Smart mechatronic driver for surgical trajectory navigation

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Abstract: The aim of trajectory navigation is to position a surgical instrument along a planned trajectory. Computer assisted navigation systems show maximal flexibility but are limited by the costs and accuracy of the used optical tracking system and the human errors during free-hand navigation. Robotic devices can reach highest accuracy but are expensive and potentially safety critical due to active electric components being close to the patient. The novel concept of a smart mechatronic driver may reach the same accuracy as using robotic systems but without active components being attached to the patient. To achieve this, the kinematic structure of the positioning device is build from pure mechanical components and a handheld smart mechatronic driver is used to adjust the device to reach the planned position. After rigidly attaching a reference platform containing x-ray opaque markers to the anatomy an image based planning has to be done to define the desired trajectory. The system then automatically calculates the necessary adjustments of the positioning device. The surgeon can then use the smart mechatronic driver as an intelligent electric screwdriver which knows how to adjust each axis. This concept has been implemented for pedicle screw placement and drilling of the guidance pin for hip resurfacing. First evaluations show that higher accuracy can be achieved in comparison to the use of optically tracked free-hand navigation.

1 Background

The introduction of computer-assisted navigation systems has led to a higher accuracy and less invasiveness of many orthopaedic, trauma and neurosurgical applications. These systems, which are generally based on optical tracking systems and information from preoperative CT-Data, intraoperative calibrated x-ray images or deformable statistical models, enable a three-dimensional planning and navigation of the envisioned intervention. During navigation, the surgeon is supported by a real-time feedback representing the position and orientation of the surgical tool in relation to the anatomy.

One of the first applications, computer assisted navigation has been introduced into, is the transpedicular instrumentation of vertebral bodies. Drilling close to sensitive structures (e.g. spinal cord) requires maximum precision to avoid the risk of perforation. Therefore, in the conventional procedure a huge number of intraoperative x-ray images are acquired resulting in high radiation exposure to the patient and the OR-team. However, despite using multi-planar x-ray images there are a huge number of perforations due to the missing three-dimensional information. The impact of navigation to this procedure was shown by Kosmopoulous and Schizas, who performed a meta-analysis of 130 ex-vivo and in-vivo studies on pedicle screw placement and showed a higher median accuracy of 95.2% in the navigated vs. 90.3% in the conventional group [KS07]. In addition, Grützner et al. showed in a clinical study, that by using 2D or 3D image based navigation the radiation dose could be reduced by 40% -70% [Gr03]. While the time for implantation of a pedicle screw according to studies from Schlenzka et al. and Arand et al. is significantly increased (5-10 min) using computer-assisted techniques due to registration and matching, a comparison of the overall operation time shows no significant differences (184 vs. 177 min resp. 105 vs. 92 min). [Sc00, Ar01]

Despite the aforementioned improvements the primarily used optical tracking systems suffer from inherent problems like limited system accuracy or an interrupted line-of-sight. Furthermore, human factors may influence accuracy during free-hand navigated implantations. Reproducible higher accuracy and thereby higher safety for the patient can be achieved by using a robotic assistance device aligning a drill sleeve based on the planning information gathered from a computed tomography [Su06]. The deviation of implanted screws, performed with the robotic SpineAssist System (Mazor Surgical Technologies, Israel), to the planned position was shown to be below 0.87 ± 0.63 mm [To07].

However, for pedicle screw implantations as well as for many other applications (e.g. the navigated drilling of the guidance-pin of hip resurfacing implants) only simple trajectory navigation has to be performed. The question arises, whether for simple trajectory navigation tasks the use of expensive navigation or robot systems is required or, if similar to stereotactic surgery, simple mechanical devices can be used instead.

2 Concept of a smart mechatronic driver for trajectory navigation

The aim of trajectory navigation is to guide an instrument (e.g. a drill) along a planned trajectory. Stereotactic frames, which are rigidly mounted to the patient, can be adjusted following a CT-based planning to position a guiding sleeve. These frames known from neurosurgery are huge and inflexible and therefore not suitable for pedicle screw or hip resurfacing implantation.

The concept of the novel smart mechatronic driver (SMD) for trajectory navigation combines the advantages of flexible intraoperative fluoroscopic navigation with the accuracy of a robotic assistance device. The high costs of robotic systems, the time-consuming sterile draping and the demanding safety concerns due to active electric components close to the patient will be countered by separating the mechanical positioning device and the actuator. This allows for the use of only one handheld actuator for the adjustment of each single axis.

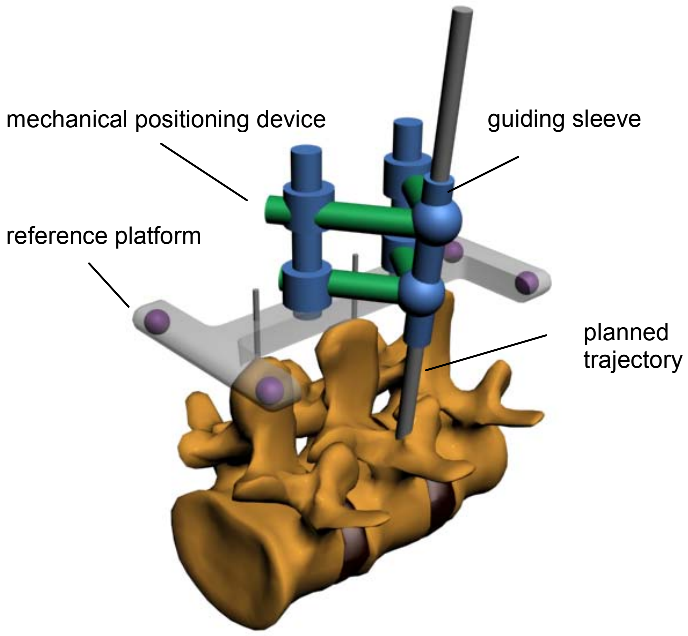


Figure 1: Reference platform rigidly fixed to the spine and the mechanical positioning device holding the guiding sleeve.

Using this system, the first step is to rigidly fix a reference platform percutaneously to the anatomy (see Figure 1). Following, an x-ray opaque registration object, which also may be integrated into the reference platform, has to be mounted to the platform. At least two multiplanar x-ray images have to be acquired containing the anatomy as well as the registration markers. Using the known marker positions of the registration object and the projected positions, the relative position of the images can be calculated. Now, the desired trajectory can be planned and its coordinates will be calculated within the coordinate system of the reference platform.

The mechanical positioning device, which can be mounted to the reference platform at a defined position, has to be adjusted to align the guiding sleeve with the planned trajectory. Based on the planned trajectory position, the required adjustment parameters for the adjusting device are determined by the system. A manual adjustment of this device is possible, but it would be either time consuming using micrometer screws or it would have a limited accuracy.

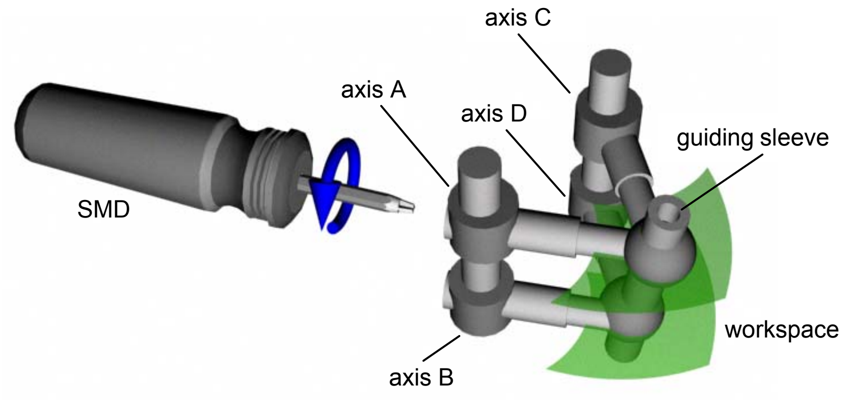


Figure 2: Concept of the smart mechatronic driver (SMD) adjusting the different axes of the mechanical positioning device to align the guiding sleeve with the planning data.

To reach maximum positioning accuracy with minimal time effort, a smart mechatronic driver has been developed (see Figure 2). It features one active drive unit and a sensorized coupling for the indentification and the connection to the respective axes of the mechanical positioning device.

After trajectory planning, the SMD receives the necessary information from the planning system (number of revolutions and sub-revolutions) to adjust each axis of the positioning device. For the adjustment of the hand-held positioning device, the surgeon has just to connect the SMD to its different axes. The SMD will perform the necessary revolutions automatically, allowing the system to be used as simple as an intelligent wireless electric screwdriver. After adjusting all axes of the positioning device and thereby aligning the guiding sleeve with the planned trajectory, the surgeon can mount it on the reference platform and insert the drill into the guiding sleeve.

3 Material and Methods

The SMD concept has been realized so far for two applications – the drilling of the guiding pin for hip resurfacing and for pedicle screw insertion for transpedicular spine fusions.

Exemplary shown in Figure 3 for hip resurfacing, the fixation device is rigidly clamped to the femoral head and a registration body is mounted on. At this first prototype the registration markers are not integrated into the fixation device. Two x-ray images were taken in which the size, position and orientation of the femoral hip-resurfacing implant can be planned in 3D. Figure 4 shows the mechanical positioning device used for hip resurfacing. The necessary 4-DoF are provided by two rotational and two linear axes.

First trials were performed with this system to evaluate the feasibility and accuracy. Simulating the drilling of the guidance pin for a hip resurfacing implant, different holes were drilled into a foam model. Entry points (N=16) as well as orientation (N=8) of the trajectory were varied.

To determine the accuracy of the system, two perpendicular calibrated x-ray images of the foam block were taken. The coordinates of the drilled holes (Ø 3.2mm) were extracted from these pictures and compared to the planned trajectory concerning positioning and angular accuracy.

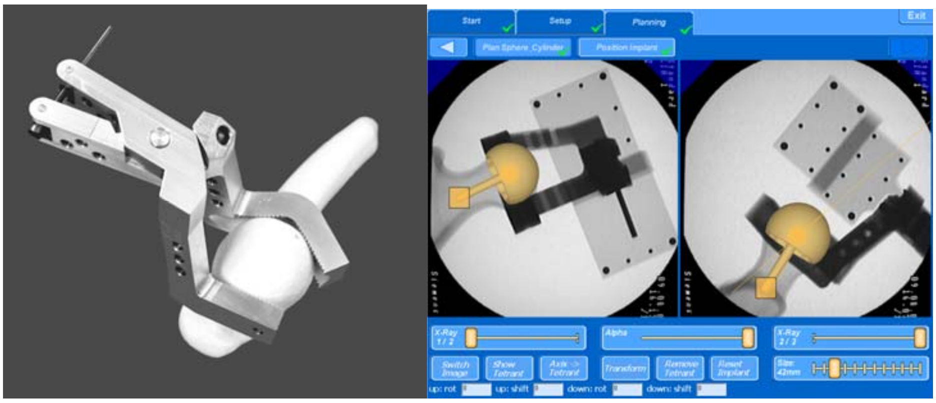


Figure 3: (left) minimally invasive fixation and reference device for hip resurfacing, (right) image based registration and 3D planning of the desired implant position

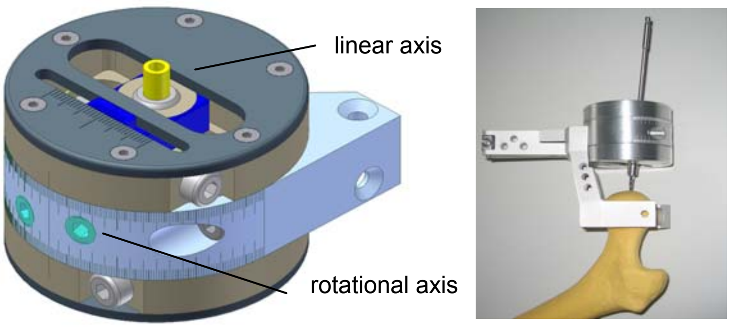
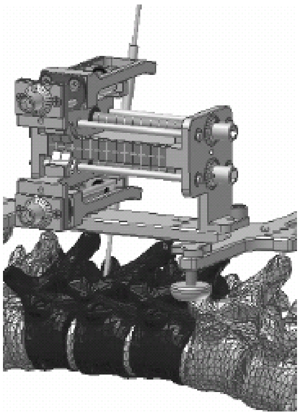


Figure 4: Mechanical positioning device for drilling of the guidance pin for hip resurfacing



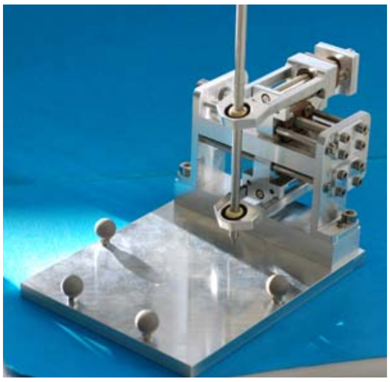


Figure 5: (left) concept of mechanical positioning device for pedicle screw placement, (right) realized device fixed on a platform for accuracy evaluations

Figure 5 (left) shows the design of the mechanical positioning device for pedicle screw placement fixed on a minimally invasive reference platform.

Preliminary Results

Initially, the accuracy of the hip resurfacing positioning device was determined at different entry points of the trajectory for parallel trajectories equally distributed in the entire workspace of the manually adjusted mechanical positioning device. The mean positioning accuracy was 0.46 mm (max. 0.93 mm), the mean angular accuracy 0.65° (max. 1.0°). Changing the orientation of the trajectory to maximum angles of the device, the mean positioning accuracy amounted to 0.48 mm (max. 1.09 mm) and the mean angular accuracy to 1.03° (max. 1.75°).

5 Discussion

It could be shown that for a reproducible and exact navigation of trajectories neither tracking systems nor complex and expensive robot systems are necessary. The order of magnitude of the preliminary achieved accuracy also reveals, that using the SMD approach may lead to better results than systems based on optical tracking.

The main advantages of the SMD approach in comparison to robot systems are the lower costs, as only one actuator is necessary, adaptable to different kinematic structures having several degrees of freedom. Since the actuator is not integrated into the positioning device, there is more available space and the actuator can be powerful for a quick adjustment of the axes. Furthermore, the intraoperative safety concept and the approval of this system are easier, as no active electric components will be in contact or close to the patient, because the positioning device will be adjusted in a hand-held position. In addition the hand-held adjustment avoids collision problems with the anatomy.

Generally, the navigation of trajectories can help to reduce the invasiveness of surgical procedures like the percutaneous fixation of the reference platform to the bone, as it is envisioned for the insertion of pedicle screws.

When using the SMD system the surgeon may confound the different links, leading to a wrong adjustment of the device. This could be avoided, when either using different mechanically coded connectors or integration of sensors like RFID into the tool tip, identifying the axes.

Besides the presented planning based on 2D x-ray images, a planning based on intraoperative fluoroscopic 3D datasets could be possible requiring the development of adequate reference bodies and algorithms. Further technical and usability evaluations of the system, especially for pedicle screw placement, are parts of ongoing work.

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