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Disclosures

• No disclosures
• Investigator initiated, industry-sponsored, FDA clinical trial
• Medel Corporation provided material support in form of device for implantation
Introduction

1. Observation – small tumors 70-80% never grow, majority of larger tumors will grow
   • Hearing will continue to deteriorate during this time, even if no growth in tumor (>50%)

[Graph showing hearing loss over time with various data points labeled SD: 100%, SD: 90-99%, SD: 80-89%, SD: 70-79%]

Stangerup et al 2010
Introduction

- Numerous studies performing cochlear implantation in patients following labyrinthectomy and/or tumor resection or in patients with tumors +/- XRT
- Surgery typically not concurrent, non-prospective
- Results following surgery open set >40% speech
- 2006 Lustig et al, 2/7 open set
- 2007 Welling et al, 4/6 open set recognition
- 2011 Roland et al, 2/5 open set recognition
- 2013 Hansen et al, marked benefit for discrim and localization in SSD patients (meniere’s/ISSNHL)
Treatment Options Acoustic Neuroma

- Translabyrinthine Approach/Labyrinthectomy – no acoustic hearing conservation, permits concurrent cochlear implantation
- If acoustic nerve is preserved, however, patient can receive a cochlear implant and develop electrical hearing on ear previously without acoustic hearing
- Enormous benefits to this with sound localization, speech understanding in noise, tinnitus suppression and improved QOL
Methods

• FDA-Approved feasibility study, 10 subject feasibility trial, 8/10 subjects currently enrolled, 5 implanted, AN = 4, Meniere’s = 1

• Criteria

  Inclusion - <1.5cm tumor, discrim<50%, PTA<70dB or severe sx

  Exclusion – known cognitive disease, size > 1.5cm
Methods

• Concurrent tumor excision by translabyrinthine approach and placement of cochlear implant, or concurrent labyrinthectomy in Meniere’s patient
• eABR and ART at time of surgery
• Testing at 1 month, 3 months, 6 months, 9 months, and 12 months
  1. Localization (11 speaker array)
  2. Speech in noise, AzBio 0dB SNR
Case Example

- 66yM, retired physician with previously observed 1.1 cm vestibular schwannoma
- Hearing had quickly deteriorated since diagnosis, speech discrim only 12%
- After counseling about his options, elected to proceed with participation in trial

6/15/16
TL Resection of VS, Concurrent CI
Localization Results

RMS Error

Unaided
(+) CI

Months

1 3 6
Conclusions

• It is possible to preserve cochlear nerve patency in all subjects with small acoustic neuromas

• A majority of these AN subjects (3/4) have functional cochlear nerves and are able to improve sound localization and speech understanding in noise

• Meniere’s patient had marked benefits in sound localization and speech understanding in noise as well
Conclusions/Future Directions

Deteriorated or lost hearing in small vestibular schwannoma

Concurrent translab resection of tumor and CI

Observation