Core Needle Biopsy Device for Breast Cancer

Jemmima Gonsalves1,6, Ashley Hong1,4, Zaria Johnson1,3, Julie Shin Kim1,2, Clara Shi1,2, Audrey Young1,3, Jiyeon Chun5

1Biomedical Engineering, 2Chemical Engineering, 3Material and Science Engineering, 4Mechanical Engineering, 5Industrial Design, 6Engineering and Public Policy - Carnegie Mellon University

INTRODUCTION

Background

- Breast cancer is the most common cancer among women in the US
- 42,000 women die from breast cancer each year
- 60% of breast cancer deaths occur in low resource areas
- Early diagnosis leads to better treatment outcomes

Diagnostic Methods

- Imaging Methods [i.e X-ray]: screens breast cancer
- Biopsies: definitive diagnosis
  - Core needle biopsy (CNB) collects sufficient amount of sample with minimal invasiveness

Current CNB Devices

- Disadvantages: non-reusable and expensive
- Result: inaccessible for low resource populations

Needs Statement

A more compact and affordable core needle biopsy device that is one-hand operable and available to healthcare workers in low resource settings to carry out biopsies independently.

PROPOSED SOLUTION

DEVICE BODY

- Dimensions: 15.5cm x 2.1cm x 1.5cm → 82% smaller than BARD* Core Needle Biopsy (17cm x 4cm x 4cm)
- Ergonomic design: allows single hand operability, improved user maneuverability, & increases intuitiveness of device
- Mechanism: Firing the device causes the cutting cannula to spring forward over the trocar, thus cutting the tissue and securing the tissue sample.

*Existing core needle biopsy device

FINAL 3D PRINTED PROTOTYPE

1. Needle: Trocar + Cutting Cannula
2. Firing Trigger
3. Plunger

TISSUE SAMPLE SIZE TEST

Method

- Needle inserted into banana which acted as breast tissue
- Sample mass was weighed after each trial
- 20 trials were performed

Success Criteria

- Reproducible (std < 0.5 g)
- Comparable to existing devices of the same gauge needle
- tissue sample size of ~ 4mg

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Mass Collected (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Banana</td>
<td>3.98 ± 0.4mg</td>
</tr>
</tbody>
</table>

SPRING LONGEVITY TEST

Method

- Mass Collection

Success Criteria

- Reproducible (perform at least 5 test cycles)

<table>
<thead>
<tr>
<th>Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device successfully performed 20+ cycles</td>
</tr>
</tbody>
</table>

FORM FACTOR TEST

Method

- User Testing: medical professionals, potential users

Success Criteria

- One-hand operability
- Ergonomic Body Shape
- Intuitiveness
- Flexibility

Test Feedback

Rectangular body with ridged edges is most intuitive

MANUFACTURING COSTS, REGULATORY PATHWAY, PATENT & REIMBURSEMENT

Manufacturing Costs

<table>
<thead>
<tr>
<th>Device</th>
<th>Device Retail Price (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD MC1410, 5/cs - 14G x 10cm</td>
<td>$1,215</td>
</tr>
<tr>
<td>BD 1606MS, 5/cs - 16G x 6cm, Needle Only</td>
<td>$1,000</td>
</tr>
<tr>
<td>Our Device (Cost price only)</td>
<td>$44.33</td>
</tr>
</tbody>
</table>

The cost price of mass manufacturing would only be $44 which would enable a low selling price between the target range of <$100.

Regulatory Pathway

- Class II device, 510(k) clearance needed

Patentability

- The core working mechanism is standard and has been patented
- The external form factor is novel and can be patented

Reimbursement

- Biopsies are defined as ‘medically necessary’ procedures
- Breast CNBs are covered by insurance
- Ideally these devices would be supplied by health ministries/government bodies and Global Health purchasers

CONCLUSION

- Ergonomic device is easy-to-use, reusable, and cost-effective (~$100)
- Improving the accessibility to breast cancer diagnoses improves outcomes and saves lives.

ACKNOWLEDGEMENT

We would like to thank Dr. Conrad Zapanta and Daniel Thomeer for their constant support and guidance through the project. We are grateful to the Undergraduate Research Office and the Department of Biomedical Engineering for their financial support for this project. We would also like to thank all the stakeholders who gave us their valuable feedback and advice our improving design interactions and in providing clinical feedback. Lastly, we express our gratitude to the CMU TechSpark for their manufacturing capabilities that we frequently used.

REFERENCES