

# Design of Sensor “Gripper” Mechanism for Use in Middle Ear Prosthesis with a Clinical Indications Analysis for the Mechanism

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## Background

- **1.5 Billion** people affected by hearing loss globally [1]
- Drawbacks with **external components** of current cochlear implants and hearing aids
- **Piezo-MEMS accelerometer (axl)** being developed by Professor Karl Grosh’s team [2] to offer solution with no external components
- Need to attach axl to ossicle bone

## My Tasks:

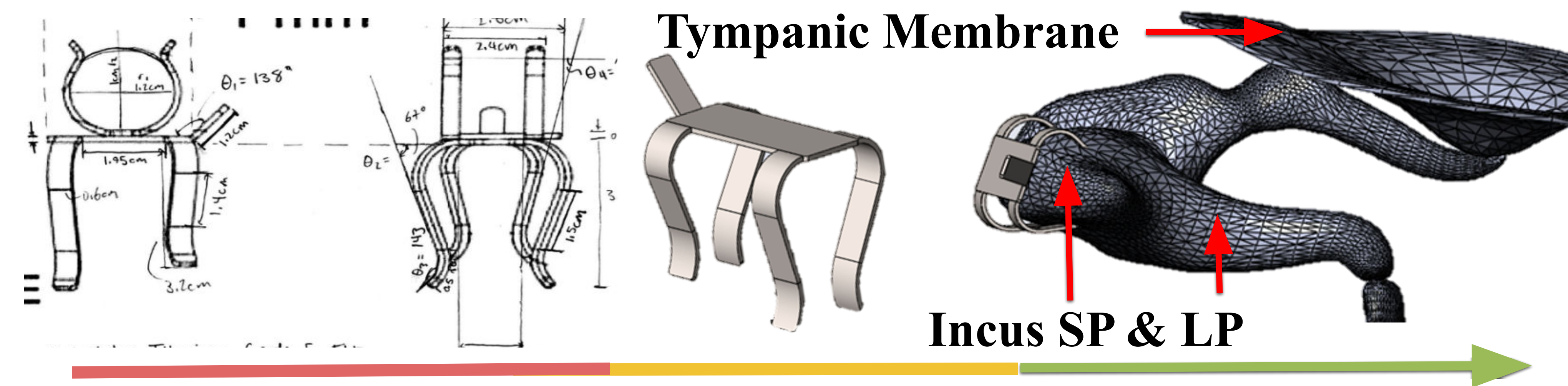
1. Designed **Gripping Mechanism** attaching accelerometer to ossicle bone in the middle ear
2. Fabricated **Prototypes** and validate by using real bones
3. Found information about **Global Cochlear Implants Market** and suggest points of intervention

## Multi-Disciplinary Approach

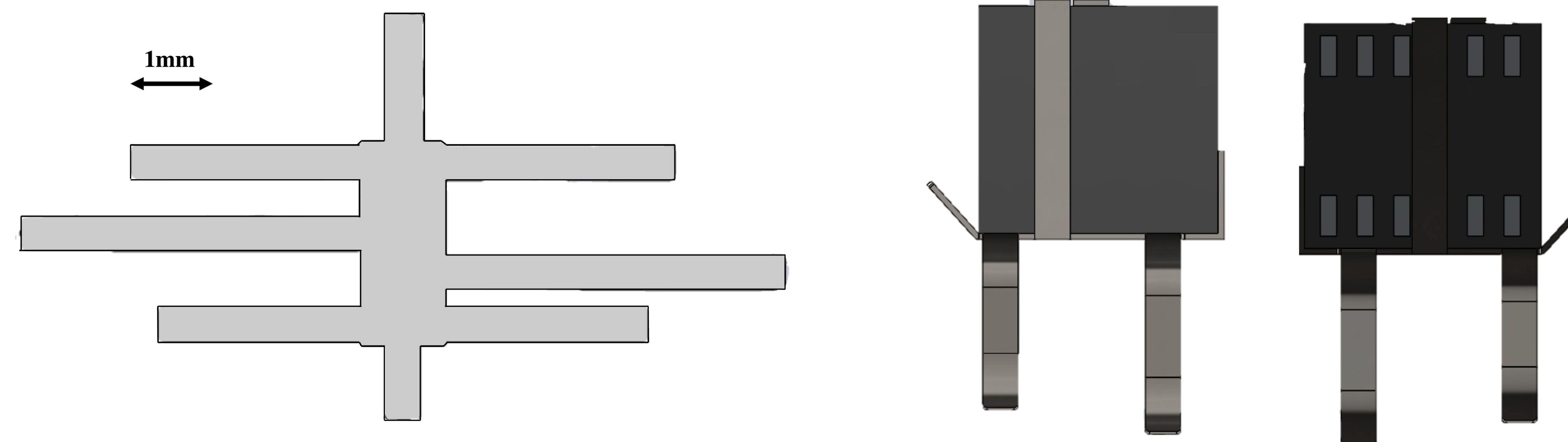
- Information obtained from **Otolaryngologist, CoE and Ross Faculty, and industry experts**
- Attended **mastoidectomy with posterior tympanotomy surgery**
- Used aspects of **competitor product** in gripper design

## Extensive Design Process

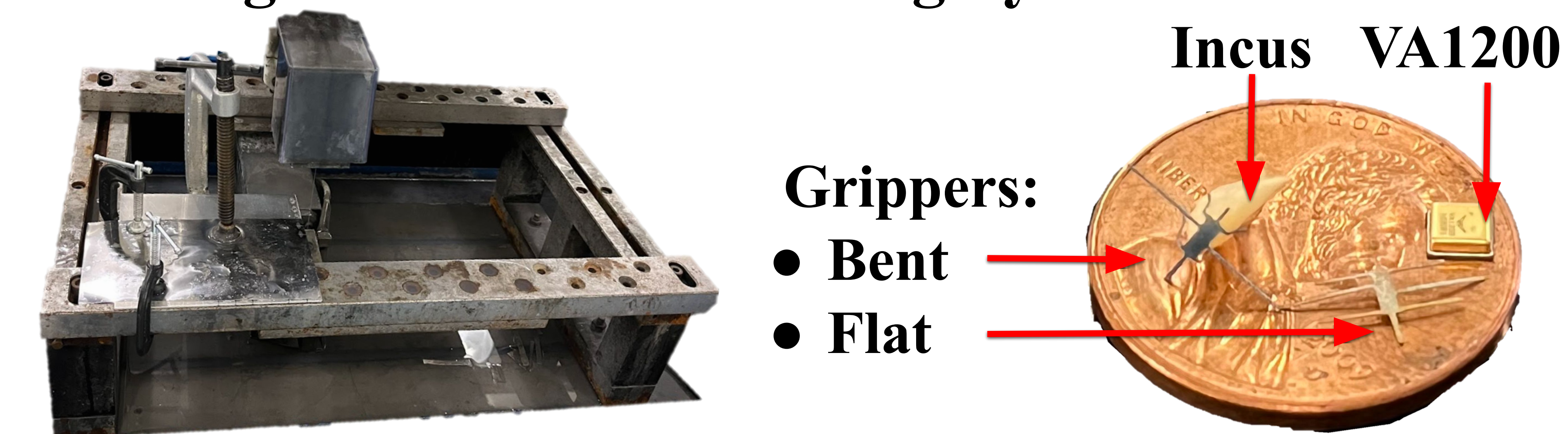
- **FA2022** - CAD modelled after **MED-EL SP Coupler** [3]



- **WN23** - Adjustments made for **CNC EDM** machining and incorporation of **Vesper VA1200** accelerometer [4]



## Fabrication in NSF Research Center for Reconfigurable Manufacturing Systems and GGBL



- **CNC EDM** used to cut flat version of gripper: **75µm** thick brass foil initially used
- **2 min** to cut **75µm** thick Ti foil with Al plate; **30 s** for brass foil
- Arms bent using **1 mm** and **0.8 mm** diameter steel dowels
- **Validated** by **successfully** attaching gripper to incus

## Clinical Indications Analysis

- **Global Cochlear Implants** market valued at **\$1.816 Billion** in 2020 with CAGR of **11.61%** [5]

Trends	Drawbacks
Technological Innovations: <ul style="list-style-type: none"> <li>● <b>Custom</b> Parts</li> <li>● <b>Smaller</b> sound processors</li> <li>● <b>Bluetooth</b> and <b>smartphone</b> connection</li> </ul>	<ul style="list-style-type: none"> <li>● <b>High Cost</b></li> <li>● \$18k-\$20k</li> <li>● <b>Highly Regulated</b></li> <li>● US FDA class III medical device</li> <li>● <b>Limited Medicare Coverage</b></li> <li>● Unnecessary to treat unilateral hearing loss</li> </ul>

## Next Step Recommendations

1. **Standardize fabrication method** for repeatability
2. Assess **robustness** and **failure modes**
3. **Test VA1200 performance** while attached to incus
4. Determine mechanism **novelty** and look into **design patents**
5. Determine requirements for **FDA approval**

References RISE: FA22 WN23

