Improving Maneuverability and Tactile Feedback in Medical Catheters by Optimizing the Valve Toward Minimal Friction

Abstract

A new extended hemostasis valve for sheaths is presented, with minimized stick-slip behavior to be used in (heart) catheterization procedures during long interventions (3–6 h). The invented extension to this existing sheath bypasses the silicone rubber sealing (hemostasis valve) and replaces it with a dedicated seal with the two functions separated: (1) sealing around the catheter being used and (2) closing the sheath when the catheter is removed (valve function). Measurements have been performed on the current and the invented seals, showing that the axial friction force is reduced, with a factor of 6.4, from 1.4 N to 0.22 N. [DOI: 10.1115/1.3054389]

Keywords: cardiovascular device, human performance/force assessment, medical device design process, minimally invasive devices

1 Introduction

Heart rhythm disorders, for example, atrial fibrillation (AF), can be treated using the minimally invasive technique called heart catheter ablation. In this procedure a catheter (a soft, thin, flexible tube with electrodes at the end, see also Fig. 2) is inserted through a vein or artery in the groin or neck of the patient and is moved into the heart (see Fig. 1). Through the electrode, radio frequency, laser, cryo (freezing), or ultrasound energy is applied to eliminate or physically destroy a specific heart tissue [1]. Catheter ablation is based on the idea that by ablating (or destroying) abnormal tissue areas in the heart, its electrical system can be repaired and the heart will return to a normal rhythm. When the applied energy is too high, the heart tissue can be perforated and complications occur [2]. Extensive lesions are created in the left atrium near the pulmonary veins (PVs) [3] in an attempt to prevent AF to originate (called re-entry) or establishing itself (focal ectopic activity or trigger) [4].

To get to the correct position within the human heart, the catheter has to be introduced into the cardiovascular system. Normally the so-called Seldinger technique [5] is used, where the catheter is inserted through a tubing (sheath, containing a valve, see Fig. 2) into the vessel. This approach prevents damage of the vessel wall and gives the possibility to easily retract and replace the ablation catheter. To avoid coagulation of the blood, the sheath can be flushed with a saline solution (see Fig. 3 [6]). The length approximates between 500 mm and 600 mm with 8–9 French (2.7–3.0 mm) inner and 9–10 French (3.0–3.3 mm) outer diameter.

The success of the procedure highly depends on the maneuverability of the ablation catheter. For the correct isolation of the abnormal electrical area in the heart, the cardiologist (with a specialization in electrophysiology) forms a closed sequence of ablation “spots” (20–40) encircling the PVs [7,8]. Normally it takes 3–6 h until correct PV isolation is obtained, mainly caused by verifying and altering the tip position and by multiple measurement of the electrical heart activity (electrocardiogram).

Since the catheter is very flexible, the slightest friction will prevent fast and accurate tip positioning, which is vital in treating only the areas intended. Experiments show that the flushed sheath offers low friction (<15% of the total friction of 1.4 N) while the rubber seal of the valve gives much friction (>85%). The positioning accuracy then seems to have a play of \( s_v = 2W/c \), where \( W \) is the friction force and \( c \) is the limited stiffness of the catheter [10]. This “virtual” play hampers a fast and precise tip actuation, so the electrophysiologist performs extra actions to place the tip on the desired heart tissue location. By pushing the catheter a bit too far, the final position is reached in a retracting motion; the

Fig. 1 Insertion of the ablation catheter in the groin area and moved toward the heart via the inferior vena cava or inserted in the neck and via the superior vena cava

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same is done for rotation. Furthermore it is desired that contact with the beating heart wall remains during the lesion creation for 1–1.5 min.

2 Improving Accuracy

A new valve is realized that overcomes or at least reduces, to a great extent, the friction between catheter tube and hemostasis valve that is present in current sheaths. Due to the ability of sealing around a large variety of diameters, the valve opening has to translate in radial direction from closed to open. This large stroke causes a large normal force on large diameter catheters, in turn, causing more friction force. Current valves may be used with a wide variety of both large catheters, up to 3 mm, and small guidewires, down to 0.35 mm. The presented dedicated valve uses a low friction sealing optimized for the use with one type of catheter diameter. This is realized by separating the two functions of the seal:

1. Sealing around the catheter being used
2. Closing the sheath when the catheter is removed

As usual in the design stage, a survey in (patent) literature is performed. In the field of laparoscopic minimally invasive surgery, long slender medical instruments (with ~8 mm in diameter) are inserted into the human body. For guidance and temporary closing so-called trocars are used, and the friction issue is known and optimized [11]. Due to larger instrument diameters, friction forces play a smaller role compared with cardiovascular applications. The stiffness of large instruments is much higher so virtual play is less there. Development in the cardiovascular field is still in progress, and a friction optimized device [12] is shown in Fig. 4. The sealing and closing valves are placed in a functional order. During insertion of the catheter (from left to right) the sealing is established before opening the valve and entering into the blood vessel, and on retraction the vessel is closed first.

A major drawback of this design is the actuation length with respect to the location of the (minimized) friction force. By placing the seal on the tip of the sheath, the catheter will buckle and wind up within the full sheath length and therefore still introduce virtual play, this time by low stiffness. Optimally the seal must be placed near the location where the electrophysiologist manipulates the catheter handle. This will result in the maximal possible maneuverability and positioning accuracy due to a larger axial and torsional stiffness. Also flushing the sheath is not possible in this setup. Undesirably, blood will enter the sheath via the valve (Fig. 4, No. 132) and may coagulate in chamber 116 (Fig. 4), “gluing” the catheter over a given length into the sheath.

3 New Design

Figure 5 displays the different functions of the new valve. This valve is designed as an add-on for currently used sheaths and will fit inside the existing tight silicone rubber seal. For extra fixation a buckle will lock on the existing housing (housing is shown in Fig. 3). Optimization toward minimal friction between catheter and seal implies that every catheter has its own surrounding seal (function (1)), which opens just enough to create good sealing on
that particular diameter, whereas the closing valve (function 2) is made independent on the instrument diameter. The catheter with an associated surrounding seal can be connected to the closing valve with a bayonet coupling.

The ideas are realized in a prototype, shown in Fig. 6, where the functions of Fig. 5 are indicated.

4 Closing Valve

Function (2) is realized using a door-valve, which is pretensioned with a torsion spring, as shown in Fig. 7. It will close immediately upon extraction of the catheter, so sealing cannot be forgotten, even in case of unintended extraction. By placing the pivot close to the catheter an optimal balance is obtained between the force in closed and open positions (see also Fig. 8). When the door is closed (aperture angle $\varphi=0$ deg), the torsion spring is rotated with $\theta=36$ deg, resulting in a moment of 2.4 N mm on the door. In an open position ($\varphi=70$ deg and $\theta=53$ deg), the moment is 1.8 N mm. The shape of the backside of the trap door causes the friction against the catheter to be minimal by a largely reduced normal force: the catheter force arm is 4.7 mm, resulting in a 0.38 N normal force.

The pivot bore diameter within the door is slightly larger than the pin diameter. Now the closed door position is fully determined by the polished face of the insertion tube resulting in a fluid tight valve. The closing force nearly acts along the centerline of the insertion tube. An acrylic glass (polymethylmethacrylate, PMMA) front plate closes the valve chamber providing visual feedback on the function (Fig. 9).

5 Surrounding Seal

Optimized on the catheter tube outer diameter, the surrounding seal function (1) is realized using 12 crescent-shaped polytetrafluoroethylene (PTFE, also known as Teflon®) disks with a thickness of 1 mm (Fig. 10). These disks, forming a labyrinth sealing around the catheter, introduce less friction. A housing containing the disks is now linked to a specific catheter diameter. The surrounding seal can be attached to the closing valve via an easy to use bayonet coupling so a fast catheter replacement still is provided.

6 Results

Experiments and measurements are performed on the friction and stick-slip behaviors within an existing valve and the new proposal. This is done in (laboratory) practice (see Fig. 11), investigating both the subsystems and the whole setup. The sheath is fixed on two places with clamps. The catheter is placed inside the
sheath and the tip is pushed with a dial gauge to measure the static friction force. Measurement results are given in Table 1.

From these measurements it can be concluded that the axial friction force is reduced by a factor of 6.4.

Future work includes additional experiments and demonstrating the capabilities of the improved valve to cardiologists. By combining their comments and ideas with a redesign using manly plastics, that prototype can be presented to potential (catheter) manufacturers for further utilization.

7 Conclusions

Current sheaths with hemostasis valves, used in catheterization procedures, obstruct a precise catheter tip motion due to a large stick-slip behavior. These induced forces are perceived as hysteresis: position accuracy seems to have play. The design of a new valve is described and validated with measurements, concluding that the axial friction force is reduced by a factor of 6.4.

Table 1 Measurement results

<table>
<thead>
<tr>
<th>Translation: pushing with dial gauge</th>
<th>Friction force (N)</th>
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<tbody>
<tr>
<td>Existing valve setup</td>
<td>1.4 ± 0.2</td>
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<td>Improved setup</td>
<td>0.22 ± 0.02</td>
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References