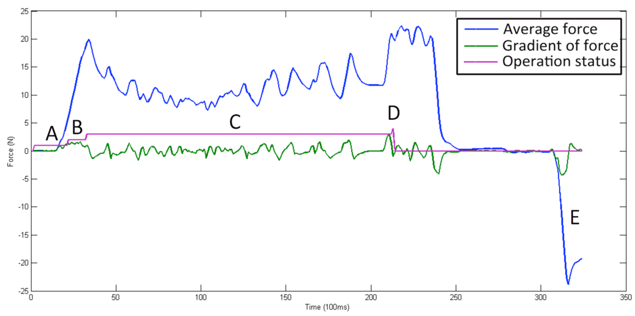


Figure. 4 and 5: The representative force signal maps of the animal study. A, Initial state, (first cortical bone remains untouched); B, Outer cortical state (an obvious force peak); C, Cancellous state (a low force level); D, Inner cortical state (the force signal began to increase) and E, Pull out state of the driller.

To validate the using of this robot system in living animals, 12 pedicle screws were inserted to two live sheep under the assist of RSSS. According to the post-operation CT, all pedicle screws fell into group A. The deviations of the entry point in lateral and axial were

1.07±0.56mm and 1.25±0.42mm, the accuracy was worse than our in vitro experiment in cadaveric sheep vertebra[22]. There are many aspects could affect the accuracy, the main aspects that cause misplacement are the total system error and the movement of the sheep.

The total system error is generated during the image reconstruction, registration and tracking process. We used the C-arm for capturing the image data, however the C-arm could also result in the image distortion, which caused by the electromagnetic fields that also generated form the C-arm[30]. This part of system error is still unsolvable whenever fluoroscopic imaging devices were still being used. The registration error is generated during the registration process. There were two registration processes during the whole surgery, one was register the animal's CT image with the animal's anatomical structure, and the other one is register the drilling device on the robotic arm to the navigation system. Point to point registration methods was limited by the physical principle: reflection. The error that introduced by reflection is inevitable. The registration and calibration error in this surgery were 0.12±0.02mm and 0.16±0.02mm. Another aspect that contributes to the total system error is from tracking system. We used the optical tracking camera that made by the NDI Company for registration and tracking processes; and the system error of the this optical tracking device is 0.30mm (supported by the NDI company). Today, all available technologies for registration and tracking have inconvenience[17], we can just minimum them.

Another reason that caused screw misplacement is the relative motion of the vertebra, which caused by respiration movement and reactive force form the drilling device. Studies reported the drilling force could be reach to 15N during the drilling process[17, 25]. However, if the cortex density is higher, the reactive drilling force could be also higher. In our experiment, the reactive drilling force is up to 30N, which result in more body shift of the vertebra. One option to solve this problem is reduction the range of motion of the related vertebra segments, which by means of additional hard ware on the spine, such as the Hover-T used in SpineAssist[31]. The other approach to eliminate this error is to use the real time registration, which have been used on SPINEBOT before[19].

Radiation exposure of patients and surgeons in the operation room is another problem that we should concern about during spinal surgery. The surgeon's experience and working style may affect the number of fluoroscopies, and long time radiation explosion will increase the malignancy rates[32, 33]. The amount of radiation exposure of C-arm is about 1,200 to 1,400 mrem/min[34], and the recommended annual limit of radiation is 2,000 to 5,000 mrem[35]. Even though the lead-vests could reduce the radiation, the risk can never be reduced to zero[35]. The radiation exposure was significantly reduced with the help from RSSS during the operation. We evaluated the radiation explosion of the sheep during the surgery. With the assist of RSSS, we only have to take one routine CT using the C-arm, and there will be no more necessary fluoroscopies.

It costs a lot of time and money to train a spine surgeon for a hospital, and all the procedures are relied on the surgeon's experience and handling skills. As the RSSS showed its ability to improve the accuracy and safety during the pedicle screw insertion, it will helpful for the young surgeons. And the learn curve may be shorted.

REFERENCES

1. Dunlap, B.J., Karaikovic, E.E., Park, H.S., Sokolowski, M.J. & Zhang, L.Q. Load sharing properties of cervical pedicle screw-rod constructs versus lateral mass screw-rod constructs. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* **19**, 803-808 (2010).

2. Savage, J.W., Limthongkul, W., Park, H.S., Zhang, L.Q. & Karaikovic, E.E. A comparison of biomechanical stability and pullout strength of two C1-C2 fixation constructs. *The spine journal : official journal of the North American Spine Society* **11**, 654-658 (2011).
3. Barnes, A.H. et al. Biomechanical pullout strength and stability of the cervical artificial pedicle screw. *Spine* **34**, E16-20 (2009).
4. Tan, S.H., Teo, E.C. & Chua, H.C. Quantitative three-dimensional anatomy of cervical, thoracic and lumbar vertebrae of Chinese Singaporeans. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* **13**, 137-146 (2004).
5. Tian, W., Liu, Y., Zheng, S. & Lv, Y. Accuracy of lower cervical pedicle screw placement with assistance of distinct navigation systems: a human cadaveric study. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* **22**, 148-155 (2013).
6. Tian, N.F. et al. Pedicle screw insertion accuracy with different assisted methods: a systematic review and meta-analysis of comparative studies. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* **20**, 846-859 (2011).
7. Devito, D.P. et al. Clinical acceptance and accuracy assessment of spinal implants guided with SpineAssist surgical robot: retrospective study. *Spine* **35**, 2109-2115 (2010).
8. Kosmopoulos, V. & Schizas, C. Pedicle screw placement accuracy: a meta-analysis. *Spine* **32**, E111-120 (2007).
9. Burch, S. Surgical complications of spinal deformity surgery. *Neurosurgery clinics of North America* **18**, 385-392 (2007).
10. Holly, L.T. & Foley, K.T. Three-dimensional fluoroscopy-guided percutaneous thoracolumbar pedicle screw placement. Technical note. *Journal of neurosurgery* **99**, 324-329 (2003).
11. Klein, S.A., Glassman, S.D., Dimar, J.R., 2nd & Voor, M.J. Evaluation of the fixation and strength of a "rescue" revision pedicle screw. *Journal of spinal disorders & techniques* **15**, 100-104 (2002).
12. Tjardes, T. et al. Image-guided spine surgery: state of the art and future directions. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* **19**, 25-45 (2010).
13. Tian, W. & Lang, Z. Placement of pedicle screws using three-dimensional fluoroscopy-based navigation in lumbar vertebrae with axial rotation. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* **19**, 1928-1935 (2010).
14. Tian, W. et al. [Study of pedicle screw placement assisted by intraoperative three-dimensional navigation in lumbar vertebrae with axial rotation]. *Zhonghua wai ke za zhi [Chinese journal of surgery]* **48**, 838-841 (2010).
15. Han, W. et al. Pedicle screw placement in the thoracic spine: a comparison study of computer-assisted navigation and conventional techniques. *Orthopedics* **33** (2010).
16. Wu, H. et al. Pedicle screw placement in the thoracic spine: a randomized comparison study of computer-assisted navigation and conventional techniques. *Chinese journal*

of traumatology = Zhonghua chuang shang za zhi / Chinese Medical Association **13**, 201-205 (2010).
17. Bertelsen, A., Melo, J., Sanchez, E. & Borro, D. A review of surgical robots for spinal interventions. *The international journal of medical robotics + computer assisted surgery : MRCAS* **9**, 407-422 (2013).
18. Shoham, M. et al. Bone-mounted miniature robot for surgical procedures: Concept and clinical applications. *Robotics and Automation, IEEE Transactions on* **19**, 893-901 (2003).
19. Kim, S., Chung, J., Yi, B.J. & Kim, Y.S. An assistive image-guided surgical robot system using O-arm fluoroscopy for pedicle screw insertion: preliminary and cadaveric study. *Neurosurgery* **67**, 1757-1767; discussion 1767 (2010).
20. Ortmaier, T., Weiss, H., Dobele, S. & Schreiber, U. Experiments on robot-assisted navigated drilling and milling of bones for pedicle screw placement. *The international journal of medical robotics + computer assisted surgery : MRCAS* **2**, 350-363 (2006).
21. Kostrzewski, S., Duff, J.M., Baur, C. & Olszewski, M. Robotic system for cervical spine surgery. *The international journal of medical robotics + computer assisted surgery : MRCAS* **8**, 184-190 (2012).
22. Tian, W. et al. A robot-assisted surgical system using a force-image control method for pedicle screw insertion. *PloS one* **9**, e86346 (2014).
23. Ying, H., Haiyang, J., Liwei, Z., Peng, Z. & Jianwei, Z. State Recognition of Pedicle Drilling With Force Sensing in a Robotic Spinal Surgical System. *Mechatronics, IEEE/ASME Transactions on* **19**, 357-365 (2014).
24. Sheng, S.R., Wang, X.Y., Xu, H.Z., Zhu, G.Q. & Zhou, Y.F. Anatomy of large animal spines and its comparison to the human spine: a systematic review. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* **19**, 46-56 (2010).
25. Pechlivanis, I. et al. Percutaneous placement of pedicle screws in the lumbar spine using a bone mounted miniature robotic system: first experiences and accuracy of screw placement. *Spine* **34**, 392-398 (2009).
26. Verma, R., Krishan, S., Haendlmayer, K. & Mohsen, A. Functional outcome of computer-assisted spinal pedicle screw placement: a systematic review and meta-analysis of 23 studies including 5,992 pedicle screws. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* **19**, 370-375 (2010).
27. Zamorano, L., Li, Q., Jain, S. & Kaur, G. Robotics in neurosurgery: state of the art and future technological challenges. *The international journal of medical robotics + computer assisted surgery : MRCAS* **1**, 7-22 (2004).
28. Wang, T. et al. Force-based control of a compact spinal milling robot. *The international journal of medical robotics + computer assisted surgery : MRCAS* **6**, 178-185 (2010).
29. Ong, F.R. & Bouazza-Marouf, K. Drilling of bone: a robust automatic method for the detection of drill bit break-through. *Proceedings of the Institution of Mechanical Engineers. Part H, Journal of engineering in medicine* **212**, 209-221 (1998).
30. L'Orsa, R., Macnab, C.J. & Tavakoli, M. Introduction to haptics for neurosurgeons. *Neurosurgery* **72 Suppl 1**, 139-153 (2013).
31. Sukovich, W., Brink-Danan, S. & Hardenbrook, M. Miniature robotic guidance for pedicle screw placement in posterior spinal fusion: early clinical experience with the

SpineAssist. *The international journal of medical robotics + computer assisted surgery : MRCAS* **2**, 114-122 (2006).
32. Mehlman, C.T. & DiPasquale, T.G. Radiation exposure to the orthopaedic surgical team during fluoroscopy: "how far away is far enough?". *Journal of orthopaedic trauma* **11**, 392-398 (1997).
33. McAfee, P.C. et al. Minimally invasive spine surgery. *Spine* **35**, S271-273 (2010).
34. Singer, G. Occupational radiation exposure to the surgeon. *The Journal of the American Academy of Orthopaedic Surgeons* **13**, 69-76 (2005).
35. Onen, M.R., Simsek, M. & Naderi, S. Robotic spine surgery: a preliminary report. *Turkish neurosurgery* **24**, 512-518 (2014).