OSSICULOPLASTY WITH J.B. CAUSSE COMPOSITE PROSTHESES

Our experience in 749 cases Robert Vincent, Benoît Gratacap and Geoffroy Vandeventer Clinique d'Otologie Jean Causse, Colombiers, France

Abstract

In ossicular pathologies, many options are available when restoration of the columellar effect is necessary. Autoplasty, heteroplasty and homoplasty have advantages and disadvantages, but considerable recent progress in the development of prostheses has changed the situation. Seven hundred and forty-nine partial i?and total prostheses (PORPs and TORPs) of composite material (Flex HA and Teflon HA), designed by Jean-Bernard Causse and developed by Microtek, have been used since January 1992, with a follow-up period ranging from six months to three years. The authors present short- and medium-term results involving all aspects of otological surgery, as well as the surgical techniques used.

Introduction

Every otologist aspires to rebuild the ossicular chain in order to restore hearing and fulfil the patient's expectations. Recent significant advances in biomaterials have influenced the use of prostheses in ossiculoplasty. From a compatibility standpoint, hydroxylapatite is the most promising implant material cur-rently in use. The nonporous and homogenous nature of dense hydroxylapatite resists penetration by granulation tissue. This aspect can be clearly seen by using scanning electron microscopy. Hydroxylapatite, when in composite form with Flex (Silastic) or Teflon, offers a wide range of use from surgery for chronic otitis media to pure funetional surgery.

Seven hundred and forty-nine partial and total prostheses **(PORPs and TORPs)** of composite material, designed by Jean-Bernard Causse and developed by Microtek, were used over a twoyear period. The authors present the short- and medium-terin results and the surgical techniques used.

Material and methods

The prostheses being used are made with a head of dense hydroxylapatite, a flexible metallic link of titanium, and a shaft of either Flex H/A or Teflon. They have a round head, 3.25 mm in diameter, and a recessed notch for the handle of the malleus. The metallic link is malleable and can be bent to almost any angle. Three prototypei?s can be used (Fig. 1):

- A partial prosthesis 526, with a hollow shaft 5 mm in length. This prosthesis may be placed on the head of the stapes.

- A total prosthesis 525, with a solid shaft 9 mm in length and 0.6 mm in diameter. This total prosthesis is used in absence of the stapes superstructure. At times, this prostheses may require stabilization with a Flex H/A 'shoe' fixed to the bottom.

- A total prosthesis 317, with a 0.4 mm diameter shaft. This type of prosthesis is used in cases of stapes fixation after an 0.8 mm stapedotomy has been performed.

Address for correspondence: Dr. Robert Vincent, Clinique d'Otologie Jean Causse, Traverse de Béziers, 34440 Colombiers, France

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Fig. 1. The Causse Flex H/A prosthesis. From left to right: partial prosthesis 526, total prosthesis 525 and total prosthesis 317.

Surgical indications and techniques

The Causse Flex H/A prostheses have a wide range of applications. It is common to adapt their use according to the *presence or* absence of the handle of the malleus and the condition of the stapes.

Handle of the malleus is present

In cases of fixation of the head of malleus, it is imperative to remove the head, in order to achieve a mobile hi?andle and obtain refixation. This should be performed after removal of the incus and sectioning of the neck of the malleus. After assessment of the malleus and incus, the condition of the stapes determines which type of prosthesis should be used.

Stitpes prescrit and inobile

In this instance, the partial prosthesis 526 is used. The Flex shaft is trimmed with a knife after the appropriate length has been determined. The head of the prosthesis is angulated to accommodate the head of the malleus. The metallic link permits antero-posterior and lateral flexion. Flexion must not be too great, *however, in* order to prevent unstable positioning. The shaft of the prosthesis is placed on the head of the stapes, then turned until the notch on its head faces the handle of the malleus. The notch fits the handle of the malleus in comfort. A notch may also be fashioned in the inferior portion of the shaft with a knife or microscissors. This *leaves room* for the stapes tendon, and improves the stability of the prostheses. In certain instances, the malleus handle may be too far anterior *relative to* the stapes head. This may occur despite sectioning of the tensor tendon. In this instance, a special prototype with an elongaêted and thinner head is used. At times, *there is* only a small distance between the handle of the malleus and the head of the stapes. Excess trimming of the shaft to the limit of insertion of the titanium may cause instability. In these cases, it is best to use another prosthesis with a shorter metallic link.

Erosion of the stapes superstructure (mobile footplate)

In this instance, prosthesis 525 should be used. The technique of positioning is the same; the shaft of the prosthesis mi?ust fit snugly onto the posterior half of the footplate and should be protected by an interposed vein graft. In order to ensure contact and stability with the stapes footplate, it may be advantageous to use a Flex 'shoe'.

Fixed footplate

In footplate fixation, prosthesis 317 is used. A posterior stapedotomy of 0.8 mm is initially performed with a diamond drill or skeeter oto-tool and argon laser, followed by vein graft interposition. Preparation of the prosthesis and positioning are as described previously.

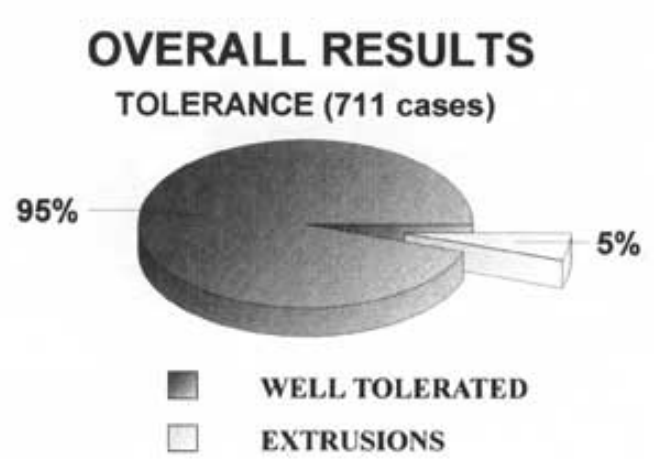
Handle of the malleus is absent

Absence of the malleus handle is often seen in cholesteatoma surgery. Very often, it is difficult to stabilize the head of the prosthesis against the tympanic membrane. If the head of the prosthesis becomes dislodged, it may come into contact with the bony tympanic frame, creating an acoustic bridge with a waste of sound energy. In order to avoid this situation, Jean-Bernard Causse advocates the use of a patch of vein under the head of the prosthesis, positioned on each side of the titanium shaft. The adventitia is placed towards the tympanie membrane.

Each of these prostheses is used depending the situation encountered. 526 PORPs and 525 TORPs are used either in chronie otitis surgery or in non-chronic otitis surgery (ossicular erosions, ankylosis, post head injury); 317 **TORPs** are used in particular in cases of otosclerosis revision surgery with erosion of the long process of the ineus, and also very often in cases of congenital defects.

Results using Causse Flex HIA prostheses

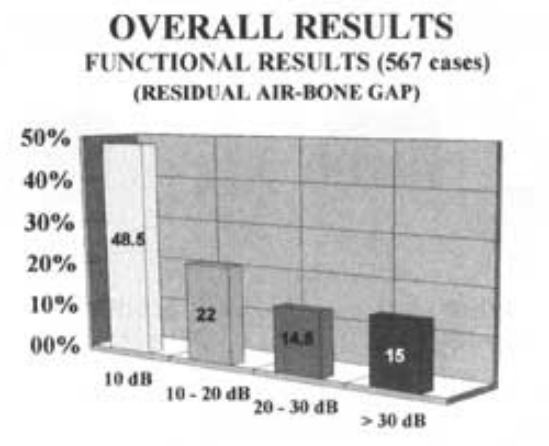
Seven hundred and forty-nine cases have been implanted with the Causse Flex H/A at the Causse Clinic, with a follow-up period i? ranging from six months to three years. At the time of writing, 572 of the patients had undergone both otomicroscopie and audiometric evaluation, 139 patients had had otomicroscopie evaluation alone and 38 patients had been lost to follow-up.



Tolerance (Fig. 2)

Overall, the prosthesis has been well tolerated. There were 39 extrusions, giving an extrusion rate of 5%. This compares favorably with the extrusion rate for other hydroxylapatite ossicular prostheses. All these extrusions were recorded within nine months of surgery and mainly in patients with poor Eustachian tube function (retraction of the tympanic membrane, Valsalva negative). Extrusions occur due to abnormal middle ear conditions : 38 of the 39 were seen in chronic otitis surgery and, in particular, in cholesteatoma surgery (35 cases). Twenty of the extrusions oceurred in patients during first stage reconstruction after cholesteatoma removal, and 15 during the second stage. Twenty of these extrusions occurred during revision surgery.

The extrusion rate is 6% for PORPS and 8% for TORPS. This rate is 1% in non-chronic and 8% in chronie otitis surgery, 8% in revision surgery, 10% in inflammatory disease of the mucosa, and 10% in case of absence of the malleus. However, the main factor seems to be poor Eustachian tube function with an extrusion rate of 19%.



Funetional results (Fig. 3)

The functional results were assessed in 567 of 572 cases. Five patients were excluded because of a postoperative decrease in sensorineural hearing level (less than 20 dB). The functional resi?ults are expressed by the residual postoperative air-bone gap as follows:

$$\text{Residual air-bone gap} = \frac{(AC\text{-}BC)\ 500\ Hz + (AC\text{-}BC)\ 1000\ Hz + (AC\text{-}BC)\ 2000\ Hz}{3}$$

where AC = air conduction and BC = bone conduction.

The best bone conduction level, whether it was obtained preoperatively or at any time postoperatively, was used to calculate the residual air-bone gap. An overall air-bone gap closure to within 20 dB was achieved in 400 cases (70.5%).

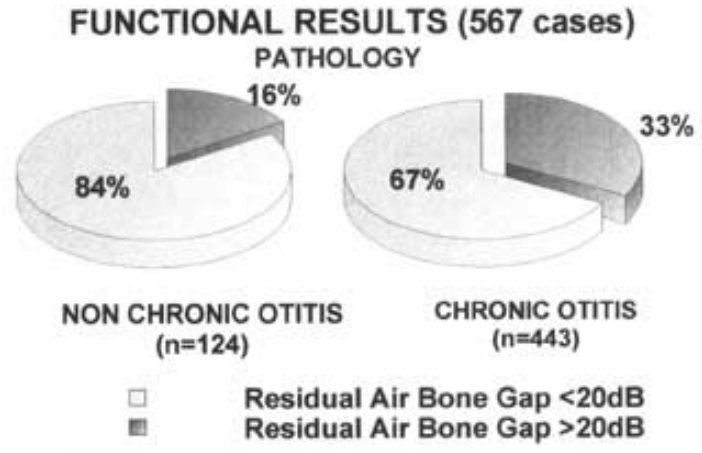


Fig. 4

The functional results were assessed according to the pathology (Fig. 4). All patients operated on for head injury, malleus fixation, ossicular erosion, or congenital defects had excellent results, with a postoperative air-bone gap of less than 20 dB in 84% of cases

In cases of chronic otitis surgery, closure of the air-bone gap to within 20 dB was obtained in 67% of cases.

There was a slight trend towards better results in first-stage reconstructions after cholesteatoma removal than in second-stage reconstructions. In first-stage reconstructions, 78% of PORPs and 67% of TORPs achieved an air-bone gap closure to within 20 dB. In second-stage reconstr-uetions, 63% of **PORPs** and 63% of TORPs achieved an air-bone gap closure t? to within 20 dB. Whatever the pathology, the air-bone gap was closed to within 20 dB in 73.5% of cases using PORPs and 67% in TORPs (Fig. 5).

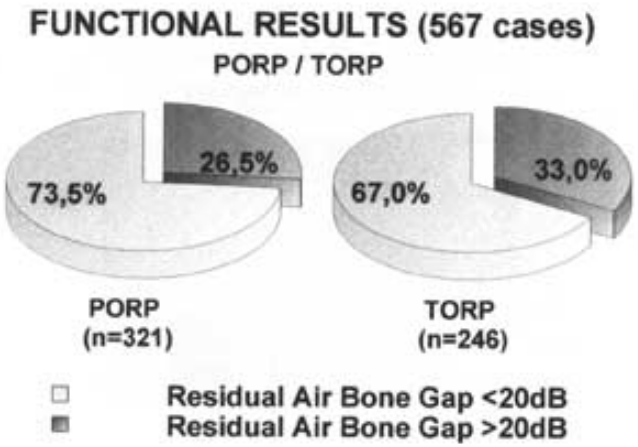


Fig. 5

The presence or absence of the malleus seems to be one of the main factors influencing the results. Closure of the air-bone gap to 20 dB or less occurred in 82% of cases where the malleus was present and in 62% where the malleus was absent (Fig. 6). This hearing level was also achieved in 650/o of cases of revision surgery, 5 1 % of cases of poor Eustachian tube function, and 65% of cases of inflammatory disease of the mucosa. These three factors also appear to be very important.

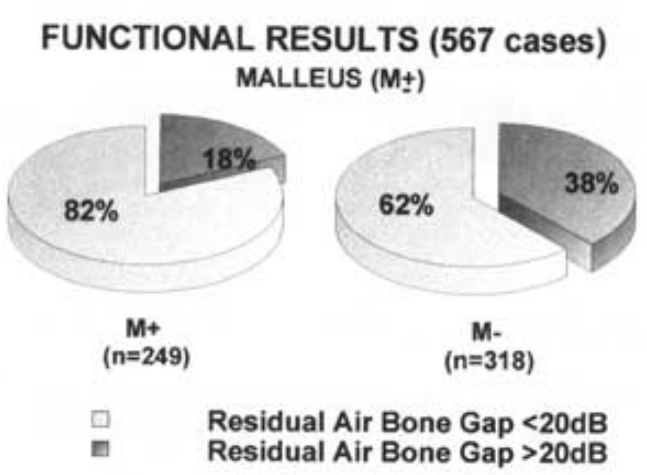
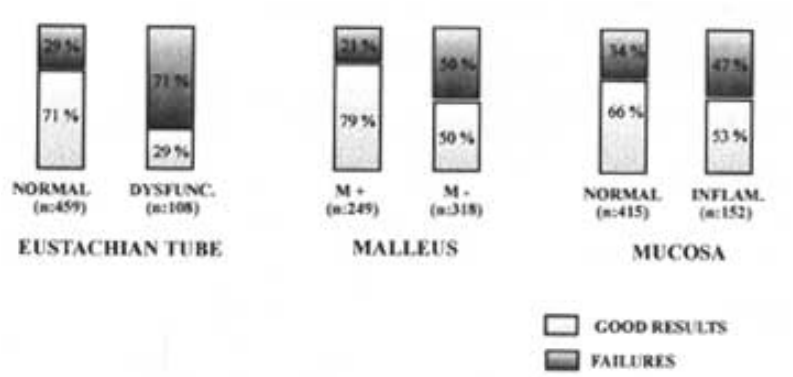


Fig. 6



Surgicalfailures (Fig. 7)

Fig. 7. Surgical failures (211 cases/37%). Incidence of the three main factors: Eustachian tube dysfunction, type of middle ear pathology and absence of the malleus.

Patients with prosthesis extrusion, sensorineural impairment or a residual air-bone gap of more than 20 dB are classified as failures.

Revision surgery

Surgical failures were seen in 44.5% of patients who underwent revision surgery and in 31.8% of patients in whom it was primary surgery.

Influence of middle ear pathology

This is an important criterium of failure. Surgical failure occurred in 42.8% of patients with chronic otitis surgery, but only in 17% of patients with non-chronic otitis surgery.

Type of prosthesis: TORP or PORP

Surgeryt? failed in 42% of cases using TORPs and in 33% using **PORPs.**

Influence of Eustachian tube function

This appears to bc the most significant criterium. Surgical failure occurred in 71% of patients with poor Eustachian tube function and only in 29% of patients with normal tubal function.

Influence of inflammatory disease of the mucosa

Surgical failure was seen in 47% of cases of inflammatory disease of the mucosa and in 34% of cases with normal mucosa.

Influence of the presence or absence of the malleus

The presence or absence of the malleus is another very important criterium. Failures occurred in 50% of cases of absence of the malleus and in only 21% of

cases of presence of the malleus.

Influence of the presence or absence of the stapes

This criterium appears to be less important than the previous one: surgical failure was seen in 46% of cases of missing stapes and in 33% of cases with the stapes present.

Discussion

According to other studies, it is obvious and not surprising that tubal funetion, type of middle ear pathology, inflammatory disease of the mucosa, and presence or lack of the malleus, appear to be the most important factors to influence results.

In this study, we must be cautious with the follow-up period which is too short to allow any real conclusions. Only a long-term assessment, of at least five years, must be our preoccupation in terms of ossiculoplasty.

However, the advantages of these composite prostheses are numerous:

- bio-compatibility and tolerance, thanks to the low adhesion and non-irritant qualities of the
t?
material. The prostheses may even be used in the presence of inflammation, which favors

their use at the time of first-stage surgery in chronic otitis media; - ease of use, no special tools (e.g., drilling) or particular skills are needed; - adaptation to different anatomical situations, - good functional results; - no risk of transmission of microbial disease, such as HIV, Creutzfeld-Jacob, etc.

As long as doubts persist about the harmlessness of homografts, and when autografts are not available, these prostheses, despite their price, remain a convenient alternative. The prospects of progress are immense both at the level of materials and at the level of design for future successful usage.

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