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# EVALUATION OF A PATIENT-MOUNTED, REMOTE NEEDLE GUIDANCE AND INSERTION SYSTEM FOR CT-GUIDED, PERCUTANEOUS LUNG BIOPSIES

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## INTRODUCTION

Computed tomography (CT) guided percutaneous lung biopsies are conducted to retrieve samples of suspected cancerous tissue for diagnosis. This paper details the design and development of Robopsy™, an economical, patient-mounted, tele-robotic, radiolucent, needle guidance and insertion system which facilitates faster more accurate lesion targeting.

Lung cancer is the most deadly cancer in the U.S, with 213,380 persons diagnosed last year and a 5-year survival rate of only 15.5% [1]. Earlier detection is essential to improving patient prognosis. A recent study conducted CT screening of 31,567 patients and demonstrated that, for those diagnosed with stage I lung cancer that underwent surgical resection within 1 month, the survival rate increased to 92% [2].

Each diagnosis, however, requires conducting a tissue biopsy and the current procedure is manual, iterative and time-consuming. While CT images identify the lesion location with sub-millimeter accuracy, this precision is not successfully utilized. Currently, the needle is inserted completely by hand in an iterative and incremental fashion. This necessitates multiple trips between the imaging console, in the control room, and the patient, in the scanner. Lung nodules smaller than 10 mm in diameter cannot be reliably sampled and the overall successful acquisition rate is approximately 77% [3]. Nor is it possible to reliably target specific portions of a tumor, such as those which have been shown to be metabolically active. Furthermore, multiple needle insertions are often necessary and with each the risk of pneumothorax (partial or full lung collapse) increases.

In addition to improving a surgeon's ability to target a lesion using CT guidance, Robopsy™ represents a new paradigm centered on simple, disposable, low-cost medical robots. Other approaches to the problem, discussed in detail in [4], include much more complicated, heavy robotic systems as well as passive laser guidance systems. Robopsy™ is available for an order of magnitude less cost and still offers sufficient functionality to improve patient care and hospital efficiency.

## DEVICE DESIGN AND DEVELOPMENT

Figure 1 shows the beta prototype. The small, lightweight, radiolucent (x-ray compliant), disposal actuator sticks and straps directly onto a patient in a CT scanner. Using a novel gimball-like mechanism and a friction drive, both constructed primarily of injection moldable snap-fit plastic parts, it grips, orients and inserts a standard, unmodified biopsy needle. By affixing the device directly to the patient and selectively gripping the needle, only when it must be manipulated, the challenge of compensating for patient respiration is addressed.

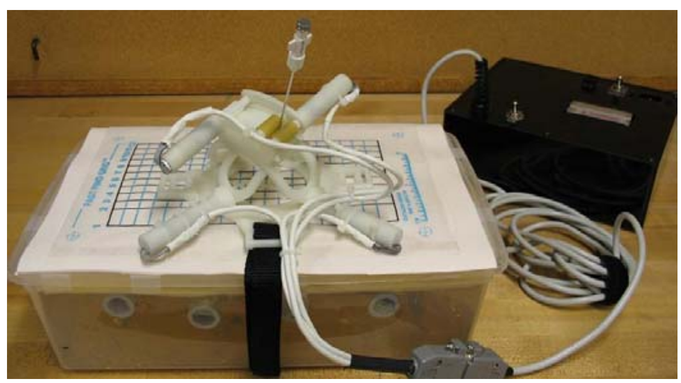

Figure 1: Beta prototype of Robopsy™ attached to a chest phantom.

The actuator is connected to non-disposable support electronics and a computer interface, which graphically displays the needle orientation and affords its intuitive remote manipulation from the radiation-shielded CT control room. Thus the radiologist simultaneously images and manipulates the needle, from insertion point right into the lesion, without entering the scanner room or moving the patient out of the bore.

 

## EXPERIMENTAL METHODS

Preliminary testing was performed with a Siemens Somatom Sensation 64 CT scanner at Massachusetts General Hospital (MGH) to validate the device's function and conduct a human factors analysis of various interface designs. A chest phantom was constructed of ballistic gelatin, having a consistency similar to human tissue. Target lung nodules were simulated with beads, ranging in size from 2mm to 20mm, cast into the gelatin below ribs of plastic piping.

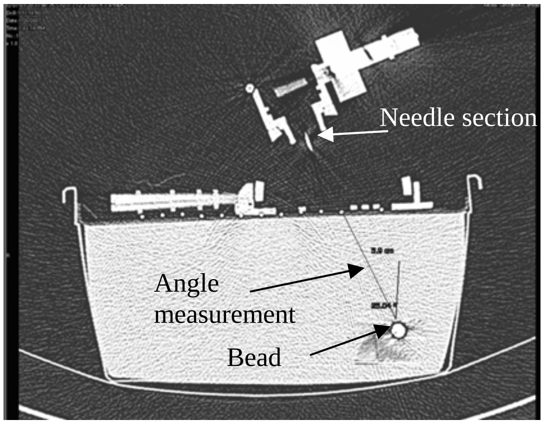


Figure 2: CT scan of Robopsy™ on thoracic phantom. Only part of the needle is visible as the needle has not yet been aligned with the CT scanner gantry.

These nodules were then biopsied by an expert radiologist in accordance with MGH's current standard procedure, described in [3], both manually and using Robopsy™. For each targeting trial, the number of individual CT scans necessary, number of insertion attempts and trial time were recorded and compared. The Robopsy™ actuator was controlled using a custom designed interface from a laptop. Angular and depth measurements for the desired needle trajectory were made with the CT scanner display software and these were used to command Robopsy™ to orient and insert the needle

## RESULTS AND DISCUSSION

Preliminary testing with the phantom, shown in Figure 2, has indicated an estimated 10 minute decrease in the time required to target a lesion, compared with the manual procedure. Further, by having the Robopsy™ system assist with trajectory planning and sample collection we believe that the total procedure time can be reduced by 20 minutes. These time savings are illustrated in Figure 3 based on experiments we have performed targeting a 10mm bead. Furthermore, we have found that fewer CT scans are required when using Robopsy™, implying a reduced radiation dose for the patient. Continued testing is indicating that it may be possible to complete the procedure with only two CT scans; the first to locate the lesion and plot the insertion trajectory, plus one further scan to confirm needle position after a single remote needle insertion. However, a scan to verify that the needle is correctly aligned before penetration through the pleura may be clinically necessary for the lung biopsy procedure.

Concurrent with further procedural testing, mechanical redesign is continuing to ensure reliable operation, address remaining manufacturability issues, optimize motor coupling to the structure and eliminate actuator backlash, which is currently limiting targeting accuracy. Furthermore, the current patient mounting strategies, adhesive and straps, will be evaluated.

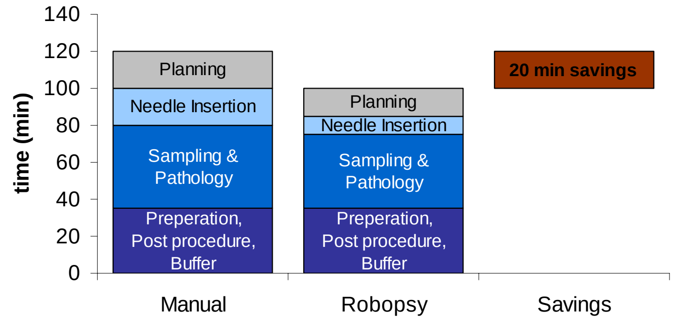


Figure 3: Preliminary testing results showing a reduction in time and no. of CT scans using *Robopsy*™.

Our initial testing shows that Robopsy™ can improve a surgeon's ability to target a lesion by enabling fuller utilization of the CT's precise positional data. Our preliminary data show that our technique has potential to reduce the procedure time and radiation dose, permit the operator to target smaller lesions more consistently and decrease the average number of needle insertions through the chest wall and pleura. Further, with the time saving a hospital can then fill a previously unavailable time slot with a standard screening CT scan. The lung biopsy procedure was chosen initially due to complications that arise due to patient respiration, making it one of the more difficult biopsy procedures to perform. Similar image-guided targeting is necessary in other biopsy procedures, RF ablation, brachytherapy seed placement and other percutaneous procedures. We believe that with minimal modification, the Robopsy™ model can be adapted and extended for these and many other applications.

## REFERENCES


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