Cochlear Implantation in Candidates With Moderate-to-Severe Hearing Loss and Poor Speech Perception

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Objectives/Hypothesis: To determine the improvement in word recognition score (WRS₆₅) after cochlear implant (CI) surgery in hearing aid (HA) users with preoperative hearing threshold ≤ 80 dB HL and inadequate speech recognition scores with HA. Secondarily, to identify predictive factors for WRS₆₅ with a CI (WRS₆₅[CI]) 6 months after surgery, derived from the standard German CI preoperative assessment.

Study Design: Retrospective chart review.

Methods: Retrospective review of all adult patients who received a Nucleus cochlear implant in the ear, nose, and throat department of the University Hospital of Erlangen between January 2010 and April 2019. The inclusion criteria were a preoperative hearing threshold ≤ 80 dB HL in the ear to receive the implantation, German as the native language, and at least 6 months postimplantation care at our center.

Results: The inclusion criteria were met by 128 patients. All but two patients (98.4%) showed a significant improvement, WRS₆₅(CI) versus WRS₆₅ with an (HA) (WRS₆₅[HA]), of at least 15 percentage points (pp). The median improvement was 55 pp with a median WRS₆₅(CI) of 70%. Three preoperative audiometric measures, the maximum word recognition score, age at implantation, and WRS₆₅(HA) were identified as predictive factors for WRS₆₅(CI). For three-quarters of the CI recipients, the score was not poorer than 12 pp below the predicted WRS₆₅(CI).

Conclusions: For patients with a hearing loss ≤ 80 dB HL, cochlear implantation should be considered when speech perception with an HA is insufficient. The prediction model can support counseling in this patient group.

Key Words: Cochlear implant, hearing aid, adult, hearing threshold, speech audiometry. **Level of Evidence:** 4

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INTRODUCTION

Cochlear implantation is an established treatment of patients with severe to profound deafness. In recent years, more and more people with considerable preoperative speech understanding have been provided with a cochlear implant (CI).^{1–5} From the clinical point of view, this population requires particular attention, as there is a risk that cochlear implantation may lead to decreased auditory abilities. Additionally, the identification of predictive factors for individual results of cochlear implantation remains a challenge.

In this context, we and others have investigated the relationships between basic audiometric measures, including

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pure-tone audiogram (PTA), hearing aid (HA) scores, and the maximum word recognition score (WRS) for phonemically balanced monosyllabic words (WRS_{max}; also often referred to as PB_{max}).^{5–9} There is a group of patients with large speech-perception gaps.^{5,6,8–10} This gap is defined as a difference between aided score and WRS_{max}^{5,6} or a clinically comparable measure.^{8–10} Such HA users represent a population where a reliable individual outcome prediction is most desirable. Recently,⁵ WRS_{max} was found useful for individual minimum prediction. In 96% of the cases, postoperative WRS with CI (WR₆₅[CI]) was found to be greater than or equal to WRS_{max}. Nevertheless, this approach is clinically meaningful only for CI candidates with preoperative WRS above 0%. Additionally, as is inevitable for a minimum predictor, an adequate prediction of the specific need for preoperative counseling of patients is still unavailable.

Therefore, the aim of the present study was to investigate the prognostic value of standard audiometric measures in HA evaluation as a part of diagnostic assessment before cochlear implantation. The inclusion criteria aimed at patients with preoperative PTA \leq 80 dB HL but with sufficiently poor speech comprehension for the use of a CI to be indicated; this can be regarded as a borderline condition for cochlear implantation. The inclusion criterion with regard to the preoperative PTA does not allow the determination of one outcomepredicting factor in the established population of CI recipients, namely, the duration of severe-to-profound hearing loss.¹¹⁻¹³ Therefore, the secondary aim of the

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study was to derive a predictive model for this population in which the duration cannot be defined.

MATERIALS AND METHODS

Subjects

We reviewed patient files from all adults who received a Nucleus cochlear implant (CI24RE, CI512, CI532, CI422, CI522) in the ear, nose, and throat (ENT) department of the University Hospital of Erlangen between January 2010 and April 2019. Inclusion criteria were preoperative hearing threshold \leq 80 dB HL in the ear to receive the implant, German as native language, sensorineural hearing loss, and at least 6 months CI rehabilitation at our center. The University of Erlangen Institutional Review Board approved this study. The study was registered under DRKS00018110 with the German register of clinical studies.

Audiometric Measures

In German-speaking countries, the Freiburg Monosyllable Test, a phonemically balanced test, is widely used. It consists of 20 phonemically balanced lists with 20 items each. Normalhearing listeners achieve 50% and 100% at 30 dB SPL and 50 dB SPL, respectively (DIN 45621). Hearing-impaired subjects with mild or moderate hearing losses typically require higher presentation levels to achieve $\mathrm{WRS}_{\mathrm{max}}\,\mathrm{scores}$ of 100%. For severe and profound hearing losses, scores of 100% are usually not achieved by all subjects, even at levels near their level of discomfort.^{14,15} WRS_{max} was determined with air-conduction headphones (DT48; Beyerdynamic, Heilbronn, Germany) in combination with a standard audiometer. One test list was presented initially at 65 dB SPL, and the correct word score in percentage was recorded. The presentation level was then increased in steps of 10 to 15 dB until a maximum score of 100% was achieved. In cases of scores below 100%, the measurement was continued at increased levels until the subject indicated that the loudness was uncomfortable. In such cases, WRS_{max} refers to the score with the last completely measured test list below the individual's level of discomfort. The audiometric limit for the speech presentation level was 120 dB SPL. Typically, for our group of CI candidates, the $\mathrm{WRS}_{\mathrm{max}}$ was measured at presentation levels of ${<}100$ dB SPL (in 19% of the cases), 105 to 115 dB SPL (71%), or 120 dB SPL (10%). The WRS_{65} with an HA (WRS_{65} [HA]) was measured in free field in an anechoic booth. The loudspeaker was placed 1.5 m in front of the patient (0° azimuth). In all measurements, each ear was tested separately. The contralateral ear was masked appropriately by using headphones (DT48; Beyerdynamic). The puretone average threshold for the frequencies 0.5, 1, 2, and 4 kHz (four-frequency pure-tone average [4FPTA]) was evaluated for each ear for air conduction.

All CI candidates had at least 3 months of HA experience. The last fitting process, including verification of HA fitting, was within the 3 months before the audiometric assessment of CI candidacy at local HA centers. Before measurements, HA function was checked technically by qualified staff. Appropriate amplification was checked by using a coupler or by in situ measurements.

Postoperative Audiometry

Postoperative scores with CI for the Freiburg monosyllabic words at 65 dB SPL (WRS₆₅[CI]), were measured 6 months after implantation. The same audiometric setup as for the preoperative WRS₆₅(HA) was used, including appropriate masking of the nontest ear.

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Data Analysis

The MathWorks (Natick, MA) MATLAB software version R2018a was used for all calculations and figures. Spearman rank correlation analysis was performed for identification of suitable input variables for a prediction model. A general linearized logistic regression model was applied to the data to predict the WRS₆₅(CI). The Kolmogorov-Smirnov test was applied to test for standard normal distribution. Significant differences were determined according to the characteristics of the Freiburg monosyllable test.¹⁶

RESULTS

Subjects

From January 2010 to April 2019, 926 adult patients received a Nucleus cochlear implant system. In this population, we identified 128 cases who met the inclusion criteria. The vast majority (n = 126) received a modiolushugging electrode. All subjects used sound processors of the series CP8, CP9, or CP10. Table I summarizes the patients' demographic characteristics, including preoperative findings. Patients are grouped according to their 4FPTA with 10-dB segmentation.

Preoperative Audiological Assessment

The relation between 4FPTA, WRS_{max}, and WRS₆₅ (HA) is shown in Figure 1. To facilitate the reference of this population to a speech-related cutoff criterion for CI candidacy, 1,6,17 subjects scoring more than 30% are highlighted.

Figure 1A and B show that the majority of the patients exhibited a $WRS_{65}(HA)$ and WRS_{max} below the average of a population^{6,18} of HA users typical for a ENT department. Figure 1C shows that the already low WRS_{max} (with headphones) did not reflect, and was less than, the $WRS_{65}(HA)$ in 85% of the cases, yielding a median speech perception gap of 25 percentage points (pp).

Postoperative CI Evaluation

The 6-month results of cochlear implantation in patients with a preoperative 4FPTA better than or equal to 80 dB HL is shown in Figure 2. Figure 2A, B, and C relate the $WRS_{65}(CI)$ to the three preoperative basic audiometric measures 4FPTA, $WRS_{65}(HA)$, and WRS_{max} , respectively. The median score was 70%, with

TABLE I. Patient Characteristics.								
No.	4FPTA, dB HL	Median Age, yr	Median WRS _{max} , %	Median WRS ₆₅ (HA), %				
7	55.8–59.8	54	40	5				
43	61.0–70.0	65	45	10				
78	70.2–80.0	65	35	0				

4FPTA = four-frequency pure-tone average; WRS₆₅(HA) = word recognition score with hearing aid; WRS_{max} = maximum word recognition score for phonemically balanced monosyllabic words.



Fig. 1. Overview of preoperative audiometric measures. (A, B) Word recognition score (WRS). (A) WRS with hearing aid (HA) (WRS65[HA]). (B) WRS_{max} with headphones to the pure-tone loss. (C) Correlates WRS_{max} with WRS_{65} (HA). The rhombs highlight recipients with a preoperative WRS_{65} (HA) above 30%. The dark solid lines in (A) and (B) refer to the average performance of HA users from an earlier study.17 The gray line shown in (C) represents the bisecting line. 4FPTA = four-frequency pure-tone average; $WRS_{max} = maximum$ word recognition score for phonemically balanced monosyllabic words.



Fig. 2. Relationship between pre- and postoperative audiometric measures. (A) Preoperative 4FPTA. (B) Preoperative 4FPTA. Word recognition score (WRS₆₅) with hearing aid (HA) (WRS₆₅[HA]). (C) Preoperative WRS_{max} to the postoperative WRS₆₅ with cochlear implant (WRS₆₅[CI]). WRS₆₅(CI) was measured 6 months after implantation. The rhombs highlight recipients with a preoperative WRS₆₅(HA) above 30%. The boxplot on the right refers to median, first, and third quartile; minimum and maximum of WRS₆₅(CI). 4FPTA = four-frequency pure-tone average; WRS_{max} = maximum word recognition score for phonemically balanced monosyllabic words.

first and third quartiles at 55% and 81.25%, respectively. The comparison of the pre- and postoperative WRS₆₅ in Figure 2B shows that 98.4% of the recipients improved by at least 15 pp. The median improvement was 55 pp. The comparison of WRS₆₅(CI) and WRS_{max} shows that four CI recipients (3%) had a score that was significantly lower than their preoperative WRS_{max}.

Generalized Linear Regression Model

Before the model fitting was performed, a correlation analysis was run across the results of routine measures in HA and CI evaluation: 4FPTA, WRS_{max} , presentation level of WRS_{max} , WRS_{65} (HA), and age. Three of these five variables correlated significantly with the $WRS_{65}(CI)$ and were therefore included in the model. The linear regression model can be arranged to give an equation for a $WRS_{65}(CI)$:

$$WRS_{65}(CI)[\%] = \frac{100}{1 + e^{-(\beta_0 + \beta_1 \cdot WRS_{max} + \beta_2 \cdot age + \beta_3 \cdot WRS_{65}(HA))}}$$
(1)

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	TABLE II.							
	Parameters of the Generalized Linear Regression Model.							
	Estimate	Standard Error	t Statistics	P Value	[β]			
βο	0.84	0.18	4.59	4×10^{-6}				
β ₁	0.012	0.0015	8.07	7×10^{-16}	1/%			
β2	-0.0094	0.0025	-3.72	2×10^{-4}	1/yea			
β3	0.0059	0.0026	2.30	2×10^{-2}	1/%			

Includes 5,120 observations, 5,116 error degrees of freedom. χ^2 statistic versus constant model: 157, *P* value = 9 × 10⁻³⁴.

The summary of the model regression is shown in Table II.

Figure 3A illustrates the fit of the model to the study population. The differences between predicted and measured WRS₆₅(CI) as shown in Figure 3B are not normally distributed ($P < 10^{-29}$). They range from -58 to +29 pp. The median absolute error was 13.5 pp. Among the 33 subjects scoring significantly below the prediction, 31 subjects improved at least by 15 pp and the median improvement was 40 pp.



Fig. 3. Predicted versus measured word recognition score (WRS) with cochlear implant (WRS₆₅[CI]). (A) The x-axis shows the predicted WRS₆₅(CI) according to Equation 1, whereas the y-axis shows the measured WRS₆₅(CI) 6 months after implantation. (B) The distribution of differences between measured and predicted scores. Negative differences correspond to cases in which the recipient's scores were below the predictions. The gray bisecting line indicates equality between model prediction and measured scores.

DISCUSSION

This study shows that cochlear implantation should be considered as a treatment option for moderate-to-severe sensorineural hearing loss for HA users with insufficient speech recognition. In the study population of HA users/CI recipients, 98.4% showed significantly improved ipsilateral speech recognition, with a median $WRS_{65}(CI)$ of 70%. An HA provision is the first-choice treatment in patients with moderate-to-severe hearing loss. However, when an established^{1,6,17} WRS-related cutoff criterion was applied to the data from a recent study in a larger population of HA users,¹⁹ it was found that a considerable percentage scored <30% in the monosyllable test. According to the indication criteria applied in most countries in recent decades, only a limited number of subjects received a CI when residual hearing was present to such a degree. The present study provides data that allow one to estimate WRS₆₅(CI) in CI candidates with a preoperative 4FPTA ≤80 dB HL.

Pure-Tone Audiogram

A correlation between the $WRS_{65}(CI)$ and preoperative 4FPTA was not observed. In previous studies, the PTA was found to have some predictive value.¹¹ This may be explained by the restriction of the current study to subjects with 4FPTA <80 dB HL. This population inevitably consists of subjects with below-average speech recognition related to the 4FPTA. An average HA user with a 4FPTA of 80 dB HL should have a WRS₆₅(HA) score of 20%, whereas a 4FPTA of 60 dB HL is associated with 50%.^{6,19} As shown in Figure. 1A, the lower the 4FPTA, the higher the proportion of underperforming HA users. Consequently, in our population, intrinsic factors limiting HA performance may be more strongly present around 60 dB HL than at 80 dB HL and thus impede a correlation between 4FPTA and $WRS_{65}(CI)$. Such intrinsic factors, if related to etiology, could not be considered, as the study population was too small to allow account to be taken of expected prevalence and effect size.¹¹

Maximum Word Recognition Score, Aided Word Recognition Score, and Speech-Perception Gap

The preoperative $\ensuremath{W\!R\!S_{max}}\xspace$ was found to have the strongest correlation with, and predictive value for, WRS₆₅(CI). As already discussed, ⁵ this finding is limited to the group of CI candidates and recipients with nonzero preoperative speech perception. Beside the contribution to the predictive model, the $\ensuremath{\mathrm{WRS}_{\mathrm{max}}}$ allows a quick check for the minimum WRS₆₅(CI). Only four recipients scored significantly lower than their preoperative WRS_{max} meaning that in 97% of the cases the WRS_{max} was reached or exceeded. The WRS₆₅(HA) has the smallest effect on outcome prediction according to Equation 1. However, it is $WRS_{65}(HA)$ together with the speech-perception gap^{8,9} that helps to identify patients with a high likelihood of benefiting from a CI. The effect of WRS₆₅(HA) might be interpreted as a tolerance of acoustic amplification (loud sounds), which might be considered a good precondition for acceptance of electrical stimulation.

Age

A higher age at implantation was found to have a detrimental effect on WRS₆₅(CI), which is in accordance with results of previous studies.^{12,20} However, these findings were derived from results in a population that did not exhibit considerable preoperative WRS. Although the detrimental effect of age itself is reconfirmed, no correlation between age and improvement was found. This does not contradict the previous studies,^{12,20} because the WRS_{max}— as the strongest prognostic factor for WRS₆₅(CI)—is negatively correlated with age, even if corrected for 4FPTA.¹⁸ Furthermore, for the second speech-related prognostic factor WRS₆₅(HA), significant age effects were found.²¹

Predictive Model and Counseling of CI Recipients

The unexplained variability in Figure 2A is evident. However, from the viewpoint of a clinician counseling a CI candidate, it might be considered a minor issue if the patient exceeds the predicted score. Consequently, an asymmetric view on descriptive statistics is appropriate; 75% of the CI recipients did not have a score poorer than 12 pp below the predicted WRS₆₅(CI).

A regression model based on average characteristics in a population of patients with widely varying characteristics will inevitably result in a considerable number of measured scores below prediction. The above interpretation offers a way of interpreting the results for practical purposes. Of special clinical relevance are those cases with the largest differences from the prediction; 17 of them missed the predicted score by more than 20 pp. Those cases highlight a recently discussed aspect of CI provision, the enigma of poor performance.²² The data in Figure 3 suggest a dynamic definition of poor performance. It is not just the absolute score that indicates a poor performance. There are two obviously poor-performing CI recipients with $WRS_{65}(CI) = 0\%$. Additionally, we consider the two subjects who scored 42.5% and 50% (Fig. 3A) to be poor performers, because they failed to meet the predicted score by more than 30 pp. Cases with a preoperative $WRS_{65}(HA)$ of 0%, together with a rather low WRS_{max} , would not necessarily be regarded as poor-performing recipients if they have a score of 50% 6 months after implantation. Future studies on poor performance, with a reference to a prediction model, may provide new insights and may lead to a clinically relevant definition of poor performance and thus to optimum utilization of professional resources.

Borderline CI Candidacy

The results suggest that in some cases of underperforming HA users, cochlear implantation might be considered an alternative. HA users with HA scores up to 50% and a 4FPTA between 60 and 80 dB HL do show improved WRS₆₅(CI) in 98% of underperforming HA users.

Language-Speci c Aspects

CI results in a German-speaking population⁵ using Freiburg monosyllables at 65 dB SPL are comparable to consonant-nucleus-consonant scores²⁰ at 60 dBA. Additionally, recent studies in Anglo-American HA users⁸⁻¹⁰ found a similar relation between $\ensuremath{WRS_{max}}\xspace$ and WRS₆₅(HA). Patients with high WRS_{max} but larger speech perception gaps⁸⁻¹⁰ may be considered as CI candidates in the presence of insufficient $WRS_{65}(HA)$. Both noncorrelation^{$\hat{8}$,10} between WRS_{max} and WRS₆₅(HA), and correlation between WRS_{max} and speech-perception gap, are in line with our findings. As discussed for the 4FPTA and its absence of correlation with $WRS_{65}(CI)$, one cannot exclude the possibility that the study population and the place of recruitment generate a negative bias; for example, a recipient with a high WRS_{max} and a high WRS₆₅(HA) is less likely to consult a hearing center. In summary, the findings in German and Anglo-American HA users represent language-independent results. Therefore, the model framework may be applicable to other languages.

Study Bias and Limits

It is evident from Figure 1 that the study population consists of HA users with $WRS_{65}(HA)$ mainly below the average for HA users. This gives rise to a PTA-dependent bias. The better the 4FPTA, the further the $WRS_{65}(HA)$ is below average. It is reasonable to assume that this bias is typical for the patient population at many CI centers, because a good HA user would not be regarded as a CI candidate. Etiology, a relevant factor, was excluded from the model framework. The prevalence of the most influential etiologies¹² is too low to be included in our analysis of 128 cases.

The study focused on speech perception in quiet. Speech testing in noise is in general a valuable measure for characterizing a recipient's performance. However, not all patients can undergo this testing procedure before or even after cochlear implantation.²³ There is a potential value in adding speech-in-noise testing to a predictive model once a test battery has been found to be applicable in this population and established in clinical routine. Objective preoperative measures may improve the model prediction as well. However, clinical routine suffers from a lack of adequate preoperative measures.²² Peri- and postoperative measures of compound action potentials are currently in the focus of many studies.^{24,25} They may potentially explain the remaining variability, yet they apparently cannot contribute to the preoperative counseling of CI candidates. To summarize, for recipients with considerable preoperative hearing, an improved objective assessment before surgery may improve outcome prediction.

CONCLUSION

For patients with a hearing loss ≤ 80 dB HL, cochlear implantation should be considered if HA use results in insufficient speech recognition. Improved speech recognition through cochlear implantation was observed in about 98% of the cases, with a median WRS₆₅(CI) of 70% 6 months after implantation. The prediction model derived may contribute to the individual CI candidate's counseling process, especially to help mold appropriate expectations regarding postimplant speech perception.

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