The Journal of Laryngology and Otology
November 1992, Vol. **106**, pp. 954–959

Use of a glass ionomer cement in otological surgery. A preliminary report

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Introduction

In spite of the continuous progress in techniques and materials, the results of ossicular reconstruction remain rather disappointing. Depending on the existing pathology, the ear may behave as a hostile milieu for ossiculoplasty (Jackson *et al.*, 1983). Chronic otitis, with or without cholesteatoma, and its sequelae are very often unfavourable to both the anatomical and functional success of surgery. Several factors, occurring either separately or simultaneously, such as a shallow tympanic cavity, erosion of bony structures, the quality of the residual chain, the type and extent of the mucosal disease and the amount of tubal dysfunction, are likely to jeopardize the achievement and the duration of a socially adequate hearing gain.

Although extrusion of the ossicular replacement prosthesis is still reported to occur in a relevant percentage of cases (Silverstein *et al.*, 1986; Mair *et al.*, 1989), dislocation of the prosthesis and, in general an unstable interface between the elements of the newly repaired chain are the most frequent causes of failure.

For these reasons, long term post-ossiculoplasty auditory status, as reported by several authors (Jackson *et al.*, 1983; Babighian, 1985; Silverstein *et al.*, 1986; Zeleny *et al.*, 1989; Grotte, 1990; Mangham and Lindeman, 1990), is generally poor, and a residual air-bone gap of 15 dB or less is seldom observed in more than 50 per cent of patients, in whom the tympanic membrane is bridged to the footplate.

In order to improve both the quality and the stability of our ossiculoplasty procedures, we started one and a half years ago to use an ionometric cement* as a bonding and sealing agent. We were introduced to this material by the reports of Geyer and Helms (1990) and by a visit to the ENT University Clinic in Würzburg, Germany.

This paper summarizes our surgical procedures and very preliminary data.

Material and methods

Ionometric bonding bone cement of polymaleinate glass ionomer is a two component system consisting of a powder and a liquid which are mixed before use.

The powder is a calcium-aluminium-fluoro-silicate glass, of particle size up to 0.1 mm. The concentration of reactive ions on the surface is reduced by deactivation which leads to a silica gel level of about 100 nm on the powder particles.

The liquid is an aqueous solution of a polyalkenoic acid, (a copolymer of acrylic and maleic acid). The ionic polymer determines the short term ionomer. By means of a specific purification step after the chemical synthesis of these polymers the monomers are completely removed.

After mixing, the basic powder and the acid set in a neutralization reaction. The set cement consists of a solid non-resorbable aluminium-calcium polycarboxylate matrix in which unreacted glass powder particles and water molecules from the polyalkenoic acid are embedded.

The bone cement is supplied sterilized by gamma-radiation. The working time is about two to three minutes, the setting time is four to five minutes. Setting and hardening of the cement involves the transfer of metal ions from the glass to the polyacid, which results in a gelation in the aqueous phase. During this transfer, the metal ions are present in a soluble form and can be attacked by aqueous liquids. However, after setting, the cement is no longer sensitive to moisture (Geyer and Helms, 1990). Its radio-opacity is the same as compact bone.

The polymaleinate glass ionomer cement has been evaluated in several animal and clinical experiments. Jonck *et al.* (1989a, 1989b) and Jonck and Grobbelaar (1990) found normal bone marrow and haemopoetic cells in close contact to the surface of the ionomeric cement without the formation of a fibrous tissue interface. A non-reactive integration of the material into the bone marrow of the animal (baboon) was observed as was promotion of bone growth (Jonck *et al.*, 1989a). No proof was reached of any cellular toxicity although prevention of cellular proliferation was reported years ago as occurring with freshly prepared cement (Kawahara *et al.*, 1977).

When implanted into the attic wall of rabbits the cement became covered of osteoid in most cases after two months. A strong bone-to-cement connection did develop thanks to osteoid, filling up all surface irregularities and small fissures. Normal mucosa covered the ionomeric cement after 28 days (Figs. 1 & 2) (Geyer, 1991).

Geyer and Helms (1990) reported the use of the glass ionomer cement in 167 patients undergoing middle-ear procedures. The material was employed in the reconstruction of the bony wall of the external auditory canal, as a granulate powder for mastoid obliteration and as pre-

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

Accepted for publication: 20 September 1992.

FIG. 1

Experimental implantation of Ionomeric Cement on the attic wall of the rabbit. Ostoid (0) grows onto the surface of the cement (AL) (Courtesy of Dr. G. Geyer).

moulded short and long columellas to repair defects of the ossicular chain.

These authors observed complete epithelialization after three months in about half of the patients with total reconstruction of the posterior canal wall, and in almost all patients with a partial reconstruction. In four cases, the cement had to be removed, because of persisting infection of the middle ear, already present before surgery. Epithelialization occurred within three months post-operatively in 20 out of 22 patients undergoing mastoid obliteration with porous granulate cement. Short columellas were inserted in 64 patients, long columellas in 30 patients. Extrusion did not occur in any instance.

The conclusions were that glass-ionomer cement is stable, easy to handle and non irritating to the adjacent tissues. In contact with bone, hardening of the cement is likely to provide a firm adhesion of the cement itself to the bone. Another advantage is the possibility of easily shaping the hardened cement with a burr in order to restore the original anatomy of the repaired structure.

Zöllner (1991) advocate the use of the ionomeric cement in neurosurgery in order to repair skull defects and to prevent CSF fistulas. Skull defects were also successfully treated by Geyer and Helms (1990). The adhesive qualities and the interfascial tensile strength of 1 to 2 N/mm^2 secure the permanent fixation of an implant to the skull bone without the need for screws.

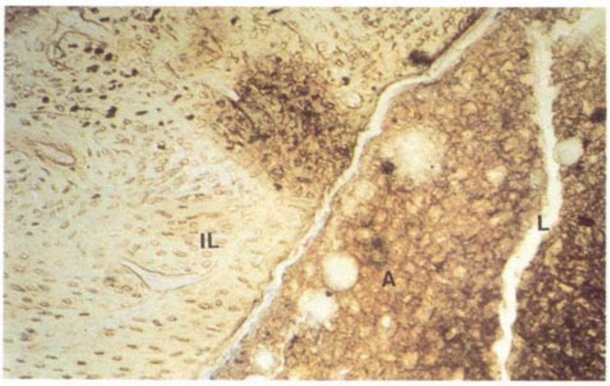

FIG. 2

Experimental implantation of Ionomeric Cement on the attic wall of the rabbit. The attic implant adheres tightly to the implantation site (IL) without signs of resorption. A fissure (L) is seen inside the ionomeric cement. (Courtesy of Dr. G. Geyer).

TABLE I

CASE MATERIAL	N. 63
REPAIR OF THE OSSICULAR CHAIN	N. 27
Malleo-incudal discontinuity	n. 5
Erosion of the long process of the incus	n. 5
Stabilization of columella prosthesis	n. 9
REPAIR OF BONY WALLS	N. 26
Posterior and/or attic wall defect	n. 16
Anterior canal wall defect	n. 1
Posterior-inferior annulus defect	n. 1
Posterior wall repositioning	n. 2
Repair of tegmen defects	n. 4
Mastoid obliteration	n. 2
STABILIZATION OF COCHLEAR IMPLANT	N. 10

This paper describes a series of 63 reconstructions performed in 56 ears of adult patients operated on between June 1990 and June 1991 at the Department of Otorhinolaryngology, Ospedali Civili Riuniti, Venice, Italy. In all instances the operation was a middle ear procedure, with or without reconstruction of the ossicular chain. The material included cases of temporal, bone trauma, iatrogenic ossicular disruption or dislocation, cochlear implant procedures and chronic otitis and its sequelae. These latter were all dry and infection-free ears, (Bellucci 1 cases), without cholesteatoma (Table I).

Materials and methods

The ionomeric cement was prepared during surgery according to the directions of the manufacturer. The cement was laid down on the ossicle(s) or the bony surface using a middle ear elevator and a plastic 5 ml syringe tipped with a plastic, transparent blunt needle. When needed, the solidified cement was properly shaped using a diamond burr and under irrigation. In most cases the cemented area was covered with a fascia layer, in order to avoid direct contact with the soft tissues or connective tissue grafts.

Procedures were as follows:

1. Repair of the ossicular chain (N27)
2. Repair of the bone walls of the tympanomastoid cleft (N26)

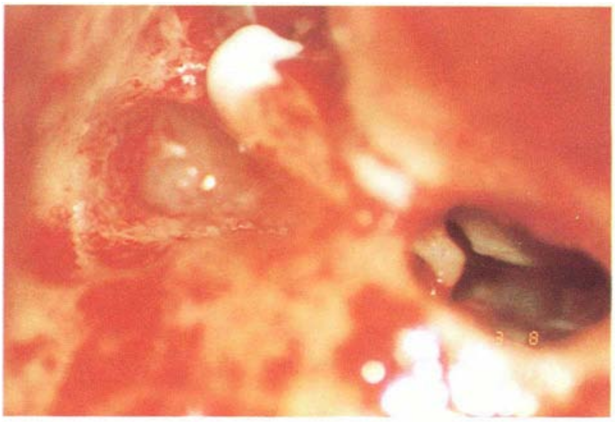

FIG. 3

A traumatic malleo-incudal disjunction has been repaired within a combined approach tympanoplasty through an antral approach. Solidified cement is seen at the junction between the head of the malleus and the incus body.

FIG. 4

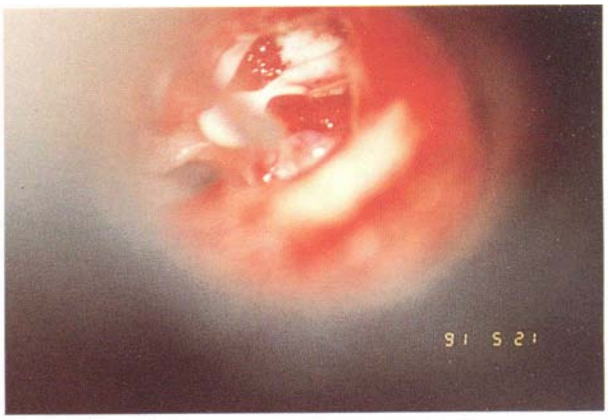

FIG. 5

FIG. 6

FIG. 7

FIGS. 4, 5, 6, 7

The process of remodelling the long process of the incus is illustrated in four different phases. The cement laid down on the ossicle and progressively shaped (Figs. 4 & 5). As the cement is set, the long apophysis is ready for completion of the surgical procedure (Figs. 6 & 7).

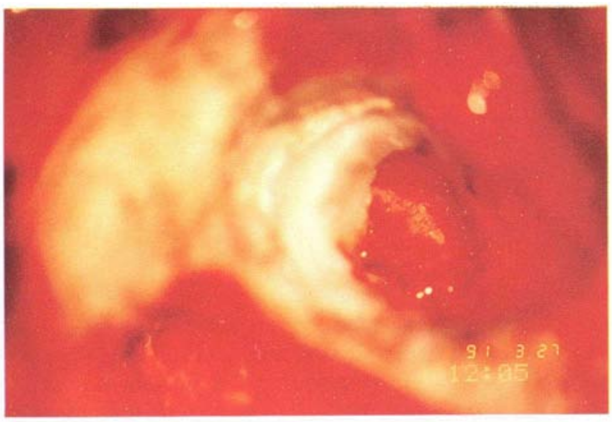

FIG. 8

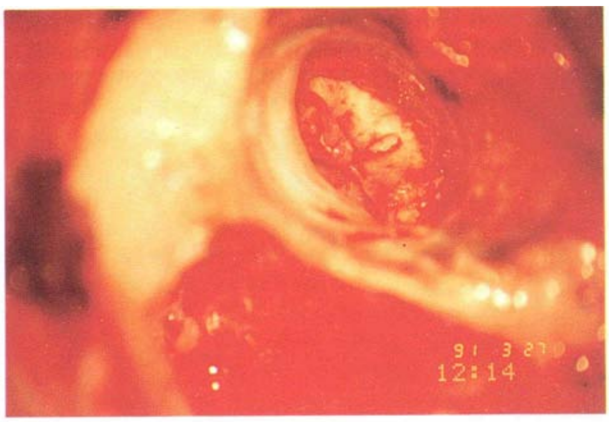

FIG. 9

FIGS. 8 & 9

Reconstruction of the posterior bony wall. The cement is laid down on the wall defect and allowed to solidfiy (Fig. 8). Subsequently, the repaired segment is remodelled to normal shape and size using a diamond burr under irrigation (Fig. 9).

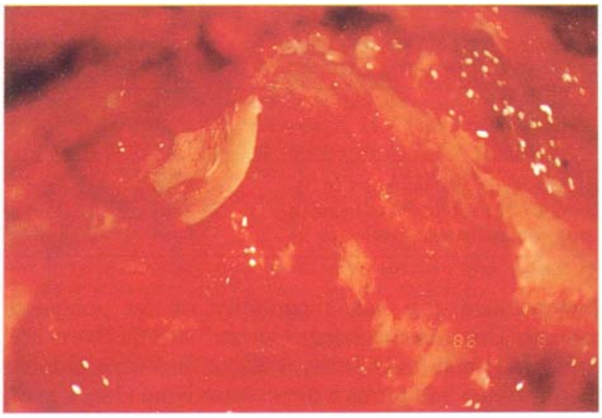

FIG. 10

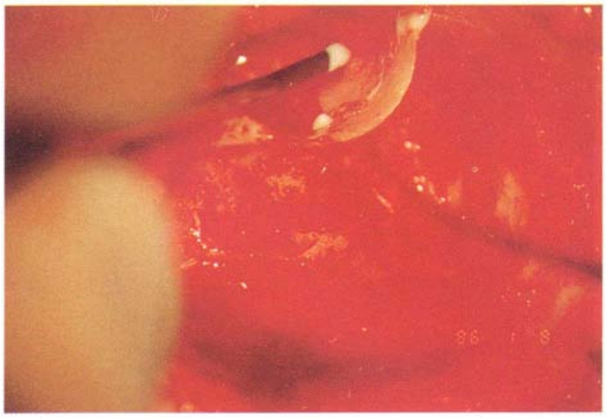

FIG. 11

FIGS. 10 & 11

A better approach can be gained to the sinus tympani in many intact canal wall operations by temporarily removing the posterior bony wall. This is well accomplished with the use of a Feldman saw. The bony fragment is subsequently repositioned (Fig. 10) and sealed to the adjacent bony structure with a small amount of cement (Fig. 11).

3. Stabilization of the cochlear implant lead wire on the posterior canal wall of postlingual adult patients. In three, the receiver-stimulator device was cemented to the squamous temporal bone.

1. Five cases of ossicular luxation (malleoincudal dysjunction) were repaired. A small amount of cement was progressively laid down at the joint site after careful repositioning of the ossicles (Fig. 3). The repair was performed either by a transantral or by a transcanal approach after removing the lateral attic wall.

   In 13 ears, the long process of the incus was found to be fractured or eroded. Seven post-stapedectomy ears are included in this group. The missing ossicular segment was remodelled layer after layer, with a small amount of cement using a House elevator (Figs. 4–7). If a dislocated piston was found it was replaced on the repair ossicle.

   In nine ears a long columella prosthesis was stabilized over the footplate using a thin cartilage shave cemented to the bony annulus or the facial ridge. The cartilage was shaped as a disc, to cover the platform of the prosthesis, or as a U encircling the shaft of the columella.

2. In 16 ears a bony defect in the posterior and/or attic wall was repaired using the ionomeric cement. The latter was first spread in a relatively large amount over the defect. A silastic disc was placed underneath to protect the underlying structures (facial nerve, oval window, etc.). After setting, the cement was precisely shaped using a diamond drill under irrigation. The silastic protection was eventually removed (Figs. 8 & 9).

In one case the same procedure was performed to repair an anterior canal wall defect, and in one other ear, the postero-inferior annulus was rebuilt.

In two cases of combined approach tympanoplasty the posterior bony canal wall was temporarily removed using a Feldman saw, in order to gain a better view of the sinus tympani region. After this area had been inspected, the bony fragment was repositioned and fixed to the adjacent bony frame with drops of cement (Figs. 10 & 11).

In four ears a defect of the tegmen antri was repaired using the ionomeric cement. Such a technique is an alternative to the use of cartilage sleeves inserted extradurally on to the floor of the middle fossa through a small lateral craniotomy. Prior to closure, a piece of temporalis fascia was inserted covering the middle fossa dura.

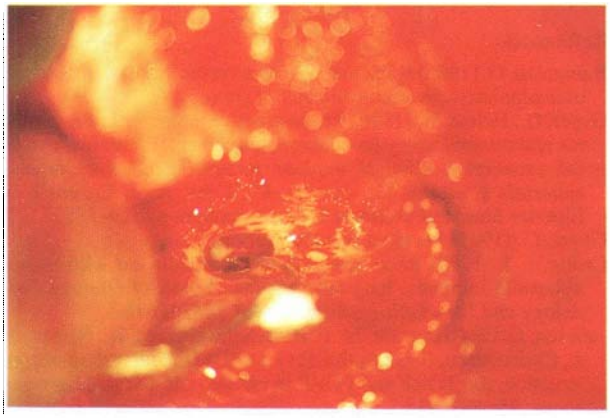

FIG. 12

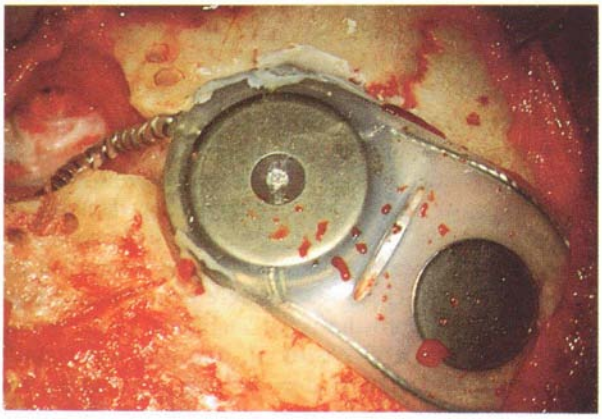

FIG. 13

FIGS. 12 & 13

Cement is usefully employed to stabilize a cochlear implant device. Either the Electrode Array (Fig. 12) or the Receiver-Stimulator (Fig. 13) can be secured to the bone using the ionomeric material.

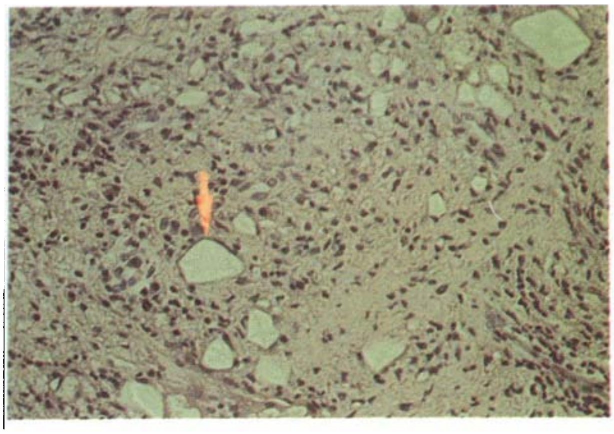

FIG. 14

A foreign body reaction was observed in three bony wall repairs. In one of these cases the cement was extruded. The histological specimen here illustrated shows an inflammatory granulomatous reaction with inflammatory cells (Lymphocytes, plasma cells and histiocytes) surrounding the amorphous cement particles (red arrow).

In two ears, the mastoid cavity was obliterated using the ionomeric cement mixed with autologous bone dust.

3. In cochlear implant procedures the multi-electrode lead wire is usefully stabilized on to the posterior aspect of the posterior bony wall using the ionomeric cement instead of non absorbable sutures. Using a plastic syringe, an amount of ionomeric cement is put over the lead wire firmly held against the posterior bony wall for a few minutes. This procedure has been used to advantage in 10 postlingual adults undergoing cochlear implantation. In three of them, the receiver-stimulator was sealed using the cement to the bony seat drilled out on the surface of the squamous temporal bone.

Preliminary results

Since the post-operative follow-up of our cases ranges from six to 18 months, no definite conclusions can be derived from our preliminary data. A few points can be emphasized.

The anatomical post-operative status was satisfactory in 56 out of 59 operated ears. Three of the 26 bony wall repair cases developed, between the second and the third post-operative months, an extrusion of the ionomeric material, either partial (2 cases) or total (1 case). This was related to an insufficient soft tissue cover onto a widely repaired surface with lack of epithelialization (Fig. 14).

With regard to the functional (auditory) post-operative status best results were achieved in the ears with a postraumatic ossicular luxation or with a post-stapedectomy erosion of the incus. In all these ears a 10–20 dB residual air bone gap was measured throughout the whole 5–4 kHz frequency range. Good results were also obtained in the ears in which the prosthesis was stabilized by the cement. In all these cases a 50–60 dB AC threshold was recorded pre-operatively, and a residual air bone gap of at the most 30 dB in the 0.5–4 kHz range was achieved (Table II).

TABLE II

OSSICULAR CHAIN REPAIR USING IONOMERIC CEMENT. POST-OPERATIVE AUDITORY STATUS. N.: 27. FOLLOW-UP 6–18 MONTHS

	Pre ABG (0.5–4 kHz)	Post ABG (0.5–4 kHz)
Malleoincudal discontinuity (n 5)	42.5 dB	15.5 dB
Erosion of long process of incus (n 13)	55.2 dB	18.0 dB
Long columella stabilization (n 9)	54.4 dB	26.8 dB

Conclusions

Experimental and clinical investigations have clearly demonstrated the biocompatibility of the ionomeric cement. This cement is incorporated into the bone both structurally and functionally, without the interposition of fibrous tissue and forms a direct bone bond (Jonck *et al.*, 1989a, 1989b). The cement-bone contact is a biological process to the bone cells' activity influenced by the cement surface ions (Jonck and Grobbelaar, 1990). It differs from the bonding process of bioglass and hydroxyapatite which depends on surface degradation and corrosion products (Jonck and Grobbelaar, 1990).

Thanks to these features and to the excellent adhesion to metals and bone, ionomeric cement may be used as a sealing and bonding agent in otosurgery.

In our preliminary experience, the cement proved suitable for repairing the ossicles, the external ear canal, the tegmen, and for the intra-aural stabilization of cochlear implant devices.

A number of advantages have been reported related to the clinical use of this material, namely its biocompatibility, absence of toxicity, adhesive qualities, bone-like physical properties and easy shaping.

Drawbacks are the high viscosity, which often makes surgical handling during the most delicate ossicular reconstructions difficult, and problems of epithelialization when large surfaces of cement come in contact with the soft tissues of the external ear canal.

We observed three failures: one total and two partial extrusions occurred in ears in which the posterior bony wall had been repaired using a relatively large amount of cement. No complications occurred with ossicular reconstructions, prosthesis stabilization and cochlear implant device fixation to the bony walls of the ear.

Our data, although very promising, are still preliminary and need to be further validated over a long term follow-up.

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https://doi.org/10.1017/S0022215100121450 Published online by Cambridge University Press

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Key words: Glass ionomer cements; Surgery, otological

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