DEVELOPMENT OF CT BASED INTERVENTIONAL RADIOLOGY TELEMANIPULATOR SYSTEM FOR SPECIFIC SPINE PROCEDURES

Victor Cesar Vargas Silveira Cunha-Cruz
Helmholtz-Institute for Biomedical Engineering / RWTH Aachen University - Chair of Medical Engineering
Pauwelsstrasse 20, D-52074 Aachen, Germany
viccesar@hia.rwth-aachen.de

Ting Wu
Helmholtz-Institute for Biomedical Engineering / RWTH Aachen University - Chair of Medical Engineering

Stefanos Serefoglou
Helmholtz-Institute for Biomedical Engineering / RWTH Aachen University - Chair of Medical Engineering

Robert Elfring
Helmholtz-Institute for Biomedical Engineering / RWTH Aachen University - Chair of Medical Engineering

Philipp Bruners
Helmholtz-Institute for Biomedical Engineering / RWTH Aachen University - Chair of Applied Medical Engineering
RWTH Aachen University Hospital – Department of Diagnostic Radiology

Andreas Mahnken
Helmholtz-Institute for Biomedical Engineering / RWTH Aachen University - Chair of Applied Medical Engineering
RWTH Aachen University Hospital – Department of Diagnostic Radiology

Klaus Radermacher
Helmholtz-Institute for Biomedical Engineering / RWTH Aachen University - Chair of Medical Engineering

Abstract. *Spine disorders affect many people all around the world. Diverse types of diagnostic and therapeutic procedures have been developed in order to relieve or heal such disorders. Procedures such as discography, bone biopsy, vertebroplasty/ kyphoplasty and radiofrequency ablation have in common the use of needle-like instruments to pin point in the spine region, which requires a previous planning using radiological images or intraoperative images, good hand-eye-coordination of the medical staff and precise tracking of the needle tip position, all in order to avoid damage of important and delicate structures in the spine area. In this paper a robotic-based telemanipulator is presented as a new option for the accomplishment of spine interventions using Computer Tomography Scan (CT Scan). Previous attempts to manipulate a needle for a general purpose procedure, mainly for soft tissues and without force feedback for the medical staff, who controls the manipulator with a joystick-like device. Our system consists of the following modules: master device, planning unit, tracking unit, robot unit, instrument module and control unit. Preliminary tests have been performed with components of previous projects of our institute in order to determine the feasibility of such system and its constraints. The discussion of these issues are presented, such as hardware and programming tasks.*

Keywords*: interventional radiology, medical robotics, telemanipulator, spine*

1. INTRODUCTION

Spine disorders affect many people all around the world. Diverse types of diagnostic and therapeutic procedures have been developed in order to relieve or heal such disorders. In the long history of surgery it always has been a basic principle to restrict the iatrogenic trauma done to a patient during surgery to a minimum (Mayer 2006). One of the main goals of Minimally Invasive Spine Surgery (MISS) is to do an efficient "target surgery" with a minimum of iatrogenic trauma. Thus, either the "access surgery" or the "target surgery" itself can be minimally invasive. The majority of minimally invasive techniques in spine surgery refer to the access and not to what is done in the target region. However, the surgical strategy depends on the localization and patho-anatomy of the region or structure which has to be treated. They determine the access, as well as the target strategy. The use of tracking systems is also an additional tool to achieve the target location.

Procedures such as discography, bone biopsy, vertebroplasty/ kyphoplasty and radiofrequency ablation have in common the use of needle-like instruments to pin point in the spine region, which requires a previous planning using radiological images or intraoperative images, good hand-eye-coordination of the medical staff and precise tracking of the needle tip position, all this in order to avoid damage of important and delicate structures.

In this paper we present the issues related with such medical procedures and their requirements. As a solution for the performance of these issues, we propose the use of a modular CT based telemanipulator system. For such procedures, precision in the placement and orientation of needles are important factors. With the use of a telemanipulator the interaction of physician-patient is lost. In order to overcome such problem, our telemanipulator searches to give a force feedback of the interaction of patient-needle for the physician, that can response to environment changes without the need of a new image exposure. A telemanipulator system reduces the need of the many displacements of patient during the procedure, inside and outside the CT scan.

2. MEDICAL BACKGROUND AND RELATED ISSUES

Semi-invasive and interventional procedures for treatment of painful spinal disorders have become increasingly popular since the 1990s (Schaeufele 2006). This is due not only to the better understanding of the pathophysiology of spinal pain and the ability to specifically identify and target painful structures with percutaneous procedures, but also because of advances in imaging technology. Similar to developments in other areas of medicine, there is an increasing demand for less invasive, outpatient procedures to alleviate patient pain. Many of these procedures allow a patient to return to his full function with minimal downtime.

The spine as the central “axis” organ can be reached from different entrances (Mayer 2006). The surgical entrance (skin incision) must be determined by the topography of the target and the access anatomy. It should be adequately placed and should have an adequate (smallest possible) size. Cosmetic aspects should also be considered (e.g., skin incision follows skin lines).

The surgical route to the target area should be the least traumatic, i.e., it should strictly follow anatomical pathways such as preformed spaces or, if this is not possible for the whole skin-target distance, it should be performed with a minimum of collateral damage to surrounding tissues. If collateral damage cannot be avoided, it should be reparable and have a negligible effect on the clinical outcome. The needle positioning and orientation precisions have an important role for such interventions. The experience and skills of the physician usually help the success of the procedure.

Positioning of the patient can strongly influence the minimally invasive exposure as well as the target surgery: lateral positioning for the access to lumbar levels L2-4 for anterior lumbar interbody fusion which eases the access to the spine even in obese patients or the knee-chest position of patients for lumbar discectomy or decompression procedures which leads to a pressure release in the epidural venous (Mayer2006). Skin incisions are supposed to be small in MISS. This implies an adequate localization as referred to the target area.

The advances in MISS are due to development of needle-based procedures along the years.

2.1. Medical procedures

In order to specify our systems parameters and also to justify the use of a new methodology, current interventional radiological procedures were studied. They are shortly described below.

2.1.1. Discography

This is a gold standard diagnostic procedure. It is an invasive diagnostic procedure that involves, under radiological guidance, the puncturing of a disc for the instillation of iodinated contrast into the nucleus pulposus. This procedure provides direct radiographic information concerning the nuclear morphological features and the integrity of the vertebral endplates and anulus (Tomecek *et al.* 2002). Discography is operator dependent and requires significant experience on the operator’s part (Schaeufele 2006). It is indicated for the evaluation and analysis of the nucleus pulposus and anular rings, disc nociception, asymmetrical disc protrusion, and when there is doubt about the MR imaging findings. Patients with previously fused lumbar segments, or with chronic low-back pain, or with radicular pain in the absence of MR imaging-documented neural compression have the indication of such procedure (Tomecek *et al*, 2002).

2.1.2. Bone Biopsy

This procedure is used to obtain samples of tissue for histopathological and/or microbiological analysis and other ancillary studies. The indication of such procedure is made, after detection of bone lesion in previous radiological exams (Ojala *et al.* 2002).

2.1.3. Vertebroplasty/ Kyphoplasty

Percutaneous vertebroplasty is defined (McGraw *et al.* 2003) as the injection of radiopaque bone cement (usually PMMA) into a painful osteoporotic compression fracture or a painful pathologic vertebral body, over pedicle structures, due to metastatic disease or a vascular tumour, with the use of imaging guidance. Such procedure intends to reach pain relief and bone strengthening (stability) (Hess 2006). Kyphoplasty has the same idea and it was developed by Kyphon company. It differs from the vertebroplasty by the use of a “balloon” to create space into the bone.

While placing the needle every anatomical structure next to the pedicle and anterior of the vertebral body is in potential danger (Hess 2006). These are the spinal cord, the nerve roots, the epidural venous plexus, the esophagus and the thyroid gland in the cervical spine, the lung in the thoracic spine, as well as the large paravertebral and abdominal vessels.

During the injection of the PMMA, which is the most critical step of the procedure, "extravasations" can occur; this can lead to pulmonary emboli as well as to compression of the spinal cord or nerve roots with permanent or transient neurological deficit and/or neuropathic pain (Boszczyk et al. 2006; Hess 2006). Other procedural complications include risk of infection, rib fractures, and prolonged bleeding. It is clear that such complications can lead to the patient's death.

2.1.4. Radiofrequency Ablation (RFA)

The Radiofrequency Ablation (RFA) consists in percutaneous insertion of a specially designed thermal resistance probe followed by controlled heating of the tissue to be removed (tumour or intervertebral disc) (Welch *et al.* 2002). M.D. Daniel I. Rosenthal (Rosenthal *et al.* 1992) was the pioneer of this technique in the treatment of Osteoid Osteoma (benign, most frequent in the legs). In the spine area this technique is used to shrink or remove disc material believed to be causing lumbar pain and/or radiculopathy. The killed tumour cells are not removed, but are gradually replaced by fibrosis and scar tissue. Thermal resistance probe inserted through a cannula that is coiled into the selected area of targeted disc. While the precise mechanism of action remains unknown, it has been shown that the application of heat to damaged disc tissue produces the therapeutic effects of the RFA procedure (Smith&Nephew 2006).

Intradiscal electrothermal therapy appears to be a very safe procedure. Few complications have been reported (Welch *et al.* 2002), and our own experience has reflected this. The most common difficulty has been inserting the needle into the L5-S1 disc space. In only rare cases cannot this level be treated and the procedure aborted. In our clinical experience there have been no postoperative infections or nerve root injuries.

The potential complications from RFA can be divided into early stage and late stage (Saal 2006). The early-stage complications can be nerve injury (needle-related and/or thermal), infection, bleeding, and burns. Late-stage complications might include rapid or accelerated disc space collapse at a treated level, or avascular necrosis due to endplate injury.

Another treatment-related problem that may occur is difficulty in threading the catheter into the disc space once the needle is adequately positioned. Threading the catheter may be difficult if the needle tip is positioned against the endplate or if the disc is extremely degenerated. It is extremely important not to force the catheter into the disc space because the catheter can be sheared off by the needle tip. Additionally, the catheter and needle must be removed as a single unit once the catheter is extended past the needle tip.

2.2. Imaging systems

Percutaneous spinal procedures are generally performed under fluroscopic X-Ray guidance, except for certain procedures, such as vertebral biopsies, which may be performed under CT guidance (Schaeufele 2006). CT scanners allow multiplanar, real-time visualization for cannula introduction and cement injections and permits rapid alteration between imaging planes without complex equipment movement or projection realignment (Mathis et al. 2003). There is also the modality of CT-fluoroscopy procedures, which permits constant monitoring of needle placement and cement injection in real-time, however it needs constant radiation exposure.

Preoperative imaging allows for careful inspection of the clinical problem to be treated as well as for precise planning of the intended intervention. On the other hand, relying upon preoperative CT scan for navigational feedback may be non-optimal when the corresponding shape of the operated vertebra is about to be altered considerably during the operation, for example, in cases of tumour removal or fracture reduction (Langlotz and Nolte 2006).

Imaging, however, is time-consuming activity (Jolesz 2005), and time is critical during surgery. Imaging not only interrupts the flow of surgeries but also adds substantial extra non surgical time to the overall duration of the procedure. On the one hand, there is the surgeon's intuition to minimize the time for imaging, and on the other hand, there is the surgeon's need for accurate guidance. These two competing issues result in a compromise that defines the current number of imaging sessions. Today, this important decision depends on the surgeon's instinct or preference and is not based on any scientific optimization method.

2.3. Radiation issues

The use of X-ray based scanners also introduces the problem of ionizing radiation exposure. This affects not only the patient but also the medical staff. Unfortunately, despite of all the training that this staff can have done, many people do not use all protection equipment correctly and exposure themselves over dosis limitation. The protection and dosis limitations of workers and general public are regulated by local and international standards. In Germany, some of these most recent regulations were stated in: "*CHV 10 Strahlenschutzverordnung (StrlSchV) / 2006*" (Radiation Protection Ordinance), *"Röntgenverordnung (RöV) / 2002"* (X-Ray Ordinance) and *"Arbeitschutzgesetz (ArbSchG) / 1996"* (Labour Protection Law). In Europe, these standards were stated in the directive 97/43 EURATOM / 1997 and 96/29 EURATOM / 1996. Currently the effective dose limitations are: for exposed workers to a maximum effective dose of

50mSv (milisieverts = $mJ.kg^{-1}$) in a single year (Art. 9 – 96/29 EURATOM, 1996) and for general public 1mSv (Art. 13 – 96/29 EURATOM, 1996).

Another aspect of radiation for the engineering field is that the exposure of some materials can alternate some of their properties (e.g. mechanical). It constraints consequently their use in radiological procedures. One example is the polymer (Mano 1991).

3. COMPUTER-ASSISTED SURGERY (CAS)

The Idea of computer-assisted orthopaedic surgery is to replay surgical action on a computer monitor in real-time providing a valuable visual feedback to the operating surgeon (Langlotz and Nolte 2006). In order to generate such feedback during spine surgery three tasks have to be fulfilled by a spinal navigation system: (a) an image or a set of images of the spine has to be provided serving as the "map" of the patient, (b) the spatial location of all important instruments has to be measured constantly in three dimensions and in relation to the operated bone, and (c) the relative instrument position has to be transferred into image space to enable visualization at the correct location.

The CAS system in these cases is used to increase safety and precision and to decrease radiation exposure to the patient and surgical staff (Yeung 2006). An example is intradiscal electrothermal therapy (IDET/RFA) with the help of fluoroscopy-based navigation (Ohnsorge *et al.* 2003).

The advantages of surgical robots and manipulators are well recognized in the clinical and technical community. Precision, accuracy, and the potential for telesurgery are the prime motivations in applying advanced robot technology in surgery (Chinzei and Miller 2001). Surgical robots require trajectory planning, which, in practice, relies upon preoperative images. If the target organ is deformable, the trajectory needs to be updated according to the magnitude of the deformation. Here, image-guided surgery is a natural solution.

To achieve all these goals, meticulous preoperative planning is necessary (Mayer 2006).Topography and volumetry of the target must be clear. This information is usually given by different imaging techniques such as MRI, CT, etc. Especially in anterior approaches to the spine, knowledge of the topography of the prevertebral space can be valuable.

Minimally invasive approaches do not allow a wide exposure and mobilization of these vessels. This can increase the risk of indirect damage to branches entering or exiting the arteries and veins. Preoperative vascular topography can be determined with help of color-coded three-dimensional CT scans which give a clear picture of the individual anatomy, but it not a popular method.

Previous works in CAS based on CT scanners for interventional radiology have been reviewed. These researches are based in the following procedures, mainly for soft tissues: Biopsy/ Delivery Therapy (Kronreif *et al.* 2004, Maurin *et al.* 2004, Masamune *et al.* 2001, Yanof *et al.* 2004, Lavalle *et al.* 1992, Loser and Navab 2000, Corral *et al.* 2004, Stoianovici *et al.* 1998) and Radiofrequency Ablation (Maurin *et al.* 2004, Corral *et al.* 2004).

4. SYSTEM CONCEPT

Based on the previous study of the current medical procedures, following needs and requirements were observed:

- Precision in the placement and orientation of the needle in order to avoid the need of many imaging exposures, mainly important for complex and severely deformed structure. It is expected to reduce iatrogenic traumas for misplacement and also unnecessary radiation exposure;
- Tracking of the needle tip for an accurate targeting of the interested structure;
- Reduction of the need of patient displacement during the procedures. In the current procedures, the patient is moved toward inside and outside the CT bore for the placement of the needle;
- Better interaction information from the needle and tissue. Experienced physicians use inconsciously their proprioception information in order to achieve the positioning and orientation of the needle, what it called as "intuition". This skill allows the physician to perform the procedure with less image shots. It is expected better interaction information can reduce considerably the learning curve for such procedures;
- The possibility to use all the available imaging tools for diagnostics during the performance of a surgical procedures;

A 6 DoF telemanipulator robot with a special end-effector is being developed to meet these requirements. On the other side the implementation of the telemanipulator also brings additional technical issues. As the interaction physician-patient disappears, the system has to be able to transmit this "interaction information" from the patient to the physician.

4.1. System goals

One of the system goals is the development of a sterilizable (robotic) mechanism for positioning and orientation of needles of different sizes to be inserted into a spine bone structures. This mechanism should work inside a CT Scan bore, yielding few artefacts on the CT images. This mechanism would be also able to measure forces along the needle axis. As part of this project is a Master/ Slave system control with proprioception information for the physician. This system should allow the insertion of planning information, and answer to this. Planning information can be used to constrain areas and movements.

These systems intend to perform the medical procedures described before and open the possibilities for the development of the new ones.

4.2. System modules and its constraints

For design purposes the system was divided in several modules (Fig. 1). The modules are presented in the following items.

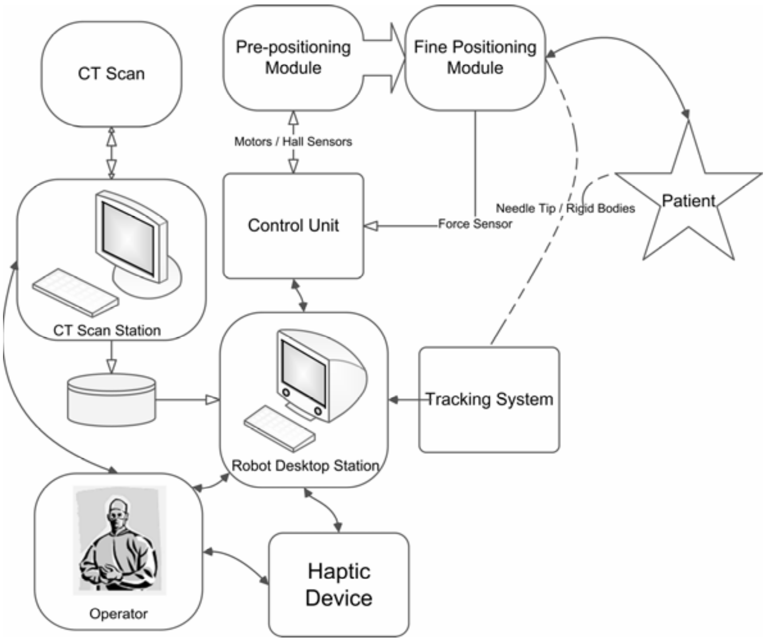

Figure 1. System concept by modules

4.2.1 Master Device

The Master Device consists of the interface system/physician. This interface will respond to the physician movements and transmit to him information from the environment. With this purpose, it uses a commercial haptic device with 6 DoF for positioning and 3 DoF for Force Feedback. This latter number of DoF for Force Feedback constrains in part the set of interactions that can be mimic to the physician. However with previous analysis of the interactions force for our procedures, it was observed the dominance of some components. With this we can concentrate in the transmission of information for such components, expecting to have the same answer from the physician and environment.

4.2.2 Planning Unit

The Planning Unit or the Robot Desktop Station, as it is represented in Fig. (1), is also part of the user interface to the physician. It is responsible to give the user necessary tools for planning the movements of the robot and communicate with the Control Units. It also has the task to control the master side of the Haptic Device. It acts as the central part to transmit/receive information from the other modules. Some of this information (such as information from Tracking System) is presented to the physician in order to give him details for further commands or interaction. This Unit works synchronised with the CT Scan Station and updates the images from the CT Scanner permanently at the user interface without losing previous commands. This updates requires a correct transition from the old image to the new one.

4.2.3 Tracking Unit

This unit provides information about the current position and orientation of the needle as well as the Pre-Positioning/ Fine Positioning Modules.

For CT-based navigation, several alternative registration methods have been proposed to improve registration accuracy, simplify the intraoperative registration procedure, or allow for registration in a less invasive manner (Langlotz and Nolte 2006). Placing fiducial markers (titanium markers) on the patient as “artificial landmarks” prior to image acquisition is a common technique for navigated cranial surgery (Popovic *et al.* 2005). Such markers exhibit strong contrast in the acquired CT scan and may be identified easily. Moreover, digitizing them intraoperatively with high precision is a trivial task that can be performed reliably and fast. However, this is related to continuous radiation exposure, that such procedure requires.

Researchers have currently been using optical (Nolte et al. 2000) and electromagnetic tracking (Wood *et al.* 2005) for spine procedures. However, there are several restrictions for the use of tracking systems in the given environment. Optical systems require a free line of sight, which may be obstructed by the CT scanner, as well as relatively large Rigid Bodies fastened to patient and tools. Due to this need for line of sight it is not possible to track the needle tip. The tracking outside the body is not suitable since it is unavoidable that the needle bends during the procedure. Although electromagnetic systems suffer from interferences from metal within the measurement volume, it is assumed possible to track the tip inside the body with sufficient accuracy.

4.2.4 Control Unit

This unit reads the force sensors and contains the control loop of the Robot Unit and the Instruments Module. It utilizes a CAN bus internally and communicates with the Planning Unit by a USB interface. The Planning Unit runs under Windows XP, which is not a real-time system. Such limitation imposes the use of additional algorithms (Abel and Bollig 2006) in order to have a better performance and transmission of information. As the system has to be controlled in a Master/Slave architecture, the states of different components have to be managed together in order to define further actions. So the problem resides in that not all the components work in synchrony.

4.2.5 Pre-positioning Module

It consists of two assemblies (Fig. 2): a passive supporting arm and an active unit. The passive arm is manually pre-positioned. The Tracking Unit measures the deviation between the planned and actual pre-positioning, which can be compensated by the active unit or the passive arm has to be repositioned.

The active unit contains 4 DoF with a combination of planar mechanisms. Together with the Fine Positioning Unit, the required tasks are performed.

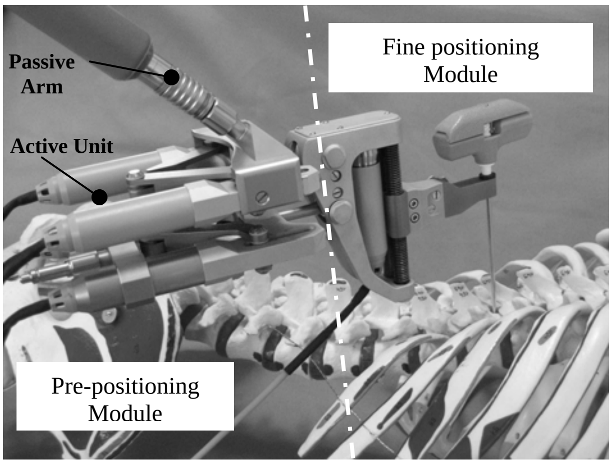

Figure 2. Pre-positioning Module and Fine Positioning Module Concept

4.2.5 Fine Positioning Module

It can hold neddles of different diameters. Normally there is no need to change the needle during a procedure. In RFA, for example, a thicker needle is used as cannula for the electrode (Rosenthal *et al.* 1992). Fig. (2) shows the concept of using an Fine Positioning during an intervention.

The basic module has 2 DoF. Additional DoF can be implemented for specific tasks. As this module will be placed directly in the CT image area, its components have to be made of specific materials to avoid artefacts and shadows on the final CT images. Another requirement for this module is the actuation of higher forces in order to perform tasks in bone structures. This module is also constrained by the available volume inside the CT bore.

5. CONCLUSIONS

In this paper a CT based interventional radiology telemanipulator system for specific spine procedures has been presented. Till now, researches for the development of CT based manipulators concentrated their efforts in procedures on soft tissues. The system presented in this paper focus the application with bone structures, so taking the advantages of these imaging systems.

Such systems intend to reduce radiation exposure of the patients and physicians, and open the possibilities for the development of new interventional procedures. This reduction is expected by the use of a planning system for an accurate positioning and orientation, and an intuitive control by a master/ slave control with force feedback device.

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