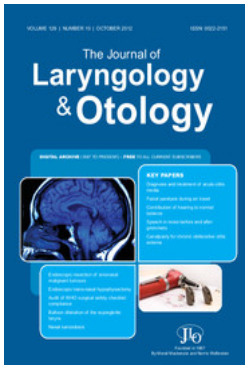

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Complications following adult cochlear implantation: experience in Manchester

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Abstract
Cochlear implantation is regarded as a safe and effective treatment for the profoundly deaf. However, a proportion of patients suffer complications after implant surgery. This paper examines the complications encountered in 240 adult cochlear implant operations performed in Manchester between June 1988 and June 2002. Minor complications were defined as those that either settled spontaneously or with conservative management. The total number of minor complications was 61 (25.4 per cent of cases). Non-auditory stimulation, which resolved with implant reprogramming, was present in 53 cases (22.1 per cent). Major complications were defined as those requiring further surgery, explantation or causing a significant medical problem, and occurred in 15 patients (6.25 per cent). These included implant extrusion, implant sepsis, electrode migration, flap-related problems, and persistent non-auditory stimulation. Nine of the 15 patients suffering a major complication required explantation. There were no post-operative deaths, cases of meningitis, nor persistent facial palsies in the series.

Key words: Cochlear Implants; Post-operative Complications; Surgical Procedures, Operative

Introduction

Cochlear implantation is a well established, safe and effective method of rehabilitation of many profoundly deafened individuals.[1] As with any surgical procedure, a proportion of patients suffer post-operative complications. Previous studies have shown a low incidence of major complications following cochlear implantation.[2–4]

A report of the early experiences of cochlear implantation in the UK by Summerfield and Marshall[5] divided complications into major and minor. Major complications were defined as electrode failure, problems requiring revision surgery, and other complications such as haemorrhage, permanent facial palsy and persistent perilymph leak. Minor complications were those that were managed conservatively by either medical or audiological interventions (e.g. wound infection, non-auditory stimulation). This study reported a major complication rate of 10.2 per cent and a minor rate of 24 per cent. It was noted that complication rates were lower in units with a high throughput of cases.

The present study examines the surgical complications encountered in 240 adult cochlear implant operations performed in Manchester between June 1988 and June 2002.

Methods

The data required for this study were collected by a retrospective review of the case notes of all adult patients who had undergone cochlear implantation between June 1988 and June 2002. All of the notes were available for review. In keeping with previous studies, major complications were defined as those requiring further surgery, explantation or causing a significant medical problem. Minor complications were those that either settled spontaneously or with conservative management.

Results

The Manchester Adult Series June 1988–June 2002 consists of 214 patients (108 men and 106 women). Candidates' ages at implantation ranged from 18 to 80 years (mean 50.4 years). The overall mean duration of deafness prior to surgery was 16.3 years (range from zero to 53 years). This included one candidate with residual hearing at implantation who was changed over from hearing aids to a cochlear implant.

The aetiology of deafness was unknown in nearly a third of cases. Meningitis was the cause of deafness in 12.6 per cent of cases and otosclerosis in 10.3 per cent. The full range of diagnoses is shown in Table I.

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TABLE I
AETIOLOGY OF DEAFNESS IN 214 COCHLEAR IMPLANT RECIPIENTS

Aetiology of deafness	Number	% of total
Idiopathic	65	30.4
Meningitis	27	12.6
Otosclerosis	22	10.3
Congenital	13	6.1
Auto-immune	12	5.6
Trauma	11	5.1
Chronic suppurative otitis media	9	4.2
Ototoxicity	9	4.2
TB meningitis/Streptomycin treatment	9	4.2
Ménière's disease	8	3.7
Mumps	4	1.9
Middle-ear surgery	3	1.4
Measles	2	0.9
Noise-induced	2	0.9
Vascular	2	0.9
Large vestibular aqueduct syndrome	2	0.9
Acoustic neuroma	1	0.5
Alport's syndrome	1	0.5
Perilymph fistula	1	0.5
Radiotherapy	1	0.5
Refsum's syndrome	1	0.5
Scarlet fever	1	0.5
Subarachnoid haemorrhage/ haemosiderosis	1	0.5
Mixed aetiology	1	0.5

The majority (73.2 per cent) of patients received multichannel Nucleus devices. Three patients with completely ossified cochleas were implanted with single channel Medel devices. A total of 239 implants were used. This figure includes 214 primary implantations, nine bilateral implantations, 10 re-implantations following device failure, three re-implantations into the same cochlea following major complications, three re-implantations into the contralateral cochlea following major complications, and one upgrade of a single channel to a multichannel device. In one case, the same device was explanted from one cochlea and re-implanted into the contralateral side.[8] The types of devices used are shown in Table II.

Minor complications

The total number of minor medical and surgical complications was 61, which represents 25.4 per cent of all operations. This figure does not include non-auditory stimulation which was present in 53 (22.1 per cent) cases. In all but one patient, these problems were resolved with device reprogramming. Balance problems were seen in 22 (9.2 per cent) of patients. Three patients (1.25 per cent of all cases) had persistent balance problems. There were five cases (2.1 per cent) of infection of the surgical flap. These all resolved with intravenous antibiotics. One patient (0.42 per cent of all cases) developed a partial post-operative facial palsy that lasted for one week and recovered completely. The full list of minor complications is shown in Table III.

TABLE II
COCHLEAR IMPLANT DEVICES USED (N = 239)

Implant type	Number	% of total
Nucleus 22M	88	36.8
Nucleus 24M	56	23.4
Nucleus 24K-contour	23	9.6
Nucleus 24K	7	2.9
Nucleus 24-double array	1	0.4
Medel C40^{+}	41	17.2
Medel C40	17	7.1
Medel S	3	1.3
Ineraid	2	0.8
Clarion Hifocus-II	1	0.4

Major complications

Fifteen patients (6.25 per cent of all cases) experienced major complications following cochlear implantation. There were no post-operative deaths, cases of meningitis, nor persistent facial palsies in this series. The rate of major complications was not influenced by aetiology of deafness, sex, nor age at implantation. A summary of the major complications is shown in Table IV.

Implant package extrusion. There were five cases (2.1 per cent) of extrusion of the implant. One case was felt to be due to an allergic reaction to the silicone of the implant casing. The implant had to be removed and re-implantation was not considered a viable option. In another case the flap was too thin and the implant extruded. This patient required explantation and reimplantation of a new device. The new implant was inserted on the same side but at a different site from the original extruded implant. Infection was the underlying cause of the remaining three implantation extrusions. Two patients underwent explantation and subsequent re-implantation. The other patient had previously received radiotherapy for a brain tumour and, after implant extrusion, had a scalp rotation flap in an attempt to cover the implant package. This subsequently broke down and the implant was removed. Further implantation surgery is not proposed.

TABLE III
MINOR COMPLICATIONS FOLLOWING 240 COCHLEAR IMPLANT OPERATIONS

Minor complication	Number	% of total
Non-auditory stimulation	53	22.1
Balance problems (transient)	19	7.9
Balance problems (permanent)	3	1.3
Tinnitus (transient)	5	2.1
Tinnitus (permanent)	3	1.3
Post-operative bleeding	5	2.1
Flap infection	5	2.1
Chorda tympani syndrome (transient)	2	0.83
Chorda tympani syndrome (permanent)	2	0.83
Altered facial sensation	4	1.7
Facial swelling (transient)	3	1.3
Otitis media	2	0.83
Surgical emphysema	2	0.83
Transient facial nerve palsy	1	0.42
Minor electrode malpositioning	1	0.42
Diathermy burn to back	1	0.42
Skin ulceration underneath magnet	1	0.42
Pinna ulceration	1	0.42
Granulation tissue bleeding	1	0.42

TABLE IV
MAJOR COMPLICATIONS FOLLOWING 240 COCHLEAR IMPLANT OPERATIONS

Major complication	Number	Number explanted	Number re-implanted
Implant package extrusion	5	5	3
Implant sepsis (intact skin)	4	3	2
Electrode migration	3	0	0
Flap too thick	2	0	0
Non-auditory stimulation	1	1	1
Total	15 (6.25%)	9 (3.75%)	6 (2.5%)

Implant sepsis. Four patients (1.67 per cent) had persistent infection (with intact skin) around their implants. Three patients required explantation: two of these had new devices inserted and the other declined the offer of re-implantation. One patient had a previously unknown catgut allergy and developed an abscess that required incision and drainage.

Electrode migration. There were three cases (1.25 per cent) in which the active electrode migrated into the middle ear after straightforward insertions. All of these patients had electrode repositioning within two weeks of their initial operations.

Flap problems. Two patients (0.83 per cent) had flap-related problems. In both patients the flap was too thick and had to be thinned at revision surgery.

Non-auditory stimulation. This initially occurred in 53 patients (22.1 per cent) but in the vast majority of cases was resolved by implant reprogramming. However, one patient (0.42 per cent) with bilateral skull base fracture had persistent facial nerve stimulation when the implant was in use. This was not improved by reprogramming and the problem was resolved by explantation and reimplantation of the same device into the opposite cochlea.

Discussion

Cochlear implantation has been shown to be a safe and effective rehabilitative aid for the profoundly deafened patient. As with other surgical interventions it is important to periodically re-evaluate potential areas of difficulty in order to develop protocols to further diminish the risk of complications.

This study represents the largest single-centre review of cochlear implant complications in the UK and reaffirms the impressive safety profile of implant operations. The incidence of complications, minor or major, was not related to age at implantation, underlying cause of deafness nor implant type.

The rate of minor medical and surgical complications in this series was 25.4 per cent. This figure rises to 47.5 per cent if non-auditory stimulation is included. These figures are in keeping with previous studies that have quoted minor complication rates (excluding non-auditory stimulation) ranging from seven to 37 per cent.[3,5,6]

Non-auditory stimulation occurs when electrical current from the implant electrode spreads out of the cochlea and causes stimulation of surrounding structures. It usually manifests as facial nerve stimulation or pain in the throat or ear. Rogue electrodes in the apical segment are associated with facial nerve stimulation and rogue basal electrodes with pain. This problem is most commonly associated with otospongiosis and fracture of the petrous bone. One patient in the present series had vestibular stimulation causing a tendency to veer to the side opposite the implant. He became a temporary non-user until device reprogramming resolved the problem. Strategies to address the problem of non-auditory stimulation that have been successfully used include reducing current levels on rogue electrodes or altering stimulus strategy. However, removal of rogue electrodes from the map is necessary in most cases.[7]

One patient had persistent facial nerve stimulation when his implant was switched on. This did not resolve with reprogramming and the implant was removed and re-implanted into the contralateral ear. Further facial nerve stimulation was minimal and the patient derived great benefit from his implant.[8]

Major complications occurred in 6.25 per cent of cases in this study. This compares well with prior series with reported rates of between three and 13.7 per cent.[4,9–11] Nine of the 15 patients suffering major complications required explantation. In addition to the effect this has on the patients concerned, this has serious financial implications and needs to be taken into account when calculating the cost of a cochlear implant programme.

Previous studies have shown the majority of surgical complications are flap-related.[2,6] In this series, there were 24 patients (10 per cent of total) who had flap-related problems (minor and major). Flap-related complications accounted for 31.6 per cent of all post-operative problems (24/76 cases with complications). In one third of these cases explantation was required. This highlights the importance of this part of the implantation procedure and the need for prompt treatment of post-operative flap complications. It is interesting to note the two cases of surgical emphysema under the skin flap. Gillett *et al.*[12] described a case of pneumocephalus following cochlear implantation and advised against Valsalva's manoeuvre in the immediate post-operative period.

Recently an increased incidence of otogenic meningitis in cochlear implant recipients has been reported.[13] To date, the Manchester Cochlear Implant Programme has had no cases of meningitis following cochlear implantation. Active immunization against *Streptococcus pneumoniae* is now recommended in the UK by the Department of Health for prospective implant candidates and patients with implants in place.

- **Cochlear implantation is regarded as a safe and effective treatment for the profoundly deaf**
- **Of the 240 adult cochlear implant operations performed in Manchester between June 1988 and June 2002, 61 (25.4 per cent of cases) had minor complications. Non-auditory stimulation was present in 53 cases (22.1 per cent). Major complications occurred in 15 patients (6.25 per cent)**
- **There were no post-operative deaths, cases of meningitis, nor persistent facial palsies in the series**

Conclusion

Cochlear implantation remains a safe and effective surgical procedure. The overall incidence of major complications is low. The majority of minor complications can be effectively managed with conservative measures.

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