A Tubular Electrode for Radiofrequency Ablation Therapy

Carlos L. Antunes, MIEEE, Tony R. Almeida, Nélia Raposeiro, Belarmino Gonçalves, Paulo Almeida, André Antunes

Abstract—In the last two decades radiofrequency ablation (RFA) has been considered a promising medical procedure for the treatment of primary and secondary malignancies. However, the needle-based electrodes so far developed for this kind of treatment are not suitable for the thermal ablation of tumors located in hollow organs like esophagus, colon or bile duct. In this work a tubular electrode solution is presented. Numerical and experimental analyses were performed to characterize the volume of the lesion induced. Results show that this kind of electrode is a feasible solution and numerical simulation might provide a tool for planning RFA procedure with some accuracy.

Keywords—3D modeling, cancer, medical therapy, radiofrequency ablation.

I. INTRODUCTION

CANCER is the world's second biggest killer after cardiovascular diseases, responsible for 7.6 million deaths in 2008. For 2010, the International Agency for Research on Cancer (IARC) estimated about 8 million deaths and 12.7 million new cases of cancer will be diagnosed. These numbers are expected to increase to 13 million deaths and 21.4 million new cases in 2030 [1].

Several types of cancer are unfortunately diagnosed on an advanced stage and only palliative cares can be considered. On cancer diagnosis like cholangiocarcinoma, esophageal cancer and colorectal cancer, the use of self-expanding metallic stents (SEMS) is an effective option for stricture problems of the hollow organ and so for improving quality of life [2-4].

A stent is a hollow metal expandable endoprosthesis,

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C. L. Antunes is with the Department of Electrical Engineering and Computer Science, University of Coimbra, 3030-290 Coimbra PORTUGAL. He is also with RIANDA Research – Centro de Investigação em Energia, Saúde e Ambiente, 3030-281 Coimbra PORTUGAL (phone: +351 239 780 237; e-mail: lemos.antunes@apdee.org).

T. R. Almeida is with the Department of Electrical Engineering and Computer Science, University of Coimbra, 3030-290 Coimbra PORTUGAL (e-mail: tony@deec.uc.pt).

N. Raposeiro is with RIANDA Research – Centro de Investigação em Energia, Saúde e Ambiente, 3030-281 Coimbra PORTUGAL.

B. Gonçalves is with Hospitais Universitários de Coimbra, Coimbra, PORTUGAL.

P. Almeida is with Hospital de Santo André, Leiria, PORTUGAL.

A. Antunes is with KAUST, SAUDI ARABIA.

usually made from nitinol (nickel-titanium alloy), steel or even chrome and cobalt alloys. Among all these types of alloys, nitinol stents present some good mechanical and biocompatibility characteristics [5, 6] turning this kind of stents into a popular endoprosthesis.

In the last decades, radiofrequency (RF) energy has been increasingly used as an alternative method for minimally invasive therapy for the treatment of primary and secondary malignancies [7, 8] and several electrode solutions have been developed attempting to heat a larger and regular volume of tissue [9]. However, all these electrodes are basically needle-based electrodes and they might not be adequate for the treatment of tumors located in hollow organs.

As nitinol stents can be used to reduce stricture problems of duct organs, these can be considered as potential electrodes for hyperthermia treatments [10].

In this paper it is intended to study the feasibility of using a stent for radiofrequency treatment of tumors. Characterization of the lesion volume induced with this kind of electrode was studied taking into account the voltage applied, the time and the geometry of the electrode itself, particularly its mesh density.

II. EXPERIMENTAL WORK

A. Preliminary Work

Preliminary work was performed to verify if it was possible to heat biological tissue with a tubular electrode. There were used samples of porcine liver and bovine liver that were acquired from a local butcher. For each liver sample, a hole was made in which the electrode was placed.



Fig. 1 Single wire soldered at a stent

Three different electrodes were used: a simple copper tube with a diameter of 12 mm and a length of 30 mm, and two nitinol stents, one with the same dimensions of the copper tube and another with a diameter of 8 mm and a length of 40 mm. The electrodes were connected to a ValleyLab

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radiofrequency generator [11] through a single wired, welded at a single point of the electrode (Fig. 1). For each trial the electrode was placed in the hole made in the each liver, and the liver sample was placed on a return electrode pad.

Three resistances temperature detectors (RTD) were used as temperature sensors. They were placed 1 cm apart from each other and away from the stent. The first temperature sensor was placed 1 cm away from the stent. The RTDs were connected to a National Instruments NI-USB-9219 acquisition board. Data was recorded and saved on a laptop using LabVIEW Signal Express software. Also values of voltage, current, power and impedance values measured by the RF generator were recorded. Fig. 2 presents one of the typical setups used along the experimental test performed.



Fig. 2 Typical setup used in the experimental procedures~



Fig. 3 (a) forceps; (b) detail of the electrical connection

B. Alternative Electrical Wiring for the Electrode

To avoid the use of a soldered wire in later experiments, an alternative electrical connection was later considered. In the following experimental procedures, the electrode was connected to the RF power generator through a BI-PAL endoscopic biopsy forceps (Cordis, NJ, USA). It consists of a 3-pull ring handle, stainless steel cutting jaws, and a coiled shaft. A wired was soldered to the forceps' shaft, which is electrically connected to the jaws. This way the electrode can be put on place, using then the forceps' jaws to connect the electrode.

C. Ex-Vivo Lesion Volume Size Characterization

For the characterization of the lesion volume size using this stent-based electrode it was considered a Boston Scientific biliar stent with a diameter of 10 mm and a length of 40 mm. The stent was placed in the liver and it was connected to the RF generator through a BI-PAL endoscopic biopsy.

Experimental work was performed on bovine livers collected at a local slaughter house, approximately two hours after abating the animals. In each liver a vertical hole with 8-9 mm of diameter was made in the center of it for placing the

electrode.

Two return electrode pads were placed at each end side of the liver so the current distribution around the electrode was as much symmetric as possible. The remaining setup consisted on the same setup used for the preliminary work.

There were performed RF ablation procedures for 5, 10 and 15 minutes, using an output voltage of 25, 50, 75 and 100V. After each procedure, the liver was cross sectioned and the lesion induced was measured. No histological examination was involved but visual observation

D. Electrical Conductivity Measurement

In order to obtain a numerical model that approaches the experimental setup considered in this work, the electrical conductivity of the livers used in the experimental procedures was measured. The measurements were performed with a four electrode probe. The electrodes were made of silver wire with a diameter of 0.4 mm, coated with AgCl to reduce artifacts. The electrodes were placed in a straight line with a 1.5 mm distance between. The two outer electrodes were used to inject current in the tissue and they were connected to a current-to-voltage amp-op circuit. The inner electrodes, that were used to measure the voltage, were connected to an instrumentation amplifier. The outputs of both amplifier circuits were read using a Tektronics TDS 1002 oscilloscope for this matter.

There were performed 2 to 5 measurements in 5 to 10 points in each liver. The frequency considered was 470 kHz which corresponds to the output voltage frequency of the RF power generator.



Fig. 4 Four-electrode prove

III. NUMERICAL MODELING

A. Description of the Theoretical Model

The problem studied in this work corresponds to the analysis of a thermoelectrical coupled field problem. At each point of the biological tissue the temperature can be expressed as [12]

$$\partial c \frac{\partial T}{\partial t} = \nabla \cdot k \nabla T + \boldsymbol{J} \cdot \boldsymbol{E} - h_b (T - T_b) - Q_m$$
(1)

where ρ is the mass density (kg/m³), *c* is the specific heat (J/kg·K), *T* is the temperature (K), *T_b* is the blood temperature (K), *k* is the thermal conductivity (W/m·K), *J* is the current density (A/m), *E* is the electric field intensity (V/m), *Q_m* is the energy due to metabolic process (W/m³) and *h_b* is the blood perfusion convective heat transfer coefficient.

The simulations were performed considering that there was no blood perfusion, so the term $h_b(T-T_b)$ was disregarded.

Also the term Q_m can be neglected because the heat generated by the metabolism of the tissue is very small compared with the energy deposition delivered by the electrode, $J \cdot E$. Eq. (1) can be simplified and rewritten as

$$\rho c \frac{\partial T}{\partial t} = \nabla \cdot k \nabla T + \mathbf{J} \cdot \mathbf{E}$$
⁽²⁾

The term J-E in (2) corresponds to energy due to Joule loss. At RF frequencies the quasi-static approximation can be considered and the biological tissue can be regarded as resistive material [13]. In this case, when a RF voltage is applied between the stent and the return pad, the resulting voltage through the domain obeys Laplace's equation:

$$\nabla \cdot \sigma \nabla V = 0 \tag{3}$$

where σ is the electrical conductivity (S/m) and V is the electric potential [V].

During the resolution of the thermoelectrical coupled field problem, equation (3) is evaluated in order to determine the distributed heat source $J \cdot E$ in (2). Then temperature distribution in the tissue is calculated. Finally the electrical conductivity is recalculated in order to go back to (3).

For solving every numerical model it was used the solver PARDISO implemented in the finite element software COMSOL Multiphysics (COMSOL, Inc. Burlington, MA, USA). It was used a computer with a Intel Core 2 Quad CPU @ 2.34Ghz, with 8Gb of RAM, on a 64 bits platform.

B. Model Geometry for Characterization of Lesion Volume Size

The geometry used for the numerical computation of the RF ablation procedure for characterize the volume of the induced lesion was based on average dimensions of the experimental setups.



Fig. 5 Representation of the 3D model created for numerical analysis

A cylindrical model of 100 mm radius and 80 mm height was created for representing the liver tissue. At the center a second cylinder of radius 5 mm and height of 55 mm represents the hollow. The electrode is place at the bottom of the hole and its dimensions are 40 mm length and 10 mm diameter. The stent is made from 24 nitinol wires with 0.25 mm diameter. Each wire is a helix with a pitch of 25 mm. Twelve of the helices are clockwise and the others are counter-clockwise. Attending to the symmetry of the problem, only a quarter of model was created (Fig. 5). The whole model have a total of 184 117 tetrahedra.

A constant voltage was applied to the stent during all RF ablation procedure. It was considered voltage values of 25, 50, 75 and 100 V applied during 5, 10 and 15 minutes. The bottom and the sides of the larger cylinder are considered at zero volts (return electrode pad).

MATERIAL PROPERTIES USED IN SIMULATION [14]					
Element	Material	$\rho [\text{kg/m}^3]$	<i>c</i> [J/kg·K];	<i>k</i> [W/m·K]	σ[S/m]
Electrode	Nitinol	6450	840	18	1.10^{8}
Hole	Air	1.202	1	0.025	0
Tissue	Liver	1060	3600	0.512	$\sigma(T)$

Table I presents the material properties used in this model [14]. The electrical conductivity of the tissue was considered temperature-dependent and simulation was performed considering temperature coefficient of 2%/°C. When temperature reaches 100°C, electrical conductivity abruptly drops. By this way it is possible to simulate the electrical insulation verified when gas forms at this temperature value [15].

Dirichlet boundary conditions for the temperature were set to 22°C for the surfaces away from the active electrode, except for the bottom plane, considered as a thermal insulator surface. The initial temperature of the tissue was set to 25°C.

C.Effect of the Geometry of the Stent on the Temperature Distribution

It was also intended in this work to perform an analysis of the influence of the stent geometry on the volume size of the lesion induced.



Fig. 6 Model representation of stents with different number of helices, varying from 4 to 24 helices

All the considerations presented in the previous section concerning the description of the model are the same, except for the SMES electrode. Again, the electrode is a stent of 40 mm length and 10 mm diameter made from nitinol wire with 0.25 mm diameter. The stent was modeled considering a set of 4, 8, 12, 16, 20 and 24 helices with a pitch of 25 mm. The helices were placed symmetrically, half of them right-handed and the other half left-handed.

Once again, only a quarter of the model was considered attending to the symmetry of the problem. The number of elements varied from 54 050 tetrahedra, for the 4 helices stent geometry, to 184 117 tetrahedra, for the 24 helices stent geometry. The number of elements grows almost linearly as the number of helices increases.

D. Determination of the lesion size

For biological tissues, thermal injury begins around 42°C, depending on the type of tissue considered. When temperature reaches 42-45°C cells become more susceptible to damage, inducing progressive cellular degeneration, considering a time window of 3 to 50 hours. As temperature increases, the time necessary for irreversible cellular damage abridges significantly and, for 50-52°C, citotoxicity can be achieved in 4 to 6 minutes. Above 60°C protein coagulation can be attained almost instantaneously, damaging key cytosolic and mitochondrial enzymes, as well as nucleic acid–histone protein complexes, resulting in cellular death [9, 16].

In this work it was intended to evaluate the dimension size after an RF ablation for 5, 10 and 15 minutes. Lesion size was defined as the region having a temperature above a temperature threshold at the end of each simulation. It was considered a temperature threshold of 50°C. There were measured the maximum height and radius of the lesion obtained at the end of each time period and the volume lesion was approximated to a cylinder.

IV. RESULTS

A. Initial Experimental Results

From the preliminary work it was observed that it was possible to achieve an effective tissue heating with this kind of electrode. Using a RF power generator conceived for conventional RF ablation, it was possible to achieve tissue damage using a simple copper tube as well as using a nitinol stens (Fig. 7).



(a) (b) Fig. 7 Lesion induced on liver (a) using a copper tube; (b) using a stent

Also, it was observed that the BI-PAL forceps can be used as electrical connector between the stent and the RF power generator. The tissue was again heated and destroyed in a regular way. Experimental results show that even for high power conditions the forceps did not present any kind of damage at the end of the experiments. It could even be reused after a large number of trials.

B. Characterization of the Volume Lesion

During experimental work there were made nearly 500 electrical conductivity measurements of the liver samples used. From this data it was obtained an average value of 0.13 ± 0.06 S/m.

During each experimental RF ablation procedure it was observed that electrical current supplied by the RF power generator increased with time while the electrical impedance measured by the RF generator drops. Fig. 8 shows the evolution of the current for an applied voltage of 75 V during 10 minutes. It can be observed that the electrical current increased during all the procedure, fact that was verified in every experimental setup. An exception occurs for an applied voltage of 100 V. In this case the RF generator reaches its maximum current output of 2 A. Also, at 100 V the electrical impedance inverts its decrease tendency above 10 minutes, sometimes leading to the shutdown of the power generator when its 999 Ω security threshold is exceeded. This is due to the carbonization of the tissue next to the electrode which induces its electrical insulation.



Fig. 8 Current measured by the RF power generator for an applied voltage of 75 V during 10 minutes



Fig. 9 (a) Tissue after 15 minutes at 25 V; (b) Tissue damage after 15 minutes at 75 V

As soon as a voltage is applied, the temperature of the tissue starts to rise. Obviously the maximum temperature achieved will depend on the time of the procedure and on the applied voltage. However, independently of the time considered, no lesion was induced in the tissue for an applied voltage of 25 V. It is shown in Fig. 9 (a) the result of a RF ablation procedure after 15 minutes at 25 V. Inspection shows that no lesion was induced in the tissue next to the electrode. On the other hand, in Fig. 9 (b) is visible the lesion induced in the tissue for an applied voltage of 75 V during 15 minutes.

Fig. 10 displays the averaged maximum temperature values measured one and two centimeters away from the stent after 5, 10 and 15 minutes. Considering a threshold of 50°C from which tissue damage can be induced, it can be verified that this threshold is hardly exceeded at 2 cm from the electrode after 5 minutes for any applied voltage.

From an applied voltage of 50 V lesion can be induced in the tissue, although the limit of lesion obtained at this voltage is somewhat unclear. It is shown in Fig. 11 the lesion induced in the biological tissue for an applied voltage of 50 V. After 5 minutes - Fig. 11 (a) – it is clear that the lesion obtained is hardly distinguished. However, as time increases the lesion becomes clearer. For 75 and 100 V the lesions induced are sharper and well delimited.



Fig. 10 Averaged maximum temperatures obtained 1 and 2 cm away from the electrode after (a) 5 minutes; (b) 10 minutes; and (c) 15 minutes.



Fig. 11 Lesion induced for an applied voltage of 50 V after (a) 5 minutes; (b) 10 minutes; and (c) 15 minutes

After each RF ablation procedure, the liver was cross sectioned and the height and the maximum width of the lesion induced were measured. The volume of the lesion was calculated and approximated to a cylindrical volume. Fig. 12 shows the average volume obtained considering the voltage applied and the time of the procedure (experimental results in solid line). As expected, a bigger lesion is obtained considering larger values of voltage and/or time. For 100 V it is possible to observe that the lesion volume does not significantly change in size after 10 minutes.

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Fig. 12 Cylindrical volume approximation of the lesion induced in the tissue. Numerical and experimental results.



Fig. 13 Maximum temperature after 15 minutes at 25 V.

Also in Fig. 12 are shown the results obtained by numerical simulation. No results are presented for an applied voltage of 25 V because, even after 15 minutes, the temperature of the tissue never reached 50°C so no lesion is induced in the tissue.

The volume of the lesion obtained by analysis of the numerical results almost agrees with measurements made after experimental procedure. However these results diverge for an applied voltage of 100 V, for which the volume obtained with numerical simulation after 5 and 10 minutes is considerable larger than the volume obtained experimentally. After 15 minutes, volumes obtained numerically and experimentally are close.

C. Effect of the Geometry of the Stent

Similar to the results of the last section, and considering a temperature threshold of 50°C, it was verified that for an applied voltage of 25 V it was not achieved any lesion even after 15 minutes, no matter how many helices the electrode had. Fig. 13 shows the maximum temperature obtained for each model, after 15 minutes. In any of the geometries considered the temperature exceeds the temperature threshold, reducing any chances of inducing a lesion.

From 50 V all results exceed the temperature threshold of 50°C. For a voltage of 50 V the geometries with less number of helices present an irregular volume of the lesion. This volume becomes regular as the number of helices increases

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and/or the time increases. Fig. 14 shows the results obtained for a four helices stent for an applied voltage of 50 V after 5 and 10 minutes. Similar results are presented for a 24 helices stent at 75 V in Fig. 15.

Considering the volume lesion obtained, the lesion volume induced with a 4 helices stent corresponds to the smallest volume achieved, independently of time and/or voltage applied. Increasing the number of helices leads to a bigger lesion volume. It is shown in Fig. 16 how the lesion volume increases with time and with the number of helices at 75 V. It can be noticed that increasing the number of helices leads to a minor volume increase.



Fig. 14 Volume delimited by a 50°C isothermal using a 4 helices stent for an applied voltage of 50 V after (a) 5 minutes; and (b) 15 minutes



Fig. 15 Volume delimited by a 50°C isothermal using a 24 helices stent for an applied voltage of 50 V after (a) 5 minutes; and (b) 15 minutes



Fig. 16 Lesion volume obtained for each stent model after 5, 10 and 15 minutes at 75 V

V.CONCLUSION

Self-expandable mechanical stents can be regarded as potential electrode for performing RF ablation therapy on tumors located in hollow organs. In this work numerical and experimental analyses were performed in order to characterize the lesion volume induced in biological tissue using this kind of tubular electrode.

Results show that it is possible to achieve a regular lesion around the electrode. Also, the volume of damaged tissue obtained can be considerable large which means precautions have to be taken in order not to injure the duct organ involved. Results obtained through numerical simulations are very close to those obtained with experimentation, providing this way an important tool to predict the dimension that might be obtained and in order to plan a RF ablation procedure.

It was observed that the electrode geometry has a significant impact on the lesion volume created. A higher stent density mesh, achieved using a larger number of helices, leads to a larger and more regular lesion. Commercial stents solutions are available that follow the geometries expressed in this work and therefore they can be used as a part of a RF ablation procedure considering minor modifications.

Temperature dependence of thermal properties of the tissue was not considered in this work due to the lack of data on this subject. Thus, this limitation of our model may lead to some inaccurate results, particularly for an applied voltage of 100 V. In this case, the rapidly temperature increase near the electrode may affect significantly the thermal and even the electrical properties of the tissue, which might explain the divergence between numerical and experimental results. However, considering the fragility of the hollow organs that undergo RF ablation procedure and the power that is delivered at 100 V, this voltage certainly will be hardly considered.

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