

A Laparoscopic Tool for Pediatric Epicardial Lead Removal

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Background

Problem

- Pacemaker placed in abdominal rather than chest cavity of pediatric patients
- Once pacemaker is removed, epicardial leads are abandoned on heart
- Only current lead removal option is open heart surgery
- Patients with abandoned leads have a decreased quality of life

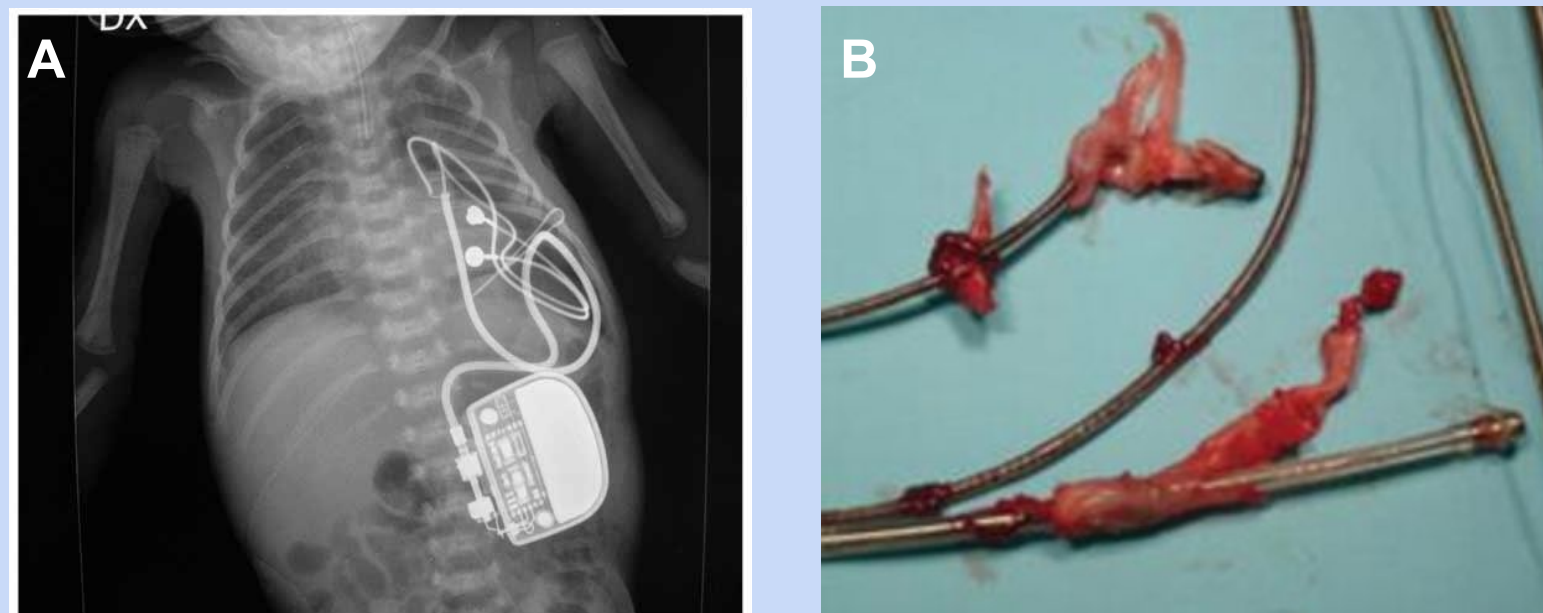


Figure 1. Epicardial leads abandoned in children. A) X-Ray image of abdominal pacemaker. Arrows point to attachment site of epicardial leads onto the heart. B) Fibrotic adhesions on removed epicardial leads from porcine model.

Objective

Design a novel epicardial lead removal device with 5 degrees of freedom for use in a pediatric population which is compatible with the port designed by Dr. Rohan Kumthekar and his engineering team at Children's National Hospital.

Design Requirements

Design Overview

- Designed for precise movements
- Designed to have 5 degrees of freedom
- Simple user inputs
- Compatible with port
- Ease of use for surgeon



Cutting Methods

Criteria	Cutting Options		
	Laser	Electrocautery	Harmonic Scalpel
Efficiency	4	4	3
Cost	1	4	2
Risks	2	3	3
Total	7	11	8

Electrocautery Benefits:

- Non-directional cutting
- 100-1200 temperature range
- Minimum risks

Prototype Design

Articulating Tip

- Designed for precise movements (**5 mm radius of curvature**)
- A single flexible piece contracted using an articulation cable

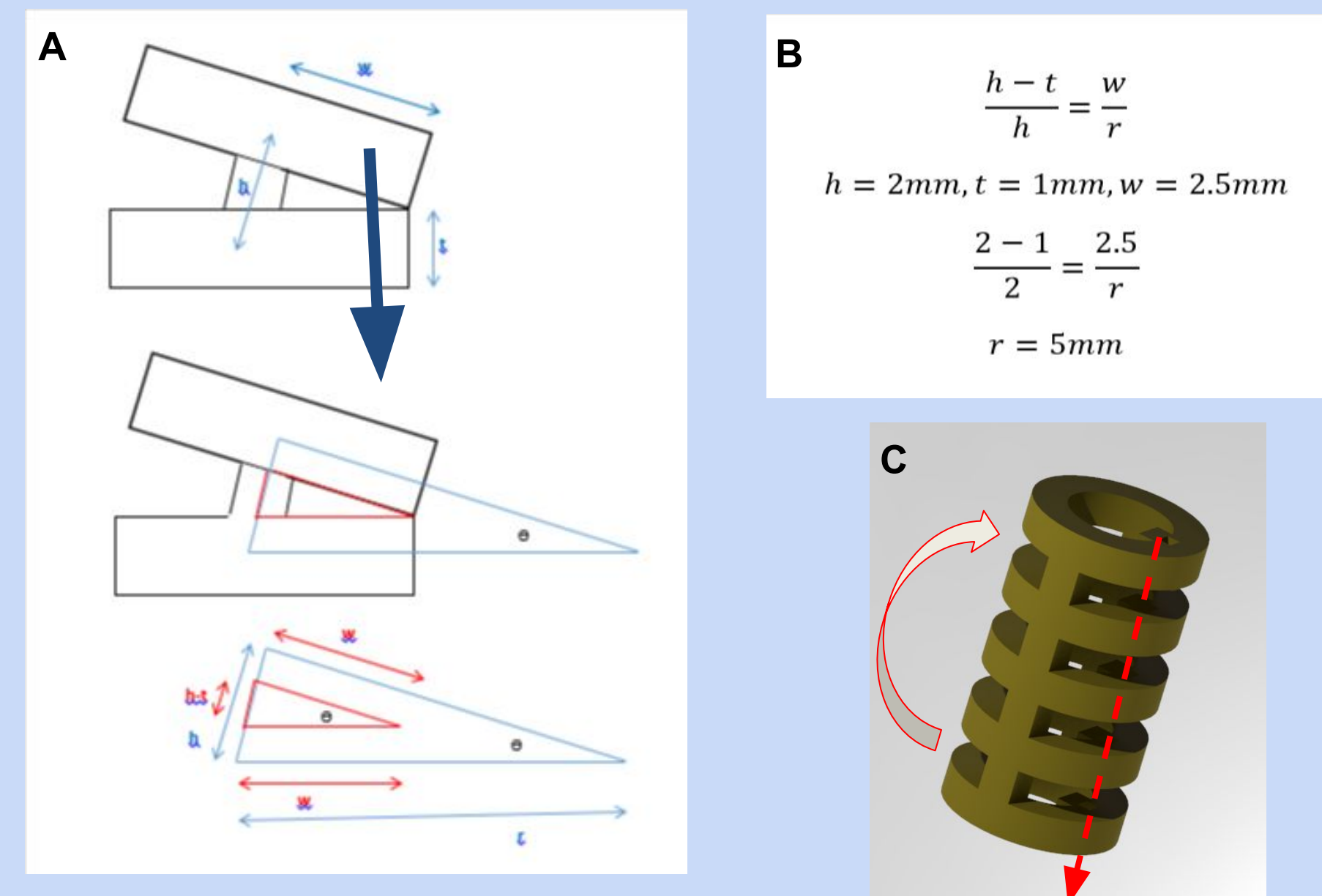


Figure 2. Tip of the device articulates by shortening a cable, which contracts the flexible piece on the end. A) Derivation of calculations for radius of curvature. Sides touch following contracture of a cable. B) Calculations of radius of curvature. C) Rendered CAD image of articulating tip. Pulling on the cable (represented by dotted arrow) causes the tip to curve towards that side.

Handle Input to Tip

- Movement of the proximal handle pulls the articulation cable and contracts the articulating tip

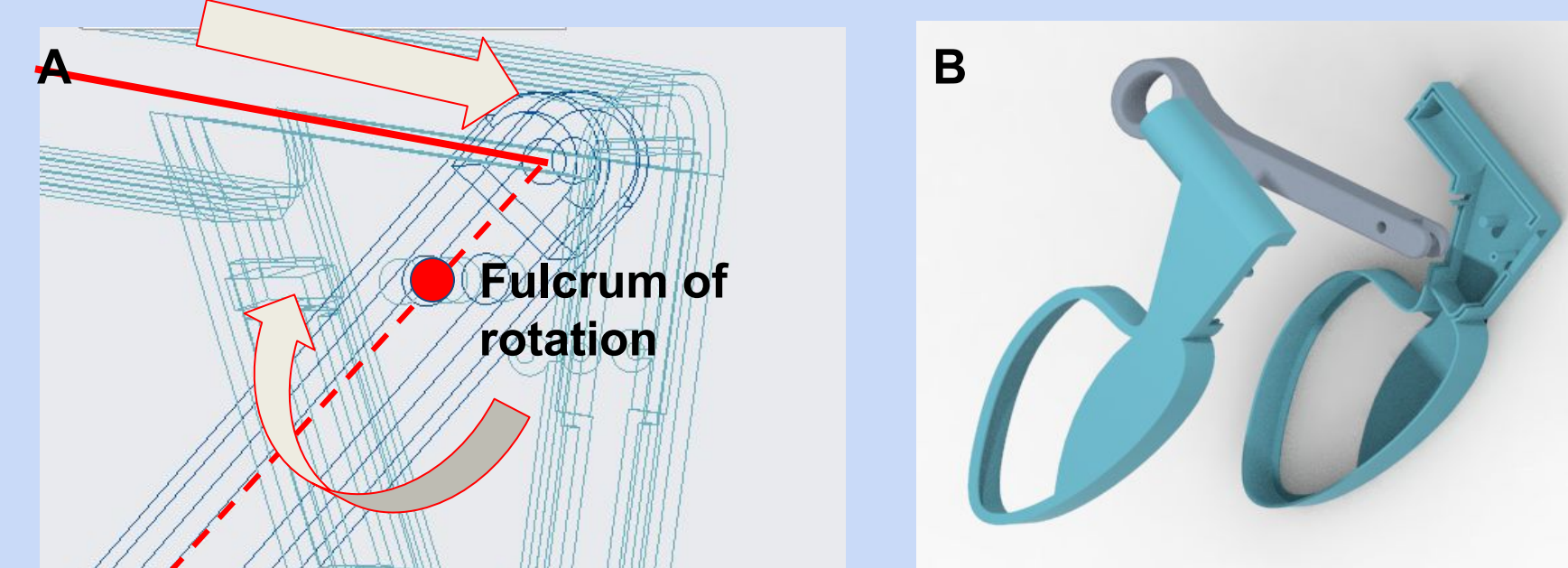


Figure 3. Handle design for movement of articulation cable. A) CAD image of assembled handle. Upon movement of the diagonal piece about the fulcrum, the cable is pulled, resulting in contracture of the tip. Solid line represents cable, dotted line represents arm of action. B) Exploded view of assembled handle.

Handle Input for Rotation

- Rotation based on the movement of two gears, one exposed and one hidden inside shell of handle
- Rotation of exposed gear with index finger leads to the rotation of the outer shell

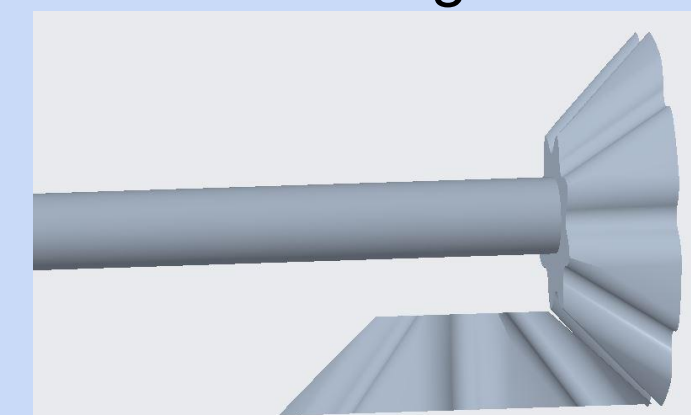


Figure 4. Gear mechanism for rotation of the device.

Discussion

Ethical Implications

- Allows for removal of leads in children, which improves quality of life by allowing child to undergo MRI scans and alleviating risk of infection of abandoned leads
- Reduces strain put on the surgeon during traditional laparoscopic surgery by increasing ergonomics and range of motion
- Promotes less invasive procedures for other surgeries

Regulatory Pathway

- Will need to file for IACUC approval for animal testing in pig model
- Will need to file for IRB approval for testing in operating rooms
- Class II Device - requires 510K
- Receive Independent Device Exemption (IDE) for clinical trials

Market Potential

- Immediate market of those in need of epicardial lead removal
- Sell the tool as an one use laparoscopic medical device to hospitals
- Market will expand with the growth of laparoscopic procedures

Future Work

Formal in vivo testing in animals models

Begin clinical trials once IDE is acquired

Explore other applications of tip such as removal of ovarian cysts or other growths safely accessed through laparoscopy where precision is required to avoid damaging important surrounding tissue

Incorporation of other functionality at tip (for example, graspers)

References

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