A Preliminary Numerical Thermal Analysis of an Endometrial Ablation Procedure Based on Foley's Catheter

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Abstract. Dysfunctional uterine bleeding (DUB) is a condition experienced by many women and is considered to be an important health issue. Over the years, many medical strategies were developed to tackle this issue and one of the most successful is the thermal balloon ablation system. In this treatment, a device is inserted in the uterine cavity of the patient and an ablation of the endometrium is achieved by a controlled thermal injury through a constant temperature intraballoon fluid. At about the same time, the medical community in low-level resources countries conceived a similar alternative to this therapy which employs a Foley's catheter filled with a saline solution but without the heating element controlling the fluid temperature. Accordingly, the purpose of this contribution is to assess the effectiveness of this alternative treatment by means of a mathematical model that predicts both the temperature of the saline solution and the uterine wall. These equations are solved utilizing the finite volume method and the numerical predictions are obtained for situations reported in the medical literature. The simulations indicate that the proposed treatment can indeed be a successful alternative to the standard ablation process under some viable circumstances which are discussed in the contribution.

Keywords: bioheat transfer, endometrial ablation, finite volume method, temperature distribution, Foley's catheter.

1 Introduction

Dysfunctional uterine bleeding (DUB) is a disorder affecting a substantial number of women during a significant part of their reproductive years. This condition usually leads to discomfort, mild or severe pain, or, in some extreme cases, anemia. It may be caused by diverse factors such as hormonal issues, structural abnormalities, or even cancer in a woman's reproductive tract. A typical DUB treatment requires a pharmacological approach through the prescription of drugs. Nonetheless, some patients are in need of a more involved treatment, and various strategies have been devised during the last 50 years to handle this important health issue. Until the late-1970, the common practice in dealing with menorrhagia usually involved hormonal treatments or, in the most severe cases hysterectomy, which is the complete removal of the uterus. However, during the early 1980's, the first generation of endometrial ablation techniques came into common clinical practice. One of the main features of this treatment is that it called for a direct visualization of the endometrial cavity and the ablation process was achieved by a neodymium-YAG laser coupled to a hysteroscope. The high cost of the equipment and the long learning curve for the medical staff to acquire the necessary expertise to properly conduct the task are often cited as obstacles to the widespread use of this therapy, Pados et al. [1]

Shortly afterwards, during the 1990's, the second-generation endometrial ablation technique becomes commercially available. In contrast with the previous strategy, it does not require a visual inspection of the uterus, and the process was reputed to be simpler. Thus, the path towards obtaining satisfactory skills to successfully perform the treatment was strongly reduced. The apparatus consists of a catheter having a diameter of about 4 to

10 mm and a length up to 16 cm, a silicone balloon, and a control unit. Once the deflated balloon is inserted in the uterine cavity, a typical 10 ml volume of fluid is pumped in while the control unit maintains the solution heated up to an 87℃ ± 5℃ temperature level. Various studies, such as the one of Vilos and Edris [2], present a more detailed discussion of the procedure and claim that an 8-minute treatment is very effective in drastically reducing the symptoms related to DUB.

In an effort to reduce costs, especially in countries with low medical resources, descriptions of a simplified, yet successful, method of thermal ablation of the endometrium started being reported in medical journals during the early years of the present century. It seems that Singh et al. [3] were the first to describe a procedure in which a Foley's catheter is inserted in the patient's organ and a 20 ml boiling saline solution is injected to inflate the balloon. The treatment lasts for about 9 minutes but in the absence of a controlling unit, the temperature of the fluid inside the catheter continually diminishes. In an attempt to enhance the performance of the strategy, the fluid is changed at every 3 minutes with a new fresh charge of boiling saline. The pathological findings reported in this contribution indicate that a depth of hyperemia of up to 7 mm can be achieved with a 12 ml volume of saline. Other medical reports, such as those of Patel and Leuva [4], Api and Api [5], Saadia et al. [6] and Khalil et al. [7], corroborate the view that this alternative low-cost endometrial ablation procedure is viable.

A careful literature review indicates that few researchers addressed the endometrial ablation problem from a mathematical point of view. Actually, the research of Baldwin et al. [8] appears to be the first contribution that presents a model for the constant temperature intraballoon fluid ablation procedure. Despite some of its simple assumptions, the proposed model is able to accurately predict that an 8-minute endometrial exposure to a hot fluid balloon can impose a 4 mm zone of tissue destruction as described in reports of the medical community. Another work, Presgrave et al. [9], addresses the same problem but simulates a malfunction of the thermal unit which keeps the intraballoon fluid at a constant temperature. As the procedure first described in Singh et al. [3] apparently remains unaddressed, this research aims at mathematically modelling this situation and presenting some initial results with due comparisons regarding previously published data.

2 Mathematical formulation of the problem

In order to evaluate the transient temperature field (T) of the endometrial ablation procedure through the Foley's catheter, the so-called Pennes' equation is employed. Despite its simplicity, the Pennes' model has been successfully applied in many bioheat transfer problems and it can be regarded as a standard heat diffusion equation with an extra term that takes into account the heat removal due to blood flow within the biological tissue. Accordingly, the one-dimensional, (x), temperature distribution, T(x,t), of the uterine wall is given by:

$$\rho c \frac{\partial T(x,t)}{\partial t} = \frac{\partial}{\partial x}\left[k \frac{\partial T(x,t)}{\partial x}\right] + \rho_b c_b \omega_b(\Omega)\left[T_b - T(x,t)\right] + \dot{Q}_m \qquad 0 < x < l \quad t > 0 \tag{1}$$

In the above equation, ρ_b, c_b, T_b and ω_b are, respectively, the density, specific heat, arterial temperature, and the perfusion rate of the blood. On the other hand, ρ, c, k are the density, specific heat, and thermal conductivity of the uterine tissue. Finally, it should be noted that $\dot{Q}_m$ is the rate of metabolic heat generation within the tissue while l is the thickness of the uterus wall.

The initial temperature distribution of the uterine wall, $T(x,t=0)$ is assumed to be constant and its numerical value is that of the arterial blood flow. Thus,

$$T(x,t=0) = T_b \qquad 0 \le x \le l \tag{2}$$

Next, a relation between the time-varying saline solution temperature and the heating of the uterine tissue is established as follows. The catheter and the outer surface of the patient's organ are supposed to be in perfect thermal contact and by performing an energy balance, it is found that:

$$\rho_{sal} c_{sal} Vol_{sal} \frac{dT_{sal}(t)}{dt} - kA_s \frac{\partial T(x=0,t)}{\partial x} = 0 \qquad t > 0 \tag{3}$$

where the subscript “sal” refers to quantities of interest such as density, specific mass, volume, and temperature of the saline solution. Also, A_s is the surface area of the catheter in contact with the uterine wall. The initial condition for the temperature of the saline solution, T_{sal}, is taken as:

$$T_{sal}\left(t=0\right)=T_{ini} \tag{4}$$

The perfect thermal contact between the Foley’s catheter and the uterine wall calls for:

$$T\left(x=0,t\right)=T_{sal}\left(t\right) \qquad t>0 \tag{5}$$

Finally, the boundary condition at the innermost layer of the uterus is taken to be adiabatic and consequently:

$$\frac{\partial T\left(x=l,t\right)}{\partial x}=0 \qquad t>0 \tag{6}$$

As indicated in eq.(1), the blood perfusion rate, ω, depends on the cumulative damage integral, $\Omega(x,t)$, which is a time dependent parameter evaluated at any given point inside the domain, $0 \le x \le l$. Its definition is given by:

$$\Omega\left(x,t\right)=\int_0^t Ae^{\left(-\frac{E_a}{RT(x,t)}\right)}dt \tag{7}$$

where A is the frequency factor of the kinetic expression, E_a is the activation energy for the burn reaction and R is the universal gas constant. For situations where $\Omega(x,t) < 1$, the blood perfusion rate is taken at its basal value and it is immediately set to zero once $\Omega\ (x,t) \geq 1$.

The numerical values and the respective units of the variables presented in the mathematical formulation are given in Tab. 1.

Table 1. Parameters values employed in the simulation.

Symbol	Value	Unit
k	0.56	W m^{-1} K^{-1}
c	3600	J kg^{-1} K^{-1}
ρ	1060	kg m^{-3}
$\dot{Q}_m$	0	W m^{-3}
ω_b	0.028	$m_b^3\ s^{-1}\ m^{-3}$
c_b	3500	J kg^{-1} K^{-1}
ρ_b	1080	kg m^{-3}
ρ_{sal}	1000	kg m^{-3}
c_{sal}	4184	J kg^{-1} K^{-1}
E_a	4.3 x 10^5	J mol^{-1}
A	5.6 x 10^{63}	s^{-1}
l	20	mm
T_b	37	°C
T_{ini}	87	°C

As a final remark, it should be noted that while the tissue temperature is evaluated within the context of a plane distribution, Baldwin [8], the volume of fluid in the catheter and the area of the uterine wall in contact with the balloon are taken to be spherical.

3 Results and discussions

Having established the mathematical formulation for the endometrial ablation of the uterine tissue using a Foley catheter, a numerical solution is sought through the finite volume method. Typical parameters which are needed for the evaluation of the temperature field and other quantities of practical interest such as the cumulative damage integral, are displayed in Tab.1 and are mostly taken from the contribution of Baldwin et al. [8]. It should also be mentioned that even though the rate of blood perfusion is assumed here as temperature independent, its numerical value is set to zero onwards as soon as the tissue reaches irreversible damage which is attained when Ω (x,t) reaches unity, Henriques Jr [10]. In addition, results are also simulated and explored for situations involving a null blood perfusion rate for the entire duration of the treatment. This particular case is related to the so-called "occlusion process" in which the pressure of the fluid inside the Foley's catheter is high enough to prevent any blood from circulating in the uterine wall.

Figure 1 shows the fluid temperature distribution associated with two complete changes of the saline solution at 180 s and 360 s. Moreover, three distinct fluid volumes inside the Foley catheter are displayed – 10, 15, and 20 ml. Some fairly interesting trends are perceived upon inspection of these results, which are simulated for the standard non-zero value of the blood perfusion rate. For the first cycle, the temperature of the saline solution starts with a maximum value of 87 °C, which is its imposed initial condition and immediately experiences a sharp decline through an approximately exponential fashion. The other two cycles begin at 180 s and 360 s, as recommended by the pioneering work of Singh et al. [3], and follow the same pattern just described.

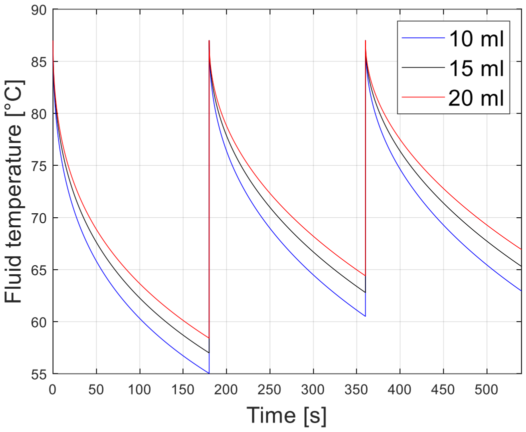

Figure 1. Saline temperature distribution for the 9-minute treatment

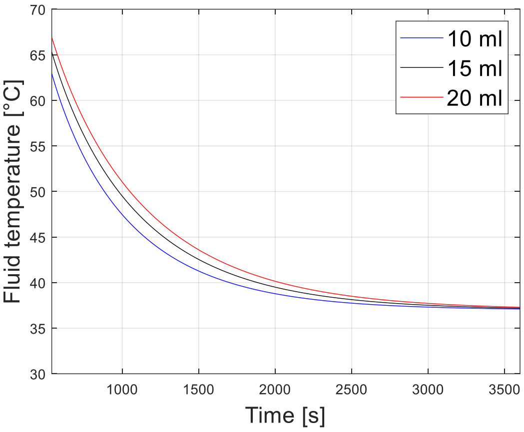

Figure 2. Saline temperature distribution after the third cycle

It is curious to notice that the fluid temperatures at the end of the first cycle are about 55.0, 57.0 °C, and 58.4 °C, which are also the temperatures of the outer layer of the uterine wall as the present formulation assumes an ideal contact between the fluid and the endometrial layer. These figures are in excellent agreement with the experimental values of Singh et al. [3] which are reported to be in the 55°C - 62°C range, suggesting that the proposed mathematical model has some merits, despite some crude simplifying assumptions. At the end of the 9-minute treatment, the simulations indicate that the temperatures of the outer endometrial layer are 62.9 °C, 65.3 °C, and 66.9 °C for catheter volumes of 10 ml, 15 ml, and 20 ml, respectively. Since these numbers are above the 55 °C threshold, which results in significant damage to the tissue, Habash et al. [11], it seems natural to investigate the temperature distribution for times beyond the end of the recommended treatment. Figure 2 addresses this issue in a situation where the Foley catheter is let to remain in contact with the uterine wall at the end of the third cycle without any fresh charge on the saline solution. As expected, the temperature declines steadily and the simulations show that it takes about 60 minutes to reach the 37°C - 37.5°C interval, which is the reported core temperature of a healthy human body.

In sequence, attention is turned to the estimation of the extent of the affected tissue by the proposed therapy. Figure 3 depicts the assessed value of the cumulative damage integral at the end of a 9-minute treatment while Fig. 4

carries the same study for the cases where the Foley's catheter is allowed to remain in contact with the patient's uterine wall until the saline solution cools down to the normal core body temperature. Two major conclusions can be drawn upon inspection of Figs. 3 and 4. The simulations indicate that there is only a meager increase in tissue damage by letting the catheter stay inside the patient's body for more than 9 minutes. Therefore, it seems to be advisable to immediately remove the catheter at the end of the third cycle to avoid the risk of an uncontrollable burn injury should the fluid inside the catheter leak. Another noticeable aspect is that the extent of the tissue affected by the 9-minute treatment, l_{dam}, lies in the 1.21mm < l_{dam} < 1.69 mm range. If one bears in mind that the reported thickness of the endometrial layer is about 1 to 4 mm, the proposed 3-cycle treatment is only fully effective in women whose endometrial layer is less than 1.7 mm. In case of need, some possible courses of action which would tend to increase l_{dam}, are working with an initial temperature of the saline solution above 87°C and/or increasing the fluid volume inside the Foley's catheter.

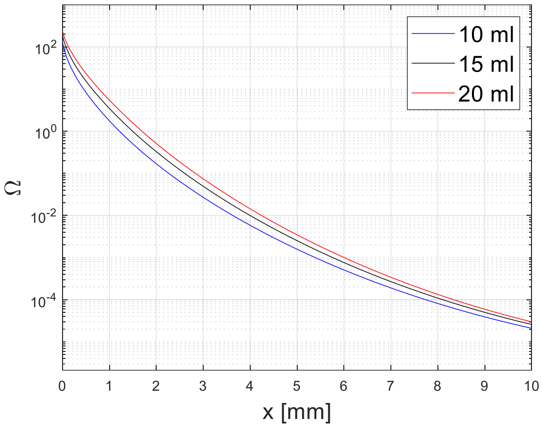

Figure 3. Cumulative integral damage along the uterine wall at the end of the 9-minute treatment

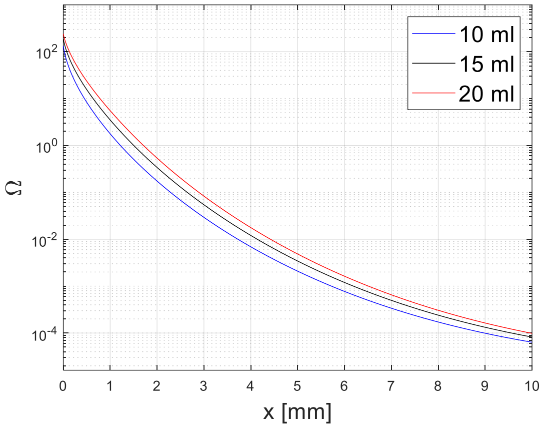

Figure 4. Cumulative integral damage along the uterine wall at the end of the 60-minute procedure

The next step is to assess the role of the rate of blood perfusion in the proposed therapy. From a mathematical point of view, this important aspect of any bioheat transfer analysis is represented by the second term on the right-hand side of eq. (1). Moreover, in this specific problem, the blood circulating inside the organ acts as a sink term dissipating heat that otherwise would contribute to elevating the temperature field of the biological tissue. Accordingly, Figs. 5 to 8 carry out the same previous study but now with the rate of blood perfusion set to zero, and these results should be perceived as an upper bound to the transient temperature distributions.

An inspection of Fig. 5 indicates that the fluid temperatures inside the Foley's catheter at the end of the first cycle are 57.7 °C, 59.5 °C, and 60.9 °C, which are only a couple of degrees higher than those reported in Fig. 1, and again lie within the 55°C - 62 °C experimental figures reported by Singh et al. [3]. At the end of the 9-minute treatment, the temperature of the saline solution attains values of 69.2°C, 71.1°C, and 72.3 °C (for volumes of 10 ml, 15 ml, and 20 ml) which are not significantly higher than their counterparts of Fig 1. However, Fig. 6 shows that at the 60-minute exposure, the outer surface of the uterine wall reaches temperature levels of 56.8°C, 58.2°C, and 59.2°C for the same set of fluid volumes. This is an indicator that, in the absence of the sink effect due to the blood perfusion, the extent of the affected tissue induced by the hot fluid inside the catheter for a given volume is more pronounced than those previously reported.

Figures 7 and 8 display the value of the cumulative damage integral at the end of the 9-minute recommended treatment and at the end of the extended 60-minute therapy for the set of the usual three volumes associated with this contribution. The trend mentioned at the end of the above paragraph can now be easily discerned. For all the three fluid volumes explored in the simulations, the length of irreversible tissue damage practically doubles in the absence of the perfusion effect reaching a figure of 3.23 mm for the case of the 20 ml volume. Should the catheter be left in contact with the patient's womb for the extended period of 60 minutes, the extent of the affected tissue is a little less than 3 mm (in the case of 10 ml volume) and may even extend beyond the 4 mm length of the endometrial layer as in the case of the 20 ml volume.

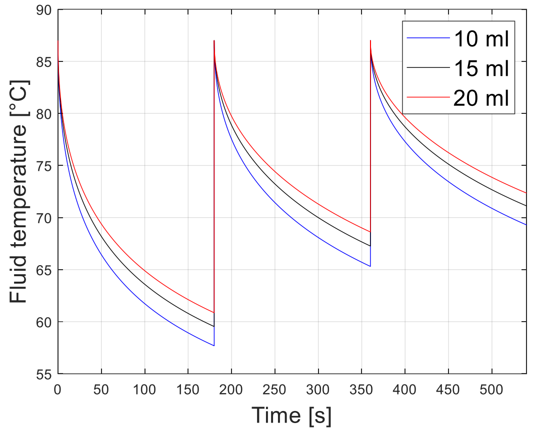

Figure 5. Saline temperature distribution for the 9-minute treatment for the case of a null perfusion

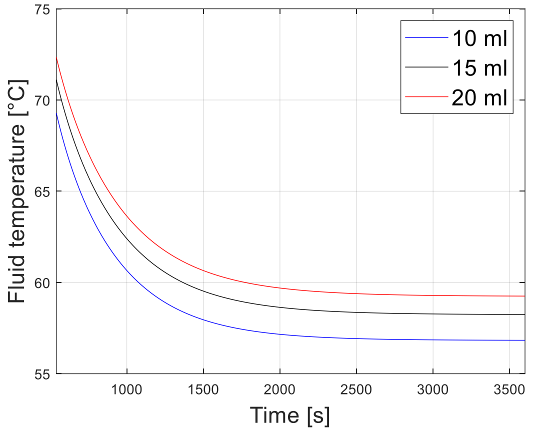

Figure 6. Saline temperature distribution after the third cycle for the case of a null perfusion

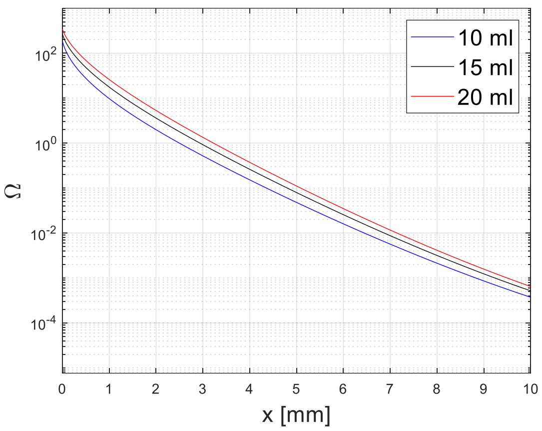

Figure 7. Cumulative integral damage along the uterine wall at the end of the 9-minute treatment for the case of a null perfusion

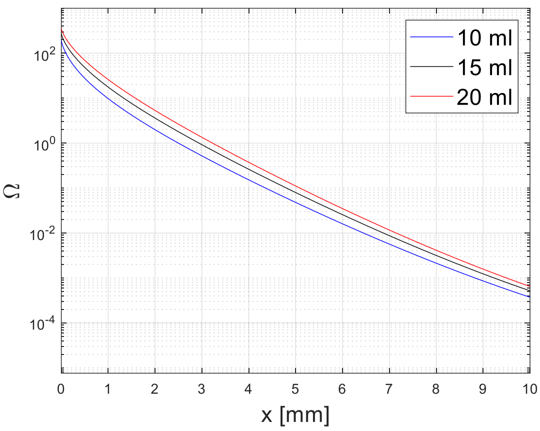

Figure 8. Cumulative integral damage along the uterine wall at the end of the 60-minute procedure for the case of a null perfusion

4 Closing remarks

One of the major purposes of this contribution is to establish a simple mathematical model for the endometrial ablation treatment when performed with a Foley catheter. The starting point is Pennes' bioheat transfer equation for the tissue temperature together with an energy balance that accounts for the natural temperature decrease of the saline solution due to the heating process of the endometrium. The model also allows for perfect thermal contact between the fluid balloon and the uterine wall together with a zero-heat flux at the end of the serosal layer. The main findings so far are summarized in Tab. 2 and as a closing comment, attention is focused on the control of the temperature at the serosal layer, T(x=20 mm, t_f), at the end of the treatment, t_f. As pointed out in the literature, Baldwin et al. [8], although there is not an incisive medical specification regarding this temperature, it is believed to be a good practice to design the endometrial ablation procedure in a such form that the serosal temperature does not exceed 42°C since this temperature level would not perform any damage to adjacent organs. An inspection of Tab. 2 reveals that for the 9-minute treatment, the serosal temperature exceeds this limiting threshold by about

2°C. However, as the mathematical model employs a perfect insulation boundary condition, the actual serosal temperature is certainly lower than those predicted by the present methodology. On the other hand, the 60-minute procedure allows for serosal temperatures well beyond the safeguard limit and this issue should be further investigated.

Table 2. Numerical values for quantities of practical interest related to the endometrial ablation through the Foley's catheter. Legend: (a) saline temperature at the end of the treatment, (b) serosal temperature at the end of the treatment, (c) length of the affected tissue, and (*) saline temperature at the end of the first cycle

$\omega_b\left[m_b^3/s/m^3_{\square}\right]$	t [min]	Case	V = 10 ml	V= 15 ml	V= 20 ml
0.028	3	(*)	55.0°C	57.0°C	58.4°C
	9	(a)	62.9°C	65.3°C	66.9°C
		(b)	39.5°C	39.7°C	39.8°C
		(c)	1.21 mm	1.49 mm	1.69 mm
	60	(a)	37.1°C	37.2°C	37.3°C
		(b)	37.0°C	37.1°C	37.1°C
		(c)	1.21 mm	1.49 mm	1.71 mm
0	3	(*)	57.7°C	59.5°C	60.9°C
	9	(a)	69.3°C	71.1°C	72.3°C
		(b)	44.0°C	44.4°C	44.6°C
		(c)	2.49 mm	2.93 mm	3.23 mm
	60	(a)	56.8°C	58.2°C	59.3°C
		(b)	56.0°C	58.2°C	59.2°C
		(c)	2.93 mm	3.73 mm	4.49 mm

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