Design and Validation of an Automated Dilator Prototype for the Treatment of Radiation Induced Vaginal Injury

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Abstract— **Vaginal stenosis (VS) is a common late complication of radiation injury caused by cervical cancer radiotherapy. It is characterized by the narrowing or shortening of the vaginal canal, which is often detrimental to patient quality of life. To address this public health problem, an expandable vaginal dilator was designed for the prevention of VS in cervical cancer survivors. Modeling and benchtop experimentation were used to iteratively characterize the relationship among dilator pressure, expansion, and the load applied to the simulated vaginal wall. Both experimental and simulation results exhibited shared trends relating pressure, dilator expansion, applied load, and resultant displacement of the modeled vaginal walls. Future work will incorporate enhanced Mooney-Rivlin material assumptions and validation of the model with in vivo tests.**

Clinical Relevance— **These results present a design opportunity and treatment paradigm shift to increase patient adherence to VS treatment after cervical cancer radiotherapy. Specifically, gradual expansion of the vaginal dilator increases comfort during the expansion of the vagina, while monitoring the dilator pressure enables the tracking of VS improvement and normalization of vaginal wall compliance.**

I. INTRODUCTION

Cervical cancer affects the lives of many women every year, with approximately 570,000 women developing this form of cancer and over 300,000 dying from it [1]. Currently, there are several options for treating cervical cancer. The most common approach involves a combination of surgery, radiation, and chemotherapy [2]. While the five-year survival rate for cervical cancer is high when compared to other types of cancer, there are several acute and late injuries that occur as a consequence of treatment [3]. In particular, an injury that occurs 3-6 months after cessation of radiation treatment is vaginal stenosis (VS), which is the narrowing and shortening of the vaginal canal (Figure 1).

Due to the lack of data examining the incidence of VS on large patient cohorts, the available data for radiotherapy associated with VS vary highly, ranging from 1.25% to 88% [4]. The use of vaginal dilators is the most common method for VS prevention. In this approach, mechanical expansion of the vaginal canal using a vaginal dilator is performed to prevent narrowing and stenosis. While the procedure can be conveniently performed at home by the patient and can be effective at expanding and keeping the vaginal canal open [5-6], the success of treatment with a standard vaginal dilator is highly
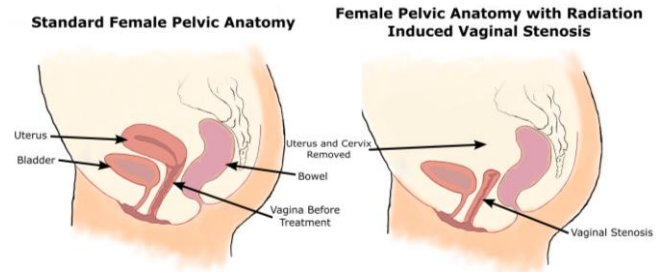

Figure 1: Schematic of female anatomy with radiation-induced vaginal stenosis

dependent on patient adherence, and ranges from 30-40% following three months of treatment [7-8]. The main reasons for low patient adherence include pain, discomfort, lack of progress monitoring, and psychological distress due to trauma experienced during curative cancer treatment [7]. Thus, there exists a medical need for a comfortable device that is effective at preventing VS while maintaining high patient adherence to treatment. In this paper, the design of a novel vaginal dilator is described, and its mechanical properties are evaluated to observe the pressure achieved inside the dilator and the load applied to the modeled vaginal walls.

II. DESIGN AND MANUFACTURING

A. Dilator Design

The inflatable vaginal dilator prototype (artistically rendered in Figure 2) includes a silicone sleeve of 2.5mm wall thickness placed over a 3D printed insertion rod with air or fluid channels. The insertion rod is connected to a plastic tube, which can be used to inflate the silicone lining with air. Figure 2 shows a computer-aided design (CAD) model of the prototype in its expanded form.
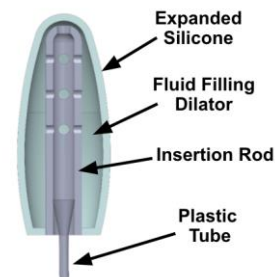

Figure 2: Schematic of inflatable vaginal dilator

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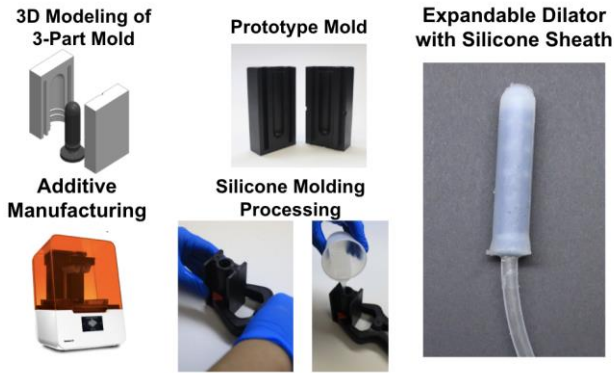## B. Manufacturing Steps and Prototype

Figure 3: Manufacturing process of vaginal dilator prototype

The prototype design includes a three-part mold with a removable insertion rod, which is illustrated in Figure 3. The mold consists of two parts that can be attached and a solid insertion rod that fits in the middle of the mold. Silicone sleeves of various wall thicknesses were created to determine the ideal wall thickness.

Smooth-on DragonSkin 10™ silicone was poured in the dilator mold according to the supplier's instructions. After the silicone was cured, both the inner and outer molds were removed. A plastic tube was inserted into the 3D printed inner rod containing air channels to enable the inflation of the dilator. The air channel rod was then placed inside the silicone sleeve for inflation and to stabilize dilator shape. Following dilator assembly, the gap between the air channel rod and the silicone sleeve was sealed with silicone and left to cure. To expand the dilator, the plastic tube can be attached to any type of air or fluid pump, which inflates the internal silicone sleeve, as depicted in Figure 2 (inflated) and Figure 3 (deflated).
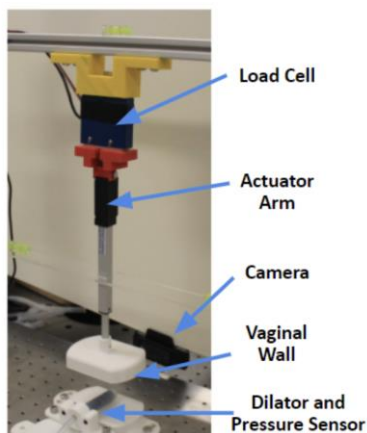
III. METHODS

A. Experimental Setup

Figure 4: Experimental setup to measure dilator expansion versus pressure and force on the adjacent vaginal walls versus pressure

The experimental apparatus depicted in Figure 4 measured vaginal dilator expansion and applied load against flat surfaces i.e., simplified vaginal walls, as a function of air pressure during dilator sleeve inflation. The fabricated dilators were clamped to the test stand facing a digital camera which facilitated axial measurement of dilator expansion. The dilator was connected to a pump and pressure sensor. During dilator sleeve inflation with room air, the pressure sensor measured the increased pressure while the camera captured dilator expansion. Additionally, two flat 3D printed plates simulating the vaginal walls were positioned on either side of the dilator 18mm apart. One plate was attached to a load cell to measure the applied load against the 3D printed wall during pressurization of the dilator.
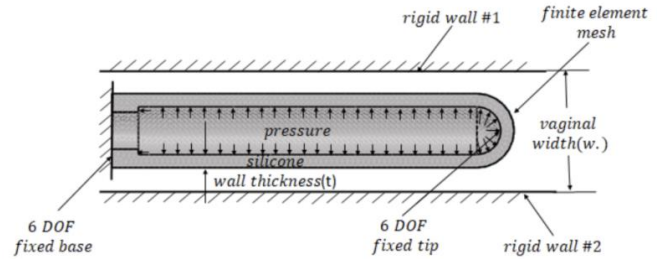
B. Finite Element Model

Figure 5: Finite element model of the vaginal dilator including dilator geometry, mesh, and boundary conditions

A finite element model was developed using Hypermesh, a commercially available software, to complement the experimental results for both dilator expansion and the applied load against the flat surfaces acting as simplified vaginal walls. The nominal model consisted of an expandable dilator sheath with a wall thickness of 2.5mm, a core diameter of 11.5mm, and a length, from base to tip, of 76mm. Approximately 30,000 4-node tetrahedron elements were used to mesh the model. Mooney-Rivlin hyperelastic material models from [9-11] were implemented for comparison and a final model was chosen by fitting the expansion experimental results to the finite element simulation output, similar to the approach proposed by Gopesh et al [9]. The best fit Mooney-Rivlin coefficients were found to be C_{01} = 70 kPa and C_{10} = 0.258 kPa. Figure 5 shows a schematic of the finite element model.

Pressure was ramped up from 0 mmHg to 362 mmHg and the dilator expanded freely until it was constrained by the two parallel walls simulating the vaginal walls (separated by a nominal distance of 18mm). The numerical results of dilator expansion (maximum cross section area) versus pressure and force against the vaginal walls versus pressure were calculated using LS-DYNA, a commercially available explicit transient finite element solver.

IV. RESULTS:

A. Experimental Results:

The relationships between the (a) pressure and dilator expansion (i.e. cross-sectional area), as well as between the (b) pressure and applied load on the flat surface were obtained (See Figure 6a and 6b). As a 60cc syringe pumped air into and out of the silicone dilator, the internal pressure was observed to increase and decrease, as expected. For case (a), where the flat surfaces are not implemented, the cross-sectional area was found to increase and decrease in response to the pressurization. At approximately 310 mmHg, the dilator began to rapidly expand in relation to pressure (Figure 6a). The maximum cross-sectional area recorded was 6.5cm^2 at a pressure of 440 mmHg, representing an increase in area of

more than 400 percent.

For case (b), where the flat surfaces were positioned with a spacing of 18mm, the applied load against one surface was shown to increase and decrease in response to pressurization only above the 310 mmHg threshold, when the dilator was rapidly expanding. The maximum load against the flat surface was observed to be 1.2 N.
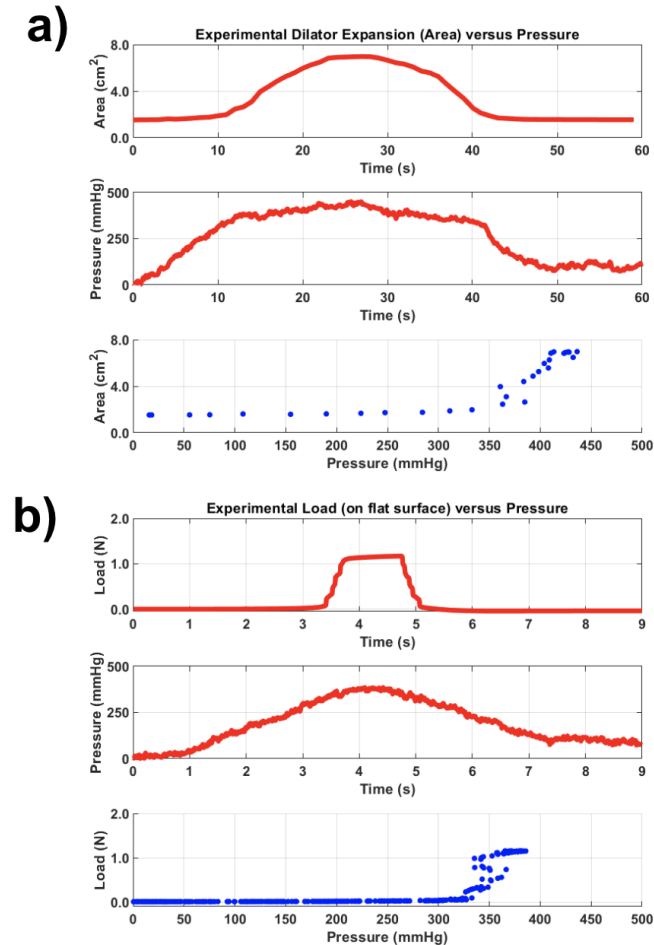

Figure 6: Experimental data for (a) dilator expansion (area) versus pressure and (b) load (on a flat surface) versus pressure

B. Numerical Results:

Finite element simulations complement the experimental study by similarly exploring the relationships between (a) von Mises Stress during expansion, (b) dilator pressure and expansion, as well as (c) pressure and applied load against rigid flat surfaces. Three Mooney-Rivlin models for DragonSkin 10^{TM} have been proposed in the literature with very different coefficients [9-11]. Figure 7a shows the von Mises Stress distribution as the proposed dilator is being expanded and Figure 7b shows results for simulated expansion with respect to pressure for each of the material models used. The experimental data is also shown for the same region of pressurization.

An improved material model was implemented based on experimental results obtained in this model in order to conduct further numerical simulations. Figure 7c shows results for the improved model for load against the rigid flat

surfaces as the dilator is pressurized. The distance between the flat surfaces simulating vaginal walls are varied from 18mm, which was the spacing used in the experimental setup, to 14mm, where the spacing between walls corresponded to the diameter of the dilator cross-section. As the wall separation distance decreased from 18mm to 14mm, the pressure threshold to measure a significant load applied to the simulated vaginal wall decreased, while the overall maximum applied load increased. The experimental results for an 18mm wall diameter are included in Figure 7c. We observe that the results vary slightly from the simulated results for an 18mm wall distance; however, they are consistent with the trends exhibited by the finite element simulations. According to the simulation, the applied load depends on both internal dilator pressure and wall distance.
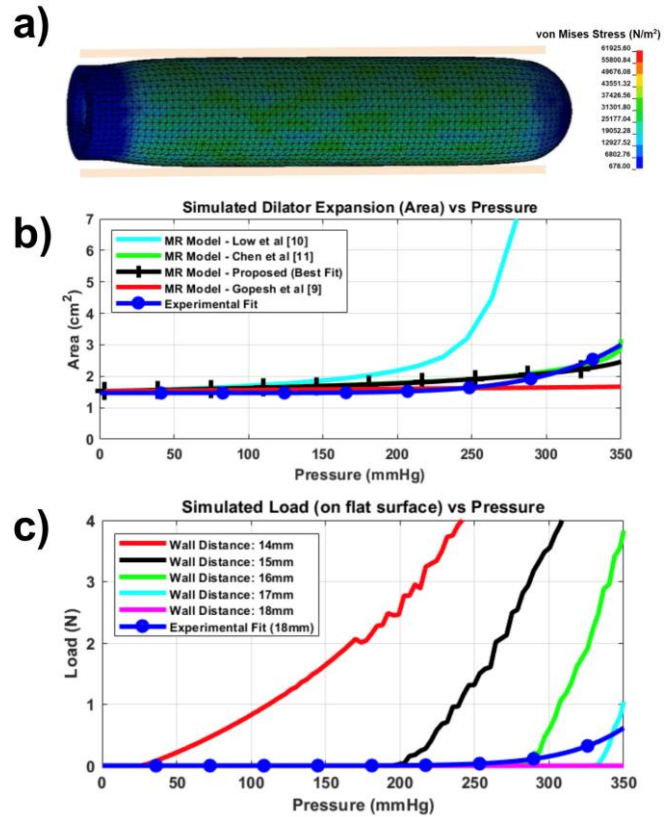

Figure 7: Finite element analysis results for (a) colorized von Mises Stress plot during expansion, (b)cross-sectional dilator area plotted as a function of pressure, and (c) load (on a flat surface) plotted as a function of pressure

V. DISCUSSION AND CONCLUSIONS

The use of pressurized, inflatable vaginal dilators for the treatment and prevention of radiation-induced VS provides a gradual expansion mechanism to mechanically expand the vaginal canal. This, in theory, would apply a more uniform, and potentially less painful and injurious, load across the vaginal wall than is possible with manual rod-shaped dilators. One of the drawbacks with current manual VS therapies is a lack of patient adherence [7]. The design of the proposed device allows for easy insertion due to the initially smaller dilator diameter (before expansion) and the stabilizing rod present inside the silicone sheath (Figure 2). Additionally, the

controlled and compliant expansion can be pressurized to maximize patient comfort. Thus, this proposed solution may be suitable for patients that have undergone pelvic irradiation and are facing the acute and long-term vaginal complications of radiation therapy.

Both experimental test results and finite element simulations showed similar trends for the relationship between pressure versus expansion and pressure versus applied load on a vaginal wall. Variations of wall distance in the established model simulated the distance between the vaginal walls, which can be used to represent different vaginal widths among women, or the development of those widths over time. As wall distance decreases, the maximum load that can be applied by the dilator on the simulated vaginal walls increases. This suggests that as vaginal width decreases, as is the case in VS, a set expansion of the proposed vaginal dilator will lead to an increased load in the vaginal walls, which would likely lead to a painful experience when using the device. Therefore, the expansion of the dilator should be personalized, with gradual expansion based on patient specific vaginal dimensions, to decrease the initial force being applied to the vaginal wall and thus improve tolerability and patience adherence.

The relationships between pressure, expansion, and applied load determined in this study can provide a measure of device efficacy at preventing, treating, and monitoring VS progression. The expansion of the proposed vaginal dilator can be estimated from the results portraying cross-sectional area as a function of pressure (Figure 7a). This relationship can be used to track patient progress by monitoring the changes in dilator pressure measurements, which indicate the resistance of the vaginal wall due to fibrotic scarring. As the scar tissue dissociates, the resistance of the wall related to pressure is expected to decline. This would allow further data on vaginal stenosis to be recorded, giving the opportunity for this condition to be further understood. Furthermore, progress tracking could serve as motivation for patients using vaginal dilators, which can improve patient adherence.

In conclusion, the rational design of a vaginal dilator containing a soft expansion mechanism capable of tracking patient progress has the potential to impact the quality of life outcome for cervical cancer survivors. An inflatable design coupled with pressure measurements indicating expansion and the applied load against the vaginal wall can increase patient adherence by providing a graded better tolerated therapy. Future work will incorporate an automated system that can analyze patient compliance and establish a closed-loop feedback mechanism for expansion for optimal comfort and therapeutic effect. Furthermore, the application of biologically active agents using the proposed dilator could be beneficial, as the two orthogonal methodologies may synergize to further enhance the healing of radiation damaged tissues. Such an integrated approach involving physical wall expansion and disruption of scar tissue, together with biologically triggered revascularization and vaginal wall rejuvenation, might significantly decrease the likelihood of a patient developing irreversible vaginal stenosis following radiotherapy.

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