The potential of the individualized treatment with the new cochlear implant electrode array FLEX34

Potential der individualisierten Versorgung mit dem neuen Cochlea-Implantat-Elektrodenträger FLEX34

Abstract

Using fine-slice imaging (CT, MRI), it is now possible to determine the cochlear length (CDL) preoperatively to cochlear implantation. This allows for individualized cochlear implant implantation adapted to the individual anatomy. Electrode arrays can be inserted virtually using the OTOPLAN4 software (CAScination, Bern, Switzerland; distributed by MED-EL, Innsbruck, Austria). The aim was to investigate how often a particularly long cochlea is present and therefore implantation of the currently longest electrode array, FLEX34, would have been possible. We examined all CI patients in our database with CDL measured via OTOPLAN4 based on the full organ of corti (CDL (full OC)) retrospectively. OTOPLAN4 also allows automatic evaluation in contrast to previous versions. To calculate the potential coverage of a FLEX34, it was assumed according to the manufacturer's instructions that the apical electrode was at a position of 33.62 mm CDL (full OC). The CDL (full OC) and the electrical cochlear coverage were compared. A total of 196 ears from 99 patients were analyzed with OTOPLAN4. The A value was 9.24±0.80 mm from 7.7 to 15 mm, the average H value was 4.12±0.43 mm from 3.0 to 5.4 mm, the B value was 6.83±0.57 mm from 3.9 to 8.4 mm and the CDL (full OC) at 36.13±2.48 mm from 30.4 to 46.4 mm (each arithmetic mean ± SD from min. to max.). Mean electrical cochlear coverage was 93.04±6.65% from 70.89% to 111.14%. In 28 cases (14.29%) the coverage was ≥100%, in 115 cases (58.67%) 90–100%, in 45 cases (22.96%) 80–90%, and in 7 cases (3.57%) 70–80%. To conclude, at our clinic, a significant proportion of patients have a very large cochlea and would potentially benefit from an even longer electrode such as the FLEX34 resulting in a higher cochlear coverage. Which cochlear coverage should be aimed for individually needs to be examined in more detail in further studies, as there is currently data that recommend around 80% coverage as well as data that suggest the most complete coverage possible to achieve the best possible speech understanding postoperatively.

Keywords: individualized cochlear implantation, FLEX34, cochlear duct length, OTOPLAN

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Zusammenfassung

Feinschichtige Bildgebung (CT, MRT) ermöglicht es, die cochleäre Länge präoperativ zu bestimmen. Dies erlaubt eine an die individuelle Anatomie angepasste Cochlea-Implantat(CI)-Versorgung. Über die Software OTOPLAN4 (CAScination, Bern, Schweiz; vertrieben durch MED-EL, Innsbruck, Österreich) lassen sich virtuell Elektrodenträger inserieren. Es wurde untersucht, wie oft eine besonders lange Cochlea vorliegt und eine Implantation des aktuell längsten Elektrodenträgers FLEX34 möglich gewesen wäre. Retrospektiv wurde bei versorgten CI-Patienten mit qualitativ ausreichender CT oder MRT das gesamte Cortiorgan hinsichtlich Länge (CDL(full OC)) und elektrischer Abdeckung mit OTOPLAN4

betrachtet, was nun eine automatische Auswertung erlaubt. Zur Berechnung der elektrischen Abdeckung wurde die FLEX34 betrachtet. Den Herstellerangaben entsprechend wurde angenommen, dass die apikalste Elektrode bei 33,62 mm CDL (full OC) liegt. Insgesamt konnten 196 Ohren von 99 Patienten analysiert werden. Der A-Wert lag bei 9,24±0,80 mm von 7,7 bis 15 mm, der H-Wert bei 4,12±0,43 mm von 3 bis 5,4 mm, der B-Wert bei 6,83±0,57 mm von 3,9 bis 8,4 mm und die CDL (full OC) bei 36,13±2,48 mm von 30,4 bis 46,4 mm (arith. Mittel ± SD von Min. bis Max.). Die elektrische cochleäre Abdeckung lag bei 93,04±6,65% von 70,89% bis 111,14%. In 28 Fällen (14,29%) betrug die Abdeckung ≥100%, in 115 Fällen (58,67%) 90–100%, in 45 Fällen (22,96%) 80–90% und in 7 Fällen (3,57%) 70–80%. Die aus Voruntersuchungen bekannte Variabilität der Länge der Cochlea bestätigte sich. Die ideale cochleäre Abdeckung ist derzeit in wissenschaftlicher Diskussion. Unter Annahme einer optimalen Abdeckung von ca. 80% kann die FLEX34 zu einer zu geringen als auch zu hohen Abdeckung führen. Hingegen wäre unter Annahme einer kompletten Abdeckung als Optimum die FLEX34 für eine Vielzahl an Patienten zu empfehlen.

Schlüsselwörter: individualisierte Cochlea-Implantation, FLEX34, Länge des Cochlea-Gangs, OTOPLAN

Introduction

In cochlear implantation, choosing the ideal electrode for each patient is crucial. The electrode arrays have gone through several conceptual changes during the past decades and as we have entered the era of personalized medicine there is a shift towards a more individualized cochlear implantation and focusing even more on the individual patient characteristics. Considering the individual cochlear anatomy is a central step in the electrode array election. It has been shown that there is a broad variation in the morphology of the cochlea, which can be estimated via the cochlea duct length (CDL) [1]. To serve this variety of cochleae different electrode arrays are needed. Especially for very long cochleae (CDL≥38 mm) there are limited options available with the longest electrode measuring 31 mm [2]. In comparison, the 31 mm straight electrode arrays of MED-EL are longer than electrode arrays from other CI manufacturers. To meet this need, an even longer electrode array was designed, the FLEX34 [3], [4], with a total length of 34 mm. Electrode selection depends on various factors like hearing preservation and anatomical anomalies [5], [6], [7]. However, several studies have revealed certain benefits of long electrodes [1], [8], [9], [10], including better speech understanding in quiet and noise, possibly resulting from a higher cochlear coverage and therefore better tonotopic mapping. Using fine-slice imaging (CT, MRI), it is now possible to determine the CDL preoperatively. This allows for individualized cochlear implant implantation adapted to the individual anatomy. Electrode arrays can be inserted virtually using the OTOPLAN4 software (CAScination, Bern, Switzerland; distributed by MED-EL, Innsbruck, Austria). The current study aimed to investigate how often a particularly long cochlea is present and therefore implantation of the currently longest electrode array, FLEX34, would have been possible.

Methods and results

We examined all CI patients in our database with CDL measured via OTOPLAN4 based on the full organ of corti (CDL (full OC)) retrospectively. OTOPLAN4 also allows automatic evaluation in contrast to previous versions. To calculate the potential coverage of a FLEX34, it was assumed – according to the manufacturer's instructions – that the apical electrode was at a position of 33.62 mm CDL (full OC). We compared the CDL (full OC) and the electrical cochlear coverage.

We analyzed 196 ears from 99 patients with OTOPLAN4. The A value was 9.24±0.80 mm from 7.7 to 15 mm, the average H value was 4.12±0.43mm from 3.0 to 5.4 mm, the B value was 6.83±0.57 mm from 3.9 to 8.4 mm and the CDL (full OC) at 36.13±2.48 mm from 30.4 to 46.4 mm (each arithmetic mean ± SD), see Figure 1 and Figure 2. Mean electrical cochlear coverage was 93.04±6.65% from 70.89% to 111.14%. In 28 cases (14.29%) the coverage was ≥100%, in 115 cases (58.67%) 90–100%, in 45 cases (22.96%) 80–90%, and in 7 cases (3.57%) 70–80%. The distribution of the cochlear coverage estimated by OTOPLAN is visualized in Figure 3. For cochleae with an electrical coverage of ≥100% the FLEX34 seems too long based on the OTOPLAN estimation's results. In 35 cases (17.86%), the CDL (full OC) was ≥38.00 mm, which can be used, for example, as a cut-off value for the implantation of a FLEX34. In three cases (1.53%), a FLEX34 was implanted.
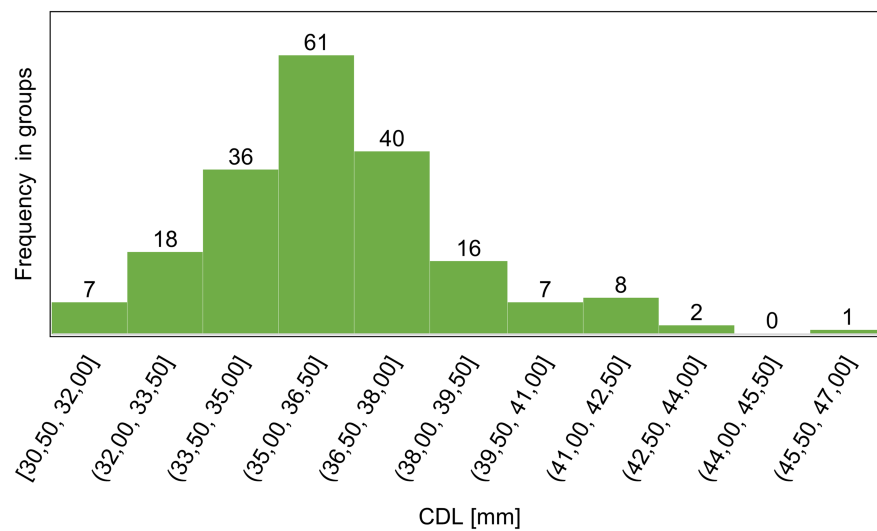
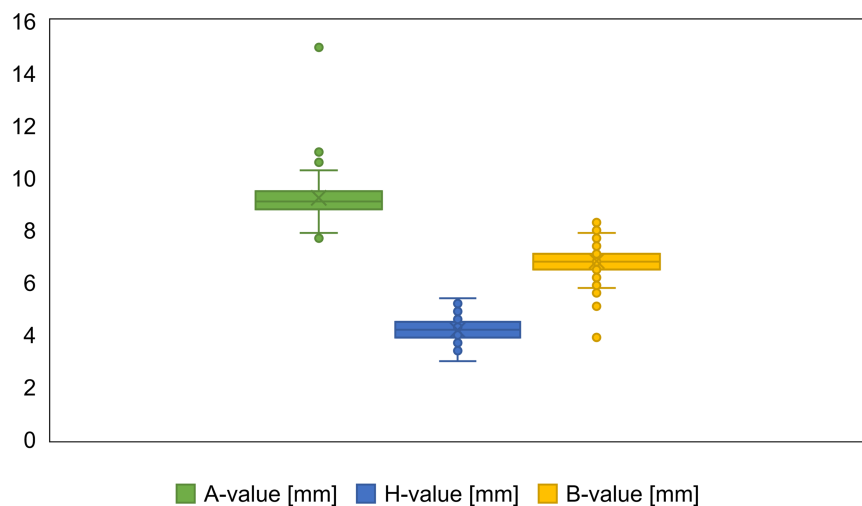**Figure 1: Grouped CDL frequency distribution in the examined patient population in mm**

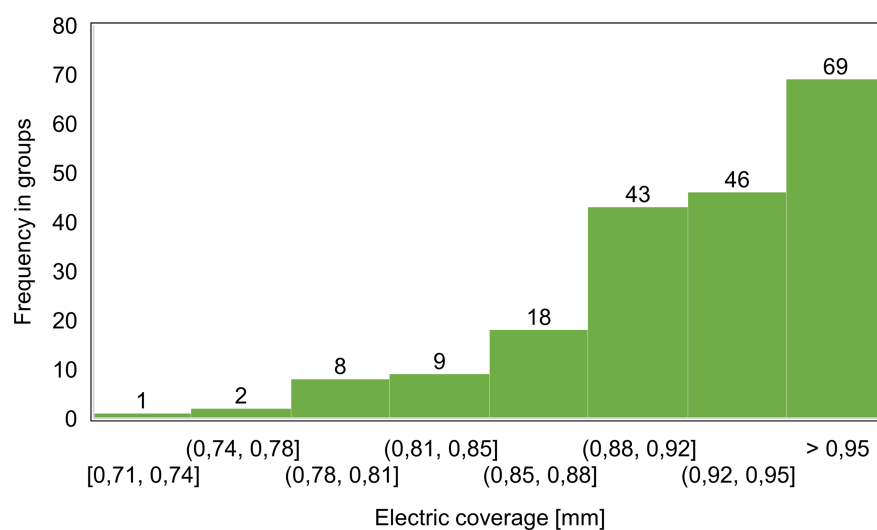**Figure 2: Average cochlear parameters in the examined patient group**

Figure 3: Grouped frequency distribution of electric coverage estimated through preoperative imaging

Discussion

The study aimed to investigate the potential application of the currently longest electrode array, FLEX 34. For this purpose, it was examined how often a very long cochlea is present using a new surgical planning software, OTOPLAN4, and thus implantation of the FLEX34 would have been possible. The hypothesis here was that there is a great application potential for longer electrode arrays such as the FLEX34. Therefore, a relevant proportion of patients with a longer CDL would need a longer electrode to reach the same and sufficient cochlear coverage. This way, they could benefit from better tonotopic matching. Several studies have shown that there is a broad range of individual CDL, ranging from 25–45 mm [11], [12], [13].

In this study, we found a relevant proportion of patients with a larger cochlear duct. These patients could benefit from a longer electrode array, specifically the FLEX34. If all patients we examined would have been implanted with a FLEX34, then around 23% would have had a cochlear coverage between 80–90% and around 3.5% between 70–80%.

In N=196 ears, we found a mean CDL of around 36 mm, which is also consistent with the literature [11], [12], [13]. Regarding the ideal cochlear coverage, the research is still ongoing. Alothman et al. reported a significantly better speech discrimination score in children with cochlear coverage >82,78% than those with a coverage <82,78% [14]. Weller et al. found that patients with a cochlear coverage between 79–82% obtained better postoperative word recognition scores than patients with a cochlear coverage <70%, however, results indicated that patients with a cochlear coverage >82% may not profit from an additional benefit [15]. Although further studies are needed, the recommended cochlear coverage of around 80% could be reached by roundabout 27% of our patients when being implanted with a FLEX34 (cochlear coverage between 70–90%). However, only in 1.5% of the cases, there was a FLEX34 implanted. On one hand, there are cochleae that got too short CDL for a FLEX34 electrode array (>100% electrical coverage). On the other hand, there is a high percentage of patients, which could receive a FLEX34 instead of shorter arrays. This group size may vary depending on the upper limit for electrical coverage set by individual surgeons due to a lack of national consensus. Especially, when an electrical coverage of around 90% or even higher is accepted, clinical applications will find a large number of FLEX34 candidates. Therefore, there is a great potential for the provision of longer electrodes in terms of individualized cochlear implantation to achieve higher cochlear coverage and thus potentially a better outcome. Eventually, this is also the basis for anatomy-based fitting, another step towards a more precise and personalized cochlear implantation.

The study has a few limitations. Firstly, we have a limited number of patients. However, when looking at the literature, we have a comparable amount, and, on the other hand, this was the first evaluation of the applicability of a comparably long electrode. Secondly, it is a retrospective study design, but then again, this was an early study to evaluate the potential. Thirdly, CDL was measured and estimated via the software OTOPLAN4 and might show slight deviations from other methods. Nevertheless, this is the latest version with an automatic and therefore reproducible evaluation that has been an established method so far.

To conclude, at our clinic, a significant proportion of patients have a very large cochlea and would potentially benefit from a long electrode array such as the FLEX34 resulting in a higher cochlear coverage. Which cochlear coverage should be aimed for individually needs to be examined in more detail in further studies, as there is currently data that recommend around 80% coverage as well as data that suggest the most complete coverage possible to achieve the best possible speech understanding postoperatively.

Notes

Conference presentation

This contribution was presented at the 26th Annual Conference of the German Society of Audiology and published as an abstract [16].

Ethics statement

Institutional Review Board Statement: The LMU Review Board, protocol number 17-227, approved this study.

Competing interests

The authors declare that they have no competing interests.

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