



## Invited Review

# Why Pre-Curved Modiolar Hugging Electrodes Only Cover The Basal Turn of The Cochlea and Not Beyond that?

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The question of why pre-curved modiolar hugging (MH) electrodes only cover the basal turn of the cochlea and not beyond that is unanswered yet in the CI field. Therefore the aim of this article is to show what the practical limitations are with the pre-curved MH electrode design in not being able to fabricate beyond one full turn. Every CI electrode design needs a metal mold with grooves for placing the platinum wires and for injecting with the silicone elastomer. Limitations in making a mold with groove that goes beyond one full turn of curvature along with the mechanical deformation of the curved silicone elastomer, prevents making a pre-curved MH electrode beyond one full turn. Electrode tip fold-over, electrode scalar deviation and the inconsistent electrode to modiolus wall proximity are the reported issues with this electrode type which does not help by any means to the operating surgeon and the pediatric candidates especially. If intra-operative imaging is recommended to confirm the proper placement of the electrode for one particular electrode design, then how many clinics in the world may have this facility and is it ethical to put the patient under more radiation risk are the natural questions that needs to be answered in the interest of the patient. Every CI brand should come out of their marketing philosophy and innovate what is essential in bringing the full benefit of the device to the patients.

**KEYWORDS:** Pre-curved modiolar hugging electrode, electrode mold, basal turn of the cochlea

## INTRODUCTION

Cochlear implant (CI) electrode design has undergone several changes in the past decade from all the three Food and Drug Administration-approved CI manufacturers with the ultimate goal of preserving the delicate structures inside the cochlea <sup>[1]</sup>. Every CI brand operating currently in various markets worldwide offers straight lateral wall (LW) positioning electrode with varying array lengths in their electrode portfolio. The intention is to cover the cochlea with electrical stimulation for varying insertion depths depending on the hearing level of the cochlea and also to accommodate the variation in the cochlear size and shape <sup>[2]</sup>. On the other hand, the pre-curved modiolar hugging (MH) electrodes are currently offered only by two CI manufacturers and that too for the average cochlear size <sup>[3]</sup>. These pre-curved MH electrodes have undergone several design changes over the years, <sup>[4,5]</sup> yet the array length that determines the angular insertion depth has not been changed.

Need for electrical coverage of the cochlea beyond the basal turn has raised different opinions among the researchers in the CI field, yet everyone agrees of the necessity of having straight LW position electrodes with varying array lengths, and that is exactly what every CI manufacturer offers in competing among each other. However, the pre-curved MH electrode design has not been made available with varying array lengths. Here comes the natural question, is there any practical limitation with the fabrication of the pre-curved MH electrode in not offering array length long enough to cover beyond the basal turn of the cochlea?

The present study explores the design capabilities and limitations in the fabrication of both straight LW positioning and pre-curved MH positioning electrodes based on the author's professional experience in designing the CI electrodes and the teachings from the patent literature <sup>[6]</sup>. A review on this will certainly aid the clinicians to come out of any biased belief in choosing the electrodes that are truly designed for meeting the patient's cochlear need with minimal clinical complications. At the end, it purely benefits the patients who expect more from the CI, and that the electrode insertion trauma inside the cochlea should not disappoint them with poorer results.

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### Every electrode design needs a metal mold for fabricating the electrode

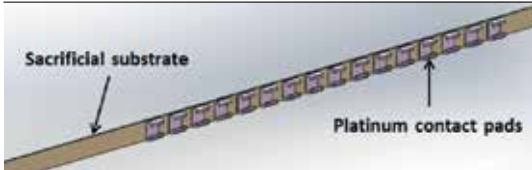

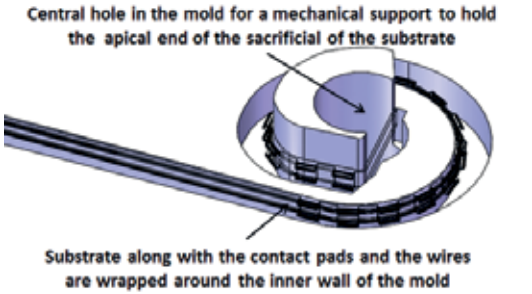

Straight LW electrodes from any CI manufacturers regardless of having stimulating channels either on one side or on both sides offer electrode arrays with varying array lengths. This is possible with the ease in fabricating the metal molds with varying lengths of the groove in which the wires and contact pads are packed and injected with a medical grade silicone elastomer. Curing the injected silicone at an elevated temperature for a certain time and on opening the mold provides the straight LW electrode a desired array length.

The lengths of all the commercially available straight LW position electrode arrays are given in Figure 2, showing the array length availability from a minimum of 16.6 mm to a maximum of 31.5 mm. On the other hand, all the commercially available pre-curved MH electrodes irrespective of the CI brand have an array length of between 17.5 mm and 19 mm.

### Manufacturing limitations that prevent making pre-curved electrodes longer than 19 mm

Unlike straight LW position electrodes that are relatively simpler to fabricate, the pre-curved electrodes involve sophisticated steps including the mold design and molding process. The basic steps involved in the fabrication of a pre-curved electrode based on the author's understanding on the electrode manufacturing process are shown in Table 1.

**Table 1.** Briefing the steps involved in the fabrication of the pre-curved electrode

Pictorial representation of the steps involved	Description of every step
	Step 1: Physically connecting the platinum contact pads to a sacrificial substrate.
	Step 2: Welding the wires to the individual platinum contacts.
	Step 3: Wrapping the sacrificial substrate with the welded platinum contacts and wires to the inner wall of the mold, pretty tightly. The apical end of the sacrificial substrate needs to be tightened with the help of any mechanical support followed by the injection of the groove with a silicone elastomer.
	Step 4: On curing the silicone elastomer, the electrode is removed from the mold, and the sacrificial substrate is removed by a suitable process depending on the material of the sacrificial substrate.

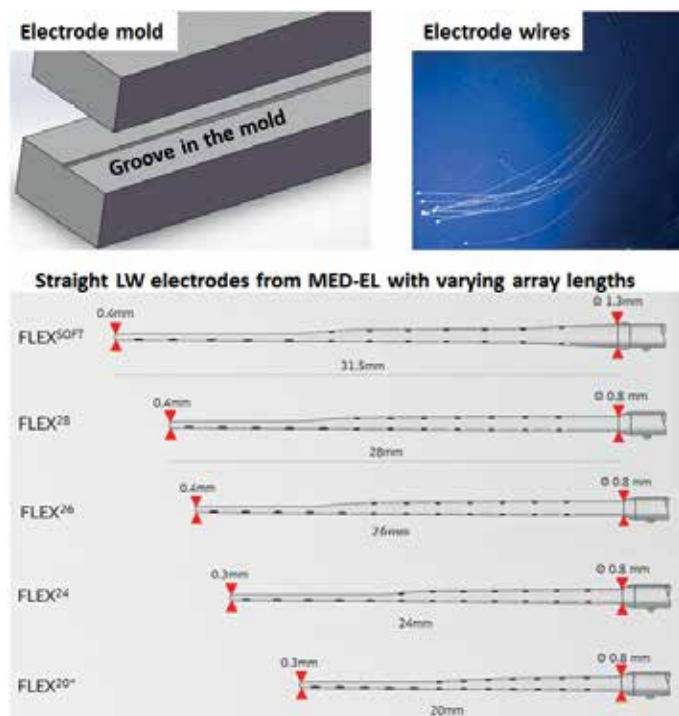
ID: inner diameter.

### Limitation 1

The inner diameter (step 4, Table 1) of the pre-curved electrode should match with the diameter of the inner wall of the cochlea in order to obtain a tight hugging position around the inner/modiolus wall. Since the commercially available pre-curved electrodes are made for the average size of the cochlea<sup>[3]</sup>, the tight MH position cannot be guaranteed in every CI case implanted with this electrode type. The mold for the pre-curved electrode needs a central hole for placing a mechanical support to which the apical end of the sacrificial substrate as shown in steps 1 and 3 is tightly coupled. This mechanical support takes relatively larger portion of the space in the mold, limiting the extension of the groove further apically as shown in Figure 3.

### Limitation 2

The straightening process of pre-curved electrodes involves application of metal stylet rod or a polymer tube, prior to the insertion of the electrode inside the cochlea. This straightening process could mechanically deform the silicone elastomer that was pre-formed. The ratio between the amount of silicone elastomer and the metal wires in the electrode array plays a vital role in keeping the pre-formed shape of the electrode array. It is a known fact that the silicone elastomer loses its shape memory when subjected to a considerable amount of strain<sup>[7]</sup>. Such mechanical deformation from the pre-curved electrode can be well understood by comparing figures 3 and 4 of Rau et al.<sup>[3]</sup> and figures 1 and 4 of Rau et al.<sup>[8]</sup>.



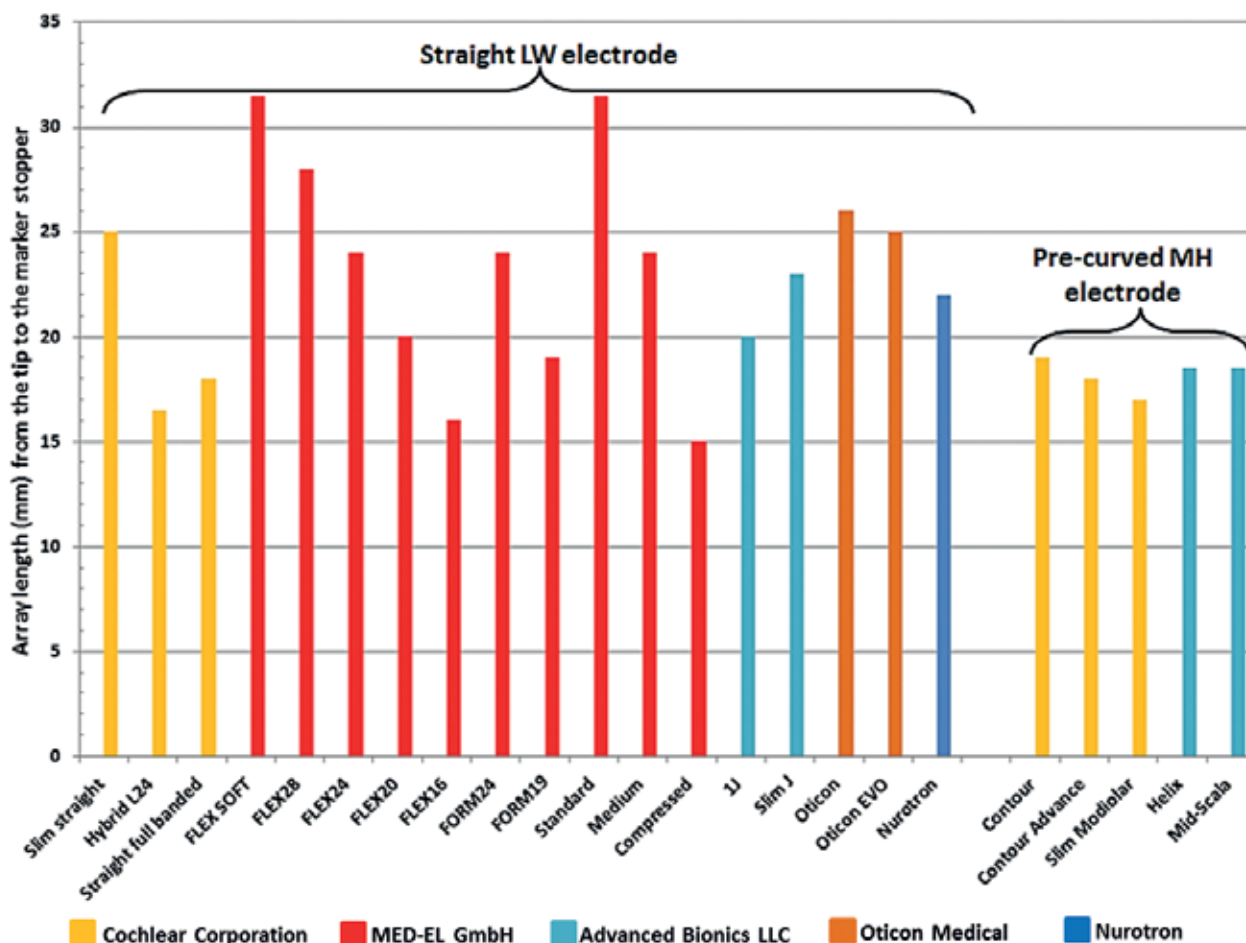
**Figure 1.** Showing the two-piece metal mold with groove for placing the electrode wires and for injecting the silicone elastomer. The finished straight LW electrode samples from various CI brands are also shown [2-4].

## DISCUSSION

Atraumatic intra-cochlear electrode placement plays a vital role in producing better audiological performance followed by the CI [9-16]. With the electrode types varying in design and insertion methods among the CI brands, it becomes challenging for the operating surgeon to consistently and atraumatically handle the electrode in every patient in which the anatomy is also different. This could result in considerable rates of intra-cochlear trauma in the opinion of the author. Ketterer et al. [9] reported on the electrode scalar deviation, which is considered as grade 3 trauma in 69 patients out of 319 patients implanted with Contour Advance electrode. They further reported on the consonant-nucleus-consonant word score which is 12% lower in cases with such electrode scalar deviation. As shown in Figure 2, the lengths of the straight LW electrode arrays are available in variety, providing the possibility of covering the cochlea with



**Figure 3.** Showing the groove (in blue) in the pre-curved MH electrode mold that cannot be extended beyond one full turn.



**Figure 2.** Showing the linear length of the electrode arrays from all the CI brands.

varying insertion depths. In contrast, the pre-curved MH electrodes, namely Contour, Contour Advance, Slim-Modiolar (Cochlear Corporation, Sydney, Australia), Helix, and Mid-scala electrodes (Advanced Bionics, CA, USA), are available with an array length of between 17.5 mm and 19 mm. When every CI manufacturer offers straight LW electrode in a variety of array lengths matching the cochlear size variation and also matching the partial deaf condition, then comes the natural question of why not the pre-curved MH electrodes as well be made available in different lengths.

The presence of the spiral ganglion cells (SGCs), which are responsible for transporting the electrical stimulation from the CI electrode, is shown to be present beyond the basal turn of the cochlea. In terms of angular insertion depth, it reaches as deep as  $630^\circ$ , which is equivalent to  $1\frac{3}{4}$  turn of the cochlea [17-33]. How far the electrical stimulation needs to be provided inside the profound deaf cochlea is under debate, but there are quite a good number of recent peer-reviewed literature showing improved hearing with electrical stimulation beyond the basal turn of the cochlea irrespective of the CI brands [10, 34-38]. Every SGC inside the cochlea has the ability to carry the electrical signal coming from the electrode to the brain, and there is no reason to eliminate some population of the SGC that are present beyond the basal turn of the cochlea. The pre-curved MH electrode at its current design cannot reach the SGC beyond the basal turn, and this is mainly owing to its design limitation that it cannot be physically made with curvature going beyond one full turn for reasons mentioned previously, and straightening the curved electrode by inserting a metal stylet rod or polymer tube mechanically deforms the curved shape of the electrode, making it difficult to go back fully to its initial curvature [3, 8].

Electrode tip fold-over [39-46] is an issue with every pre-curved MH electrode owing to its design feature, and the main reason for the tip fold-over is the premature pulling of the stylet rod. Though there are colored markers available in the electrode array that instruct the surgeon when to start pulling the stylet rod out, the size and the shape of the cochlea greatly vary, and in that situation, the colored marker does not provide enough help. Manufacturers of pre-curved MH electrode are well aware of the electrode tip fold-over issue, and this is clearly reflected in Briggs et al. [5]. They surmised that "Insertion dynamics and the incidence of tip fold-overs were found to progressively improve. Further relaxation of the distal curvature was achieved by reducing the intra-cochlear array length (modiolar wall length) from 19 to 17.5 mm, equating to an approximate  $30^\circ$  reduction in the intended design depth of  $420^\circ$ - $450^\circ$  to  $390^\circ$ - $420^\circ$ ." The Slim-Modiolar electrode, which is the latest release from the cochlear corporation at the time of writing this article, is only 17.5 mm in comparison to the Contour Advance electrode, which is 19 mm. The reason for shortening the array length of the Slim-Modiolar electrode is to reduce the occurrence rate of tip fold-over, as understood from Briggs et al., [5] which directly jeopardizes the ability to cover the complete population of the SGCs. McJunkin et al. [41] recommended intraoperative imaging to control the tip fold-over issue with the pre-curved electrode but did not address issues, such as how many clinics in the world have the intraoperative imaging facility and the additional radiation risk to the patient.

Electrode scalar deviation is another electrode insertion issue with every pre-curved MH electrode type irrespective of CI brand owing to the application of a stiff metal stylet rod or a stiff polymer sheath in

straightening the electrode from its pre-curved configuration during electrode insertion. Such electrode scalar deviation reports to have a direct negative effect on the patient's postoperative hearing using the CI [9-16].

One of the main marketing features of the pre-curved MH electrode is the closer electrode to the modiolar wall proximity. Owing to the variation in the size and shape of the cochlea, one-sized pre-curved MH electrode may not be able to provide tight hugging of the modiolar wall, and this has been clearly reported by both McJunkin et al. [41] and Wang et al. [47]. It is important to stress what Wang et al. [47] reported in their article that "Our results show that perimodiolar EAs, more often than not, do not sit adjacent to the modiolar wall where they are likely most effective."

Explantation of pre-curved MH electrodes is still not a widely discussed topic in the CI field. Every electronic device has a life-time, and this is well applicable to the CI as well. Every 20-25 years, the CI needs to be replaced and during revision surgery, the pulling of the pre-curved electrode out of the cochlea exerts a considerable amount of force on the modiolar wall of the cochlea, which could potentially cause intra-cochlear structural damage that was also a concern reported by Tykocinski et al. [4]. In contrast to this concern, Todt et al. [48] reported no damage to the modiolar wall with perimodiolar electrode pull-out in cadaveric temporal bones.

Every CI brand has a design philosophy which they derive mainly from the manufacturing know-how. While the Cochlear Corporation takes the "Hearing Zone" concept and projects the message that there is no need for electrical stimulation beyond the basal turn is highly questionable with the clear understanding on the practical limitation in fabricating pre-curved electrode beyond one full turn. Electrodes from Oticon Medical (Denmark) and MED-EL GmbH (Austria) are longer than 25 mm and that provides the possibility to cover  $1\frac{3}{4}$  turns of the cochlea in capturing the entire population of SGC. Every CI brand should emerge of their marketing philosophy and make what is essential in bringing the full benefit of the device to the patients, for what patients pay enormous amount of money.

## CONCLUSION

It is distinctly clear that manufacturing of a pre-curved MH electrode with curvature beyond one full turn is practically not possible, and this should not preclude the benefits of providing electrical stimulation beyond the basal turn of the electrode. Electrode tip fold-over, electrode scalar deviation, and inconsistent electrode modiolar wall distance associated with pre-curved MH electrodes need to be well understood before recommending this electrode type to pediatric patients, especially those who are expected to undergo several revision surgeries in their life-time.

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