ENT Updates

REVIEW

ENT UPDATES 12(2):97-109
DOI: 10.5152/entupdates.2022.22213

Design of a Cochlear Implant Electrode

ABSTRACT

Present-day electrode design is the result of 40 years of continuous effort of collaboration between cochlear implant manufacturers and clinicians. There are currently 2 types of electrodes on the market: straight and pre-curved. It is accepted that preservation of intra-cochlear delicate structures should be attempted even in non-hearing preservation surgery. This demands a flexible electrode array to minimize the incidence of electrode scalar translocation. It is known that the neuronal cell bodies are distributed inside the cochlea to an angular depth of 680°, which is equivalent to a linear length of approximately 18-30 mm, considering the overall variation in human cochlear size. This requires electrode arrays in various lengths to match the differences in cochlear size and to cover the majority of the neuronal cell bodies with electrical stimulation. The fixed size and the shape of pre-curved electrodes seems a deficit because it prevents the electrode from tightly hugging the modiolus in every cochlea. This is because it can neither accommodate the size variation of the cochleae nor reach the second turn of the cochlea with electrical stimulation. Nor does it accommodate the special population of patients with inner-ear malformations, in whom the central modiolus trunk is either fully or partially absent, which demands that electrode contacts are placed proximally to the lateral wall of cochlea. In this case, the straight configuration electrode is a better choice. Explantation of the electrode array years after the implantation should also warrants attention as reports on explantation forces in cochlear models seem to indicate that the force is greater in pre-curved electrode arrays. The future looks promising for drug-eluting electrodes, to minimize the inflammation and to even regenerate neuronal elements, but even when using drug therapy the cochlea should be free from any trauma, as for during reimplantation surgery.

Keywords: Cochlear implant, straight electrode, pre-curved electrode, electrical stimulation, trauma

INTRODUCTION

The modern multichannel cochlear implant (CI) is the *state-of-the-art* treatment option to restore hearing in individuals of any age group *with severe-to-profound* sensorineural hearing loss (SNHL).[1] The CI technology has reached its maturity following 40 years of continuous research and developmental activities in collaboration between CI manufacturers and clinicians worldwide.[2] The CI has 2 components, one being the implantable component that includes the implant electronics and the intra-cochlear electrode, and the other an external component including the audio processor and the radio link coil. The audio processor receives the audio signal from the environment, breaks it down to frequency-based digital signals, and transfers it to the implant electronics via the radio frequency link. The implant electronics convert those digital signal inputs to frequency-specific electrical impulses which are then delivered to the cochlea through the intra-cochlear electrode array that is placed along the cochlear lumen longitudinally from base to apex. The intra-cochlear electrode is at the junction of creating the implant—neural interface in transferring the electrical stimulation from the implant to the delicate sensorineural elements.[3] This creates the need for electrode arrays to possess certain key characteristics with which they can be safely implanted to transfer the electrical stimulation in a meaningful way to create close to natural hearing.[4]

Currently, 2 types of CI electrode arrays are on the market: one being straight and the other pre-curved in configuration.[5] There is an ongoing debate in the CI field comparing the 2 electrode types and the opinion in the CI field on which is better is divided. A profound understanding of overall variations in the size, shape, and anatomy of the inner ear helps us

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Cite this article as: Dhanasingh A. Design of a cochlear implant electrode. *ENT Updates.* 2022;12(2): 97-109.

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Received: *May 23, 2022*
Accepted: *July 8, 2022*
Publication Date: *September 2, 2022*

to create the key requirements for the ideal CI electrode design. It is essential for clinicians to know the difference between the electrode types from every aspect of its design, including its ability to comply with differences in the shape of the cochlear basal turn; its flexibility, to minimize the rate of intra-cochlear trauma; and its physical length, to provide electrical stimulation to the second turn of the cochlea.

This article aims to briefly cover the history of early CI research, the evolution of multichannel electrode arrays from the early days up to the present day, and to cover the scientific reasons explaining the necessity to have electrode arrays of different lengths, that are flexible in nature, and the use of longer length electrodes in practice. Furthermore, the article covers recently published evidence on the hearing benefits associated with providing electrical stimulation to the second turn of the cochlea. Details on the manufacturing limitations associated with certain types of electrodes should help to relate the shortcomings reported in the literature. Also, this article briefly covers the electrodes of the future.

History of Early Research on Cochlear Implant

The first clinical trials on the CI started in 1951 and the very first single-channel CI was implanted in a patient in Paris by Charles Eyries. This device was developed by Andre Djourno, who was a professor of medical physics in Paris, France.[6] In the United States, Dr William House developed and implanted the single channel CI in patients as early as 1965.[7] The single channel CI device did not allow patients to understand spoken words without lipreading.[8] This motivated other university research groups at that time to develop and implant multichannel CIs. St. Antoine hospital in Paris performed the first implantation of a multichannel CI encapsulated in epoxy resin in the year 1976 which became a commercially available CI device under the brand Neurelec in 1986, which was bought by William Demant Holding in the year 2013 and renamed as Oticon.[9] In 2022, Oticon was bought by Cochlear®. The Technical University of Vienna implanted their first microelectronic multichannel CI technology encapsulated in hermetic glass in the year 1977 and it took 12 additional years to commercialize their technology under the MED-EL brand name in the year 1989.[10] The University of Melbourne implanted the microelectronics multichannel CI technology encapsulated in epoxy resin in the year 1978 and they started commercializing their technology under the Cochlear® brand name in the year 1981.[11] Around the late 1970s, a few other firms like Chorimac in France, Laura in Belgium, and Ineraid in the United States investigated the CI but with no success in commercializing the outcome.[12] The University of California in San Francisco implanted a passive 4-channel CI encapsulated in epoxy resin in the year 1978 and they commercialized their CI technology under the Advanced Bionics brand name in the year 1991.[13] In the late 1980s and in the beginning of 1990s, all 4 of these CI manufacturers came up with different designs of intracochlear electrode arrays based on their knowledge and understanding at that time on electrode manufacturing "know-how," the availability of tools, and the anatomy of the inner ear, to support their implant electronic and stimulation strategies. In the year 2006, another CI manufacturer Nurotron Biotechnology emerged in China and was supported technologically by the University of California, Irvine.[14]

Evolution of Multichannel Electrode Design

The multichannel microelectronic CI device required the electrode array design to deliver frequency-specific electrical stimulation across the longitudinal length of the fluid-filled scala tympani (ST). The world's first microelectronic multi-channel device (1978) from MED-EL had 8 evenly spaced paired platinum (Pt) contact pads exposed on both sides of the electrode array in a straight configuration for a length of 30 mm to cover the entire frequency range of the cochlea.[15] The Nucleus 22 device from Cochlear® (1981) had 22 evenly spaced Pt contact pads exposed on one side of the electrode array in a straight configuration for a length of 25 mm to cover mainly the basal turn of the cochlea.[16] The Clarion device from Advanced Bionics (1987) had the spiral intracochlear electrode of length 25 mm with 16 spherical contacts arranged in 8 near-radial bipolar pairs for stimulation of discrete segments of the cochlea (first pre-curved configuration electrode type).[17] The straight electrode configuration did not need any special insertion tool to place inside the ST, whereas the curved configuration electrode needed a Teflon-made, straight tube, to straighten the curved electrode prior to the insertion. After inserting the electrode together with the Teflon tube into the cochlea, the Teflon tube was gently retrieved enabling the curved electrode to curl along the inner wall of the cochlea. This was the very first development of multichannel electrodes from these 3 major CI manufacturers. At that time, CI manufacturers in collaboration with the clinicians were busy evaluating the patients and it was never clear if the electrodes from the first generation would be the final design moving into the future.

In 1996, MED-EL further fine-tuned its 8-channel electrode into a 12-channel electrode with a length of 31.5 mm to cover the entire frequency range and it was made commercially available as the "STANDARD" electrode array.[18] Electrode design progressed further with the introduction of the positioner, which is a dummy silastic element adjacent to the electrode pushing the stimulation electrode channels adjacent to the inner wall of the cochlea.[19] This was developed by Advanced Bionics in the early 2000s, but unfortunately, the positioner was associated with an increased risk of meningitis and was taken off the market.[20] In the same year, Cochlear® introduced their pre-curved peri-modiolar positioning electrode under the commercial name "Contour" to cover mainly the basal turn of the cochlea.[21] The motivation for the pre-curved configuration was to bring the stimulating electrode channels adjacent to the central modiolus, to reduce the stimulus levels. Around this time, MED-EL further expanded its electrode portfolio by introducing the "MEDIUM" and the "COMPRESSED" electrodes, of length 24 mm and 16 mm, respectively, to match the inner ear with abnormal anatomies. The Advanced Bionics developed a straight configuration electrode of 22 mm in length to cover mainly the basal turn of the cochlea and was introduced to market in 2003 under the commercial name "1J."[22] Though this electrode is considered an outer wall electrode, it still had some pre-curved configuration resembling the letter "J," hence the name 1J.[23] In 2004, MED-EL introduced the first "FLEX" electrode variant with a length of 31.5 mm under the commercial name "FLEX SOFT." The difference between STANDARD and FLEX SOFT is that in the STANDARD electrode the apical 5 channels are paired and opened on both sides of the electrode array for the electrical stimulation to escape, whereas on the FLEX SOFT, the apical 5 channels are single and open only on one side (Figure 1A).[24] This made the apical end of the FLEX

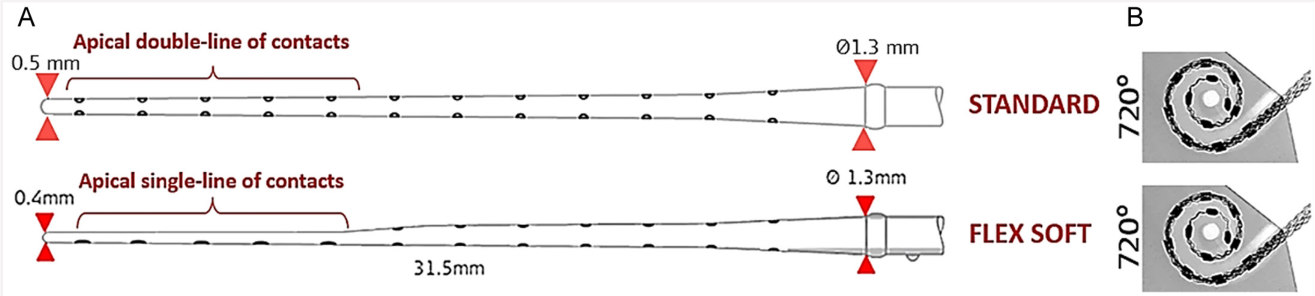

Figure 1. A, B. (A) Comparison of STANDARD and FLEX SOFT electrode in the side view showing the difference in the apical 5 channels. (B) Electrode insertion angular coverage by both STANDARD and FLEX SOFT electrodes.

electrode highly flexible with smaller cross-sectional dimensions. Figure 1B shows the electrode insertion angular coverage by both of these electrodes.

Early in 2005, Advanced Bionics introduced their first version of the pre-curved peri-modiolar electrode under the commercial name "HELIX," to cover the basal turn of the cochlea.[22] In the same year, Cochlear® introduced their second generation pre-curved peri-modiolar electrode under the commercial name "Contour Advance™" that had the conical tip which was flat-rounded in their first generation pre-curved electrode.[25] There was no difference in terms of the angular insertion depth covered by both the Contour and Contour Advance electrodes.

In the following years, up until 2020, MED-EL introduced a series of FLEX electrode variants, in different array lengths in the chronological order of 24 mm, 28 mm, 20 mm, and 26 mm, to provide a range of angular insertion coverage, matching the needs of cochleae with various level of low-frequency residual hearing and also to accommodate cochlear size variation as reported in the literature.[26] In 2011, Cochlear® introduced a shorter-length straight configuration electrode of 15 mm in length specially for patients who are candidates of electric acoustic stimulation.[27] In the consecutive year, Cochlear® introduced another straight electrode configuration of 20 mm in length (between the electrode tip and the first marker at the basal end) under the commercial name "Slim Straight," which they claimed as the electrode for preserving intra-cochlear structures and low-frequency residual hearing.[28] Naturally, this raises the question of whether pre-curved electrodes are capable of preserving the residual hearing or not. This electrode can also be inserted to a maximum length of 25 mm if inserted up to the second white marker. Neurelec, now called Oticon, introduced their straight electrode configuration of length 26 mm under the commercial name "Digisonic®" SP in the year 2004, which is longer than the straight electrodes from Cochlear® and Advanced Bionics.[29] Later they introduced another straight electrode of 25 mm in length under the commercial name "Digisonic® SP EVO." In 2006, Nurotron introduced their straight electrode of 22 mm in length with the aim of covering close to 400° of angular depth.[14]

In 2013, Advanced Bionics introduced another pre-curved configuration electrode under the commercial name "Mid-Scala" electrode, and the array was 18.5 mm in length which was similar in length to all the other pre-curved electrodes at that time. The commercial claim of this electrode is that it claims it can be positioned in the mid of ST without touching any of the inner surface of the ST. Somehow the CI field has misunderstood this electrode concept and continued calling it as a peri-modiolar electrode.[30] Around 2016, Cochlear® introduced yet another pre-curved configuration electrode under the commercial name "Slim Modiolar" that was only 17.5 mm in comparison to the Contour Advance electrode length of 18.5 mm.[31] This electrode is inserted with the polymer tube as a straightener which is very similar to the Clarion device from Advanced Bionics, released in 1987. In 2017, Advanced Bionics introduced another straight configuration electrode called "Slim J" that is 23 mm in length. This electrode was the slimmer version of its predecessor the 1J electrode.[32] Circa 2021, Cochlear® introduced the "Slim20" electrode which is straight in configuration for a length of 20 mm, for patients with residual hearing extending from 1000 Hz.[33] This electrode can be compared to the FLEX20 electrode from MED-EL. Figure 2 compares the array lengths of electrode variants from all 5 CI manufacturers.

Altogether, there are 19 variants of straight configuration electrode types commercialized by all 5 CI manufacturers, ranging in length from a minimum of 15 mm to a maximum of 34 mm. It is to be noted that out of 19 variants of straight configuration electrodes, MED-EL owns 10 of those. In contrast, pre-curved configuration electrode types were commercialized by only 2 CI manufacturers in 5 variants of similar length. All these electrode variants were implanted in 100s of 1000s of patients so far, yet no consensus is available as to which type of electrode and which insertion depth is ideal in patients with profound or partial deafness. Although the trend is going in favor of the straight configuration electrode, it minimizes electrode insertion complications, according to the latest published systematic literature review.[35] Without a doubt, it is within the interest of every CI manufacturer to bring the best electrode to clinical use, in terms of its surgical handling, preservation of the intra-cochlear delicate structures, and in matching the overall inner ear anatomical variations. However, the limiting factor is the manufacturing *know-hows* of every CI manufacturer, they direct their electrode design and philosophy, but they should not jeopardize their overall implant technology in providing the greatest possible benefit to CI patients. Even after 40 years of continuous research in the CI field, there is no strong evidence supporting the superiority of pre-curved electrodes over the straight electrode types.[35-39]

The Need for Electrode Arrays of Different Lengths to be Available

The optimal placement of the electrode array inside the cochlear lumen is one of several factors that affect the post-operative

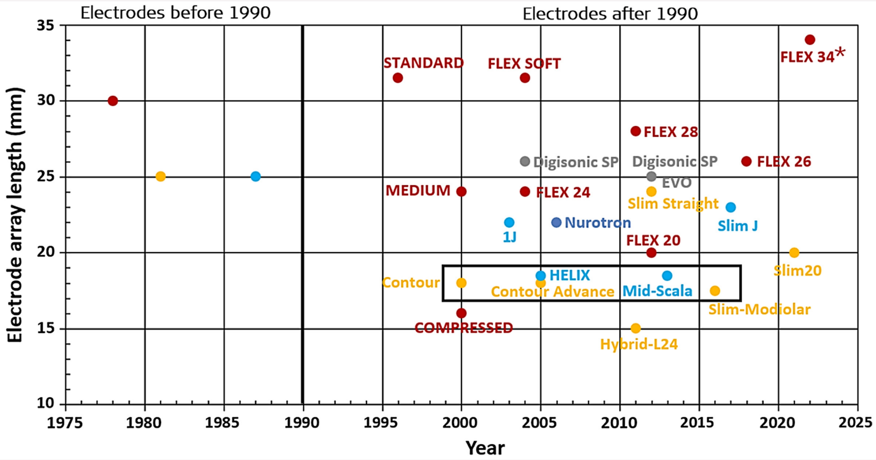

Figure 2. Comparison of electrode array lengths across time from all 5 CI manufacturers. Note that the STANDARD electrode from MED-EL that was introduced in the year 1996 is still actively used in the CI field. The X-axis shows the year at which the different electrode variants were released in the market and Y-axis shows the length of the electrode array. Electrode variants inside the black rectangle refer to pre-curved type electrodes from Cochlear® and Advanced Bionics. *Corresponds to electrode under development. CI, cochlear implant.

hearing outcomes with a CI. While we wish to see the normal anatomy of inner ears with 2½ cochlear turns in every patient, unfortunately 20%-30% of children with congenital SNHL have inner ear anatomies that deviate from the normal anatomy.[40] Figure 3 displays three-dimensional (3D) images of a variety of inner ear anatomies as seen from the pre-operative images of the right-side ear from patients with a CI. The electrode that matches the cochlea with 2½ turns (Figure 3A) may not be matching the cochlea with only 1½ turns (Figure 3B), or less than that (Figure 3C-G). The short electrode array that suits the cochlea with only ½ a turn (Figure 3H) may be too short for cochleae with 2½ (Figure 3A) or 1½ turns (Figure 3B). The inner ear anatomical types like incomplete partition types I (Figure 3I), II (Figure 3J), III (Figure 3K), and cavity-type malformations (Figure 3L) lack the central modiolus trunk and the neural elements are believed to be present along the outer wall. This makes the straight electrode type in various array lengths a better electrode choice than the pre-curved electrode type that has stimulation contacts positioned along the inner curvature of the electrode. Even in normal anatomy cochleae with 2½ turns, the pre-curved electrode type can never provide good electrical stimulation beyond the basal turn due to manufacturing and handling limitations that prevent making it longer than what it already is (see Section Manufacturing Limitations and Common Beliefs Associated with Pre-curved Electrode Type for more details).

Within the normal anatomy inner ear with 2½ cochlear turns, the overall size variation of the cochleae is huge as measured by the A-value (basal turn diameter), which is an indirect measure of cochlear duct length (CDL). The A-value has been reported to

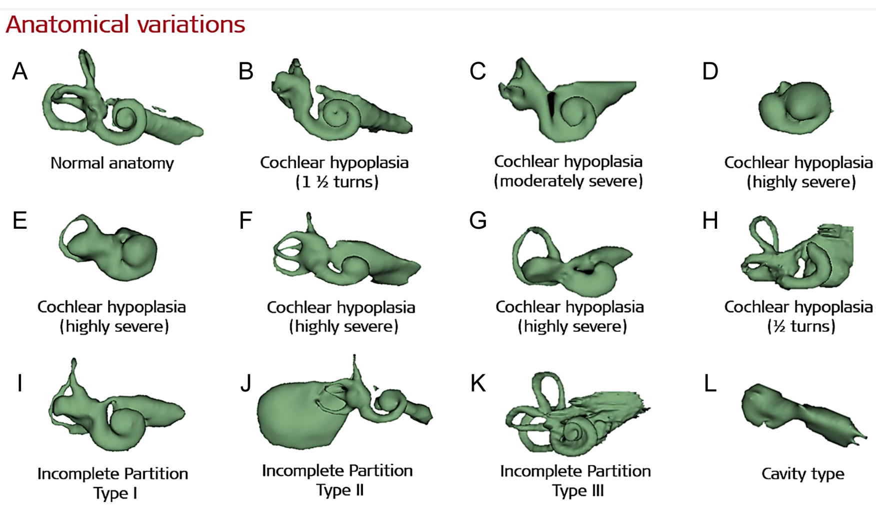

Figure 3. A-L. Human inner ear anatomical variations three-dimensional images of inner ear with various anatomical types. (A) Normal anatomy with 2½ turns; (B) mild cochlear hypoplasia with 1½ turns; (C) moderate cochlear hypoplasia; (D-H) severe cochlear hypoplasia; (I) IP type I; (J) IP type II; (K) IP type III; and (L) cavity malformation. IP, incomplete partition.

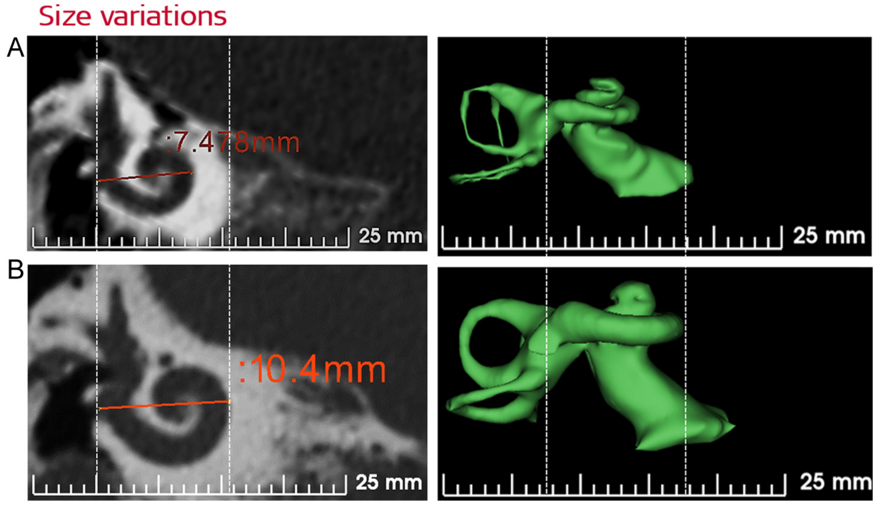

Figure 4. A, B. Cochlear size comparison. (A) Smaller cochlear size with an A-value of 7.5 mm and (B) a larger cochlear size with an A-value of 10.4 mm. The vertical white dotted line shows the difference in cochlear size between the 2 samples.

vary between 7 mm and 11 mm for which the CDL would correspondingly vary between 25 mm and 40 mm.[41] This being the fact, one length electrode array can never match the CDL variation. Figure 4 shows 2 extreme sizes of cochlea as measured by the basal turn diameter. Figure 4A refers to the smaller-sized cochlea with an A-value of 7.5 mm, whereas Figure 4B refers to the larger-sized cochlea with an A-value of 10.4 mm. The currently available pre-curved electrode type is only available in a predetermined size, whereas the size of the cochlear basal turn varies, and this prevents the pre-curved electrode type from providing a consistently tight "modiolar hugging" placement in every case.

The anatomical and size variations observed in the human cochleae draws attention to the clinical demand for electrode arrays of different lengths. MED-EL realized this requirement from early on and therefore offers flexible straight electrode types in various lengths ranging from 16 mm to 31.5 mm as shown in Figure 5.

While the assessment of cochlear size from pre-operative images requires some effort, it is worth the effort, as choosing an electrode array length that does not match the cochlear size could result in either under- or over-insertion. Figure 6A is a case example showing the FLEX28 electrode (28 mm in length) over-inserted inside a cochlear size of 10.2 mm as determined by the A-value. Figure 6B shows the FLEX28 electrode with its array length. Technically, for cochleae with an A-value of ≥9 mm, a FLEX SOFT electrode (31.5 mm in length) would be an optimal length electrode.

The Need for Flexible Electrode Arrays

The flexibility of the electrode array is referring to the electrode's ability to shape itself to the changing contour of the cochlear lumen, not traumatizing the delicate intra-cochlear structures, yet making it possible to place it fully inside the cochlea. The cochlea is like a black box when viewed from the facial recess/posterior tympanotomy and inside the promontory bone; the shape of the cochlea can be highly variable. While we envision every cochlea being a perfectly round shape (Figure 7A) to assist the smooth insertion of the electrode array, there are cases with more triangular or elliptical-shaped basal turns (Figure 7B and C). For the electrode to navigate inside the cochlear lumen

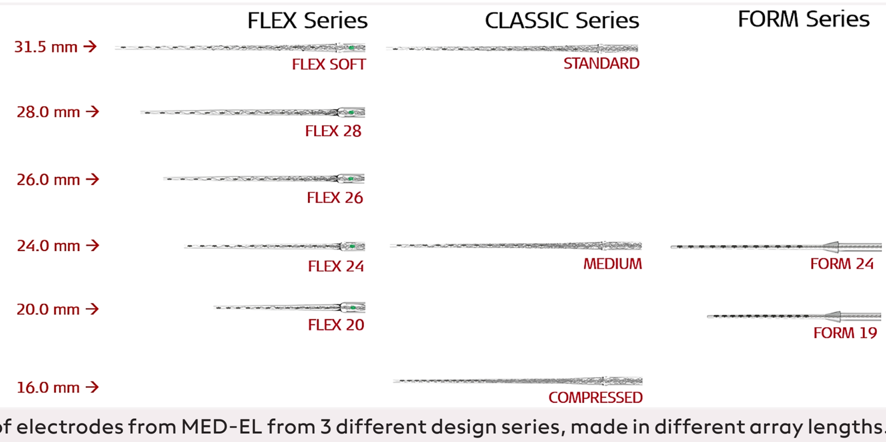

Figure 5. Portfolio of electrodes from MED-EL from 3 different design series, made in different array lengths. Note that electrode variants in the FORM series are only for cochleae with malformed anatomy.

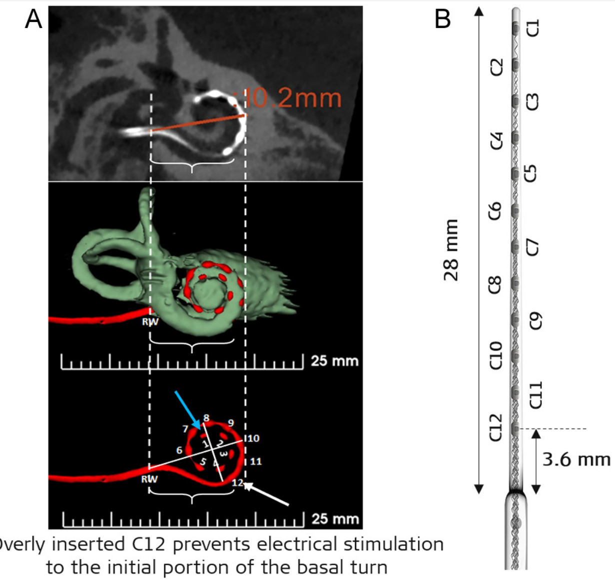

Figure 6. A, B. Need for pre-operative cochlear size evaluation further to CI surgery. (A) FLEX28 electrode over-inserted inside a bigger-sized cochlea with an A-value 10.2 mm. The basal most channel (C12) is placed too deep inside the cochlea as pointed out by the white arrow, yet the most apical channel (C1) is only 630° of angular depth as pointed out by the blue arrow. (B) FLEX28 electrode dimensions. CI, cochlear implant.

and accommodate the natural shape of the cochlea, the electrode array has to be flexible enough in nature. This will prevent the electrode from piercing through the delicate structures at the abrupt turns, as is the case in the triangular-shaped basal turn shown in Figure 7B. The currently available pre-curved configuration electrodes are only available in a predetermined shape (Figure 7D); whereas the shape of the cochlear basal turn varies, and this prevents the pre-curved configuration electrode from providing a consistent tight modiolar hugging placement in every case.[42]

The ST of the cochlear lumen is where the electrode array is intended to be implanted. The ST lumen is close to being straight within the first 180° of angular depth starting from the round window (RW) entrance, beyond that, the cochlea takes a real turn. It is widely reported in the literature that in cases with electrode scalar deviation (ESD), at an angular depth of 180° from the RW entrance is where the electrode would deviate from the ST to the scala vestibuli (SV),[43] as shown in Figure 8.

Recently in 2022, Van de Heyning et al[34] from the HEARRING group (https://www.hearring.com/) performed a detailed literature review of 39 articles that reported on the ESD. They found that from 1983 implantations with pre-curved electrode types, 567 implantations experienced ESD, making an incidence rate of 28.6%; whereas, from 1090 implantations with straight electrode types, 120 implantations were found with ESD, giving an incidence rate of 11%. In 2021, Jwair et al[43] performed a meta-analysis of 5 cohort studies comparing ESD between straight and pre-curved electrode types and it showed that straight electrode types had a lower translocation rate (7% vs. 43%) and that the ESD is negatively associated with speech perception scores. Looking at these reports, it gives a profound understanding that straight electrode types have the least incidence of ESD compared to the pre-curved electrode types, justifying the necessity for highly flexible electrode arrays. A combination of the shape variations seen in cochlear basal turn, stiffness of the electrode array (which could highly be influenced by the metal stylet rod used in the pre-curved electrode), and the surgical approach applied by the operating surgeon could influence the incidence rate of ESD.

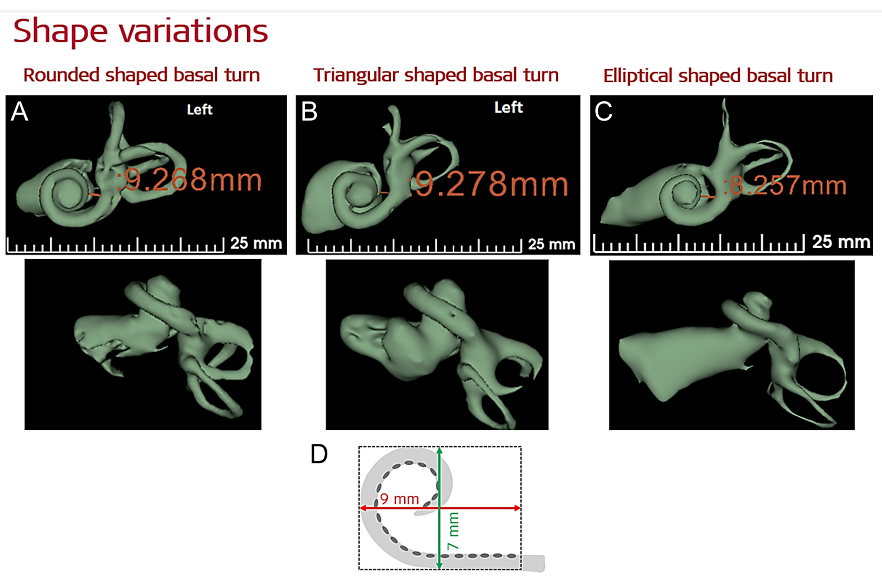

Figure 7. A-D. Comparison of the shape of the cochlear basal turn. (A) Round-shaped basal turn; (B) triangular-shaped basal turn; (C) elliptical-shaped basal turn; and, (D) fixed size and shape of pre-curved type electrode.

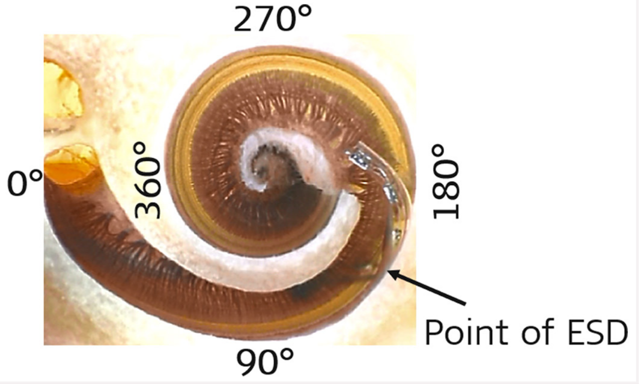

Figure 8. Cochlear dissection showing the point of electrode scalar deviation. Reproduced by permission of Prof. Peter Roland from University of Texas Southwestern.

One way of measuring the stiffness of the electrode array is through electrode insertion force measurement experiment in the lab set-up. An in-house electrode insertion force measurement experiment involving automated insertion tool inserting the electrode at a constant speed of 0.5 mm/s in acrylic ST phantom models showed that 3 of MED-EL's FLEX electrode variants having a similar insertion force of approximately 40 mN at the full insertion depth position. At an insertion depth of 20 mm (pink vertical dotted arrow line in Figure 9), which marks the full insertion of FLEX20 electrode, it showed an insertion force of 40 mN, whereas for FLEX24, it was bit above 10 mN (blue horizontal dotted arrow line) and for FLEX28 it was <10 mN (red horizontal dotted arrow line). This experiment shows that when the electrode contact pads are separated wide apart which is the case with FLEX28 and FLEX24 compared to FLEX20, the stiffness of the array reduces drastically which is seen with lower insertion forces.

Schuster et al[44] have earlier reported that the force needed to penetrate the basilar membrane from ST to SV was measured to be between 40 mN and 120 mN with an average value of 88 mN. Compared to this value, the electrode insertion force of 40 mN as measured for the FLEX electrodes is at the lower limit to cause any damage to the basilar membrane.[44] This could well explain why flexible electrodes have a lower incidence of ESD.

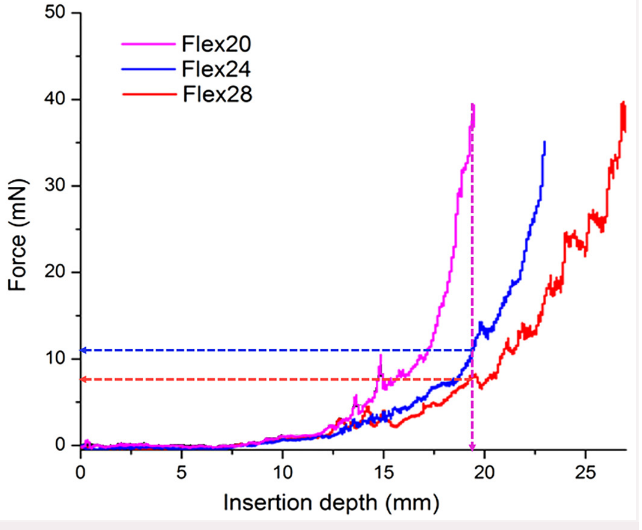

Figure 9. Electrode insertion force in milli Newton measured at the full insertion of electrode length inside the ST phantom model. ST, scala tympani.

The immediate counter argument would then be how easy it is to insert a flexible, longer-length electrode fully inside the cochlea. Recent reports by Canfarotta et al.[45] Dutrieux et al.[46] Riemann et al.[47] and Högerle et al[48] confirm that full insertion of a flexible straight configuration electrode of 28 mm or 31.5 mm in length is possible in-patient cases. Figure 10 shows the angular coverage of 540° with the FLEX28 and 720° with the FLEX SOFT electrodes, in 2 different cases with no information available on the cochlear size.

The Need for Longer-Length Electrode Arrays

The CI device is designed in a way so as to provide electrical stimulation to the sensory neural fibers in the organ of Corti, from which the electrical stimulation is carried further to the spiral ganglion cell bodies (SGCBs), located in the Rosenthal's canal in the mid-modiolus trunk and further to a higher level at the auditory pathway. The organ of corti is developed almost to 2½ turns of the cochlea which is equivalent to 900° of angular depth and the SGCBs are distributed to an angular depth of 680°-700°.[49] This was well captured in the high radiation synchrotron image of the human cochlea as reported by Li et al[50] and illustrated by the yellow portions presented in Figure 11A. Theoretically, to cover the entire frequency range of the cochlea with electrical stimulation, the electrode has to be physically placed at least to an angular coverage of 680°. Figure 11B shows the histological slice of the mid-modiolar section of the human cochlea with a straight electrode type covering 2 full turns of the cochlea. The cross-sectional dimension of the electrode matches very well to the cross-sectional dimension of the ST. It is reported that in normal hearing subjects, there are 33 000 SGCBs on average distributed up to 680° of angular depth. It is important to look at segment IV of the cochlea that extends from 400° of angular depth onward; in this portion, there are 25% of the total number of SGCBs, which is equivalent to ≈7200 SGCBs in number,[49] as shown in Figure 11C. If the electrode is not physically placed in the second turn, then the segment IV of the cochlea will be deprived of the much-needed electrical stimulation to stimulate 25% of the total number of the SGCBs. Figure 11D shows the deficiency of a pre-curved electrode type because it is not able to cover segment IV of the cochlea electrically.

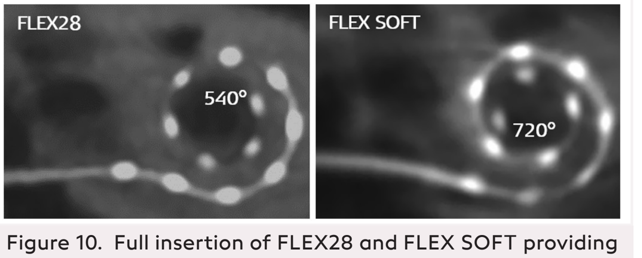

Figure 10. Full insertion of FLEX28 and FLEX SOFT providing an angular insertion depth of 540° and 720°, respectively. Note that the cochlear size in these cases is not known and the angular depth would vary accordingly to the cochlear size.

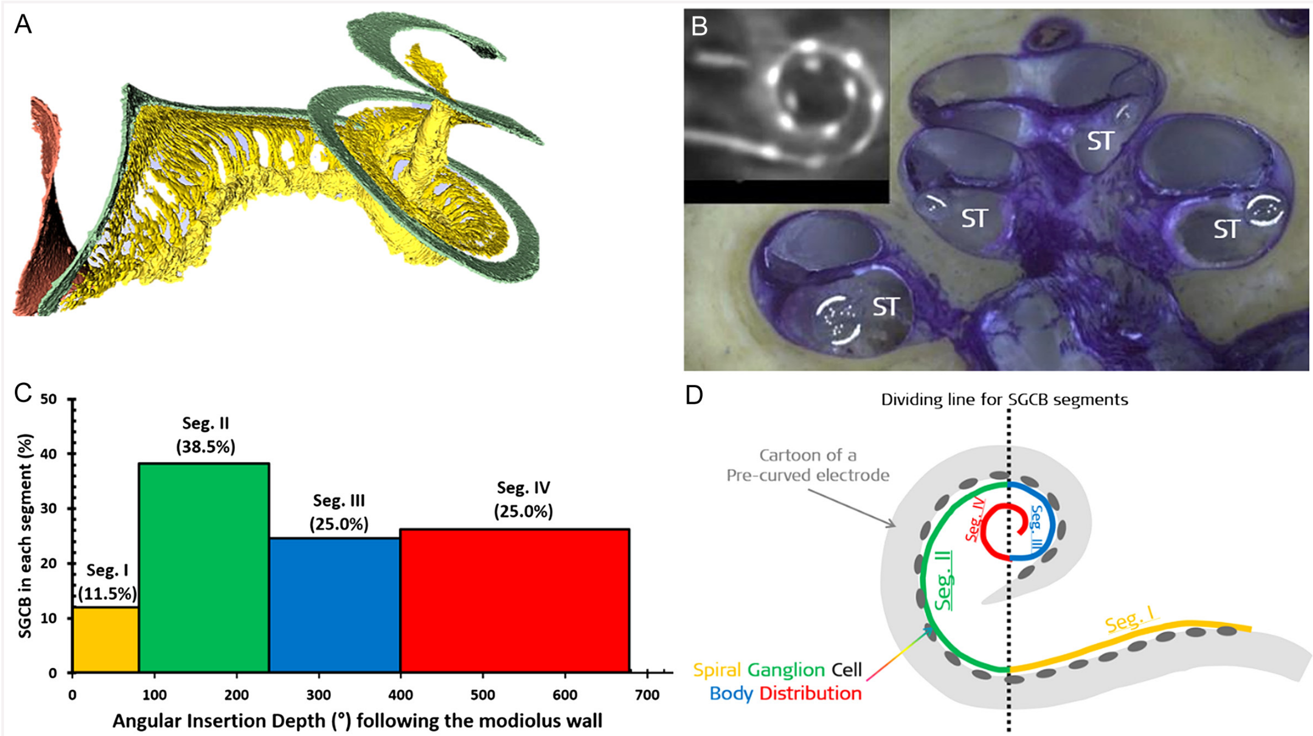

Figure 11. A-D. Distribution of neuronal elements inside the cochlea. (A) The synchrotron high radiation image of the human cochlea shows the presence of SGCBs up to the end of the second turn of the cochlea (Source: Courtesy of Dr. Hao Li and Dr. Helge Rask-Andersen, University Uppsala, Sweden, and Prof. Hanif Ladak and Dr. Sumit Agrawal, Auditory Biophysics Laboratory, Western University, London in Ontario, Canada). (B) Histological image of the mid-modiolar section of human cochlea with a flexible straight electrode type covering almost 2 turns of the cochlea (Reproduced by permission of Prof. Lenarz, Hannover medical school, Hannover, Germany). (C) Distribution of SGCBs in all 4 segments of the cochlea. (D) The deficiency of the pre-curved electrode is that it is not able to cover the segment IV of the cochlea electrically. SGCBs, spiral ganglion cell bodies.

There are numerous peer-reviewed published reports from worldwide clinics, as listed in Table 1, demonstrating the hearing benefits associated with electrical stimulation of the second turn of the cochlea.

It is to be noted that regardless of the electrode type and the stimulation strategy, which varies among the CI manufacturers, the electrical stimulation provided to segment IV of the cochlea, beyond the basal turn, has been reported to benefit the patients providing better audiological outcomes. All these scientific reports support the placement of the electrode in the second turn of the cochlea as shown in Figure 12.

It is often debated in the CI field that brain plasticity will take over any mismatch between the frequencies allocated to electrode channels, in the case of shorter-length electrodes, and natural tonotopic frequencies of the cochlea. Dorman et al[59], reported in a population of 5 female post-lingually single-sided deafened CI users implanted with the mid-scala electrode, which is a pre-curved electrode type, that even after 35 months of CI use, the patients experienced an upward shift in frequency. This is one piece of evidence indicating that brain plasticity is limited when there are large differences between frequencies in the input signal and the tonotopic frequencies.

The current challenge in the CI field is not about whether a CI can help deaf patients to hear something or not; instead, the real challenge is about providing close to natural hearing, as a normal hearing subject would hear. Cochlear implant in single-sided deaf (SSD) subjects is a perfect condition to appreciate the benefits of electrical stimulation to the second turn of the cochlea as the patients can compare the CI hearing from the ipsilateral ear with their natural hearing from the contralateral ear. If the CI hearing from the deaf ear is not in synchrony with the natural hearing from normal hearing ear, the patients may not appreciate using the CI. Thomas et al[60] reported their experience on the acceptance level of CI among 21 congenital SSD children aged <12 years. Eleven out of 21 children were implanted with a MED-EL CI device: 4 with the FLEX28 electrode array (28 mm) and 7 with the STANDARD (31.5 mm). Nine out of 21 children were implanted with a Cochlear® device: 4 with the Contour Advance electrode array (18 mm) and 5 with the Slim Straight electrode array (20 mm). The remaining one child was implanted with an Advanced Bionics' Mid-Scala electrode array (18.5 mm). When the parents of these children were asked if CI was the right choice for their children and about their satisfaction with CI, out of 11 parents of MED-EL recipients, 8 parents rated their appreciation as very high with 10 points, 2 parents rated high with 9 points, 1 parent rated with 8 points, and data were not available from 1 parent. Out of 10 parents of other brand device recipients, only 2 parents rated very high with 10 points, 2 parents with 9 points, 2 parents with 8 points, 1 parent with 6 points, and the rest graded with <5 points.

Table 1. List of Scientific Reports from World-wide Clinics Showing Electrode Variants from Different Cochlear Implant Manufacturers, Reported Angular Insertion Depths, and the Correlation Between the Angular Insertion Depths and Hearing Outcomes

Studies	Region of Origin	Electrode Type	AID°	Correlation Between AID and Hearing Performance
Buchman et al[51]	United States	MEDIUM and STANDARD	423° to 657°	+ve
Hilly et al[52]	Canada	1J	<360° to >360°	+ve
O'Connell et al[38]	United States	Slim Straight	290° to 600°	+ve
Büchner et al[53]	Germany	FLEX20-24-28	360° to 480° to 585°	+ve
Helbig et al[54]	Germany	FLEX28	350° to 730°	+ve
Nassiri et al[55]	United States	Slim Modiolar	360° to 450°	+ve
Canfarotta et al[56]	United States	MEDIUM and STANDARD	460° to 720°	+ve
Lyutenski et al[57]	Germany	Mid-Scala to FLEX28	360° to 560°	+ve
MacPhail et al[39]	United States	Slim Modiolar and Slim Straight		Better outcome associated with Slim Straight
Canfarotta et al[58]	United States	FLEX28 vs. FLEX SOFT	571° to 628°	+ve

AID, angular insertion depth.

The ideal situation to compare the quality of hearing offered by the longer length straight type electrode and the pre-curved electrode type would be with both electrode types, one on each side in bilaterally implanted patients with a post-lingual deafness. There were 2 reports from 2011, with 6 patients altogether implanted with the STANDARD straight electrode type on one ear and Contour Advance pre-curved electrode type on the other ear, and the subjects were asked which side they experienced close to natural hearing. Except for 1 patient, all other 5 patients experienced less natural, less pleasant, and a tinnier sound with the pre-curved electrode type, whereas on the straight longer length electrode implanted side, they experienced more natural, more pleasant, and less tinny sound that demonstrates the importance of electrical stimulation in the second turn of the cochlea.[61,62]

Manufacturing Limitations and Common Beliefs Associated with Pre-curved Electrode Type

While the straight configuration electrode type is available in a wide range of lengths, the pre-curved electrode type is only available in a length that covers the basal turn of the cochlea and not beyond. This is a question which is often overlooked

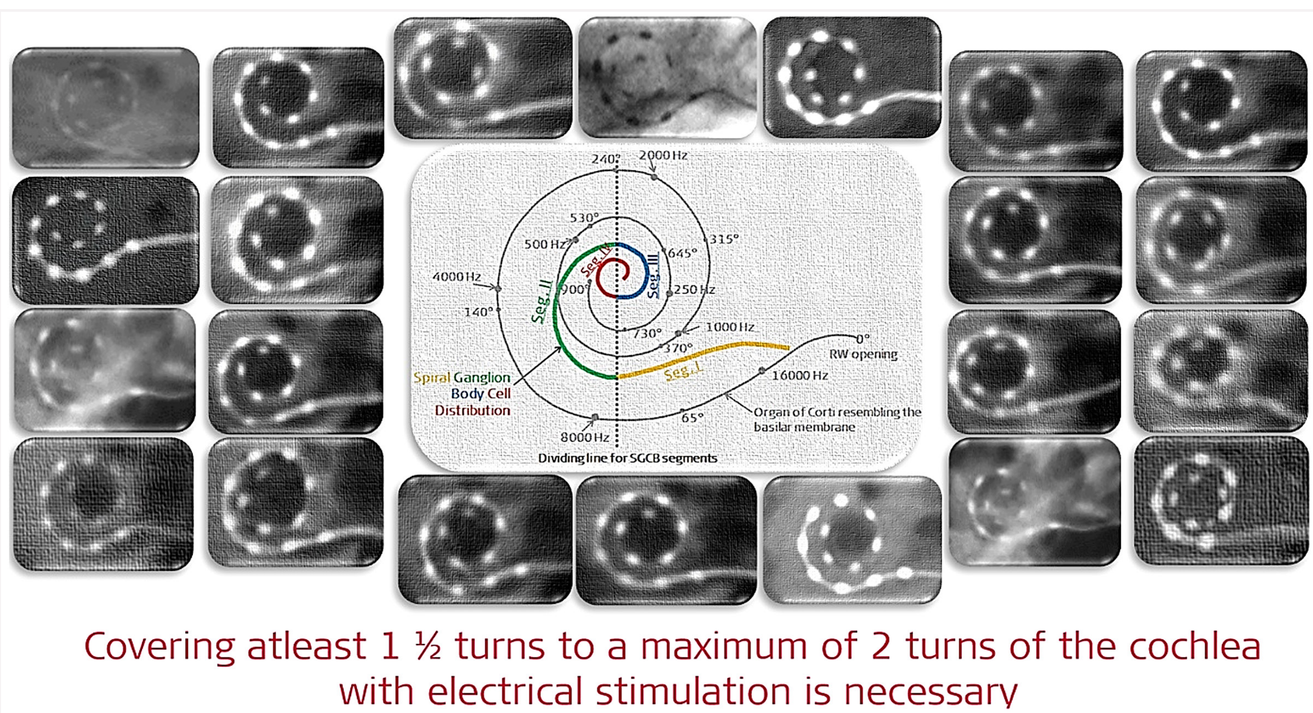

Figure 12. Post-operative images of cochlea showing the electrode placement in both the basal and the middle turn. The center image shows the distribution of spiral ganglion cell bodies.

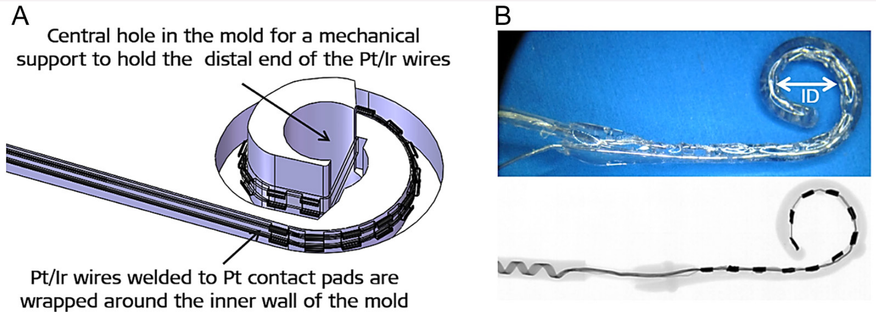

Figure 13. A, B. Fabrication of pre-curved electrode type. (A) Mold tooling showing groove in which the platinum/iridium wires are positioned and the central hole for the cam fixture to keep the wires under slight tension. (B) Prototype of a pre-curved electrode.

among the clinicians in the CI field as the manufacturing details of the CI electrode may not be interesting and can be complicated to understand. The final shape of the electrode, whether it is straight or pre-curved in configuration, depends on how the Pt/Iridium (Ir) wires are shaped before being encapsulated with the medical-grade silicone elastomer. For shaping the Pt/Ir wires, metal mold halves with grooves reflecting the final shape of the electrode are needed. To keep the wires in the appropriate position within the mold groove especially in pre-curved electrode type, the wires need to be kept under tension and for this a cam-like fixture is needed in the center of the mold as shown in Figure 13A. This would occupy the space in the center of the mold preventing the curvature of the mold groove to extend beyond a certain angulation. The limitations associated with the electrode mold tooling is one factor that prevents the pre-curved electrode type being fabricated beyond a maximum of 420°-450° of curvature.[63] Figure 13B is a prototype of the pre-curved configuration electrode for demonstration purposes only, fabricated by MED-EL, and this is to show that fabricating a pre-curved electrode is not an impossible task for MED-EL.

Even with advanced mold tooling and manufacturing techniques, if the pre-curved configuration electrode is fabricated with a curvature beyond 420°-450° of angulation, how the electrode would be straightened without breaking it before inserting it inside the cochlea and without causing intra-cochlear electrode tip fold-over (ETFO) become critical questions. The reason why the length of the pre-curved type slim modiolar electrode was reduced to 17.5 mm from its predecessor the Contour Advance, with a length of 18.5 mm, was to reduce the incidence rate of ETFO.[32] This is another factor that prevents the pre-curved configuration electrode being fabricated with a curvature beyond a maximum of 420°-450°. Recently in 2022, the HEARRING group of experts did a detailed literature review of 25 articles that reported on ETFO and found that an incidence rate of 5.3% is associated with the pre-curved electrode, compared to 0.5% with the straight electrode type regardless of the CI brand.[35]

Compared to the limitations associated with pre-curved electrode type, the straight electrode design involves relatively easy manufacturing procedures. The metal mold halves with straight groove of any desired array length as shown in Figure 14A is packed with Pt/Ir wires as shown in Figure 14B and injected with medical-grade silicone elastomer. Heat curing the injected silicone elastomer for a certain time and upon opening the mold halves provides a straight electrode of the desired length as shown in Figure 14C.

One of the motivating reasons for peri-modiolar placement of the pre-curved electrode is to reduce the stimulus level, thereby reducing the battery consumption. In 2015, Jeong et al[64] compared the battery consumption of the Contour Advance (pre-curved configuration) to the Slim Straight (straight configuration) electrode, both implanted on each side of the same patient. They concluded that although the level of electrical energy required for auditory stimulation seems to be lower for the peri-modiolar electrode array than for the laterally placed array, the dynamic range and the amount of battery consumption was similar.

The other common belief around the pre-curved electrode type is its ability to minimize facial nerve stimulation (FNS) due to its peri-modiolar placement, compared to the straight electrode type. In 2005, Smullen et al.[65] reported that 19 out of 600 CI patients experienced FNS following CI surgery from their patient population collected between 1993 and 2003. There was a similar rate of FNS as associated with both the nucleus peri-modiolar electrode (16 of 250 [6.4%]) and straight electrode (13 of 190 [6.8%]). In 2011, Berrettini et al.[66] reported 11 patients experiencing FNS out of 119 patients. Out of the 11 patients with FNS, 10 patients were implanted with a pre-curved electrode type and 1 patient with a straight electrode, both from the same CI manufacturer.

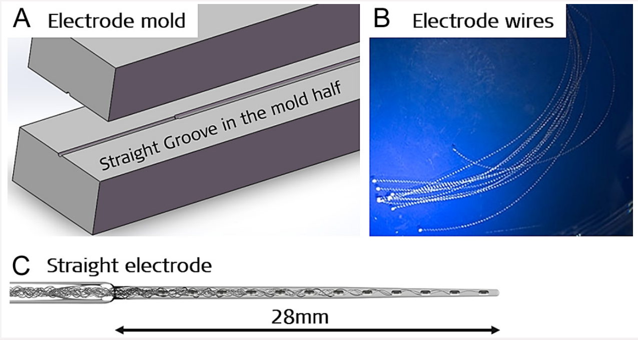

Figure 14. A-C. Fabrication of straight electrode type. (A) Electrode mold showing groove in straight configuration. (B) Platinum/iridium wires. (C) Prototype of a straight electrode.

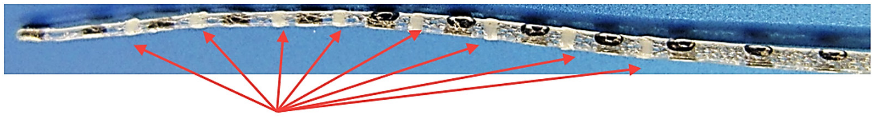

Figure 15. MED-EL's dexamethasone eluting electrode array with the dexamethasone containing silicone rings, loaded between the stimulating electrode channels.

Explantation of the electrode after years of implantation is often underreported in the CI field. Recently in 2022, Asfour et al[67] reported the force needed to explant pre-curved versus straight configuration electrodes from a plastic cochlear model. For the Contour Advance and Slim Modiolar electrode, both being pre-curved in configuration, it needed an approximate force of 70 mN and 50 mN on average, whereas for the Slim Straight electrode, it needed only 30 mN on average, regardless of the insertion depth (20 mm, 24 mm, or 28 mm). A personal communication from Prof. Dr. Wolf-Dieter Baumgartner from Vienna General Hospital, Austria, indicates that in real patient conditions, with new bone formation around the electrode inside the cochlea, the actual force needed to explant a pre-curved configuration electrode would be even higher than the 70 mN as reported by Asfour et al.[67]

What the Future Holds for Cochlear Implant Electrode?

Passive elution of drug particles from the electrode array is certain in the near future. This is reflected in the recent report from MED-EL on the first implantation of dexamethasone eluting electrode (FLEX28 from MED-EL) as shown in Figure 15 in patients by Prof. Thomas Lenarz and his colleagues from Hannover Medical School in Germany.[68] Cochlear® is also investigating the possibility of coating the electrode with dexamethasone as per the report by Briggs et al.[70] Dexamethasone is reported to have anti-inflammatory effects and minimizes the fibrous tissue formation around the electrode.[70]

MED-EL recently introduced a single-use passive device called inner ear catheter, which allows the CI surgeon to introduce any otoprotective drugs or cell-based biopharmaceuticals inside the ST before the CI electrode insertion process.[68] Figure 16A shows inner ear catheter with the silicone reservoir with septum at the back end, and Figure 16B shows how the inner ear catheter can be operated with an insulin syringe to push the drug solution.

In order to further reduce the manual electrode insertion trauma, robotic-assisted electrode insertion tools like RobOtol® and iotaSOFT® were developed by Collin Medical and Iotamotion, respectively.[35] These tools are commercially available and have reported success in patient cases. It is the personal wish of the author to have electrodes in the future with an implantable connector that would allow the decoupling of the implant electronic case from the electrode. This would create the possibility to replace the implant electronic case while leaving the implanted electrode untouched during reimplantation surgery which would support structure preservation.

CONCLUDING REMARKS

This review shed light on the requirements of an ideal CI electrode array design to accommodate the overall variations reported in the size, shape, and anatomy of the human inner ear, as well as minimizing the intra-cochlear electrode insertion trauma. It is agreed in the CI field that any degree of intra-cochlear trauma should be minimized during the electrode insertion process, and as the current scientific evidence indicates at the time of writing this article, the straight configuration electrode is less traumatic compared to the pre-curved configuration electrode. Moreover, scientific reports from clinics worldwide have shown the hearing benefits associated with electrical stimulation in the second turn of the cochlea. Manufacturing limitations and the intention to minimize the ETFO are 2 key reasons that prevent extending the curvature of the pre-curved configuration electrode types beyond 420°–450° of angulation. Before choosing an electrode for implantation, the clinicians should think about

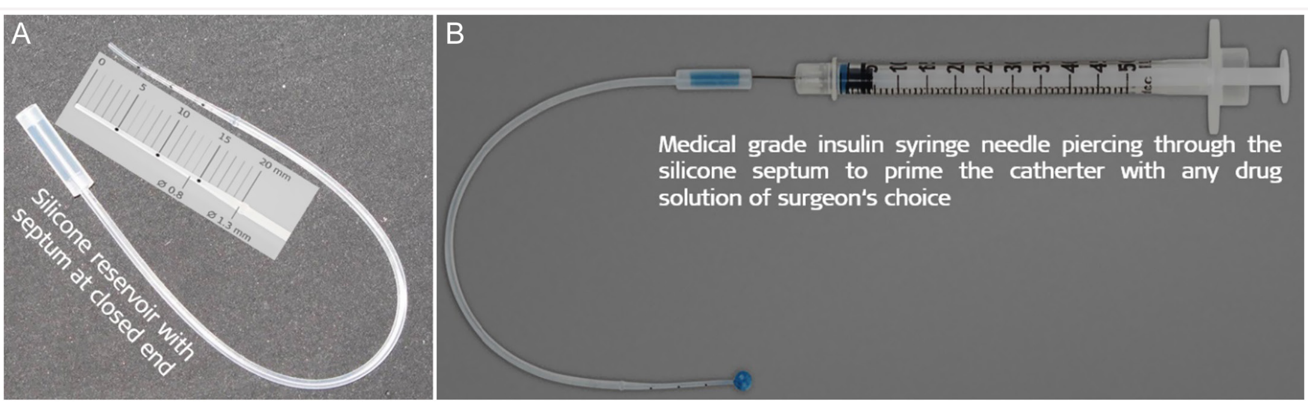

Figure 16. A, B. (A) Inner ear catheter with silicone reservoir with septum at the back end of the catheter, and the reduction of intracochlear part of catheter length to 20 mm. (B) Insulin syringe needle piercing and filling the reservoir with drug solution.

how the explantation of the electrode years after implantation could affect the cochlear health of the patients. In every aspect of the CI electrode array design, the straight configuration electrode seems to be proximal to the ideal CI electrode array design and that is one of the key reasons for every CI manufacturer to offer the straight configuration electrode type in their product portfolio.

Peer-review: Externally peer-reviewed.

Acknowledgments: Author thanks Dr. Una Doyle from MED-EL for editing a version of the manuscript.

Declaration of Interests: The author is an employee of MED-EL GmbH, which is one of the 3 major CI manufacturers.

Funding: The author declared that this study received no financial support.

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