The Journal of Laryngology and Otology
April 1999, Vol. **113,** pp. 321–325

Clarion® cochlear implants: surgical implications

R. Filipo, M.D., M. Barbara, M.D. Ph.D., S. Monini, M.D., P. Mancini, M.D.

Abstract
The surgical aspects of 34 Clarion® cochlear implants, positioned during a five-year period on 31 profoundly-deaf subjects as primary (11 children, 20 adults) and revision surgery (one child, three adults) were taken into consideration. Intra- and post-operative complications related to the specific structure of this device were considered along with the benefits obtained by update of the hardware and surgical approach. A smaller thickness of the internal receiver as well as the shifting from a retro-auricular/sub-temporal (RA-ST) to an endaural-retromastoid (EA-RM) approach have contributed to a dramatic drop in post-operative complications, such as skin defect or device extrusion. Special care should, however, be taken when cochlear implantation is planned in ears with chronic otitis or its surgical sequelae. From the two revised cases (hardware failure, electrode displacement) in whom re-implantation in the same side was performed, it has been demonstrated that the helicoidal shape of the electrode carrier is not inducing any additional trauma to the cohlear structure.

Key words: Cochlear implant; Surgery; Reoperation; Intraoperative complications; Post-operative complications

Introduction

In terms of favourable outcome in cochlear implant programmes, proper selection and rehabilitation of the patients have tended to be considered more important than the surgical procedure. Nevetheless, apart from major clinical issues, such as treatment of total or subtotal cochlear ossification or congenital abnormalities, some surgical details could still be worth discussing in order to avoid rare, but possible intra- and post- operative complications.

Clarion® multi-strategy cochlear implants have proved to be extremely helpful for the sensory and social recovery of profoundly hearing-impaired patients of any verbal age, shortening or making, in some adult (post-lingual) cases, post-operative rehabilitation almost unnecessary (Schindler *et al.*, 1995).

Our cochlear implant programme, which started in 1993, has opted for this device right from the beginning, first in adults, thereafter in children. The insertion of the internal part of the Clarion®, presently composed of a 31 × 25 × 6 mm internal receiver and a helicoidal-shaped electrode carrier, needs unusual surgical steps which have undergone slight modifications over the years.

In this paper, a five-year experience with the Clarion® device implanted both in adults and in children is presented, mainly focusing on intra- and post-operative problems specifically related to this implant model.

Materials and methods

Since March 1993, 39 cases of cochlear implant surgery have been carried out at our Institution (Table I). Thirty-six of them were Clarion® devices implanted in 31 patients: 11 in primary and one in revision surgery in children (<16 years); 20 in primary and four in revision surgery in adults, with replacement of the same device in one patient. Age, cause of deafness, location of the receiver, state of the cochlea at surgery, type of surgery (primary or revision), necessity for plastic revision, middle-ear status, hardware generation and date of operation are listed in Table II.

According to the progress of the hardware, three generations of Clarion device were used (Figure 1):

I. Device 37 × 25 × 6mm, with Silastic® plate covering the electrode array (eight primary cases);
II. Device 37 × 25 × 6mm, without Silastic® plate (three primary, one revision case);
III. Device 31 × 25 × 6mm, without Silastic® plate (20 primary, 3 revision cases).

Surgical technique

The retro and supra-auricular region were widely shaved and prepped. Under hypotensive anaesthesia and pneumatic/electric monitoring of the facial nerve function, two different surgical approaches were used (Figure 2):

From the Department of Otolaryngology, University of Rome 'La Sapienza', 00185 Rome, Italy.
Accepted for publication: 21 December 1998.

https://doi.org/10.1017/S0022215100143889 Published online by Cambridge University Press

TABLE I
COCHLEAR IMPLANTS SURGERY CARRIED OUT BETWEEN MARCH 1993 AND FEBRUARY 1998

39 IMPLANTS

3 MED-EL

36 CLARION©

11 CHILDREN		20 ADULTS	
11 PRIMARY	1 REVISION	20 PRIMARY	4 REVISIONS

(1) A retroauricular incision (RA), carried out 3 cm behind the retroauricular crease, for a sub-temporal (ST) placement of the receiver;
(2) A posteriorly-extended endaural incision (EA) for a retro-mastoid (RM) placement.

In the EA-RM technique, before starting with mastoidectomy, it has been necessary to create a bony well for housing of the ceramic receiver, in order to have it as close as possible to the level of the external cranial curvature, thus avoiding ugly and potentially dangerous outward bulging. Non-absorbable sutures were then passed through the cortex surrounding the receiver for its final stabilization.

A limited mastoidectomy was then carried out, followed by facial recess approach, widened supero-inferiorly and medio-laterally in order to obtain a proper visualization of the round window niche as well as comfortable introduction of the instruments used in the subsequent steps of the procedure. In some cases, enlargement of the mastoidectomy cavity or lowering of the most lateral part of the external canal wall were also necessary.

A rather large cochleostomy was then carried out in order to allow a proper lodgement of the electrode-carrier instrument, for an unforced insertion of the helicoidal, elastic electrode into the scale tympani afterwards sealed with bone dust and fibrin glue.

In the RA-ST cases, the internal aspect of the temporal muscle was at this point elevated from bone, in order to position the receiver underneath. As a general rule, before closing the cavity, special care was paid to anchoring the lead within the mastoid cavity, purposely drilled without saucerized

TABLE II
PATIENTS WHO UNDERWENT CLARION© COCHLEAR IMPLANTATION

No.	Yrs	Cause	Loc.	Co.	S.	VII	Plast.	Middle ear	Gen.	Date
1	31	Sudden deafness	ST	N	P	N	NO	N	1st	3/93
2	57	Unknown	ST	N	P	N	YES	N	1st	3/93
3	37	Otosclerosis	ST	N	P	IP	NO	N	1st	7/93
4	62	Otosclerosis	ST	O	P	N	NO	N	1st	7/93
5	12	Viral	ST	N	P	N	NO	N	1st	9/93
6	52	Meningitis	ST	N	P	N	YES	N	1st	4/94
7	14	Unknown	ST	N	P	N	NO	N	1st	4/94
8	28	Histiocytosis	ST	N	P	N	NO	Rad.mastoidectomy	2nd	4/94
9	5	Unknown	ST	N	P	N	NO	N	3rd	5/94
10	14	Unknown	RM	N	P	N	NO	N	2nd	10/94
11	48	Chronic otitis	RM	N	P	N	YES	Rad.mastoidectomy	1st	12/94
12	13	Viral	RM	N	R	N	NO	N	3rd	6/95
13	63	Progressive	RM	N	P	N	NO	N	3rd	6/95
14	17	Viral	RM	N	P	N	NO	N	3rd	6/95
15	68	Chronic otitis	RM	N	P	N	NO	Rad.mastoidectomy	2nd	7/95
16	20	Rubella	RM	N	P	N	NO	N	3rd	10/95
17	5	Kernicterus	RM	N	P	N	NO	N	3rd	11/95
18	49	Chronic otitis	RM	N	R	N	NO	N	3rd	12/95
19	20	Unknown	RM	N	P	N	NO	N	3rd	1/96
20	14	Unknown	RM	N	P	N	NO	N	3rd	5/96
21	14	Progressive	RM	N	P	N	NO	N	3rd	6/96
22	60	Ototoxicity	RM	N	P	N	NO	N	3rd	7/96
23	50	Progressive	RM	N	P	N	NO	N	3rd	2/97
24	30	Viral	RM	N	P	IP	NO	N	3rd	2/97
25	52	Ototoxicity	RM	N	P	DP	NO	N	3rd	2/97
26	53	Otosclerosis	RM	N	P	N	NO	N	3rd	4/97
27	54	Ménière's disease	RM	N	P	N	NO	N	3rd	4/97
28	60	Unknown	RM	N	R	N	NO	N	2nd	6/97
29	68	Chronic otitis	RM	N	P	N	NO	Chronic otitis	3rd	6/97
30	53	Otosclerosis	ST	N	R	N	YES	N	3rd	9/97
31	7	Unknown	RM	N	P	N	NO	N	3rd	10/97
32	4	Unknown	RM	N	P	N	NO	N	3rd	10/97
33	67	Typhoid	RM	N	P	N	NO	N	3rd	11/97
34	4	Unknown	RM	N	P	N	NO	N	3rd	12/97
35	8	Unknown	RM	N	P	N	NO	Chronic otitis	3rd	12/97
36	51	Progressive	RM	O	R	IOS	NO	N	3rd	2/98

Loc = placement of the internal receiver (ST: Sub-temporal; RM: Retro-mastoid); Co = Condition of the cochlea during cochleostomy (N: Normal; O: Ossified); S = type of surgery (P: Primary; R: Revision); VII = Facial nerve function after surgery (N: Normal: IP: Immediate palsy; DP: Delayed palsy; IOS = Intra-operative stimulation); Plast = Necessity for post-op plastic revision; Middle ear = Condition of the middle ear cleft (N: Normal); Gen = Generation of the Clarion© implant.

https://doi.org/10.1017/S0022215100143889 Published online by Cambridge University Press

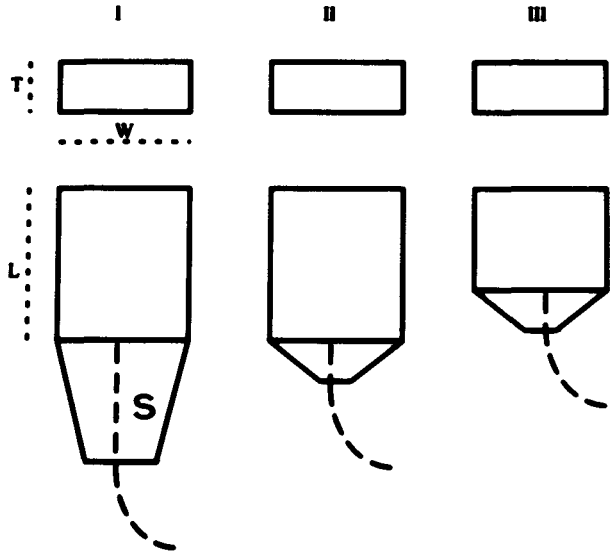


FIG. 1

The three hardware generations of Clarion® receiver. While thickness (T) and width (W) remained the same, the Silastic® (S) protection was removed in the 2nd generation, and the length (L) shortened in the 3rd generation.

margins. In this regard, several proposals have been suggested, such as the split bridge technique (Balkany and Telischi, 1995) or the use of bone cement (Kempf *et al.*, 1996).

Before skin closure, back-telemetry of the electrodes and, in the last five cases, stapedial reflex elicitation, were also routinely carried out.

The RA-ST approach was carried out in the first eight patients (five adults, three children) and was then replaced by the EA-RM approach in the following cases, including three revisions. In the EA-RM patient who needed to be revised, a ST positioning of the receiver was performed.

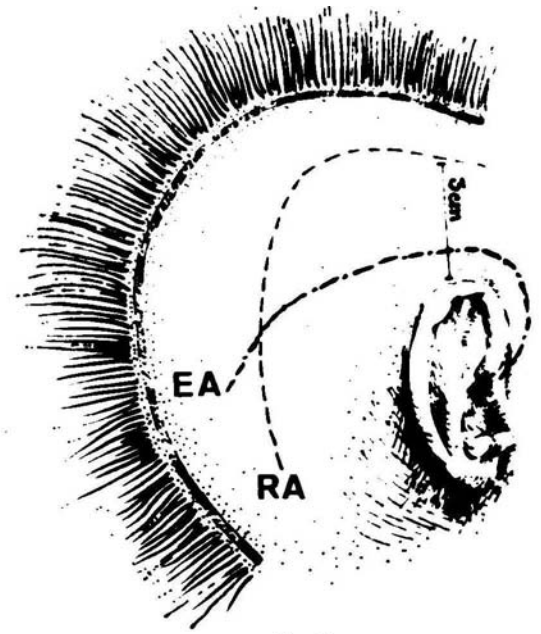


FIG. 2

The two main approaches used: RA = retro-auricular; EA = endaural. This latter is inferiorly prolonged in order to ease the inferior displacement of the surgical flap.

Mean follow-up with 30 months, ranging from four to 61 months.

Results

In three out of five patients with chronic ear disease or its surgical sequelae, a preliminary rehabilitative procedure (two reconstructions of radical cavity, one tympanoplasty) was performed six to eight months before cochlear implant surgery.

Intra-operative

Cochlear ossification was found in two patients with normal computerized tomography (CT) findings and no history of otosclerosis or meningitis: in one of them it was localized in the posterior portion of the basal turn, in the other one it occupied the entire cochlear lumen. In this latter patient, the decision was taken to implant (successfully) the other ear during the same surgical session. In the other case, cochlear ossification was the cause of an erroneous placement which caused progression of the electrode into the posterior labyrinth, thus requiring revision surgery, with a more extensive drilling of the basal turn and successful reinsertion of the same undamaged electrode.

Apart from the aforementioned cases, extra drilling of the cochlear lumen was never required and the intracochlear progression of the helicoidal electrode array was never hampered. Moreover, cochlear ossification was not found in the three post-otosclerosis patients nor in the one post-meningitis patient.

In the children's group, it was never possible to lodge the receiver exactly at the level of the external skull surface, within the bony niche, even after total dural exposure.

In one patient, progressively deafened by an unknown cause, stapedial reflex elicitation provoked facial nerve twitching when all electrodes from basal to apical were stimulated.

Post-operative

In four of the eight patients (50 per cent) implanted with a first generation device and an RA-ST placement, inferior sliding of the receiver occurred within the first post-operative year, namely after three, five, six and eight months. In three of them (37.5 per cent), due to the consequent skin defect, revision surgery was necessary: with closure of the skin defect in two patients; with EA-RM same-side reimplantation in the other one.

The latter patient's story deserves a further description. In fact, this 12-year old boy showed a sudden halt in rehabilitative improvement, 13 months after implantation, along with the inferior displacement of the receiver. Both reasons prompted us to perform revision surgery via an EA-RM approach for the positioning of a new implant (third generation). The old implant, analysed by the manufacturer, was found to have been damaged by an electric shock which had uncoupled the external and internal antennae. During surgical

https://doi.org/10.1017/S0022215100143889 Published online by Cambridge University Press

revision, the receiver was found to have slipped from the temporal muscle, causing the Silastic® protection to protrude under the thin overlying retroauricular tissues. Re-growth of bone around the rim of the mastoidectomy was also found, whilst the electrode was encased in fibrosis which totally obliterated the mastoid bowl as well as facial recess opening. While removing the old electrode from the cochlea, no particular resistance was experienced, nor with reimplantation of the new electrode which was easily carried out. After five weeks, the implant was again switched on and the boy started to show normal progress with rehabilitation.

One of the three patients with a radical cavity received an EA-RM positioning of the device after a preliminary reconstructive procedure, which six months after surgery gave rise to skin damage followed by extrusion. For this reason, after an unsuccessful preliminary closure of the defect, the patient underwent a successful new implantation in the opposite ear.

One out of 22 (4.5 per cent) EA-RM implanted patients was revised for plastic closure of a small skin defect, with ST placement of the receiver.

Three adult patients displayed a grade 3/6 facial palsy, immediate in two, delayed (two weeks post-op) in the other patient. All of them recovered within the first post-operative month. The patient with intra-operative involuntary facial nerve stimulation did not display similar behaviour when the implant was activated five weeks post-operatively.

Discussion

The extremely positive functional results obtained with Clarion® devices have since the beginning overshadowed the few, sometimes troublesome, local complications related to surgery (Welling *et al.*, 1993; Trabalzini and Babighian, 1996). However, as one of the first Clarion® cochlear implant programmes in Europe, it has been possible to personally observe the benefits received from upgrade of the device and modification of part of the surgical technique.

One of the major problems has regarded the integration of the receiver underneath the surgical flap. The initial proposal to place it underneath the temporal muscle (Schindler and Kessler, 1992) aimed at creating a reliable protective barrier. Unfortunately, this location has been associated with inferior displacement of the receiver in 50 per cent of our first generation cases, which has eventually led in a few cases to skin damage or defects requiring surgical re-intervention. First generation Clarion® implants were, in fact, provided with a rigid plastic protection of the lead coming out from the receiver, presumably responsible for the traumatic effect on the overlying tissues. In the few second generation devices implanted with the RA-ST approach, in fact, the reduced size of such protection has never caused any problem even if an inferior displacement had occurred. Whether such a problem was caused by the thickness of the receiver or whether the receiver itself, in some subjects, was particularly sensitive to activities (chewing, etc.) of the temporal muscle, is difficult to establish. In fact, our change of surgical strategy, i.e. shifting from RA-ST to EA-RM, which has coincided with a similar policy in USA, has definitively solved the problem in all the adult patients with a normal middle ear cleft.

Chronic middle-ear disease and childhood deserve some further recommendations. When facing middle-ear pathology, such as was the case in a limited number of our study group (16.7 per cent), the choice of a single-stage versus two-stage operation or surgical incision, in order to spare the retro-auricular vascular supply (Nakajima *et al.*, 1995) should be taken into account.

In only one of the children, cochlear implantation was performed in the presence of coexisting subacute otitis media, without eardrum perforation but with middle-ear granulation tissue. In this specific case, due to a narrow facial recess and poor visualization of the promontory, bony canal down technique was performed without interruption of the overlying external ear canal skin and tympanum which up to now (12 months follow-up) has not provoked any eardrum retraction/defect.

In all other cases, our policy has been to always perform cochlear implantation after treating the middle-ear pathology, i.e. by carrying out eardrum repair in two cases and by reconstructing an old radical cavity in the other two patients. Nevertheless, one patient of the latter group (EA-RM) developed, six months after cochlear implantation, skin damage and defect which had to be surgically revised. In this case, it is possible to assume that the two previous operations had greatly modified the vascularization of the retroauricular region which had never caused problems until coming in contact with a foreign body such as the receiver (Harris and Cueva, 1987). A thorough history of ear pathology and related operations (open or closed tympanoplasty, stapedectomy, etc.) is therefore of utmost importance for any cochlear implant candidate.

When dealing with paediatric patients, due to the dimensions of the skull, one should always foresee a slight external protusion of the receiver, despite a deep niche drilled down to the dural sheath. In this regard, pre-operative CT scan evaluation may be helpful for the selection of the best place for the positioning of the receiver. It may be assumed, however, that skull growth could rather be responsible for withdrawal of the electrode-carrier from the cochlea than of displacement of the receiver from its cranial position.

It is thus possible to conclude that the EA-RM approach has definitively met our expectations both for the absence of post-operative complications and for aesthetic reasons, since it has allowed, even in males, to hide most of the external components of the device.

As far as the intracochlear insertion of the device is concerned, it is well known that the Clarion® device needs a special instrument to facilitate the introduction of the elastic helicoidal tube. Some

https://doi.org/10.1017/S0022215100143889 Published online by Cambridge University Press

authors, in this regard, claimed that Clarion® devices could be harmful for cochlear integrity (Welling *et al.*, 1993). The case in whom, due to the hardware failure, it was necessary to explant and reimplant a new device has allowed us to achieve information about this. As expected for a child, the mastoid cavity was found to be partially reossified with extensive fibrosis surrounding and fixing the electrode-carrier as far as at the cochleostomy site. Moreover, the removal of the previously-inserted lead was not hampered and the lead itself, once removed, showed slight distortion but not irreversible damage. Also the reimplantation of a new device occurred without any difficulty. From this experience, some further conclusions can be reached. First, all the intra-operative efforts to guarantee a stable positioning of the lead within the surgical cavity could perhaps be avoided, since post-operative fibrosis seems to act favourably in this respect. Secondly, the non-linear shape of the carrier does not represent an additional factor in intracochlear mechanical damage. The near-normal intra-operative impedance values as well as the improvement shown when the rehabilitative procedure was restarted, are reliable proof of a totally atraumatic re-implantation procedure.

As far as facial nerve problems are concerned, the post-operative VII nerve deficit occurring in three patients of our study group and recovering completely within the first post-operative month seems not to be as important as facial nerve stimulation after activation of the implant, more likely to occur in cases of cochlear otosclerosis (Muckle and Levine, 1994). Post-operative facial palsy has previously been reported with different incidence (Cohen and Hoffman, 1991, Webb *et al.*, 1991; House and Luxford, 1993; Trabalzini and Babighian, 1996; Lalwani *et al.*, 1998) and facial nerve intra-operative monitoring is recommended for the purpose and it has been carried out in all our cases. The case of facial nerve twitching during intra-operative electric stimulation (stapedial reflex elicitation) should warn about the possibility of this complication when the implant is eventually activated. Fortunately, the case in our series did not display facial stimulation after implant activation, previously described in only one Clarion® case (Bigelow *et al.*, 1998).

It is possible to conclude that advances in the hardware of the Clarion® cochlear implant has allowed implant teams to overcome all the minor, at times troublesome, problems experienced with the first generation of the device. Future progress should, therefore, aim at a further thinning of the receiver which would be especially useful in children.

From a technical point of view, the EA-RM has proved to be reliable as far as post-operative complications are concerned. The only EA-RM patient with flap problems, which had to be surgically revised, was later on found to be affected by pancreatic neoplasm, possibly contributing to induce infection and skin necrosis at retroauricular level. However, patients with middle-ear pathology or who underwent middle-ear surgery must be carefully evaluated, due to the greater risk for skin defect in the post-operative period.

In our experience, furthermore, the elastic memory which characterizes the helicoidal shape of the electrode carrier of Clarion® implants, would not seem an additional traumatizing factor for the inner ear neural structures, an observation which is supported by the ease of explantation and reimplantation.

References

Balkany, T., Telischi, F. F. (1995) Fixation of the electrode cable during cochlear implantation: the split bridge technique. *Laryngoscope* **105:** 217–218.

Bigelow, D. C., Kay, D. J., Rafter, K. O., Montes, M., Knox, G. W., Yousem, D. M. (1998) Facial nerve stimulation from cochlear implants. *American Journal of Otology* **19:** 163–169.

Cohen N. L., Hoffman, R. A. (1991) Complications of cochlear implant surgery in adults and children. *Annals of Otology, Rhinology and Laryngology* **100:** 708–711.

Harris, J. P., Cueva, R. A. (1987) Flap design for cochlear implantation: avoidance of a potential complication. *Laryngoscope* **97:** 755–757.

House, J. R. D., Luxford, W. M. (1993) Facial nerve injury in cochlear implantation [see comments] *Otolaryngology – Head and Neck Surgery* **109:** 1078–1082.

Kempf, H. G., Issing, P. R., Lenarz, T. (1996) Ionomer cement in cochlear implant surgery- applications and long-term outcome. *Laryngorhinootologie* **75:** 388–391.

Lalwani, A. K., Larky, J. B., Wareing, M. J., Kwast, K., Schindler, R. A. (1988) The Clarion® multi-strategy cochlear implant—Surgical technique, complications and results: a single institutional experience. *American Journal of Otology* **19:** 66–70.

Muckle, R. P., Levine, S. G. (1994) Facial nerve stimulation produced by cochlear implants in patients with cochlear otosclerosis. *American Journal of Otology* **15:** 394–398.

Nakajima, H., Imanishi, N., Minabe, T. (1995) The arterial supply of the temporal region and the vascular basis of various temporal flaps. *British Journal of Plastic Surgery* **48:** 439–450.

Schindler, R. A., Kessler, D. K. (1992) Preliminary results with the Clarion® cochlear implant *Laryngoscope* **102:** 1006–1013.

Schindler, R. A., Kessler, D. K., Barker (1995) Clarion® patient performance: an update on the clinical trial. *Annals of Otology, Rhinology and Laryngology* **166:** 290–292.

Trabalzini, F., Babighian, G. (1996) Problem in cochlear implant surgery. *Acta Otorhinolaryngologica Italica* **16:** 105–108.

Webb, R. L., Lehnardt, E., Clark, G. M. (1991) Surgical complications with the cochlear multiple-channel intracochlear implant: experience at Hannover and Melbourne. *Annals of Otology, Rhinology and Laryngology* **100:** 131–136

Welling, D. B., Hinojosa, R., Gantz, B. J., Lee, J. T. (1993) Insertional trauma of multichannel cochlear implants. *Laryngoscope* **103:** 995–1001,

Address for correspondence:
Maurizio Barbara, M.D., Ph.D.,
Institute of Otorhinolaryngology,
University of Rome 'La Sapienza',
00185 Rome, Italy.

Fax: +39(6)4454864
e-mail: m.barbara@pronet.it

https://doi.org/10.1017/S0022215100143889 Published online by Cambridge University Press