Problem Statement

- Each year, millions of animals and human cadavers are used in research settings, driving up the costs of discovery and design of new medical devices.
- Anthropomorphic phantoms provide a cheaper, reusable option for testing new devices.
- Currently, coloanal phantoms for colonscopy device testing are not widely available and accurate, even using gastrointestinal (GI) phantoms for endoscopy device testing do not exist.

Needs Assessment

- Fidelity of Model
  - Look and feel as real as possible
  - Closely match dimensions and material properties of human organs
- Durability
  - May be used repeatedly for extended periods of time without wear
  - Can be removed from suspension and cleansed
- Targets
  - Polyps in the large intestines
  - Locations of routine screening in stomach
  - Can be altered between trials

Primary Objective

- Create a repeatable protocol for the development of two gastrointestinal phantoms to test potential new endoscopic and colonscopy screening devices:
  - Upper GI: esophagus, stomach, upper ⅓ of duodenum
  - Lower GI: colon, rectum
- Embed targets in the phantoms to represent physiological phenomena

Design Components: Materials and Features

### About Ecoflex and Dragon Skin

Ecoflex is a platinum-catalyzed super soft silicone rubber product designed for medical research applications. It is both highly elastic and durable, allowing for repeated stretching with no permanent deformation. Dragon Skin is a high-performance platinum-catalyzed silicon rubber product designed for special effect applications. It is also highly durable but slightly less elastic and holds a more rigid form.1-4

<table>
<thead>
<tr>
<th>Material</th>
<th>Tensile Strength (MPa)</th>
<th>Modulus (MPa)</th>
<th>Elongation at Break (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecoflex 30-10</td>
<td>0.83</td>
<td>0.06</td>
<td>900</td>
</tr>
<tr>
<td>Dragon Skin 10</td>
<td>2.27</td>
<td>0.15</td>
<td>1000</td>
</tr>
</tbody>
</table>

### Curing Protocol

1. Sand 3D printed segment to ensure smooth surface to prevent tears
2. Mix ⅔ Quarter Part A + ⅓ Quarter Part B thoroughly
   - a. Makes one 10 m³ layer
   - b. Add dye to make pinkred
3. Spread thin layer of mixed Ecoflex on surface with sponge brush and rotisserie
4. Let cure for at least 4 hours, while still rotating around rotisserie for at least 2 hours.
5. Repeat to create 6 layers
   - a. Optional: insert one layer of pantyhose material between layers 3 and 4 to add tensile strength
   - b. To remove:
     - Carefully pull back one edge of Ecoflex
     - Add soap between Ecoflex and 3D mold to help separate
     - Gently peel back remaining Ecoflex, adding more soap as needed

### Upper GI Structure & Function

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Esophagus</th>
<th>Stomach</th>
<th>Superior Duodenum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>2.0 cm (inner)</td>
<td>3.2 cm (outer)</td>
<td>10 cm (widest point)</td>
</tr>
<tr>
<td>Length</td>
<td>40 cm</td>
<td>30 cm (greater curvature)</td>
<td>5 cm</td>
</tr>
<tr>
<td>Tensile strength</td>
<td>1.3 MPa</td>
<td>0.5 MPa</td>
<td>0.92 MPa</td>
</tr>
</tbody>
</table>

### Esophagus Creation Process

Step 1: Create PVC pipe and rubber-coated wooden dowel rod exactly matching human esophageal dimensions

Step 2: Pour dyed Ecoflex into mold to create our hollow cylinder esophagus

### Stomach Creation Process

Step 1: Create a smooth, curved Styrnoform mold covered in protective tape, then attach braided insulated wire via hot glue to mimic gastric nodule

Step 2: Cure Ecoflex to stomach; the first, second, and third iterations developed the stomach from a smooth, clear prototype to our flesh-toned, textured final phantom

### Lower GI Structure & Function

<table>
<thead>
<tr>
<th>Colon Location</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stomach</td>
<td>3D printed model with added wires to create haustral folds.</td>
</tr>
<tr>
<td>Antrum</td>
<td>3D printed model.</td>
</tr>
<tr>
<td>Gastric Curvature of Body</td>
<td>3D printed model.</td>
</tr>
<tr>
<td>Lesser Curvature of Antrum</td>
<td>3D printed model.</td>
</tr>
<tr>
<td>Insulcus Anularis</td>
<td>3D printed model.</td>
</tr>
<tr>
<td>Lesser Curvature of Body</td>
<td>3D printed model.</td>
</tr>
</tbody>
</table>

### Polyp Creation Process

Step 1: Acquire a compiled set of CT scans of a human patient’s colon which was converted to a file suitable for 3D printing

Step 2: Break up the file into 8 pieces to enable printing of the colon in our design studio without outside resources

Step 3: Print 6 pieces of colon and glue each piece together with super glue in the proper orientation for a reproducible, accurate, and detailed model of a human colon

Step 4: Cure Ecoflex to 3D model as mold spins on a commercial rotisserie at 5 rpm so that the Ecoflex cures evenly

Step 5: Remove cured colon from mold for final iteration of our synthetic phantom for lower GI device testing

Step 6: Install internal magnets to the inside of the colon in order to attach removable polyps for testing

### Polyp Contrast Results

- We found our phantoms to have a very similar average contrast compared to human polyps.
- In addition, our polyp contrast should be low, so as to mimic sessile polyps: the most difficult polyps to locate during colonoscopy.

### Arduino Tracking and LED Results

- Research of Ecoflex electrical properties confirmed that the material is a suitable insulator (between ~3 MV/m- and nesrene rubber—up to 26.7 MV/m-1 dielectric strength), ensuring minimal current noise or cross-talk within wires or in direct contact with the polymer.
- Testing of LDR detection in Ecoflex confirmed no significant change in light transmittance in dyed and clear Ecoflex.
- Sufficient light signal changes in both instances were transmitted through polyps and other phantom structures greater than ⅓”, which is no thicker than our greatest thickness throughout the phantoms.

### Conclusions

- We have designed a system for generating inexpensive, realistic, synthetic tissue phantoms of the upper and lower GI tract for testing in new medical device testing.
- Our phantoms are accurate in terms of dimensions and material properties when compared to a real GI tract.
- We introduced interactive features to simulate stomach points of interest and colon polyps with light-controlled LEDs and removable magnets, respectively.
- Our work is reproducible and useful to the STORM lab, among other research labs, and has the potential to be useful to medical device testing labs around the world.

### References

- [1] Taylor Cannon, Samantha Kopinsky, William McKinney, Tanner Nelson, Maggie O’Connor, Max Puidak, Alexander Smith, Ethan Vanderwalker, Advisors: Dr. Keith Obstein; Dr. Matthew Walker III
- [2] Poly CONTRAST Results: We found our phantoms to have a very similar average contrast compared to human polyps.
- [3] Arduino Tracking and LED Results: Research of Ecoflex electrical properties confirmed that the material is a suitable insulator (between ~3 MV/m- and nesrene rubber—up to 26.7 MV/m-1 dielectric strength), ensuring minimal current noise or cross-talk within wires or in direct contact with the polymer.
- [5] Our work is reproducible and useful to the STORM lab, among other research labs, and has the potential to be useful to medical device testing labs around the world.

Acknowledgements

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