

Automated Skin Punch Biopsy Tool

 Maria Bermudez¹, Daniela Del Grande¹, Nikolas Lialios¹, Katia Ponce¹, Lizbeth Ramirez¹, Sergio Rico¹

 Dr. Christopher Plaisier, PhD¹, Desiray Armstrong², Nicole Murray, RN, MS², Bailey Bellaire²
¹School of Biological and Health Systems Engineering, Arizona State University

²CND Life Sciences

Clinical Need

Background: Skin punch biopsies are commonly performed by dermatologists to diagnose skin cancer and inflammatory diseases. Recently, an innovative method for diagnosing synucleinopathies with skin punch biopsy samples was developed, leading neurologists to begin performing the procedure. However, neurologists typically lack experience with the procedure as it is not routine for their specialty.

Clinical Problem: Many of the biopsy samples received for diagnostic purposes have poor integrity and cannot be used. These samples may have been **pinched**, obtained with **insufficient volume**, or collected at an **incorrect angle** and often result in the patient undergoing another biopsy procedure. Feedback from these clinician suggests that the issue stems from difficulties with the biopsy tool kit.

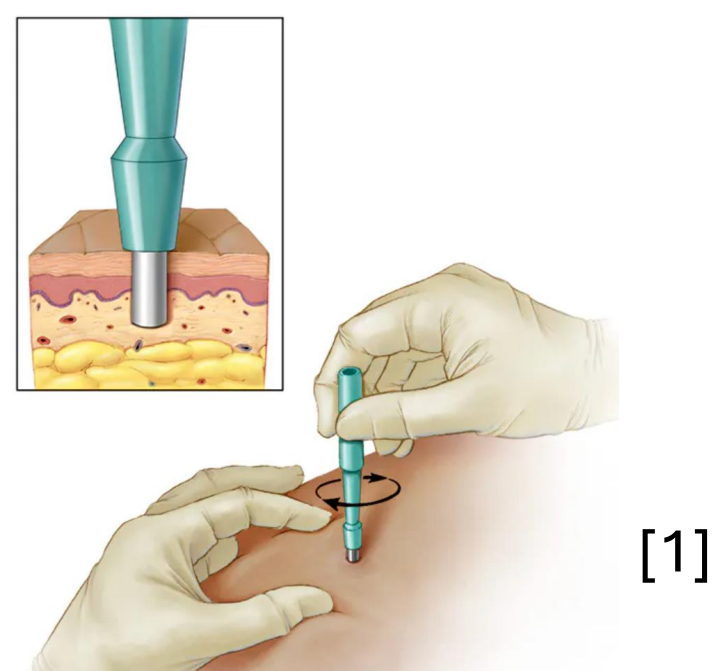


Figure 1: Skin punch biopsy procedure.

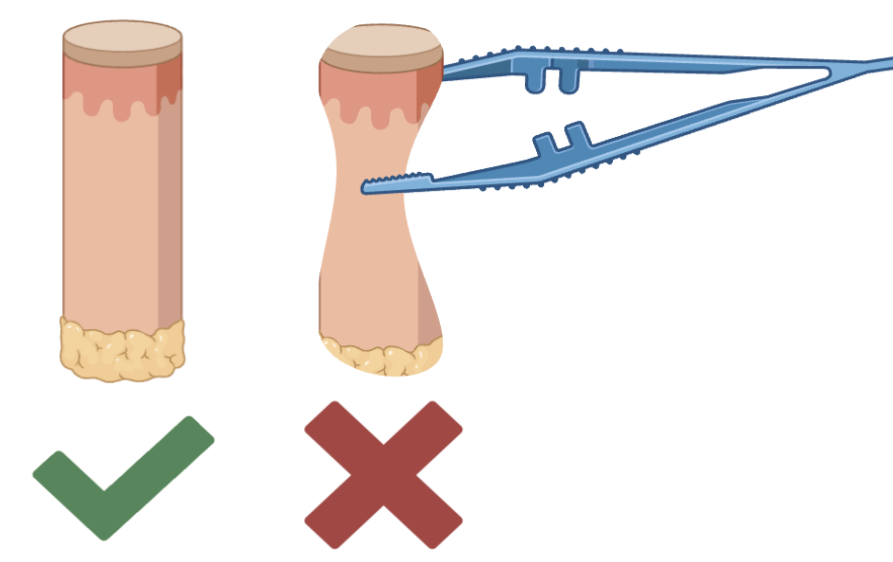


Figure 2: Effective vs Ineffective biopsy sample.

Mission Statement: BioCut is committed to innovation, precision, and compassion by developing diagnostic solutions that enhance patient care and support clinicians.

Final Technical Model

Equations

Vacuum

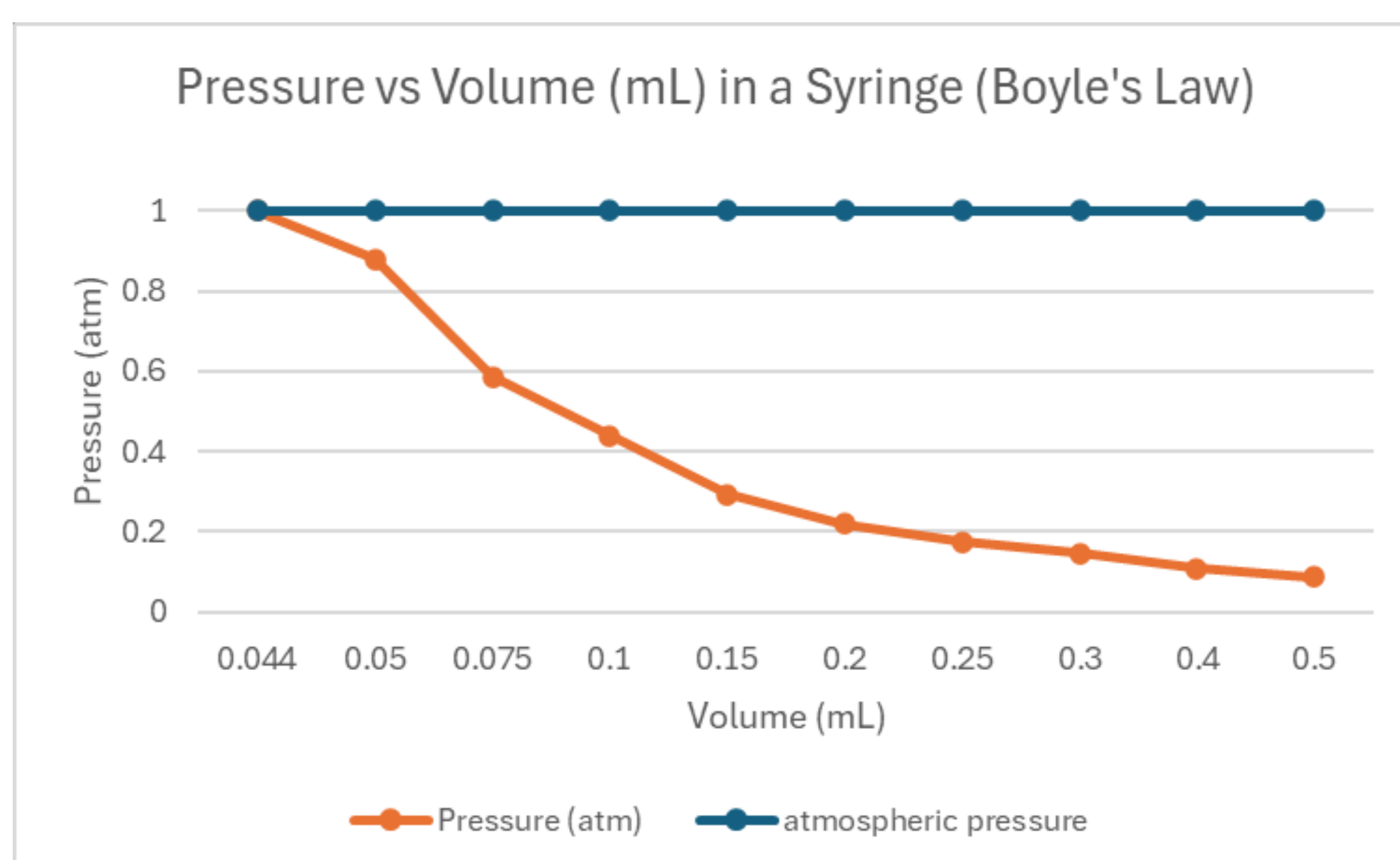
Spring

Syringe

 Boyle's Law
 $V_1 * P_1 = V_2 * P_2$
 $P = -k * \Delta x$

 Boyle's Law
 $V_1 * P_1 = V_2 * P_2$

Mathematical models: Our model focuses on the pulling mechanism of a syringe, which creates a negative pressure that creates suction at the tip of the syringe. Using this model, the vacuum will be difference in pressure caused by the increase in volume. This suction will be used to extract the sample without external tools.



Final Product Specifications

Metrics	Specifications
Syn-One Test/diagnostic sensitivity	>95% sensitivity
Number of steps in procedure	Reduce by 2
Vacuum Suction Strength (orange)	0.901 atm
Cost per kit (\leq \$8)	\leq \$4/tool
Number of usable samples per procedure	\geq 3 equal samples
No deviations from current procedure	Depth: 5 mm Diameter: 3 mm

Table 1: Table shows metrics and final product specifications that are part of the design criteria.

Prototype

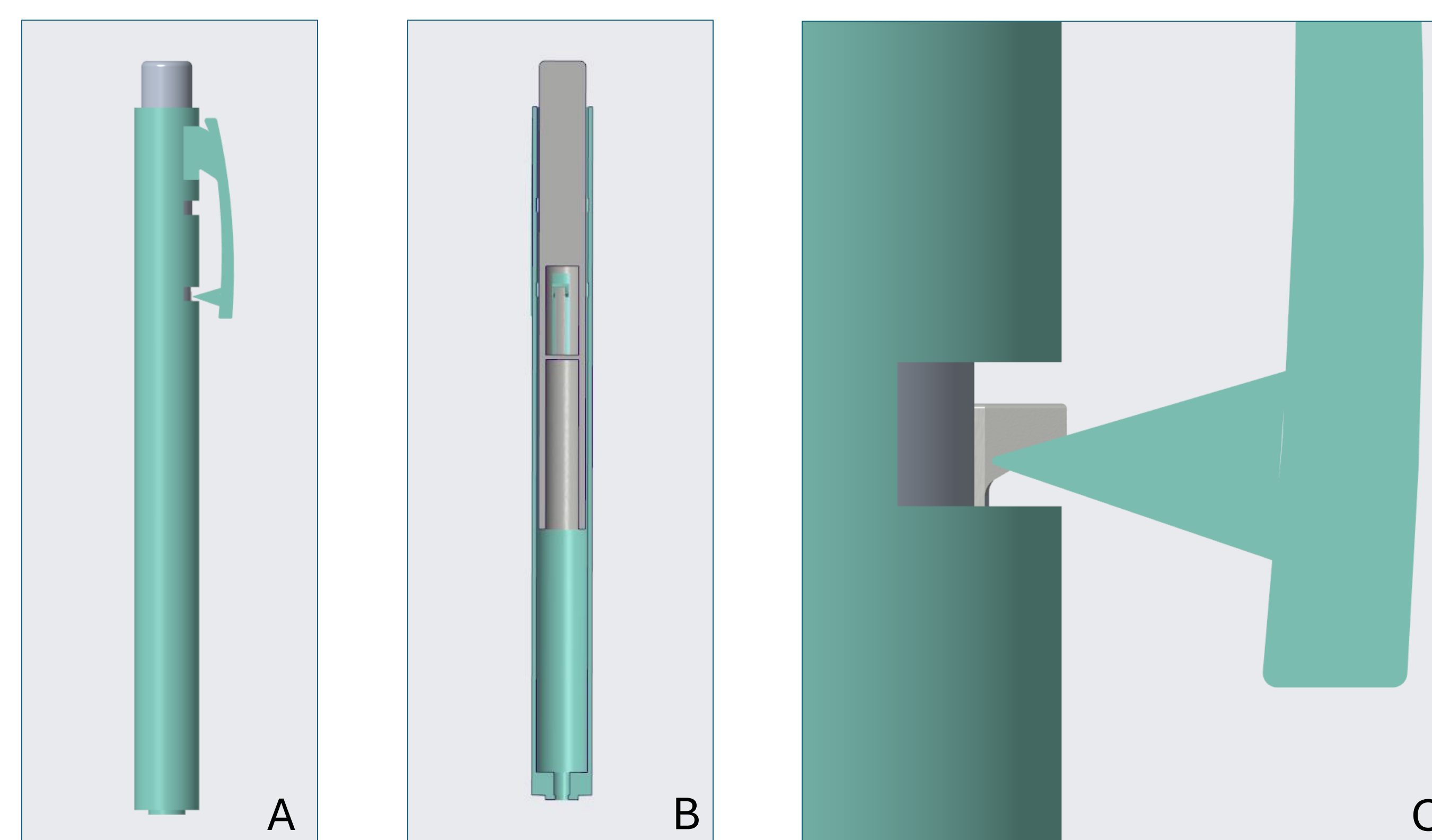


Figure 3: Final prototype of the automated skin punch biopsy tool. (a) Full assembly of the device including the main body and plunger components. (b) Section view of the tool showing the internal arrangement of the plunger, locking features, and sample collection pathway. (c) Close up view of the locking mechanism illustrating how the plunger is secured and released during operation

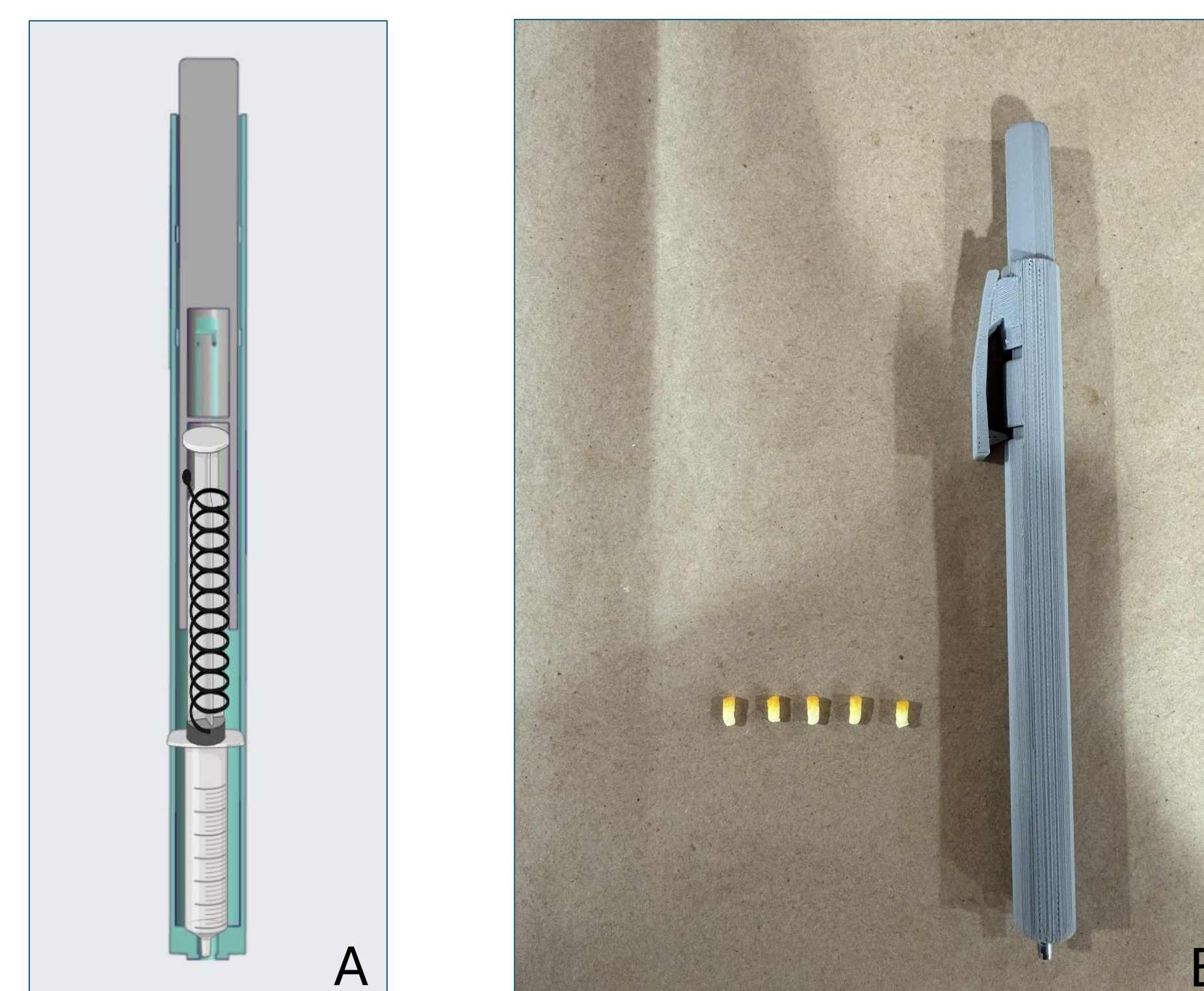


Figure 4. (a) Section view of the automated skin punch biopsy tool showing the internal syringe and spring mechanism used to generate suction during sample collection. (b) Physical prototype of the tool shown next to orange samples collected during testing.

Verification Results

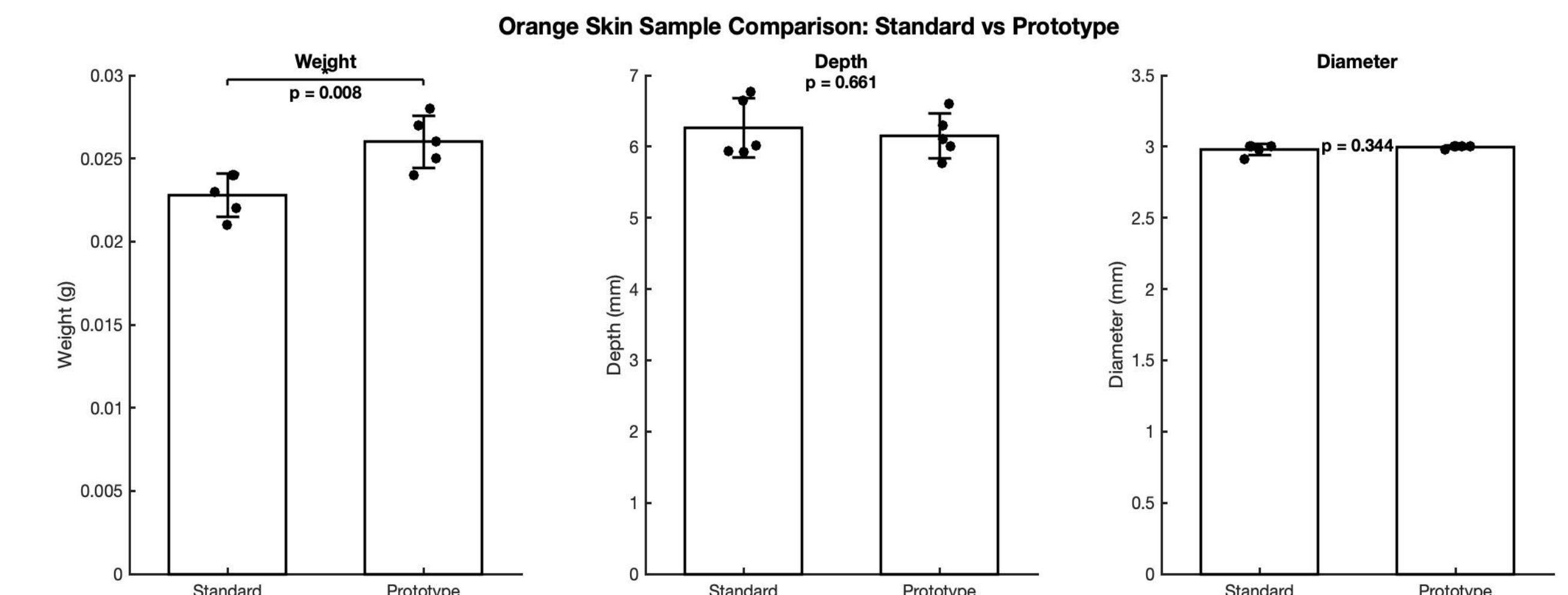
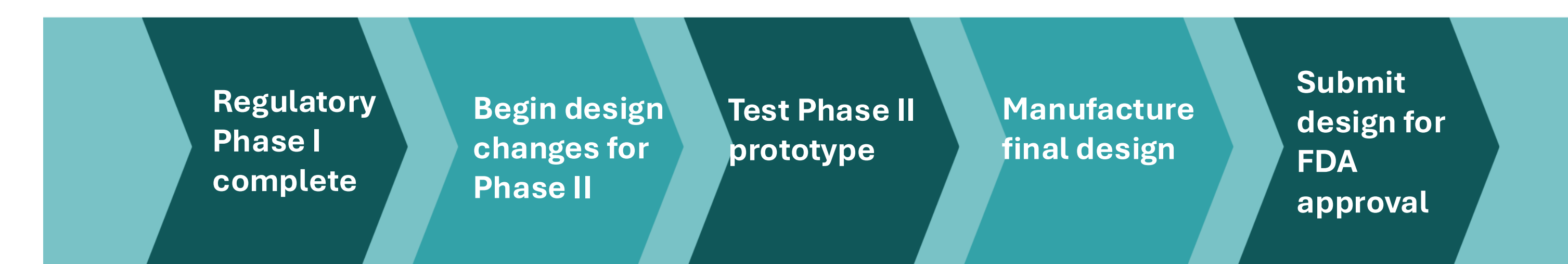


Figure 5: Orange Skin Sample Integrity Test

Testing Outcomes: After comparing the average weight, depth, and diameter of 5 samples taken with the standard biopsy tool and our prototype, a two-tailed t-test ($\alpha < 0.05$) showed that there was no significant difference between the average depth ($p = 0.66$) and diameter ($p = 0.34$) of the samples. There was a significant difference in weight ($p = 0.02$), but only by 0.0032g.

Design Status & Future Steps



Current Project Status: Phase I of this project has been completed. This involved obtaining punch samples from an orange (peel) using the current prototype. This initial testing proved successful, as samples were consistently able to be obtained and released from the prototype as intended. However, when testing on pig's skin, the negative pressure created was not large enough to draw out the sample from the skin.

Next Phases: The next phase of this project involves modifying the design of the current prototype to create a bigger negative pressure differential that will be sufficient enough to draw out the sample from pig skin. After testing this new prototype, manufacturing materials and protocols will be finalized in order to begin manufacturing. After that, the project will move into the regulatory phase by preparing a 510(k) Premarket Notification to the FDA, including device description, intended use, design controls documentation, risk analysis, biocompatibility data, and bench testing results, to demonstrating substantial equivalence to a legally marketed predicate device.

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References

[1] "Punch Biopsy." Mayo Clinic, Mayo Foundation for Medical Education and Research, www.mayoclinic.org/tests-procedures/skin-biopsy/multimedia/punch-biopsy/img-20005764. Accessed 15 Nov. 2025.