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ROBOTIC ELECTROMAGNETIC AND OPTICAL NAVIGATION PLATFORM FOR MINIMALLY INVASIVE SURGICAL INTERVENTIONS

Lucian Gheorghe GRUIONU, Răzvan-Sabin STAN, Anca Loredana UDRISTOIU, Andreea Valentina IACOB, Stefan UDRISTOIU, Cătălin CONSTANTINESCU, Gabriel GRUIONU

Abstract: *Early diagnosis in lung cancer often requires finding and biopsy peripheral nodules located in the parenchyma of the lung, outside the small airways. Because bronchoscopes are too wide to reach the small peripheral airways, the surgeon advances blindly a sharp biopsy needle from the bronchoscope into the lung tissue in the approximate direction of the lesion which comes with a high risk of misdiagnosis. To improve the accuracy of the biopsy procedure, real time X-ray (fluoroscopy) is implemented, exposing the patient and physician to harmful radiation. We have recently developed a prototype of robotic electromagnetic and optical navigation robotic (ENDORO) and computer (iMTECH) platform, which is affordable, easier to manipulate in the operating room and assists both diagnosis and surgical removal of malignant lesions. Once the pre-clinical and clinical feasibility is demonstrated, we plan to continue product development and clinical trials in a dedicated medical device facility.*

Key words: *electromagnetic navigation, robotic surgery, optical navigation, medical device.*

1. INTRODUCTION

Lung cancer, one of the most important death cause every year at global level, has a survival rate >75% if caught early, during stage I [1,2]. A timely diagnose demand investigation of peripheral nodules, predominately outside small airways.

Currently, patients undergo radiologic imaging of the lungs to identify a suspicious nodule or lesion often prompting diagnostic procedures. In bronchoscopy a video camera is inserted into the airway but due to its size, malignant lung nodules in the small airways cannot be investigated. To biopsy them, the bronchoscopist has to advance the biopsy needle without guidance through the lung tissue in the approximate direction of the lesion to collect a small amount of tissue for biopsy. In present, a sufficient accuracy of the procedure is obtained using real time fluoroscopy, exposing the patient and physician to unsafe radiation. In present, minimally invasive lung interventions and computer assisted surgery present a practical but not optimal solution. Equipment and procedure high costs, targeting accuracy, size of the system and complexity of suitable instruments are the main problems.

Image-guided medical interventions (IGMI) use a specific software to overlay video images during procedure on virtual images of the anatomical structures and to guide the physician and target the surgical site [3]. IGMI use pre-operative tomographic images to create a 3D map of the anatomy and electromagnetic or optical sensors to localize and track the position of surgical tools or therapeutic devices. The computer algorithm consists in patient preoperative data registration, display of the tool tip position in the anatomy volume defined from CT/MRI data, comparison between the preoperative data and intraoperative reality [4]. Optical/electromagnetic tracking equipment compute the positions of rigid or flexible surgical instruments relative to a coordinate system. Optical tracking systems (OTS) use a video camera to track a rigid object (i.e. the handle of a rigid instrument) in the field of view of the camera [5]. We have considerable experience with the Polaris System from

Northern Digital Inc. with active and passive infrared trackers in a single tracking system for rigid instruments such as laparoscopy forceps. The electromagnetic tracking systems (ETS) use a limited non-harmful electromagnetic field and a sensor on the tip of the instrument which is detected and interposed on the virtual 3D map of the patient's anatomy. ETS can track flexible instruments such as catheters and biopsy needles inside the body. ETS uses small sensor coils (<0.5 mm diameter and 8 mm length) embedded in surgical instruments to track inside the body. ETS has been used before by our team for tracking instruments for bronchoscopy [6-8]. Our core team members have already used both OTS and ETS tracking technologies to develop the IMAGINE surgical navigation software for bronchoscopy, endoscopy and endovascular applications [9-18]. Robotic surgery was developed to enhance the capabilities of surgeons in minimally invasive procedures. The market leader for robotic surgery is the Da Vinci robot (Intuitive Surgical) for laparoscopy. The control system of the robot makes use of control wheels and dials to directly control the tools. Themost important robot-guided bronchoscopy platform, Monarch^{TM} robot (Auris Health Inc.) combines bronchoscope camera views with computer-assisted navigation using virtual anatomy of the patient's lung. An alternative to the Monarch, CorPath GRX from Corindus/Siemens Healthineers AG is a new robotic system which manipulates catheters rather than bronchoscopes but is designed for coronary and peripheral vascular interventions rather than lung cancer. Although it can manipulate a catheter the CorPath robot is using harmful radiation, fluoroscopy which although is not reaching the doctor, is still reaching the patient and nurse. Despite several useful features, the existing medical robotics technology still have important technical limitations which makes them inaccessible for the majority of hospitals: high cost (production, maintenance and surgery costs), limited use and efficacy (highly technical procedure, no training in medical school, few long term studies), large size of the system (takes up OR room, large footprint in the hospital, cumbersome robotic arms) and lack of suitable instruments (lack of surgical instruments for many procedures, human assistants still do part of the procedure). To address the clinical and technical need, we developed a prototype of a robotic electromagnetic and optical navigation robotic (ENDORO) and computer (iMTECH) platform which is more affordable, easier to manipulate in the operating room for both diagnosis and surgical removal of malignant lesions.

2. MATERIALS AND METHODS

The ENDORO robotic system consists of a planning and navigation software, iMTECH, a biopsy catheter with a pre-bended trackable sensor, and a 2-degree-of-freedom (2DOF) robot that can automatically insert and guide a flexible catheter to reach a specific target in bronchial system (fig.1a). For thoracoscopy procedure (fig. 1b) we develop rigid forceps and laparoscopy camera with optical markers for tracking (fig. 1c). The robot has a compact design with two degrees of freedom that generates insertion and rotational motions to the flexible instruments.

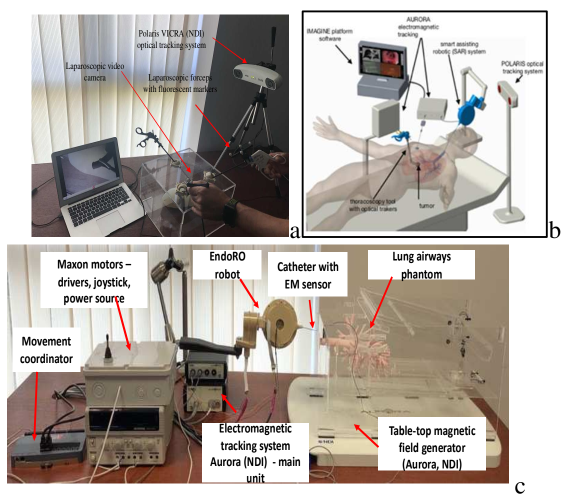

Fig. 1. Robot prototype (a); testing the optical tracking component of the ENDORO system (b), the one-stop procedure platform includes instruments with EM tracking manipulated by ENDORO robotic system, iMTECH software that control robot movements, and laparoscopic instruments with optical tracking (c).

The instrument can be any clinically available guidewires or catheters, and can be navigated in manual or autonomous driving mode (Fig. 1a). In the linear motion, the robot insert and extract the catheter at a specific speed. During rotational motion the instrument is twisted while it is advanced or retracted inside of the airways through the linear motion.

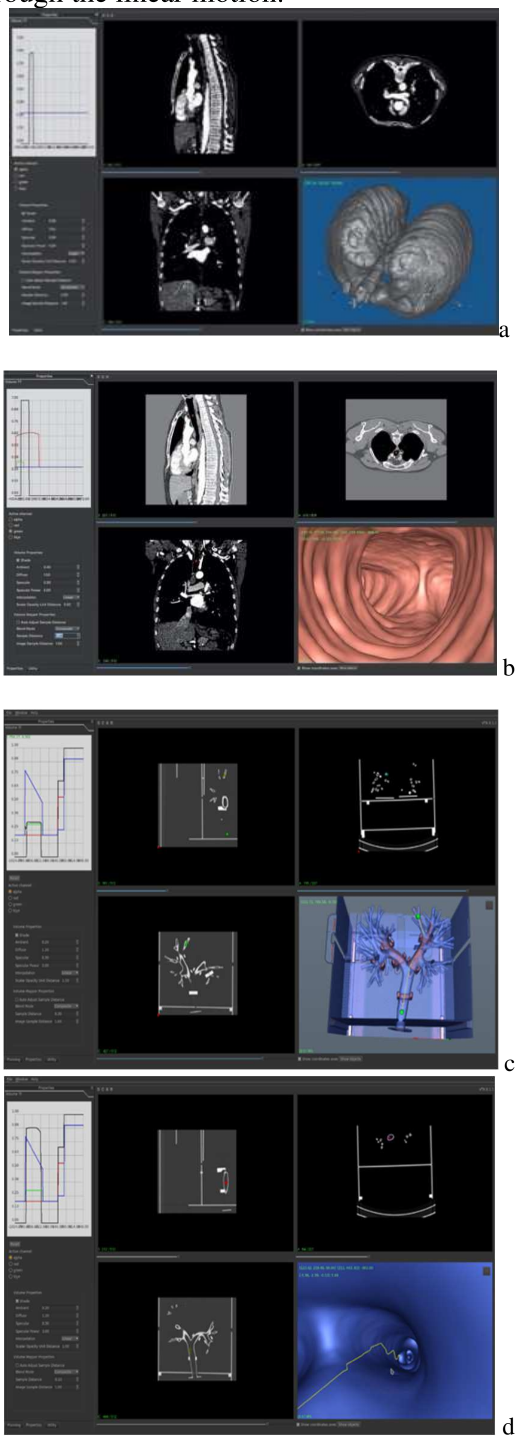

Fig. 2. iMTECH screens: 3D reconstruction of patient's anatomy (a), virtual bronchoscopy (b), navigation pane (phantom) external view (c), and internal view (d).

The robot is controlled by two Maxon (Maxon Motors AG) electric motors (A-max 16 Ø16 mm, 1.2 Watt) with compatible encoders (MR, Typ M, 512 CPT, 2 Channels) and planetary gearheads GP 16 A Ø16 mm, 0.1 - 0.3 Nm, connected to a motion controller P849-MC508 (Trio Motion Technology Ltd.) trough drivers developed in our lab. For optical navigation during the thoracoscopy procedure, we used the Polaris (optical) Systems also from Northern Digital Inc. with passive infrared markers in the same coordinate system as the robot (Fig. 1c). Using the electromagnetic tracking system (ETS) AURORA from Northern Digital Inc. (Fig. 1a) and our navigation software (iMTECH) (Fig. 2), the robot navigates the biopsy instrument to the target without X-ray scanning. The instrument consists of a multi-lumen catheter with a pre-bended tip and a 6 degrees of freedom ETS sensor mounted in one the channels while another is used for a classic flexible biopsy needle.

The instrument is advanced in the working channel of the bronchoscope and extended outside to a nodule in the lung periphery where the bronchoscope cannot reach due to its size [19]. After the target is reached and confirmed, the biopsy needle can be used for standard biopsy collection. The navigation software consists of a pre-procedure module for target and procedure planning using patient's CT scan (Fig. 2), and a navigation module used by the robot to navigate. The system's testing was performed using a silicone lung phantom that can simulate the breathing motion (Fig. 1, a). The results were saved and could be reloaded during the surgical procedure to inform the clinician. The prototypes of the ENDORO system and testing devices were manufactured and assembled in our Laboratory of Microtechnologies and Medical Engineering (LMME) from University of Craiova [20].

We 3D printed most of the mechanical parts and cases for ENDORO, to have an optimal design for this robot, using the laboratory existing 3D printers (one FDM and one SLA plastic printers and one advanced DMP metal powder printer). Advanced materials like light and tough aerospace ULTEM polymer and a titanium alloy powder was used to decrease the robot dimensions and weight and mini Maxon motors with position encoders and planetary gearheads were used for actuation.

3. RESULTS

Prior to surgery/testing, a marker disc is placed on the model/subject surface and the testing subject undergoes a CT scan. On the CT series, an arbitrary target "lesion" is chosen at the periphery of the model's bronchial tree. The CT scan is uploaded in the iMTECH software to create a 3-D map of the lung anatomy. As part of the procedure planning, the software computes the optimal pathway between an entry point and "lesion". The ENB procedure steps are:

- A dual lumen catheter with an Aurora Type 2 sensor is inserted in the bronchoscope channel.
- The Aurora electromagnetic field generator system is placed under the subject and is connected to the main unit, PC and to the software. An automatic registration will be performed using the iMTECH registration module.
- The bronchoscope is advanced towards the "lesion" by hand up to a point when it becomes too large for the size of the airways (order 3-4 of bifurcation).
- From that point, the catheter will be extended outside the bronchoscope channel and guided with the ENDORO robot using the iMTECH software towards the "lesion".
- Once the target is reached, a brush biopsy needle can be inserted in the second channel of the catheter and a biopsy of the target "lesion" is performed according to standard practice.
- A fiducial marker is placed via the working channel of the bronchoscope to mark the target location prior to a surgically induced pneumothorax.
- The bronchoscope will be removed prior to the ONL procedure.

Thoracoscopic forceps for blunt dissection have Polaris optical markers installed on their handle (fig. 1, b). Three access ports will be used, irrespective of the lobe or segment where the "lesion" is located. An additional CT scan is performed to identify the fiducial marker after pneumothorax relative to the active marker disc. An additional software registration is performed. The dissection forceps will be advanced towards the target fiducial marker to minimize the distance between the marker and the tip of the instrument on the computer screen. The diagram for the one-stop diagnostic and treatment procedure for lung nodules combining both bronchoscopy and thoracoscopy and navigation using electromagnetic tracking, optical tracking and robotics is presented in the Figure 1.c.

The system's accuracy was tested by two teams of medical doctors and engineers using a joystick in manual mode, also in the automatic control mode, with and without breathing motion simulation. The initial registration between physical phantom and its virtual volume reconstructed from CT scan was performed using one external marker previously mounted close to the tracheal entry point. The doctors reached the targets at the periphery of the lung in 8.1 ± 0.5 min in the manual mode vs. 15.5 ± 1 min in the automatic mode. The optical navigation module was tested by externally reaching the proximity of the EM sensors with the tip of a rigid tool, with markers mounted on its handle.

4. DISCUSSION AND CONCLUSIONS

Our ENDORO/iMTECH platform is innovative at three levels: medical, technological and commercial potential.

The medical innovation is represented by performing a one-stop diagnostic and treatment procedure. The platform includes customized flexible instruments for bronchoscopy and the electromagnetic tracking system controlled by ENDORO robot for reaching and taking biopsy from lesions during bronchoscopy.

The ENDORO/iMTECH platform also includes laparoscopic instruments with optical tracking capabilities to help the surgeon precisely perform the thoracoscopic resection during the same procedure without the need of additional registration procedure or fluoroscopy scanning. The novelty of the ENDORO/iMTECH system over other existing robotic systems is very clear: the platform is the first system that uses optical and electromagnetic navigation simultaneously, eliminates the use of harmful radiation to the surgeon and patient by integrating a proprietary surgical navigation software platform, iMTECH developed previously [15,16], easier to install and use in any operating room due to its 75% smaller profile than competitor's products, easier to adopt by a wider market, less expensive to manufacture and more affordable (< 10% competitor's price). From a technological innovation perspective, the iMTECH software combines the most advanced and innovative solutions for image-guided medical interventions: positioning/navigation of multiple flexible and rigid instruments to be used for internal and external medical procedures at the same time, advanced registration algorithm using anatomical landmarks and autocorrection during the procedure, with improved precision over the existing systems, novel compact and reliable REONB robot for flexible instruments navigation inside the human body.

The anticipated clinical novelty of using the ENDORO system demonstrated in the present study are: overall reductions in the navigation times to reach distant targets, reduced contact with the airways wall, reduced overall catheter tip motion with economy of movement, improved catheter stability within target airways for efficient wire and device exchange, shorten the learning curve for complex procedures, avoid the occupational hazards for interventional radiologist such as malignancy, and orthopedic injury.

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Platformă robotică cu navigație electromagnetică și optică pentru intervenții chirurgicale minim invazive

Abstract: Diagnosticul precoce în cancerul pulmonar necesită adesea localizarea și biopsia nodulilor periferici din parenchimul pulmonar, în afara căilor respiratorii mici. Deoarece bronhoscopul este prea mare, pentru a ajunge la căile respiratorii periferice mici, chirurgul avansează fără vizualizare cu un ac ascuțit de biopsie care este extins din bronhoscop în țesutul pulmonar în direcția aproximativă a leziunii, procedură ce prezintă un risc ridicat de diagnostic greșit. Pentru a îmbunătăți acuratețea procedurii de biopsie, se utilizează radiografia cu raze X în timp real (fluoroscopie), expunând pacientul și medicul la radiații dăunătoare. Recent echipa noastră a dezvoltat un prototip de platformă robotică cu navigație optică și electromagnetică (ENDORO) și software-ul (iMTECH), care este accesibilă ca și costuri, ușor de manipulat în sala de operație și care ajută atât la diagnosticarea cât și la îndepărtarea chirurgicală a leziunilor maligne. Odată demonstrată fezabilitatea pre-clinică și clinică, intenționăm să continuăm dezvoltarea prototipului și să realizăm studii clinice într-o unitate medicală specializată în dispozitive medicale.

Lucian Gheorghe GRUIONU, PhD Eng. Habil., Professor, Faculty of Mechanics, University of Craiova, lucian.gruionu@edu.ucv.ro, 0721244200, Calea Bucuresti nr. 107 Cod. 200512 CRAIOVA.

Răzvan-Sabin STAN, PhD Student, Faculty of Mechanics, University of Craiova, stanrazvansabin@gmail.com, 0746055854, Calea Bucuresti nr. 107 Cod. 200512 CRAIOVA

Anca Loredana UDRISTOIU, Ph.D. Eng. Assoc. Prof. Faculty of Automation, Computers and Electronics, University of Craiova, Romania, anca_soimu@yahoo.com, 0741040508, Blvd. Decebal nr. 107, Craiova, România.

Andreea Valentina IACOB, PhD, Eng., Assist. Prof. Faculty of Automation, Computers and Electronics, University of Craiova, Romania, andr33a_soimu@yahoo.com, 0745100703, Blvd. Decebal nr. 107, Craiova, România.

Stefan UDRISTOIU, Ph.D. Eng. Assoc. Prof. Faculty of Automation, Computers and Electronics, University of Craiova, Romania, s_udristoiu@yahoo.com, 0722711024, Blvd. Decebal nr. 107, Craiova, România. Infigo Consulting SRL, Carcea, Dolj, Romania

Cătălin CONSTANTINESCU, Ph.D. Eng. Assoc. Prof. Faculty of Automation, Computers and Electronics, University of Craiova, Romania, catalin_1972@yahoo.com, 0723492338, Blvd. Decebal nr. 107, Craiova, România.

Gabriel GRUIONU, PhD. Eng. Assist. Prof., Indiana University School of Medicine, Indianapolis, United States of America, INNES Global, Craiova, Romania, gruionu@gmail.com, +1 (928) 863-8764, Krannert Institute of Cardiology 1800 N. Capitol Ave., E400 Indianapolis, IN 46202