The Effectiveness of a Middle Ear Implant in Some Cochlear Implant Candidates

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Disclosures

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Middle Ear Hearing Implants in Some CI Patients

Overview

PB Max and Speech Perception Gap (SPG) in severe HL

- Prediction of middle ear implant (MEI) WRS

Aid in counseling patients who are candidates for both

- Cochlear implant
- Implantable hearing device such as MEI

Performance of MEI patients who were also CI candidates
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MEI (Maxum)
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MEI (Maxum)
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MEI (Maxum)

Surgery

• Transcanal approach similar to stapedectomy
• Application of magnet to incudostapedial joint
• Application of surgical cement
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Hearing criteria – MEI vs. CI
Audiological Concept

- Aided word recognition is limited by cochlear damage
- Residual cochlear potential can be characterized by “true” PB max – maximum word recognition under earphones
- PB max is the upper limit of Aided WR

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Ideal Aided WR = PB max

If Aided WRS is less than PB max, there is a Speech Perception Gap

\[ SP \text{ Gap} = PB \text{ max} - \text{Aided WRS} \]
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Speech Perception Gap

SP Gap = 92% - 48% = 44%

PB max = Cochlear Potential

* MAXUM FDA Clinical Study

**OTX Confidential**
Study

Methods

• Retrospective study
  – 12 consecutive cases in 11 patients

• Pre-op – PB Max (UCL-5), Unaided and aided WRS (at 50dB), HF PTA (2K, 3K and 4K)

• Post-op testing at 2 to 11 months
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MEI Results
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MEI Results

Unaided Air Conduction Thresholds

Frequency (Hz)

Threshold (dB)

Average
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Study

Results

- One patient (female) was excluded due to lack of Aided WR testing prior to implant
  - 10 patients, 11 ears
- Gender - 7 male, 3 female
- Average age – 63 years (51-79)

Hearing results

- Unaided HF PTA – 77.4 dB
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Hearing Results

HF Gain

<table>
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<th>dB</th>
<th>HA</th>
<th>Maxum</th>
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9 of 11 patients were candidates for a CI based on speech recognition scores.

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MEI vs. Aided CNC WRS

All 11 patients had significant WR improvement with MAXUM

AVERAGE CNC
MAXUM: 65%
Hearing Aid: 23%
Improvement: 42%
Can we predict outcomes?

CONCLUSIONS:
A patient’s PB max may be reasonably used to predict WRS outcomes with MAXUM prior to implantation.

SPG may be used to estimate the WRS improvement with the Maxum over the hearing aid.
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PB Max Predicts MAXUM Outcomes

*Chang, CY, et al. Comparison of MAXUM and Hearing Aid Performance to Word Recognition Performance Obtained under Earphones. Otol Neurotol (submitted)*
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CI Candidates
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Aided CNC WR Scores

* Chang, CY, et al. Comparison of MAXUM and Hearing Aid Performance to Word Recognition Performance Obtained under Earphones. Otol Neurotol 2017 (submission)
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MAXUM vs. Aided CNC vs. PB max

Candidates for CI and MAXUM

CI only Candidates

Avg MAXUM WRS 60%

Avg HA WRS 12.5%

* Chang, CY, et al. Comparison of MAXUM and Hearing Aid Performance to Word Recognition Performance Obtained under Earphones. Otol Neurotol (submitted)
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Hearing Results - CI Candidates PB Max >60%

WRS - Individual Patients

Avg MAXUM WRS 67.4%

Avg HA WRS 14.9%

MAXUM Improvement 52.5%
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Implant vs. Aided CNC WR

MAXUM outcomes are comparable to CI (subjects with good pre-op CNC) for patients meeting CI candidacy and MAXUM indications

• Wazen, et al. Comparison of CI and HA Performance to PB max. In submission.
• Chang, CY. Comparison of an Electromagnetic MEI and HA Performance to Word Recognition Obtained Under Earphones. In submission.
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Conclusions

Significant SP Gaps can and do exist in some HA patients

- PB max + REM cannot always predict HA outcomes
- PB max can reasonably be used pre-operatively to predict MAXUM outcomes
Conclusions

Patient selection

• Some CI candidates have PB max >60% and also qualify for MEI.

• Our data show that patients who qualify for both a CI and MEI can do very well with MEI and may be considered for MEI rather than CI.
Conclusions

MEI advantages in select patients

• Less invasive surgery
• Little chance of cochlear damage
• Lower cost
Conclusions

Additional patient data would help confirm the findings of this small study.