The Journal of Laryngology & Otology (2008), ***122***, *682–686.*

doi:10.1017/S0022215108002545

Main Article

Cartilage 'shoe': a new technique for stabilisation of titanium total ossicular replacement prosthesis at centre of stapes footplate

D Beutner, J C Luers, K B Huttenbrink

Abstract

Objectives: After tympanoplasty using a total ossicular replacement prosthesis, many unsatisfactory hearing results are due to dislocation of the prosthesis.

Material and methods: We developed a cartilage guide for stabilising the total ossicular replacement prosthesis in the oval window niche. An oval-shaped piece of cartilage measuring 2.5 × 3.5 mm with a central hole was precisely punched out of a thin cartilage plate. The cartilage was placed in the oval niche, and its hole centred the prosthesis on the stapes footplate.

Results: Hearing results in 52 patients confirmed acoustically the effectiveness of this method of total ossicular replacement prosthesis stabilisation on the stapes footplate. Subsequent 'second-look' surgery revealed stable ingrowth of the cartilage 'shoe' into the oval niche.

Conclusion: Such a cartilage shoe might address one of the causes of unsatisfactory hearing following ossicular chain reconstruction with a total ossicular replacement prosthesis.

Key words: Tympanoplasty; Cartilage; Otologic Surgical Procedures; Prostheses and Implants

Introduction

In order to obtain a successful hearing result after reconstruction of a middle-ear defect, one must provide both an intact, vibrating tympanic membrane and a ventilated middle ear, in order to achieve reliable conduction of sound energy. The defect in the ossicular chain is reconstructed with a prosthesis. Recently, an increasing number of industrially produced, alloplastic implants have become available. Such implants must fulfil two requirements: the material must be biocompatible (i.e. it must be accepted by the body tissues), and the prosthesis must be anchored to the remnants of the ossicular chain. It is essential that the prosthesis is attached in a firm and stable manner. A loose connection not only results in inefficient energy transfer but also creates a risk of dislocation. This is associated with a significant conductive hearing loss, up to the so-called transmission block of 50–60 dB. Furthermore, scar formation, haematoma or displacement, caused by variations in ambient static pressure, constitute risk factors for post-operative dislocation of a successfully surgically implanted prosthesis.[1] Apart from biological reasons, prosthesis displacement is the most common cause of unsatisfactory hearing after such surgery.[2–4]

In order to more successfully manage cases of type III tympanoplasty with a preserved stapedial arch, we developed a self-retaining, lightweight, titanium prosthesis, fastened onto the stapes head with a clip mechanism.[5] However, if the stapes suprastructure is missing, stable coupling of the prosthesis to the footplate is more complicated. Total ossicular replacement prostheses (TORPs), commonly used for such large columella type III tympanoplasty procedures, only 'adhere' to the footplate by water adhesion forces. Clinical observations indicate that only rarely does a firm union develop between a TORP and the stapes footplate. Hence, inadequate coupling at the TORP–footplate interface may be an important cause of a persistent post-operative air–bone gap, and hence poor acoustic results, compared with partial ossicular replacement prostheses.[2]

Suggestions on how to achieve a more stable, firm coupling at the TORP–footplate joint have been proposed. Fisch and May[6] have recommended the use of a small spike at the tip of the prosthesis shaft, which fits into a perforation of the footplate. However, this mechanically convincing idea is considered by many otosurgeons to pose a potential risk for chronic otitis media, due to the opening of the inner ear. Another proposal, involving specially designed silicone sheets, could not guarantee permanent placement of the TORP.

From the Department of Otorhinolaryngology, Head and Neck Surgery, University of Cologne, Germany.
Accepted for publication: 3 March 2008. First published online 19 May 2008.

In order to overcome these problems, and following successful use of cartilage in tympanoplasty,[7,8] we designed a cartilage 'shoe' which fitted into the oval window niche. A central perforation guided the prosthesis onto the footplate centre and prevented dislocation. To facilitate such surgery, we designed a cartilage punch. Experimental testing in temporal bones, using laser Doppler vibrometry, demonstrated reliable sound transfer through this central cartilage perforation onto the footplate.[9] Simulated massive scar fixation of the cartilage shoe, by application of histoacryl glue, resulted in a reduction of only 5 dB of sound conduction. These promising temporal bone results were taken as a basis for clinical application.

This paper describes use of the cartilage punch and reports our clinical experience with the cartilage shoe in 52 patients undergoing TORP tympanoplasty.

Materials and methods

In cooperation with the Heinz Kurz Company (Dusslingen, Germany), we developed a cartilage punch (Figure 1a) to enable production of a standardised cartilage shoe. This punch consisted of an oval outline punch (2.5×3.5 mm) and a centre hole punch (0.8 mm), connected with a spring. The central hole punch telescoped into the outline punch with the help of the spring attachment. Figure 1b shows the cartilage shoe with its central hole for incorporation of the prosthesis shaft of the 'Aerial' type titanium prosthesis (Heinz Kurz). In cases where remnants of the stapes crurae persist, the cartilage shoe can be easily trimmed at both poles (Figure 1c).

This retrospective study examined all patients who had undergone a TORP tympanoplasty using the cartilage shoe technique in the department of otolaryngology, head and neck surgery, University of Cologne (a tertiary referral centre), over a two-year period (May 2005 to May 2007). Patients were identified via a search of the operating theatre logbooks. Data collected from patients' notes included the following variables: gender, age, surgical technique, procedure and audiometric outcome. Post-operative pure tone audiograms were obtained three weeks after surgery following removal of the surgical dressing. In each case, post-operative air–bone gaps were calculated using post-operative air conduction and post-operative bone conduction thresholds at the frequencies 500, 1000, 2000, 3000 and 4000 Hz. The average five-frequency (i.e. 500, 1000, 2000, 3000 and 4000 Hz) air–bone gap was also calculated.

Statistical analysis was performed using the Statistical Package for the Social Sciences version 10.0.7 for Windows software package (SPSS Inc, Chicago, Illinois, USA). The Wilcoxon test for dependent groups was used to compare all parameters before and after treatment. All tests were two-sided, and p values of less than 0.001 were considered as significant.

Results and analysis

The cohort consisted of 52 patients (31 male and 21 female), with a median age of 40.7 years (range six to 66 years). Patient and surgical procedure data are shown in Table I, which also shows the relative diagnostic contribution of cholesteatoma (50 per cent) and chronic otitis media (50 per cent). Revision cases predominated (67.3 per cent), and there were similar numbers of canal wall down ($n = 27$) and canal wall up ($n = 25$) procedures.

The optimal cartilage thickness for creation of the shoe was found to be 200–300 μm, harvested from the concha or tragus.[9] Placement of the cartilage shoe into the oval window niche was straightforward in every case. In five cases, persistent remnants of the stapes suprastructure meant that trimming of the cartilage shoe poles was required (Figure 1c). The resultant rectangular-shaped cartilage shoe fitted tightly between the stapedial crura, guaranteeing a stable and reliable coupling. Figure 2a shows a typical example after TORP insertion. The TORP, with its stand-alone prosthesis head, could be used as a girder, supporting the tympanic membrane reconstruction with cartilage or fascia, especially in canal wall down mastoidectomy, similar to the central pole in a tent. Six months later, 'second look' surgery ($n = 3$) in cholesteatoma cases always revealed stable ingrowth of the cartilage shoe into the oval window niche, as shown in Figure 2b.

Patients' audiometric results are shown in Figure 3. Bone conduction thresholds remained stable. At the time of post-operative dressing removal, the air–bone gap was reduced to 21 dB (down by 13 dB from a pre-operative average of 34 dB) (Table II). Patients' post-operative air–bone gaps significantly differed from their pre-operative results (Wilcoxon test; $p < 0.001$ for each frequency). Testing at all frequencies showed an improvement in the air–bone gap (Table II). Interestingly, the auditory results obtained by open and closed procedures were comparable, with air–bone gaps of 21.9 and 21.0 dB, respectively.

Discussion

In recent years, titanium has become the favourite alloplastic material for the reconstruction of a destroyed ossicular chain.[10–12] Besides its excellent biocompatibility,[13–15] this material shows definite mechanical benefits. Stable and reliable coupling between titanium prostheses and the remaining ossicular rudiments are essential in order to achieve satisfactory hearing results following ossiculoplasty.[16] Tilting and/or dislocation of the prosthesis, which prevents direct prosthesis–bone contact, are the major causes of poor post-operative audiometric results.[2–4] Especially in cases in which only the footplate remains, stable insertion of an ossicular prosthesis is a great challenge to the otosurgeon. In such cases, current clinical practice involves perioperative adjustment of the TORP on the footplate with connective tissue or cartilage.[6,17,18] However, an intra-operatively stable TORP placement potentially runs the risk of dislocation after closure of the ear. The reconstruction can fail due to a multitude of causes, e.g.: haematoma, scar tissue formation, middle-ear effusion, or atmospheric pressure changes with displacement of the reconstructed

https://doi.org/10.1017/S0022215108002545 Published online by Cambridge University Press

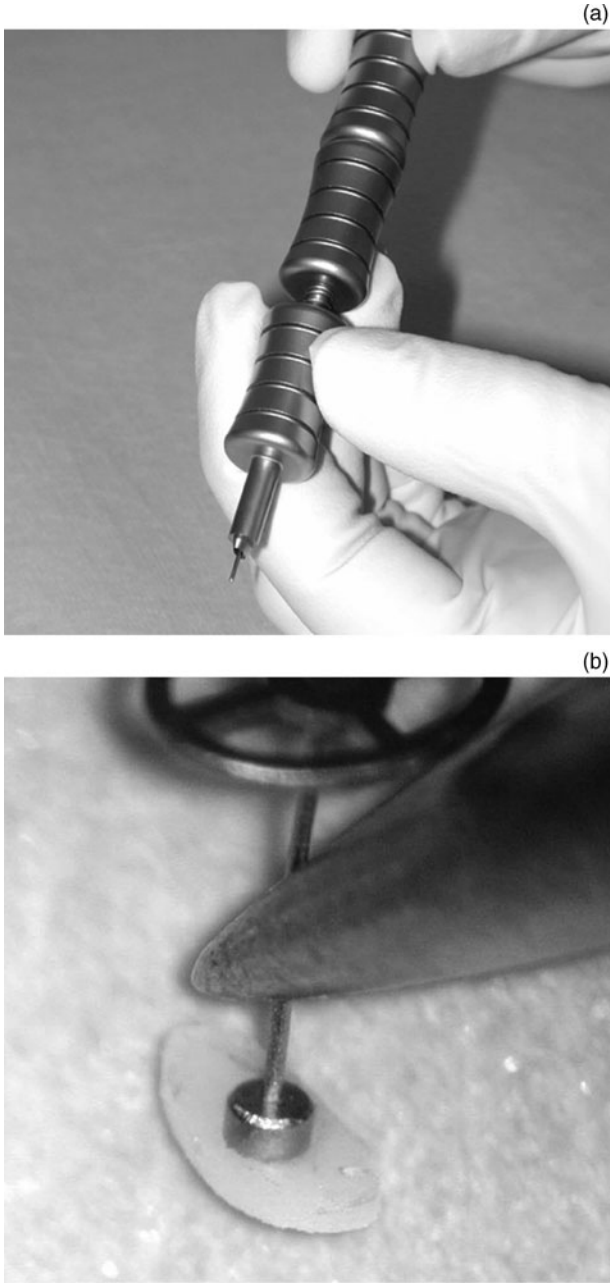

FIG. 1
(a) The cartilage punch used to produce the cartilage 'shoe', consisting of an outline punch, a centre hole punch, a spring and an ejection needle. (b) The cartilage shoe, incorporating the prosthesis foot of a titanium total ossicular replacement prosthesis. (c) The anterior and posterior poles of the cartilage shoe can be cut away in cases with persistent crura remnants.

tympanic membrane. To overcome these problems, stable fixation on the footplate is mandatory.

This paper describes the use of a cartilage shoe, which is placed in the oval niche on the footplate, as a new technique for stabilisation of a TORP. The presented short-term hearing results are promising, but long-term results with a larger sample size will need to be analysed in order to ensure the permanent acoustic quality of this reconstruction. Until now, we have not encountered a single case with a

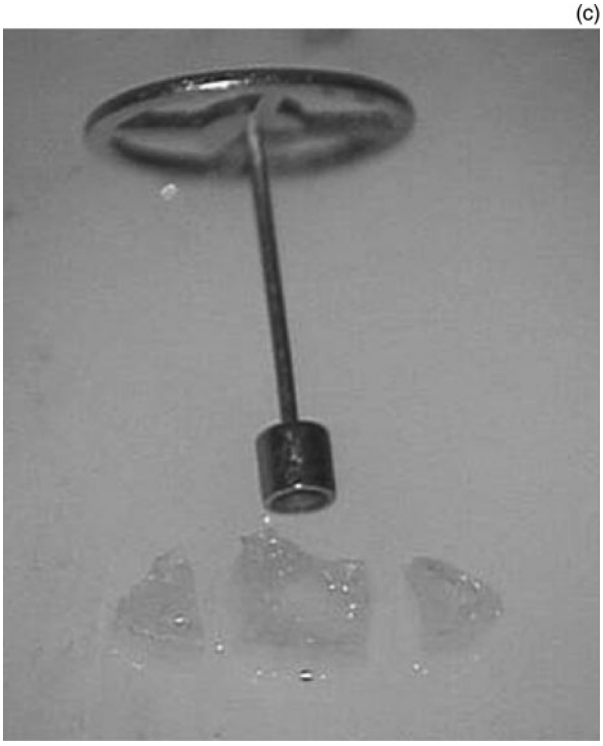

FIG. 1
Continued.

large post-operative air–bone gap (indicating complete disruption of the TORP–footplate interface). With a reduction of the air–bone gap to 21 dB (down by 13 dB), the auditory results for the cartilage shoe technique are comparable to those obtained with other prostheses.[10–12,19–25] Moreover, since we were obliged to monitor post-operative hearing at the time of dressing removal (due to unreliable follow up at later intervals), further reduction of the air–bone gap could be expected in the long term,[5] as the post-operative middle-ear effusion typically impairs middle-ear sonic transfer. However, our audiometric data are comparable with previously published results only to a limited extent, because different criteria were used. Additionally, many other factors besides the TORP itself determine the auditory results of the procedure, such as staging of ossicular reconstruction, acoustic quality of the tympanic membrane, aeration of the middle ear and tubal function. In our department, ossicular reconstruction was always performed simultaneously with surgery to eradicate disease e.g. tympanomastoidectomy. Better hearing results can be expected following staged ossiculoplasty with a stable middle ear and intact tympanic membrane.

With regard to tissue handling, it is important to note that the cartilage plate should be denuded from the adherent perichondrium prior to punching. A puncture through the stringy perichondrium often requires additional trimming. To trim the cartilage plate to a specific thickness, we use a cartilage cutter device (Heinz Kurz company, Dusslingen, Germany) which can produce cartilage plates of between 0.7 and 0.1 mm thickness. The cartilage

https://doi.org/10.1017/S0022215108002545 Published online by Cambridge University Press

TABLE I

PATIENT AND SURGICAL DATA

Parameter	*n* (%)
Gender	
Female	21 (40.4)
Male	31 (59.6)
Pathology	
Cholesteatoma	26 (50.0)
Chronic otitis media	26 (50.0)
Revision case	35 (67.3)
Procedure	
Canal wall up	25 (48.1)
Canal wall down	27 (51.9)

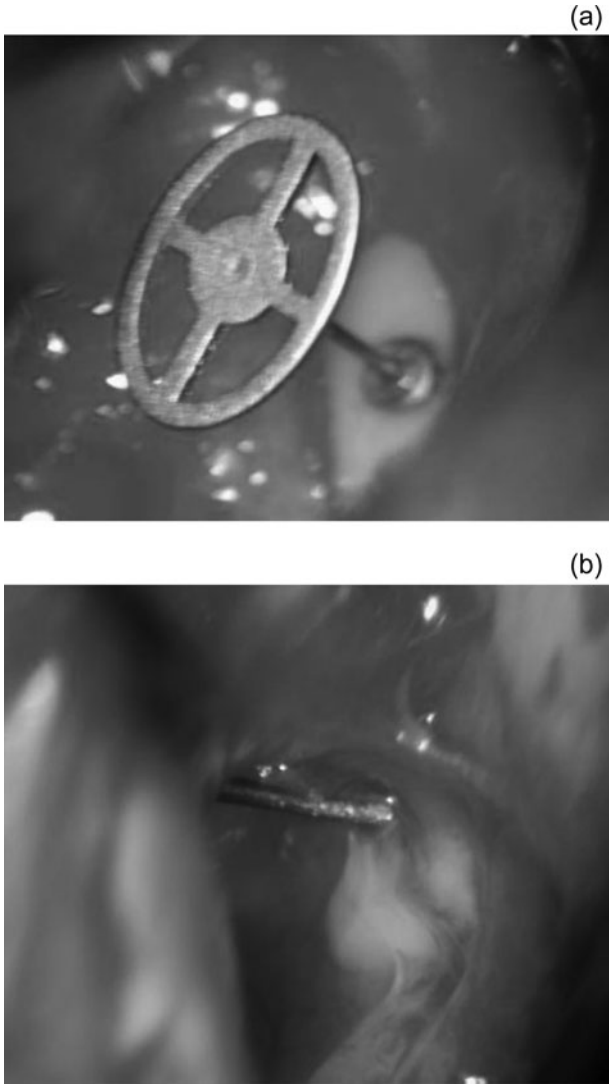

FIG. 2

(a) Intra-operative view of the cartilage 'shoe' in the oval window niche, guiding a total ossicular replacement prosthesis (TORP) onto the footplate centre. (b) View at revision surgery, showing a reliable TORP position, without pathological findings.

shoe should be punched out of the thinnest cartilage plate, preferably 0.2–0.4 mm, in order to reduce friction of the TORP in its guide hole.

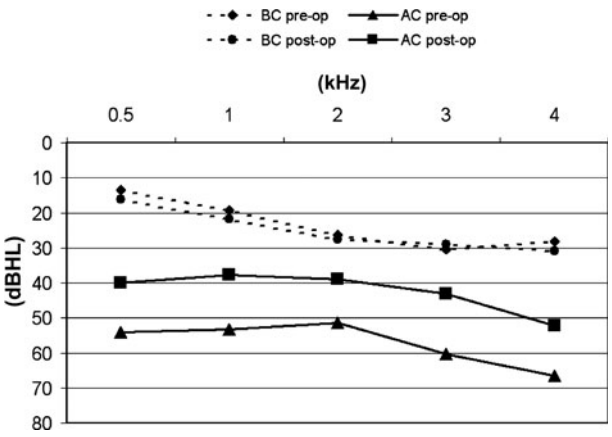

FIG. 3

Patients' pre- and post-operative audiometric results, for use of a cartilage 'shoe' in type III tympanoplasty ($n = 52$).

The surgeon should ensure that any remaining granulation tissue is completely removed from the bony surface of the niche and the footplate, in order to achieve optimal contact with the bony footplate and to obtain maximum stabilisation of the reconstruction. Remnants of cholesteatoma tissue in the oval window niche preclude obliteration by the cartilage shoe.

- **After tympanoplasty using a total ossicular replacement prosthesis (TORP), unsatisfactory hearing results are often due to dislocation of the prosthesis**
- **This paper reports a new method of TORP stabilisation, using a cartilage 'shoe' placed in the oval window niche**
- **Initial, short-term hearing results in 52 patients confirmed the quality of TORP anchoring on the stapes footplate**
- **The risk of TORP dislocation can be diminished by using such a cartilage shoe**

The marginally larger diameter of the cartilage shoe (2.5 × 3.5 mm), compared with the stapes footplate,[26] is a prerequisite for a secure and tight grip between the promontory and facial canal wall.

The cartilage shoe stabilises the TORP on the centre of the footplate surface, which is the optimal site for energy transfer.[27] Ingrowth of connective tissue into the contact zone between the TORP and the footplate, resulting in diminished transfer characteristics, must be avoided. The cartilage shoe by itself does not prevent lifting of the prosthesis, as the prosthesis base is not firmly attached to the bone of the footplate. Therefore, the prosthesis head is always covered by cartilage plates of the reconstructed tympanic membrane, which hold the prosthesis base in good contact with the footplate.

In order to achieve an even more stable attachment, we designed a TORP holder with

https://doi.org/10.1017/S0022215108002545 Published online by Cambridge University Press

TABLE II
PATIENTS' AUDIOMETRIC RESULTS*

	PTA (dB)	ABG (dB)
Pre-op	57.1	34.4
Post-op	42.5	21.5
Improvement	14.6	12.9

*For 0.5–4 kHz. PTA = pure tone average; ABG = air–bone gap; pre-op = pre-operative; post-op = post-operative

osseointegration on the stapes footplate. Animal experiments and finite element model simulation[28] have been performed, but this technique requires definitive placement of the TORP at a second stage. However, a major drawback of a TORP durably fixed to the stapes footplate might be a potential risk of cochlear damage. As we know from case studies, iatrogenic extraction of the stapes can occur by accident,[29] although native osseous integration of a titanium prosthesis on the stapes footplate has not been demonstrated with convincing evidence. Therefore, as long as osseointegration is not an issue in current clinical practice, we would favour the cartilage shoe technique in columella type tympanoplasty. Future studies of long-term audiometric results will need to exclude non-mechanical factors, such as persisting aeration problems, in order to specify the long-term acoustic quality of the reconstruction *in vivo*.

Acknowledgements

Professor K-B Huttenbrink is one of the 2008 *Journal of Laryngology & Otology* Visiting Professors.

References

1 Huttenbrink KB. Biomechanical aspects of middle ear reconstruction. In: Jahnke K, ed. *Current Topics in Otolaryngology - Head and Neck Surgery. Middle Ear Surgery: Recent Advances and Future Directions.* Stuttgart: Thieme, 2004;23–51
2 Huttenbrink KB. Surgical treatment of chronic otitis media. III: Middle ear reconstruction [in German]. *HNO* 1994;**42**:701–18
3 Katzke D, Steinbach E, Schodermaier C. The evaluation of allogenous incus transplants removed during revision tympanoplasty [in German]. *Arch Otorhinolaryngol* 1982;**235**: 525–8
4 Smyth GDL. TORPS: how have they fared after five years? *J Laryngol Otol* 1983;**97**:991–3
5 Huttenbrink KB, Zahnert T, Wustenberg EG, Hofmann G. Titanium clip prosthesis. *Otol Neurotol* 2004;**25**:436–42
6 Fisch U, May J. *Tympanoplasty, Mastoidectomy and Stapes Surgery.* Stuttgart, New York: Thieme, 1994
7 Murbe D, Zahnert T, Bornitz M, Huttenbrink KB. Acoustic properties of different cartilage reconstruction techniques of the tympanic membrane. *Laryngoscope* 2002; **112**:1769–76
8 Zahnert T, Huttenbrink KB, Murbe D, Bornitz M. Experimental investigations of the use of cartilage in tympanic membrane reconstruction. *Am J Otol* 2000;**21**:322–8
9 Huttenbrink KB, Zahnert T, Beutner D, Hofmann G. The cartilage guide: a solution for anchoring a columella-prosthesis on footplate [in German]. *Laryngorhinootologie* 2004;**83**:450–6
10 Dalchow CV, Grun D, Stupp HF. Reconstruction of the ossicular chain with titanium implants. *Otolaryngol Head Neck Surg* 2001;**125**:628–30
11 Ho SY, Battista RA, Wiet RJ. Early results with titanium ossicular implants. *Otol Neurotol* 2003;**24**:149–52
12 Krueger WW, Feghali JG, Shelton C, Green JD, Beatty CW, Wilson DF *et al*. Preliminary ossiculoplasty results using the Kurz titanium prostheses. *Otol Neurotol* 2002;**23**: 836–9
13 McComb H. Osseointegrated titanium implants for the attachment of facial prostheses. *Ann Plast Surg* 1993;**31**: 225–32
14 Schwager K. Titanium as an ossicular replacement material: results after 336 days of implantation in the rabbit. *Am J Otol* 1998;**19**:569–73
15 Schwager K. Titanium as a biomaterial for ossicular replacement: results after implantation in the middle ear of the rabbit. *Eur Arch Otorhinolaryngol* 1998;**255**:396–401
16 Eiber A, Freitag HG, Schimanski G, Zenner HP. On the coupling of prostheses to the middle ear structure and its influence on sound transfer. In: Rosowski JJ, Merchant SN, eds. *Second International Symposium on Middle-Ear Mechanics in Research and Otosurgery*, Kugler Publications: The Hague, The Netherlands, 2000;297–308
17 Jahnke K. Progress in microsurgery of the middle ear [in German]. *HNO* 1987;**35**:1–13
18 Plester D, Hildmann H, Seinbach E. *Atlas of Ear Surgery* [in German]. The Netherlands: Kohlhammer Verlag, 1989
19 Berenholz LP, Rizer FM, Burkey JM, Schuring AG, Lippy WH. Ossiculoplasty in canal wall down mastoidectomy. *Otolaryngol Head Neck Surg* 2000;**123**:30–3
20 Brackmann DE, Sheehy JL, Luxford WM. TORPs and PORPs in tympanoplasty: a review of 1042 operations. *Otolaryngol Head Neck Surg* 1984;**92**:32–7
21 Farrior JB, Nichols SW. Long-term results using ossicular grafts. *Am J Otol* 1996;**17**:386–92
22 Goldenberg RA, Driver M. Long-term results with hydroxylapatite middle ear implants. *Otolaryngol Head Neck Surg* 2000;**122**:635–42
23 House JW, Teufert KB. Extrusion rates and hearing results in ossicular reconstruction. *Otolaryngol Head Neck Surg* 2001;**125**:135–41
24 Quaranta N, Fernandez-Vega FS, Piazza F, Zini C. Closed tympanoplasty in cholesteatoma surgery: long-term (10 years) hearing results using cartilage ossiculoplasty. *Eur Arch Otorhinolaryngol* 2001;**258**:20–4
25 Zenner HP, Stegmaier A, Lehner R, Baumann I, Zimmermann R. Open Tubingen titanium prostheses for ossiculoplasty: a prospective clinical trial. *Otol Neurotol* 2001;**22**: 582–9
26 Anson JB, Donaldson JA. *Surgical Anatomy of the Temporal Bone and Ear*, 2nd edn. Philadelphia, USA: WB Saunders, 1973
27 Asai M, Huber AM, Goode RL. Analysis of the best site on the stapes footplate for ossicular chain reconstruction. *Acta Otolaryngol* 1999;**119**:356–61
28 Neudert M, Berner M, Bornitz M, Beleites T, Ney M, Zahnert T. Osseointegration of prostheses on the stapes footplate: evaluation of the biomechanical feasibility by using a finite element model. *J Assoc Res Otolaryngol* 2007;**8**:411–21
29 Sudhoff H, Lindner N, Gronemeyer J, Dazert S, Hildmann H. Study of osteointegration of a titanium prosthesis to the stapes: observations on an accidentally extracted stapes. *Otol Neurotol* 2005;**26**:583–6

Address for correspondence:
Prof Karl-Bernd Huttenbrink,
Professor and Chairman,
Department of Otorhinolaryngology, Head and Neck Surgery,
University of Cologne,
Kerpener Strasse 62,
50924 Cologne, Germany.

Fax: +49 221 478 4793
E-mail: huttenbrink.k-b@uni-koeln.de

Professor K B Huttenbrink takes responsibility for the integrity of the content of the paper.
Competing interests: None declared