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Performance of ionomeric cement (Ionocem®) in the reconstruction of the posterior meatal wall after curative middle-ear surgery

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Abstract

The hybrid bone-substitute ionomeric cement is suitable for restoring the original anatomy of the posterior canal wall. During a four-year period the posterior meatal wall was rebuilt with ionomeric cement in 74 patients. The canal wall was totally rebuilt in 38 patients, two-thirds rebuilt in 22 cases, and one-third rebuilt in 14 cases. On the meatal side, the canal wall was covered by a musculo-periosteal (Palva) flap. In the majority of cases, the drum was closed with (cartilage)-perichondrium. Revisions were performed in 27 patients (due partially to cholesteatoma, and/or poor visualization of radical mastoidectomy cavities). The ears were non-infected at the time of operation.

Permanent epithelialization of the bone replacement material was achieved in 57 cases, with secondary closure of a cutaneous defect of the meatal wall being required in six cases. The auditory canal wall had to be removed in 17 patients owing to deficient soft-tissue coverage, persistent inflammation, and/or partial adhesive processes with development of cholesteatoma. In terms of surgical technique, utilization of the material over a follow-up period of maximally seven years proved it to be a sophisticated procedure for reconstructing the meatal wall. Despite the finesse of the surgical technique employed, the overall failure rate of 31 per cent was inadmissibly high. Implantation of the material should therefore be restricted to middle ears with permanent ventilation and no trace of infection.

Key words: Ionomeric cement; Bone cements; Mastoid, surgery

Introduction

In operations for eradication of chronic middle ear disease (usually presenting as cholesteatoma), the preservation of the posterior canal wall presents a challenge to the otological surgeon (Jansen, 1985; Plester *et al.*, 1989; Tos, 1995). The transient removal of bone segments in osteoplastic epitympanotomies (Wullstein and Wullstein, 1986) or the temporary dissection of the posterior canal wall (Feldmann, 1977) allows restoration of a near-normal anatomy.

However, due to the large extent of bone destruction usually present, reconstruction of the auditory canal wall with other tissues or materials is required. Autogenous tissue has proved to be of value (Helms, 1996), as opposed to allogenic materials which by and large have fallen into disfavour because the risk of infection transmission cannot be reliably excluded (Geyer, 1992b). Tos (1995) published an exhaustive survey of current reconstructive techniques using autogenous, allogenic and alloplastic materials. Included in the small group of alloplasts are materials such as Plastipore (Johns, 1981; Shea *et al.*, 1984), glass ceramics (Reck, 1985; Geyer, 1992b), hydroxyapatite (Grote and Lutgert, 1989; Lenis, 1990; Black, 1991) and ionomeric cement (Geyer and Helms, 1990; Geyer and Helms, 1993). The author in places critically reviews their suitability for rebuilding the meatal wall in patients with air-containing mastoid cavities (Tos, 1995).

A preliminary report of the results obtained after reconstruction of the posterior meatal wall, with follow-up ranging up to 4.5 years, has been presented before (Geyer and Helms, 1990). With patient follow-up now extending over more than seven years, the present progress report should contribute to the evaluation of the performance of the bone substitute (Ionocem®, a product of Ionos GmbH and Co. KG, Seefeld/Germany) in canal wall reconstruction.

Material and methods

Characteristics of the material

Glass ionomeric cements are hybrid bone substitutes which were developed in 1969 by Alan Wilson in the 'Laboratory of the Government Chemist', London, and found a place as a filler for

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dental applications (Wilson and McLean, 1988). Ionomeric cement has been specifically adapted for application as a bone replacement material. The reaction between calcium-aluminium-fluorosilicate, a basic glass, and polymaleic acid is minimally exothermic (Ionos, 1995). As the neutralization reaction proceeds, the initially low pH (1.6 as measured in the cement) increases within five minutes, attaining values above 4 (Ionos, 1995). Encapsulation of the glass particles by the polymaleinate is exceedingly stable, resulting in a composite which hardens after approximately 15 minutes (Lübben *et al.*, 1996) and can be shaped at will, like a ceramic material, using commercial diamond burrs with constant water irrigation. On hardening, intimate hydrogen bonding of the cement to the adjacent hard tissue (e.g. bone) and metals is achieved. The continuous bonding zone between the cement and bone is virtually impermeable to water (Geyer *et al.*, 1994; Borrmann, 1996). When applying freshly mixed cement onto a layer of previously hardened material, the bond developing at the site of contact equals the strength of a specimen fabricated in a single process (Ionos, 1995). As a cement blank can be manipulated without fear of producing chipping, it is a candidate material for varied applications, for example as ossicle replacement (Geyer and Helms, 1997).

Ethics committee

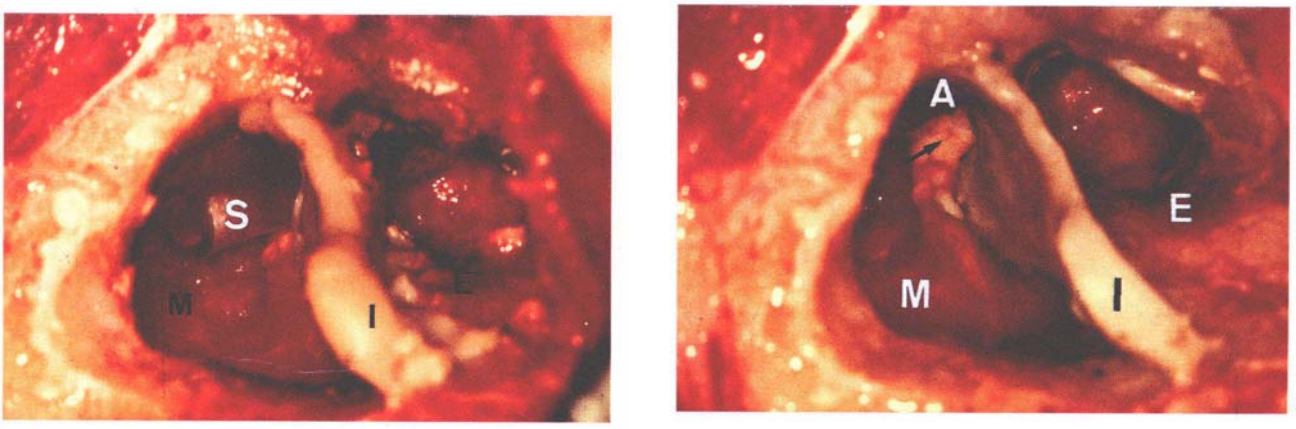
Based on the promising results obtained in dental practice and extensive animal studies (Jonck *et al.*, 1989a, 1989b; Geyer, 1992a; Wiedenmann, 1992; Städtgen, 1994; Rager, 1996), the Ethics Committee of the University of Würzburg approved the clinical application of the bone substitute in head and neck surgery.

Selection of surgical procedure

Even when a thorough pre-operative diagnosis is available, problems may frequently arise intra-operatively when the surgeon, depending on the extent of the pathological process and the patient's middle ear status (Bellucci Classification (Bellucci, 1973)), needs to make an immediate decision about the most promising reconstructive technique. In such instances it must be appraised whether after otological rehabilitation (mostly of ears with chronic bony suppuration) preference should be given to rebuilding the meatal wall or to obliteration of the mastoid cavity, or whether a small cavity should be retained for spontaneous epithelialization to occur (Helms, 1996).

Material-specific technique for reconstruction

The operative principles that govern the restoration of the posterior canal wall with ionomeric cement have been described elsewhere (Geyer and Helms, 1990; Geyer, 1992a; Geyer and Helms, 1993). A disc of cement is inserted, while still viscous, between the meatal floor and the roof to serve as canal wall replacement. A silicone tube is placed transiently to form the antral cavity (Figure 1a). Using a diamond-plated burr with continuous irrigation, the fully matured material is modelled in such a way as to restore the approximate anatomy of the external auditory meatus (Figure 1b). In conclusion, a large pedicled soft tissue (Palva) flap is rotated to line the meatal surface of the cement (Geyer and Helms, 1993). The flap is generously proportioned in order to preclude any gap formation in the soft tissue covering, thus allowing for the physiological shrinkage that tends to occur in the thin epithelial lining of mastoid cavities over alloplastic materials. It is also possible to overlay the Palva flap with additional epithelium. Tympanic membrane grafting (e.g. with perichondrium) and ossicular reconstruction (e.g. with Ionos® ossicle) are carried out along the principles described by Helms and Geyer (Geyer and Helms, 1996; Helms, 1996).



(a) (b)

FIG. 1

Reconstruction of the posterior meatal wall (right ear) with ionomeric cement. M: mastoid, E: external meatus.
a. Cement disc (I) placed between roof and floor of meatus prior to hardening, silicone tube (S) ensuring antral patency.
b. Patent aditus ad antrum (A), bone paté (arrow) over horizontal semicircular canal (closure of fistula), trimmed ionomeric cement (I).

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Patients

Pre-operative period

Over a four-year period, surgery for rebuilding the posterior canal wall was performed in 74 patients utilizing freshly mixed ionomeric cement. Fourteen patients underwent one-third reconstruction, 22 patients had two-thirds reconstruction, and 38 underwent total reconstruction. The patients comprised 35 women and 39 men, with average ages around 41 years. Initially, juveniles under age 18 were not operated on with Ionocem®. Previous surgery had been performed at least once in 27 cases. Twenty-one patients presented with radical mastoid cavities which were difficult to visualize but showed no irritational response at the time of operation. In all the ears there was no trace of acute inflammation and the drums were air-containing. Cholesteatoma had developed in 51 cases, and partially adhesive processes with a crescent-shaped air space over the tympanic side of the tubal ostium were seen in 15 patients.

Post-operative period

Packings (silicone strips, tetracycline-impregnated gelatin sponge) were removed from the external meatus at three weeks post-operatively. The auditory canal was cleansed and disinfected (using, for instance Castellani's solution). Audiograms were obtained and the external auditory canal and the drum were examined microscopically to ensure absence of any defects.

The patient could be followed up to seven years with one year as the shortest, and seven years as the longest period of follow-up. The average post-operative follow-up was 3.3 years.

Results (Table I)

Meatal walls reconstructed with cement

Soft tissue cover

In 47 of the 74 patients the canal walls were covered completely by soft tissue after three weeks, with granulation tissue present in 17 cases. After six months, complete epithelization with only minimal irritation had occurred in 49 patients, and inflammation with formation of granulation tissue was encountered in 19 cases. Incomplete epithelialization over the alloplastic canal walls was seen after three weeks in 12 cases. Epithelial deficits were most frequently encountered over large cement surfaces (patients with total reconstruction), with predominant location at the transition from the implant to drum and at the free tip of the Palva flap. After six months, epithelial deficits were demonstrable in 17 patients. In three cases, there was spontaneous closure of the cutaneous defects (measuring approx. 2×2 mm).

Tympanic membrane

Notwithstanding the stabilizing effect of the perichondrial graft, granulation tissue was found to have developed in 10 patients near the medial rim of the rebuilt canal at the transition to the vibrating portion of the drum. This was paralleled by progressive drum retraction with subsequent tissue fracture near the cement border. In four of the patients, squamous epithelium (recurrent cholesteatoma) had grown into the defective site.

Revision surgery

Revisions were performed between three and 48 months following surgery in a total of 23 ears. The procedures included 16 total canal wall reconstructions (out of 38), six two-thirds reconstruction (out of 22), and one case of one-third reconstruction (out of 14). Deficits in epithelialization and persistent inflammation were the most frequent findings (in 17 patients). The surgical treatment adopted in these cases involved removal of the auditory canal walls and creation of a radical mastoid cavity which in five of the patients was obliterated with Ionogran®. At revision it was seen that all the implants had become firmly fixed into position; overgrowth of the cement by a delicate osteoid layer was also observed occasionally (Figure 2). In six patients, soft tissue

TABLE I

RECONSTRUCTION OF POSTERIOR MEATAL WALL WITH IONOMERIC CEMENT (N = 74)

	3/3-reconstruction (n = 38)		2/3-reconstruction (n = 22)		1/3-reconstruction (n = 14)	
Middle ear	3 weeks postop.		3 weeks postop.		3 weeks postop.	
complete ventilation	23		18		14	
partial ventilation	15		4		0	
External auditory canal						
	3 weeks (postop.)	6 months (postop.)	3 weeks (postop.)	6 months (postop.)	3 weeks (postop.)	6 months (postop.)
no irritation	19	22	18	15	10	12
inflammation	10	12	3	5	4	2
unprotected cement	9	11	3	5	0	1
Canal skin						
spontaneous closure	—		2		1	
operative closure	4 (3–10 months postop.)		1 (36 months postop.)		1 (3 months postop.)	
Removal of cement						
4 months	12		5		0	
48 months postop.						

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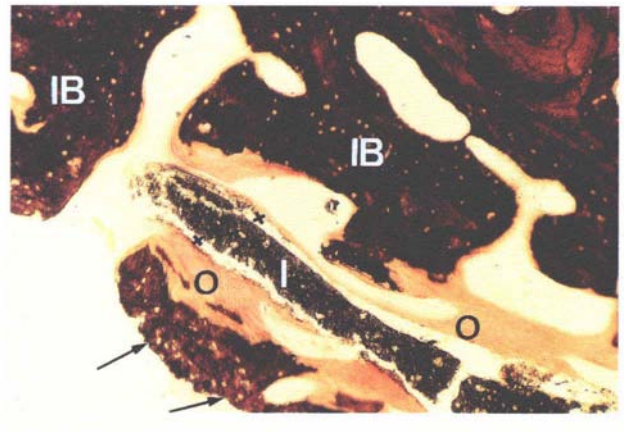


FIG. 2

Planum mastoideum biopsy obtained from a patient at 6.5 months post-operatively. A cuff of bone (arrows) is seen to migrate over the ionomeric cement (I) with no interposition of a fibrous tissue layer. IB: bony implant bed, O: osteoid, x: bone gap produced during processing.

lesions could be repaired by placing cartilage in an underlay fashion under the epithelial defect (Figure 3).

In one patient, a musician, the meatal wall had been reconstructed with ionomeric cement. Complete breakdown of a Ceravital TORP prosthesis (implanted prior to the introduction of the Ionos partial and total prostheses) had necessitated revision surgery 4.5 years later (Figure 4a). At revision it was seen that the entire mastoid was lined with normal middle ear mucosa and the cement surface (approx. 2 × 2 cm) was covered by tenuous, firmly fixed mucosa. There was no evidence suggesting either implant resorption or dislocation. The sound conduction system was reconstructed with a Ionos total prosthesis.

Discussion

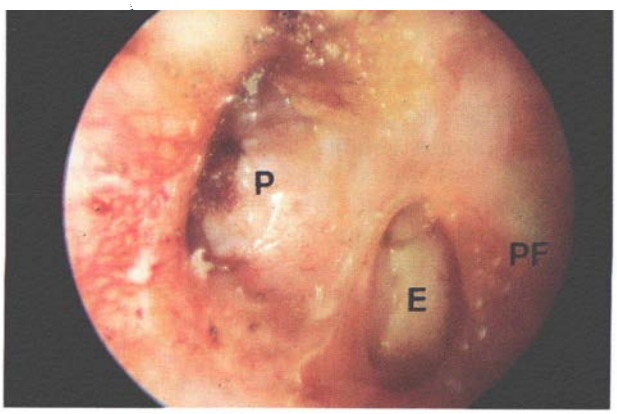
Situations requiring the reconstruction of the posterior auditory canal wall included, for example, large mastoid cavities which were difficult to inspect, vertigo in patients with a wide external meatus and inadequate coverage of the labyrinth immediately subjacent to the thin cavity lining. Apart from the basic need for otological rehabilitation, the decision to restore the normal anatomy of the external auditory canal was also prompted by the patients' wish to be able to swim or even dive without the constant hazard of developing annoying, intractable ear infections. In addition, it was considered that after eliminating the radical mastoid cavity, improved hearing should result (Hartwein, 1988).

Ionomeric cement/bone bonding

In view of the stable, continuous cement-bone bond that develops on hardening, the bone substitute is the material of choice for rebuilding the posterior canal wall (Geyer and Helms, 1990; Geyer, 1992a; Geyer and Helms, 1993). Materials such as Plastipore (Johns, 1981; Shea *et al.*, 1984), glass ceramics (Reck, 1985) and hydroxyapatite ceramics (Grote, 1990; Lenis, 1990; Black, 1991) require individual trimming to size and forcing the material into position between the floor and the roof of the external meatus (Filipo and Barbara, 1988; Tos, 1995). Bone was found to grow into the hydroxyapatite ceramic, followed after some years by its total absorption (Zöllner *et al.*, 1983; Grote and Lutgert, 1989; Grote, 1996). There have been reports that handling of bioactive glass ceramics in particular is very time-consuming (Reck, 1985; Filipo and Barbara, 1988). Residual 1 mm gaps between the glass ceramic and bone allowed the ingrowth of squamous epithelium with subsequent development of cholesteatoma (Reck *et al.*, 1987).

Epithelialization of the posterior meatal wall

In the 49 patients in whom epithelialization of the ionomeric cement implant was complete within six months, the soft-tissue graft usually maintained its stability over the years (Table I). In three cases, a meatal cutaneous defect of approx. 2 × 2 mm closed spontaneously over the cement with the ears



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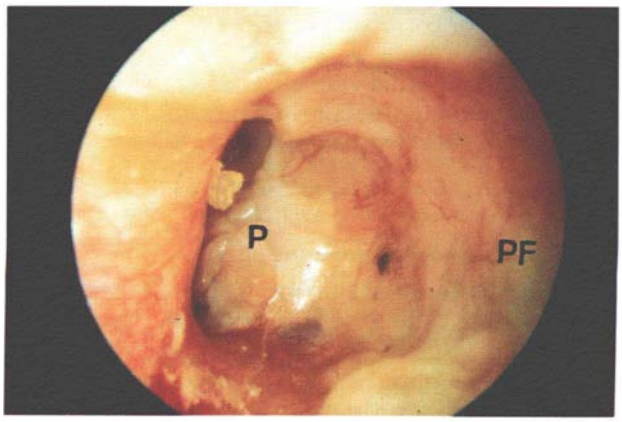

(b)

FIG. 3

Posterior meatal wall (left ear) rebuilt with ionomeric cement. P: tympanic membrane cover, PF: Palva flap.
a. Epithelial defect (E) over the cement (at 3 months post-operatively).
b. Perichondrium-closed epithelial defect over cemented meatal wall (at 4.5 years post-operatively).

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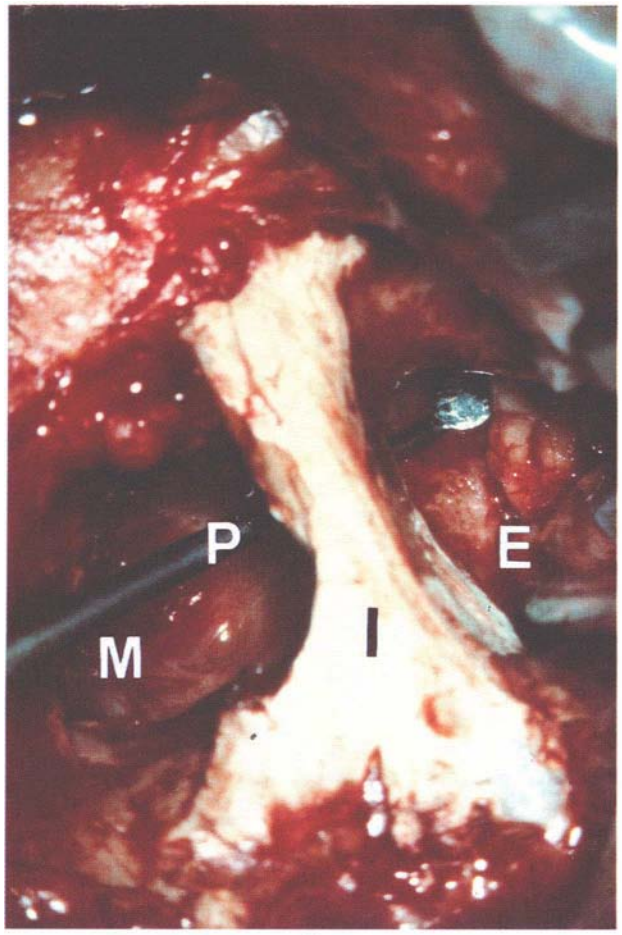

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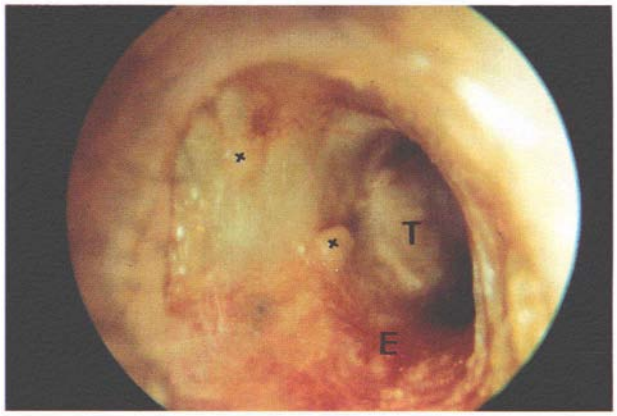

(b)

FIG. 4

Posterior meatal wall (right ear) rebuilt with ionomeric cement.

a. I: meatal wall (at 4.5 years post-operatively), M: mastoid bone fully lined by mucosa, E: external meatus. Probe (P) in patent antrum.

b. E: fully epithelialized external meatus at 1.9 years after surgery for hearing improvement (Fig. 4a). Also visible are cartilage chips (x) placed on ionomeric cement as soft-tissue support, T: tympanic membrane cover.

showing no trace of any irritation. In a few cases, Grote *et al.* (Grote and Lutgert, 1989) also observed spontaneous epithelialization of minor defects over hydroxyapatite. In the revisions performed over a period of maximally 48 months following implantation of Ionocem®, epithelial deficits had developed early. As these patients quite frequently did not show any signs of infection in the external auditory canal and also elected not to undergo further surgery, no revisions were done. Overall, the meatal epithelium overlying the ionomeric cement displayed gaps calling for correction in 31 per cent of the cases. In contrast, Grote *et al.* (Grote and Lutgert, 1989; Grote, 1990) reported epithelial defects which had to be revised in no more than 10 per cent of the meatal walls rebuilt with hydroxyapatite.

Tympanic membrane covering

Medial displacement of the tympanic membrane was associated in 20 cases with the growth of granulation tissue at the transition between implant and drum. The observation that the stable perichondrium utilized for drum reconstruction tends to become atrophic has also been reported by Black, 1991, who described atrophy at the medial implant edge above hydroxyapatite. In our patients, ingrowth of squamous epithelium into the defect had occurred in four cases.

Revision surgery

Epithelialization

In the presence of non-infected auditory canals, six of 23 epithelialization defects could be permanently closed by placement of cartilage underlays (Figure 3). The impaired transport of cerumen to the external auditory canal due to the epithelial interstices could thus be remedied. In the remaining 17 patients the canal wall had to be removed because of persistent inflammation, fracture at the drum margin, epithelial deficits.

Implant adherence

In the above situations, attachment of Ionocem® to the bone was found to be stable and continuous. Occasionally a delicate layer of osteoid had grown over the cement (Figure 2). The revision procedure included removal of the meatal walls with subsequent creation of a radical mastoid cavity, followed – when indicated – by obliteration with Ionogran® and a rotated Palva flap. In one patient in whom revision surgery had to be performed at 4.5 years post-operatively due to an audiological problem, it was seen that the implant had maintained its former stability and position with no signs of discontinuities (Figure 4a). Grote (Grote, 1996) reported complete replacement of hydroxyapatite with bony tissue at six years post-implantation.

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Conclusion

Restoration of the normal anatomy of the posterior meatal wall by means of the biocompatible and biostable ionomeric cement (Jonck *et al.*, 1989a, 1989b; Geyer and Helms, 1990; Geyer, 1992a; Geyer and Helms, 1993) is an elegant operative technique which in the hands of skilled surgeons can be performed with ease.

The result is critically dependent on two criteria:

(1) The requirement for sufficient meatal soft-tissue coverage using, for example, a Palva flap.

(2) The need for constant and reliable middle-ear ventilation because in poorly aerated middle ears an adhesive process or retraction pockets will inevitably develop in the tympanic membrane cover.

Following surgery, the external meatus should ideally be wide and completely epithelialized with self-cleansing properties (Figure 4b). In well aerated middle ears and epithelialized auditory canals, the ear does not need special attention. Together with normal cerumen production, a self-cleansing meatal function will be obtained with time.

In the majority of cases the underlying disease process is associated with a dysfunction of middle-ear ventilation. Irrespective of the material implanted, the failure rate in such cases is high and has necessitated revisions in nearly one-third of the patients (31 per cent), even though the clinical histories and findings, together with a highly refined surgical technique, would appear to have warranted a favourable outcome after reconstructing the posterior canal wall with Ionocem®. However, stable and rewarding operative results are attainable in individual cases (Figure 4). In patients with stable middle-ear ventilation, the preferred treatment is to rebuild the posterior meatal wall with autogenous materials such as cartilage (Helms, 1996) or to utilize obliterating techniques with cartilage or granular alloplasts (Ionogran®) (Geyer and Helms, 1990; Geyer, 1992a; Geyer and Helms, 1993; Tos, 1995; Baier *et al.*, 1997).

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