Development of a robotic system for spinal surgery

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Streszczenie

Kręgosłup człowieka składa się z 24 ruchomych i 9 połączonych kręgów. Ważne elementy układu nerwowego znajdują się we wnętrzu otworu kręgowego osłoniętego przez otaczającą go kość. W wyniku wypadków lub chorób mogą się pojawić schorzenia, które muszą być leczone chirurgicznie. Ze względu na dużą gęstość ważnych tkanek w tym rejonie, takich jak układ nerwowy lub krwionośny, powodzenie operacji zależy w dużym stopniu od dokładności, z jaką może być ona przeprowadzona. W obecnie używanych metodach manualnych duże znaczenie ma doświadczenie i dyspozycja chirurga.

Aby rozwiązać te problemy opracowano nowy system zrobotyzowany do operacji kręgosłupa. Składa się on z mechanizmu robota pozycjonowanego za pomocą struktury pasywnej, optycznego systemu pomiarowego, urządzenia wejściowego, identyfikacji położenia operowanych kręgów, algorytmów i oprogramowania do planowania operacji i nawigacji. System został przebadany na denatach z udziałem chirurga, osiągając bardzo dobre rezultaty. Omówiono wyniki badań, zaproponowano możliwości dalszych ulepszeń i inne zastosowania systemu.

Introduction

The adult human mobile spine consists of 24 articulated vertebrae and the adult non-mobile spine is made up of 9 fused vertebrae. Critical neural structures lie inside the spinal canal, protected by the surrounding bone. The spinal cord extends from the skull base to the junction of the first and second lumbar vertebrae, and the remainder of the spinal canal contains the nerves of the cauda equina. Trauma or certain disease processes destroying the protective bony spine may result in catastrophic neurologic problems, therefore much of spinal surgery focuses on restoring the stability and protective capacity of the vertebral column. This involves the placement of metal implants for restoration of mechanical stability of the spine.

Spinal stabilization frequently entails placement of pedicle screws within the vertebrae. One of the challenges is to optimize screw placement into an anatomical structure (ie the pedicle) which is not directly visible to the surgeon. Mechanical efficiency of the fixation construct depends to a large extent on optimal screw placement. Avoidance of iatrogenic

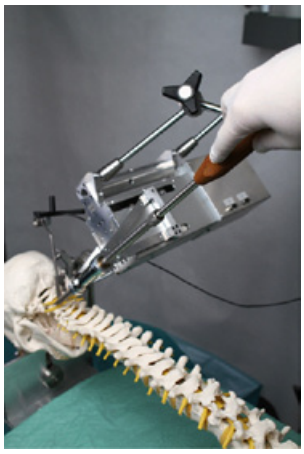

Figure: Elements of the system for spine surgery: M- marker of the optical tracking system, R- robot, PS- arms of the passive structure

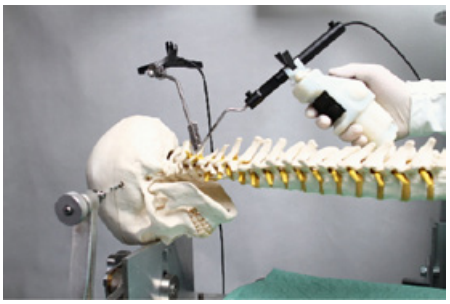

Figure : Surgical Input device used for patient registration

complications related to the neural structures and adjacent vascular structures also depends to a large extent on optimal screw placement. Therefore spinal fixation remains a challenging and often high risk procedure, particularly so in the cervical spine

With standard freehand techniques, the screw trajectory is judged visually based on pre-operative imaging and on the surgeon's experience and anatomic knowledge [1]. Fluoroscopic images may be taken to verify the precision of the chosen trajectory. Such techniques require access to widely available spinal instrumentation systems, with no requirement for additional equipment. Therefore the technique relies heavily on the surgeon's experience and can be subject to human error. Precision is also an issue as the fluoroscopic images provide limited information. The technical challenge requires good manual skills and coordination and the ability to mentally visualize in 3D the surrounding anatomy. Due to these technical challenges, a screw misplacement rate in the spine of 30-50% has been reported [2].

Navigation systems already exist which measure the position of surgical instruments and patient position in the operating room. From the extensive research in state of the art spine surgery a clear answer to where and when navigation technology should be used remains elusive [2]. Due to improved accuracy of image-guided procedures over freehand techniques, the capacity for screw placement in all parts of the spine (e.g. cervical) is enhanced. However, image-guided spinal surgeries are still done with freehand technique, albeit aided by image guidance. Tracked instruments are still subject to inherent inaccuracies because of human constraints as such manual precision can be subject to human variability. This technique is demanding on the surgeon as he needs to coordinate real-world surgery with virtual surgical planning on the screen. Inherent errors, if they occur, may be significant, and for this reason staff training is important. Despite thorough verification of the registration accuracy, problems are common. Accuracy indicators in the operating room do not necessarily reflect absolute precision and can be misleading [3, 4].

Few attempts have been made to introduce robotic systems in spinal surgeries. A Miro robotic system for general medical applications was developed by the German Aerospace Center DLR. It is designed for surgical telemanipulation with extended software support. The robotic part of the system consists of three, 7-degrees-of-freedom, lightweight robotic arms [5]. In the proposed set-up for the spine surgery the robot hold directly the driller and is navigated by surgeon using impedance control and taking into account pre-operative planning.

The Mazor SpineAssist robotic system for spine surgery consists of a compact, 6-degrees-of-freedom, robot attached to the spine with a base platform and a work station for planning and navigation [6]. The system can be used only in the lower spine, where the margin for error is much greater. Registration is based on matching between pre-operative CT scans and intra-operative fluoroscopic images acquired with a calibrated C-arm. In the next step, the robot, moves to the calculated spatial position and the surgeon performs surgery via the tool guide. During the intervention the robot acts as a tool holder (passive guidance). The system was tested with good results [7].

Other developments in robotized spine surgery involve: the Cooperative Robotic Assistant [8], Spinebot [9] and Universal Prismatic Spherical Robot but none of them provides a complete solution for spine surgery planning and execution with the capacity to place implants in the whole spine.

In this paper the design of a robotic system using upper cervical spine surgery as a test model is described. Compared with above mentioned systems it has several advantages. Robotic assistance addresses the issues of handheld techniques. This compact robot is held by a passive supporting structure and the design of this kinematic chain is adapted for operating in the cervical spine with capability for use throughout the whole spine. The system uses standard commercially available surgical instruments. Screw trajectory is defined by the robot based on surgical planning, but the drilling and implant insertion is performed by the surgeon so that he has direct

visual and tactile feedback. The system incorporates a new surgical input device, intended for use directly from the sterile field, with an adapted user interface for ease of use in the operating room.

Surgery workflow and system elements

The system consists of a compact robot positioned over the patient by a passive supporting structure. There is also an optical tracking system, surgical input device and workstation with software for planning and navigation. The system elements are shown in figure 1. Preoperative surgical planning is performed defining optimal screw trajectories. Following surgical exposure, individual vertebral registration is carried out. Approximate robot positioning is manually done by the surgeon after unlocking the passive structure. The surgeon displaces the passive structure holding the robotic device so that the screw trajectory lies within the robot's workspace. At this this point the robot starts to automatically follow pre-planned trajectory. The passive structure is now locked in position. Kirschner wire placement and screw placement are performed through the instrument guide.

A robot with four degrees of freedom was developed for the surgical system. It has two moving arms, rigid and flexible, connected with a drill guide holder which creates a parallel kinematic chain (ref. Figure 1). Combining arms translations in plane perpendicular to the trocar axis, two rotations and two translations of the drill guide holder are achieved. The kinematic chain is mechanically irreversible which is favourable for the security during power cut. Mechanical play in the system was countered in a whole chain. For control and optimization, robot kinematic and dynamic models were defined. Tests were done to ensure robot rigidity and necessary adjustments were carried out. In the experimental setup, a separate robot control device was connected by Ethernet to the workstation running navigation software.

The robot is positioned using the passive supporting structure which has a workspace sufficiently generous to attain the required position in space needed during surgeries. The passive structure can be adapted for use in different surgeries, e.g. ENT. As a result, the robot can be used on bilaterally and at multiple spinal levels which is often required in spine surgeries.

The system uses an optical tracking system which consists of a camera, sterilisable active markers and a pointer. Markers are attached to the robot and the vertebra to be navigated. The pointer can be used to define point coordinates in space. The marker's position and rotation have a certain measurement noise affecting accuracy on the vertebrae.

In the operating room surgeon needs to interact with the system in an intuitive and efficient manner. A new surgical input device was developed for this purpose and is shown in figure 3. It is a wireless joystick which has buttons, a switch and a trackball. It has accelerometers and a gyroscope and can be integrated into a trackable pointing instrument. Buttons have assignable functions which are activated depending on context of the application. For example to define a point during patient registration or to control the robots position with accelerometers etc. User can select one of the modes with a button. The trackball is used to adjust the 3 dimensional viewer of the navigation software. The input device has a fixation for attaching the pointer of the trackable pointing instrument.

The navigation software assists the surgeon in the operating room. It's workflow is adapted to the surgery. It controls all devices of the system. Navigation software implements registration algorithms. The surgeon can verify accuracy of tracking and registration by correlating the virtual and real world. A central part of the user interface is a 3 dimensional viewer where the target anatomy, the robot, the trackable pointing instrument and markers are rendered in real time.

Experiments

Six cadaver experiments to test the system were done at department of anatomy of the University Hospital of Lausanne CHUV, Switzerland, in collaboration with the department of neurosurgery. The entire system was assembled to closely approximate operating room conditions. An experienced neurosurgeon did the planning and carried out the cadaver tests. As a surgical model to test the feasibility of the system, placement of transarticular C1/C2 screws was chosen as one of the most technically demanding, and requiring a very high precision. The rationale behind this being, that if the robotic device were sufficiently precise for this technique, it would meet or exceed the need for precision of implant placement throughout the rest of the spine.

Following the cadaver tests, results were documented on post-implantation CT scans. Measure of screw placement error is composed of a translational and a rotational part. Translational error is the distance between the axis of the placed screw and planned trajectory at the pars (isthmus) of the C2, the zone of highest risk in C2 instrumentation. Rotational error is the angle between the placed screw and the planned trajectory. Results are shown in table 1. Significant errors of screw 2 placement in experiment III and IV were due to "minor" drill slippage at the entry point on the vertebrae where there is an oblique angle between the bone surface and the drill trajectory. This issue was resolved by adapting drilling technique.

The purpose of these experiments was to verify the system concept and identify potential sources of error. Several improvements were sequentially implemented throughout the experiments.

Standard manual surgical technique was adapted for this application. Several modifications were developed in order to avoid drill slippage on the surface of the vertebrae and K-wire bending before reaching the bone.

Results

Accuracy of the screw placement in six cadaver experiments is shown in table 1. The mean translational error is 1.94 [mm] and mean rotational error is 4.35° (excluding solved problems with drill slippage). These errors are comparable to clinical results using a standard handheld technique according to our experience. The experiments enabled to identify several sources of error which have been since amended. In last experiment, in which all mentioned improvements were implemented in the system, very high accuracy was attained (0.41 [mm] and 2.56°, ref. experiment VI in Table 1). Further cadaver testing is planes to validate our preliminary results.

Conclusions and Future Work

This paper presents a development and a feasibility study of a robotic system for cervical spine surgery. The experiments showed that it can be used in this type of surgery. "Surgery" done with the proposed system does not appear to take more time for the procedure in comparison with standard image guided freehand techniques.

Additional research among surgeons was performed in the goal of discovering their specific needs in the context of spine surgeries. The results have shown that apart from issues with screw implant precision, surgeons are concerned about X-Ray exposure of the medical staff. In the operating room many intra-operative images are taken in order to verify precision which leads to a very high radiation doses. They confirm that system should work on the whole spine and should assist principally in placing screw-based implants. Use of non-cannulated tools and pedicle probe is preferred to solutions involving K-wire due to bending effect on the sides of cortical bone. Apparently there are many problems linked to currently used navigation techniques. In some cases big errors appear caused by a detaching marker frame from the vertebrae. During multi-level operations, when many vertebrae are operated, repeating registration for each vertebra is not practical. For this reason surgeons place implants on many levels while tracking only one which at least demands additional precision verification techniques that are not present. Currently the surgical workflow contains many laborious tasks (e.g. pre-operative PC-based planning, registration, fluoroscopic verification). These would be removed by introducing precise systems (no need for fluoroscopic verification), automatic registration and intra-operative planning.

Potential advantages of the proposed system include improved precision of spinal implant placement, improved patient and surgeon security with a reduction of inbuilt errors, possible reduction in surgical experience needed to safely perform such procedures. Undoubtedly, success at the craniocervical junction (ie first and second cervical vertebrae) with precise implant placement would indicate that similar techniques and methods could be applied at other spinal levels in the thoracic and lumbar areas.

Some limitations exist in the proposed system. Even though each part of the system was tested together and separately for feasibility purposes it needs validation of reproducibility of accuracy with further cadaver experiments superior to that described in the current literature. Ex-vivo experiments had been conducted and proved that needed accuracy can be achieved. Ultimately sterile draping of the robotic device and the adjacent passive structure will need to be envisaged prior to any clinical testing.

Table: Accuracy of the screw placement in the six cadaver experiments done with the proposed system

Experiment	Screw	Translational error [mm]	Rotational error [°]
I	1	3,47	8,92
II	1	1,36	4,19
III	1	1,81	6,6
	2	5,14	8,33
IV	1	2,42	4,25
	2	6,19	4,97
V	1	2,4	2,37
	2	1,95	3,6
VI	1	1,68	2,31
	2	0,41	2,56

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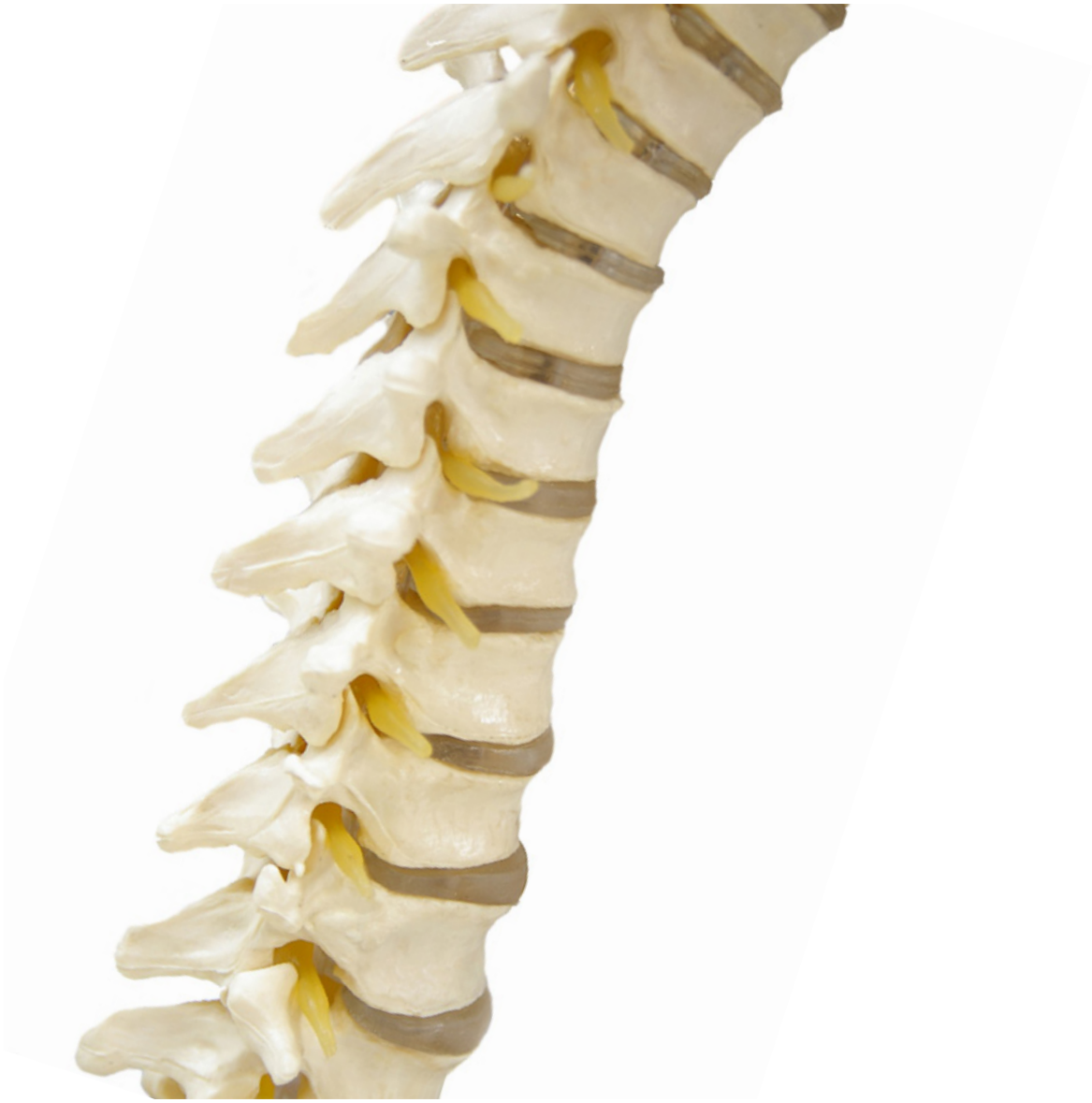

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