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Review article

Stabilizing interventional instruments in the cardiovascular system: A classification of mechanisms



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ABSTRACT

Positioning and stabilizing a catheter at the required location inside a vessel or the heart is a complicated task in interventional cardiology. In this review we provide a structured classification of catheter stabilization mechanisms to systematically assess their challenges during cardiac interventions. Commercially available, patented, and experimental prototypes of catheters were classified with respect to their stabilizing mechanisms. Subsequently, the classification was used to define requirements for future cardiac catheters and persisting challenges in catheter stabilization. The classification showed that there are two main stabilization mechanisms: surface-based and volume-based. Surface-based mechanisms apply attachment through surface anchoring, while volume-based mechanisms make use of locking through shape or force against the vessel or cardiac wall. The classification provides insight into existing catheter stabilization mechanisms and can possibly be used as a tool for future design of catheter stabilization mechanisms to keep the catheter at a specific location during an intervention. Additionally, insight into the requirements and challenges for catheter stabilization inside the heart and vasculature can lead to the development of more dedicated systems in the future, allowing for intervention- and patient-specific instrument manipulation.

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1. Introduction

Due to the dynamic cardiothoracic environment, catheter interventions in the heart and vasculature are influenced by heartbeat, breathing, and blood flow [1,2,3]. As a result, a threefold problem is created, namely that the catheter shifts from its intended position, the instrument-tissue interaction is inaccurate, and the maintenance of continuous and uniform instrument-tissue contact is cumbersome.

Catheter shift is the result of beating heart motion and lack of vessel wall support inside the heart [1,2]. Specifically, due to

the patient's cardiothoracic activity as well as accidental movements by the interventionist, the catheter may dislocate from its intended position. As an example, in Trans-Myocardial Revascularization (TMR), the laser tip that creates the revascularization channels can reportedly shift from its intended position [2,4,5]. As a consequence, the TMR approach may not be reliable for creating channels with reproducible depth and relative position between channels. As another example, during Percutaneous Transluminal Coronary Angioplasty, a dilatation balloon is advanced inside the lesion and inflated to increase the vessel diameter. Because the balloon is in contact with the lesion and the latter can be lubricous, the balloon may shoot forward or backward through the vessel [6,7].

The second problem relates to inaccurate instrument-tissue interaction. The success of a procedure via a trans-catheter route largely depends on the ability to manipulate tissue in an effec-

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tive and reliable manner [8,9]. For example, catheter-based valve repair requires complex actions such as identification of multiple local spots arranged over the valve annulus, placement of anchors for implantation of a new device, and grasping leaflets and performing sutures [10,11]. The ability to manipulate tissue using trans-catheter techniques has not yet reached the level of accuracy and precision of more invasive surgical methods such as during open heart surgery [9]. Additionally, a number of cardiac and non-cardiac procedures require specialized tissue manipulation, such as in taking biopsies and grasping thin membranes. Injection of growth factors or genes is yet another example of a catheter intervention that requires accurate interaction between instrument and tissue [2,12,13,14].

The third problem relates to maintaining continuous and uniform instrument-tissue contact during the entire procedure. Several studies have reported that ablation lesions (created to isolate an electrical rhythm disturbance in the heart) during cardiac ablation procedures are more successful when the depth and location can be controlled precisely [15,16]. Because rigid ablation catheters cannot conform to complex 3D structures, it is a difficult task to create complex lesions, such as on the ostium or the coronary sinus, or to operate in arrhythmic patients, because of their irregular heartbeat [1,17,18]. Further problems arise once the catheter needs to be repositioned to create a lesion at an adjacent location, causing the previous instrument-tissue contact to be lost [1]. In Fujiwara *et al.* [16] the lesion size was associated with the contact force, which in turn might affect catheter stability. Based on clinical data, Fujiwara *et al.* [16] concluded that the most important factor for making accurate lesions was the time during which the catheter remained stable during the ablation.

In an effort to improve catheter stability, various approaches have been investigated, including drug administration to reduce heart rate and contraction [19], external stabilization of the heart [20], robotic and steerable systems [8,9,14,21], and contact force monitoring [1]. Schmidt *et al.* [22] showed that it remains difficult to maintain catheter stability at specific sites in the cardiovascular anatomy, even with robotic navigation systems, and that existing solutions for catheter stability rely on high technical skills and experience of the operator [22].

A different approach is to stabilize the catheter in position with respect to the cardiovascular environment. To solve some of the aforementioned problems, this approach aims to maintain continuous contact between catheter and tissue during the procedure. A number of such mechanisms have been patented or developed; however, the advantages and disadvantages of these mechanisms remain relatively unexplored. Additionally, questions on how these mechanisms can be incorporated in catheters and adopted in cardiac procedures remain. Accordingly, in this review we present a structured classification of existing and patented mechanisms for catheter stabilization inside the heart, in an effort to systematically assess the challenges of catheter use in cardiac interventions and to define requirements and challenges for future application-driven design of catheter stabilization mechanisms. In the context of this review, stabilizing is defined as *creating and maintaining stable contact between the instrument tip and the tissue under external disturbances such as movement, flow, or force.*

2. Methods

2.1. Literature search

The Espacenet database and Scopus were used to retrieve patents and scientific literature on catheter development as well as experimental work on stabilizing mechanisms. The search query included search terms both for the stabilizing property and for the instrument type and was defined as following: (*stabilizing OR an-*

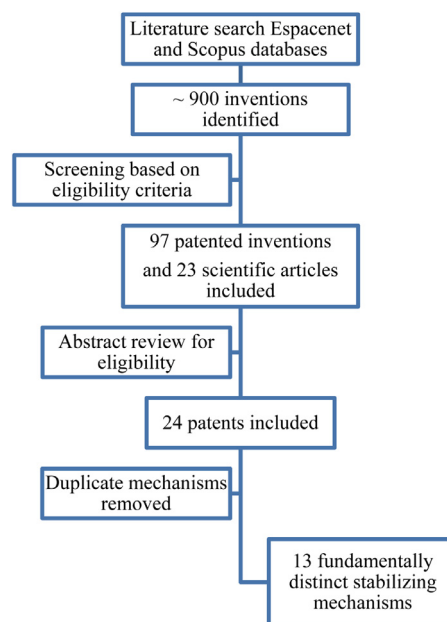


Fig. 1. Flow chart of literature search process.

ching OR positioning OR immobilizing) AND (catheter OR sheath* OR device OR instrument*).* Subsequently, scientific literature was consulted to find clinical trials with any of the proposed inventions. Because the majority of the works was already intended for cardiac applications, it was decided to not use any keywords describing the medical field. Additionally, no limitations were set for the publication year.

2.2. Eligibility criteria

The main inclusion criterion was that a work described stabilizing mechanisms in or for medical catheters and sheaths. Additionally, it was required that the stabilizing mechanism was located at the distal tip of the catheter to secure a stable contact with the cardiovascular tissue during treatment. Stabilization mechanisms at the proximal part of the catheter, used to secure a cardiac catheter externally to the operating room table or at the entrance point of the patient's body were excluded. Catheters at any stage of development were included. Finally, for the benefit of presenting a comprehensive overview of available and potentially applicable stabilizing mechanisms, stabilizing catheters that were not specifically designed for cardiac purposes were also included (e.g., a biliary catheter).

2.3. Screening process and results

The initial search query resulted in approximately 900 patented inventions, out of which 97 were according to the aforementioned criteria. The scientific literature search led to 23 trials with stabilizing catheters. The abstracts of the retrieved 97 patents and 23 scientific papers were assessed by the first and forth author; 24 patents were deemed eligible and included in our review. A total of 13 fundamentally distinct stabilizing mechanisms were identified. Fig. 1 shows an overview of the literature search and screening process.

2.4. Fundamental working principles

Based on the stabilization method in the catheter tip, two main categories were identified: *surface-based* and *volume-based* stabi-

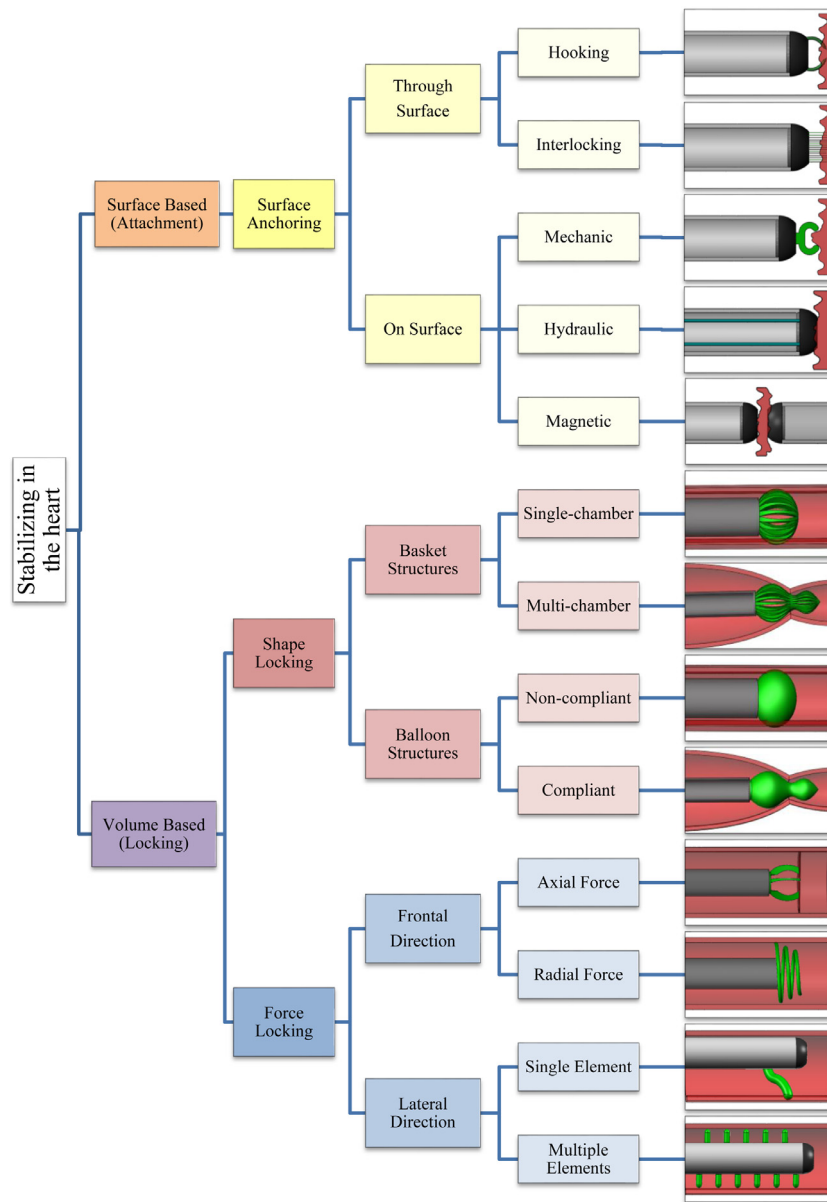


Fig. 2. Complete schematic overview of stabilizing mechanisms for catheters in the heart.

lization, in which the surface and the volume inside a cardiovascular structure are used to stabilize a catheter, respectively. Within the first group, stabilization was found to be achieved by means of *anchoring* the instrument tip to the surface tissue layer, whereas in the latter group, stabilization could be further classified into either *shape* or *force locking* in the tissue volume by the instrument tip.

2.5. Paper lay-out

Fig. 2 shows the identified categories and sub-categories. In the next sections, the results are discussed for each category, together with the most recent examples of catheters or similar instruments using the described stabilization mechanism. For each sub-category, first some general information is presented, after which specific mechanisms are discussed based on the found works, followed by a discussion of the advantages and disadvantages of the mechanisms. Finally, future requirements and challenges for stabilizing catheters are assessed after which a final perspective on the topic is given.

3. Results: stabilization by surface anchoring

One of three main methods to stabilize instruments with respect to the tissue is by means of surface anchoring. Surface anchoring is achieved by through-the-surface or on-the-surface mechanisms.

3.1. Through-the-surface anchoring

3.1.1. Hooking

A number of anchoring mechanisms use deployable hooks that vary in terms of length, shape, or number of hooks. The hooks are deployed from the instrument and are attached to the surface by penetrating through the surface to maintain the position of the instrument [23].

Abrams *et al.* [24] described a through-the-surface retractable hook mechanism for an electrophysiology catheter, see Fig. 3a. The hook mechanism is flexible and stored in a rigid lumen. Upon sliding the mechanism out of the lumen, the structure unfolds into

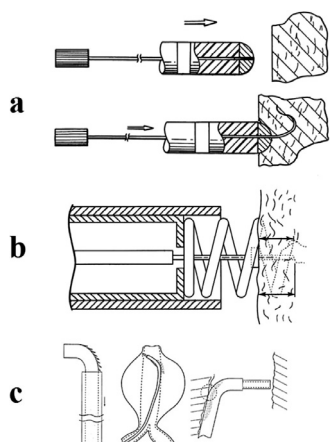


Fig. 3. Patented examples of through-the-surface anchoring by a) Abrams [24], b) Sabbah [25], and c) Trout [27].

a hook-like shape. This structure anchors the entire instrument to the endocardial heart tissue until an ablation procedure is carried out at one location. To create multiple ablation lesions, the hooks are retracted and deployed again at the next location. Sabbah *et al.* [25] described a similar mechanism in their patent for an injector mechanism to control depth of medication delivery into myocardial tissue, as shown in Fig. 3b. The instrument includes an open screw mechanism that anchors in the myocardium and positions the tip. A needle is then advanced through the open screw to realize the myocardial injection.

Lessick *et al.* [2] used a catheter with a retractable anchoring needle to study catheter sliding during contraction of the heart. After correcting for respiration effects, they found that a minor improvement in catheter stability was achieved when using the catheter with the stabilizing needle compared to using it without needle. However, the authors only studied sliding of the catheter, without taking dislocation of the tip by the dynamic cardiac environment into account [2].

Using retractable anchors to stabilize the catheter inside the heart is an invasive method due to the (partial) penetration of anchors in the cardiac tissue, possibly leading to perforation [26]. Studies reported that scar tissue was created by inserting needles in the myocardium [26,28]. In addition, temporary use of retractable anchors is complex regarding withdrawal and (re)fixation of the catheter at subsequent locations [26,28].

3.1.2. Interlocking

Instead of hooks, some anchoring mechanisms may use multiple smaller protruding elements such as Velcro- or barb-like structures that interlock with the tissue structure. The elements are typically manufactured from metallic or polymeric wires, or can result from surface texturing techniques such as ion texturing and electronic discharge machining.

Trout *et al.* [27] described the concept of a trans-catheter technique for aortic aneurysm repair, shown in Fig. 3c. The catheter contains a surface with multiple microbarbs to maintain contact with the cardiac wall. The inventors proposed a microbarb diameter in the range of 0.013–0.254 mm (0.0005–0.010 inches) and a length in the range of 0.254–2.540 mm (0.01–0.1 inches). Upon pulling steering wires at the catheter handle, the barbs at the tip are extended and lock against the tissue.

The use of multiple barbs to stabilize an implant, such as an artificial valve or a stent graft, has been reported in a number of studies [26,28]. These studies showed that the barbs allow fixation maintenance despite blood flow and cardiac motion, which shows their potential for catheter stabilization.

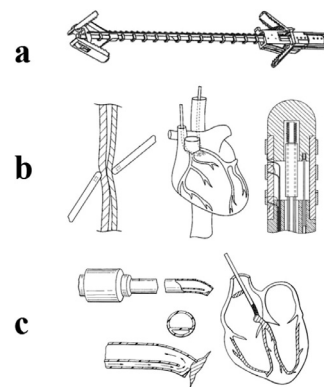


Fig. 4. Patented examples of anchoring on the surface by a) Cohen [29], b) Grunewald [17], and c) Weldon [36].

3.2. On-the-surface anchoring

3.2.1. Mechanical anchoring

Rather than penetrating the tissue surface, a number of mechanisms achieve stabilization by anchoring the instrument on the tissue surface. The simplest form of anchors makes use of two gripper-like structures that grab around the tissue instead of puncturing it. Once the catheter is placed at the preferred location, it applies a force on the cardiac wall in two opposing directions to secure the tissue. To disconnect the system, the gripper-like structure is opened and the instrument is retracted.

Cohen *et al.* [29] described an example of such an instrument in their patent for a releasable tissue anchoring mechanism, shown in Fig. 4a. Their proposed instrument has two sets of spreadable non-protruding grippers that can be positioned each on an opposite tissue side. Both sets of grippers can then be moved toward each other to bring the two tissue regions closer, thereby stabilizing the instrument with respect to the tissue.

Compared to the through-the-surface anchoring, on-the-surface anchoring is a relatively simple method that allows relatively fast stabilization of an instrument against the cardiac wall. Additionally, it does not puncture the heart. Nevertheless, tissue damage is still a risk, due to high pressures exerted on the tissue.

3.2.2. Magnetic anchoring

In the past decades, the use of magnetic materials and systems in the field of interventional cardiology [30,31] has grown. Magnetic materials and systems have the purpose of guiding, navigating, attaching, or even visualizing certain areas. Whereas magnetic navigation under MRI is gaining popularity, its application for catheter stabilization remains unexplored. The general idea behind using magnetic forces for catheter stabilization is that either two catheters or a catheter and an external instrument that both contain a magnetic element (such as electromagnets, permanent magnets, or ferromagnets) are used together. This can lead to one instrument stabilizing the other and preventing moving or shifting.

Grunewald *et al.* [17] described a magnetic stabilization method of a catheter location sensor for use during cardiac mapping and ablation, shown in Fig. 4b. In this case, a reference catheter is used together with the stabilizing catheter with both having an electromagnet included in the tip. Electromagnets in the form of current-carrying coils and solenoids are used, in which the coil wires run through a lumen inside the catheter tubing and sheath. The reference catheter is then placed inside a heart chamber; while the stabilizing catheter is placed on a tissue layer at the opposite side of the vascular structure such as in the coronary sinus. A current is subsequently passed through the coil to create a magnetic field [17].

Magnetic systems have been used in clinical settings for navigation purposes [31] and are relatively safe [32]. As such, using electromagnets for stabilization can potentially be combined with magnetic steering. However, it is unclear whether the strength of the magnetic field in these mechanisms is sufficient for stabilization.

3.2.3. Hydraulic anchoring

A hydraulic anchoring mechanism uses fluid flow between the tissue and the instrument to create a negative pressure and stabilize the instrument at place. Such instruments generally consist of a contact face at the catheter tip with multiple openings in flow communication with a suction mechanism [33]. Fluid retraction leads to a negative pressure gradient inside the catheter, allowing it to grasp the tissue that is in contact. The resulting connection does not only stabilize the catheter tip, but also allows a tissue section to be isolated inside the hollow point at the tip [20]. Openings with different shapes have been proposed to create the required tissue isolation [34,35].

Weldon *et al.* [36] patented a hydraulic system allowing catheter stabilization by means of fluid suction, shown in Fig. 4c. Intended as an electrophysiology catheter for cardiac ablations, the patent describes an instrument in which a tissue section is pulled inside a suction cap. The catheter is designed with two separate longitudinal lumina: one with an open end to function as the isolation mechanism that draws the tissue inside and one with a closed end to administer fluid for the anchoring of the catheter. A vacuum pump is used to withdraw the fluid and allow the tip to anchor to the tissue. A similar system was developed by Vonderwalde *et al.* [37] for locally anchoring a catheter during a chronic total occlusion (CTO) intervention. The tip of this device has one or multiple flares that are flexible enough to be compressed inside a guiding sheath during the navigational part of the procedure. Once the catheter has reached the required position inside the heart or vasculature, the sheath is pulled back to allow the flared tip to expand.

Drawbacks are related to creating a suction force on tissue, especially in regions that have already weakened. For example, haemorrhages are known to occur as a result of too high negative pressures, thereby causing accumulation of blood, tissue rupture, and scarring of the heart muscle [20,38,39].

4. Results: stabilizing by shape locking

The second main group of stabilizing mechanisms makes use of shape-locking mechanisms. This method allows stabilization by making use of expandable shapes. More generally, the volume of a heart chamber or vessel is used to stabilize the catheter inside. The majority of commercially available stabilizing mechanisms belong to this category, and as such there is a large variety in these catheter types. A first differentiation can be made between basket and balloon locking structures.

4.1. Shape locking with basket structures

Shape-locking basket structures exist in a variety of shapes, sizes, and configurations. Depending on these structural characteristics, forces are exerted in different directions to create and maintain a stable position of the catheter inside the heart or in a vessel. In all cases, the structure of the stabilizing mechanism that occupies the anatomical volume is open and allows blood to flow through it. Basket structures are advanced through the cardiovascular system in folded state inside a catheter and expand upon retraction of the catheter. Basket structures can further be subdivided into single-chamber baskets which are mechanisms

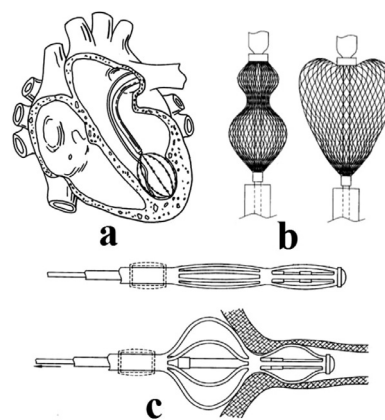


Fig. 5. Patented examples of shape locking with basket structures by a) Kordis [41], b) Ahmed [46], and c) Esposito [45].

that are placed in a single cardiac chamber or vessel, and multi-chamber baskets which are mechanisms that connect multiple cardiac chambers or vessel structures.

4.1.1. Single-chamber basket

A single-chamber basket stabilizes the catheter by expanding inside a single cardiac chamber or vessel. The expanded state can take a variety of sizes, shapes, and configurations, depending on the vessel or cavity it is used in. The mechanisms are generally manufactured using shape-memory materials to create foldable struts, or synthetic polymers such as polyurethane which can be moulded into different expandable structures [40].

An early example of an enclosing basket mechanism was proposed in 1997 by Kordis *et al.* [41] in a patent for deploying and stabilizing cardiac mapping and ablation catheters, see Fig. 5a. The patent describes an invention in which two catheter tips come together. One tip has an expandable 3D structure to stabilize in a cardiac chamber, whereas the second one is pushed through the 3D structure to carry out the ablation. Another example of such a mechanism is a delivery catheter described by Kipperman *et al.* [40]. This catheter contains a folded stabilizing guidewire with a 3D expandable structure at its tip. The mechanism is designed to be adaptable to the shape of the left ventricular apex and other vessels or cavities with structural shapes. Finally, a commercially available catheter of this type is the basket-shaped Bard® HD Mesh Ablator Catheter (CR Bard Inc., Massachusetts, USA) [42] that is used in electrophysiology procedures. The catheter is meant for use in pulmonary veins (PV) with a diameter of 25 to 30 mm. Dello Russo *et al.* [43] confirmed that the use of this catheter, compared to no use, led to higher stability and better contact with the cardiac tissue. In addition, its use led to improvements in the local electrogram, showing the heart's electrical activity recordings. Based on these findings, Dello Russo *et al.* argued that the mechanism is particularly recommendable for patients whose cardiac anatomy does not allow for stable contact of regular circular mapping catheters [43].

The main advantage in using a single-chamber basket stabilizing mechanism lies in the creation of a large surface area upon expansion of the mechanism. This allows the system to distribute the forces over a large contact area of the vessel or cardiac walls [43]. Lickfett *et al.* [44] argued that such mechanisms are an improvement compared to existing catheters, because during cardiac ablation procedures the mechanisms allow safe transitioning from the left atrium to the PV [44].

4.1.2. Multi-chamber basket

Multi-chamber baskets follow the same working principle as single-chamber baskets, with the difference that the former expand in multiple spaces. This means that multi-chamber baskets have relatively more complex shapes than single-chamber baskets. Multi-chamber baskets are generally meant to be placed in between branching vessels, between a vessel and larger organ structure, or intended to connect multiple cardiac chambers together.

Esposito *et al.* [45] patented such a system for a mapping and ablation catheter which was intended for use in vessel structures in or near the heart, shown in Fig. 5c. They proposed a catheter tip with a stabilizing mechanism that is adapted to placement in a cardiac vessel such as the PV ostium. The stabilizing tip mechanism was designed with multiple slits cut in its outer walls. A sheath covers the catheter and once retracted from the catheter, the sheath and catheter move relative to one another and allow the stabilizing tip mechanism to expand in radial direction [45]. In the expanded state, the mechanism exerts pressure on the branching vessel walls and thus stabilizes the catheter inside. Ahmed *et al.* [46] patented another multi-chamber basket which was intended as a coronary sinus catheter, shown in Fig. 5b. Their invention described multiple baskets with various shapes, each formed by a mesh-like material [46].

An example of an available multi-chamber basket catheter is the Constellation Multi-electrode Basket Catheter (MBC) [47] (Boston Scientific, Boston, USA), which is folded into a guiding sheath and is deployed upon retraction of the sheath. This catheter is meant for use during atrial ablation procedures to assist in the detection of complex arrhythmias. The stabilizing mechanism is meant to connect between atrium and veins with a diameter of 31 mm. Preclinical and clinical tests have shown that the MBC can adapt to the size and 3D anatomy of most veins as well as to the transition zone between the atrium and the vein [48]. Additionally, it was shown that the system is able to provide accurate tissue contact due to its configuration [48].

Applying basket structures using mesh-like mechanisms or slits cut in material, requires materials and shapes that do not break when they are in folded or expanded state [49,50]. Disadvantages of these mechanisms relate to the size of the delivery sheath: mechanisms that expand to a large state require a large delivery sheath in folded state too. Additionally, fast deployment must be prevented to minimize the risk of cardiac events. Moreover, clinical studies using the MBC showed that small thrombi could attach to the basket structure, although not leading to any clinical effects [48]. Other major complications indicated that contact between the ablation catheter tip and the basket catheter needs to be avoided, because this contact could lead to coagulation and potentially cause embolism or damage to the catheter [48].

4.2. Shape locking with balloon structures

Similar to basket structures, balloon structures expand in an anatomic region to stabilize the catheter or connect multiple spaces for stabilization. The different types of balloons are commonly distinguished based on their level of compliancy [51]. Multiple balloon catheters are commercially available as of today and are commonly used in ablation of atrial fibrillation procedures [52,53]. Due to their similarities with basket-shaped mechanisms, the category is further subdivided into single-chamber and multi-chamber balloons in this review. An important difference between balloon- and basket-structures is that blood is less likely to flow through or along the balloon mechanism.

4.2.1. Single-chamber balloons

Single-chamber balloons for stabilization exist in a variety of configurations. For example, multiple balloons can be organized

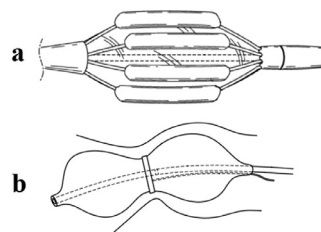


Fig. 6. Patented examples of shape locking with balloons by a) Madrid [55] and b) Drasler [65].

in parallel around a sheath to allow an inner lumen or in series to allow blood to flow by. Due to generally low compliancy, single-chamber balloons expand less than multi-chamber balloons when the pressure is increased. Additionally, single-chamber balloons do not conform to the chamber or vessel they are placed in, but rather have a predefined shape [51,54]. Most single-chamber balloons have been designed for heart valve repair, cardiac ablation, and treatment of CTOs.

Madrid *et al.* [55] patented a single-chamber balloon mechanism, intended to stabilize the catheter shaft across the aortic arch in a number of heart valve procedures, including implantation of an artificial valve. This balloon mechanism consisted of a catheter with a valve delivery system on the inside and an expandable portion made of multiple inflatable balloons. Its balloons can be arranged in a parallel configuration or inside one another, as shown in Fig. 6a. Daniels *et al.* [56] patented a similar invention for use with a guiding catheter. Their stabilizing mechanism consisted of a balloon covering the catheter and was able to lock the catheter tip in place inside the vessel to be treated.

A commercially available catheter with a single-chamber balloon mechanism is the Arctic Front Advance Cardiac Cryoablation Catheter (Medtronic, Minneapolis, MN, USA) [57,58], which is used in circumferential PV isolation with the cryoablation technique. The catheter is available in sizes of 23 and 28 mm in balloon diameter and can be inflated once placed inside the PV ostium under guidance of a sheath. Neumann *et al.* [18] treated 346 patients and required stabilization during the treatment time of approximately 300 s per ablation location.

The use of balloon-like structures has a successful history for multiple purposes in interventional cardiology apart from stabilizing. They have proven to be useful and effective in opening obstructed vessels and in enlarging and preparing vessels or valves before implantation of a larger diameter device such as a stent or artificial heart valve, and have been used frequently in cryoablation procedures [59,60,61]. In circumferential ablation, the use of balloon catheters has shown to be more effective and safe than regular catheters [18,62,63]. Despite the positive study outcomes, it has been reported that using balloons requires more technical skills and experience than regular catheters [64]. Additionally, researchers found that phrenic nerve injury is a potential complication during the use of balloon systems [18,62,63]. The complication is not life-threatening, however, and is frequently resolved over time.

4.2.2. Multi-chamber balloons

Multi-chamber balloons are similar mechanisms as multi-chamber baskets and stabilize by expanding in multiple connecting cardiac or vascular structures. The mechanisms are used to connect the space in which the treatment takes place with another space in which the catheter is stabilized. In other cases, the stabilization can take place inside branched vessels or in multiple chambers. Accordingly, there is a large variety in possibilities, but also complexity of possible shapes, sizes, and configurations. Due to generally high compliancy of the used balloon materials, this type of balloon

conforms to the chamber it is placed in and expands more when pressure is increased until it reaches an anatomic boundary [51].

Drasler *et al.* [65] patented a multi-chamber balloon system focusing on a valvuloplasty catheter with transapical cardiac valve implantation, shown in Fig. 6b. They designed a dogbone shaped balloon with a smaller waist portion and two larger diameter ends. When centring the balloon inside the valve, one end of the dogbone is used to extend the valve diameter for preparation of the implantation. The other end of the dogbone is used to stabilize the catheter and balloon position in between the two cardiac chambers and thus prevent migration of the mechanism. The waist portion of the dogbone enlarges in diameter when more fluid enters the balloon until it contacts the valve annulus. By using a more compliant material for the waist portion than for the two ends, it is ensured that only the waist portion and not the two ends increase in diameter when fluid enters the balloon.

A commercially available catheter with the multi-chamber balloon mechanism is the Hyperform™ Occlusion Balloon System (Medtronic, Minneapolis, MN, USA) hyper compliant balloon catheter [66], which is used in the treatment of vascular occlusions and aneurysms. Youn *et al.* tested the feasibility, safety, and effectiveness of the balloon system to assist in the treatment of wide-necked intracranial aneurysms [67]. They treated 34 patients with the system and reported that the balloon was able to stabilize the microcatheter in the aneurysm during the treatment in which coil delivery took place in the aneurysm. Because of the hypercompliance of the balloon, Youn *et al.* reported that the balloon was able to adapt its shape based on the anatomy. In another example, Dainese *et al.* used a dogbone shaped balloon catheter during transcatheter aortic valve replacement [68]. They found that by inflating the balloon two times, they were able to approach the aortic root sequentially, stabilize the valve in inner and outer position, and correctly position the valve.

Compared to single-chamber balloons, the use of multi-chamber balloons with high compliancy makes it easier to connect between multiple anatomical regions or stabilize a catheter in between branched structures [67]. The balloons conform to the anatomical structures and can therefore be used regardless of differences in shape and size of anatomy in different patients. However, there are chances that the blood flow will be obstructed by the balloons. Shapiro *et al.* reported thromboembolic complications during balloon-assisted aneurysm treatment [69].

5. Results: stabilization by force locking

In contrast to shape locking, force locking aims at using local pressure to stabilize an instrument inside the volume without clamping around tissue. As a result, the contact between instrument and tissue is point-based rather than surface-based, and the concerning volumes are thus not completely enclosed or connected. Two main subcategories of force locking mechanisms can be distinguished based on the location of the locking mechanism on the catheter: force locking in frontal direction which locks inside the volume with a mechanism at the catheter front, and force locking in lateral direction which locks inside the volume with a mechanism at the catheter sides.

5.1. Force locking in frontal direction

Force locking mechanisms in frontal direction are intended to stabilize the instrument against the cardiac wall by using elements located at the front of the catheter. These elements can exist in a variety of shapes, sizes, and configurations. Depending on the number and location of the frontal elements, push forces are exerted at a number of locations to create and maintain a stable po-

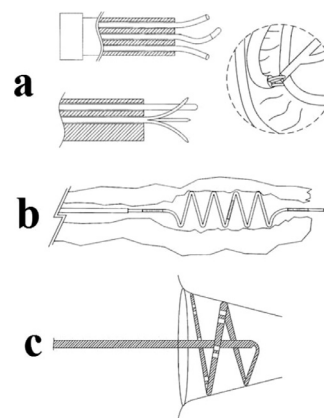


Fig. 7. Patented examples of force locking in frontal direction by a) Doyle [70], b) McFann [75], and c) Kim [76].

sition of the catheter inside the heart or vasculature. Frontally located mechanisms can further be subdivided into mechanisms that work in axial or radial direction.

5.1.1. Axial force locking mechanisms

In frontal force locking mechanisms with axial force, the stabilizing mechanism is located at the catheter tip and applies forces in axial direction to stabilize the catheter. Stabilization is achieved as the result of local force application and therefore local stretch of the cardiac wall. The mechanism can additionally require a certain level of flexibility from the frontal elements in order to compensate for the beating heart motion.

Doyle *et al.* [70] patented an axial force stabilization mechanism for a biliary catheter, shown in Fig. 7a. Their invention aimed at enhancing stabilization during biliary tree interventions using an endoscope with an inner lumen. Stabilizing members are included and extend from the catheter tip. The authors described a system with three stabilizing members, but the design allows up to ten members with either similar or different shapes. The surface of the stabilizing members can be roughened in order to create high friction with the tissue surface.

A commercialized catheter having an axial force stabilizing mechanism is the PentaRay® NAV High-Density Mapping Catheter (Biosense Webster Inc., California, USA) [71]. This catheter has five legs that extend from the tip which are intended for placement against the endocardial surface. The catheter became available in 2012 and was meant for mapping of cardiac structures and for obtaining electrograms. Mastrine *et al.* [72] evaluated the catheter in a case study of a patient suffering from atrial fibrillation and used it to map tachycardia. In 2014 Biosense Webster advised not to use the catheter in patients with prosthetic valves and decided to recall it [73,74].

Axial force mechanisms do not require the whole stabilizing mechanism to be surrounded by tissue. A negative side-effect is that connection between instrument and tissue is not highly reliable, as stabilization depends mainly on force in the axial direction. Additionally, the mechanism requires an external force to push the catheter in axial direction, whereas other mechanisms require only local forces. Finally, challenges regarding the small dimensions of the stabilizing leg structures may arise, such as breaking or disconnecting [74].

5.1.2. Radial force locking mechanisms

In frontal force locking mechanisms with radial force, the stabilizing mechanism is located at the catheter tip and applies forces

in radial direction to stabilize the catheter. The mechanism includes mostly medical wire-like structures, such as guidewires. Using various materials and manufacturing techniques, a number of structures have been developed. Because the mechanisms are intended to exert a radial force, they require to be surrounded by a tissue layer. The mechanism is therefore best applicable in vessels.

McFann *et al.* [75] described a radial force stabilizing mechanism for a guidewire, shown in Fig. 7b. Their mechanism consists of a catheter with an internal guidewire that has a structure with a helical orientation. Once the catheter reaches the entrance of a vessel, the guidewire catheter is advanced, folding out its helical structure. Due to the large diameter and helical orientation of the guidewire, it exerts an outward radial force in the vessel it is placed in. Another example of such a system intended for use during cardiac mapping and ablation procedures was patented by Kim *et al.* [76], shown in Fig. 7c. Here, the stabilizing mechanism is constructed from a single piece of foldable and flexible shape-memory material that can be given any desired shape in advance. The idea is that the pre-shaped element will fit into any specific cavity or location once it has released from its covering sheath.

Two examples of commercially available instruments with radial force mechanism are available for cardiac ablation procedures: the Livewire Spiral HP™ Catheter (St. Jude Medical, Inc., Minneapolis, USA) [77] and the Lasso 2515 Variable Circular Mapping Catheter (Biosense Webster Inc., California, USA) [78]. Both are meant to record circumferential potentials in the PVs and are stabilized in position by insertion in the PVs in closed state, after which they are deployed and retracted in the direction of the left atrium to ensure stabilization using the shape of the PVs.

Stabilizing a catheter inside a vessel or cardiac cavity by radial force leads to reliable stabilization. Using different 3D shaping options, the shapes can be designed specifically for each application. However, the use of radial force exertion requires the stabilizing structure to be surrounded by tissue walls. This limits the applicability of the mechanism to mostly vessels. Evaluation of the commercially available systems showed that when the overall diameter of the deployed stabilization mechanisms is too small, it may not provide accurate tissue contact and thus limit the recording of the PV potentials [79].

5.2. Force locking in lateral direction

Force locking mechanisms in lateral direction are intended to stabilize the instrument against cardiac tissue by using elements located at the sides of the catheter. The laterally placed elements can take a number of configurations and be placed in an orientation that is serial, parallel, tethered, or at random on the catheter sides. In this category we differentiate between the use of a single element and multiple elements arising from the catheter sides.

5.2.1. Single-element force locking mechanisms

A single element that arises from the catheter sides to create stabilization is also known as a tethered configuration. Here the catheter has a main longitudinal body from which a stabilizing element branches away at a certain position along the catheter length.

Roop *et al.* [15] patented a single-element system intended as a guiding sheath for use together with an ablation catheter, shown in Fig. 8a. In this invention, the sheath has a stabilizing end that contacts the tissue, while the treating ablation catheter deploys from a slot inside the main sheath body. This allows the ablation catheter to move along different positions over the stabilizing sheath while allowing freedom of movement up to a certain degree. An additional degree of stabilization is created when the treating ablation catheter is captured inside the slot in which lateral movement of the catheter is restricted.

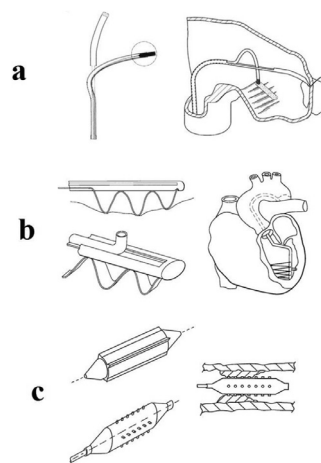


Fig. 8. Patented examples of force locking in frontal direction by a) Roop [15], b) Saadat [80], and c) O'Brien [7].

Use of a single-element mechanism can provide multiple degrees of stabilization; however, the tethered element requires a large space in order to achieve freedom of movement.

5.2.2. Multiple-elements force locking mechanisms

This category concerns the use of multiple stabilizing elements that allow for force locking in lateral direction. Pre-shaped elements can be used that are pushed outside of a channel, or the elements can be incorporated in the outer catheter surface. Additionally, the elements can have a parallel, serial, or random configuration.

Saadat *et al.* [80] developed such a system with stabilization members that appear in a serial configuration from the catheter sides, see Fig. 8b. Their instrument is intended for surgery on an interior wall of a vessel or hollow organ such as the heart or inside brain cavities. One side of the catheter holds another slidable interventional catheter within a groove. The opposite side of the same catheter has a stabilizing mechanism that consists of flexible and extending elements. Altogether, this allows the lateral side with the stabilizing elements to be placed against one side of the tissue while counteracting reaction forces are generated at the opposite side. When placed inside the ventricle, the elements can be pushed out as much as required to provide stabilization along different positions of the ventricle wall with different diameters.

O'Brien *et al.* [7] patented a system in which a balloon catheter has multiple parallel elements for stabilizing the catheter inside a vessel during angioplasty procedures, see Fig. 8c. In this case, as the stabilization elements are placed on the outer surface of a balloon, the system contained both a shape-locking mechanism (the balloon structure) and a force locking mechanism (the expanding elements).

A system such as that described by Saadat *et al.* [80] has the potential advantage that it is adjustable to any heart size. An important disadvantage concerns the end-effector, such as an ablation tool, which needs to be located at an angle relative to the longitudinal catheter axis—an unusual position for the ablation tip. Additionally, the development of mechanisms such as in O'Brien *et al.*'s [7] patent requires complex manufacturing methods in which a large number of detailed structures are placed on a balloon. The inventors proposed a polymeric material such as PET (polyethylene terephthalate) to be heated, extruded, and expanded to create a balloon by blow molding, and to adjust the legs to create a shape, sharpness, and configuration as required. As this is a rather time-consuming process, manufacturing challenges remain.

6. Discussion

6.1. Classification

Having the aim to provide insight into stabilizing mechanisms for transcatheter cardiac procedures, we proposed a structured classification of existing solutions. We distinguished between two main types of stabilization mechanisms, surface-based and volume-based, with the former primarily using a surface in the cardiovascular environment and the latter requiring a 3D structure for stabilization. Depending on the type of intervention, different stabilizing methods are necessary. While this requires the development of instruments for specific procedures, it also allows optimization of the stabilization process for a specific treatment.

6.2. Applicability to the heart

Stabilization of instruments is arguably more critical in cardiovascular procedures than in procedures elsewhere in the body, because of the continuous motion in the heart region. At the same time, limitations are posed by the dynamic heart environment, and one must be cautious to not disturb the natural processes and tissue structures. Some of the proposed stabilization mechanisms are thus less suitable for use in the cardiac environment. For example, solutions requiring protruding through the tissue can be damaging to the cardiac wall. Additionally, contact of instruments with the cardiac wall may lead to arrhythmias at electrically active locations and must thus be avoided.

Another important point of consideration is the actuation of the stabilization mechanisms inside the heart. A stabilization catheter system with actuation separate to that of the treatment catheter requires additional control and handling during the procedure. It is therefore important that difficulties associated with the extra control do not outweigh the added value of the stabilization mechanism. Several of the presented solutions are therefore intended only for a specific procedure. While this poses limitations in terms of applicability of the instrument to other procedures, it is beneficial to the specific procedure it is designed for.

A final important topic regarding the cardiac applicability concerns the basket and balloon structures that have been found in a number of commercially available catheter systems. Whether or not they were specifically intended for stabilization, due to their foldable structures and relative safety for use in the heart, these technologies appear currently the most promising for stabilization. Because the location of the stabilization is application-specific, the design of these structures depends on the anatomic region in which they are used.

6.3. Future recommendations

The future of stabilization within the cardiovascular system largely depends on the field of application. We therefore recommend investigating the need for stabilization in a number of cardiac procedures. Depending on the procedure, it may be that stabilization is not required for effective treatment, or that the effects of stabilization are outweighed by the added complexity to the procedure. It is thus important to know which procedures can potentially benefit from stabilization of catheters and other instrumentation, in order to develop multi-functional and more dedicated instruments.

Higher stability of the catheter tip leads to improved contact force management and a more effective treatment in the ablation of atrial fibrillation. We therefore recommend investigating the effects of the existing stabilizing mechanisms on electrophysiology procedures in particular. In addition, it is advised to investigate

how stabilization can serve contact force management and the development of new techniques to improve control over the exerted amount of contact force.

To optimize the potential value of stabilizing catheters in the heart, the future lies in combining the treatment catheter with a mechanical stabilization function. However, it is important not to over-engineer the catheters and only incorporate a stabilization function when clinically relevant.

7. Conclusion

Having identified the need for improved and more stable instrument-tissue contact, this review presented a categorization of catheter stabilizing mechanisms and assessed the remaining challenges. We identified a total of 13 fundamentally different mechanisms for stabilization of cardiac catheters. Basket and balloon structures are the furthest developed mechanisms as well as the most available ones. The classification may be used as a design tool for more dedicated systems in the future. To adopt stabilizing mechanisms in various cardiac procedures, the stabilizing mechanisms must be designed for specific procedures and if possible, combined with treatment catheters. Useful tools are particularly foreseen in the field of electrophysiology as the use of mapping and ablation catheters requires long periods of catheter-tissue contact.

Declaration of Competing Interest

None declared

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Ethical approval

Not required

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