Comparison of Insertion Depth and Hearing Preservation Results between HiFocus 1j and HiFocus Mid-Scala Electrodes in Pediatric Population

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Abstract

Background Various electrodes are available with a range of features and designs to fulfil anatomical and geometrical variations of the cochlea. The HiFocus 1j (1j) electrode developed by Advanced Bionics LLC is a lateral wall electrode designed to cover up to 1.5 turns or approximately 540°of the cochlea. The HiFocus Mid-Scala (HFms) was recently introduced and designed for structure preservation with a target insertion depth of 420°.

Objective To evaluate the average insertion depth and variation, and to assess the potential for hearing preservation with 1j and HFms electrodes in children.

Methods A group of prelingually deafened children with regular anatomy who received the HiRes90K implant (either 1j or HFms electrode) underwent a plain radiography investigation shortly after the surgery to determine the angular insertion depth. The median age in each group was 3.6 years (1j) and 4.3 years (HFms). The amount of residual hearing was measured through audiometry prior surgery and then monitored at device activation and 1,3, 6, and 12 months later.

Results Seventeen subjects were included for calculation of insertion depth. The median insertion depth and the variation for the 1j electrode was higher than for the HFms electrode (1j 476°; 443°–540°, HFms 413°; 390°–468°). Only eleven subjects were assessed for hearing preservation. Complete hearing preservation was achieved in seven subjects (five HFms and two 1j) and partial loss was observed in two subjects (one HFms and one 1j).

Conclusion Both 1j and HFms electrodes are suitable for young children. Their flexible design allows round window insertions. The HFms group showed higher rates of hearing preservation (HP) than the 1j group.

Keywords
- insertion depth
- hearing preservation
- electrode design
- electrode array

Introduction

A Cochlear Implant (CI) provides a standard treatment for severe to profound deafness and consists of an externally worn sound processor, a receiver/stimulator placed under the temporalis muscle and an electrode array inserted into the cochlea. The aim of the surgeon is to insert the electrode array into the cochlea with minimal damage to the surrounding structures, preserving any remaining hearing. This is particularly important as preservation of residual hearing has been identified as a factor predicting good post-operative speech perception.[1–3]

The array is inserted into the cochlea either by opening the round window or drilling a cochleostomy and damage can initially occur at the point of insertion or when the cochlear implant array is introduced further into the

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cochlea.[4–7] The primary goal is to place the electrode into the scala tympani (ST), throughout its entire length and without dislocation through the partition into the scala vestibuli, thus rupturing or damaging the basilar membrane.[4] Even if residual hearing can be preserved in the initial stages, it may deteriorate over time, as a result of foreign body cell reactions and fibrosis.[8] Good electrode design and surgical technique can both contribute to minimizing trauma.

Advanced Bionics (AB, Valencia, CA, United States) has introduced a new pre-curved electrode array, HiFocus Mid-Scala (HFms), that is designed to be positioned in the ST with no contact either to the inner (modiolar) or to the outer (lateral) wall of the ST. Two studies have evaluated this electrode in temporal bones and found that the array could be inserted atraumatically into the ST without damage to the basilar membrane.[9,10] The electrode array rested either close to the medial wall with 50% of electrodes positioned in a truly mid scala position.[9] Clinical evaluations have been conducted in both adults and children. Hunter et al[11] retrospectively reviewed 47 adults implanted with the HFms electrode (50 ears) and investigated preservation of residual hearing in a sub group of 39 ears where preoperative hearing in the implanted ear was less than 90 dB HL at 250 Hz. They found that hearing preservation was in line with the rates reported in other studies, although only 13 subjects had reached the 1-year evaluation point. In the study by Svrakic et al,[12] retrospective data were gathered from a mixed group of adults and children comparing HFms and HiFocus 1j (1j) electrodes. Short-term hearing preservation (up to 3 months) was reported at frequencies where a given subject had preoperative pure-tone thresholds of 100 dB HL or better. Hearing preservation was reported as an absolute shift in threshold in dB HL at each individual frequency and a significant difference in hearing preservation was found between the two electrodes. They also reported on a possible link between insertion depth and preservation of hearing, suggesting that insertions beyond 450° were associated with a greater degree of threshold shift, although they found no difference in angular insertion depth between electrode types. A prospective clinical study was conducted by Benghalem et al.[13] In this study, children were implanted with the HFms and were prospectively compared to children implanted with the 1j. Residual hearing at 500 Hz, at 6-month post-surgery was reported and was preserved to within 10 dB HL of the preoperative audiogram for all seven HFms children. Results based on the Skarzynski formula[14] were better than those reported by Hunter et al,[11] with complete or partial hearing preservation in six out of seven subjects in the HFms group.

The objective of this study was to provide further pediatric data in a group of prospectively recruited subjects with more residual hearing that those reported by Benghalem et al,[13] Children implanted with the HFms were compared to a control group of subjects implanted with the 1j electrode, implanted by the same surgeon using the same surgical techniques. Insertion depth and hearing preservation results were reported.

Methods

Seventeen children were prospectively recruited and implanted at a single tertiary clinic. Subjects were included who had bilateral severe to profound sensorineural hearing loss. The inclusion criteria only required subjects to be suitable cochlear implant candidates with bilateral severe to profound sensorineural hearing loss, and a measurable preoperative residual hearing was not required. All subjects opting for a surgery and meeting the inclusion criteria were invited to participate in the study. In our country, the funding for CI is mainly private. Each of the two electrodes is offered as part of a system package with a specific configuration of external components. Parents will choose a specific system based on cost and most suitable configuration of externals for each child. One child was bilaterally implanted with each type of electrode, thus nine ears were implanted with the 1j electrode and nine with the HFms electrode. The demographics of both groups are given in ►**Table 1**. Exclusion criteria were any cochlear malformation and ossification, cochlear nerve dysplasia/aplasia, and children with complex needs (►**Table 1**).

A subject consent form was signed for all subjects, by a parent or guardian for their data to be collected and used in the study, and ethical approval was given by the ethics review board of the implant center under the reference number: KEMHRC/VSP/Dir.Off/EC/2095.

All devices were implanted by one surgeon using the same minimally invasive soft surgery surgical technique. A small, 6-cm retroauricular incision was made with minimal mastoidectomy and large posterior tympanotomy, with skeletonization of facial nerve and corda tympani, if required. Both types of electrodes were inserted via the round window with the insertion tool provided by the manufacturer. Drilling of the round window lip or niche was performed, if needed. There was no electrode lubrication used except for saline, and steroids were administered intravenously at the time of induction of general anesthesia. A steroid solution was placed in the middle ear until insertion of the electrode. All subjects were given postoperative steroids for 4 days.

The HFms electrode was inserted up to the first blue marker, and then inserted into the cochlea by gently forwarding the slider on the tool and thus expelling the electrode from the stylet. At the final point, when the slider approached its end, the electrode was released from the stylet and detached from the tool. This step typically occurred when the second blue marker was just at the level of round window. The 1j electrode was inserted using the insertion instrument and the metal insertion tube. The tube with the 1j electrode loaded was first orientated so that the contacts were facing the modiolus, the tip of the tube was then gently placed over the round window and the insertion started by continuous and slow forwarding of the insertion tool slide. Once the metallic reference contact had reached the round window, the tool was withdrawn while the slider was further pushed to disengage the tool from the electrode.

The angular insertion depth of the electrodes was determined postoperatively using a Pleophos D, Klinoskop, 33MA,

Table 1 Subject demographics, implant details, and hearing thresholds

Subject	Age at implant (years)	Etiology	Electrode	Pre-implant PTA 250Hz	Pre-implant PTA 500Hz	Pre-implant PTA 1kHz	1-year PTA 250Hz	1-year PTA 500Hz	1-year PTA 1kHz	X-ray
KEM01	4.2	since birth	1j	90	95	100	NR	105	115	443
KEM02	2.2	unknown	1j	70	80	80	80	80	100	522
KEM03	3.7	congenital	1j	85	100	100	90	NR	NR	450
KEM04	4.8	since birth	1j	60	85	95	70	85	105	448
KEM05	1.8	unknown	1j	70	85	80	70	85	105	540
KEM06	4.3	since birth	HFms	85	90	95	75	95	105	463
KEM07	5.4	congenital	HFms	90	95	105	75	80	80	413
KEM08	3.2	congenital	HFms	80	90	110	85	90	110	451
KEM09	1.8	Wardenberg	HFms	80	100	100	85	90	105	407
KEM10R	4.5	since birth	1j	85	100	100	85	110	120	443
KEM10L	4.5	since birth	HFms	90	100	110	85	95	100	390
KEM11	1.7	since birth	1j	80	100	110	85	110	120	510
KEM12	4.9	since birth	HFms	85	90	100	80	85	95	410
KEM13	1.8	since birth	HFms	80	110	120	85	110	120	460
KEM14	10.2	since birth	HFms	80	95	95	NA	NA	NA	404
KEM15	2.5	unknown	HFms	80	85	100	90	110	NR	468
KEM16	3.6	since birth	1j	85	110	NR	NR	110	NR	476
KEM17	6.6	unknown	1j	NR	NR	NR	NR	NR	NR	527

Abbreviations: NR, no response; NA, not available.
Note: The X-ray column gives the angular insertion depth of each electrode array.

Siemens Ltd. planar X-ray machine and a modified Stenver's view.[15] Scans were performed within 3 months of the surgery date. As the round window is not visible on an X-ray, the vestibular system was used as a zero reference point to calculate the angle of insertion depth and angular insertion depths measured according to the method described by Marsh et al.[16] An example of the insertion depth measurement is shown in ►**Fig. 1**.

Hearing preservation was evaluated using pure tone audiometry with air conduction thresholds at 250 Hz, 500 Hz, 1 KHz, 2 KHz, and 4 KHz. In children older than 2 years at inclusion, the individual ear thresholds were measured using a Madsen Itera II audiometer and Tecmo Techmuff MT 30+ headphones. In the younger children, the thresholds were measured in free-field condition using two Sound Field Loudspeakers (Sonex, Switzerland) placed at 45 degrees azimuth and 1-meter distance from the subject. For these subjects, individual ear information could not be obtained. The maximum output levels for headphone testing were 110 dB HL at 250 Hz, and 120 dB HL at 500 Hz, 1 kHz, 2 kHz, and 4 kHz. Measurements were conducted preoperatively, at activation, and at 1, 3, 6 months, and 1-year post activation, in both implanted and contralateral ears.

Statistics

A non-parametric Mann–Whitney *U* test was used to compare median values between groups.

Subjects

Seventeen children were included, 16 unilaterally implanted and 1 sequentially bilaterally implanted with a 1j in the first ear and a HFms in the second. This gave nine 1j ears and nine HFms. Individual hearing profiles are shown in ►**Fig. 2** and although there was more variance in thresholds for the 1j group, there was no statistically significant difference between groups for a four-frequency average of 250, 500, 1000, and 2000 Hz ($p = 0.6$).

The median age at implant for the 1j group was 3.6 ± 1.6 years and 4.3 ± 2.6 years for the HFms group; there was no significant age difference between the groups ($p = 0.6$).

Results

All subjects were included for calculation of insertion depth. Only children with individual ear data, where hearing thresholds were measured under headphones, were included for hearing preservation evaluation.

It was possible to calculate insertion depth from the postoperative X-rays in all subjects hence data for nine 1j ears and nine HFms ears. The results are shown in ►**Fig. 3**. They indicate that the 1j electrode was inserted deeper into the cochlea than the HFms and that the difference was statistically significant. The median insertion depth for the HFms group was 413° (390°–468°) and for the 1j group it was 476° (443°–540°). (Mann–Whitney *U* Test: $U = 16$; $z = 2.1$; $p = 0.03$).

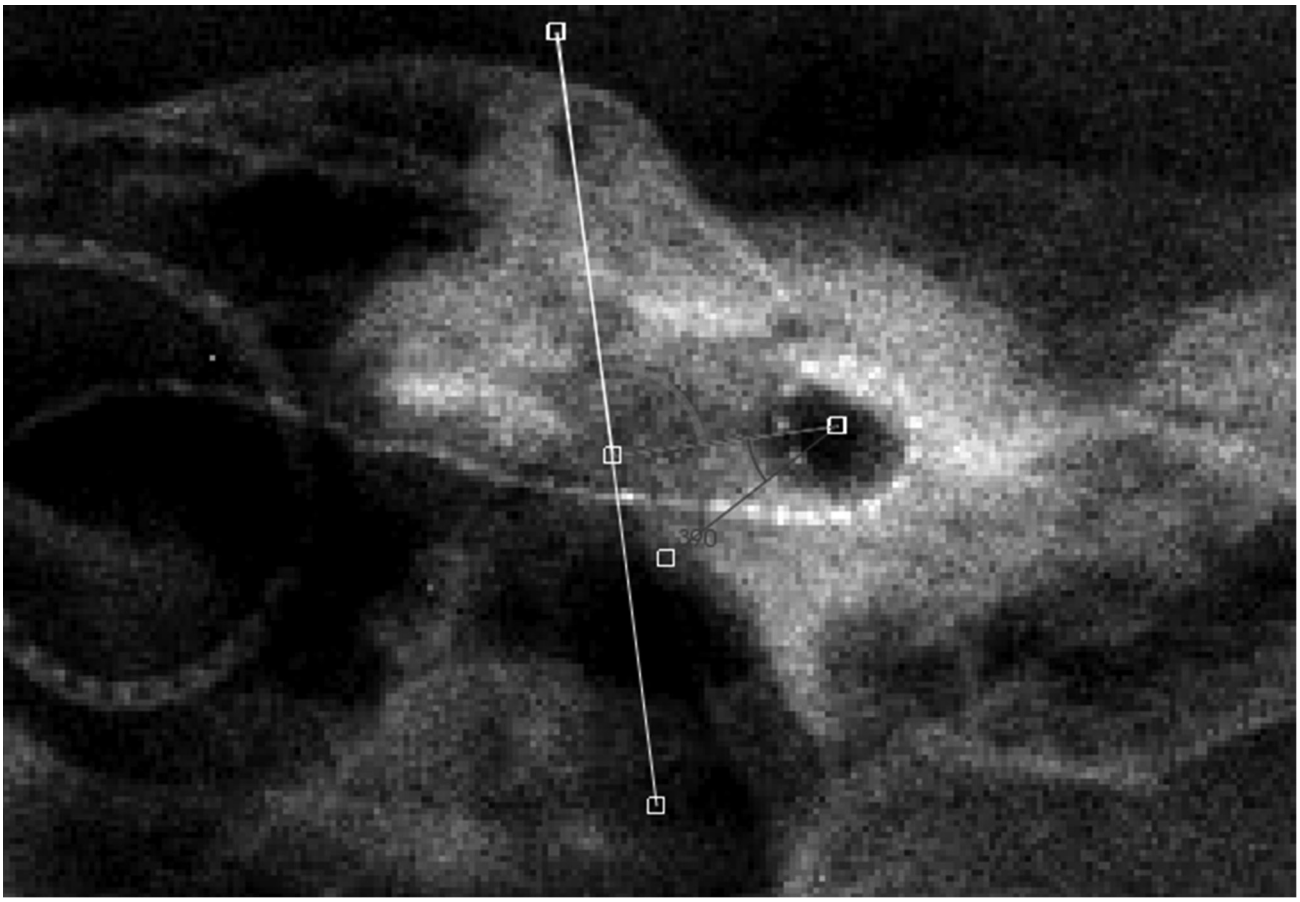

Fig. 1 An example of insertion depth calculation with plain radiography for the HFms electrode (KEM10L) based on Marsh et al.[16]

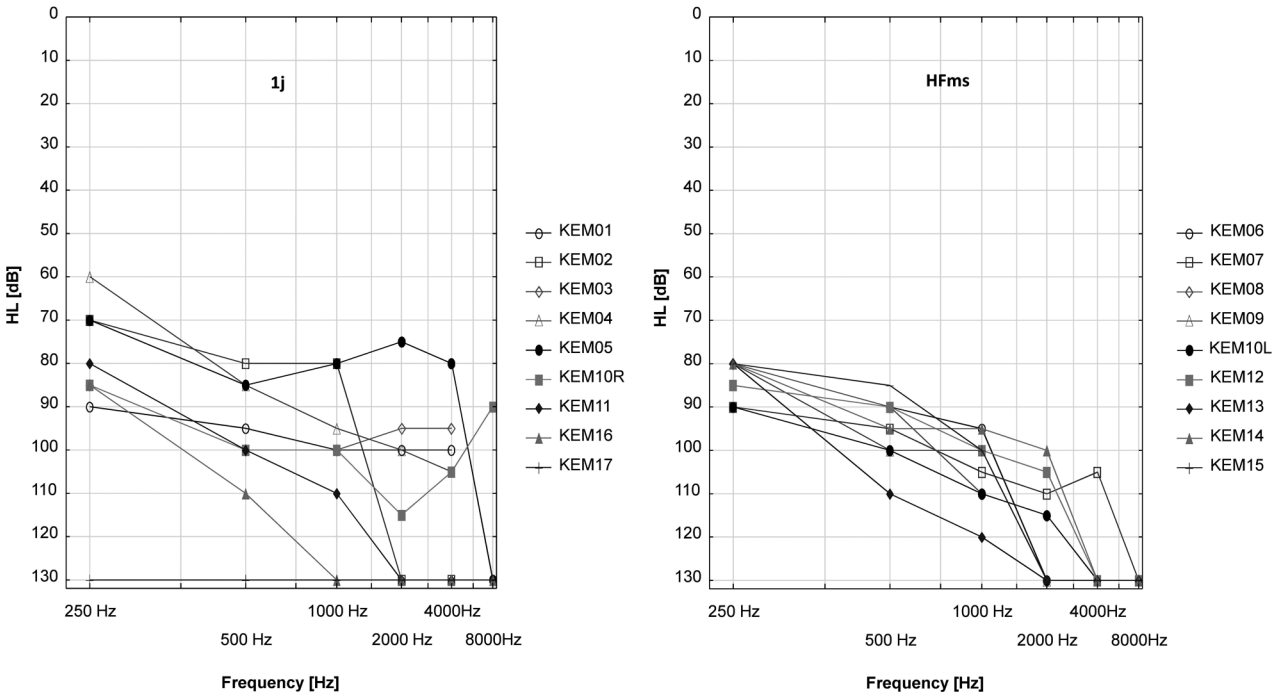

Fig. 2 Individual preoperative threshold values for all 17 subjects. One bilateral subject had a HFms in one ear and a 1j in the other ear, giving 18 ears in total.

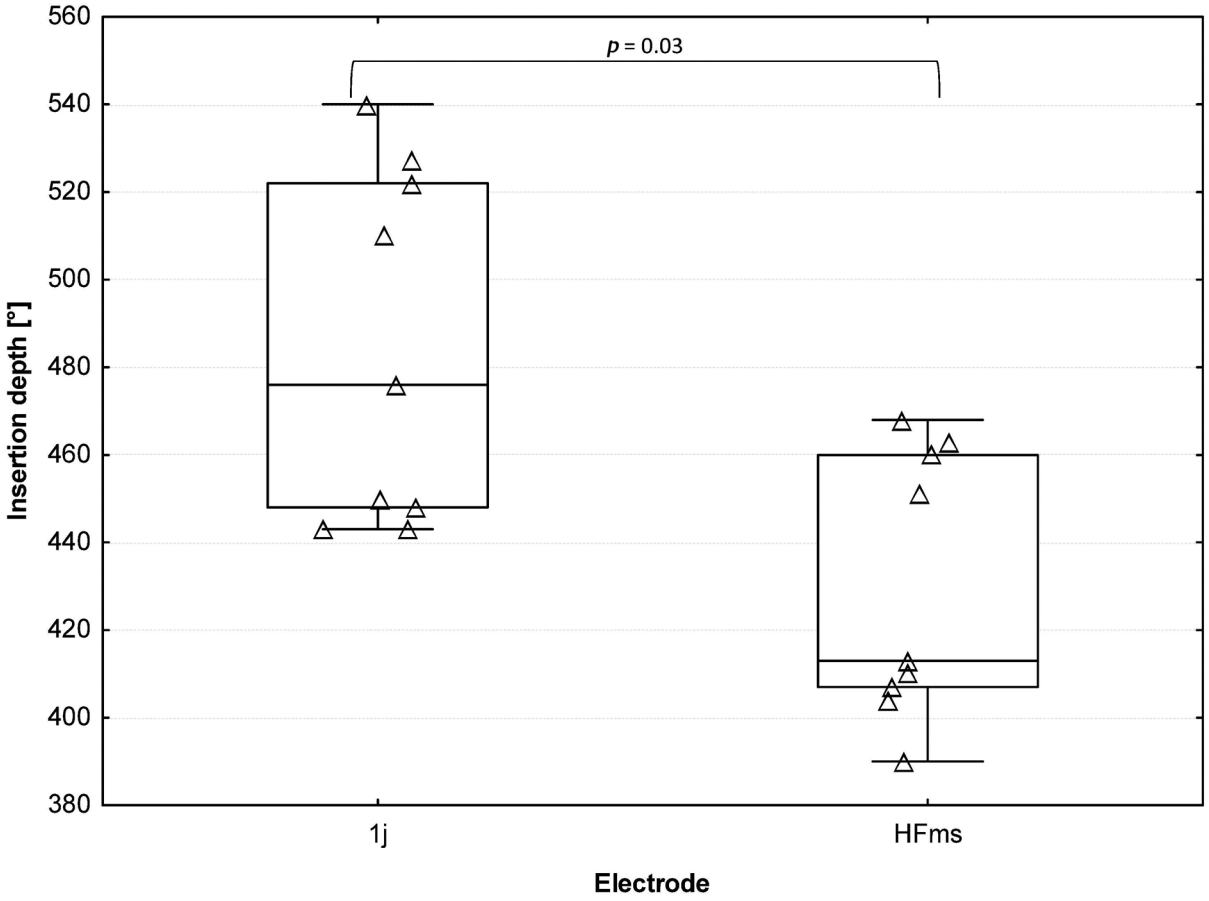

Fig. 3 Angular insertion depths for each electrode array type. *N* = 9 ears in both groups. Box plots show the median, first, and third quartiles. Whiskers show the maximum and minimum values.

It was only possible to assess hearing preservation by ear for 13 subjects, as 4subjects were too young to perform audiometry under headphones and were assessed in the sound field. One additional 1j subjects had no measurable hearing at the initial preoperative appointment. In one further HFms subject, the 1-year appointment was not attended, so no data point was included for this time period. This gave overall 11 subjects with six ears in the HFms group and six ears in the 1j group, where hearing preservation in the implanted ear could be assessed.

Scatter plots for individual subject thresholds preoperatively and at 1 year at 250 Hz, 500 Hz, 1000 Hz, and 2000 Hz are shown in ►**Fig. 4**.

It should be noted that in some subjects the maximum levels of the audiometer were exceeded, so the final auditory threshold values could not be accurately measured. Due to the low levels of preoperative hearing in the sample, four HFms subjects and four 1j subjects had preoperative thresholds at 250Hz or above the vibrotactile threshold of 85 dB HL for this frequency, which restricted the ability to record the threshold shift accurately.

In ►**Fig. 5**, hearing preservation rates are shown over time, based on the change in threshold as a percentage of the overall hearing loss as suggested in the consensus statement by Skarzynski et al.[14] The Skarzynski formula states that a hearing preservation (HP) percentage can be calculated using the formula:

HP (%) = [(Pure tone average postop – Pure tone average preop)/(120 – Pure tone average preop)] × 100

Complete HP is defined as a 0% to 25% loss, partial HP as a 25% to 75% loss and minimal HP as a loss less than 75%. Based on a PTA average of 250, 500 and 1000 Hz, at 1-year post surgery, five out of six HFms ears had complete hearing preservation and one partial hearing preservation. In the 1j group at 1-year post activation, two out of six had complete hearing preservation, one had partial, and two had minimal hearing preservation. One 1j subject lost all residual hearing at activation but contralateral hearing thresholds indicated that levels in this ear were in fact improving as the child became better at performing the test.

Statistical analysis showed that at 1 year, there was a significant difference (p = 0.03; z = −2.12) in hearing preservation rates between the 1j and HFms, although as sample numbers are small, this must be interpreted with caution.

Discussion

The HFms electrode array was inserted into the cochlea, without difficulty, in all nine children. The median angular insertion

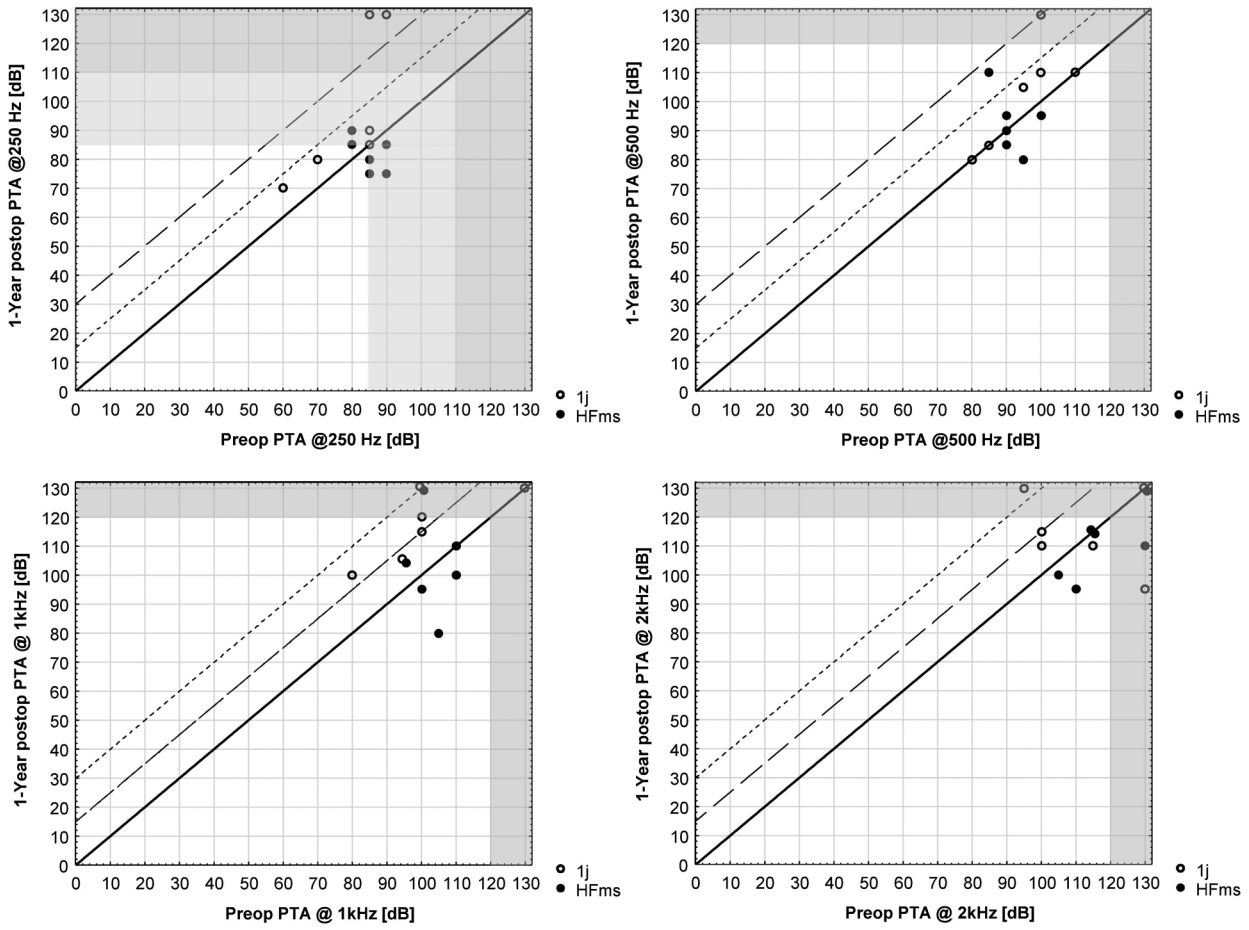

Fig. 4 Scatter plots of auditory thresholds in dB HL for all subjects where hearing preservation could be measured pre-implant and at 1-year postsurgery. *N* = 6 in the 1j group and *N* = 6 in the HFms group. Open circles indicate the 1j electrode array and filled circles the HFms electrode array. Values along the bold line indicate that hearing did not change between pre- and postoperative measures. Dotted lines represent a threshold shift of +15 and +30 dB. Dark gray areas indicate the maximum output of the audiometer and the vibrotactile threshold level at 250 Hz.

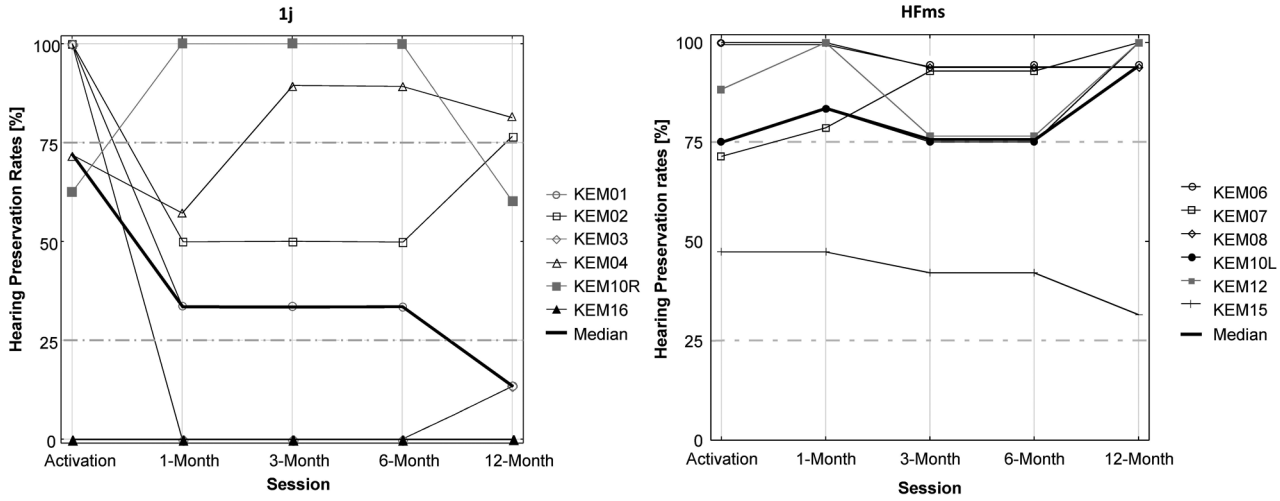

Fig. 5 Percentage rates of hearing preservation based on the Skarzynski et al[21] formula are shown for 1-year pos surgery for six 1j ears and six HFms ears. The bold line indicates the median values. Values of 75 to100% indicate complete hearing preservation, 25 to 75% partial hearing preservation, and less than 25% minimal hearing preservation.

depth recorded for the HFms was 413° (390°–468°), which is on the lower end of the range reported in other studies (398°–435°) (►**Table 2**). However, a number of other factors must be considered when comparing values across studies; the method of calculation of angular insertion depth, the size of cochlea, and the position and method of entry into the cochlea (round window or cochleostomy). When compared to the children with the 1j electrode in this study, for the HFms group the insertions were shallower by 63°and that difference was significant. There also appeared to be less variation in the depth of insertion of the HFms, a finding also reported by other authors (Benghalem[13] and Svrakic[12]). The HFms is shorter than the 1j and thus a shallower insertion depth might be expected; however, it is designed to follow a more medial path around the cochlea compared to the 1j (a lateral wall electrode), resulting in a deeper insertion. In temporal bone studies, the HFms was found to occupy mid scala, lateral wall, or perimodiolar regions of the scala tympani, with a tendency toward a perimodiolar position proximal to the basal turn and a lateral position in the basal turn (Frisch[9] and Hassepass[10]). The difference in insertion depth between electrode arrays found here may be indicative of a more lateral position of the HFms.

None of the patients included in the sample had functional residual hearing, thus the preservation of hearing was essentially used as indicator that the insertion was not traumatic (Balkany et al).[17] In India, the funding for cochlear implantation is private and consequentially 80 to 90% of recipients are children with profound hearing losses, as those with some functional hearing tend not to come forward for implantation. This limited our study to a pediatric population with minimal residual hearing preimplant.

Many studies report HP outcomes on the basis of threshold difference, which may underestimate the impact of losing that hearing on the individual user.[18] For subjects with a small amount of residual hearing, a 10-dB drop, for example, would have a greater impact than for a recipient with more hearing. The formula proposed by Skarzynski et al[14] accounts for this by expressing the amount of hearing preserved as a percentage of the total hearing before surgery and is the most appropriate method for our study group. Using this approach, the HFms performed well in terms of percentage of hearing preservation with five out of six ears having complete hearing preservation at 1-year post implant. Hearing preservation was maintained up to at least 1-year post surgery. In the subjects who did not return for the 1-year follow-up, hearing at 6 months was partially preserved. In the 1j group at 1-year post activation, two out of six had complete hearing preservation, but one 1j subject lost all residual hearing at activation. We investigated hearing in the contralateral ear for this subject to see if hearing thresholds had dropped overall for this child but found that hearing thresholds in this ear were in fact improving, as the child became better at performing the test. The HFms tended toward better HP than the 1j and although statistical analysis of such a small group must be interpreted with caution, there was a significant difference in median rates of HP between the groups at 1-year postop. Better HP results in the HFms compared to the 1j were also found in other similar studies[11–13] Svrakic et al[12] collected retrospective data from a large group of adults with more residual hearing than those reported here, but only provided HP data for 3-month postsurgery. We know that further hearing loss can take place over time, as a result of foreign body cell reactions and fibrosis and short-term follow-up can give an unrealistic picture of the potential for HP.[8] Surgeries for the two arrays were also performed by different surgeons using a cochleostomy, unlike here where the same surgeon performed all procedures via the round window. They did not use the Skarzynski formula but reported losses in dB by frequency and found both a clinically and statistically significant difference between the arrays. Benghalem et al[13] conducted a prospective study similar to this one and reported HP in the same way. Three out of seven subjects (42%) in the HFms group had their residual hearing completely preserved at 500 Hz, three partially preserved, and one minimally preserved, with a shift from 105 db HL to 115 dB HL; the 1j group lost more hearing with no subjects with complete HP and five subjects had a complete loss of residual hearing. Hunter et al,[11] only recruited a sample of HFms users and 55% of the group had partial or complete HP at 6 months, a lower proportion than reported here or in Benghalem et al,[13] but in a much larger sample of 20 ears with more residual hearing. The surgical technique also differed from the one used in this study with a mixture between cochleostomy and round window approaches. HP results reported for other manufacturers' electrodes report slightly lower percentages of complete and partial preservation than found here. Mertens et al[19] found that 27% subjects had complete HP, 45% had partial HP, and Santa Maria et al[20] found that 22.2% had complete HP and 66.7% partial HP. However, although larger than our sample, group sizes were still less than 20 subjects.

The limited amount of preoperative residual hearing in our sample introduced two major complicating factors

Table 2 Insertion depth table for HFms from various studies

Study	Surgical approach	Angular depth of insertion 1j (Standard deviation)	Angular depth of insertion HFms (Standard deviation)
Current study	Round window	476° (40)	413° (30)
Hassepass et al[10]	Round window		398° (40)
Frisch et al[9]	Round window		436°
Benghalem et al[13]	Round window	439°	435°
Svrakic et al[12]	Cochleostomy	431° (64)	389° (34)

into the accuracy of recording any drop-in hearing following implantation. These were in influence of vibrotactile thresholds at low frequencies, especially 250 Hz and the limits of the audiometer output at high frequencies. In other studies, these have been controlled in different ways. Svrakic et al[12] selected only those with preoperative thresholds better than 100 dB HL in their retrospective sample; however, subjects where thresholds at 250 Hz may have been vibrotactile were still included.[11] retrospectively selected subjects with preoperative audiometric thresholds less than or equal to 85dB HL at 250 Hz on the basis that the target gain via acoustic amplification would theoretically be achievable preoperatively, and Benghalem et al,[13] only reported on results at 500 Hz where measurable hearing was present. Hearing levels for some children seemed to improve over the study period, which can be explained as a learning effect from repeating the test measures. Indeed, audiograms were often repeated in-between assessments enhancing this effect. A conductive overlay is also sometimes present at activation due to significant amount of blood and fluid, which disperses over time, resulting in an improvement in thresholds after activation.[11]

The critical issues of hearing preservation in general are not only the choice of the right electrode, but also the combination of steroid use, surgical technique, and the degree or length of insertion. Insertion depth may be a factor to consider when comparing the HP results in this group. The debate between optimum coverage of all frequencies across the cochlea versus the need to insert the array more deeply continues. Svrakic et al[12] found that there was a significant effect of angular depth of insertion on HP regardless of surgeon, with deeper insertions resulting in worse HP. They suggested 450 degrees as the cutoff where HP was affected by insertion depth. Micro-anatomical analysis by micro-CT indicated that a 420-degree insertion depth was optimal between cochlear coverage and available space within the scala tympani.[21] O'Connell et al[22] also found that deeper insertions were associated with worse short-term HP. If this is correct, then the deeper insertions recorded for the 1j in our data may explain the lower HP rates over the HFms group.

Conclusions

The HFms electrode array was inserted into nine pediatric ears with no difficulties. The median insertion depth of 413 degrees suggested optimal levels for cochlear coverage and hearing preservation and was significantly lower, with less variation, than for the 1j electrode array. Residual hearing in the HFms group was completely preserved in five out of six subjects at 1-year post surgery, which was significantly better than the preservation rates in the 1j group. The higher rate of hearing preservation and lower insertion depths for the HFms electrode array may be linked, as suggested by other authors, but a larger data set is needed to explore this area further.

Conflict of Interest
None declared.

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