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A REMOTE NEEDLE GUIDANCE SYSTEM FOR PERCUTANEOUS BIOPSIES

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ABSTRACT

This paper describes a teleoperated needle guidance and insertion tool to assist doctors in performing minimally invasive percutaneous biopsies remotely under computed tomography [CT] guidance. Robopsy is a user-friendly robotic device that grips, positions and inserts a biopsy needle while the patient is imaged to provide the radiologist with simultaneous needle position feedback. Patient care is improved through more precise targeting and shortened procedure times. Robopsy is made primarily of simple, lightweight, snap-together, disposable plastic parts and modular motors; contrasting devices are heavy, complex and expensive. It is designed to be taped onto a patient so as to passively compensate for respiratory chest motion and, additionally, it incorporates a novel feature, which compensates for passive needle oscillation. The design process is outlined and the first prototype presented. Initial results from testing on a cardiac phantom indicate that artifacts from the device in the CT images are negligible and that the device can successfully orientate and insert a needle remotely.

INTRODUCTION

Needle biopsies are performed to retrieve a sample of human tissue or fluid for histological and chemical analysis. A 14 to 20 gauge needle is inserted through a patient's skin until it reaches the target site from where the sample is extracted. When it is desirable to target a particular lesion, such as those common in patients treated for lung cancer, the process is often carried out under the guidance of Computer Tomography. This results in an iterative procedure whereby, following an initial scan to target the biopsy site and planning the insertion trajectory, in terms of angle and depth, the needle is gradually inserted and the patient is repeatedly scanned to verify the needle position. Often the CT gantry is tilted to coincide with the needle's plane of insertion thus the metallic needle is clearly visible in a single CT scan slice. This iterative procedure necessitates that a doctor and support staff continually shuttle between the radiation-shielded control room (during scanning) and the CT room (when manipulating the needle) and that the patient be moved in and out of the CT scanner's ring.

Biopsy procedures are routinely carried out per year in the United States at a patient cost of approximately $3000 each. This is based on the presence of, at minimum, a doctor, nurse technician and anesthesiologist, as well as the cost per hour to use a $1.5m machine. Typical procedure time is $1\frac{1}{2}$ hours, of which a significant proportion is spent on the iterative targeting procedure. This is an essentially manual procedure and only passive aids exist, which although capable of decreasing procedure time, do not facilitate the near real–time feedback doctors' desire. As such, only lesions bigger than 10 mm diameter can be targeted.

The design team's task was to create a needle guidance system to assist radiologists in targeting lesions during CT guided biopsies. The device designed by the project team and tentatively named Robopsy is small and compact, being made nearly completely of disposable plastics. Once the needle is positioned in the Robopsy device with its tip at the insertion point, the doctor may exit the CT room and control the needle's insertion angle and depth remotely through an intuitive interface, while simulta-

neously scanning the patient to verify its position relative to the lesion. In addition, the device provides a "third hand" to hold the needle and aid the doctor during the actual collection of the sample. Optimistically a one-third reduction in scheduled procedure time could be attained. The challenge of compensating for patient breathing motion is addressed by placing the device directly on the patient and through a special design feature which only firmly grips the needle when absolutely necessary.

DESIGN REQUIREMENTS

Before conceptualizing any device it was necessary to fully understand the nature of a biopsy procedure as well as the functional requirements for the, as yet, undefined device. The design process began with detailed discussions with Drs. Rajiv Gupta and Jo–anne O. Shepard. In addition, a lung biopsy was observed. These requirements included, in approximate order of importance:

1. Pitch and roll — The device must be able to tilt the needle relative to the skin surface to specified angles then make fine adjustments in increments of 1°. A cone of 30° was identified as the work zone.
2. Insertion and retraction — The device must be able to insert and retract the needle in increments of 1 mm with sufficient force. This was estimated at 10 N [1], but testing later suggested this to be excessive and testing indicated that it was about 3.5 N.
3. Chest motion — the rise and fall of the chest must be compenstated for if the needle is held in a fixed reference frame.
4. Compensation for internal motion — The rise and fall motion of the chest coupled with the non–linear (with depth) motion of internal organs means that a needle held firmly, once inside the lung, will lead to tearing of the lung's pleura.
5. Scan transparency — No metallic components may be placed in the scan plane which would impart obscuring artifacts to the image.
6. Sizing — The device must be designed to fit within the confines of the CT machine, a space of approximately 300 mm between a patient and the top of the scanner ring.
7. Patient access must not be restricted by the device.
8. Targeting of a spherical region of 5 mm diameter would be optimal.
9. Safety — In the event of a malfunction the device must be manually overridable as well as provide provision for an emergency stop.
10. Sterilization — Using disposable plastic components wherever possible would address this and the requirement to use non–metallic components.
11. Intuitive interface — Provisions must be made for the doctor's interface to provide one-to-one mapping with the needle motion.
12. Removability — The nature of post procedure treatment necessitates that the device be removed independent of and before the needle.
13. Horizontal translation — Initially, the doctors requested the ability to translate the needle in a 20 mm square box relative to the patient surface before descending and piercing the skin. This was determined to be unnecessary after observing a biopsy procedure which indicted that the insertion point was precisely predetermined and a small incision made at the site to secure the needle tip and provide an angular pivot point.
14. Vision system — The ability to mount a camera on a stand near the device to permit the doctor to view its operation and mind the patient was identified as necessary and easily provided for, but outside the technical scope of this project.
15. Force feedback — An added bonus would be the ability to sense, possibly through a haptic interface, the penetration force, which currently helps the doctor tactily identify the tissue being penetrated. While still under consideration, this was deemed to potentially add unnecessary complexity, especially with the provisions for real-time visual feedback.
16. Cost/commercialisability — Biopsies are not especially expensive medical procedures, therefore the design project goal was to create a simple, highly functional, inexpensive device that would result in a procedure cost/time savings greater than its retail price.
17. Elegance/simplicity — Patients are often only partially sedated during biopsy procedures and so the device must not scare them. This may sound trivial, however a review of current patents and devices did not always indicate that this had been a design consideration.

PRIOR ART

A detailed patent review and search for current commercial devices was conducted. Had a viable solution been identified the project would have been abandoned.

U.S. Patents

The patent search yielded various assistance devices, none which successfully and practically addressed the need for a CT compatible, patient mounted robot. Indeed, some patents were quite vague, such as [2] which detailed a "computer controlled system for guiding the needle device" with a CT, MRI or ultrasound vision system. Other more specific patents, such as [3] appear to be scaled-down versions of typical industrial robots. The

majority of devices were passive guide devices such as [4] which mounts on the head of an ultrasound transducer. [5] proposes a Cartesian frame upon which lasers are mounted which project intersecting laser beams "to mark the location of the tumor and to guide the biopsy needle." Passive protractor–like guidance aids also exist, for example [6].

Commercial Products

Four commercial CT guidance products were examined: the SimpliCT from NeoRad, Oslo, Norway, the PatPos Invent from LapLaser, Lneburg, Germany, the Innomotion from Innomedic GmbH, Herxheim, Germany and the daVinci Sugical System from Intuitive Surgical, Sunyvale, CA. In addition, three devices still under development were considered.

The SimpliCT consists of a laser mounted on a wheeled stand. It is positioned over the patient, the appropriate compound insertion angle, as determined from the preliminary scan is 'dialed in.' Then the needle is simply inserted by hand along the laser beam often in a single pass. The device is being used in a number of hospitals worldwide with positive responses and decreased procedure times [7]. The PatPos Invent performs a similar function from a gantry mounted to the CT machine. However, the gantry must be mounted to the CT machine [8]. Innomotion provides a non-ferrous, MRI compatible, hydraulically driven needle insertion device. It extends over the patient and is mounted to the machine bed [9].

It is recognized that various advanced telemetric and robotic surgery devices exist, for example the daVinci Surgical System from Intuitive Surgical in Sunningvale, California. This device is FDA cleared and currently being used for various laparoscopic procedures [10]. It is much larger and more complex than the device presented in this proposal and is better suited for an operating theatre than a CT room.

More comparable to the device described in this proposal is the combination PAKY-RCM system being developed by researchers at the Johns Hopkins URobotics (Urology Robotics) program [11]. This consists of a 7 DOF articulating arm which is used to position a 2 DOF remote center of motion robotic module (RCM) and attached 1 DOF radiolucent percutaneous access of the kidney (PAKY) needle driver. Once the needle tip is positioned at the insertion point, the RCM module provides a compound angle, and the PAKY, which has been found CT compliant, inserts it with a plastic friction drive. This device is described extensively in [12], [13], [14].

Lastly, two French teams are developing competing devices sharing many end goals and motivations with Robopsy, although the embodiments are completely different. The CT-Bot from the INSA and LSIIT in Strasburg [15], [16], [17] and the CT and MR Compatible Light Puncture Robot (LPR) from the TIMC-GMCAO in Grenoble [18] were both designed to insert a biopsy needle percutaneously under image guidance while compensating for patient respiration. The CT-Bot is patient mounted and activated electronically and has a mass of 2 kg. The LPR, actuated pneumatically, is both CT and MRI compliant and it rests upon a patient while connected to a surrounding frame. Both represent different approaches as compared to Robopsy, most fundamentally they trade greater complexity, weight and cost for additional degrees of freedom.

Figure 1. Examples of existing products: the SimpliCT, PatPos and Innomotion.

DESIGN DEVELOPMENT

Three primary degrees of freedom were identified. Two correspond to the compound angle of the needle trajectory, with respect to the patient's saggital and transverse axes. They will be referred to as θ, tilting from head to toes, and ϕ, tilting side to side. The third corresponds to the insertion and retraction of the needle, nominally a vertical perpendicular to the patient's surface. This is referred to as the z-axis. An additional degree of freedom was identified as corresponding to whether the needle was held tightly "clamped" or "unclamped." The mechanical design was divided into two parts: the needle orientation and the z-axis which encompassed both the clamping and insertion processes. Together these comprised the Orientation Module.

In its current iteration, the Control Module consists of four miniature stepper motors which "plug into" the Orientation Module and are connected to supporting electronics contained in a box that would be placed on a trolley near the patient. This, in turn, is connected via USB cable to a laptop, or Interface Module through which the doctor controls Robopsy, that can be located in the control room. While the Orientation Module design is nearly complete, the current prototype represents only one implementation of the Control and Interface Modules. Other possible embodiments will be discussed later.

Preliminary Design

Initial research indicted that while various devices existed to manipulate a needle, albeit in a less than optimal manner, no one had successfully compensated for chest motion, save to try and track the position of the chest and perform active closed loop compensation. Therefore, after considering remote arms that would reach over the patient, it was decided that the device should mount to a patient's chest (or back as necessary), with adhesive tape and/or straps. This way half the problem was ad-

dressed. The relative internal organ motion was addressed with the z-axis design. Fulfilling the scan transparency requirement lead to the decision that the Orientation Module would be made entirely of plastic. With a proper design all components could be injection moulded and snapped together, thus also addressing sterilizability concerns by making a disposable device. In addition, a small plastic device would be easy to remove independently of the needle, and as was later pointed out, could be simply clipped in half if necessary.

Orientation Module

After initial consideration of a conceptual design of a Cartesian device, it was realized that the ability to translate the needle insertion point was largely redundant. It was therefore decided that, in-line with current medical practice, the insertion point is determined a priori. This also leads to substantial mechanical simplification with the removal of two degrees of freedom.

With the revised task of pivoting a needle around a fixed point, a much simpler, elegant design was possible. The simpler the design, the easier it would be to control, address safety concerns, manufacture, design an intuitive interface and optimally place actuators outside of the scan plane. Directly driving the joints was selected as the most straightforward actuation technique. The natural solution was a mechanism having a primarily spherical geometry, such that all components would share a common centre point, which would correspond as closely as possible with the pivot point on the patient's skin surface.

This approach was initiated through the consideration of a "wrist tendon actuator" device designed by Mark E. Rosheim and described in [19] which mimics the motion of human joints through an actuated ball-and-socket mechanism. The ball is fixed and two straps running orthogonally over the surface cause the socket to pitch and roll. Subsequently circular gimbal mechanisms were investigated. These consist of three hoops fixed one within the other. The inner two hoops are free to spin, and in doing so describe a sphere within a sphere, each having the same centre point. Clearly, attaching actuators to the innermost hoop would be difficult with it rotating relative to the middle hoop. Therefore, a method of actuating two hoops independently with respect to a fixed reference plane was sought. Such a method by which the two angles are decoupled made the forward and inverse kinematics simple.

This mechanism employs two semi-circular structures ("hoops") attached to a fixed base which is mounted to the patient. The base has an outer diameter of 100 mm, tabs excluded. This was selected as large enough to yield a sufficiently strong structure to impart the necessary estimated forces to the needle as well as be handled by a doctor, yet still have stable footing on the curved surface of a patient. This dimension was maintained through the design process and proved sufficient to meet structural needs.

Each hoop is actuated independently, via an as yet unspecified method. The axes of the two hoops are aligned in the same plane and their intersection point is the mechanical pivot point. This is located 8 mm above the actual pivot point on the skin surface. Tabs are provided for securing the base to a patient with tape. They were later improved. The two slits, in the hoops, provide a double track such that a carriage contained within both slots will be driven to describe a semi–sphere. A needle contained within such a carriage will thus describe a cone shape which can be set to the desired 30°. The carriage design will be described fully in the section addressing the z-axis.

The design has the advantage that the slop between the carriage and the hoops results in a small angular error. For example, 0.1 mm of clearance results in a maximum angular error of 0.1°.

This preliminary design was rapid prototyped and examined. From the figure it can be seen that the top and the bottom surfaces of the hoops were flat in one direction. This was found to require unnecessary clearance between the hoops as well as cause jamming. Therefore, it became evident that the mechanism should be designed entirely out of spherical surfaces, that way all components would nestle together and share a common centre point.

Z-axis and "Waggle Mode"

The design of the z-axis yielded its own special set of functional requirements including:

1. The device must be able to handle varying size needles.
2. Rapid and slow incremental insertion/retraction must be possible. Sometimes the doctor inserts a needle rapidly during a single exhalation of the patient whereas at other times fine adjustments are desired.
3. For safety, the doctor must be able to back–drive the mechanism instantly.
4. A non–ridged rest position, i.e. when the needle is not being actively inserted/retracted is essential. Were a needle held firmly the relative internal breathing motion would have a tearing effect on organs.
5. On command, independent gripping is desirable.

These considerations lead to a process description of grip, push, release and most importantly, the concept of a novel "waggle mode." The waggle mode specified that the needle should be free to wobble in any direction approximately 10° degrees off its central position as measured directly in the middle of the carriage. This necessitated a carriage with a corresponding cone-shaped hole which allows a $10–15^\circ$ cone of movement and a corresponding widening of the slot width.

Various methods of coupling insertion and gripping motion were explored via such mechanisms as those found in propelling pencils, drill chucks and screw extruders. The solution was to employ a friction drive in the form of two rollers, with at least one powered, coupled with a mechanism that would clamp them

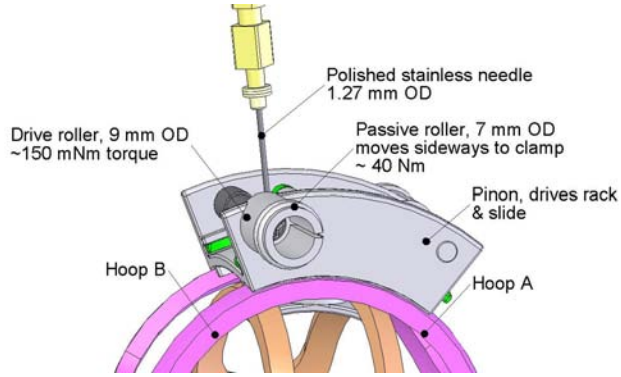

Figure 2. Z-Axis detail (cut away view).

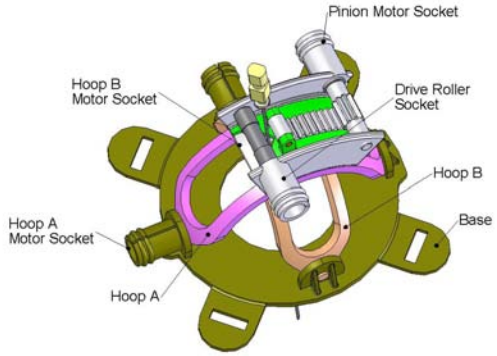

Figure 3. Top view of the solid model of the prototype.

around the needle. Now the challenge became gripping the needle upon demand and driving it from its centre position. Failure to return the needle to the central position before moving it would result in an incorrect trajectory. Additionally, the large hole allows the device to be removed before the needle so that the patient can be instantly bandaged upon needle removal.

The final embodiment shown in Fig. 2. This is a detail of the Z–axis and shows the drive rollers and slide. The slide closes, from one side, over the circular "waggle window" to clamp the needle. The powered drive roller then inserts or retracts the needle.

In Fig. 3 the carriage is shown engaging both hoops. Shown in black is the drive roller, which is fixed to the carriage casing. It is coated with a high friction neoprene rubber. The passive roller is fixed to the slide, which runs in a slot in the carriage. Both the slide and the carriage are composed of spherical surfaces as described previously. The slide is equipped with an integrated moulded in rack which is driven with a pinion mounted to the carriage. It appears that the needle is not being held in its centre position, in the middle of the carriage, as it would be were slides to move in from both sides. This is compensated for via software control and the center position maintained. Upon initiating clamping Hoop B moves 15° to the right, drawing the carriage with it simultaneously as the slide closes. Upon unclamping Hoop B moves back to its original position, thus the needle is again free to "waggle" around its doctor specified position.

PROTOTYPE

Figures 3 and 4 show solid models of the prototype.

Following the principles of Design for Manufacture and Assembly, all components snap and push together. First the carriage is pushed through Hoop A then hoop B, which is then rotated 90° to lock in place. The hoops are then are slightly compressed and snapped between the mating tabs. Then the pinion is pushed through the motor socket which is of larger diameter than the opposing bearing hole. The motor will, in turn, secure the pinion.

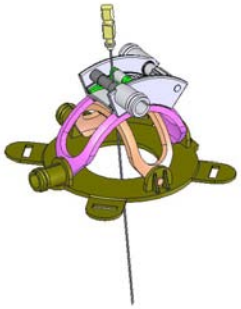

Figure 4. Side view of the solid model of the prototype.

The slide's passive roller is assembled and slid into its track from the carriage side opposite the pinion. Finally, the drive roller to which rubber has been attached is slid into place. Since each device is designed to be used only once, no bearings are used, simply plastic pins, or nubs, in matching holes. The base is equipped with tabs for taping and slots for securing straps.

The only special work is the application of rubber to the drive roller and the attachment of the gears to the motor shafts. These are specially designed and tapered to engage, regardless of small manufacturing errors, matching moulded sockets in Hoops A and B, the Pinion and the Drive Roller. With a little refinement, all components should be easily injection moulded. Currently the motors are prevented from rotating in their sockets with a band on the outside; this will be optimised. Ideally at the end of a procedure the doctor would simply unclip the motors, which had never contacted a patient, and discard all the plastics.

Upon completion of the solid model and verification of the strength of critical components it was SLA rapid prototyped. The final product required nearly no finish work, only light sanding on some of the pivot points. The motor and wiring and installation was completed and the device was taken to Massachusetts General Hospital for CT compatibility testing. Then the Con-

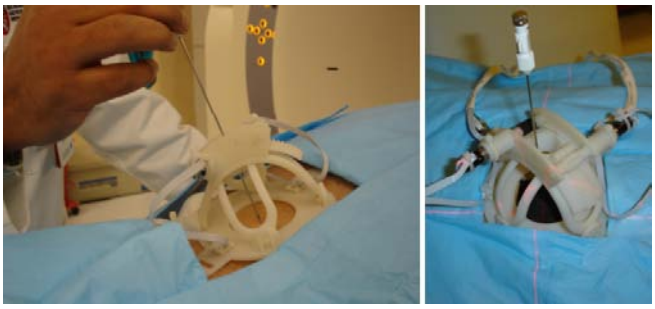

Figure 5. Prototype undergoing testing at Massachusetts General Hospital.

troller module was constructed, with each motor plugging into a 4-conductor telephone socket and a temporary software interface was written. Functional testing was conducted and performance exceeded all expectations. The Robopsy device is shown en situ in Fig. 5. The completed device, with all motors and cabling attached had a mass of 260 g. Without the cabling, but including the motors its mass is close to 150 g.

STRUCTURAL ANALYSIS

The bulk of the structural analysis during the design phase was done by hand using elastic and plastic theory and conservative approximations. Finite element analysis was then later used to verify structural integrity, with particular attention paid to structural elements that did not lend themselves well to hand calculations.

The hoops were not a particular structural problem, and they were initially designed to have a high stiffness in the direction of insertion of the needle rather than to conserve material.

During design, hand calculations were used to ensure safety factors of 5 in the carriage, a structurally challenging part. This was done under the realization that stress concentrations of approximately 3 would be present. After more detailed finite element analysis, safety factors were found to be at least 1.5 — a number that agrees well with the initial assumptions.

Static finite element analysis of the structure was carried out using CosmosWorks 2004 to validate first–order calculations made of the structure. The material was modeled as Nylon based on the assumption that the final device will be made from injection moulded plastic. The material properties of the SLA material used in prototyping are similar. Each component was analysed separately and the loads and boundary conditions that were applied were based on calculated interaction forces and constraints between the parts. In considering the load on the hoops and base a worst case scenario was assumed in that the 10 N of force was applied to the middle of the lower hoop.

Figure 6 depicts the stress distributions of the slider. Similar analysis were carried out for other parts, the main results of which can be found in Tab. 1.

Table 1. Safety factors of key structural elements.

	Max. Stress	SF
Hoop	8.5 MPa	5.5
Base	8.0 MPa	5.9
Rubber Roller	9.1 MPa	5.2
Teeth on Rack	12.6 MPa	3.7
Teeth on Pinion	22.7 MPa	2.1
Passive Roller Support	31.9 MPa	1.5

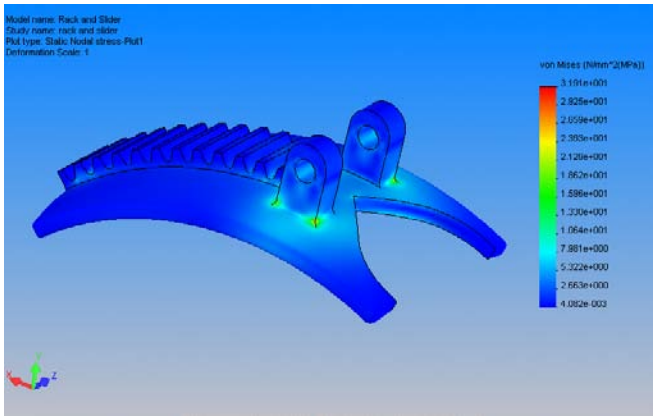

Figure 6. Stress distributions of slider.

Hertz contact stress analysis was used in the design of the friction drive to ensure that the contact stresses between the needle and the rollers were not excessive. Rubber was placed on the drive roller to decrease the contact stresses and improve traction. This increased the frictional coefficient between the needle and roller, thus decreasing the required clamping force, as well as increasing the contact area.

ACTUATION AND CONTROL

ARSAPE Stepper motors were chosen for their low volume and weight. A series AM 1020 Motor was selected with a planetary gear head with a 256:1 reduction. The step angle of the motor is 18° and so with the gear reduction an angular position resolution of 0.07° was obtained. Additionally, stepper motors allow the device to be controlled “open loop”, which is generally adequate for systems that operate at low accelerations under static loads. The motors are driven in current mode and have a max torque output of 200 Nmm and a rated output speed of approximately 60 rpm at 100 Nmm based on intermittent operation.

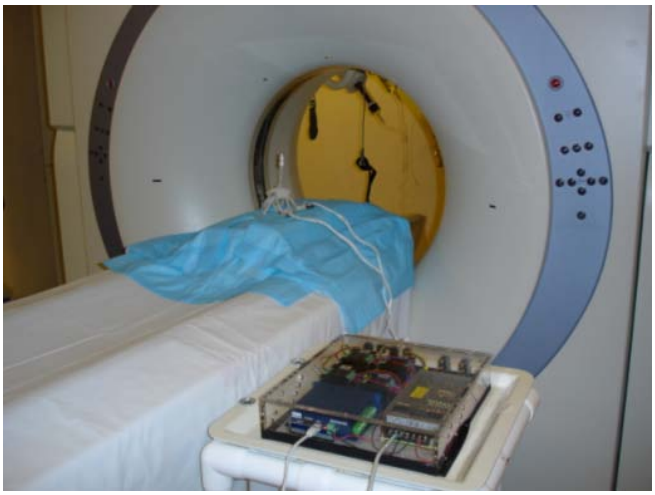

Figure 7. The Robopsy control box.

The device thus has the ability to orientate the needle at a speed of 360 °/s, go from clamped to unclamped in 1 s and insert the needle at a rate of 20 mm/s.

The control box (Fig. 7), located on a trolley next to the CT bed, is plugged into a standard 120 V wall outlet and connected via a USB cable to a computer located in the control room. Inside the box are off–the–shelf components; a USB stepper motor controller, power supply and four stepper motor drivers. They allow Robopsy to be actuated remotely from the CT control room.

Currently, the device is controlled with a custom software interface. Working from a reference position with the needle in the upright position, the angles may be entered and the needle commanded to attain that position. Small 0.5° "jogs" are also possible. The user inputs are converted into desired rotations and speed and sent to the controller which in turn sends step commands to the individual motor drivers. The needle insertion depth is similarly controlled.

The current preliminary software interface will serve the purposes of mechanical testing and validation. Its replacement will incorporate joystick–based control. An additional Interface Module could be placed on the trolley along with the control box, allowing the doctor to control Robopsy so as to serve as a third hand when collecting samples.

TESTING AND VALIDATION

The purpose of this device was to provide needle alignment and insertion capability. A design requirement for the device was that it did not produce artifacts in CT scans. Initial testing of the device was done in the Radiology Department at Massachusetts General Hospital on a Siemens Somatom Sensation 64 machine. The device was controlled via the custom software interface by the doctor in the control room while it was placed on a cardiac phantom (Fig. 8). The needle orientation and depth were adjusted by the doctor while a number of scans were taken.

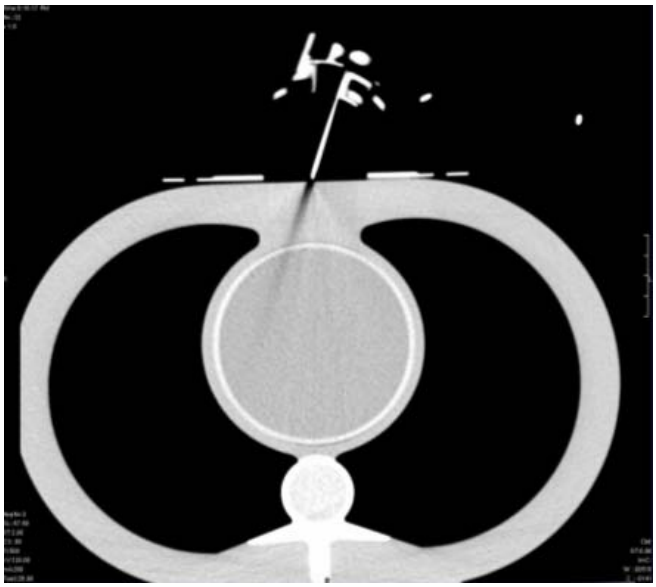

Figure 8. A CT scan of the device showing that no significant artifacts are produced.

It can be seen that having the hoops actuated by small motors away from the plane of the needle that artifacts from the metal in the motors is negligible. As well as this the motors for clamping and inserting the needle are above the needle insertion point and so contribute minimal distortion.

FUTURE WORK

Testing indicates that the Robopsy device is capable of attaining its stated goals. The remaining tasks include:

1. Optimisation of the structure to minimise weight and waste of material.
2. Further size reduction — A slightly smaller device would better fit the curved surfaces of a patient.
3. Patient mounting — A design optimisation of the base would include testing and selecting of various patient attachment solutions.
4. Exploration of remote cable drives, which would be preferable to on-board motors.
5. If motors are retained, they must be made to simply plug in and out of the Orientation Module, or alternatively, motors small enough to fit the device, yet inexpensive enough that they may be discarded with the device must be obtained.
6. Cable management — However actuation is provided to the Orientation Module, all components must be combined into a single flexible unit.

7. Interface — The Interface Module is as yet incomplete, a haptic interface would be ideal.
8. Optimisation of needle insertion — The Z-axis Module must undergo more extensive testing to verify that it reliably provides the desired insertion force and precision, even when the needle is moist with bodily fluids.

CONCLUSIONS

Testing of the Robopsy prototype has validated both the concept and design. Moreover, the response from Massachusetts General Hospital's representatives has been positive.

The geometry of the design is a natural result of the required semi–spherical workspace with a pivot point close to the skin, resulting in simple kinematics and a parallel structure. The "waggle window" addresses physicians' concerns that the internal organs might be damaged by a firmly gripped needle due to their relative motion. The design of the "waggle window" and friction–drive carriage allows for a range of standard biopsy needles to be used. The device will serve as a third hand for doctors, which can be either remotely or locally controlled.

It remains to verify the reliable function of each component and optimise some elements. No major problems are foreseen in the critical path towards the final design for animal tests. The second prototype will be used for testing, first on store bought turkeys, then, conditional upon receiving the appropriate permissions, a porcine model.

The Robopsy device is currently protected by a provisional patent. It appears that a commercialised version would prove a great aid to doctors during CT guided biopsy procedures. The device would improve patient care through decreased procedure time and sedation time as well as by aiding the targeting of smaller lesions than are currently accessible by hand. For the hospital this would also represent greater throughput and better return on investment. Moreover, coupling the existent CT equipment, without modification, to form part of a closed loop feedback system would maximise its capabilities. In further iterations, it might even be possible to connect the Robopsy software directly to the CT software to allow "point and click" targeting.

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