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A New Minimally Invasive Heart Surgery Instrument for Atrial Fibrillation Treatment: *first in vitro and animal tests*

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Abstract

The paper presents a new robotic system for beating heart surgery. The final goal of this project is to develop a tele-operated system for the thoracoscopic treatment of patients with atrial fibrillation. The system consists of a robot that moves an innovative end-effector used to perform lines as in the Cox-Maze technique. This device is an electrode mesh that is introduced in the thorax through a trocar and is deployed inside the left atrium, where it can create selective ablation lines at any atrial region, using radio frequency. The current version of the umbrella has 22 electrodes. Using visual feedback from an ultrasound based navigation system, the surgeon can choose which electrodes on the mesh to activate. Once the umbrella is in contact with the endocardium of the left atrium, at the expected position, the surgeon activates the chosen electrodes sequentially. The umbrella can then be moved to another position. In vitro and in vivo animal tests have been carried out in order to test and improve the instrument, the robotic system and the operative procedure.

Keywords: surgical robotics, heart surgery, RF ablation, PDMS.

Introduction

Atrial fibrillation is a widespread heart arrhythmia. Several treatments already exist based on drugs or on surgery. This paper deals with a novel minimally invasive instrument developed for the beating heart atrial fibrillation surgical treatment performed with the assistance of a robotic system.

In this field, several surgical robots exist. The product to date from Computer Motion is the Zeus minimal invasive surgical robot system used for endoscopic cardiac intervention like coronary artery bypass grafting⁽¹⁾. Intuitive Surgical provides the da Vinci or da Vinci S surgical system also for minimal invasive cardiac intervention. The Robodoc from Integrated Surgical Systems is more specialized in preparing bones for prosthetic implants. These robots are equipped of minimal invasive instruments like graspers, scissors, scalpels, cautery instruments, etc. with are miniaturization of the classical instrument used in invasive surgery.

The aim of this research is to develop a device, with a design inspired from the left atrium morphology, that is inserted in it, allowing the surgeon to plan and achieve ablation lines anywhere in the endocardium. The ablation lines are obtained by the activation of different independent electrodes that are positioned as desired by the robotic system. Finally, ablation lines will block multiple re-entrant electrical signals that move randomly throughout the muscular cells of the atria, in atrial fibrillation.

1 Subject presentation

1.1 Atrial fibrillation

Atrial Fibrillation (AF) is the most common heart arrhythmia and results basically from multiple re-entrant electrical signals that move randomly throughout the atria's muscular cells. Classically, electrical re-entrant impulses are associated with decreased atrial refractory periods, decreased electrical conduction speed and increase in the atria's muscular volume. More recently it has been demonstrated that AF changes atrial electric properties resulting in a potential self-perpetuating phenomenon⁽²⁾.

AF affects about 1 in 20 people above 60 years old and its prevalence is on the rise in our aging population⁽³⁾. Affecting almost 1% of the general population in USA, its prevalence is expected to rise 2.5 - fold by 2050⁽³⁾.

AF related overall costs are very significant. It has been estimated in USA that these costs are between US \$9300 and \$18900 per patient / year, while in the UK they represents about 1% of all National Health Service expenditure^(2,3).

The major complications in patients with AF are thromboembolic accident related, increased heart failure rate, higher stroke incidence and increased mortality rate^(2,3).

AF is associated with a significant decrease in quality of life, which can be improved by restoring sinus rhythm⁽⁴⁾.

In the currently accepted classification, two or more episodes of AF is termed recurrent AF. Recurrent AF can be paroxysmal (attacks spontaneously end after 7 days or less), per-

sistent (requiring electric or pharmacological cardioversion) or permanent (no sinus rhythm permanently sustained after cardioversion)⁽⁵⁾.

It has been demonstrated that with the use of antiarrhythmic drugs, sinus rhythm can be maintained in only 50% to 65% of the patients⁽²⁾.

1.2 Therapy evolution

For those patients whose sinus rhythm cannot be maintained with drug therapy and those whose who have other problems such as drug intolerance, alternative treatments have been tried, including surgical approaches⁽²⁾. The first surgical procedure developed for atrial fibrillation (AF) management was the "corridor" procedure in 1985, where, in an open heart intervention, sutures were used to isolate the atrial free wall from the septum, forcing the electrical pulses to pass in a pathway (the "corridor") from sinus node to atrioventricular node⁽²⁾. This technique proved to be a long term relatively ineffective method, as about 27% of the patients later developed other atrial arrhythmia⁽²⁾. In 1987, Cox introduced a new open heart surgical technique, the "maze" procedure⁽⁶⁻¹⁰⁾. In this procedure, performed under cardiopulmonary bypass, the left atrial appendage is excised, ablation lines are created around the pulmonary veins, and a sophisticated circuit of blocking lines is formed in order to canalise the electric pulses from the sinus node to the atrioventricular node. This eliminate large potentially re-entrant regions and defines a maze-like ablation pattern⁽⁴⁾. In almost 5 years experience, Cox claimed a 98% effectiveness with this technique in treating atrial fibrillation and restoring atrioventricular synchrony⁽¹¹⁾. However, the Cox-Maze procedure is extremely invasive, as it needs the heart to be stopped and requires the use of cardiopulmonary bypass⁽⁴⁾. In addition, the Cox-Maze procedure has a 2% - 3% perioperative mortality rate and is characterised by potential complications, such as sinus node dysfunctions⁽²⁾. Currently, the procedure has been modified twice, to improve the results and simplify the complexity of the technique, giving it the name of the Cox-Maze III procedure⁽⁵⁾.

More recently, Cox-Maze III surgery has been compared with a technique in which a similar pattern of lesions is created using a radio frequency device. The results are almost the same, proving that radio frequency is an effective and easier method of creating ablation lines in an open heart procedure⁽¹²⁾. Another group of 132 patients underwent open heart radio frequency (RF) ablation and the technique was shown to be safe and very effective in restoring long term sinus rhythm⁽¹³⁾.

Further interest in atrial fibrillation mechanism lead Haissaguere et al. to search for spontaneous initiation of AF. He discovered that about 64% of the patients studied presented a unique point of origin, around the pulmonary veins, and to report a large percentage of ectopic foci⁽¹⁴⁾. In their study, the patients had been treated by beating heart radio frequency catheter ablation and 62% had no AF recurrence. Another study showed that isolation of pulmonary veins by RF catheter ablation in a beating heart, in patients with paroxysmal AF, can achieve a 70% success rate, when associated with the use of antiarrhythmic drugs⁽¹⁵⁾. A more recent study from Haissaguere and al. (2003) showed that following operator learning curve, a rate of 70% effectiveness can be achieved by beating heart RF catheter ablation around the pulmonary veins, and that a 5% additional success rate can be obtained in chronic

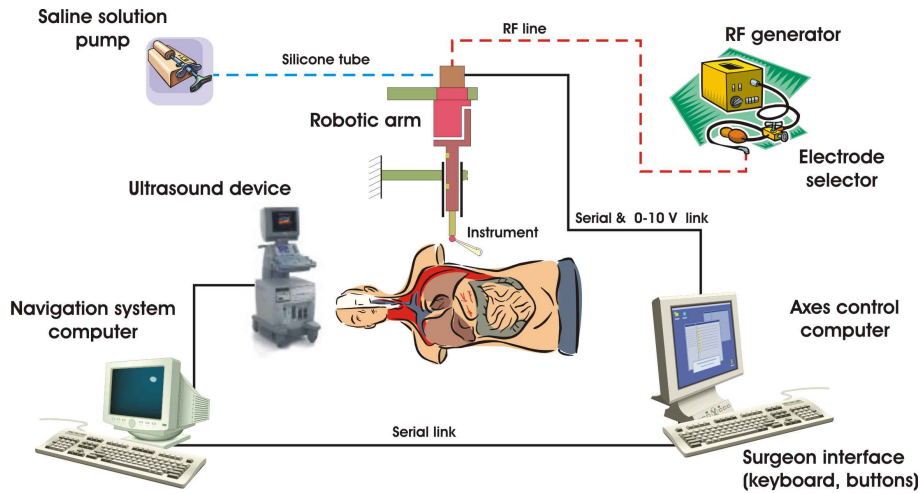


Figure 1: complete surgical system.

AF by creating extra ablation lines⁽¹⁶⁾. These results suggest that, on the one hand, catheter ablation needs a skilled operator and, on the other hand, that 70% effectiveness may be the maximum for ablation around pulmonary veins only.

Some others limitations of RF catheter ablation are that for obtaining effective ablation lines, the contact between the electrodes and the tissue must be optimal and constant, which is difficult with these flexible devices⁽¹⁷⁾. Another possible failure of current minimally invasive RF devices is related to the difficulty of creating complete lesions lines which are necessary to stop re-entrant impulses⁽¹⁸⁾.

Finally, an even more recent device has been made to create RF ablation lines in a beating heart with a different approach, namely: clamping circular regions externally from the heart (epicardial ablation)⁽¹⁷⁾. This technique is still limited to ablation in regions around vessels of the heart and atrial appendage.

The ideal instrument should be able to use a minimally invasive technique, i.e. a beating heart procedure, to create continuous and transmural ablation lines using RF which requires a good and continuous contact between the electrode and tissue. It should also be possible to accomplish ablation almost everywhere in the atrial cavity. The combination of such features should lead the device to be as effective as the Cox-Maze open heart procedure. This is exactly what the new micro robotic ablation device has been designed for.

2 Surgical system

To perform the ablation lines in the beating heart a multi-degrees of freedom surgical system has been developed (see figure 1). The patient is placed on a table in a lateral position. The surgeon control a robot arm to deploy and position the ablation device in the left atrium.

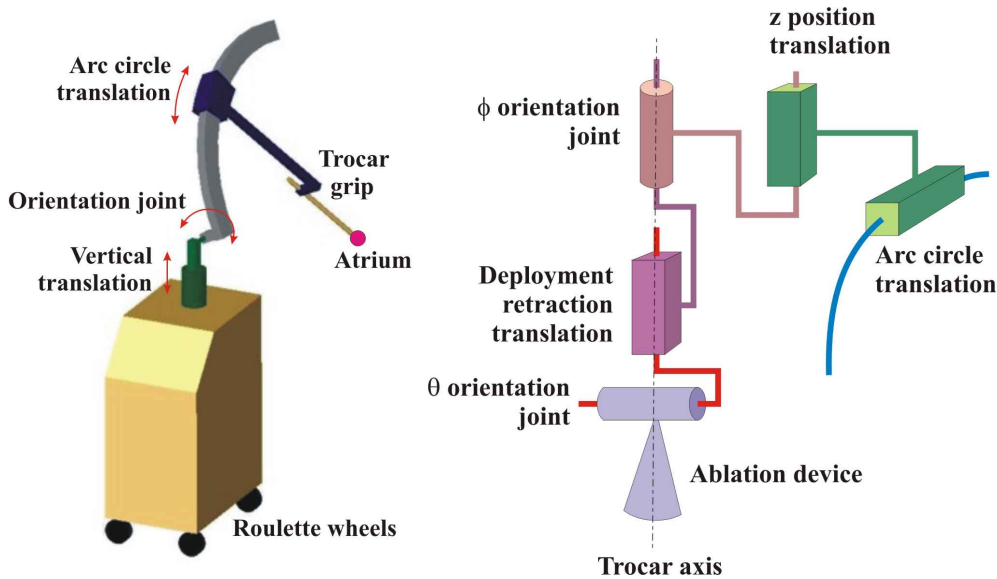


Figure 2: atrium stabilization kinematic (left), ablation device kinematic (right).

The ablation lines are made with an RF generator and a saline solution cooling system. The instrument and the anatomical landmarks are localized with the ultrasound echographic navigation system.

The peripheral subsystems include an RF generator, connected to the ablation device via an electronic unit which allows electrodes selection. The surgeon can select one or several electrodes among the 22 available, using micro-switches. A saline solution pump is also connected to the instrument and can be activated during RF ablation, in order to cool the electrodes.

2.1 Robotic Arm

The goal of the robotic arm is to deploy, position and retract the ablation device. A preliminary phase is necessary and consists in stabilizing the atrium around the entry point of the ablation device. To perform this, a trocar beforehand introduced and maintained with a purse string into the atrial appendage, is connected to the robot. Consequently the robot kinematic is designed with several mobilities used to align the trocar grip, before locking it on the trocar (see figure 2 (left)). It consists in 3 translations and 3 rotations obtained by 4 roulette wheels, a vertical translation, an orientation joint and an arc circle translation which have a rotation center located a few centimeters above the trocar grip. These mobilities are only used at the beginning and at the end of the intervention. They are locked during the deployment, positioning and retraction of the ablation device.

An other kinematic has been designed to move the ablation device into the atrium. This kinematic is fixed on the arc circle translation and is composed of 4 motorized axes which operate in position closed-loop (see figure 2 (right)). They are also driven by the axis control

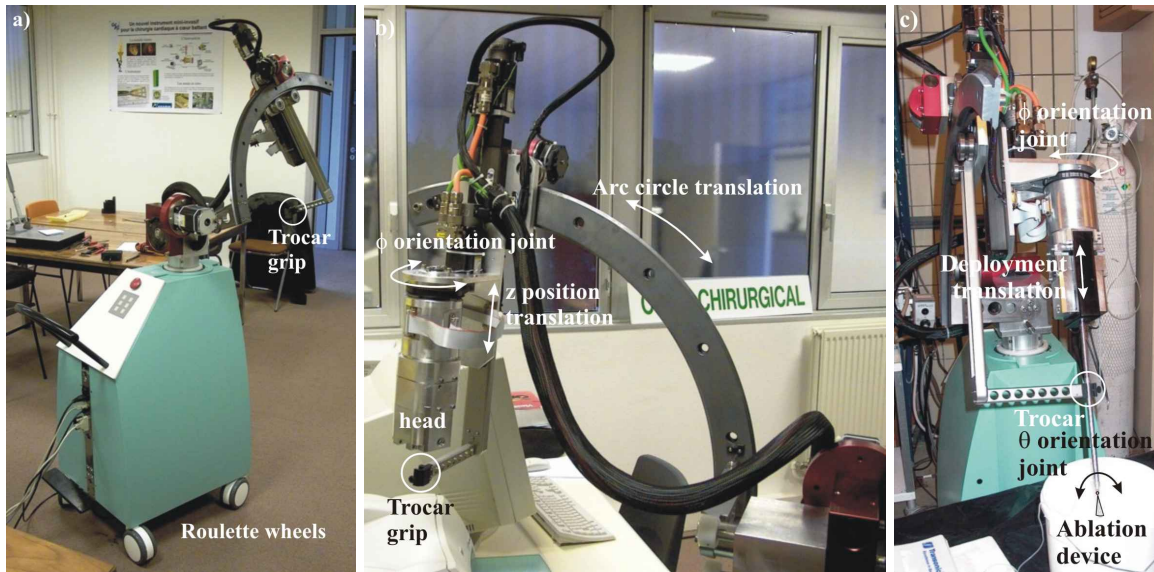


Figure 3: robot presentation (a,b), robot equipped of the ablation device (c)

computer. The ablation device is a large electrode mesh which has the particularity to be retractable into a tube at the beginning and at the end of the operation and deployed once introduced in the atrium through the trocar for the operation. The deployment/extraction translation is used in that purpose while the z position translation for introduction. θ and ϕ orientation joints and the z position translation are used to position and apply the device onto the endocardium. The specifications of these axis are summarized in the following table.

Axis	Range	Resolution	Speed
z	400 mm	0,1 mm	25 mm/s
deployment	95 mm	0,1 mm	1,2 mm/s
θ	$\pm 100^\circ$	1°	$25^\circ/s$
ϕ	$\pm 180^\circ$	1°	$40^\circ/s$

The robot arm has been developed according with these specifications. The different parts of the robot are shown on figure 3. The ablation device, which is plugged in the robot (see figure 3c), has been designed as a single use tool without actuators. The motors that activate the deployment and θ orientation are outlying in the head. The device is described in the next section.

2.2 Ablation device

The new concept for atrial fibrillation treatment reported here is related to the use of a special ablation device (see figure 4). This device, so-called "umbrella", is a single use tool which has an electrode mesh inlaid in a waterproof PDMS material¹. It is plugged in the head once

¹PolyDiMethylSiloxane, biocompatible silicone rubber from Nusil Technology - USA



Figure 4: single use ablation device.

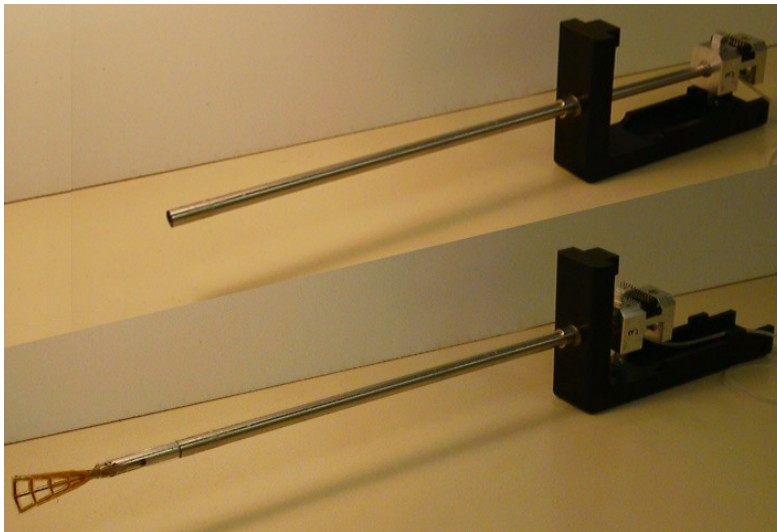


Figure 5: retracted/deployed umbrella.

the robot is placed and locked on the trocar. The umbrella is very flexible and is able to be retracted in the supporting tube (see figure 5). Among the 22 independent electrodes distributed on the umbrella surface, 6 have a small size and the others a large size.

Once introduced in the left atrium through the trocar and deployed, the umbrella is oriented and positioned in a suitable contact with the endocardium surface (see figure 6). This relative stiffness is obtained with pseudo-elastic shape memory alloy wires integrated in the PDMS. By this way, the device can reach the hemisphere situated around the atrial appendage but also the opposite hemisphere in the blood flow while the heart is beating. The 22 independent electrodes are supposed to perform a part of the Cox-Maze ablation lines without umbrella repositioning. The electrode configuration should permit to do all the lines with ten or so consecutive positioning and reduce the ablation time in comparison with the actual catheter technique. In order to improve the RF ablation effectiveness, the umbrella also integrates a water cooling system formed by a network of silicone (PDMS) pipes. An external

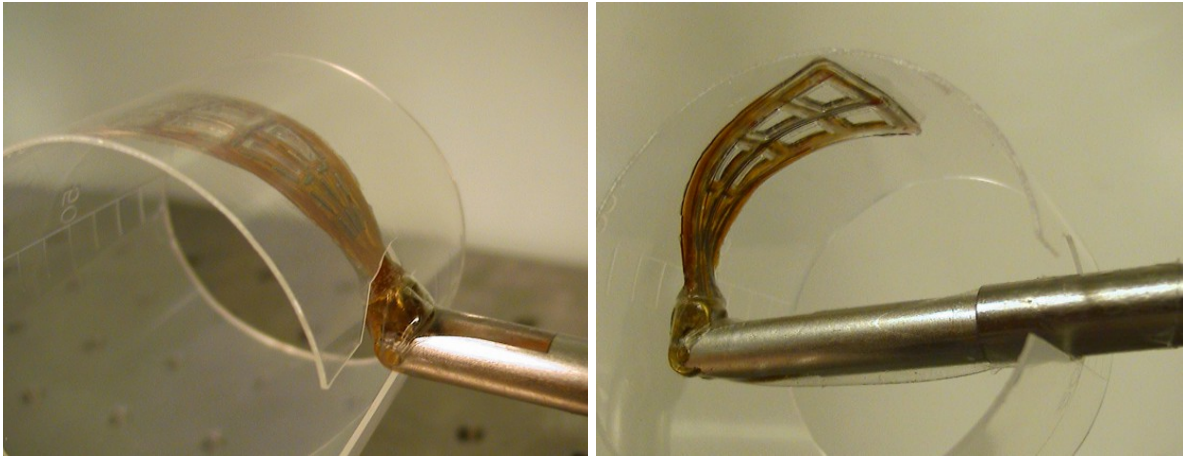


Figure 6: umbrella applied around the appendage hemisphere and the opposite hemisphere.

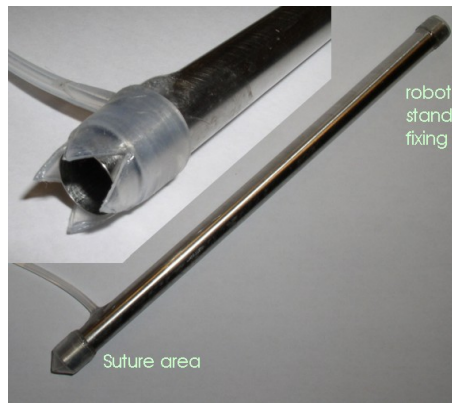


Figure 7: trocar tube.

pump injects a saline solution, reaching each electrode on the umbrella's surface by thin buses (0.25 mm in diameter).

The surgical procedure is performed by positioning the RF electrode mesh on the atrial endocardium using the degrees of freedom provided by the robot. According to the data obtained by the navigation system i.e. the mesh current position, the anatomical landmarks and the planned ablation lines, the umbrella is moved and applied in a previously defined area. Then the surgeon activates, from among the 22 independent electrodes, those which fit the desired ablation line. This procedure is repeated until the whole desired ablation lines are completed.

2.3 Trocar

For the correct and real-time umbrella tracking, a fixed reference point is needed. This point is the left atrial appendage and must remain fully stabilized. We used a 220 mm in length and 10 mm in diameter trocar fixed, by one hand, to the left atrial appendage with a purse string and, by the other hand, to the robot trocar gripping. The ablation device is introduced through it and can translate along and rotate around its axis (see figure 7). It is equipped of silicone waterproof tips and of a silicone bleeding tube.

2.4 Control software

The surgeon controls the 4 ablation device mobilities through a specifically developed graphical user interface (i.e. several intuitive windows sequentially given by the control software). Thus he will follow the initialization procedure, the ablation device introduction and deployment. On the main windows he can activate a mobility gap and follow all the movements during the positioning phase. The navigation system helps the surgeon to define which axis must be activated to obtain a desired positioning.

The C^{++} program has two components. The low level component manage the closed loop controls and the inter-system communications, using RTX², which is a real time module. The high level component is the surgeon interface and use a Windows process that exchanges data with the RTX process. By this mean, the interface is user-friendly but also time deterministic, allowing to ensure a reliable axes control.

2.5 Navigation system

A 3D echographic navigation system³ is used for locating, positioning and calculating the umbrella pathway in the atrium. In this paper, navigation system details are not presented. The purpose is to present the first in vitro and in vivo tests, concentrating on the performance of the instrument. To date the navigation system has been tested but not used to guide the surgeon during umbrella positioning in a beating heart. These first series of tests reported here have been used to validate the mechanical system.

The navigation system gets axes positions from the *axes control computer* in real time. A 3D umbrella reconstruction is processed and displayed in a 3D environment including anatomical landmarks. The landmarks are regularly updated with a transoesophageal ultrasound system. The umbrella reconstruction and sensed image are also correlated. The system displays the completed ablation lines. The details of the navigation are given by M. Hastenteufel⁽¹⁹⁾.

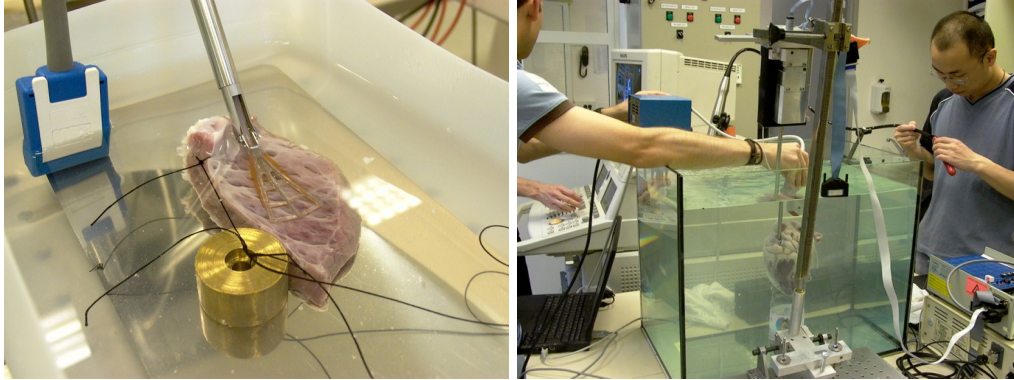


Figure 8: in vitro tests: RF ablation (left), echographic umbrella positioning (right).

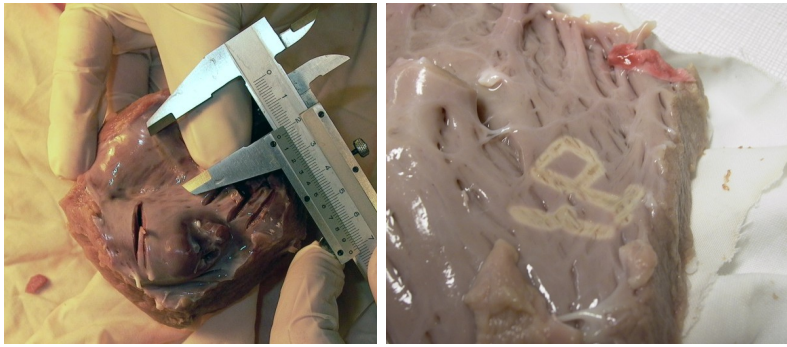


Figure 9: ablation line made by two large electrodes (left), several electrodes (right).

3 In vitro tests

Several in vitro tests have been performed in order to validate instrument positioning, as well as the effectiveness of the RF ablation. Some of these were performed in an entire veal heart using an echographic system, others used ventricle pieces (see figure 8).

3.1 RF ablation tests

Trials consisted of testing the umbrella on a veal ventricle piece placed in warm water (see figure 8 (left)). A saline solution was injected into the umbrella with a 100 ml/h flow, the RF power was manually controlled under impedance measurement feedback and the ablation duration was 300 s. The RF generator was model Neuro N 50⁴. The ablation lines were created using the two electrode types (see figure 9) : the large electrodes are 7 mm long, 0.5 mm width and make lesions of 10 mm length, 3.5 mm wide and 3 mm deep. The small electrodes

²Ardence Inc. - Waltham (USA)

³developed by the Deutsches KrebsForschungsZentrum (DKFZ) - Division Medical and Biological Informatics - Heidelberg (Germany)

⁴Stockert GmbH - Freiburg (Deutschland)

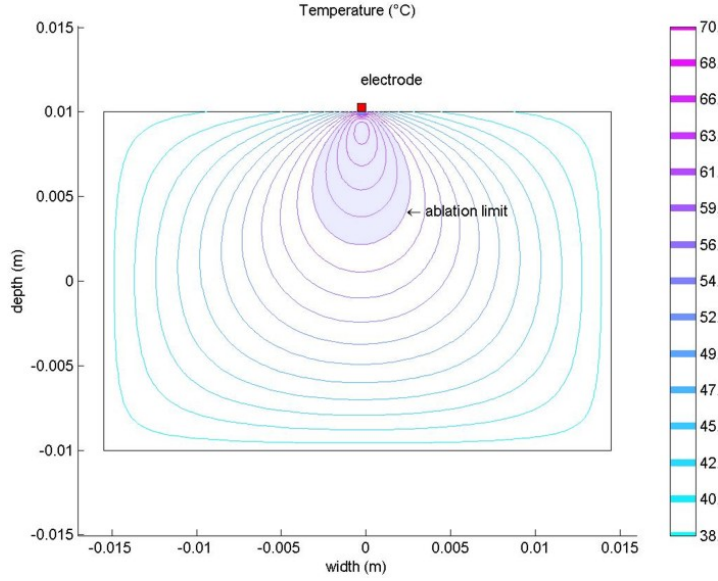


Figure 10: ablation simulation: isotherm cut.

are 2 mm long, 0.5 mm width and make lesions having 3 mm length, 3.5 mm wide and 1.5 mm deep. Ablation using a small electrode was always performed at the same time as a large one, as the generator used did not allow measurement of the very high impedance of an individual small electrode. When two adjacent electrodes were simultaneously fed, an entire overlapped ablation lesion was obtained.

Other tests will be performed to define if one ablation shot can be achieved using more than two electrodes simultaneously. Currently the ablation depth is too small, i.e. around 3 mm. Obtaining transmural ablation on fibrillating atria normally requires a 4 mm minimum depth. To simulate and understand RF behaviour, a model describing the electrode effect on a tissue has been built. It involves modeling the tissue as a conductive medium, subject to an electric potential. Potential distribution V is given by the Laplace equation:

$$-\text{div}(\gamma \overrightarrow{\text{grad}} V) = 0 \quad (1)$$

where γ is the tissue electrical conductivity. The temperature distribution T in permanent regime is calculated using the bioheat equation⁽²⁰⁾:

$$\lambda \text{div} T + \gamma (\text{grad} V)^2 = 0 \quad (2)$$

where λ is the tissue thermal conductivity.

This model is processed with Comsol⁵ software. The parameter values are obtained from tungjitkusolmun⁽²⁰⁾. A good accuracy has been observed between the model and reality. The ablation depth find by the model is 3, 1 mm, which is similar to the experiments. Furthermore,

⁵Comsol Inc. - Los Angeles (USA)

the simulation has shown that the convection around the electrode has a big influence on the ablation depth. The depth reaches 7 mm when a forced convection is applied (see figure 10). According to the simulation results, a new prototype of a single electrode, reproducing a small part of the umbrella, has been built and tested. In this design, a forced cooling canal has been placed over the electrode. The cooling fluid circulation has been set to more than 3600 ml/h in a closed loop circuit. The achieved ablation depth measured on ventricular pieces were about 5 mm in comparison with 3 mm in the case of initial cooling. The new closed loop cooling system has to be designed and then integrated into the umbrella. All the results presented in the next section have been done without modifications of the ablation device cooling system. To date, the design modifications of the umbrella haven't started.

3.2 Umbrella positioning

Mechanical flexibility is very important for correct umbrella deployment as well as ensuring a good contact between the electrodes and the atrial endocardium during the RF ablation process. The flexibility is provided by several pseudo-elastic shape memory alloy wires, moulded in the PDMS. These Nitinol 6% strain wires allow an extreme curvature and a moderate pressure in the atrium. The tests done in a veal atrium demonstrated the ability of the instrument to fit the curvature (see figure 8). In case of bad contact, the impedance measurement performed by the RF generator warns the RF operator, in real time, of the need to reposition the umbrella.

4 In vivo tests

The first in vivo study was performed at the animal lab of the department of intensive care medicine⁶. Animals received humane care in compliance with the Guide for the Care and Use of Laboratory Animals. The goal was to evaluate the instrument and the robotic system, in real conditions.

4.1 Operation description

Under general anesthesia, a sheep was placed in right lateral decubitus. A left thoracotomy was performed followed by a small pericardial window. The left atrial appendage was easily identified and a purse string (Prolène 4/0) was sutured at the base of it. After heparinization, the trocar was inserted into the left atrium via the purse string. Then, the robot base was brought and adjusted to the correct position, in order to fix the trocar on it. The sterilized ablation device was plugged in the robot head and the introduction procedure was performed (see figure 11). Due to a minor design error, interference between the trocar and the device damaged the silicone cap placed at the umbrella base, leading to a saline solution leakage into the ablation device mechanism. In spite of this failure, the procedure continued without any consequences for the sheep. The umbrella was deployed successfully and moved inside the left atrium.

⁶Université Libre de Bruxelles, Belgium : director Prof J.L. Vincent *MD, PhD*

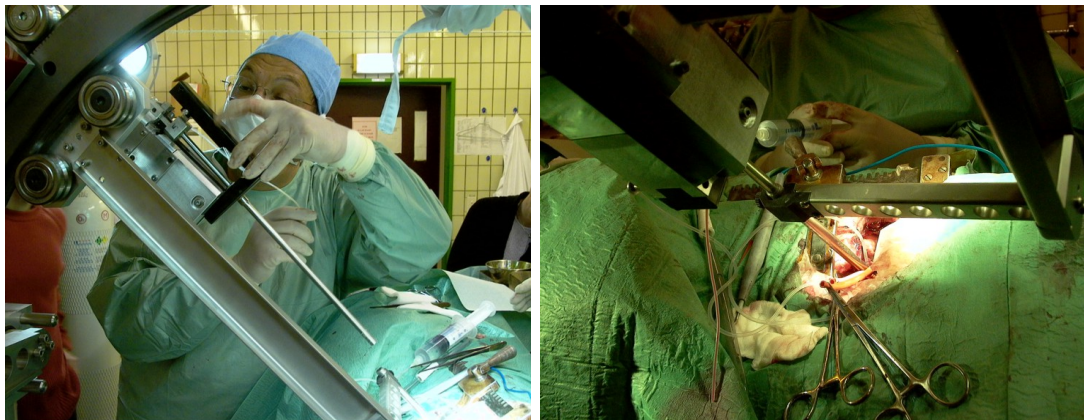


Figure 11: in vivo tests: instrument unplugged (left), umbrella deployed in the atrium (right).

Transoesophageal ultrasound images were acquired. It was difficult to localize the umbrella and anatomical landmarks with the poor image quality provided by the echograph. This appeared to be due to variation between sheep and human anatomy. This problem prevented us from positioning the instrument in relation to the anatomical landmarks, and hence performing any RF ablation. At this point, further testing of navigation tasks were postponed to the next set of animal trials.

According to the surgical protocol, the instrument was removed, in a open heart procedure (after the animal sacrifice). Some fibrin deposit could be found in the instrument's surface. During the procedure, the sheep remained clinically stable, under general anesthesia for more than 2 hours. These first tests showed that the instrument can be safely introduced in a beating and stabilized left atrium.

4.2 Perspectives

The tests showed that the ablation device and the robot are mechanically validated. Some minor design changes are required to avoid interference and leakages. The design of the new umbrella, with a forced closed loop cooling system, need to be carried out. Some extra tests are also needed to define if there is a coagulating effect on the surface of the instrument.

5 Conclusion

This new robotic instrument for Beating Heart Atrial Fibrillation Treatment should open a new approach to surgical intervention. With reduced invasivity this method should offer to the surgeon the possibility of using an original instrument specially designed for making ablation lines in the left atrium. Because of its specific purpose, the instrument is positioned and activated by a robot, able to control precisely the pathways desired by the surgeon.

The development of the instrument is in progress. At this time, the first in vitro and in vivo functional tests have been performed. These tests validated the technological choices made for the umbrella itself and for the peripheral elements used to introduce, to orient and to cool the electrode mesh. Minor engineering reviews are in progress. Later, some extra in vivo and in vitro will be performed, in order to validate the integration of the entire system. A less invasive procedure using thoracoscopy must be studied in order to avoid the left thoracotomy.

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