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Original Article

Insertion Results and Hearing Outcomes of a Slim Lateral Wall Electrode

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BACKGROUND: The clinical outcomes of cochlear implantation vary for several reasons. It is necessary to study the different electrodes and variables for further development. The aim of this study is to report the clinical outcomes of a new slim lateral wall electrode (SlimJ).

METHODS: Data of 25 cochlear implantations in 23 patients with the SlimJ electrode were retrospectively collected. The insertion results were assessed by image fusion of the preoperative computed tomography (CT), magnetic resonance imaging (MRI), and postoperative cone-beam CT. The hearing outcomes were evaluated by the improvement of speech recognition in noise, measured preoperatively and at follow-up. Postoperative pure-tone thresholds were obtained in cases with preoperative functional low frequency hearing [PTA (0.125-0.5 kHz) ≤ 80 dB HL].

RESULTS: The preoperative mean speech reception threshold (SRT) was +0.6 dB signal-to-noise ratio (SNR) (SD ± 4.2 dB) and the postoperative −3.5 dB SNR (SD ± 2.3 dB). The improvements between the preoperative and postoperative SRT levels ranged from 0.0 to 15.1 dB, with a mean improvement of 4.2 dB (SD ± 3.6 dB). Residual hearing in low frequencies (mean $PTA_{(125\text{-}500\ Hz)}$) was preserved within 30 dB HL in 70% and within 15 dB HL in 40% of patients who had preoperatively functional low frequency hearing. Mean insertion depth angle (IDA) was 401° (SD ± 41°). We observed scalar translocations from scala tympani to scala vestibuli in 2 ears (9%).

CONCLUSION: The relatively atraumatic insertion characteristics make the SlimJ array feasible for hearing preservation cochlear implantation. The hearing outcomes are comparable to those reported for other electrodes and devices.

KEYWORDS: Cochlear implants, speech intelligibility, speech perception

INTRODUCTION

Hearing outcomes in patients with cochlear implants vary widely. Although the exact reasons for this variation are still unclear, several factors have been considered to be responsible for it, such as insertion trauma, etiology, duration and severity of hearing loss, age at implantation, and residual hearing.[1,2]

Insertion trauma has been shown to negatively affect residual hearing and postoperative hearing outcomes. The most favorable location for the electrode is scala tympani (ST), as it has been associated with superior hearing outcomes.[3,4] During insertion, the electrode array may penetrate through the basilar membrane, entering either the scala media (SM) or scala vestibuli (SV). Damage to SM allows perilymph and endolymph to mix, resulting in the disappearance of the intracochlear potential, which can result in a complete loss of residual hearing.[5] Even if located within the ST, the electrode array can elevate the basilar membrane or even fracture the osseous spiral lamina, resulting in the loss of residual hearing. Electrode array insertion through the round window (RW) membrane has been shown to be associated with more reliable hearing preservation than insertions via cochleostomy.[6,7] Short lateral wall electrodes have achieved the best results in terms of hearing preservation. Depending on the definition of hearing preservation, the preservation rates for short lateral wall electrodes with active lengths of ≤20 mm vary from 54 to 88%.[8-11] For longer lateral wall electrodes, i.e., >20 mm active length, preservation rates of 11%-78% have been reported.[9,12,13]

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Long electrodes may provide better spectral coverage and thus may contribute to better speech perception in noise; however, deep insertions are associated with a higher risk for trauma and deterioration of residual hearing. Short electrodes carry a lower risk for insertion trauma, but they may miss to stimulate important cochlear neural tissue, which may lead to suboptimal hearing outcomes for electric stimulation.[7,10] The mechanical properties of the electrode array play a major role in ensuring an atraumatic insertion. Lateral wall electrodes or straight electrodes settle along the lateral wall and carry a lower risk for insertion trauma and a loss of residual hearing loss than precurved arrays.[14-16]

A slim straight lateral wall electrode (SlimJ) (HiFocus™ SlimJ, Advanced Bionics, Valencia, Calif, USA) has been designed to facilitate atraumatic insertions.[17] In 2 temporal bone (TB) studies, consistent ST placement was observed, and there was only 1 translocation in a total of 21 temporal bones.[18,19] Only 2 studies have examined the clinical outcomes of the SlimJ in a total of 40 patients[20,21] and therefore further investigations are warranted.

The aim of this study is to report on the surgical and audiological outcomes in consecutive patients implanted with the SlimJ at our institution.

MATERIAL AND METHODS

The HiFocus™ SlimJ electrode has been introduced into clinical practice in our department after a preclinical trial in human TBs.[19] The electrode is 23 mm long with an active length of 20 mm. A total of 23 patients and 25 ears have been implanted with the SlimJ in the time period from 2017 to 2020. Patient data were collected from medical records. The patients were treated according to our clinic's protocol, and informed consent was obtained prior to treatment. This study has the approval of the Committee on Research Ethics University of Eastern Finland (Approval No: 5551876).

The standard speech-in-noise test, the Finnish Matrix Sentence Test (FMST), was used to measure the hearing performance.[22] Randomized 20-sentence test lists and a nonfluctuating speech-spectrum-shaped noise at a constant level of 65 dB sound pressure level (SPL) were used as speech and noise signals.

The speech reception threshold (SRT) was determined with an adaptive test method. The SRT is the signal-to-noise ratio (SNR), at which 50% of the test items are correctly recognized. The FMST has been validated for cochlear implant recipients in a prior study and was found to be reliable for testing their speech-in-noise performance.[23] The test provided consistent results with good test–retest reliability within $\pm$1 dB in repeated measurements for CI users. The mean slope of the speech recognition curve was 14.6% $\pm$ 3.6% dB.

Speech-in-noise measurements were performed in the best-aided condition. The patients were tested bilaterally with a possible hearing aid preoperatively and either with bimodal or electric only stimulation postoperatively, whichever option offered the best speech perception. Postoperative speech-in-noise testing (FMST) was administered between 5 and 15 months after surgery; in 1 patient, only the 24-month postoperative SRT was available. The variability in timing is due to the different follow-up periods that the patients had reached at the time of the study.

The best-aided preoperative and postoperative hearing outcomes were compared to elucidate the performance benefit of the CI rehabilitation. We used the unilateral results of the implanted ear in 1 patient who had an asymmetric sensorineural hearing loss.

Audiograms were performed preoperatively for the whole group. Patients with a PTA value of 80 dB HL or less at 125-500 Hz were considered to have functional residual hearing.[24] Hearing preservation was considered complete when the shift of mean PTA $_{(125\text{-}500\ Hz)}$ was $<$15 dB and partial within 15-30 dB. A shift over 30 dB was considered a loss of residual hearing.

All surgical procedures were carried out according to our institution's protocol for hearing preservation surgery. Preoperatively, intravenous dexamethasone (7.5 mg) and cefuroxime (1.5 g $\times$ 1) were administered. A transmastoid approach with posterior tympanotomy was used in all cases, except for 1 patient operated via a suprameatal approach due to a narrow facial recess. In case of unfavorable view of the RW membrane, the bony overhang was drilled for a better visibility of the membrane. Dexamethasone soaked gelatin sponge was placed on the RW membrane while the implant bed was drilled. The RW membrane was then punctured with a needle, and an electrode soaked in dexamethasone slowly inserted via the RW ($>$2 minutes).

Our clinical protocol for cochlear implantation includes a preoperative evaluation with magnetic resonance imaging (MRI) and high-resolution computed tomography imaging and postoperative evaluation of CBCT (cone-beam computed tomography) images on the first postoperative day. Image fusion reconstructions of the preoperative and postoperative registrations were created for the study with the image fusion software, BrainLab (iPlan Net 3.6.0 Build 77, BrainLab AG, Munich, Germany) to create artifact-reduced images and obtain a more accurate assessment of electrode location. 3D models of the electrodes were created using Hounsfield unit thresholding and then overlaid on the preoperative MRI and CT images.[25-27]

The insertion depth angle (IDA) and the scalar location of the electrode for its full length were determined on the postoperative CBCT and the image fusion reconstructions, respectively. The scalar location of the electrode was indicated as ST and SV whenever determinable.

The data was analyzed with Statistical Package for the Social Sciences Statistics software, version 22.0 (IBM SPSS Corp.; Armonk, NY, USA). Continuous variables are expressed as means and medians with ranges. Spearman correlation was used to measure the relationship

MAIN POINTS

- The slim lateral wall is feasible for hearing preserving cochlear implantation.
- Residual hearing in low frequencies (mean PTA(125-500 Hz)) was preserved within 30 dB HL in 70% of the patients.
- Favorable overall hearing outcomes (i.e., speech intelligibilty in noise) were achieved in majority of the patients.

between variables. Group comparisons were executed by independent sample *t*-test or 1-way analysis of variance tests. *P*-values less than .05 indicate statistically significant results.

RESULTS

The mean age at surgery was 68 years (SD ± 13 years). All electrodes were fully inserted. With the exception of 2 cochleostomies, the insertions were carried out through the RW. The mean IDA was 403° (SD ± 41°), ranging from 330° to 510°, and the median was 390°.

Twenty out of 25 insertions were located in the ST along the full electrode length. Two electrodes were intentionally placed into the SV due to obliteration of the ST caused by cochlear otosclerosis. We found 2 scalar translocations (8%) from ST to SV occurring at an IDA of 180°. In 1 case, a scalar location could not be explicitly determined because of severe artifacts in CBCT image.

Preoperatively, 10 out of the 23 patients had functional low-frequency residual hearing (≤80 dB HL average for 125-500 Hz). The mean and median values of preoperative $PTA_{(125\text{-}500\ Hz)}$ were 52 dB HL (SD ± 13 dB) and 50 dB HL, respectively. The mean postoperative $PTA_{(125\text{-}500\ Hz)}$ was 74 dB HL (SD ±13 dB), and median was 75 dB HL at the mean of 10 months' follow-up (range: 2-36 months). The mean and median deterioration of hearing thresholds were 22 dB HL (SD ± 12 dB) and 17 dB HL, respectively. Four ears (40%) experienced a complete preservation of residual hearing [$\Delta PTA_{(125\text{-}500\ Hz)}$ (<15 dB HL)], a partial hearing preservation (within 15 and 30 dB HL) was achieved in 3 ears (30%), and in 3 ears the mean $\Delta PTA_{(125\text{-}500\ Hz)}$ was over 30 dB HL, corresponding to the loss of residual hearing (30%). The mean preoperative and postoperative hearing thresholds (250-4000 Hz) for the patient with residual hearing are illustrated in Figure 1.

Six patients had functional low-frequency residual hearing ($PTA_{(125\text{-}500\ Hz)} \leq 80$ dB HL) postoperatively, and 4 of them were fitted with electric-acoustic stimulation (EAS). Two patients stopped using EAS because of irritation of the ear canal and 2 patients did not experience any benefits from EAS with low-frequency residual hearing levels of 75 and 55 dB HL. The recipients continued with electric-only listening.

The results for speech perception in noise are shown in Figure 2. Twenty-1 patients were able to complete the adaptive measurement protocol of the FMST. Sixteen patients (69%) used bimodal

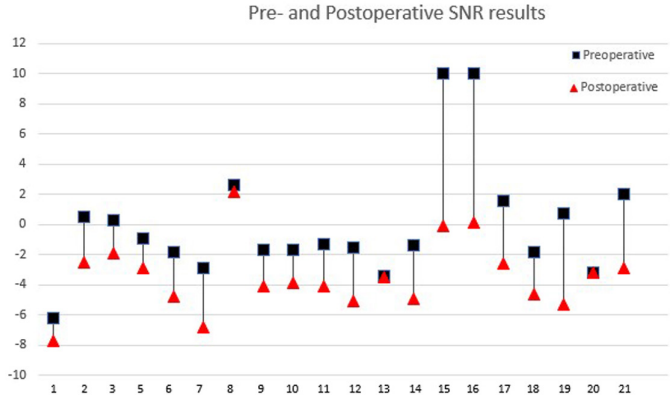

Figure 1. The mean preoperative and postoperative hearing thresholds (250-4000 Hz) for the patient with residual hearing (N = 10).

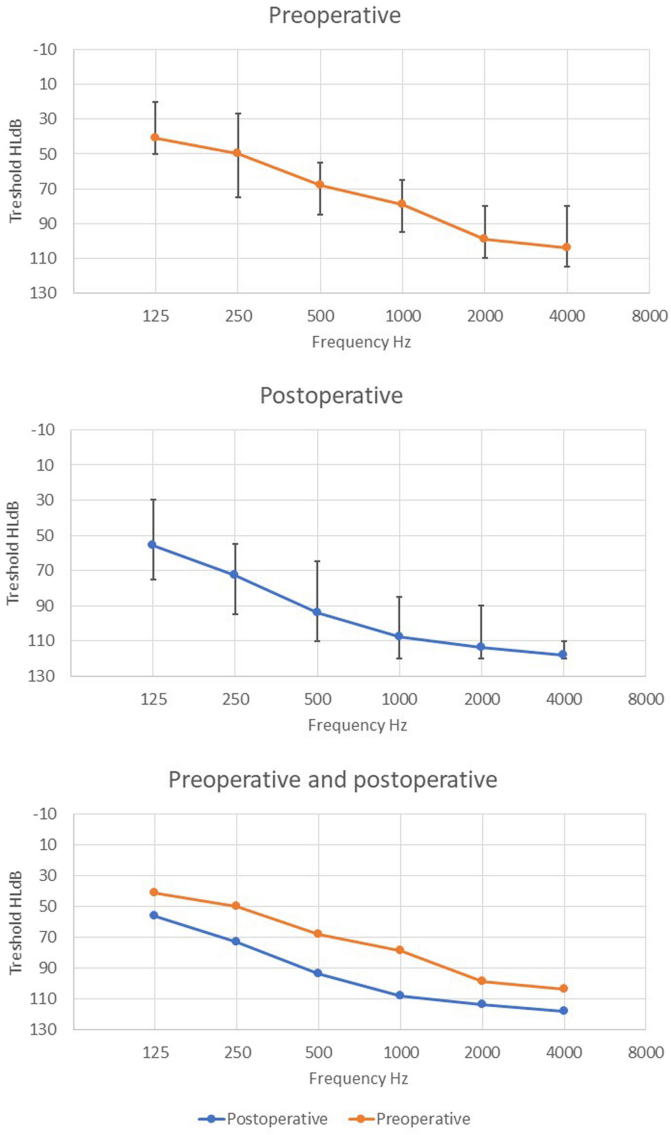

Figure 2. The preoperative and postoperative SNR (signal-to-noise ratio) of the patients. Numbers corresponding the patients in demographics (Table 1).

stimulation, 5 patients (22%) were unilateral CI users, and 2 patients (9%) had a bilateral implantation. We observed 1 device failure occurring 2.5 years after surgery. The hearing outcomes of this patient were measured before the changes were observed in the impedance profile. The SRT improved after implantation in 20 patients. The preoperative SRT (n = 21) varied from −3.4 to +10 dB SNR, with the mean being +0.6 dB SNR (SD ± 4.2 dB) and the median being −1.30 dB SNR, respectively. The postoperative SRT varied from −7.7 to +2.2 dB SNR, with a mean of −3.5 dB SNR (SD ± 2.3 dB) and the median of −3.9 dB SNR. The difference between the preoperative and postoperative SRT levels ranged from ± 0.0 to −15.1 dB, with mean of −4.2 dB (SD ± 3.6 dB) and the median of −3.0 dB. The improvement was statistically highly significant ($P < .001$).

We detected no significant correlation between the SRT shift and IDA ($r = 0.346$, $P = .135$), age at surgery ($r = .293$, $P = .209$), electrode location, or trauma ($P = .853$). There were no significant differences in the hearing outcomes when comparing patients with different etiological backgrounds ($P = .154$).

Table 1. Demographics of the Patients.

Implantation	Gender	Etiology	Side	Approach	Age at Operation	IDA [Degrees]	Electrode Location	SRT Pre-op (dB SNR)	SRT Post-op (dB SNR)	PTA $_{(125\text{-}500\ Hz)}$ Pre-op (dB HL)	PTA $_{(125\text{-}500\ Hz)}$ Post-op (dB HL)
1	M	KID, connexin26	Right	RW	41	380	ST	−6.2	−7.7		
2	F	SNHL	Right	RW	68	390	ST	0.5	−2.5	38	67
3	M	SNHL	Left	RW	65	360	ST	0.3	−1.9		
4	M	SNHL	Right	RW	86	360	ST	–	–		
5	M	Cochlear otosclerosis	Left	C	40	420	SV	−0.9	−2.9		
6	F	Mb Meniere	Right	RW	73	390	ST	10	−5.1	60	90
7	M	SNHL	Left	RW	79	350	ST	−2.9	−6.8	62	76
8	F	Mb Meniere	Right	RW	83	330	ST	2.6	2.2	47	55
9	F	SNHL	Left	RW	81	430	Dislocation to SV	−1.7	−4.1		
10	M	SNHL	Left	RW	69	450	ST	−1.7	−3.9		
11	M	Mb Meniere	Left	RW	74	390	ST	−1.3	−4.1		
12	M	SNHL	Left	RW	72	460	ST	−1.5	−5.1	75	85
13	F	Rieger sndr	Right	suprameatal	50	390	ST	−3.4	−3.5		
14	M	SNHL	Right	RW	43	510	ND	−1.4	−4.9		
15	M	SNHL	Left	RW	76	440	ST	10	−0.1	63	75
16	F	SNHL	Right	RW	80	430	ST	10	0.1		
17	M	SNHL	Left	RW	81	380	ST	1.6	−2.6	40	57
18	M	Mb Meniere	Right	RW	70	400	ST	−1.8	−4.6		
19	F	Otosclerosis	Left	C	56	380	SV	0.7	−5.3		
20	M	SNHL	Left	RW	69	360	ST	−3.2	−3.2		
21	M	SNHL	Left	RW	72	400	ST	2	−2.9	60	92
22*	F	SNHL	Left	RW	61	460	ST	–	–	37	72
23*	F	SNHL	Right	RW	63	400	ST	–	–**		
24^	F	SNHL	Right	RW	70	390	Dislocation to SV	−1.8	−4.8	50	92
25^	F	SNHL	Left	RW	72	375	ST	−4.8	−5.0		

Preoperative functional residual hearing, PTA 80 dB HL or better at 125-500 Hz, is reported in the table. C, cochleostomy; F, female; IDA, insertion depth angle; KID, keratitis ichthyosis deafness syndrome; M, male; PTA, pure tone average; RW, round window; SNDR, syndrome; SNHL, sensorineural hearing loss; SNR, signal-to-noise ratio; SRT, speech reception threshold; ST, scala tympani; SV, scala vestibule.*^* Represents both ears of one patient, ^ represents both ears of one patient. **FINSIMAT −0.9 dB (SNR).

DISCUSSION

Less data are available about the clinical results with the novel SlimJ electrode with respect to the surgical and audiological outcomes. The SlimJ has shown consistent IDA throughout the TB studies, with a mean of 432° (SD 40°) by Lenartz et al, 380° (SD 30.4°) by Dietz et al, and in the clinical studies, with a mean of 393° (SD 62°) by Lenarz et al and mean of 403° (SD ± 41°) in this study.[18-20] The cochlear coverage appears to be adequate for pure electrical stimulation. In the TB study by Dietz et al, no correlation was found between IDA and cochlear size.[19] Preoperative planning for lateral wall electrodes is advisable for achieving the intended IDA.

We found a scalar dislocation rate of 8%, which is comparable to those reported for other lateral wall electrodes.[16,28,29] Lenarz et al reported no translocations with SlimJ in 20 clinical patients, whereas Schwam et al did not investigate the electrode location with SlimJ.[20,21] A recent meta-analysis examining the surgical results of 2046 ears implanted with a lateral wall electrode found a scalar dislocation rate of 6.7%.[29] The overall incidence of scalar dislocation, including all types of electrodes, was 22%. In our study, the 2 translocations occurred at an IDA of 180°. The location is similar to the scalar translocation reported in the TB study with SlimJ by Dietz et al.[19]

Hearing preservation can be used as an indicator of trauma. The greatest decline in residual hearing level in the group was found in a patient with a scalar dislocation to SV at 180° with a drop of 37 dB (from 50 dB HL to 92 dB HL) and a loss of functional low frequency hearing.

The study by Lenarz et al included 20 patients with significant residual hearing in low frequencies (<80 dB HL [125-500 Hz] implanted with the SlimJ and followed up for 4 months. Consistent ST placement and an adequate insertion depth for full electrical stimulation were evident in all 20 patients. A total of 13 patients reached the longest follow-up time of 4 months. At 4 months, 7 out of 13 patients had a low-frequency hearing loss $PTA_{(125\text{-}500\ Hz)}$ of <15 dB HL, 3 patients between 15 and 30 dB HL, and 3 patients >30 dB HL. The median loss of residual hearing was 12.5 dB HL.[20]

In the study of Schwam et al, preoperatively, 24 patients had functional residual hearing. These investigators used a different classification for hearing preservation: 6 patients had hearing loss of ≤ 10 dB HL, 8 patients had ≤ 20 dB HL, and 10 patients had > 20 dB HL. The mean shift in the low-frequency pure-tone average was 20 dB, which meant that there were 9 patients with considerable (≤80 dB) residual hearing postoperatively.[21] In our study, complete preservation was achieved in 4/10 patients after a mean of 10 months of follow-up, which is comparable to the results published by Lenarz et al and Schwam et al[20,21] In previous studies, the hearing preservation rates for other standard-length electrodes have been reported ranging between 11% and 84%.[9,12,13,30]

The mean SRT estimates for Finnish CI recipients have been defined in 2 studies. The mean SRT for the unilateral CI condition in 78 recipients was —3.5 ±1.7 dB SNR.[23] Similarly, for a clinically representative group of 80 CI users with their preferred device configuration, corresponding to our "best aided" condition, the mean SRT estimate was −4.2 dB SNR (SD 2.1).[31] This is rather well in line with the current study [mean −3.5 SNR (SD ± 2.3 SNR)], where the average improvement was 4.0 dB, which is a considerable improvement in performance and within the range of our clinical objective.

In the SlimJ study conducted by Lenarz et al, speech perception in quiet improved from preoperative to postoperative situations in every patient. The speech perception in noise was measured only postoperatively, with a constant improvement from 1 month to 4 months in all studied subjects. Hochmair–Schulz–Moser sentence scores[32] in a fixed +10 dB signal-to-noise ratio were 12% (SD ± 16) at 1 month (n = 20) and 30% (SD ± 29) at 4 months (n = 12). In the trial conducted by Schwam et al, the preoperative and postoperative Arizona biomedical sentence recognition test (AzBio)[33] scores in quiet were available for 20 adults, with the average time to last functional testing being 8.8 months. These patients achieved significant monaural (24.1-48.3, $P = .004$) and binaural (46.1-65.9, $P = .002$) improvements when examined postoperatively. Speech audiometry results are test- and language-specific, and thus it is not possible to make a comparison of the postoperative outcomes.

The Slim Modiolar Electrode (Cochlear Company, Sydney, Australia) has been studied in a group of 17 patients with the FMST using the same methodology as applied here.[30] The mean preoperative SRT of the group was −1.2 dB SNR (range from −6.8 to +10.0 dB SNR). The postoperative SRT was −5.2 dB SNR (range from −8.5 to −0.7 dB SNR). The improvement of 4.0 dB is equivalent to the shift detected in this study (improvement of 4.0 dB). The previous sample differs considerably from the individuals treated here in several aspects (age at insertion, residual hearing, etc.) and is therefore not comparable.

Conducting the FMST in CI patients is only possible when the patients have sufficiently high speech recognition scores in quiet. The inclusion criteria for adaptive measurements in noise is word scoring of 70% or greater at a +10 dB SNR presentation level at the 65 dB SPL noise level. Two patients had insufficient speech recognition to accomplish the test both preoperatively and postoperatively. However, 1 of them was able to score 71% at +10 dB SNR at the 2-year follow-up. The other patient recently completed the Finnish simplified matrix sentence test with a score of −0.9 SNR after receiving her bilateral implant.[34] There were 2 patients who showed no significant improvement in their SRTs after implantation, yet they still considered the implant to be beneficial and continued with implant listening.

One subject experienced a device failure of the HiRes Ultra implant, and this patient underwent a revision surgery 2.5 years after the primary surgery. Approximately 1 year after the first implantation, the recipient experienced sound distortions. The impedances of contacts E12-E16 decreased gradually and were eventually suspiciously low. The ECAP response could not be elicited any longer, and there was a gradual degradation of speech perception starting during the second year of use. Electrical field imaging analysis tool showed atypical responses on E9-16. This is analogous with previous cases reported by Gärtner et al (2021). They identified 1 device failure manifested by sound distortion and exceptionally low impedances in the E09-E13 channels. It was suspected that fluid ingress at the ground electrode had caused short circuits in the electrode pocket.[35] Schwam et al identified 3 suspicious cases indicative of device failure out of 61 implantations during the mean 9.2 months' follow-up time (range 1-22 months).

The limitations of this study are its retrospective nature, the heterogenic and small sample size, as well as the variability in the follow-up time. The follow-up schedules varied due to the individual needs of the patients, taking into consideration the long distance some had traveled to reach the hospital. Conversely, the use of unselected clinical data is a strength of this study. Quality measures were clinically applied and therefore available for evaluation (preoperative and postoperative threshold measurements, speech perception in noise, and imaging data). In this study sample, intraoperative electrocochleography was not applied; it can be speculated that had it been possible to utilize intraoperative monitoring, then the hearing preservation results may have been improved.

The relatively atraumatic insertion characteristics make the SlimJ array a good option for hearing preservation cochlear implantation. The hearing outcomes were similar to those reported for other electrodes and devices.

Ethics Committee Approval: This study was approved by Ethics Committee of University of Eastern Finland (Approval No: 5551876, Date: January 31, 2021).

Informed Consent: Informed consent was obtained from the patients who agreed to take part in the study.

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