

L'ossiculoplastie avec la prothèse

L'ossiculoplastie avec la prothèse en composite de J. B. Causse : notre experience sur 500 cas Ossiculoplasty with J. B. Causse composite prosthèses : our experience with 500 cases

R. Vincent - B. Gratacap - G. Vandeventer (Béziers)

Résumé

En pathologie ossieulaire, il existe plusieurs options lorsqu'il s'agit d'une restauration de la columelle. L'autoplastie, l'hétéroplastie et l'homoplastie présentent des avantages et des inconvénients, mais la situation a beaucoup évolué grÇce aux récents progrès importants réalisés dans la mise au point des prothèses. 500 prothèses totales et partielles (PORP et TON) en matériau composite (Flex HA et Teflon HA), conçues par Jean Bernard Causse et réalisées par Microtek, ont été utilisées depuis janvier 1992 jusqu'en décembre 1993. Les auteurs présentent les résultats à court et à moyen terme sur tous les aspects de la chirurgie otologique, et les techniques mises en œuvre.

Mots-clés : Ossiculoplastie, hydroxylapatite, flex, prothèse en composite, Porp-Torp.

Summary

In ossicular pathology, many options are available when the restoration of the columellar effect is required. Autoplasty, heteroplasty and homoplasty have advantages and disadvantages, but considerable recent progress in development of the prosthesis has changed the state of the situation. 500 partial and total prostheses (Porp and Torp) of composite material (Flex HA and Teflon HA) designed by Jean-Bernard Causse and developed by Microtek, were used from January 1992 until December 1993. The authors present results at short and middle term involving all aspects of otologic surgery, as well as surgical techniques that were used.

Key-words : Ossiculoplasty, hydroxylapatite, flex, composite prosthesis, Porp-Torp.

Every otologist aspires to rebuild the ossicular chain to restore hearing and fulfill the patient's expectations. Recent significant advance

in biomaterials, influences the use of prostheses in ossiculoplasty. From a compatibility stand point, hydroxylapatite is the most promising implant material currently in use.

The nonporous and homogenous nature of dense hydroxylapatite resists penetration by granulation tissue. This aspect can be clearly seen 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 functional surgery. 500 partial and total prostheses (Porp and Torp) of composite material, designed by J.B. Causse and developed by Microtek, were used during 2 years.

The authors present results at short and n-iiddle term and surgical techniques that were used.

MATERIALS AND METHODS

The prostheses that are in use, are made of a head of dense hydroxylapatite, a flexible metallie link of titanium, and a shaft of either Flex H/A or Teflon. The prostheses 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 nearly any angle. Three prototypes may be used (fig. 1) :



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

- 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. The total prosthesis is used for absence of

the stapes superstructure. At times, this prostheses may require stabilization with a Flex HIA "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 is performed.

SURGICAL INDICATIONS AND TECHNIQUES

The Causse Flex 1-YA prostheses have a wide range of applications. It is common to present their use according to the presence or absence of the handle of the malleus and the condition of the stapes.

Handle of malleus present

In cases of fixation of the head of malleus, it is imperative to remove the head, in order to achieve a mobile handle and present 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 may be used.

Stapes present and mobile : In this instance, the partial prosthesis 526 is used. The Flex shaft is trimmed with a knife after the appropriate length is determined. The head of the prosthesis is angulated to accommodate the head of the malleus. The metallic link permits anteroposterior 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 face the handle of the malleus. The notch fits the handle of the malleus in comfort (fig, 2)

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 (fig. 3).

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 elongated and thinner head is used. At times, there is little 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, one would use prosthesis 525. The technique of positioning is the same ; the shaft of the prosthesis must fit snugly on the posterior half of the foot plate 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 0,8 mm is initially performed with diamond drill or skecter oto-tool and Argon Laser, followed by vein graft interposition. Preparation of the prosthesis and positioning are as described previously.

Handle of malleus absent

Absence of the malleus handle is often seen in cholesteatoma surgery. Many times, 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, J.B. 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 toward the tympanic membrane.



Fig. 2 : Surgical view of a partial 526 Causse Flex WA prosthesis (right ear). The notch on the head of the prosthesis fits the handle of the malleus.

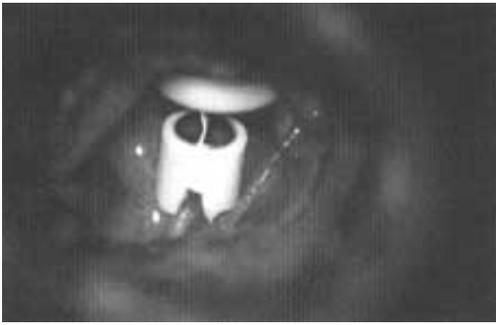


Fig. 3 : Surgical view of a Porp 526 (letêt ear) showing the notch fashioned in the inferior portion of the shaft, to leave room for the stapes tendon.

Each of these prostheses is used depending the situation encountered. 526 Porp and 525 Torp are used either in chronic otitis surgery or in on chronic otitis surgery (ossicular erosions, ankylosis, post head unjury ...). 317 Torp is particularly used in case of otosclerosis revision surgery with erosion of the long process of the incus and also very often in case of congenital defect.

Figure 4 is an endoscopic picture of a right ear, showing the ideal position of the head of a prosthesis (Torp) placed under the handle of the malleus and in contact with the tympanic membrane (one year after surgery).



Fig. 4 : Endoscopic picture of a right ear showing the ideal position of a Torp at one year after surgery.

RESULTS USING THE CAUSSE FLEX H/A PROSTHESES

Five hundred cases have been implanted with the Causse Flex H/A at the Causse Clinic, with a follow up period ranging from 6

months to 2,5 years. At the time of this writing, 415 of the patients underwent both otomicroscopic and audiometric evaluation, 60 patients had otomicroscopic evaluation alone and 25 patients were lost to follow-up.

Tolerance (Table 1)

Overall, the prosthesis has been well tolerated. There were 20 extrusions, for an extrusion rate of 4 %. This compares favorably with the extrusion rate for other hydroxylapatite ossicular prostheses. All of these extrusions have been recorded within 6 months of surgery and mainly in patients with poor Eustachian tube function (retraction of the tympanic membrane, Valsalva negative).

Extrusions occur from abnormal middle ear conditions (fig. 5), 18 of the 20 were seen in chronic otitis surgery and particularly in cholesteatoma surgery (16 cases). 14 of the extrusions occurred in patients during first stage reconstruction after cholesteatoma removal,

and only 2 during second stage. 12 of these extrusions occurred in revision surgery : the extrusion rate for Porps is 4 % and 4 % for Torps ; this rate is 2 % for non chronic otitis surgery and 5 % in chronic otitis surgery, 7 % for revision surgery, 5 % for inflammatory disease of mucosa and 5 % of case of absence of malleus. But the main factor seems to be a poor Eustachian tube function with an extrusion rate of 12 %.

Functional results (table II)

The functional results were assessed for 411 of 415 cases. Four patients were excluded because of a post operative decrease in sensorineural hearing level (less than 20 dB). Functional results are expressed by the residual post operative air-bone gap as follows

Residual Air-Bone gap :

(AC-BC) 500 Hz + (AC-BC) 1000 Hz + (AC-BC) 2000 Hz

Where AC = Air conduction; 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.

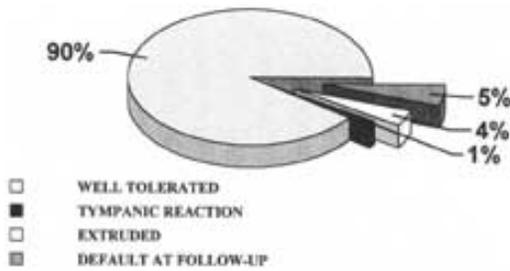


TABLE 1 : Overall results of 500 cases using the Causse Flex H/A prostheses.



Fig. 5 : Endoscopic picture of a left ear, showing the extrusion of a Porp, six months after surgery.

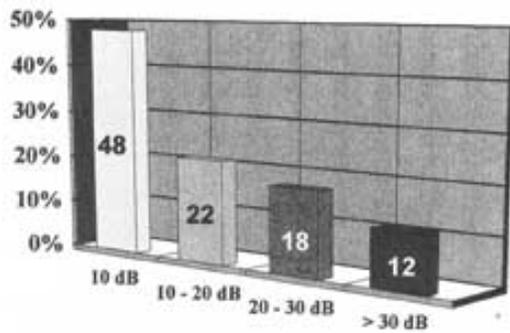


TABLE II : Functional results (residual air-bone gap) in 411 cases using the Causse Flex H/A prostheses.

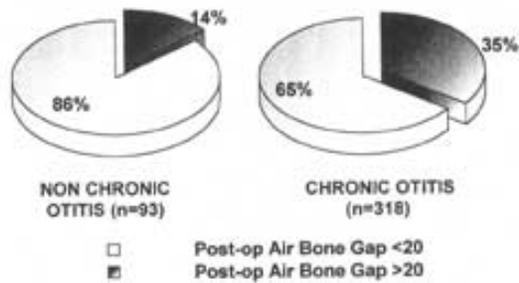


TABLE III : Functional results according to pathologic conditions using the Causse Flex H/A prostheses.

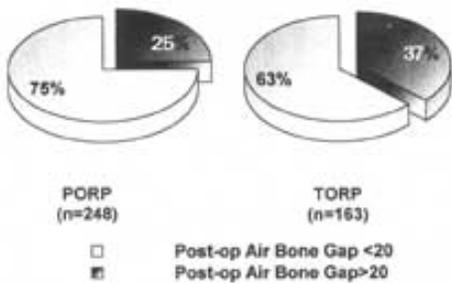


TABLE IV : Functional results according to the type of prostheses (Porp and Torp).

An overall air bone gap closure to within 20 dB was achieved in 288 cases (70 %).

The functional results were assessed according to pathology (table 111). All the patients operated for head injury, malleus fixation,

ossicular erosion, and congenital defects had excellent results, with a post operative airbone gap less than 20 dB in 86 % of cases. In cases of chronic otitis surgery, closure of the air-bone gap to within 20 dB was obtained in 65 % of cases.

There was a slight trend toward better results in first stage reconstructions after cholesteatoma removal than in second stage reconstructions. In first-stage reconstructions, 80 % of Porps and 68 % of Torps achieved an airbone gap closure to within 20 dB. In second stage reconstructions, 65 % of Porps and 54 % of Torps achieved an air-bone gap closure to within 20 dB. Whatever the pathology has been, the air-bone gap was closed within 20 dB in 75 % of cases using Porps and 63 % in Torps (Table IV). The presence or absence of malleus seems to be one of the main factors that influences the results. Closure of the air-bone gap to 20 dB or less occurred in 83 % of cases of malleus present and in 62 % of cases of malleus absent. This hearing level was also achieved in 60 % of cases of revision surgery, in 53 % of cases of poor Eustachian tube function, and in 58 % of cases of inflammatory disease of mucosa. These three other factors appear to be also very important.

Surgical failures

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

Revision surgery : surgical failures were seen in 44 % of patients who underwent revision surgery and in 27 % of patients for whom it was a primary surgery.

Influence of the middle ear pathology : this is an important criteria of failure. Surgical failure occurred in 39 % of patients with chronic otitis surgery, and only in 16 % of patients with no chronic otitis surgery.

Type of the prosthesis : Torp or Porp ; the surgery failed in 41 % of cases using Torps and 29 % using Porps.

Influence of the Eustachian tube function : it appears as the most significant criteria. Surgical failure occurred in 54 % of patients with poor Eustachian tube function and in 29 % of patients with normal tubal function.

Influence of the inflammatory disease of the mucosa : surgical failure was seen in 46 % of cases of inflammatory disease of

mucosa and 30 % of cases of normal mucosa.

Influence of the presence or absence of the malleus the presence or absence of malleus is another very important criteria.

Failures occurred in 43 % of cases of absence of malleus and only in 19 % of cases of presence of malleus.

Influence of the presence or absence of the stapes this criteria appears to be less important than the previous one : surgical failure was seen in 40 % of cases of missing stapes and in 29 % of cases of presence of the stapes.

DISCUSSION

According to other studies, it is obvious and not surprising that tubal function, type of middle ear

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pathology, and presence or lack of malleus appear to be the Most important factors that influence the results in our experience.

In this study, we must be cautious with the followingup period that is too short to give real conclusions. Only a long term assessment, at least 5 years, must stay our preoccupation in term of ossiculoplasty.

But the advantages of these composite prostheses arc numerous :

- bio-compatibility and tolerance thanks to the lowadhesion and no irritant qualities of the material. The prostheses may be used even in the presence of inflammation, this favours their use even at the time of first stage surgery in chronic otitis media ;**
- ease of use, without special tools like drilling or a particular skill ;**
- adaptation to different anatomical situations ,**

- good functional results ;
- no risk of transmission of microbial disease, as HIV, Kreutzfeld-Jacob...

As long as doubts persist as to the harmlessness of homografts, and when the availability of autograft is not possible, these prostheses, despite their price, remain a convenient alternative. The prospect for progress is immense as much as at the level of materials, as at the level of design for future successful usage.

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