Design of a Fine-Needle Aspiration Biopsy Device for Thyroid Nodules

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Introduction

- The thyroid is a butterfly-shaped gland in the front of the neck that helps regulate metabolism, body temperature, and various growth and development functions.
- Abnormal growths of thyroid tissue, otherwise known as nodules, sometimes appear within the thyroid.
- When nodules larger than 10 mm are found, one of the initial tests performed is a fine-needle aspiration (FNA) biopsy to identify the tissue in question.
- The essential element of an FNA biopsy is a thin hollow needle, usually ranging from 0.50-0.90 mm in diameter.
- In order to obtain an adequate amount of tissue for diagnosis, the physician oscillates the needle within the nodule at a rate of 3 strokes per second for approximately 5-7 seconds.

Problem Statement

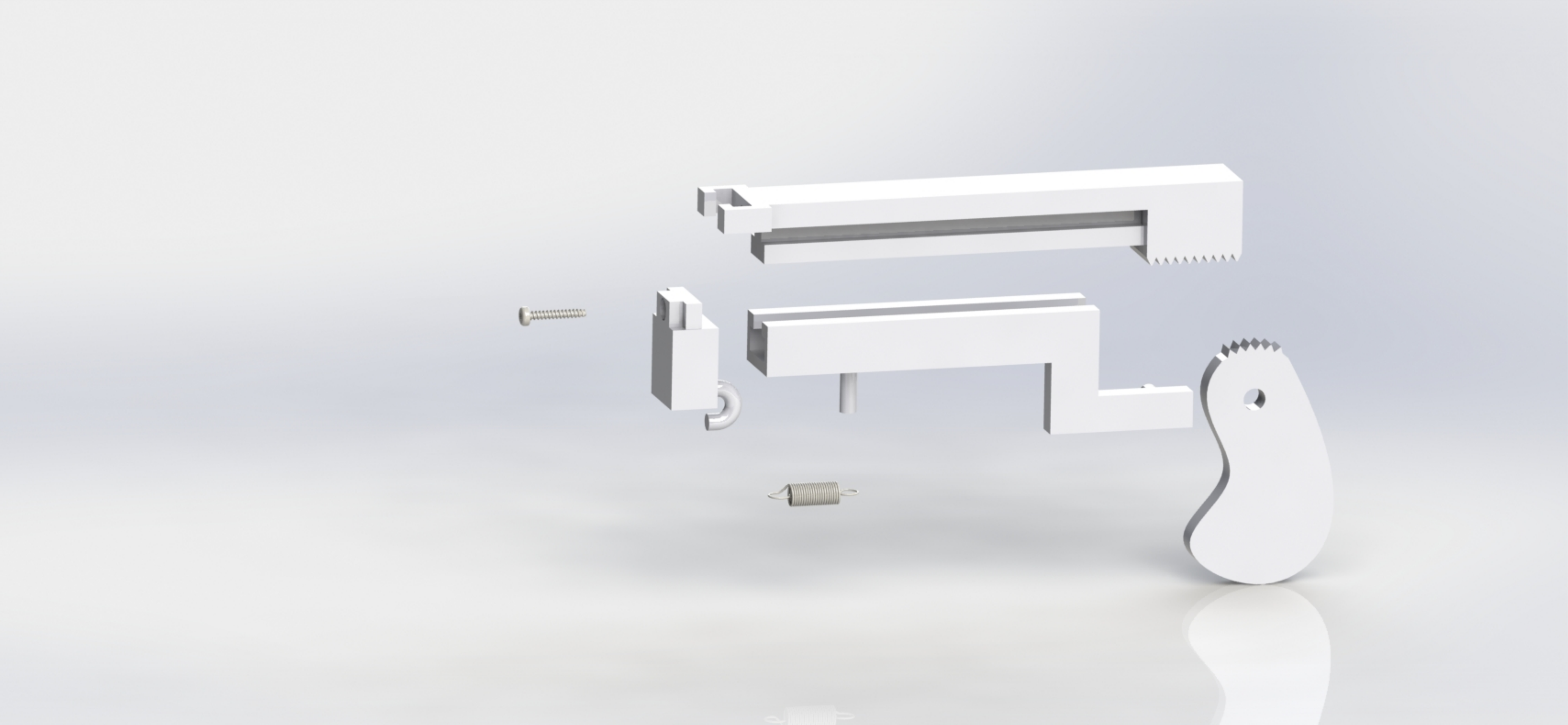
- While other devices currently exist to assist in FNA biopsies, none remove the repetitive whole wrist or arm movements needed to collect the sample.
- A new FNA biopsy device would have to adhere to the same standards as existing models, including maintaining sterility and utilizing current biopsy needles, as well as replicating the current procedure as closely as possible to allow easy adoption in clinical practice.

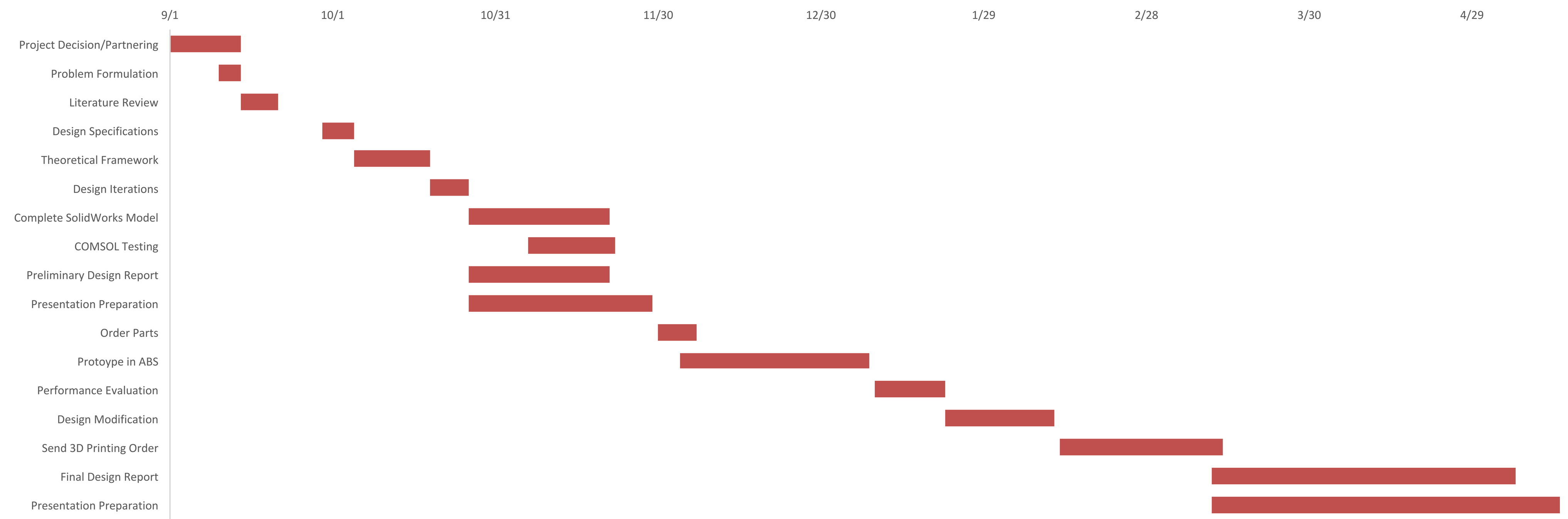
Design Specifications

- Clamping and oscillation mechanism should withstand .2 N. [3]
- Maximum stroke length should be less than 10 mm. [2]
- In order to maintain a sterile needle, the device itself must be able to be sterilized, at least where it comes into contact with the needle.

Design Constraints

- Department of Engineering and Computer Science provides a budget of $240.
- The parts of the biopsy device that come in contact with either the biopsy needle or the patient must be able to undergo adequate sterilization.
- Must be comfortable, intuitive, and efficient enough for user (physician) to agree to adopt in current clinical practice.
- Must adapt to existing needles of different gages and manufacturers.
- The limits of the James White Library's 3D printer must be taken into account for prototyping, as the printer resolution will determine what size the smallest device features must be.
- Designing, printing, assembly, and testing must be completed by May 2017.





Design Solution

- Universal needle attachment
- Single-axis motion
- Motive force
- Resistive force
- Pure mechanical design
- 3D printing focus

Single-Axis Motion

- Greatly improves the precision of needle oscillation while decreasing the number of user-dependent factors.
- Accomplished through a walled track that restricts a moving plate from both up, down, and side to side motion, leaving only forward and backward motion.

Motive Force

- Powers the oscillation mechanism.
- A trigger linked to the moving plate converts rotational displacement into linear displacement.
- A gear arc on the trigger top meshes with teeth embedded in the moving plate. As the trigger is pulled, it rotates around a fixed point, pushing the plate, and therefore the needle, forward.

Resistive Force

- Retracts the needle to complete the oscillation.
- A properly placed spring would resist any forward motion of the moving plate.
- After the trigger is pulled and the plate is pushed forward, the user can release force on the trigger and the spring will return the plate to its original position.

Performance Evaluation

- Clamping and oscillation mechanism should withstand .2 N. [3]
- Maximum stroke length should be less than 10 mm. [2]
- In order to maintain a sterile needle, the device itself must be able to be sterilized, at least where it comes into contact with the needle.

Acknowledgments

Thanks to our advisors, Dr. Gunnar Lovhoiden and Dr. Michael Spieth, as well as Andrews University's Department of Engineering and Computer Science for supporting senior design projects.

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