UNC Pediatric Auditory Brainstem Implant Clinical Feasibility Study

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DISCLOSURES

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UNC Pediatric ABI Feasibility Study

- The purpose is to demonstrate the safety and efficacy of the Nucleus 24 Multichannel Auditory Brainstem Implant:
  - to demonstrate safety of the surgical procedure,
  - to determine effective methods for device stimulation,
  - and to learn about the potential for auditory benefit beyond that experienced with the CI
- May provide the preliminary experience for a larger scale clinical trial
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Candidates

- 10 pre-linguistic young children (18 mos to 5 yrs. of age) and 5 post-linguistic children (<18 yrs of age)
- Have experienced failed cochlear implantation (CI) OR have been unable to receive a CI secondary to cochlear malformation or CND
- No developmental/cognitive delays that would impede progress
- Appropriately motivated family
Intraoperative Electrophysiological Measures

Provide information for surgical placement of electrode paddle

- Responses may be obtained from any neural generators
- Obtaining EABR results intra-operatively does not predict auditory stimulability
- EABR results do not predict MAP stimulation levels
Intraop Electrically-Evoked ABR
Post Operative Device Stimulation

- General anesthesia
- Removal of stitches, facial nerve monitor, palate electrode
- Repeat EABR from OR
- Switch to programming software and use MAP parameters
- Stimulate at higher pulsewidth and current levels to identify channels that provoke other cranial nerve stimulation
Device Programming

Goal is similar to CI patient programming
- Establish audibility by setting electrical threshold and comfort levels
- Knowledge of tonotopic organization of Cochlear Nucleus is limited
- Want to avoid stimulation of other cranial nerves
  - Facial, Glossopharyngeal, Vestibular, Vagus
  - Manifests as facial twitching, balance disturbance, coughing, choking, sensation in mouth, throat, tongue, palate, heart rate changes
Programming considerations

- 8 mm electrode array with 3 rows of seven electrodes on a silicone mesh pad – determine which elicit auditory sense
- Stimulation can produce non-auditory side effects
- Inexperienced listeners are unable to differentiate non auditory from auditory percepts
- Want to avoid VII, IX and X cranial nerve response
- Pitch ranking important for optimal fitting; children can’t provide that information; close observation needed
- Most likely, we are creating the auditory template that will develop with time and meaningful use
Device Programming

Custom Sound 4.1 software with Freedom SP
- SPpeak Coding Strategy – 250 Hz
- MP+1 grounding
  - discrete stimulation
  - less channel interaction
  - greater potential number of channels
  - efficient use of power
- Behavioral measures of electrical Thresholds Levels
- Explore Comfort levels conservatively and adjust based on behavioral responses in soundbooth
Post Fitting Electrophysiological Measures

- Measure electrically evoked cortical auditory-event related potentials (eERP)
- Explore potential association between objective threshold estimates based on eERP and behavioral measures
Results: Type I response
Results: Type II response
Results: Thresholds

- P55: 1 µV, 193 CU
- P75: 2 µV, 216 CU

S1: 163 CU, 158 CU
S2: 190 CU, 188 CU
Findings to date (3-18 months of experience)

- Surgery safe but not free from risk
- 5/5 wearing processors consistently
- Behavioral device mapping
  - Range 7-15 active electrodes
- 4/5 have detection in soundbooth at 20-55 dBHL
- 4/5 have measureable eERP
- Measures may be helpful in determining MAP parameters
• 3/5 demonstrate early auditory behaviors beyond detection and respond to MAP changes
• Progress is S...L...O...W
• Visual support for language development is essential
• An experienced team approach is necessary

We have a lot to learn
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