THE MED-EL COMBI 40+ COCHLEAR IMPLANT SYSTEM: PRELIMINARY RESULTS IN THE UNITED STATES

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The MED-EL COMBI 40+ Cochlear Implant System was introduced internationally in 1996 and the first device in the United States was implanted at the end of 1997. The COMBI 40+ is currently under IDE study in the United States for both adults and children. The protocols include a variety of test measures, including recorded sentence and word tests, a telephone test, and questionnaires. The studies are repeated measures design with each subject serving as their own control.

The intent is to evaluate the safety and efficacy of the device as it will be used upon market approval. Therefore, all programming options may be freely selected by the investigators in order to optimize fitting. The maximum stimulation rate is 18,180 pps and the default strategy is High Rate CIS (Continuous Interleaved Sampling). A High Rate N-of-M strategy is also available. Key device features include a very thin profile of 3.95 mm, low energy consumption, and a deep insertion electrode (31 mm). Two additional electrode configurations are available for partially or fully ossified cochlea: compressed (13 mm), and split (4+7) electrode arrays.

Preliminary results obtained in the IDE study will be presented. US data will also be compared to data from Europe. Worldwide safety and reliability data will be presented, as will an update of the IDE study status.

2.01-05

THE IMPORTANCE OF STIMULATION RATE IN PULSATILE STIMULATION STRATEGIES IN COCHLEAR IMPLANTS

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Objective: High stimulation rates in pulsatile strategies implemented in modern cochlear implants can be expected to have beneficial effects on understanding due to two possible reasons: Better temporal representation of the acoustic signal and more natural nerve firing since hypersynchronization possibly can be avoided. The goal of this study was to assess the influence of the stimulation rate over a wide range and with different stimulation strategies.

Design: Performance of six experienced adult COMBI40+COMBI40+ users was tested with monosyllable word tests. The number of active stimulation electrodes was reduced down to six in order to achieve a maximum stimulation rate of 3000 pulses per second on each of the remaining channels. Performance was tested at stimulation rates of 200, 400, 800, 1500 and 3000 pps with three different stimulation strategies: CIS, jittering CIS (JCIS) and random order stimulation (RND).

Results: Speech understanding exhibited a strong dependence on the stimulation rate. The best performance was achieved at the highest rate, most inferior performance at the lowest rate. The results are significant for the 3000 pps vs. the 900 pps and for the 3000 pps vs. the 400 pps conditions. The same pattern was found for all three stimulation strategies, although on different levels.

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2.01-06

INTERNATIONAL EVALUATIONS FOR THE MED-EL PEDIATRIC POPULATION

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Purpose of the study: Evaluate progress in perceptual skills for children using a multichannel MED-EL cochlear implant system.

Method used: The international collaboration of centers throughout Europe has resulted in the development of a common battery of tests adapted into 12 different languages. The Evaluation of Auditory Responses to Speech (EARS) brings together a series of test tools that have commonly been used to assess the benefit of Auditory Responses to Speech (EARS).

Results obtained: This presentation will provide data on those children who have had preoperative and at least a 3-month postoperative evaluation out of more than 150 children, ranging in age from 9 months to 16 years, 7 months who have already undergone assessments. The population of children includes those who are German-, English-, French-, Polish, Spanish- or Flemish-speaking. Current findings will be summarized for data gathered from 4 closed-set and 3 open-set measures. Details from the questionnaires will be described.

Conclusions: Initial results suggest that the EARS battery provides a means to track the progressive changes in auditory perceptual development (detection, discrimination, identification, recognition and comprehension) as children gain experience with signals transmitted through the cochlear implant.

2.01-04
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Pyman, B.; Clark, Graeme M.; Saunders, Elaine; Cohen, Lawrence T.; Cowan, Robert S. C.; Treaba, C.; Dahm, M.; Tykocinski, M.

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