

The Use of Malleus Allografts in Ossiculoplasty

Jean-Philippe Vercruyse, MD; F. Erwin Offeciers, PhD; Thomas Somers, PhD; Isabelle Schatteman, MD; Paul J. Govaerts, MD

Objective: To assess the functional performance of remodeled malleus allografts in a malleus-footplate assembly in terms of hearing results and mid long-term stability. **Study Design:** A retrospective study of 60 consecutive patients who underwent a malleus allograft ossiculoplasty from 1993 until 2000. In all cases the incus and the stapedial arch were missing as the result of cholesteatoma (49), chronic otitis (5), incus necrosis resulting from stapes prosthesis (5), and congenital ossicular malformations (1). In all cases malleus allografts were remodeled to form a malleus-stapes assembly. **Results:** The audiometric results, using such an ossiculoplasty, revealed an overall median gain of 18.3 dB at 2 months, 22.3 dB at 6 months, and 25 dB 1 year postoperatively on Fletcher frequencies. An air-bone gap closure within 20 dB was achieved in 81% of all cases 1 year postoperatively. No cases of extrusion have been seen in our series. **Conclusion:** Our findings suggest that malleus allografts are capable of generating good and stable functional results as malleus-stapes assembly. **Key Words:** Malleus, allograft, homograft, ossiculoplasty.

Laryngoscope, 112:1782-1784, 2002

INTRODUCTION

In cholesteatoma and long-term ear surgery the middle ear ossicles often have to be removed because of pathological destruction. The replacement of these ossicles has always been a challenge in middle ear surgery.¹ The use of allogeneic ossicles was first introduced by House et al.² Several artificial materials have also been used over time, often with successful restoration of hearing.³⁻⁶ Despite early encouraging results with porous and ceramic prostheses, the ubiquitous implementation of these materials was hindered by high extrusion rates and the absence of convincing long-term results.⁷⁻⁹ In contrast, hydroxyapatite seems to offer promising perspectives.⁶ Long-term

results with hydroxyapatite showed air-bone gap closures within 20 dB in 68% of the cases.⁴ However, even with this material, high extrusion rates have been reported when there was contact with the tympanic membrane.¹⁰ Allogeneic ossicular bone has the obvious advantages of being "as natural as possible"¹¹ and readily available. The alleged risk of transfer of infectious diseases, such as Creutzfeldt-Jacob disease (CJD) and HIV, is not the issue of the present report, but, in brief, it can be said that transmission of CJD has been reported in 10 cases after implementation of dura mater grafts.¹² However, it has never been reported after transplantation of tympano-ossicular allografts. In addition, the incidence of CJD is extremely low (1:1000000), and stringent criteria for donor selection should exclude donors at risk for CJD. With regard to HIV, it has been shown that the current preservation techniques are safe with regard to HIV transmission.¹³ In Belgium, allogeneic tissue banks are defined and strictly regulated by legislation (Belgisch Staatsblad, June 13, 1996). Allogeneic material is routinely used by the Antwerp School of Otology and has been reported to be useful for the reconstruction of tympanic membrane and isolated ossicles.¹⁴⁻¹⁸

A specific indication is the ossicular reconstruction in case of a missing stapedial arch and incus. An allogeneic malleus can be remodeled in such way that it can be used as a malleus-footplate assembly. The present study reports on a retrospective analysis on this remodeling technique and on the results of this type of ossiculoplasty.

PATIENTS AND METHODS

A retrospective evaluation has been carried out of ossicular reconstructions by use of remodeled malleus allografts. Sixty consecutive cases were included that were surgically treated between December 1993 and December 2000. The cause of the ossicular lesion was cholesteatoma in 49 patients (81.7%), chronic otitis media in 5 patients (8.3%), incus necrosis attributable to a stapes prosthesis in 5 patients (8.3%), and congenital ossicular malformations in 1 patient (1.7%). All ossicular lesions were characterized by the absence of the stapedial crura and the absence of an intact incus. The original malleus was intact and mobile in 60% (n = 36) cases, and in 40% (n = 24) the malleus head was removed because of fixation in the attic or to improve the visualization of the attic in cholesteatoma ears. The original stapedial footplate was intact and mobile in 90% of the cases. In

From the University Department of Otolaryngology, St. Augustinus Hospital, University of Antwerp, Antwerp-Wilrijk, Belgium.

Editor's Note: This Manuscript was accepted for publication May 16, 2002.

Send Correspondence to Paul J. Govaerts, MD, MS, University Department of Otolaryngology, St. Augustinus Hospital (University of Antwerp), Oosterveldlaan 24, B-2610 Antwerp-Wilrijk, Belgium. E-mail: dr.govaerts@eargroup.net

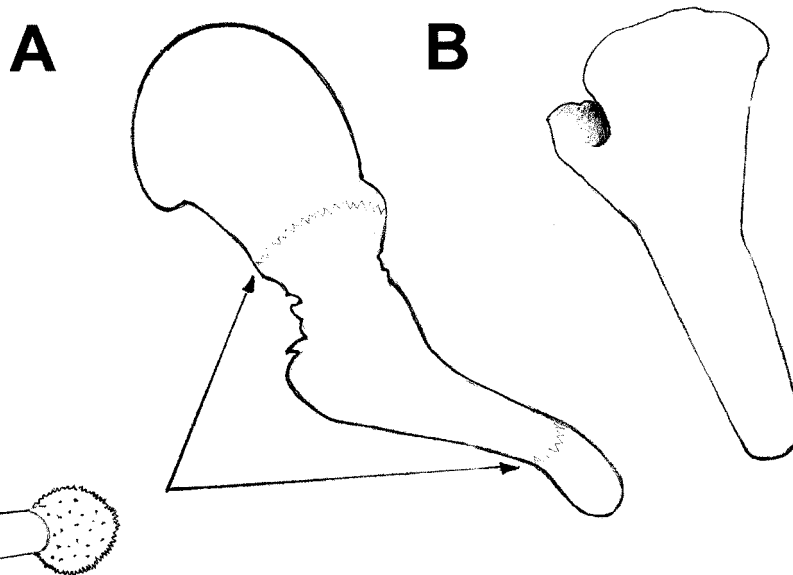


Fig. 1. The allogeneic malleus (A) is drilled in a Y-shaped structure (B). A part of the malleus head and handle of the allogeneic malleus are removed using the drill (arrows).

the remaining 10%, the original stapedial footplate had previously been replaced with a vein graft or perichondrial graft during stapes surgery for otosclerosis. During hypotensive general anesthesia, a transmeatal tympanotomy was performed. An allogeneic malleus was obtained from the tympano-ossicular tissue bank and was remodeled and inserted between the malleus (handle) and the stapes footplate or its replacement vein or perichondrium graft in the oval window. The graft was remodeled to a Y-shaped structure to fit closely in the neck of the original malleus (Figs. 1 and 2). Fibrin glue (Tissucol) was used to immobilize its contact at both ends. After putting the tympanomeatal flap

back in place, sponges with antibiotic ointment were left in place for 5 days.

Several variables were studied: gender, side, surgeon, age, indication of the operation, the ventilation of the middle ear cavity, a history of previous ear surgery, the presence or absence of an intact stapes footplate, and the preoperative and postoperative disease. Audiometry with bone and air conduction was performed preoperatively and at 2, 6, and 12 months after surgery. All audiometric measurements were performed in a sound-proof room with an audiometer calibrated according to the International Standards Organization standards. No response to air-conducted sound was coded as 120 dB, and to bone conducted sound as 80 dB. Missing values were coded as such. Five-parameter statistics were used to describe the audiometric variables.¹⁹

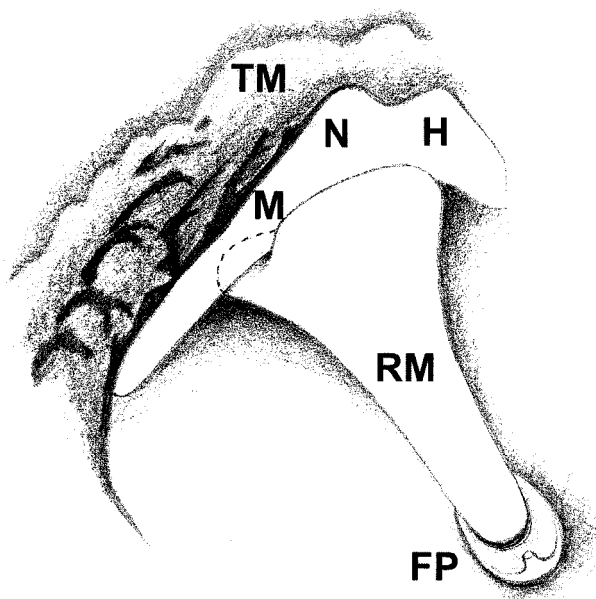


Fig. 2. The remodeled malleus (RM) is put in place between the neck of the original malleus and the stapes footplate (FP). TM, tympanic membrane; M, original malleus handle; N, original malleus neck; H, original malleus head.

RESULTS

The average age of the patients was 37.2 years (range, 5.54–70.8 y). The male-to-female ratio was 53:47, and the right-to-left-side ratio 53:47. Six patients (10%) had never undergone surgery at the same ear. Four of them showed active disease (cholesteatoma) at the time of surgery. Fifty-four patients (90%) had previously undergone either a tympanoplasty ($n = 49$) or a stapedotomy ($n = 5$). Thirteen of these cases showed active disease at the time of surgery. The remaining 41 were either planned second stages after primary cholesteatoma surgery ($n = 6$) or purely functional revisions for conductive hearing loss ($n = 35$). The preoperative ventilation state of the middle ear cavity was evaluated by the surgeon and was scored as normal or “as good as normal” in 88.3% ($n = 53$) and as poor in 11.7% ($n = 7$) of cases.

The audiometric results at 2, 6, and 12 months are presented in Figure 3. The overall median gains were 18.3 dB at 2 months, 23.3 dB at 6 months, and 25 dB at 12 months. The median gains are outlined in Figure 3. The air–bone gap closures for the Fletcher frequencies (0.5, 1, and 2 kHz) were within 20 dB in 81% of cases at 12 months after surgery.

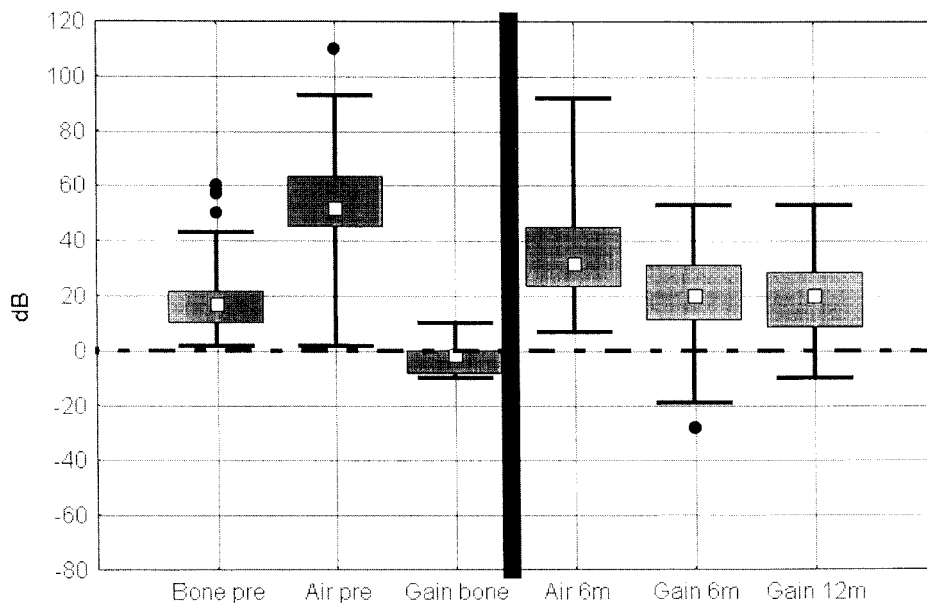


Fig. 3. Audiometric data. The preoperative bone- and air-conduction thresholds (all Fletcher frequencies) are shown (left). Hearing gain of the remodeled malleus expressed as a median gain (in decibels) of the Fletcher indices at 2, 6, and 12 months after surgery (right). Bars, minimum to maximum; large rectangles, 25% to 75%; small squares, median. Bullets are outliers.

DISCUSSION

It is known that ossiculoplasty in the absence of stapedial crura tends to yield worse results than in the presence of an intact stapes. The present study reports on the use of remodeled allogeneic malleus grafts positioned between the original malleus and the stapes footplate. It is shown that such an allograft assembly is capable of generating good and stable functional results (Fig. 3). The problems frequently encountered with artificial materials, such as extrusion, have not been seen in our series. The only failure, when using this technique, is related to the improper fit of the prosthesis resulting in bad functional gain or to adverse physiological middle ear condition such as a lack of aeration. We think that this allograft ossiculoplasty is a stable, safe, and reliable technique.

BIBLIOGRAPHY

- Austin DF. Ossicular reconstruction. *Arch Otolaryngol* 1971; 94:525-535.
- House WF, Patterson ME, Linthicum FH. Incus homografts in chronic ear surgery. *Arch Otolaryngol* 1966;84:148-153.
- Deguine C. Ossiculoplasty: evaluation and perspectives. *Acta Otorhinolaryngol Belg* 1991 45:81-86.
- Grote JJ. Reconstruction of the middle ear with hydroxylapatite implants: long-term results. *Am J Otol* 1987;8: 396-401.
- Wehrs RE. Hearing results with the incus and incus stapes prostheses. *Laryngoscope* 1991;101:555-556.
- Wehrs RE. Incus interposition and ossiculoplasty with hydroxyapatite prostheses. *Otolaryngol Clin North Am* 1994; 27:677-688.
- Sanna M, Ganoletti, Magnani M, Bacciu S, Zini C. Failures with Plastipore ossicular replacement prosthesis. *Otolaryngol Head Neck Surg* 1984;92:339-341.
- Sellari-Franchesini S, Piragine F, Brushini P, Berutini S. TORPS-PORPS: causes of failure. *Am J Otol* 1987;8: 551-552.
- Yamamoto E. Long-term observation of ceramic replacement prostheses (CORP). *Laryngoscope* 1988;98:402-404.
- Shinohara T, Gyo K, Saiki T, Yanahiga N. Ossiculoplasty using hydroxyapatite prosthesis: long-term results. *Clin Otol* 2000;25:287-292.
- McGee M, Hough JV. Ossiculoplasty. *Otolaryngol Clin North Am* 1999;32:471-488.
- Martinez-Lage J, Poza M, Sola J, et al. Accidental transmission of Creutzfeldt-Jacob disease by dural cadaveric grafts. *J Neurol Neurosurg Psychiatry* 1994;57:1091-1094.
- Janssens de Varebeke S, Gouben P, Beuselinck HK, Somers T, Offeciers FE, Govaerts PJ. Tympano-ossicular allografts and HIV transmission. *Am J Otol* 1998 19:704-708.
- Marquet J. Twelve years of experience with homograft tympanoplasty. *Otolaryngol Clin North Am* 1977;10:581.
- Schilder AGM, Govaerts PJ, Somers T, Offeciers FE. Tympano-ossicular allografts in childhood cholesteatoma. *Int J Pediatr Otolaryngol* 1997;42:31-40.
- Claes J, Van de Heyning PJ, Creten W. Functional and anatomical results of allograft tympanoplasty. *Otolaryngol Head Neck Surg* 1990:351-354.
- Janssens de Varebeke S, Govaerts PJ, Somers T, Offeciers FE. The 'two-hole' ossiculoplasty technique. *Laryngoscope* 1996;106:507-510.
- Hamans EPPM, Govaerts PJ, Somers T, Offeciers FE. Allograft tympanoplasty type I in the childhood population. *Ann Otol Rhinol Laryngol* 1996;105:871-876.
- Govaerts PJ, Somers T, Offeciers FE. Box and whisker plots for graphic presentation of audiometric results of conductive hearing loss treatment. *Otolaryngol Head Neck Surg* 1998;118:892-895.