Hearing Preservation With the Use of Flex\textsuperscript{20} and Flex\textsuperscript{24} Electrodes in Patients With Partial Deafness

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Objective: To evaluate the impact of electrode length on hearing preservation (HP) in Partial Deafness Treatment–Electrical Complement (PDT-EC) subjects.

Study Design: Retrospective case review.

Setting: Tertiary referral center.

Patients: Twenty-three PDT-EC patients (with preoperative air-conduction thresholds $\leq$ 30 dB up to 500 Hz) were divided into two groups: Flex20 electrode (Med-EL GmbH, Innsbruck, Austria) (12 patients) and Flex24 electrode (Med-EL GmbH, Innsbruck, Austria) (11 patients).

Interventions: All participants were subjected to minimally invasive cochlear implantation using the round window approach.

Main Outcome Measure(s): Pure tone audiometry (125–8000 Hz) was performed preoperatively and at 1, 6, 12, and 24 months postoperatively. HP was established using the HEARRING group formula. Speech understanding was assessed preoperatively and at 12 and 24 months postoperatively.

Results: Analysis of HP for every individual indicates that more than half the patients with Flex20 and Flex24 had complete HP at 6 months follow-up. None of the patients from either group had complete loss of hearing. At activation, average air-conduction thresholds for low frequencies (125–500Hz) were slightly better for the short electrode ($M = 29.03$) than for the long ($M = 39.10$) but the difference was not statistically significant ($p = 0.067$). The effect of electrode (Flex20 versus Flex24) was not significant in terms of pure tone audiometry and speech recognition at long-term follow-up.

Conclusions: In the early postoperative period, complete HP was possible in a majority of patients from both groups, but slightly better HP outcomes were achieved by Flex20. In the long term, the length of the electrodes does not affect the degree of HP or speech understanding.

Key Words: Cochlear implant—Hearing preservation—Med-EL Flex electrodes—Partial deafness treatment.

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bioethics committee after recruiting only 13 patients: six in a group with shorter electrodes (medium, 20.9 mm) and seven in a group with longer (standard, 26.4 mm) electrodes. The reason was that the results of a preliminary statistical analysis 6 months postoperatively revealed that the use of the longer electrodes was associated with significantly better speech understanding. The authors suggested that deeper insertion angles with the standard arrays produced greater degrees of cochlear coverage in the apical regions and a better or more natural tonotopic place representation during stimulation. However, it should be noted that the authors did not specify the precise hearing thresholds of their patients, saying just that they were “standard candidates for cochlear implantation” and “had moderate to profound hearing loss and poor speech perception ability” in the preoperative period (without precisely specifying the hearing thresholds in both groups).

The methodological diversity of research conducted in the area of HP—particularly in terms of reporting initial hearing status—creates difficulties in comparing results and drawing conclusions based on appropriate meta-analyses (11). To assess the impact of electrode length on HP outcomes, it is necessary to conduct a study in a homogeneous group of PDT patients in terms of their preoperative residual hearing. This is particularly important in patients with normal or nearly normal hearing (<30 dB HL) up to 500 Hz and severe-to-profound hearing loss above 500 Hz. According to the classification of Skarzynski et al. (12,13), these patients qualify as Partial Deafness Treatment—Electrical Complementation (PDT-EC).

The aim of this study was to evaluate the impact of electrode length on HP in a selected group of adults with PDT-EC receiving one of two kinds of flexible electrodes: the longer 24 mm electrode array or shorter 20 mm electrode array.

MATERIALS AND METHODS

Eligibility Criteria

Records of all cochlear implantation conducted in our center were carefully studied to make sure that the participants complied with the following eligibility criteria:

1) implanted at age 18 years or older;
2) postlingual onset of deafness;
3) preoperative hearing loss qualifying a patient into the PDT-EC group according to Skarzynski et al. (12) (i.e., air-conduction thresholds ≤30 dB HL up to 500 Hz and severe-to-profound hearing loss above 500 Hz);
4) full medical and audiometric documentation of pre- and postoperative (minimum 24 mos) hearing results;
5) use of a minimally invasive surgical approach through the round window according to the Skarzynski six-step procedure (13,14) and a fully inserted Flex20 or Flex24 electrode set.

Participants

The evaluated group consisted of 23 patients with PDT-EC. Subjects were implanted unilaterally with a Med-EL cochlear implant (CI) (Med-EL GmbH, Innsbruck, Austria) between August, 2014 and July, 2016. The participants were divided into two groups based on the electrode length.

One group (n = 11) received the longer Flex24 electrode. This is a 24-mm electrode array featuring Flex-Tip technology and designed for combined Electric Acoustic Stimulation (EAS) with insertion of less than 1.5 turns. It has 19 platinum electrode contacts with an active stimulation length of 20.9 mm. Diameter at the basal end is 0.8 mm and dimensions at the apical end are 0.5 × 0.3 mm.

The second group (n = 12) received the shorter Flex20 electrode. This 20-mm electrode array also features Flex-Tip technology and has a diameter at the basal end of 0.8 mm and dimensions at the apical end of 0.5 × 0.3 mm. However, its 19 platinum electrode contacts have a shorter active stimulation length of 15.4 mm, designed for cases of partial deafness or other specific needs or surgical preferences.

The decision to use the shorter or longer electrode was based on preoperative air-conduction thresholds. In both groups of PDT-EC patients, the results of pure-tone audiometry confirmed hearing thresholds of less than or equal to 30 dB HL up to 500 Hz. However, the Flex20 was offered to patients with more residual hearing (<75 dB HL) at 750 and 1000 Hz. If subjects had less residual hearing, they were assigned the longer electrode.

One month postoperatively, 22 subjects were programmed with electric stimulation only, due to well-preserved low-frequency hearing thresholds. The acoustic unit (system Duet) was activated 1 month postoperatively in one patient with the Flex24 who had postoperatively air-conduction thresholds of 60 to 75 dB HL for low frequencies (125–500 Hz). This patient also used hearing aid in the non-CI ear. Additionally, after 12 months follow-up, we observed a significant deterioration of hearing thresholds (to 30–85 dB HL) at low frequencies in one subject with Flex24, so the acoustic unit was also activated in this case.

Surgical Procedure

The decision on qualifying the PDT-EC patient for cochlear implantation was made on the basis of a lack of sufficient benefits from conventional hearing aids (obtaining a score of ≤60% in the monosyllabic word test in the best-aided condition) and appropriate motivation to undergo treatment. All procedures were conducted by the same senior surgeon from our tertiary referral center. In all cases, a minimally invasive surgical approach through the round window according to the Skarzynski 6-step procedure (14) with full insertion of CI electrode was used. Steroids were given in all patients with PDT: 0.1 mg/kg of body mass per day of dexamethasone administered intravenously in two equal doses per day (about 0.5 h before cochlear implantation and 3 h after). Dosing with steroids was continued for 3 to 4 days (15).

Audiometric Assessment and Hearing Preservation

Hearing threshold measurements were conducted on all patients five times: preoperatively, 1 month after the operation (at activation), 6 months after the operation, 12 months after the operation, and 24 months after the operation. HP was calculated based on pure-tone audiometry at 11 audiometric frequencies (0.125, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6, and 8 kHz) and was calculated using the Skarzynski et al. (16) formula:

\[
HP = \left(1 - \frac{PTA_{\text{post}} - PTA_{\text{pre}}}{PTA_{\text{max}} - PTA_{\text{pre}}}\right) \times 100\% 
\]
In this equation, PTA_{pre} is the pure tone average measured preoperatively, PTA_{post} is the pure tone average measured postoperatively, and PTA_{max} is the maximum level generated by a standard audiometer (provided in detail on the HEARING Internet site (17)). The HP values can be divided into: loss of hearing (no detectable hearing), minimal HP (range, 1–25%), partial HP (26–75%), and complete HP (>75%).

**Speech Understanding Evaluation**

The Pruszewicz monosyllabic word test was conducted in free-field at the preoperative period under unaided and aided configurations (with hearing aids) under the best conditions. The test was conducted in quiet and in noise at a signal-to-noise ratio of +10 dB. The signals were presented at 65 dB SPL. The Pruszewicz monosyllabic word test in free-field was also used to assess auditory benefits after cochlear implantation at the 12 and 24 months follow-up.

**Ethical Considerations**

All procedures were in accordance with the ethical standards of the responsible institutional review board (approval KB.IFPS:12/2018) and of the Helsinki Declaration. The first author of the current work was the principal investigator. Due to the retrospective nature of the study, no informed consent was obtained from the participants.

**Statistical Analyses**

Mixed-design analysis of variance (ANOVA) was conducted to determine the impact of electrode length on audiometric results:

1. air-conduction thresholds for all audiometric frequencies (125–8000 Hz)
2. air-conduction thresholds for low audiometric frequencies only (125–500 Hz)
3. word recognition in quiet and noise.

The level of statistical significance was established at \( p < 0.05 \). For statistical analysis, IBM SPSS Statistics v.24 software (IBM, New York, U.S.A.) was used.

**RESULTS**

Characteristics of the study participants (sex, operated ear, etiology of hearing loss, age at operation, and age at diagnosis) according to group (shorter or longer electrodes) are presented in Table 1.

**Hearing Preservation in PDT-EC Groups**

The average pre- and postoperative air-conduction hearing thresholds in each group of Flex^{20} and Flex^{24} electrodes are shown in Figure 1. Exact descriptive statistics of pre- and postoperative air-conduction thresholds are presented in the supplementary table, http://links.lww.com/MAO/A821. The HP outcomes for each postoperative follow-up period (activation to 24 months follow-up) are presented separately for patients with Flex^{20} and Flex^{24} electrodes in Table 2.

The analysis of HP results for each individual indicates that in the short-term (up to 12 months follow-up), all
patients with Flex\textsuperscript{20} and Flex\textsuperscript{24} had complete or partial HP. Importantly, none of the patients from either group had complete loss of hearing in the long term (up to 24 months follow-up). In one patient with Flex\textsuperscript{20}, complete HP was observed up to 6 months postsurgery, and then a gradual, substantial deterioration of hearing occurred to reach a minimal HP at the long-term (24-month) follow-up.

The average pre- and postoperative air-conduction thresholds across all audiometric frequencies (125–8000 Hz) and low-frequencies (125–500 Hz) for both groups of patients are summarized in Table 3.

### Average Air-Conduction Threshold Across All Frequencies (125–8000 Hz)

Overall, there was a significant effect of time on the mean audiometric thresholds: $F = 28.79; \ p < 0.001; \ \eta^2 = 0.578$. For both sets of electrodes, mean air-conduction threshold across all frequencies was the smallest before implantation but remained stable from activation until 24 months postoperatively. The effect of electrode was nonsignificant: $F = 1.93; \ p = 0.179; \ \eta^2 = 0.084$. There was no significant interaction effect (time x electrode): $F = 0.60; \ p = 0.597; \ \eta^2 = 0.028$, but it was noticed that there was a difference between sets of electrodes at the activation period (1 month after implantation). The overall mean air-conduction thresholds were better for the short electrode ($M = 74.34$) than for the long electrode ($M = 81.03$), but only at activation ($p = 0.029$).

### Average Air-Conduction Threshold for Low Frequencies (125–500 Hz)

For low frequencies, the effect of time on audiometric thresholds was statistically significant: $F = 14.27; \ p < 0.001; \ \eta^2 = 0.405$. For both sets of electrodes, mean air-conduction threshold across low frequencies was the smallest before implantation but remained stable from activation to 24 months postoperatively. The effect of electrode was nonsignificant: $F = 1.07; \ p = 0.312; \ \eta^2 = 0.049$. There was no significant interaction effect (time x electrode): $F = 0.83; \ p = 0.451; \ \eta^2 = 0.038$, but at activation mean air-conduction thresholds for low frequencies were slightly better for short electrodes ($M = 29.03$) than for long electrodes ($M = 39.10$) but the difference was not statistically significant ($p = 0.067$).

### Table 2. Hearing preservation outcomes for groups of patients with Flex\textsuperscript{20} and Flex\textsuperscript{24} electrodes at each follow-up

| Hearing Preservation Evaluation | Complete HP n (%) | Partial HP n (%) | Minimal HP n (%) | Loss of Hearing n (%) |
|---------------------------------|-------------------|------------------|-----------------|----------------------|
| **Period** | Flex\textsuperscript{20} | Flex\textsuperscript{24} | Flex\textsuperscript{20} | Flex\textsuperscript{24} | Flex\textsuperscript{20} | Flex\textsuperscript{24} | Flex\textsuperscript{20} | Flex\textsuperscript{24} |
| At activation | 8 (66.7) | 8 (72.7) | 4 (33.3) | 3 (27.3) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Result 6 months | 6 (50.0) | 7 (63.6) | 6 (50.0) | 4 (36.4) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Result 12 months | 5 (41.7) | 6 (54.5) | 7 (58.3) | 5 (45.5) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Result 24 months | 5 (41.7) | 5 (45.5) | 6 (50.0) | 6 (54.5) | 1 (8.3) | 0 (0) | 0 (0) | 0 (0) |

### Table 3. Average pre- and postoperative air-conduction thresholds across all audiometric frequencies (125–8000 Hz) and for low audiometric frequencies only (125–500 Hz) in groups of patients with Flex\textsuperscript{20} and Flex\textsuperscript{24} electrodes

| Range of Frequencies Tested | 125–8000 Hz | 125–500 Hz |
|-----------------------------|------------|-----------|
| **Period**                  | Min | Max | $M$ | SD | Me | Min | Max | $M$ | SD | Me |
| Flex\textsuperscript{20} (n = 12) | Preoperative | 54.55 | 79.32 | 64.13 | 7.09 | 62.27 | 5.00 | 30.00 | 19.86 | 7.29 | 20.00 |
| At activation | 57.73 | 85.45 | 74.34 | 7.56 | 76.13 | 11.67 | 56.67 | 30.00 | 16.22 | 25.83 |
| Result 6 months | 64.09 | 91.36 | 75.61 | 7.95 | 74.09 | 6.67 | 66.67 | 30.00 | 16.22 | 25.83 |
| Result 12 months | 61.82 | 97.73 | 78.03 | 10.32 | 75.68 | 6.67 | 71.67 | 33.47 | 19.42 | 27.50 |
| Result 24 months | 61.82 | 104.55 | 81.44 | 13.06 | 75.63 | 6.67 | 81.67 | 40.14 | 25.17 | 28.33 |
| Flex\textsuperscript{24} (n = 11) | Preoperative | 49.09 | 81.82 | 68.59 | 68.59 | 67.22 | 10.00 | 30.00 | 20.76 | 6.47 | 21.66 |
| At activation | 73.18 | 92.50 | 81.03 | 81.03 | 80.45 | 25.00 | 73.33 | 39.09 | 14.05 | 35.33 |
| Result 6 months | 70.91 | 88.64 | 80.02 | 80.02 | 79.54 | 21.67 | 63.33 | 37.72 | 11.29 | 35.00 |
| Result 12 months | 68.18 | 97.27 | 81.79 | 81.79 | 79.53 | 21.67 | 73.33 | 40.00 | 16.55 | 35.02 |
| Result 24 months | 71.82 | 100.00 | 83.18 | 83.18 | 80.45 | 21.67 | 75.00 | 42.58 | 17.82 | 33.33 |

SD indicates standard deviation.
Speech Understanding in PDT-EC Groups

Before surgery all patients reported a lack of benefit from conventional hearing aids. Ten of 23 patients used a unilateral hearing aid before surgery of which only two reported regular use of the prosthesis. Only one patient used bilateral hearing aids before surgery. After cochlear implantation, this patient (with Flex24) continued to use bilateral stimulation (electroacoustic stimulation in the implanted side and a hearing aid in the non-CI ear). The others 22 of 23 patients used monaural electrical stimulation (including one patient using electroacoustic stimulation).

The results of the Pruszewicz monosyllabic word test conducted preoperatively and at 12 and 24 months after surgery are shown in Figure 2.

The results showed a steady improvement over time in speech understanding in quiet and noise for both groups of patients. A significant improvement in speech understanding was also observed in the single patient using Flex20 in whom a minimal HP was observed at the 24-month follow-up. In this patient (with electroacoustic stimulation in the operated ear), understanding of monosyllabic words increased from 5 to 90% in quiet and 0 to 75% in noise at the 24-month follow-up.

Word Recognition in Quiet

The effect of time was statistically significant: $F = 106.58; p < 0.001; \eta^2 = 0.856$. For the short electrodes, mean speech recognition in quiet was 26% before implantation and improved to 73% at 12 months and to 78.5% at 24 months postoperatively. For the long electrodes, mean speech recognition in quiet was 30% before implantation and improved to 78.5% at 12 months and to 86.5% at 24 months postoperatively. The effect of electrode was nonsignificant: $F = 0.75; p = 0.398; \eta^2 = 0.040$. There was no significant interaction effect (time x electrode): $F = 0.84; p = 0.428; \eta^2 = 0.045$. Word recognition in quiet was similar for both electrodes in each period.

Word Recognition in Noise

The effect of time was statistically significant: $F = 95.59; p < 0.001; \eta^2 = 0.839$. For the short electrodes, mean speech recognition in noise was 7.5% before implantation and improved to 57.5% at 12 months and to 67% at 24 months postoperatively. For the long electrodes, mean speech recognition in noise was 6.5% before implantation and improved to 58% at 12 months and to 72% at 24 months postoperatively. The effect of electrode was nonsignificant: $F = 0.02; p = 0.885; \eta^2 = 0.001$. There was no significant interaction effect (time x electrode): $F = 0.25; p = 0.754; \eta^2 = 0.014$. Word recognition in noise was similar for both electrodes at each period.

DISCUSSION

Ongoing scientific and clinical studies on preserving cochlear structure and potentially preserving residual low-frequency hearing have resulted in the development of thinner, shorter, and more flexible LW electrodes (18). According to the manufacturer, both the Flex20 and Flex24 LW electrodes, with insertion depths of less than 1.5 turns, makes it possible to reduce trauma and increase the chance of HP. A special
tapered tip and ultra-flexible wave-shaped wires have been developed to increase mechanical flexibility. We found that at the first follow-up (at activation), slightly better HP outcomes were seen in PDT-EC patients which used the short, flexible 20 mm electrodes. At longer follow-up, electrode length was not associated with degree of HP.

When evaluating HP after CI, a limitation of our study is lack of information about the location of the electrode within the cochlea. A CT scan is not routinely performed on all patients undergoing cochlear implantation. It is widely accepted that to limit trauma during electrode insertion, the electrode array should be positioned entirely within the ST (6). Some evidence has suggested that LW electrodes are more likely to reside solely within the ST than other array designs (3,4,6).

Wanna et al. (19) compared outcomes between LW and PM electrodes and found that more LW electrodes (89%) resided completely within the ST than did their PM counterparts (58%). When they compared three surgical approaches, the authors concluded that both enlarged RW and standard RW procedures had higher rates of complete ST insertion than did cochleostomies, and this pattern held true regardless of the electrode type. Mady et al. (4) assessed whether electrode type (LW and PM) with full-length arrays produced by the same manufacturer affects HP. At short-term (1 mo) follow-up, LW electrodes were associated with significantly better HP than MP electrodes. At long-term (1 yr) follow-up, electrode type was not associated with HP or outcomes of speech perception. However, the authors note that at a long-term follow-up, less patients in the LW group had audiometric testing data than did patients in the PM group. Surgical approach also differed by electrode type, and insertion of the electrode via the round window was more frequently performed in the group of patients who received the LW electrode. Achieving an improvement in speech understanding is an important goal in the treatment of deafness and partial deafness. The better that preoperative residual hearing may worsen over time following CI is in line with previous reports (25,26). Most of our PDT-EC patients had progressive hearing loss, which was confirmed by audiometric testing. Our observation that residual hearing may worsen over time following CI is line with previous reports (4,27). In the light of these findings, we suggest that using the longer Flex24 electrode in PDT-EC patients may be a better approach.
choice, especially in the long-term. However, to make a firm conclusion on this, we need additional studies. Due to the small sample size of our study, its power was not adequate to detect statistical significance (it was lower than 80%). To have a sample size adequate for detecting a difference between the Flex$^{20}$ and Flex$^{24}$ electrodes 24 months after implantation, it be necessary to set up an inter-center collaboration and collect results from a large group of PDT-EC patients.

CONCLUSION

In early postoperative observations, complete HP was possible in the majority of patients from both groups, although slightly better HP outcomes were achieved by the Flex$^{20}$. In the long-term, however, the electrode length (20 or 24 mm) does not affect the degree of HP or speech understanding, at least in the hands of an experienced otosurgeon. Considering that HP is also possible using a deeply inserted long electrode array, and that most patients have progressive hearing loss, the use of a longer, flexible electrode seems to be a better choice.

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