ChemImage®

White Paper

Innovative Molecular Chemical Imaging Technology to Improve Outcomes for Robot-Assisted Surgical Procedures

Keywords: Minimally invasive surgical procedures, robotic surgery, enhanced patient outcomes, diagnostic surgical imaging, molecular chemical imaging, endoscope, intra-operative imaging tool, distinguishing tumor margins, digital hyperspectral imaging, affordable care act, faster patient recovery

ABSTRACT

Robots were first used medically in 1985, and today robots have impact in laparoscopy, neurosurgery, orthopedic surgery, urology, gynecology and various other medical disciplines. This white paper provides a summary of initial work which has been completed by the scientific team at ChemImage, primarily focusing on Molecular Chemical Imaging (MCI) to aid in the visualization of anatomic structures when using robotics.

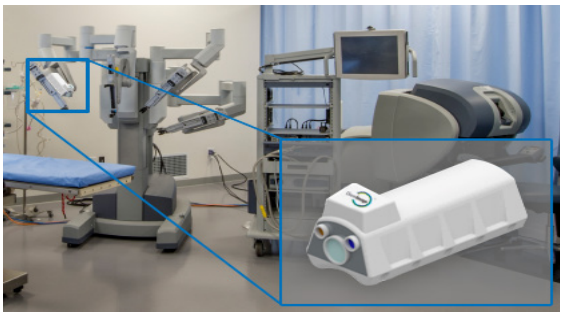

Figure 1. Concept of ChemImage module integrated into commercially available robot

DISCUSSION

Robotic surgery has become one of the most important advancements in the field of medicine. Incorporating advancements made in minimally invasive surgical procedures, robotic surgery today reduces incisions, blood loss, pain, and provides patients with a faster recovery time relative to non-robot-assisted procedures. Robotic assisted tools provide the surgeon with the intra-operative capabilities to improve the precision of surgery by precisely articulating the movement of a surgeon's hands through the robotic equipment itself which enables the miniaturization of movements not otherwise possible. Robotic surgery can even correct for natural tremors present in every surgeon's hands, demonstrating incredible potential to improve outcomes and reduce hardships for surgical patients of all kinds.

Current robotic surgical platforms primarily use visible imaging cameras to guide surgical procedures. However, recent advances in fluorescence imaging can provide enhanced visualization for surgeons, but fluorescence imaging has limited applicability to the imaging of anatomic structures. Robotic surgical platforms will benefit from additional improvements in imaging technology development that will enable visualization of anatomic structures, for both normal and diseased tissue. We anticipate that such developments will minimize the learning curve for training on robotic surgical platforms by providing real-time diagnostic information which will simplify surgical procedures and enhance patient outcomes.

ChemImage's expertise, technology and intellectual property can enhance robotic surgical imaging by enabling robotic platforms to also be diagnostic platforms. In essence, surgical robotic systems become intelligent. To facilitate diagnostic surgical imaging, ChemImage is developing a MCI endoscope incorporating a sensor suitable as intra-operative imaging tool for visualizing anatomical structures and distinguishing tumor margins in real time.

The clinical and scientific teams at ChemImage have demonstrated, in investigational studies, effective discrimination of a variety of anatomic structures such as bladder, uterus, colon, ureter, vasculature, prostate and kidney, as well as cancer tumor margins within bladders, prostates and kidneys. These investigational studies have been performed under Institutional Review Board approval, and have demonstrated the clinical feasibility of MCI, including the capability to image in real-time and in the presence of obscurations such as blood, fat and surrounding tissue.

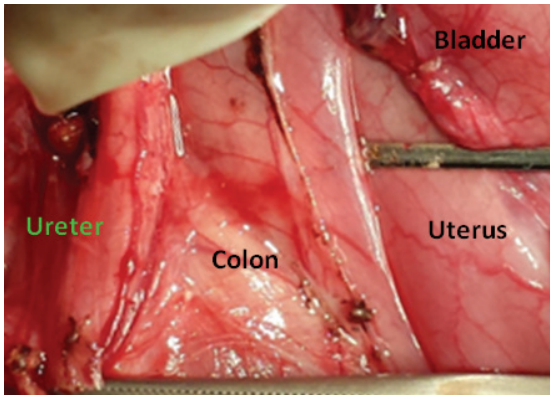

Figure 2. Representative fields of view of of an in vivo RGB image

Employing digital hyperspectral imaging, MCI can analyze and classify tissue structures by harnessing intrinsic spectral signatures to provide highly specific image contrast, without the use of contrast agents. Through the use of this patent-pending MCI sensor technology and innovative, real-time software designed to capture and visualize diagnostic information, the ChemImage MCI endoscopic system is on the development path to aid surgeons to gain a deeper understanding of tissue anatomic structures intra-operatively.

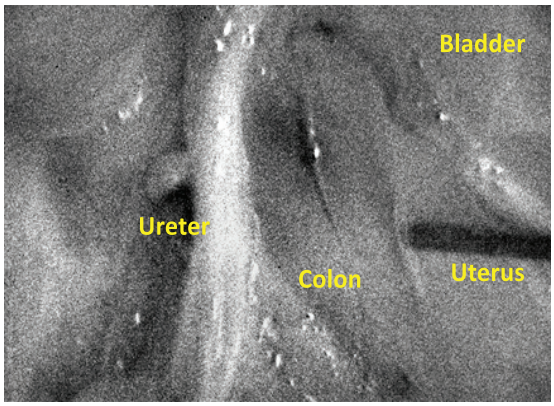

Figure 3. The image above shows tissue discrimination with Area Under Receiver Operating Characteristic (AUROC) of .83

The MCI endoscope does not require use of contrast agents and employs visible/near-infrared reflectance hyperspectral imaging technology. The MCI endoscope is well suited for the detection of anatomic structures and tumor margins which otherwise may be very difficult to observe using visible light or fluorescence imaging, particularly for surgeons new to surgical robotic platforms. The highly advanced nature of the information collected and analyzed by molecular chemical imaging allows for the determination of the molecular composition of structures in ways simply not possible with the human eye.

MCI endoscopy offers numerous potential applications in the field of medicine and surgical oncology, in particular. Normal, pre-cancerous, and cancerous tissues all exhibit unique spectral signatures which, when analyzed using MCI and advanced discrimination algorithms, enable clinicians to observe tissues in a diagnostic mode in real time without having to remove any tissues for later pathology laboratory analysis. Precise identification of tumor margins will improve the likelihood of the entire tumor being removed during the initial surgery. This will reduce the need for re-surgery to remove any remaining tumor, impacting not only patient comfort and convenience, but also the chance of tumor regrowth. Ultimately, this would lead to reduced patient mortality due to the cancer. In addition, the removal of cancerous growths in the body can often have a devastating impact to surrounding tissues, especially due to the complex nature in which cancerous and healthy tissues are integrated within specific anatomical structures. This has been one of the major reasons why recovery from procedures such as prostatectomy, mastectomy, nephrectomy, cystectomy, hysterectomy, bilateral salpingo-oophroectomy, colectomy, and other operations used to physically eliminate cancerous growths in patients can result in serious pain and possibly even long-term damage. In addition, these procedures can also lead to

complications that may reduce the likelihood of positive outcomes. By minimizing damage to healthy tissues associated with surgical procedures, patients will not only have an easier recovery, but are also more likely to heal faster and more thoroughly, with fewer complications.

Surgeons utilizing advanced robotic surgical techniques can complement the very precise articulated movements made possible by robots with a precise identification of tissue structures, and objective discrimination of those tissues to be removed from those that should remain. MCI holds much promise in polypectomy procedures in which smaller tumors are removed from otherwise healthy organ systems. In short, the diagnostic, high-definition nature of the molecular information captured through hyperspectral imaging systems means that surgeons can substantially reduce surgical margins and minimize damage to any surrounding tissues. The outcomes for patients could be that they will experience less blood loss and pain associated with the procedure and faster healing, without any sacrifice to the safety or efficacy of the procedure. Patient outcomes should be significantly enhanced while associated costs to health care systems should be reduced.

Also, ChemImage MCI endoscope technology has applications beyond oncology. For example, minimally invasive procedures that depend upon endoscopy to navigate through the various biological structures of the human anatomy will benefit from MCI technology. In robot-assisted kidney surgery or hysterectomies, hyperspectral imaging and analysis could be used to differentiate between the ureter and surrounding fat tissues. In gallbladder removal, it is important to avoid any damage to the common bile duct, and hyperspectral imaging could allow surgeons to clearly distinguish this structure from surrounding arteries to ensure optimal incisions. Transplant surgeries, a field in which minimally invasive procedures have rarely succeeded due to their complex nature, have begun to be performed with robotic assistance in tandem with advanced imaging techniques. The use of the advanced information acquisition and processing represented by MCI should advance this emerging field.

MCI sensor technology can be incorporated into endoscopes and robotic systems providing surgeons with an innovative training platform to better understand complex surgical areas during a procedure with real time feedback. Advances in medicine have proven to be one of the most important drivers of extended life spans and improved quality of life for people around the globe. These advances have often been inspired by newly developed technologies or made in conjunction with them. Hyperspectral imaging was initially developed with mining and geology in mind, later finding applications in military, agriculture, surveillance, pharmaceuticals, materials analysis, and many other diverse areas. Medical and diagnostic imaging is arguably the best use of this very ubiquitous hyperspectral imaging technology, both for what it can do for patients and medical economics.