Flow Limitation During Forced Expiration in an Airway Model - BME 200/300

Product Design Specifications

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Section 304

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Function

Flow limitation is the phenomenon in which increasing respiratory effort no longer increases airflow beyond a certain point during forced exhalation, because the airway itself becomes the limiting factor rather than muscles driving expiration [1, 2]. During forced expiration, intrathoracic pressure rises sharply and can exceed the pressure inside the airway, resulting in the airway walls, specifically the bronchi, to narrow and eventually reach a choke point past which further effort in exhalation cannot increase flow [3]. This mechanism is central to interpreting spirometry, since flow-volume curves reflect the mechanical properties of airways rather than respiratory muscle effort alone [4, 5]. It is most relevant to obstructive diseases such as asthma, cystic fibrosis, and COPD, where airway walls are more prone to premature collapse or are already narrowed by inflammation, mucus, or loss of elastic recoil. This leads to prominent flow limitation occurring during forced exhalation [6]. This device will model the branching anatomy of the airway and use flexible materials to replicate the compression and collapse that occurs in the affected patient population. This will allow the users to visualize the equal pressure point (EPP) and the resulting choke point as it moves distally through the airway. The device is intended to physically demonstrate flow limitation during forced expiration for use in an educational teaching video. The final video will be used to teach medical fellows and students how these airway mechanics underlie clinical measures such as spirometry, and how they explain and monitor these obstructive conditions that experience flow limitation.

Client requirements

- The device must demonstrate flow limitation during forced expiration by visibly showing the choke point and EPP and the compression travelling distally through the airway, from the lower trachea, through a few generations of branching, and downstream towards the alveoli.
- The final device must be 3D-printed, stay permanently in ECB, and only needs to support a pre-recorded video, spanning 6 to 10 seconds, for teaching fellows and medical students about flow limitation.
- The airway model must mimic a simplified model of the branching anatomy observed in lungs. A multi-compartmental design is preferred, ideally a four-compartment model, but a minimum of two compartments is required.
- The material used to make the branches of the airway model must be thinner and more flexible than last year's model, so that choke point can shift asymmetrically across the generations of branches.
- The box that housed last year's model should be reused, unless the box proves to be insufficient.
- The team must stay under a budget of $1000.

Design requirements

1. **Physical and Operational Characteristics**
    a. *Performance requirements*
        i. The device must visually demonstrate flow limitation in an airway model and the movement of the choke point throughout the airways as forced expiration occurs. The movement of the choke point towards the alveoli must be visible enough to be seen on a 6 to 10 second video for demonstration purposes. The model must also accurately model

human airways with at least two but ideally four chambers (1 or 2 generations of bifurcation) with adequate elasticity to return to an uncompressed state when pressure is removed, allowing the demonstration to be re-ran a minimum of 100 times without losing elasticity in the model airways. The device must be able to contain pressures of at least 2.3 kPa above atmospheric pressure with no leakages to accurately represent conditions in the human anatomy surrounding the airways [7]. These conditions in the human airways are not consistent from person to person, especially in patients with obstructive airway diseases; airways in patients with COPD have increased compliance (stiffness) compared to healthy lungs, while airways in patients with asthma have thickened walls due to excess mucus [8]. The device should have a level of adjustability in airway stiffnesses, applied pressures, and lengths to reflect how different disease states and loading conditions affect the movement of the choke point during forced expiration.

b. *Safety*
    i. As part of its regular function, the device will be connected to compressed air via a hose. Use of pneumatic-powered tools and hoses are regulated according to OSHA standard 1910.243(b) [9], which requires a tool retainer to prevent accidental ejection of the hose and that the hose and hose connections be designed to withstand the pressure demands without failure. The device itself must also be rated to maintain normal operational pressures with no risk of explosion. The materials used in the device, especially those accessible to users, should be non-toxic, and the device itself should have limited sharp edges and pinch points.
c. *Accuracy and Reliability*
    i. The most important component that the device must accurately model is the visible formation and movement of the choke point upstream two generations during forced expiration [10]. The device should also model true human airway transmural pressures of 2.3 kPa and average compliance of 0.225 l/cmH_2O with variance along the airway as closely as possible [7, 11]. However, the focus should be on modeling accurate choke point behavior. This choke point movement must be visibly demonstrated with no mechanical failures or major changes in pressure values for a minimum of 100 simulated runs of forced expiration.
d. *Life in Service*
    i. The success of the device will be evaluated based on the criterion that the model is able to produce visibly discernable choke points along the airway, closer to the alveoli, during forced expiration. This event should have a sufficient time constant, around 6 to 10 seconds per the client's request, for quality interpretation by the students who will watch the video. The device should be capable of completing a minimum of a 100 simulation cycles across testing, operation, and the final video recording without degradation of mechanical performance or loss of the flow limitation effect.
e. *Shelf Life*
    i. Although the device will not be reused after the completion of the video, any components with a defined shelf life shall be stored per their manufacturer specifications, and will remain within their rated shelf life up to the date of the final video recording. Prior to use

for the final video recording, the device will be stored at standard room conditions (20-22℃, ambient humidity) in room 1070 at Engineering Centers Building.

f. *Operating Environment*
    i. Beyond the controlled temperature (20-22℃) and pressure (1 atm) of the testing environment, the device is not expected to be exposed to significant humidity variation, dust, corrosive fluids, or vibrations outside normal laboratory benchtop conditions. The device will be operated and tested exclusively by the undergraduate students on team "Flow State". There are no unforeseen hazards or exposure to outdoor elements, insects, or high-shock loading given the controlled indoor lab setting.

g. *Ergonomics*
    i. The device should be easy to move and transport as needed for any testing needed with the team. The device should not need to be moved often or at all after all testing and fabrication is done since the client is looking for the team to demonstrate how the device works via video. In addition, the model should be easy to properly use and demonstrate the choke points. Applying force and pressure via a compressed air hose should only require one hand to prevent any strain while also being able to operate and model the specific flow limitations and pressure points.

h. *Size*
    i. The physical model will be able to sit on a lab bench and be large enough to see visibly in the video representation. The pressure chamber from the previous design will remain the same dimensions around 20 × 20 × 20 cm with acrylic thickness of 20 mm [17]. This is equipped with pressure taps for measuring box pressure, upstream/airway pressure and downstream pressure. The main airway tubing should be from 15 mm to 18 mm to stimulate the correct adult airway geometry. The flexible section should have a very small thickness of 0.5 mm to 1.0 mm in order to properly demonstrate the airway model [12].

i. *Weight*
    i. The maximum load constant (LC) is set at 23 kg to ensure safety when transporting these objects [13]. The acrylic chamber weighs 12 kg, well within the limit of safety for the object [17]. The lung model inside the chamber will weigh no more than 0.454 kg as it will be created with flexible materials ensuring that using the model is as effortless as possible.

j. *Materials*
    i. The material used to model the airway must be sufficiently flexible to show visible compression at the location of the choke points. Ideally, the material will match the biological properties of the airway walls as closely as possible, including a Young's modulus of 0.17 - 0.65 MPa [14] and a Poisson's ratio of 0.41 - 0.45 [15]. Additionally, the material must exhibit a gradient in compliance (dA/dPtm) to ensure the choke point travels distally [16]. This gradient will be accomplished by varying the material thickness, meaning that the material chosen must be viable at a wide range of thicknesses. The alveoli must be modeled using a thin, balloon-like material that is able to expand as the model takes in air, and this material must be conducive to a tight, leak-proof seal with the airway model. The vacuum chamber to be used is fully transparent and is composed of pressure-resistant acrylic with a thickness of 20 mm [17]. This material will resist

deformation and leakage, and allow for complete visualization of the airway model throughout testing.

k. Aesthetics, Appearance, and Finish

i. The final product must clearly display the full length of the airway model so that the distally moving choke points are visible throughout the respiratory cycle. The product must replicate the airway in an intuitive manner such that students understand how the anatomy of the model correlates with human anatomy, and labels should be included to indicate key anatomical features for added clarity. Most students will access the model through a video demonstration, so the product must be conducive to video recording.

2. **Production Characteristics**

a. Quantity

i. Per client requirements, one prototype is required. In order to allow for widespread viewing of the model, a video displaying the key features of the model will also be provided to the client.

b. Target Product Cost

i. The vacuum chamber from the previous project, which cost $466.83 [17] and has already been covered by the past client budget, will be reused. The total additional cost of the airway model materials to be used in this iteration is estimated to remain under $150. The client has provided a total budget of $1000 for this semester, which is well beyond the estimated semester project cost.

3. **Miscellaneous**

a. Standards and Specifications

i. The model will operate using compressed air for testing and the final video demonstration. All operators of the model, and surrounding observers, must wear adequate eye protection in the front and side of the eyes to protect from potential flying debris [18]. Air receivers on the device should be equipped with an indicated pressure gauge to safely observe the pressure delivered to the device [19]. Safety valves, indicating, and controlling devices should be installed and located so they cannot be readily rendered inoperable [19].

b. Customer

i. The client, Dr. Chris Green, is professor emeritus in the Division of Pulmonology and Sleep Medicine at the University of Wisconsin - Madison. Dr. Green has requested a device that accurately models Flow Limitation for instruction of medical students. The model will result in a final video that should show an understandable depiction of the device. This will be achieved by slowing down the demonstration to show the movement of choke points and depicting multiple cycles. The model should have at least two chambers with four chambers being the most preferable to show the distal movement of choke points.

c. Patient-related concerns

The client requests a short video demonstrating the model in use to be used in classrooms. Because of this, there is no posed risk to the client or patient. With this in mind, there will only be an emphasis on keeping the operator safe. First is biosafety and

toxicity. The materials used to print the 3D model of the airways should be constructed of materials that are nontoxic and non-degassing under pressure to prevent chemical inhalation by the user. Another concern is pressure and shattering. The pressurized chamber should be able to withstand significantly more pressure that the model inside will need to be pressurized to. Brittle materials such as glass should not be used. Lastly is sterilization and maintenance All surfaces and materials should be able to be disinfected and cleaned with standard disinfection without degradation or ruin.

d. Competition

Existing market and research solutions only provide computational statistics based on computer generated models or static anatomic models, leaving a gap between a physical model that can visualize pressure and chokepoints. The first model of competition was created by the department of Mechanical Engineering at Yamaguchi University created models of the airways by developing a computational fluid dynamics (CFD) that reconstructs a patient's airways directly from CT scan data. The drawback of this model is it does not include an exterior pressure system and pressure drops and changer or chokepoints [20]. The second model is called the Polak and Yutchen Computation Model. This mathematical model demonstrates wave speed flow limitation and choke point formation across the bronchial tree during forced expiration. This model takes place solely in a computer model called *silico*, removing the opportunity to see a 3D model. The physical demonstration provides a visual representation of a pressured chamber and moving choke points [21].

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