The Journal of Laryngology and Otology
November 1992, Vol. **106**, pp. 949–953

Ionomeric bone cement in neuro-otological surgery

RICHARD T. RAMSDEN, F.R.C.S.,* RORY C. D. HERDMAN, F.R.C.S.,* RICHARD H. LYE, PhD., F.R.C.S.**

Abstract
The use of a polymaleinate glass ionomer cement in 80 neuro-otology cases is described. It has proved of great value in translabyrinthine acoustic neuroma surgery, reducing the incidence of CSF fistula to nil. It is the method of choice for fixation of the Nucleus cochlear implant, and has many other applications in the field of otology and neuro-otology. It is easy to use and appears to have no side effects.

Introduction

Ionomeric bone cement is a polymaleinate glass ionomer first developed by Wilson and Kent for use in dental surgery (Wilson and Kent, 1972). Subsequent work by Jonck *et al.* (1989a and 1989b) established its role in the field of orthopaedic surgery particularly in hip replacement in which it has certain clear advantages over polymethylmethacrylate. In recent years its potential in otolaryngology has been explored. In this communication one year's preliminary experience in the use of ionomeric bone cement in neuro-otology is described.

Ionomeric cement is a polymaleinate glass ionomer formed as a result of a neutralization reaction between powdered calcium aluminium fluorosilicate, a basic glass, and polycarboxylic acid, a monomer free polyalkenoic acid. It is manufactured by the IONOS* company and is presented as a two component system. The acid, in a blister pack (Fig. 1) is squeezed into a capsule containing the glass powder (Fig. 2) and mixed in a shaker (Fig. 3). The resulting cement is squeezed out of the capsule and is ready for use (Fig. 4). It remains workable for five minutes before hardening.

The setting reaction is minimally exothermic and the cement does not shrink during setting. The cement can set on moist bone but once set is impermeable to water. It is placed in position and moulded to shape using a fine dissector or elevator. It can be drilled like bone using a diamond burr within five minutes.

Material and methods

Between May 1991 and July 1992 ionomeric bone cement has been used in a total of 80 neuro-otological and skull base procedures performed at Manchester Royal Infirmary (Table I).

Fixation of Nucleus Mini 22 Channel Cochlear Implant (N = 15)

The lead electrode of the Nucleus cochlear implant is fixed at two points as it crosses the mastoid. In adults these are the posterior surface of the posterior wall of the external auditory canal, and in a groove beneath the mastoid cortex in the region of the lateral sinus. In addition cement may be used to stabilize the receiver stimulator in the bony recess cut to accommodate it (Fig. 5). In children the buttress of bone between the fossa incudis and the posterior tympanotomy opening is preferred for the distal fixation point because of potential problems of mastoid growth. The cement is much quicker and easier to use than the previous method employed which involved the use of Dacron slings passed through anchoring holes in the mastoid cortex. Furthermore the Dacron has been reported as causing necrosis and breakdown of the skin of the external audi-

*IONOS Medizinische Produkte, GmbH, D-8031 Seefeld, Germany.

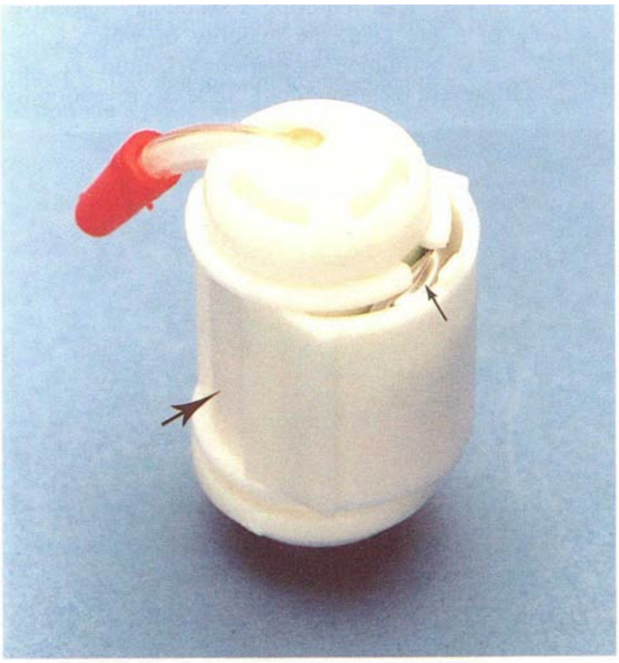

FIG. 1
The capsule (large arrow) contains glass powder. The blister pack (small arrow) contains polycarboxylic acid.

From the Departments of Otolaryngology* and Neurosurgery,** Manchester Royal Infirmary, Oxford Road, Manchester M13 9WL.
Accepted for publication: 20 September 1992.

TABLE I

Procedure		Number of cases
Acoustic neuroma surgery		46
Translabyrinthine	43	
Suboccipital	3	
Repair CSF leak (previous acoustic surgery)		3
Seal Eustachian tube		8
Glomus jugulare	3	
Petrous apex cholesteatoma	4	
Patulous Eustachian tube	1	
Reconstruct mastoid cortex		2
Fixation of Nucleus cochlear implant		15
Other		6

tory canal (Lehnhardt, 1991 personal communication), and in one case from our series it was responsible for the development of a small area of infection in the overlying skin flap which fortunately responded to conservative measures. An alternative method of fixation at the fossa incudis buttress employs the use of a platinum loop. It is difficult, time consuming and frustrating.

Prevention of CSF fistula in acoustic neuroma surgery (N = 46)

One of the recognized complications of acoustic neuroma surgery is CSF leakage from the posterior fossa by way of the mastoid air cells through the middle ear and Eustachian tube to the nose or nasopharynx. In particular the translabyrinthine approach has been criticized for the high incidence of this problem, although the retrosigmoid route also carries some risk because of the frequent need to open into the mastoid air cells when carrying out the craniectomy. In our own early experience there was an incidence of CSF leak requiring a secondary operative procedure of 5 per cent, the majority of which complicated translabyrinthine operations (Dutton *et al.*, 1991). Our present technique for CSF leak prevention in the translabyrinthine operation is as follows. After tumour removal, the incus is removed and the middle ear filled with small pieces of muscle. Ionomeric bone cement is then used to seal off the attic and aditus thus creating a watertight barrier between the middle ear and the translabyrinthine cavity (Figs. 6, 7, 8). It is attached to the outer attic wall, the outer flange of the lateral semicircular canal, the fossa incudis and the tegmen. Care is taken to avoid contact with the facial nerve, although there is no evidence to suggest that the cement is neurotoxic. A small quantity of cement is then placed in the vestibule to prevent possible leakage through the oval window past a subluxed

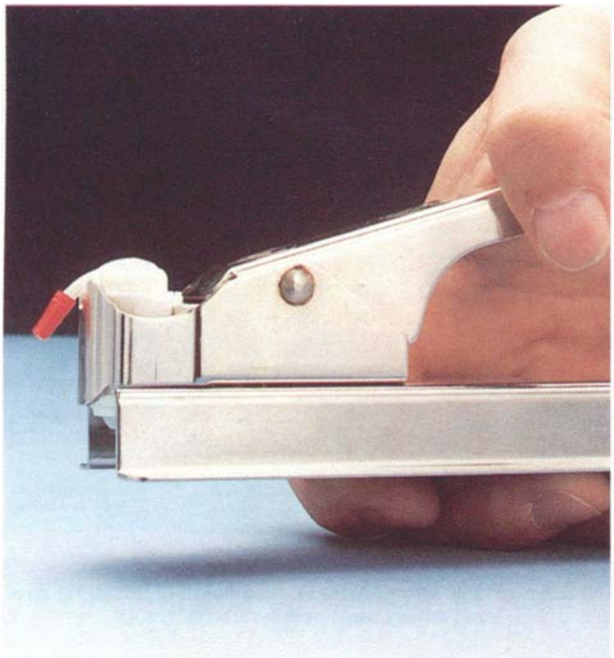

FIG. 2
The acid is squeezed into the glass powder.

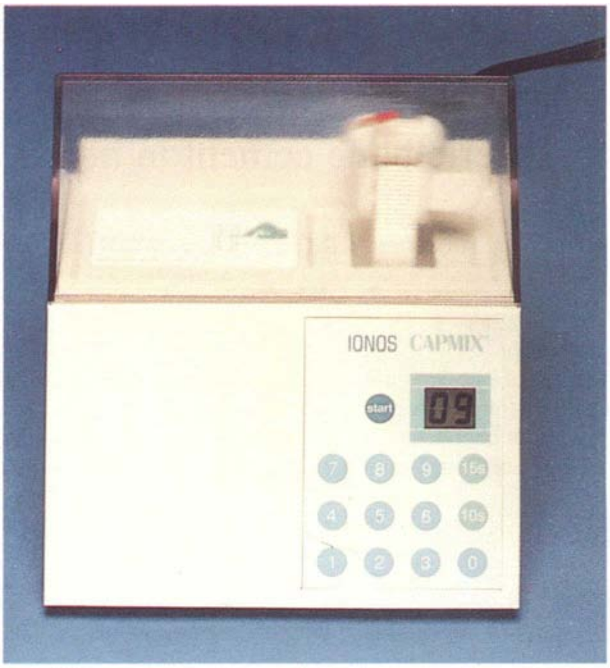

FIG. 3
The mixture is agitated for 10 seconds.

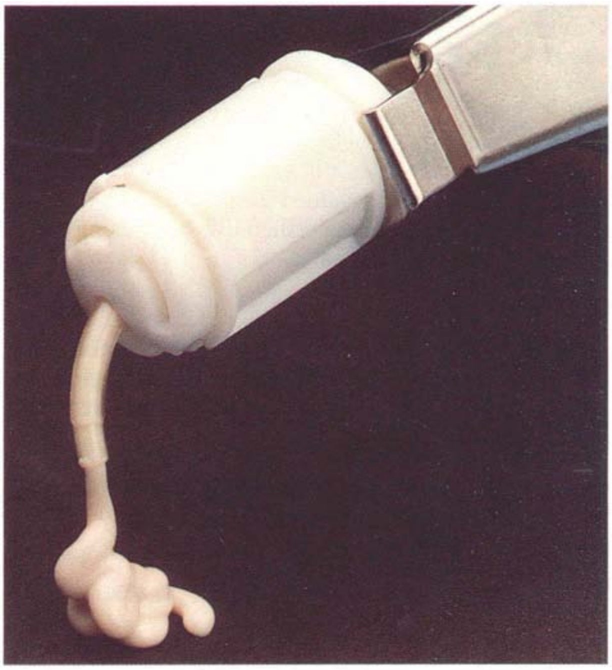

FIG. 4
The cement is squeezed out ready for use.

https://doi.org/10.1017/S0022215100121449 Published online by Cambridge University Press

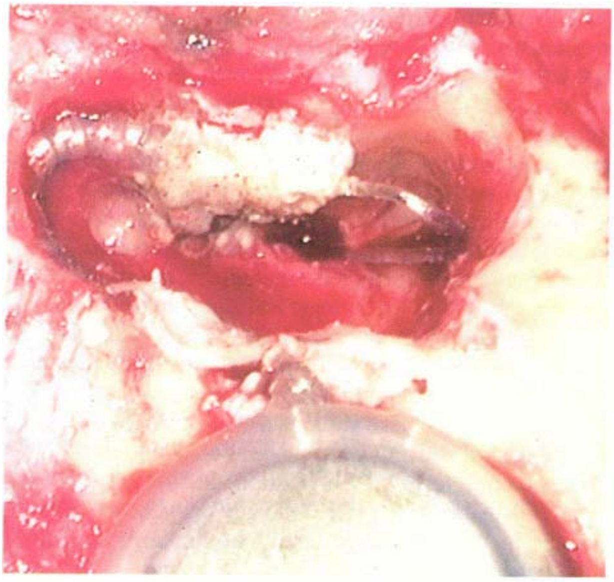

FIG. 5
Fixation of Nucleus cochlear implant lead.

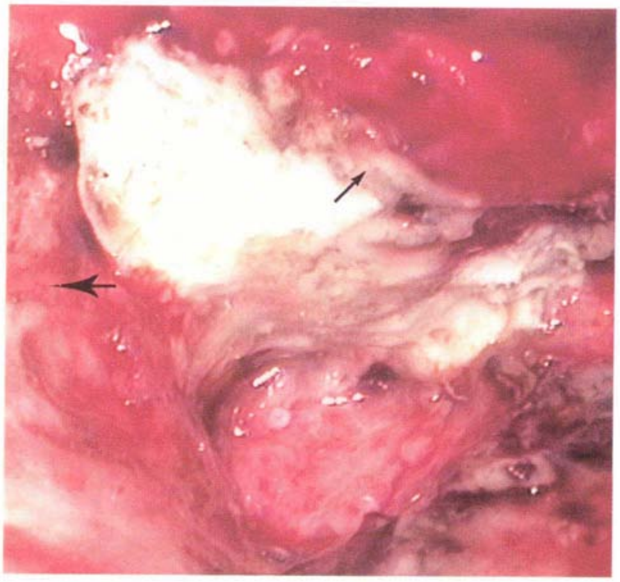

FIG. 7
Attic area sealed with ionomeric bone cement (large arrow: middle fossa, small arrow: external meatus).

stapes. A sheet of temporalis fascia or rectus sheath fixed in position with Tisseel is then used to seal the posterior fossa, and strips of fat are packed into the cavity in the usual manner. Closure is in two layers; a superiorly pedicled periostial flap and skin. Since the introduction of ionomeric bone cement 43 translabyrinthine operations have been performed, and the incidence of CSF leakage has dropped to 0 per cent. Ionomeric cement has also been used in three cases of retrosigmoid acoustic neuroma surgery to seal the mastoid air cells where previously muscle or bone wax would have been used. There was no instance of leakage in these three cases. In addition three cases of CSF leakage from previous acoustic neuroma surgery were treated. Two of these were retrosigmoid operations and one a translabyrinthine approach. All were successfully treated by opening the mastoid and sealing the attic in the manner described above. In one a posterior tympanotomy was also performed and the cement injected into the Eustachian tube opening through an intravenous cannula (Fig. 9).

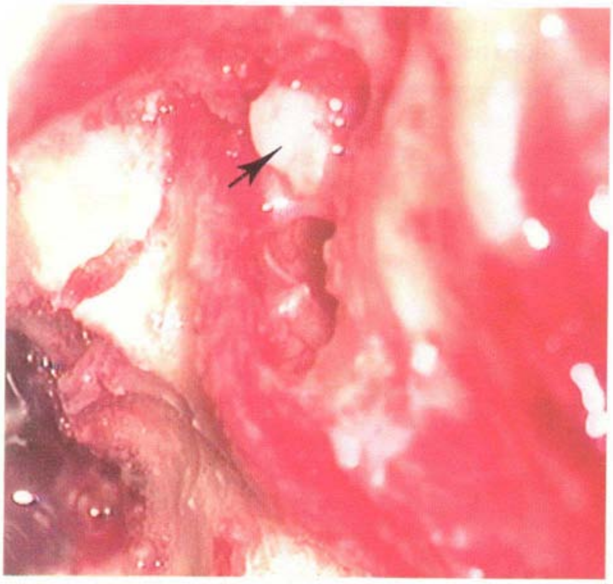

FIG. 6
Attic area after translabyrinthine removal of R acoustic neuroma (malleus head arrowed).

Eustachian tube obliteration (N = 8)

In four cases of petrous apex cholesteatoma and three of extensive glomus jugulare tumours, ionomeric bone cement was used to seal the Eustachian tube to prevent CSF leakage and it was also employed to seal off the internal meatus when it had been opened. It was also used with good effect in one case of patulous Eustachian tube syndrome in a patient with terminal cancer. The cement was injected through an intravenous cannula under direct vision via a posterior tympanotomy approach.

Reconstitution of the outer table of the mastoid (N = 2)

This technique was employed in two patients with large

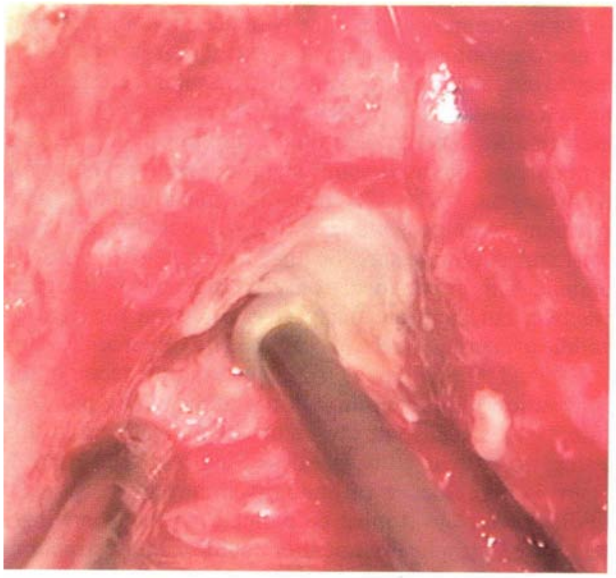

FIG. 8
Cement is drillable in five minutes.

https://doi.org/10.1017/S0022215100121449 Published online by Cambridge University Press

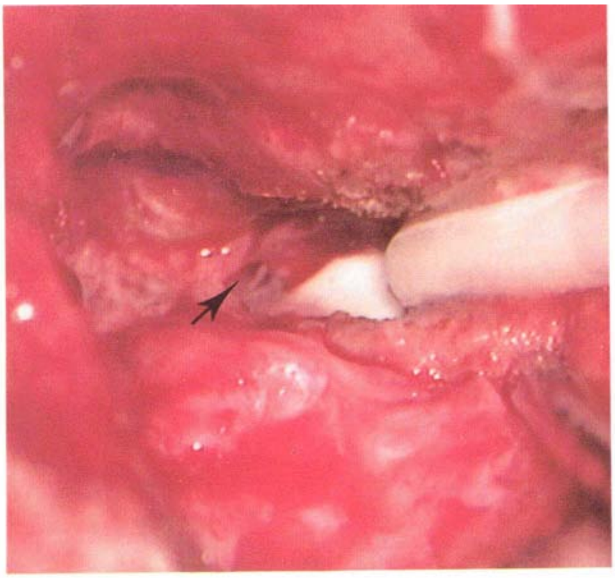

FIG. 9
Injection of cement into Eustachian tube (arrowed) through posterior tympanotomy (R ear).

surgical defects following removal of extensive glomus tumours. Both patients developed large CSF collections under the skin flaps which tracked down into the neck. The leaks were repaired by cementing preformed pieces of cement sheet to the edges of the mastoidectomy defect (Fig. 10).

Additional applications

Ionomeric cement has also been used for repair of tegmen defects (once after excision of an endaural cerebral hernia), to restore protective covering to a lateral sinus varicocoele, and to reposition the posterior meatal wall when that structure had been removed for access in glomus surgery.

Discussion

Our preliminary experience with glass ionomer cement in neuro-otological surgery suggests that it is a versatile, easy to use, and safe substance. In particular it has brought about a substantial improvement in the prevention of CSF leakage after acoustic neuroma and other major petrous bone surgery. It is an elegant and time saving technique for anchoring the Nucleus 22 channel cochlear implant. There are many more possible uses that will occur to the otologist and skull base surgeon once he has begun to use the cement. This report deals only with a neuro-otological practice, but there are many possibilities in the field of middle ear surgery, as have described by Geyer and Helms (1990) and by Babighian (1992), for example repair of the outer attic wall, obliteration of mastoid cavities and ossiculoplasty. Because of the nature of the patients in this series, no patient with useful hearing has been treated. There is no evidence of ototoxity in any of the clinical studies so far but it must be pointed out that there have been no electrophysiological or cochlear microstructural studies yet performed. No adverse effects have been observed in this preliminary study; in one patient in whom the cement was used to reconstitute the posterior canal wall, there has been a failure of soft tissue to grow over the cement, and it is recommended that in this situation viable soft tissue is used to cover the cement.

Geyer and Helms (1990) published their experience using glass ionomer cement in 167 patients undergoing otological surgery in a one year period. Fifty-one patients underwent partial or complete reconstruction of the posterior canal wall after mastoid surgery. The canal wall was reconstructed using glass ionomer cement which was covered either with pedicled canal skin or a periosteal flap. Twelve out of 13 patients who underwent 1/3 reconstruction had complete epithelialization, 14/19 who had 2/3 reconstruction completely epithelialized and 9/19 who underwent total reconstruction completely epithelialized by three months. These authors also reduced the size of 22 mastoid cavities using a porous granulate and in all cases obtained complete epithelialization. They have also used incus prostheses and bridged the gap between stapes arch and the incus with no extrusions in the early post-operative period.

Glass ionomer cements are used in dental surgery as a filling and luting material and have several attractive features; they have a physiological setting temperature, they bond very efficiently to hydroxyapatite and they are resistant to the moist conditions in the mouth. There have also been trials using it instead of methyl methacrylate as a cement in orthopaedic surgery, the advantages being that it does not have such an exothermic setting reaction and it is bioactive (Jonck *et al.*, 1989b).

The characterization of the bone/glass interface has been studied both *in vivo* and *in vitro* (Hatton *et al.*, 1991). *In vitro,* in primary bone organ cultures, cells with osteoblast like morphology were found in contact with the glass ionomer cement surface and transmission electron microscopy revealed a calcified collagen extracellular matrix with interdigitating collagen fibres at the bone/cement interface. *In vivo* experiments were performed by implanting rods or granules of glass ionomer cement into predrilled holes in the femora of rats. The animals were sacrificed at set intervals and the interfaces examined using both light and transmission electron microscopy. At two weeks the granules were found to be surrounded by new bone which had also formed in the depressions on the sur-

FIG. 10
Repair of mastoid cortex using preformed cement shapes.

face of the granules and the interface consisted of a narrow proteinaceous band. At six weeks there was direct interdigitation of mineralized extracellular bone matrix with the glass ionomer cement. Aluminium and silicon were present in bone adjacent to the interface and it was thought likely that fluoride, calcium and phosphate ions were also exchanged although for technical reasons these were not detected.

Glass ionomer cement has been reported to perform poorly *in vitro*, possibly because it was found to release a mildly cytotoxic fluoride containing leachate (Brook *et al.*, 1991). However Jonck *et al.* (1989a) found no inhibitory influence of the cement on osteoblasts. These authors raise the possibility that the slow release of fluoride ions from the cement may actually have beneficial effects on osteogenesis and point out that it has been found that sodium fluoride strengthened the adhesive bond of glass ionomer cement to both enamel and dentine (Powis *et al.*, 1982).

Conclusion

Glass ionomer cement is a biocompatible bone replacement substance new to the field of otology. It is versatile, easy to use and appears to be safe, with no adverse effects in the patients treated in this series. Further work is underway to study the possible toxicity of the substance to the organ of Corti and the facial nerve, but preliminary results suggest that it is safe. It is of particular value in neuro-otology for the prevention of CSF leakage following acoustic neuroma surgery and other skull base procedures, but also has many possible uses in reconstructive middle ear surgery.

References

Babighian, G. (1992) Use of glass ionomer cement in otological surgery. A preliminary report. *Journal of Laryngology and Otology*, **106:** 000–000.

Brook, I. M., Craig, G. T., Lamb, D. J. (1991) *In vitro* interaction between primary bone organ cultures, glass ionomer cements and hydroxyapatite/tricalcium phosphate ceramics. *Biomaterials*, **12:** 179–186.

Dutton, J. E. M., Ramsden, R. T., Lye, R. H., Morris, K., Keith, A. O., Page, J., Vafadis, J. (1991) Acoustic neuroma (schwannoma) surgery 1978–1990. *Journal of Laryngology and Otology*, **105:** 165–173.

Geyer, G., Helms, J. (1990) Reconstructive measures in the middle ear and mastoid using a biocompatible cement—Preliminary clinical experience. *Clinical Implant Materials, Advances in Biomaterials*, **9:** 529–535.

Hatton, P. V., Craig, G. T., Brook, I. M. (1991) Characterization of the interface between bone and glass ionomer (polyalkenoate) cement using transmission electron microscopy and XRay microanalysis. Paper presented at the European Conference on Biomaterials. Chester, UK.

Jonck, L. M., Grobbelaar, C. J., Strating, H. (1989a) Biological evaluation of glass ionomer cement (Ketac-O) as an interface material in total joint replacement. A screening test. *Clinical Materials*, **4:** 201–224.

Jonck, L. M., Grobbelaar, C. J., Strating, H. (1989b) The biocompatibility of glass ionomer cement in joint replacement: bulk testing. *Clinical Materials*, **4:** 85–107.

Powis, D. R., Folleras, T., Merson, S. A., Wilson, A. D. (1982) Improved adhesion of a glass-ionomer cement to dentine and enamel. *Journal of Dental Research*, **61:** 1416–1422.

Wilson, A. D., Kent, B. E. (1972) The glass-ionomer cement: A new translucent dental filling material. *Journal of Applied Chemistry and Biotechnology*, **21:** 313.

Address for correspondence:
Mr R. T. Ramsden, F.R.C.S.,
Department of Otolaryngology,
Manchester Royal Infirmary,
Oxford Road,
Manchester M13 9WL.

Key words: Glass ionomer cements; Surgery, neuro-otological