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Validation of Robotically-Assisted System for Spinal Procedures

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Abstract for Computer Assisted Surgery Journal
This paper presents a validation method implemented in pedicle screw insertion for spinal fusion procedures, utilizing a miniature robotic system. In an instrumented dry bone spine, the entire process was examined from planning through registration to robot positioning. Comparing the resulting screw position to the planned one it was found that the robotic system had achieved an overall accuracy at tool tip better than +/-1.25mm.

Introduction

Successful application of robotic assisted surgery in active or semi-active modes requires an accurate execution of a long list of steps, such as: pre-operative 3D image handling, pre-operative planning, 2D to 3D registration, robot calibration and correct surgical tool positioning.
All the above steps should be accomplished with high accuracy and simplicity so that, for example, in the common procedure of pedicle screw insertion used in spinal fusion, the pedicle screw is positioned with greater accuracy than is achieved by the free hand of the surgeon.
This paper presents a validation process of a miniature (dimensions are 60mm height and 250 grams weight) robotically-assisted pedicle screw positioning system conducted on a carefully instrumented dry bones spine. Proposed routine verifies the overall chain starting by pre-operative planning, proceeding through intra-operative X-ray imaging and computer-based registration and finalized by guiding the robot to the predicted position and inserting the K-wire through the guiding sleeve. Numerous papers dealt with the surgical robots and the associated registration problem e.g. [1,2], but to the best of the authors' knowledge there is no standard for validation of robotically-assisted orthopedic procedures before in-vivo clinical trials. We believe that the method suggested here is one way to approach this issue.

Materials and Methods

In this investigation, we applied a miniature robotic system to perform pedicle screw positioning in a series of dry bones experiments. Pre-operatively the surgeon plans the surgery on a CT data by manipulating the screws to the preferred locations. Intra-operatively, a clamp is mounted onto the bone (spinous process). Then special X-ray opaque passive targets are attached to the clamp and fluoroscopic images, containing both the targets and the vertebra, are taken from one or several directions. These 2D images are processed and registered to each other and to the pre-operative 3D model of vertebra derived from CT images, yielding the assessment of the desired drilling axes location respective to the clamp coordinate system. The passive target is then detached from the clamp and replaced by robot that performs targeting of the guiding sleeve to be co-axial with registered pre-planned drill line.
In order to verify the accuracy of this procedure, a special test was conducted in which the accuracy was assessed for each separate step and the overall procedure as a whole.
A special translucent "jig" was constructed that included an accurately machined frame to which dry lumbar spine was rigidly affixed. The frame was equipped with X-Ray opaque spheres implanted at known locations that can be detected by the imaging devices and constitute the jig's coordinate system. In addition the jig was equipped with a moveable rigid beam, that can be positioned at several known accurate locations relative to the jig, and to which either a passive X-ray targets or miniature robot directing the guiding sleeve are fixed.
Special fiducial holes were drilled by an expert surgeon through the pedicles of the dry bones vertebrae. For better visualization on a CT images, these holes were filled with removable X-Ray opaque fiducial pins.
Then the following step-by-step validation process was conducted:

1. Two sets of CT data were acquired: one with and another without fiducial pins inserted. Special means were applied to ensure same position of jig relative to CT machine for both acquisitions.

2. Centers of the visible cross-sections of X-Ray opaque spheres attached to jig, and centers of the visible cross-sections of fiducial pins were accurately located on CT images and used to derive the location of fiducial drillings respective to jig coordinates.
3. In the planning phase the surgeon determined the drilling line along the axis of the clearly visible filled hole on three cross section views of the vertebra.
4. Passive targets were attached to the beam, and the jig was subjected to fluoroscopic imaging from two views.
5. Registration of the 2D fluoroscopic images containing both the target and the vertebra to the 3D CT model was performed. As a result, the coordinates of the planned drill axis were transformed into the coordinate system of the beam.
6. The robot was then attached to the beam and aligned its end-effector to the desired drill line resulted from registration process. To verify the position accuracy K-wire was inserted through the guiding sleeve in the attempt to hit the fiducial drills in the pedicle.

Validation of the planning module and registration module was performed separately and independently by comparing the numerical results delivered by each component, to the same parameters derived directly from the CT images upon stage 2 and the known geometry of the jig. Then, the overall accuracy was calculated assuming errors of each part statistically independent. Finally, the accuracy and robustness of the overall procedure was tested by measuring the discrepancy between the K-wire inserted through the robot's sleeve and the actual axis of pre-drilled fiducial hole.

Discussion

Planning module was validated by pixel-based comparison of the planned screw axis overlaid on the CT data to the axis of fiducial pin inserted into the pre-drilled hole. It was found that this planning method resulted in an error of up to 0.3mm.
Registration module was validated by comparing parameters of the drilling axis in the beam coordinate system, assessed as a result of registration (validation step 5) with respect to the same parameters obtained upon validation of stage 2 with respect to the jig coordinates, and transformed into the beam coordinates utilizing its known position relative the jig. Deviations of the two lines within the pedicle were found to be within 0.9mm.
Robot module: The robot structure and performances are described in Shoham et al [3]. The accuracy was checked in the entire robot work volume by CMM machine and found to be better than 0.5mm.
Beam assembly: In the experiments we used a sufficiently rigid construction to support the robot relative to the bone. However, in actual operation one should account also for the actual clamp-bone rigidity. Numerous experiments have been conducted to identify the bone-clamp attachment strength and rigidity. Some of these results reported in Wolf et al [4] and other experiments with insertion forces applied to K-wire resulted in deviation at the entry point of up to 0.2mm.
Derived Overall Accuracy: Assuming independent sources of error, the total error resulted from planning, registration, robot and clamp stability calculated to be 1.1mm.
Direct Measurement of the Overall Accuracy was performed by attaching small plastic pipes to the entrance of pre-drilled fiducial holes and attempting to hit the inner gap of the pipe with the 2.5mm K-wire guided by the robotic system. By

moving the supporting beam into different fixed positions machined on the jig and targeting the robot to different fiducial holes we managed to carry 25 independent tests. When the inner diameter of the pipe was set to 5mm the insertion was successful in all 25 cases thus achieving an overall accuracy of better than +/- 1.25 mm.

Conclusions

In this paper we presented a validation method applied to the robotic-assisted pedicle screw insertion procedures.

Utilizing a dedicated jig and fiducial inserts, we have assessed and learned both the error contribution of each component of the chain – from planning through registration to robot positioning, as well as the overall system accuracy.

It was proven by 25 independent tests that the robotic system had achieved an overall accuracy better than +/-1.25mm at tool tip which is consistent with the evaluation of the overall accuracy calculated by the accuracy of each separate component.

The proposed method, applied here for validation of the pedicle screw guiding system, can be extended, as well to similar robot-assisted orthopedic surgery.

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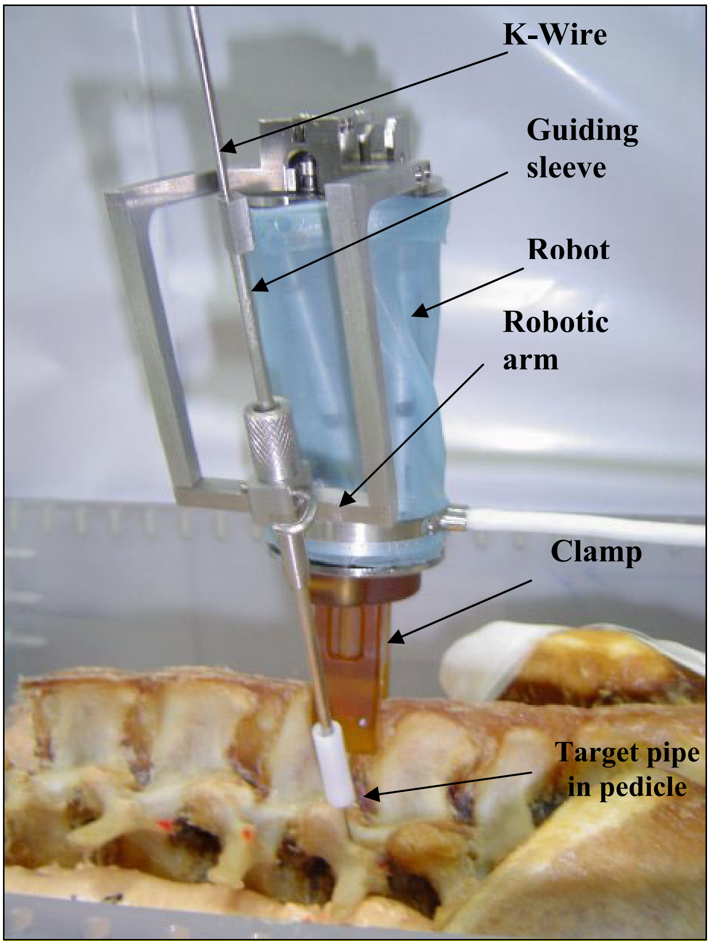

Mazor's SpineAssist miniature robot guides a K-wire into a pipe located along the axis of a drilled-hole in a pedicle.