SURGICAL COMPLICATIONS WITH THE COCHLEAR MULTIPLE-CHANNEL INTRACOCHELEAR IMPLANT: EXPERIENCE AT HANNOVER AND MELBOURNE

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The surgical complications for the first 153 multiple-channel cochlear implant operations carried out at the Medizinische Hochschule in Hannover and the first 100 operations at the University of Melbourne Clinic, The Royal Victorian Eye and Ear Hospital, are presented. In the Hannover experience the major complications were wound breakdown, wound infection, electrode tie erosion through the external auditory canal, electrode slippage, a persistent increase in tinnitus, and facial nerve stimulation. The incidence of wound breakdown requiring removal of the package was 0.6% in Hannover and 1.0% in Melbourne. The complications for the operation at both clinics were at acceptable levels. It was considered that wound breakdown requiring implant removal could be kept to a minimum by making a generous incision and suturing the flap without tension.

KEY WORDS — cochlear implant, complications, deafness, surgery.

INTRODUCTION

The first University of Melbourne prototype multiple-channel cochlear implant was implanted on Aug 1, 1978. The first Cochlear multiple-channel cochlear implant for clinical trial was implanted on Sept 14, 1982. Since then, 100 implantations using the Cochlear device have been carried out by the Cochlear Implant Clinic at The Royal Victorian Eye and Ear Hospital in conjunction with the Department of Otolaryngology at the University of Melbourne. The results on the first 153 operations at the Medical Academy (Medizinische Hochschule) in Hannover are also included in this paper. Many more Cochlear devices have been implanted by other cochlear implant units. Sufficient experience has now been obtained to assess the results of the operation and analyze the surgical complications.

There are only a few articles in the literature that provide adequate information on the complications of implantation. Thielemeier¹ does, however, report details on the House Ear Institute results. Out of 269 operations there were four cases of wound breakdown. These were attributed to the coil's being too close to the wound edge. Three breakdowns were corrected by a secondary flap and one required explantation. One patient required the removal of the device to correct a cerebrospinal fluid fistula. No other complications, including meningitis or serious infection, occurred. The Institute's significant complication rate was therefore 2%.

Harris and Cueva² reported on a case of wound breakdown with exposure of the device (a Cochlear

multiple-channel implant). This breakdown occurred with a C incision's being used in a patient with a previous postauricular scar. It was thought that the C incision together with a postauricular scar compromised the blood supply to the flap. The problem was corrected with the rotation of scalp flaps, and the implant was successfully covered.

Cohen et al³ have conducted an extensive survey of surgeons in the United States implanting the Cochlear multiple-channel device. In the Cohen et al survey 108 of 115 surgeons (94%) responded to a questionnaire. A total of 459 Cochlear devices had been implanted, of which 60% were the standard device and 40% the smaller mini-device that became available in October 1986. There were 55 complications reported, for an overall rate of 12% (Table 1³). There were no deaths; there were 23 (5%) major complications and 32 (7%) minor complications. Major complications were those requiring explantation or further operation or causing a significant medical problem. Minor complications either settled spontaneously or with simple measures. On statistical analysis, the complication rate was significantly less for the mini-device, but further analysis suggested that this difference was due to the increased experience of the surgeons, rather than any difference between the devices.

This paper will assess the results of the Cohen et al survey and present the surgical results from the Medizinische Hochschule, Hannover,⁴ and the University of Melbourne Cochlear Implant Clinic at The Royal Victorian Eye and Ear Hospital.

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TABLE 1. TOTAL COMPLICATIONS:
UNITED STATES EXPERIENCE IN 459 PATIENTS

Complications	No.
Flap-related	
Major	
Scalp breakdowns leading to removal of implant	9
Minor	
Local treatment of flap problem	16
Implant-related	
Major	
Meningitis	1
Severe facial nerve stimulation leading to implant removal	1
Compressed electrode	4
Incorrect electrode position	4
Perilymph fistula	3
Exposure of mastoid bowl electrode	1
Minor	
Facial nerve weakness with recovery	8
Minor facial nerve stimulation that was programmed out	3
Minor change of taste	2
Transient dizziness	2
Tympanic membrane perforation that healed	1

Information from Cohen et al.⁹

RESULTS

Table 2 shows the complications for the first 153 patients operated on at the Medizinische Hochschule in Hannover. The Table shows that there were wound breakdown problems with the inverted-U flap, which led to the development of an extended endaural flap that was considered to be more satisfactory. Furthermore, the overall complication rate for the first 34 patients was double that of the second 119. This could also indicate not only, as with the American data, that increased surgical experience and expertise is one of the main factors in reducing complications, but also that the extended endaural flap guarantees a more secure healing of the wound. There was one case of flap breakdown, and the device had to be explanted. This patient was reimplanted 3 years later in the same ear. The extended endaural flap was used for the second operation.

There were nine cases in which an electrode tie eroded through the external auditory canal skin. Initially a Dacron tie was placed in the posterior bony external canal wall, a technique originally used by the Melbourne Clinic. In one of the cases of skin and bony necrosis, the exposed electrode lead was pulled out while the patient was cleaning the canal. The same device was successfully reimplanted. The problems with delayed necrosis of the skin of the outer ear canal led to a change in the technique in which the knot was placed on the cortical bone near the mastoid tip, and as a consequence skin breakdown was reduced.

There was one case of electrode slippage at an early stage. This patient had a radical mastoid cavi-

TABLE 2. TOTAL COMPLICATIONS:
HANNOVER EXPERIENCE IN 153 PATIENTS

Complications	34 Inverted-U Flaps	119 Extended Endaural Flaps
Flap-related		
Major		
Wound breakdown and infection (device removed and reimplanted successfully 3 years later)	1	0
Wound infection, severe but controlled	3	0
Minor		
Infection in wound (uncomplicated)	3	2
Air under flap	0	2
Seroma	1	1
Implant-related		
Major		
Electrode tie erosion of external auditory canal skin		9
Electrode slippage (radical cavity, device removed)		1
Increase in tinnitus (persistent)		6
Facial nerve stimulation		1
Minor		
Transient facial nerve palsy		3
Transient taste disturbance		2
Transient vertigo or imbalance		3
Preoperative selection		
Failure to implant (ossified scala tympani)		2

ty that had been created for complications from scarlet fever. There was no possibility of fixing the electrode, and because of subsequent infection the device was finally removed. Failure to implant in two patients occurred because of bony tissue in the scala tympani. The opposite cochlea was not implanted because the computed tomographic scan and/or magnetic resonance imaging showed it to be totally ossified as well.

An increase in tinnitus occurred in six patients during electrical stimulation with the prosthesis,⁵ but without any influence on performance. In all patients this tinnitus was in the operated ear, but the problem was not so severe that the device had to be removed. In one of the last cases in the Hannover series, facial stimulation occurred at current levels below the comfortable listening level. This was controlled by programming out the electrodes concerned, without any observable effect on speech understanding.

The Melbourne Cochlear Implant Clinic has implanted 97 patients with 100 Cochlear multiple-channel devices. Three patients had two implants. Two had the opposite ear implanted because of poor performance on the first side. The third had the same ear reimplanted because of device failure following the application of a retro-fit magnet overlying a standard device. A total of 100 implan-

TABLE 3. TOTAL COMPLICATIONS:
MELBOURNE EXPERIENCE IN 100 PATIENTS

Complications	No.
Flap-related	
Major	
Wound breakdown with exposure of package and infection (device removed)	1
Minor	
Infection in wound (uncomplicated)	1
Eyeglass frame pressure	1
Air under flap (transient)	2
Seroma	1
Thick skin flap (persistent 1, transient 7)	8
Keloid scar	1
Implant-related	
Major	
Electrode tie erosion of external auditory canal skin	1
Persistent increase in tinnitus	1
Minor	
Partial electrode slippage	2
Transient facial nerve paralysis	2
Transient taste disturbance	1
Facial or tympanic nerve stimulation	3
Transient vertigo or imbalance	6
Temporary increase in tinnitus	6
Preoperative selection	
Failure to implant (hemorrhage 1, fibrosed scala tympani 1)	2
Anesthetic-related	
Bronchospasm (anesthetic complication)	1

tations have therefore been performed. The surgical complications and adverse effects are shown in Table 3.

With the University of Melbourne results it is noteworthy that most of the major complications occurred in the early cases. The wound breakdown, however, was later in the series and probably occurred because a small inverted-U flap was used to avoid a ventriculoperitoneal shunt previously inserted for hydrocephalus. During operation a mastoid emissary vein was found that required the package to be implanted higher than expected. In addition, a tie was not placed over the package to immobilize it, and it rotated superiorly. These three factors resulted in the upper edge of the device's pressing on the overlying incision. The wound breakdown was also associated with infection and it is not certain if it was secondary or a causal agent. In addition, it should be noted that the only two cases of infection in the series of 100 operations occurred when the operation was carried out in a day operating room when the main operating room was closed. Although the horizontal laminar flow units providing filtered air were used, the operating room was cramped and crowded and these conditions compromised sterility. The problem of pressure from the side arms of the eyeglass frames on the skin overlying the edge of the package was due to the mini-implant's being placed too far anteriorly. The patient had a serious visual disorder and wore very

thick heavy lenses requiring the sides of the eyeglass frames to exert a lot of pressure to hold them in place. In the patient with the excessively thick skin flap, the magnet was unable to hold the external antenna in position. This case was an early mini-implant, and the surgical technique has been revised. Now if the scalp flap is 6 mm thick, the deep fascial flap is not sutured over the antenna section of the implant, or alternatively, it is excised. The patient with the keloid had problems in the siting of the antenna, and the scars required excision.

The fistula in the skin of the external auditory canal was caused by a Dacron tie in the bone of the external canal. A cholesteatoma formed and revision was required. A significant increase in tinnitus occurred after implantation in seven patients. In three this symptom settled in a few days with no treatment other than reassurance. In one patient the tinnitus was associated with an acute anxiety reaction. He had had similar anxiety reactions in the past and this one was rapidly controlled with intravenous diazepam. In three patients the increased tinnitus was more prolonged. All had psychological problems. One had the tinnitus in the operated ear, one had it in the nonoperated ear, and in the third it was widespread. In two of these patients the tinnitus was controlled with psychiatric care and tranquilizers. The other patient, who may have had Munchausen syndrome, attributed several problems such as tinnitus and widespread pain to the presence of the implant, which was otherwise functioning satisfactorily. The implant was eventually removed.

The two cases of partial electrode slippage required a revision operation to push the arrays back to their original position. The slippage occurred because the Dacron ties had not been checked originally. This conclusion was reached when the videotapes of the operations were reviewed.

Three patients had facial and/or tympanic nerve stimulation in some electrodes at a level below the comfortable listening level. This problem was controlled by programming out these electrodes. Other patients had tympanic nerve stimulation from electrodes at or outside the round window. These electrodes had much higher thresholds than the intracochlear ones and were not useful for hearing. Again, they were programmed out and not used in the speech processor.

One failure to implant occurred in a case of severe hemorrhage from a mastoid emissary vein, and the other in a patient who had the scala tympani filled with fibrous tissue. In both cases the opposite side was subsequently implanted successfully. One case of bronchospasm occurred at the induction of anesthesia and was probably due to aspiration of gastric contents.

Incisions. A) C-shaped (Reprinted with permission from Cochlear Corporation Surgical Procedure Manual). B) Inverted-U (Reprinted with permission from Cochlear Corporation Surgical Procedure Manual). C) Extended endaural (Reprinted with permission.⁴)

DISCUSSION

Cochlear implantation is a rehabilitative surgical procedure, and ill effects should be minimized. Proper patient selection and care with anesthetic and surgical techniques are both very important. In the three series covered by this paper there have been 712 cochlear implantations performed with the Cochlear multiple-channel prosthesis. There have been no deaths, and the one major medical complication was a case of meningitis that responded well to treatment. There have been a variety of problems occurring at the implant site. Most have been transitory or have responded to local measures. These are temporary inconveniences. Others have required prolonged treatment, revision, or even explantation. These will be considered in detail. In comparing the results obtained in the United States, Hannover, and Melbourne, it should be noted that in Hannover and Melbourne all procedures were performed by a small group of very experienced surgeons, whereas in the United States more than 108 surgeons performed 459 operations.

The most significant complication reported in the three series was wound breakdown. This was a major complication requiring removal of the package in nine cases in the American series (2.0%), in one case in Hannover (0.6%), and in one case in Melbourne (1.0%). In the remaining cases either revision with secondary skin flaps or local measures controlled the problem. In the one Hannover patient with flap necrosis successful reimplantation was carried out 3 years later in the same ear. In the Melbourne case the electrode was left in situ, but the device was removed. This was carried out rather than repairing the defect with a rotation or transposition flap, as a localized pocket of pus was found at revision. The child received a successful reimplantation 6 months later.

In the American series most of the problems were associated with the anteriorly based C-shaped flap

(see Figure, A), but as this flap was the one most commonly used it is difficult to determine whether it leads to an increased rate of wound breakdown compared to other designs. Cohen et al³ emphasize the importance of proper flap design and size, and in particular state that it should be generous, well away from the implant, and sutured without tension. With regard to the C-shaped incision, some surgeons, particularly inexperienced ones, make the flap too small by not placing the incision far enough posteriorly, or by creating an insufficiently broad base. If the inferior limb is taken beyond the inferior margin of the pinna, the blood supply to the flap from the posterior auricular artery may be cut.² The combination of a wound sutured under tension over the implant and poor blood supply will lead to flap necrosis. Another pitfall with the C-shaped flap is well described by Harris and Cueva.² The C-shaped flap was used in a patient who had had a previous mastoidectomy via a post-auricular incision. There was necrosis of the posterior portion of the flap despite hyperbaric oxygen. The necrosed portion sloughed, exposing the device, which was successfully covered with scalp advancement and rotation flaps. They have therefore advocated the use of the inferiorly based inverted-U flap (see Figure, B) in such cases.

The inverted-U flap developed in Melbourne is suitable for the Cochlear multiple-channel implant.⁶ This has been satisfactory in the 98 cases in which it was used in Melbourne. In the one patient in whom wound breakdown occurred the incision was compromised because of a verticuloperitoneal shunt. On the other hand, the C-shaped incision was used in two cases in Melbourne. In one the inferior limb cut an unexpectedly large mastoid emissary vein, resulting in a torrential hemorrhage that was extremely difficult to control, and the operation had to be aborted. The inverted-U incision would have allowed better exposure of the emissary vein in order to control the bleeding. In the second case in

which the C-shaped incision was used, access to the round window was difficult, and its approach through the posterior tympanotomy was compromised by the C-shaped incision.

The inverted-U incision was used in the first 34 procedures performed in Hannover, but there were four cases of severe wound infection. One of these required revision using a bridge flap, and the other three needed secondary suture after cleaning the wound. The incision was then modified into an extended endaural one (see Figure, C⁴). This incision was used in the next 119 implants, with only two cases of minor wound breakdown, which were controlled with local measures. The reason for the severe infection and flap breakdown with the inverted-U flap in one case in Hannover was the too-early fitting of the device 3 days after operation, when pressure from the original spring headset resulted in necrosis of tissue over the device.

In Hannover and Melbourne we have been meticulous in planning, measuring, and marking the incision in every patient. The care of the flap is also very important. It should not be crushed by instruments and should be kept warm and moist during the procedure. It should be sutured in layers and not under tension. Care must also be taken with any underlying fascial flap.

The problems of erosion of canal skin and fistula formation with Dacron ties placed in the bony ear canal were not related to the flap design. In the early Hannover patients the ties were positioned in the deep part of the outer ear canal, where the skin is very thin and predisposed to breakdown. The technique was subsequently modified so that the tie was placed more externally in the ear canal, where the skin is thicker. Fascia was placed between the skin and the Dacron tie. However, in Hannover, to avoid this problem completely the electrode is now fixed to the back of the bony canal wall with poly maleinate glass ionomer cement (Ketac-cem, ESPE Fabrik Pharmazeutischer Präparate GmbH & Co KG, Seefeld, Germany), used by dentists to fix tooth crowns. This method has been used from patient 145 onward.

In Melbourne, the Dacron tie in the posterior bony canal was abandoned after the first initial series, and for some time reliance was placed on two ties around the thick proximal lead wire. The ties were placed in the mastoid cortex superiorly in the region of the supramastoid crest in the majority, or inferiorly near the mastoid tip. It was also found that if there were only one tie, and this was not made very secure, electrode slippage could occur. To improve the situation and place a tie at a site that would not move in relation to the round window in the growing young child, a technique has been developed in Melbourne by which a platinum multistranded wire is placed around the bridge of

bone below the fossa incudis and then crimped around the thin distal section of the lead wire. At the point of fixation the electrode is protected by a Silastic sheath.

In the American series there were cases of electrode compression or misplacement. The misplacement was primarily due to the insertion of the electrode into a hypotympanic cell. These were errors of surgical technique and were a feature of inexperience and insufficient training. Problems with perilymph or cerebrospinal fluid leaks occur typically in cases of congenital abnormalities or skull fractures. In these cases the entry point into the scala tympani should be carefully sealed with fibrous tissue. If necessary the whole middle ear and mastoid must be packed.

Difficulties with eyeglass frames can be avoided if the implant is sited at least 1 cm behind the posterior root of the pinna. Skin flap thickness must also be watched if problems with the magnet are to be avoided. The thickness of the tissue over the antenna should not exceed 6 mm. If this occurs a deep fascial flap should be sutured away from the antenna section or an area of fascia excised. The problem of elevation of the skin flap with nose-blowing can be avoided by packing the aditus as well as the posterior tympanotomy with tissue. It can also be controlled by applying pressure dressings until it has stopped.

No significant injuries to the facial nerve have occurred in any of the cases reported, and this success can be attributed to the overall experience of the otologists performing the operations. However, care must always be taken when carrying out the posterior tympanotomy as well as in avoiding the tympanic membrane and posterior canal skin.

Mastoid emissary veins should be looked for radiographically. If a large one is present the skin flaps and siting of the implant can be adjusted to avoid it. If bleeding occurs it can usually be controlled with pressure, bone wax, or crushed muscle. In one Melbourne case the bleeding was so heavy and persistent that the operation had to be abandoned.

Failure to implant or to stimulate the auditory nerve are largely problems related to the preoperative evaluation, in particular radiography and electrical stimulation of the promontory. Even with abnormal x-ray findings, however, it has been shown that in partially ossified cochleas it is possible to insert electrode arrays for 25 to 26 mm along the scala tympani when the bone, which is situated in the basal turn near the round window, is removed.⁷ With more complete fibrosis or ossification of the scala tympani it is possible to enter the scala vestibuli and make the insertion. If both scalae are fibrosed or ossified, a gutter in which the multiple-electrode intracochlear array is placed can be created around the basal turn.⁸ Alternatively, extra-

cochlear electrodes could be introduced into separate holes drilled at specific points around the basal turn.⁹ Finally, the unpredictable response of tinnitus to treatment applies as much to cochlear implantation as any other treatment modality. It is very important that the patient is made aware of this.

SUMMARY

The complication rates for the 153 implants in

Hannover and 100 implants in Melbourne are within acceptable limits. An analysis of the results shows that with attention to detail, complications can be kept to a minimum. Care in the design and management of the flap can also keep wound breakdown to a minimum. The flap must be placed well clear of the margin of the implant, have a good blood supply, be kept moist and warm during operation, and be sutured without tension.

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REFERENCES

1. Thielemeier M. Status and results of the House Ear Institute Cochlear Implant Project. In: Schindler R, Merzenich M, eds. Cochlear implants. New York, NY: Raven Press, 1985:455-60.
2. Harris JP, Cueva RA. Flap design for cochlear implantation. Avoidance of a potential complication. *Laryngoscope* 1987; 97:755-7.
3. Cohen NL, Hoffman RA, Stroschein M. Medical or surgical complications related to the Nucleus multichannel cochlear implant. *Ann Otol Rhinol Laryngol* 1988;97(suppl 135):8-13.
4. Lehnhardt E, Hirshorn MS. Cochlear implants. Berlin, Germany: Springer-Verlag, 1986:128-32.
5. Battmer RD, Heermann R, Laszig R. Suppression of tinnitus by electrical stimulation in cochlear implant patients. *HNO* 1989;37:148-52.
6. Clark GM, Pyman BC, Bailey QE. The surgery for the multiple-electrode cochlear implantation. *J Laryngol Otol* 1979; 93:215-23.
7. Balkany T, Gantz B, Nadol JB Jr. Multichannel cochlear implants in partially ossified cochleas. *Ann Otol Rhinol Laryngol* 1988;97(suppl 135):3-7.
8. Webb RL, Pyman BC, Franz BK-H, Clark GM. The surgery of cochlear implantation. In: Clark GM, Tong YC, Patrick JF, eds. Cochlear prostheses. Edinburgh, Scotland: Churchill Livingstone, 1990:153-79.
9. Franz BK-HG, Kuzma JA, Lehnhardt E, Clark GM, Patrick JF, Laszig R. Implantation of the Melbourne/Cochlear multiple-electrode extracochlear prosthesis. *Ann Otol Rhinol Laryngol* 1989;98:591-6.

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