

CERVICAL BIOPSY DEVICE

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BACKGROUND

Need for Procedure

- 2 to 3 million abnormal PAP smears per year require a cervical biopsy follow-up, creating a large demand for an improved cervical biopsy device

The Procedure

- Physician applies a vinegar or an iodine solution to cervix, which turns abnormal cells white or dyes normal cells darker, respectively.
- Types of biopsies:
 - Cone biopsy – cone-shaped wedge of tissue
 - Punch biopsy – uses punch instrument
- Tissue samples sent to pathologist to test the tissue for cancerous cell growth

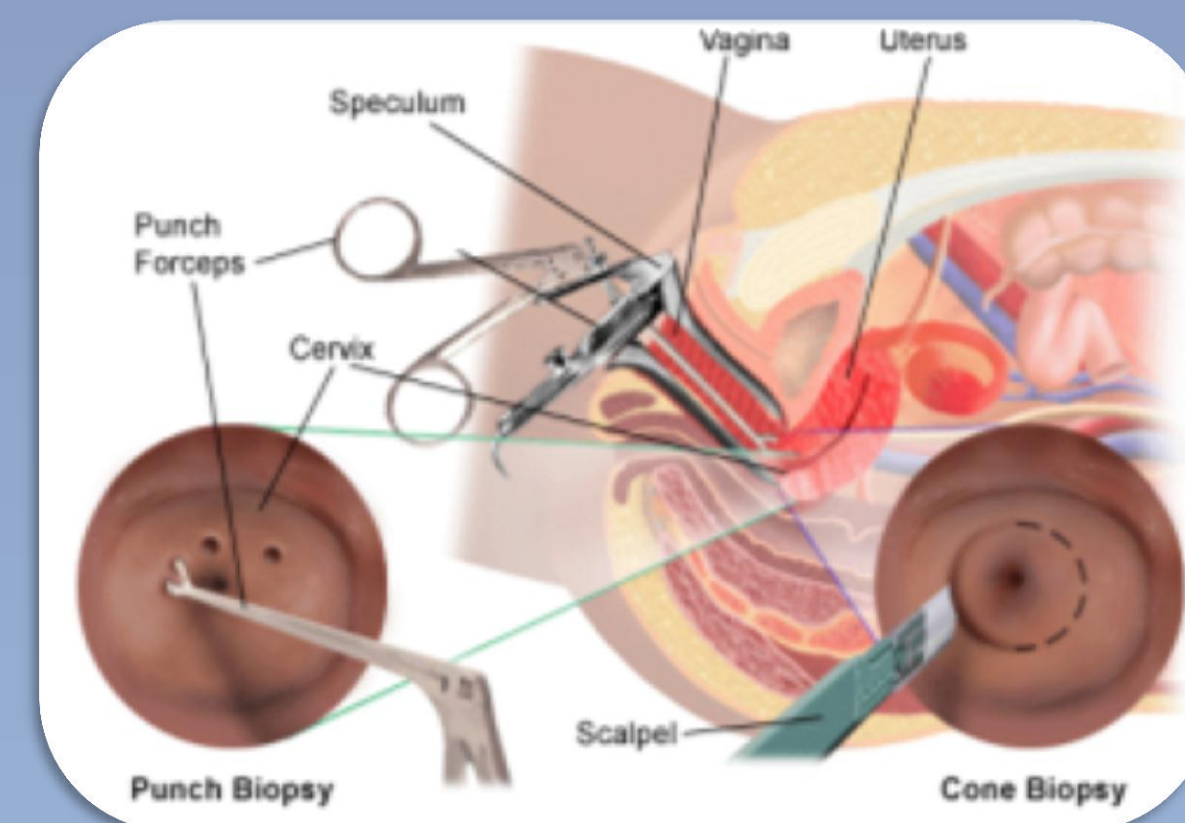


Figure 1. Cervical Biopsy Procedure

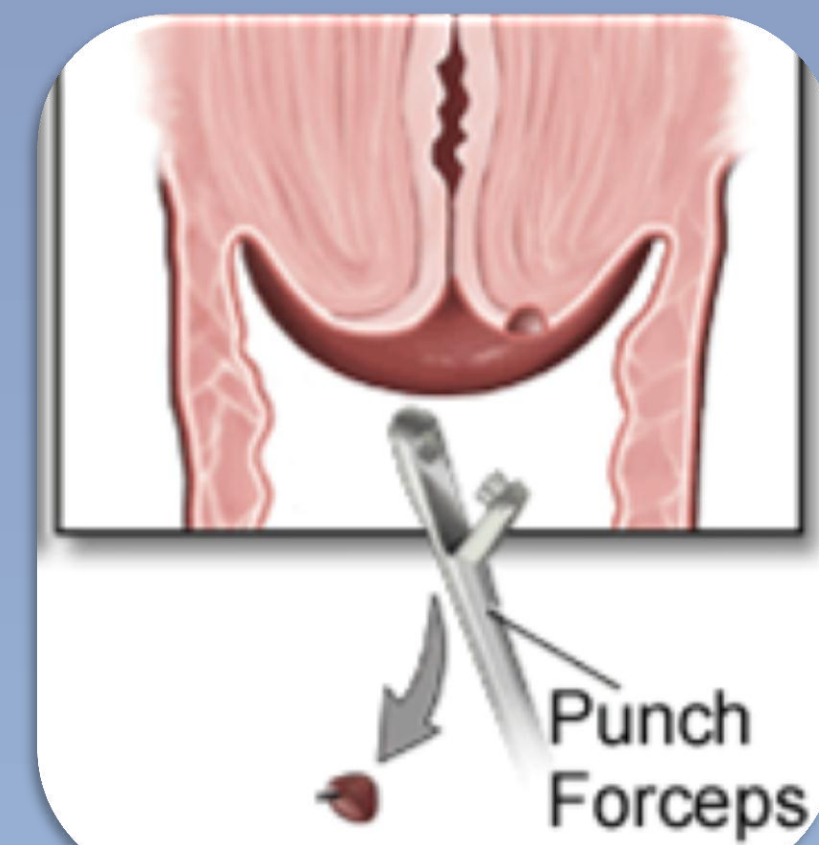


Figure 2. Punch Biopsy

Current Devices

- Kevorkian forceps, the Tischler forceps, and the Baby Tischler forceps
- Similar in method of obtaining the biopsy sample
- Simple design allows for easy use
- Difficult to secure device against the cervix
 - increased patient discomfort
 - inconsistent biopsy sample sizes

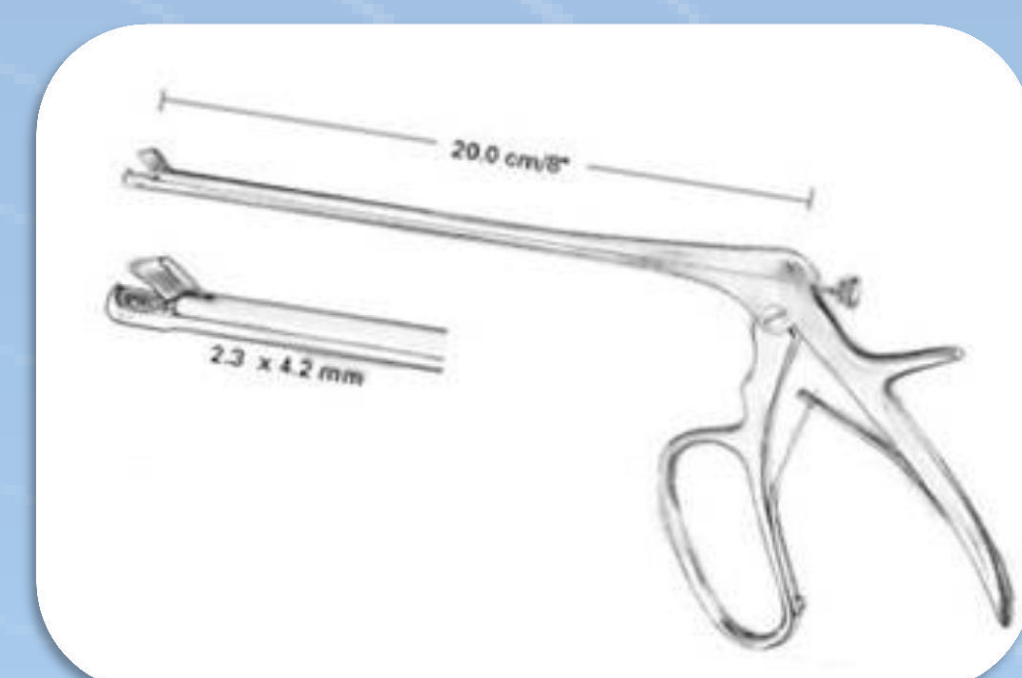


Figure 3. Baby Tischler forceps (left) and Kevorkian forceps (right)

MOTIVATION

Since current devices struggle to obtain consistent sample sizes, there is a demand in the market for a cervical biopsy device that has better contact with the tissue of the cervix and retrieves consistent biopsy sample sizes.

DESIGN CRITERIA

- Produce at least a 4 mm³ biopsy
- Produce consistently sized biopsies
- Be able to be sterilized
- Low cost per use
- Made of a sturdy, non-bendable material
- Appropriate sizing for insertion into the vagina

FINAL DESIGN

Initial Spring Design

- Relies on spring to generate necessary blade force
- Difficult to prove that spring could generate the force needed to make complete cut

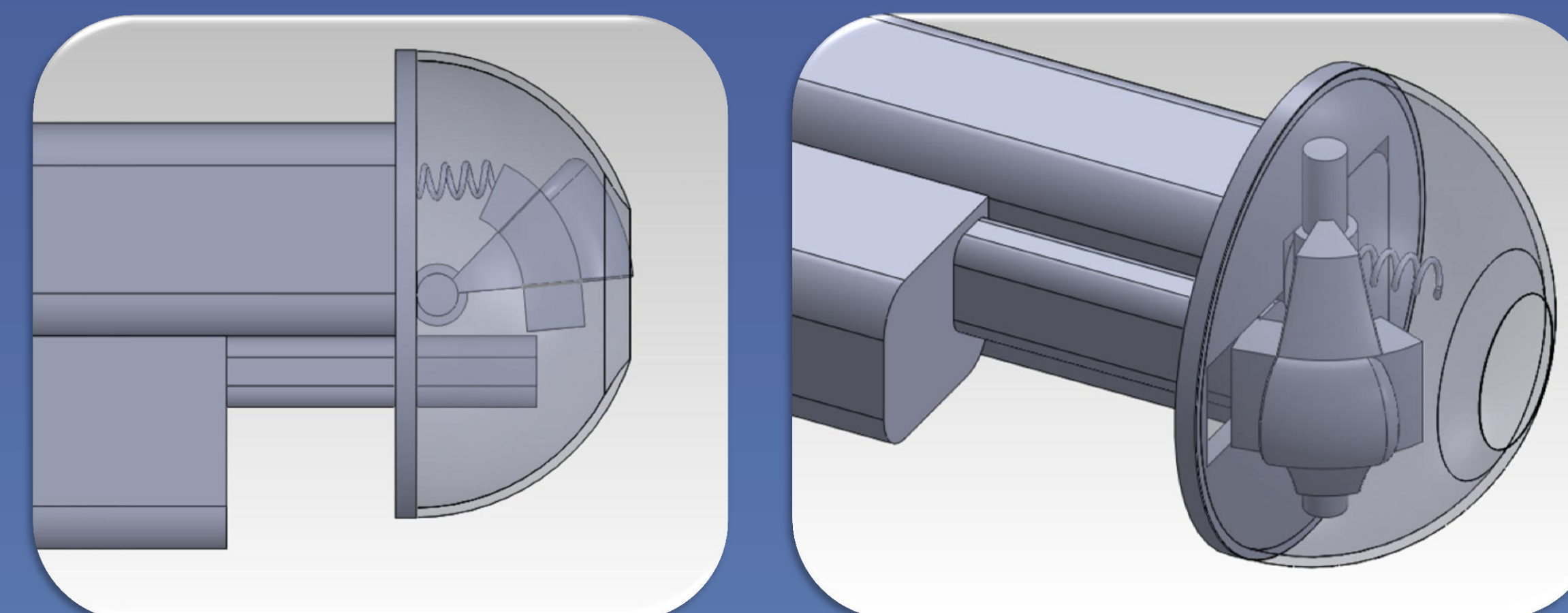


Figure 4. Top view (left) and right view (right) of the tip of the spring design

Final Hinge Design

- Mechanical system of bars and pins to relate the motion of squeezing the handle to the rotation of the blade
- Ergonomic handle fits the shape of the physician's hand
- Blocks on the blade ensure that the sharp end of the blade never comes in contact with other metal parts
- Movement of the handle is limited to the distance required for the blade to complete its rotation so physician will know when biopsy is complete
- Blade has shovel-like shape and will hold the biopsy for easy removal

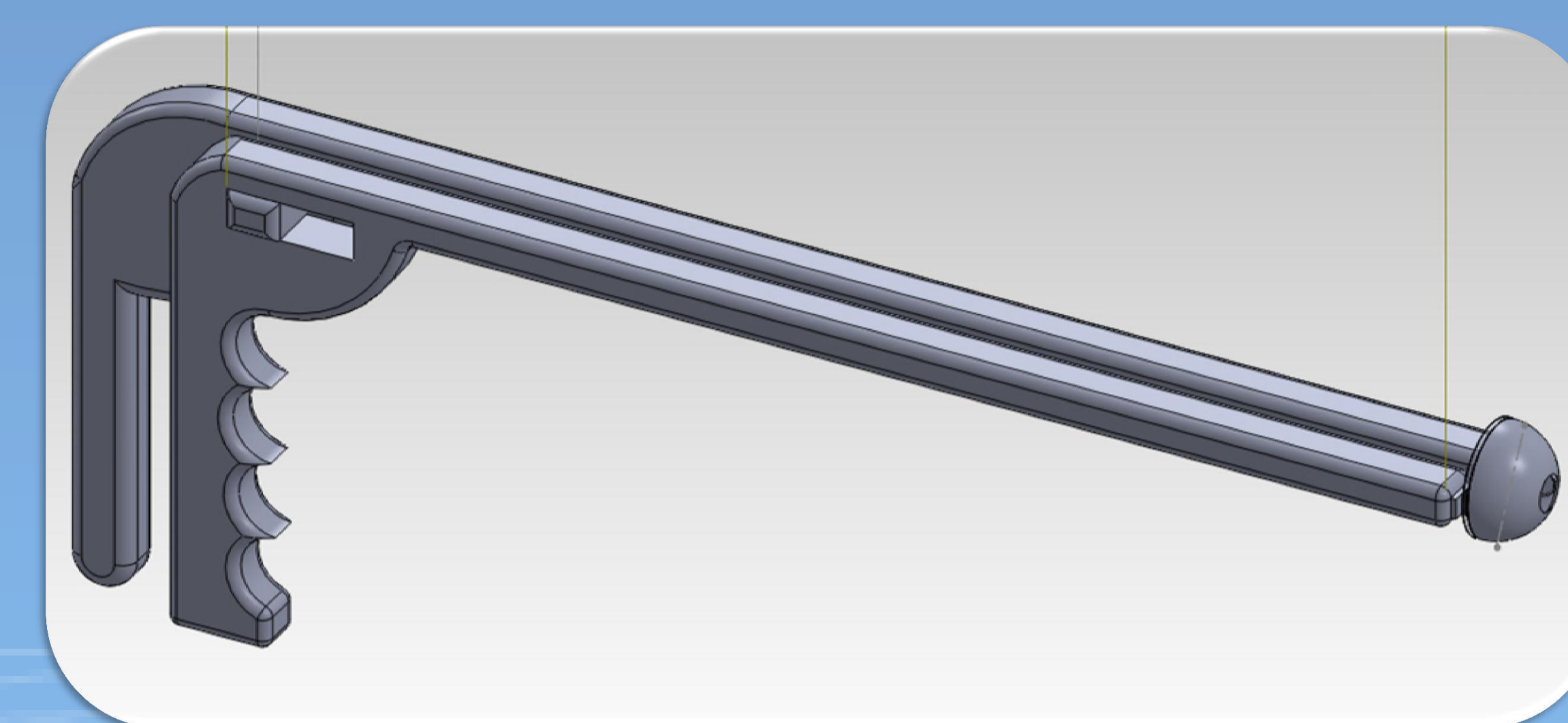


Figure 5. Final design

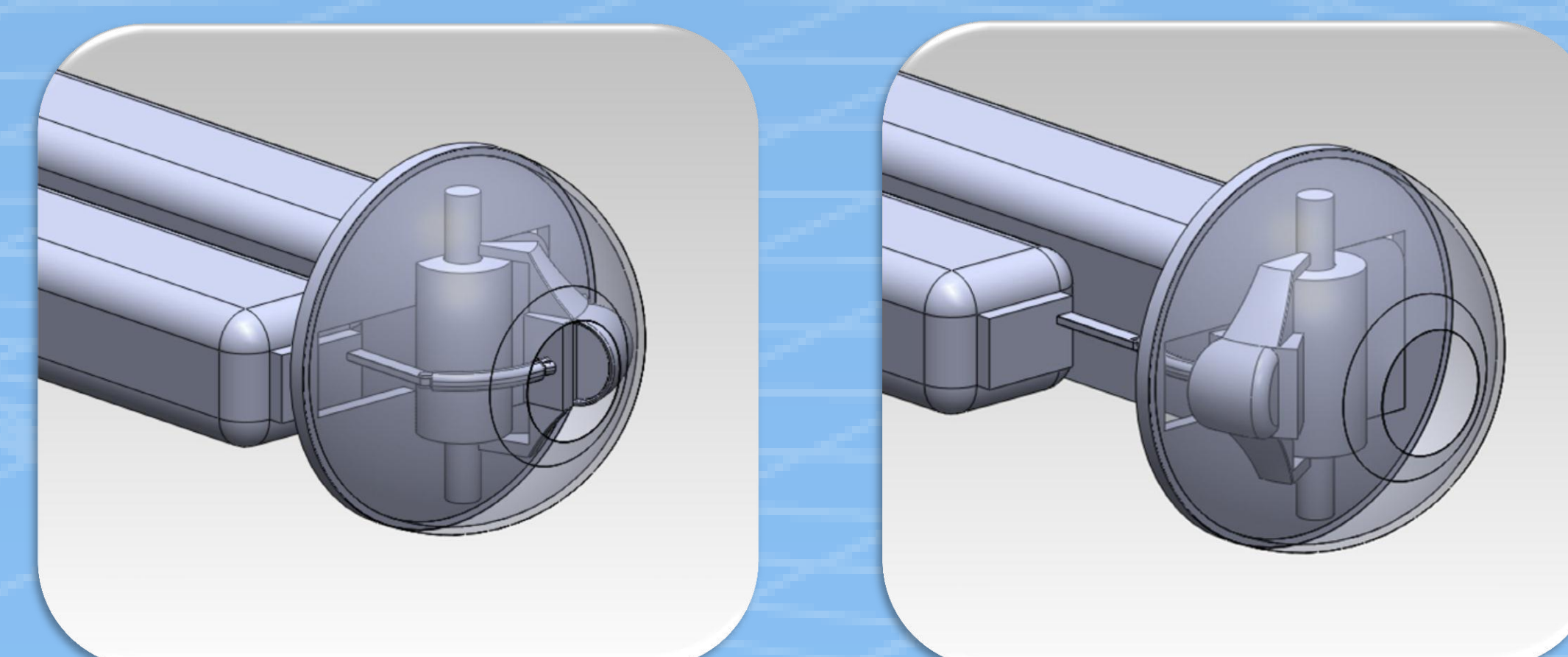


Figure 6. Device tip before (left) and after (right) pulling the trigger

SWIPE CUT TEST

Method

- Metal sheet with 0.63 cm hole placed on top of fruit or chicken
- Applied pressure to sheet until bubble formed through hole
- Cut horizontally with a razor blade attached to a rod across sample
- Placed cut sample on graph paper to determine size of biopsy

Measurement

- Measure the volume of the biopsy samples using ImageJ

Conclusion

- Each sample provided sufficient biopsy sizes but the chicken proved most consistent

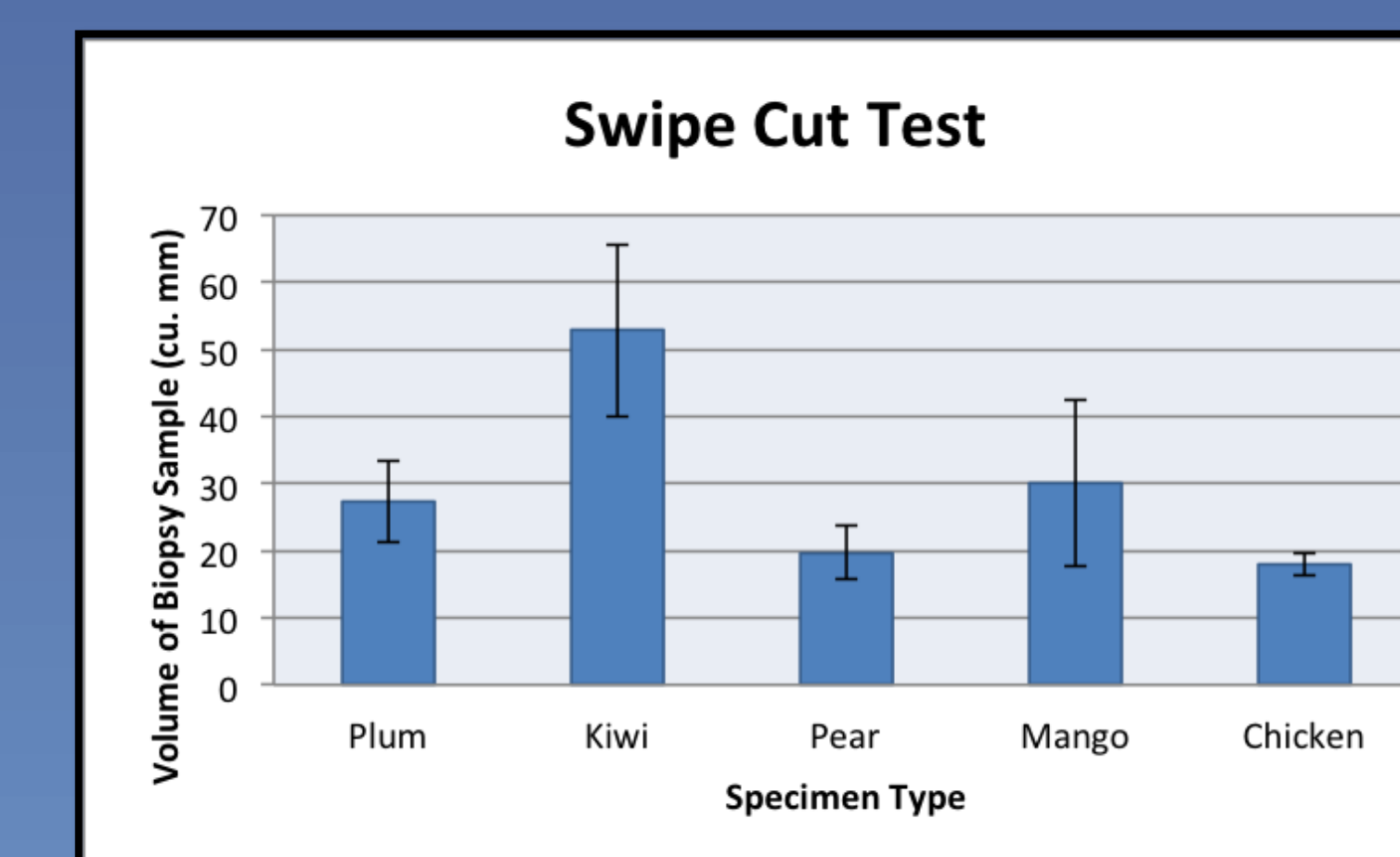


Figure 7. Swipe cut test results



Figure 8. Performing swipe cut with razor blade

"BUBBLE" TEST

Method

- 4 strings attached to corners of rectangular metal sheet with hole of 0.63 cm diameter
- Skewered fruit and chicken with metal rod and held under sheet
- Added weights to strings to apply increased force

Measurement

- Measure force at which fruit or chicken bubbles into hole

Conclusion

- The device should be pushed against the cervix with between 0.5-2 N of force

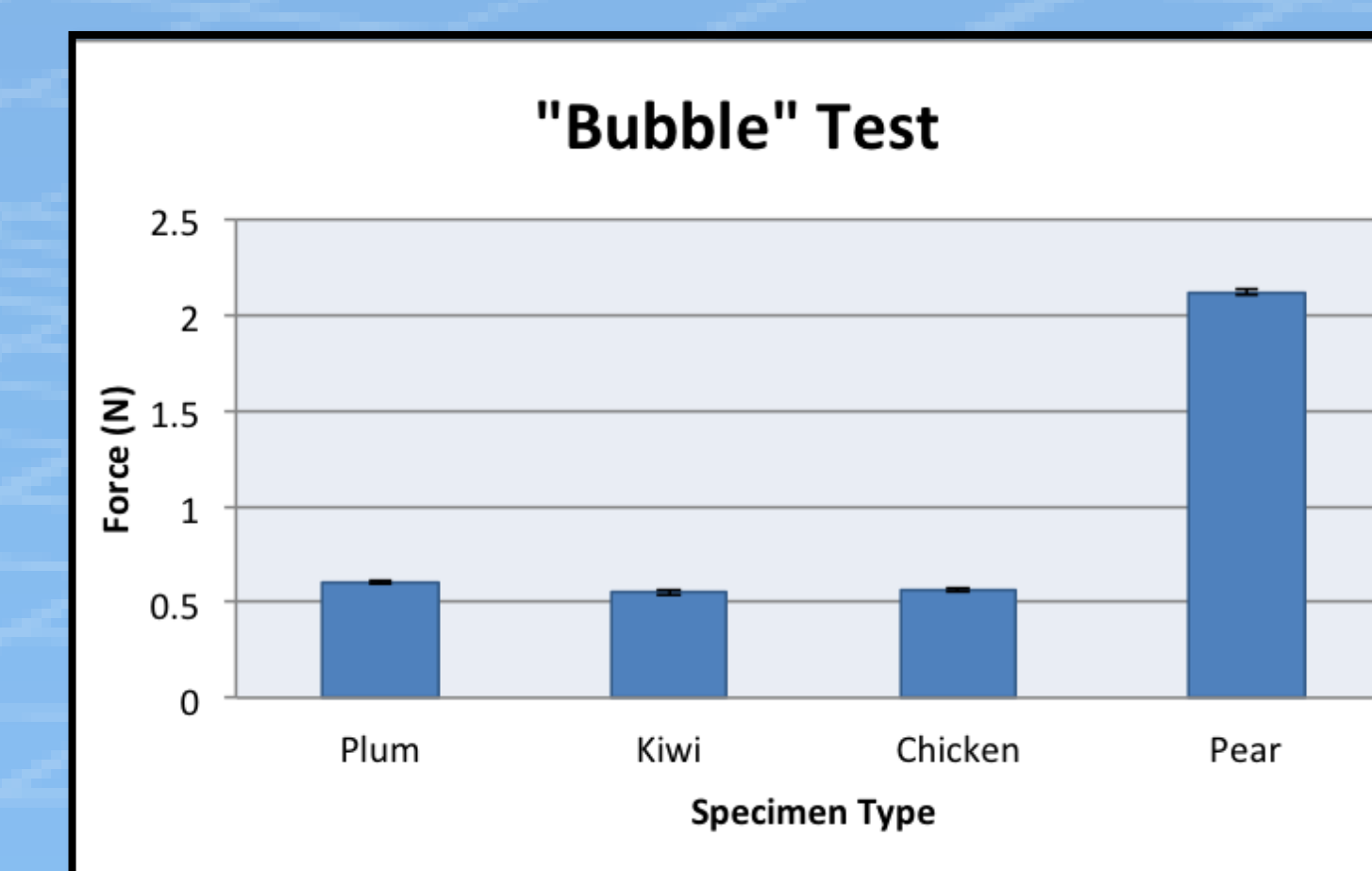


Figure 9. "Bubble" test results

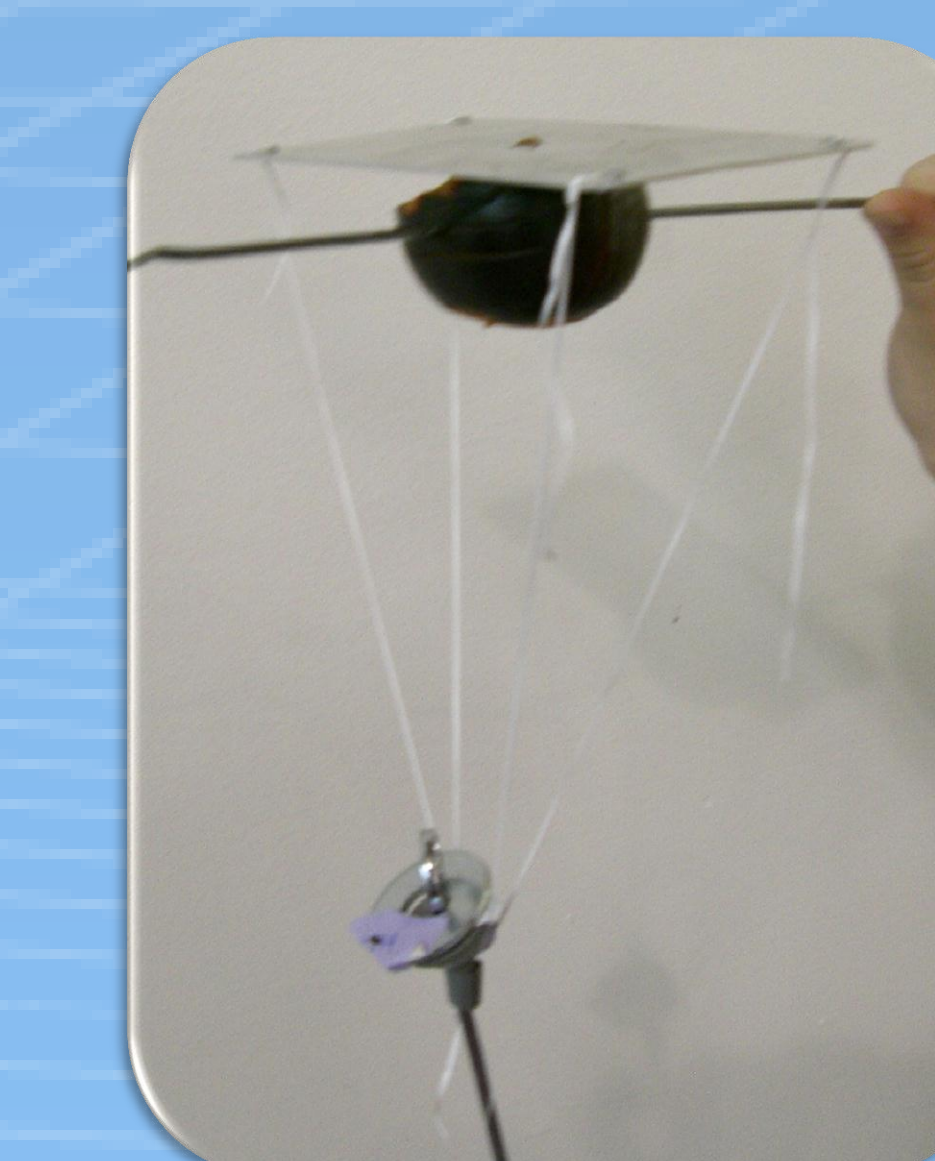
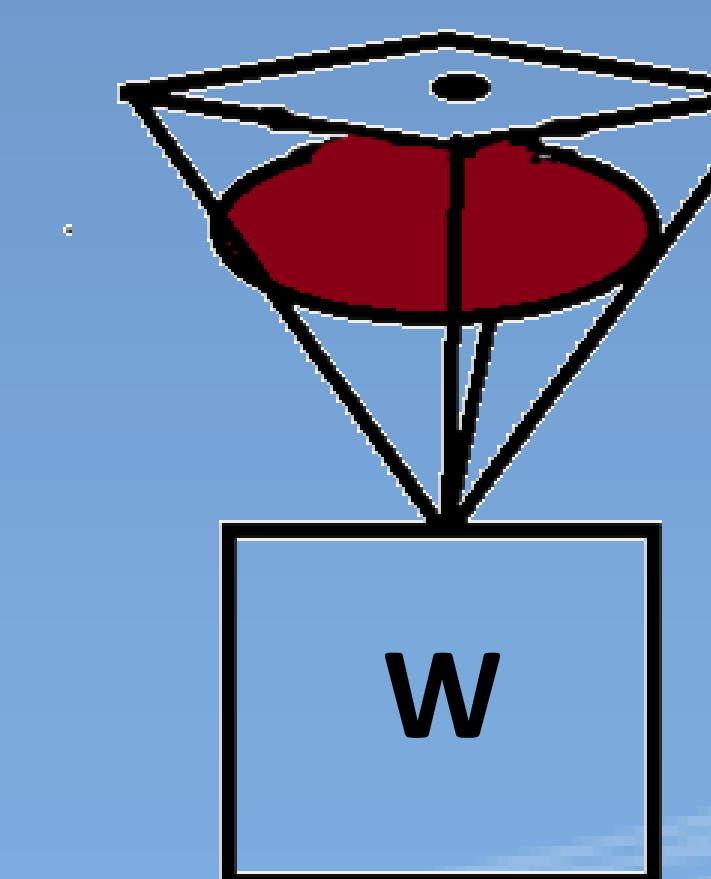


Figure 10. Setup of the "Bubble" test (two images above)



Figure 11. Setup of Cutting Force test without weight (left) and with weight added (right)

CUTTING FORCE TEST

Method

- A razor blade connected to a rod was clamped vertically over the testing subject (fruit or chicken drumstick)
- Weights added onto the rod

Measurement

- Measured force required for the slanted tip of the blade to insert into the testing subject

Conclusion

- The force provided by the physician's pull of the trigger needs to be at least 1.50 N

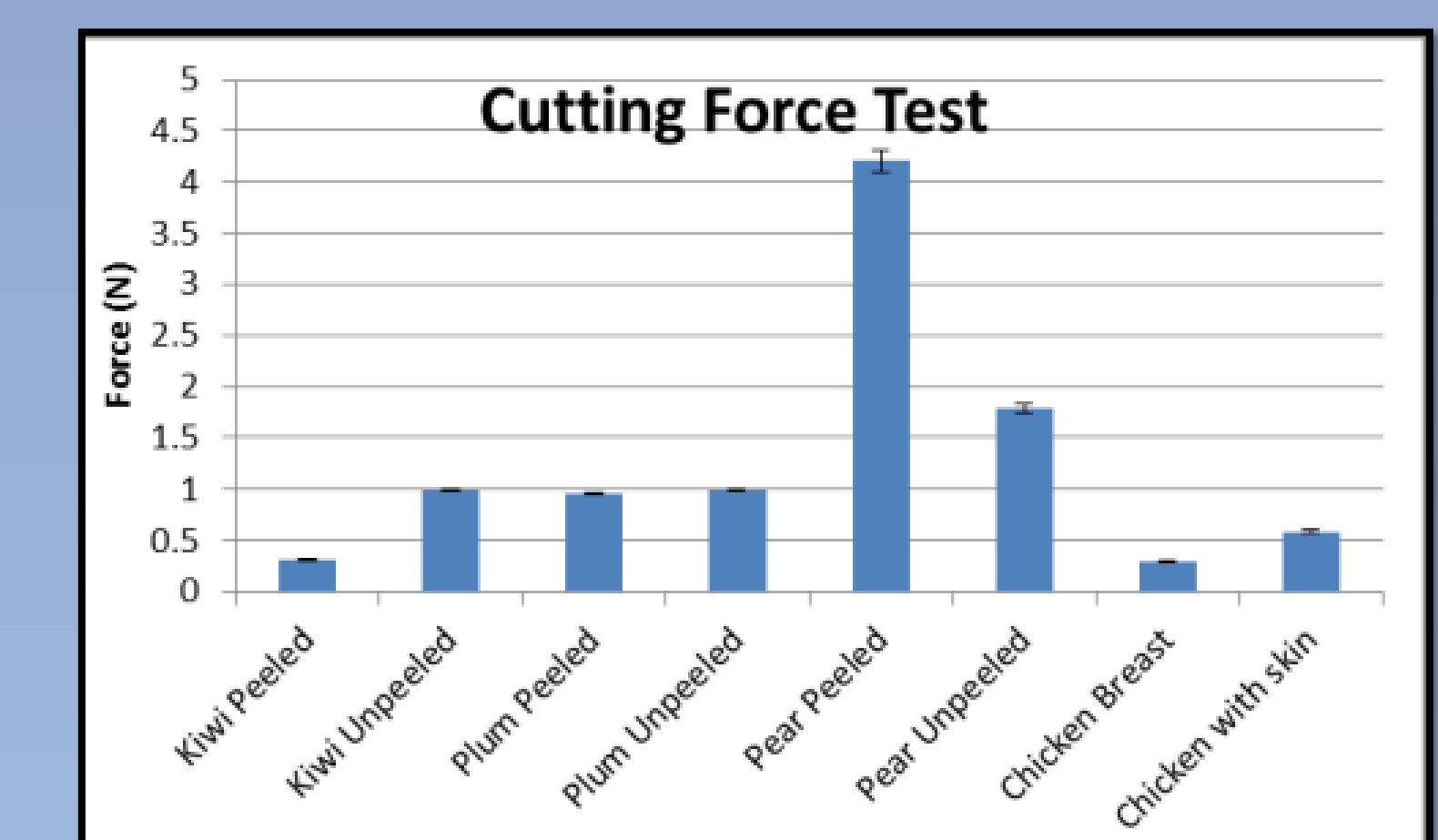


Figure 12. Cutting Force test results

FUTURE WORK

Immediate Future:

- Reassess dimensions of device
- Increase speed and strength of blade cut
- Consider the difficulties of manufacturing
- Get an estimate for the cost of production

Future Semesters:

- Assess the possibility of incorporating external suction by making the rod hollow
- Test with an entirely complete prototype

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- www.stjohnprovidence.org/StaywellTesting/img.aspx?1614
- All SolidWorks images produced by Hannah Pezzi