Autonomous Robotic Magnetic Guidewire Navigation during Endoscopic Retrograde Cholangiopancreatography (ERCP): Improving and Increasing Procedure Success Rate

1 Abstract

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a medical procedure used to diagnose and treat disorders of the bile ducts, pancreas, and gallbladder. It combines endoscopy and fluoroscopy to examine and intervene in these areas of the digestive system. ERCP has become the preferred therapeutic option for many pancreaticobiliary conditions. Successful ERCP requires deep cannulation (i.e., the insertion of a catheter or cannula) of the common bile duct and/or main pancreatic duct via the major duodenal papilla.

Since the advent of ERCP, selective biliary cannulation (SBC) has remained not only the first and rate-limiting step of the procedure, but also one of the most technically challenging portions. SBC is the precise placement of a catheter or cannula into the bile ducts within the liver, ensuring that only the specific duct or ducts of interest are accessed while avoiding unintended cannulation of other nearby structures. Complications occuring while trying to achieve SBC happen in up to 30% of cases with failed biliary cannulation occuring in up to 20% of cases.

In this work we suggest to leverage a small permanent magnet affixed to the tip of a clinically-used guidewire. The guidewire will be manually deployed through a clinical duodenoscope while steered by a permanent magnet *external* to the patient. This external magnet will be autonomously guided by a robotic arm. By placing this external magnet in specific poses, we can leverage the magnetic interaction between the external magnet and the small magnet on the guidewire. This enables us to exert forces and torques on the guidewire from outside of the patient's body. We will leverage this concept to steer the guidewire down specific branches of the bile ducts.

Our work is part of a growing interest within the field of robotics regarding the utilization of magnetic techniques for remote manipulation and wireless actuation. Indeed, recent groundbreaking work describe a teleoperated robotic neurointerventional platform based on magnetic manipulation. However, there is little-to-no *automation* in existing systems and our ultimate goal, starting with this proposal, is to develop an autonomous robotic magnetic guidewire navigation system for ERCP.

2 Scientific Background

2.1 Clinical Background

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a medical procedure used to diagnose and treat disorders of the bile ducts, pancreas, and gallbladder (see Fig. 1). It combines endoscopy and fluoroscopy (X-ray) to examine and intervene in these areas of the digestive system. ERCP has become the preferred therapeutic option for many pancreaticobiliary conditions. Successful ERCP requires deep cannulation (i.e., the insertion of a catheter or cannula) of the common bile duct and/or main pancreatic duct via the major duodenal papilla.

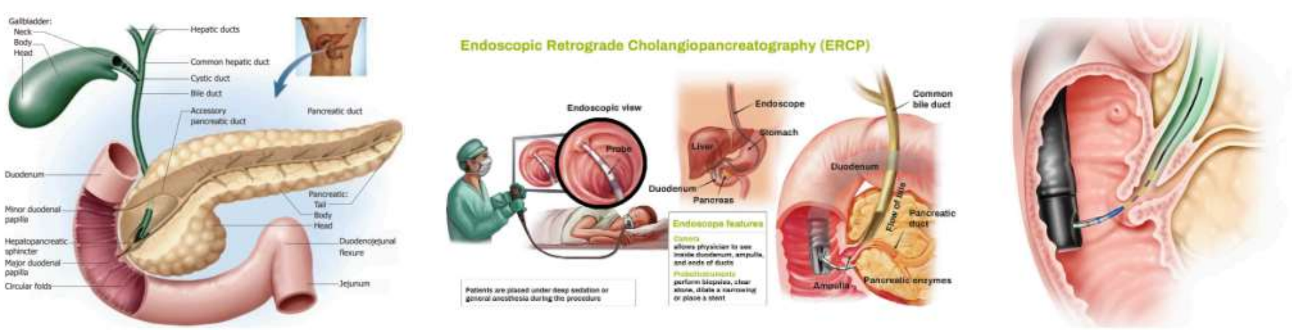
Since the advent of ERCP, selective biliary cannulation (SBC) has remained not only the first and rate-limiting step of the procedure, but also one of the most technically challenging portions. SBC is the precise placement of a catheter or cannula into the bile ducts within the liver, ensuring that only the specific duct or ducts of interest are accessed while avoiding unintended cannulation of other nearby structures

Complications occuring while trying to achieve SBC range from 4% to 30% [5, 19]. Failed biliary cannulation occurs in up to 20% of cases and itself is associated with a higher risk of complications including post-ERCP pancreatitis (PEP), bleeding, delayed therapy, and others [19].

Current methods for SBC. Standard methods of SBC include (i) contrast-assisted cannulation and (ii) guidewire assisted cannulation (to be explained shortly). In these methods, the majority of duodenoscopes[1] use a sphincterotome (Fig. 2a) as it can be directed to the biliary duct by pulling or relaxing the cutting wire and allows for sphincterotomy (the cutting of the sphincter) if necessary.

In contrast-assisted cannulation (the use of contrast dye to improve the visualization of the ducts

[1]Duodenoscopes are specialized endoscopes that are used primarily for ERCP. They are side-viewing (rather than forward-viewing) endoscopes that have the advantage of looking at the major duodenal papilla en-face.



(a) (b) (c)

Figure 1: (a) Anatomy of digestive system (source: Boston Scientific). (b) ERCP procedure (adapted from `https://www.gutworks.com.au/endoscopy-ercp-eus-procedure-murdoch-perth/`). (c) Selective biliary cannulation (SBC) (source: Boston Scientific).

during the procedure), the surgeon often requires repetitive probing and multiple attempts of injecting contrast; factors that contribute to its association with high rates of PEP [3].

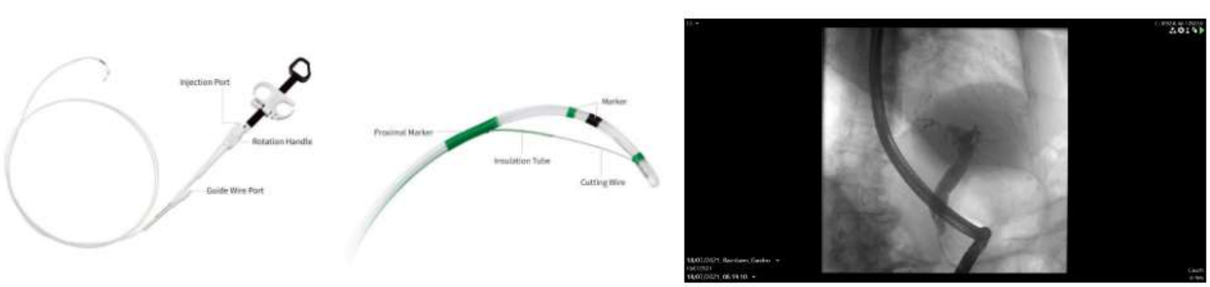
In guidewire assisted cannulation (the use of a guidewire to aid in the navigation of the catheter or cannula through the ductal system), a soft, hydrophilic guidewire serves as a tract that achieves desired duct selection without injection of contrast. The most common guidewire used is a 0.025-0.035-inch diameter hydrophilic tip guidewire [17, 15]. Hydrophilic tip guidewires (guidewires coated with a coating that becomes slicker when exposed to water or blood) are commonly used because of their reduced friction and ease of pushing. Guidewires with angled tips have been shown to lead to shorter cannulation times, likely because the angled tips are better able to follow the "S" shape of the intraduodenal segment of the bile duct and/or turn cephalad into the biliary system [18].

2.2 Robotic & Magnetic Manipulation in Medical Applications Background

Over the course of the last two decades, there has been a growing interest within the field of robotics regarding the utilization of magnetic techniques for remote manipulation and wireless actuation with the predominant focus of this research being on controlling micro-robots [1]. However, there has been an emphasis on controlling medical robots as well. This line of research is driven by the fact that biological tissues are essentially transparent to relatively weak and slowly varying magnetic fields.

In today's medical landscape, a wide array of magnetically driven medical devices has been developed, each designed for specific anatomical regions of the body [13]. Generally speaking, these devices can be categorized into two groups: (i) permanent magnetically driven devices (our work falls under this category) and (ii) electromagnetically driven devices.

The earliest examples of magnetic catheter manipulation can be dated back to 1951 where Tillander [16] demonstrated the advantages and opportunities offered by magnetic guidance. Specifically, Tillander demonstrated the use of magnetic fields to guide a surgical catheter inside the human body.



(a) (b)

Figure 2: (a) Sphincterotome. Figure adapted from `http://www.finemedix.com/en/pf/finetome/`. (b) X-ray image obtained during contrast-assisted cannulation.

Since then dramatic progress has been made (see, e.g., [8, 9, 20] with the most closely-relevant work to ours is the recent groundbreaking work by Kim et al. [7] who describe a teleoperated robotic neurointerventional platform based on magnetic manipulation. Their system, depicted in Fig. 3 consists of a magnetically controlled guidewire, a robot arm with an actuating magnet to steer the guidewire, a set of motorized linear drives to advance or retract the guidewire, a microcatheter, and a remote-control console to operate the system under real-time fluoroscopy. They show that their system allows for a smaller number of undesirable catheter steering maneuvers compared to manual control.

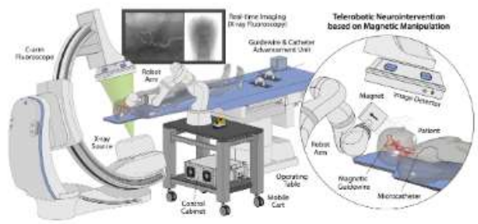


Figure 3: Telerobotic neurovascular interventions system by Kim et al. Figure adapted from [7].

3 Research Objectives and Significance

Successful SBC requires the ability of manipulating the tip of the guidewire into the right direction. As mentioned earlier, even in the hands of experienced endoscopists, SBC can fail in up to 20% of cases [17]. Multiple attempts at SBC increases the time patients spend under anesthesia, increases the risk of PEP, and delays therapeutic options [19]. Thus, any technique that can increase the ability to manipulate the tip of the guidewire, potentially, can improve and increase the rate of successful SBC. To this end, in this work we propose to make use of advances in the field of continuum robots [4, 10] and autonomous motion planning for minimally-invasive surgery [11] to propose a magnetic guidewire which will be robotically navigated during ERCP to improve and increase the procedure's success rate and reduce procedure duration.

Specifically, the goal of this work is to build a proof-of-concept (POC) system that demonstrates the potential benefits of a magnetic guidewire autonomously navigated by a robot during ERCP. This will lay the necessary foundation for an NSF-BSF application with our US collaborator to tackle the multitude of challenges that will arise in the project. This system includes setting up PI' Salzman's lab to conduct initial experiments as well as laying out the algorithmic foundations to allow for autonomous robot planning capabilities.

As we detail in Sec. 5, our team is uniquely-positioned to address this challenging endeavour. Dr. Salzman from the Technion is an expert in robot motion-planning algorithms while Dr. Khamaysi from Rambam provides the clinical background as well as access to the OR. Our team is supported by Dr. Kuntz, a robotic expert in medical robots for minimally-invasive surgery with relevant background in magnetically-actuated systems.

Broader Impact As outlined in Sec. 2, this work is part of a growing interest within the field of robotics regarding the utilization of magnetic techniques for remote manipulation and wireless actuation. Indeed, recent groundbreaking work describes a teleoperated robotic neurointerventional platform based on magnetic manipulation. [7]. However, there is little-to-no *automation* in existing systems and our ultimate goal, starting with this proposal, is to develop autonomous robotic magnetic guidewire navigation. While we are concentrating on ERCP, we see the challenges and opportunities as generic and foresee the impact of our work reaching other procedures such as, but not limited, to neurovascular interventions.

4 Methods and Research Plan

As described in Sec. 3, in this work we aim at building a POC system that demonstrates the potential benefits of a magnetic guidewire autonomously navigated by a robot during ERCP. This requires developing both the necessary robotic setup and laying out the algorithmic foundations in order to map out the algorithmic challenges that we will need to address along the way. To this end, we start (Sec. 4.1) with a general description of our system. We then continue (Sec. 4.2) with the robotic setup we will need to conduct our research. Finally, we conclude (Sec. 4.3) with a general description of the algorithmic problems we will address in the work.

4.1 Approach

We propose to fix a small permanent magnet to the tip of a clinically-used guidewire which will be manually deployed through a clinical doudenoscope and autonomously steered by a permanent magnet *external* to the patient. Indeed, this has been shown to be an effective approach (though with no advanced autonomous planning capabilities) in collaborator Kuntz's existing work where an external magnet is held and manipulated by a robot arm (see Fig. 4a and [12, 14]).

(a)

(b)

Figure 4: (a) Robot arm and magnet setup from collaborator Kuntz's prior work. (b) Three robotic manipulators at the Computational Robotics Lab led by PI Salzman.

By placing this external magnet in specific poses, we can leverage the magnetic interaction between the external magnet and the small magnet on the guidewire. This enables us to exert forces and torques on the guidewire from outside of the patient's body. We will leverage this concept to steer the guidewire down specific branches of the bile ducts.

More formally, in order to steer the guidewire, we will use an externally-applied magnetic field using the following well-established magnetic principles [1]. The small magnet at the guidewire's tip can be modeled as a dipole $\boldsymbol{m}_n$ (units A·m^2), which is a vector pointing from its magnetic south pole to its north pole. The magnitude is a product of the volume of the magnet (units m^3) and its material-dependent average magnetization, approximately 10^6 A/m for NdFeB (a common material for magnets and one we intend to leverage). Applying a magnetic field $\boldsymbol{b}$ (units T) at the location of the center-of-mass of the guidewire's magnet generates torque $\boldsymbol{\tau}$ (units N·m) as the guidewire's dipole attempts to align with the applied field:

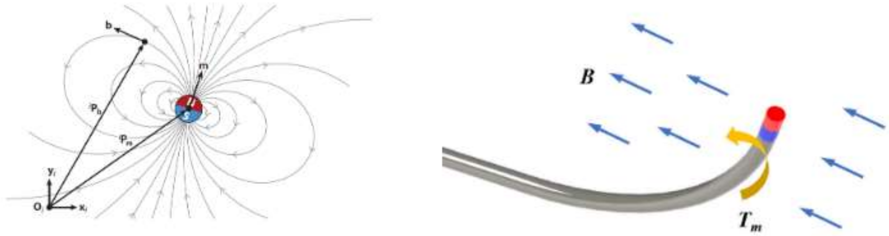
$$\boldsymbol{\tau} = \boldsymbol{m}_n \times \boldsymbol{b}. \tag{1}$$

The field's spatial derivative generates a force $\boldsymbol{f}$ (units N):

$$\boldsymbol{f} = (\boldsymbol{m}_n \cdot \nabla)\boldsymbol{b}. \tag{2}$$

However, this magnetic force $\boldsymbol{f}$ scales with the distance between the two magnetic sources d as $\|\boldsymbol{f}\| \propto d^{-4}$, in contrast to torque $\boldsymbol{\tau}$, which scales as $\|\boldsymbol{\tau}\| \propto d^{-3}$ [1]. For this reason we will leverage magnetic torque to steer the guidewire. We can model the field of the external magnet as a point dipole with strength $\boldsymbol{m}_e$. The field can then be expressed as

$$\boldsymbol{b} = \frac{\mu_0}{4\pi\|\boldsymbol{p}\|^3}\left(\frac{3\boldsymbol{p}\boldsymbol{p}^{\mathsf{T}}}{||\boldsymbol{p}||^2} - \mathbb{I}_{3\times 3}\right)\boldsymbol{m}_e. \tag{3}$$



(a) (b)

Figure 5: (a) A magnetic dipole, represented by a vector $\boldsymbol{m}$ at position $\boldsymbol{P}_m$ generating a dipole field whose streamlines exit the north pole and enter the south pole. Figure adapted from [1]. (b) Magnetic catheter / guidewire. Figure adapted from [6].

where $\mu_0 = 4\pi \times 10^{-7}\,\mathrm{T{\cdot}m/A}$ is the permeability of free space, $\boldsymbol{p}$ (units m) is the displacement vector from the external magnet to the guidewire's magnet, and $\mathbb{I}_{3\times 3}$ is the identity matrix. Using Eq. (1) and Eq. (3), we can compute the torque, given the poses of the two magnets (and their geometry), that the external magnet will apply to the guidewire magnet. For a visualization, see Fig. 5.

However this is the inverse of the problem we need to solve. In the simplest version of the problem we have from the physician as input a *desired* torque (computed by knowing in which direction we want to steer the guidewire's tip), and we need to compute a pose for the external magnet that achieves that torque while satisfying a set of constraints. This is the focus of the algorithmic contributions required.

4.2 Robotic setup

We will heavily leverage the existing robotic infrastructure at PI Salzman's lab. Specifically, the lab contains, among others, three robotic manipulators as depicted in Fig. 4b. Namely, the most expensive part of the project (in terms of hardware) already exists in PI Salzman's lab and does not need to be purchased. However, we will need to adapt the lab to support research on magnetic manipulation of guidewires. This will include (i) 3D printing a mock-up of the relevant parts of the digestive system, (ii) adding a magnet to a guidewire and (iii) setting up and calibrating an external magnet affixed to an (existing) robot manipulator and (iv) setting a sphincterotome through which the guidewire will be manually inserted and retracted.

Fig. 6 contains a silicone mock-up of one biliary bifurcation used in previous research of Dr. Khamaysi. We plan to have a series of such mock-ups ranging from simple bifurcations (as in Fig. 6) to complete anatomical reproductions of the entire digestive system. These will be used to both demonstrate a POC system as well as test our algorithmic development.

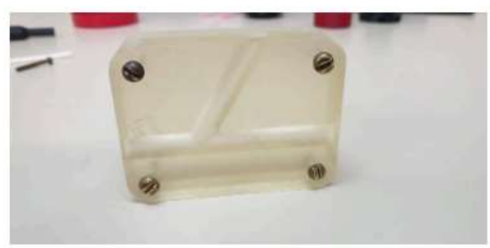


Figure 6

4.3 Algorithmic Framework for Magnetic Guidewire Navigation

Our ultimate goal is for the autonomous system to work in concert with the clinician. As part of a pre-operative stage, the clinician describes the path the guidewire is anticipated to traverse. This will be used in a (possibly computationally-intensive) preprocessing stage of the robotic system that will plan how to effectively help with guidewire navigation while accounting for the multitude of physical constraints in the OR (e.g., the clinician's workspace and the moving X-ray machine). During the procedure, the system will leverage the computations performed in the preprocessing stage to plan a path for the robotic arm in realtime that will seamlessly assist in manipulating the guidewire.

As an intermediate goal, we plan to tackle a slightly simpler problem that addresses the most urgent clinical challenge: guidewire navigation during SBC. Here, we assume that our system is only used when the clinician has placed the guidewire at the entrance of the bile duct and is faced with the challenge of navigating it to a specific duct. This simplifies the set of constraints placed on the system (e.g., the X-ray machine is fixed and does not move). However, even this simpler problem requires addressing the following key framework components (i) localizing the guidewire, (ii) obtaining input from the clinician via some interface, (iii) planning the motion of the manipulator holding the external magnet.

We now briefly cover how we plan to address each of the aforementioned components: From Eq. (1) and Eq. (3) it can be seen that we need to know the 5-DOF poses of both the guidewire magnet and the external magnet to compute the torque. To this end, we will compute the guidewire magnet's pose using bi-plane fluoroscopy. The external magnet's pose can be easily computed using the robot's joint encoders.

As mentioned above, the input will be a desired bending direction and magnitude for the guidewire, given to the algorithm by the physician as they look at the fluoroscopy. Based on straightforward beam mechanics [2], we can determine a desired torque from the bending direction and magnitude.

The lowest-order challenge then is to compute a pose for the external magnet that exerts this desired torque on the guidewire. This can be done using traditional optimization, wherein we vary a hypothetical external magnet pose as decision variables and minimize the difference from the achieved torque at that pose and the desired torque. However, this does not account for the aforementioned constraints on the manipulator's workspace. Fig. 7 shows Dr. Khamaysi during an ERCP depicting how cluttered the workspace is. While we are in the initial POC stage, we are already well aware of such challenges which will add more constraints on our system. Consequently, part of the work we plan to do as part of this POC is to understand what is the minimal workspace required for the robotic arm to successfully assist in guidewire navigation.

Figure 7

5 Collaboration Importance

Our team includes PI Dr. Iyad Khamaysi, PI Dr. Oren Salzman and collaborator Dr. Alan Kuntz. As we demonstrate below our team is uniquely-positioned to address this proposed research. Specifically, Dr. Khamaysi from Rambam provides the clinical background and access to the OR. This will provide an intimate understanding with the challenges that need to be solved. Moreover Dr. Khamaysi will continuously provide clinical feedback on the methods developed. Dr. Salzman from the Technion is an expert in robot motion-planning algorithms who will develop the autonomous planning capabilities. Of specific relevance to this proposal is his work on algorithmic motion planning for minimally-invasive surgery for which he was invited to give an early-career spotlight talk at the recent at International Joint Conferences on Artificial Intelligence (IJCAI) [11].

Collaborator Kuntz is a robotic expert in medical robots for minimally-invasive surgery with relevant background in magnetically-actuated systems. Kuntz's expertise are key in the development of a magnetically-manipulated system which is why we target a joint NSF-BSF application following the proof of concept that will come out of the work we propose here. Dr. Salzman and Dr. Kuntz have a proven record of working together on planning algorithms used in the context of minimally-invasive surgery with a total of five joint publications in leading robotic conferences and journals.

PI Khamaysi is the director of the Advanced Endoscopy Unit and an attending physician in the Department of Gastroenterology at Rambam Health Care Campus. He is the author of dozens of publications in peer-review journals and has five patents for a number of different clinical devices and medications. He is also a member of Physicians for Human Rights in Israel, and in that role has been actively working to advance availability and quality of gastroenterology and endoscopy in the European Gaza Hospital. His research interests include clinical and experimental endoscopy, pancreatic cancer research, experimental animal models of acute pancreatitis, rheology of pancreatic cyst fluid, and medical device innovations. He is the recipient of (among others) two grants from the Israel Innovation Authority as well as one KAMIN grant.

PI Salzman is an assistant Professor at the Computer Science department at the Technion. His research focuses on addressing the computational challenges that arise when planning motions for robots. Combining techniques from diverse domains such as computational geometry, graph theory and machine learning, he strives to provide efficient algorithms with rigorous analysis for robot systems with many degrees of freedom moving in tight quarters. Oren has published over sixty peer-reviewed conference and journal papers. He has received the best paper and best student paper in ICAPS 18 and ICAPS 19, respectively as well as a nomination for the best-paper award at RSS 21. He is the recipient of (among others) two NSF-BSF grants as well as two MOST grants.

Collaborator Kuntz is an assistant Professor at the Kahlert School of Computing (KSoC) and the Robotics Center at the University of Utah where he leads the Kuntz Research Lab, an interdisciplinary research lab focusing on robotics and computational methods with medical applications. Dr. Kuntz's work has been nominated for best paper and/or best student paper in multiple venues including the International Symposium on Medical Robotics. He is the Principle Investigator on multiple National Science Foundation grants involving flexible medical devices for minimally-invasive intervention including via magnetic manipulation. Prior to joining the KSoC faculty at Utah, Dr. Kuntz was a postdoctoral scholar in the Medical Engineering and Discovery Lab at Vanderbilt University. He completed his PhD in computer science in the Computational Robotics Research Group at the University of North Carolina at Chapel Hill

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