The design and development of a peri-modiolar electrode array

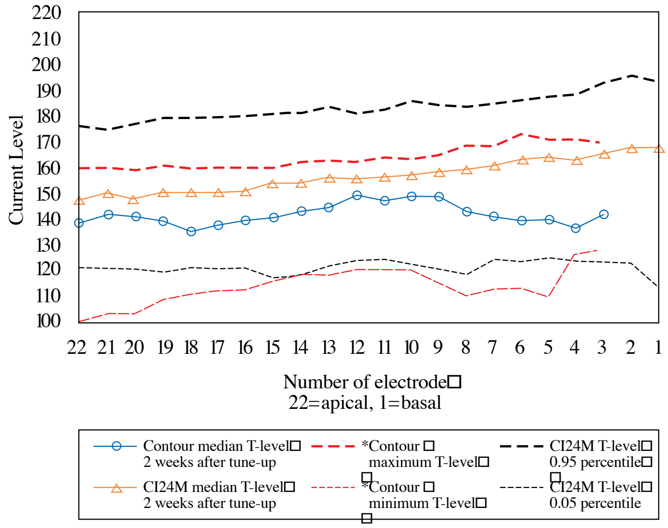
Introduction

Ideally, multi-channel cochlear implants electrically stimulate relatively localised regions of the auditory nerve. However, histologic and radiologic studies have demonstrated that most electrode arrays lie along the lateral wall of the scala tympani and are, therefore, not in an optimal position to stimulate the spiral ganglion cells[1]. Investigations have shown that locating the electrode array closer to the spiral ganglion cells can result in a reduction in the stimulation threshold[1].

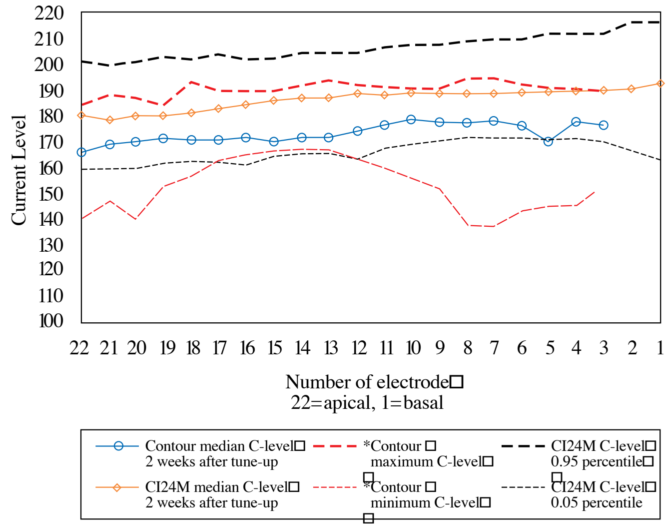
A variety of methods of implementing a peri-modiolar electrode array have been investigated by Cochlear and internationally respected, academic investigators[2]. Various options to achieve modiolar proximity have been rigorously evaluated in a simultaneous manner; these are described below. Following six years of collaborative research, the outcome of this product development process was the Nucleus® 24 Contour which fulfils the requirements for an effective and safe peri-modiolar electrode array.

Cochlear approaches the release of new implant technology carefully. Safety and clinical data collection is in progress with several worldwide investigators. Preliminary psychophysical data shown below would indicate a positive trend towards reducing power consumption and achieving greater modiolar proximity. For a fuller discussion of these data please refer to the clinical experience section at the end of this paper.

Contour and CI24M T-levels 2 weeks after tune-up



Contour and CI24M C-levels 2 weeks after tune-up



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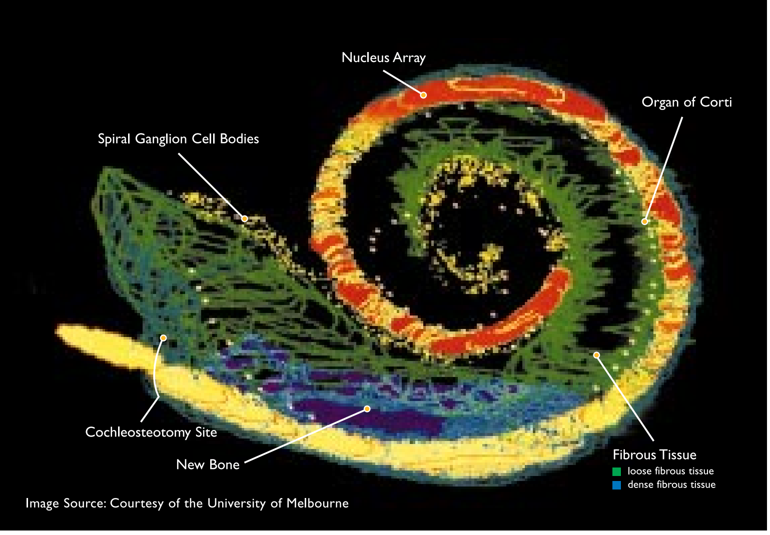


Image Source: Courtesy of the University of Melbourne

Why use a Peri-modiolar Array?

Although a straight but flexible electrode array can be safely inserted into the scala tympani of the human cochlea, it tends to lie along the outer wall[1,3]. By contrast, locating an electrode array next to the modiolus and, therefore, closer to the spiral ganglion cells can result in a reduction in the stimulation threshold and an enlarged dynamic range[1].

The image above shows the Nucleus® straight electrode array in the cochlea. The curvature follows the lateral wall rather than the spiral ganglion cell bodies (SGCs) which are the target for stimulation.

A variety of methods of implementing a peri-modiolar electrode array have been investigated by Cochlear and the cochlear implant community. Various options to achieve modiolar proximity have been rigorously evaluated and are described below.

The peri-modiolar approach to the design of an electrode array has the potential to offer a number of future clinical benefits for cochlear implant recipients:

- More functional channels because of the potential to stimulate the auditory nerve fibres in a more selective manner[1]
- Lower power consumption because of the close contact between the electrodes and the target neurons, thus providing the possibility of speech processor miniaturization[1]
- More patients can enjoy greater battery longevity

Research into all of these areas is being undertaken by a number of research collaborators working with Cochlear.

Design Requirements & Goals

Cochlear has investigated the use of peri-modiolar electrodes for more than six years.

The research programme is driven by the following requirements. The array had to:

- Be located close to the modiolus[1]
- Conform with a variety of modiolar shapes
- Allow more selective stimulation of the ganglion cells
- Be safely and easily implanted
- Be inserted in the least invasive manner possible
- Be easily fixed near to the round window
- Exert no static forces on intracochlear tissue
- Be relatively simple to manufacture

Design Considerations

The basis of any electrode array design is the cochlea anatomy. This has been studied by several groups[4,5,6]. They have shown that the cochlea has reached its final shape and size at birth and that its dimensions remain unchanged throughout life. Both the height and width of the scala tympani decrease rapidly within the first 1.5 mm of the round window and they continue to do so with increasing distance from this structure. The width of the scala tympani is consistently greater than its height. The cross sectional area decreases as the distance from the round window increases.

Knowledge of the dimensions and three dimensional arrangement of the cochlea and the ganglion cells has influenced the design of peri-modiolar electrode arrays. Several designs have been investigated in an attempt to develop a suitable electrode array which lies closer to the modiolar wall – these are described briefly below.

Alternative approaches to designing a peri-modiolar electrode array

Electrode plus Space Filling Positioner: Space Filling Positioners, made from biocompatible insulating materials, have been used to push the electrode array close to the modiolar wall. These devices are inserted after the electrode has been inserted into the scala tympani. The positioner acts like a wedge: it fills the space between the lateral wall of the cochlea and the electrode array. However, the pressure exerted by the positioner on the basilar membrane and the stria vascularis can lead to considerable damage. The tube-like shape of the scala tympani can direct the positioner up toward the basilar membrane, which can cause the membrane to rupture[7].

Electrode array with positioning wire: This approach involves the use of a straight electrode array with a fine guide wire attached to its tip. After the electrode array has been inserted, the guide wire is pushed further in, thus causing the electrode array to curve along the modiolus. Several prototypes have been studied using human temporal bone specimens[8]. Although implantation could be performed without significant damage to the intracochlear morphology in some cases, trauma was observed in other cases. However, explantation regularly caused varying degrees of tissue damage, depending on the technique used to remove the implant[8]. The majority of the intracochlear architecture was destroyed by re-implantation and subsequent removal of the electrode array.

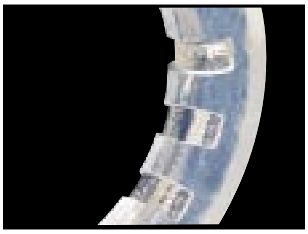
Pre-curved electrode array inserted with an insertion tool: The mean basal width of the scala tympani is approximately 3 mm and the mean apical width is approximately 1.5 mm[6,9]. This allows a pre-curved electrode array to bend within the first turn of the cochlea but it may also fold over during further insertion. In order to prevent this, the pre-curved electrode array must be kept straight by means of an insertion tool. The tube of the insertion tool is inserted through the cochleostomy for a distance of approximately 6 mm, and then the electrode array is further inserted by sliding it out of the tube. For ease of insertion and to minimise the risk of folding over occurring, the apical part of the electrode array is only slightly bent. This could compromise the fit in the apical region of the cochlea.

Electrode with Hydrogel®: An electrode array which self-curls due to the presence of a hydrophilic backing is one approach to solve this bioengineering and surgical problem. Electrode arrays made with Poly Acrylic Acid (PAA) hydrogels which swell in water were manufactured and tested for shape characteristics and biocompatibility[10]. PAA was proven to be biocompatible for intracochlear implantation. However, the degree of swelling of the PAA hydrogel was difficult to control and the PAA carrier fills the cochlea when swollen, which can generate similar problems to those highlighted for the Electrode plus Space Filling Positioner described above.

Pre-curved electrode with Poly Vinyl Alcohol: An alternative method to hold a pre-formed electrode array straight during the insertion process is to coat it with Poly Vinyl Alcohol (PVA). The PVA dissolves in water once inserted into the cochlea, and allows the array to bend into the desired position[11]. More research is needed, however, to determine the PVA coating which has the optimum dissolution time, and to ensure its biocompatibility.

Introducing the Nucleus® 24 Contour

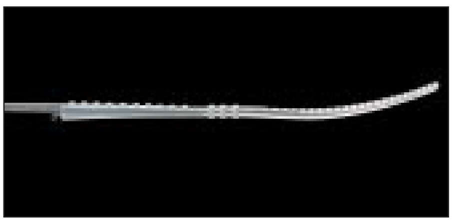
The drawbacks of the designs of peri-modiolar electrode arrays described above led the Cochlear R&D personnel to adopt a novel approach to electrode design. The physiological shape of the Nucleus® 24 Contour facilitates a predictable closeness between the electrode array and the modiolar wall. The half banded electrode array has a maximum diameter of 0.8 mm and tapers to a tip diameter of 0.5 mm.



The half banded electrode array of the Contour

When the electrode array is inserted to a depth of 25 mm from the round window, it occupies around 25% of the cross sectional area of the scala tympani. However, because the scala tympani is smaller in height than width at this point, the electrode array represents around 50% of the height of this structure. It does not cause pressure on the cochlear architecture because of its non-space filling design.

The electrode array of the Nucleus® 24 Contour is pre-shaped so that it follows the modiolar wall when it is in its relaxed state [11,12,13]. During the insertion process, it is held straight by means of a malleable stylet housed within the lumen (central cavity) of the electrode array.



Apart from the electrode array itself, no additional devices, such as a guide wire or a positioner, are inserted. This keeps the risk of tissue damage and reactions to a minimium[12].

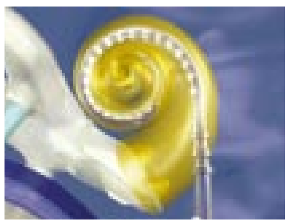
After the removal of the stylet, the electrode array curls toward the modiolar wall and the tip moves deeper into the cochlea. The physiological, pre-determined final position is reached when the silastic is in a relaxed state and, thus, no force is applied to the cochlear structures There is no need for any extra devices, such as space filling positioners or wires, to force the half-banded array into position. The Contour design does not rely on any force being applied to the electrode array and the cochlear structure in order to hold it in place. Hence, the surgeon does not need to balance the benefit of deep insertion of a wire or a positioner against the risk of damaging the cochlea structures.

The shape of the Nucleus® 24 Contour is unique in the pursuit an atraumatic peri-modiolar electrode array: the curve of the electrode array naturally follows the contour of the human cochlea. The physiological shape of the Nucleus® 24 Contour enables the electrode array to be placed safely next to the modiolar wall. As a result, the twenty two electrodes lie next to the spiral ganglion cells. Despite this close proximity, the contoured shape of the electrode array means that the cochlea and its blood supply are not under static force which minimizes the risk of obliteration and enhances spiral ganglion cell survival[12]. The blood supply to the auditory nerve is unimpeded because static force is not required to hold the electrode array in place. In addition, the metabolism of the cochlea is maintained because the stria vascularis is untouched and so changes to the hydrodynamics in the scala vestibuli are kept to a minimum. The trend towards providing patients who retain some residual hearing with cochlear implants means that avoiding damage to the cochlear structures is a critical issue.

Mechanism of action of the Nucleus® 24 Contour

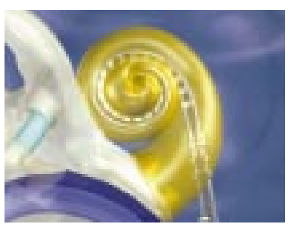
Electrode array with Stylet is introduced into the Cochlea

The Stylet (shown in blue) holds the array straight



Optimal insertion depth is achieved

Stylet removal has commenced



Stylet removal is now complete. The half banded electrode array is now lying closer to the Modiolus with no static force being applied to the lateral or medial wall

The specific cochlea spiral shape of the relaxed electrode array and its virtually straight shape for easy insertion are safety features which preserve the delicate structure of the cochlea and thus minimise the formation of fibrous scar tissue. Scarring is also minimised because only one structure, rather than an array plus a positioner, is implanted. Hence, the patency of the cochlea is preserved, which is a prerequisite for focused electrical stimulation and future re-implantation, if required. This enables all patients to take advantage of future developments in implant technology, as well as being particularly useful for paediatric recipients.

Improvements have also been made in the receiver platform in order to simplify surgery. The receiver stimulator platform used in the Nucleus® 24 Contour is smaller, rounder and easier to place than current devices. In addition, its lead exits are vertically aligned, thus preventing cross over from occurring and allowing right and left ear implantation to be carried out more easily.

Clinical Experience with the Nucleus® 24 Contour

A clinical trial is currently ongoing in which the functionality and safety of the Nucleus® 24 Contour is being assessed primarily in adult subjects with patent cochleae. During the study, the surgical procedure and surgical tools will be validated. X-Rays will be taken to determine the electrode position. Psychophysics as well as speech perception performance, will be used to evaluate the clinical benefits of achieving greater modiolar proximity.

Preliminary data

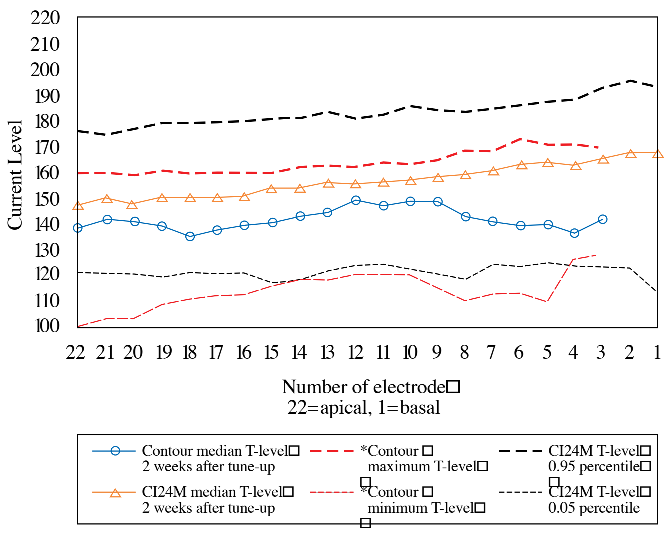
In deciding to use a peri-modiolar array it would be expected that a reduction would be seen in T levels[1]. Preliminary clinical data suggests that the Contour T levels are approximately 15 current levels (CL) below that of the comparative CI24M data.

Two weeks after tune up, Contour subjects (N=8) had a median T level of 140CL. The comparative CI24M data was 156CL. This difference was found to be highly significant. A similar reduction was found in the C level data with an average C level of 173CL for the Contour compared to 185 for the CI24M.

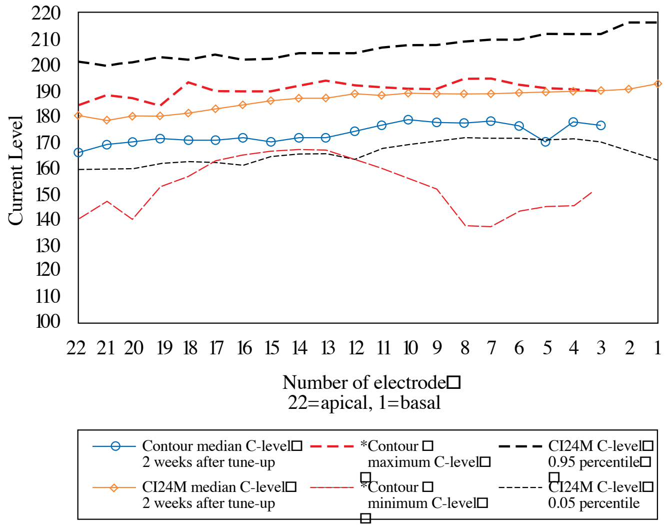
The graphs below represent T and C levels over individual electrodes.

The blue line with circles represents the median value of the Contour for eight subjects. The median T/C levels for the Contour are below the median values for the CI24M (represented by the orange triangled line, N=136). The dashed red lines give the minimum and maximum Contour T/C levels. Additionally, for comparison the 0.05 and 0.95 percentiles of the CI24M data are represented by the black dotted lines.

Contour and CI24M T-levels 2 weeks after tune-up



Contour and CI24M C-levels 2 weeks after tune-up



Summary

The Nucleus® 24 Contour is characterised by:

- Close proximity of electrode array to the spiral ganglion cells
- Safe and straightforward implantation technique which allows re-implantation to be performed if necessary
- Least invasive option – no additional devices to hold array next to the modiolar wall
- No static forces exerted on the intracochlear morphology

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