Otology seminar

2002/8/21  ByR3 蕭士軒

History:
- Wilska 1935: 10 mg iron prosthesis onto the tympanic membrane - clear tone
- Vernon 1972: piezoelectric crystal device

Why Middle ear implant?
- Hearing impairment: 315/1000 > 65y/o, “deaf and dump”, cosmetics
- High frequency response limitation: acoustic feedback
- Small receiver: large distortion at low frequency
- Sound distortion in noisy environment
- Electro-acoustical and mechanical feedback: proximity of microphone and receiver – limit maximal gain and causing ringing and noise
- The occlusion effect: 20 dB in the low frequency
- Local factor: skin erosion of EEC or repeated AOE
- Professional problems: Musician, sports, word required ear phone, work with heat or sweat production
- Severe high frequency SNHL

Disadvantage:
- Surgery is required
- Performance of the implantable hearing aid
- Ossicle chain manipulation
- Possible foreign body reaction
- Need more clinical experience
- More expensive

Engineering principle

![Diagram](image.png)

**Figure 1.** Hearing devices.

- Output and transducer or vibrator
  - Force or output
- Frequency response
- Size and weight
- Long-term stability
- Biocompatibility—operation safety, toxicity, body reaction
- Bias force

- Models
  - Piezoelectric device: contact mode
    - 1.0 um, SPL 100 dB
  - High-voltage, high-impedance device
  - Low frequency response and resonant peak at nature frequency
  - Maximum power: $10^{4-5}$ J/m$^3$

- Electromagnetic device: noncontact mode
- Force:
  - Number of coil, magnitude of the current, permeability, shape and orientation, distance

- Magnetostrictive device

*Figure 5. Structure of a magnetostrictive actuator.*
Loading effect

**Table 1. COMPARISON OF MECHANICAL STIMULATION METHODS**

<table>
<thead>
<tr>
<th>Design Factor</th>
<th>Piezoelectric Dimorph</th>
<th>Magnetostrictive Rods</th>
<th>Electromagnetic Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy density (J/m³)</td>
<td>$10^3$</td>
<td>$10^{4-5}$</td>
<td>$10^6$</td>
</tr>
<tr>
<td>Impedance level (ohms)</td>
<td>$10^{6-7}$</td>
<td>$10^{7-6}$</td>
<td>$10^{7-7}$</td>
</tr>
<tr>
<td>Frequency response (Hz)</td>
<td>poor/low</td>
<td>good (const.I)</td>
<td>good (const.I)</td>
</tr>
<tr>
<td>Size and volume</td>
<td>small</td>
<td>large</td>
<td>medium</td>
</tr>
<tr>
<td>Packaging</td>
<td>difficult</td>
<td>difficult</td>
<td>moderate</td>
</tr>
</tbody>
</table>

Const. I = constant current drive.

- Total implantation vs. partial implantation
  - TICA: Totally implantable communication assistance device
  - Leysieffer and Zenner 1990, University of Tübingen, Germany
  - Europe: 1998, for severe high-frequency SNHL
  - Piezoelectric device
    - Minimal power consumption: 1uW
    - 0.5mm coupling probe in titanium disk, 0.4g
    - Sensor: 0.4g, 4.5 mm L-shaped sensor, under the skin of posterior wall of EAC
    - MRI?, titanium

**Figure 8.** Loading effect on human temporal bone response (loading on malleus). Measurement of incus. Diamond = 0 mg; square = 65 mg; circle = 110 mg.
- Distortion: minimal

- Type

- Result:

- Adverse effect: scar formation of EAC, post-op seroma, temporary threshold shift, and partial skin necrosis...

Partially implantable MEI

- Piezoelectric device: Rion device E-type (Japan) J. Suzuki, Teikyo university
- **Advantage:** function more than 10 years, no wearing discomfort, no SNHL at long-term use, high satisfaction
- **Disadvantage:** ossicle manipulation
- **Sound Tec device**
- **Electromagnetic device**

- **Otologics MET**
- **Criteria:** FDA, Phase I and II
Atticotomy

Vibrant SoundBridge:

- Electromagnetic device: Symphonix devices, Inc., San Jose, CA, U.S.A.

- VORP: vibrating ossicular prosthesis
- FMT: floating mass transducer
- Criteria: FDA phase III

Loading effect:
- Vibrant D vs. P
  - P: 2-channel analog processor
  - D: 3-channel digital processor
  - Result:
Conclusion

Reference:
10. Luetje CM et al: Plase III clinical trial results with the Vibrant Soundbridge
implantable middle ear hearing device: a prospective controlled multicenter study.