FlexiValve: Engineering Portable Adaptive Valved Holding Chambers for pMDI Users

Dignity Health.

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Unmet Clinical Need

- Patients with asthma or COPD using pressurized metered-dose inhalers (pMDIs) often need a Valved holding chambers (VHC) to improve lung delivery (Figure 1). Of the 26.8 million Americans with asthma, only 10–13 million or 46% are VHC users indicating a large unmet clinical need exist.
- Using a pMDI alone can cause much of the drug dose to deposit in the oropharynx instead of reaching the airway. In addition, technique-related human-factor errors also contributes to reduce lung delivery.
- VHCs can improve pMDI drug delivery by reducing coordination demands and supporting better aerosol delivery allowing the spray to enter the chamber as a high-velocity jet with an estimated dynamic pressure ranging from 540 Pa to 960 Pa.
- Consistent drug dose depends on key device design factors that include valve function, electrostatic control, seal quality, as well as human factors, such as breathing technique and cleaning practices.
- However, an emerging unmet need is reduced VHC bulkiness when not is use.
- FlexiValve's collapsible mouthpiece overcomes current pMDI limitations while maintaining device function

Figure 1. Valved Holding Chamber with pMDI

Design and Development Methodology

	Design Controls of Valved Holding Chamber					
Product	Cost-effective	Portable (easy to carry)	Flexible / collapsible chamber body	Airtight sealing at interfaces	Modular assembly (separable end caps)	Locking mechanism for compressed storage
AeroChamber Plus Flow-Vu (commercial)	√			√	√	
OptiChamber Diamond (commercial)	√			√	√	
FlexiValve (concept/prototype)	√	√	√	√	√	√

➢ **3D Design in SolidWorks**

• Developed a parametric CAD model that allowed changes in VHC chamber length and diameter, wall thickness, end collars, and interface tolerances across design concept iterations.

• Benchmarked OptiChamber Advantage specifications for baseline reference

•Multiple Component Design Concept: corrugated chamber body, mouthpiece cap, and inhaler end cap with a valve seat ledge for one way flow.

➢ **Prototype Fabrication Stratasys and Formlabs 3D Printing**

• Planned hybrid printing with rigid ABS end caps on a Stratasys printer to keep interfaces stable and repeatable.

• Planned collapsible corrugated chamber body on a Formlabs SLA printer using Elastic 50A resin to support repeatable compression and spring back.

• Designed assembly for press fit or simple clamping to maintain alignment and a continuous internal airflow path.

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Virtual Prototype Design and Fabrication

Design Concept 1 (Fig 2) VHC Smooth Hollow Tube (Baseline CAD Geometry)

• **Chamber body (hollow, open ends):** 116.0 mm length, 52.5 mm OD, 48.9 mm ID, 1.8 mm wall, 8.0 mm end collars, 56.0 mm collar OD

• **Mouthpiece cap**: 49.0 mm length, 10.0 mm insert, 48.3 mm insert OD, 26.0 mm bore, 4.0 mm flange

• **Inhaler cap:** 32.0 mm length, 10.0 mm insert, 48.3 mm insert OD, 26.0 mm bore, 4.0 mm flange

Design Concept 2 (Fig 3) Addition of VHC Corrugated Features

• Added ring corrugations along the 100.0 mm center section (5.0 mm pitch, 1.5 mm radial height) while keeping smooth end collars for end-cap attachment

• **Rationale**: thin-walled tubes can ovalize and buckle under bending/compression, creating kinks that restrict airflow

• Corrugations create repeatable "fold points," spreading deformation across many small hinges for controlled collapse and improved portability

Design Concept 3 (Fig 4-6) Optimized Corrugated Features and Assembly

• Increased corrugation amplitude from 1.5 mm radial (V2) to a 2.5 mm ridge radius from the tube (V3) to increase folding stroke and hinge-like collapse

• Added a thin ridge wall **(0.5 mm)** to reduce fold stiffness and make compression easier and more repeatable

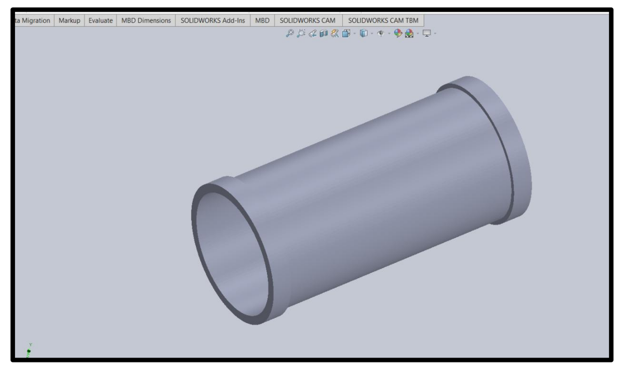

Figure 2. FlexiValve Chamber Body (Concept 1)

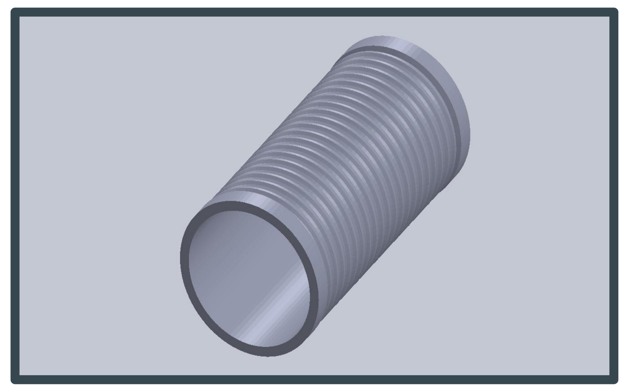

Figure 3. FlexiValve Chamber Body (Concept 2)

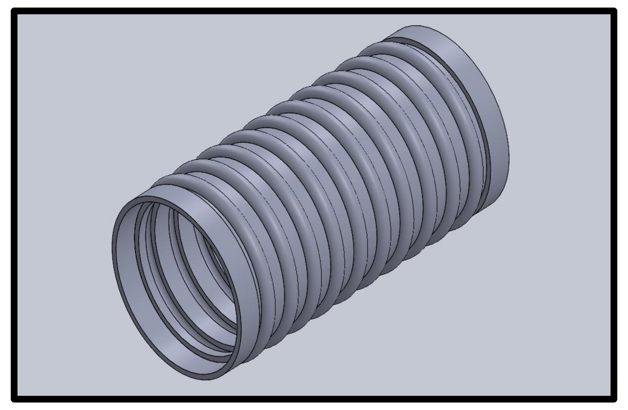

Figure 4. FlexiValve Chamber Body (Concept 3)

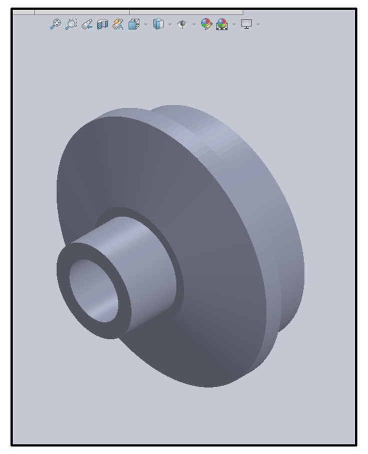

Figure 5. FlexiValve Inhaler Cap:

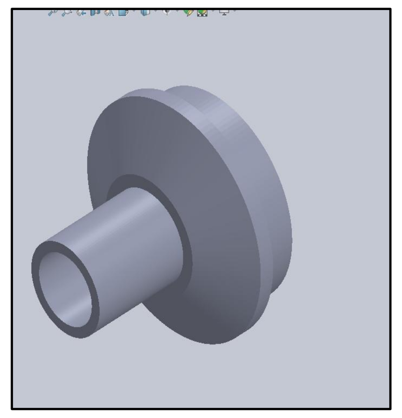

Figure 6. FlexiValve Cap Mouthpiece

Physical Prototype Results

Figure 7. FlexiValve Cap Mouthpiece (3D-Printed)

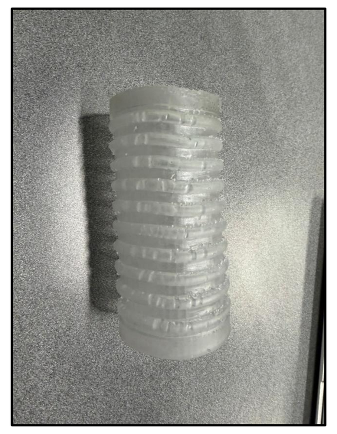

Figure 9. FlexiValve Chamber Body (3D-Printed)

Figure 8. FlexiValve Inhaler Cap (3D-Printed)

VHC Assembly Components

Summary, Conclusions and Future Directions

Key Takeaways from CAD results:

• CAD design iterations progressed from a smooth chamber to corrugated designs to enable controlled collapse and reduce kinking risk.

• Final Concept (3) increased corrugation stroke and reduced ridge stiffness to promote easier, more hinge like compression.

• Next steps include benchtop validation and benchmarking, adding a storage lock, and comparing TPU versus Elastic 50A including antistatic options.

Key Conclusions:

• FlexiValve demonstrated feasibility of a portable, compressible VHC through iterative CAD guided by collapsible tube and bellows principles

• The final concept incorporated ring corrugations to support repeatable collapse while maintaining a continuous airflow path and stable end cap interfaces.

•**Expected Benefit**: smoother accordion-like collapse with lower kinking risk, supporting adaptive VHC reduction for storage when not in use

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