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Profound deafness treated by the Ineraid multichannel intracochlear implant

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Abstract
Twelve deaf adults and two deaf children were treated with the Ineraid (formerly Symbion) four channel intracochlear implant between September 1989 and October 1991 at Addenbrooke's Hospital in Cambridge. All were post-lingually totally deaf and had found themselves beyond the reach of hearing aids. The effect of the implant upon the patients ability to lip-read was tested with the speech tracking test, BKB sentences (comparable to CID sentences) and Boothroyd word lists (comparable to NU6 word lists). All patients showed an improvement in their ability to understand speech with the help of the implant. Discrimination of speech without lip-reading was tested with Boothroyd word lists and BKB sentences, eight patients (57 per cent) demonstrated some 'open set' speech discrimination. The acceptability of the carbon percutaneous pedestal is discussed from the patient's, audiologist's and surgeon's points of view.

Key words: Cochlear implant; Speech discrimination tests

Introduction

The Department of Otolaryngology at Addenbrooke's Hospital, Cambridge has held special clinics for profoundly deaf adults since 1984. The Ineraid four-channel intracochlear implant became available to our group in May 1989 and has been used for post-lingually deafened adults and two children aged nine and 13 years.

The Ineraid (formerly Symbion) cochlear implant is distinguished by a percutaneous pedestal or plug which protrudes through the scalp allowing direct electrical contact between a wearable speech processor and electrodes within the cochlea. Stimulation is an electrical analogue of speech delivered through four bandpass filters to four intracochlear electrodes. Previous investigators have found that this device gives patients good speech perception (Gantz *et al.*, 1988; Dorman *et al.*, 1989; Teig *et al.*, 1992). The purpose of this paper is to report the nine-month results and to examine the acceptability of the percutaneous pedestal.

Materials and methods

Selection of patients

Fourteen patients were selected from a total of 106 patients referred by otolaryngologists or audiological physicians between 1985 and 1991. Six patients received single channel UCH/RNID devices prior to May 1989. All were tested by pure tones using a Grayson Stadler GS1 16 audiometer and up to 120 dB HL (except at 125 Hz and 250 Hz where the limits are 95 and 115 dB respectively). Where no auditory responses were obtained at these levels at 250, 500, 1000, 2000 and 4000 Hz the patients were put forward for ultra-high definition CT scans of the cochleas. The ear for implantation was provisionally selected as the one showing greater cochlear patency and potential for insertion of a long electrode array. A promontory stimulation test was next performed on the intended ear using a standard transtympanic electrocochleography needle and sine wave stimulation at 45, 60, 90, 125 and 250 Hz. Conflict between test results was resolved by choosing the more recently deafened ear with the clearer scan and the better subjective sound sensation on trial electrical stimulation. Many patients were rejected because of residual hearing aidable with a powerful hearing aid and many because of obliterated cochleas on CT scan. No patient who passed these two investigations failed to report some sound sensation on the promontory test. Table I is a bar chart showing the age at which each patient became deaf and the age at implantation. Table II shows the cause of deafness in each case.

Structure of the percutaneous pedestal

The pedestal is made of carbon in the form of graphite which has been 'pyrolyzed' (Williams, 1981). (Figures 1 and 2). The manufacturing technique is to coat an undersized graphite model of the article in hard carbon by putting it in a vertical tube with a heater (Figure 3). A mixture of an inert gas (argon) and a hydrocarbon gas (methane) is heated to 1500°C and passed over the model. Because of the high temperature the hydrocarbon cracks and deposits carbon on the surface. Careful control of the variables allows a hard, strong, coat about 2 mm thick to form over the model. This is called low temperature (LTI) carbon

From the East of England Cochlear Implant Centre, Addenbrooke's Hospital, Cambridge.
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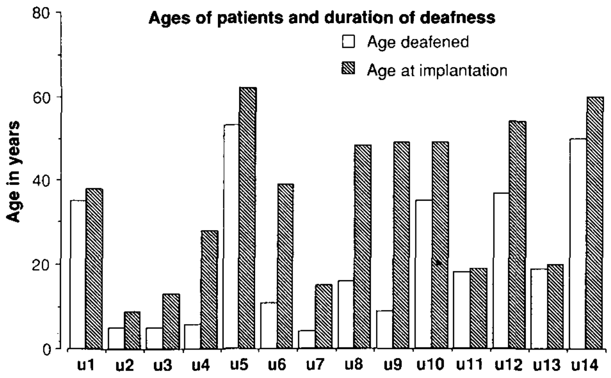
TABLE I

AGES OF PATIENTS AND DURATION OF DEAFNESS



Multichannel cochlear implants Cambridge Ineraid series 1992.

and its trade name is Pyrolyte® carbon. The pedestal is more brittle than bone and is designed so that less force is required to cause pedestal fracture than to cause skull fracture (Parkin, 1990).

The design was settled at the Department of Otolaryngology at the University of Utah School of Medicine in 1976 and an early report of its use as an external connector for a multichannel cochlear implant came in 1978 (Eddington *et al.*, 1978).

Foreign body reactions

Artificial heart valves were coated with graphite in 1963 (Gott *et al.*, 1963) and a new form of glazed carbon produced in 1967 (Cowlard and Lewis, 1967). Vitreous carbon has subsequently been used in heart valves (Sharp *et al.*, 1978) and in middle ear prostheses and grommets (Blayney *et al.*, 1986; Schrader and Jahnke, 1989). Minimal foreign body reaction is described by these authors. Transmission electron microscopy studies (Schrader and Jahnke, 1989) of carbon implants in gerbil mastoids show excellent biocompatibility. The smooth non-porous surface of vitreous carbon demonstrated a low wetability and no foreign body reaction was reported.

The Ineraid® pedestal is attached unmodified to a flattened site on the temporal bone and the holes for the screws which attach it to the bone are predrilled in the pedestal and glazed like the other surfaces.

The disadvantages of a direct connection system

A foreign body reaction to the pedestal or through the skin is to be expected. Carbon has low tissue reactivity and the smoothness of the surface keeps the area of carbon–tissue interface to a minimum. A histological report on tissue next to the pedestal for nine months in a nine-year-old girl is shown in Figure 4. Infection at the pedestal site would be a major disadvantage if it were frequent or severe. Results in this small series and in a much larger series by Parkin (1990) show that it is not.

Daily cleaning around the pedestal is recommended and occasional changes of the central electrical pin complex by surgeon or audiologist are required to keep the connections bright and the contacts good. Fracture of the pedestal in sport or a fall is possible. The fact that the pedestal is relatively brittle is a disadvantage for implant function but in as much as it may spare the patient a possible skull fracture, may be thought to confer some degree of benefit.

Instructions to patients

Patients receive a demonstration of how to clean the pedestal with a cotton bud dipped in mild antiseptic solution, and are instructed to do this daily (Figure 5). If the patient has difficulty reaching the area a relative is asked to take responsibility for cleaning around the pedestal. Hair washing requires no special precautions, any shampoo or water entering the connector pins or the crevice where scalp meets pedestal is dried with a hairdryer. The strong solutions used for permanent waving or bleaching of hair are not recommended on or in the pedestal and a rubber cap is provided to seal the connector pins. This cap is also recommended when the patient goes swimming. In practice the cap is difficult to fit and harder to remove and is often omitted with, as yet, no significant consequences.

Surgical technique

The site of the pedestal is marked on the scalp about

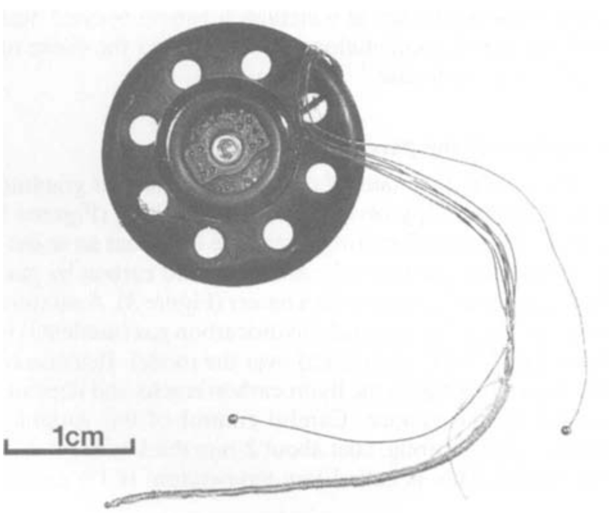


FIG. 1
Plan of pedestal.

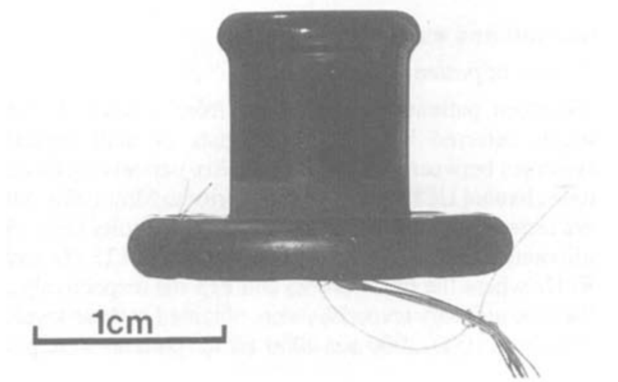


FIG. 2
Elevation of pedestal.

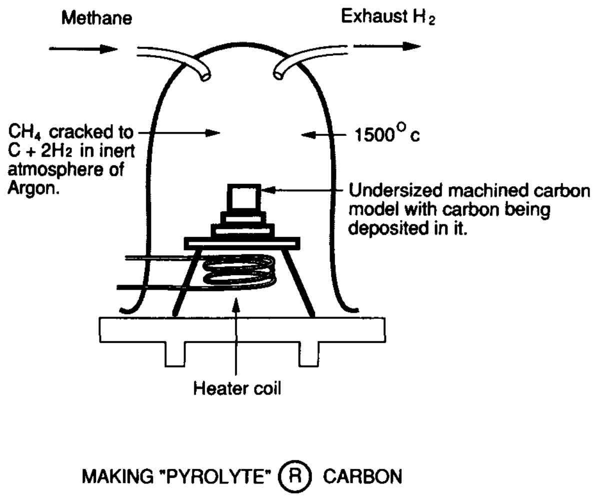


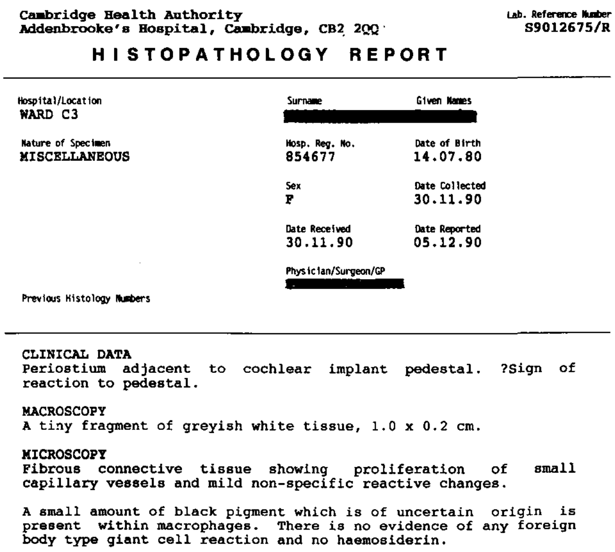
FIG. 3

Manufacture of pedestal.

2.5 cm behind and 1 cm above the free edge of the pinna. The incision described as an inverted 'U' is used, the important point being to make sure that when closed with sutures the line is 2.5 cm clear of the pedestal. A scalp flap based upon the posterior auricular artery is raised and a separate periosteal flap prepared and lifted. The purpose of this is seen at the end of the operation when the flange of the pedestal and the heads of the screws which secure it to the bone may be completely covered with the periosteal flap before the scalp is replaced. Cortical mastoidectomy with a posterior tympanostomy slot into the middle ear gives access to the round window area. The cochleostomy is made just anterior to the round window and the electrode bundle gently passed as far as it will go into the *scala tympani* without buckling. The incision is closed with clips, the circular hole punched in the scalp to allow the pedestal to protrude serves as the only drain.

Post-operative electrode position

A plain X-ray to see the electrodes is taken on the first post-operative day (Figure 6). Of the 14 cases 11 electrodes had passed between 20 and 24 mm into the cochlear duct measuring from apical ball to round window. One electrode had passed by about 16 mm and two by about 12 mm. The Ineraid is designed to deliver four frequency bands at centre frequencies 500 Hz (to the most apical electrode) 1000 and 2000 Hz (to the intervening electrodes) and 3800 Hz (to the most basal electrode). Koenig's calculation of place and pitch within the human cochlea (Koenig, 1949) demonstrates the optimal placement if electrical stimulation is to correspond to tonotopic organisation (Table III). Figure 7 demonstrates the insertion achieved in patient u4, with measurements taken from the plain film X-ray. If the apical electrode is passed to 24 mm the remainder spaced out at 4 mm intervals correspond well to the tonotopic organization of the cochlea. Even at 20 mm a good result may be obtained because electrodes stimulate cochlear neurones and dentrites are not essential (Linthicum *et al.*, 1991). The spiral ganglion reaches no higher than the middle of the second turn of the Organ of Corti (Ariyasu *et al.*, 1989). The further the electrodes lie from this desirable position the more 'transposing' (in the musical sense) the patient will have to do and the less natural or intelligible the sound.


Cambridge Health Authority
Addenbrooke's Hospital, Cambridge, CB2 2QQ

Lab. Reference Number
S9012675/R

HISTOPATHOLOGY REPORT

Hospital/Location
WARD C3

Surname Given Names
[redacted]

Nature of Specimen
MISCELLANEOUS

Hosp. Reg. No.
854677

Date of Birth
14.07.80

Sex
F

Date Collected
30.11.90

Date Received
30.11.90

Date Reported
05.12.90

Physician/Surgeon/GP
[redacted]

Previous Histology Numbers

CLINICAL DATA
Periostium adjacent to cochlear implant pedestal. ?Sign of reaction to pedestal.

MACROSCOPY
A tiny fragment of greyish white tissue, 1.0 x 0.2 cm.

MICROSCOPY
Fibrous connective tissue showing proliferation of small capillary vessels and mild non-specific reactive changes.

A small amount of black pigment which is of uncertain origin is present within macrophages. There is no evidence of any foreign body type giant cell reaction and no haemosiderin.

FIG. 4

Switch on and tuning

One month after surgery the implants are switched on. Of the six intracochlear electrodes the most apical four are most often used unless one of these has very poor electrical impedance. The device is then tuned to give a satisfactory free-field audiogram i.e. hearing thresholds for 500, 1000, 2000 and 4000 Hz at about 35 dB HL. Testing begins after a period of 20 hours of auditory training delivered in the first three months usually at weekly intervals.

Aetiology of deafness

Table II lists the cause of the hearing loss in each case and in diagrammatic form the success or otherwise of passing the electrode into the cochlea. The effects of implantation are summarized.

Results

Tables IV, V and VI illustrate the results for single words (Boothroyd word lists), BKB sentences and connected discourse tracking. Live voice was used for these tests. Recorded material is less prone to variations in delivery and is to be preferred. The tests were all performed by the same member of the implant team, as at this time recorded material was not available. Each bar chart shows score of words correct in the usual modes of vision alone, vision plus audition and audition alone.

The Ineraid multichannel implant as an aid to lip-reading

All patients improved their lip-reading scores using the implant in all tests. The greatest improvement was seen in the BKB sentence lists and in connected discourse tracking and the least in the lists of single words.

Discrimination of single words without lip-reading

Boothroyd word lists (Bench and Bamford, 1979) are

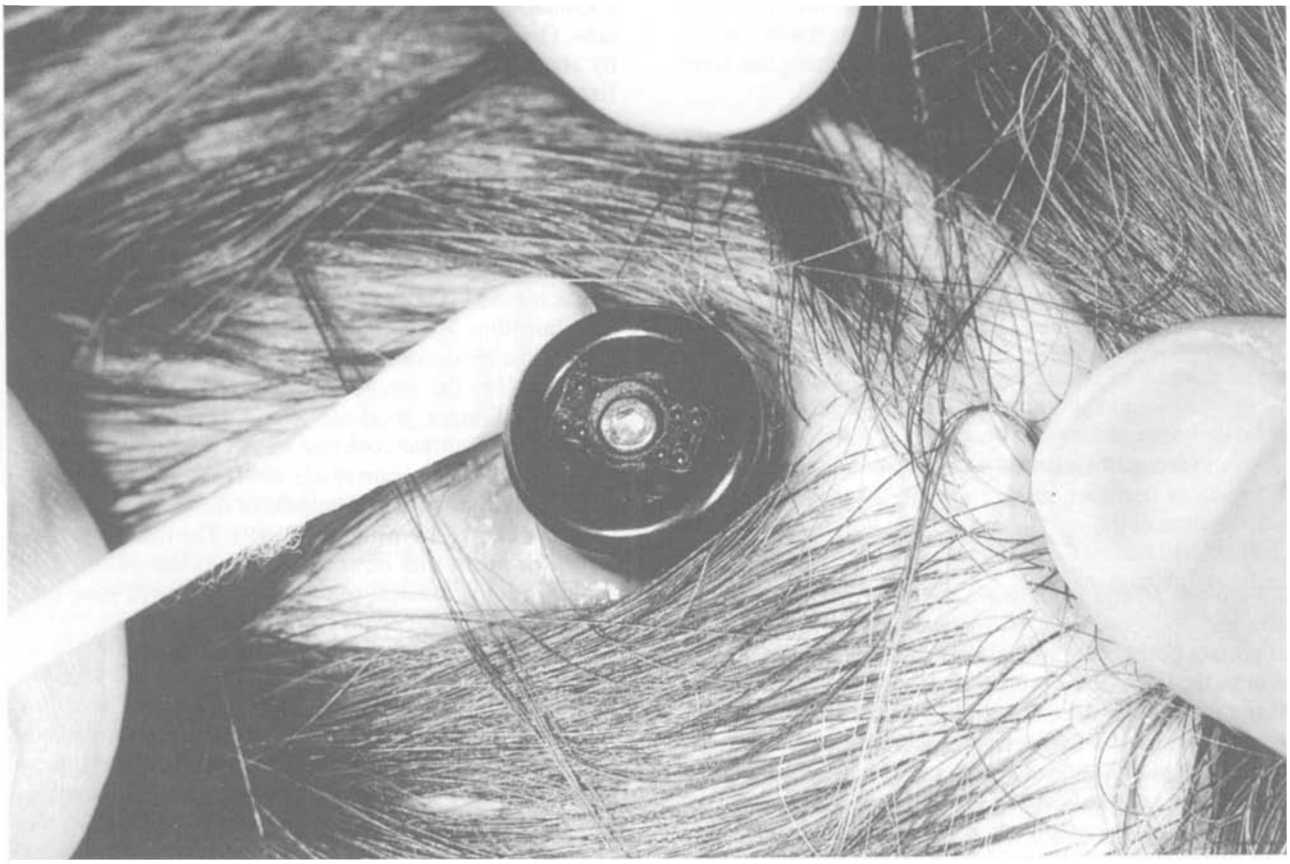


FIG. 5
Cleaning the pedestal.

comparable with NU 6 word lists and are the most difficult task for an implant user because there are none of the contextual cues found in sentences or narrative. Seven out of 14 patients achieved 25–50 per cent and two 50 per cent or more open set speech discrimination of words in the 'hearing only' mode.

Discrimination of sentences without lip-reading

BKB sentences (Bench and Bamford, 1979) are similar to CID sentences and are less difficult to discriminate than single words and more closely approximate the tasks facing the user in everyday conversation. Two patients out of 14 achieved 20–50 per cent and four 50 per cent or more open set speech discrimination of sentences in the 'hearing only' mode.

FIG. 6
Electrode insertion of patient u4.

Connected discourse tracking

When input from the implant was added to lip-reading all patients improved their score in words per minute. A standard text was employed choosing an unseen section of the story for each test situations. Table VI shows the increase in discourse tracking with input from the implant.

Discussion

Why do some patients get better results than others? Statistical analysis is impractical with such small numbers of patients, but some factors are self-evident. The depth of insertion of the electrode is the first concern of the surgeon and, in an intracochlear multichannel device the first concern of the audiologist who has to make it work.

Patients with poor results and partial electrode insertion

The two patients with smallest scores (u2 and u3) had labyrinthitis ossificans, the result of meningitis. In each case this partly obliterated the cochlear duct and despite extensive drilling no clear passage could be found. Postoperative X-rays showed that only two or three of the 0.5 mm ball electrodes were within the cochlea (Gray *et al.*, 1991).

The three main tests by which implants are judged i.e.

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TABLE II
CAMBRIDGE INERAIDS 1992

u	Age	Aetiology	Insertion	Years deaf	Result	Comment
1	37	Barotrauma/viral	6	3	Open set + telephone 50%+	
2	13	Bacterial meningitis	3	5	Aid to lip-reading	Speech improved
3	9	Bacterial meningitis	3	5	Aid to lip-reading	Speech improved
4	28	Measles labyrinthitis	6	22	Closed set	Slow progress
5	61	Ménière's disease	6	8	Open set + telephone 50%	Single channel 1985: Upgraded 1990
6	38	Head trauma	5	26	Aid to lip-reading	Signs
7	15	Bacterial meningitis	6	11	Closed set	Language poor
8	48	Head trauma	6	38	Closed set	
9	49	Bacterial meningitis	6	40	Closed set	
10	50	Otosclerosis/failed stapedectomies	6	4	Closed set	
11	20	Viral	6	1	Open set 25%	After 3 months
12	56	Bacterial meningitis	6	13	Open set 25%	After 3 months
13	20	Bacterial meningitis	6	1	Open set 25%	After 3 months
14	60	Chronic otitis	6	3	Closed set	After 3 months

single words, sentences and speech tracking all depend upon the memory for speech each patient carries with them after hearing has disappeared. Two factors influence this, the first is the degree of daily exposure to speech a patient enjoys through lip-reading and speaking, and the second is the level of the speech and language complexity acquired in childhood. The two cases discussed next fall one each into these categories and seem to have had relatively poor results because of it.

Patients with poor results due to limited language

In a third case a patient (u 6), although normally hearing until the age of ten had married a girl who signed because she had become aphasic after a childhood tonsillectomy. The patient's employment was with a deaf publishing group with signing deaf employees and manual signs were the dominant means of communication at home and at work.

The fourth patient (u 7), was a fifteen-year-old boy who had been deaf since meningitis at the age of three years. He had been educated in a signing deaf residential school with others who were born deaf. On leaving school he sought the company of hearing friends as his lip-reading ability made it possible to understand them, although his powers of speech were limited to a hundred or so words. Restricted word and sentence lists were used that were known to be within his lexicon. Efforts were made to avoid turning an open set test into a closed or rehearsed set test and the results shown reflect as accurately as possible, his discrimination with the implant. On straightforward BKB sentences and Boothroyd word tests his scores were zero in all columns.

TABLE III
KOENIG'S CALCULATIONS OF PITCH AND PLACE WITHIN THE HUMAN COCHLEA

Frequency	Distance from basal end in per cent of total length	Insertion (in mm) of 32 mm duct
500	78	25
1K	63	20
2K	49	16
4K	34	11

The patient's view of the pedestal

A questionnaire was sent to each patient with a percutaneous pedestal and the results are tabulated in Table VII.

The audiologist's view of the pedestal

The pedestal allows direct electrical contact with the cochlea. This is valuable in four ways:

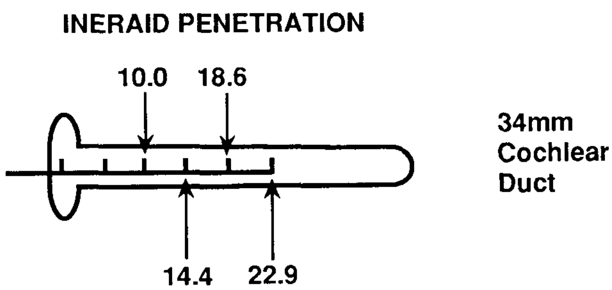

FIG. 7

Electrode position of patient u4 measured from X-rays. Compare with Koenig's calculation of frequency sites within the cochlea in Table III.

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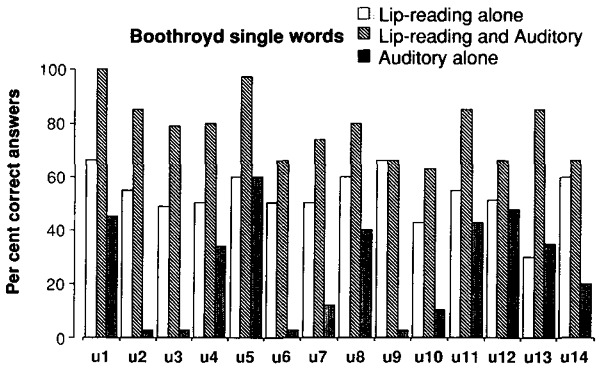
TABLE IV
BOOTHROYD SINGLE WORDS



Multichannel cochlear implants Cambridge Ineraid series 1992. Note: u1–u9. Results at 6–13 months (between 10 and 20 hours auditory training); u10–u14. Results at 3 months (between 10 and 20 hours auditory training); u7 has limited language.

(a) During the operation. Electrical impedances of between 3K and 30K Ohms are usually obtained between each intracochlear electrode and the reference or ground electrodes. A sterile test cable is passed to the surgeon for these measurements which are repeated as soon as the wound has been closed. Zero impedence indicates a short circuit (electrode tips touching in a kink of the array for example) and very high impedence indicates a broken array. In either case the audiologist advises the surgeon to try again with a new electrode.

(b) At the 'switch on'. The impedences measured at operation can be compared with those measured after a month of healing and fibrosis around the array. Four electrodes of the six implanted into the cochlea are chosen to transmit the four channels. In all our patients these were the most apical electrodes, but the impedance test allows the audiologist to determine which electrodes may be damaged or otherwise unsuitable for electrical stimulation.

(c) Fault tracing. If one channel or frequency band becomes 'dead' it can be readily established whether the fault lies in the speech processor, in the pedestal connections, or within the patient.

(d) New strategies of stimulation. The direct contact that the pedestal allows with the intracochlear electrodes has proved invaluable in the design and implementation of new coding strategies. The most exciting innovation (Wilson *et al.*, 1991), employs the use of interleaved pulses of electrical stimulation (continuous interleaved sampling) and has improved the speech perception of six Ineraid patients who have tried it.

Surgeons view of the pedestal

(a) Pedestal complications in 12 adults and two children are tabulated (as suggested by Parkin and Randolph in 1991) into the five groups (Table VIII).

(b) Infection at the pedestal site. A bead or droplet of liquid is sometimes visible at the junction of scalp and pedestal. This is not associated with any particular symptoms but stains the bedclothes at night. Swabs sent for bacteriological culture on four occasions in three patients have grown *Staphylococcus aureus*. Treatment with oral antibiotics for one week has been sufficient to cure the problem on each occasion.

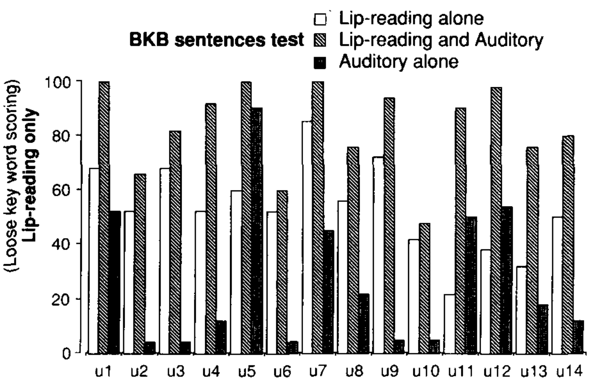
Pedestal becoming loose

One patient, aged 36 years (u 1) and the first in our series, suffered a very severe attack of ulcerative colitis six weeks after implantation and septicaemia developed. The disease was marked by weight loss and muscle wasting, and took six further weeks to get under control. When he was well enough to continue auditory training he had lost 16 kg (20 per cent body weight) and the pedestal was loose. When held between finger and thumb it could be moved about 3 mm in all directions. There was no loss of implant function. Revision surgery was necessary to tighten two and reposition three of the stainless steel bone screws. The scalp flap healed well for the second time and the implant continued to function well.

Recession of scalp

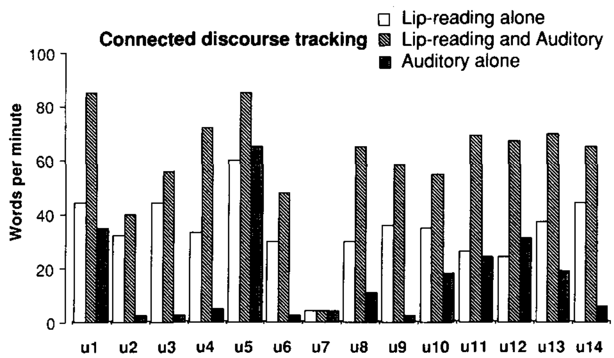
The pedestal is designed so that the outer flange is invisible under the skin of the scalp. When for any reason the scalp recedes more of the pedestal becomes visible and if recession proceeds eventually a bone screw becomes visible. While this is not detrimental to implant function it is unsightly and the gap created forms a crust. Six months after surgery a 4 mm gap appeared on the inferior area of the pedestal in one patient. Two of the screw heads could be seen when the crust was removed. The patient was a nine-year-old girl deafened by meningitis aged five years.

TABLE V
BKB SENTENCES



Multichannel cochlear implants Cambridge Ineraid series 1992.

TABLE VI
CONNECTED DISCOURSE TRACKING



Multichannel cochlear implants Cambridge Ineraid series 1992.

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TABLE VII

THE PATIENTS' OPINIONS ON LIFE WITH A PEDESTAL, ELICITED BY QUESTIONNAIRE

Feature	Outcome		Comments	
Discomfort or irritation	None with pain			
	Irritation	6	Intermittent itching	
	No irritation	8	and crusting	
Sleeping position	Sleep on either side	12	Stain the pillow occasionally	4
	Can't sleep on plug	2	Do not	10
Plugging in and out	No difficulty			
	Unaided	13		
	Need help	1	Nine-year-old child	
Cleaning	Unaided	8	Some forgot to do it	
	Needing help	6	daily with no ill effects	
Activities	Unrestricted	12	None take part in contact sports.	
	Feel restricted	2	Two have given up swimming.	

Because the family had to move far from an Implant Centre, revision surgery was planned to relocate the pedestal in the centre of the hole in the scalp.

At operation it was found that the pedestal was firmly attached to bone with no granulation tissue or infection (Figure 8). None of the five bone screws were loose. A collar of fibrous tissue had grown around the base of the pedestal and a piece abutting the carbon of the pedestal was sent for histological examination (Figure 4). The electrode leads had become encased in new bone and moving the pedestal would risk breaking them. The problem was solved by replacing the scalp flap in a higher position by excising 4 mm of skin from the upper border. This had the effect of obliterating the gap beneath the pedestal and covering the exposed screws.

Effect of the implant on tinnitus

Eight of the 14 patients complained of pre-operative tinnitus (57 per cent). In one case tinnitus resolved after operation but before 'switch on'. Of the remaining seven, five found that the intensity of their tinnitus was reduced whilst using the device and two found the intensity unchanged. In no patient was tinnitus made worse by implantation or stimulation.

Reliability and maintenance

The plug and pedestal interface is robust and reliable but prone to collecting debris. The debris comprises skin scales, hairs, desiccated discharge and dirt from the environment. From time to time a patient reports partial loss of signal and inspection reveals a dirty plug, which may also be shown by an increase in electrical impedance. Removing and cleaning the central portion (pin saver) in an ultrasonic bath restores the signal. Some patients require this to be done up to four times a year others only once or twice. The mean pin saver change interval is 4.9 months.

TABLE VIII

PEDESTAL COMPLICATIONS IN CHILDREN AND ADULTS

Class		Adults (12)	Children (2)
0	No problems	5	0
1	Itching, tenderness, crusting	2	0
2	Inflammation or granulation requiring oral antibiotics or topical treatment	4	1
3	Pedestal problems requiring parenteral antibiotics or surgery	1	1
4	Severe problems requiring pedestal removal	0	0
5	Pedestal fracture requiring removal	0	0

Conclusion

Fourteen post-lingually deafened patients were implanted with the Ineraid four-channel cochlear implant and all improved their lip-reading scores at 3–9 months post-'switch on', seven out of 14 achieved some open set discrimination of single words.

The percutaneous pedestal came loose in one patient with ulcerative colitis and the scalp receded from the pedestal in another patient. Both were re-operated and continue to use the device. Other complications were occasional local infections around the pedestal which required oral antibiotics and topical antiseptics. The pedestal causes irritation and there is discharge in some patients some of the time.

When an Ineraid patient has a problem with the device, a change of the eight pin connector in the centre of the pedestal usually solves the problem.

Acknowledgements

Mr Yu Chuen Tan provided the electronic and technical support for this programme and his contribution is gratefully acknowledged. The investigation of tinnitus in this series of patients was undertaken by Zebunissa Vanat as part of a larger study. Clerical and secretarial support of this project was cheerfully and efficiently provided by Mrs Jane Oakes and Mrs Jill Woolley.

Since April 1991 the Cambridge Multichannel Implant Programme has received funding from the Department of Health for deaf adults. Patients u9–u14 were implanted as part of this undertaking.

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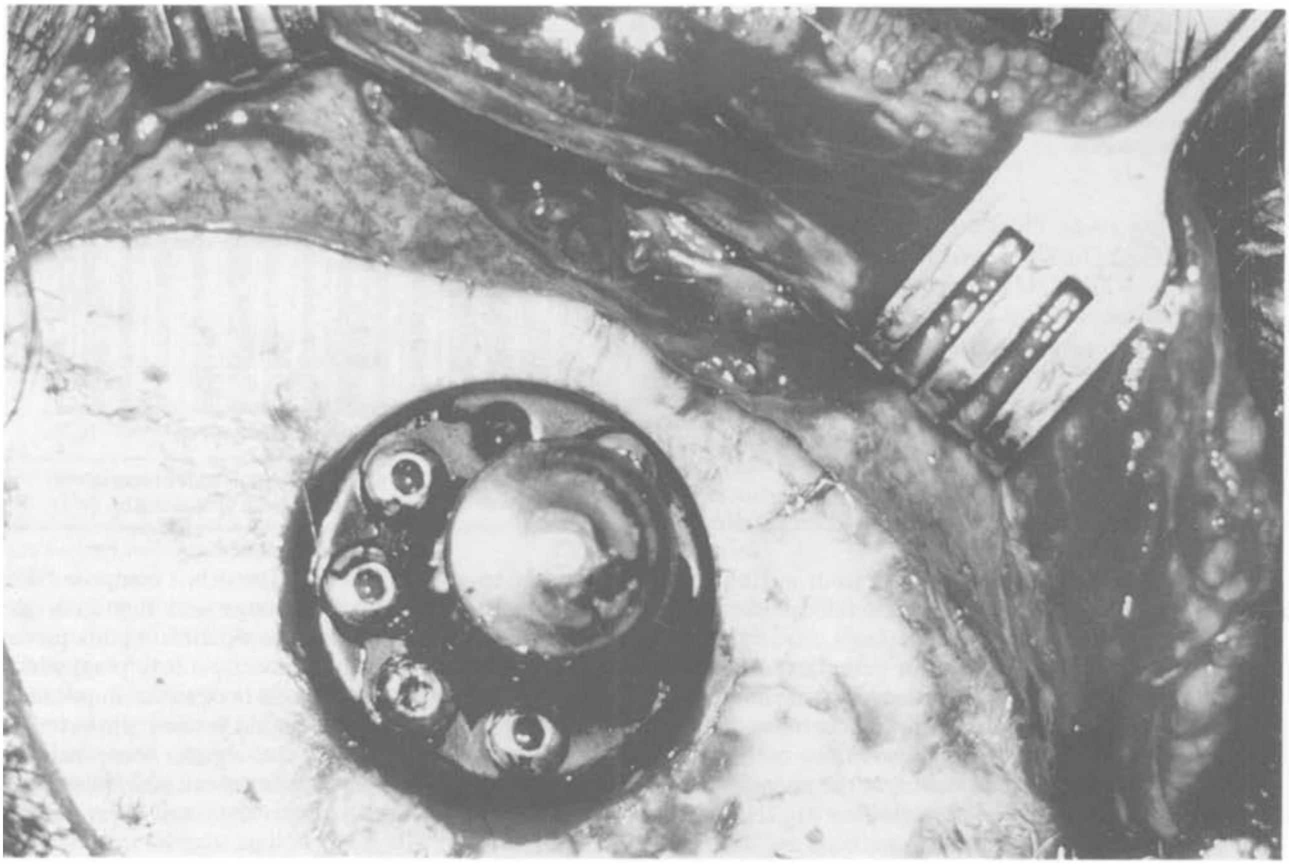

FIG. 8

Revision surgery for scalp recession at six months. Note bone has overgrown the wires leading from the pedestal.

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