RoPuc:

Precise biopsy procedure with a robotic arm

Artykuł recenzowany

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Streszczenie

Wczesna diagnostyka zmian w tkankach ludzkich jest gwarantem skutecznego leczenia, w tym leczenia onkologicznego. Biopsja pod kontrolą CT umożliwia badanie tkanek dostępnych do tej pory głównie w trakcie otwartej biopsji chirurgicznej. Wymaga jednak wysokiej precyzji przy wprowadzaniu igły biopsyjnej oraz obarczona jest ryzykiem wielokrotnie powtarzanych skanów przy wprowadzeniu ręcznym. Operujące zdalnie precyzyjne urządzenia robotyczne stanowić mogą istotną alternatywę dla tradycyjnego podejścia. Autorzy prezentują w artykule wstępne rezultaty projektu prowadzonego w ramach grantu DIH-HERO, wykorzystującego technologię robotyczną ARIA/BATEO firmy ACCREA Engineering do zastosowania przy biopsji tkanek płuc, wątroby czy nerek.

Abstract

Early diagnosis of lesions in human tissue is a guarantee of effective treatment, including oncological treatment. CT-guided biopsy enables examination of tissues previously available mainly during open surgical biopsy. However, it requires high precision when inserting the biopsy needle and carries the risk of repeated scans when inserted manually. Remotely operated precise robotic devices may be an important alternative to the traditional approach. In this paper, the authors present the initial results of a project carried out under the DIH-HERO grant, using ACCREA Engineering's ARIA/BATEO robotic technology for lung, liver or kidney biopsy.

Problem

In the modern ageing societies, the demand for specialized medical care becomes higher, whereas a worldwide lack of physicians is observed. Forecasts warn that this lack will grow worse in the near future [actionforglobalhealth.eu]. Robotics plays a key role in a mankind development. When we take into account gradually rising healthcare demands, we need to pay attention to the role of medical robotics.

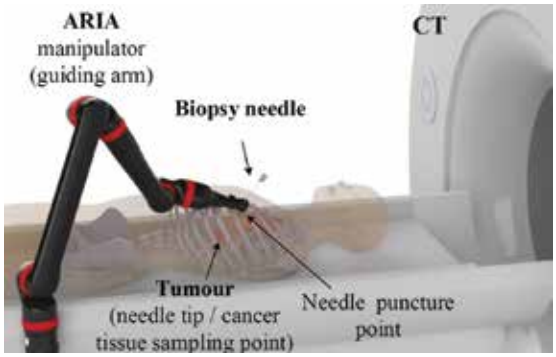
Thanks to the specific approach, facilitating the use of specialized equipment designed to work inside the body cavities through one or more trocars, the surgery itself is especially beneficial for the patient, as causing less trauma, pain and blood loss, while leaving smaller skin scars, effectively reducing the duration of hospital stay.

Image-guided biopsy procedure is an area where accuracy and space efficiency is essential. Despite robotic device's paramount precision, its cost-effectiveness is invaluable due to the workforce reduction with simultaneous capacity increase. Additionally, in a time of an increase in a number of patients, time saving is crucial. Within the field of oncology, percutaneous strategies have developed, in which biopsy and removal of tumors are performed by means of a needle through the skin utilizing image-guidance. Such procedure, performed in the traditional way, relies on manual insertion of the needle by the doctor. Needle insertion is time consuming and most of the time target tissues cannot be reached due to their small sizes.

Solution

Robot-assisted biopsy procedure is another alternative that can help out the surgeon to inject the needle precisely, while omitting the risk of medical errors due to tremor, fatigue etc. Since 2019, ACCREA Engineering Poland has been developing an assistive robotic device aimed at helping diagnosticians by motorizing the movement of a needle for a biopsy procedure. Robotic approach provides higher stiffness and precision by a more stabilized robotic manipulator compared to human hands. The first functional prototype device is based on an off-the-shelf ARIA/BATEO robotic arm designed by ACCREA in the course of an R&D grant-based project L2R. In 2020 ACCREA had been granted funding from DIH-HERO, supporting the proposal aiming at demonstrating the feasibility of new, innovative and enhanced robotic solution in abovementioned field. The target system is further destined to reach Clinical Trials Phase by October 2023, supported by PL NCBR grant agreement.

The proposed system will utilize the tailor-made medical image processing software paired with state-of-the-art robotic devices, allowing for an easy, point&click biopsy procedure planning and execution, performed based on CT scans (abdomen, chest) of desired tissues.



System Description

The main system components are, see figure, the CT Scanner, the Guiding Arm, CT Imaging Workstation and DICOM-based Robot Control Module DRCM. A Biopsy Needle is connected to the guiding arm using a dedicated Needle-Robot Interface. The arm is paired with control interfaces: i) Robot Interaction Module RIM for direct physical interaction (by means of pushing and pulling the arms with the physician's hand) and also with ii) a joystick placed in the control room of the CT scanner, controlling the arm via DRCM. The device is connected to the CT Bed using a universal Bed-Robot Interface. The DRCM reconstructs the imaging data, uploaded to the Module from CT Imaging Workstation in DICOM file, and calculates the best trajectory for robot's alignment with the Vector of Entry VoE, which is based on the point of the human tissue to be examined ET and an Optimal Entry Point OEP selected by the radiologist. After alignment, the diagnostician inserts the biopsy needle along the path set out by Needle-Robot Interface, to the depth calculated by DRCM.

Implementation & Evaluation

During the course of RoPuc project, ACCREA successfully adapted their 6 Degree of Freedom robotic ARIA/BATEO robotic arm technology to meet the requirements derived with assistance on project's Clinical Partner, Grosshadern Clinic of Ludwig Maximilian University of Munich.

The device had been equipped with an aluminium, CNC-manufactured precise end-effector guiding the biopsy needle, and with ACCREA's own 6DoF Force/Torque sensor-based Robot Interaction Module for easy prepositioning. Once in the CT room, the device's experimental software with uploaded CT scan of the patient, enables the user to select desired points of tissue collection and skin puncture, based on which calculates the vector of entry and

in effect – position of the robot. The user may check the projected movement of the arm from home position to working position in the same software using Pre-Biopsy procedure, where a 3D visualization of both arm and body is depicted.

The verification and validation of the results were conducted during two stationary trials:

1) Szpital na Klinach Living Lab – June 4th 2021, Kraków, PL

2) Klinikum Großhadern of the Ludwig Maximilian University of Munich – June 23rd-24th 2021, Munich, DE

Both trials were led by Prof. Dr. med. Konrad Karcz, Head of Minimally Invasive, Robot-Assisted Surgery and Surgical Technological Innovations at LMU Munich and a Medical Consultant for RoPuc project.

Both rounds aimed at presenting and testing the overall workflow during minimally invasive surgery, although the first one was conducted using ARIA arm V1.1 as a basis, while the second – using ARIA V2. First steps were to test interfaces responsible for integration within the testing environment – intervention room or CT room. Next, the arm was covered in sterile drape, which in real-life conditions would reduce the risk of contamination. Lastly, the DCRM software was tested and the accuracy of the robot-induced tissue-collection point was checked. Trials shown, that the arm at this point reaches the desired end-point with approximated accuracy of +/- 7,5 mm, affected by a number of factors: (i) the accuracy of alignment between robot's and body's coordinate frames; (ii) the reduced stiffness of lightweight structural components of the robotic arm, superior for initial ARIA/BATEO wheelchair use-case, but problematic in clinical applications.

Summary & Acknowledgements

Imaging and robotic technologies provide additional support for the doctor or diagnostician to perform procedures in a safer and more accurate way. A CT-guided biopsy usually results in fewer complications and excludes the need for general anaesthesia, ensuring faster recovery times.

The integration of imaging and robotic technology can act as a 'third hand and eye' for the diagnostician, avoiding the need to repeatedly switch eyes between the patient and the monitor. Using robotics during this procedure makes it even safer and faster. In addition, the reduction in the number of follow-up scans necessary when performing the procedure manually results in a minimum of x-ray exposure time and indirectly reduces the cost of the procedure, resulting from less operation of the imaging device.

The importance of diagnostics in modern medicine is increasing, which is reflected in the market

size. The market for kidney diagnostics is projected to grow at a CAGR of ~5.2% from 2019 to 2026, for lung diagnostics at a CAGR of 7.7%, for liver diagnostics even at a CAGR of 8.1%. This is accompanied by an increase in the size of the global smart biopsy devices market at a CAGR of 5.6% during the period 2019-2026. This demonstrates the fact that modern technologies (especially robotic) will find increasing demand in the coming years.

Validation trials had shown that the idea behind the RoPuc system proves to be applicable in laboratory conditions, with possible introduction to real-life environment and ultimately to market.

ACCREA Engineering would like to thank NEO HOSPITAL Group for the permission to perform a validation run at Szpital na Klinach in Kraków.

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Tematyka pracy nawiązuje do zagadnień wczesnej diagnostyki zmian w tkankach ludzkich. Ta kwestia jest bardzo istotna, w szczególności ma zasadniczy wpływ na proces leczenia zmian o charakterze nowotworowym. Zastosowanie biopsji pod kontrolą CT umożliwia pobieranie i w dalszej kolejności badanie tkanek. Do tej pory były one pobierane głównie podczas otwartej biopsji chirurgicznej. Taki sposób pobierania tkanek wymaga dużej precyzji przy wprowadzaniu igły biopsyjnej. Dodatkowo obarczony jest ryzykiem wielokrotnie powtarzanych skanów przy wprowadzeniu ręcznym. Z tego też względu dla zapewnienia wymaganej precyzji ruchów w pracy zaproponowano zastosowanie precyzyjnego urządzenia robotycznego. W pracy zaproponowano wstępne rezultaty realizowanego projektu prowadzonego w ramach grantu DIH-HERO. Autorzy wykorzystali technologię ARIA/BATEO firmy ACCREA Engineering do zastosowania przy biopsji tkanek z płuc, wątroby czy nerek. Wstępne wyniki przeprowadzonych testów wskazują, że zastosowanie takiego podejścia skutkuje poprawą bezpieczeństwa pacjenta w trakcie realizacji tego rodzaju procedury. Ponadto, możliwość zmniejszenia liczby skanów kontrolnych niezbędnych przy ręcznym wykonywaniu zabiegu skutkuje minimalnym czasem naświetlania promieniami RTG, co również wpływa na obniżenie kosztów zabiegu.