Modelling of an Innovative Directional Ultrasonic Atherosclerosis Treatment Device

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Introduction

Atherosclerosis prevalence keeps increasing worldwide because of the sedentary lifestyle and aging of the population. It is a pathology which is characterized by the build-up of plaque on the artery walls. While it has no incidence at the beginning, the blood flow can be severely altered in the most advanced cases. Atherosclerosis can lead to lethal consequences.

Several methods can be used to allow for a normal blood flow recovery; they are known as angioplasty. Whereas some of them rely on the flattening of the plaque, many atheroscleroses require to be properly removed. The removal can be made by different methods including ultrasonic waves.

The present article introduces a modelling of the latter method and focuses on the generation of the ultrasonic waves which produces cavitation. Whereas existing angioplasty ultrasonic devices producing cavitation have a single degree of freedom and generate a cavitation field only in one direction, the present device is driven not by only one piezoelectric actuator but by three independent piezoelectric actuators. Therefore, the generated cavitation field can be oriented and focused on specific areas of the artery wall and better target the plaque.

The model includes a coupling between the ultrasonic tip mechanical movement and the acoustical behaviour of the aqueous environment surrounding the tip. The acoustical field allows for a precise prediction of the cavitation generation and the Rayleigh-Plesset equation provides predictions of the bubble's dynamic.

Thanks to the simulation results, a proof of concept was established, and the directional abilities of the device have been optimised.

Theory

Ultrasonic atherosclerosis treatments devices are already used, and they function in an aqueous environment. They are made of one piezoelectric actuator which imposes structural mechanical waves to a wire that is guided by a sheath towards typically a $1\,mm$ radius spherical tip. The tip then moves periodically at the frequency of the actuator. The device discussed in this publication (Figure 1) is different from traditional solutions in that several piezoelectric actuators (not represented) act together on the tip. As the tip is immersed in an aqueous solution, the liquid near the tip propagates ultrasonic waves. The pressure field generates gaseous bubbles which are called cavitation bubbles: these bubbles release a very high density of energy locally while bursting. And finally, this energy density disintegrates the plaque. The new proposed design permits to control the orientation of the pressure field and to focus the cavitation bubbles in targeted directions.

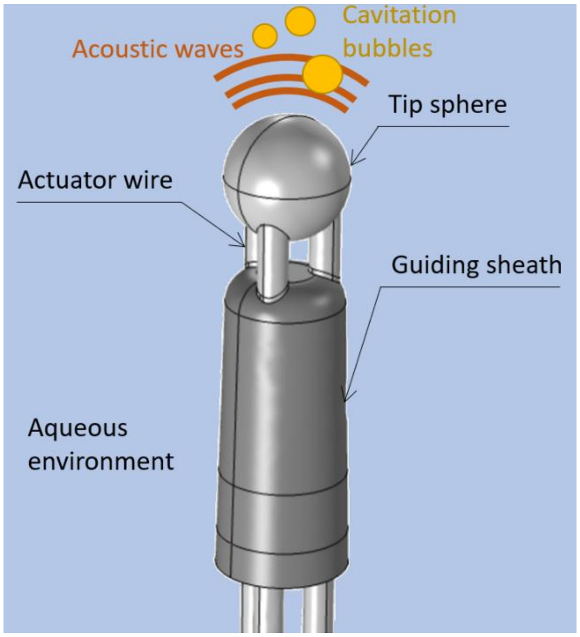

Figure 1 - Ultrasonic device tip and wires

Governing Equations

To model the behaviour of the device and the aqueous environment, different physics must be coupled:

a) Solids deformation

The solids deformations in the wires and the tip are considered. The displacement field $\boldsymbol{u} = \{u, v, w\}$ is computed:

$$\rho\omega^2\mathbf{u} + \nabla \cdot \boldsymbol{\sigma} = 0$$

with ρ the solid density, ω the pulsation, $\boldsymbol{\sigma} = \boldsymbol{C}(E,\nu) \cdot \boldsymbol{\varepsilon}$, $\boldsymbol{\varepsilon} = \frac{1}{2}(\nabla\boldsymbol{u} + \nabla\boldsymbol{u}^T)$ and with E and ν respectively Young's modulus and Poisson's ratio of the material.

The domain and boundary conditions are defined as specified in **Figure 2**.

The solid deformations are solved in the frequential domain.

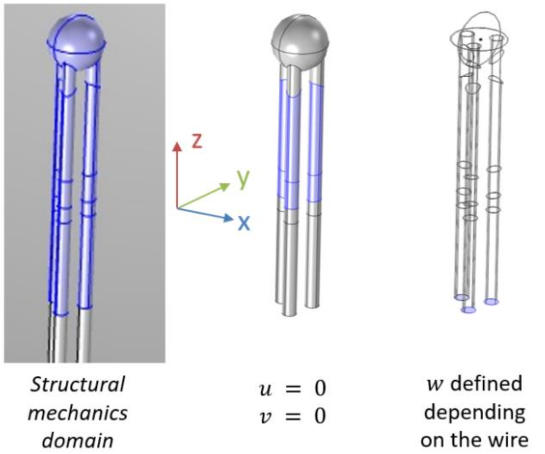

Figure 2 - Structural mechanics domain (purple, left) and boundary conditions (purple, centre and right)

b) Pressure acoustics

The fluid behaviour is represented according to the following equation:

$$\nabla \cdot \left(-\frac{1}{\rho_c}\nabla p_t\right) - \frac{k_{eq}^2 p_t}{\rho_c} = Q_m$$

with ρ_c the liquid density, p_t the total pressure, $k_{eq}^2 = \omega^2/c^2$, ω the pulsation, c the speed of sound in the domain and Q_m a custom made monopole domain source applied at the vicinity of the domain boundary to absorb the waves and model an infinite domain. The domain and boundary conditions are defined as specified in **Figure 3**.

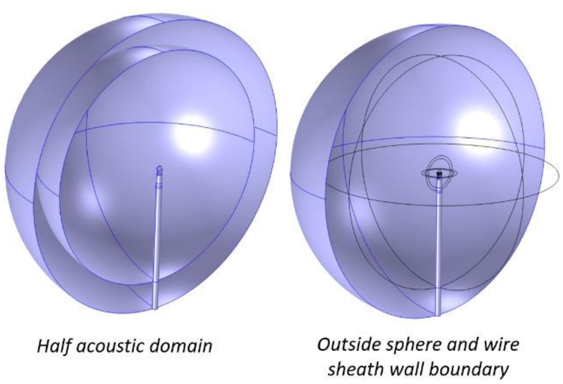

Figure 3 - Domain and boundary condition of the acoustic domain

Besides, the sphere tip and the end of the wire are immersed in the aqueous solution. The tip moves fast within the liquid and therefore a weak coupling is applied:

$$-\boldsymbol{n} \cdot \left(-\frac{1}{\rho_c}\nabla p_t\right) = -\boldsymbol{n} \cdot \boldsymbol{a_0}$$

with $\boldsymbol{n}$ the normal outer vector and $\boldsymbol{a_0} = (\ddot{u} \quad \ddot{v} \quad \ddot{w})$ the acceleration of the tip and wire immersed in the liquid (see boundary in **Figure 4**) .

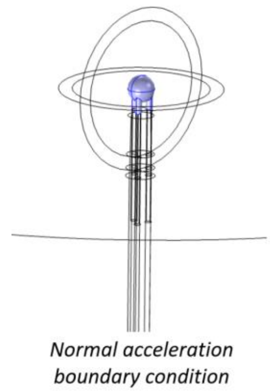

Figure 4 - Coupling between the structural mechanics displacement and the acoustic domain

The pressure acoustics is solved in the frequential domain.

c) Bubble dynamic

While the acoustic pressure of the fluid is driven by the tip, it generates the condition for cavitation to appear. Cavitation occurs when the bonding forces within a liquid are not able to withstand the traction forces applied by low pressure. Then, a small bubble is locally created, and its growth or reduction can be very sudden. It is the environment pressure that will lead it to radius changes. The Rayleigh-Plesset ordinary differential equation[1] has been selected in this study to describe the dimension variation of the bubbles in the vicinity of the tip:

$$R\ddot{R} + \frac{3}{2}\dot{R}^2 = \frac{1}{\rho_c}\left[\left(p_0 + \frac{2\sigma}{R_0}\right)\left(\frac{R_0}{R}\right)^{3k} - \frac{2\sigma}{R} - \frac{4\mu\dot{R}}{R} - p_\infty(t)\right]$$

with $k = C_p/C_v$, R_0 the bubble radius under standard condition of temperature and pressure, σ the surface tension, μ the liquid viscosity, p_0 the ambient pressure and p_∞ the pressure imposed by the acoustic pressure field far from the bubble.

This equation is applied everywhere in the liquid and it is solved in the time domain over several cycles of the tip dynamic.

d) Coupling

A one way coupling is applied between the different physics (see Figure 5). The structural mechanics imposes an acceleration to the fluid at the boundary between solid and liquid domains. In its turn, the pressure of the fluid is the driving force of the bubble dynamic.

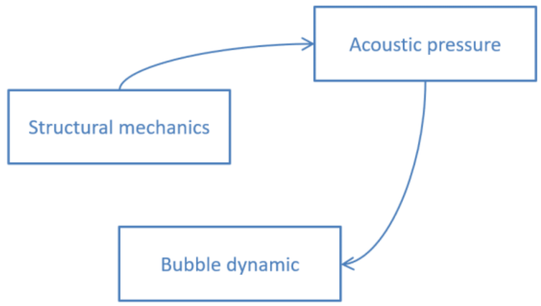

Figure 5 - Multiphysics coupling

Constitutive relations

At this stage of the model development, constant material properties over the working conditions are relevant:

a) Solid

The wires and the tip in the model described are made of titanium. This metal is relevant for medical applications because of its biocompatibility:

Property	Symbol	Value	Unit
Density	ρ	4940	kg/m^3
Young's modulus	E	105	GPa
Poisson's ratio	ν	0.33	$-$

Table 1 - Solid properties

b) Liquid

In this study the liquid surrounding the tip is an aqueous solution with the following properties:

Property	Symbol	Value	Unit
Density	ρ_c	1000	kg/m^3
Viscosity	μ	0.001	$Pa \cdot s$
Speed of sound	c	1481	m/s
Water/water vapor surface tension	σ	0.07	N/m
Heat capacity at constant pressure	C_p	2010	$J/(kg \cdot K)$
Heat capacity at constant volume	C_v	1578	$J/(kg \cdot K)$

Table 2 - Liquid properties

Solving method

The method used here is composed of two steps. At first, the structural mechanics is solved with the acoustic pressure in the frequential domain. Then the pressure field calculated is used as a source term for the bubble dynamic. The latter is solved in the time domain.

Results and discussion

Different study cases are developed in this study. One of them is an experimental validation case, whereas the others are test cases to evaluate the ability of the device to generate a directional ultrasonic pressure field.

a) Experimental validation case

Wesley L. Nyborg[2] has presented an experimental result at $f = 30\ kHz$ which is the typical operating condition for the device. This case is a single wire, which describes a piston motion. The amplitude of the motion imposed to the sphere is 50 μm and the tip has the same radius of 1 mm than the present device. The observed maximum pressure at the top of the tip is 9 atm.

Under the same conditions, the pressure field at the tip predicted by the model is 9.5 atm (see **Figure 6**). This shows the relevance of the present model about pressure prediction.

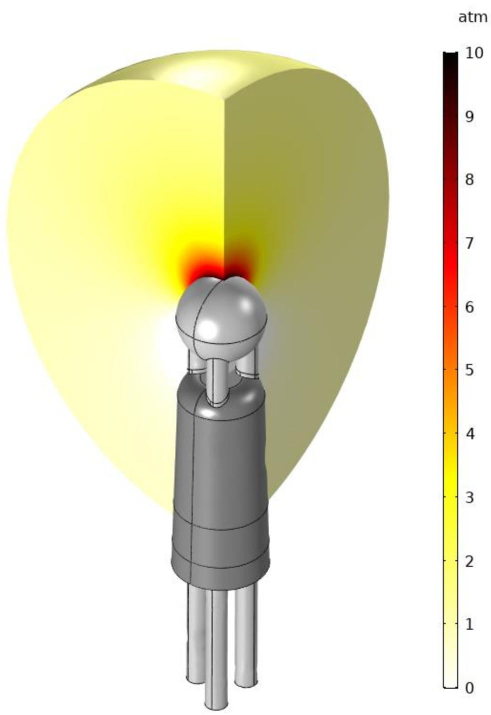

Figure 6 - Pressure field of the experimental validation case

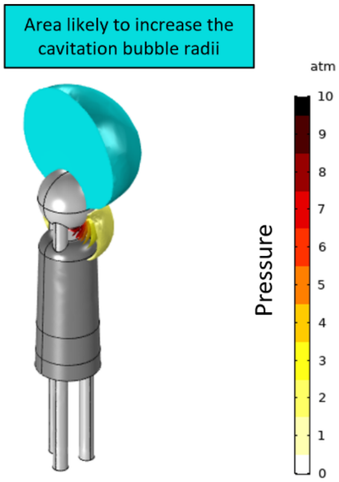

Figure 7 - Pressure distribution at the tip vicinity and area of pressure (in teal colour) reaching the vapor pressure of water

Figure 7 shows the pressure levels together with the area likely to increase the cavitation bubble radii. Comparing to the **Figure 6**, the phase is in opposition and the high-pressure area is below the tip whereas the low pressure area is on the top. This configuration is similar to the classical single actuator device where the pressure distribution is not directional.

b) Case 1

A first case is simulated at 30 kHz, different wire motion amplitude, but they all have the same phase (see **Table 3**).

Case 1: 30 kHz		
Wire 1	Amplitude	20 μm
	Phase	0 °
Wire 2	Amplitude	40 μm
	Phase	0 °
Wire 3	Amplitude	60 μm
	Phase	0 °

Table 3 - Case 1 description

The predicted pressure field is directional (see **Figure 8**) and the bubbles with a radius high variation amplitude (and therefore able to disintegrate the plaque) are localised in a controlled specific area around the tip.

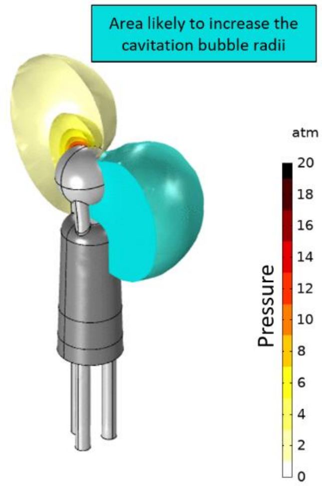

Figure 8 - Pressure distribution at the tip vicinity and area of pressure (in teal colour) reaching the vapor pressure of water

To analyse the results of the Rayleigh-Plesset equation, a time representation becomes necessary. For this purpose, 4 different points specified in **Figure 9** are investigated and the pressure and bubble radius at the points are plotted against time in **Figure 10**. The initial bubble radius is set to $R_0 = 10\ \mu m$.

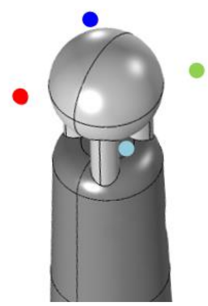

Figure 9 - Investigated points

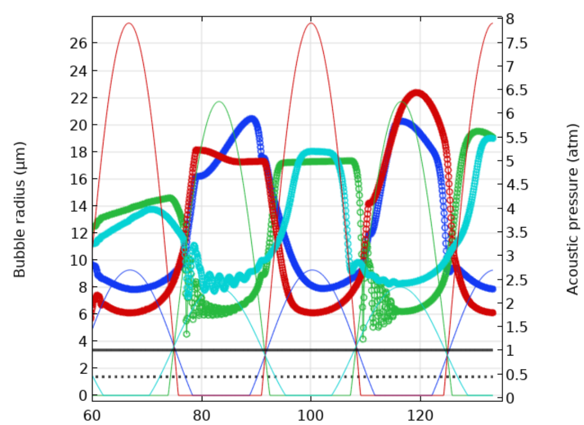

Figure 10 - Case 1 acoustic pressure (line -) and bubble radii (circles -o-) at the investigated points

The bubble dynamic and acoustic pressure are displayed for the 3rd and 4th period simulated as previous periods are very dependent on the initial conditions. Bubble radii are different depending on the investigated points. Whereas the green and turquoise locations generate a high frequency oscillation of the bubble radii, the blue and red location experience a bubble dynamic which simply follows the pressure variation. This shows that the cavitation can be oriented according to the needs of the practitioner and the high frequency oscillations of the bubble can be created in the desired area to concentrate the disintegrating energy on the plaque.

a) Case 2

Another case is simulated at 30 kHz, with the three same wire amplitude, but their phases are different (see **Table 4**).

Case 2: 30 kHz		
Wire 1	Amplitude	40 μm
	Phase	0 °
Wire 2	Amplitude	40 μm
	Phase	120 °
Wire 3	Amplitude	40 μm
	Phase	240 °

Table 4 - Case 2 description

The predicted pressure field is directional and the bubbles with a radius high variation amplitude (and therefore able to disintegrate the plaque) are localised in a controlled specific area around the tip.

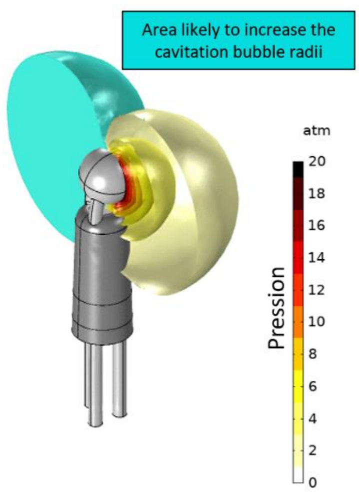

Figure 11 - Pressure distribution at the tip vicinity and area of pressure (in teal colour) reaching the vapor pressure of water

To analyse the results of the Rayleigh-Plesset equation, the time representation is used. The 4 different points specified in **Figure 9** are investigated again and the pressure and bubble radius at the points are plotted against time in **Figure 12**.

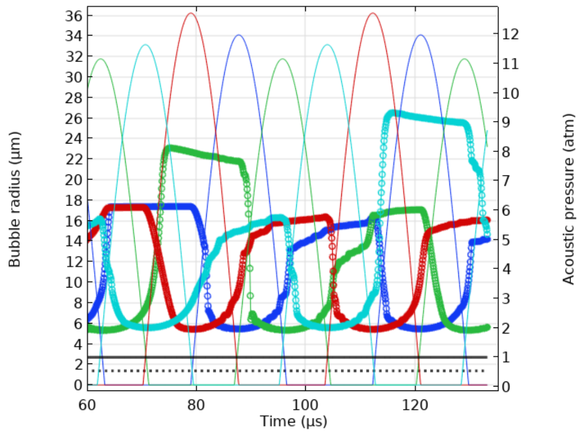

Figure 12 - Case 2 acoustic pressure (line -) and bubble radii (circles -o-) at the investigated points

During the 3rd and 4th period simulated all the location investigated show a behaviour which is not likely to generate high frequency oscillation of the bubble radii. Instead, the bubble radii tend to follow the pressure variation. This shows that a moderate amplitude and a tip following a too regular path (here it almost describes a horizontal circle) can result to moderate effects on the plaque.

Conclusions

A model able to predict cavitation bubble dynamic has been described in this article. The input parameters of the model are the ones a practitioner applies through the piezoelectric actuator, whereas the output of the model is the area where the high frequency oscillations are imposed by the bubbles. This enables to determine the operating conditions required to remove the plaque and proceed to an ultrasonic atherosclerosis treatment. The energy can be focused in the desired area which allow more precise and shorter interventions.

References

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2. Wesley L., N. Basic Physics of Low Frequency Therapeutic Ultrasound. in *Ultrasound Angioplasty* 1–23 (1996).