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Original Article

Hearing Preservation After Cochlear Implantation with the Advanced Bionics HiFocus™ SlimJ Electrode Array

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BACKGROUND: Successful cochlear implantation depends on many factors, one of which is the electrode type. The aim of this study was to evaluate it in terms of the preservation of residual hearing, as well as to investigate the effects of patient age and preoperative low-frequency hearing loss.

METHODS: Twenty-three patients were implanted unilaterally with the HiFocus™ SlimJ electrode array. Pure tone audiometry (0.125-8 kHz) was performed preoperatively and at 1, 3, and 6 months postoperatively. Hearing preservation was established using the HEARRING group formula.

RESULTS: Residual hearing was preserved in all patients. For hearing to be preserved, it was found that preoperative low-frequency hearing levels were more important than age.

CONCLUSION: Residual hearing was preserved in all the patients who received the HiFocus™ SlimJ electrode array. Hearing preservation depended more on a patient's preoperative low-frequency hearing threshold than their age.

KEYWORDS: Cochlear implantation, cochlear implants, hearing loss, hearing preservation

INTRODUCTION

Cochlear implantation is a standard method of treating patients with severe to profound hearing loss, either due to age or other reasons, and who have received insufficient benefits from hearing aids.[1-3] Cochlear implantation is intended to improve the patient's everyday life, allowing them to hear sounds, localize them, and listen in a noisy background. Entering the world of sound is the beginning of aural rehabilitation and a better lifestyle.[3]

The basis of a cochlear implant (CI) is the provision of electrical impulses that stimulate the auditory nerve. Initially, it was thought that a CI could only be placed in adults and children who were post-lingually or pre-lingually deaf.[4] It is now known that it is also possible in other groups, including patients with unilateral deafness[5] or partial deafness.[6] The latter has become possible through the expansion of candidacy criteria to include those with low-frequency hearing from 0.5 to 1.5 kHz[7] but with no hearing at high frequencies.[6,8] These patients undergo a procedure called Partial Deafness Cochlear Implantation (PDCI).[8,9] The cochlea is very delicate and can be damaged during implantation, resulting in residual hearing loss.[10] The surgeon's challenge is to preserve the cochlea and retain residual hearing at low frequencies.

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Various methods can be used to reduce trauma and maximize hearing preservation (HP) during implantation. They include surgical techniques,[11,12] atraumatic electrodes,[11] and preoperative steroids.[2,13,14] For example, it is possible to significantly reduce surgical trauma during the insertion of the electrode array by using the Skarzynski 6-step surgical procedure for PDCI.[11,15] In the center, the round window approach with a straight electrode was considered as the best choice for avoiding inner ear trauma.[11]

Selecting an appropriate electrode is not always easy. The surgeon needs to consider, above all, the protection of the cochlear structure and the anatomy of the patient's inner ear. Generally, 2 types of electrode arrays can be used: perimodiolar or lateral wall.[16,17] In 2017, the Food and Drug Administration approved the HiFocus™ SlimJ electrode (Advanced Bionics, Valencia, CA, USA), which is a lateral wall design meant to minimize cochlear damage.[18] This electrode is designed to work with the Advanced Bionics HiRes Ultra implant (as is the pre-curved HiFocus™ Mid-Scala electrode). The choice of straight or curved allows the surgeon to choose an electrode suited to the anatomy of the patient's inner ear.

Here, the HiFocus™ SlimJ electrode array with 23 mm of insertion depth was applied. This electrode is essentially straight but has a gentle curvature, allowing it to be placed close to the lateral wall (the Mid-Scala electrode was developed as a perimodiolar electrode, which could increase the risk of translocation to scala vestibuli).[19,20] In addition, the electrode allows the surgeon to choose between the round window approach and cochleostomy, but in all the cases, the round window approach was chosen. In such an approach, the reduction of some part of the bony overhang is recommended to adjust the electrode shape. Being able to choose the better approach during surgery is another advantage of the SlimJ.

The presented study aimed to provide an assessment of how, following implantation, the Advanced Bionics HiFocus™ SlimJ electrode array performed in terms of HP.

METHODS

In this study, 23 patients were enrolled and were implanted with the Advanced Bionics HiFocus™ SlimJ electrode. The same experienced surgeon performed all surgeries. The Ethics Board of The Institute of Physiology and Pathology of Hearing approved the study on January 30, 2020 (KB.IFPS:21/2020). All patients signed an informed consent form prior to participation.

Audiometric Thresholds

Pre- and postoperative pure tone audiometry thresholds were measured in a soundproof cabin using a Madsen Itera II (GN Otometrics, Denmark) with calibrated earphones (TDH-39P, Telephonics, NY, USA) with a routine protocol. The pure tone audiometric frequencies were 0.125 to 8 kHz for air conduction and 0.25 to 4 kHz for bone conduction. If there was no audible percept at a given frequency, the hearing level was assigned to be the audiometer's maximum output. Pure tone audiometry was conducted before implantation and at 1, 3, and 6 months afterwards.

Inclusion and Exclusion Criteria

Each candidate had to fulfill the inclusion criteria: pure tone audiometric thresholds ≤80 dB HL at 125, 250, and 500 Hz, 18 years of age or older, meeting typical candidacy requirements for cochlear implantation, no cochlear abnormality that might prevent full insertion of the electrode array, and no additional handicap that would prevent study procedures from being followed. Exclusion criteria included chronic otitis media, malformed cochlea, auditory neuropathy spectrum disorder, presence of ear tubes, and prior middle ear surgery or trauma. The study protocol defined all criteria.

Hearing Preservation

There are several methods of determining HP.[21] The most common is the one agreed upon by the HEARRING group in 2013.[2,21] This tool can be used for every hearing implant and does not depend on the user's preoperative hearing levels. There are 4 categories of HP – Complete HP, Partial HP, Minimal HP, and Loss of hearing – with respective percentage rates of >75%, 25-75%, 0-25%, and no measurable hearing. This standard tool allows comparison between studies, meta-analysis of results, and the collection of data in line with evidence-based medicine.[2,22] The formula for calculating the degree of HP, *S*, is:

$$S = \left[1 - \left(\frac{(PTApost - PTApre)}{(PTAmax - PTApre)}\right) * 100\right][\%]$$

Where S is percentage preservation; PTApost is postoperative pure tone audiometry; PTApre is preoperative pure tone audiometry; and PTAmax is the maximum output level for a particular frequency.

Surgical Techniques

In the center, all patients were taken for surgical procedures according to the Skarzynski 6-step surgical procedure.[11] This approach is minimally invasive and avoids damage to the cochlear structures, offering a potentially safer alternative to the traditional cochleostomy approach. It is especially beneficial for patients with anatomical challenges or those requiring a more delicate insertion of the electrode array.[23,24]

Statistical Analysis

Descriptive statistics (range, mean, SD) were used to describe quantitative variables. Categorical variables were calculated as percentages. A Wilcoxon signed-rank test was performed to compare hearing thresholds before and after implantation; the relationship between variables was established using the Pearson correlation coefficient. Hierarchical regression analysis was used to examine the impact of age and hearing thresholds on HP. The level of statistical significance was set at $P < .05$. The analysis was performed using IBM SPSS Statistics v.24 (IBM SPSS Corp.; Armonk, NY, USA).

MAIN POINTS

- This study shows that hearing preservation (HP) depended more on a patient's preoperative low-frequency hearing threshold than their age.
- The Advanced Bionics HiFocus™ SlimJ electrode array enables HP.
- In all patients, residual hearing was preserved.

Measures

The primary outcome measure was HP, calculated by comparing hearing thresholds in the 6-month postoperative period with the preoperative hearing thresholds, according to the formula above. A secondary outcome measure was the low-frequency pure-tone average (LF-PTA) of hearing thresholds across 0.125, 0.250, and 0.5 kHz based on the pre- and 6-month postoperative measures.

Subjects

Between March 2020 and May 2020, 28 patients were recruited to the study. Five patients were lost to follow-up, so the final sample consisted of 23 patients (23 ears). There were 10 men and 13 women aged between 20 and 76; the mean age was 55.1 years (SD = 13.5). There were 13 right ears and 10 left ears implanted.

RESULTS

Hearing Thresholds

Table 1 shows hearing thresholds before cochlear implantation and 1, 3, and 6 months after surgery.

As seen in Table 1, hearing thresholds at low frequencies were better than 80 dB HL in the preoperative period. They were, on average, 46.96 dB HL at 0.125 kHz, 51.96 dB HL at 0.25 kHz, and 65.87 dB HL at 0.5 kHz.

One month after surgery, a general deterioration of hearing thresholds was observed. The mean change at 0.125 kHz was 11.1 dB (SD = 12.8) and was statistically significant ($Z = 3.36$; $P < .001$). The mean change at 0.25 kHz was 19.1 dB (SD = 15.3) and was statistically significant ($Z = 3.74$; $P < .001$). The same was true for 0.5 kHz, where the mean change was 19.1 dB (SD = 15.0) and again was statistically significant ($Z = 3.91$; $P < .001$). Changes for other frequencies were also statistically significant, the greatest change being observed for 4 kHz ($M = 9.1$ dB; SD = 13.4), while the smallest change was for 8 kHz ($M = 3.9$ dB; SD = 10.3).

After 3 months, hearing thresholds had not changed significantly compared to 1 month, and after a further 3 months, they had not changed further. Finally, hearing thresholds 6 months after surgery were compared to those before surgery. The mean changes (pre-op vs. 6 months post-op) are shown in Table 2.

Hearing Preservation

Hearing preservation captured quantitatively ranged from 0% to 100%; the mean HP was 58.8% (SD = 0.32) 6 months after surgery. Hearing preservation was assigned to one of 3 categories (no measurable hearing, minimal, partial, complete), as shown in Table 3.

Overall, there were no patients who had no measurable hearing (loss of hearing) after their CI, meaning that all patients had at least minimally preserved hearing. At 6 months after their CI, 39.1% of patients had their hearing preserved completely, 43.5% partially, and 17.4% minimally.

Low-Frequency PTA

LF-PTA values for the pre- and postoperative periods are shown in Table 4.

Table 1. Mean Hearing Thresholds Before Cochlear Implantation and 1, 3, and 6 Months After Surgery According to Pure Tone Audiometry

	kHz	Min	Max	M	SD
Pre	0.125	10	75	46.96	15.72
	0.25	10	70	51.96	16.29
	0.5	20	80	65.87	14.82
	1	60	120	89.35	18.17
	2	70	120	99.13	18.50
	4	70	120	105.00	17.52
	8	55	100	95.22	10.39
1 mth	0.125	20	85	56.82	15.93
	0.25	20	100	70.23	19.91
	0.5	40	110	85.00	17.06
	1	75	120	99.57	14.53
	2	85	120	107.61	11.95
	4	85	120	114.13	10.94
	8	80	100	99.13	4.17
3 mths	0.125	25	70	52.35	11.61
	0.25	35	95	70.56	17.31
	0.5	60	120	87.37	17.11
	1	75	120	100.26	15.68
	2	75	120	107.63	12.40
	4	80	120	113.16	11.330
	8	75	100	98.16	6.06
6 mths	0.125	15	90	57.39	21.99
	0.25	20	100	69.78	22.49
	0.5	35	115	85.43	19.54
	1	75	120	100.65	15.47
	2	80	120	110.22	12.57
	4	80	120	116.09	9.29
	8	70	100	98.04	6.53

M, mean; Max, maximum; Min, minimum.

As can be seen in Table 4, the mean LF-PTA change between pre- and postoperative periods was 15-17 dB. The mean change between pre- and 6-month postoperative LF-PTA was 15.9 dB (SD = 13.6) and was statistically significant ($Z = 3.87$; $P < .001$). One month after surgery, the LF-PTA drop in hearing was less than 15 dB for more than half the patients (52.2%), for 34.8% it was between 15 and 29 dB, and for just

Table 2. Mean Changes in Hearing Thresholds at 6 Months Compared to Pre-Op Measures

Frequency	Mean Change	*Z*-Value	*P*
0.125 kHz	$M = 10.4$ dB (SD = 15.4)	$Z = 2.80$	.005
0.25 kHz	$M = 17.8$ dB (SD = 14.2)	$Z = 3.74$	<.001
0.5 kHz	$M = 19.6$ dB (SD = 15.4)	$Z = 3.86$	<.001
1 kHz	$M = 11.3$ dB (SD = 20.4)	$Z = 2.40$	.016
2 kHz	$M = 11.1$ dB (SD = 15.7)	$Z = 2.87$	.004
4 kHz	$M = 11.1$ dB (SD = 16.3)	$Z = 3.02$	.003
8 kHz	$M = 2.8$ dB (SD = 10.5)	$Z = 1.27$	.206

Table 3. Hearing Preservation After Cochlear Implant Classified as Minimal, Partial, and Complete. Data are given as the number of patients (with the percentage in brackets)

	Minimal	Partial	Complete
1 month	1 (4.3)	15 (65.2)	7 (30.4)
3 months	2 (10.5)	12 (63.2)	5 (26.3)
6 months	4 (17.4)	10 (43.5)	9 (39.1)

13% it was 30 dB or more. At the 6-month follow-up, the figures had changed to 47.8%, 21.8%, and 30.4% respectively.

Hearing Thresholds in the Non-Operated Ear

We followed hearing thresholds in the non-operated ears. Average hearing thresholds across all frequencies in the non-operated ears varied between 10.7 and 101.5 dB HL. The mean preoperative level was 63.8 dB HL (SD = 24.8). Six months after implantation, the levels were about the same, between 10.9 and 103.6 dB HL; the mean was 66.7 dB HL (SD = 24.4).

Is Age or Preoperative Hearing Threshold More Important?

Hierarchical regression analysis was conducted to assess the impact of age and hearing thresholds on HP. Hearing preservation (a quantitative indicator) measured 6 months after CI implantation was treated as the dependent variable, while age and PTA-LF before surgery were taken as potential predictors. When the relationship between variables was examined, it was found that the correlation between HP and age was statistically non-significant ($r = -0.36$; $P = .091$). However, the correlation between HP and LF-PTA was greater and statistically significant ($r = -0.43$; $P = .043$). The data are shown in Figure 1.

As shown in Table 5, only Model 2, based on 2 predictors, was statistically significant (and explained 23.7% of the variance). Age was found to be a non-significant predictor of HP, explaining only 8.9% of the variance in HP by itself. When LF-PTA was included in the model, the explained variance increased to 23.7%, making LF-PTA a significant predictor of HP. The interaction effect of both predictors was not statistically significant ($P = .067$). In summary, hearing thresholds as measured by LF-PTA appear to be more important than age in predicting HP.

DISCUSSION

This study has assessed HP in 23 subjects who were implanted with the Advanced Bionics HiFocus™ SlimJ electrode. Although this lateral wall electrode has been available since 2017, only a few studies have looked specifically at its HP potential.[25,26] Complicating matters, the definition of HP and methods for measuring and classifying it have yet to be fully specified. There are 2 main methods, that of the HEARRING group and the use of low-frequency pure-tone average (LF-PTA), which have both been used to classify HP.[26,27] The aim is to create a number that reflects how well hearing is preserved—in terms of everyday function—and use this number to form distinct HP categories. This issue has been widely discussed in the articles cited here, and it is generally agreed that differences in methods used need to be taken into account when study results are compared.[27]

Table 4. Low-Frequency Pure-Tone Averages in the Implanted Ears. Low-frequency pure tone average was calculated as the average of 0.125, 0.25, and 0.5 kHz

	Min	Max	*M*	SD
Pre	18.33	73.33	54.93	13.76
1 mth	26.67	96.67	71.45	16.15
3 mths	46.67	110.00	72.63	16.93
6 mths	23.33	101.67	70.87	20.45

M, mean; Max, maximum; Min, minimum.

Regarding the HEARRING method, all the patients had measurable hearing after cochlear implantation (HP in group = 100%, mean HP = 58.8%). Six months after implantation, 39.1% of the patients had their hearing preserved completely, 43.5% partially, and 17.4% minimally. These results are similar to those reported by other researchers.

Van de Heyning et al[28] systematically reviewed HP rates with the Med-El medium and longer-length lateral wall electrodes. In cases receiving the Med-El Flex 24 electrode array via a round window and followed up for 4 months, HP preservation in the group was 95.2%.

Both the Advanced Bionics SlimJ and the Med-El Flex 24 electrodes have a similar length (23 and 24 mm) and angular insertion depth (mean 432° and 440°), making them comparable.[29] Nevertheless, outcomes can differ due to factors such as electrode design, surgical technique, and the follow-up period.

Lee et al[30] showed results for 4 different electrodes (Nucleus CI 422/522, Med-El Flex 28, Advanced Bionics 1J, and Oticon Neuro 2). Although these electrode arrays differ from the Advanced Bionics SlimJ, satisfactory HP was achieved. Based on classifications of

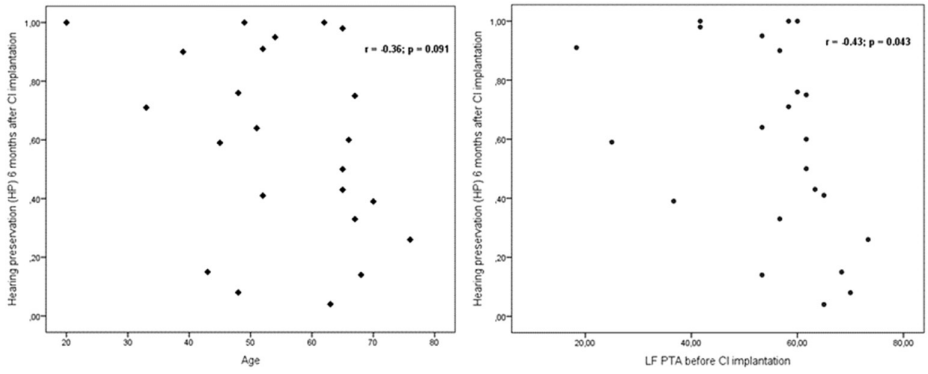

Figure 1. Left panel: correlation between hearing preservation (HP) 6 months after receiving a cochlear implant and age. Right panel: correlation between HP at 6 months and low-frequency pure tone average before cochlear implantation.

Table 5. Regression Models for Hearing Preservation 6 Months After Cochlear Implantation, Taking as Predictors Age and Low Frequency Pure Tone Average Before Cochlear Implantation

		R^2 adj	Predictors	β	t	P
Model 1	$F=3.14$; $P=.091$	8.9%	Age	−0.36	−1.77	.091
Model 2	$F=4.42$; $P=.026$	23.7%	Age	−0.36	−1.91	.071
			LF-PTA	−0.42	−2.26	.035
Model 3	$F=2.81$; $P=.067$	19.8%	Age	−0.34	−1.70	.105
			LF PTA	−0.42	−2.20	.040
			Age*LF-PTA	−0.03	−0.17	.867

β, standardised regression coefficient; *t*, value of test statistic; *P*, statistical significance; R^2_{adj}, adjusted coefficient of determination.

complete, partial, or minimal, HP was achieved in 21%, 35%, and 12%, respectively. Overall, HP in the group was 68%.

In their multicenter comparison of the SlimJ electrode, Eitutis et al[25] shed useful light on the HP issue. Their subjects were implanted with the Advanced Bionics HiRes Ultra Mid-Scala or SlimJ electrodes, and it was found that, overall, HP was better for the straight electrode array (mean HP 54%) than for the midscalar one (mean HP 41%). These results are in line with the figures obtained in the current study (mean HP 58.8%), although there were some differences in the methodology of calculating the results. In that study (34), the degree of HP was calculated using the modified HEARRING group formula. Only 250 and 500 Hz thresholds were included in the calculations instead of all thresholds up to 8 kHz, and the data were collected between 3 and 6 months after CI surgery instead of at a fixed time point.

Functional HP is one of the main goals of modern cochlear implantation. Essentially, maintaining residual hearing leads to better postoperative CI outcomes.[27] There is still a need to achieve a consensus on which method of presenting functional results is the best. However, it is generally believed that frequencies in the 125-500 Hz range are the most important because effective postoperative EAS (Electric Acoustic Stimulation) stimulation is possible in this range.[31]

Among straight types of CI electrodes, HP at low frequencies varies across studies. Generally, HP has been good, with a median hearing loss ranging from 10 to 30 dB, depending on the LF-PTA calculation method used and the postoperative observation time. Lenarz et al,[26] who first investigated HP of the Advanced Bionics SlimJ electrode, found a median hearing loss of 16 dB at 1 month post-surgery and less than 15 dB at 4 months, which aligns with the results (mean LF-PTA change between preoperative and postoperative periods at 1 month, 3 months, and 6 months of 15-17 dB). Lenarz and colleagues also reported that, at 1-month post-surgery, LF-PTA hearing loss for 50% of subjects was less than 15 dB, for 35% of subjects it was between 15 and 30 dB, and for 15% of subjects it was more than 30 dB. Following the same calculation method for hearing loss, this study's results work out to be 52.2%, 34.8%, and 13% at similar observation points. Thus, both studies show very similar HP results for similar subject groups.

Harris et al[32] has shown that, at 1-month post-surgery, LF-PTA hearing loss for 34.5% of subjects was less than 15 dB, for 22.5% of subjects it was between 15 and 30 dB, and for 43% of subjects it was more than 30 dB. Such results are somewhat less encouraging than ours, but it should be noted that Harris and colleagues used 2 different types of electrode arrays, a perimodiolar HiFocus MidScala and a straight HiFocus SlimJ, and so the data are not really comparable. The HiFocus MidScala electrode, a pre-curved type with a stylet, appears more prone to producing cochlear trauma. In the work of O'Connell et al,[33] and looking only at patients receiving a MidScala electrode, LF-PTA hearing loss for 28% of subjects was less than 15 dB at activation; for 28% of subjects it was between 15 and 30 dB, and for 44% of subjects it was more than 30 dB.

Straight electrode arrays from other manufacturers have been the subject of similar studies. Jurawitz et al[34] reported that recipients of the Cochlear Hybrid L24 electrodes had a median hearing loss of 10 dB at the initial fitting and 15 dB after 24 months. Results for the Cochlear CI422 electrode were 14.4 dB and 30 dB, respectively. Generally, this shorter electrode array is characterized by better HP, with a mean threshold below 15 dB.

Finally, it is of interest to turn attention to 2 other factors examined here that affect HP: age and pre-operative LF-PTA. In the regression model, only pre-operative LF-PTA significantly predicted HP. This finding is consistent with that of other authors. Lee et al[30] reported that the pre-operative hearing threshold at 250 Hz was significantly associated with higher rates of HP, especially if the threshold was equal to or better than 60 dB HL (in the group, the pre-operative average value was 52 dB HL). Similarly, Wanna et al[27] confirmed in a large cohort that the lateral wall pre-operative threshold at 250 Hz predicted long- and short-term HP. Again, age was not statistically significant in either of the 2 works cited.

It should be noted that preservation of LF-PTA is a key factor in understanding speech, particularly in noisy environments, and is also important for achieving successful rehabilitation after implantation. It is known that better LF-PTA levels before implantation lead to better outcomes.[35] In particular, Lorens et al[35] reported that, compared to standard CI subjects, HP at low frequencies was very important for speech understanding in a group of partial deafness patients.

This study has some limitations that should be taken into account when interpreting the results. First, the sample size was relatively small, consisting of 23 patients, all recruited from a single center. This may limit the generalizability of the findings to larger populations. In addition, there was no comparison group with an alternative electrode array, which prevents direct comparisons of outcomes between different electrode array types. Future studies with larger, multi-center cohorts and comparison groups would help to validate and extend the findings.

CONCLUSION

Satisfactory HP is possible using the Advanced Bionics SlimJ electrode. High rates of HP obtained with this electrode in the study suggest it is suitable for the surgeon seeking an electrode with adequate cochlear coverage. Moreover, it was found that pre-operative LF-PTA is a factor that contributes more to HP than the patient's age. The better the preoperative thresholds at low frequencies, the higher the chance of preserving residual hearing following cochlear implantation.

Data Availability Statement: Due to the nature of the research and legal (General Data Protection Regulation) requirements, supporting data is not available.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of The Institute of Physiology and Pathology of Hearing (approval number: KB. IFPS:21/2020, date: January 30, 2020).

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

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