

Assistive Drinking Device For Dysphagia due to Parkinson's Plus Diseases

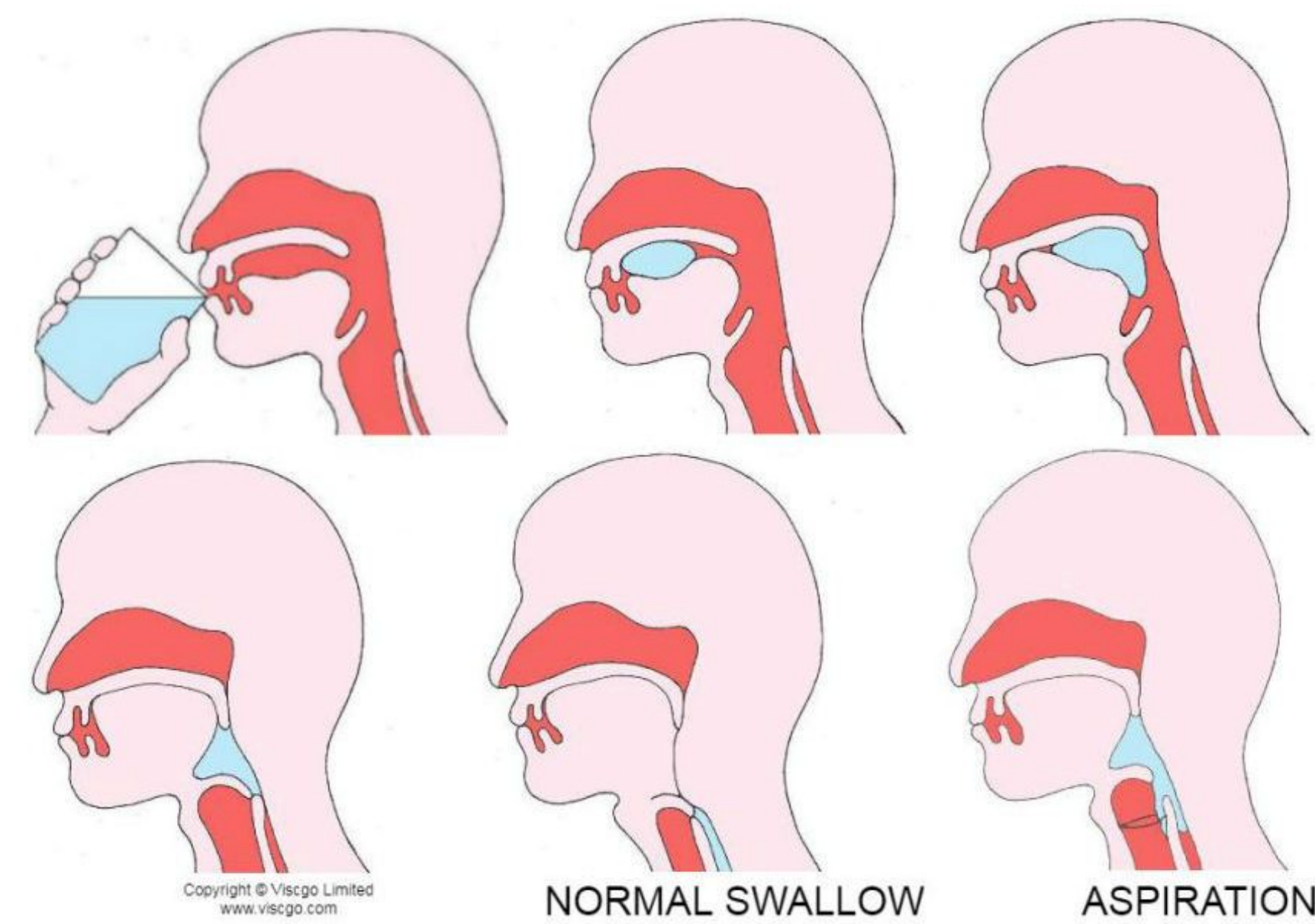
Nisha Bhargava^{1,4}, Chris Huynh^{1,2}, Brian Gormley^{1,3}, Alyssa Theroux¹, Brian Woolley^{1,2}
¹ Biomedical Engineering, ² Chemical Engineering, ³ Material Science Engineering, ⁴ Mechanical Engineering



Background

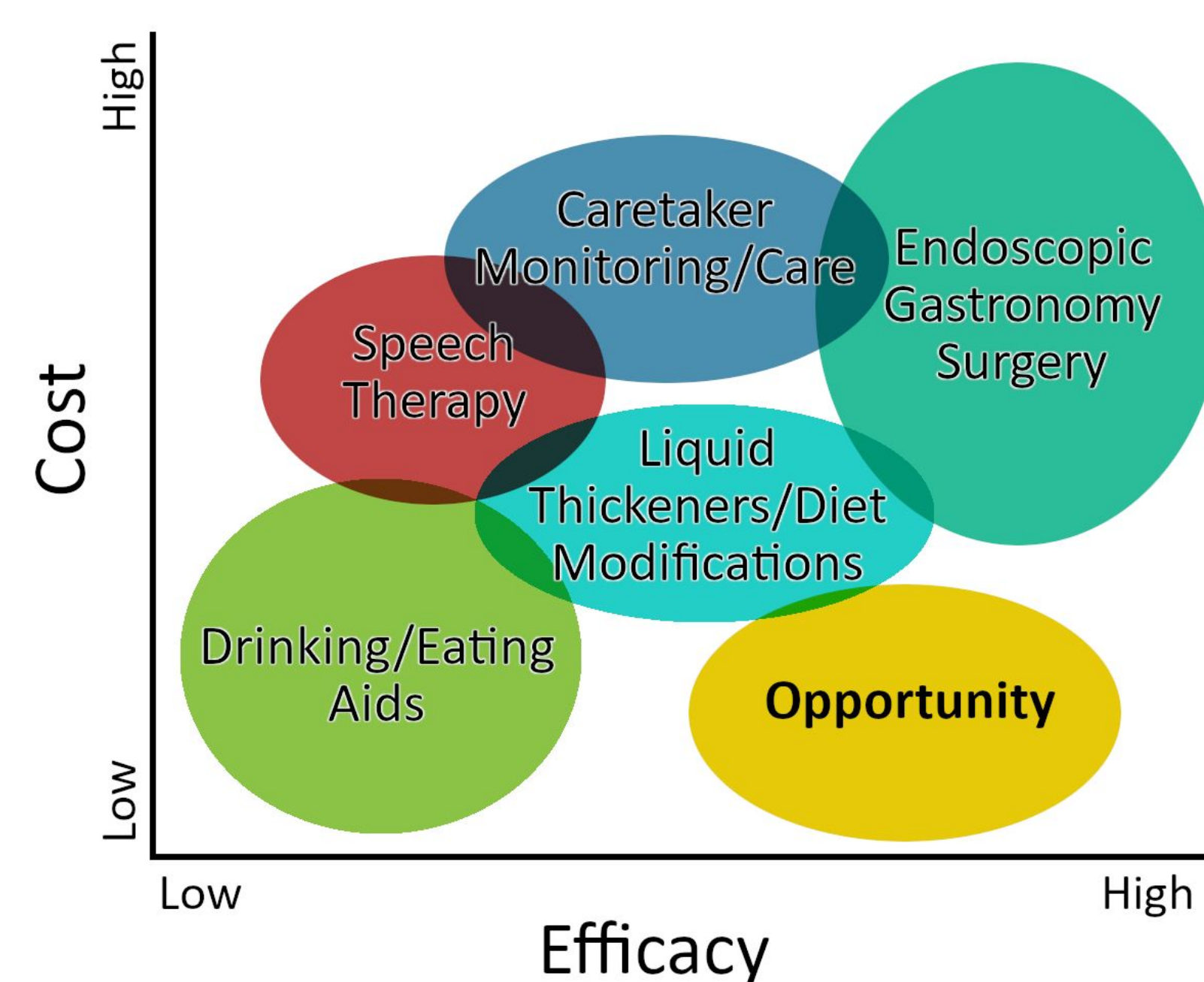
Problem

- Progressive Supranuclear Palsy
 - Result of neuronal loss due to tau protein build up
 - Nearly 50% of patients with neurodegenerative disorders develop dysphagia within 5 years of diagnosis¹
- Neurogenic Dysphagia: difficulty swallowing due to neurological disorder



Existing Solutions

- Solutions target reducing incidence of aspiration
- Treatment must evolve as disease progresses
- End stage treatment is placement of feeding tube to bypass swallowing



Needs Statement

A way to reduce aspiration in patients who have difficulty swallowing caused by Parkinson's and Parkinson's plus diseases that allow for safe ingestion of liquids.

Product Specification

- Small, adjustable bolus delivery
- Time/Volume Control
- Reusable
- Hot/cold, thin/thick liquids
- Durable
- Washable

Proposed Solution

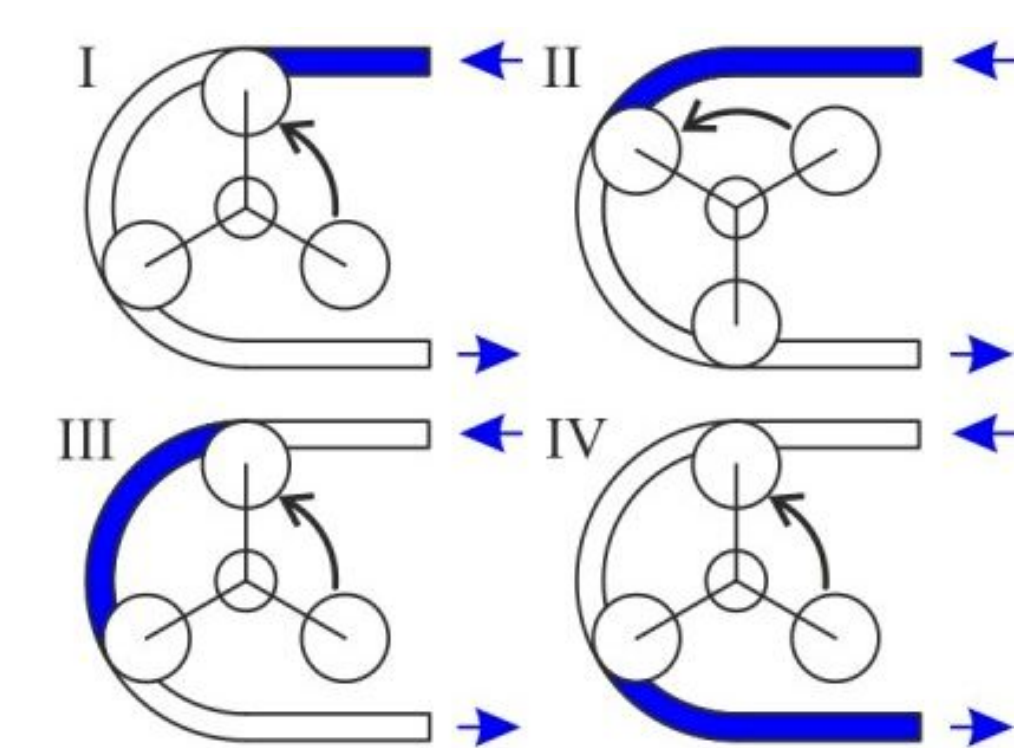
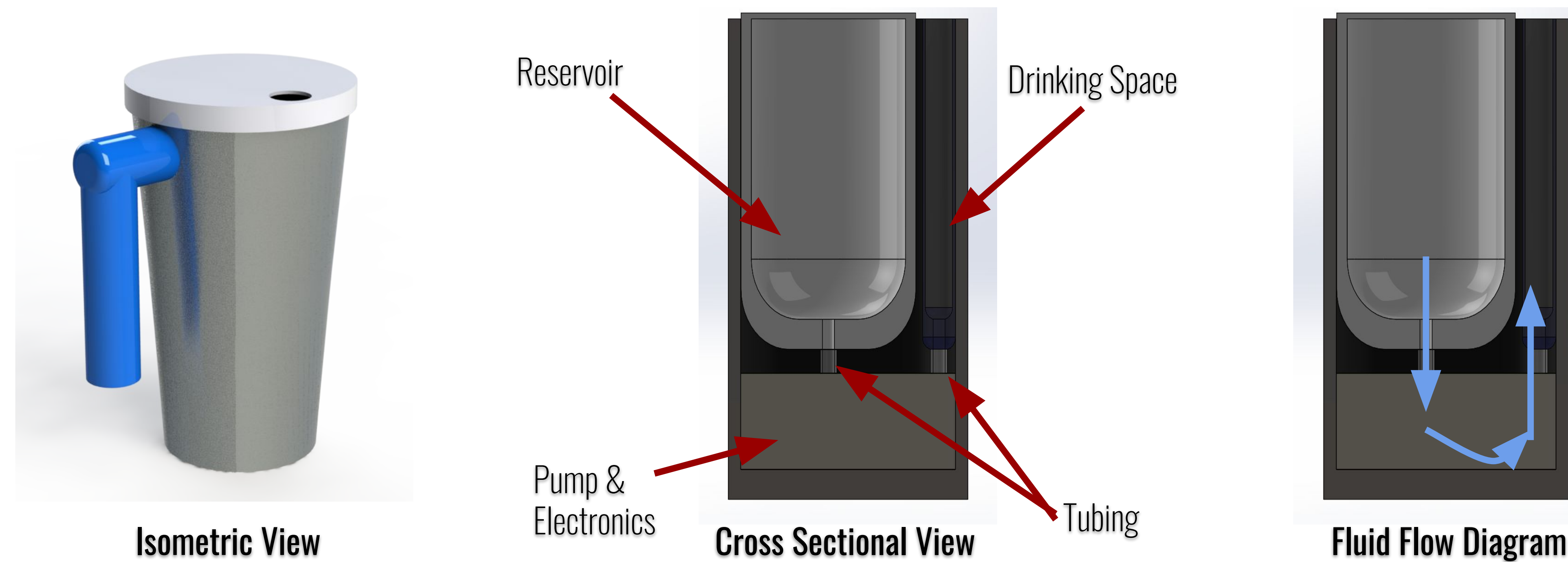


Figure 1. Peristaltic pump schematic. Rotor rotates, rollers create vacuum to draw fluid in and compress tube to force fluid out outlet.

- Fluid is pumped from closed-off reservoir to drinking space where patient can access the fluid for drinking
- Time-delayed bolus delivery system requires patients to wait a set time before receiving another bolus
- Peristaltic pump is powered by 12V DC Motor controlled by Arduino
- Pump is time-calibrated to deliver bolus of desired volume

Testing

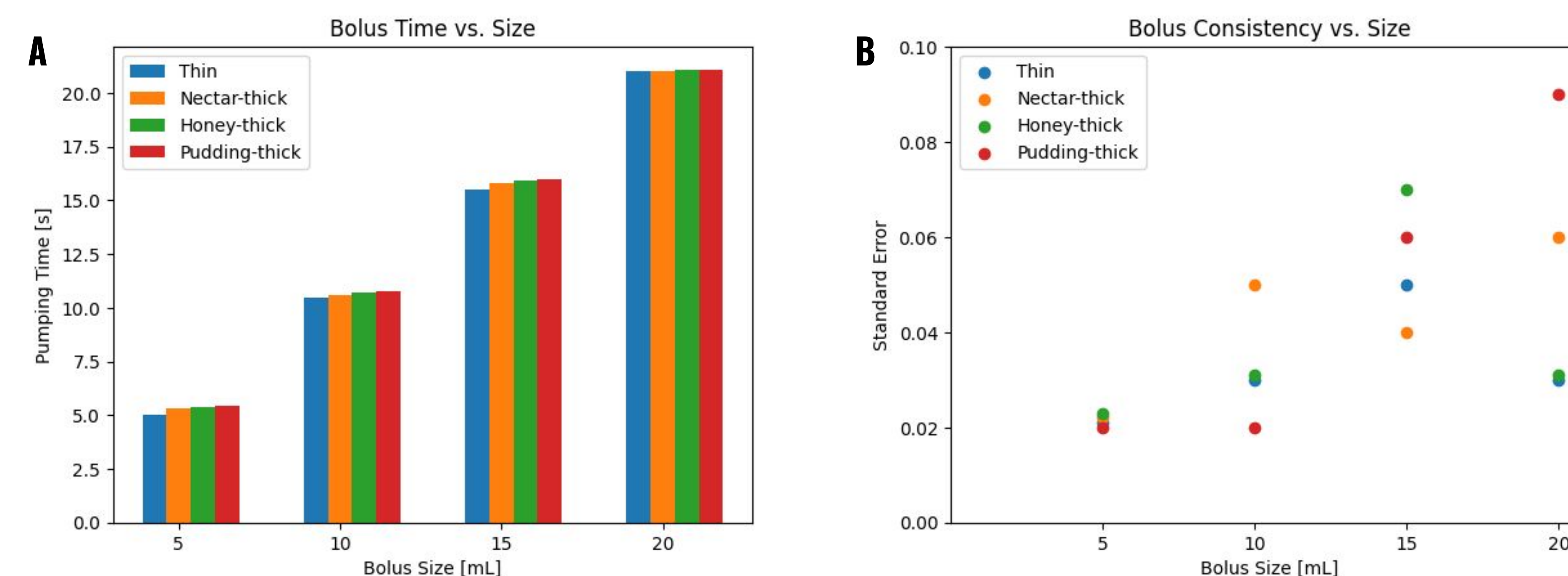


Figure 2. (A) Time required to deliver bolus volume for fluids of varying viscosity. (B) Consistency of bolus size quantified by standard error for fluids of varying viscosity. For testing purposes, fluids of varying viscosity were formulated following instructions of a commercial thickening agent, DysphagiAide[®].

- Bolus error increases as bolus size increases
- Bolus error is approximately equivalent for fluids of varying viscosities
- Increasing viscosity does not significantly impact time required to deliver bolus of given volume
- Due to shear-thinning properties of common fluids, varying viscosity has minimal effect on pump performance

Table 1. Descriptions and approximate viscosity ranges for liquid consistencies outlined by the National Dysphagia Diet (NDD).²

Classification	Description	Viscosity [cP]
Thin	Liquids (e.g., water, juice, tea)	1-50
Nectar-thick	Pours easily, but thicker than water	51-350
Honey-thick	Flows more slowly, requires more effort to drink	351-1750
Pudding-thick	Requires spoon to eat	> 1750

Cost, Patent, Reimbursement

Manufacturing Costs

	Initial Cost	Iterative Cost/Unit	Cost/Unit (1 Year)	Cost/Unit (10 Years)
Impact Extrusion Aluminum	\$75,000	\$2.00	\$9.50	\$2.75
Injection Molded Pump	\$50,000	\$1.00	\$6.00	\$1.50
Total	\$125,000	\$3.50	\$15.50	\$4.25

Patentability

- The motorized design of this device fulfills both the "absolutely new" and "working" requirements, making it patentable.

Reimbursement

- This is a Class 1 device, so it will not require a 501(K), nor a PMA.³

Conclusions

- Device concept represents an improvement on existing assistive drinking devices that enables patients to drink independently, thereby reducing the burden on caretakers
- Current prototype provides basic volume over time control
- Fluids of varying viscosity are well tolerated by peristaltic pump
- Pump controlled by DC motor achieves accurate and consistent bolus delivery
- Future Work
 - Iterate on design to make more compact and ergonomic
 - Integration of mobile app to enable remote monitoring and adjustment of bolus size and time delay settings
 - Clinical testing of prototype by patients and caregivers

Acknowledgements

We express our gratitude to Dr. Zapanta and Jarrett Boyd for their valuable support and guidance during the course of this project. Furthermore, we extend our appreciation to Dr. Edward Burton and his patients for serving as inspiration for this project and for providing valuable clinical feedback that assisted us in enhancing our design.

References

- Miller-Patterson C, Han JH, Yaffe K, et al. Clinical and neuroimaging correlates of progression of mild parkinsonian signs in community-dwelling older adults. *Parkinsonism & Related Disorders*. 2020;75:85-90. doi:https://doi.org/10.1016/j.parkreldis.2020.05.0232.
- Carly, Steele CM. Thickened Liquids for Dysphagia Management: a Current Review of the Measurement of Liquid Flow. *Current Physical Medicine and Rehabilitation Reports*. 2018;6(4):220-226. doi:https://doi.org/10.1007/s40141-018-0197-63.
- General Controls for Medical Devices. U.S. Food and Drug Administration. Published 2019. https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices