Development of Surgical Instrument to Improve Decortication Surgery for a Trapped Lung

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Background
A trapped lung is a result of fibrous pleuritic and often caused by a constant, benign, or unilateral pleural effusion. Each year, there are about 150,000 cases of pleural effusion that can lead to a trapped lung, which prevents the lung from fully expanding due to a restricting fibrous visceral pleural peel. Decortication is the procedure to peel the thick, inelastic pleural peel from the lung via video-assisted thoracoscopic surgery (VATS) or an open thoracotomy.

1. Identify Problem/ Clinical Need
The VATS procedure is used in 60.6% of decortication surgeries with increasing rates. Complications still occur in about 39.3% of procedures and mortality occurs in 3.1% while major morbidity occurs in 15.6% of patients. The current surgical tools used in the decortication procedure are poorly standardized and patient outcome relies on surgeon expertise. Furthermore, the surgeons currently visually check the tissue to determine when “90% tissue removal” has been achieved.

<table>
<thead>
<tr>
<th>Need</th>
<th>Characteristic</th>
<th>Metric</th>
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<tr>
<td>Can Remove Tissue</td>
<td>Speed of Blade</td>
<td>&gt; 2500 RPM</td>
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<tr>
<td>Indication of Layer</td>
<td>Sensor Accuracy in Detecting Tissue</td>
<td>&gt; 90%</td>
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<tr>
<td>Can Remove Tissue</td>
<td>Sharpness of Blade</td>
<td>&lt; 15 Degrees Blade Angle</td>
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<td>Easy to Manipulate within Body</td>
<td>Area of Interest End of Device</td>
<td>&lt; 2 cm</td>
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<tr>
<td>Reduces Surgery Time</td>
<td>Time to Complete Surgery</td>
<td>&lt; 3 Hours</td>
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Table 1. A list of customer needs with characteristics and metrics.

Need: There is a need to develop a surgical device that can aid with the decortication procedure by allowing surgeons to quantify the tissue and effectively remove it.

2. Develop Early Prototype for Customers

Tissue Detection
- Detect Tissue
- Detect Fibrous Tissue

Tissue Removal
- Remove Tissue
- Remove Fibrous Tissue

Fig 2. Design concept of the device, where the circular blade rotates and shaves ~1 mm depth of tissue with every pass. The detachable head has various depths.

Fig 3. Product metrics and their correlation to customer needs.

3. Develop Experiments to Test Device Designs

Fig 4. (A) Balloons layered with pig skin with lines to indicate where to place the transducer. (B) Pig lungs layered with a silicone layer.

Fig 5. Models used to test ultrasound component with the Vevo 3100 Preclinical Imaging System FUJIFILM VisualSonics.

Fig 6. Example of the ultrasound component using relative difference and a single factor ANOVA, looking at the (A) Ballon Model and (B) Pig Model.

Fig 7. (A) Oscillating and (B) rotary blades used in testing.

Fig 8. Tissue removal results with various blade types and movements.

4. Finalize Design and Develop Surgical Instrument

Surgical Device Abilities:
1. Detect Fibrous Tissue ➔ Ultrasound Component
2. Remove Fibrous Tissue ➔ Oscillating Blade
3. Remove Waste from Chest Wall Cavity ➔ Aspirator

Fig 9. (A) A model blade that encompasses the main removal mechanism of the prototype. (B) The modeled tissue detection ultrasound sensor that enables the user to scan the lung throughout the duration of use. (C) An aspirating tube that disposes of fibrotic tissue removed during surgical decortication. (D) Compiled model of components made of stainless steel and thermoplastics.

This surgical instrument meets the need for a device to quantify the fibrous tissue and effectively remove it from the trapped lung by incorporating the oscillating blade and ultrasound. This will significantly reduce complications.

Future Work
- Further verification and validation of the previous animal model testing with the alpha prototype both in vivo and ex vivo
- Further development of the ultrasound component that is compatible with the device made for the minimally invasive VATS procedure
- Test the device in a clinical setting to determine the safety and efficacy

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