Proceedings of the 29th Annual International
Conference of the IEEE EMBS
Cité Internationale, Lyon, France
August 23-26, 2007.

Human Factors Design for Intuitive Operation of a Low-cost, Image-Guided, Tele-Robotic Biopsy Assistant

Nevan C. Hanumara, Conor J. Walsh, Alexander H. Slocum, Rajiv Gupta, Jo-Anne Shepard

Abstract—**This paper details the design and interface development of *Robopsy*™, an economical, tele-operated, patient mounted, disposable needle guidance and insertion system to assist radiologists in performing minimally invasive percutaneous biopsies remotely under CT guidance. Testing with a phantom in a realistic surgical setting was conducted to ensure that the interface was intuitive and facilitated smooth integration of the device into current procedure. Ease of learning and operation is critical in order to encourage rapid adoption of this new medical robotics model.**

I. Introduction

IMAGING technology is revolutionizing interventional medicine; however practitioners lack tools which fully utilize, in real-time, the coordinate positional data provided by Fluoroscopy, Computed Tomography (CT) and Magnetic Resonance Imaging (MRI). These tools must be able to operate remotely, within the confines of imaging equipment, and be either x-ray or magnetically compliant. In addition, minimally invasive procedures are frequently performed on an out-patient basis and are not well suited to large-scale medical robotic operating suites, as discussed in [1], which manipulate multiple tools via haptic interfaces. There is a clear need for an alternative to these large and expensive machines. The tele-robotic manipulator and user interface described herein for aiding CT-guided percutaneous lung biopsies, explores the hypothesis that a relatively simple device with an intuitive interface designed for good human factors, can improve a well-defined procedure.

II. Current CT-Guided Lung Biopsy Procedure

Lung cancer is the highest mortality cancer in the U.S, with 213,000 persons diagnosed annually and a 5-year survival rate of only 15.5%. Earlier detection is essential to improving patient prognosis [2]. Diagnosis involves inserting an annular biopsy needle percutaneously into the lesion, then once placed, removing the needle's plug and deploying a tool to obtain a tissue sample for histological analysis.

An initial CT scan identifies the lesion's position with sub-millimeter accuracy and using the CT display's tools, angle and depth measurements are made to the lesion from the insertion point. This is identified via a metallic grid, placed on the patient, which is visible in the scan as a series of bright dots. Then, in the current procedure, using these precise measurements, the needle is imprecisely inserted manually, with virtually no physical guides, in an iterative procedure. During this, CT scans of the patients, which indicate the needle tip location, alternate with incremental tilts and advancements of the needle. Each cycle necessitates sliding the patient in and out of the scanner bore and the medical team moving back and forth between the control room and scanner. Currently, lesions smaller than 10 mm cannot be reliably targeted, with an overall acquisition rate of only 77%, and multiple needle insertions are often needed, with each insertion increasing the risk of pneumothorax, full or partial lung collapse [3]. Each biopsy consumes approximately 2 hours of scanner time at a cost of $700 per hour. Radiologists report that the procedure is fatiguing due to the stress of accurately placing the needle and avoiding surrounding vital structures.

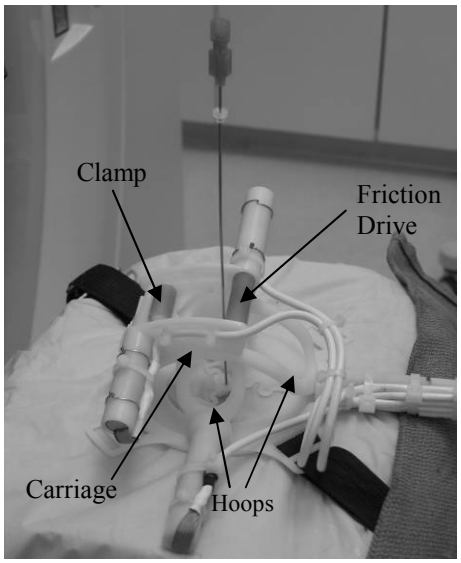

Fig. 1. *Robopsy*™ Beta prototype. The disposable actuator is shown strapped to a phantom. The needle is not currently gripped by the device and is free to move.

Manuscript received June 22, 2007. This work was supported by the Center for Integration of Medicine and Innovative Technology (CIMIT), a Boston area medical and academic consortium, www.cimit.org, Proof of Principle award 06-20. Additional thanks to the staff of MIT, CIMIT and the Massachusetts General Hospital.

N. C. Hanumara is a Doctoral Candidate in the Massachusetts Institute of Technology's Dept. of Mechanical Engineering, Cambridge, MA 02139, U.S.A. (617.258.8541, hanumara@mit.edu)

C. J. Walsh is a Doctoral Candidate in the Massachusetts Institute of Technology's Dept. of Mechanical Engineering. (walshcj@mit.edu)

A. H. Slocum is the Neil & Jane Pappalardo Professor of Mechanical Engineering at the Massachusetts Institute of Technology. (slocum@mit.edu)

R. Gupta is Director of the Massachusetts General Hospital Volume CT Lab and a fellow in the Radiology Dept. (rgupta1@partners.org)

J. O. Shepard is Director of Thoracic Radiology at the Massachusetts General Hospital. (jshepard@partners.org)

III. ROBOPSY™ BIOPSY ASSISTANT DESCRIPTION

The patent-pending *Robopsy*™ device is being designed in collaboration between the Massachusetts General Hospital (MGH) and MIT's Precision Engineering Research Group. The project began in 2004 and originated in the hospital's Radiology Dept. with the recognition of the deficiencies in the current percutaneous lung biopsy procedure. Shown in Fig. 1 is the lightweight, disposable ~200 g, actuator which is peel-and-stick adhered (and strapped if necessary) over the insertion site, located with the assistance of the metallic grid. Remotely from the control room, a radiologist directs it to grip, orient and insert the needle into the lesion, while able to image simultaneously. Thus that the loop is closed through the radiologist and the needle's position can be verified in near-real-time. The patient remains in the scanner and procedural accuracy is increased and duration decreased.

Following Dreyfuss's focus on function [4], the current manual procedure was studied with the aim of identifying those steps that would benefit from mechanization and those that are currently satisfactory. This minimized the mechanism's degrees of freedom (DOF) and complexity. To this end, both the initial trajectory planning and final sample collection phases were considered acceptable, but the needle positioning and insertion were deemed sub-optimal. Thus, the robot is designed to control depth into the thorax and two angles, towards the patient's head or feet (in and out of the scanner bore) and left or right with respect to the CT slice. A crucial fourth DOF was identified: the gripping and releasing of the needle. It is only held rigidly, when absolutely necessary, which prevents laceration due to internal organ motion during respiration. Finally, by mounting directly to the patient, the device passively compensates for vertical respiratory motion and unexpected movement.

By identifying the minimal essential DOF, a simple device, with only four axes emerged. These are driven by 10 mm diameter micro DC servo motors which provide high torque and fidelity in a clean, reliable package. Being metallic, they are positioned so as to lie outside the CT image scan plane. A more detailed description of the design process is available in [5]. A carriage rides in two concentric, nested hoops, with axes at right angles which rotate so that the carriage describes a 50° cone of motion. The carriage consists of a friction drive whose two rollers clamp, and unclamp, around the needle via a rack and pinion drive. The entire structure is composed of injection moldable, snap together, plastic parts, which are x-ray compliant, i.e. create minimal artifacts when scanned. Post-procedure the inexpensive structure is discarded while the expensive electronics are retained. Competing devices, analyzed in [6], provide neither the same level of control and guidance nor portability and are considerably more expensive.

IV. SIMULATED CT-GUIDED PROCEDURE

In order to perform mechanical testing and validation, better understand the features necessary for intuitive operation of *Robopsy*™, and conduct human factors analyses of various interface designs, the actual lung biopsy procedure was simulated in a typical surgical setting. This was done on a Siemens Somatom Sensation 64 CT at MGH.

For initial testing a uniform and sanitary thoracic phantom was constructed from ballistic gelatin (used to simulate human flesh for armaments testing) that was cast around plastic pipes, which mimicked ribs which were to be avoided. Embedded glass beads of 2 to 20 mm, which are clearly visible under x-ray, served as targets.

This phantom was positioned on the CT bed, as a patient would be, and the standard biopsy procedure performed by a trained interventional radiologist. The lesion (bead) identification, insertion point selection and trajectory planning, avoiding the ribs (pipes), were conducted as usual. Then instead of inserting the needle manually, the device was affixed right over the metallic grid, as shown in Fig. 2.

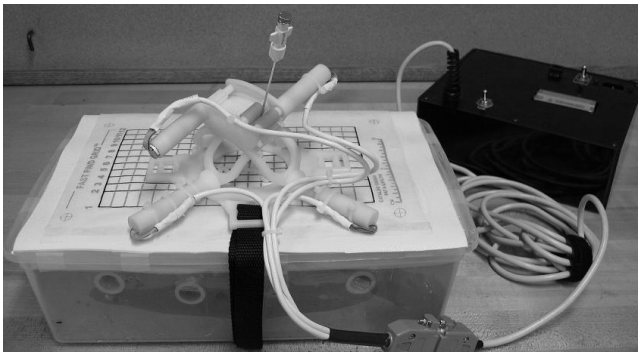

Fig. 2. *Robopsy*™ attached to the thoracic phantom consisting of ballistic gelatin with embedded simulated ribs and glass bead targets. The metallic grid is under the device and the portable control electronics are visible at right.

Fig. 3 indicates how the radiologist spatially orients the needle. Beginning with the needle clamped in the upright position, but not inserted, the radiologist considered the off plane angle and tilted the needle with *Robopsy*™, until it was completely visible in the scan plane. Then the needle was tilted left or right in this scan plane to the desired in plane angle. Finally, after confirming correct angular orientation, it was inserted, with minor adjustments, to the desired depth. This process is detailed in Fig. 4.

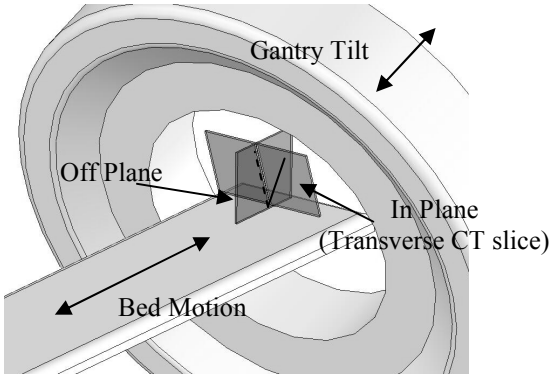

Fig. 3. Schematic of the angles used by a radiologist to orientate a biopsy needle. The transverse plane corresponds with the CT slice and the off plane view is approximated by flipping through slices.

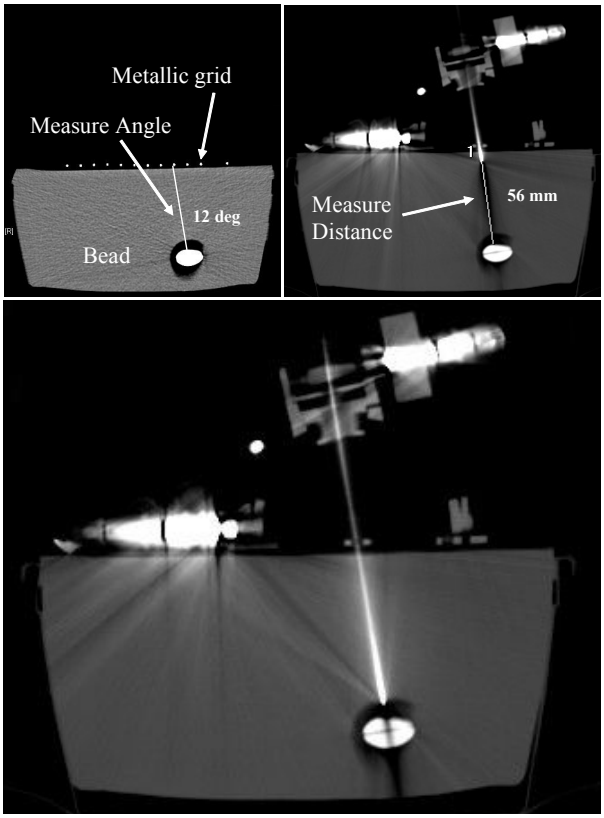

Fig. 4. Top, left: CT slice viewed by the radiologist during the trajectory planning stages. Top right: Device placed and needle aligned, aimed at 20 mm simulated lesion. Distance to target measured. Bottom: Needle successfully touching center of bead with minimal scan distortion.

For each insertion attempt the total positioning and insertion time and number of scans were recorded. This data was compared to manual lesion targeting trials, following standard protocol, with the same phantom. This testing is ongoing, and results are beginning to indicate that, under ideal conditions, no more than three scans should be necessary to align and insert a needle: after placement and initial alignment, after adjustment, and after insertion to confirm correct placement. An estimated time savings of up to 20 minutes will be possible. In addition, the device will enable targeting specific regions of the lesion, important since there may be regions of necrotic tissue which yield inconclusive diagnoses. From observing radiologists' difficulties in conducting initial trials with the device, it was evident that the user interface needed to correspond completely with the standard steps and angular perspectives of the well structured current procedure.

V. Interface Design

Equally challenging and essential as the mechanical design, was the development and refinement of the graphical user interface (GUI), used by the radiologist to direct *Robopsy*™ from the CT control room. Because the device is presented as a low cost, simple, portable medical robot which offers substantial procedural gains, market research has indicted a high willingness to "try it" provided that the learning curve is shallow; the target training period is one afternoon. Good human factors and user-centric design as espoused by Dreyfuss [4] and Normand [7] and detailed by Sanders and McCormick [8] are paramount.

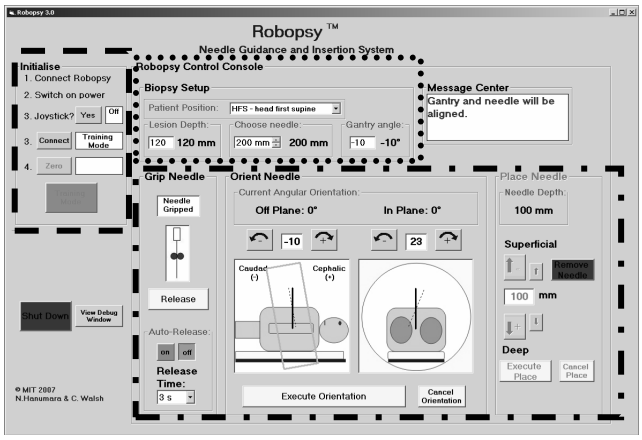

Fig. 5. Graphical User Interface: Connection (▬ ▬), Procedure Preparation (• • • •), Motion Planning and Execution (▬ · ▬) panels.

To facilitate easy modification, the GUI, shown in Fig. 5, was programmed in Visual Basic 6. Positional commands and gain values are sent to the off-the-shelf 4-axis micro-servo motor controller and amplifier via the manufacturers' proprietary ActiveX toolbox. Once the interface is finalized, both will be replaced with hard code and custom electronics.

After planning the insertion point and trajectory, the device is secured on the phantom and the graphical user interface opened on a laptop PC. A few preparatory steps are necessary. Firstly, the device is plugged into the control box and connection initiated and confirmed. Secondly, the patient position is indicated, i.e. supine or prone and head or feet first into the scanner bore. This causes the display to present a stylized image of a patient in the same perspective as the actual patient. Thirdly, the lesion depth is entered into the planning panel and the interface indicates the necessary needle length.

During trials the subject operators were carefully observed and notes taken regarding difficulties and errors and the interface modified before the next round of testing. As an example of the importance of human factors, a previous interface version was found confusing because the radiologists were required to select their own needle length and consistently did not understand the need to choose a needle longer than normal, so that the device could grip it. Simply removing this unnecessary option and automating needle selection eliminated all confusion. Finally, the gantry tilt angle is entered and the off plane view updates to show the tilted gantry.

Surprisingly difficult was bridging the gap between the coordinate systems used by engineers and radiologists. While engineers can intuitively think in compound angles and coordinates, a radiologist positions a needle with respect to a patient's body. It became clear that it was important to provide the same in plane and off plane views, rather than a three dimensional perspective. These are clearly visible in Fig. 6. The stylized patient showing a head, arms, feet and a navel is indispensable in making sure that radiologists don't

become confused and are comfortable that the device will not move in an unexpected direction. In addition to changing the image, setting the patient position causes labels, such as caudad and cephalic, to change appropriately. Previously, directions were labeled with positive (+) and negative (-) directions, which are standard for engineers, but have no relation to the human body.

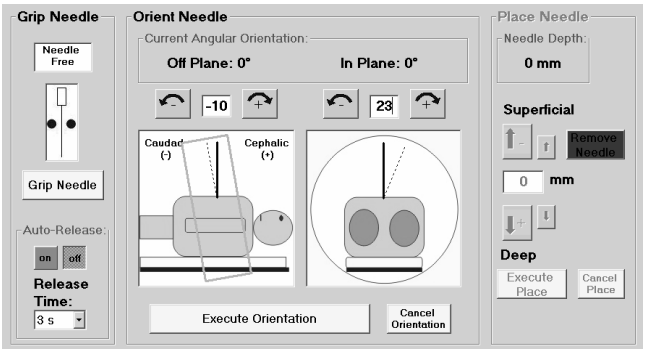

Fig. 6. Detail of the motion planning and execution panel. Off plane and in plane views are provided. Angles and depths entered into the boxes or by clicking the arrows. A preview is generated and motion either executed or cancelled by buttons below.

The potential for user overload and erroneous actions is minimized by layering functions. The user must first select a needle length and indicate the lesion depth before any of the motion planning features become active. Then no single action can cause motion. The needle's position is displayed as a solid line and clicking the arrow keys or entering an angle or depth value generates a preview dashed line. This preview can then be cancelled or executed with a separate pair of buttons. All mappings are one to one, such that the needle image moves in the same direction as the actual needle visible through the control room window. The clamping and unclamping is automatic, though the clamp can be activated manually, such as when a sample is being collected, in order to steady the needle while the radiologist inserts a biopsy gun or finer needle through its annulus.

Error rejection is both passive and active, with inaction always preferable to motion. For example, if one out of two inputs in nonsensical, both motions are blocked. Depth and angles must be adjusted separately such that no potentially injurious sweeping motions, which would insert and angle simultaneously, are permitted. Though measurements are made in both centimeters and millimeters, the interface operates with millimeters so as to always err on the side of caution.

The radiologists on the *Robopsy*™ design team now exhibit ease of use with the current interface version and indicate that the learning curve is short. Now that reliable operation is possible, porcine trials will soon begin. Nevertheless, interface testing will continue in a controlled fashion with fresh, uninitiated radiologists.

Still needed is a way to transfer the measurements directly from the CT display to the interface. This will necessitate accessing the CT machine's software and importing the selected CT slice, corresponding to the needle's plane, into the *Robopsy*™ interface. Ideally the user would click on the top and the bottom of the device to register its position and account for any tilting of the device, due to the patient not providing a flat mounting surface. Then the center of the lesion would be indicated, and after a short verification procedure, the needle would be inserted without further guidance from the radiologist. Under best conditions, only one planning scan and one post-insertion scan to confirm placement, would be necessary.

VI. Conclusions and Future Work

In this paper we have detailed the design and interface development of *Robopsy*™, an economical, tele-operated, patient mounted, disposable robotic needle guidance and insertion system. The careful integration into current procedure and good user interface human factors were ensured through testing with a phantom in a realistic surgical setting. The interface was designed for ease of operation and a short learning curve, both essential if this and related technologies are to be adopted widely.

While designed for lung biopsies, *Robopsy*™, could be used for other procedure where probes must be inserted into a patient under image guidance, such as lung, kidney, liver and pancreas biopsies, RF ablation, and prostate brachytherapy seed placement. Fluoroscopic interventions could be conducted remotely with minimal radiation doses for the medical team. Modifications may be necessary in order to affix the device to different corporal structures. The device aims to reduce procedure time and cost while improving accuracy and patient care.

Moreover, the novel model of lightweight, low cost, disposable medical robotics is extensible to other procedures. With different graphical interfaces the same computer and control electronics could be connected to different robotic end effectors to facilitate a wide range of interventional procedures.

References

[1] Guthart, G.S.; Salisbury, J.K., Jr., "The Intuitive telesurgery system: overview and application." Paper IEEE ICRA 2000, April 24-28, 2000, p. 618-621, vol.1

[2] American Lung Association, "*Trends in Lung Cancer Morbidity and Mortality."* Epidemiology and Statistics Unit, September 2006

[3] Michael M. Maher, M.D. and Jo-Anne O. Shepard, M.D. et al., "Percutaneous Needle Biopsy of the Thorax: A Technical Atlas." MGH, Department of Radiology, Harvard Medical School.

[4] H. Dreyfuss, *Designing for People.* New York: Simon and Schuster, 1955.

[5] S. R., Barrett, N.C. Hanumara, C. J. Walsh, A. H. Slocum, R. Gupta, J. O. Shepard, "A remote needle guidance system for percutaneous image guided biopsies," presented at the 2005 ASME DETC, Long Beach, CA, Sept. 24-28, 2005, Paper DETC2005-85387.

[6] C. J. Walsh, N.C. Hanumara, A. H. Slocum, R. Gupta, J. O. Shepard, "Evaluation of a Patient Mounted, Remote Needle Guidance and Insertion System for CT-Guided, Percutaneous Lung Biopsies," presented at the 2007 ASME Biomed, DETC, Irvine, CA, June 7-8, 2007, Paper BIOMED2007-38080.

[7] D.A. Norman, *The Design of Everyday Things*. New York: Basic Books, 1988.

[8] M. S. Sanders, *Human Factors in Engineering and Design*. New York: McGraw-Hill, 1993.