Vaginal Dilator Stress Control System

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***Abstract*– Vaginal dilation therapy (VDT) is the leading treatment for vaginal stenosis, an adverse side effect to radiation treatment in gynecological cancers. An expandable balloon dilator is an ideal form of VDT as it permits a more comfortable and gradual dilation experience for the patient, which decreases the chance of imparting too much stress on the vaginal canal and causing scar tissue. A negative feedback, stress control system model of expandable balloon VDT was created to further ensure that treatment would maintain a target stress for safe dilation. Using proportional control, the control system reached the target safe stress within 20 seconds at a flow rate of 5mL/s without any overshoot, demonstrating its ability to create stable, comfortable and gradual dilation.**

I. Introduction

Gynecological cancer patients who have undergone pelvic radiotherapy commonly develop a condition called vaginal stenosis.[1] Vaginal stenosis is characterized as the narrowing and shortening of the vaginal canal due to the formation of post-radiation fibrous tissue.[2] The disorder greatly affects the patient's quality of life by causing pain, swelling, discomfort, and bleeding. In addition, the state of the vaginal canal prevents doctors from performing pelvic examinations, which are important to patients' basic health checks and integral in monitoring any recurrences of cancer.[3] The preferred treatment for treating vaginal stenosis is vaginal dilation therapy (VDT).[2] However, currently available vaginal dilators have a low patient adherence rate.[1] The rigid nature of the expanding dilator exerts a force on the vaginal canal, causing discomfort and pain during use. Discrete dilation can impart an excess amount of stress on the vaginal wall, which can result in the formation of scar tissue.[5]

Our senior design project team is designing and prototyping an expandable silicone balloon dilator as an alternative to discrete dilators.

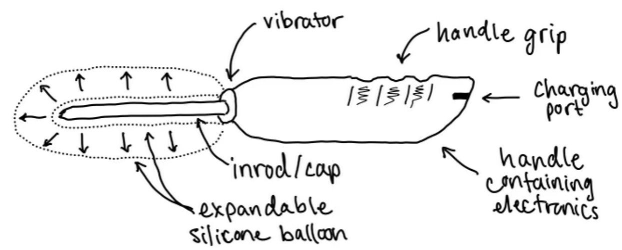

Figure 1: Labeled diagram of expandable balloon dilator design.

Expandable balloon dilators offer a more comfortable and controlled patient experience by allowing for gradual dilation.[2] However, there is still the issue of imparting ample stress on the vaginal canal to effectively treat stenosis without applying too much, which could counterintuitively create more fibrosis. As such, we propose a stress control system which maintains a target stress for safe dilation without scarring. A closed-loop negative feedback system will model the radial expansion of the balloon dilator and the stress that is exerted on the vaginal tissue as a result.

II. Biosystem

A vaginal dilation control system can be represented by the components shown in *Fig 2*. Our stress measurement method is based on an electrical bio-impedance signal obtained from the flow of ions in the saline solution that is being used to inflate the expandable silicone balloon. This impedance is proportional to the radius of expansion of the balloon. This radius combined with the pressure measurement from the pressure sensor gives a value for the hoop stress around the vaginal canal.

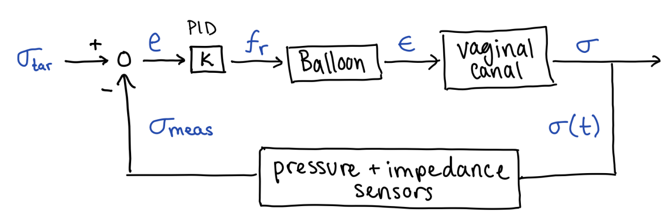

Figure 2: Schematic diagram of a vaginal dilation system. Important components include the PID control of the motor, the expandable balloon, the vaginal wall, and the pressure and impedance sensors.

The error between the target stress and measured stress controls whether the motor turns on or off. The motor then controls the flow rate of saline into the silicone balloon. As saline flows into the balloon, the volume gradually expands, increasing the radius of our balloon. The balloon then makes contact with the vaginal canal and expands the canal's radius (under the assumption that these radii are the same). The expansion of the balloon results in a force exerted on the vaginal wall and a strain in the vaginal wall tissue. Using the stress-strain relationship of the vaginal tissue viscoelastic Kelvin-Voigt Model, the measured hoop stress can be found.

III. Methods

A. Key Assumptions

In order to simplify our model, several key assumptions are made. First, the balloon and vaginal canal are modeled as perfect cylinders with constant length. In reality, since the balloon is made of the same material all over, there would be expansion of the balloon in all directions, including lengthwise expansion. This would coincide with a pressure being imparted on the apex of the vagina. We chose to not account for this and instead assume there is only radial (hoop) strain/stress rather than lengthwise strain/stress. Along these lines, we make the assumption that radii of expansion for the balloon and vaginal canal are the same, and the thickness of the silicone of the balloon is negligible. In other words, the radius change within the balloon is the same as the radius change of the vaginal canal as they expand.

Next, it is assumed that the balloon expands uniformly and radially outwards and that the vaginal wall tissue is static, viscoelastic and homogeneous, and that deformation of the vaginal tissue is reversible. In reality, the dilator aims to cause irreversible deformation in the vaginal tissue so that the vaginal canal gets larger with VDT. Due to these biomechanical properties, we modeled the vaginal tissue with the Kelvin-Voigt model for viscoelastic materials.

In this model, the balloon is inflated with a saline solution rather than air as in our senior design project proposal. This simplification allows us to calculate the electrical impedance in the balloon which can give the radius of expansion to determine the stress of the balloon. Additionally, liquids become easier to model volumetrically compared to air due to the compressibility of air.

Finally, we linearly approximated the radius equation to simplify the model: $r^2 = 2r$. This linear approximation is centered around r = 1.0 cm. We chose this radius value because the expansion of the dilator stays between 0.70 and 1.82 cm, so the approximation should be valid in this range.

B. Mathematical Model

Considering the simplifications made by the assumptions above, the transfer function of our control system is derived as follows. First, we must understand the stress that is being measured is the hoop stress around the circumference of the cylindrical vaginal canal, which is given by *Equation 0*. The values for the radius (r) and thickness (w) of the vaginal wall in this formula results in the target stress given in *Table 1*.

$$(0) \qquad \sigma = \frac{P \cdot r}{w}$$

The pressure and impedance sensors experience a time delay before the measurement reaches the PID controller. The effect of this time delay on our stress measurement is shown in *Equation 1*. The error in the stress measurement as compared to the target stress is given by *Equation 2*. The error value applies a correction on the flow rate of saline out of the pump based on the proportional control term given by *Equation 3*. Taking the Laplace transform of these equations gives the transfer functions of the pressure and impedance sensors, $\frac{\Sigma(s)}{\Sigma_{meas}(s)}$, as well as the PID controller, $\frac{F_r(s)}{E(s)}$.

$$(1) \qquad \frac{d\sigma_{meas}}{dt} = \frac{1}{\tau_{meas}}\left[\sigma(t) - \sigma_{meas}(t)\right]$$

$$(2) \qquad e(t) = \sigma_{tar}(t) - \sigma_{meas}(t)$$

$$(3) \qquad f_r(t) = K_p e(t)$$

As saline flows into the silicone balloon, the volume inside the balloon increases. The volume inside the balloon is related to the flow rate of saline by the relationship given in *Equation 4*. Since the balloon is assumed to be a perfect cylinder, the radius of expansion can be approximated by the linear approximation of volume given in *Equation 5*. Taking the Laplace transform of these equations gives the transfer function of the expandable silicone balloon, $\frac{R(s)}{F_r(s)}$.

$$(4) \qquad V(t) = \int_0^t f_r(t)dt$$

$$(5) \qquad V(t) = \pi r_B^2 h_B \rightarrow V(t) = 2\pi r_B h_B$$

Once the balloon meets the vaginal wall, there is a stress and strain applied to the vaginal tissue. The strain is calculated by the relationship in *Equation 6*, which can then be substituted into the stress-strain relationship of a viscoelastic Kelvin-Voigt Model given in *Equation 7*. The resulting equation will be the hoop stress as a function of the radius of expansion, and taking the Laplace transform gives the transfer function of the vaginal canal, $\frac{\Sigma_{meas}(s)}{R(s)}$.

$$(6) \qquad \epsilon(t) = \frac{r(t) - r_B}{r_B}$$

$$(7) \qquad \sigma(t) = E_{VC}\epsilon(t) + \eta_{VC}\frac{d}{dt}\epsilon(t)$$

These seven equations makeup the system of ODE's for this vaginal dilation system and the resulting transfer functions for each component of the system. Combining these four transfer functions gives the transfer function of the entire stress control system given in *Equation 8*, with all related parameters given in *Table 1*.

$$(8) \qquad H(s) = K_P \cdot \frac{E_{VC}}{2\pi h_B r_B} \cdot \frac{1 + \frac{\eta_{VC}}{E_{VC}}s}{s(1 + \tau_{meas}s)}$$

Parameter	*Value*
Target Stress	$\sigma_{tar} = 1\ kPa$
Measured time	$\tau_{meas} = 0.5\ sec$
Proportion control	$K_P = 5$
Radius of balloon	$r_B = 0.7\ cm$
Length of dilator	$h_B = 3.4\ cm$
Radius of vaginal canal	$r_{VC} = 1.5\ cm$
Modulus of vaginal tissue	$E_{VC} = 4.3\ kPa$ [4]
Viscosity of vaginal tissue	$\eta_{VC} = 2.9\ kPa$ [4]

Table 1: Table of parameters relating to silicone balloon and vaginal canal.

Unfortunately, values for viscosity and Young's modulus of the vaginal canal cannot be found in current literature. We assume that the viscosity and young's modulus of the vaginal canal is comparable to that of the soft tissue of the chest wall.[4] Similarly, the target stress of pressure for vaginal dilation is not apparent from literature, so an arbitrary value is given. Finally, the radius and length values in *Table 1* are measured from the vaginal dilators and vaginal phantoms at the Talke Lab.

C. *Simulink*

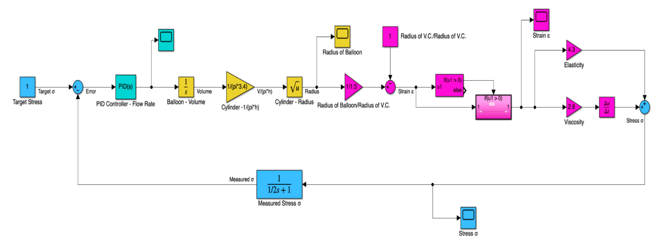

Figure 3: Simulink block diagram of negative feedback stress control system. Measurement and target stress components are in blue. PID control component is in cyan, balloon components are in yellow and vaginal canal components are in pink.

Using the above equations and parameters, we created a simulink model for the feedback control system (*Figure 3*). The target stress is subtracted by the measured stress (blue) and fed into the PID (cyan). The PID creates a flow rate which enters a cylindrical silicone balloon (yellow). The balloon's radius increases and makes contact with the vaginal canal and causes a change in the vaginal canal's radius (pink). This change in radius causes a strain on the vaginal tissue. The strain is then related to the stress using the Kelvin-Voigt viscoelastic model. The pressure/impedance sensor then measures the stress of the tissue. The system then takes this measurement and uses negative feedback to make corrections in the flow rate of the pump until target stress is achieved.

The simulink model determined the PID parameters based on whether they made logical sense in the real world. The output flow rate of the PID system should be achievable by a reasonably sized pump. The time the user waits for the balloon to fill up must be reasonable (i.e. a couple seconds). Finally, the strain on the vaginal wall must not be excessive, while the stress must be achievable by a realistic pressure exerted by the pump.

IV. Results and Analysis

A. *Time Domain Response*

Using proportional control the system achieved the desired target within 20 seconds at an achievable flow rate of a small pump (5 mL/sec). The PID controller (*Figure 4*) outputs a constant flow rate (5 mL/sec) until the balloon makes contact with the vaginal canal (4 sec), and then it begins to slow down. Meanwhile, the radius of the balloon (*Figure 5*) continues to increase, which causes a strain in the vaginal tissue (*Figure 6*) once the balloon makes contact with the vaginal canal. The stress/strain relationship of the Kelvin-Voigt model outputs a stress (*Figure 7*) that is measured by the pressure/impedance sensors. This measurement is fed back into the system and a target stress is achieved within 20 seconds.

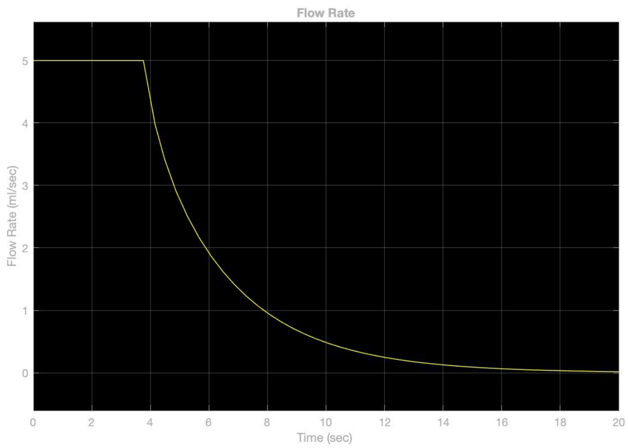

Figure 4: Simulink plot of the flow rate in mL/sec of the PID controlled pump. The pump starts at a constant flow rate of 5 mL/sec and then slows when contact is made with the vaginal canal. As the error term in the system decreases, the flow rate decreases until the system reaches the target.

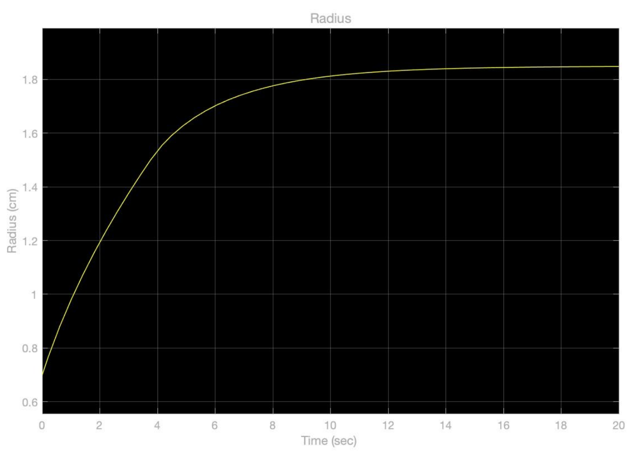

Figure 5: Simulink plot of the increase in the radius of the balloon in cm as the balloon fills up from the saline flow rate of the pump. We see a nearly linear increase at constant flow rate and a slower increase when the flow rate slows. The radius of the dilator begins at 0.70 cm and settles at 1.82 cm.

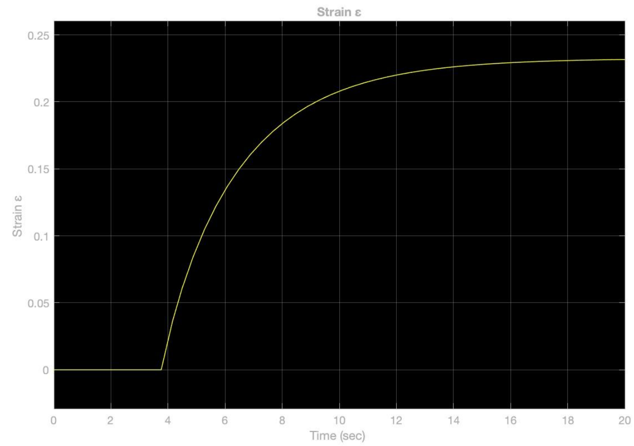

Figure 6: Simulink plot of the strain on the vaginal tissue is zero until the balloon makes contact with the vaginal canal. The strain then increases gradually and settles at 0.23.

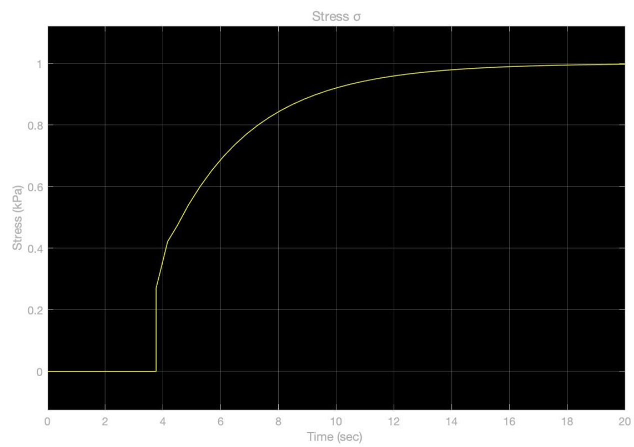

Figure 7: Simulink plot of the stress on the vaginal tissue is zero until the balloon makes contact with the vaginal canal. The contact creates a sharper response in the stress than the strain and it gradually increases and settles at the target 1 (kPa).

B. Frequency Response

$$H(s) = 1.4377 \cdot \frac{1 + 0.6744\, s}{s\,(1+0.5\, s)} \tag{9}$$

The frequency response of the system is found using the transfer function given by *Equation 9* above, where we see a stable system in the open loop transfer function with a minimum phase margin of 90° (*Figure 8*). Using the simulink model, real world constraints and the bode plots, we can see how using proportional control is sufficient for the closed loop system stability. Further adding integral control would only bring down the phase margin to nearly zero at higher frequencies, making the system less stable.

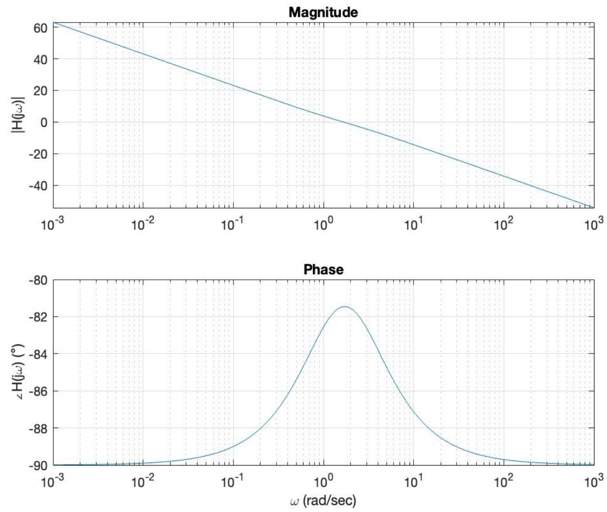

Figure 8: The Bode plot of the open loop transfer function. We see a small peak in the phase response due to a half second delay in the stress measurement by the sensors.

V. Discussion

Some of the errors in this model come from treating the vaginal canal as a perfect cylinder. In reality, the vagina is not a true cylinder, so there may be parts of the vaginal canal that experience more stress/strain than others, which our model doesn't take into account. Similarly, our model does not account for the lengthwise expansion of the balloon, which is arguably the most important part of dilation therapy. Physician Jyoit Mayadev argues that dilation at the apex of the vagina is the most important, as this is where the vagina will begin to close up or shorten in length unless dilated.

Another assumption made that can affect the accuracy of this model is the radius approximation. This linear approximation was made for systems where the dilator only expands between 0.70-1.82 cm. However, for extreme stenosis cases where hardly any expansion is tolerated, or for more healthy vaginas that can tolerate much more expansion, this approximation fails. Instead, a new linear approximation would have to be made to better fit the expansion range for each case.

In the future, with more experimental data, our parameters would become more accurate to better inform the model. A different model for viscoelastic tissues could be potentially used that could account for slightly irreversible deformation in the vaginal tissue. Finally, we would eventually hope to switch to a model using air instead of saline as this is what our current device actually uses. However, this would mean changing our model entirely to target pressure rather than hoop stress, and using an air pressure sensor to measure the pressure rather than using both pressure and impedance sensors to measure hoop stress.

This device could have a future as a diagnostic tool that could map out the extent of the vaginal stenosis of a patient over time by using both pressure and electrical impedance to measure several tissue properties that current devices can not measure, such as radius, strain, stress, and perhaps viscosity and elasticity. Since these parameters are not easily found in current literature, this novel device can revolutionize the way we treat all stenosis conditions.

VI. Conclusion

The goals for this project were to create a model of balloon vaginal dilator therapy for a patient with vaginal stenosis to ensure comfortability and effectiveness of treatment. A slow gradual stress/strain on the vaginal tissue is preferred, as it would give the patient a better user experience while at the same time it could potentially prevent fibrosis from intense stress/strain. This was accomplished by using proportional control that allows for more gradual expansion for the already stable system with no overshoot integrator derivative control would create. The next steps of the project would be to experimentally determine more accurate parameters and models, and then model the device with air instead of saline to use in the actual device we are working on for our Senior Design project.

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