The Journal of Laryngology and Otology
June 1995, Vol. **109,** pp. 542–544

An unusual cause of cochlear implant failure

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Abstract
We present a cochlear implant failure previously unidentified and unreported. Following successful implantation and activation of a Cochlear Mini 22 system, a distressing barrage of crackling noises was heard by the patient despite repeated programming with threshold and comfort level adjustment. The implant soon became nonfunctional and integrity testing showed deficient electrical responses and abnormal surface measured wave forms. Investigation of the explant, following reimplantation with an identical system, showed a defective trim capacitor, an electric component of the internal circuit in the stimulator. Paired Student's *t*-test showed a marginally significant increase ($p = 0.047$) in effective threshold level and a highly significant decrease ($p = 0.0002$) in maximum comfort level for the second implant compared to the first implant.

Key words: Cochlear implant, complications

Introduction

Although the reliability of the Cochlear Mini 22 electrode cochlear implant system is exemplary, it is continuing to improve as knowledge gained from production experience and analysis of failed devices is applied to enhance its design and manufacture.

The reported failure rate for the Cochlear Mini 22 system implant, over a two-year period, is only 1.29 per cent as compared to the Model 7700 3/M House device which had a failure rate of 28 per cent (Wallenburg *et al.*, 1993). The majority of the Cochlear Mini 22 system failures occur within the first six years; these are classified into either 'soft' or 'hard' failures when the implant is unable to perform its intended function (Cohen *et al.*, 1988; Webb *et al.*, 1991; Wallenberg *et al.*, 1993). 'Soft' failures are characterized by a deviation from the intended specification without a total loss of function. An example would be an electrode short circuit, which can easily be resolved by excluding the faulty electrode from the programme in the speech processor. 'Hard' failures involve the total loss of function of the implanted device and, therefore, require its surgical removal. Such faults include contact of the electrical device with body fluids and breakage of the junction between the receiver stimulator and emerging micro-cable. The former problem occurred with the 3M/House device, but this has now been resolved by hermetic sealing of the implant (Wallenberg *et al.*, 1993).

There are several potential causes for cochlear implant failure and these have been thoroughly reviewed by several authors (Cohen *et al.*, 1988; Cohen and Hoffman, 1991; Webb *et al.*, 1991;).

The cochlear implant failure described here required the removal of the implant and assessment of the possible adverse effects.

Case report

A 56-year-old secretary was referred to the ENT Department at St Mary's Hospital with profound bilateral hearing loss, that had gradually deteriorated over the past 15 years so that she now gained little benefit from powerful bilateral hearing aids. Despite thorough investigation no aetiological factors were found. She also complained of bilateral mild to moderate non-pulsatile tinnitus. She was otherwise asymptomatic and gave no relevant family or past medical history.

Implantation with a Cochlear Mini 22 implant was undertaken on the left side in March 1992. All electrodes were introduced into the patent cochlea without difficulty. The patient attended for programming and activation three weeks after implantation. At this time effective threshold (T-levels) and maximum comfort (C-levels) were determined and were assessed as being satisfactory. Electrodes 8 to 22 were programmed in common ground mode and electrodes 1 to 7 were excluded as they showed too narrow a dynamic range.

She was seen two weeks later and reported hearing intermittent loud crackling and clicking noises. She then had repeated programming of the device in various modes including common ground, bipolar, bipolar + 1 and bipolar + 3 with little success. On trying to adjust the T- and C-levels she found the responses unpredictable and on switching on the implant she could hear a distressing barrage of noise described like 'Chinese fire crackers'. Despite the noises the patient persevered and tried to use the implant with the speech processor. After a period of two months the sound became softer and disappeared completely.

On detailed assessment of each electrode she reported hearing nothing except some high pitched clicks on the most basal electrodes 1 and 2 in various programming modes.

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This paper was presented at The 2nd European Symposium on Cochlear Implantation, Montpellier, France, May 1994.
Accepted for publication: 24 February 1995.

TABLE I
A COMPARISON OF T- AND C-LEVELS BETWEEN FIRST AND SECOND IMPLANTS FOR 13 MATCHED PAIRS OF ELECTRODES

		First implant		Second implant	
Frequency bands	Electrodes	T-level	C-level	T-level	C-level
400	22	48	91	48	66
550	21	54	90	65	83
700	20	60	104	67	91
850	19	72	114	80	105
1000	18	81	118	83	115
1148	17	91	135	109	127
1319	16	74	127	105	127
1741	14	96	155	107	121
2000	13	98	150	99	125
2297	12	96	147	96	113
2639	11	96	133	104	114
3482	9	74	130	83	95
4000	8	94	117	80	91

Integrity testing determined T- and C-levels for electrodes 1 and 2 only, with no hearing sensation being obtained on other electrodes. The surface-measured wave forms demonstrated abnormal morphology and amplitude growth. Physical attempts were made to normalize implant electrical function, including cooling the receiver/stimulator with an ice pack and applying pressure to the receiver/stimulator but these failed to produce a satisfactory response. The implant was obviously not functioning according to specification and the patient was counselled and advised not to wear her speech processor.

At reimplantation five months after the initial procedure the micro-cable leading to the round window was noted to be surrounded by a thin layer of connective tissue and was easily withdrawn from the cochlea. The electrodes of the new implant were re-introduced into the tunnel in the cochlea created by the previous electrode without difficulty.

Investigations on individual components of the explant and electrical tests at the Cochlear Quality Assurance Laboratories in Sydney, Australia, indicated a defective trim capacitor, an electronic component of the internal circuit in the stimulator.

All 22 electrodes that were reimplanted were functional. However, as with the previous implant some were excluded. Comparing the series of created electrode maps in common ground mode between the first and the second implants, it appeared that the T-levels in about half of the electrodes were raised and the C-levels reduced, narrowing the dynamic range (Table I). Statistical analysis using the paired Student's *t*-test compared T- and C-levels between the first and second implant for 13 matched pairs of electrodes. The mean change in T-level was 6.46 with a standard error of 2.92 and Student's *t*-value of 2.21, with 12 degrees of freedom, giving a significance level of 0.047. The mean change in C-level was 16.54 with a standard error of 3.13 and a Student's *t*-value of 5.92, with 12 degrees of freedom, giving a significance level of 0.0002.

The analysis showed a marginally significant increase in T-levels and a highly significant decrease in C-levels for the second implant compared to the first implant.

Discussion

Due to the smooth tapered design of the Cochlear Mini 22 system electrode array it has been claimed that replacement is relatively easy and re-implantation successful. Surgical trauma caused by electrode insertion has been assessed in animal (Clark *et al.*, 1975; Jackler *et al.*, 1989) and human cadaveric temporal bones (Shepherd *et al.*, 1985). The former studies concluded that an electrode array passed along the basal turn through the round window should result in minimal or no trauma, provided the insertion was gentle and no force was applied after resistance was first experienced. Slight differences in position, however, of the electrode in the scala tympani could alter the T- and C-levels between the first and second implants. In the latter study, nine human cadaveric temporal bones were serially sectioned and examined microscopically following electrode array insertion. The results indicated minimal mechanical damage, occurring primarily in a localized region of the spiral ligament, which should not result in significant neural damage.

Several authors have reported on reinsertion of cochlear implants under a variety of clinical situations (Liderman *et al.*, 1987; Gantz *et al.*, 1989). Parisier *et al.* (1991) looked at audiological profiles in two children who underwent nucleus-to-nucleus revision for device failure. Their results indicated that reinsertion is safe, technically feasible and that the audiological performance of the electrical threshold and the electrical dynamic range had not deteriorated following revision surgery.

As with other authors (Liderman *et al.*, 1987; Gantz *et al.*, 1989; Parisier *et al.*, 1991), our experience showed that reimplantation was technically feasible and not affected by intracochlear scarring or bone growth. In contrast, however, audiological assessment between the first and second implant showed a marginally significant increase in T-levels and a highly significant decrease in C-levels for the second implant when compared to the first implant. There are a number of possible explanations for the deterioration in electrical threshold T-level, C-level, and electrical dynamic range observed for the second implant.

The defective trim capacitor, an electrical component of the internal circuit of the stimulator, may have caused the output not to have reached the expected level resulting in artificially higher C-levels being recorded with the first implant. This would explain why the C-levels of the second implant were lower than those of the first implant. Despite the fact that electrode reinsertion into the cochlea was technically easy, slight differences in position of the electrodes in the scala tympani may have altered the T- and C-levels. An electrode positioned close to the modiolus requires lower levels of electrical stimulation for excitation of the auditory nerve than an electrode positioned at the outer wall of the scala tympani. A third possibility, although speculative, is that the abnormal functioning of the trim capacitor may have, in some way, adversely affected the cochlea with subsequent changes in T- and C-levels.

https://doi.org/10.1017/S002221510013066X Published online by Cambridge University Press

We would like to stress that abnormal noises and crackling with difficult programming, following successful implantation, may indicate an electrical implant fault. A detailed literature search has failed to find a similar cause for reimplantation.

Acknowledgement

We would like to thank Emil Kupek from the Department of Medical Statistics, for his help and advice.

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