Otologic Surgery

Daniel L. Rothbaum, MD
Jaydeep Roy, PhD
Louis L. Whitcomb, PhD
Russell Taylor, PhD
Gregory Hager, PhD
Dan Stoi

John K. Niparko, MD
Howard Francis, MD
Otologic Surgery

- Operating microscope
- High dexterity
- Constrained access
  - Restricted range of motion
  - Obstructed view
Ear Anatomy

- External ear
- Middle ear
- Inner ear
External Ear

- Auricle
- External auditory canal
- Tympanic membrane
- Canal dimensions
  - 1 cm diameter
  - 2.5 cm long
Middle Ear

- Tympanic membrane
- Ossicles
  - Malleus
  - Incus
  - Stapes
- Oval window
- Round window
- Eustachian tube
Myringotomy and PE Tubes

- Recurrent otitis media
- Most common ear surgery
- Approximately 1.4 million tubes placed annually
Myringotomy and PE Tubes
Tympanoplasty (type I)

- Reconstruct eardrum
- Secondary to chronic middle ear infections and non-healing perforations
Tympanoplasty with Ossicular Reconstruction

- Replace malleus (type II) or malleus and incus (type III) with prosthesis
- Eardrum repair (as necessary)
Tympanoplasty with Ossicular Reconstruction

- Replace all three ossicles (stapes, incus, malleus) with prosthesis
- Type IV tympanoplasty
- Repair eardrum (as necessary)
Stapedotomy

- Otosclerosis with stapes footplate fixation
- Prosthetic stapes (piston prosthesis)
Inner Ear

- Cochlea
- Semicircular canals
- Utricle and Saccule
Cochlear Implantation

- Sensorineural hearing loss
- Electronic stimulation of the cochlea
Considerations in Otologic Surgery
Considerations in Ear Surgery

- **Access**
  - Space versus invasiveness trade-off

- **Manipulation**
  - Confined spaces
  - Micro-manipulations
Transmeatal Approach

- Most minimally invasive approach
- Confined space
  - Decreased range of motion
- Coaxial
  - Reduced depth perception
  - Obstruction of view
Limitations of Microsurgery

- **Limitations**
  - Positional accuracy (15-20 microns)
  - Optical limitation of 10 microns

- **Reducing limitations will:**
  - Increase surgical performance
  - Allow *new* surgical procedures
  - Make surgery better, safer, faster, cheaper
Conceptual Overview

Part I: Stapedotomy
• Use stapedotomy as a model procedure to develop a robotic-assist for otologic surgery
• Improve existing surgeries

Part II: Accessing the Scala Media
• Use robotic assistance to permit new surgical approaches
Part I: Middle Ear Surgery

Stapedotomy
Part I: Stapedotomy

- Technically difficult operation
- Clear variations in outcome based on surgeon experience
- Potential complications
  - Hearing loss
  - Vertigo
  - Tinnitus
Applying the Steady Hand robot to Stapedotomy

- Fenestration of the stapes footplate with a micro-pick

- Crimping of the piston prosthesis to the incus
Steady Hand Robot

1-DOF INSERTION MODULE

3-DOF BASE (XYZ) MODULE

2-DOF RCM MODULE

1-DOF ROTATION MODULE

6-DOF FORCE SENSING MODULE

INSTRUMENT/GUIDING HANDLE
Steady Hand in Stapedotomy

Fenestration Trials
Force Scaling:

- Tactile feedback
- Test various robot modes (vs. free-hand):
  - Unscaled force feedback
  - Amplified force feedback
Locating the Fenestration: Displacement

- Mark desired fenestration site
- Before and after images
- Measure difference between centers of desired and actual fenestrations
- Displacement (mm)
Forces at the Oval Window: Load Cell Measurements

- Max Force (N)
- Cumulative Force (Ns)
Steady Hand in Stapedotomy

Fenestration Trials

DATA
## Free-Hand vs SH 1:1 vs SH 2:1

**Fellows & Attendings TOGETHER**

<table>
<thead>
<tr>
<th></th>
<th>Free-Hand (mean)</th>
<th>SH Robot 1:1 Force Feedback (mean)</th>
<th>SH Robot 2:1 Force Feedback (mean)</th>
<th>P-value</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displacements (mm)</td>
<td>0.178</td>
<td>0.150</td>
<td>0.160</td>
<td>0.648</td>
<td>1-way ANOVA</td>
</tr>
<tr>
<td>Max Force (N)</td>
<td>6.43</td>
<td>6.08</td>
<td>5.35</td>
<td>0.087</td>
<td>1-way ANOVA</td>
</tr>
<tr>
<td>Cumulative Force (Ns)</td>
<td>69.93</td>
<td>37.83</td>
<td>47.43</td>
<td>0.081</td>
<td>1-way ANOVA</td>
</tr>
</tbody>
</table>
# Free-Hand vs. SH Robot 2:1

*Adjusted for Fellow/Attending*

<table>
<thead>
<tr>
<th>Dependent variable (multiple linear regression)</th>
<th>Coefficient (Robotic Assistance: 0=FH; 1=SH 2:1)</th>
<th>P-value</th>
<th>R²</th>
<th>Independent Variables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displacement (mm)</td>
<td>-0.017</td>
<td>0.60</td>
<td>0.032</td>
<td>Surgeon 0 = Fellow (F) 1 = Attending (A)</td>
</tr>
<tr>
<td>Max Force (N)</td>
<td>-1.08</td>
<td>0.04</td>
<td>0.08</td>
<td>Robotic Assistance 0 = Free-Hand 1 = SH Robot with 2:1 Force Scaling</td>
</tr>
<tr>
<td>Cumulative Force (Ns)</td>
<td>-22.09</td>
<td>0.17</td>
<td>0.04</td>
<td></td>
</tr>
</tbody>
</table>
## Displacement

### Grouping SH 1:1 & SH 2:1 together

<table>
<thead>
<tr>
<th>Independent Variables:</th>
<th>Coefficient Value (mm)</th>
<th>P-Value</th>
<th>Dependent Variable: Displacement (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robotic Assistance Coefficient</td>
<td>-0.006</td>
<td>0.81</td>
<td></td>
</tr>
<tr>
<td>Surgeon Coefficient</td>
<td>-0.023</td>
<td>0.40</td>
<td></td>
</tr>
</tbody>
</table>

**Independent Variables:**
- **Surgeon**: 0 = Fellow (F), 1 = Attending (A)
- **Robotic Assistance**: 0 = Free-Hand, 1 = SH Robot with either 1:1 or 2:1 Force Scaling
## Displacement

**FH vs SH 2:1**

<table>
<thead>
<tr>
<th>Independent Variables:</th>
<th>Coefficient Value (mm)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robotic Assistance Coefficient</td>
<td>-0.017</td>
<td>0.601</td>
</tr>
<tr>
<td>Surgeon Coefficient</td>
<td>-0.037</td>
<td>0.251</td>
</tr>
</tbody>
</table>

**Dependent Variable:** Displacement (mm)

**Independent Variables:**
- Surgeon:
  - 0 = Fellow (F)
  - 1 = Attending (A)
- Robotic Assistance:
  - 0 = Free-Hand
  - 1 = SH Robot with 2:1 Force Scaling
### Fellows vs Attendings

**FH, SH 1:1 & SH 2:1 TOGETHER**

<table>
<thead>
<tr>
<th></th>
<th>Fellow (mean)</th>
<th>Attending (mean)</th>
<th>P-value</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displacement (mm)</td>
<td>0.166</td>
<td>0.159</td>
<td>0.75</td>
<td>Student t-test for 2 samples</td>
</tr>
<tr>
<td>Max Force (N)</td>
<td>5.97</td>
<td>5.89</td>
<td>0.84</td>
<td>Student t-test for 2 samples</td>
</tr>
<tr>
<td>Cumulative Force (Ns)</td>
<td>57.99</td>
<td>44.66</td>
<td>0.26</td>
<td>Student t-test for 2 samples</td>
</tr>
</tbody>
</table>
## Fellow vs. Attending: Free-Hand ONLY

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Fellow (mean)</th>
<th>Attending (mean)</th>
<th>P-value</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displacement (mm)</td>
<td>0.236</td>
<td>0.100</td>
<td>0.01</td>
<td>Student T-test for 2 samples</td>
</tr>
<tr>
<td>Max Force (N)</td>
<td>6.30</td>
<td>6.60</td>
<td>0.72</td>
<td>Student T-test for 2 samples</td>
</tr>
<tr>
<td>Cumulative Force (Ns)</td>
<td>68.76</td>
<td>71.53</td>
<td>0.92</td>
<td>Student T-test for 2 samples</td>
</tr>
</tbody>
</table>
## Fellow vs. Attending: 
**SH 2:1 ONLY**

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Fellow (mean)</th>
<th>Attending (mean)</th>
<th>P-value</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Displacement (mm)</strong></td>
<td>0.135</td>
<td>0.186</td>
<td>0.15</td>
<td>Student T-test for 2 samples</td>
</tr>
<tr>
<td><strong>Max Force (N)</strong></td>
<td>5.46</td>
<td>5.22</td>
<td>0.72</td>
<td>Student T-test for 2 samples</td>
</tr>
<tr>
<td><strong>Cumulative Force (Ns)</strong></td>
<td>54.87</td>
<td>39.46</td>
<td>0.36</td>
<td>Student T-test for 2 samples</td>
</tr>
</tbody>
</table>
FH vs. SH 2:1:  
**Fellows ONLY**

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>FH (mean)</th>
<th>SH 2:1 (mean)</th>
<th>P-value</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displacement (mm)</td>
<td>0.236</td>
<td>0.135</td>
<td>0.04</td>
<td>Student T-test for 2 samples</td>
</tr>
<tr>
<td>Max Force (N)</td>
<td>6.30</td>
<td>5.46</td>
<td>0.25</td>
<td>Student T-test for 2 samples</td>
</tr>
<tr>
<td>Cumulative Force (Ns)</td>
<td>68.76</td>
<td>54.87</td>
<td>0.55</td>
<td>Student T-test for 2 samples</td>
</tr>
</tbody>
</table>
### FH vs. SH 2:1: Attendings ONLY

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>FH (mean)</th>
<th>SH 2:1 (mean)</th>
<th>P-value</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displacement (mm)</td>
<td>0.100</td>
<td>0.186</td>
<td>0.01</td>
<td>Student T-test for 2 samples</td>
</tr>
<tr>
<td>Max Force (N)</td>
<td>6.60</td>
<td>5.22</td>
<td>0.11</td>
<td>Student T-test for 2 samples</td>
</tr>
<tr>
<td>Cumulative Force (Ns)</td>
<td>71.53</td>
<td>39.46</td>
<td>0.21</td>
<td>Student T-test for 2 samples</td>
</tr>
</tbody>
</table>
Fenestration Trial Summary:  
*SH Robot (vs. Free-Hand)*

- Applies **less force** at oval window (particularly at 2:1 force scaling)
  - **Maximum force:** decreases **17%** from 6.4 to 5.4 N
    - p-value = 0.04
  - **Cumulative force:** decreases **32%** from 70 to 47 Ns
    - p-value = 0.17
- No real difference in ability to target the fenestration
Fenestration Trial Summary: *Fellows (vs. Attendings)*

- **DISPLACEMENT:**
  - **Free-Hand**
    - *Worse at targeting* the fenestration
  - **SH Robot**
    - *Improved targeting* of the fenestration using the SH Robot
    - *In contrast to attendings* who have decreased ability to target the fenestration using the robot

- **FORCE:**
  - **Free-Hand**
    - *No difference* in forces applied at oval window (Maximum and Cumulative Force)
  - **SH Robot**
    - No significant difference in effect of SH Robot on forces applied at oval window (Maximum and Cumulative Force)
Steady Hand in Stapedotomy: 
*Future Directions*

- **Enhance Robot Capabilities**
  - More sophisticated control algorithms
  - Force Scaling
  - Better end effectors

- **Better match robot strengths to appropriate tasks**
  - For example, fenestration versus crimping

- **Animal trials**
  - If demonstrate improved performance measures with the robot
Part II: Inner Ear Surgery

Accessing the Scala Media of the Cochlea
Hearing Loss

- 28 million people in the United States
- People losing hearing earlier in life
- Age-related hearing loss
  - 30% of adults 65 years and older
  - 50% of adults 75 years and older


Hearing Aids

- Only 25% of those who could benefit from a hearing aid actually use one\(^1\)
- $1.5 billion market worldwide\(^2\)


Pathophysiology of Hearing Loss

- **Conductive hearing loss**
  - Problem in conduction of the acoustic signal
  - Outer and Middle ear

- **Sensorineural hearing loss**
  - Problem in conduction and/or processing of the neural impulse
  - Inner Ear, Auditory Nerve, Brain
Sensorineural Hearing Loss

- Loss of inner hair cells
- Located in the scala media of the cochlea
Surgical Problem:
Access the Scala Media

- Insert a needle in the Scala Media
  - Deliver therapy
  - Hair cell regeneration
  - Treat cause instead of symptom

http://www.science.mcmaster.ca/Psychology/psych2e03/sound_audsystem/cochlea.jpg
Defining the problem: Access the Scala Media

- **Navigation**
  - 20 micron resolution
- **Positioning**
  - 25 micron resolution
- **Injection**
  - 1 nanoliter
Navigation: 
*Imaging the Scala Media*
Navigation: Imaging the Scala Media
Academic Acknowledgements:

- MADLAB
  - Eugene de Juan
  - Patrick S. Jensen
  - Aaron Barnes
  - Sue L. Wu
  - Terry Shelley
  - Jay Burns
- ERC
  - Rajesh Kumar
  - Jason Wachs
- Surgeons
  - John Niparko
  - Howard Francis
  - Lawrence Lustig
  - Daniel Lee
  - David Friedland
  - Andre Haenggeli
- Materials testing
  - Robert Cammarata
  - Ingrid Shao
  - Han Seo Cho
Corporate Acknowledgements:

- Xomed
  - Tino Schuler
  - George Bowen
- Storz Instruments
- Smith and Nephew Instruments
- Sawbones Corporation
- Dentsply Caulk Corporation

- Harwick Chemical
- Jeneric / Pentron Corporation
- Kerr Corporation
- Stryker Leibinger
- Dow Corning
- Ferro Corporation