formation. The commonest sites of osteoneogenesis appeared to be 1) along the outer wall of the scala tympani, usually extending from the region of the round window membrane, 2) beneath the osseous spiral lamina (Fig 2), and 3) within the fibrous tissue surrounding the electrode tract.

The total volumes of new bone and fibrous tissue in the scala tympani of each cochlea are shown in the Table. The Mann-Whitney U test applied to the histologic data demonstrated the presence of a significant overall correlation between the presence of bone paté and/or trauma and the intracochlear growth of new bone \( (p = 0.01) \). However, there did not appear to be a significant correlation with fibrous tissue formation \( (p = 0.19) \).

Multiple regression confirmed a significant correlation between the volume of new bone in the scala tympani of a cochlea and the mean change in ABR threshold of that cochlea. This relationship, however, did not appear to hold true for the growth of fibrous tissue. Using the same nonparametric tests and selecting individual cochleas with specific insertion parameters for statistical comparison, it was possible to show that in the presence of both endosteal trauma and bone chips, there was no significant difference in the amount of intracochlear new bone \( (p = 0.25) \) and fibrous tissue \( (p = 0.46) \) between cochleas that had been implanted with electrodes containing no EHDP and those that had been implanted with EHDP electrodes. Furthermore, in the presence of bone chips, endosteal trauma, whether intentional or not, exerted no significant influence on the amount of intracochlear osteoneogenesis and fibrous tissue formation, no matter whether EHDP was present or not. Finally, in the absence of demonstrable trauma and in the presence of EHDP, the introduction of bone chips made no significant difference to the amount of new bone \( (p = 0.36) \) or fibrous tissue \( (p = 0.17) \) that subsequently formed.

**DISCUSSION**

The present study demonstrates in the experimental animal the ease with which new bone and fibrous tissue can form within the scala tympani in response to the implantation of an electrode array, and that such tissue growth is associated with an elevation of ABR threshold for the cochlea. In addition, endosteal trauma and bone chips are both associated with an increased risk of intracochlear osteoneogenesis. However, once new bone and/or fibrous tissue form, the actual amount of tissue growth is not predictable, and the relative roles of trauma and bone chips may not easily be separated. This implies that other factors are involved in the pathogenesis of intracochlear new bone growth, for instance, the local cochlear microenvironment and host factors such as infection, causing biologic variation between cochleas of different animals. In addition, EHDP did not appear to have made any significant difference to the extent of new bone and fibrous tissue growth within the cochlea. The finding of a highly significant correlation between the extent of intracochlear new bone growth and elevation of ABR thresholds in this study indicates that intracochlear osteoneogenesis may be associated with a significant deterioration in the hearing function of a subject.

**CONCLUSION**

Intracochlear osteoneogenesis and fibrous tissue growth represent a real pathologic complication of cochlear implantation, for which no effective therapeutic or prophylactic measure is presently available, apart from the adoption of a general cautious surgical approach minimizing the risks of endosteal trauma and introduction of minute bone chips into the scala tympani. The mechanism of intracochlear osteoneogenesis is complicated and is likely to be multifactorial.

**REFERENCES**


**INITIAL INVESTIGATION OF THE EFFICACY AND BIOSAFETY OF SODIUM HYALURONATE (HEALON) AS AN AID TO ELECTRODE ARRAY INSERTION**

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**INTRODUCTION**

Stimulation of residual neural elements by electrodes inserted into the cochlea to produce the perception of speech and environmental sounds in profoundly deaf people is a fundamental aim of cochlear implantation. The multiple-channel cochlear implant utilizes the tonotopic arrangement of the organ of Corti to also achieve place pitch perception by stimulating different electrode bands. It may be possible to improve the range of pitches perceived by present cochlear implant patients by inserting the electrode array more deeply.
To help achieve this, investigators have used sodium hyaluronate as a lubricant for electrode insertions. It was felt deeper insertions were produced with sodium hyaluronate. Before introducing this substance as part of the surgical protocol for the Melbourne Cochlear Implant Clinic, it was decided to investigate its efficacy in aiding deeper insertions of the electrode. In addition, it was also necessary to determine if sodium hyaluronate, in conjunction with cochlear implantation, had adverse effects on the inner ear. This study was undertaken to address these issues.

METHOD

A temporal bone study was used to investigate the depths of insertion achieved using sodium hyaluronate as a lubricant. Six human cadaver temporal bones were implanted within 24 hours of death. The same surgeon who was experienced in implantation performed all the insertions. A standard surgical approach was used for access to the basal turn and a cochleostomy created. A drop of sodium hyaluronate was placed through the cochleostomy and a drop spread on the array before inserting the electrode. After insertion, the electrode was secured in place using a platinum wire tie. Four previously unused banded multiple-channel practice electrodes, with identical dimensions and properties to electrodes implanted in patients, were used. Two of the electrodes were used for two insertions, after carefully checking that the electrode was undamaged after the initial insertion. Each bone was then submitted to x-ray analysis to demonstrate the electrode within the cochlea.

Digitized images of the electrode were analyzed by computer, by means of a modification of a technique described by Marsh et al to measure the angular depth of insertion of the individual bands (Fig 1). The insertion depth was designated as that of the most apical electrode band. However, with this initial study, because of time constraints, electrodes were not inserted into additional temporal bones without Healon as a control. A similar analysis of the radiographs of 22 patients...
with patent cochleas implanted without the use of sodium hyaluronate was carried out as a control. As we have found with a previous temporal bone study that the average depth of insertion is less than that obtained at surgery, the temporal bone data present a worst-case situation (Clark, personal communication).

To investigate the biosafety of sodium hyaluronate, an animal study was undertaken. Six healthy cats with normal tympanic membranes and normal hearing thresholds, as assessed by click auditory brain stem response (ABR), were selected. Anesthesia was induced by intravenous ketamine and Rompun and an endotracheal tube was inserted. Under strict aseptic conditions the round window was exposed and the round window membrane opened. In one ear one drop of sodium hyaluronate was instilled through the round window. A dummy feline Silastic silicone rubber (Dow Corning Corp) electrode with four platinum bands with a drop of sodium hyaluronate spread on it was inserted through the round window. The other ear was also implanted with a dummy electrode with 0.9% sodium chloride solution used as a control. Throughout the procedure the animals' respiratory rate, end-tidal carbon dioxide and temperature were closely monitored. Anesthesia was maintained with intramuscular ketamine. A dilute solution of cloxacillin was instilled after implantation, and a long-acting intramuscular penicillin was given. Four months after surgery, frequency-specific ABR measurements at 1, 2, 4, 8, 12, and 24 kHz using tone pips were made to establish the hearing thresholds for both ears of each implanted cat. The cats were in a sound-proofed room during the measurements. This study was approved by the Animal Ethics Committee of the Royal Victorian Eye and Ear Hospital.

**RESULTS**

**Insertion Distances.** The maximum angular depths of the electrodes inserted into the temporal bones with use of sodium hyaluronate are shown in Fig 2. The mean depth of insertion was 411°. An example of the reconstituted radiograph of an inserted array is shown in Fig 3. In the control group of 22 patients implanted without the use of sodium hyaluronate, the maximum angular depth of insertion for each electrode is shown in Fig 4, with the mean being 335°. While these results suggest that significantly deeper insertions were obtained with sodium hyaluronate (Student's t test: p = .034), it should be pointed out that there were substantial differences between the two groups. The first group comprised temporal bones implanted by a single surgeon using sodium hyaluronate, while the second comprised patients implanted by various surgeons without sodium hyaluronate.

**Hearing Thresholds.** The frequency-specific ABR thresholds were converted to decibel (sound pressure level) thresholds by means of a calibration table. The hearing thresholds were plotted as audiograms (Fig 5). In cats 772 and 770 the hearing threshold was lower in the control ear than in the ear in which sodium hyaluronate had been used. Cats 777, 768, and 776 had lower hearing thresholds in the ear with sodium hyaluronate than in the control ear. There was no difference between the thresholds obtained for the two ears of cat 767. A two-tailed paired t test comparing the sodium hyaluronate and control thresholds for all six cats over six frequencies gave a p value of .013, indicating a significant difference between the sodium hyaluronate and control groups, with the former having lower thresholds. However, as three cats had lower hearing thresholds with sodium hyaluronate and two had higher thresholds, the loss of hearing is likely to be due primarily to the effects of surgery rather than to the test substance.

**DISCUSSION**

The insertion depth of the electrode generally achieved in cochlear implantation allows for stimulation of the auditory nerve fibers as far as the region of 1,000 Hz. As important speech information is contained at frequencies lower than this, it is desirable to achieve deeper insertions of the elec-
trode. Normally the electrode is inserted into the cochlea through a surgically created fenestration in the basal turn. The array is advanced until slight resistance is felt. Attempts to force the array more deeply can damage the cochlea and the electrode. In an attempt to facilitate insertion of electrodes that were proving difficult to insert, German investigators began using a substance called sodium hyaluronate or hyaluronic acid. Previous studies in which sodium hyaluronate was applied to a lesioned round window membrane did not reveal cochlear ototoxicity. Not only did it seem to act as a lubricant, helping the electrode to glide into the cochlea, but it also appeared to allow the achievement of deeper insertions.

Sodium hyaluronate is a biologic substance found in the ground matrix of many tissues. It already has a number of clinical uses, chiefly in ophthalmology, where it is used in corneal surgery to maintain the volume of the anterior chamber and to protect the endothelium of the cornea. An attempt has been made to use it as a healing agent for reconstructive middle ear surgery, but no significant benefit was found with its use. Our study has shown that significantly deeper insertions may be achieved with sodium hyaluronate used as a lubricant, substantiating the original observations of Lehnhardt. We have partly addressed the issue of biosafety in measuring the hearing thresholds after implantation. There was no deterioration in the thresholds that could be attributed to sodium hyaluronate. In fact, in three cats the thresholds were lower in the ears in which that substance had been used. This may be reflecting a cytoprotective effect of sodium hyaluronate.

Further work is necessary to assess morphologic changes in the cochlea associated with the use of sodium hyaluronate in cochlear implantation. In particular, it will be necessary to examine hair cell damage, loss of spiral ganglion cells, and the inflammatory reaction to the electrode. The cochleas of the cats used in the above study are being prepared for this investigation.

SUMMARY

Sodium hyaluronate has potential uses as an electrode lubricant in cochlear implant surgery. Deeper electrode insertions were achieved in six temporal bones implanted with sodium hyaluronate, compared to 22 patients implanted without sodium hyaluronate. Preliminary bio safety studies measuring hearing thresholds of six cats 4 months after implantation with dummy electrodes did not show evidence of ototoxicity caused by sodium hyaluronate. Until the bio safety studies are complete, we cannot recommend sodium hyaluronate for routine use, but the results so far are promising.

ACKNOWLEDGMENTS — The authors would like to acknowledge the help of Julianna Silverman with temporal bone radiography and of Trevor Carter with statistical analysis.

REFERENCES

MONITORING THE ELECTRICALLY EVOKED COMPOUND ACTION POTENTIAL BY MEANS OF A NEW TELEMETRY SYSTEM

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INTRODUCTION

It has been shown that behavioral thresholds in cochlear implant patients are well correlated to the electrically evoked auditory brain stem response (EABR). It is likely, therefore, that the electrically evoked compound action potential (ECAP), which is closely related to the EABR, will also show a similar correlation with behavioral threshold. Automatic measurement of a patient’s ECAP would allow the patient’s behavioral threshold level to be set automatically without any conscious input from him or her. It would offer the opportunity to greatly expedite the process of threshold setting and would be particularly useful in the case of young children, whose behavioral threshold levels can be difficult to judge. With this end in mind, an experimental system has been designed that allows the ECAP to be recorded with either scala tympani or extracochlear electrodes. The system, which uses a modified version of a standard cochlear implant, applies a biphasic stimulation pulse and records the ECAP a short time later. The recorded signal is transmitted by telemetry through the implant receiver coil to an external transmitter-receiver coil and is recovered and stored on computer. With the appropriate software it is then a relatively simple matter to determine the details of an evoked response.

This paper presents the results of trials of the system on a guinea pig. The experiments were designed to evaluate the parameters to be used to obtain the clearest ECAP signal, with particular regard to the variables stimulating electrode position, stimulating electrode mode (bipolar or monopolar), sensing electrode position, sensing electrode mode, stimulation rate, and artifact cancellation scheme.

SYSTEM OVERVIEW

The system uses a modified version of the Nucleus 22-electrode implant to provide a normal stimulation pulse.
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Donnelly, M. J.; Cohen, L. T.; Clark, Graeme M.

Title:
Initial investigation of the efficacy and biosafety of sodium hyaluronate (healon) as an aid to electrode array insertion

Date:
1995

Citation:

Persistent Link:
http://hdl.handle.net/11343/27429