

Hearing Preservation With a New Atraumatic Lateral Wall Electrode

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Introduction: Many individuals have some residual hearing which should be preserved with cochlear implantation. To achieve this goal electrode arrays must fulfil certain design requirements. A new thin lateral wall electrode array (HiFocus SlimJ) was systematically designed on the basis of μ CT studies of human cochlea anatomy. The primary objective of this study was to report on initial retrospective hearing preservation results from a cohort of subjects consecutively implanted with this electrode. Secondary objectives were to report on insertion depth and speech perception results for this new array.

Methods: Twenty subjects with considerable residual hearing in low frequencies were consecutively implanted with the SlimJ electrode array. The electrode was inserted slowly through the round window and the insertion process was controlled by intracochlear electrocochleography measuring cochlear microphonics through the cochlear implant.

Postoperative cone beam computed tomography was conducted and precise scalar location and angular insertion

depth was estimated following image fusion with the preoperative images.

Results: Low frequency hearing at 1 month postsurgery was preserved within 30 dB HL in 85% of subjects and within 15 dB HL in 50% of subjects. Mean angular insertion depth was 393 degrees (SD 62 degrees) with a range from 294 to 520 degrees. All electrode contacts in all subjects were identified within scala tympani.

Conclusion: The SlimJ electrode array is easy to handle for atraumatic insertion through the round window, adjusted insertion depth controlled by electrocochleography measurements, and reliable fixation at the posterior tympanotomy. Hearing preservation rates are encouraging on the short term. We aim to further report on larger data sets and long-term outcomes. **Key Words:** Cochlear implantation—Cochlear implants—ECochG—Hearing preservation.

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Cochlear implantation aims to improve hearing without damaging cochlear structures and subsequently preserve residual hearing. Many cochlear implant (CI) recipients have some residual hearing which should be preserved and to achieve this goal electrode arrays must fulfil certain design requirements. The array must be positioned within the scala tympani (ST) over its entire length and dislocation through the basilar membrane should be avoided (1–5). Preserving the cochlear structures and residual hearing results in better postoperative performance, allows the use of electro-acoustic stimulation, resulting in better speech perception (1,6–8) and does not exclude the user from future treatment options.

The array must also be thin enough to be easily inserted through the round window, which ensures initial placement in the ST, and is associated with better hearing preservation (9–12). Thin arrays with small tip diameters not only facilitate insertion via the round window but produce minimal fluid displacement during insertion, potentially reducing the risk of cochlear trauma (13,14).

The array must provide sufficient spectral cochlear coverage to enable good postoperative speech perception and an insertion angle of 480 degrees is to be sufficient to cover the entire length of the spiral ganglion (15–17). Deeper electrode insertions than this can be associated with a higher risk of trauma, worse hearing preservation (2,4,18–22). Short arrays such as the L24 Hybrid (Cochlear Ltd.), which provides an insertion depth of approximately 270 degrees and electrical stimulation up to around 2000 Hz, do the least damage; however, they tend to be used where there is good functional residual hearing in the ear to be implanted and the lower frequencies can be stimulated acoustically (7,23).

The position of the array within the ST once inserted can also influence outcomes. Precurved arrays with a

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perimodiolar position provide more focused stimulation and potentially better pitch discrimination (2,24). However, the mechanisms to hold these types of array straight for insertion often result in a thicker, stiffer device increasing the risk of trauma, and precluding insertion through the round window (5,25–27). Although straight electrode arrays are located along the lateral wall, they have a lower tendency to translocate into scala vestibuli, are easier to handle, and stand a better chance for preservation of residual hearing. They are the current device of choice for the majority of surgeons when hearing preservation is a primary goal (9,11,28–31).

The new lateral wall electrode (HiFocus SlimJ, Advanced Bionics, Valencia, CA 91355 USA) was systematically designed on the basis of μ CT studies of human cochlea anatomy (32). Special attention was given to the lateral height profile of the scala tympani along the cochlear partition. The main goal is reliable structure preservation surgery using round window insertion, with minimal disturbance of the cochlear fluids and a wide electrical coverage of the full frequency range. It has unique properties in terms of controlled surgical handling. Temporal bone studies conducted in two centers with the SlimJ show consistent placement in the ST with only one translocation across 21 bones and evidence of basilar membrane lifting in only one or two contacts in seven bones (33,34). This is a comparable result to temporal bone data reported for other types of slim straight arrays such as the Cochlear Nucleus SRA and Med El Flex electrodes (11,35,36). These types of arrays have shown good hearing preservation results with median postoperative hearing losses ranging from 15 to 20 dB HL (21,37–39). Currently, however, there are no studies reporting hearing preservation results in users of the SlimJ electrode array. The primary objective of this study was to report on initial retrospective hearing preservation results from a cohort of subjects consecutively implanted with the SlimJ electrode. Secondary objectives were to report on insertion depth and speech perception results for this new array.

Electrode Design

The SlimJ is 23 mm long with 16 active electrode contacts and allows for easy round window insertion due to the tip design. A blue marker indicates to the surgeon when the electrode array is fully inserted. The wing located at the most proximal part of the SlimJ is used to grip the electrode steadily and helps to ease the insertion process. The electrode diameters are smaller than that of the scala tympani along the cochlea to minimize risk of trauma to intracochlear structures (32).

METHODS

Twenty subjects were consecutively implanted with the SlimJ electrode array between September 2017 and May 2018. Subjects who had chosen an Advanced Bionics device and had a pure-tone average for frequencies 125 to 1.5 kHz better than 90 dB in the ear to be implanted and had a normal cochlea anatomy were offered the SlimJ. Other than that, there were no specific inclusion or exclusion criteria.

Details of the preoperative hearing thresholds for all subjects are shown in Figure 1. Other demographic details are provided in Table 1. The institutional internal review board has confirmed the disclosure of the results obtained retrospectively from clinical records with the scientific community.

Surgical Technique

All the devices were implanted using the same soft surgical technique through a classic transmastoid and posterior tympanotomy approach. The round window was fully exposed by removing the bone overhang if necessary. A bone groove for fixation of the electrode was drilled at the inferior part of the facial recess (Fig. 2A). The round window membrane was incised using a hypodermic needle. The SlimJ electrode was then inserted very slowly, using the standard electrode forceps (40). The residual hearing was monitored during the insertion process by electrocochleography (ECochG) where the surgeon receives instant feedback on any amplitude changes of the cochlear microphonics at a given frequency (Fig. 2D). A drop of the cochlear microphonics signal is considered a consequence of the electrode interfering with the basilar membrane movement (41). At this point the insertion was stopped, the electrode either pulled back or rotated until the signal had recovered and the insertion process was either finished or continued (Fig. 2B). Otherwise, the insertion proceeded until the blue reference marker was at the level of the round window. The wing was fixed in the drilled groove to prevent any potential electrode movement postoperatively (Fig. 2C). The round window was sealed applying a drop of venous blood around the electrode. Corticosteroids were applied systemically at the start of the surgery.

Imaging and Postoperative Electrode Position

The electrode array position within the ST was confirmed postoperatively using cone beam CT (CBCT) (isometric voxel size: 125 μ m). Insertion depth was measured according to the standard cochlear coordinate system where the middle of the round window is the 0 degree reference and the rotational angle from this point up to the middle of the most apical electrode (el. 1) is calculated (42). An image fusion technique as described by Dietz et al. (33,43) and Dees et al. (44) was used to establish the position of the electrode array within the cochlea (Fig. 3, A–C).

Pure-tone Audiometry

Ipsilateral pure-tone thresholds were measured under HDA200 headphones using a Homoth Audio4000 audiometer preoperatively and at 1 and 4 months postoperatively. Results are reported as a low frequency average of 125, 250, 500, 750, 1000, and 1500 Hz. Preservation of hearing is reported as a change in the low frequency average to allow comparison to previous work reporting results for other types of lateral wall electrode (21,23).

Speech Perception

Speech perception was measured preoperatively and at 1 and 4 months postoperatively. Speech perception was measured in the free field as part of routine clinical follow-up. Standard tests included Freiburger Monosyllables in quiet (45), presented preoperatively at 80 and 100 dB SPL and postoperatively at 65 dB SPL, and Hochmair-Schulz-Moser (46) sentences in noise. Speech intelligibility in noise was measured with speech and noise presented coincidentally from one speaker positioned at 1 m directly in front of the subject at +10 dB signal to noise level. The speech level was set at 65 dB SPL and speech shaped

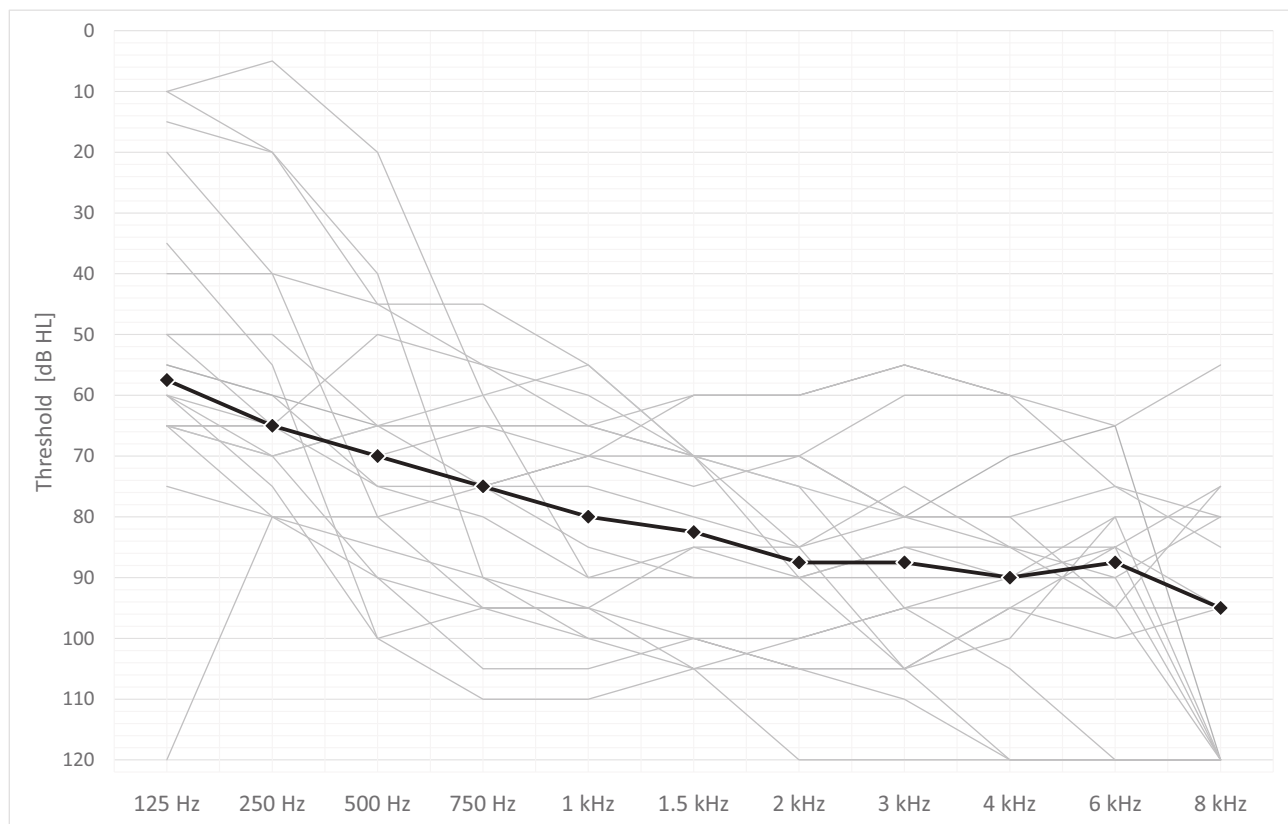


FIG. 1. Preoperative pure-tone thresholds for all 20 subjects. The thick black line indicates the median values. All subjects had some measurable hearing in the ear to be implanted.

noise at 55 dB SPL. Two lists (20 sentences each) were used for each processing condition and the percentage of words correct averaged across both lists. Before testing, at least two practice lists were presented to minimize training effects during the test. The number of practice lists was increased if the subject was not familiar with the material.

All subjects used a Naida Q90 speech processor with HiRes Optima speech processing strategy. Subjects were tested unilaterally either in the electro-acoustic stimulation or electric only condition, depending on their fitting. In the five subjects with a contralateral hearing aid and the two subjects with unaided residual hearing in the contralateral ear, the best aided results were used.

Statistics

Descriptive results are presented giving median and mean values for pre- and postoperative hearing thresholds, speech recognition, and insertion depth. Correlation analysis was performed using a Pearson r coefficient.

RESULTS

Insertion Characteristics

Mean angular insertion depth was 393 degrees (SD 62 degrees) with a range from 294 to 520 degrees. The median value was 375 degrees. Insertion angles in relation to the blue reference marker are provided in Table 1. The maximum extracochlear length was 3.5 mm and in two cases the most proximal electrode contact (E16) was

either at or just outside the round window due to significant changes with ECoChG response amplitude. The distance of the reference marker from the round window and the insertion angle were significantly correlated, Pearson’s $r = 0.56, p = 0.001$. There was no correlation between the hearing preservation results and the insertion angle, Pearson’s $r = 0, p = 0.98$.

Postoperative CBCT with image fusion confirmed that all electrode arrays were positioned in the ST along their entire length. An example of the fusion image is given in Figure 3D.

In 6 out of 20 subjects the blue marker was estimated to be more than 2.5 mm outside the cochlea where the most proximal electrode contact number 16 was located just at the round window. In these subjects the electrode 16 was deactivated at switch on session to avoid a potential nonauditory stimulation.

Hearing Preservation

Hearing preservation results at 1 and 4 months post-surgery are presented in Figure 4 A and B. At first fitting 10 subjects had a low frequency hearing loss for averaged frequencies 125 to 1500 Hz of ≤ 15 dB HL, seven subjects a loss between 15 and 30 dB HL, and three subjects a loss of > 30 dB HL. Median hearing loss for the whole group was 16.3 dB HL. At 4 months 7 out of 13 subjects had a hearing loss of ≤ 15 dB HL, 3 between 15 and

TABLE 1. Demographic details of the study sample and details of pre- and postoperative average low frequency pure-tone thresholds in dB HL

Subject	Age at Implant (Yrs)	Etiology	Preop Mean PTA 125 Hz–1.5 kHz	1-mo Postop Mean PTA 125 Hz–1.5 kHz	4-mo Postop Mean PTA 125 Hz–1.5 kHz	Scalar Location of Array	Distance Reference Contact to Round Window (mm)	Angular Insertion Depth	EAS Use
ID A	35.5	Unknown	70	90	68	ST	0.8	434	No
ID B	19.5	Congenital	86	96	93	ST	2.3	330	No
ID C	70.0	Sudden	63	98	94	ST	2.5	343	No
ID D	19.5	Congenital	88	98	105	ST	1.7	350	No
ID E	53.3	Sudden	65	78	68	ST	2.8	350	No
ID F	70.9	Unknown	83	116	105	ST	3.0	390	No
ID G	41.9	Prelingual, oxygen shortage at birth	60	74	NA	ST	−0.5	511	No
ID H	69.4	Sepsis	68	74	71	ST	0	370	Yes
ID I	53.3	Perilingual/ niemann pick type- C	61	109	118	ST	1	373	No
ID J	78.8	Unknown	68	97	111	ST	0.5	492	No
ID K	69.8	Unknown	49	69	NA	ST	3	294	No
ID L	75.7	Unknown	69	91	85	ST	3.1	360	Yes
ID M	39.6	Unknown	45	53	NA	ST	3.5	370	Yes
ID N	27.2	Unknown	64	74	NA	ST	1.8	360	No
ID O	33.8	Perilingual	73	74	66	ST	−0.5	475	Yes
ID P	48.2	Perilingual, Usher-Syndrome	75	68	69	ST	1.2	380	Yes
ID Q	54.5	Unknown	44	63	57	ST	1.5	376	Yes
ID R	31.2	Prelingual, sudden	89	93	NA	ST	1.3	389	No
ID S	54.8	Sudden	88	116	NA	ST	0.5	400	No
ID T	56.9	Congenital	85	112	NA	ST	0	520	No

Not applicable (NA) indicates subjects who have not reached this evaluation point. Postoperative details are given for the position and insertion depth of the array within the cochlea and the distance of the blue reference contact to the round window, as measured on the cone beam CT scan.

30 dB HL, and 3 greater than 30 dB HL. Median hearing loss at 4 months postsurgery for the group of 13 subjects who had reached this stage was 12.5 dB HL.

Speech Perception

Speech perception results are shown in Figure 5. Scores improved from preoperative to 1-month postsurgery for all subjects. Mean monosyllabic word scores in quiet for the group were 49% (SD ± 32) at 1-month postsurgery (n = 20) and 70% (SD ± 30) at 4 months postsurgery (n = 12). Hochmair-Schulz-Moser sentence scores in a +10 dB signal-to-noise ratio were 12% (SD ± 16) at 1 month (n = 20) and 30% (SD ± 29) at 4 months (n = 12).

Scattergrams are shown in Figure 6A and B as described by Gurgel et al. (47) showing pre- and postoperative hearing thresholds and word recognition scores in a standardized format. The figures combine speech perception and hearing threshold data and show the number of subjects whose speech perception or thresholds have either improved or worsened after implantation. Postoperative data is taken for 1 month after CI surgery, i.e., at

CI activation, as this is the most complete data set. Further improvement in word recognition was observed at 4 months postactivation.

DISCUSSION

The experience from a previous temporal bone insertion study showed that the new array has favorable mechanical properties for easy handling and smooth insertion without severe damage (34). The intraoperative experience was similar. The insertions went smoothly without resistance. The electrode wing gives reliable directional and rotational control of the array during insertion, allows to adjust the insertion depth easily and to secure the position of the array at the facial recess.

Dietz et al. (33) reported similar experiences. Stiffness is a key factor in limiting insertion forces in straight electrode arrays; cochlear damage mainly occurs at the point of contact with the outer wall. Beyond this point lateral wall pressures steadily increase and translocation of the array may occur (20,35,48). The new lateral wall array is designed to be more flexible horizontally than

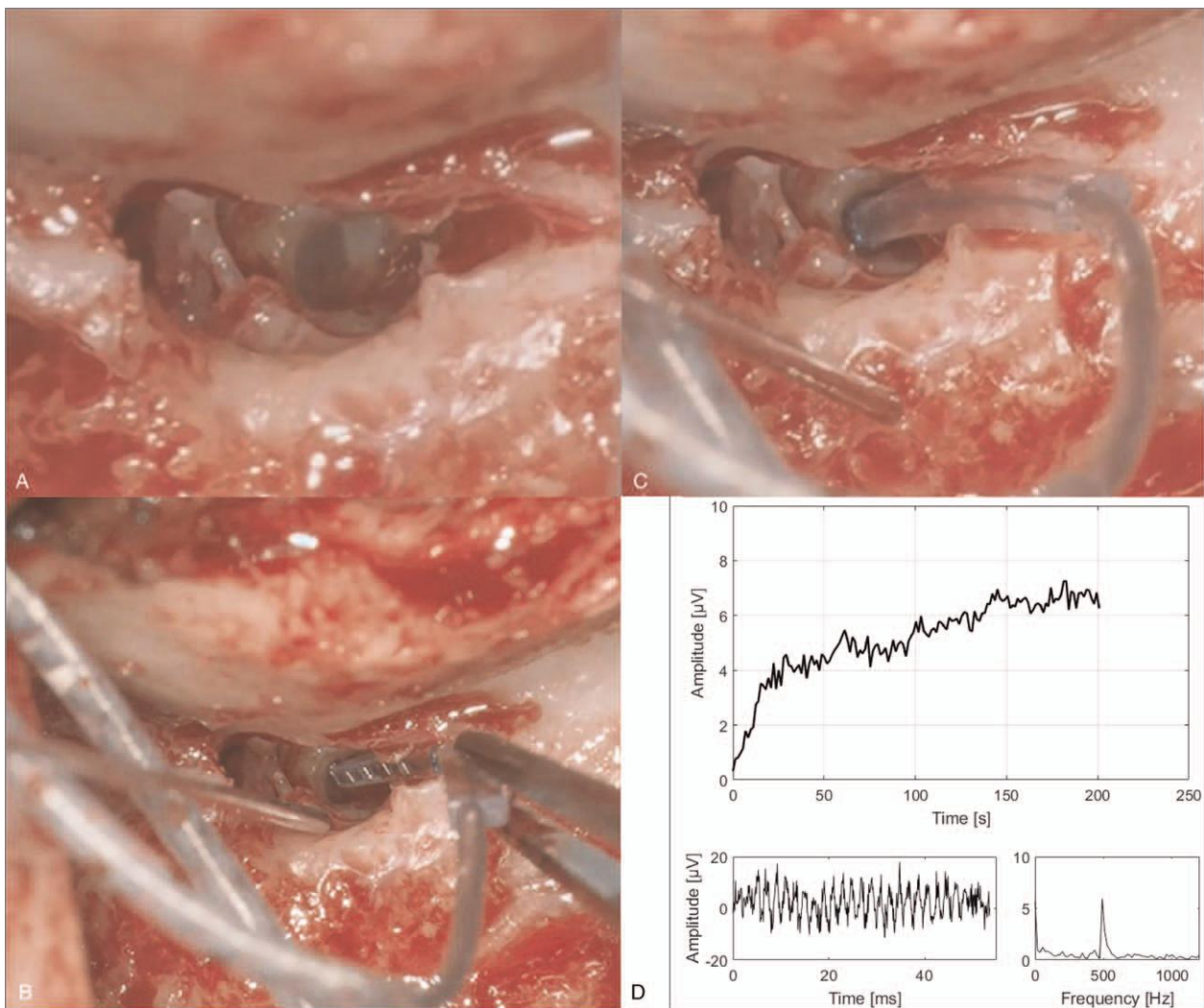


FIG. 2. Showing (A) the posterior tympanotomy, round window, and the bony groove drilled at the inferior part of the posterior facial recess, (B) SlimJ electrode insertion process with electrocochleography monitoring, and (C) completed insertion with the wing fixed in the bony groove, (D) intracochlear electrocochleography measuring cochlear microphonics at an acoustic stimulation frequency of 500 Hz. The raw signal (lower left trace) is analyzed using FFT (lower right). The time course of the amplitude at 500 Hz with the FFT shows a steady increase indicating the preservation of residual hearing.

vertically to help avoid translocations and damage to the basilar membrane, while maintaining the smooth insertion characteristics along its entire length.

In this clinical sample all arrays were positioned within the ST without any translocation through the basilar membrane into the scala vestibuli. This is in line with the findings in temporal bone studies which also showed very consistent positioning in the ST (33,34). The mean angular insertion depth of 393 degrees was also consistent with the findings in temporal bone studies; however, there was a wider range of insertion depths (range 226 degrees). In temporal bone data collected in this center the average angular insertion depth across the 10 bones was 432 degrees from the round window with a range of 40 degrees. In the temporal bone study by Dietz et al. (33) the mean angular insertion depth was 380 degrees with a range of 100 degrees. However, a greater variation in

insertion depth can be expected in patients than in temporal bones. Based on a drop in the ECoChG signal the electrode array was not inserted fully up to the blue marker. Without the ECoChG feedback allowing the surgeon to stop the insertion, the electrode could otherwise have been potentially inserted slightly deeper and the mean insertion depth increased. In two cases the array was inserted beyond the blue reference marker which resulted in deep insertions, although the deepest insertion was with an array inserted just up to the marker. This reflects the well documented wide range of cochlear duct length (49). The angular depth of insertion and position of the marker relative to the round window were strongly correlated, providing assurance that the position of the marker is a useful indicator for insertion depth. The insertion depth and hearing preservation results were not correlated, which means that other factors might

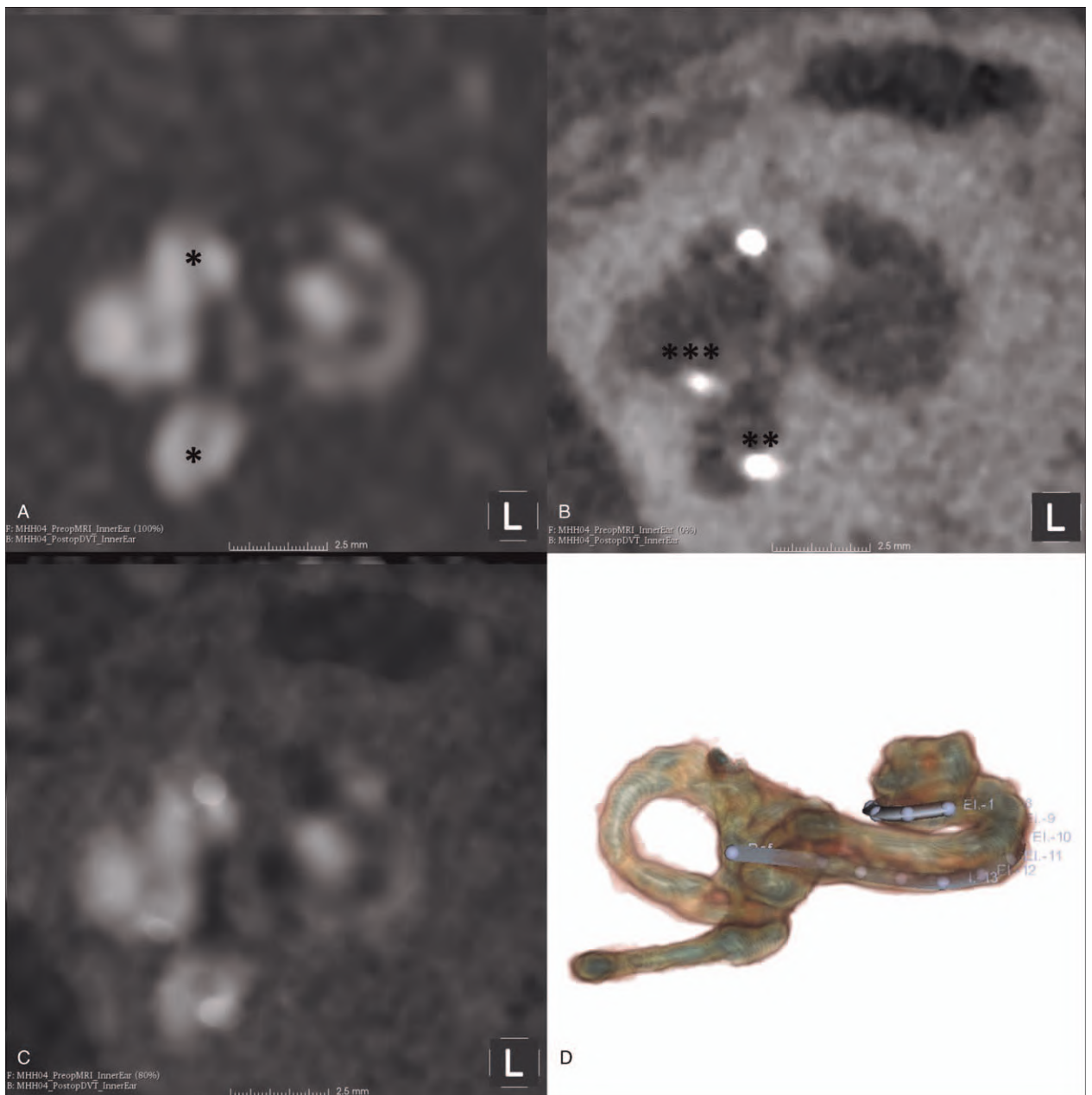


FIG. 3. Illustration of the scalar assessment based on the image fusion technique. Preoperative T2-weighted MRI image (A) with visible scala separated by the basilar membrane (*). Postoperative CBCT showing SlimJ electrode contacts (B) in the first (**) and second (***) turn. Automatically coregistered or fused image (C) supports identification of individual electrode contacts in relation to the basilar membrane (*). Three-dimensional reconstruction of the fused image (D) showing the electrode array positioned within the ST of subject A along its entire length.

contribute to the hearing loss. It might also reflect the above-mentioned variability in cochlear anatomy. Besides the length, the height of the scala tympani and the type of the cochlea also have to be taken into consideration (32). ECochG conducted via the implant provided immediate feedback on cochlear function and allowed the surgeon to adapt the insertion angle and depth accordingly. The use of ECochG in this way has the potential to provide feedback on hearing preservation during surgery. Previous work has shown that trauma

tends to occur in the final phase of the insertion and avoiding this using the ECochG results may be why some hearing preservation was achieved, despite angular insertions of 360 degrees or more (50). The relationship of the ECochG recordings to the hearing preservation measures will be reported in more detail in a separate article.

Speech perception results showed that sufficient spectral coverage was provided to give good speech perception results for the group. The speech perception of all subjects improved with use of the CI compared with

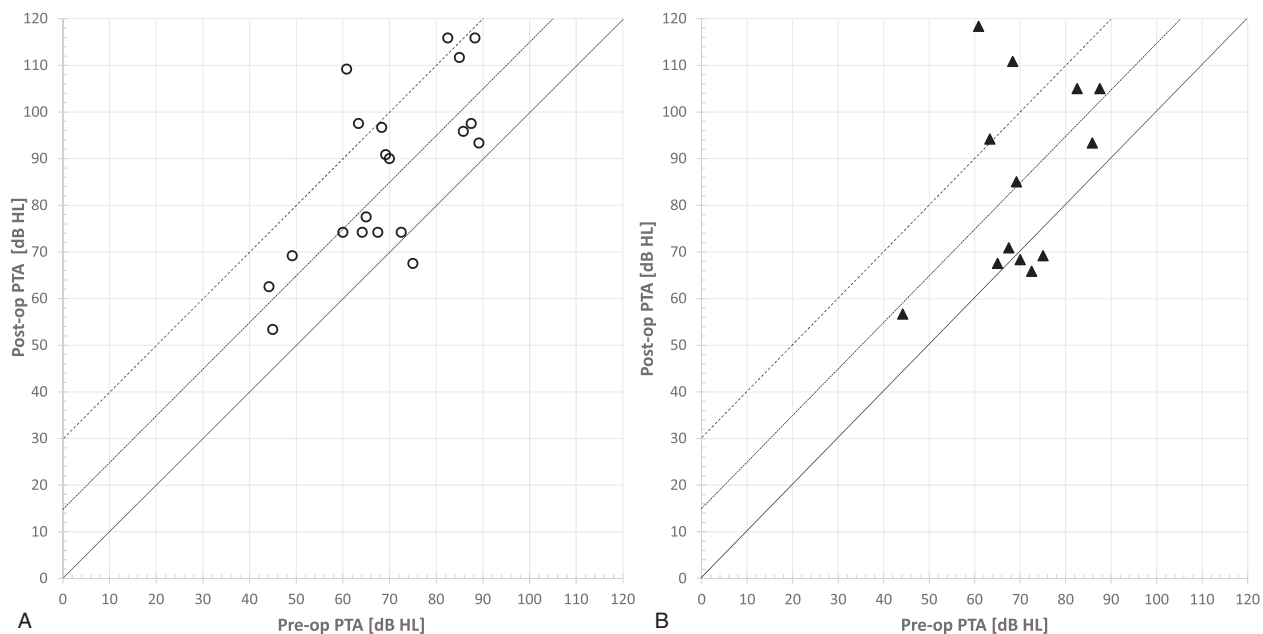


FIG. 4. Hearing preservation results for the low frequency pure-tone average (PTA) of 125 to 1500 Hz. The solid line indicates no change in hearing and the dotted lines the 15 dB shift and the 30 dB shift. Results at time of first fitting are shown for 20 subjects (A) and at 4 months postop (3 mo after first fitting) for 13 subjects (B).

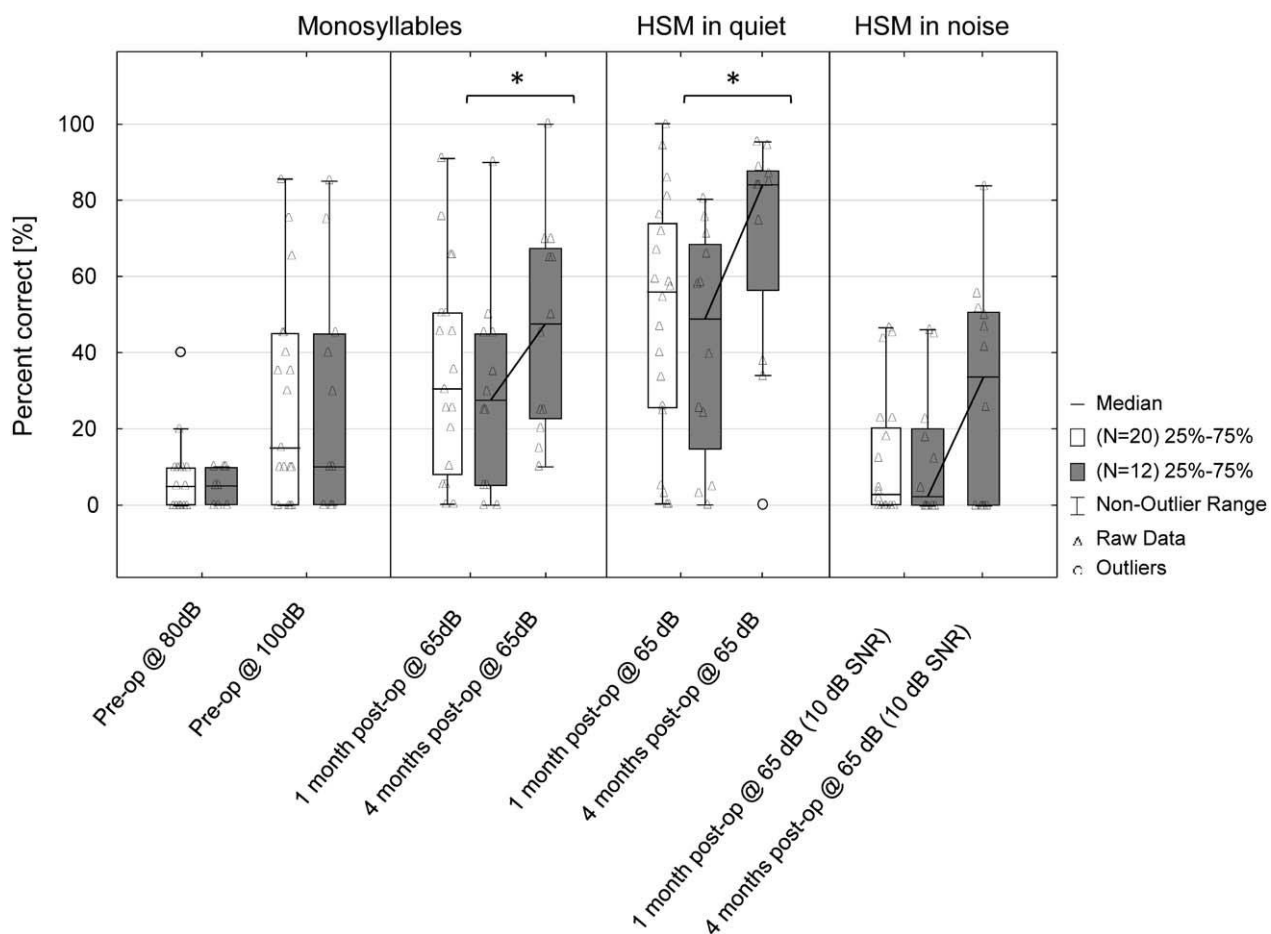


FIG. 5. Median speech perception scores for Freiburg monosyllables in quiet and HSM sentences in +10 dB of speech shaped noise at 1 and 4 months postsurgery. n = 20 (open boxes) at 1 month postsurgery and n = 12 (gray boxes) at 4 months postsurgery. Marked differences are significant at level $p < 0.05$.

		Word Recognition Score (%)									
		100 - 90	89 - 80	79 - 70	69 - 60	59 - 50	49 - 40	39 - 30	29 - 20	19 - 10	9 - 0
Pure Tone Average (dB HL)	0-10										
	11-20										
	21-30										
	31-40										
	41-50										
	51-60										
	61-70							1	1	1	3
	71-80						2	1	1	1	
	81-90						2		1		1
	91-100							1	1	1	

A

FIG. 6. Scattergram of results for the 20 subjects. Pure-tone averages of 500 Hz, 1, 2, and 3 kHz are represented on the y axis and word recognition scores are represented on the x axis. Each number represents the number of patients whose audiometric data place them into a certain square. *A*, Preoperative threshold and word recognition data for 18 subjects. Two subjects had pure-tone averages of greater than 100 dB HL. *B*, Change in scores between preoperative data and data recorded at 1-month postsurgery.

preoperative scores. This included those subjects with shallow insertion depths of around or less than 360 degrees. Five subjects had a perilingual hearing loss (defined as occurring at 2–4 yrs of age) with poor speech perception scores both pre- and postoperatively.

The hearing preservation results were positive with a median hearing loss of 16 dB HL at 1 month postsurgery and less than 15 dB HL at 4 months postsurgery. These preliminary results show the electrode array has promising hearing preservation potential which is comparable with other types of electrode array designed to be located at the lateral wall and minimally invasive. Skarzynski et al. (51) reported that hearing was well preserved with the Nucleus CI422 slim straight electrode array at 12 months postsurgery in adults with a 15 dB HL median increase at thresholds 125 to 1000 Hz at 13 months postsurgery and Jurawitz et al. (23) showed similar results, with a median postoperative loss of hearing at thresholds from 250 to 1500 Hz of 19 dB HL at 12 months. In this group, at 1 month, 85% of subjects had a loss of hearing of less than 30 dB HL. Helbig et al. (52) reported 12 months results for a variety of arrays (Cochlear SRA, MED-EL Standard, Medium, and

Flex) and found that 41% of subjects had at least partial low frequency hearing preservation (up to 500 Hz), defined as between 10 and 30 dB of hearing loss. This was a more limited frequency range than reported here. Hearing preservation can be used as a marker of trauma. The SlimJ electrode shows characteristics of an atraumatic electrode which can be inserted deep enough to provide good auditory performance with electrical stimulation only. The demonstrated potential for hearing preservation allows the use of electric-acoustic stimulation in many patients. The insertion depths can be adapted to the individual cochlear geometry and be monitored through ECochG. The implant system can be used for individualized cochlear implantation.

Limitations

The short duration of follow-up and the number of subjects with no data at 4 months postsurgery limits the applicability of the data as we know that hearing loss following surgery can progress over the first year. Missing data can introduce bias as these subjects tend to be the poorer performers. However, the subjects without 4-

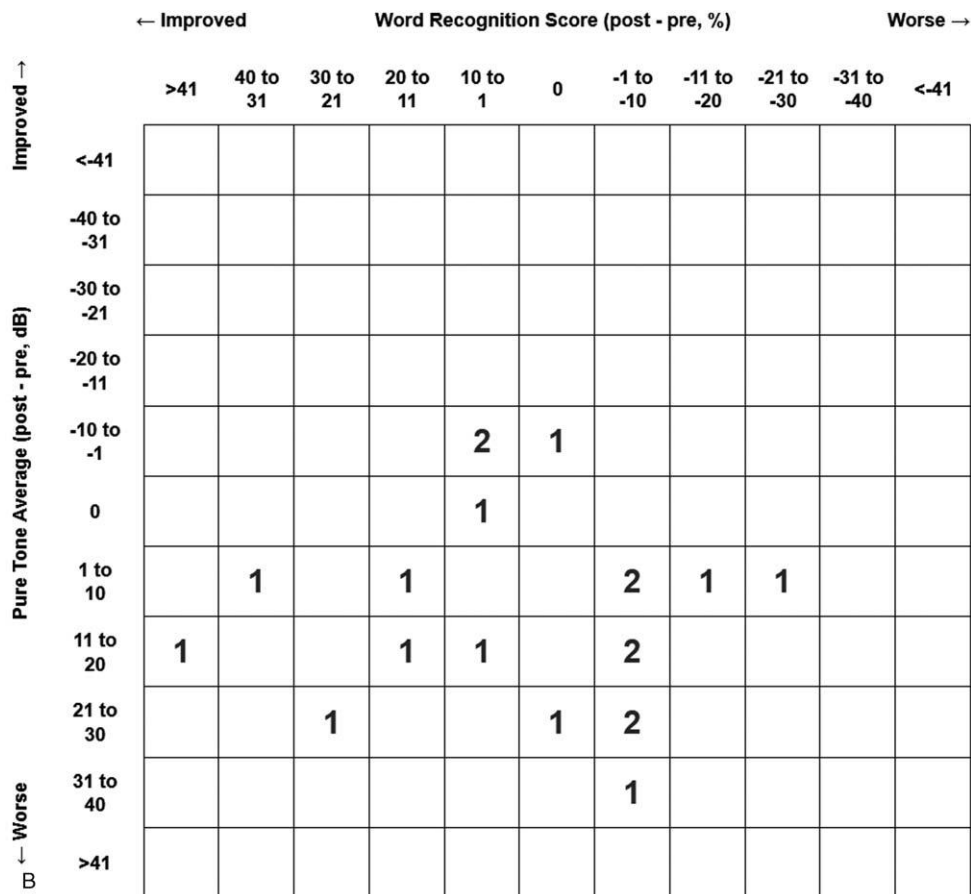


FIG. 6. (Continued).

month data had not reached this point in their evaluation. The patient group was not homogeneous, with a range of EAS candidates and standard CI candidates. All surgery was performed by the same surgical team using a specific technique based on the use of ECOchG, which limited insertion depth in some cases and may have contributed to the hearing preservation, thus the results may not be applicable to other teams using other approaches.

Future studies will focus longer term follow-up in a larger cohort of subjects and make comparisons to other electrode array types used within our institution as well as expand on the ECOchG results.

CONCLUSIONS

This article reports about the first clinical experience with a systematically designed atraumatic cochlear implant electrode. The electrode array is easy to handle for atraumatic insertion through the round window, adjusted insertion depth, and reliable fixation at the posterior tympanotomy. Hearing preservation rates are very encouraging. Low frequency hearing at 1 month postsurgery was preserved within 30 dB HL in 85% of subjects and within 15 dB HL in 50% of subjects. These results were consistent with the CBCT findings, which showed

that all 20 electrode arrays were positioned within the ST with no dislocation. Angular insertion depth was limited with the use of ECOchG and ranged from 294 to 520 degrees. No linear correlation was found between insertion depth and hearing preservation. All subjects gained speech perception benefit when using the CI.

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