Data Summary

Cochlear™ Slim Modiolar Electrode (CI532)

PREFERENCE

PRESERVATION

PERFORMANCE

PLACEMENT

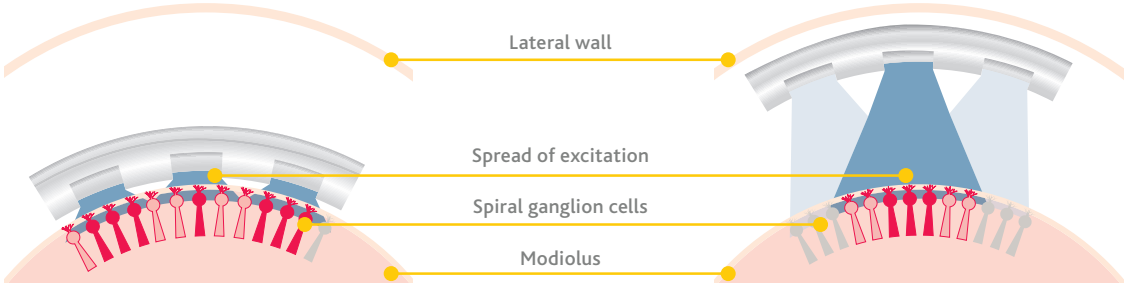
Hear now. And always

Cochlear®

CI532: Setting a New Benchmark in Perimodiolar

Cochlear's perimodiolar electrodes deliver focused stimulation due to their closer proximity to the hearing nerve. When compared with lateral wall electrodes, perimodiolar placement reduces channel interaction because there is less spread of electrical current across the electrodes.[1] The Slim Modiolar Electrode (CI532) combines the best performance advantage of being close to the hearing nerve with a slim, atraumatic design to preserve structures.

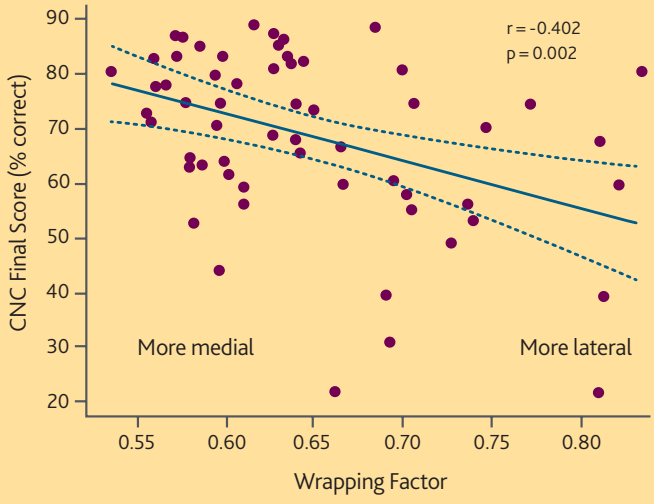
ELECTRODE POSITIONING



PERIMODIOLAR ELECTRODE
Smaller spread of excitation with perimodiolar placement

LATERAL WALL ELECTRODE
Larger spread of excitation with lateral wall placement

Modiolar proximity matters



Modiolar Proximity vs CNC Final Score at 24 months (n=59)[2]

Closer to the Hearing Nerve[7]

PREFERENCE

PREFERENCE MATTERS

- CI532 and the flexible sheath delivery has enabled surgeons to base their approach on each patient
- Can be successfully inserted via round window, extended round window and cochleostomy[4]

PRESERVATION

PRESERVATION MATTERS

- Designed to minimize insertion trauma and preserve the integrity of the inner ear structures[7]
- Consistent scala tympani placement ensures structural preservation of cochlea
- Across multiple studies and case studies, CI532 has demonstrated greater than 90% scala tympani placement[4,5,6]

PERFORMANCE

PERFORMANCE MATTERS

- Positioning the electrode close to the hearing nerve provides significant performance benefits[2]
- 94% of patients were satisfied or very satisfied with their hearing performance after obtaining a CI532[5]
- 42% increase in mean CNC word score at 3 months[5] (n=90 patients)

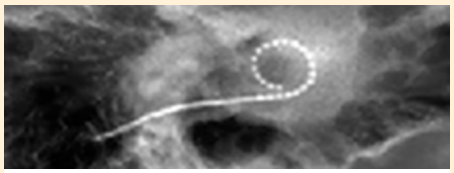
PLACEMENT

PLACEMENT MATTERS

- Electrode is designed to be even closer to the hearing nerve[7]
- Significantly thinner (up to 60%) than any other pre-curved electrode with a tighter curl for proximity to the modiolus[3]

Close to the Hearing Nerve

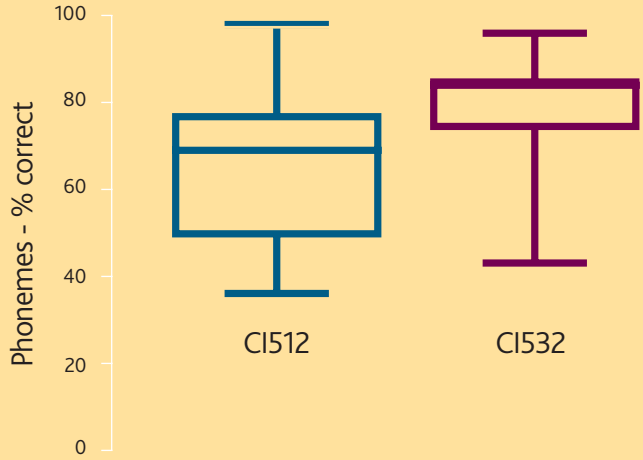
Slim Modiolar Electrode CI532



Slim Straight Electrode CI422

The Slim Modiolar Electrode is positioned closer to the hearing nerve, compared to a more lateral wall electrode. *Image courtesy of RVEEH, Melbourne, Prof. Robert Briggs, 2016*

Hearing outcomes



In a study comparing CI532 and CI512 outcomes at 12 months post-op, speech performance of 18 CI532 subjects was significantly better (80% vs 69%) than a matched group of 31 CI512 subjects (p=0.017).[8]

WANT TO LEARN MORE?

Interested in gaining experience with CI532 and learn more about the data supporting this electrode? Contact your Cochlear representative to set-up time to practice electrode insertions and find out about upcoming webinar and training courses.

Aschendorff A, Briggs R, Brademann G, Helbig S, Hornung J, Lenarz T, Marx M, Ramos A, Stover T, Escude B, James CJ. Audiol Neurootol. 2017;22(3):169-79. Epub 2017/10/24. https://www.ncbi.nlm.nih.gov/pubmed/29059669

STUDY INFORMATION

Affiliation:

University of Freiburg, Medizinische Hochschule Hannover, University of Toulouse, Clinique Pasteur Toulouse, Universitario Insular Materno Infantil Las Palmas.

Aim:

To characterize the final scalar position of the Slim Modiolar Electrode and to record surgical experiences with the electrode.

Study Design:

Multicenter, multinational, prospective observational study of adult cochlear implant candidates. The primary outcome was final scalar position as measured by Flat-Panel Volume (FPV) CT imaging. Subjective surgical experience was also reported.

Number of Patients:

45 Subjects across 8 study centers

CLINICAL INVESTIGATION OF THE NUCLEUS® SLIM MODIOLAR ELECTRODE

RESULTS

Adults with postlingual hearing loss underwent unilateral implantation with a CI532 device.

- Insertion approach: RW (44%), extended RW (22%), cochleostomy (34%)
- Intraoperative plain X-ray imaging performed on all patients
- Satisfactory initial electrode position: n = 40 (89%)
- Reinsertion: n = 5 (6.7%)
  - 2 cases of tip fold-over
  - 1 case where array was inserted deeper than desired
  - 1 case where the array came out of the cochlea during fixation of lead wire
  - 1 case where the surgeon felt there was too much resistance during removal of sheath
- Tip fold-over, based on intraoperative X-ray/fluoroscopy: n = 2 (4%)
  - One device replaced with CI512 (Contour Advance)
  - One device replaced with back-up CI532 (Slim Modiolar)

Scalar position

- Complete scala tympani insertion, with no translocation, in 100% of cases
- Mean CI532 insertion angle from center of round window to most apical electrode = 402.7° (SD 31.8°)

Surgical Questionnaire: % of Surgeons that stated "agree" or "strongly agree"

- Loading the electrode was rated as uncomplicated (96%)
- Advancing the electrode through the sheath was uncomplicated (96%)
- The stopper was stable during insertion (93%)
- Insertion of the sheath into the cochlea was uncomplicated (76%)
- The stopper prevented over-insertion of the sheath (87%)
- Removal of the sheath was uncomplicated (84%)

CONCLUSIONS

- Complete scala tympani insertion, with no translocation, in 100% of cases.
- Mean CI532 insertion angle from center of round window to most apical electrode = 402.7° (SD 31.8°).

Matthias Hey, Thomas Wesarg, Alexander Mewes, Silke Helbig, Joachim Hornung, Thomas Lenarz, Robert Briggs, Mathieu Marx, Angel Ramos, Timo Stover, Bernard Escude, Chris J. James & Antje Aschendorff (2018): Objective, audiological and quality of life measures with the CI532 slim modiolar electrode, Cochlear Implants International, DOI: 10.1080/14670100.2018.1544684

STUDY INFORMATION

Affiliation:

Unversitatsklinikum Schleswig-Holstein, University of Freiburg, Klinikum der J. W. Goethe-Universitat, Universitatsklinikum Erlangen, Medizinische Hochschule Hannover, University of Melbourne, Centre Hospitalier Universitaire de Toulouse, Complejo Hospitalario Universitario Insular Materno Infantil, Clinique Pasteur, Cochlear France SAS

Aim:

Report on electrode array measurements for CI532 including: ECAP thresholds, electrode impedances, psychophysical comfort levels, as well as speech perception results pre- and post-operatively and standardized evaluations of quality of life.

Study Design:

Patients were implanted with CI532 electrode. Electrically evoked compound action potential thresholds and impedances were measured using automatic NRT intraoperatively, at activation and at six months post implant. Pre- and post-operative measures of words in quiet and sentences in noise were made in multiple languages. Quality of life was assessed using The Speech Spatial Qualities questionnaire (SSQ)

Number of Patients:

45 Patients (44 with CI532, 1 with CI512)

AUDIOLOGICAL AND QUALITY OF LIFE MEASURES WITH THE CI532 SLIM MODIOLAR ELECTRODE

RESULTS

The 44 adult patients, which were discussed in this study, were implanted with CI532 electrode. The full surgical results of these patients were outlined in Aschendorff et al.

Objective Measures:

- 40 of the 44 arrays had intra-operative measurements attempted on every electrode. The additional four subjects were excluded from further analysis
- Intra-operative ECAP thresholds were obtained for 90% of the 40 tested arrays
- It was concluded that objective ECAP and impedance measures for the electrode were as expected and similar to results reported for other array types

Speech Performance

- Due to the multinational study, speech perception measures were collected in multiple languages

  Phoneme Recognition Scores

  – Median increase of 60% in implant ear and 49% in best-aided condition of phoneme

  Word Recognition in Sentences in +10dB of noise

  – Scores increased significantly from pre-op to three and six months post activation for both implant ear and best-aided

  – Median scores increased by 71% for implant ear and 73% for best aided condition at 6 months

Quality of Life:

- 30 of 45 subjects completed SSQ ratings
- Significant increases compared from pre-op to 6 months. Mean gain in scores for speech scale was 2.2 points, for the spatial scale 2 points and for the qualities scale 1.9 points
- Glasgow Benefit Inventory was completed by 42 subjects and gave scores significantly above zero for general subscale and total score, indicating a measurable benefit was provided

CONCLUSIONS

- ECAP and impedance measures were as expected and similar to results reported for other array types. Speech perception and quality of life had significant improvements from pre-operative state to 6 months.

Data on File at Cochlear Americas. The data presented does not highlight the primary outcome of the study, which will be published at a later time.

STUDY INFORMATION

Affiliation:
Cochlear-sponsored study

Aim:
To characterize the performance of the CI532 Cochlear implant in a group of post-lingually deafened adults and provide a dataset to be used as a comparative 'baseline' for future evaluations.

Study Design:
Multicenter, prospective nonrandomized study. The primary objective was mean CNC word recognition in quiet at 6 months, with secondary objectives of mean AzBio sentence in noise score at 6 months and mean Health Utility Index score at 6 months. Additional quality of life metrics, surgical questionnaire and imaging were also performed.

Number of Patients:
100 adult cochlear implant candidates across 13 centers

CLINICAL EVALUATION OF THE COCHLEAR NUCLEUS CI532 COCHLEAR IMPLANT IN ADULTS

RESULTS

Subject Demographics

Characteristic	Mean (S.D.)	
Age at Implantation	67.7 years (14.2) | Range: 23 – 91	
Gender	59 males (66%) | 31 females (34%)	
	Ipsilateral Ear	Contra Ear
	Mean (SD)	Mean (SD)
Duration of Hearing Loss	27.2 years (14)	26.6 years (14)
Duration of SP HL	8.3 years (6)	8.3 years (6)
Pre CI CNC Word Score	15% (12%)	23% (16%)
Pre CI AzBio +10 Score	15% (18%)	25% (22%)

Surgical Result Summary:
- Surgical Approach: 60% Extended Round Window, 30% Round Window, 10% Cochleostomy
- 95% of the cases had an uneventful insertion of the electrode according to the surgical questionnaire
- 95% of surgeries involved intra-operative steroid use
- 91% of arrays were found to be in the scala tympani
- Average wrap factor of 59.6% for electrodes placed in scala tympani

Mean Speech Perception Performance at 3 Months (N=90)
- Speech perception significantly improved in both quiet and noise
- Mean CNC word score was 57%, up from 15% pre-operative
- Mean AzBio +10 score was 34%, up from 19% pre-operative

Hearing Satisfaction at 6 months:

82% OF PATIENTS DEMONSTRATED A CLINICALLY SIGNIFICANT IMPROVEMENT FROM BASELINE IN OVERALL HEALTH UTILITY INDEX SCORE

94% OF PATIENTS WERE SATISFIED OR VERY SATISFIED WITH THEIR OVERALL HEARING PERFORMANCE

CONCLUSIONS
- With consistent scala tympani placement and close proximity to the hearing nerve, this study showed significant improvements in hearing outcomes at a 3 month time point and a significant improvement in patient satisfaction.

Shaul C, Dragovic AS, Stringer AK, O'Leary SJ, Briggs RJ. J Laryngol Otol. 2018 Nov; 132(11):1000-10006. Epub 2018 Oct 29. https://www.ncbi.nlm.nih.gov/pubmed/30370884

STUDY INFORMATION

Affiliation:

The Royal Victorian Eye and Ear Hospital, Melbourne, Australia

Aim:

To identify the intracochlear electrode position and determine correlation to speech perception with Contour Advance® (CI512) and Slim Modiolar (CI532)

Study Design:

Single center prospective cohort study of adults receiving CI512 or CI532. Scalar localization using Cone-Beam CT and speech recognition were assessed.

Number of Patients:

110 Patients (92 with Contour Advance, 18 with Slim Modiolar)

SCALAR LOCALIZATION OF PERIMODIOLAR ELECTRODES AND SPEECH PERCEPTION OUTCOMES

RESULTS

Scalar Localization:

- 100% of Slim Modiolar electrodes (n=18) had a complete Scala Tympani insertion
- 13 Contour Advance electrodes deliberately inserted into scala vestibuli due to anatomical changes
- Of the 79 Contour Advance electrodes intended to be inserted within scala tympani, 58 (73%) had a complete ST insertion

Speech Recognition by Scalar location of CI512 patients:

- Speech perception scores revealed better scores for scala tympani localization at 12 months. The differences were significant (p=0.013) when the 22 pre-lingual patients were excluded.
- Mean phoneme score at 12 months was 69.1% for those post-lingual patients with scala tympani location (n=41) compared to 54.2% in scala vestibuli (n=6) and 50% with a translocation (n=10)

Comparison of CI512 to CI532 patients:

- All CI532 patients had post-lingual onset hearing loss
- Comparison between CI512 and CI532 were only performed using post-lingual patients of both electrodes
- 12 month post-op phenome scores were significantly higher for CI532 when comparing to CI512.

Table: Comparison between matched post-lingual patients with CI512 or CI532 electrodes (with all electrodes localized in scala tympani)

Parameter	CI512 Electrode	CI532 Electrode	P-value*
Patients (n)	31	18	-
Age (mean (SD); years)	66.3 (15)	62.2 (16)	0.28
Deafness duration (mean (SD); years)	16.6 (13)	12.7 (7)	0.41
Pre-op phoneme score (mean (SD); % correct)	21.2 (16)	26.1 (22)	0.11
3-mth post-op phoneme score (mean (SD); % correct)	64.9 (19)	73.1 (16)	0.08
12-mth post-op phoneme score (mean (SD); % correct)	69.4 (17)	79.5 (14)	0.017†

The groups were matched by removing the CI512 electrode group patients with lower quartile pre-operative phoneme scores. *Analyses conducted using the Mann-Whitney U test. †$p < 0.05$. SD = standard deviation; pre-op = pre-operative; mth=month; post-op = post-operative

CONCLUSIONS

- Cone-beam computed tomography was valuable for demonstrating electrode position. The rate of scala tympani insertion was higher in CI532 than in CI512 electrodes. Scala vestibuli insertion and translocation were associated with poorer speech perception outcomes.

Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to helping people with moderate to profound hearing loss experience a life full of hearing. We have provided more than 550,000 implantable devices, helping people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to innovative future technologies. We have the industry's best clinical, research and support networks.

That's why more people choose Cochlear than any other hearing implant company.

References:

1. Polonenko et al. Stimulation parameters differ between current anti-modiolar and peri-modiolar electrode arrays implanted within the same child. The Journal of Laryngology & Otology. 2016; 130(11):1007-1021. https://www.ncbi.nlm.nih.gov/pubmed/27739380
2. Holden LK, et al. Factors affecting open-set word recognition in adults with cochlear implants. Ear Hear. 2013;34:342–360. https://www.ncbi.nlm.nih.gov/pubmed/23348845
3. FUN1142: Electrode Comparison Brochure
4. Aschendorff et al. Clinical investigation of the Nucleus Slim Modiolar Electrode. Audiology & Neurotology. 2017; 22:169-179. https://www.ncbi.nlm.nih.gov/pubmed/29059669
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6. Cuda, D, Murri, A. Cochlear Implantation with the nucleus slim modiolar electrode (CI532): a preliminary experience. European Archives of Oto-Rhino-Laryngology. 20017; 12:4141. https://www.ncbi.nlm.nih.gov/pubmed/29032420
7. Data on File: EA32 Electrode Insertion Safety and Performance Study Report (D473386). 2015.
8. Shaul C, Dragovic AS, Stringer AK, O'Leary SJ, Briggs RJ. Scalar localization of peri-modiolar electrodes and speech perception outcomes. J Laryngol Otol 2018; 1-7. https://doi.org/10.1017/S0022215118001871
9. Matthias Hey, Thomas Wesarg, Alexander Mewes, Silke Helbig, Joachim Hornung, Thomas Lenarz, Robert Briggs, Mathieu Marx, Angel Ramos, Timo Stover, Bernard Escude, Chris J. James & Antje Aschendorff (2018): Objective, audiological and quality of life measures with the CI532 slim modiolar electrode, Cochlear Implants International, DOI: 10.1080/14670100.2018.1544684

As your partner in hearing for life, Cochlear believes it is important that you understand not only the benefits, but also the potential risks associated with any cochlear implant or hybrid implant.

For complete information about risks and benefits of cochlear implantation, please refer to the Nucleus Package Insert available at www.Cochlear.com/US/NucleusIndications.

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