# An Integrated Engineering Methodological Framework for the Optimization of a Tracheostomy Speaking Valve

Arianna Verbosky

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# Acceptance of Senior Honors Thesis

This Senior Honors Thesis is accepted in partial
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Honors Program of Liberty University.

______________________________
Hector Medina, Ph.D.
Thesis Chair

______________________________
Mark Atwater, Ph.D.
Committee Member

______________________________
David Schweitzer, Ph.D.
Assistant Honors Director

______________________________
Date

# Abstract

The purpose of this thesis investigation is to develop and present an iterative methodological framework for the optimization of a particular tracheostomy speaking valve which integrates the use of engineering computational, experimental, and analytical methods and tools. Background information related to tracheostomy speaking valves as well as the methods and tools to be implemented in the methodological framework are presented. The designed framework and results of its initial implementation as well as recommendations for future work are also discussed. Ultimately, the development and implementation of this integrated framework has the potential to be extended to the optimization of other tracheostomy speaking valves and respiratory devices.

# An Integrated Engineering Methodological Framework for the Optimization of a Tracheostomy Speaking Valve

## Introduction

The ultimate goal of engineering design and optimization is to assist engineers in finding solutions to improve the quality of life for people in all areas of society, one person at a time. Specifically, for patients with tracheostomies, their quality of life may be improved greatly through the use of tracheostomy speaking valves [1]. However, several patients who use these valves struggle with breathing through them due to the inherent pressure drop and flow resistance across the valves that does not coincide with their individual needs, especially if the patient is an active worker [1, 2]. Through the implementation of an iterative engineering methodological framework, the integrated application of computational, analytical, and experimental methods holds great potential for the optimization of tracheostomy speaking valves.

### Thesis Statement

The purpose of this thesis investigation is to develop an iterative methodological framework for the optimization of a particular tracheostomy speaking valve which integrates the use of engineering computational, experimental, and analytical methods and tools. The goal of this optimization is to minimize the pressure drop across the valve itself to increase the ease of inhalation through the valve for a patient while also maintaining the structural stability of the valve itself with each design iteration. The development and implementation of this integrated methodological framework has the potential to be extended to the optimization of other tracheostomy speaking valves and respiratory devices to contribute to the improvement of quality of life for patients.

## Background and Rationale

This study was developed to serve a particular tracheostomized patient with an active lifestyle who struggles to get sufficient oxygen through a Passy Muir speaking valve (PMV). The immediate focus of this investigation is thus to contribute to an effort to improve this particular person’s quality of life by working to develop a methodological framework to effectively optimize the PMV. While this effort is aimed at improving the quality of life for one person, the knowledge and methods from this study also have the potential to be applied in other efforts to optimize respiratory valves and devices for a variety of patients. In the past, there has been some work done to experimentally characterize the flow characteristics of the PMV and other similar speaking valves. However, integration of modern computational tools along with advanced analytical and experimental methods provides a unique opportunity to optimize these valves and meet patients’ needs. Similar integrated frameworks have been employed for the optimization of a variety of valves in other industries but would still need to be significantly adapted and synthesized to be applied in the optimization of tracheostomy speaking valves. The focus of this investigation is thus to contribute to the development of an integrated framework specific to the optimization of a PMV as well as the potential future optimization of other tracheostomy speaking valves.

# Literature Review

## Tracheostomy

A tracheostomy has been defined as a permanent or temporary opening or airway created surgically by a tracheotomy procedure in the trachea of a human patient in order to allow for more direct access to the lower airway for a variety of reasons and purposes [1, 3-5]. Usually, a tracheostomy is located between the second and third tracheal cartilage rings in the front of the patient’s neck and was originally used to bypass upper airway obstructions and to maintain an open airway in patients whose larynx had been removed [4]. Because tracheostomies redirect the flow of air to bypass the upper airway, tracheostomized patients are limited in their upper airway functions related to coughing, tasting, smelling, and swallowing, as well as the warming, humidification, and filtering of air entering the lungs [5-8]. Tracheostomies also prevent speech production in patients as the exhaled air also bypasses the patient’s vocal cords [1, 4, 6, 9]. The loss of speech production abilities has also been found to negatively impact social and care giver interactions as well as the overall quality of life for patients with tracheostomies [10-12].

## Tracheostomy Speaking Valves

The most common option for restoring speech production in tracheostomized patients in recent years is through the use of tracheostomy speaking valves [5, 11]. A speaking valve attaches to the tracheostomy tube proximal opening and functions as a one-way valve that allows air to be inhaled through the tracheostomy tube opening and then closes during exhalation to redirect the exhaled air back up through the upper airway and past the vocal cords to allow for speech production [2, 3, 5, 10, 12-14]. Several studies have been undertaken to investigate several claimed and observed benefits of using tracheostomy speaking valves. Overall, the restoration of speech to tracheostomized patients has been found to greatly improve their quality of life [1, 9]. Some other claimed benefits of using speaking valves by their manufacturers include improved verbal communication, improved swallowing functions, the possible reduction of the occurrence of aspiration, improved cough strength, more effective secretion management, improved oxygenation, effectiveness in weaning from mechanical ventilation, and improved airway hygiene and humidification [1, 2, 7, 8, 14]. There have been very few observed adverse effects of using speaking valves in tracheostomy patients recorded in the literature [1,15,16]. One example of those adverse effects is an increase in expiratory pressure and resistance when the speaking valve was introduced [15]. Ideally, speaking valves are meant to open during inhalation and to provide air flow with as little resistance as possible [2]. The increase in expiratory pressure and resistance leads to an increased work of breathing and poor tolerance of speaking valves in some patients [15]. Another debated adverse effect is the remaining occurrences of aspiration in tracheostomized patients using speaking valves [16].

### Passy Muir Speaking Valve (PMV)

The tracheostomy speaking valve of primary interest in this particular study is the Passy Muir speaking valve (PMV) (see Fig. 1). The PMV functions as a one-way flapper speaking valve and was designed to attach to a standard external 15-mm tracheostomy tube hub [6, 10, 17]. The valve contains a silicon diaphragm flap that remains closed at atmospheric pressure and opens during inspiration once a large enough flow has been generated

Fig. 1. CAD model of Original Passy Muir Speaking Valve (PMV) Design

to displace the valve flap [8, 15, 18]. The PMV is one of the few valves approved by the USDA for use with a ventilator and has also become one of the most commonly used and studied valves in patients and research investigations [19]. Passy et al., claims that the use of the PMV has been observed to produce good-quality and spontaneous speech in patients [4, 9, 12, 19]. Furthermore, one study reports that the use of the PMV has been observed to improve olfactory functions and secretion management and may also reduce the occurrence of aspiration in patients [14]. Other previous studies have observed that the PMV appears to effectively improve the consistency and quality of speech produced in selected tracheostomized patients as well as to ease the process of weaning a patient off of mechanical ventilation [14].

## Speaking Valve Characterization and Optimization

The focus of optimizing a speaking valve such as the PMV is to minimize the air-flow resistance by decreasing the pressure drop across the valve through geometrical modifications to the valve structural design while also maintaining the structural stability of the valve [20, 21]. Thus, in the optimization methodological framework developed in this study, the valve must be characterized according to its flow and structural characteristics.

### *Flow Characterization of Speaking Valve*

In optimizing a speaking valve such as the PMV, the valve must be characterized according to its flow characteristics to evaluate the performance of the original valve design and to help compare against each subsequent design iteration. In previous studies, the resistance and pressure drop curves when plotted against the flow velocity of the fluid flowing through the valve have been used to characterize valves of various types [21, 22]. Usually, these curves have been experimentally obtained by blowing air through the valve at a variety of different flow velocities and measuring the pressure drop across the valve [21]. From the pressure drop and flow velocity data, the flow resistance coefficient of the valve may be determined and used to characterize its overall aerodynamic performance and behavior [22]. The flow characterization of a valve may be accomplished through both computational and experimental methods and tools such as Computational Fluid Dynamics (CFD) analyses and flow experimental testing.

**Computational Fluid Dynamic (CFD) Analysis.** CFD has been defined by Garcia-Todoli et al. to be “the use of a computer-based tool for simulating the behavior or systems involving fluid flow, heat transfer, and other related physical processes” [23]. Essentially, CFD analyses allow for the investigation of complex flow patterns and parameters that are often difficult or expensive to study using solely experimental and/or analytical methods. These CFD approaches have been implemented in a variety of applications including buildings, aircrafts, industrial processes, motor vehicles, the medical field, and the characterizations of valves in various industries [23, 24], just to name a few. Particularly, CFD analysis methods have been applied in a variety of studies involving the characterization of respiratory devices, one-way valves, and human airway structures [20, 23-27]. Increasingly, CFD models and analyses are being adopted and applied to analyze the flow characteristics of various valves due to their increasing computational robustness [24, 25]. A PMV functions in a very similar manner as a one-way flap valve, which essentially contains an elastic diaphragm-like flap that deforms in one direction due to the pressure of a flowing fluid and then closes when the fluid flows in the opposite direction [22, 25]. Often, the flap is made of a flexible material such as silicone so that it flexes to allow the fluid to flow around the deformed flap in one direction and then prevent flow in the opposite direction with a good seal [22, 28]. Many of the CFD methods that are used to model check valves and one-way flap valves may also be applied and adapted to model and simulate the flow behavior of the PMV.

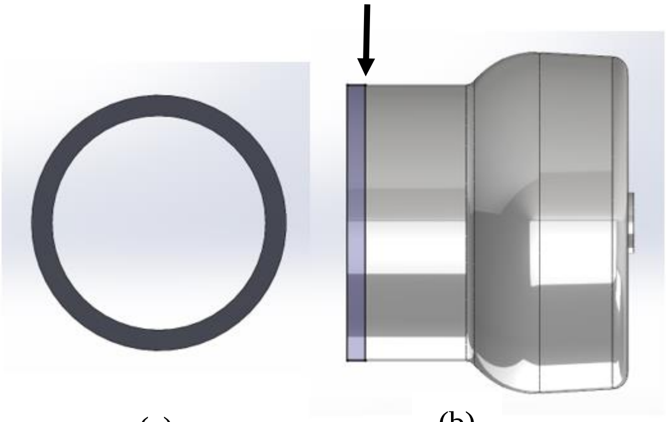
***CFD Model Verification and Validation: Flow Experiment.*** However, despite the growing robustness of the CFD models and techniques, the computational results are not always completely reliable and must be verified and validated with experimental results [23, 24]. The purpose of verification is to make sure that the model is solving the governing equations that accurately model the physical phenomena of the system's behavior and characteristics [24]. Validation of a CFD model, on the other hand, means checking the results of the computational model against experimental data to ensure that the simulated model is a close enough approximation to the reality of the physical behavior of whatever system is being modeled [24].

In order to verify and validate the CFD results for characterizing the flow characteristics of the PMV, a flow experimental test method will be needed. There have been several recent studies aimed at developing experimental methods to test and characterize the aerodynamic behavior of tracheostomy speaking valves [8, 11, 15, 18, 29-31]. In each experimental set-up contained in the literature, several key elements are usually present: a controlled source of flow, a "mount" for the speaking valve being investigated, pressure and flowrate measuring devices or sensors placed before and after the valve in the flow circuit, a computer or other method of data collection and recording, and all the necessary connections to direct the airflow through the flow circuit [8, 11, 15, 18, 29-31]. The specific parameters that are of interest to each experimental set-up in the analysis and calculations involved in each study include the flow resistance coefficient, the inspiratory pressure or effort required to open the valve, and the pressure drop across the valve [8, 11, 15, 18, 29-31].

### ***Structural Characterization of Valve***

In addition to the flow characterization of the valve, the structural and mechanical characteristics of the valve must also be determined in order to ensure that as each valve design iteration is developed to minimize the pressure drop across the valve, the valve design still maintains its structural stability and integrity. The structural characterization of the valve will entail using a combination of computational, analytical, and experimental methods and tools to characterize the material used in the original valve design, as well as to investigate the structural behavior of the valve design when it is subjected to a compressive loading.

**Material Characterization: Ring Compression Test.** In order to be able to characterize the material used in the original PMV design, a method to determine the elastic modulus and Poisson’s ratio from a ring-shaped specimen (taken from the valve design as shown in Fig. 2) was investigated. Some recent studies indicate that there is an interest in the development of a standard compression testing method which uses ring shaped specimens to experimentally and analytically determine a material’s elastic modulus and other mechanical properties [32, 33]. Because ring specimens require very small amounts of material to manufacture when compared to other more standard tensile and compressive testing specimens, researchers are interested in utilizing them to characterize the mechanical properties of small-volume materials and components [32]. Similar methods from these studies could potentially be applied to the material characterization of the original PMV design.



(a) (b)

Fig. 2. (a) Ring Shaped Specimen (b) Location of where Ring Specimen would be cut from original PMV Design

**Structural FEA Computational Methods.** In many recent studies, the structural and mechanical characterization of a valve or other part of interest has been accomplished increasingly through computational static structural analysis methods using a Finite Element Analysis (FEA) software package such as ANSYS or ABAQUS [34, 35]. Such studies have been applied by many researchers to study the structural stability of various kinds of parts and valves when subjected to a specified set of loading and boundary conditions [34]. Essentially, structural analysis using FEA methods entails discretizing an often-complex model into smaller and simpler elements to then describe the stress-strain behavior in each element [34, 36]. The FEA software then synthesizes the elemental stress-strain results into a representation of the entire part as a cohesive whole [34, 36]. FEA has also been employed in the characterization of materials to determine their mechanical properties through simulating compressive, tensile, and other mechanical tests in various configurations [34, 35]. ANSYS Static Structural 2021 R2 is one FEA software sub-package which can be used to perform a 3D linear static structural analysis to investigate the total and directional deformation as well as equivalent and principal stresses observed in a part when it is subjected to a specific set of loading and boundary conditions [34, 36].

***Structural FEA Model Verification and Validation: Compression Experiment*.** In order to verify and validate the structural FEA model of the PMV, a standard experimental compression test must also be performed using the same loading and material parameters as well as boundary conditions applied in the structural FEA model [36]. Typically, the compressive properties of a plastic material are determined through a compressive experimental test, performed in accordance with the standard ASTM D695 or ISO 604 Plastics [37, 38].

## Methods

In this particular study, an iterative and integrated engineering framework involving computational, experimental, and analytical methods was designed and begun to be implemented in the optimization of a Passy Muir speaking valve (PMV). Overall, the purpose of the optimization is to modify the geometry of the valve in order to decrease the overall pressure drop and inspiratory resistance of the valve while still maintaining the structural stability and integrity of the valve itself. In order to accomplish this, the original valve design and each subsequent design iteration must be characterized according to its flow and structural characteristics. Overall, each valve iteration will be characterized according to its flow characteristics computationally through CFD analyses and experimentally through a flow experimental set-up. Additionally, each valve iteration will be characterized according to its structural characteristics computationally through structural FEA simulations and experimentally through a standard compression test. Furthermore, in order to increase the accuracy and usefulness of the structural FEA simulations, the material parameters of the original PMV design must also be determined.

This will be accomplished analytically through the application of a closed-loop solution of the deformation of a ring and experimentally through a ring compression test, as used in previous studies [32, 33]. A conceptual schematic of the developed methodological framework is pictured in Fig. 3.

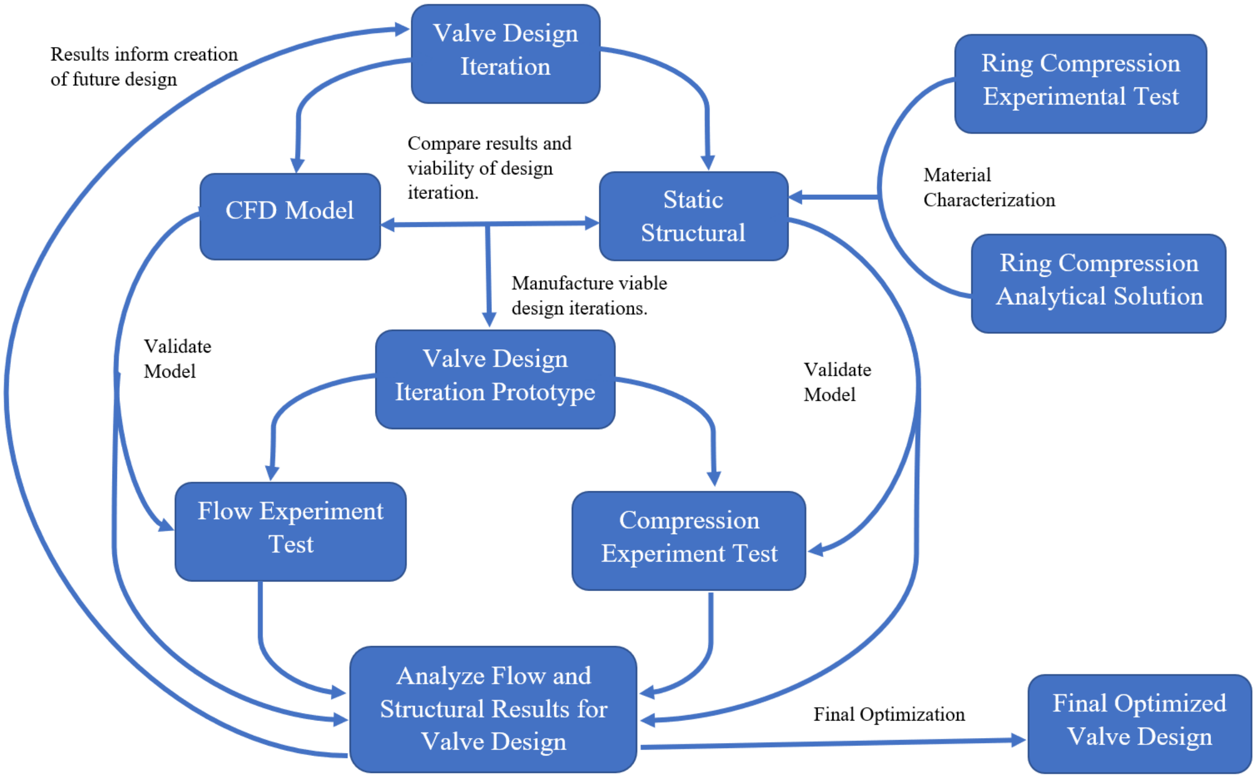


Fig. 3. Conceptual Schematic for Developed Methodological Framework for Optimization of Passy Muir Valve

## CFD Model and Analysis

The overarching purpose of the CFD models and analyses is to computationally characterize the PMV design iterations according to their flow characteristics. Through using computational methods such as CFD, physical and material resources may be conserved as each design iteration is tested and analyzed virtually before a physical prototype needs to be fabricated for experimental testing. A series of initial CFD models were created to start building up an initial model to start characterizing the flow characteristics of the original valve geometry. First, a CFD model was created for the valve with a constant flowrate flowing into the valve without the flap introduced into the model. Future work would continue to eventually produce a more robust model to simulate the actual valve and its usage more accurately. Once that more robust CFD model has been developed, then the PMV design iterations can be run in the model to start comparing the results of each iteration to the original design to optimize the PMV. In the following sections, the set-up of the initial models that have been created and more specific recommendations for future work are described.

### ***CFD Original PMV Design Model Without Flap***

The purpose of first creating an initial CFD model of the original PMV design without the introduction of the flap while experiencing a constant inlet flow velocity was to begin the construction of the initial baseline CFD model. Primarily, this first model iteration was also to be used to attempt to isolate the effect of the rest of the geometrical features from the effect of the flap on the flow characteristics of the PMV. A Computer-Aided Drafting (CAD) model was generated of the original PMV design using SolidWorks 2022, with the flap not included in the model (see Fig. 1). From the CAD model of the valve, a model of the fluid domain geometry including the volume of fluid inside of the valve and just outside of the inlet face was also generated in SolidWorks 2022. The fluid domain geometry CAD model was then inputted into ANSYS Workbench 2021 R2 and the geometry was meshed using tetrahedral elements and a specified element size of 2.5e-04 m. In total, the mesh contains 532,201 nodes and 3,059,738 elements. The mesh was then inputted into ANSYS Fluent 2021 R2 and the initial baseline CFD model was set up based off of model and simulation parameters used in previous similar studies [23-27]. The material of the fluid was selected to be air from the Fluent database. The inlet was defined to be a velocity inlet with a constant flow velocity of 4 m/s along the longitudinal axis of the PMV and the outlet was defined to be a pressure outlet. All surfaces of the fluid geometry that meet the solid faces of the valve itself and the middle support for the valve flap were all assigned to be stationary, no slip walls, with the Fluent default roughness settings. After the solution for the model had converged, the results parameters that were of interest included the flow velocity, static pressure, dynamic pressure, and total pressure at the valve inlet and outlet faces. In order to ensure that the number of mesh elements was sufficient to achieve a converging solution, three meshes were generated using the same meshing scheme but with element sizes of 2.5e-04, and 2e-04 m and then a similar meshing scheme with an element size of 3e-04 m and a mesh refinement with a factor of 2 at areas of geometrical interest (such as around the ribbing, main structural flap support bar, and the fillets) [36]. The results from these three meshes were then compared to determine how significantly the results varied from each other. If the variations in the results are all found to be relatively insignificant, then mesh convergence can be said to have been achieved, which essentially means that the number of mesh elements is high enough that the results will be independent of the meshing scheme itself [36]. Of the three meshes compared, if mesh independence is achieved, then the mesh with the lowest number of elements will be used for post-processing and analysis to save time and computational resources while also maintaining the convergence of the model solution itself. A parametric study was then conducted varying the constant inlet flow velocity from 1 to 10 m/s for the meshed PMV flow domain geometry to further characterize the flow behavior of the valve. Except for the inlet flow velocity, all other parameters in the model remained the same in order to isolate the effect of a varying constant flow velocity on the overall pressure drop across the valve.

### Structural FEA Computational Model

The purpose of the structural FEA model is to computationally characterize the structural strength and stability of the PMV design iterations. The results from this model will help to ensure that the geometrical modifications made to improve the flow characteristics do not negatively affect the structural integrity of the valve itself when subjected to a compressive force. Through using a computational model, physical and material resources may be conserved as each design iteration is tested and analyzed virtually before a physical prototype needs to be fabricated for experimental compressive testing. Essentially, the CAD model of each valve iteration geometry would be created, starting with the original PMV design. The flap would not need to be included since it will not impact the structural performance of the PMV itself when it is subjected to a compressive force. The PMV CAD model would then be imported into ANSYS Workbench 2021 R2 and meshed using a similar meshing scheme as used for the CFD model. The structural FEA model simulation will then be set up using ANSYS Static Structural 2021 R2 with a constant compressive force being applied perpendicular to the inlet face of the valve while the outlet face is assigned a fixed boundary condition. The stress and displacement results from the structural FEA simulations could then be used to compare the structural stability of each PMV design iteration to the original PMV design and then to each other to ensure that any geometrical modifications made to improve the flow behavior of the valve will not negatively affect the valve’s structural integrity. The material of the original PMV design will also need to be investigated and experimentally characterized in order to be able to accurately simulate the structural behavior of the valve in the structural FEA model. The material and mechanical properties of the polymer used in the valve itself are not published by Passy Muir and so must be experimentally determined, particularly the elastic modulus and Poisson's ratio of the material. One experimental method that may be used is that of a ring compression test, where thin ring samples could be cut off the outlet face of the valve . From the analytical solutions for the deformation of a thin ring, the elastic modulus and Poisson's ratio may be determined [32, 33]. Further work would remain to be done to further develop an experimental set-up and method to characterize the mechanical properties of the original valve's material. Once the elastic modulus and Poisson's ratio have been determined, they may be introduced into the structural FEA model to simulate the mechanical behavior of the valve more accurately when subjected to a compressive load.

## Flow Experiment

The purpose of the flow experiment is to experimentally verify and validate the results of the CFD models to ensure that the model is a useful approximation of the actual valve flow behavior. Together with the CFD model, the flow experiment will be used to characterize the flow characteristics of the PMV design iterations. The essential elements required for the flow experimental set-up include a controlled airflow supply, a flow measurement device, a pressure difference measurement device, a data acquisition device, a mount for the valve itself, a flow tube, and all the necessary connections needed to complete the flow circuit. A schematic of the flow experimental set-up is pictured in Fig. 4. Essentially, the controlled air supply will be the source of a constant flow or a flow simulating breathing directly into the flow tube containing the tracheostomy speaking valve. A pressure and flowrate measurement will be recorded before and after the speaking valve using a data acquisition device such as a computer in order to experimentally measure the pressure drop across the valve.

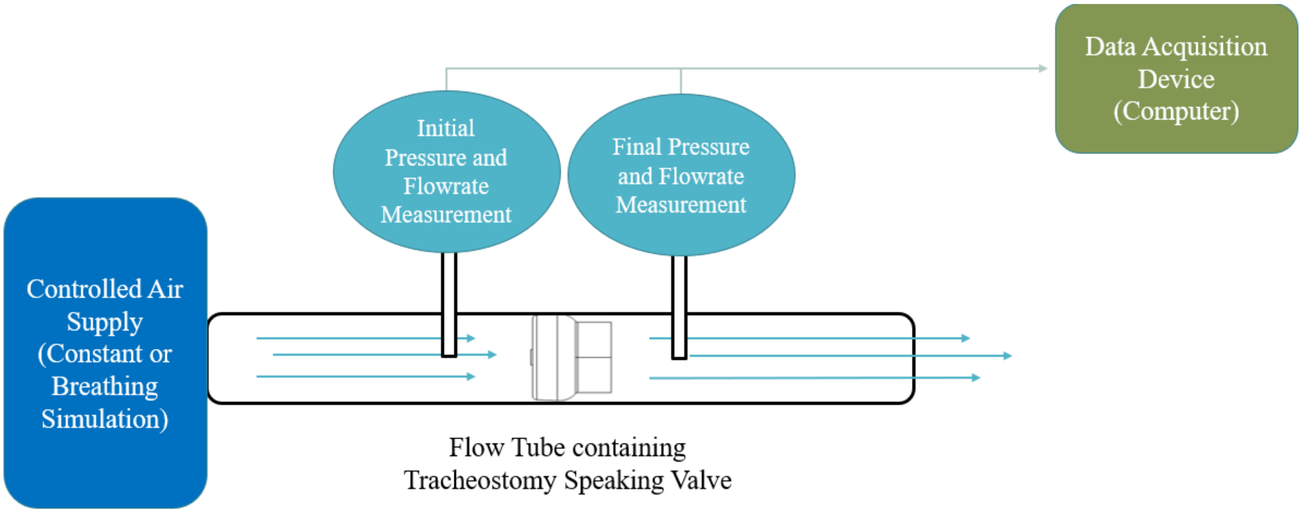


Fig. 4. Schematic of Flow Experimental Set-Up

Ideally, the controlled air supply would be able to be controlled to provide a constant air flow at a specified velocity as well as to simulate a flow pattern resembling human breathing. The pressure and flowrate measurement devices placed before and after the valve would be used to measure the flow velocity and pressure drop across the valve and to compare the experimental data to the CFD results. A data acquisition device such as a computer would have to be used to interpret and record the signals from the pressure and flowrate measurement devices. The flow tube would be used to create a controlled environment around the mounted valve and to direct the airflow through the valve itself. In performing the experiment, the controlled air supply would be adjusted to produce a flow similar to that specified in the CFD model of the valve design iteration being tested. Each valve iteration would be 3D-printed or manufactured from the geometry modeled in each respective design iteration CAD model. The valve would then be mounted and installed into the flow tube. While the airflow is being supplied, either as a constant air flow or as a breathing simulation pattern, pressure and flowrate measurements will be recorded just before and just after the valve to calculate the pressure drop and monitor the flowrate across the valve. The experimental data collected will then be compared to the CFD results to verify and validate the computational model.

## Compression Experiment

The purpose of the compression experiment is to experimentally validate the results of the structural FEA models to ensure that it is a useful approximation of the actual structural behavior of the PMV design iterations when subjected to a standard compression test. Together with the structural FEA model, experimental compression tests will be used to characterize the structural characteristics of the PMV design iterations. The compression tests would be performed on 3D-printed or otherwise manufactured physical prototypes of the PMV design iterations. The experimental set-up and methodology would follow a standard compressive test as specified in ASTM standard D695: “Standard for Compressive Properties of Rigid Plastics” [38]. Using a universal INSTRON testing apparatus, each PMV design iteration prototype would be compressed at a constant strain rate between two rigid metal plates until fracture. The strain rate will be assigned as specified in the testing standard. The results from the experimental compression test would then be compared to the structural FEA model results as well as among the PMV design iterations and to the original PMV design structural stability in order to verify the computational results and further investigate the structural integrity and stability of each proposed PMV design iteration.

# Results and Discussion

Overall, the methodological framework for an integrated engineering approach to optimize the valve using a combination of computational, experimental, and analytical methods was developed and begun to be implemented. The following sections detail some specific results from the parts of the methods that were begun to be applied as well as a discussion of the results and potential of the overall methodological framework.

## CFD Model and Analysis

In this study, a CFD model of the original valve fluid domain geometry without the presence of the flap was developed and studied using the methods described in the previous sections. First, the mesh convergence study was performed in order to ensure the results from the CFD model would be independent of the meshing scheme. The percentage difference between the results from the three meshes studied were all less than 1.05% and thus the variations in the results due to the variations in the meshing schemes were insignificant. Thus, the model can be said to have achieved mesh independence and the results from the mesh with the smallest number of elements may be used to decrease computational resources without compromising the convergence of the solution. The detailed results from the three meshes used in the mesh convergence study with the percentage difference between the three meshes are contained in Table I.

TABLE I
RESULTS FROM MESH CONVERGENCE STUDY FOR CFD MODEL OF PMV WITHOUT FLAP

| **Output Parameter** | **CFD Valve Mesh 1** | **CFD Valve Mesh 2** | **CFD Valve Mesh 3** | **AVG** | **%Difference Mesh 1 to 2`** | **%Difference Mesh 1 to 3** |
|---|---|---|---|---|---|---|
| Number of Elements | 3,059,738 | 3,131,930 | 5,970,845 | | | |
| Inlet Velocity [m/s] | 4 | 4 | 4 | 4 | 0.00% | 0.00% |
| Outlet Velocity [m/s] | 5.391 | 5.386 | 5.404 | 5.394 | 0.09% | 0.24% |
| Inlet Total Pressure [Pa] | 44.34 | 44.10 | 44.32 | 44.251 | 0.52% | 0.04% |
| Outlet Total Pressure [Pa] | 22.54 | 22.37 | 22.70 | 22.53 | 0.77% | 0.71% |
| Inlet Dynamic Pressure [Pa] | 9.792 | 9.795 | 9.794 | 9.794 | 0.03% | 0.02% |
| Outlet Dynamic Pressure [Pa] | 22.67 | 22.43 | 22.79 | 22.63 | 1.04% | 0.56% |
| Inlet Static Pressure [Pa] | 34.55 | 34.32 | 34.45 | 34.44 | 0.68% | 0.30% |
| Outlet Static Pressure [Pa] | 0.00 | 0.00 | 0.00 | 0.00 | 0.00% | 0.00% |
| Total Pressure Drop [Pa] | 21.80 | 21.74 | 21.62 | 21.72 | 0.28% | 0.82% |

Fig. 5 contains the total pressure drop contours from CFD Valve mesh 1 across the valve when the flow velocity was set to be a constant speed of 4 m/s. The numerical results from this simulation are contained in Table II.

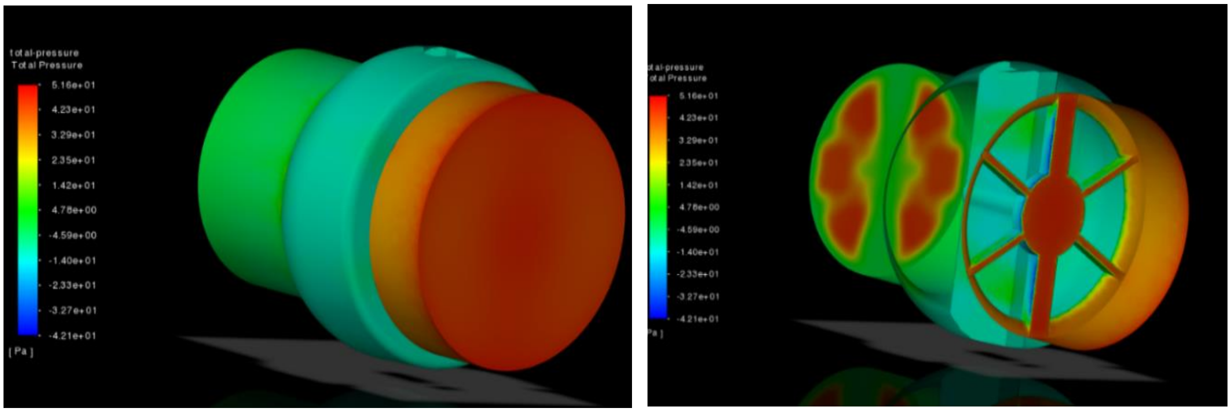


Fig. 5. Total Pressure Contours from CFD Model without Flap (a) External Fluid Domain View (b)Internal Fluid Domain View

TABLE II
NUMERICAL RESULTS FROM CFD MODEL WITHOUT FLAP

| **Parameter** | **Inlet (Average)** | **Outlet (Average)** | **Difference across Valve (Inlet – Outlet)** |
|---|---|---|---|
| Flow Velocity | 4.000 [m/s] | 5.391 [m/s] | -1.391 [m/s] |
| Total Pressure | 44.335 [Pa] | 22.537 [Pa] | 21.798 [Pa] |
| Static Pressure | 34.554 [Pa] | -4.472e-03 [Pa] | 34.550 [Pa] |
| Dynamic Pressure | 9.7921 [Pa] | 22.666 [Pa] | -12.874 [Pa] |

Additionally, a parametric study comparing the pressure drop to the flow velocity was performed using the same meshing scheme and CFD model parameters used in the model previously described. In the study, the flow was varied at 10 different flow velocities, ranging from 0.5 m/s to 9 m/s. This study was performed to further investigate the flow characterization of the valve. Fig. 6 contains the plots of (a) the Total Pressure Drop vs. (Flow Velocity)$^2$ and (b) Log – Log plot of Total Pressure Drop vs. Flow Velocity from this parametric study.

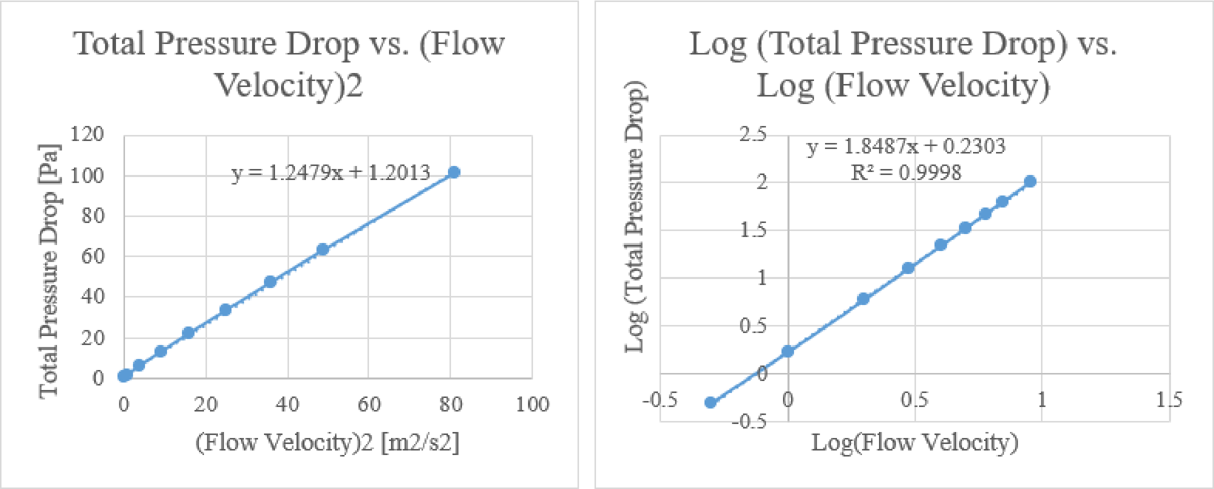


Fig. 6. (a) Plot of Total Pressure Drop [Pa] vs. (Flow Velocity)$^2$ from Parametric Study, (b) Log-Log Plot of Total Pressure Drop vs. Flow Velocity with Regression Equation Displayed

As demonstrated in Fig. 6, the total pressure drop across the valve and the squared flow velocity appear to have very nearly a proportional relationship for the Reynolds number range of 480 to 8725. This information will be useful as the flow characteristics of the original valve continue to be characterized as the CFD model is further developed in future work.

***Discussion***

From the initial CFD model results, the PMV without the flap was found to have a total pressure drop of about 21.798 Pa when the valve is subjected to a constant flow velocity of 4 m/s. Experimental work remains to be done to verify these results and to ensure that the model is an accurate approximation of the real valve flow characteristics and behavior. In developing the initial CFD model and framework, the use of computational methods such as CFD to characterize the flow characteristics of the original valve design was demonstrated. If this investigation continues, then subsequent valve iterations will be able to be modeled, simulated, and analyzed using the parameters and methods applied in this CFD baseline model to characterize the pressure drop and behavior of the flow flowing through the valve itself.

### ***Recommendations for Future Work***

There remains a significant amount of future work to be able to optimize the valve and further develop the robustness of the CFD model to continue implementing this investigation and optimization. Future work on developing this baseline CFD model will include introducing the presence of the valve flap as both a static flap and as a dynamic flap into the valve geometry (using Fluid-Structure Interaction methods (FSI)), prescribing an inlet flow velocity pattern that simulates human breathing (using analytical methods for mathematically modeling a breathing flow pattern), and introducing design iterations with geometrical modifications to be simulated in the baseline CFD model.

## **Flow Experiment**

In designing the flow experiment to be used to verify and validate the CFD model results, a conceptual model of the experimental set up (see Fig. 3) was developed based off of experimental set-ups from previous studies related to the flow characterization of tracheostomy speaking valves and other respiratory valves. The key components and materials for the flow experimental set-up were identified and several options for procuring those components were investigated. Table III identifies and details the options that could be used for the flow experimental set-up in a tabular format.

TABLE III

PROPOSED OPTIONS FOR FLOW EXPERIMENTAL SET-UP COMPONENTS

| **Component** | **Purpose** | **Options for Procurement/Implementation** |
|---|---|---|
| Air Supply | To supply a controlled air supply to be able to experimentally validate the CFD models | • Air Generator (constant air supply)<br>• Breathing simulator<br>• Portable Ventilator (simulates breathing) |
| Pressure Measurement Device/Sensor | To measure the pressure drop across the valve to compare to CFD model results | • Pressure Transducer Probe<br>• Manometer<br>• Differential Pressure Measurement device |
| Flowrate Measurement Device/Sensor | To measure the flowrate just before and after the valve to compare to CFD model results | • Vane anemometer<br>• Differential Flowrate Measurement device |
| Data Acquisition Device | To record, interpret, and display the experimental results | • Laptop Computer<br>• Software for measurement devices |
| Physical models of Valve Design Iterations | To physically represent the geometries of the valve design iterations for experimental testing | • 3D-printed valve design iterations<br>• Prototypes made by other rapid manufacturing methods |
| Flow Tube | To direct the air through the valve from the controlled air supply and to close the flow circuit | • Clear, smooth plastic or glass tubing<br>• PVC pipe |

### ***Recommendations for Future Work***

Further work remains to be done to procure the components needed to implement the experimental method and to assemble the flow circuit. The connections between the experimental components will also need to be designed and manufactured. Many of the connections may be made out of Silicon Rubber and cast into 3D-printed molds designed to fit each component interface or created using other available materials and manufacturing methods and tools. Once the flow circuit has been created and set up, the measurement devices will need to be calibrated and checked for any internal measuring bias. Each PMV design iteration that decreases the pressure drop and also maintains the structural integrity when compared with the original PMV design will be prototyped and manufactured using 3D printing or other rapid manufacturing techniques. Each prototype used for the flow experimental testing will need to have a smooth finish and ideally will contain a silicon diaphragm flap similar to that of the original PMV design. The results from each experimentally tested prototype will be used to verify and validate the CFD model of each viable PMV design iteration until an optimal final design is produced.

## Structural FEA Model

Some work has been done to initially set up a structural FEA model simulating a compressive test of the valve geometry. The CAD model of the original valve was modeled in SolidWorks 2022 and then inputted into ANSYS Workbench 2021 R2, where it was meshed. An initial simulation was performed in ANSYS Static Structural 2021 R2 where the valve was subjected to a fixed boundary condition at the outlet face and a compressive force of 500 N at the inlet face. However, the material parameters of the original Passy Muir speaking valve design remain to be determined from a ring compression test with samples from the original valve. Therefore, the results from the compression simulation have not yet been finalized.

### *Recommendations for Future Work*

Once the ring compression test has been performed and the original valve material characterized, the material parameters will be included in the structural FEA model. The model will then be checked for mesh convergence using a similar method used for the CFD model. Once mesh independence has been achieved, the results from the structural FEA model will be analyzed and recorded. In future work, as geometrical modifications are made to try to optimize the flow characteristics of the valve, each design iteration will be checked in the Static Structural model to compare how the results compare to the baseline model. The goal will be to keep the structural stability, strength, and integrity of each valve iteration to be either the same or greater than the original valve design.

### Compression Experiment

The testing standard to be used for the compression experimental testing was selected to be ASTM D695, and the components needed for the experimental set-up were also determined. However, there remains work to be done to implement the experimental set-up for the experimental compression tests. The essential components for the implementation of the standard compression experiment are specified in a tabular format in Table IV. Each PMV design iteration prototype that is fabricated for the flow experimental testing will also be fabricated in the same manner for the compression experiment. The flap will not need to be included for the compressive test prototypes since the flap does not contribute to the structural performance of the valve structure itself. The load at failure obtained from the compression experiment will then be used to verify and validate the structural FEA model of each viable PMV design iteration until an optimal final design is produced.

TABLE IV
PROPOSED OPTIONS FOR COMPRESSION EXPERIMENTAL SET-UP COMPONENTS

| **Component** | **Purpose** | **Options for Procurement/Implementation** |
|---|---|---|
| Tension/Compression Universal Testing Machine | To produce a controlled compressive loading using a constant strain rate and to record and measure the force and displacement at each specified time step | • INSTRON mechanical testing system |
| Data Acquisition Device | To record, interpret, and display the experimental results | • Laptop Computer<br>• Software for data reading and recording |
| Physical models of Valve Design Iterations | To physically represent the geometries of the valve design iterations for experimental testing | • 3D-printed valve design iterations<br>• Prototypes made by other rapid manufacturing methods |

## Overarching Methodology Framework

Overall, an iterative methodological framework was developed and begun to be implemented to integrate the use of a variety of engineering computational, analytical, and experimental methods in the optimization of a PMV. The CFD model and structural FEA model will be used to computationally evaluate and analyze the flow and structural characteristics of the original PMV design and each subsequent PMV design iteration. A combination of analytical and experimental methods will be employed in the ring compression test to characterize the material parameters of the original PMV design to be implemented in the structural FEA model. Experimental methods will be employed through the flow and compression tests to verify and validate the computational models as well as to further investigate the performance of the original PMV design and each developed valve design iteration. Together, the computational, analytical, and experimental results have the potential to provide a comprehensive and detailed analysis to be able to characterize and optimize the valve according to its flow and structural characteristics. Thus, the results from applying the described iterative and integrated optimization framework have the potential to provide a comprehensive understanding of the PMV design itself and to allow for more efficient and effective work to be accomplished in the design and optimization process. While the methodological framework has begun to be applied in the initial development of some baseline models and experimental set-up designs, further work remains to be done to fully implement the framework and to begin optimizing the valve.

## Conclusion

The integration of computational, experimental, and analytical tools and methods into one comprehensive optimization framework for a tracheostomy speaking valve introduces a unique collaboration between the fields of engineering and biomedical sciences. While this framework has not yet been completely implemented, the design and initial set-up of the models and methodologies has been done and will continue to be developed and eventually applied in the larger research effort of optimizing the PMV. Overall, the developed framework may be implemented in future work to further the optimization of the PMV to serve the patient for whom this investigation was originally intended to benefit. Ultimately, the development and implementation of this integrated methodological framework has the potential to be extended to the optimization of other tracheostomy speaking valves and respiratory devices to improve the quality of life of patients all around the world.

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