Novel Minioptical Tracking Technology in Minimally Invasive Surgery

by

Christopher Richard von Jako, M.S.

M.Sc., Nuclear Engineering (1993)
Radiological Sciences and Technology
Massachusetts Institute of Technology
Cambridge, MA

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Supervisors: Prof. Tamás Dóczi, M.D., Ph.D., D.Sc.
Dr. Attila Schwarcz, M.D., Ph.D.

Department of Neurosurgery
University of Pécs, Medical School
Pécs, Hungary
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1. Introduction

Today, most people are familiar with GPS (global positioning system) navigation devices and their value for determining the device's current location on earth. This thesis focuses on the development of a surgical navigation system that is directly coupled to medical imaging systems so that information on a target location from the medical images can be used for more accurate diagnosis and treatment of disease. In particular, this thesis focuses on enabling additional and improving upon specific percutaneous procedures where a trocar needle or cannula is inserted into the body towards a target under image guidance.

During the past two decades the increasing trend in surgery has been to focus on less invasive methods. Over this time, various techniques in minimally invasive surgery (MIS) have successfully minimized the pain and morbidity associated with open surgery while maintaining, in suitable circumstances, the associated diagnostic or therapeutic goals of the procedures with quicker recovery times. Therefore, when possible and appropriate, patients and physicians overwhelmingly prefer MIS.

One of the main challenges in MIS is to direct an interventional instrument to the correct target without the benefit of direct visualization, while avoiding iatrogenic injury to organs and tissues. By utilizing direct vision or miniature video cameras and a light source, physicians have been able to manipulate interventional instruments and perform surgery while visualizing their progress following the instrument's placement into the body via one smaller incision used for direct minimal invasive direct access (MIDAST™) or keyhole surgery, several small incisions (laparoscopy), or natural orifices (endoscopy).

The utilization of diagnostic imaging modalities (e.g., CT or MRI) is also a method in some MIS procedures to view an interventional instrument inside the body and determine its location and direction in relation to an intended target. As with MIDAST, laparoscopic, and endoscopic techniques, the effective use of intraoperative imaging for interventional guidance is highly dependent on the skill and experience of the physician. A number of trial and error cycles may be required in which repeated scans are taken, especially when the target is small or the optimal path to the target is challenging.

Surgical navigation (sometimes referred to as image-guided surgery) is a technology that gained wider acceptance over the past fifteen years in a number of surgical specialties (e.g., neurosurgery, ENT surgery, etc.). This technology enables physicians to locate and track the path of interventional instruments in relation to pre-acquired images, which is analogous to the way a GPS locates a car using stored roadmaps. Today, surgical navigation systems utilize either optical or electromagnetic (EM) tracking technology in order to register the spatial location of a navigated instrument. In clinical practice, this process allows the instrument to be viewed virtually and continuously on a computer monitor in relation to the pre-acquired diagnostic images of the patient's anatomy.

The foundation of a surgical navigation system is to assist the physician in accurately aligning, driving, and placing an interventional instrument, thereby potentially: 1) allowing the selection of the optimal personalized surgical plan by enabling expanded and intelligent pre-planning capabilities, 2) increasing procedural accuracy while reducing the risks of surgical errors, 3) reducing procedure time, 4) when available in the operative setting, reducing the number of intermediate intraoperative imaging scans, and 5) reducing patient and physician radiation exposure from an intraoperative imaging source that may utilize ionizing radiation such as a C-arm or CT scanner.

Current surgical navigation tracking methods are not without limitations. Most are bulky, complex and thus time consuming, can often involve technology-challenging compromises that hinder standard clinical workflow, and constitute costly setups that may discourage or simply not allow routine use in MIS applications. In contrast, a new tracking technology that alleviates some of the traditional compromises is the focus of this thesis.

2. Aims of Thesis

This thesis focuses on the development of methods and systems for accurate instrument placement under image guidance. Understanding the limitations of the current surgical navigation approach, the first aim was to design, test, and describe in detail a new flexible, simple, and accurate tracking technology platform for percutaneous instrument placements that obviates the deficiencies of current surgical tracking systems. Thus, a new surgical navigation tracking technology was developed.

The new technology is a miniaturized implementation of the optical tracking technology without some of the traditional compromises. Utilizing only two fairly inexpensive, small components, this thesis introduces the novel minioptical tracking technology platform.

The next aim was to utilize the new minioptical tracking technology to enable an untapped percutaneous procedure. Surgical navigation has not been well utilized in interventional radiology mainly due to cost as well as some other constraints. Thus, this aim was to adapt the miniopitical tracking system for interventional lung and liver applications. A clinical feasibility study was developed and conducted for both applications in order to evaluate and demonstrate the safety, effectiveness, and accuracy.

The third aim was to enhance an existing surgical navigation application. This involved demonstrating the viability of applying the new minioptical tracking technology platform in neurosurgery. The system was to be adapted, bench tested for accuracy and workflow integration in a nonclinical setting for stereotactic intracranial applications. The final aim was to explore the flexibility in the technology platform by looking at some future potential applications.

3. Novel Minioptical Tracking Technology

3.1 Introduction

The minioptical tracking technology platform features three main components: 1) a miniature, lightweight video camera that is attached onto a standard interventional instrument (e.g., biopsy needle); 2) an adhesive registration sticker with video and radiological X-ray imaging visible markers; and 3) 3-D tracking software loaded into a computer workstation.

The registration sticker is sterile and attaches to the patient prior to CT imaging, and the sticker contains coincident reference markers that are visible on both a video image and a diagnostic image. The colored reference markers that are located on top of the sticker create the video data, and the radiopaque reference markers that are contained within the sticker create diagnostic data. These coincident reference markers enable the registration of an

interventional instrument into imaging space. Video images are acquired from the video camera mounted on an interventional instrument. Based on these images of the location of the colored reference markers, the software enables tracking of a virtual instrument while being advanced towards a user-selected anatomical target. The computer displays 3-D tracking software with a simulation of the instrument on the CT images, providing guidance information to assist the user in directing the instrument to the target.

3.2 Accuracy Testing

A custom bench test set-up was used to evaluate the performance and spatial accuracy of the system. The bench tests were performed using a custom test chamber. The test chamber consisted of a box with target plates positioned at various depths from the registration sticker that was mounted on the top panel. Each target plate contained 25 1-mm machined target holes filled with radio-opaque dye. Simulating the use of the clinical device, these radio-opaque holes were detected with a CT scanner and provided the baseline for accuracy assessments.

Following a calibration step, an 18-gauge trocar needle was directly placed in each one of the target holes in all the plates, and measurement deviations from the target holes were calculated by the system. These tests were repeated for a total of 225 points. Utilizing the measured deviations from the minioptical tracking system software, the laboratory mean 3-D navigation accuracy and the associated standard deviation were calculated.

3.3 Results

The bench test accuracy of the minioptical tracking system is dependent on performance of the video camera, the attributes of the registration sticker, and CT imaging parameters. The resulting accuracy data demonstrate a good correlation with phantom coordinates and the CT images. Based on the 225 target points collected, the mean 3-D navigation accuracy is 1.54 ± 0.64 mm. This is well in line with other navigation systems reported in the literature.

4. Minimally Invasive Lung Intervention Clinical Study

4.1 Introduction

CT-guided needle biopsies are an established technique in the evaluation of suspicious pulmonary nodules. The technique has limited morbidity and mortality. Increased utilization of thoracic CT has led to a significant increase in detection of indeterminate pulmonary nodules, particularly nodules that are smaller. These small nodules present a management dilemma as repeat interval observation CT studies may not be appropriate if the nodule has demonstrated interval growth from previous CT studies. Consequently, there has been a corresponding increase in demand for sampling these more challenging lesions.

Various techniques such as CT-guided fluoroscopy, which provides quick updated fluoroscopy images from the CT scanner, have been used in an effort to improve success rates but these techniques require significant modification in hardware and clinical technique.

The purpose of this clinical feasibility study was to evaluate the utility of the minioptical tracking system in facilitating CT-guided biopsies of lung nodules, by prospectively measuring its effectiveness and safety across multiple institutions and interventional radiologists.

4.2 Materials and Methods

A Research Ethics Board approved, multi-center, prospective, single-arm, un-blinded feasibility study was conducted in four hospitals with seven experienced radiologists.

All patients scheduled for CT-guided biopsies of a suspicious lung nodule at one of institutions were screened for compliance with the study inclusion and exclusion criteria. The first 48 who met the criteria were invited to participate in the study. In an effort to ensure diversity in the nodules evaluated, patients were grouped according to the mean size of their suspect lung nodules and the protocol required enrolling 20% patients with lesions between 1.0 cm and 1.5 cm, 40% between 1.5 cm and 3.0 cm, and 40% with larger than 3.0 cm. Enrollment of patients into each group was terminated as soon as that group reached its target number. In addition, a procedure complexity classification was defined with a More Complex and Less Complex groups. The complexity criterion was based on the target location and the patient's overall medical condition.

The primary efficacy endpoint of the study was the success rate in placing the biopsy needle in a location suitable for obtaining tissue samples from the suspicious lung nodule. After navigating the biopsy needle to the nodule, the radilogist carefully reviewed the CT images taken to determined a success.
Throughout the procedure and mandatory follow-up, all adverse events (AEs) were prospectively recorded and quantified in order to document the safety.

There were several important modifications made to the minioptical tracking system in order to participate in the lung feasibility study. First, the camera mounting system that allows it to be mounted to various interventional instruments was modified to allow for more flexibility. Additionally, a design modification was also made in the registration sticker that allowed for easier removal at procedure end. Finally, design modifications were made to the software from the original prototype in order to provide an easier user experience. Specifically, updates were made to the graphical user interface.

4.3 Results

The cohort consisted of 28 males and 20 females with an average age of 66.7 years (range of 36 to 89). The average lesion size was 3.3 cm (range of 1.0 - 9.2 cm). All of the interventions, regardless of grouping by lesion size or complexity, met the primary efficacy endpoint of 100% placement of the procedure needle at a location suitable for obtaining a tissue sample from the target lung nodule as determined by the investigator. These data confirm the efficacy of the minioptical tracking system for percutaneous CT-guided lung interventions.

There were no device-related or unexpected AEs recorded. The AEs observed during the study were expected complications from the lung biopsy procedure itself. The majority of the observed AEs was either mild or moderate in nature, and did not result in any lasting issues for the patient. A total of 29 patients (60.4%) experienced an AE, a rate that reflects the

known complications from any CT-guided lung biopsy procedure. The AEs were higher with smaller lesions and More Complex group, consistent with the more challenging nature.

5. Minimally Invasive Liver Intervention Clinical Study

5.1 Introduction

The use of CT-guidance for liver interventions has become an accepted standard of care for diagnostic biopsies and therapeutic ablations where ultrasound guidance does not adequately visualize the lesion and there is a difficult and narrow safe instrument tract to the lesion. CT-guidance for liver biopsies has been reported to have high accuracy. Therapeutic ablations for primary or secondary malignancies can be curative for selected patients, but the efficacy is dependent on accurate instrument placement. Major complication rates are low and procedure-related mortalities are rare for both procedures.

As described earlier, the effective use of CT-guidance is highly dependent on the skill and experience of the radiologist and may require a number of trial and error cycles in which repeated CT scans are may be performed. This is true when the target is small or deep, or the optimal path to the target is at a difficult angle.

The purpose of this clinical feasibility study was to evaluate the effectiveness and safety of the new optical tracking system to facilitate CT-guided instrument placement for liver interventions.

5.2 Materials and Methods

A Research Ethics Board approved, two-center, prospective, single-arm, un-blinded feasibility study was conducted with four experienced radiologists.

All patients scheduled for CT-guided liver biopsies or ablations at one of the participating institutions were screened for compliance with the study inclusion and exclusion criteria, and the first 20 who met the criteria were invited to participate in the study. In an effort to ensure diversity in the nodules evaluated, patients were grouped with: 1) at least five cases of lesion size equal or less than 2.0 cm in maximum diameter, 2) at least two cases of intervention in the left lobe, 3) at least two cases of lesions deeper than 8 cm from the skin, 4) at least three cases of decubitus patient positioning.

As in the lung study, targeting accuracy was the primary efficacy endpoint and was defined by the ability to place the instrument at a location suitable for the planned intervention. The investigator carefully reviewed the final instrument position on the post-placement CT images to determine this. Safety was again documented by evaluating all the AEs.

There were again several improvements made to the system in order to enhance its use for liver procedures. The registration sticker was again significantly modified to allow greater flexibility in the procedure. Improvements were made again to the software that allowed more automatation to save procedure time.

5.3 Results

The cohort consisted of 13 males and 7 females with an average age of 63.1 years (range of 38 to 80). Most of the patients, 70%, underwent CT-guided liver biopsy while the remainder had CT-guided ablation therapy. The average lesion size was 3.1 cm (range of 1.1 - 6.9 cm). All of the interventions, regardless of lesion size or the specialized criteria, met the primary efficacy endpoint of a 100% placement of the procedure instrument at a location suitable for the planned intervention as determined by the investigator as determined by the investigator. These data confirm the efficacy of the minioptical tracking system for percutaneous CT-guided liver interventions. Again, there were no device-related or unexpected AEs recorded. Only one patient had a mild AE, and it resolved without intervention.

6. Minimally Invasive Brain Intervention Study

6.1 Introduction

Prior to neurosurgical navigation systems, neurosurgeons utilized diagnostic images to construct a mental 3-D model of the patient's brain, plan the optimal surgical entry, and perform the surgical procedure with direct or microscopic vision. Today, navigation has become common, frequently the standard of care for intracranial procedures. The technology has reduced craniotomy sizes and has helped avoid harm to healthy eloquent brain areas. However, several shortcomings with the current navigation technology may discourage routine use or not allow it at all. In contrast, a further adaptation of the minioptical tracking system for neurosurgical applications is described below in a laboratory feasibility study.

6.2 Materials and Methods

There were two significant design modifications to the system to allow it be utilized in brain procedures. The first was a significant modification to the registration sticker, and the second was to the software in order to compensate for the registration sticker design change. This design change was significant enough to prompt another custom bench test to evaluate the minioptical tracking system performance accuracy.

The same custom test chamber, as in the previous accuracy test, was utilitzed. The 18-gauge trocar needle was again directly placed in each one of the 1 mm target holes in all the plates, and measurements of deviations from the target holes were calculated by the system. These tests were repeated for a total of 225 points. Utilizing the deviations from the minioptical tracking system software, the laboratory mean 3-D navigation accuracy and the associated standard deviation were calculated.

Once the accuracy was determined to be adequate, a feasibility study was conducted on an anthropomorphic head phantom. The interior of the head phantom was redesigned and modified in order to securely hold a biopsy phantom. This phantom allowed for simulation of the brain with 20 visible discrete radiological targets. A brain biopsy needle was then placed in these targets with the aid of the newly modified minioptical tracking system.

6.3 Results

6.3.1 Bench Test Experiment

Based on the 225 target points collected on our test chamber, the mean 3-D navigation accuracy is 1.41 ± 0.53 mm. This is more accurate than the previous system version and well in line with other navigation systems reported in the literature for neurosurgical procedures.

6.3.2 Anthropomorphic Head Phantom Experiment

The head phantom's 20 small CT visible targets had a mean volume of 0.14 cm^3 (0.01 - 0.84 cm^3), and the targets were located in various locations with a mean depth of 6.0 cm (4.0 - 10.8 cm) from the head phantom's surface.

As in the previous studies, the success rate was determined by reviewing the postoperative CT images in order to confirm the biopsy needle was located within the target. All targets, regardless of size or depth, met the primary efficacy endpoint of 100% placement of the procedure needle within the target. Critically, only one intervention was required to hit each target. Thus, each target was hit with only one interventional pass, confirmed with a CT scan, and no other passes or modifications were required. This result confirms the effectiveness of the interventions performed in this feasibility study.

7. Thesis Conclusions

The minioptical tracking technology platform presents real progress and potentially a significant paradigm shift in some of the traditional and non-traditional surgical navigation applications due to its inherit attributes compared to current methodology. The three surgical applications were identified and successfully tested with this new technology platform for accuracy and efficacy. The new technology platform allows greater flexibility, simplicity, and cost effectiveness while maintaining the much-needed accuracy for critical MIS procedures as compared to conventional surgical navigation systems.

8. Future Work

The final aim of the thesis was to explore additional applications for the novel minioptical tracking technology platform, which would further add to the system's claim of flexibility. In conjunction with the team in Pécs, we explored the potential to integrate the tracking system into a MRI environment. The system performed well in its initial feasibility testing, but more needs to be done on improving the MRI sticker design.

Moreover, the potential for spinal applications was explored. Several tests were conducted with CT-based procedures in several institutions in Europe. However, conceptually, the technology would need to work with a fluoroscope in order to be best adapted to spinal-based procedures. Greater modifications would be needed in the sticker design and software in order to allow this further testing.

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Professor Cosman became one of the youngest tenured Physics Professors at MIT. In 1991, he became Professor Emeritus at MIT and succeeded his father as President and CEO of a Boston medical device company, known as Radionics, until he sold the business to Covidien in 2000. Professor Cosman provided me my first opportunity in the medical device field when he offered me at position at Radionics following graduate school in 1993. For the next seven years, he continued to mentor me as I excelled through the many opportunities he presented. I then had the privilege of managing the Radionics business from 2003 to 2007.

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