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A Variable Stiffness Catheter Controlled with an External Magnetic Field

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***Abstract*— Remote magnetic navigation of catheters is a technique used to perform radiofrequency ablation of heart tissue in order to treat cardiac arrhythmias. The flexible magnetic catheters used in this context are in some cases not sufficiently dexterous to navigate the complex and patient-specific anatomy of the heart. To overcome such limitations, this paper proposes a new approach that relies on the integration of variable stiffness segments into a magnetic catheter. The magnetic variable stiffness (VS) catheter presented here is based on silicone and a low melting point alloy (LMPA) that transforms from a solid to liquid phase upon joule heating. This dramatically changes the bending stiffness of the segment in which it is integrated, improving dexterity. Compared to standard catheters, a VS catheter can partially (just one segment) or completely lock its shape (shape fixity) in order to explore a larger 3D volume inside a magnetic navigation system, thus extending regions of the heart that can be reached for performing ablation procedures.**

I. INTRODUCTION

Radiofrequency (RF) ablation has been widely adopted to treat cardiac arrhythmias [1]. Most procedures currently rely on manual navigation of catheters within the heart [2]. For a typical procedure, a sheath is first inserted into the right femoral artery and passed up into the heart via the ascending aorta. A 2.3 mm diameter catheter is inserted into the sheath and emerges from it in the right atrium of the heart. The catheter can then be manipulated into various locations on the inner heart wall chambers in order to deliver RF energy to ablate specific tissue in areas responsible for the generation of abnormal electric signals. The position of the catheter tip is controlled by rotating/pushing/pulling the catheter shaft and by deflecting the tip with a pulling wire attached to the distal end.

Since the anatomy of the heart is complex and patient-specific, selecting a catheter with suitable curvature is extremely important for the success of the medical procedure. For this reason, a number of solutions have been developed to increase the dexterity of such catheters. For example, in [3] a catheter is used that is able to bend in two directions with different deflection curves. In [4][5] a steerable introducer sheath (i.e. Agilis NxT from St. Jude Medical) is used to reach hard-to-access areas of the heart.

Recently, remote magnetic navigation has been demonstrated to be a more controllable alternative to manual

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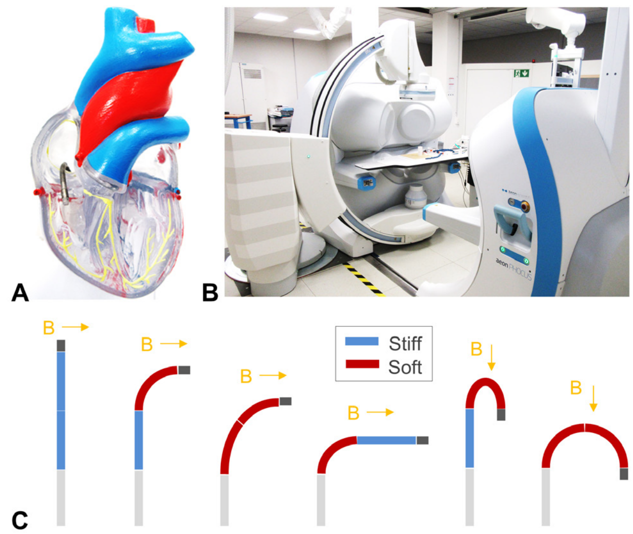

Fig. 1 A) Variable stiffness (VS) catheter inside a heart model to illustrate a foreseen application. B) Magnetic manipulation system Aeon Phocus used for VS catheter testing. C) Some configurations that a catheter with two variable stiffness segments (VSSs) can adopt, depending on the direction of the magnetic field and on the deformability state of its VSSs. In the configuration on the left, the shape of the catheter is completely fixed.

navigation [6][7]. This technique reduces X-ray dose to the patient [8] and allows the standardization of the medical procedure by lowering the impact of the operator's skills on the outcome [9]. In remote magnetic navigation, an external magnetic field is used to deflect the magnetic tip of the catheter. The commercially available catheters are composed of an ablation tip, flexible segments, and permanent magnets. Usually, three magnets are separated by flexible sections [10], which is important for obtaining an alignment of the tip to the applied magnetic field. The catheter length can be increased or reduced by using a mechanical translation mechanism. The main limitation of remote magnetic navigation is that different magnetic fields cannot be applied at different magnet positions in the workspace (i.e. the field affects everything in the workspace) [11]. Therefore, it is not possible to navigate through the body by adopting multiple curvatures in 2D and 3D without using support provided by contact with the heart chamber wall.

In order to overcome such limitations, we propose a proof-of-concept catheter for radiofrequency ablation that includes variable stiffness segments (VSSs) and a magnetic tip (Fig. 1 A). The VSSs are based on a low melting point alloy (LMPA) and enable the tuning of stiffness and deformability of the tip of the catheter, while the magnetic

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tip can be controlled by an external magnetic field (Fig. 1 B).

The variable stiffness (VS) approach improves both dexterity and stability. Selectively locking one or more flexible joints of the catheter allows for several degrees of freedom despite the application of a single magnetic field (i.e. under actuation). Therefore, complex 2D and 3D shapes can be realized by the device (Fig. 1 C). It is also possible to fix the entire structure in place (i.e. shape fixity) during the ablation procedure for better support and surgical precision (Fig. 1 C).

II. Design and Development of the Variable Stiffness Catheter

A. Selection of the variable stiffness strategy

A variable stiffness (VS) catheter for cardiac ablation and remote magnetic navigation has specific requirements. In the stiff state, it should resist the bending torque due to magnetic field (i.e. 0.003 Nm) and the contact force (0.2 N) between heart wall and catheter tip during the ablation [12]. In the soft state, it should easily bend and align as much as possible in the direction of the magnetic field. The diameter of the catheter should be less than 2.5 mm.

In the field of minimally invasive surgery, the integration of variable stiffness backbones and outer tubes is a known solution for promoting stability, especially for instruments operating in extra-vascular environments (e.g. intestine, abdomen) [13]. In this case, a number of designs have been proposed based on tension-stiffening of friction-locking beads [14], combinations of concentric tubes [15], phase change materials [16], and granular and layer jamming [17] [18]. Among intravascular catheters, given the dimension constraints, few examples can be found based on material stiffening (i.e. using materials that undergo stiffness variation under certain stimuli), and are mainly limited to low melting point materials (e.g. polymers [19] and alloys [20]).

In this work, we selected a low melting point alloy (LMPA) as the variable stiffness material due to its large stiffness change and its high absolute stiffness when solid [21]. LMPAs are phase change alloys that transform from solid to liquid at relatively low temperatures [22]. Their potential use in biomedical applications (e.g. micro devices for vessel exploration, material for bone repair) is of current research interest [23]. Among LMPAs, Cerrolow 117 has a 47°C melting temperature and is stable in air. Below the melting temperature, it is a solid characterized by a stiffness of 3 GPa, a tensile strength of tens of MPa, and strain-at-break of around 3% (mechanical characterization described in [21]). Above the melting temperature, it is a liquid with low viscosity. Cerrolow 117 undergoes phase change faster than other phase change materials (i.e. wax and SMP), due to a more than one order of magnitude higher thermal conductivity *[24] [25]*. Being liquid at high temperatures and containing toxic elements such as Cadium, Cerrolow 117 requires encapsulation for biomedical applications.

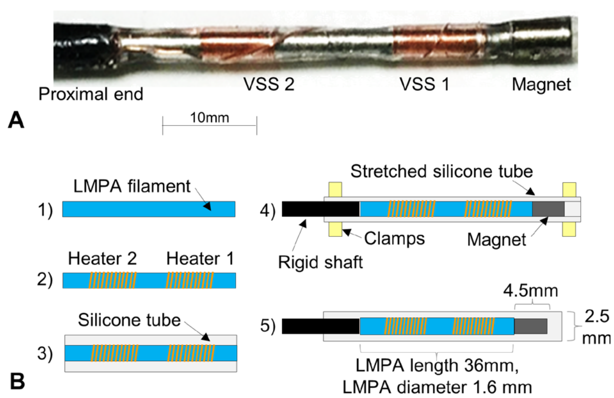

Fig. 2 A) Proof-of-concept of a variable stiffness catheter, with two variable stiffness segments (VSS1 and VSS2) and a magnet on the tip. The heaters corresponding to VSS1 and VSS2 are clearly visible before the heaters are covered with LMPA. B) Fabrication process of the variable stiffness catheter. Step 1: A cylindrical filament of LMPA is obtained by sucking molten LMPA into a silicone tube (1.5mm internal diameter, 2.5mm external diameter, length 45mm) placed on a heated plate (set to 100°C). After LMPA solidification, the tube is removed. Step 2: conductive copper wires (radius 0.05mm, resistivity $1.68\times10-8$ Ω/m) are wound around the LMPA filament at *60* turns per centimeter to create two independent heaters (~10 mm length). Step 3: A new silicone tube is forced around the filament to completely encapsulate it. Step 4: pre-stretching (25%) is imposed on the tube in the longitudinal direction by forcing it to slide along the unstretched solid LMPA core. Then, the ends of the tube are sealed by gluing a rigid shaft at the proximal end and a magnet at the tip. The pre-stretching of the silicone tube is maintained by clamps (in yellow). Step 5: Due to the pre-stretching, when the catheter is heated above >47°C, the silicone encapsulation reaches a new equilibrium state. The final dimensions of the LMPA core are 1.64 mm diameter and 36 mm length (i.e. a 20% shorter length and a slightly bigger LMPA diameter compared to step 4).

B. Description of the variable stiffness catheter based on LMPA

Fig. 2 A shows the VS distal end of the proposed magnetic catheter based on LMPA. It is composed of a core of Cerrolow 117 (HiTech Alloys, USA; composition by weight: 45% bismuth, 23% lead, 19% indium, 8% tin, 5% cadmium), two heaters, a magnet (MagnoFlush catheter magnet) and a silicone tube that encapsulates the entire structure (platinum cured silicone, Silex LTD, UK). The two heaters, obtained by coiling enameled copper wire, correspond to two independent variable stiffness segments (VSSs): when current (e.g. 0.8-1 A) is injected into the copper wire, the temperature of the LMPA increases above the melting temperature and the VSS becomes soft. In this state, the mechanical performance of the VSS is roughly that of the silicone encapsulation, as already shown in [21][25]. Within an external magnetic field, the soft VSS behaves like the flexible segments in standard catheters, allowing the alignment of the magnet to the direction of the magnetic field (Fig. 3). When the LMPA solidifies inside the magnetic field, the VSS becomes rigid and retains the deformed shape. In this state, the LMPA core sustains tensile and compressive loads (e.g. due to the magnetic field oriented in a different direction compared to the magnet direction), while the contribution of the silicone encapsulation is negligible (Fig. 3 B).

Given the spatial constraints, no cooling system is integrated. The cooling of the VSSs in blood relies on convective heat transfer.

A reheating-and-cooling cycle applied to the deformed and/or fractured VSS restores its original straight shape (i.e. the shape of the silicone encapsulation) and its mechanical properties in the solid state (i.e. Young modulus, maximum stress and strain). Such a restoration of the mechanical properties after fracture (self healing), which was demonstrated in [25], also occurs in the presence of an external magnetic field.

The VS catheter is fabricated according to the steps described in Fig. 2 B (see the caption). The pre-stretching of the silicone encapsulation (step 4) is fundamental for obtaining the above mentioned self-healing feature [25]. Silicone encapsulation is important not only for containing the molten alloy but also for thermal insulation (thermal conductivity at 100°C in the range of 0.2-0.3 $Wm^{-1}K^{-1}$), electrical insulation, and biocompatibility with human tissues and body fluids.

The chosen LMPA is radiopaque, and, thus, it is visible in X-Ray images (Fig. 3 A). During the procedure, this feature allows the electrophysiologist to monitor the position of the catheter with a mapping system and a fluoroscope.

III. Variable Stiffness Catheter Performance

In an external magnetic field B, the magnet in the catheter tip, characterized by a magnetic dipole m and a position p, experiences a magnetic torque T_m:

$$T_m(p) = m \times B(p).$$

Such a torque, which is proportional to the magnetic field magnitude, is zero when the magnetic dipole m is aligned with the magnetic field B and is maximal when a 90° angle exists between B and m. For this reason, in order to apply a control torque on the magnet, a misalignment angle between the external magnetic field and magnet direction is required (Fig. 5 A). Assuming a short catheter length outside of the insertion sheath and relatively low magnetic gradients (i.e. in the order of 0.3 T/m for navigation inside torso), the gravity and magnetic force can be considered as disturbances and ignored. The current injected in the VSS generates a magnetic torque that is negligible (it is two orders of magnitude smaller than the one generate by the permanent magnet).

A. Shape Fixity of Variable Stiffness Catheter

In the rigid state, the VS catheter is able to withstand, without deflection or fracture, a torque of 0.003 Nm (obtained by applying a magnetic field magnitude of 100 mT and a misalignment angle of 90°) (Fig. 4). As explained above, this torque corresponds to the upper limit of the range of torques normally used in cardiac procedures with magnetic navigation systems.

The configurations of the VSSs (i.e. the shape of the catheter) does not influence its shape fixity capability within this range of torques and of curvatures of the bent tip (Fig. 4 A, B).

B. Deflection Curves of Variable Stiffness Catheter

In the flexible state, the catheter, specifically its soft VSS, can bend into different curvatures (Fig. 3, Fig. 5 A).

The curvature of the catheter experiencing a specific magnetic torque depends on its bending stiffness and, therefore, on its Young modulus, cross section, and length outside the insertion sheath. For example, the shorter the length the more limited the curvature of the catheter.

With a VS catheter, it is possible to change the Young's modulus of one or more segments. It is also possible to vary the length of the flexible part subjected to bending without translation of the catheter. In order to characterize such a flexible behavior we heated both VSSs above 47°C and then varied the magnetic field inclination angle by a 10° step every half second (constant magnetic field magnitude of 100 mT). The tip inclination angle was then extracted with image processing using a Hough line transform. The VS catheter is able to closely follow the direction of the external magnetic field. Fig. 5 B shows that the misalignment angle is smaller

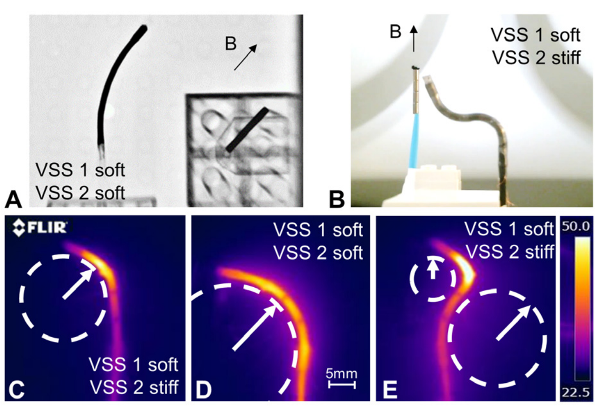

Fig. 3 Different configurations adopted in an external magnetic field (generated by the remote navigation magnetic system Aeon Phocus) by the VS catheter having one or more VSSs in the flexible state. A) X-ray image of the VS catheter with VSS1 and VSS 2 in the flexible state; on the right, a magnetic field indicator is shown. B) VS catheter in an S-shaped configuration that cannot be adopted by standard magnetic catheter; such a shape is obtained by bending the soft VSS2, and then softening VSS 1 after the complete cooling down of VSS2. C, D, E) Infrared images, captured using a FLIR infrared camera; the different curvatures that can be achieved are shown in white.

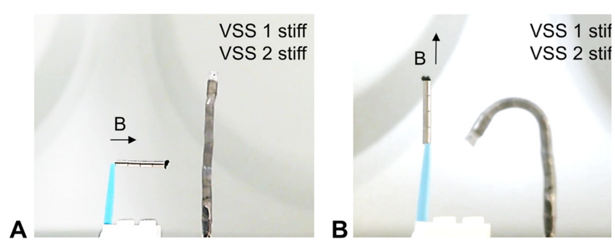

Fig. 4 A) The catheter is in its completely rigid state (VSS1 and VSS 2 stiff) and maintains its shape (straight in A and curved in B) even if the magnetic field points to different directions, as shown by the magnetic field indicator.

than 35° for maximal magnetic fields inclination (180°).

As expected, if VSS1 is soft, the flexible part of the catheter is shorter and the misalignment angle for the same inclination of the magnetic field is larger compared to the completely soft case (i.e. VSS1 and VSS2 soft)(Fig. 5 C).

When compared to a standard catheter (MagnoFlush, MedFact Enginneering GmbH, Lorrach, Germany) with the same flexible length outside the sheath (16 mm, excluding the ablation tip and magnet), the bending performance of the VS catheter (VSS1 soft) is superior (Fig. 5 C).

Bending of the VS catheter is not limited to a 2D plane (as shown in images). Each soft VSS can deflect in a different 3D direction (see video, first sequence). This results in a rotational non-symmetric catheter shape.

The minimum bending radii of the VS catheter (considered approximately constant) with one or two soft VSSs are 7mm and 12mm, respectively. On the contrary, the curvature of the MagnoFlush catheter varies due to the presence of rigid additional magnets in between the distal flexible segments.

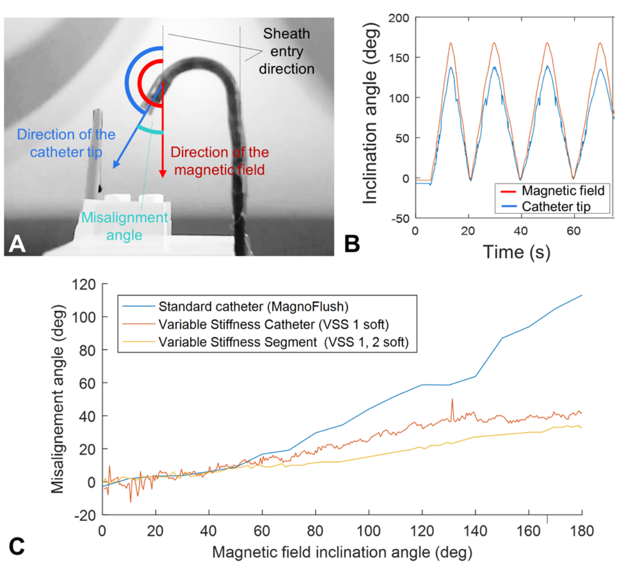

Fig. 5 A) The VS catheter with VSS1 soft and VSS 2 stiff in an external magnetic field. The directions and the inclination angles of the magnetic field and of the catheter tip are shown in red and blue, respectively. The inclination angles are defined with respect to the sheath entry direction (corresponding, in our case, to the vertical direction). The angle between the directions of the magnetic field and catheter tip is defined as the misalignment angle and is shown in green. B) Inclination angle of the catheter tip, measured while varying the magnetic field inclination angle between 0° and 180° and back to 0° with step of 10° every 0.5s. C) Misalignment angles obtained while varying the magnetic field inclination with a standard MagnoFlush catheter and the VS catheter. The data for the VS catheter were collected in two cases: with just the distal VSS1 soft, and with both VSSs soft. The data for the VS catheter were collected with a higher sampling rate. The length of the standard catheter outside the sheath was 16mm (excluding the ablation tip and magnet); this length is comparable to that of the VS catheter with VSS1 soft (excluding the magnet). Representative curves are shown for clarity.

C. *Workspace of the Variable Stiffness Catheter*

The VS catheter can adopt a large set of complex 2D and 3D configurations depending on the direction of the magnetic field and on the deformability state of its VSSs. Some of those configurations are in regions of the workspace that cannot be easily reached by standard catheters (Fig. 6). For example, in our analysis of the workspace of a standard magnetic catheter (Fig. 6 A, B), we pointed out region 4 as impossible to reach without using a contact point with the heart wall (important for atrial flutter ablation). Fig. 6 C shows how such a region can be reached with a VS catheter. The approach is to bend the VSS2 to a maximal inclination angle of approximately 135° and fix it in place. Then the VSS1 can be softened and bent an additional 135°. At this point, the catheter tip has reached a total inclination angle of 270°. By adding more than two VSSs, even larger inclination angles can be reached.

In region 3 (Fig. 6 A), we can use a similar approach by first shaping and locking in place the VSS2 and then shaping the soft VSS1. The impact on the tip motion is inverted. An insertion of the catheter moves the tip backward and a retraction moves the tip forward.

For navigation in zone 2 (Fig. 6 A), the VSSs of the VS catheter should be in a flexible state. Thus, the catheter can

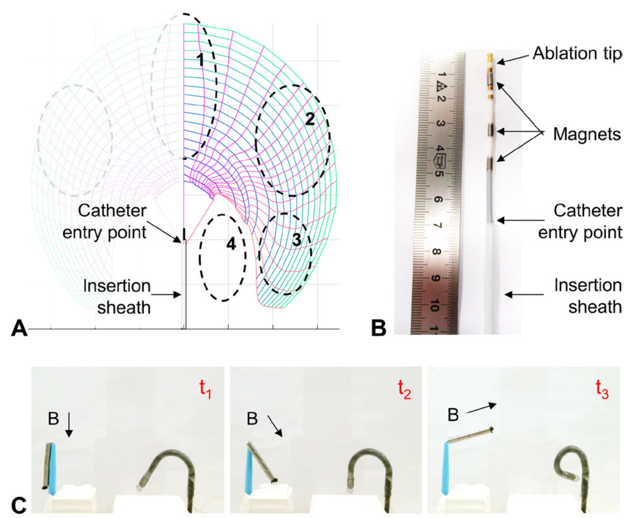

Fig. 6 A) Symmetric workspace of a standard catheter (MagnoFlush) for different catheter lengths and magnetic field directions. The green to blue lines represent tip position for a constant catheter length. The pink lines represent tip position for a constant magnetic field direction. The ellipse 1 points out a zone where disturbances have a large impact as no magnetic torque is applied for an aligned magnetic field and magnet. The ellipse 2 shows a zone were the catheter is easy to control. In Zone 3 insertion of the catheter will not move the tip forward. The ellipse 4 point out some tip location that cannot be reached without using contact point with the heart wall. Increase of the inclination angle to 180° results in non-stable tip position. At 180°, there is no magnetic torque to maintain the tip into the 2D plan and the tip can rotate around the catheter axis. B) MagnoFlush catheter. C) Sequence. The snapshot t_1 displays the bending of the catheter with only the first flexible region flexible. In snapshot t_2 and t_3 the first segment is rigid and the second segment is flexible and controlled by the external magnetic field.

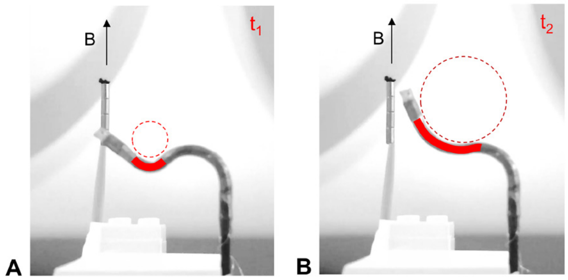

Fig. 7 VSS 1 in an external magnetic field heated for A) 6 s, B) 17 s. The red line and the red dotted circles indicate the soft segment of VSS1 and the curvature, respectively.

be controlled like a standard catheter. In this case, the VS catheter has an insertion curve without discontinuities, unlike a standard magnetic catheter with three rigid magnets separated by the flexible sections. Discontinuities are avoided because the VS catheter has only one magnet at the tip, and the bending behavior is homogeneous along the entire catheter length in the fully flexible state.

The VS catheter provides additional ways of navigating in region 1 (Fig 6 A). In fact, having only one VSS flexible or having a first segment slightly bent avoids having a long straight catheter with no magnetic torque acting on it.

D. Thermal Behavior of Variable Stiffness Catheter

The phase change of VSSs (from solid to liquid) is due to current injection in heaters, and its duration depends on the input current provided. When subjected to a magnetic torque of 0.003Nm (magnetic field of 100mT and misalignment angle 90°) and 1 A current flowing into the heater, the VSSs change phase and start to move in the direction of the magnetic field after a heating time of 3±1.5 s (average value on 9 phase transitions, VSS preheated with previous experiment).

In the current design, the two VSSs are on the same LMPA core, which constitutes the body of the VS catheter itself. This means that a protracted heating of a single VSS results in the propagation of the heat along the catheter body, beyond the length of the single heater (8 mm). With a short heating duration (heating time 2 to 10 s; injected current 1 A), only a short segment becomes flexible (soft length ranging between 10 and 16 mm). If the heating time is longer, the soft section length increases up to the other VSS. Fig. 7 illustrated this effect. Observations of the catheter bending show a close to constant segment curvature (red dotted circles).

In this phase of the work, we monitored the temperature of the external surface of the silicone encapsulation by means of either a thermal camera (Fig. 3 C, D, E) or miniature thermistors (SMD 0402, Vishay) glued on to the silicone. These measurements were biased by the time needed for the heat to diffuse into the thickness of the silicone encapsulation. We expect that blood flow may help in removing the heat.

We expect the phase change time to be suitable for clinical use as only a limited number of very short transitions is required. Fine position control is done by changing the magnetic field direction or inserting/retracting the VS catheter. An ablation is a procedure that can last a couple of hours and each RF ablation spot requires approximately 20s of heating [26]. It has been reported that temporary damage to a cell arises when a cell reaches a temperature of 50°C and is permanent at a temperature of 62°C [26]. With the VS catheter at 47°C, the maximum temperature a cell can reach after prolonged contact is 47°C. The energy that we injected into our VS catheter is between one and two watts, which is more than an order of magnitude lower than the energy required for RF ablation.

The phase change of VSSs (from liquid to solid) strongly depends on the working environment (i.e. temperature of the body and blood flow).

IV. Discussion and Conclusion

In this work, we presented a proof-of-concept of a magnetic, variable stiffness (VS) catheter to be used for cardiac ablation. Our results highlight the usefulness of the variable stiffness approach as a solution for improving dexterity and stability in compact dimensions as compared to current catheters. Specifically, the combination of a phase change material, such as a low melting point alloy (LMPA), and magnetic steering showed impressive potential for improving this medical procedure.

Similar to standard magnetic catheters, the position and shape of the VS magnetic catheter can be controlled by mechanical translation of the catheter shaft (e.g. through an insertion/retraction mechanism), mechanical rotation of the catheter shaft, and deflection of the flexible segment/s of the tip (VSSs in soft state) through the external magnetic field. Our findings show that, during these procedures, the states (soft/stiff) of the VSSs exiting the insertion sheath influence the tip motion, thus greatly enriching its motion possibilities. For example, during the mechanical translation of the catheter shaft, if the VSS is rigid, the VS tip will translate in the direction of the insertion sheath. If the VSS is flexible, the orientation of the VS tip and the torque acting on the tip itself will depend on the length of the flexible segment outside the sheath. During the mechanical rotation of the catheter shaft, the VS catheter in the rigid state will rotate around the insertion sheath axis. If the VS catheter is in the flexible state instead, the rotation will change the position of the tip magnet and this will result in changing the applied torque and the shape of the flexible VSSs.

Compared to a standard magnetic catheter, the VS catheter has a larger workspace and is able to adopt out-of-plane 3D configurations (i.e. rotational non-symmetric catheter shapes). When a fixed length of VS catheter is outside the sheath, it can vary its deflection curvature/s and adapt to specific functions and 3D anatomies simply by changing the stiffness of its body segments.

The VS approach allows for multiple catheter procedures. Within the same volume, multiple VS magnetic catheters with different functions can be controlled independently despite being subjected to the same external magnetic field.

For example, one VS catheter (e.g. a mapping catheter, with one or more VSSs in the soft state) can be moved by the magnetic navigation system for identifying the areas to be ablated while the other VS catheter (e.g. the ablation catheter, in rigid state) remains fixed in place. Vice versa, the VS mapping catheter can be locked in a reference location to monitor electrocardiogram signal while the VS ablation catheter is moved to reach the tissue to be ablated.

The present study explored the feasibility and the potential advantages of a VS catheter controlled by an external magnetic field. We are currently in the process of investigating an effective way to monitor and control the temperature of the VSSs without increasing the dimension of the device (e.g. monitoring the resistance of the alloy or of the conductive wire constituting the heaters). Not toxic Bismuth-based alloys [23] might be adopted as an alternative to Cerrolow. Future work will then focus on the optimization of the dimensions of the VS catheter (e.g. minimization of the amount of LMPA, number of heaters and distance among them) and on the control in a realistic clinical scenario (e.g in liquid at body temperature).

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