SECTION 2. BIOMEDICINE

COCHLEAR IMPLANTATION: OSTEONEOGENESIS, ELECTRODE-TISSUE IMPEDANCE, AND RESIDUAL HEARING

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INTRODUCTION

This study was undertaken to find out how new bone is produced in the implanted cochlea, and the effects of fibrous tissue and new bone growth on electrode-tissue impedance. This knowledge is essential, as bone and fibrous tissue in the cochlea could account for variations in patients' speech perception performance. The study was also carried out to examine the effects of implantation on residual hearing. This information is also important, as cochlear implant speech perception results in profoundly deaf people are now better on average than severely or profoundly deaf people obtain with a hearing aid. Consequently, more people will need to be considered for cochlear implantation in ears with some residual hearing. In this case we need to know to what extent residual hearing is affected by implantation.

METHODS

Factors responsible for new bone formation were studied in the cat by comparing the effects of three different procedures on nine ears, with a control on three ears. With the control, an electrode was implanted alone. The first procedure had endosteum on the outer wall of the scala tympani scraped and blood injected; the second had endosteum scraped, blood injected, and bone dust instilled; and the third had endosteum scraped, blood injected, and bone dust instilled plus chronic electrical stimulation. The animals were sacrificed after 12 weeks and their cochleas decalcified, sectioned, and stained. Cochleas were sectioned in a horizontal plane, graphically reconstructed, and divided into the lower and upper regions of each turn. The lower and upper regions in each basal turn were further divided into two equal sections. The degree of new bone and fibrous tissue in the scala tympani was graded from 1 to 4 for each cochlear region according to an estimate of the extent of the tissue within the scala. The grading was 1 (<10%), 2 (10% to 25%), 3 (25% to 50%), and 4 (>50%). The population of ganglion cells was graded from 1 to 4 for each region of the cochlea. The grading was 1 (<25% of normal), 2 (25% to 50%), 3 (50% to 75%), and 4 (>75%). An estimate of the combined population of outer and inner hair cells was made, resulting in a grading from 0 to 7. Zero meant all hair cells in that region were absent, and 7 meant a normal population.

The tissue in the electrode track was graded from 0 to 6 according to the following criteria: 0, a large portion of track with no adjacent fibrous tissue; 1, very thin incomplete fibrous capsule; 2, nearly complete fibrous capsule up to two cells thick; 3, mature thin fibrous capsule; 4, mature thick fibrous capsule; 5, mature thick fibrous capsule with some adjacent new bone; and 6, mostly enclosed with new bone.

The resistive impedance between each electrode pair was calculated from the initial voltage of the first phase of a biphasic current pulse applied across the electrode pair. A related measure of total impedance was calculated from the peak voltage.

The click-evoked auditory brain stem response (ABR) thresholds were obtained by averaging the evoked responses to 500 presentations of 100-microsecond rarefaction clicks. The responses were recorded from electrodes on the vertex (positive), nape of neck (negative), and thorax (reference).

The research was carried out under the guidelines estab-

Fig 1. Summary of average degree of fibrous tissue formation, new bone growth, and populations of outer and inner hair cells and residual spiral ganglion cells in lower and upper basal turns of cochlea for control (ctrl) and procedures aimed at inducing new bone formation.
RESULTS AND DISCUSSION

The summarized histologic findings for the procedures to induce new bone formation, as well as the control, are shown in Fig 1. It can be seen that for all procedures there was usually a small amount of new bone and a moderate amount of fibrous tissue in the scala tympani. There was no significant difference between procedures by Fisher's exact test regarding the degree of fibrous tissue, new bone formation, population of hair cells, or population of ganglion cells. The lack of any significant difference between the control and procedures 1, 2, and 3 was probably due to the fact that infection was demonstrated in two out of three controls. The small numbers in each procedure could also explain why no differences were seen between the procedures. It was observed, however, that there was an increase in the grading of tissue density if there was trauma to the basilar membrane or infection occurred. For this reason the cochleas were grouped across procedures according to the underlying cause of the histopathology. The groups were "implanted alone" (4 cochleas); "implanted and infected" (5 cochleas); and "implanted and traumatized" (2 cochleas). One cochlea was not included as the electrode came out prior to sacrifice. Because of the small samples and nonparametric data, the Mann-Whitney test was used to test for differences between the groups. When the group "implanted alone" was compared with "implanted and infected," there was no significant difference at the .05 level between the groups for new bone and fibrous tissue gradings, and hair cell and ganglion cell populations. When the comparison was made between the "implanted alone" and combined "infected and traumatized" groups, the hair cell population was significantly higher for the "implant alone" group (p = .04). The lack of any difference for the "infected" group was probably due to a delay required for the effects of infection to be observed. When the "traumatized" cochleas were included, the observed difference was mostly due to the more rapid effects of trauma on hair cell viability.

Pearson's correlation test was used to test for any association between new bone growth, fibrous tissue, and hair cell and ganglion cell populations. The results showed the degree of new bone formation was significantly correlated with fibrous tissue growth (p < .01). In addition, fibrous tissue growth was significantly correlated with hair cell loss (p < .01). On the other hand, fibrous tissue and bone growth combined did not correlate with the hair cell population. These findings suggest that certain factors that cause fibrous tissue and bone formation, such as trauma, will result in an early loss of hair cells. On the other hand, other factors, such as infection or just...
implantation per se, may result in bone formation, but the effects on hair cells are delayed or do not occur.

The next part of the study showed the total and resistive impedances over time (Fig 2) and examined the relation between the impedances and the overall grading of fibrous tissue and new bone growth within the scala tympani. The statistical analysis, however, showed no correlation. On the other hand, the study also examined the relationship between tissue growth and impedance by plotting the impedance against the grading of the tissue around the electrode track. The results are shown in Fig 3 and analyzed statistically. The results showed there was good correlation between total impedance and tissue grading that was statistically significant when using a regression analysis. This applied to both apical and basal electrodes, and bipolar and bipolar plus one stimulation. The impedance was particularly high when there were inflammatory cells in the sheath. There was no significant difference for the impedances for bipolar and bipolar plus one pairs.

The high impedances seen in the presence of inflammatory cells were probably due to the packing of the cells, with the consequent reduction in low-impedance pathways of intercellular spaces.

The study also showed that the histopathologic findings were related in general with the click-evoked ABR thresholds (Fig 4). In particular, it was noted that initial surgical trauma had a marked effect on click-evoked ABR thresholds if the electrode penetrated the basilar membrane. If the electrode abutted against the basilar membrane or there was significant fibrous tissue and bone in the scala tympani that could dampen the basilar membrane vibration, there was an elevation in threshold. It was also observed that the electrode could be inserted and later removed with some elevation of threshold but still usable hearing. However, when the ABR thresholds were compared for the "implanted alone" and "implanted and infected" cochleas by the Mann-Whitney test, there was no significant difference. When the comparison was made between the "implanted alone" and combined "infected and traumatized" groups, there was also no significant difference. This negative result was probably due to the fact the click-evoked ABR stimulates a broad area of the cochlea beyond the region of the reduced hair cell population in the basal turn, as well as to the small numbers in the series.

**CONCLUSION**

This study did not show a significant difference between the degree of fibrous tissue and bone formation in the scala tympani or the hair cell and ganglion cell populations, and the implantation procedure. This applied whether the implant was made alone or combined with scraping the endosteum, injecting blood, instilling bone dust, or chronic electrical stimulation. The negative conclusion may have been due to the high incidence of infection seen and the small numbers of bones in each group. The hair cell population was, however, significantly less for infected and traumatized bones than for those unaffected. In addition, bone formation correlated significantly with fibrous tissue growth, and fibrous tissue correlated with hair cell loss. An important clinical finding was that impedance correlated with the grading of tissue around the electrode track, and this was particularly high when inflammatory cells were abundant.