WIDEXINVESTIGATION

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INVESTIGATING THE USE OF A **NEW ENERGY** SOURCE FOR **HEARING AIDS**

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Introduction

Traditionally, Zinc-Air cells have been used to power hearing aids, and lately, rechargeable batteries have seen an increase in popularity. With the introduction of the WIDEX ENERGY CELL™, WIDEX offers a true alternative to both these options, an option that takes the users' needs for reliability, efficiency and usability into account. However, the journey to a reliable, efficient and user-friendly final system has not been taken lightly. This paper details an early pilot clinical investigation in the development of the WIDEX ENERGY CELL technology.

Purpose

The purpose of the pilot clinical investigation was:

- To evaluate the reliability of hearing aids that use ENERGY CELL Technology by investigating whether the users who wore the experimental hearing aids experienced power dropouts.
- To explore whether sound artifacts related to ENERGY CELL pressure equalization were audible and perceived as annoying by hearing aid users.

Background: Fuel Cell technology in a hearing aid

Fuel Cell technology has been used for many years. Today, applications of Fuel Cell technology can be seen in the car industry and in power back-up systems. The experimental device for the pilot clinical investigation utilized WIDEX ENERGY CELL technology which is based on Fuel Cell technology. In Fuel Cell technology, as well as in WIDEX ENERGY CELL technology, chemical energy is converted into electrical energy. The ENERGY CELL includes a stainless-steel reservoir, which can contain approximately 0.2 mL methanol solution. The methanol and water inside the ENERGY CELL are converted into protons, electrons and carbon dioxide via an anode catalyst. When the protons and electrons meet air inside the ENERGY CELL, they react and the electrical energy is produced. The biproducts from this reaction are water and carbon dioxide. The ENERGY CELL requires a daily refill (0.2 ml) of methanol from a Refill Unit (which was not ready for use in this pilot clinical investigation). The ENERGY CELL is refilled in just 20 seconds and can keep the hearing aid fully powered for at least 24 hours.

Figure 1 The experimental hearing aid.

Method

Participants

Ten participants completed the pilot clinical investigation. Five were male, five were female. They were aged between 66 and 89 years, with a mean age of 74 years, ranging from 66 to 89 years of age. The hearing losses of the participants varied from mild to moderate as illustrated in Figure 2.

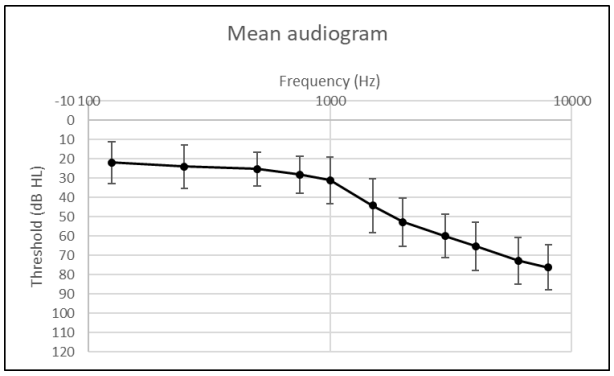

Figure 2 Participants' audiograms shown as means and standard deviations.

The inclusion criteria for the pilot clinical investigation were the following:

- Being informed about the study and signing the informed consent form.
- Experienced hearing aid users who had used hearing aids for more than one year.
- Willingness to come to Widex headquarters every day for refilling of the ENERGY CELL power source.
- At least 18 years of age (and having full legal capacity).
- Binaurally fitted hearing aids (hearing aids on both ears).
- Mild to moderate hearing loss within the device specifications, and more specifically within the recommended fitting range of the S or M receiver (small or medium 'speaker' of the hearing aids).
- Preferably the hearing losses across the group of participants should vary in degree and configuration to challenge the fitting range and hence the power consumption of the experimental hearing aids.
- Both hearing losses allowing open fit ear tips and hearing losses requiring closed or vented ear molds were represented.

Exclusion criteria were the following:

- Widex employees.
- Pregnant women.
- Malformation of ear or ear canals.
- Hyperacusis (abnormal sensitivity to loud sounds).
- Documented cognitive impairments such as e.g. Alzheimer's or dementia.
- Employed by or otherwise affiliated with competitors.

Experimental hearing aid

Participants were fitted with experimental UNIQUE hearing aids, modified so they were able to utilize WIDEX ENERGY CELL technology. The hearing aids were fitted with S or M EASYWEAR receivers and Instant open, Instant Tulip, CRET soft or Custom hard ear-tips, depending on the participants' hearing loss and outer ear shaping. Also, participants were provided with a hearing aid remote control (RC-DEX).

Design

The pilot clinical investigation was designed as a case study collecting data on the use of a new experimental hearing aid using WIDEX ENERGY CELL technology. Both objective (hearing aid log data) and subjective data (collected through the "Fuel Cell study questionnaire") were collected and analyzed.

Each day the participants reported on the following questions:

- Have you experienced sound dropouts for a shorter or longer period of time?
- Have you experienced audible intake of air in the hearing aid? (A bubbly sound).

At the pilot clinical investigation visits (which fell on five working days) the following procedure was followed:

- The investigator or project participant went through the comments in the filled-in "Fuel Cell study questionnaire" with the participant.
- The experimental hearing aids were refilled by a trained employee.
- The Widex log was saved from the hearing aids and the log was restarted.

Results

Data collected via the "Fuel Cell study questionnaire" and via the hearing aid log data provided numerical data to be analyzed quantitatively. Also, the study was designed as a case study where participants were encouraged to express their observations on the experimental hearing aids. These approaches to

gathering data called for a mixed method approach of drawing on both quantitative and qualitative methods.

In theory, 10 participants x two hearing aids x five test days could equal 100 test days reported subjectively. In practice, 97 test days or 48 test data pairs containing left and right hearing aid log data were logged.

Subjectively reported power dropouts

Participants' reporting on major (> 10 minutes) and minor (< one minute) power dropouts are summarized in Table 1 and Table 2. No power dropouts between 1 and 10 minutes were reported.

	Major power dropouts > 10 minutes				
Participant	Day 1	Day 2	Day 3	Day 4	Day 5
1	0	0	0	0	0
2	0	0	1	1	1
3	0	0	0	0	0
4	0	0	0	0	0
5	0	0	0	0	0
6	0	0	0	0	0
7	0	0	0	0	0
8	0	0	0	0	0
9	0	0	0	0	0
10	0	0	0	0	0

Table 1 Subjective reporting of major power dropouts. Numbers refer to number of times dropout was observed during a day.

	Minor power dropouts < 1 minute				
Participant	Day 1	Day 2	Day 3	Day 4	Day 5
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	1	0	1	0
5	0	0	0	0	0
6	0	0	0	0	0
7	0	0	0	0	0
8	0	0	0	0	0
9	0	1	1	0	0
10	0	0	0	0	0

Table 2 Subjective reporting of minor power dropouts. Numbers refer to number of times dropout was observed during a day.

One of 10 participants experienced three occurrences of major power dropouts (in one hearing aid), corresponding to one major power dropout experienced for 3 % of the total test days (three major power dropouts / 100 test days). All three cases were rated as 10 = "very annoyed" on a scale from 0 – 10. Observations of more than one major power dropout per day did not occur.

Two of 10 participants experienced two occurrences each of minor power dropouts, corresponding to a single minor power dropout experienced on 4 % of the test days (four minor power dropouts / 100 test days). Observations of more than a single power dropout in one hearing aid per day did not occur. The four cases were rated as 0, 1 and 5 on the same 10-point scale as before. In other words, participants were either "not annoyed" at all or found the incident "acceptable".

Log data

To test power reliability, the experimental hearing aids were set up to log three parameters with a log interval of eight minutes, running for maximum 34 hours:

- Voltage over time.
- Sound level over time.
- Battery alarms active (in this case meaning low fuel alarms).

Log data were stored as text files at each visit and the log was restarted. Using Matlab, descriptive graphs were generated from the text files. An example of logged voltage over time is shown in Figure 3.

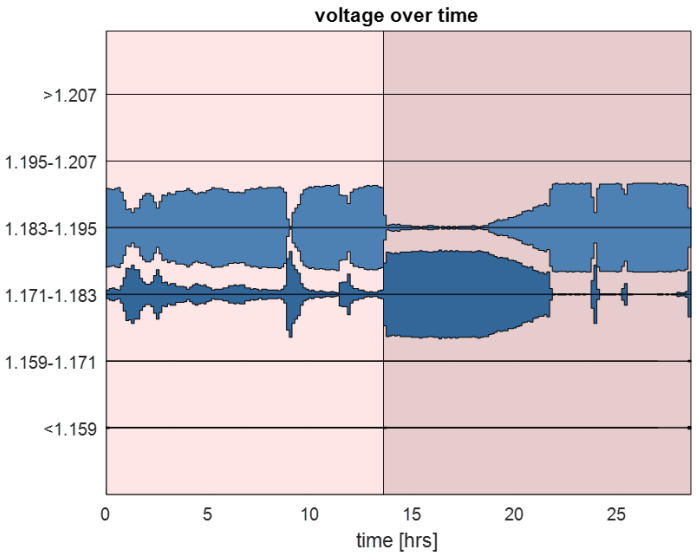

Figure 3 Example of log data on voltage over time.

The voltage, which provides data on the reliability of energy supply in the experimental hearing aids, is illustrated with blue in the example in Figure 3. When analyzing voltage over time, the 97 test days' hearing aid log data were included in the analysis. The actual distribution of the sum of minutes per voltage level across participants is displayed in Table 3.

Voltage level	Minutes
>1.207	0
1.195 – 1.207	31155
1.183 – 1.195	88969
1.171 – 1.183	21235
1.159 – 1.171	9
<1.159	45

Table 3 The distribution of the sum of minutes per voltage level across participants.

Voltage was stable in all hearing aids. In other words, the energy supply in the experimental hearing aids was reliable. Shifts between the step above and below 1.183V to 1.195V were observed (as was also the case in the example in Figure 3) but only as could be expected since the step size was very small. During a total of nine minutes, the voltage was logged in the interval from 1.159V to 1.171V, and in 45 minutes below 1.159V. Mostly, voltage levels below 1.159 were observed in the log startup. In a few cases, decreased voltage levels were observed at the end of logging, before powering out the hearing aid. Only in one exceptional case, a prolonged voltage level below 1.159V was logged for about 40 minutes in the end of logging.
Turning the hearing aids on and off to reboot the experimental hearing aids is indicated with a vertical line in Figure 3. Participants were encouraged to reboot the hearing aids every night, and additional reboots in log data were also considered when analysing for possible power dropouts.

In a few cases, logged sound level over time was considered when analysing for possible dropouts.

Low energy alarms were only observed five times in the logs, and the Participants reported that they did hear the relevant notification, and that the hearing aids stopped working shortly after.

Audible ENERGY CELL pressure equalization
When the ENERGY CELL consumes methanol, a vacuum occurs, and the ENERGY CELL equalizes the pressure by taking in air. This may generate a soft bubbly sound. Participants' reports on audible ENERGY CELL pressure equalization are summarized in Table 4 and ratings of annoyance related to audible ENERGY CELL pressure equalization are summarized in Table 5.

	Audible ENERGY CELL pressure equalization				
Participant	Day 1	Day 2	Day 3	Day 4	Day 5
1	1	0	0	0	0
2	1	0	1	3	0
3	>1	2	1	1	0
4	0	1	0	1	0
5	0	0	0	2	2
6	0	0	0	0	0
7	0	2	3	>3	0
8	0	0	0	0	0
9	0	0	0	0	4
10	0	1	0	0	0

Table 4 Reporting on audible ENERGY CELL pressure equalization. Numbers refer to number of times the sound was observed during a day.

	Annoyance				
Participant	Day 1	Day 2	Day 3	Day 4	Day 5
1	0	-	-	-	-
2	0	-	0	0-0-5	-
3	0	0-0	0	0	-
4	-	0	-	5	-
5	-	-	-	1-1	2-2
6	-	-	-	-	-
7	-	7-7	7-6-6/7	5-5-7	-
8	-	-	-	-	-
9	-	-	-	-	4*0/1
10	-	0	-	-	-

Table 5 Reporting on annoyance by audible ENERGY CELL pressure equalization. Participants rated the annoyance on a scale where 0 was 'not annoyed', 5 was 'acceptable' and 10 was 'very annoyed'.

Audible ENERGY CELL pressure equalization was experienced by eight of 10 participants. The occurrence was between zero and four events per day per participant. For two participants, the sound was not audible, while for others it was low (five participants) or acceptable (two participants). Only a single participant rated the sound release as annoying. In total, across 10 participants and five days, 30 reports were made. Of these 30 reports, 66.7% were ratings between 0 and 2, where 0 was "not annoyed". 13.3% were ratings of 5, i.e. "acceptable". 20% of ratings were 6 or 7 where 5 was "acceptable" and 10 was "very annoyed". The audible ENERGY CELL equalization was not observed every day for any of the participants.

Other observations
In the "Fuel Cell study questionnaire", participants were asked whether they had other comments concerning the experimental hearing aids and were encouraged to express their observations. The observations indicated that overall hearing aid performance was not compromised.

Discussion
Subjectively reported power dropouts
Four minor power dropouts (4% of total test days) were reported by two participants. However, these incidences could not be related to the ENERGY CELL. One participant was able to change hearing aid program in the situations, which would not be possible if the experimental hearing aid was out of power. The other two incidences occurred during streaming from a smartphone and could have been caused by streaming dropouts and were not suspected to be related to the ENERGEY CELL. Only sound dropouts caused by power dropouts could be related to the ENERGY CELL. For this reason, none of the reported incidents concerning minor dropouts could be classified as ENERGY CELL related power dropouts.

Three major power dropouts (3% of total test days) were reported by one participant. The occurrences of major power dropouts occurred in just one experimental hearing aid. The cause was evaluated to be due to the handcrafted experimental device, and therefore is very unlikely to occur in the final design of the device.

Log data on power dropouts
As the logged voltage was found to be stable over time, the logged voltage levels did not indicate any power dropouts. Only in a single case, an analysis of log data could indicate a possible major power dropout. The combined indications were:

- Potential log failure (difference in the number of logged hours of the right and left hearing aid).
- Events of moderate sound levels were shifted in time when comparing left and right hearing aid.
- A boot on the right hearing aid.

As already stated, the plausible cause of this possible power dropout, which was also reported subjectively, was the handcrafted experimental device, and therefore is not expected to occur in the final design of the device.

Audible ENERGY CELL pressure equalization
ENERGY CELL pressure equalization were audible to eight out of 10 participants and noticed in both quiet and noisier surroundings. Since the participants were explicitly asked to detect possible sound artifacts, the sounds were likely to be more noticeable than if they had not been asked. The rating of the annoyance caused by the sounds was in general low: 0 - 2 = "not annoyed" or 5 = "acceptable". It seemed that due to the handcrafted prototypes of the experimental hearing aids, the audible ENERGY CELL pressure equalization varied between devices. One participant reported annoyance between 5 and 7, where 5 = "acceptable" and 10 = "very annoyed. The specific experimental hearing aid was analyzed, and a malfunction in the handcrafted experimental device seemed to be the cause, as the sound was also audible during investigation of the malfunction.

From a clinical perspective, the ratings of the annoyance of the reported audible ENERGY CELL pressure equalization did not indicate any interference with the efficacy of the hearing aid, except for the one malfunctioning device, where again, the issue was associated with the handcrafted experimental device and is not expected in the final design.

Clinical relevance and importance
This pilot clinical investigation pioneered in introducing ENERGY CELLs in experimental hearing aids. The results were clinically relevant as the experimental hearing aids were used as normal hearing aids in situations representative of normal use. The participants used the hearing aids as they would use their own hearing aids. The results were of high importance at early stages of development, and the inputs guided the decisions made.

Limitations of the pilot clinical investigation
A drawback of the pilot clinical investigation with regard to overall conclusions about general use was that the Refill Unit for refilling the experimental hearing aids was not included in the investigation. This meant that the investigation could only run for a limited period, due to the inconvenience for the participants in coming to WIDEX headquarters every day to have their experimental hearing aids refilled.

Conclusion

The experimental devices, used for the pilot clinical investigation of WIDEX ENERGY CELL technology in a hearing aid, proved to work as intended in everyday listening environments. Overall, the performance of the experimental devices was not compromised by the use of the WIDEX ENERGY CELL power source and was found to be clinically acceptable.

This pilot clinical investigation proved valuable in assisting early product development. We were able to conclude, even at that early development stage, that WIDEX ENERGY CELL technology offers a true alternative to Zinc-Air batteries or rechargeable batteries. Based on the feedback from real users from their daily lives, as well as the data we produced in the process, we were able to proceed and improve the product until it met the high standards we have for our hearing devices at Widex.