

The Donatello Snare

Senior Design Group 16

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Introduction

- Necrotizing Pancreatitis occurs when the pancreas forms a cyst of auto-digested tissue
- Can be caused by either alcoholism or an occluded pancreatic duct or duodenal papilla due to injury or illness
- Pancreas produces inactive digestive enzymes, like trypsin, which self-activate in a chain reaction inside the pancreas due to either reduced apoptosis as a result of chronic alcoholism or blockage of the pancreatic duct
- Autodigestion is eventually contained by a wall of scar tissue, forming a cyst (WOPN) which is on average 11 to 17cm in diameter containing both semi-solid and liquified necrotic tissue and typically between 10% - 40% solid by volume
- In 2015, there were 36,500 patients treated, with a steady increase in the number of cases over the last 10 years
- Common prognosis for an untreated case is death due to multiple organ failure
- An average of 20% of people that receive treatment still die
- Two types of procedures; open surgery and endoscopic surgery
- Lack of a specialized tool for endoscopic surgery results in an average of 4-6 procedures needed to remove the remaining solid mass which is on average roughly the size of a navel orange

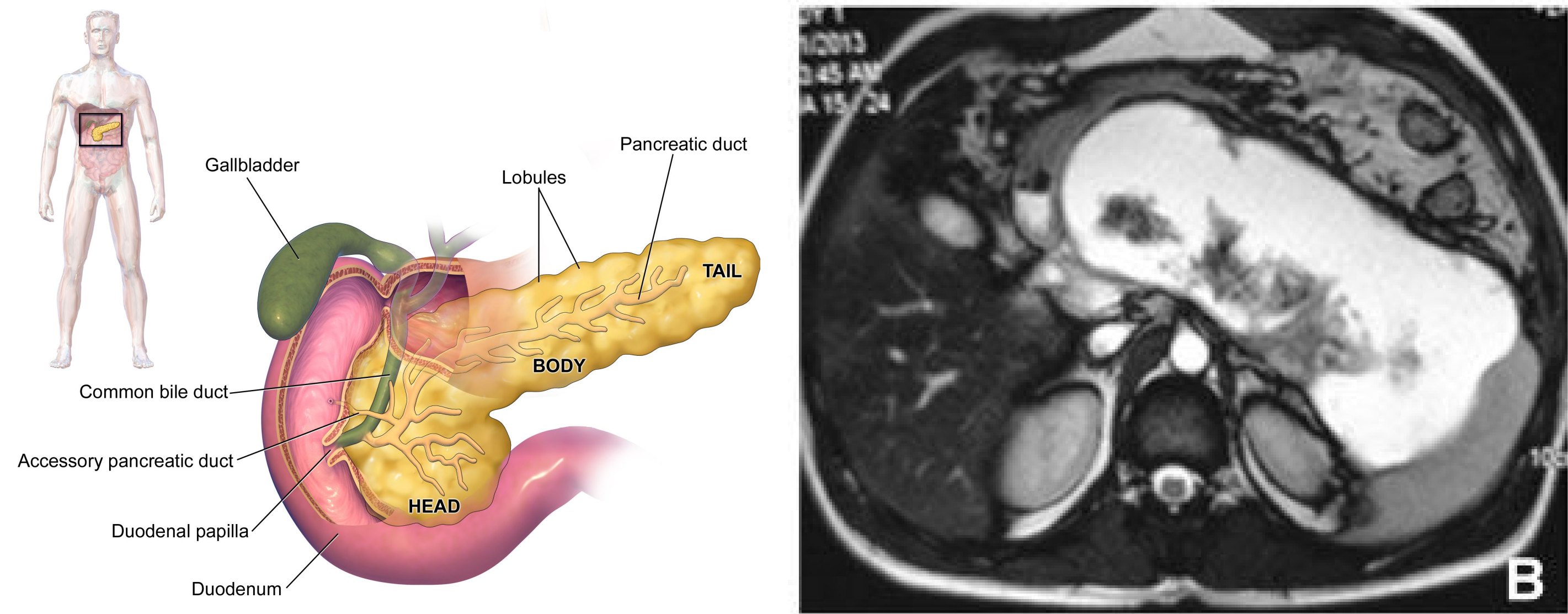


Figure 1. On the left, the anatomy of a human pancreas can be seen. On the right, a CT scan of a patient with Necrotizing Pancreatitis is shown with the liquified contents of the cyst showing bright white.^{1,2}

Methods

Requirements

- Needs to fit through working channel of endoscope
- When expanded, must fit through AXIOS stent
- Easy to use, with ergonomic handle
- Must be able to remove material
- Needs to break up material but not damage the rind of the necrotizing mass

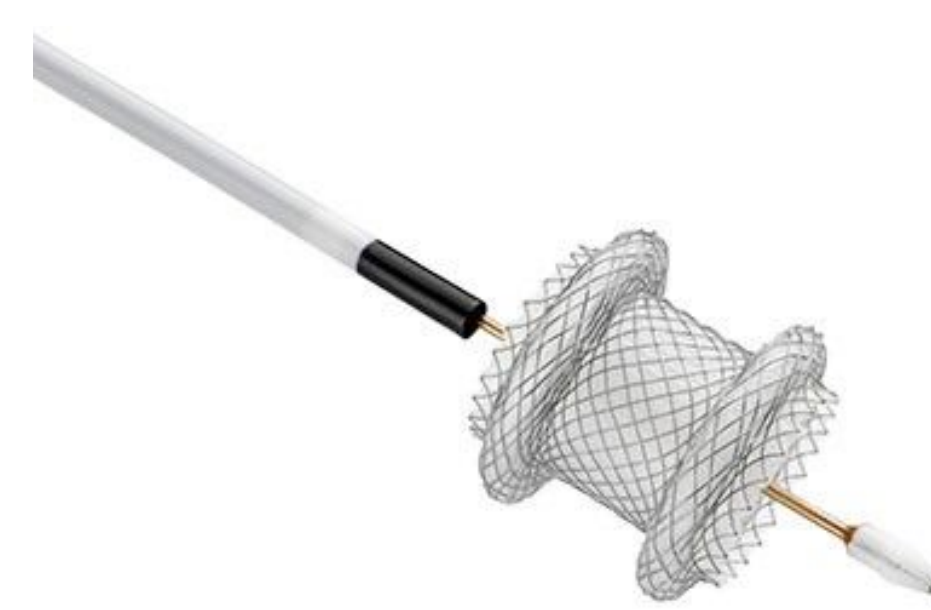


Figure 2. A fully extended AXIOS™ stent used as a port to reach the necrotizing mass through the stomach³

Design

- Prototype 1:** Basket shape braided 316L stainless tip
- Prototype 2:** Nitinol flat wire tip

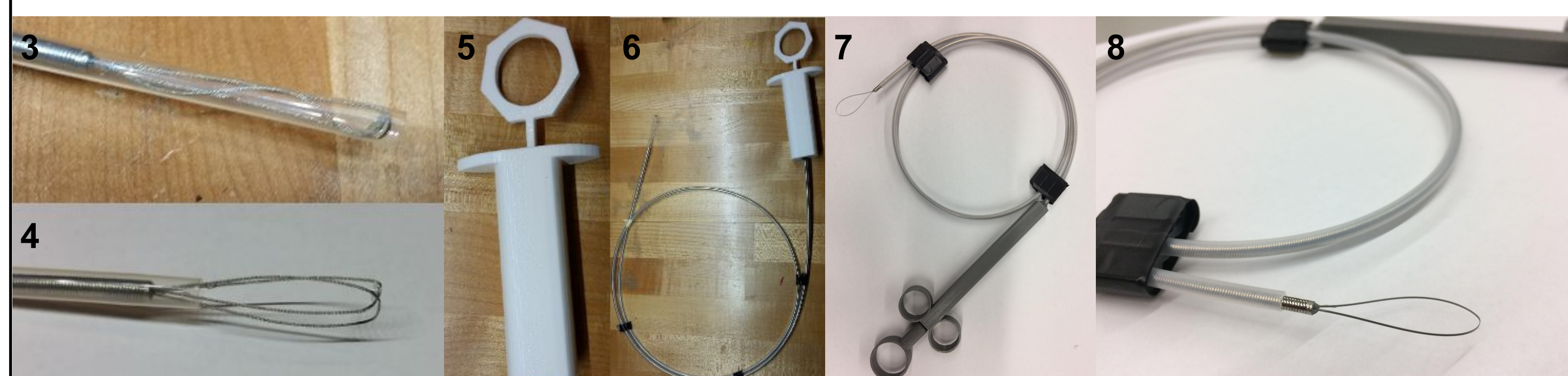


Figure 3. Retracted basket tip - Figure 4. Extended basket tip - Figure 5. Original handle - Figure 6. Full first generation prototype - Figure 7. Full second generation prototype - Figure 8. Extended flat wire tip

Testing

- For effectiveness, three trials were run for current devices that are used in the procedure and our prototype, measuring the time and amount removed
- Ran these trials for both low and medium thickness
- In the analog test, the material was extruded into laminar fluid flow. The length of the extruded material is proportional to its shear strength.
- This was done for for homogenized avocado, normal avocado, and trypsinized pancreas

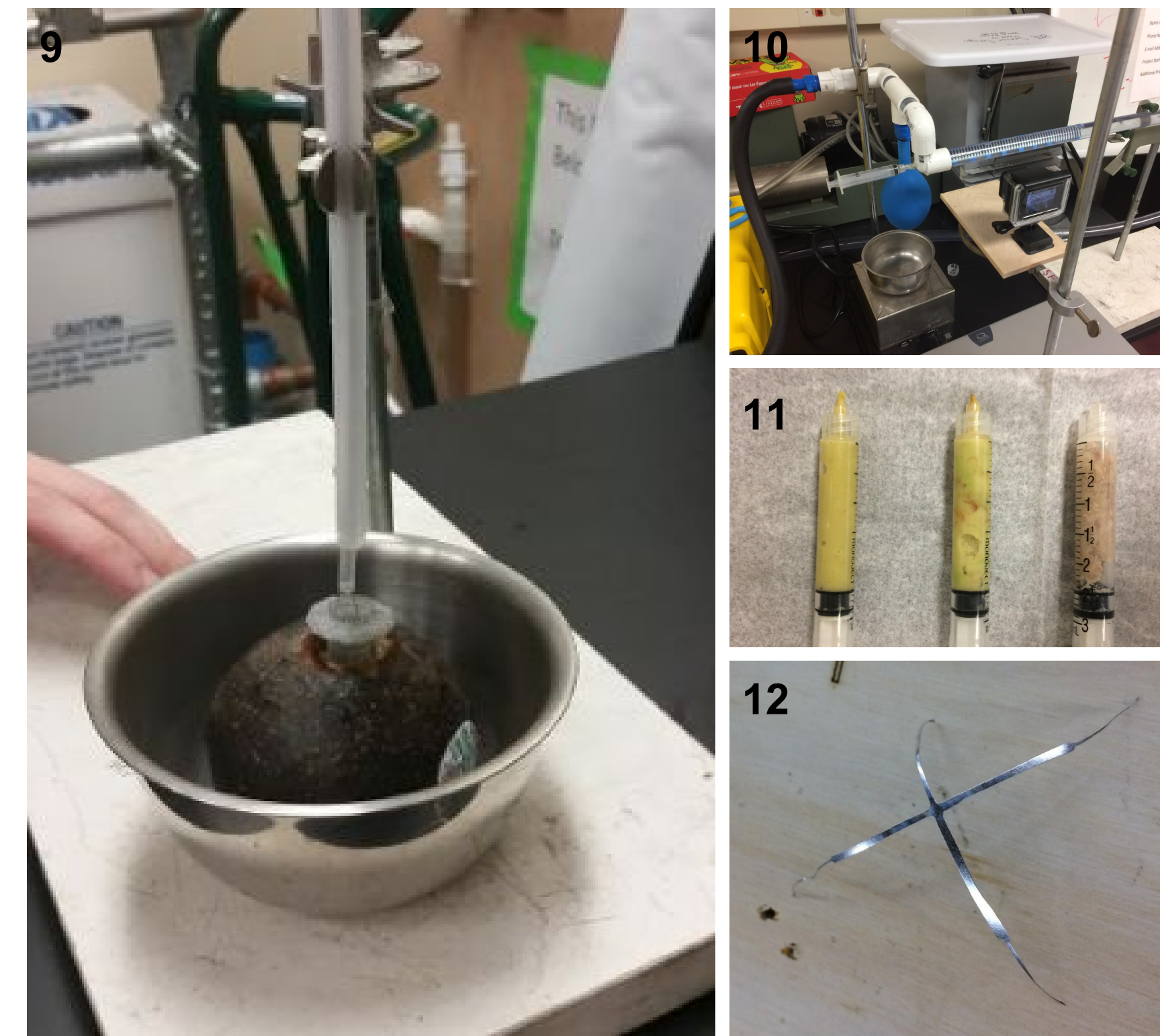


Figure 9. Apparatus used for efficacy testing - Figure 10. Shear-extrusion apparatus used in analog validation Figure 11. From left to right, syringes of homogenized avocado, raw avocado, and trypsinized pancreas Figure 12. Unsuccessful attempt at creating a 3rd generation prototype blending the basket and flat wire designs by laser cutting a 2D design into foil

Results

Effectiveness Results

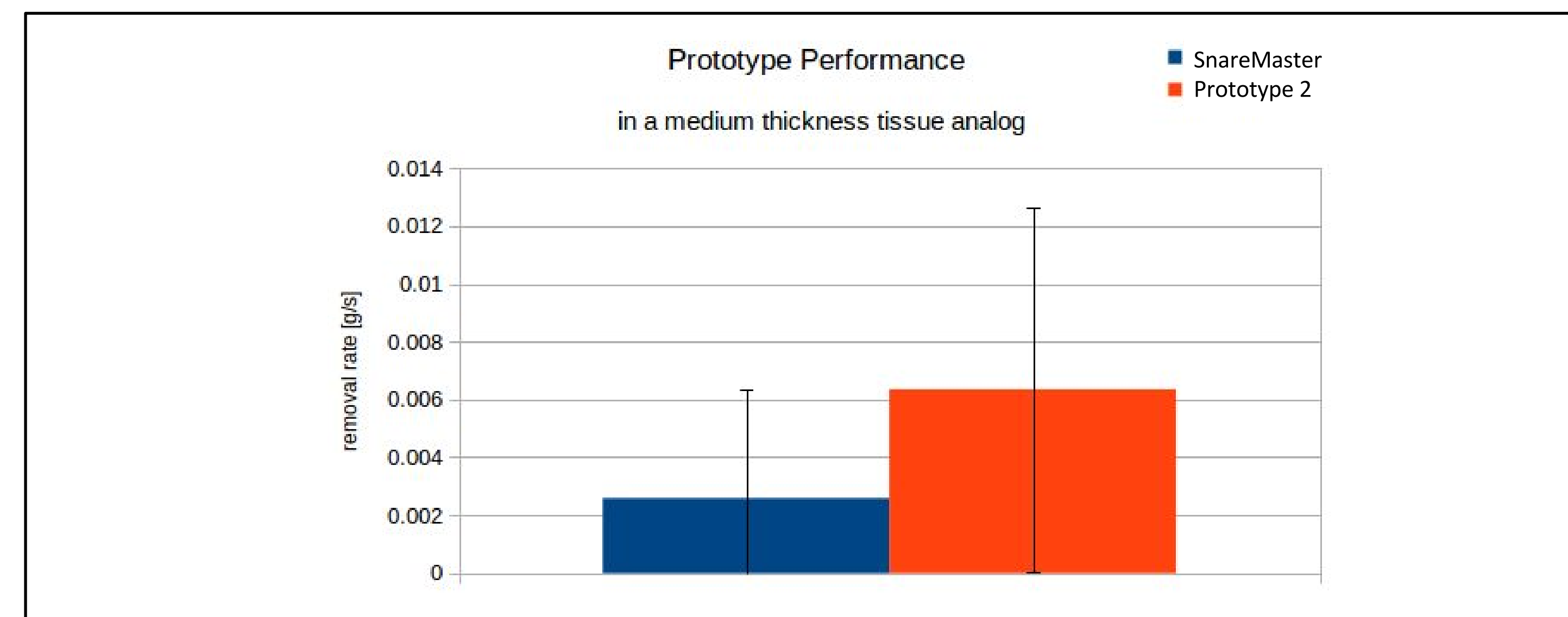


Figure 13. The removal rate of the Prototype is significantly higher than that of the existing SnareMaster device in a medium thickness analog material, $p=0.00403$

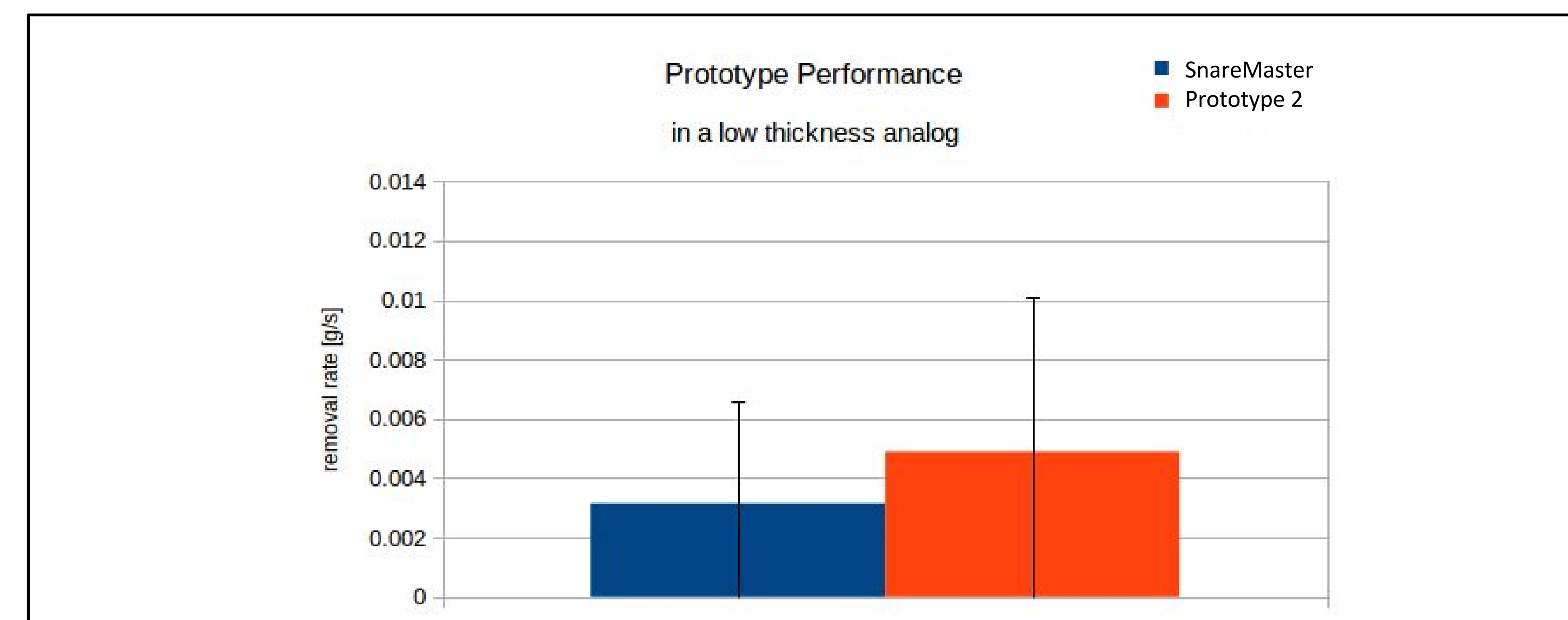


Figure 14. The removal rate of the Prototype is significantly higher than that of the existing device in a low thickness analog material, $p=.085$

Verification of Analog Material

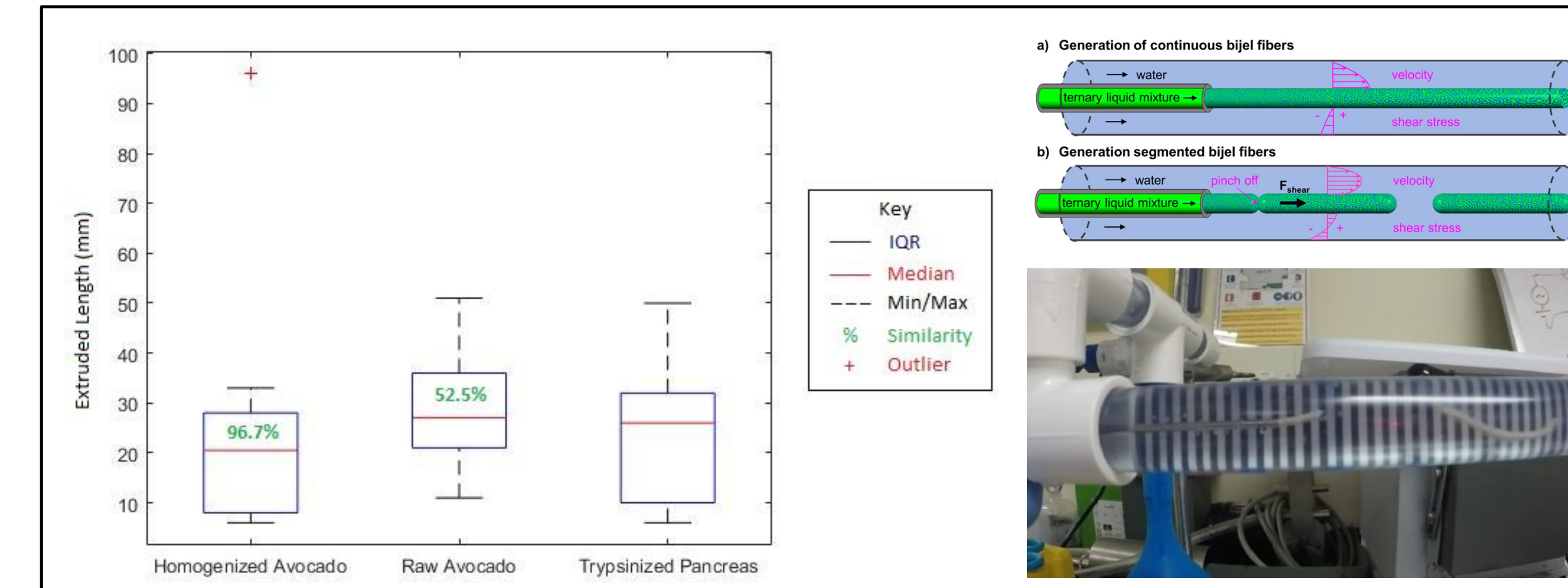


Figure 15. The average length of shear-extruded fibers in analogue verification test for homogenized avocado and raw avocado as compared to real trypsinized pancreas, as shown in a box and whisker plot with data similarity determined by Student's t-test⁴

Results (cont.)

Visual Results

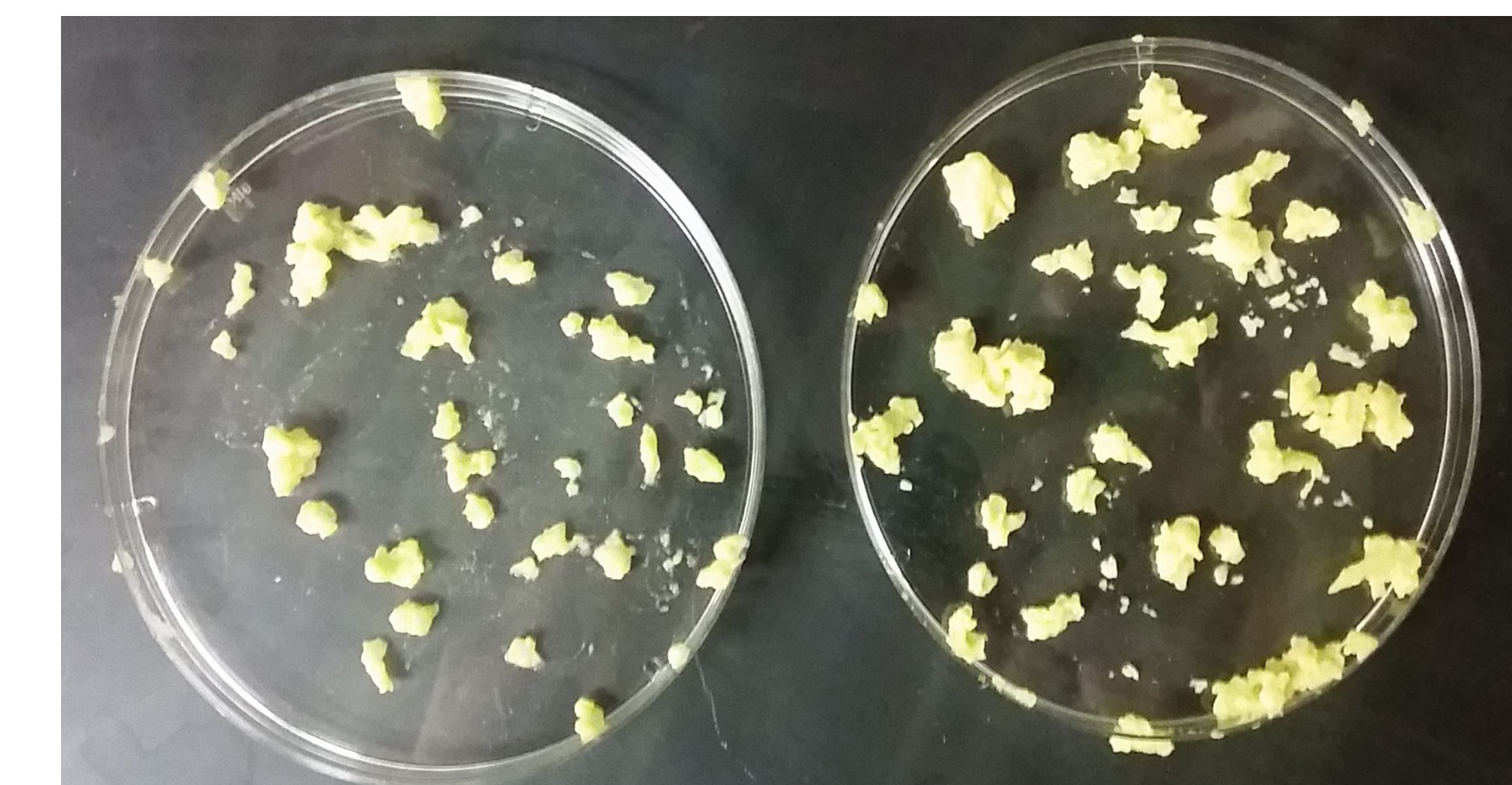


Figure 16. Quantitative results from a trial of the effectiveness testing. In the plate on the left, Olympus SnareMaster was used. In the plate on the right, Donatello Snare was used

Conclusions

- Our device was more effective at removing the analog material when compared to the Olympus SnareMaster for both the low and medium analog test
- We were able to create an analog material that is similar to trypsinized pancreas

Future Steps:

- Make a more ergonomic handle made using injection molding
- Test different thicknesses of flat wire
- Test different modifications to flat wire, such as bends or small teeth, as well as 2D shapes stamped from Nitinol foil

References

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- Rana, Surinder S., Vinita Chaudhary, Ravi Sharma, Vishal Sharma, Puneet Chhabra, and Deepak K. Bhasin. "Comparison of Abdominal Ultrasound, Endoscopic Ultrasound and Magnetic Resonance Imaging in Detection of Necrotic Debris in Walled-off Pancreatic Necrosis." *Gastroenterology Report* (2015): n. pag. Web.
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