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Automated Skin Punch Biopsy Tool

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BioCut SKIN PUNCH BIOPSY

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 are difficult to analyze. These samples may have been **pinched**, obtained with **insufficient volume,** or collected at an **incorrect angle** and may result in the patient undergoing another biopsy procedure. Feedback from clinicians suggest that the issue stems from challenges with the biopsy tool kit.

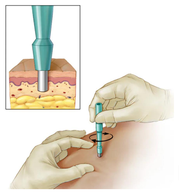

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Figure 1: Skin punch biopsy procedure.

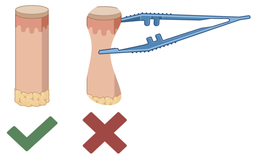

Figure 2: Effective vs ineffective biopsy sample.

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 V1*P1=V2*P2	P=-k*Δx	Boyle's Law V1*P1=V2*P2

Mathematical Models: The Boyle's Law model describes how pulling the syringe plunger increases volume, which lowers internal pressure. This decrease in internal pressure creates an increasing pressure difference relative to atmospheric pressure, generating suction at the syringe tip. This pressure difference allows for sample extraction without additional tools.

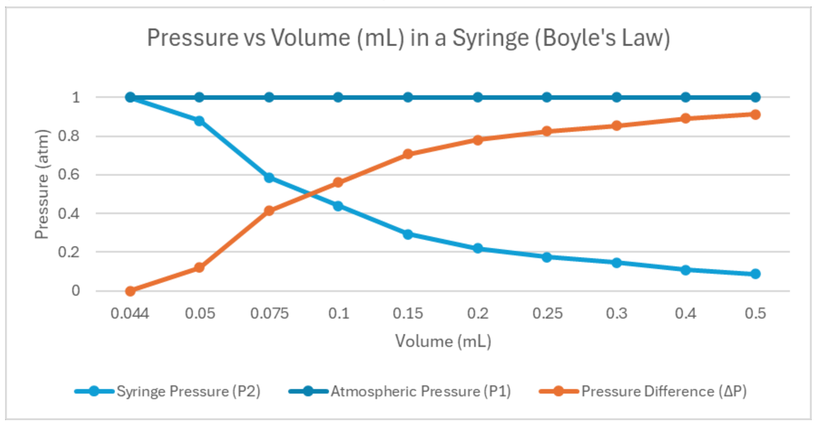

Figure 3: Boyle's Law Model of 1 mL syringe

Final Product Specifications

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

Table 1: Metrics and final product specifications of the design criteria.

Prototype

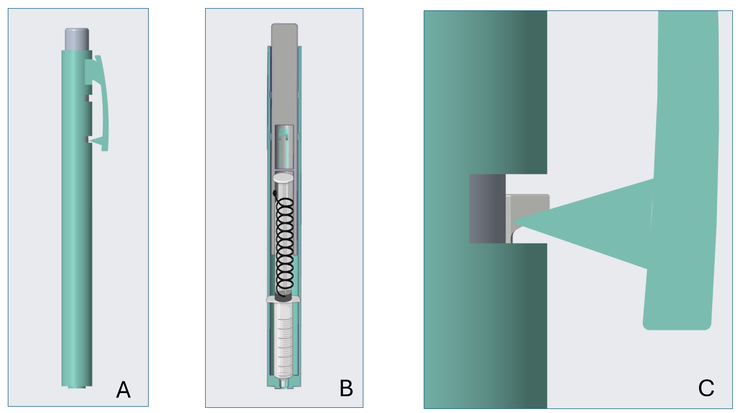

Figure 4: Final prototype of the automated skin punch biopsy tool. (a) Full assembly of the device including the main body and plunger components. (b) Section view of the automated skin punch biopsy tool showing the internal syringe and spring mechanism used to generate suction during sample collection. (c) Close up view of the locking mechanism illustrating how the plunger is secured and released during operation.

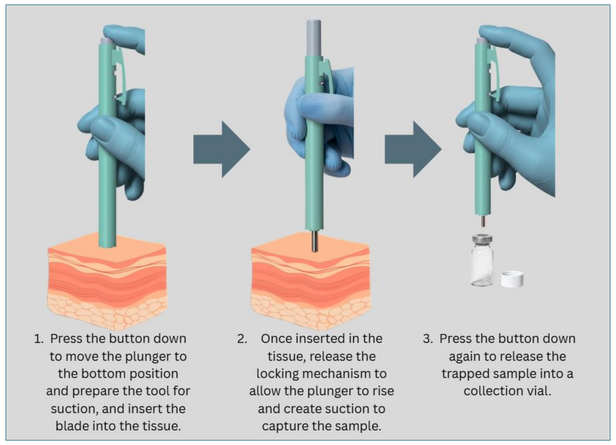

Figure 5: Operating sequence of the spring-loaded punch biopsy tool. First, the plunger is pressed to the bottom position to prepare the tool for suction before insertion into the tissue. Next, the locking mechanism is released while the tool is inside the tissue, allowing the plunger to rise and create suction to capture the sample. Finally, the plunger is pressed again to release the trapped sample into a collection vial. **Image generated utilizing Canva Pro Image Generation*

Verification Results

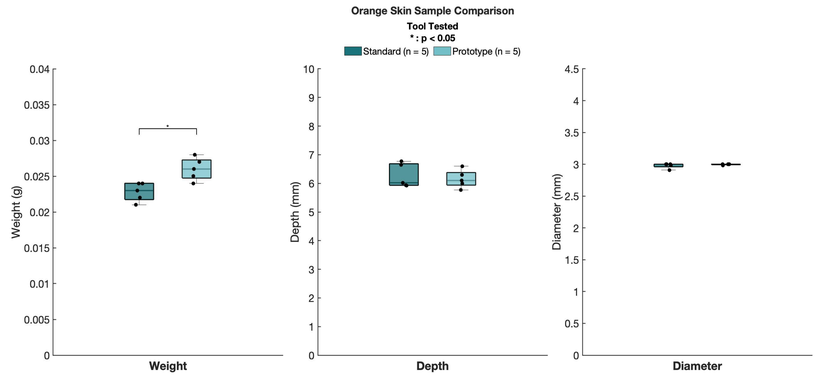

Figure 6: Orange Peel Sample Integrity Results

Testing Outcomes: 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) by 0.0012g.

Design Status & Future Steps

Current Project Status:

- Phase I was completed by obtaining punch samples from an orange using the current prototype.
- Testing on the orange was successful, with samples consistently obtained and properly released.
- Testing on porcine skin revealed insufficient negative pressure to effectively draw out the samples.

Next Phases:

- Modify the current prototype to generate a larger negative pressure differential sufficient to extract samples from porcine skin.
- Test the updated prototype to verify improved performance.
- Conduct formal design verification and validation to ensure device meets all requirements.
- Perform usability/ human factors testing to confirm safety and effectiveness.
- Prepare and submit a 510(k) Premarket Notification to the FDA with all necessary device documentation.

Acknowledgements

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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.