

Introduction

Motivation:

- 30,000 people have asthma attacks and 5,000 individuals are hospitalized every day.
- The combination of a small surface area and lack of force distribution on the traditional top-down push design makes it difficult for children, elderly, and individuals with neuromuscular diseases to self-administer a dose of asthma medication.

Cost of Product

Area Adapter

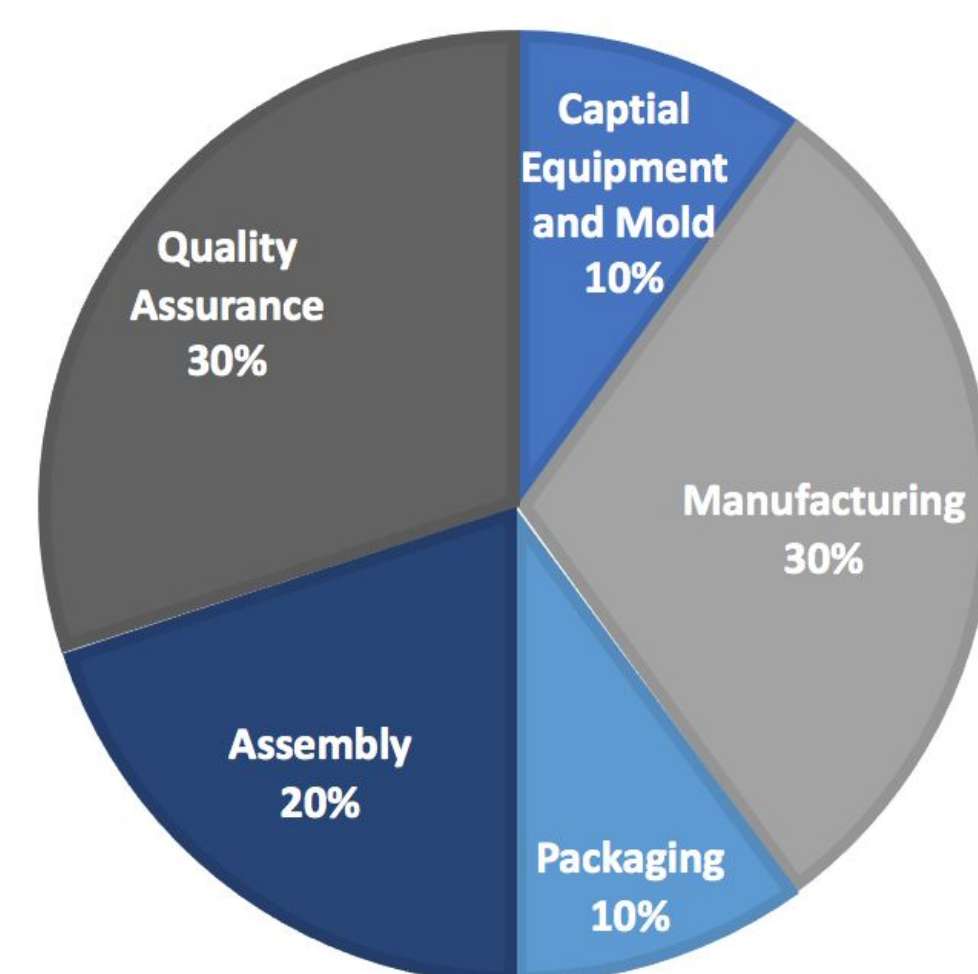
- Manufacturing Cost(per unit) : \$7

Squeeze Adapter

- Manufacturing Cost(per unit) : \$10

Manufacturing Parameters

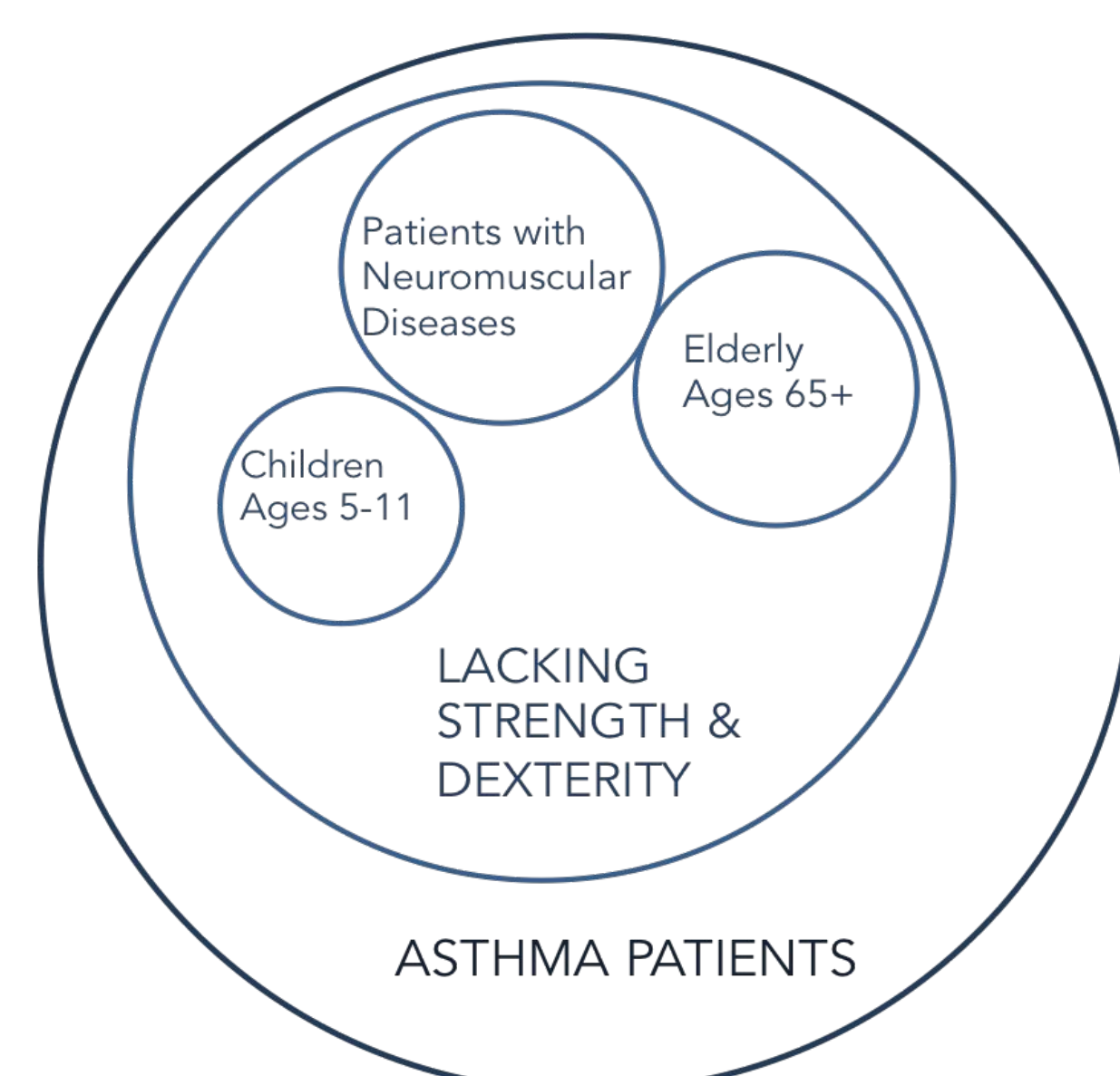
- Assuming 1,500 units per batch of injection moulding
- Selling Price : \$17



Potential Market and Impact

Product Users

- People who require assistance using an asthma inhaler
- People who suffer from neuromuscular disease, elderly over age 65, children under age 12



Market Size

- 105 million people in U.S. have neuromuscular disease are over age 65 and/or are under age 12
- ~ 8 % of population has asthma
- Results in a potential market of 8.5 million in U.S.

Distribution

- Distribution through pharmacies and medical practices

Competitors

- Aerogen Solo
 - (+) more effective drug delivery
 - (-) bulkier, more costly
- Dry Powder Inhalers (alternative product)
 - (+) better update of medication by patient
 - (-) more costly
 - (+/-) dispenses different types of medication

Inhaler Adapters

Area Adapter

Designed to increase surface area for users to apply medication with ease



- Users push down on the three tabs similar to current inhalers
- By increasing the surface area, less force is required
- Size of inhaler is increased by 20% with the adapter

Squeeze Adapter

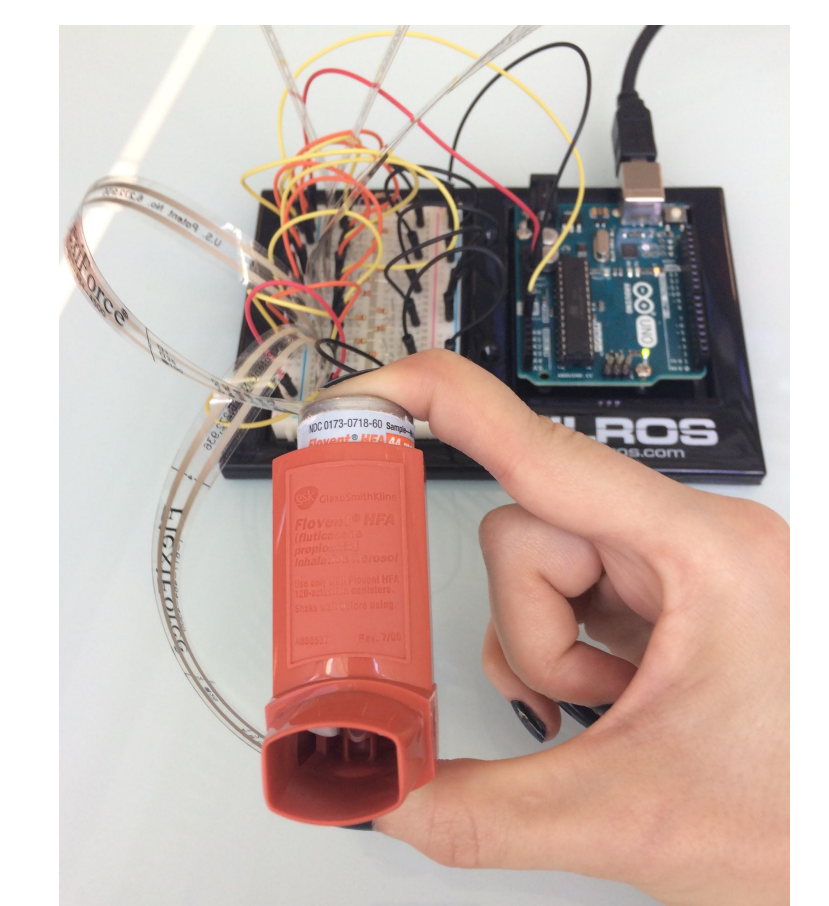
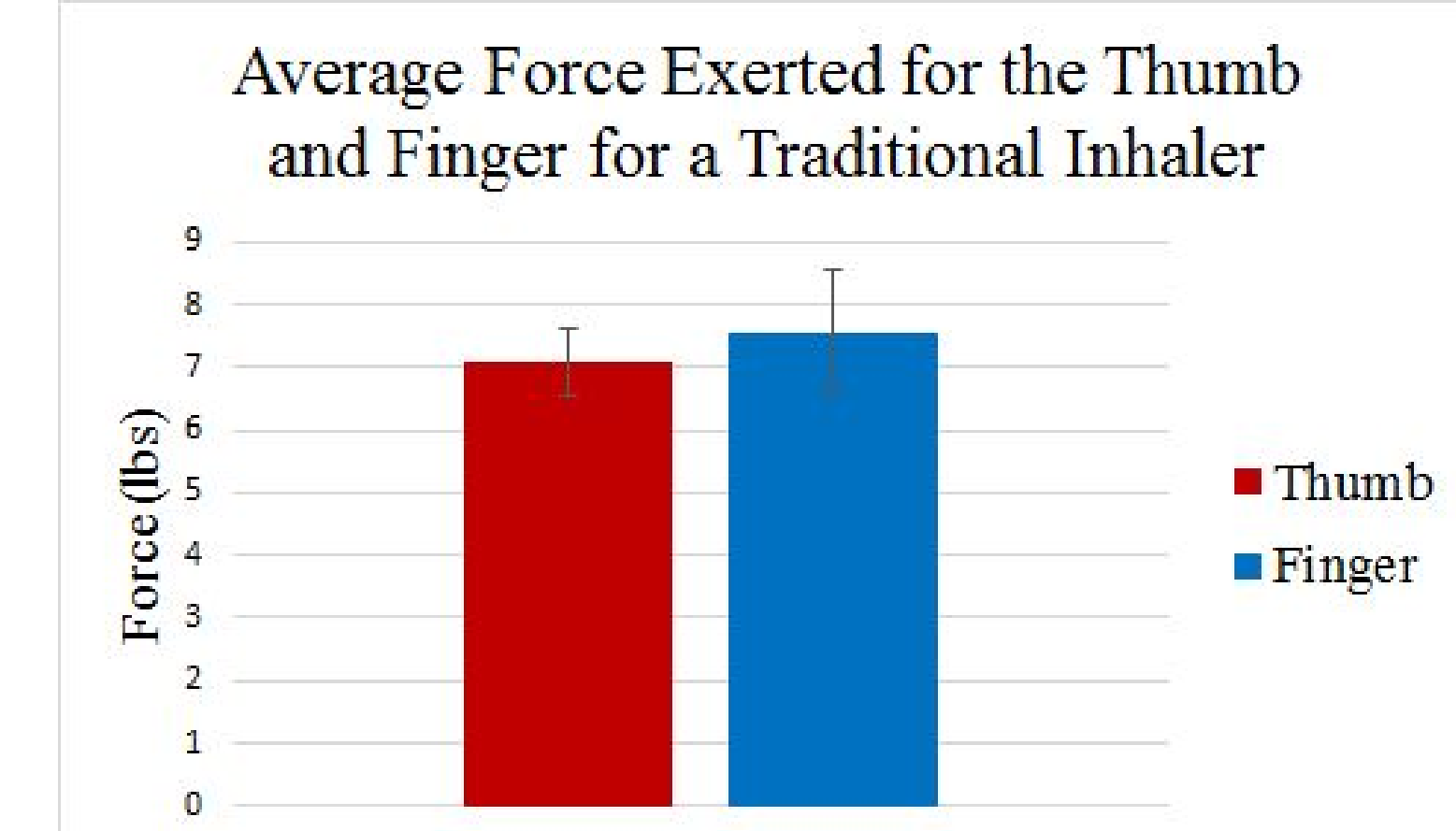
Allows users to squeeze instead of push down to operate



- The squeeze mechanism redirects the force exerted from lateral into a vertical direction
- Each adapter uses the entire hand rather than a single (or multiple) finger(s)
- Size of inhaler is increased by 65% with the adapter

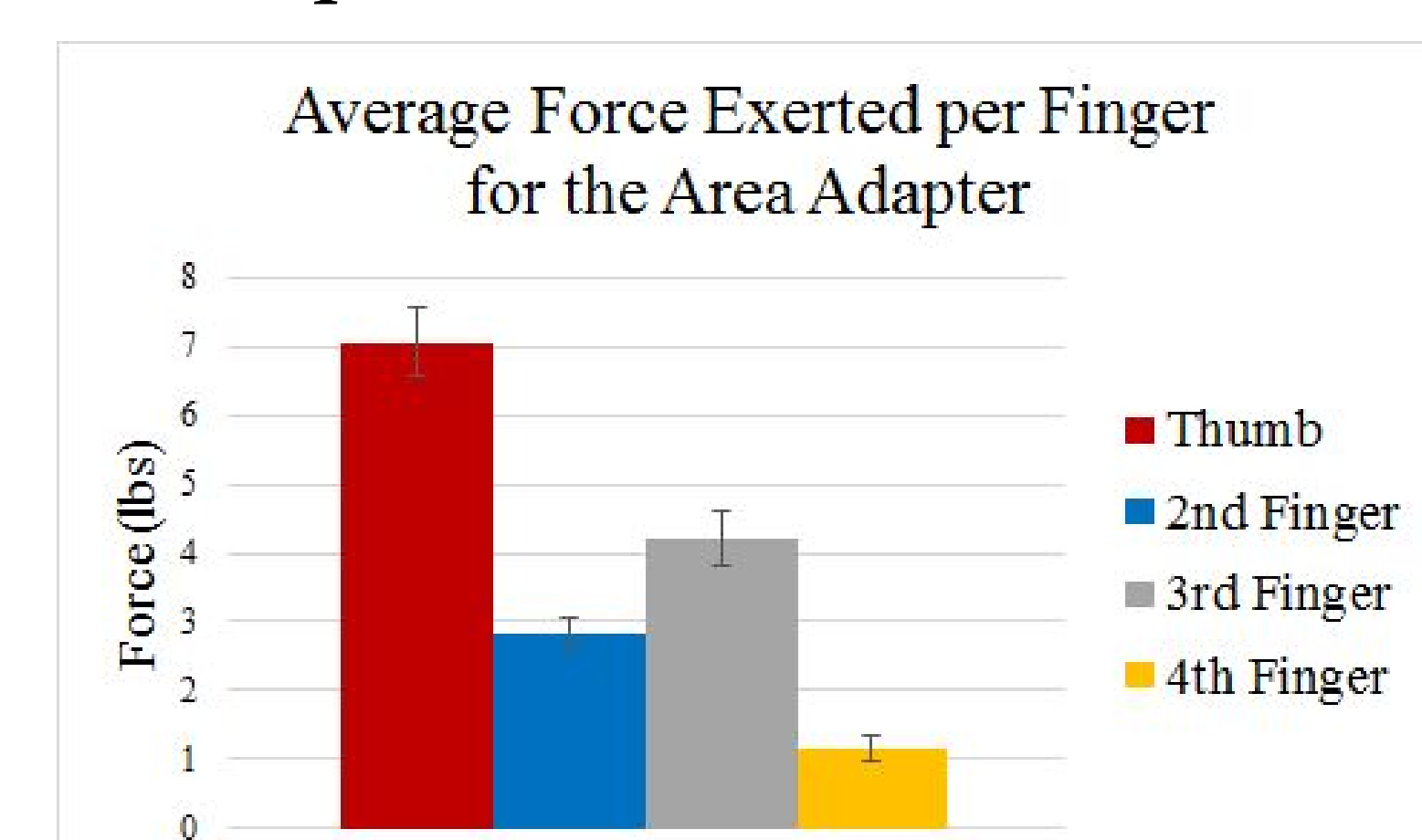
Testing and Results

Standard Inhaler



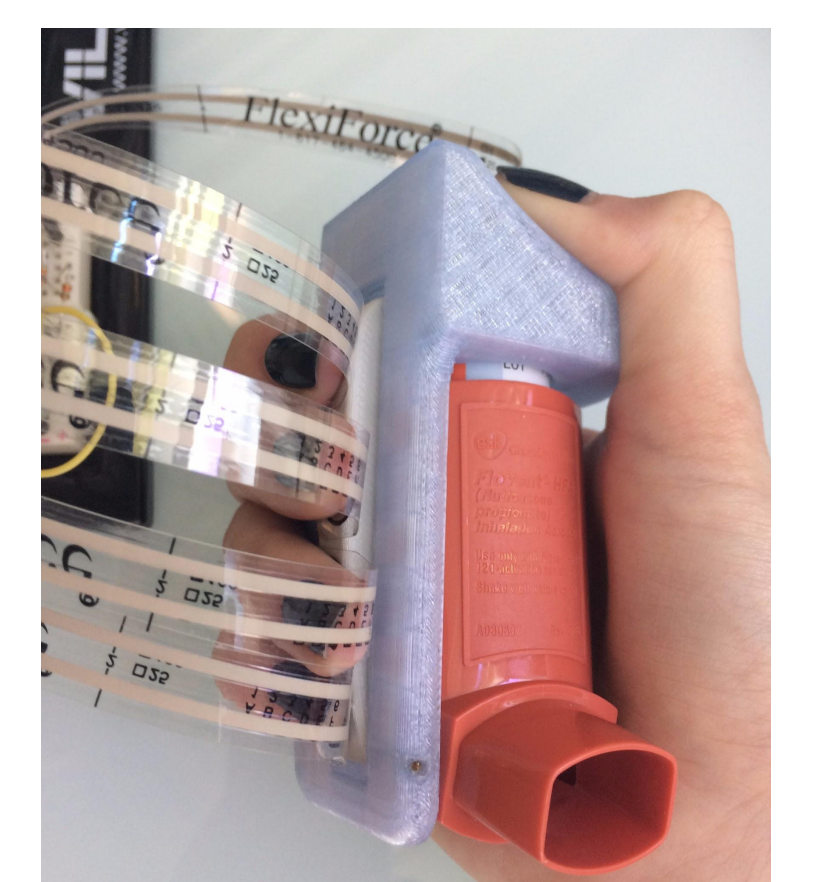
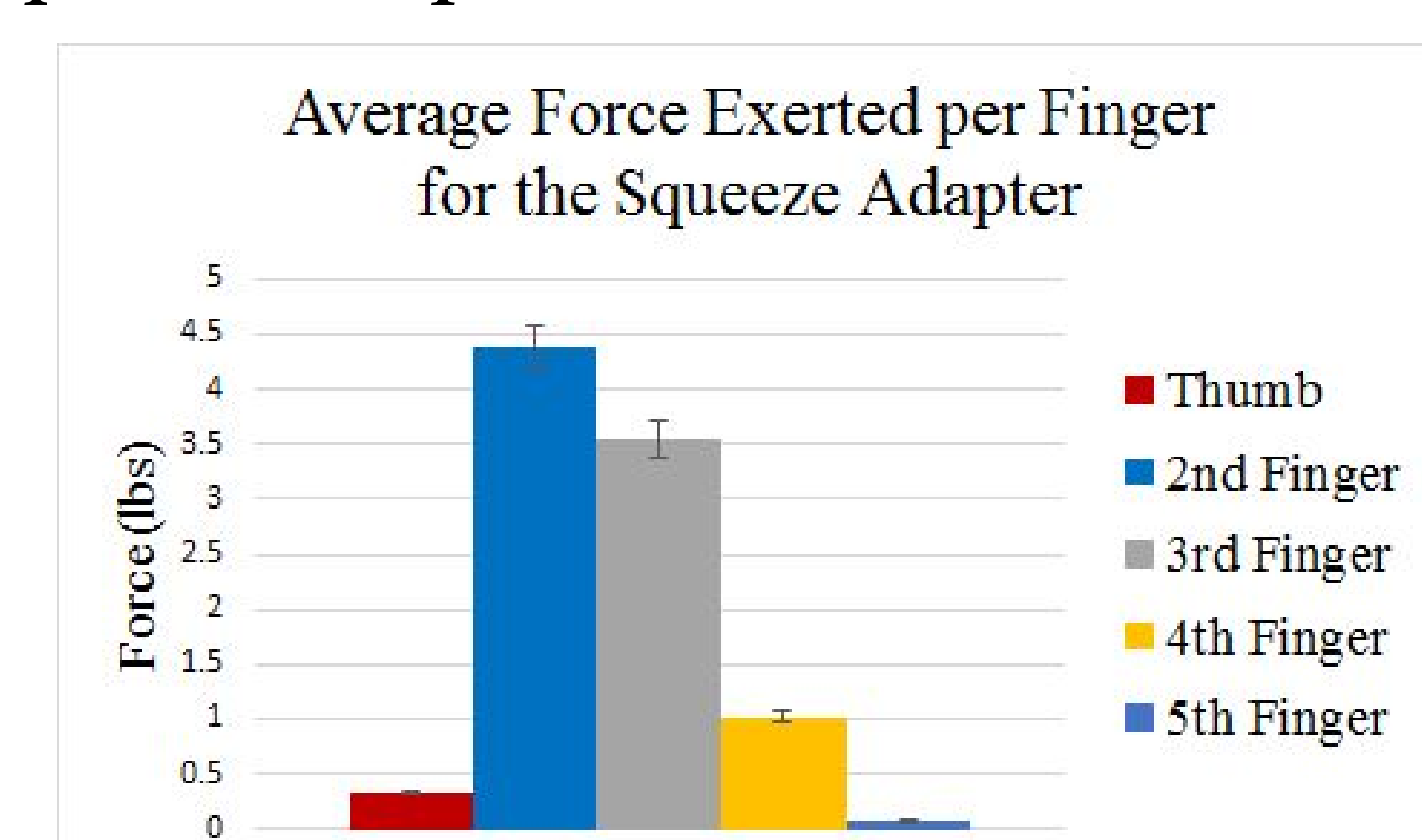
- Requires 7.6 pounds of force

Area Adapter



- Requires 8.2 pounds of combined finger force showing 10% design inefficiency
- Decrease in at least 48% force per finger

Squeeze Adapter



- Requires 9.4 pounds of combined finger force showing 25% design inefficiency
- Decrease in at least 45% force per finger

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References

- "Asthma Statistics | AAAAI." *The American Academy of Allergy, Asthma & Immunology*. N.p., n.d. Web. 10 Nov. 2016.
- "Asthma's Impact on the Nation Data from the CDC National ..." N.p., n.d. Web. 10 Nov. 2016.
- "Data and Statistics." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 2014. Web. 10 Nov. 2016.
- "Digital Dose Inhaler Market Size | Industry Report, 2024." *Grandview Research*, July 2016. Web. 14 Dec. 2016.
- "Medscape Log In." *Medscape Log In*. N.p., n.d. Web. 10 Nov. 2016.
- "Meter Dose Inhaler (MDI) Testing." *Piper Medical*, n.d. Web. 24 Nov. 2016.
- "Neuromuscular Disorders - Alfred Mann Foundation." *AMF*. Alfred Mann Foundation, n.d. Web. 14 Dec. 2016.
- "News." *CDC Reports Annual Financial Cost of COPD to Be \$36 Billion in the United States*. N.p., n.d. Web. 10 Nov. 2016.
- "Which Respiratory Conditions Require Inhalers?" *Alot Health*. N.p., 2016. Web. 10 Nov. 2016.

Anticipated Regulatory Pathway

- Inhalers are classified as ear, nose and throat drug administration devices, which are housed under the Office of Device Evaluation
- According to the FDA, inhaler adapters are Class I devices
 - Low-risk device
 - 510(K) is not required; need proof of safety and effectiveness
 - Premarket notification application and FDA clearance not required
- According to FDA, inhaler adapter has manufacturing and marketing requirements:
 - Proper listing and labeling
 - GMP not required