Workshop on Enabling Technologies for Image-Guided Robotic Interventional Procedures

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As the field of medical robotics evolves, new techniques and technologies enable breakthroughs in the capabilities of next generation systems. In this workshop, we intend to bring together innovators in new techniques for modeling, analysis, and control of medical robotic systems. The focus of the workshop is to discuss the new technological breakthroughs in a multi-disciplinary forum where these concepts may be merged with or integrated into other technologies to expedite developing clinical systems. The purpose is to create a venue where these new ideas can be coupled with innovation in enabling technologies for image-guided robotic surgery and to help foster a sense of community among a wide variety of researchers to help take these concepts and core technologies from the lab to the clinic.

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Superhuman Performance of Surgical Tasks by Robots using Iterative Learning from Human-Guided Demonstrations

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Abstract
In the future, robotic surgical assistants may assist surgeons by performing specific subtasks such as retraction and suturing to reduce surgeon tedium and reduce the duration of some operations. We propose an apprenticeship learning approach that has potential to allow robotic surgical assistants to autonomously execute specific trajectories with superhuman performance in terms of speed and smoothness. In the first step, we record a set of trajectories using human-guided backdriven motions of the robot. These are then analyzed to extract a smooth reference trajectory, which we execute at gradually increasing speeds using a variant of iterative learning control.

We evaluate this approach on two representative tasks using the Berkeley Surgical Robots: a figure eight trajectory and a two handed knot-tie, a tedious suturing sub-task required in many surgical procedures. Results suggest that the approach enables: (i) rapid learning of trajectories, (ii) smoother trajectories than the human-guided trajectories, and (iii) trajectories that are 7 to 10 times faster than the best human-guided trajectories.

The Berkeley Surgical Robots performing a knot-tie.

References
A novel platform for Scar-Less Robotic Surgery: The ARAKNES Project

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Abstract. A brief overview of the ARAKNES European Project towards the development of an innovative platform for scar-less surgery is given in this paper. In particular, the proposed platform and its advantages with respect to the state of the art are analyzed and briefly discussed.

Keywords: Robotic surgery, single port laparoscopy, natural orifices transluminal surgery.

1. Introduction

Robotic surgery is increasingly common in clinical practice thanks to the wide spread of the Intuitive Surgical’s (http://www.intuitivesurgical.com) Da Vinci system [1]. Stereoscopic vision, combined with improved dexterity, are the two distinctive features motivating the success of this platform. The Da Vinci system provides surgeon with a transparent teleoperation of three laparoscopic instruments and one stereoscopic camera. Thanks to a highly advanced robotic design of the actuated tools, human hand dexterity is almost restored. By combining this feature with depth perception provided by the stereoscopic vision system, the surgeon is able to perform laparoscopically complex tasks that would have otherwise required open surgery. Despite of all this, several limitations still apply. The Da Vinci system requires four 12-mm diameter accesses – three for the instruments and one for the camera – and an additional 5-mm service access. Additionally, the surgeon is immersed in the user console, thus loosing the perception of what is going on in the operative room. Several examples of robotic platforms for scar-less or endoluminal surgery are under development by different research groups around the world [2-4]. However, being this a multidisciplinary and highly complex task, a concerted effort coming from different research-leading groups is probably the most appropriate way to develop the next generation of surgical robots.

2. The ARAKNES Project

The ARAKNES Project (www.araknes.org) is part of the 7th Framework Programme of the European Commission and involves 11 partners, including companies, universities and research centres. The basic concept of the ARAKNES platform stems from the innovative idea to transfer the technologies of bi-manual laparoscopic surgery to either the single port [5] or the endoluminal [6] approach, thus further reducing the operative trauma and enhancing the therapeutic outcome of minimally invasive surgical procedures. Referring to Fig. 1, the system architecture of the ARAKNES platform is mainly composed by the user console and the robotic platform. The first one, working under the surgeon control, acts as a master in teleoperating the robot and provides visual and force feedback. Peculiar features making this console more advanced than state of the art systems are increased ergonomics, force feedback...
and an open design preventing the surgeon to be totally immersed into the console. Other features, such as eye tracking [7] and preoperative imaging data fusion [8], are available upon surgeon request.

Fig. 1. The ARAKNES operative room.

As regards the robotic unit, two access possibilities are envisaged in the ARAKNES scarless architecture. The primary solution consists of an umbilical access, taking advantage of the Karl Sorz “Cuschieri Endocone™” port (www.karl-storz.com). A modular bimanual robot, provided with a stereoscopic camera, is introduced through the Endocone, as in Fig. 2.

Fig. 2. The ARAKNES robot operating through the umbilical access.
3. Conclusions

The ongoing efforts of the ARAKNES European Project towards scar-less robotic surgery were briefly discussed in this paper. In particular, system architecture and peculiar advantages with respect to the state of the art were analysed. Actually a first prototype of the system has been fabricated and assembled and it is now under test.

References

Sensor and Actuator Technologies for MR-guided Interventions

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Abstract:

MRI is an ideal imaging tool for guiding and monitoring biopsy and local therapy of prostate. The high sensitivity and specificity to focal lesions and abnormalities, combined with real-time monitoring of the delivery process and subsequent physiological changes hold great potentials. The limited workspace in the closed MRI scanner does not allow the physician to access to the patient during imaging, and has motivated researchers to investigate robotic assistance for MRI-guided interventions. The objective of our research is to make conventional diagnostic closed high-field (>1.5T) MRI scanners available for guiding interventional procedures. The multifaceted approach includes development of control systems, sensors and actuators. Research on sensors includes fiber optic multi-axis force-torque sensors and absolute fiber optic position encoding. Research on actuators includes piezoelectric actuation schemes, pneumatic and hydraulic stepping motors, precision pneumatic control and dielectric elastomer actuators. The system architecture is based on a modular shielded robot controller that sits in the scanner room 1-2 m from the bore and can interface with these sensor and actuators. It communicates over the OpenIGTLink protocol on fiber optic Ethernet to a navigation and control workstation in the console room. Current applications in development include prostatic needle placement for precision biopsy and brachytherapy seed placement and DBS electrode placement interventions, offering significant improvements in accuracy, workflow, surgical time and morbidity.

Figure 1. Modular MR-Compatible robot controller that sits in the scanner room containing an embedded PC, power regulation, motor control and fiber optic communications (left) and custom low-noise piezoelectric motor driver circuit that resides in the controller enclosure (right).
Figure 2. System architecture (left), configuration in the MRI scanner room (center) and an MR-compatible arm for image-guided deep brain stimulation lead placement (right).

References:


Motion compensation for ultrasound-guided robotic heart surgery

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RSS 2010 Workshop on
Enabling Technologies for Image-Guided Robotic Interventional Procedures

Abstract

To treat defects within the heart, surgeons currently use stopped-heart techniques. These procedures are highly invasive and incur a significant risk of neurological impairment. We are developing methods for performing surgery within the heart while it is beating. New real-time 3-D ultrasound imaging allows visualization through the opaque blood pool, but this imaging modality poses difficult image processing challenges due to poor resolution, acoustic artifacts, and data rates of 30 to 40 million voxels per second. To track instruments within the heart we have developed a Radon transform-based algorithm. Implementation using graphics processor units (GPUs) enables real-time processing of the ultrasound data stream. For manipulation of rapidly moving cardiac tissue we have created a fast robotic device that can track the tissue based on ultrasound image features. This allows the surgeon to interact with the heart as if it was stationary. Our in vitro studies show that this approach enhances dexterity and lowers applied forces. To complete integration of ultrasound imaging with the robotic device we have developed a predictive controller that compensates for the imaging and image processing delays to ensure good tracking performance. We will present results from in vivo testing of this technology in atrial septal defect closure and mitral valve annuloplasty procedures. Recent efforts are directed applying this motion-compensation technology to robotic catheter systems.
References


Platforms for Targeting Tumors with Magnetotactic Carriers and Flagellated Bacteria Controlled by Computer

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Abstract:

Medical robotics have evolved from interventional robotic platforms located outside a patient and designed to perform minimally invasive surgeries, to smaller untethered implementations such as the well-known camera pills dedicated for operations inside the digestive track. But one of the trends in medical robotics is to conduct interventions with smaller untethered devices in regions that are out-of-reach to modern medical robotic platforms. Tumor targeting is an example of such interventions where medical robotics relying on untethered devices small enough to travel in the human vasculature could play a major role. Cancer therapy aims at developing agents that will selectively destroy cancer cells while sparing normal tissues. But most current available cancer chemotherapeutic agents target DNA or the enzymes involved in DNA replication, destroying all rapidly dividing cells, including normal dividing cells in vital tissues. The low chemotherapeutic index of these agents results to severe generalized toxic effects when injected in the patient at dosages necessary to kill tumor cells. Therefore, robotic platforms capable of navigating devices or micro-carriers into the complex vascular network to deliver therapeutics to a tumor using the most direct route, would improve cancer therapy by reducing substantially the secondary toxicity by lowering the amount of therapeutics in the systemic circulation while ensuring that a sufficient amount of therapeutic agents reaches the tumoral lesions. To accomplish such direct targeting, a combination of magnetic micro-carriers and flagellated magnetotactic bacteria controllable by computer and capable to deliver therapeutics through the microvasculature is investigated. In this presentation, a short description of these micro-carriers with their advantages and limitations will be presented with emphasis on how they complement each others to achieve enhanced targeting deep in the human body. To control these micro-carriers, new platforms are developed. These platforms rely on MR-imaging to track the position of these micro-carriers in the vascular network. This information is then used to control them in order to maximize targeting using a new robotic approach.

Relevant Web Links: http://www.nano.polymtl.ca/
Figure: Basic schematic showing the paths taken by the robotic micro-carriers for targeting a tumor for the delivery of therapeutic agents

Some References:

Robust 3D motion tracking for robotic-assisted beating heart surgery

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Abstract

The past decades have witnessed the notable development of minimally invasive surgery (MIS). The benefits of this modality of surgery for patients are numerous, shortening convalescence, reducing trauma and surgery costs. In this context, robotic assistance aims to make the surgical act more intuitive and safer. In the domain of cardiac MIS, heartbeat and respiration represent two important sources of disturbances. Even though miniaturized versions of heart stabilizers have been conceived for the MIS scenario, residual motion is still considerable and has to be manually canceled by the surgeon.

Our work focuses on computer vision techniques for estimating the 3D motion of the heart relying solely on natural structures on the heart surface for active compensation of physiological motions. We have developed in [1] a visual tracking method for estimating the 3D deformation of a region of interest on the heart surface based on the visual feedback of a stereo endoscope. The method is robust to illumination variations and large tissue deformations (Figure 1).

Figure 1 – A target region of interest on the heart tracked in 3D using the method based on the Thin-Plate Spline model proposed in [1].
For increasing tracking robustness facing occlusions and tracking failures, motion prediction is integrated to the visual tracking task. In [2], a time-varying dual Fourier series for modeling the quasi-periodic beating heart motion is proposed. For estimating the parameters of the Fourier series, a probabilistic framework is based on the Extended Kalman filter (EKF) is used [3]. Finally, the heart motion prediction is integrated in the visual tracking framework, creating a unified method for estimating the temporal motion and spatial deformation of the heart surface. Experimental results have shown the effectiveness of the proposed methods.

References

Continuously Flexible Robots, an Enabling Technology for Less Invasive Surgical Procedures

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Abstract:

A wide variety of continuum (continuously flexible) surgical devices have been developed over the past few years, and it is clear that continuum devices have been - and will continue to be - key enablers of less invasive surgical and diagnostic access within the human body. Even prior to the introduction of robotic control and guidance, manual continuum tools such as catheters, bronchoscopes, colonoscopes, etc. illustrate the clinical benefits possible with even relatively simple designs. Thinner and more maneuverable continuum devices promise to enable novel, less-invasive procedures. In the Medical & Electromechanical Design lab at Vanderbilt, we are developing concentric tube continuum robots and bevel steered needles, among other designs. This talk will address recent results in design optimization, sensing, modeling, planning, and real-time control of such robots. One initial clinical application area of these robots is to treat large and geometrically complex tumors via acoustically induced hyperthermia, through a single entry point in the organ surface, under three-dimensional ultrasound guidance. We also see potential in other clinical applications including diagnosis and treatment in distal portions of the lung via the throat.

Relevant Web Links: http://research.vuse.vanderbilt.edu/MEDLab/

Figure Caption: (a) A concentric tube continuum robot known as an Active Cannula (b) the degrees of freedom of an Active Cannula (c) 3D Ultrasound view of an active cannula embedded in Bovine Muscle (with superimposed 3D illustration of the cannula) (d) acoustic ablation probe extending from cannula tip with ablated tissue (e) several supimposed runs of bevel-steered needles.
References:

Robotic Guidance for Microsurgical Laser Bone Processing in ENT Surgery

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Abstract—Minimal traumatic interventions on bony tissue necessitate development of image-guided and robot assisted surgery methods suitable to achieve high accuracy and precision. In case of ENT surgery cochlear implantation (CI) is a prime example for microsurgical requirements. Laser ablation as a contact-free method allows microsurgical bone removal and in combination with robot guidance inherits a high potential. A prototype system was established, consisting of a robot positioning a scan head which deflects the laser with high accuracy. Further, a microscope guarantees visual observation in a way familiar to surgeons.

The overall workflow includes preoperative planning and simulation of the cochleostomy procedure. During the intervention, the surgeon is inspecting the progress through the surgical microscope and can adjust the laser pulse positions at any time. Laser ablation is further controlled by visual servoing, allowing automatic pulse adjustment in case of approaching the inner lining membrane of the cochlea.

The integrated setup was evaluated in an experimental operating room. Preoperative planning was performed on a three-dimensional model of an ex-vivo human temporal bone. The target point on the promontory and the desired cochleostomy angle was chosen. After registration the robot automatically positioned the scan head into the correct preplanned location in respect to the temporal bone and the cochleostomy with diameter of 0.6 mm could be performed successfully.

I. INTRODUCTION

Within the last decades minimally invasive and minimally traumatic surgery gain more and more relevance in clinical practice. Laparoscopic surgery, either manual or with robotic assistance, is well established nowadays and introduced a new age of surgery. However, one can conclude that medical interventions not dealing with soft tissue could not profit from minimally invasive or minimally traumatic approaches so far.

In case of ENT surgery, especially surgery at the skull base, a huge amount of bone needs to be removed in order to get access to the situs. For an approach towards e.g. the inner ear region, a large volume of the temporal bone (mastoid) has to be manually removed with a surgical drill. In order to reduce the bone loss and thereby facilitate skull base surgery with minimal traumatization for the patient, current research efforts lead to linear paths, which are hardly to perform freehand because of risk structures. Thus surgical concepts necessitate image-guidance and robot assistance. A feasibility study revealed the possibility of accessing the inner ear through linear bore holes [1]. Thereby endoscopic surgery through compact bone becomes feasible.

In regard of the extension of indication for cochlear implantation (CI), improvement of electrodes and efforts towards defining influencing factors for minimally traumatic cochleostomy and electrode insertion, mechatronical support in the frame of CI surgery is a major research topic. One approach is percutaneous cochlear implantation (PCI), which is characterized by drilling a linear path from the lateral skull to the cochlea through the facial recess with support of a microstereotactic frame [2, 3]. Autonomous robot assistance with a drill and a tool for automatic cochlear electrode insertion could be another possibility to support surgeons [4, 5].

Beside passing risk structures on the way towards the inner ear and the correct insertion of the electrode, the most crucial part of cochlear implantation is the cochleostomy. The function preserving cochleostomy (so called soft surgery [6]) is one surgical technique, where the endost has to be kept intact while drilling the cochleostomy through the bony promontory. The transition from bone to membrane takes place within several microns. Thus, not the direction is the main problem but the drilling depth with an accuracy demand of around 0.1 mm has to be supported. Highly accurate robots with positioning accuracy in the range of few microns are one possibility for autonomous assistance [7]. Sensory for measuring the transition of bone to soft tissue is a key issue. Several approaches were proposed: measure of length in combination with CT data acquisition [8], force-torque analysis [9, 10], acoustical [11] or our optical identification approach.

We are proposing laser ablation as a contact-free and precise method for cochleostomy. Short-pulsed laser ablation inherits the potential for pulse-wise parameterized microsurgical bone removal [12]. We developed video camera-based sensory for surveillance of the situs during CI in order to meet the accuracy requirements [13, 14]. Further, we established a prototype system for robot assisted laser bone ablation [15, 16], with robot assisted laser based cochleostomy as one application scenario [17]. Within this contribution we present the integrated prototype and the first OR applicable system for robot assisted laser based cochleostomy.
II. METHODS

A. Preparation
An ex-vivo human temporal bone from the Department for Anatomy of the University Hospital Düsseldorf was used for the experiment. The temporal bone specimen was prepared conventionally with a mastoidectomy and posterior tympanotomy and four titanium screws were inserted as fiducials for point-based registration. Afterwards a CT dataset was acquired (slice distance 1 mm, inplane resolution 0.238 mm). The temporal bone was segmented and the surface model was generated by using the imaging software OsiriX. Figure 1 left illustrates the surface model. Further, the location of the fiducials were determined by point picking.

Fig. 1. Preoperative planning of laser ablation. The target point on the cochlear and inclination angle is defined.

B. Planning
After the surgeon defined the target point on the promontory of the cochlear and the desired angle manually (respectively the end point in the scala tympani), the diameter of the cochleostomy channel was defined with 0.6 mm. The resulting bony volume to be removed during cochleostomy is about 0.3 to 1 mm$^3$. Figure 1 right illustrates the planned trajectory.

This geometrically defined cochleostomy then needs to be transferred into an ablation pattern, i.e. laser pulse positions. With each laser pulse a defined Gaussian shaped bone piece is removed. The dimensions are dependent on the pulse energy and beam diameter. The planning strategy was already reported in [12].

C. OR-Setup
The system was established in an experimental OR. Our prototype for robot assisted laser cochleostomy consists of a precise robot, a scan head attached to the robot’s flange, an articulated mirror arm for delivery of the beam from the laser source, a microscope and a digital camera. Figure 2 illustrates the system in our experimental operating theater. In the following the system components are described in detail.

The CO$_2$ laser source is a Rofin Sinar SCx10 slab laser (Rofin Sinar Technologies Inc., Plymouth, USA) with a wavelength of 10.6 $\mu$m, TEM$_{00}$ beam profile, and a maximum output power of 100 W. Typically obtained pulse energies are around 22 mJ for pulses with 80 $\mu$s duration.

In order to distribute the laser pulses across the tissue quickly and with high accuracy, a laser scanning system is utilized. The two-dimensional galvanometric scan head (Colibri, Arges GmbH, Wackersdorf, Germany) has an accuracy in deflecting the laser of 20 $\mu$rad. To focus the laser beam a single element ZnSe lens (48TSL100, ULO Optics, Stevenage, United Kingdom) with a specified focal distance of 101.3 mm is mounted to the scan head. The lens has f-theta characteristics, i.e. the laser beam is focused onto a plane. At the focal plane, the laser beam has a diameter of 0.2 mm. The laser beam is delivered through a passive articulated mirror arm (Laser Mechanisms Inc., Michigan, USA) to the scan head.

Our developed methods for robot assisted laser osteotomy are independent of the specific robot model. For this experiment we utilized a cleanroom robot (Stäubli RX90B CR, Stäubli Tec Systems GmbH, Bayreuth, Germany, stated repeatability 0.02 mm). For highly accurate registration we used a measurement arm (Faro Platinum, stated accuracy for point probe 0.005mm, FARO Europe GmbH & Co. KG, Konntal-Mnchingen, Germany).

The digital camera (Canon EOS 450D) is mounted onto a camera adapter from a surgical microscope (Zeiss OPMI pico, Carl Zeiss AG, Oberkochen, Germany). The optical path of the surveillance is superimposed with the optical path of the laser by using a dichroic beam combiner. This ZnSe beam combiner is directly attached to the scan head. The microscope is attached to the operating table on a retaining arm, which allows manual adjustment to the scan head and the correct angle of incidence for surveillance once after the robot moved into the target position.
D. Simulation

Reachability and feasibility are key issues for robot assisted medical interventions. Hence, we developed a simulation environment which facilitates pre- and peri-operative studies of the setup and intervention. After acquiring the registration this information is used and the robotic procedure is simulated. Figure 3 illustrates the simulation of the experiment situation and the robot in the target position.

E. Cochleostomy Execution

The human temporal bone was fixated in a Mayfield clamp like device on the operating table. For registration of the specimen the location of the four fiducials was measured using the measurement arm. Additionally three defined locations on the scan head were measured in order to determine the spatial relation between the specimen and the robot system in its home position. The registration was calculated using the standard point-based registration method.

With the registration information, the planning coordinates of the cochleostomy trajectory were automatically transferred into the actual patient coordinate system. The robot then moved the scan head into the planned target location in respect to the temporal bone. The microscope was then manually adjusted to meet the optical axis ($45^\circ$ to the laser beam axis) and facilitate the correct view onto the situs.

By using the pilot laser (encoupled red laser diode), the laser target point was visualized for the surgeon. This step allows manual adjustment of the target point, for example if its location is not perfect after registration. Once the final target position of the laser is established, laser based cochleostomy starts. It is important to notice, that the robot is not moving anymore. It is just used to position the scan head in the appropriate position. The preplanned laser pulses are accomplished by the galvanometric mirrors inside of the scan head with high precision. As laser parameters we chose empirically a pulse energy of 22 mJ. Ex-vivo experiments showed that each of these laser pulses remove a Gaussian shaped bone piece with a diameter of around 200 $\mu$m and a depth of 100-120 $\mu$m.

The cochleostomy was performed under visual observation by the surgeon through the surgical microscope. Figure 4 shows the microscopic view onto the situs shortly after the laser ablation started. Before entering the cochlea, the laser pulse positions were manually adapted in order to prevent a breakthrough of the inner lining membrane. Figure 5 shows the experiment execution and manual inspection of the progress of the cochleostomy by the surgeon.

III. RESULTS

The registration had a fiducial registration error of 0.18 mm. After registration the robot positioned the scan head into the preplanned target location successfully. Visual observation of the situs worked well through the microscope. The cochleostomy had a diameter of 0.6 mm and was clearly visible. By using the microscope, the surgeon could perform the intervention in a familiar situation. Surgeons can imagine to use this arrangement of devices in real surgery. Further, the surgeon is in charge of observing the laser ablation and can adjust the pulse positions at any time.

Introducing the dichroic beam combiner to the system, necessitates recalibration since the focal point slightly shifted. However, adding the beam combiner still left enough distance to the bony surface thanks to the focal distance of about 110 mm.

IV. CONCLUSION

Transferring our methods into an OR feasible setup was successful. Further we could show, that the complete workflow is suitable and working effectively. Hence, we could proof our concept for a robot assisted laser based cochleostomy setup.

However, a pilot study with several temporal bones has to follow now and demonstrate accuracy of the method. Postoperative image and histological analysis in order to verify the results are mandatory. It is important to notice, that the conventional CT resolution may not be sufficient to visualize the cochleostomy with its diameter of 0.6 mm. Hence, it could
be necessary to apply high precision $\mu$CT or digital volume tomography (DVT) to obtain a high resolution.

In regard of further automation of the cochleostomy procedure, our image processing algorithms for detecting the lining membrane have to be enhanced. Integration of sensory with depth perception is in the scope of our future work, e.g. coaxial sensory like optical coherence tomography (OCT) instead of reflected-light microscopy. The penetration depth of OCT in bone is minimum 150 microns and with this at minimum one pulse before leaving the bone and perforating the membranous lining of inner ear. This measurement method and the possibility of adjusting the ablation depth by choosing the correct pulse energy for every single laser pulse inherit a high potential towards precise microsurgical bone processing. Many surgical disciplines could profit from this methodology.

ACKNOWLEDGMENT

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REFERENCES


MRI Compatible Surgical Systems: Analysis of Actuator Compatibility Methodologies and System Effectiveness

Gregory A Cole and Gregory S. Fischer

Abstract—This paper presents the development of an actuation scheme that enables real-time MRI-guided surgical interventions. Described is the system architecture, the development of a piezoelectric actuator system including custom motor modules, motor driver modules and system validation. The results indicate that these modules can be effectively utilized to create precision motion within the MRI space without interfering in a significant way with image quality. The combination of these modules in different orientations can then expedite the effective development of actively driven MR compatible devices. This approach will expand the number of procedures benefiting from live image guidance at a much faster rate than through the development of individual systems from start to finish.

I. INTRODUCTION

Diagnostic magnetic resonance imaging (MRI) is one of the most effective imaging modalities available to the medical professional for viewing internal soft tissue structures [1]. The ability to use this imaging modality for live guidance during surgical procedures would prove invaluable for manipulating internal structures that are difficult to reach for procedures such as deep brain stimulation (DBS) or percutaneous prostatic intervention. Robotic assistance for guiding instrument placement in MRI for neurosurgery began with Masamune, et al. [2]. Subsequently, Chinzei, et al. [3] developed a general-purpose robotic assistant for open MRI that has been adopted for neurosurgery. A high dexterity MRI-compatible system for neurosurgery, known as the neuroArm, is presented by Sutherland, et al. [4]. While these systems are effective, they both share a similar drawback: they cannot move under their own power while simultaneously imaging.

Developments in MRI-compatible motor technologies include Tse et al. who described an air motor for limb localization in [5]. [6] described an actuation method with hydrostatic transmission to power the robot near the scanner from outside the shielded MR room. [7,8] presented the development of dielectric elastomer actuators. There is additional work being developed by others in the area of pneumatically actuated robotic devices such as the PneuStep [9]. While these devices do not depict the entire state of the art, they do highlight the problem being addressed: the current inability to generate and control precision electromechanical motion during live high-field (greater than 1.5T) closed-bore MR imaging without affecting the quality of the image. One problem presented by devices such as the pneumatic stepper motor, or the elastomer actuator is presented similarly by many actuator technologies: scaling these devices in size, speed or torque in any significant way requires significant redesign of major aspects of the system. A simple to implement, easily scalable precision actuation system, that is rapidly configurable is required for the improved development of MRI guided robotic interventions.

II. MODULAR MRI COMPATIBILITY

The engineering design process has classically been focused on standing on the shoulders of giants: research projects and devices similar to the one you would like to build and utilize as many proven techniques as possible to streamline the path to invention. This process works fantastically due to the hundreds of years and millions of giants who’s shoulders offer available purchase. MRI compatible robotics however is a new developing field that has sparse selections of prior art available for the most basic of its design constructions: actuators, controllers, and rigid construction materials. This lack of prior art or ‘giants’ has lead to very large development times for even basic MRI compatible actively actuated devices, and developers find themselves inventing new actuation systems specifically tuned for each device. The work presented below intends to create a modular actuation and control system capable of supporting a variety of actuator sizes and styles. In addition to this, a ‘toolbox’ of materials and support components have been tested for compatibility with the MRI scanners and the medical industry, that can also be used in the construction of MRI compatible devices. The final product of all of these advances, is that once a procedure that would benefit from live, in-situ MRI guidance is identified, an armature can be easily designed to create the motions involved with the procedure. Once the linkage to create the desired motions is designed, actuator design can then be scaled to produce the

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desired torque, speed, and output angles. Next, the linkage system can be populated with the required components, such as encoders, fiducials, and pressure sensors. Finally, the required driving circuitry and control computer can be selected. At this point the entire system has been designed and can be constructed and tested. This procedure may sound like standard practice to the average engineer, however most of the standard types of products utilized above simply do not exist in an MRI compatible form, which is what the current work addresses. In order to showcase the effectiveness of the systems of actuators controllers, and components created, one implementation of a sample system, an armature for the implantation of Deep Brain Stimulation electrodes, is presented.

III. SYSTEM ARCHITECTURE

As discussed above, the system architecture was structured to allow engineers in the future to design MRI compatible devices in much the same manner as non-MRI compatible devices, without having to be concerned with the compatibility. To this end, we developed or identified the following devices and materials specifically for use in the MRI machines:

1. Scalable actuators
2. Actuator drivers with distributed processing
3. High current, high efficiency DC-DC converters
4. Encoder drivers
5. Computer
6. Communication system
7. Encoder
8. Rigid armature and joint materials

While this list may not be exhaustive, it does create a 'shelf' from which ‘off the shelf’ MRI compatible actively driven systems can be constructed. The example implementation of Deep Brain Stimulation electrode placement, as well as several other implementations, has a specific implementation as shown in Fig. 1.

As can be seen, a workstation external to the scanner room communicates with both the robot controller and the image server connected to the scanner. This workstation is where the images from the scanner, and the input from the user are interpreted to commands sent to the robot controller within the scanner room. The robot controller then interprets the commands from the workstation with the geometric dimensions of the actual linkage system in the scanner to motor commands, which are then sent to the actuator drivers. These commands are interpreted and executed via feedback control loop from the encoders.

Utilizing this system architecture of distributed processing, each level of processing only interprets the user commands with regards to the unique system knowledge it has access to. The workstation, sporting the most high powered processor, is responsible for analyzing the MRI images into a 3D image, which is then analyzed by the user and the first level of commands are produced. In the next level of processing, the scanner room computer system, interprets the commands, usually in the form of a 3D image space intervention location, in terms of the specific kinematics of the robotic system, into joint positions. These joint position commands are then sent to the embedded processing systems of the driver boards which utilize encoder feedback and control loops to achieve the desired orientation, which can then be verified via targeting fiducials located on or near the end effector. The speed this systems operates is sufficient to run a real time guided motion. The equipment for the DBS system is shown in Fig. 2.

![Figure 1: System architecture of the DBS needle placement device.](image1)

![Figure 2: Diagram of location and type of equipment in the DBS placement device (top) Image of armature and fiducial tracking marker. Demonstrates compatibility of equipment with the scanner (bottom).](image2)
IV. MODULE EXAMPLE: MOTOR DRIVER

Due to its unique construction and characteristics, the piezoelectric motor is very well suited for use in an MRI environment[10]. The ceramic construction and non magnetic force generation make it capable of being operated in the MRI bore without causing image interference. Piezoelectric motors can be quite a challenge to implement however because unique arbitrary waveforms are required to drive them most effectively [11]. In order to make a wide variety of piezoelectric motors available to MR designer, the piezoelectric driver board was created as one of the modules in the development systems. As can be seen in Fig. 3, the block diagram of the board consists of a processor used to communicate with the control computer and control an FPGA which is used to generate the wave outputs.

The encoder inputs are integrated with the card to further distribute the processing and allow independent feedback controls coupled with each axis. By adopting this architecture, the boards can be programmed to interpret a plain position or velocity command from the control computer, and generate the driving waveforms for a specific actuator. This allows a single driver to be used with a large variety of implementations of a piezoelectric motor.

V. VERIFICATION OF MODULES:

For the most part, this systems effectiveness has been verified, though the prototype has not yet completed testing. The most difficult aspect of creating this toolkit was making sure that all of the individual components, and the system as a whole would not interfere with image quality. Of course it is also important to create a system that can produce the precision motion desired, but this aspect of the device is more easily accomplished. Initial tests results were very promising, and in the opinion of the author, the best MR compatibility results for electromechanical systems ever recorded. See Fig. 4 for qualitative results. As can be seen in Fig. 5 the signal loss averaged under 1% but was always less than 2% under the four imaging sequences studied.

We chose T1 and T2 diagnostic/anatomical imaging protocols, FGRE real-time imaging protocol, and EPI functional imaging protocol sequences to study. As can be seen the normalized SNR, or signal to noise ratio, was calculated using a Matlab image subtraction technique, where
scanner images with the system running were subtracted pixel by pixel from baseline images of the same fiducial in the same position without the equipment in the room.

VI. DISCUSSION

It has been shown that these modules can be effectively utilized to create precision motion within the MRI space without interfering in a significant way with image quality. The piezoelectric motors utilized in this round of testing are highly scalable, in terms of size, torque, speed, and power and thus are a very versatile type of actuator to use. Additionally, the moving neural implantation armature is an example of a successful combination of these modules to perform a useful task. Upon completion of the testing of the initial prototype additional prototypes for other procedures will be created to further verify the systems effectiveness as well as develop new components.

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A novel active ureteroscope prototype for efficient semi-automatic vaporization of kidney stones

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I. INTRODUCTION

Kidney stones is a very frequent pathology. Estimations say that about 10% of people over 40 years of age in industrialized countries are affected, with a recurrence rate of 53% [1]. Among the techniques recommended by the European Association of Urology to treat this pathology [2], ureteroscopy allows the surgeon to treat stones of sizes up to 20 mm with a mini-invasive approach.

When the stone is larger than 4 mm it cannot pass the ureter and therefore must be treated inside the kidney. The operation process is the following: after introduction of the device into the kidney via natural ways, the surgeon navigates to find the stone and places it properly. A laser fiber is then introduced in the operating channel to eliminate the stone. A red light passes through the fiber to show the surgeon where the fiber points to. When the fiber points towards the stone, the surgeon pushes a pedal activating the power laser. The laser is pulsed at a 1 Hz rate while the pedal is pushed. The role of the surgeon is to smoothly sweep the surface of the stone by bending and rotating the ureteroscope while shooting with the laser. This operation would allow to vaporize the stone. However, the poor maneuverability of the device - it can only be bent on one plane from the outside - and backlash in the transmission mechanism make the operation uneasy. As a result, stones are often fragmented and brought to the outside one by one with a basket wire. Moreover, this operation is time consuming (about 1 hour to treat a stone of 1 cm diameter).

We propose to assist the surgeon in the vaporization task in order to reduce the operating time and avoid fragmentation of stones. The operation remains the same until the push on the laser pedal. At this stage our system handles the vaporization task automatically, under control of the surgeon: the next impact points of the laser appear on the video image, and the surgeon can stop the process if a laser shot is to be made outside the stone. This is allowed by the fact that the laser shooting rate is around 1 Hz.

The system we developed is depicted on Fig. 1. The actuation of the system relies on shape memory alloy (SMA) wires [3], [4]. The control of the system is made through a visual servoing scheme based on the ureteroscopic images. Those images are segmented to extract a safe region inside the stone which is used to plan a sweeping movement of the fiber.

II. ACTUATION THROUGH SMA WIRES

A. Integration

Nickel-Titanium wires were used as actuators. When heated, this metal has the property to change its crystallographic organization, from a martensite to an austenite phase. This results in a shortening of the wire of 4 to 8% of its total length. Hence, wires integrated to the distal tip of a catheter can bend it, as shown on Fig. 2.

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factor of 2 was chosen, which led to wires of 2.5 cm length. 175 μm diameter wires were used. The outer diameter of the prototype was 4 mm, which is the inner diameter of the ureteral sheaths commonly used for ureteroscopy.

A validation was made at the urology department of Pitié-Salpêtrière Hospital (Fig. 4). The ureteroscope was put on a testing bench, pointing towards a kidney stone of 13 mm diameter. The SMA wires were heated by an electrical current controlled by the operator. The prototype was found to be effective to reach the extreme points of the kidney stone. The SMA wires were first heated one at a time to test the extreme limits of the system, then two by two to test complex movement generation.

Moreover, the actuation of the distal tip by an urologist, using the built-in cables of the ureteroscope, was compared to the actuation using the SMA wires. The latter resulted in a much smoother movement of the tip of the ureteroscope. This is mainly due to backlash in the cables which harden the generation of small precise movements by the surgeon.

To command a smooth sweeping of the surface of the stone, a careful planning of the movements of the ureteroscope tip is needed. For that, we implemented an image based control of the SMA actuators. A good segmentation of the ureteroscopic images gives the information about the stone position in the image, then a path is computed for the sweeping of the kidney with the fiber. This path is used to command the movement of the ureteroscope distal tip through visual servoing.

A. Segmentation of the ureteroscopic images

The segmentation of ureteroscopic images is quite difficult. First of all, kidney stones come in different chemical compositions, resulting in different shapes, colours, and textures [5]. Moreover, the fiber bundle of the ureteroscope is also fragile, and black dots frequently appear on the image. An algorithm was developed taking these constraint into accounts. It was kept very simple because of the fact that this particular problem had never been handled in the past.

A region growing algorithm was used. This simple algorithm starts from a given seed and compares the neighbouring pixels to the seed using a similarity criterion and a stopping criterion. As the algorithm starts when the surgeon pushes the pedal, the laser fiber then points towards the stone. It projects a red spot on the surface of the stone, which can easily be detected due to its well-defined colour and high luminosity. The centroid of this red spot is then used as seed for the region growth. Four similarity criterion were defined, using variations of the Average Homogeneity Criterion defined by Tremeau and Borel in [6], and the stopping criterion was a simple threshold on this criterion.

The algorithm parameters were first tuned, then refined and validated on a large database of 923 images taken from 9 videos. The videos contained images of calculi of 4 different chemical compositions, and sizes varying from 9 to 19 mm. The images were first manually segmented by an expert to serve as ground truth. Then, the images were segmented by the algorithm using different sets of parameters, and each segmentation was compared to its ground truth using quantitative error measurement indicators such as Precision, Recall, compactness, and Yasnoff measure. The tuned algorithm was then tested on the validation image bank and it was found to be effective, and robust regarding the biological variation of kidney stones.

The developed algorithm has a computational time of 31 frames/s, which allows to run it at the video framerate of 25 frames/s. An example of segmented image is shown on Fig. 5.

B. Visual servoing

A visual servoing scheme was developed. It doesn’t rely on any formal relation between the heating current and the shortening of an SMA wire. Equations linking the temperature to the shortening of the wire exist, but our system doesn’t embed a temperature sensor. Therefore, the relation between
the electrical current in input and the resulting movement has been determined experimentally. Considering the fact that the ambient temperature is constant (which is reasonable owing to liquids injected in the kidney during the operation), the electrical current which passes through the SMA wires could directly be linked to the displacement of the tip of the ureteroscope. This relation was intergated in the control scheme. The movement of the ureteroscope results from a vectorial composition of the movements produced by the SMA wires individually (Fig. 6). The regulation was made through a simple PI regulator.

**C. System bandwidth**

The algorithm frequency is greater than 30 Hz and the video is acquired at 25 Hz. Hence, the system bandwidth is mainly limited by the dynamic of the SMA wires. The heating and cooling times of the SMA wires were found to be 0.4s and 1.0 s respectively. However, the proposed control scheme aims at limiting the influence of the cooling time as it never lets the system evolving under the sole effect of the natural convection. Exploiting the antagonistic positionning of the SMA wires (Fig. 3), it always maintains the system under the control of one active SMA wire at least, whatever the commanded displacement is. Additionally, a cooling water can be used by the surgeon during the ureteroscopy in order to facilitate the cooling of the wires. Practically, the system bandwidth was found to be more than 2.5Hz, which is sufficient, compared to the laser shooting rate of 0.8 Hz.

**D. Validation**

The visual servoing scheme and bandwidth were tested with a simple tracking experiment. The prototype was put on a testing bench, pointing toward a blank page, and a subject aimed at the blank page with a red laser pointer. When the red spot was detected on the ureteroscopic image, the ureteroscope was configured to move quickly to bring the red point in the center of its image (Fig. 7). The ureteroscope was able to bring every point in its field of view to the center of the image with good accuracy. It also showed a good repeatability of the movements. The bandwidth was found to be 2 Hz, which is less than the value found previously due to the fact that the ureteroscope did not operate in cold water, which lenghtened cooling times for the SMA wires.

**IV. CONCLUSION AND FUTURE WORK**

An active ureteroscope prototype was developed, which could afford the urologists an answer to the problem of effective vaporization of kidney stone during ureteroscopy.

Three SMA wires were integrated to the distal tip of the device and tested. A visual servoing scheme was made, and the control of the ureteroscope through simple image computations was sucessfully achieved. An algorithm for kidney stone segmentation on ureteroscopic images was developed, and tuned for a general use, with minimal set-up from the surgeon.

The structure of the active ureteroscope is particularly interesting, because the rest of the operating process remains the same : the surgeon does not need to learn new procedures or to use new devices : he uses the same device the same way, but the long and difficult task of vaporizing the kidney stone is made automatically, just by pushing a pedal. Of course, the whole operation is made under surgeon control, mainly for security concerns.

One of the main remaining tasks is to use the results of the segmentation algorithm to compute a ureteroscope trajectory that is suited for kidney stones vaporization. Security is also very important : the SMA actuation requires a current from 500 up to 1000mA, so they must be electrically isolated in the final prototype. Temperature is not much of a concern, because the high temperature involved in the SMA wires is local, and the temperature of the water
injected in the kidney during surgical operations can be chosen in consequence.

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Toward Automation of Image-Guided Microstereotactic Frames: A Bone-Attached Parallel Robot for Percutaneous Cochlear Implantation

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Abstract—To increase efficacy of therapy delivery and prevent injury to nerves, arteries, brain tissue and other delicate structures during minimally invasive intercranial surgeries, it is desirable to design devices that exceed the positioning accuracy of traditional stereotactic frames. Microstereotactic frames (i.e. bone-attached rigid fixtures custom-made for each patient) are capable of high accuracy, but require manufacturing delays. Repurposing a strategy originally developed for knee arthroplasty and spinal procedures, in this paper we propose to streamline clinical workflow by replacing the microstereotactic frame with a miniature parallel robot, which we refer to as an Automated, Image-Guided, Microstereotactic (AIM) Frame. Here, we illustrate the AIM Frame concept by addressing Percutaneous Cochlear Implantation (PCI) surgery. We describe a first-prototype AIM Frame that can be seamlessly integrated into the surgical and technological workflow of PCI.

Index Terms—Cochlear implant, parallel robot, Gough-Stewart platform, minimally invasive surgery (MIS), Microtable, bone-attached robot

I. INTRODUCTION

ACCURACY and precision are paramount concerns for minimally-invasive surgeries targeting small structures embedded in surrounding tissue. Stereotactic frames are used to locate physical targets identified on medical images or anatomical atlases, and have been in clinical use for over 50 years. However, they are not used in applications requiring sub-millimetric accuracy, including cochlear implant surgery. In these cases, rigid, non-adjustable frame systems attached directly to the bone are favored, in view of their superior accuracy. The major drawback to use of existing microstereotactic frames is the time delays associated with manufacturing them. The only currently commercially available option, the STarFix™ (FHC, Inc., Bowdoin, ME) requires a delay of several days – in the middle of the surgical procedure – for off-site manufacturing.

To provide an immediately available solution that can simplify clinical workflow when microstereotactic frames are required, we propose use of bone-attached parallel robots. Previously, several researchers have demonstrated the efficacy of bone-attached robots for establishing a fixed relationship between a robot’s coordinate frame and a surgical target. Plaskos et al. [1], Song et al. [2], and Wolf et al. [3], have designed bone-attached parallel robots for knee arthroplasty. Similarly, the Mazor SpineAssist robot [4] is a commercially available bone-attached parallel robot designed for pedicle screw placement in the spine.

Both [3] and [5] use variations of the Gough-Stewart parallel robot architecture, which provides six degrees of freedom, and has been widely studied and previously applied to industrial applications ranging from robotic milling to telescope mirror positioning [6]. Parallel robots have been favored for bone-attached surgery due to their stiffness, high payload-to-weight ratio, and potential for high positioning accuracy.

We address Cochlear Implant (CI) surgery in this paper as a case-study, to illustrate our Automated, Image-Guided, Microstereotactic (AIM) Frame approach to high-accuracy intercranial targeting. Cochlear implants are electronic devices that can restore a sense of hearing to individuals who have severe or total hearing loss. In a cochlear implant system, an external microphone and sound/speech processing unit transmits signals through the skin to a subcutaneous receiver, which applies electrical impulses to an electrode array implanted inside the cochlea, stimulating the nearby auditory nerve.

The current procedure for CI surgery requires removal of temporal bone through a process called mastoidectomy, using a hand-operated drill to gain access to the cochlea, which is located at a depth of approximately 35 mm. During drilling, several sensitive anatomical features embedded in the bone must be identified and preserved. These include the facial nerve, damage to which can result in permanent ipsilateral facial paralysis, and a nerve called the chorda tympani which controls taste sensation on the ipsilateral tip of the tongue. These two nerves are separated by approximately 2 mm at the facial recess, through which the electrode array must pass. To prevent injury, the surgeon must relate a three-dimensional mental map of critical subsurface features to anatomical landmarks exposed during drilling, relying on hand-eye coordination and memory to avoid cutting these nerves or encroaching on the ear canal (which can lead to infection).

In recent years, a minimally-invasive technique called Percutaneous Cochlear Implantation (PCI) has been developed to reduce the risks and time required for traditional CI surgery [7], [8]. The procedure utilizes a microstereotactic frame to accurately locate surgical targets. The PCI procedure begins with placement of three self-tapping metal anchors with spherical heads on the temporal bone. A computed tomography
Fig. 1. The Microtable, a microstereotactic frame for percutaneous cochlear implantation surgery, a minimally-invasive treatment for deafness is currently undergoing clinical validation studies.

(CT) scan of the anchors is acquired and software is used to automatically localize the centers of the spherical heads and an optimal trajectory to the cochlea is automatically computed from segmented image information [9]. Next, a bone-attached microstereotactic frame called a Microtable (machined from a plate of thermally resistant plastic) is designed to guide and constrain a drill and insertion tool to the planned drill trajectory. Finally, the Microtable is fabricated using a Computer Numeric Control (CNC) milling machine near the operating room, sterilized, and attached to the bone anchors as shown in Fig. 1 to serve as a guide for the drill and insertion tool, which lock securely to it. The PCI technique is currently undergoing clinical validation [7]. It is hypothesized that the PCI technique will consistently require approximately 60 minutes to complete (the estimated operative time for CI surgery ranges from 70-150 minutes depending on the experience of the surgeon [10]). A mean drill tip accuracy of 0.37 ± 0.18 mm [11] has been demonstrated. The total time required for fabrication, sterilization, and delivery of each Microtable is approximately 30 minutes.

To reduce the total operating time while achieving accuracies similar to those obtained via a Microtable, the Automated Image-Guided Microstereotactic (AIM) Frame system proposed in this paper uses a sterilizable Gough-Stewart parallel robot mounted on a standardized, rigid, pre-positioning frame. This paper discusses the intended role of the AIM Frame in PCI surgery, and describes the design of a first prototype.

II. SURGICAL WORKFLOW

We propose that the AIM Frame can fit seamlessly into the clinically-validated PCI surgery process introduced by Labadie et al. [7], with the use of a rapidly-adjustable robot replacing design and fabrication of a Microtable. While PCI surgery is used as an example in the following discussion, note that the methods and devices introduced may be generalized to other similar intracranial procedures.

The proposed PCI pre-surgical process as modified to include an AIM Frame is shown in Fig. 2. First, a pre-positioning frame designed using prior clinical data (described below) is used to guide insertion of three bone screws, which fix the pre-positioning frame to the skull. Next, a CT scan allows identification of both patient anatomy and three titanium spheres on top of the pre-positioning frame. Custom software is then used to segment critical anatomy, localize the centers of the spheres, and identify a target and trajectory with respect to the sphere locations. A miniature Gough-Stewart parallel robot is then positioned so that a tool attachment platform on its top platform aligns with the desired trajectory. The robot is then disconnected from its power source and attached securely to the spheres on top of the pre-positioning frame. After attachment, the robot serves as a locked, microstereotactic frame upon which a surgical drill and cochlear implant insertion tool can be attached during surgery.

III. A FIRST AIM FRAME PROTOTYPE

Our current AIM Frame prototype is shown in Fig. 3. The mechanical components consist of a rigid pre-positioning frame that is mounted to the skull with surgical screws, a robot that attaches to titanium spheres on the pre-positioning frame, and an electronic equipment enclosure. Both the base frame of the robot and the pre-positioning frame have large holes through their centers to allow the surgical tools (drill and cochlear implant insertion tool) to pass through to the target. Both the top platform and base platform of the AIM Frame are milled from polyetherimide, an autoclavable thermoplastic that maintains high rigidity and tensile strength at high temperatures. The joints and all fasteners are made of autoclavable metals. The pre-positioning frame will be made from an
Fig. 3. The AIM Frame and pre-positioning frame prototypes, attached to the temporal bone of a human skull.

autoclavable polyetherimide, though the first prototype is made from acrylonitrile butadiene styrene (ABS).

A. Pre-positioning frame

The pre-positioning frame, shown in Fig. 4, serves three functions. First, it acts as a template to guide the surgeon to insert the bone anchors at the appropriate locations and orientations (perpendicular to the bone surface). Second, the spheres on the top of the pre-positioning frame act as fiducial markers for registering CT images to the robot’s coordinate frame. Third, the pre-positioning frame orients the robot such that when it is attached and in its nominal position (with all actuators at equal lengths), it will be as close as possible to the statistically expected drill trajectory, based on actual drill trajectories in prior clinical validation studies (see Fig. 6). This aligns the robot’s workspace as closely as possible to the necessary workspace, minimizing the distance each actuator must travel to reach the space of possible desired trajectories, allowing the robot to be as small and light as possible. The robot itself attaches to the fiducial marker spheres on top of the prepositioning frame, using the gripping mechanism described in [11].

To design the pre-positioning frame for our AIM Frame for PCI, we performed an analysis of PCI trajectories from a sample of eight prior Microtable clinical trials. These trajectories were planned using the algorithm of Noble, et al. [9], which performs automatic segmentation of temporal bone CT scans to identify important anatomical structures and determine an optimal trajectory that avoids the facial nerve and accesses the cochlea. A computer rendering of the segmented structures along with a planned trajectory is shown in Fig. 5. The pre-positioning frame was designed to align the nominal position of the robot with the vector from the mean entry point to the mean target point in the eight clinical trials. Fig. 6 depicts the eight desired trajectories from our sample of PCI clinical data, in a coordinate system placed at the center of the base frame of the AIM Frame prototype mounted on the pre-positioning frame. The robot is shown in its nominal, unadjusted pose, where the tool attachment port on the top platform is centrally located with respect to the PCI trajectories.

B. Gough-Stewart Platform

The robot component of the AIM Frame is based on a 6-6 Gough-Stewart parallel robot architecture, consisting of two platforms connect by six actuated prismatic joints as shown in Fig. 6. The ends of each prismatic joint are connected to passive ball joints, arranged to form the vertices of a semi-regular hexagon on each platform. This robot design was selected for ease of application, since there is a large body of existing literature describing it and its inverse kinematics are well-understood.

Fig. 4. An oblique (A) and top (B) view of the pre-positioning frame prototype attached to a skull. The pre-positioning frame is used to orient the attached robot for efficient utilization of its workspace.

Fig. 5. Trajectories are calculated by custom software that segments anatomical structures to identify the cochlear target and a trajectory for the drill and cochlear implant insertion tool.
A schematic diagram of the AIM Frame with PCI trajectories from actual clinical data. The robot, a Gough-Stewart platform, has been oriented by a pre-positioning frame (not shown), so that that it is centrally located with respect to the trajectories.

While the 6 DOF afforded by the Gough-Stewart platform are more than strictly necessary (only 4 DOF are required for aligning an axisymmetric tool to a trajectory), it may sometimes be valuable to include redundant degrees of freedom, which may be utilized as free parameters for avoiding link collisions, minimization of encoder uncertainty propagation, and avoidance of singularity loci. We intend to investigate in future work the tradeoff between the simplicity of the mechanism (reduction of motors and thereby cost), and the desirability of including redundant degrees of freedom, and also to explore alternate parallel robot designs, comparing them in terms of error propagation, stiffness, kinematic conditioning, etc.

C. Actuators and Sensors

The robot is actuated by six Squiggle SQL 3.4 linear piezoelectric motors (New Scale Technologies; Victor, NY). Each motor consists of a leadscrew engaged in a threaded nut. Piezoelectric plates attached to the nut induce ultrasonic standing waves which cause rotation and translation of the lead-screw [12]. These motors were chosen for their high power-to-weight ratio, small size, and high resolution of motion. Each motor weighs 1.2 g and can generate bidirectional motion with 2 N maximum output force. The stator package is 3.4 mm × 3.4 mm × 10 mm. The motors can extend and retract at 4 mm/s while exerting 1 N. We estimate (conservatively) that the required positioning time for PCI trajectories will be under 5 s. When the power source is removed, the motors lock and are not backdrivable. The suitability of these motors for direct exposure to repeated sterilization is not known, though we have subjected one motor to a standard autoclave sterilization cycle (270.0°F, 4 min. sterilization time, 1 hr., 13 min. total cycle time), and another to ethylene oxide gas sterilization (130°F, total cycle time of 14 hrs., 59 min.). Qualitatively, we did not observe any degradation of performance for either motor following sterilization.

Each motor is enclosed in a bolted aluminum fixture forming a prismatic joint which may be extended and retracted by the motor, as shown in Fig. 7. The fixture also houses a TRACKER Position Sensor (New Scale Technologies; Victor, NY), a Hall Effect-based encoder with a minimum resolution of 0.5 μm. The TRACKER is used for closed-loop control.

D. Control hardware

Each motor is powered by a separate MC-1100 motor controller (New Scale Technologies; Victor, NY). Each motor controller is connected via a Universal Serial Bus (USB) connection to a USB hub, which in turn connects to a personal computer with a single USB cable. The control electronics (motor control boards and USB hub) are housed in a separate electronics box. The electronics box is connected to the robot with a single, detachable, three-foot cable. Detaching the robot and control cable allows these components to be sterilized (it is not necessary to sterilize the electronics box, since it is sufficiently remote from the patient and can be covered in a plastic bag in the operating room).

E. Control Software

To orient the top platform of the AIM Frame to a desired trajectory, the inverse kinematics of the robot are used to determine required joint displacements. For parallel robots, mathematical expressions for inverse kinematics are often quite simple (for a derivation of Gough-Stewart platform inverse kinematics, see [13]).

Custom software written in MATLAB (Mathworks; Natick, MA) is used for trajectory generation. Each trajectory is planned as a straight line path from the robot’s “home” position to the required position, and uses inverse kinematics.
to calculate leg lengths at a sequence of closely spaced via points along the trajectory. New Scale Pathway software (New Scale Technologies; Victor, NY) is used to interface with the motor controllers and execute the trajectories. Each motor is independently controlled using a proportional-integral-derivative feedback loop.

IV. Conclusion and Future Work

We have presented the concept of an AIM Frame for highly accurate minimally invasive intracranial access. Our system transfers to a new area of the body and set of surgical applications the successful paradigm previously developed by others for bone drilling and reshaping in the knee and spine, namely use of a bone-attached miniature parallel robot. Our initial case study presented in this paper was to design a prototype bone-attached Gough-Stewart parallel robot specifically for the application of cochlear implantation via the PCI technique. We also described how such a robot can be seamlessly integrated into the established PCI surgical and technological workflow by first adjusting it to align with the desired trajectory, then locking it in place by removing power, and finally attaching it to the patient.

In future work, we intend to experimentally evaluate the positioning accuracy of the AIM Frame using the “virtual targets” method introduced by Balachandran et al. [14], with an atlas of cochlea targets obtained from prior Microtatable clinical trials. Prior to testing, it will be necessary to calibrate the robot, to account for manufacturing tolerances. It may also be useful to optimize design parameters of the robot to minimize the propagation of encoder uncertainties to the top platform, although since the encoder resolution is high, it is not yet clear whether this will be necessary. A comprehensive review of calibration and optimization methods relevant to the Gough-Stewart platform may be found in [6]. We also intend to explore alternate parallel robot configurations beyond the Gough-Stewart architecture, to determine if there may be a structure even better suited to PCI and/or other intracranial procedures.

The chief clinical advantages of the AIM Frame concept we propose are higher potential accuracies in intracranial procedures, which can be expected to increase efficacy and decrease complication rates. We believe it likely that if the AIM Frame concept does indeed prove capable of the higher accuracies we foresee, it will have the potential to enable many new procedures like PCI that are not approachable with traditional stereotactic frames.

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Active Needle Steering System for Percutaneous Prostate Intervention in High-field MRI

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Abstract—This paper presents the design of a magnetic resonance imaging (MRI) compatible needle steering system actuated by piezoelectric actuators for prostate brachytherapy and biopsy. Our guiding vision is to design a modular needle driver that can be coupled to a generic gross positioning stage to enhance MRI-guided prostate surgery accuracy and decrease operational time. After reviewing pertaining robot assisted needle driver systems in MRI, ultrasound and computed tomography (CT) environments, we articulate the design challenges and requirements of robotic system for close bore interventional MRI surgery. The paper presents a modular 3-degrees-of-freedom (DOF) needle platform coupled with a representative MRI-compatible 3-DOF z−y−z stage. This system is proposed to serve as a slave robot to deliver radioactive seeds in an MRI-guided force feedback teleoperation framework. Moreover, it suffices to be a generic robot platform to provide the needle positioning and orientation task in a diverse array of proposed needle steering scenarios. With a kinematically parallel robot embodiment, the positioning module provides linear position control with high system rigidity. The modular needle driver simultaneously provides needle cannula rotation and independent cannula and styli prismatic motion. The device mimics the manual physician gesture by two point grasping and direct force measurement of needle axial puncture and lateral forces by two fiber optic force sensors. The CAD model and the fabricated prototype are presented and the experiment with phantom trial is analyzed to demonstrate the system compatibility.

Keywords: Optical Force Sensor, MRI Compatible, Haptic Feedback, Needle Driver, Prostate Needle Brachytherapy.

I. INTRODUCTION

Prostate cancer continues to be the most common male cancer and the second most common type of cancer in human. The estimated new prostate cancer cases (192,280) in 2009 account for 25% incident cases in men [1]. The current “gold standard” transrectal ultrasound (TRUS) for guiding both biopsy and brachytherapy is accredited for its real-time nature, low cost, and apparent ease of use [2]. However, TRUS-guided biopsy has a detection rate as low as 20%−30% [3] and the seeds cannot be effectively observed in image. On the other hand, MRI-based medical diagnosis and treatment paradigm capitalizes on the novel benefits and capabilities created by the combination of high sensitivity for detecting seeds, high-fidelity soft tissue contrast and high spatial resolution. The challenges, however, arise from the manifestation of the bidirectional MRI compatibility requirement - both the device should not disturb the scanner function and should not create image artifacts and the scanner should not disturb the device functionality [4]. Moreover, the confined physical space in closed-bore high-field MRI presents formidable challenges for material selection and mechanical design.

Needle steering becomes an interesting and practical technique to enhance placement accuracy which is deteriorated by needle insertion and tissue deformation in recent years. Bevel needle steering continues to flourish with the combined techniques of nonholonomic modeling and image guided feedback control. Mahvash et al. have [5] experimentally demonstrated that increased needle velocity is able to minimize tissue deformation and damage and reduce position error which is essential for prostate percutaneous therapy. [6] presented a cable driven 5-DOF manipulator with fault-tolerant needle driver for percutaneous needle insertion which functionally satisfies our motion requirement.

Tsekos, et al. [7] presented a thorough review of MRI compatible systems for image-guided interventions. Chinzei, et al. developed a general-purpose robotic assistant for open MRI [8] that was subsequently adapted for transperineal intraprosthetic needle placement [9]. Krieger et al. presented a 2-DOF passive, un-encoded, and manually manipulated mechanical linkage to aim a needle guide for transrectal prostate biopsy with MRI guidance [10]. Stoianovici et al. described a MRI-compatible stepper motor and applied it to robotic brachytherapy seed placement [11]. The patient is in the decubitus position and seeds are placed in the prostate transperineally. More recently, the work by [12] and [13] has pioneered the design of teleoperation system in MRI environments.

In this paper, we present a 3-DOF needle driver equipped
with fiber optic needle interaction force sensors as slave robot to provide haptic feedback. Fig. 1 shows a prototype robot in the bore of a 3T MRI scanner with a phantom. This paper is organized as follows: Section II describes the system requirement and design consideration. Section III presents the detailed needle driver design including the force sensing module, needle clamping mechanism, needle loading mechanism and Cartesian positioning module. The key contribution of this paper is the generic needle driver with novel clamping mechanism. Finally, a discussion of the system and future work is presented in Section IV.

II. DESIGN REQUIREMENTS

Besides the stringent MRI comparability requirements and space limit, the design consideration needs to address a couple of issues. First, we need to fulfill the functional requirements of needle insertion, while at the same time, the system should be able to provide simple procedure and practical in clinical application. From the surgeons’ perspective, we want to mimic the manual procedure which is relatively uncomplicated [14] and easily adaptable. Some design requirements and methodology to address them are briefly described here.

1) Cannula rotation about its axis with cannula insertion. The independent rotation and translation motion of the cannula can increase the targeting accuracy while minimize the tissue deformation and damage.
2) Stylet prismatic motion to facilitate seed delivery.
3) Safety. Instead of using mechanical stop, the piezoelectric actuators as frictional motors are capable of creating 10N of force, when unpowered they can supply up to 16N of holding force per motor.
4) Compatibility. The frames of the robot are built up with acrylic. With limited amount of brass fasteners and aluminum rail, it should be compatible in the bore.
5) Operation in confined space. To fit into the scanner bore, the width of the driver is limited to 7cm and the operational space when connected to a base platform is able to cover the traditional TRUS 60 x 60mm temple. 6) Sterilization. Only the needle clamp and guide make contact with the needle and are removable and sterilizable.

III. NEEDLE STEERING SYSTEM

Usually, a needle steering system requires insertion and cannula rotation motion. This task becomes more complicated for a MRI brachytherapy preloaded needle in terms of extra styllet translational motion to mimic the physician gesture that first move the cannula and styllet in a coordinated manner and then retract the cannula to deliver the seeds. Based on an early design of a force sensor [15] and a haptic system [16], [17], this section demonstrates an updated needle driver. This driver can be used for 3-DOF brachytherapy, 2 concentric pre-bent cannulas [18] or more generally 2-DOF needle steering.

The patient is positioned in the supine position with the legs spread and raised with similar configuration to that of TRUS-guided brachytherapy. MRI bore’s 60cm diameter constraint necessitates reducing the spread of the legs. Considering this configuration and the robot workspace, the width of the robot is limited to 7cm with two layer structure. The lower layer embedded with a linear piezoelectric motor drives the linear carriage and the upper layer provides cannulation rotation motion and stylet prismatic motion. This structure aims to minimize the “between-leg” space while the lower Cartesian stage takes advantage of the “under-leg” space.

To create the force and motion in an MRI compatible system, we selected the piezoelectric motor (PiezoMotor, Uppsala, Sweden) and optical encoders (U.S. Digital, Vancouver, WA) with shielded differential signal lines [19]. A CAD model of the needle driver and the physical prototype are shown in Fig.3. The underlying mechanical design principle is to make the motion DOF decoupled and simplified. Since for preloaded needle brachytherapy, the needle cannula and styllet should be inserted and retracted independently. We follow the coarse to fine manipulation design method, and
the kinematics of the system is shown in Fig. 2. The blue shaded is the needle driver which includes a revolute joint to perform needle rotation (discussed in subsection III-A) and two collinear prismatic joints to independently actuate the needle canula and stylet. The green shaded is the gross Cartesian stage with 3-DOF (discussed in subsection III-C).

A. Needle Rotation Mechanism

Rotation of the needle about its axis may be implemented to drill the needle in to limit deflection as described by Masamune, et al. [20] and Wan, et al. [21]. On the other hand, by taking advantage of the intrinsic asymmetry property of bevel needles, the needle driver may be used to steer the needle similar to traditional treatment for mobile robots and some mobile manipulators in [22]. Webster, et al. [23] explored the modeling and control of bevel steering techniques along trajectories defined using techniques described by Alterovitz et al. [24]. For different needles (brachytherapy and biopsy application), the rotation part can be the cannula for the brachytherapy needle or the whole shaft of diamond shape biopsy needle.

B. Force Sensing Module

We have developed a 3-DOF fiber optic force sensor that provides in-vivo measurement of needle insertion forces to render proprioception associated with brachytherapy procedure [16]. Even though the sensor can monitor axial force and two lateral forces, to guarantee fast and convenient needle loading, the sensor is connected with an offset plate to measure only the lateral forces at the needle tip. A separate 1-DOF sensor is used to measure axial insertion force. This setting is preferable than the design [6] that the needle assembly held an off-the-shelf 6-DOF hollow force sensor (not MRI compatible) by mechanical fastening. The latter design is difficult for needle loading because of the configuration of putting the needle through the center.

C. Cartesian Positioning Module

The modular needle designer is worked on a variety of platforms. We have developed a generic Cartesian positioning stage that may be used with it. To guarantee the MRI compatibility, the linear stage is mainly made of cast acrylic machined by laser cutter and some high strength plastics PEEK. The scissor structure can support the needle rigidly and ensure high stability. Each linear axis is constructed by linear slide and carriage (Igus, Inc., CT) which are made of anodized aluminum, a proven MRI compatible material.

This driver is modular for percutaneous intervention in the sense that it can be conveniently integrated with generic positioning stage like the Cartesian positioning stage that we have developed or orientation stage developed by our collaborator [25] which provides insertion pitch and yaw motion and is especially desirable to overcome pubic arch interference problem.

D. Universal Needle Clamping Mechanism

To design a needle driver that allows a large variety of standard needles to be used with the system, a new clamping device rigidly connect the needle shaft to the driving motor mechanism is developed as shown in the left corner of Fig. 3. This mechanism is a collet mechanism and a brass hollow screw is twisted to fasten the collet thus rigidly lock the needle shaft on the clamping device. The clamping device is connected to the rotary motor through a timing belt that can be freely fastened by moving the motor housing laterally. The clamping device is generic in the sense that we have designed 3 sets of collets and each collet can accommodate a width range of needle diameters. The overall needle diameter range is from 25Gauge to 7Gauge. By this token, it can not only fasten brachytherapy needle but also biopsy needle or most other standard needles instead of designing some specific structure to hold the needle handle as those in [12].

E. Needle Loading Mechanism

Once a preloaded needle or biopsy gun is inserted, the collet can rigidly clamp the cannula shaft. Since the linear motor is collinear with the collet and shaft, we need to offset the shaft to manually load the needle. We designed a brass spring preloaded mechanism shown in right corner of Fig. 3 that can provide lateral passive motion freedom. The operator can squeeze the mechanism and offset the top motor fixture then insert the loaded needle through plain bearing housing and finally lock with the needle clamping. This structure allows for easy, reliable and rapid loading and unloading of standard needle.

F. Tracking Module

To achieve dynamic global registration between the robot and image coordinates a z-shape passive tracking fiducial [26] is attached on the robot upper plate proximal to the needle tip for convenient imaging purpose (shown in Fig. 4). This Z-frame is capable of providing the full 6-DOF pose of the frame (the robot, with respect to the scanner) with any arbitrary transverse MR image slicing through rods. The end-effector location with respect to the fiducial frame is
computed in terms of the kinematics and encoder positions and transformed to the representation in the image coordinate system.

IV. DISCUSSION

We presented a novel needle driver and a plurality of MRI compatible mechatronic devices consisting of a optical force sensor and a linear stage. The needle driver can provide needle cannula rotation and stylet translation motion while the cannula translation is engendered by the 3-axis stage. The design is capable of positioning needle and increase the operation autonomy and thus reduce operation time.

Initial comparability test verified the system architecture and electrical setting. We are in the process of electrical test and building a fully functional prototype to evaluate the MRI-compatibility and targeting accuracy. This compatibility test with the same actuator [19] and control hardware in the scanner room has confirmed that no pair showed a significant signal degradation with a 95% confidence interval. A needle steering system in MRI environment is being tested. Detailed quantitative performance experiments and results would be reported soon.

After the building of physical prototype, a small amount of driver and stage deflection was observed. This could be addressed by replacing acrylic with more rigid plastics materials like PEEK. Because of needle-tissue interaction, needle insertion model (kinematic or dynamic model) should be considered to actively control the needle motion by steering or minor needle tip correction to enhance targeting accuracy with real-time MRI guidance.

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Percutaneous Cochlear Implantation via Image-Guided Customized Frames


Abstract—Cochlear implantation is a surgical procedure for treatment of patients with hearing loss. The traditional surgical procedure involves invasively drilling out a major portion of the bone behind the ear to expose anatomic structures and achieve access to the cochlea followed by insertion of an electrode array into the cochlea to simulate the auditory nerve. A surgical technique, called percutaneous cochlear implantation (PCI), has been proposed to reduce the invasiveness and time of the surgery. PCI involves drilling a linear path from the skull to the cochlea avoiding damage to vital anatomy. Accurate drilling is achieved by implanting markers in the bone surrounding the ear and using a customized microstereotactic frame that mounts on the markers and constrains the drill to the desired trajectory. The PCI method has been validated on 27 patients during traditional cochlear implant surgery by mounting the frame, passing sham drill bits through the frame, and ensuring that each bit reaches the cochlea while avoiding the facial nerve.

Index Terms—Percutaneous cochlear implantation, microstereotactic frame, minimally-invasive.

I. INTRODUCTION

COCHLEAR implantation (CI) is performed for treating patients with sensorineural hearing loss by stimulating the auditory nerve. An electrode array is inserted into the cochlea and coupled to an internal receiver, which forwards it to the electrode array in the inner ear, bypassing the cochlea entirely. The current surgical technique for cochlear implantation, termed a mastoidectomy and posterior tympanotomy, is based on a wide surgical exposure so as to clearly identify anatomic landmarks to avoid injury to critical structures [1] such as facial nerve, which when damaged causes paralysis of the ipsilateral side of the face, and chorda tympani, which when damaged causes loss of sensitivity of the ipsilateral tongue tip. The surgery begins with an incision of approximately 6 cm behind the ear. The cortical bone overlying the mastoid is removed using a drill, and the major landmarks of the mastoid are identified. A boney plate is then drilled away to visualize the incus and the horizontal semicircular canal. The facial nerve is visually identified by incrementally removing bone over its suspected position preserving bone of ≈ 0.5 mm thickness. Posterior tympanotomy that involves opening into the middle ear is then performed via the facial recess, which is the region bounded by the facial nerve posteriorly and the chorda tympani, anteriorly (Figure 1). Next, under direct visualization, the round window of the cochlea is identified, and a hole is made into the basal turn of the cochlea. At this point, the implant is secured to the skull by drilling a divot which matches the contour of the implant and securing the internal receiver in place. The electrode is then inserted into the cochlea, and the incision is closed, burying the implant below the skin.

This traditional surgical technique is widely invasive and requires an average of 171 minutes [2]. In this paper, we describe an alternative minimally-invasive technique for performing cochlear implantation called percutaneous cochlear implantation (PCI) that uses image-guided customized microstereotactic frames for performing the surgery. This technique has the potential to reduce the average surgical time to about 60 minutes.

Figure 1. Traditional CI surgery. Left panel shows patient positioned. Right panel (magnified view) shows drilled mastoid. Vital structures to be avoided during surgery are labeled. The target—the cochlea—is indicated by the yellow starburst. As an indication of the scale of the photo in the right panel, the larger diameter of the starburst is approximately 1.5 mm.
II. PERCUTANEOUS COCHLEAR IMPLANTATION

Percutaneous cochlear implantation (PCI) is a technique of drilling a linear path from the lateral skull to the cochlea through the facial recess avoiding damage to critical structures such as the facial nerve and the chorda tympani. A safe linear drill path is planned based on the patient’s computed tomography (CT) scan that defines the anatomy, and it is critical to drill accurately along this planned path with submillimetric accuracy to avoid damage to the critical structures around the path. This accuracy can be achieved via customized microstereotactic frames that will mount on bone-implanted markers and constrain the drill along the desired trajectory.

PCI technique using customized microstereotactic frames includes the following steps: (1) implanting three fiducial markers into the bone surrounding the ear, (2) obtaining a CT scan, (3) automatically planning a safe surgical trajectory in the CT scan from the surface of the skull to the cochlea, (4) designing and constructing a microstereotactic frame that will mount on bone-implanted markers and constrain the drill along the desired trajectory.

We have tested two microstereotactic frames—the commercially available STarFix™ microTargeting™ Platform (FHC Inc., Bowdoin, ME) and the recently developed Microtable—both of which achieve the accuracy necessary for PCI [3-7]. The STarFix™ platform, which is FDA-approved for use in deep-brain stimulation surgeries, is manufactured using rapid-prototyping technology at a centralized facility away from the hospital. Hence, there is a minimum of two days delay between the placement of markers and surgery causing inconvenience to both patient and surgeon.

The Microtable (Figure 2) was developed at Vanderbilt University to avoid this inconvenience. It can be constructed using a standard milling machine within few minutes [4]. The microtable consists of a tabletop with three legs each of which mounts on a fiducial marker. The tabletop contains three holes to accommodate the three legs and a fourth hole, called the “target hole”, to aim the surgical tool along the desired trajectory. For a given surgical procedure, the microtable is customized to mount on the fiducial markers with the tabletop perpendicular to the desired trajectory and with the top of the target hole 75 mm away from the cochlea. The desired leg lengths are selected and all the holes are countersunk to complete the custom design.

When Microtable is used in conjunction with an intraoperative CT scanner, the whole PCI procedure can be performed inside the operating room in one setting, as explained in the following section.

III. CLINICAL VALIDATION PROTOCOL

We are currently performing clinical validation studies with institutional review board approval to verify if the microtable can guide a sham drill bit to the cochlea without damaging critical structures. An adult patient who is between the ages 18 and 80 years, scheduled for traditional cochlear implant surgery, and has no severe health conditions according to the surgeon and anesthesiologists is chosen as a suitable candidate for the study. Validation study is then conducted if the patient provides informed consent. The current protocol for conducting the validation study in the operating room is as follows.

1. Pre-operative trajectory planning. When a pre-operative CT scan from a traditional CT scanner is available, automatic planning is performed on this CT scan to choose the safe drill trajectory for PCI. Structures in the ear region such as the facial nerve, the chorda tympani, the cochlea, the labyrinth, the ossicles, and the external auditory canal are segmented automatically using previously published methods [8, 9]. The safe drill trajectory that aims at the scala tympani of the cochlea and avoids the facial nerve is then automatically determined [10]. (Figure 3). The trajectory thus obtained is verified by the surgeon. Automatic trajectory planning takes approximately three minutes on an Intel Xeon 2.4 GHz dual quad-core
64-bit machine with 10 GB random access memory. When a preoperative CT is not available, the planning is performed later using the intraoperative CT scan.

2. Fiducial markers implantation. When the patient is prepped and the incision behind the ear for a traditional cochlear implant surgery is made, three anchors are implanted surrounding the temporal bone—one at the mastoid region, one at the region posterior to the sigmoid sinus, and one at the supra-helical region (Figure 4). An extender with spherical tip is attached to each anchor. The spheres act as fiducial markers for designing and mounting the microtable. (Note that the large incision seen here is a consequence of validation during a traditional implant approach. For PCI, three much smaller incisions would be made, one for each anchor, and a fourth smaller incision for the drill.)

3. Acquisition of intraoperative CT scan. An intraoperative CT scan is acquired using xCAT ENT CT scanner (Xoran Technologies, Ann Arbor, MI). After CT scanning, the traditional CI surgery continues. Steps 4 to 6 below are performed in parallel to the traditional CI surgery.

4. Intraoperative trajectory planning. The centers of the spherical fiducial markers are automatically localized in the intraoperative CT. If a preoperative plan is available, segmentations and trajectory from the preoperative CT is transformed to the intraoperative CT using the registration based on mutual information method [11] (Figure 5). If the preoperative plan is not available, segmentation and trajectory planning are performed on the intraoperative CT. The preoperative CT is preferred for planning, when it is available, because of the superior quality of the scans from traditional CT scanner [12] which can provide better results. This step takes about four minutes.

5. Design and construction of customized Microtable. The design for the customized Microtable is based on the sphere locations and the desired trajectory. A custom Matlab (The Mathworks, Natick, MA) program automatically determines the location of the holes on the tabletop and the desired lengths for each of the legs, generates the G-code commands to construct the tabletop using the CNC milling machine, and creates a virtual model of the Microtable to illustrate the assembly. The holes in the tabletop are then cut with a CNC machine (Ameritech CNC, Broussard Enterprises, Inc., Santa Fe Springs, CA) in just under four minutes. Legs of specified lengths are then fastened via nuts in the appropriate holes, and a quality assurance check is conducted. Assembly and quality assurance together require approximately two minutes.

6. Sterilization. The Microtable is immediately transported to the substerile room near the operating room for sterilization. After sterilization, the Microtable is available to the surgeon for validation.

7. Validation. Once mastoidectomy and posterior tympanotomy are completed and the cochlea is visible, the traditional CI surgery is interrupted for a few minutes to validate the PCI technique. The sterile Microtable is mounted on the spherical fiducial markers (Figure 2). A sham drill bit of 1 mm diameter is passed through the target hole of the Microtable. Video and photo documentation of the position of the drill bit on the plane defined by the facial nerve and chorda tympani is acquired to determine the safety distance from the two structures (Figure 6). Documentation is also obtained to determine whether a true drill bit would have produced a cochleostomy. If clearance is present, a 2 mm sham drill bit is also passed through the target hole and documentation obtained. The Microtable is then removed, the markers are removed from the patient’s head, and the traditional CI surgery continues.

8. Distance measurements. The documented pictures are then processed to determine the closest distance of the center line of the drill bit to the facial nerve and and chorda tympani.
IV. RESULTS

Clinical validation of PCI using Microtable was performed during traditional cochlear implant surgeries of 27 patients \( (N = 27) \). For 5 of these 27 patients, the trajectory was chosen manually by the surgeon because the software performing automatic path planning was still under development. For 7 of these 27 patients, the intraoperative CT scanner was not available. Hence, the anchor implantation and acquisition of CT scan was performed a few days before the surgery. The CT scan was acquired using the traditional CT scanner. Path planning was performed on this CT, and the Microtable was designed and constructed before the surgery date. The Microtable design was based on the anchor locations in the CT. On the day of the surgery, the anchors were exposed when ready for validation, spheres attached, Microtable mounted, and validation performed. For all other patients, the protocol explained in Section III was followed.

For all 27 Microtables, the validation was performed successfully. In all the cases the drill bit was correctly aimed at the cochlea and avoided the facial nerve. For one ear, the chorda tympani was hit. That patient had extremely narrow facial recess, and it was decided to sacrifice chorda tympani during the trajectory planning. The mean ± standard deviation of the closest distance of the center line of the drill bit to the facial nerve and chorda tympani were 1.17 ± 0.33 mm and 1.23 ± 0.33 mm respectively. These results show that, if the surgery were performed using the PCI technique, it would have successfully targeted the cochlea while avoiding the critical structures.

V. CONCLUSION

Described herein are a minimally-invasive technique for cochlear implantation called percutaneous cochlear implantation (PCI) using customized microstereotactic frames and the clinical validation studies to demonstrate it. PCI involves targeting the cochlea via a single drill path from the lateral skull to the cochlea avoiding critical structures. IRB-approved protocols were used to perform the clinical validation using a microstereotactic frame called Microtable on 27 patients by passing sham drill bits through the Microtable. The validation was successful in all cases with no injury to either the facial nerve or the chorda tympani, except for a planned hit to the chorda tympani in one case. The results demonstrate the feasibility of PCI.

More clinical validation studies that include drilling to the cochlea and inserting the implant through the drilled path using Microtable are required to transform this PCI technique to clinical implementation.

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