Design and implementation of a miniaturized cooling system for Trans-Esophageal Echocardiographic probes in minimally invasive cardiac surgery

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INTRODUCTION

Minimally invasive surgery (MIS) for cardiac procedures was adopted in the late 90s as a valid alternative to open-heart surgeries, allowing for a minor operative trauma and for a faster post-operative recovery [1]. The recent development of real-time three-dimensional trans-esophageal echocardiography (RT-3D TEE) has enabled various trans-catheter procedures [2]. However, recent studies have highlighted the occurrence of esophageal lesions following TEE-guided cardiac interventions. Namely, blind probe insertion, advancement of improperly placed probes, and repeated adjustment for optimal instrument guidance, along with prolonged use-induced heating, appear to be the primary causes of complications [3].

Additionally, in the context of MIS, the presence of reliable imaging techniques is of paramount importance, as surgeons operates without a direct view of the surgical site. Specifically, by using a trans-esophageal probe for minimally invasive cardiac interventions, fluoroscopic imaging (i.e., an x-ray-based technology) and ultrasound images are relied on simultaneously. The major reason for using a dual imaging technique is that, to date, for avoiding any potential thermal damage to the esophagus internal walls, TEE commercial probes automatically switch off once a temperature threshold of 42.5°C is reached [4]. Therefore, imaging techniques based on the use of ionizing radiation continue to be the gold standard in these clinical practices. Additionally, US image quality decreases as temperature increases. In order to overcome these technological drawbacks and facilitate the advancement towards the use of US images, the creation of a miniaturized cooling device for trans-esophageal ultrasound probes is required. The aim of this work is to design and implement a cooling system for TEE-guided cardiac minimally invasive interventions.

MATERIALS AND METHODS

According to clinical needs and following medical specifications, a silicone cap into which the probe is inserted was designed. The cap is equipped with a miniaturized inner tube in which cooling fluid, i.e., water, flows at a constant temperature of 25°C (Figure 1).

Heat exchange phenomena were studied by means of thermo-fluid dynamic simulations conducted using COMSOL Multiphysics as software interface. Although the pipe diameter is 2 mm only, turbulent flow was verified due to the complexity of the circuit geometry. From the simulation environment, 30 seconds seem to be sufficient to guarantee cooling, considering a continuous water flow. Based on the results obtained in the simulation environment, the manufacturing process and, subsequently, the control strategies were defined.

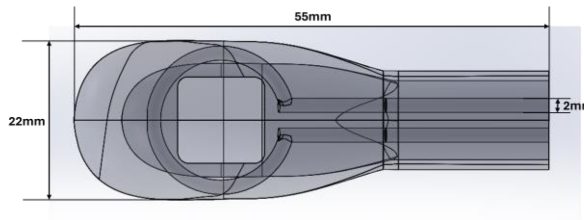

Figure. 1. CAD representation of the cooling system design.

The manufacturing procedure involves casting of a platinum silicone (Smooth-Sil 936) inside of a 3D printed mould realised with an Original Prusa i3 MK3s+ 3D printer (Prusa Research, Czech Republic). The system is controlled by an Arduino code, based on the temperature values that are recorded by two thermistors (Amphenol, Thermistor NTC. MC65F502BN). The device that ensures the water flow is a non-self-priming micro-pump (TCS-Micropumps, M200S-V), which means that a filling circuit will be required for its operation. The pump will activate when the sensors read a specific temperature threshold value, and this is the main difference to the simulation environment in which the flow is considered continuous. Two different thermistors were placed onto the prototype: one inside of the cap (A) and a similar one outside of it (B), as sketched in Figure 2. Temperature values recorded by the sensors have been then compared with the data calculated in COMSOL, in order to validate the simulation results.

For the purpose of investigating the performance of the system, the first step was to define the experimental set-up, which consists of: (i) an ultrasound station and its TEE probe (GE 6VT-D, GE Healthcare); (ii) the control system and a water reservoir; (iii) an environment simulating the physiological conditions of the human esophagus. In practical terms, this translated into making a silicone phantom in the shape of a hollow cylinder, inside which the probe with the cap was inserted. The whole system was immersed in water at a controlled temperature of 36-37°C (physiological temperature of the human body). A temperature limit of 39°C was set as critical threshold. The considered time interval is 2h10min, since the typical duration for minimally invasive cardiac surgery procedures is 2h [3]. To test the

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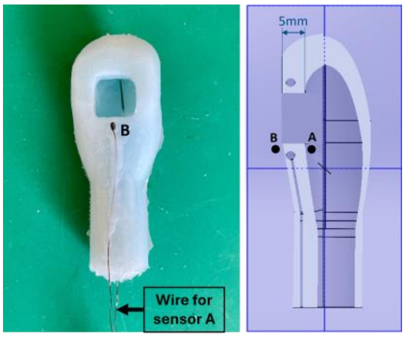
repeatability of the system, five repetitions were performed, and mean and standard deviation values were extracted. In addition to the situation in which the cooling system is active, two other conditions, i.e., the probe alone and the probe equipped with the passive silicone cap only, i.e., without the active cooling system, were tested, in order to have a complete characterization of the system.



a) b)

Figure. 2. Appearance of the silicone cap and sensor positioning: a) Front view of the sensorised silicone cap; b) Cross-sectional CAD view, highlighting the position of the thermistors (A, B) and the cooling channel.

RESULTS

The system was tested by using a TEE probe. Once inserted on the probe, the cap leaves the transducer completely free, which is crucial for the quality of ultrasound imaging. It is necessary that the thickness between the transducer and the inner walls of the esophagus is minimal in order to ensure contact. Furthermore, in clinical practice the probe could be inserted into a plastic casing and drowned in gel to further improve acoustic coupling.

In order to properly test the system, temperature trends were monitored with regard to both the probe and the water simulating the physiological conditions of the human esophagus. In all the five performed repetitions, evaluating 2h10min as time frame, the probe temperature never exceeds 39°C. These results are shown in Figure 3.

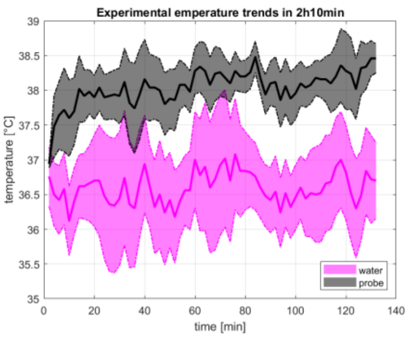


Figure. 3. Experimental values of probe (black) and surrounding water (magenta) temperature trends.

Going through three different experimental configurations, i.e., the probe alone, the probe equipped with the passive silicone cap only and the probe with the active cooling system, the results relating to these tests can be found in Figure 4. It can be stated that the insulating properties of the silicone result in a dual effect: on one hand, the passive silicone further hinders the dissipation of the heat produced by the probe due the Joule effect; on the other hand, when the cooling system is active and therefore the water is inside the cap, the cooling effect is permanently maintained.

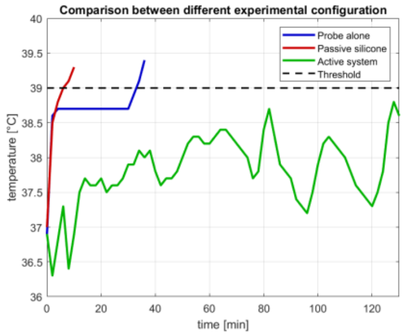


Figure. 4. Comparison between different experimental configurations, considering a critical threshold of 39°C (dashed line) at which tests are interrupted.

Moreover, in order to assess the clinical interest in such a device, a group of 10 healthcare professionals involved in the use of TEE probes was inquired: a generally positive feedback is reported as 75% of the surveyed doctors are in favour of integrating the cooling device into their clinical practice.

CONCLUSION AND DISCUSSION

In order to answer to clinical needs and to address safety and technological problems that are currently limiting the RT-3D TEE cardiac surgery establishment, a miniaturized silicone cap equipped with an internal tube network in which a cooling fluid, i.e., water, flows at a constant temperature of 25°C was realised. A robust and easy-to-use control strategy was implemented and an intuitive interface was build. The cooling system was extensively tested showing promising functioning of the system. Future efforts will be dedicated to improve both the mechanical design, specifically in terms of cap thickness optimization, and the control strategies, by introducing a self-priming pump. These solutions will pave the way to the integration of the device into clinical practice, also given the generally positive feedback received from healthcare professionals.

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