Flexible Instruments for Endovascular Interventions

Improved Magnetic Steering, Actuation, and Image-Guided Surgical Instruments

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Endovascular surgery has gained broad acceptance in the last few years. The current practice of endovascular procedures is limited by factors including patient-specific operation requirements, high-risk surgery procedures, and time-consuming operations. To address this, magnetically actuated surgical catheters have been introduced to the field of surgical robotics. Recently, advances in steerable catheters and developments in magnetic steering have been studied. However, limited research has been conducted to quantify the effectiveness of magnetic actuation for catheterization procedures. Endovascular interventions employing magnetically actuated catheters deliver the promise of higher accuracy and shorter duration when compared to current, manual techniques. Moreover, they allow surgeons access to areas of cardiovascular systems that cannot be reached with standard, minimally invasive techniques.

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Flexible Surgical Instruments

The field of surgical robotics employs technological developments that incorporate engineering systems to assist in medical procedures. This support, which has gained increased acceptance in the last few years, allows clinicians to complete complex surgical techniques with more precision, flexibility, and control than what is possible with conventional techniques. Endovascular surgery, one of the procedures undertaken by clinicians, utilizes relevant anatomy knowledge along with cutting-edge, minimally invasive technology. Endovascular surgeons and clinicians treat heart conditions and problems affecting the blood vessels, such as aneurysms. Surgical instruments, e.g., grafts, tubes, endoscopes, or catheters (commonly sharing a similar structure to continuum manipula-

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tors), are specifically designed devices that treat such problems. These instruments are manually inserted into the body, duct, or vessel, and they are used for fluid drainage, disease treatment, or reaching specific sites in the body for targeted drug delivery [1]. Catheters are typically steered from the femoral artery vein found near the groin or arm to the target site (the heart).

Flexible surgical instruments are most commonly used in laparoscopic surgeries—e.g., angiography; angioplasty; and arterial, aortoiliac, renal artery, and femoropopliteal- and infrageniculate-arterial interventions [2]. These complex procedures share common challenges regarding precise catheter navigation, which is required for successful treatment [3]. Although accessing areas is usually technically feasible, manually steering and positioning catheters in the target vessel is challenging and requires the clinician to undergo expensive, time-consuming training [4]. This makes the steering accuracy highly dependent on the abilities of a clinician [5], [6].

Multiple commercial solutions have been designed to alleviate these problems. Tendon actuation and guidewires remain the most common means of helping the clinicians navigate the endovascular catheters with higher accuracy [7], [8]. Nevertheless, limitations like buckling and friction of the tendons and cables tend to surface, limiting the solution's effectiveness [9]. In these cases, the surgical procedures for endovascular and cardiac repair may increase the risk of complications. These complications are caused by an artery being too narrow to permit passage of surgical instruments, the site of an aneurysm being too close to a vital organ or to important aorta branches, or being inaccessible (e.g., ophthalmic or basilar tip aneurysms) [10]. Therefore, these types of procedures may not always be feasible for certain patients.

As a result, alternative steering methods have been devised to improve the accuracy and reliability of catheter navigation. Among these methods, the magnetically controlled catheter actuation and navigation systems, or magnetic manipulation systems (MMS), have been introduced [11], [12]. Using magnetic systems to steer catheters (Figure 1) allows for high-precision steering in the endovascular network, less radiation exposure, and shorter procedure times than conventional navigation systems [13], [14]. Moreover, they provide enhanced steering capabilities to clinicians performing minimally invasive surgical procedures [15].

Thus far, research on magnetic actuation of endovascular catheters has been limited to single case studies, and little is known about the taxonomy of magnetic actuation for endovascular catheterization procedures. A broad definition applies to the original para-operational device (POD), founded in the 1960s [16], and is based on external static magnetic fields and field gradients or on alternating magnetic fields to propel and steer magnetic catheter tips intravascularly. The classification of magnetic actuation is characterized by the combination of the following features: magnetic actuation system, magnetic catheter elements, and visualization and control methods for catheter steering.

Magnetic Instruments and Systems

The theory of magnetic steering has experienced two major stages of evolution in the past decade. Original studies involving the actuation and steering of magnetic instruments describe active actuation involving solenoid coils and magnetic resonance (MR) scanners, and passive actuation involving permanent magnets and electromagnets. Recently, these actuation methods have been adapted, and methods for visualizing, controlling, and tracking the instruments inside the human body have been developed. In accordance with previous studies, catheters are equipped with various magnetic components, e.g., ferromagnetic spheres, steerable microcoils, and single- or multiple-permanent magnets attached to the catheter body or tip (Figure 2). The use of each particular component has both benefits and limitations, which are highly dependent on the framework used. Table 1 compares the different catheter components used in relevant studies.

Theory: Magnetic Actuation

The steering of magnetically actuated catheters is achieved by exerting wrenches caused by the Lorentz force on the flexible body of the instrument. The resulting internal bending moment propagates along the catheter toward its base, corre-

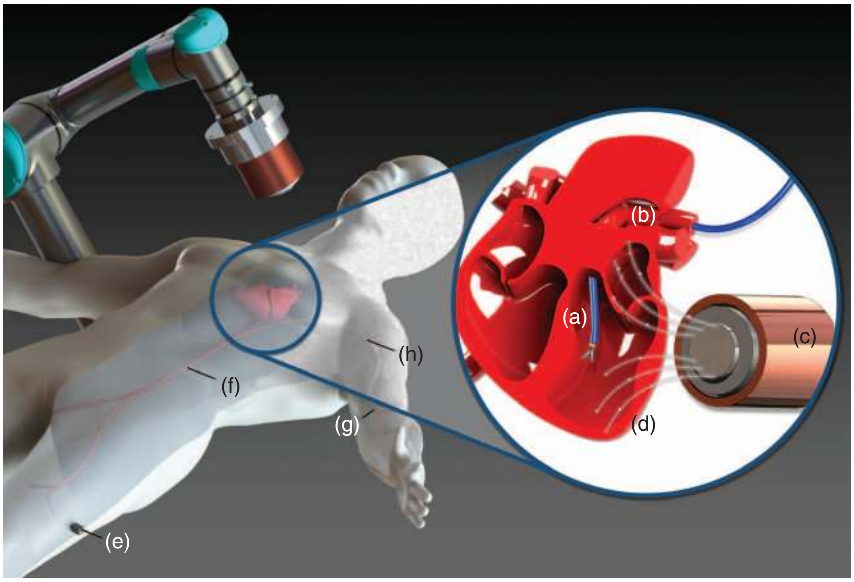

Figure 1. A representative illustration of (a) a magnetic catheter being placed (b) inside the aorta and (c) through the aortic valve by an electromagnetic coil. The electromagnetic coil produces (d) an external magnetic field. A typical cardiac intervention would involve the insertion of (e) the catheter in the groin to access (f) the aorta or, alternatively, (g) the arm to access (h) the brachial artery. The electromagnetic coil can also be adapted to be a permanent magnet for the same application.

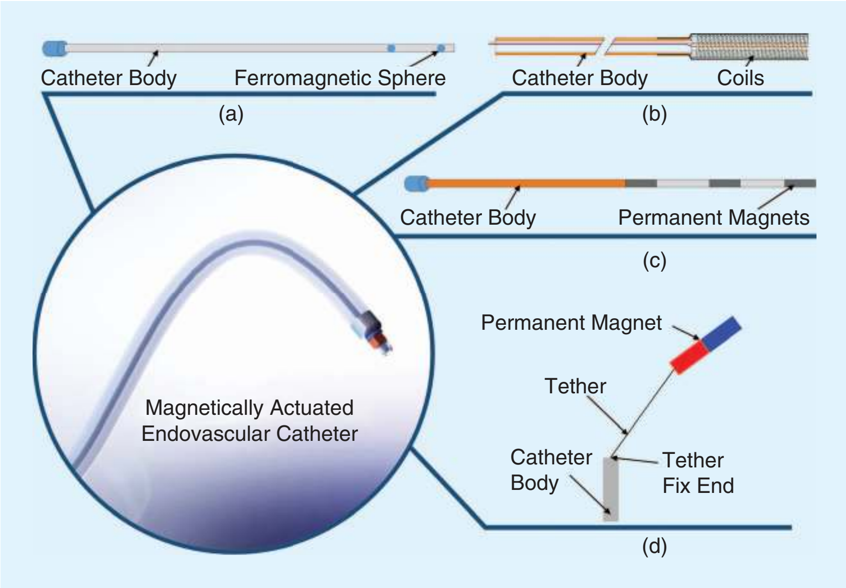

Figure 2. Four different catheter concepts showing (a) the use of ferromagnetic spheres at the catheter tip, (b) a custom clinical-grade microcatheter prototype with a solenoid coil at the distal tip adapted from [17], (c) multiple neodymium permanent magnets in a flexible catheter, and (d) a permanent magnet connected to the distal end of a catheter by a string-like tether [18].

lating with the Euler-Bernoulli beam theory. By controlling the magnetic wrenches, the user can drive the deflection of the catheter to achieve the desired configuration of the device, most often expressed in terms of the catheter tip pose. The Lorentz force itself occurs between the magnetic component of the catheter [described by its dipole moment ($\mathbf{m} \in \mathbb{R}^3$)], located at a position ($\mathbf{p} \in \mathbb{R}^3$), and experiencing the external magnetic field ($\mathbf{B}(\mathbf{p}) \in \mathbb{R}^3$). The resulting wrench ($\mathbf{W} \in \mathbb{R}^6$) comprises force ($\mathbf{F} \in \mathbb{R}^3$) and torque ($\mathbf{T} \in \mathbb{R}^3$), and is defined as

$$\mathbf{W} = \left[\frac{\mathbf{F}}{\mathbf{T}}\right] = \begin{bmatrix} \nabla(\mathbf{m} \cdot \mathbf{B}(\mathbf{p})) \\ \mathbf{m} \times \mathbf{B}(\mathbf{p}) \end{bmatrix}. \quad (1)$$

Each method of exploiting magnetic interaction (1) for catheter steering is highly device specific, with numerous, diverging approaches presented. This creates a significant challenge to provide a useful classification for magnetically actuated catheters, as the principles behind such devices can vary significantly. Nevertheless, in each case, the magnetic interaction occurs between two principal agents: the dipole $\mathbf{m}$ attached to the device and the field $\mathbf{B}(\mathbf{p})$, which is a property of the external environment.

Based on that notion, the magnetically actuated catheters are divided into two groups. The first group consists of magnetic catheters, which are actuated by modifying the catheter dipole $\mathbf{m}$ in a static magnetic field. Such catheters are called *active magnetic instruments*, as they require electrical or mechanical power to be transmitted to the catheter tip. In contrast, the second group of magnetic catheters comprises instruments that host permanent dipole and are actuated by varying the external field $\mathbf{B}(\mathbf{p})$. These catheters do not host any active elements and are steered merely by exploiting their response to a changing external environment. Therefore, they are called *passive magnetic instruments*.

Active Magnetic Actuation

Active magnetic systems are primarily based on the interaction between variable magnetic dipoles generated by microcoils and the magnetic field provided by MR scanners. Earlier work [19] demonstrates that the strong magnetic field in an MR scanner offers a unique environment for steering flexible devices (Figure 3). A solenoid embedded on a catheter induces a magnetic moment ($\mathbf{m} \in \mathbb{R}^3$), given by the following:

$$\mathbf{m} = nI\mathbf{A}, \quad (2)$$

where $n \in \mathbb{Z}^+$ is the number of turns in the solenoid, $I \in \mathbb{R}$ is the input current, and $\mathbf{A} \in \mathbb{R}^3$ is the vector cross-sectional area of the solenoid. The magnetic field provided by an MR scanner is static and produced by powerful, superconducting electromagnets. Therefore, the catheter with microcoils is actuated by controlling $I \in \mathbb{R}$, and thus changes the dipole moment $\mathbf{m}$ of a microcoil. As a result, a variable magnetic torque $\mathbf{T}$ can be prescribed. Moreover, since the magnetic field inside the MR bore is homogeneous, the field gradients are zero in the entire workspace, and results in the magnetic force $\mathbf{F}$ being zero. The total magnetic wrench is therefore a pure torque, allowing for two degrees of freedom (2 DoF) actuation sufficient for the deflection of the catheter tip. Nevertheless, the orientation of the field $\mathbf{B}(\mathbf{p})$ is constant and parallel to the symmetry axis of the MR bore, but no torque can be generated in that direction. The effect of the resulting actuation singularity can be overcome by including multiple components in the catheter, each with a different dipole direction [20].

The theory behind steering catheters with the magnetic field of an MR scanner has traditionally been investigated on currents running through a wire solenoid or Helmholtz-type coils [19]. The exception is the use of ferromagnetic spheres in the catheter tip [Figure 2(a)] demonstrated by Gosselin et al. [21]. Using spheres in an MR setting has shown some promise [22]; however, since they create large artifacts during the in vivo image capturing of the catheter, it is difficult to navigate into smaller branches.

Another example of a catheter with microcoils on the tip [Figure 2(b)] demonstrates a three-axis coil by Roberts et al., which was wound up on a 1.5 Fr cylindrical catheter and guided inside a 2 T MR scanner [19]. Losey et al. [17] designed the magnetically assisted remote-controlled endo-

Table 1. A comparison between catheter components (grouped according to active and passive actuation) used in studies for magnetic navigation in endovascular procedures.

Catheter Components	Magnetic System and Studies	Advantages	Limitations
		Active Magnetic Actuation	
Ferromagnetic spheres	MR scanner [21], [22]	• More ferromagnetic material allows for larger magnetic forces. • Artifacts caused by spheres can be used for tracking. • Small spheres can be easily removed to reduce artifacts.	• Multiple ferromagnetic spheres introduce undesired dipole–dipole artifacts. • Heavy spheres cause the catheter tip to drop and induce large slide friction against vessel walls. • Only low saturation magnetization materials can be used.
Microcoils	MR scanner [5], [19], [20], [23]–[25]	• Can be guided under MR imaging navigation; hence, no radiation exposure. • Has the potential, as a radio-frequency transmitter-receiver, to enhance imaging of soft tissues near the catheter tip. • Reduced levels of artifacts can be helpful for tracking of the catheter tip.	• Resonant heating of coils requires additional heat reduction techniques. • DC current causes imaging-related artifacts. • Fabrication of microcoils using the laser lathe technique limits size. • Microcoils require high magnetic fields and are restricted to active actuation using MR scanners.
		Passive Magnetic Actuation	
Permanent magnets	Electromagnets [18], [30], [31], [36], [38] Permanent magnets [32], [42], [88]	• Can generate high deflection forces. • Exhibits a large field-strength-to-volume ratio. • Can be manufactured in various shapes and sizes. • Enables catheter tip to reach difficult positions within the vasculature.	• Multiple magnets along the body of a catheter are difficult to control individually. • Multiple curvatures between magnets cannot be adopted in two-dimensional and 3-D, without using support from vasculature contact. • Most actuation systems use mathematical models related to single-magnet-tipped catheters only.

vascular catheter (MARC), which was specifically guided inside an MR unit bore. Settecase et al. [20] continued the theory of Roberts et al., and demonstrated the steering of the MARC inside a 1.5 T magnetic field. Their findings expressed an accurate deflection prediction, but it was also confirmed that the catheters could only tolerate a maximum current of 1 A for more than 1 min before the wire insulation melted. This drawback was further investigated by Hetts et al. [23] who determined that the upper boundary of electrical currents were safely usable in a 1.5 T MR scanner. Their findings indicated minimal injury to vessel walls using applied currents of less than 300 mA, but also revealed problems related to steering the catheter in branches with various orientations. To specifically address such shortcomings, Liu et al. [24] presented the three-dimensional (3-D) kinematic modeling of a new, steerable robotic ablation catheter system using the actuation of a 3 T MR scanner.

Similarly, Liu et al. [25] presented a catheter embedded with a set of current-carrying microcoils that was actuated by MR. In their latest study, they presented a prototype with a single axial coil and two orthogonal coils to allow for control of the 3-D deflection. A challenge of using microcoils is the final tip diameter after construction, which may cause the catheter to become obsolete for use in smaller cerebral and cardiac vessels; although, it has been suggested that future prototypes could be constructed from laser-lithographed coils with very thin heat-shrink tubing [17]. This would then allow for smaller coils.

The use of MR scanners for the active actuation of magnetic instruments is promising and provides a unique opportunity for the development of new endovascular catheter steering mechanisms. With orthogonal coils, catheters can be steered in multiple directions inside an MR scanner. However, it remains a challenge to generate torques parallel to the direction of the MR magnetic field because of the steering principle of alignment between the fields. Furthermore, surgical procedures using magnetic actuation are commonly not performed in an MR scanner because of either hospital workflow or cost considerations. A number of studies addressed these drawbacks by utilizing passive actuation.

Passive Magnetic Actuation

Passive actuation involves catheters being externally actuated by electromagnets or external permanent magnets (Figure 4).

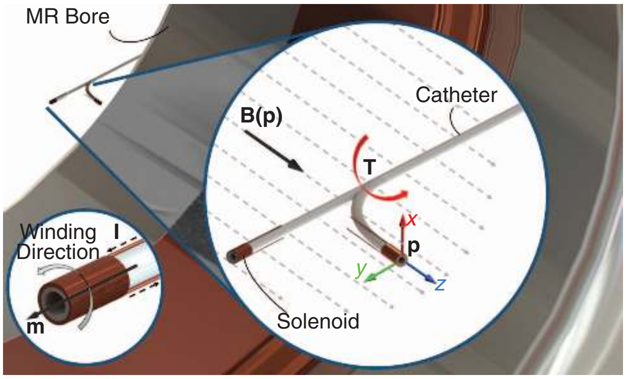

Figure 3. The deflection of a catheter with a solenoid tip inside an MR scanner. Once a current **I** is applied, the magnetic field $\mathbf{B}(\mathbf{p})$ induces a torque **T** on the solenoid tip **p** to cause a parallel alignment of the dipole moment direction **m** with the direction of the magnetic field of the scanner. The inset shows the wire solenoid wound around the catheter tip.

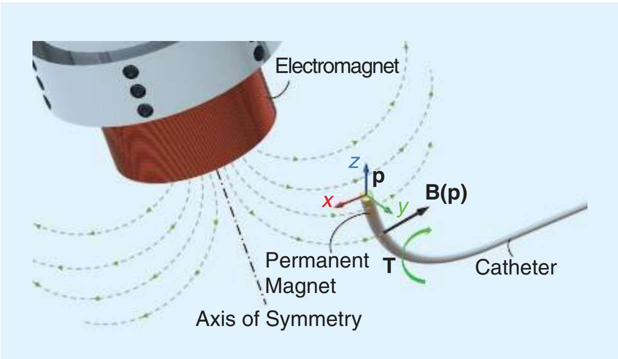

Figure 4. The torque that acts on a magnetically tipped catheter, with the permanent magnet center point positioned at a point **p** from an external electromagnet. The magnetic field $\mathbf{B}(\mathbf{p})$ induces a torque **T** to cause an alignment of the catheter tip.

While adhering to Hopkinson's law [26], electromagnets are capable of producing steerable magnetic fields, dependent upon the current that flows through the windings of the coil. Multiple electromagnets can thus provide passive actuation in different directions. In contrast, a field generated using external permanent magnets is constant, and therefore steered by changing the position of the permanent magnet itself [27], [28]. Passive actuation also relies on the wrench produced by a magnetic field. This external field can be relatively smaller since the constant dipoles usually take much higher values. Passively actuated catheters typically experience both the magnetic force $\mathbf{F}$ and torque $\mathbf{T}$ from (1) when exposed to a magnetic field $\mathbf{B}(\mathbf{p})$, as the gradients of the field are rarely zero. The torque specifically aligns the magnetic dipole direction of the magnetic element with the applied field, and can, therefore, be used to specify alignment direction for basic steering. The force then pulls the magnet in the direction of the field gradient.

Permanent magnets attached to endovascular catheters [Figure 2(c)] have delivered significant results regarding accuracy and predictable passive magnetic navigation. The majority of magnetically tipped catheters used in studies are constructed using an alloy of neodymium-iron-boron (Nd-Fe-B), also called *NeodymiumN*. This ferromagnetic material is widely utilized in catheter designs because it has strong magnetization, making it an excellent candidate for steering catheter tips [29]. Studies using both electromagnets [30], [31] and permanent magnets [32] for passive actuation have utilized Nd-Fe-B magnets in their catheter models, although the majority has implemented single magnetic components. Recently, Edelmann et al. [33] demonstrated the modeling of different catheter geometries with multiple magnetic components and various boundary constraints. However, the exact magnitudes of forces acting upon such catheter tips are, in some cases, limited by the relative stiffness of catheters [34]. Chautems et al. [18] presented a solution (called the *tethered magnet*) by replacing a flexible catheter tip with a string-like tether [Figure 2(d)].

Commercial and noncommercial systems that use the principle of passive actuation have been developed. Tunay [35] managed to determine the position and orientation of a catheter tip in real time by external electromagnetic means and illustrated an improved predictable navigation in two-dimensional (2-D) planes when compared to manual actuation. Deflection was accomplished with the assumption that the spatial variation of the field from (1) is small enough that the force is negligible. Boskma et al. [36] also demonstrated a magnetically actuated catheter in 2-D using the interaction between permanent magnets embedded inside the tip, and external electromagnetic fields. A homogeneous magnetic field was used to steer the catheter in 2-D space using two Helmholtz coils while also assuming the magnetic force to be zero.

Tunay [37] again demonstrated the static deflection of a magnet-tipped catheter, but this time extended the navigation of catheters to operate and work within a 3-D space. The focus on 3-D was also demonstrated using an electromagnetic system developed by Gang et al. [38], which exerts both force and torque from (1) by controlling the field magnitude, direction, and gradient. The direction of a magnetized electrophysiology ablation catheter was automatically controlled and allowed for accurate navigation. Today, the system exists as one of the commercially available electromagnetic systems [39] called the *catheter guidance control and imaging* (*CGCI*) system, developed by Magnetecs Corporation. A noncommercial system, the Institute of Electrical Engineering (IEE) Magnetic Navigation System (MNS) [40] provides real-time navigation of a catheter in a beating heart and is under development by the IEE, Chinese Academy of Sciences. As opposed to the CGCI, the magnetic field of this system is fairly homogeneous in the navigation region, such that only sufficient torque is exerted on a catheter tip. The Aeon Phocus [41] is another noncommercial electromagnetic catheter steering system for treating cardiac arrhythmias, and it operates in a similar fashion to the CGCI with submillimeter accuracy.

In contrast, a commercially available catheter control system, the Niobe MNS, uses two permanent magnets to guide magnetic catheters. Guidance is accomplished by mechanically rotating the magnets, which navigates catheters with magnetic tips. With regard to (1), deflection is achieved through torque exerted by a magnetic field interacting with a permanent magnet in the catheter tip. The Niobe successfully demonstrated the control of soft catheters having three magnets on the distal tip in a study conducted by Choi et al. [42]. Results from this study showed decreased radiation exposure and safe and effective procedures [43]. Furthermore, Kratchman et al. [32] demonstrated the guidance of a magnet-tipped rod along arbitrary 3-D trajectories using a single, robot-manipulated permanent magnet. The magnet was attached to a 6-DoF serial robot, which demonstrated trajectory following and obstacle avoidance using resolved-rate motion control. Table 2 summarizes specifications of existing and representative technologies concerning passive magnetic systems.

When considering actuation techniques, electromagnets have often been preferred due to their ability to control the field strength by changing the coil current [44]. However, substantial field generation results in a significant temperature rise within the coils. The main advantage of permanent magnets is that they exhibit a nondecaying magnetization and do not require currents to generate a magnetic field as with electromagnets [36]. This makes it difficult to use during studies that require instruments to track or visualize catheters, which may be damaged by constant exposure to magnetic fields [45].

Field adjustment is another factor that distinguishes permanent and electromagnetic actuation methods. Permanent magnet strength is influenced by its materials; the strength of an electromagnet can be adjusted by the amount of electric current that flows through the coil. This can result in the same electromagnet being used for different levels of magnetic field strength, and therefore, various applications when one permanent magnet can only be demonstrated with one particular field strength. This rapid manipulation of an electromagnet's magnetic field can be used on a wide range, although the continuous supply of electrical energy makes it the more costly method.

Visualization and Control

Guidance and tracking of surgical instruments can be improved significantly using a variety of imaging modality methods. Using these methods not only allows visualization of the structure of the blood vessel, the vessel wall, and all aspects of the anatomy within the field-of-view, but also shows functional information about the instrument within

Table 2. A summary of four main passive magnetic systems for endovascular procedures.

	Magnets					
Actuation System (Company)	**Type**	**Number (Maximum Field)**	**Actuation**	**Arrangement**	**Applications and Studies**	**Reported Accuracy**
IEE MNS[1] (non-commercial)	Electromagnets	8 (0.22T)	Aligned spherically surrounding the subject's torso		Cardiac arrhythmias Electrophysiology [40]	$<$ 1 mm
CGCI[2] (Magnetecs Corporation)		8 (0.16T)	Placed around the subject's torso Fixed position		Cardiac arrhythmia mapping and ablation Atrial fibrillation (AF) ablation [38], [58], [91]	1.9 ± 0.4 mm
Aeon Phocus (Aeon Scientific)		8 (0.10T)	Placed around the subject's torso Fixed position with rotation around subject		Mapping and ablation of arrhythmias, such as AF [18], [34]	0.42 mm[3]
Niobe (Stereotaxis)	Permanent magnets	2 (0.08T)	Aligned externally to each side of the subject Mechanically positioned using computer-aided motors		Radiofrequency catheter ablation Ablation of AF [3], [13], [27], [28], [42], [77], [88], [89], [94]	$<$ 1 mm

[1] IEE MNS
[2] CGCI
[3] Based on extrapolated data from the results of [33]. Limited information has been published on the Aeon Phocus. According to [18], the accuracy depends greatly on the measurement conditions (operation inside a moving heart or in a static model).

the vessel. In the case of the latter, image-based tracking methods can be used to track the instrument, e.g., a needle or catheter tip [46], [47].

Imaging Modalities

Previous studies have stated the importance of real-time clinical imaging modalities to provide magnetic motion control systems with the position of surgical instruments and targeted drug delivery systems [48], [49]. Some of the techniques used to observe the movement of surgical devices include: obtaining images by dark-field microscopy [50]; using fluoroscopy as an imaging modality [51]; and MR [52], although several health risks, design challenges, and limitations to clinical studies exist for these methods [53]. Furthermore, existing work has demonstrated the use of electromagnetic trackers on catheter bodies or tips [54], [55]. Their application, however, is not suitable in electromagnetic actuation systems.

Endovascular procedures that are being conducted under X-ray guidance have proven to be rapid and efficient when compared to MR guidance [56]. Using X-rays can also produce images from areas such as bone, retroperitoneum, and lungs, not well seen by ultrasound (US) guidance [57]. Unfortunately, X-ray and fluoroscopy techniques cause several safety hazards due to the exposure of both patients and surgeons to ionizing radiation [58]. Furthermore, conventional computerized tomography (CT) scanning delivers insufficient soft tissue visualization [53] and no real-time images during the procedure [59]. Even when images are produced successfully, CT-guided procedures can be complicated in uncooperative patients and in organs that are prone to respiratory motion (e.g., the aorta, liver, and lung) [60].

Alternatively, MR has been investigated as a novel, passive imaging modality for visualizing robotic catheters [19], [24], [53], [61], [62]. Interventional MR offers a high contrast for soft tissue and 3-D volumetric image reconstruction [63] and no ionizing radiation [64], a clear advantage over conventional X-ray angiography. The promise of endovascular MR-guided procedures, however, remains unrealized in part because of the lack of MR-compatible catheters and guidewires that the user can safely navigate and track efficiently in real time [65], especially with strong magnetic fields (1.5 T or greater) [63]. Furthermore, MR has a low image acquisition rate [66], making it more difficult to navigate conventional catheters and electrical components safely [67].

US imaging has served as an imaging modality in endovascular studies for both 2-D and 3-D environments [68]–[71]. As with MR-imaging modalities, one of the prominent advantages of US imaging is that it causes no ionizing radiation, allowing for longer and safer surgical procedures. Instrument visibility and tracking accuracy can be enhanced and automatically guided [72] using robust US-image analysis techniques.

For visualization only, the majority of interventions involve the use of real-time X-ray fluoroscopy imaging [53]. Due to the previously mentioned drawbacks to its use, MR and US have again become attractive alternatives for instrument visualization. Cannon et al. [73] investigated 2-D- and 3-D-US as stand-alone imaging modalities during interventional tasks. The objective was to improve the applications to eventually include intracardiac surgery and fetal surgery, while also potentially improving the results of solid organ interventions. Kesner and Howe [70] demonstrated a combination of US guidance and force control to guide and visualize a robotic catheter for its application in cardiac ablation. The goal was to precisely track and manipulate the intracardiac tissue structures because of the fast tissue motion and the potential for applying damaging forces. The MR scanner used by Liu et al. served as both a means of active actuation and imaging modality to provide sufficient tip and shaft visualization [24]. They aimed to model the deflection motions of the catheter inside the left atrium. Boskma et al. [36] investigated the use of US images as a viable alternative to fluoroscopy for the real-time visualization and control of a robotic catheter. A 2-D-US modality was used to control the catheter in a stationary environment.

The efficacy of surgical procedures clearly depends on successfully detecting the parts of the cardiac tissue that need to be investigated. As in the "Visualization and Control" section, using imaging modality methods allow for both visualizing and detecting surgical instruments. In the case of flexible surgical instruments, image modalities enable either catheter tip or target-tissue tracking in both 2-D and 3-D images. Among the medical imaging devices, 2-D-US imaging is the most commonly used modality, and methods to improve it are continually being researched using additional control techniques form part of this research area. Additional control enables clinicians to shift their focus from the manipulation task itself to more sophisticated medical tasks, e.g., ensuring correct target trajectories and ablation conditions.

Control Methods

Minimizing the invasiveness of surgical procedures requires instruments to move accurately within the target vessel during trajectory following. Furthermore, endovascular procedure outcomes depend greatly on the correct positioning of the catheter tip. For instance, during catheter ablation, the catheter is positioned inside the heart and requires consistent contact between its tip and the cardiac tissue. Achieving accurate positioning is challenging, especially in the presence of cardiac and respiratory motions. Moreover, the complexity of the vasculature limits the use of preprogrammed trajectories where an exact knowledge of the path from the insertion point to the target location is necessary.

Realizing the appropriate control method for both trajectory following and catheter localization requires sufficient information about the system dynamics, e.g., a force-deflection relationship of an ablation catheter, or a current-field map in the case of an electromagnetic passive actuation system. Consequently, accurate mechanical models and continuous device localization are specific fundamental requirements of control strategies for magnetic catheter actuation [74]. Mechanical models used for accurately describing the system and environment include Euler-Bernoulli beam deflection [35], rigid link approximation [75], the Cosserat rod theory [32], and pseudorigid body modeling [76]. The localization of catheters has been demonstrated by accurately using electromagnetic tracking [27] and by observing the device shape and orientation using MR, US, and fluoroscopy.

Open-loop control of magnetic catheters has been established and demonstrated in animals [27] and humans [77]. However, effective open-loop control is challenging to implement, since many of the catheters used in these procedures exhibit nonlinear behavior [78]. Further drawbacks include measurement and environmental noise, as well as inaccuracies in terms of result output due to the absence of a feedback mechanism.

In contrast, closed-loop control involves constant feedback of the position of the catheter to ensure more accurate catheter positioning. Tunay et al. [79] introduced one of the first real-time, closed-loop automated MMS in 3-D. In a study by Degirmenci et al. [54], a robust method for the closed-loop control of a 4-DoF catheter tip was successfully demonstrated. O'Donoghue et al. [80] also presented a novel closed-loop current feedback amplifier for controlling a magnetic field used for catheter position sensing. Closed-loop control in a constrained setting, e.g., a patient vasculature, remains a significant challenge because of vessel wall friction and physiological disturbances. To address this problem, Edelmann et al. recently demonstrated a model-free method enabling the direct control of a flexible endoscope with an electromagnetic steering system [74]. This approach presented a novel way of implementing catheter control since there is no need for device configuration or precise model formulation, making it a critical improvement to a wide range of endovascular procedures.

Discussion

The intended applications for steerable surgical instruments impact cardiology and interventional radiology fields the most. These fields cover interventions such as peripheral and cardiac procedures, including angiography, angioplasty, and ablation [70]. Clinical trials have reported beneficial effects in the use of steerable catheters in interventional cardiology, while most studies concern advances in cardiac catheter technology and interventions [24], [30], [70], [73], with a main focus on passive magnetic actuation systems.

The broad range of applications of catheterization within minimally invasive surgeries demands additional improvements of surgical instruments. As the underlying steering technologies' applicability differs per clinical procedure type, different catheters or flexible devices should be developed accordingly. The chosen method of actuation influences the structure and assembly of the catheter, especially for magnetically driven systems. For example, during angiography, a catheter will be inserted into the bloodstream to deliver contrast agents. For angioplasty, a thin catheter with an expandable balloon will be used to widen narrowed or obstructed arteries or veins. For targeted drug delivery, more focus is placed on developing multilumen catheter bodies, whereas, for catheter ablation therapy, tools to attach on the catheter tip are more critical. For the remaining interventions, targeted maneuvering and steering from an insertion point require a flexible catheter with a fully controllable tip.

The developments found in magnetically actuated catheters are of high scientific value, as their applications are still unique among minimally invasive surgery. However, specific challenges were identified in the methods and solutions provided for steerable catheters.

Challenges

From experimental results of the literature reviews, some limitations were introduced with regards to the actuation type, catheter model, and control methods. Several studies sought to design catheters that can be remotely controlled in MR systems, though all revealed some limitations.

For example, the acute angles of origin that target vessels arise from branches influence the orientation of the catheter tip relative to the bore of the MR scanner. These angles result in some alignments of the catheter to scrape the walls of the vessel and cause damage. Furthermore, since the coils generate a heating effect, high temperatures in the near vicinity of the catheter tip may cause damage to surrounding vessel walls and sensitive tissue [81], [82].

Problems like the accuracy of closed-loop control strategies [83], 2-D-US tracking algorithm inaccuracies and 2-D plane visualization limitations [36], small operational workspaces [84], and magnetic field estimation inaccuracies [30] seem to arise frequently. Studies that take place in stationary environments tend to simplify complex scenarios; however, additional tracking uncertainties may occur because of the reduced visibility of the catheter [85]. These identified limitations result in the pursuit of further navigation and tracking methods, which are either less expensive or require minimal manual intervention. Several strategies to minimize these challenges can be followed, e.g., implementing improved control methods and introducing mobile magnets with longer steering distances.

Outlook

Magnetic actuation methods are finally transitioning from being mere research interests to actual clinical tools. Magnetic actuation and steering systems have been incorporated in various applications, such as the use of catheters as scanning instruments for optical imaging techniques [86], assisting in the placement accuracy of coronary stents [87], and the use of catheter ablation (with force sensing catheter tips) for the treatment of symptomatic atrial fibrillation [88]. Other studies have also demonstrated the use of radio-frequency ablation magnetic catheters [31], precise and reproducible catheter manipulation for endocardial mapping [77], and endovascular navigation [23]. The findings of magnetic actuation have improved the study of electrophysiology for diagnostic and therapeutic purposes [89], [90], as well as automatic angle adjustment and pointing [91], [92].

When compared to standard catheter systems, magnetic systems provide an increased level of control, decreased device sizes, faster procedure completion, and increased safety [17], [44]. Early studies using remote magnetic navigation for the ablation of various types of arrhythmias have demonstrated improved safety and equivalent efficacy when compared to manual techniques [93], [94]. Magnetically actuated catheters are safer than pull-wire and smart material-actuated catheters, which require a specific stiffness to maintain the catheter shape during cardiovascular interventions [51].

With the incorporation of improved automatic catheter actuation technology, it is expected that surgical procedure durations and radiation exposure will decrease. Combining this technology with more effective imaging modalities, e.g., enhanced US imaging, MR-compatible robotics, and real-time shape sensing for flexible instruments [95], may significantly improve clinical outcomes. In some cases, stabilization of the catheter tip requires position feedback and a relatively fast control rate. To address this, studies have presented miniature sensors inside the catheter body [96]. Fiber Bragg grating sensors can be used to acquire information about the interaction forces and the shape of the instrument.

The realization of alternative automatic navigation during closed-loop steering of continuum manipulators under the guidance of a clinically relevant tracking modality, can be introduced in future work. Existing tracking and control systems can be replaced with a 3-D-US imaging system to overcome the difficulties presented by an active cardiac environment, e.g., continuous blood flow and beating heart motion. Electromagnetic coils can then be implemented together with lightweight, flexible, and collaborative industrial robots that let the user automate repetitive and complex tasks in multiple DoF. In the same way, permanent magnets can be attached to robot end effectors to provide a constant magnetic field. Finally, catheter designs can be improved and fabricated to extend the range of applications. Catheter tip bending studies, with a focus on deflection angles, the incorporation of microcoils along the catheter body, and multi-magnet configurations will be achieved in future applications.

Conclusions

An overview of different approaches to the improvement of the magnetic steering, actuation, and image-guided tracking of catheters was presented in this article. Several endovascular surgery-based research publications were discussed according to predefined categories, and similar studies and related work in the field of endovascular surgery were researched. Their limitations and proposed solutions were summarized and evaluated according to the type of actuation systems they incorporated, their intended clinical applications, and the imaging modalities for visualization. The potential for other areas in endovascular interventions are stem cell therapy, difficult coronary artery procedures, drug delivery, and tissue biopsy. Even though these systems are only the first step to magnetic navigation with high performance, the current tested principles and results seem to confirm that the magnetic actuation methods for surgical catheters are valid and should be considered as a milestone in the development of safer, automated procedures.

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