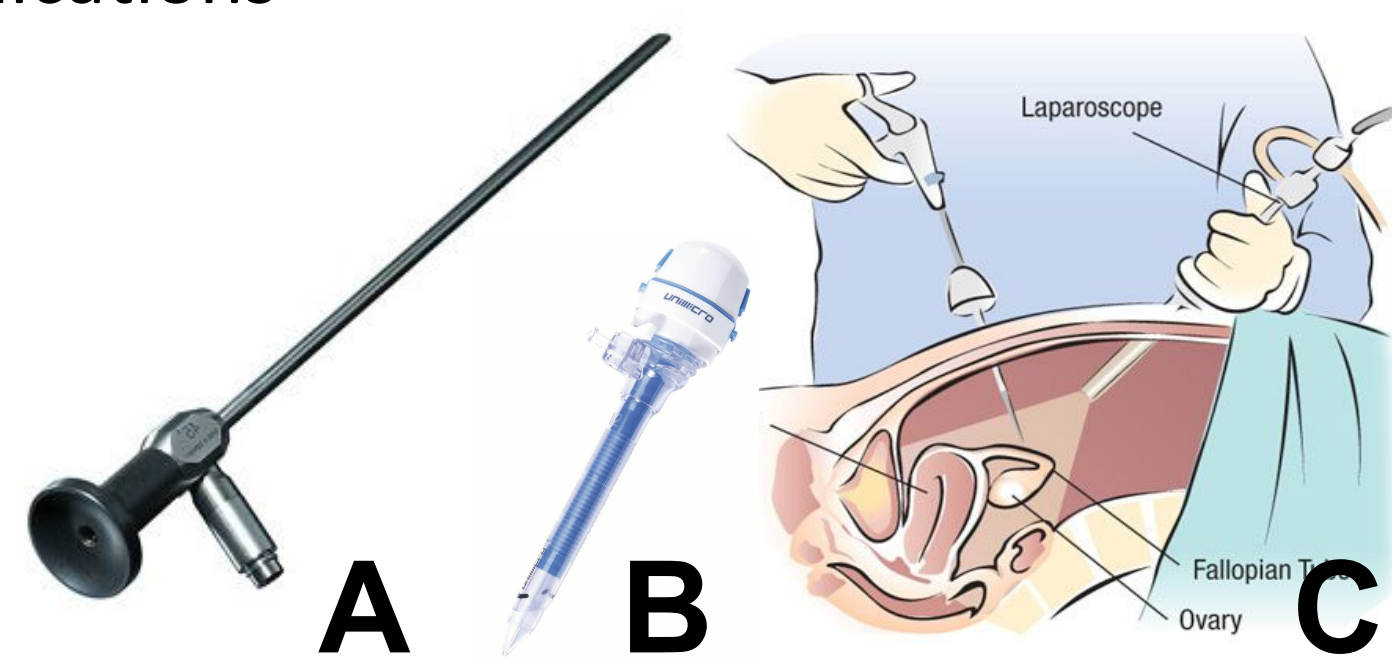


DISEASE STATE

- **Laparoscopic Surgery**
 - Over 15 million worldwide, 3.5 million in U.S. per year^[1]
 - Minimally invasive surgery that eliminates large incisions
 - Camera inserted into body to increase visualization
 - For various pathologies/ conditions involving the abdominal area and pelvic organs
- **Current Problem**
 - Surgeons frequently remove scope from patient
 - Results in increased surgical time, risk of infection, and post- surgical complications

Figure 1. A) Laparoscope, containing the camera inserted into the body; B) Trocar, placed through the abdomen during laparoscopic surgery and serves as a portal for the laparoscope into the body; C) Laparoscopic surgery.



OBJECTIVES

1. Clean the lens of a laparoscope inside the patient's body
2. Achieve mechanical success of prototype
3. Conduct successful efficacy testing of wiper blade on the lens
4. Ensure biocompatible, low cost, and ergonomic

COMPETITORS & MARKET GAPS

ClickClean

- Shields lens with device trigger that interchanges soiled film for new, clean film^[2]

Clarify

- Scope is removed from the body and cleaned with trocar wipes, microfiber cloth, and a warming hub^[3]

Flowshield

- Lens has vortex barrier of carbon dioxide dry gas delivered by external tube, which shields and defogs the lens^[4]

Current Market Gaps:

1. Safety - remain inside the patient
2. Simplicity - easy but effective mechanism for cleaning
3. Ease of Use - lightweight and easy operation
4. Cost Effectiveness - low cost solution

REGULATORY PATHWAY

- Considered Class II medical device under the Food and Drug Administration (FDA)
- Requires 510(k) premarket notification to FDA for sale in U.S.
 - Demonstrate substantial equivalence to competing FDA approved device
 - Could be tested against ClickClean, Clarify, or Flowshield

OUR SOLUTION - LEN(S)WIPE

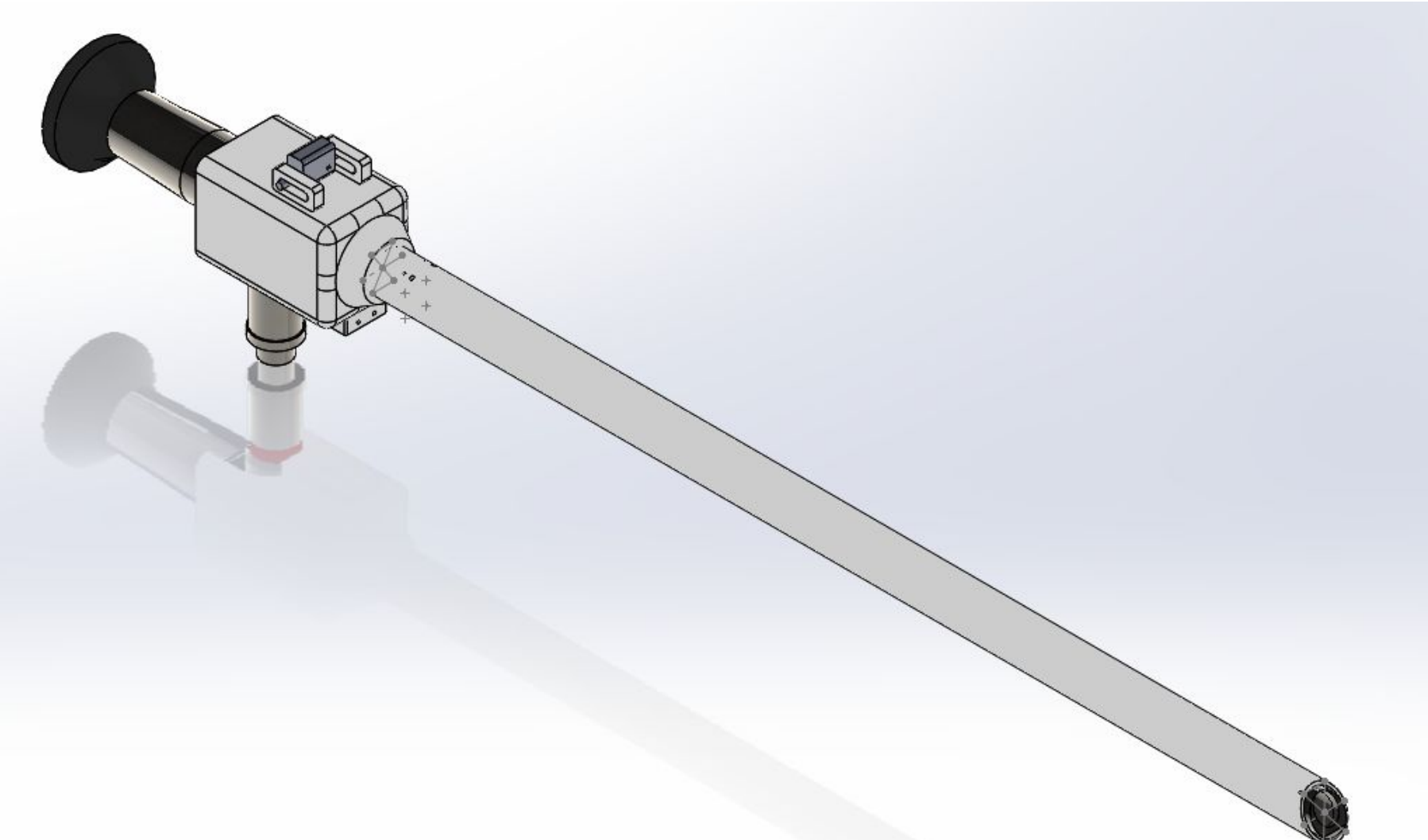


Figure 2. Isometric CAD model of Len(s)wipe on a laparoscope.

- Spring- wire system with trigger activation and a sleek, ergonomic design
- Wire runs through tube to connect extension springs to lens wiper and back through tube to an activating trigger on the top of the device

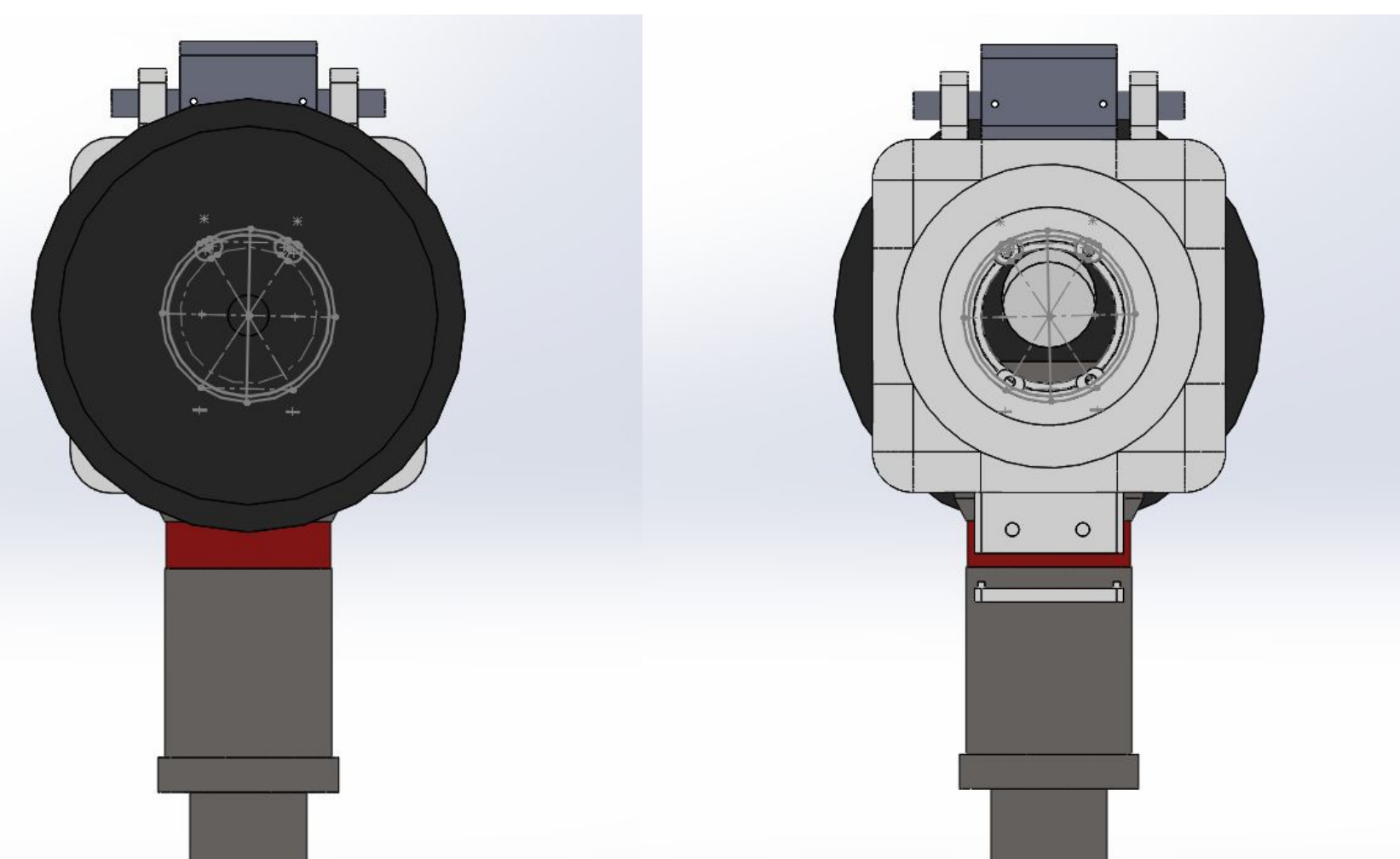


Figure 3. End views of CAD model of Len(s)wipe, showing trigger on top and spring box on bottom.

- Tube slides over the laparoscope with a tight, sealed fit, adding 2.9 mm in diameter to the laparoscope
- Device fits into trocar, wires are out of contact with the body
- Expect device to cause reduction of ~12 min per hour of surgery

MANUFACTURING

- **Materials**
 - UHMWPE fishing line
 - Extension springs
 - Silicone squeegee blade
 - Threaded islets
 - ABS and PLA 3D printing filament
- **Prototyping Methods and Cost**
 - 3D printing for tubing/ casing
 - Hand manufacturing for threading the wire
 - **Current Cost: \$8.39 → Selling Price: \$40.00**

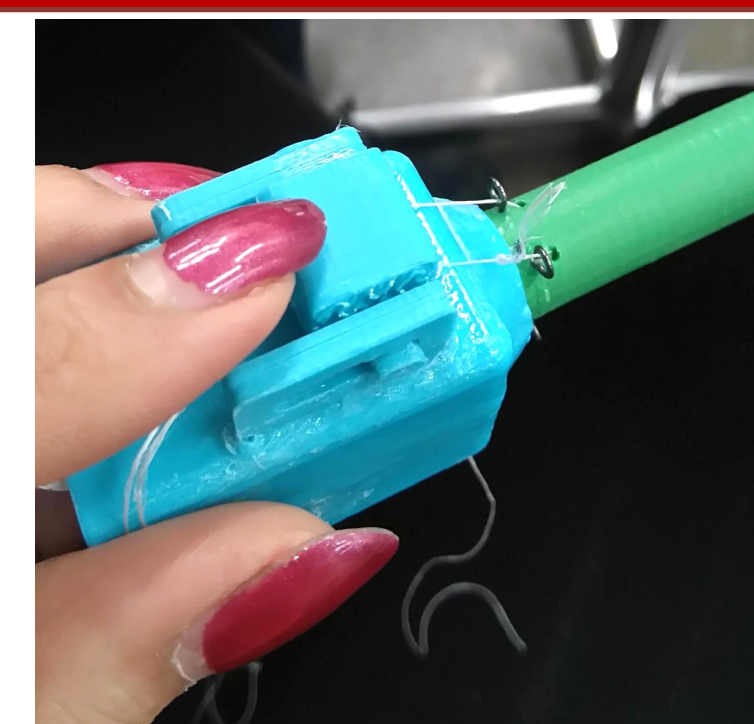


Figure 4. ABS handle (blue) with the spring triggered mechanism.

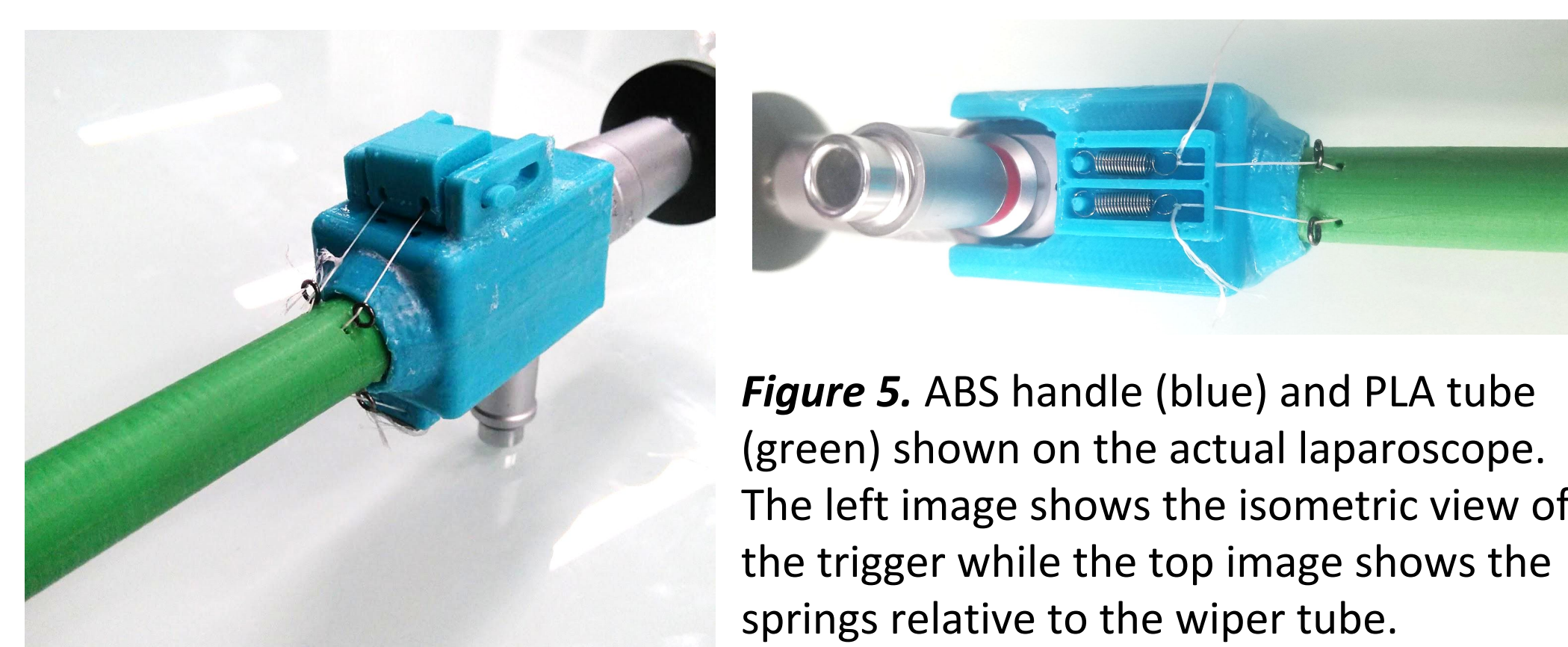


Figure 5. ABS handle (blue) and PLA tube (green) shown on the actual laparoscope. The left image shows the isometric view of the trigger while the top image shows the springs relative to the wiper tube.

EFFICACY TESTING

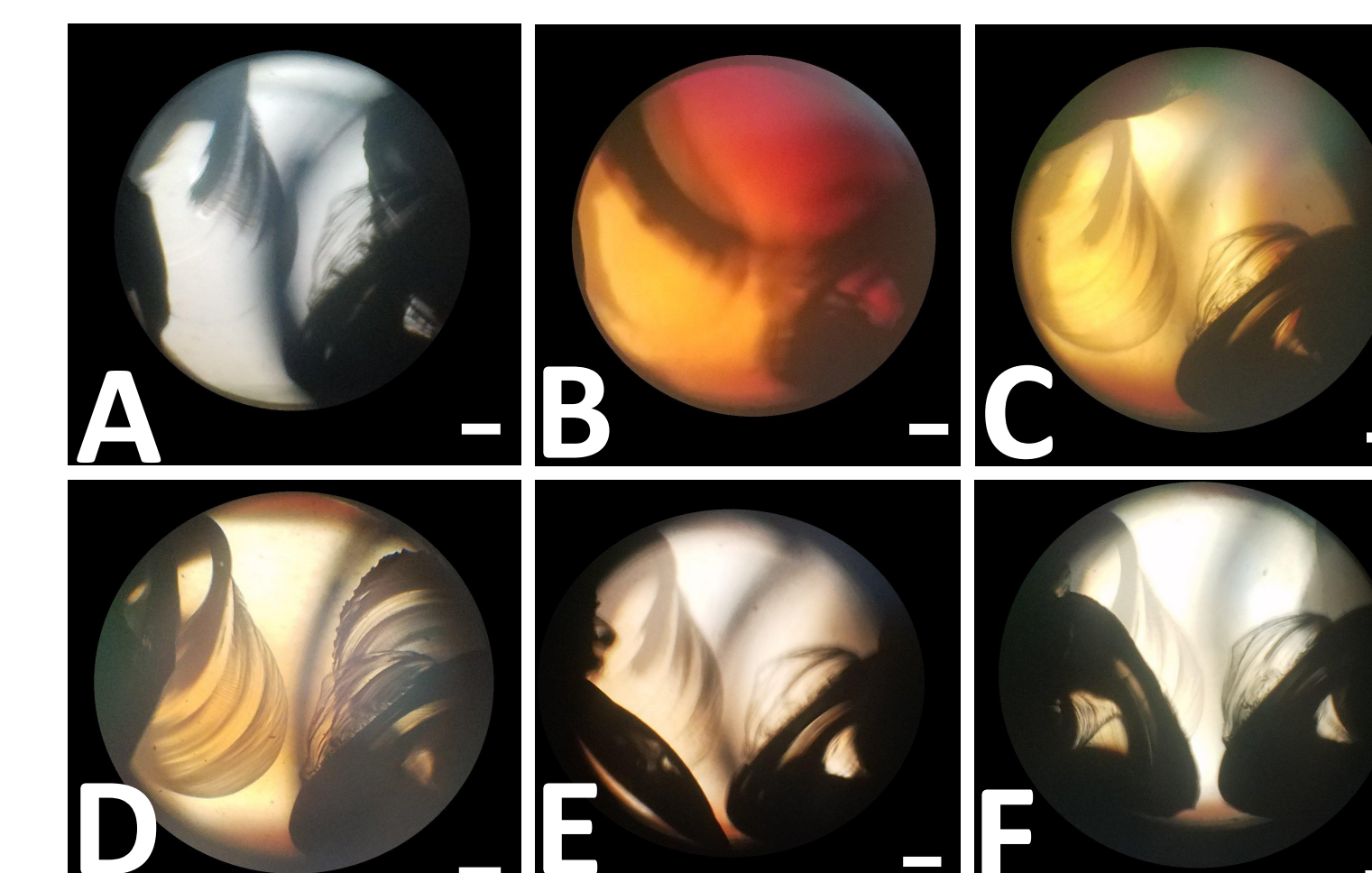
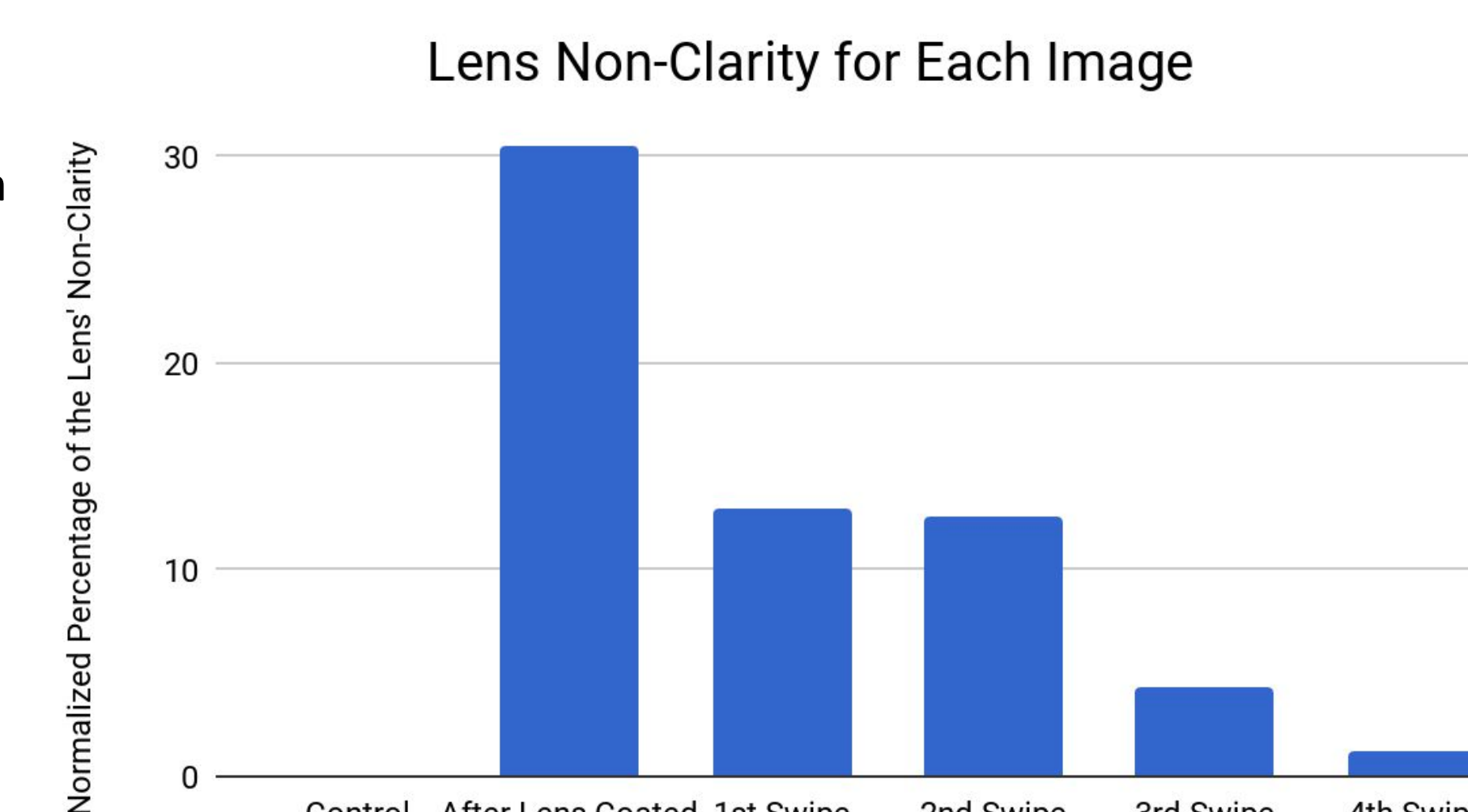


Figure 6. Representative images through the (cracked) laparoscope. Scale bar = 1 mm. A) Control image taken before testing; B) After lens was coated in chocolate syrup; C) 1st Swipe; D) 2nd Swipe; E) 3rd Swipe; F) 4th Swipe.

Figure 7. Graph of percentage of non-clarity for each image in Figure 6, normalized to the control. With each subsequent swipe, the percentage of non-clarity decreases and the clarity of the lens approaches the control.



CONCLUSIONS & FUTURE WORK

Conclusions

- Verification of theoretical function and efficacy of our device
- Sleek and more ergonomic design offers comfort and is an improvement from last year's design
- The wires are contained within the tubing so as to keep them secure and free from contact with the body
- Low cost solution compared to competition

Future Work

- Test fully manufactured device with blood and bodily fluids
- Manufacture samples with proposed manufacturing materials and technology
- Create secondary model with lateral switch mechanism

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