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.3 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.1 Previous studies in which sodium hyaluronate was applied to a lesioned round window membrane did not reveal cochlear ototoxicity.4,5 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 cataract 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.6

Our study has shown that significantly deeper insertions may be achieved with sodium hyaluronate used as a lubricant, substantiating the original observations of Lehnhardt.4 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 biosafety 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 biosafety studies are complete, we cannot recommend sodium hyaluronate for routine use, but the results so far are promising.

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**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).1 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 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
between any two selected electrodes. Two other electrodes are selected as sense electrodes. The voltage between these electrodes is then sampled at programmable points in time over the next 2 milliseconds or so. These voltages are amplified on-chip by a programmable gain amplifier and transmitted in real time (through the transmitter-receiver coil system normally used to power and code the implant) to an external card located in a computer. Here the received data are decoded and stored in computer memory for further processing.

EXPERIMENTAL PROCEDURE

For these experiments a modified version of the system described above was used. The 22-electrode implant was replaced with a functionally identical device mounted in a box with flying leads to the electrode array. The normal 22-electrode array was replaced with a 6-electrode array of similar design to suit the size of the guinea pig cochlea. Two extracochlear electrodes were also connected by flying leads to the implant. All other parts of the system were as described above.

A guinea pig was anesthetized using ketamine (35 mg x Kg\(^{-1}\)) and xylazine (3.5 mg x Kg\(^{-1}\)) with supplemental doses administered during the experiment as required. The bulla was exposed and opened and the electrode array was inserted into the scala tympani through an incision in the round window membrane. The insertion was such that the most basal electrode lay at the mouth of the round window. The extracochlear electrodes consisted of two 1.5-mm-diameter platinum balls that were inserted into muscle in the animal's neck.

For the experiments reported here stimulation applied was a continuous, constant-current, biphasic pulse train of pulse width 30 microseconds per phase and rate 200 Hz unless otherwise specified. The recorded samples were taken at approximately 160-microsecond intervals, with the first occurring at around 250 microseconds after the onset of stimulation. The amplifier gain was 60 dB, although the voltages reported are corrected to the actual voltages seen at the electrodes. Unless otherwise noted, results are presented with a "double pulse" artifact cancellation scheme. This method applies two consecutive pulses to the electrodes, separated by 0.5 millisecond, and records the signal after the second pulse. This recording is assumed to be purely artifact (the assumption being the first pulse would have recruited the nerve). It is then subtracted from a recording taken after a single pulse to yield the neural response. To reduce noise on the signal, the values presented are all averages of 20 individual recordings. The intracochlear electrodes are numbered throughout this
paper from most basal (1) to most apical (6). The extracochlear electrodes are labeled A and B.

RESULTS

Figure 1 shows the results of a series of recordings taken with increasing current amplitude. The stimulation electrode (sinking current during phase 1) was electrode 6, and its reference was electrode 4. The sensing electrodes used were electrode 1 referenced to extracochlear electrode A. Although hard to discern from this Figure, the ECAP can first be observed on the signal at 150 µA stimulation amplitude. It then increases monotonically with stimulation amplitude. Figure 2 shows a single plot of the highest-amplitude recording in the series, showing the raw data obtained from a single pulse recording (dashed line), that obtained after the double pulse (dotted line), and the corrected data (solid line).

The effectiveness — defined by the magnitude of the first peak in the recordings — of different stimulation and sensing modes and positions was investigated and the results are summarized in the Table. The stimulus amplitude for this data was set at 0.5 mA for all monopolar stimulation and 2 mA for all bipolar stimulation. Other stimulus parameters were as per the standard mentioned previously.

A check was done of the ECAP as a function of the rate of applied stimulus pulses to attempt to determine the fastest rate at which ECAPs could be collected without affecting the recorded signal. Rates were varied between 33 Hz and 200 Hz (the highest rate available with the software being used), and no appreciable difference could be determined between any of the recordings. This test used the same electrodes and conditions as those used in the first line of the section in the Table labeled “bipolar stimulus, monopolar sense.”

After several hours of anesthesia the animal was given an overdose of anesthetic and successive ECAPs were noted to diminish in magnitude until no ECAP response could be observed at 20 minutes postmortem. A check was then performed on two different artifact cancellation schemes. A postmortem recording using double pulse artifact cancellation with the same conditions as in Fig 1 is shown in Fig 3. A recording using the same conditions but using a reversed polarity pulse cancellation technique is shown in Fig 4. Here the polarity of the stimulation pulses was alternated during the recording, and 20 cycles were averaged in the normal way.

DISCUSSION AND CONCLUSIONS

A new telemetry system has been developed that is capable of recording and transmitting ECAP data to an external system in which it can be analyzed and developed. Such a
system could be used to automatically predict behavioral threshold levels. This system could conceivably be combined with a similar system capable of providing data on the onset and growth of the stapedius reflex, which has been shown to be correlated to the behavioral comfort level. A system is envisaged that is capable of setting a patient's threshold and comfort levels quickly and easily with no need for the intervention of the patient or clinician.

The sizes, shapes, latencies, and thresholds of the ECAPs presented here are in broad agreement with data presented elsewhere for cats and humans. From the Table it appears that monopolar sensing is much more effective in recording the ECAP signal than bipolar sensing. The ECAP signal appears to reduce as the sense electrode (in monopolar sense mode) is moved away from the stimulus electrode(s) and monopolar stimulation), with recordings taken from sense electrodes adjacent to the stimulus electrode(s) being roughly 35% greater in magnitude than those from sense electrodes at the opposite end of the array. Signals recorded using a stimulus at the basal end of the cochlea (electrode 1) were much reduced in magnitude over those from other parts of the array, presumably because electrode 1 was at the mouth of the round window and therefore in less intimate contact with the neural population than the other electrodes.

Premortem and postmortem results confirm that the recorded ECAP is genuinely neural in origin and not unduly influenced by stimulus artifact, which is effectively removed by either of two artifact cancellation schemes.

REFERENCES

SPIRAL GANGLION CELL SURVIVAL IN LABYRINTHITIS OSSIFICANS: COMPUTERIZED IMAGE ANALYSIS

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Obstruction of the cochlear scalae by ossification and fibrosis, which can now be imaged by computed tomography, has been proposed as a predictor of ganglion cell survival. Subjects for this histopathologic temporal bone study were 12 profoundly deaf patients with labyrinthitis ossificans. Controls without ossification were 16 normal-hearing patients and 16 profoundly deaf patients. All temporal bones were graphically reconstructed. Computerized image analysis obtained the percentage of scala obstruction in 12 temporal bones with labyrinthitis ossificans. Statistical analyses could demonstrate no relationship between spiral ganglion cell survival and obstruction. There was much interindividual variability in ganglion cell count among the 44 temporal bones. Ganglion cell survival was significantly less in the two deafness groups than in the normal group, but did not differ significantly between the two deafness groups. Therefore, cochlear labyrinthitis ossificans is not a predictor of ganglion cell survival and should not be a contraindication to cochlear implantation.

INTRODUCTION

Labyrinthine injury resulting in profound deafness with cochlear ossification, or labyrinthitis ossificans (LO), can occur after many types of otologic insult, but is most dense and extensive in cases of childhood meningogenic meningitis. Temporal bone tomography has predicted cochlear ossification in 60% of children found to have LO intraoperatively, and computed tomography (CT) has predicted LO in 73% of adults.

Cochlear LO no longer prevents cochlear implantation. Spiral ganglion cell survival in LO remains an issue in the selection of candidates for cochlear implantation, however.
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