PRECURVED ELECTRODE ARRAY AND INSERTION TOOL

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INTRODUCTION

Future improvements in the performance of patients using cochlear implants largely depend on improving the electrode array design. In particular, it is necessary to produce an array that would lie in the desired portion of the scala tympani while minimizing insertion trauma to the cochlea.

Several studies have suggested that intracochlear electrodes often do not locate in the optimal position for stimulation. During the surgical insertion procedure, a straight electrode array tends to engage the outer wall of the scala tympani. This produces more widespread neural excitation than is desirable and results in diminished resolution of speech perception. However, optimal stimulation is obtained from locating the electrodes next to the spiral ganglion cells, which in humans lie within the central axis of the cochlear spiral or modiolus.

Computer modeling studies of the electrically stimulated cochlear current flow have predicted that a medial placement of electrodes reduces the radial spread of neural excitation. In an animal study, electrically evoked auditory brain stem responses were recorded while varying the location of a Cochlear (Nucleus) banded electrode array within the scala tympani of the cat cochlea. The results have shown that positioning of the array closer to the modiolus increases the dynamic range of electrode pairs while reducing the stimulation thresholds. This indicates that a larger channel capacity as well as a lower power consumption would be facilitated if the electrodes follow the internal part of the cochlear spiral. As a result, speech perception in cochlear implant patients would improve. There could also be gains in speech perception, as an electrode array positioned close to the modiolus could be designed with a narrower interelectrode spacing and thus be capable of providing more channels of stimulation.

Moreover, a medially placed electrode array will attain a greater depth of insertion with the same array length because of its smaller radius of curvature, and it will thus extend the perceivable frequency range toward lower frequencies. Another important consideration is the minimization of trauma to the cochlea. Previous studies have also shown that straight electrode arrays tend to distort the spiral ligament, basilar membrane, or other structures during insertion, possibly causing trauma and creating insertion difficulties.

This study describes a precurved electrode array and its insertion tool that could achieve a deeper and safer insertion, lower current threshold and power consumption, and finally, improved auditory perception.

MATERIALS AND METHODS

The design of a precurved electrode array required the shape of the scala tympani to be accurately defined. Eleven adult human cochleas were used in this study. A small hole was drilled at the apical end of each cochlea, and the round window was opened. The cochlea was then dehydrated in absolute alcohol. Silicone rubber was injected into the scala tympani through the round window, and was allowed to cure at room temperature for 48 hours. Finally, the mold was removed from the cochlea by drilling the overlying bone. The molds were positioned under a video camera connected to an image analyzer, and axial projections of the scala tympani were recorded and digitized. An exponential function providing the best fit for the experimental data was derived to represent the curvature of the inner wall of the scala tympani. The following expression for the optimal shape of the longitudinal axis of the array was obtained: R(θ) = Ae^B(θ+C), where R is the radial distance of the longitudinal axis of the array from a center, θ is the angle about the center (0 ≤ θ ≤ π/2), and A, B, and C are values obtained from the experimental data.

On the other hand, there would be little benefit from carefully characterizing the shape of the implant array unless it maintains the advantages of the prior array. The Nucleus Minisystem-22 banded electrode array is smooth and flexible and has graded stiffness. The circumferential surface of the electrodes ensures that charge densities are kept low to avoid electrode corrosion and damage of neural tissue.

This design also provides a tolerance for the positioning of the electrode array relative to the scala tympani inner wall. The array tapers from a maximum of 0.6 mm to a tip diameter of 0.4 mm, so that its dimensions are significantly lower than those of the scala tympani canal. All these characteristics are maintained in the precurved array design developed at the University of Melbourne. Platinum electrode rings are indi-
Individually welded to Parylene-coated platinum alloy wires, and these are then molded in the designed shape with silicone rubber. A prototype precurved electrode array is illustrated in the Figure, A. The array comprises an angled portion, a straight portion including electrodes, and a curved portion also including electrodes. The tip region, containing the first three bands, does not conform to the exponential curve, as this would be a very tight curve for the electrode array to pass through the basal turn. It is instead only slightly curved. Finally, it is evident that the new array, although precurved, is not sided; that is, one implant can be manufactured for and inserted into either the left or the right cochlea.

Because of the surgery of cochlear implantation and the physical shape of the scala tympani, the electrode array needs to be held straight as it is inserted into the basal turn. An insertion tool has been designed and constructed, so that the electrode array can be temporarily straightened in it and then released directly into the scala tympani. The insertion tool is illustrated in the Figure, B. Its tip part comprises a tube with a slit provided longitudinally and a flexible rod within the tube, enabled to move longitudinally by actuating a knurled wheel. The rotation of the wheel is in the opposite direction to the electrode insertion direction; that is, the actuating finger moves back in order for the electrode array to move forward. This arrangement has the advantage of providing the surgeon with excellent tactile information, while avoiding any tendency to push the instrument forward during insertion and possibly cause trauma to the cochlea.

In use, the curved and straight portions of the electrode array are placed into the tube such that the curve of the array is directed away from the slit. Following exposure of the scala tympani, the tool is inserted into the straight portion of the
basal turn, typically about 6 mm in through a cochleotomy. The tube is marked at 5, 6, and 7 mm from the tip to indicate the appropriate insertion depth. The rod is then moved forward and the array advanced directly into the curved portion of the scala tympani, resuming its predetermined shape. When the array has been inserted as far as possible into the cochlea, the instrument can be removed without disturbing the electrodes.

RESULTS

A suitable die for custom manufacturing of precurved electrode array prototypes was constructed. The die was initially tested with Silastic and rings-only models of the array. The models were examined under magnification with use of a light microscope equipped with a calibrated graticule. A constant 0.03-mm drift of the measured diameters from the rated ones was recorded; that is, prototypes made with this die taper from a maximum of 0.63 mm to 0.43 mm at the apical end. This minor difference was considered to have little if any effect on mechanical and insertion studies. Ten precurved electrode array prototypes were manufactured for these studies. The electrode manufacturing technique incorporates the technology developed for the production of the Nucleus 22 straight-banded electrode array. While maintaining the same axial interelectrode spacing as in the straight electrode array design, each precurved prototype has 22 potentially active electrode rings.

Mechanical tests of repeatedly straightening the electrode array in the insertion tool and then releasing it were done with two of the prototypes. This study has shown that the array resums its spiral shape after the restraining forces disappear. Measurements of the radius from the spiral center to the longitudinal axis of the electrode array were taken and averaged before the test, and after the 1st and 10th cycles of straightening and releasing of the array. A comparison between the corresponding shapes of the electrode array is illustrated in the Figure, C. The radius of the spiral portion increases by 20% on average following the first mechanical test, but remains almost unchanged after the subsequent tests. The spiral angle decreases accordingly, from $5\pi/2$ rad to around $2\pi$ rad ($360^\circ$).

A number of insertions in open cochleas were performed with two other prototypes. Results were recorded and indicated that the precurved electrode array remained close to the inner wall of the scala tympani after insertion. A view from the apical end of the cochlea with a precurved implant is illustrated in the Figure, D.

Finally, six precurved electrode array prototypes were tested under simulated surgical conditions. The implantation procedure was modeled using human temporal bones. One prototype buckled and came loose during surgery, while the other five were successfully inserted. The reason the first implantation failed is seen in the need for further refinements tested under simulated surgical conditions. The implantation resumes its spiral shape after insertion and lies close to the inner wall of the scala tympani. A section of the cochlea with a precurved electrode array implant is shown in the Figure, E. As evident from this section, the stimulating electrodes are positioned next to the modiolus on one side and close to it on the other side of the section, which was cut through the tip part of the array.

DISCUSSION

Mechanical tests and insertions in open cochleas and human temporal bones have revealed that the array resums its predetermined shape after being straightened and released. The curved portion of the electrode array, however, describes approximately 1 turn about the central axis of its geometric spiral, compared to the initial 1/4 turns. This result is obviously accompanied by an increase in the distance between the stimulating electrodes and the modiolus. In addition, the tip region of the array is designed not to follow the exponential curve, but to be only slightly curved for ease of insertion. Anatomic and pathologic variations of the cochlea could also result in differences in the distance between an electrode and the inner wall for several electrodes positioned along the array. It can therefore be expected that not all stimulating electrodes lie next to the modiolus, but that some lie in proximity to it. This assumption was confirmed by the results from insertion tests.

On the other hand, the depth to which the precurved electrode array can be inserted is limited by the total length between its tip and the beginning of its angled portion. The length of the precurved array is 18 mm when straightened in the inserting tool. Results from insertions revealed that the array is fully inserted to an average depth of over 1 turn of the scala tympani. Increasing the straight portion of the electrode array by adding a number of "stiffening" banded electrodes would lead to a region of active rings distancing itself from the modiolus. It is therefore desirable that the length of the curved portion of the array be increased, but without the tip region becoming too tight and so creating insertion difficulties.

The main aim in improving the design of scala tympani electrode arrays is to locate the electrodes in the optimal position for stimulation and minimize damage to the cochlear structures. This study shows that the precurved banded electrode array lies close to the modiolus after insertion and achieves greater than average insertion depths with the aid of a suitable insertion tool. The issue of trauma secondary to insertion of the new array will be assessed by histologic examination of the implanted cochleas. The present data provide an engineering basis for the development of further improved intracochlear electrode arrays.

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REFERENCES


COCHLEAR IMPLANT RELIABILITY

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INTRODUCTION

The reliability of cochlear implants is important for patients and clinicians when making the decision to use an implant. Patients will frequently ask questions such as "What is the likelihood of my implant’s malfunctioning, and how likely is this to happen several years after surgery?"

Most reliability measures that are commonly used are based on statistical assumptions and therefore may not reflect the actual performance history of a device. The cumulative experience report (CER), otherwise known as cumulative survival analysis, is an effective means of presenting historical performance data and is the accepted reliability measure in the pacemaker industry.¹ Comparative reliability data for cochlear implants have been published for the Nucleus and 3M devices only.²

This paper discusses several measures of reliability and their merits. Reliability data from Cochlear Pty Limited are used to explain the CER. The influence of factors such as device numbers and implant lifetimes, which are the basis for reliability claims, is reviewed, and the impact of design improvements is shown.

DEFINITIONS

Reliability is defined as “the probability of a device performing its purpose adequately for the period of time intended under the operating conditions encountered” (quoted from the Electronics Industries Association in the United States). Another similar definition of reliability is “the probability that a device will survive without failure for a stated period of time, under stated conditions of use.” It is important to note that reliability is related to probability and therefore involves confidence levels and statistical reasoning. The other important element is time. Without a time definition, the concept of reliability has little meaning.

In general, a device failure can be defined as “the inability to perform its intended function.” We can differentiate between so-called soft and hard failures. Soft failures are characterized by a deviation from the specification without a total loss of function. The hard failures that are discussed in this paper involve the total loss of function and, therefore, require further surgery to remove and replace the implant. There are different causes of failure that relate to the design, manufacture, and user. Design refers to an inherent characteristic of the device. Manufacturing-induced failures are usually random defects introduced by component or process variations. A user-induced failure, for example, could be a severe blow to the implant site due to an accident.

PERFORMANCE MEASURES

The device experience must be established in order to derive performance measures. From 1985 to June 1994, 8,804 patients were implanted with the Nucleus Minisystem-22 implant. The number of implants that are in service for a given time period is shown in Fig 1. The accumulated experience which is found by adding the number in each period is 23,518

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