*The Journal of Laryngology & Otology (2009), **123**, 492–496.*

doi:10.1017/S0022215108003691

Main Article

Post-operative problems and complications in 313 consecutive cochlear implantations

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Abstract

Objective: To describe problems and complications associated with cochlear implantation, and their management, in a Danish patient population comprising both paediatric and adult patients.

Design: Retrospective chart review.

Setting: Tertiary referral centre.

Subjects: Three hundred and thirteen consecutive cochlear implantations were studied. The median age of the study population was 10 years. Sixty per cent of patients were children and 40 per cent were adult; 52 per cent were female and 48 per cent were male.

Intervention: Two hundred and ninety-four patients received a Cochlear Nucleus® implant. The remaining 19 received an Advanced Bionics implant.

Main outcome measure: Presence of problems and complications after cochlear implantation.

Results: Post-operative complications were found in 15.7 per cent of patients. The majority of these complications (11.2 per cent) were minor; 4.5 per cent were major. The major complications included one patient with meningitis, one patient with multiple antibiotic resistant *Staphylococcus aureus* infection of a radical cavity, and one diabetic patient who developed a severe skin infection and whose implant became exposed.

Conclusion: Cochlear implantation is a safe procedure within the studied setting. However, it is essential that careful attention be paid to surgical planning and technique, and it is important that healthcare staff and patients be aware of the possible problems and complications.

Key words: Cochlear Implantation; Postoperative Complications; Surgery; Bilateral Deafness

Introduction

When attending meetings on the topic of cochlear implantation or discussing outcomes with colleagues, one is often left with the impression that this procedure is almost without complications. Several years ago, much attention was directed towards patients developing meningitis following cochlear implantation.[1–5] However, with the development of a modified implant (by Advanced Bionics, Valencia, California, USA) and the initiation of pneumococcal vaccination, the incidence of meningitis as a complication of cochlear implantation seemed to decrease. Nevertheless, a detailed search of the literature yielded reports of both minor and major complications associated with cochlear implantation.[3,6–19] Such complications are a concern to patients and their families, and to the healthcare staff involved in their care, and awareness of such complications is thus essential. Furthermore, the resulting additional in-patient workload, as well as the burden to the health economy, are also relevant. Assessment of cochlear implant complications should take into account the drastic increase in the number of procedures performed at our department since 1998 (Figure 1).

In our institution, patients undergo initial ambulatory investigation and diagnosis within the audiology department. The expected clinical course for admitted patients is: operation on day one, discharge on day two and removal of surgical strips on day seven. The audiology department begins auditory stimulation after four weeks. Thereafter, hearing and communication skills should develop in accordance with the patient's age and previous hearing experience.

Our clinical hypothesis is that all patients will follow the expected course. However, as we (and others, as mentioned above) have observed, for a few patients this is not the case. Thus, the aim of this study was to identify the range of post-operative problems and complications associated with cochlear implantation.

Materials and methods

Over a nine-year period from January 1998 to March 2007, a total of 313 implantations were performed in

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Accepted for publication: 14 July 2008. First published online 10 October 2008.

300 patients by three surgeons at the cochlear implantation centre in West Denmark (Figure 1). Eleven patients underwent bilateral cochlear implantation. Two patients required re-operation on the same side. In nine patients, a previously implanted, single channel electrode was removed and a multi-channel device inserted. In 294 patients, various generations of the Nucleus® multi-channel device (Cochlear, Sydney, Australia) were used. In the remainder of the patients, an Advanced Bionics (Valencia, California, USA) device was implanted.

One hundred and eighty (60 per cent) patients were children (ages zero to 17 years included). Their median age at the time of operation was 2.8 years (range six months to 17 years). Fifty-three per cent were girls and 47 per cent were boys. The median follow-up time after surgery was 44 months (range five to 115 months).

One hundred and twenty adult patients (40 per cent) were included, with a median age of 50 years (range 18 to 79 years). Of these patients, 50 per cent were female and 50 per cent male, and the median follow-up time was 32 months (range five to 114 months).

Antibiotics were administered only peri-operatively, except in cases of inner-ear malformations or previous meningitis or skull base fracture. In such cases, patients were treated for 24 hours post-operatively with intravenous antibiotics, followed by oral antibiotics for a week.

Problems and complications were considered in terms of: longer length of hospital stay, additional out-patient visits, readmissions, and further treatment with antibiotics and/or surgical intervention. The abnormal clinical courses were categorised by time of onset of complications (i.e. early, intermediate or late) and complication severity (minor or major). They were also categorised by the presence or absence of: anterior swelling (in the temporal region and/or periorbitally, leading to longer hospital stay or extra out-patient visits); wound problems; skin problems; ear or central nervous system infections; or device-related problems.

Patients with complaints related to the external part of the device, to vertigo or to taste disturbance were excluded. (At the time of writing, a separate, prospective study regarding vertigo and taste disturbances following cochlear implantation was being conducted at our department, and data will be presented elsewhere. However, the total incidence of these complaints was approximately 5 per cent).

Finally, the treatment modality used to manage the complication was recorded.

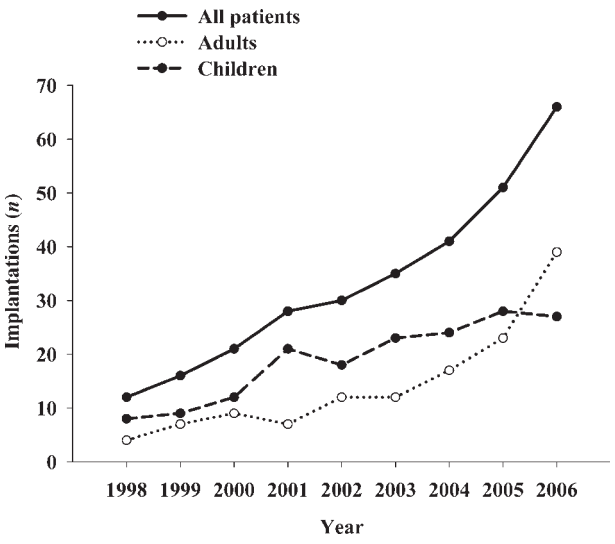

FIG. 1
Number of cochlear implantations per year.

Results

A total of 49 abnormal clinical courses were identified involving 45 patients, corresponding to 16 per cent of the entire patient population. Twenty-eight of these aberrant courses (28/45; approximately 62 per cent) occurred in children. These children had a median age of three-and-a-half years (range one to 14 years). The male to female ratio was 1:1.6. The remaining 17 aberrant courses occurred in adults (17/45; approximately 38 per cent), with a median age of 53 years (range 25 to 78 years). In adults, the male to female ratio was 1:2.4.

The complications and their severity are listed in Table I.

The most frequent complication was difficulty in wound healing (e.g. swelling, discoloration, defects, exposure of sutures, haematoma and abscess); this was seen in almost half of the aberrant courses. Included in this category were five children (aged one-and-a-half to three-and-a-half years) who injured themselves on the operated side of the head. Three of these patients developed haematomas or abscesses in the area of the surgical wound, and two developed necrotic skin over the implant.

Ear infections were the second most frequent complication, dominated by one or more episodes of otitis media. In a single case, multiple antibiotic resistant *Staphylococcus aureus* was isolated from a radical cavity (attributable to nosocomial infection

TABLE I
COMPLICATIONS OF COCHLEAR IMPLANTATION

Complication	Cases (*n* (%))	Incidence (%)*
Major		
Meningitis	1	
MRSA in radical cavity	1	
Necrotic skin or exposed implant	2	
Haematoma or abscess†	7	
Reposition of electrode	3	
Total	14 (29)	4.5
Minor		
Anterior swelling	5	
Minor wound problem	21	
Ear infection	8	
Device-related problem	1	
Total	35 (71)	11.2
Total (major & minor)	49 (100)	15.7

*For 313 operations over the study period. †Requiring surgery.
MRSA = methicillin-resistant *Staphylococcus aureus*

https://doi.org/10.1017/S0022215108003691 Published online by Cambridge University Press

acquired in the intensive care unit after cochlear implantation surgery). The infection was eradicated with the implant in place. Only one case of meningitis was identified, in a four-year-old boy with Klippel–Feil syndrome and a Mondini defect, with presence of a CSF gusher at surgery. Noncapsular *Haemophilus influenzae* was cultivated from the cerebrospinal fluid. The patient recovered completely with the implant in place. Problems related to the internal part of the device accounted for 16 per cent of cases of complications; these included misplaced, displaced or exposed electrodes. None of the implanted electrodes were dysfunctional.

Almost 75 per cent of the aberrant clinical courses involved complications of minor severity (Table I). The major complications included a case of meningitis, an infection of a radical cavity with multiple antibiotic resistant *S aureus*, and a diabetic patient with recurrent severe skin infections and complete exposure of the implant for several weeks before readmission. Also included in the group of patients suffering major complications were those who required some form of revision surgery.

The time from surgery to development of complications is shown in Table II. The majority of complications occurred soon after surgery; these comprised primarily anterior swelling and wound problems. The late complications were mainly due to skin problems (five of six patients; two with necrosis over the edge of the implant, one with complete exposure of the electrode, and one each with abscess and haematoma (these two were due to secondary trauma)).

Twenty per cent of patients suffering complications required only observation, without antibiotic or surgical intervention (Table III). The majority of patients (71 per cent) were treated with antibiotics alone or combined with minor wound surgery or skin flap reconstruction. The diabetic patient with complete exposure of the electrode and skin defect was ex-planted. In two cases in which the electrode was introduced into the vestibule at surgery, the patients were reimplanted with a new electrode. In the single case in which a well functioning electrode was partly extruded from the cochleostomy, the same electrode was easily reintroduced.

Discussion

This retrospective review of 313 consecutive cochlear implantations in 300 patients found that a total of 16 per cent of cases followed an unexpected clinical course, dominated by early problems with wound healing. No fatal outcomes were observed, but major complications occurred in 4.5 per cent of patients. Most problems (e.g. misplaced electrodes and skin flap problems) were corrected with only a small additional risk to the patient. The incidence of major complications in our study is comparable with that of other studies, and was at the lower end of the range, as seen in Table IV. We believe that the centralisation of cochlear implantation, resulting in a large number of procedures being performed by a small number of units and surgeons, is the basis of our low complication rate. Antibiotics were the most common intervention, while surgery played a minor role.

TABLE II

ONSET OF COCHLEAR IMPLANTATION COMPLICATIONS

Onset	Cases (*n* (%))	Incidence (%)*
Early (≤1 mth)	33 (67)	10.5
Intermediate (2–6 mth)	10 (20)	3.2
Late (>6 mth)	6 (12)	2.0
Total	49 (100)	15.7

*For 313 operations over the study period. Mth = months

TABLE III

TREATMENT MODALITIES* USED FOR COCHLEAR IMPLANTATION

Treatment	Cases (*n* (%))*
Observation	10 (20)
Antibiotics	35 (71)
Wound revision†	7 (14)
Skin flaps	2 (4)
Reimplantation	2 (4)
Ex-plantation	1 (2)
Replacement of displaced electrode	1 (2)
Total	58

*Several modalities were used in some of the 49 patients resulting in a total of 58 treatments. †Puncture or incision.

- **This study assessed post-operative complications associated with 313 cochlear implant operations performed at a teaching hospital**
- **In the studied setting, cochlear implantation was a safe procedure for correction of bilateral deafness; however, post-operative complications occurred in some patients**
- **Major complications occurred in 4.5 per cent of patients, requiring either intensive antibiotic treatment and/or re-operation**
- **It is important that healthcare and teaching staff be aware of the possible problems and complications of cochlear implantation, both early and late onset, so these can be promptly addressed**

After audiological fitting of their implant, cochlear implantation patients are mainly in contact with their general practitioner, local hospitals and teaching staff. Therefore, it is of the utmost importance that these professionals are familiar with the possible complications of cochlear implantation, including those that can develop in the long term. Furthermore, with regards to cost-effectiveness, it is important to estimate the additional load on cochlear implantation centres caused by post-operative problems. Most aberrant courses were identified either because the patient presented with a complaint or a planned control at the audiological department. The ensuing consultation at the ENT department of the cochlear implantation centre resulted in medical and/or surgical intervention in eight out of

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TABLE IV

COCHLEAR IMPLANTATION COMPLICATIONS: OTHER AUTHORS' FINDINGS*

Study	Year	Children or adults?	Operations (*n*)	Complications (%)		Remarks
				Total	Major	
Black *et al.*[8]	2007	C	221	26.7	5.9	
Postelmans *et al.*[18]	2007	C + A	112	36	3.6	
Dodson *et al.*[10]	2007	C + A	345	9.3		1 subdural haematoma
Arnoldner *et al.*[6]	2005	C + A	342	12.2	5.0	2 cholesteatomas
Dutt *et al.*[11]	2005	A	111	18	3.2	
Kandogan *et al.*[14]	2005	C	227	18.9	12.3	10% traumatic CI breakdown
Lassig *et al.*[17]	2005	C + A	875		5.1	Only surgical revisions
Bathia *et al.*[7]	2004	C	300	18.3	2.3	3 cholesteatomas
Cunningham *et al.*[3]	2004	C + A	733		3.0	Only infections
Green *et al.*[12]	2004	A	240	25.4	6.3	9 ex-planted
Gysin *et al.*[13]	2000	C	112	9	4	
Proops *et al.*[19]	1999	A	100	39	3	1 cerebral infarct
Kempf *et al.*[15,16]	1997/9	C	366		7.2	
Cohen *et al.*[9]	1988	A	459	12	4.8	Survey, 172 surgeons

*Only studies assessing a minimum of 100 surgical procedures were included. C = children; A = adults; CI = cochlear implantation

10 cases. There were only a few cases in which an ENT department consultation seemed unnecessarily delayed. Since complications may occur at any time after implantation, it is difficult to recommend a fixed follow-up regimen. However, due to the risk of silent otitis media, retraction pockets and cholesteatoma (none of which were encountered in our patient population), patients ought to be seen regularly by an ENT specialist. In all cases of suspected post-implantation complications, we recommend that patients should be offered a re-examination at the cochlear implantation centre within a few days.

In comparison with other studies (Table IV), our results are striking in several respects. Our rate of major complications was at the lower end of the range.[3,6–19] It should be noted that we did not experience any problems related to the facial nerve, nor (as already mentioned) did we have any cholesteatomas or fatal outcomes. However, it is important to note that the other studies cited may not be comparable regarding study population, surgical methods and implant devices used, follow-up regimen, criteria for inclusion of complications, and treatment of complications, and also regarding other factors such as variations in funding for different departments.

Conclusion

Based on the current study, it can be concluded that cochlear implantation is a safe procedure within the studied setting. However, it is essential that careful attention be paid to surgical planning and technique, and it is important for healthcare staff and patients to be aware of the possible problems and complications.

References

1 Bluestone CD. Bacterial meningitis in children with cochlear implants. *N Engl J Med* 2003;**349**:1772–3
2 Cohen NL, Roland JT Jr, Marrinan M. Meningitis in cochlear implant recipients: the North American experience. *Otol Neurotol* 2004;**25**:275–81
3 Cunningham CD 3rd, Slattery WH 3rd, Luxford WM. Postoperative infection in cochlear implant patients. *Otolaryngol Head Neck Surg* 2004;**131**:109–14
4 Josefson D. Cochlear implants carry risk of meningitis, agencies warn. *BMJ* 2002;**325**:298
5 Reefhuis J, Honein MA, Whitney CG, Chamany S, Mann EA, Biernath KR, Broder K, Manning S, Avashia S, Victor M, Costa P, Devine O, Graham A, Boyle C. Risk of bacterial meningitis in children with cochlear implants. *N Engl J Med* 2003;**349**:435–45
6 Arnoldner C, Baumgartner WD, Gstoettner W, Hamzavi J. Surgical considerations in cochlear implantation in children and adults: a review of 342 cases in Vienna. *Acta Otolaryngol* 2005;**125**:228–34
7 Bhatia K, Gibbin KP, Nikolopoulos TP, O'Donoghue GM. Surgical complications and their management in a series of 300 consecutive pediatric cochlear implantations. *Otol Neurotol* 2004;**25**:730–9
8 Black IM, Bailey CM, Albert DM, Leighton SE, Hartley BE, Chatrath P, Patel N. The Great Ormond Street Hospital paediatric cochlear implant programme 1992–2004. A review of surgical complications. *Cochlear Implants Int* 2007;**8**:53–67
9 Cohen NL, Hoffman RA, Stroschein M. Medical or surgical complications related to the Nucleus multichannel cochlear implant. *Ann Otol Rhinol Laryngol Suppl* 1988; **135**:8–13
10 Dodson KM, Maiberger PG, Sismanis A. Intracranial complications of cochlear implantation. *Otol Neurotol* 2007;**28**: 459–62
11 Dutt SN, Ray J, Hadjihannas E, Cooper H, Donaldson I, Proops DW. Medical and surgical complications of the second 100 adult cochlear implant patients in Birmingham. *J Laryngol Otol* 2005;**119**:759–64
12 Green KM, Bhatt YM, Saeed SR, Ramsden RT. Complications following adult cochlear implantation: experience in Manchester. *J Laryngol Otol* 2004;**118**: 417–20
13 Gysin C, Papsin BC, Daya H, Nedzelski J. Surgical outcome after paediatric cochlear implantation: diminution of complications with the evolution of new surgical techniques. *J Otolaryngol* 2000;**29**:285–9
14 Kandogan T, Levent O, Gurol G. Complications of paediatric cochlear implantation: experience in Izmir. *J Laryngol Otol* 2005;**119**:606–10
15 Kempf HG, Johann K, Weber BP, Lenarz T. Complications of cochlear implant surgery in children. *Am J Otol* 1997;**18**(6 Suppl):S62–3
16 Kempf HG, Johann K, Lenarz T. Complications in pediatric cochlear implant surgery. *Eur Arch Otorhinolaryngol* 1999;**256**:128–32
17 Lassig AA, Zwolan TA, Telian SA. Cochlear implant failures and revision. *Otol Neurotol* 2005;**26**:624–34
18 Postelmans JT, Cleffken B, Stokroos RJ. Post-operative complications of cochlear implantation in adults and

https://doi.org/10.1017/S0022215108003691 Published online by Cambridge University Press

children: five years' experience in Maastricht. *J Laryngol Otol* 2007;**121**:318–23
19 Proops DW, Stoddart RL, Donaldson I. Medical, surgical and audiological complications of the first 100 adult cochlear implant patients in Birmingham. *J Laryngol Otol* 1999;**24** (suppl):14–7

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Dr L V Johansen takes responsibility for the integrity of the content of the paper.
Competing interests: None declared