JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICINE 6 (1995) 745–748

Biomaterials in the reconstruction of the human middle ear

M. PINILLA*, J. R. GARCÍA BERROCAL, R. RAMÍREZ-CAMACHO
Servicio de Otorrinolaringología Clínica Puerta de Hierro. Universidad Autónoma de Madrid. Madrid, Spain

J. BUJAN
Departamento de Morfología Celular. Universidad de Alcalá de Henares. Madrid, Spain

E. JORGE HERRERO
Servicio de Cirugía Experimental, Clinica Puerta de Hierro, Universidad Autónoma de Madrid, Madrid, Spain

The use of biomaterials for reconstruction of the ossicular chain in middle ear involves a different approach from that associated with other regions of the organism. The features of the implantation site and the composition of the prosthesis are responsible for functional failures that result from deterioration or extrusion of the implant. Since the fifties, different types of materials, both biological and synthetic, have been employed in the attempt to achieve the ideal middle ear prosthesis. We present a reprospective study of 166 patients who underwent ossicular chain reconstruction involving autografts and homografts of cartilage or auditory ossicle ($n = 104$) or synthetic prostheses ($n = 62$). We compare prostheses of different compositions on the basis of the cases of extrusion and the histological deterioration encountered with each. In our experience, polymers are associated with frequent extrusion and deterioration of the biomaterial, while the results are better with biological implants and those made of hydroxyapatite.

1. Introduction

The possibility of anatomical and functional reconstruction of different parts of the human body that have been damaged by disease or by the surgical procedures necessary for its eradication is one area of medicine that has required the concourse of several scientific disciplines in the attempt to prevent the organism from rejecting the foreign element and ensure that the replacement functions.

The implantation of prostheses into the organism is widely extended throughout all the medical specialties, particularly in maxillofacial surgery and orthopedics. Over the past forty years, surgical procedures have been developed in the field of otorhinolaryngology for the reconstruction of the ossicular chain damaged by different types of chronic otitis media. Traditionally, implants of ossicles and cartilage from the patient himself or from tissue banks were used. In the last 20 years, the use of biocompatible materials to occlude cavities or reconstruct disease-damaged structures has become widespread. Combinations of polymers, composites made of polymers with carbon fibres and bioactive or bioinert ceramics have been used successively in the construction of prostheses.

Nevertheless, the characteristics of the middle ear differ widely from those of other implantation sites in the organism. On the one hand, ossicular replacement prostheses (ORP) are situated between bone (footplate or stapes head) and white tissue (tympanic membrane) and are surrounded by air (Fig. 1). On the other hand, these prostheses must be functional and able to transmit small vibrations (sound waves). Finally, under certain unfavourable circumstances, they can be subjected to changes in pH as a result of inflammation of the ear; this can alter the composition of the prosthesis, thus explaining why the rate of extrusions of polymeric implants is over 20.2% [1, 2], far surpassing initial reports [3].

This study deals with the analysis of the different types of prostheses implanted into middle ear that produced suppurative or surgical sequelae.

2. Material and methods

A retrospective study was carried out of 166 patients who had undergone surgery for reconstruction of the ossicular chain and were followed for a period of one to 23 years. In all, 62 prostheses were used for total or partial ossicular replacement. The prostheses employed were Proplast^{Tm} (polytetrafluoroethylene and vitreous carbon; $n = 30$), Plastipore^{Tm} (high molecular weight polyethylene; $n = 19$), Fluoroplastic^{Tm} ($n = 4$)

*Correspondence to Dr Mayte Pinilla Urraca, Antonio Machado, 23, 7-C, 28035 Madrid, Spain.

0957–4530

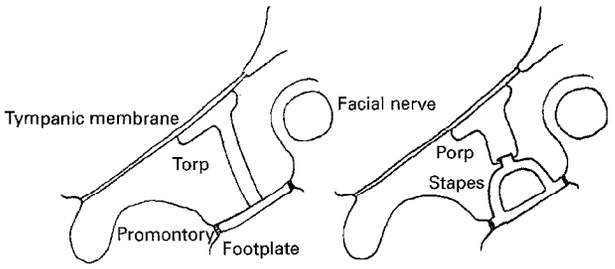

Figure 1 Illustration of the placement of the total ossicular replacement (TORP) (left) and the partial ossicular replacement (PORP) (right) in the tympanic cavity. The TORP can be seen intercalated between the tympanic membrane and the stapes footplate, while the PORP joins the footplate to the stapes superstructure.

and hydroxyapatite ($n = 9$). In the remaining 104 surgical procedures, autografts ($n = 74$) or homografts ($n = 30$) of cartilage (tragal or septal) or ossicle (incus or a fragment of the mastoid cortex) were used.

All the patients were assessed periodically by means of otomicroscopic and audiometric examination, and tympanotomy was performed to remove a failed implant when the patient was willing to undergo reimplantation. When extrusion was detected, the prosthesis was withdrawn in the outpatient clinic. Some of these implants were processed for histological study or scanning electron microscopy.

3. Results

The data gathered from reviewing the clinical histories indicate that biological autografts and homografts were used more frequently ($n = 104$) than biocompatible prostheses ($n = 62$). None of the patients receiving homografts, autografts or hydroxyapatite prostheses presented extrusion. This event did occur, however, in five of the 30 patients receiving the Proplast^{Tm} implant, in one of the four patients who received Fluoroplastic^{Tm} prostheses ($n = 4$) and in five of those with Plastipore^{Tm} ($n = 19$) . The mean length of time between prosthesis placement and extrusion was 16 months (Fig. 2).

Another important factor was the deterioration observed in the reconstructed system in those cases in which the middle ear could be assessed by surgical procedure. This was evident in four of the 62 cases in which polymers were used (all in the Proplast^{Tm} group) and in four cartilage implants among the 104 biological grafts, all four of which had become reabsorbed. The mean length of time between prosthesis placement and failure or deterioration was 36 months.

Standard histological study demonstrated a relative integrity of the Plastipore^{Tm} prostheses, which were seen to be surrounded by a thin network of connective tissue, although a foreign body reaction to the stem of the prosthesis did occur on occasion (Fig. 3). On the other hand, the Proplast^{Tm} prostheses presented a marked destructurization of the plastic component, with regrouping of the graphite particles, causing fractures in the structure of the prosthesis and enabling the penetration of bacteria that contributed to the deterioration of the material. These findings were confirmed under scanning electron microscopy (Fig. 5), which disclosed the existence of bacteria and macro-

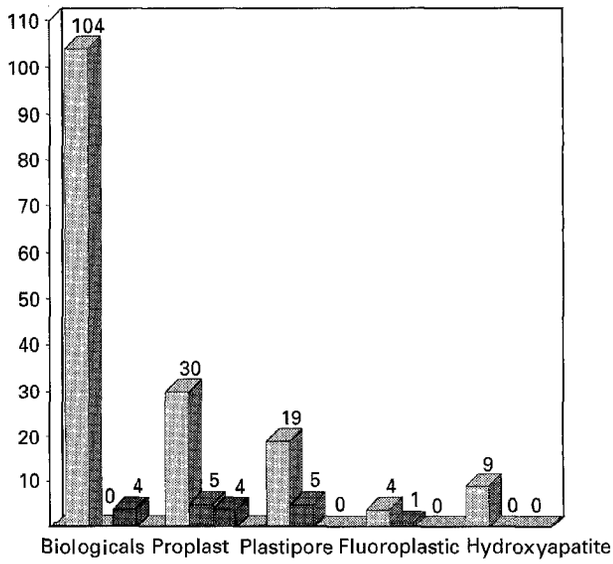

Figure 2 Patients ($n = 166$) implanted according to the different reconstruction techniques, as well as the cases of extrusion or deterioration observed in each group. ▨: total; ▨: extrusion; ■: deterioration.

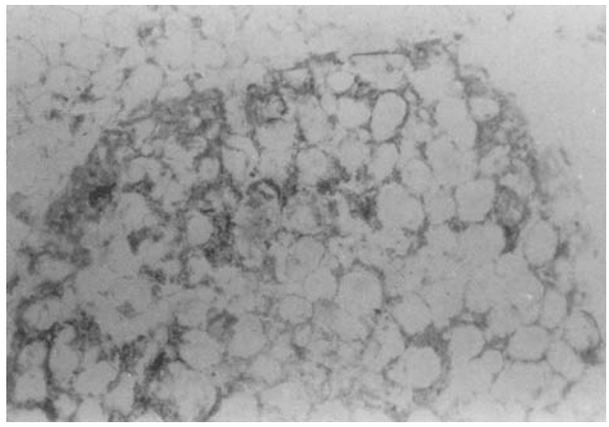

Figure 3 Photomicrograph of a transversal section of the stem of a Plastipore^{Tm} prosthesis showing plastic filaments surrounded by a fibrous cellular interweave (HE × 125).

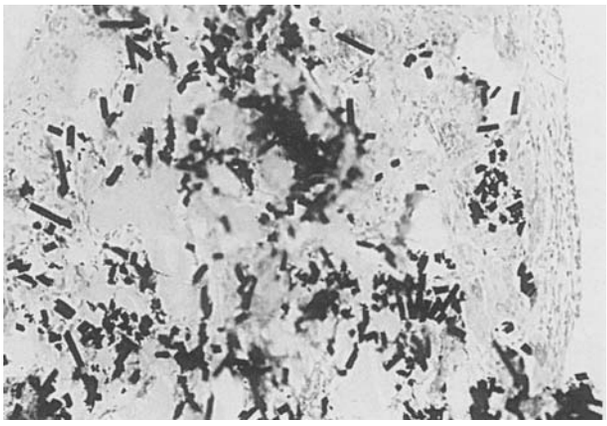

Figure 4 Histological image of a Proplast^{Tm} prosthesis removed 10 years after implantation, containing an irregular tissue structure alternating with areas of polymer, irregular clusters of black-stained graphite and homogeneous areas representing calcification nuclei (HE × 1000).

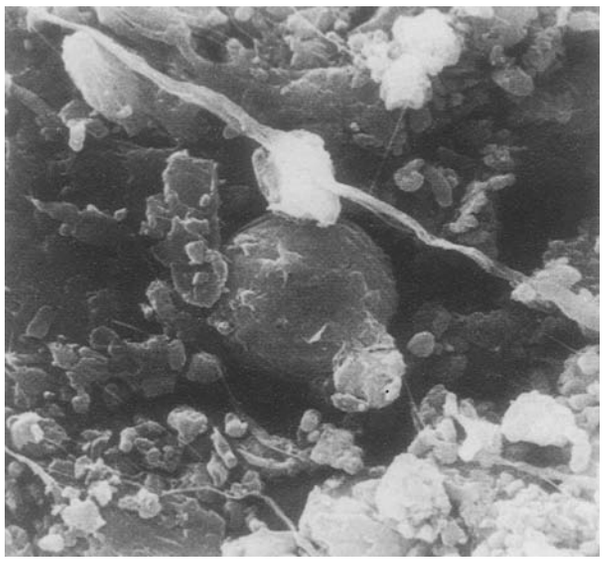

Figure 5 Scanning electron microscopy image of a fragment of a Proplast^{Tm} prosthesis used for the reconstruction of the posterior wall of the external auditory canal twelve years earlier. The presence of bacteria and a monocyte-macrophage indicating infection within the material (× 3000).

phages that digested the ends of the graphite particles to which they became bound by visible filaments, resulting in a clear deterioration of the prosthesis.

4. Discussion

Although the theory behind ossicular chain reconstruction established in the fifties by Zollner [4] and Wullstein [5] is based on providing stable systems that transmit sound waves to the inner ear, this concept is still questioned by the otologist. The introduction in the seventies of the ossicular replacement prosthesis based on substituting the incus–crural unit (TORP) or the incus alone (PORP) [6, 7] was highly encouraging given its availability and the wide variety of designs.

Many factors influence the outcome of ossiculoplasty: on the one hand, those intrinsic to the ear itself (Eustachian tube function, underlying disease and the state of the rest of the ossicular chain), and on the other, extrinsic factors (the surgical technique and the design and composition of the prosthesis).

Early in the introduction of functional surgery, Wullstein [8] employed an acrylic–vinyl ring to cover the space between the tympanic membrane and the base of the stapes. The attempt was a failure because of the limited biocompatibility of this material. In 1974, Shea and Homsy [9] introduced the so-called Proplast^{Tm} , a prosthesis made of polytetrafluorethylene and vitreous carbon. The initial publications reported satisfactory results, but in 1978, this material was replaced by Plastipore^{Tm}, a prosthesis made of high-density polyethylene [10]. The use of these two materials is based on their capacity to induce the formation of a fine mucosal covering (interface) that coats them, while permitting the penetration of the native tissues of the patient, producing an internal fibrous interweave that secures them. This reaction of the host to a foreign substance must be intense enough to allow the stable attachment of the prosthesis to the structures of the tympanic membrane. However, long-term studies have disclosed an exceedingly high incidence of extrusions of both materials. Thus, it was necessary to protect them by means of a cartilage autograft or homograft which separated them from the tympanic membrane [11, 12] to prevent necrosis of the latter structure due to contact with the prosthesis.

Despite this effort, long-term follow-up of patients with biocompatible prostheses has revealed an exceedingly high prevalence of extrusions. Some authors [1] report an incidence of late extrusions (four years after placement) as great as 10%, and these rates increase as follow-up continues, as in our series, where the incidence reached 20.8%. However, over prolonged follow-up periods, some authors observe, as we did, a decrease in the auditory gain, which remains satisfactory in only 22% of patients with the Plastipore^{Tm} prosthesis [2].

The failure of the Proplast^{Tm} prosthesis is attributed to its deformation; however, in the case of the Plastipore^{Tm} prosthesis, the lack of microscopic evidence of an appreciable deterioration leads us to consider that the cause of the failure (displacement, extrusion) does not lie in the prosthesis itself, but in the implantation site or its tendency to induce local reactions. In addition, patients with polymeric prostheses who present reinfection may fail to respond to antiinfectious therapy. These reasons have led to a decrease in the initial enthusiasm for biocompatible polymeric prostheses. Therefore, the search was begun for new materials, among which the bioactive ceramics made of calcium silicate (CeravitalÙ) represent an encouraging alternative. Nevertheless, given the extensive erosion of these implants [13] as well as a rate of extrusion of nearly 8% [14, 15], this prosthesis is not considered ideal either.

The experience of otosurgeons has shown that implants made of tissue (cartilage, ossicle or fragments of the mastoid cortical plate) are well tolerated either as homografts or as autografts. It has been observed that they act as inert tissues, the surface layers of which are revascularized to varying degrees by the recipient. The rate of extrusions is practically zero [16], but the main problem associated with their use is their capacity to adhere to the walls of the tympanic cavity, a tendency which diminishes their medium-term mechanical function. The report of frequent necrosis secondary to chondromalacia when cartilaginous grafts are used [17] is reflected in 4 cases studied by us in which an intraoperative check-up revealed that the implants had been reabsorbed; this rate (4%) is very low.

Recent knowledge concerning infectious disease transmission has changed the implantation strategy in the otologic operating room. The possible transmission of hepatitis B virus or acquired immunodeficiency syndrome makes a thorough preoperative study of the donor absolutely necessary. However, this is not possible in the case of contamination by slow-developing viruses or other biological forms that can resist standard sterilization systems [18]. Therefore,

the use of homografts is being progressively abandoned in favour of autografts whenever available.

The development of a totally synthetic graft, similar to the tissue being replaced, led to the introduction of a new material, hydroxyapatite [19], which is available in both dense and porous forms (Fig. 6); it was initially used in odontology and orthopedics. Moreover, since this substance can be placed in direct contact with the tympanic membrane without intercalating additional cartilage or tissue, there is a lower rate of extrusion.

Figure 6 Scanning electron microscopy overview of a hydroxyapatite total ossicular replacement (TORP) removed two years after implantation showing a fine mucosal coating over the platform and the upper part of the stem (× 19).

Figure 7 Scanning electron microscopy image of the prosthesis in Fig. 6 showing the dense hydroxyapatite globules of which it consists. They can be seen to be covered by a fine fibrous interface.

Studies in animal models indicate the absence of fibrous encapsulation and the existence of what may be a chemical bond between the implanted hydroxyapatite and the surrounding bone, while these structures become lined with a mucosal interface similar to that of the rest of the middle ear [20] (Fig. 7).

Our experience with this material is presently limited to nine cases, with shorter follow-up periods than with the rest of the materials but, to date, extrusions have not occurred. However, there is a tendency toward atrophy of the tympanic membrane, a fact which contradicts earlier opinions.

Consequently, there is no ideal type of prosthesis, despite the improved results obtained with materials having a composition similar to that of bone. Thus, it will be necessary to study the phenomena taking place within the prosthesis and the surrounding tissues in greater depth, as well as the chemical changes that induce suppuration and can affect the function of these implants or alter and degrade the materials of which they are composed.

References

1. H. SILVERSTEIN, A. B. MCDANIEL and R. LICHTENSTEIN, *Laryngoscope* **96** (1986) 159.
2. G. D. L. SMYTH, *Otolaryngol. Head Neck Surg.* **90** (1982) 343.
3. J. J. SHEA, J. R. EMMETT and G. D. L. SMYTH, *ORL* **39** (1977) 9.
4. I. ZOLLNER, *J. Laryngol. Otol.* **69** (1955) 637.
5. H. WULLSTEIN, *Laryngoscope* **66** (1956) 1076.
6. J. SHEA, *ibid.* **86** (1976) 239.
7. J. L. SHEEHY, *Clin. Otolaryngol.* **3** (1978) 451.
8. H. WULLSTEIN, In Proceedings of the Fifth International Congress on Oto-Rhino-Laryngology, **104** (1953) p. 104.
9. J. J. SHEA and C. A. HOMSY, *Laryngoscope* **84** (1974) 1835.
10. J. J. SHEA and J. R. EMMETT, *Arch. Otolaryngol. Head Neck Surg.* **104** (1978) 191.
11. M. C. SHEA, in Proceedings of the Shea–Shambaugh 5th International Workshop on Middle Ear Microsurgery and Fluctuant Hearing Loss (1976) p. 348.
12. D. E. BRACKMANN and J. L. SHEEHY, *Laryngoscope* **89** (1979) 108.
13. A. W. BLAYNEY, J. P. BEBEAR, K. R. WILLIAMS and M. PORTMANN, *J. Laryngol. Otol.* **100** (1986) 1359.
14. R. RECK and J. HELM, *Am. J. Otol.* **6** (1985) 280.
15. G. BABIGHIAN, *Am. J. Otol.* **6** (1985) 285.
16. R. A. RAMIREZ-CAMACHO, *Arch. Otolaryngol. Head Neck Surg.* **107** (1981) 608.
17. S. N. MERCHANT and J. B. NADOL Jr., *Otolaryngol. Clin. North Am.* **27** (1994) 813.
18. M. E. GLASSCOCK, C. J. JACKSON and G. W. KNOX, *Arch. Otolaryngol. Head Neck Surg.* **114** (1988) 1252.
19. J. J. GROTE, W. KUIJPERS and K. DE GROOT, *ORL* **43** (1981) 248.
20. J. J. GROTE, C. A. VAN BLITTERSWIJK and W. KUIJPERS, *Am. Otol. Rhinol. Laryngol.* **95** (Suppl. 123) (1986) 1.

Received 29 June
and accepted 4 July 1995