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Closed tympanoplasty in cholesteatoma surgery: long-term (10 years) hearing results using cartilage ossiculoplasty

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Abstract The aim of this retrospective study was to evaluate the long-term hearing results of using costal cartilage prostheses in ossicular chain reconstruction procedures in subjects operated on for a middle ear cholesteatoma with an intact canal wall tympanoplasty. Thirty-six patients (four with bilateral disease) followed up for 10 years who underwent an ossiculoplasty with a cartilage prostheses between January 1987 and December 1989 constituted the population studied. All the subjects underwent a staged intact canal wall tympanoplasty with mastoidectomy. Ossiculoplasty with total or partial chondroprosthesis was performed during the second stage. The long-term outcome was evaluated in terms of hearing according to the guidelines of the Committee on Hearing and Equilibrium (1995), and in terms of complications (anatomical and functional). In 18 patients a partial cartilage ossicular replacement prosthesis (PORP) was used, while in 22 a total cartilage ossicular replacement prosthesis (TORP) was used. In the PORP group the mean preoperative air–bone gap (ABG) was 22.4 dB hearing level (HL); before the second stage the ABG was 37.9 dB HL, at 2 years it was 12.1 dB HL, at 5 years 15.3 dB HL and at 10 years 15.8 dB HL. In the TORP group the mean preoperative ABG was 31.6 dB HL; before the second stage the ABG was 41.1 dB HL, at 2 years it was 14.4 dB HL, at 5 years 17 dB HL and at 10 years 18.5 dB HL. In both groups the number of cases with a postoperative ABG of < 20 dB HL remained stable ($P > 0.05$) over time. The failure rate was 17.5%, but only in 5% of cases was a functional revision needed. No cases of extrusion of the prostheses were encountered. The use of a chondroprosthesis is associated with functional results similar to those obtained by other authors. The efficacy of the prostheses remains stable over time and is associated with a very low rate of complications and failures. In this series no extrusion occurred and in no case did an infectious disease develop after cartilage transplantation.

Introduction

The reconstruction of the ossicular chain was first described by Zöllner [30] in 1955. Since then several other attempts have been made and several materials, biologic and synthetic, have been proposed for ossiculoplasty.

In our department, when autologous ossicles were not available we initially used dentine [29] and later a Plastipore prosthesis [22]; however, while the former were difficult to obtain and to manage intraoperatively, the latter produced a high rate of extrusion that was only partially reduced by the interposition of cartilage between the tympanic membrane (TM) and the head of the shaft.

In order to overcome these problems, in 1984 we began to use homologous costal cartilage prostheses. Several authors have reported that cartilage grafts are not suitable for ossicular chain reconstruction because of the high incidence of degeneration of chondrocytes and resorption [2, 3, 17, 26–28]. In this study, in order to determine the postoperative stability of cartilage prostheses we reviewed the long-term (10 years) hearing results in a group of patients operated on in our department for a middle ear cholesteatoma, in whom a staged intact canal wall tympanoplasty with mastoidectomy (ICWT) was performed and cartilage prostheses were used in ossicular chain reconstruction.

Materials and methods

Between January 1987 and December 1989 150 ossiculoplasty procedures were performed in our department. Candidates for this study were patients affected by middle ear cholesteatoma whose ossicular chain was reconstructed with a chondroprosthesis during the second stage of an ICWT. The clinical chart of each patient

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was reviewed and all patients were contacted and invited to visit our clinic in order to have a complete audiological and clinical follow-up. In order to analyze the long-term stability of the prostheses only those patients with a 10-year follow-up were studied. The study group consisted of 36 patients. Mean patient age was 38 years (range 7–69 yr); 14 were females and 22 males. Four patients had bilateral middle ear damage and were operated on both sides. Thus, we analyzed the results of 40 ossiculoplasties.

The ossiculoplasty was performed in the course of a second stage ICWT in all cases. During the first operation the tympanic membrane (TM), when necessary, was reconstructed using calf jugular vein (Parmatymp®), allogenic costal cartilage or temporalis fascia. The ossicular chain was reconstructed with a partial cartilage ossicular replacement prosthesis (PORP) when the stapes superstructure was present or with a total cartilage ossicular replacement prosthesis (TORP) when the stapes superstructure was missing.

The follow-up examination included micro-otoscopy and pure tone audiometry. The guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology Head and Neck Surgery [8] were followed and the pure-tone average (PTA) was calculated as the mean of 0.5, 1, 2 and 4 kHz thresholds, since at that time we did not routinely measure the pure tone threshold at 3 kHz. Air–bone gaps (ABG) were calculated from air conduction (AC) and bone conduction (BC) thresholds determined in each study. Postoperative hearing gain was calculated from the PTA before the ossiculoplasty (second-stage ICWT) and at last follow-up examination. The change in the postoperative bone conduction was calculated as the preoperative minus the postoperative pure tone bone conduction average, obtained 6 weeks after surgery, at 1, 2 and 4 kHz.

Statistical analysis of the results was performed with non-parametric tests.

Preparation of the prosthesis and surgical technique

The cartilage is harvested from the costochondral region of young donors whose tissues and organs have been designated for tissue and organ donation. Donors are screened for hepatitis antigen, HIV infection and neurologic disorders by serology and history; subjects with risk factors or positive serology are excluded.

The costochondral region of these subjects is harvested in an operating room in a sterile way at the end of the transplant procedure, after all the organs have been taken. The cartilage is then immersed in a rifampicin 50% solution for 24 h. The next day, in a sterile laboratory, the perichondrium is detached from the ribs and blocks of different shapes and sizes are cut. The blocks are then placed in a 70% alcohol solution in a specimen bottle with a plastic seal. The cartilage can be used 20 days after the preparation but not after more than one year.

When the surgeon has determined that an implant is needed a smaller or larger cartilage block is removed from the vial, according to the reconstructive needs. The chondroprosthesis is sculpted from the cartilage block with a sharp instrument and can be trimmed with a scalpel or a diamond burr.

After the exact distance between the TM and the stapes or the footplate has been determined, a T shaped chondroprosthesis is prepared.

When the stapes is present and mobile a PORP is sculpted. At the end of the shaft an indentation (1 mm wide and 0.5–1 mm in depth) is created with a diamond burr in order to accommodate the capitulum of the stapes. The head of the prosthesis is placed in contact with the TM or the graft used for its repair. The short arm of the T mimics the malleus handle if it is missing. When the malleus is present the prosthesis can be placed parallel to it or a groove can be created in order to accommodate the handle. If the prosthesis is too long or the shaft is too large, it can be trimmed with a sharp instrument until the right shape and dimensions are obtained.

When the stapes superstructure is absent a TORP is prepared. In this case the shaft is longer than in a PORP but the head of the T shaped prosthesis is the same. The end of the shaft is placed on the footplate, while the head, as for the PORP, is in contact with the TM or the graft used for its repair. The shaft of the implant can be trimmed in order to obtain the right length and extent; one or more in situ attempts may be necessary. Because of their flexibility and elasticity, cartilage prostheses rarely damage the stapes or the footplate during the surgical maneuver.

If the footplate is fixed, it can be removed and the oval window can be grafted with calf jugular vein (POG® – Parma Oval Graft) or other autologous materials (perychondrium, fascia, etc.) and the TORP can be placed on the graft. When the prosthesis is in its appropriate position it can be stabilized with fibrin glue or a gelatin sponge.

Results

Forty ossiculoplasties with a 10-year follow-up were reviewed. In 18 of these a PORP was utilized while in 22 a TORP was necessary.

PORP

The pre-operative ABG was 22.39 dB HL (SD 11.6 dB HL). Before the 2nd stage operation the ABG was 37.9 dB HL (SD 10.86 dB HL). At 2 years post-surgery the mean postoperative ABG was 12.1 dB HL (SD 8.1 dB HL). In 15 cases (83.3%) the ABG was < 20 dB HL and in 17 (94.4%) it was < 30 dB HL.

At the 5-year follow-up the mean ABG was 15.3 dB HL (SD 9.7 dB HL). In 14 cases (77.7%) the ABG was < 20 dB HL and in 17 (94.4%) it was < 30 dB HL.

At the 10-year follow-up the mean ABG was 15.8 dB HL (SD 10.9 dB HL) (Table 1). In 13 cases (72.2%) the ABG was < 20 dB HL and 16 (88.8%) it was < 30 dB HL (Table 2).

Table 3 shows the mean and the standard deviation of the postoperative gain at different follow-up times. Statistical analysis revealed that the postoperative ABG was significantly lower than the preoperative ABG at 2 years ($P = 0.0435$), while at 5 years and 10 years the difference nearly reached statistical significance ($P = 0.074$). The postoperative ABG was significantly better than the pre-2nd stage ABG ($P < 0.001$). ABGs at 2, 5 and 10 years were not significantly different. The average postoperative gain decreased slightly and not significantly ($P > 0.05$) over the years.

Table 1 Mean air–bone gap (ABG) and standard deviations (SD) from the PORP and TORP groups at different follow-up times

ABG	PORP		TORP	
	Mean	SD	Mean	SD
Pre 2nd stage	37.9	10.8	41.4	11.2
2 years	12.1	8.1	14.4	8.1
5 years	15.3	9.7	16.9	9
10 years	15.8	10.9	18.5	9.9

Table 2 Percentage of cases falling in the different ABG bins in the PORP and TORP groups

	PORP				TORP			
	Pre 2nd	2 yr	5 yr	10 yr	Pre 2nd	2 yr	5 yr	10 yr
ABG 0–10 dB HL	0	50	33.3	44.4	0	36.4	31.8	18.2
ABG 11–20 dB HL	5.6	33.3	44.4	27.8	4.6	40.9	31.8	54.5
ABG 21–30 dB HL	22.2	11.1	16.7	16.7	13.6	18.2	27.3	18.2
ABG > 30 dB HL	72.2	5.6	5.6	11.1	81.8	4.5	9.1	9.1

Table 3 Post-operative gain in the PORP and TORP groups at different follow-up times

	PORP		TORP	
	Mean	SD	Mean	SD
2 years	25.8	13.6	27	15.9
5 years	22.6	16.6	24.5	15.6
10 years	22.2	17.7	23	17.6

TORP

In 22 cases the prosthesis was placed on a mobile footplate. The mean preoperative ABG was 31.6 dB HL (SD 11.9 dB HL).

At two years the mean ABG was 14.4 dB HL (SD 8.14 dB HL). In 17 cases (63.6%) the ABG was < 20 dB HL and in 21 (95.45%) it was < 30 dB HL.

At five years the mean ABG was 16.9 dB HL (SD 9 dB HL). In 14 cases (63.6%) the ABG was < 20 dB HL and in 20 (90.9%) it was < 30 dB HL.

At the 10-years follow-up the mean ABG was 18.4 dB HL (SD 9.9 dB HL) (Table 1). In 16 cases (72.72%) the ABG was < 20 dB HL and in 20 (90.9%) it was < 30 dB HL (Table 2).

Statistical analysis revealed that the postoperative ABG was significantly lower than both the preoperative and pre 2nd stage ABG at 2 years, 5 and 10 years ($P < 0.05$). The average gain decreased slightly and not significantly over time (Table 3).

When the PORP and TORP groups were compared we found that the only significant difference ($P = 0.0188$) was in the mean pre-operative ABG. The two groups did not differ in terms of postoperative ABGs; in addition the postoperative gain did not differ.

Postoperative bone conduction change

The average postoperative high frequency bone conduction change in all the ossiculoplasty procedures was 5.2 dB HL (SD 12.6 dB HL). In two cases (4.5%) the average bone conduction threshold decreased by more than 10 dB HL, in 26 (64.6%) it remained stable and in 12 it increased by more than 10 dB HL (30.6%). No dead ears were encountered postoperatively.

Failures after the second-stage operation

In two patients recurrent cholesteatoma occurred; a revision canal wall tympanoplasty was performed in one patient and a revision intact canal wall tympanoplasty in the other patient. In one patient a perforation of the TM occurred and was not repaired. In four patients a retraction pocket occurred. Functional revision was needed in one patient where the prosthesis was replaced twice because it was found to be short the first time and malacic the second time.

No cases of extrusion were encountered and to our knowledge no infectious disease or Creutzfeld Jakob disease (CJD) has so far developed in any patient.

Discussion

Our results show that the use of a homologous costal cartilage prosthesis is associated with good and stable postoperative hearing and a low incidence of failures. The long-term hearing function in ears reconstructed with either a PORP or a TORP remained stable over time. The postoperative ABGs were significantly lower than the preoperative ABGs at all follow-up times and the postoperative hearing gain decreased slightly and not significantly over time. The number of patients with a functional failure (ABG >30 dB HL) at 10 years was between 9 and 11%.

As previously noted, in this group of patients the presence of the stapes superstructure influenced only the preoperative ABG but not the postoperative hearing. Both partial and total prostheses had the same mean postoperative gain when the ABG preceding the second-stage operation, and thus the ossiculoplasty, was considered. However the percentage of patients with an ABG of 0–20, although not significant, was higher in the PORP group than in the TORP group at 2 and 5 years, while at 10 years no differences were evident.

Goode and Nishihara [14] reported that the “ideal” ossiculoplasty should have the following characteristics: (a) prosthesis mass lower than 40 mg; (b) proper tension of the prosthesis; (c) angle between TM and the stapes less than 45 degrees; (d) prosthesis with a head angled at about 30 degrees in order to increase the surface area connected to the TM.

Costal cartilage prostheses let us perform ossicular chain reconstruction procedures that fulfill all these requirements. T shaped cartilage prostheses have a weight

not exceeding 40 mg; in addition we can sculpture prostheses of the required shape and length with extreme ease according to the intraoperative findings. The angle with the stapes footplate or superstructure often approximates to 0 degrees; in fact the head of the prostheses is placed under the TM, not under the malleus, and the angle between the head and the shaft can be varied according to the intraoperative findings. The proper tension for the prostheses is obtained by trimming the shaft. Performing the ossiculoplasty during the second-stage operation lets us insert the prostheses when the TM is intact and the middle ear space is stable, making the operation easier.

Both the partial and total chondroprostheses showed good stability over time and the number of functional revisions required was negligible. Although the TORP shaft is longer and thinner than in a PORP, chondromalacia and resorption did not occur more frequently than in the PORP group. The reason for the long-term stability of these prostheses could be found in both the physical characteristics of the material and the stability of the middle ear cavity.

Costal cartilage is thicker and more resistant than the conchal or tragal cartilage which is usually used in middle-ear surgery. The use of 1×1 cm cartilage blocks lets us sculpture very robust prostheses that seldom necrose or lose their stiffness. The stability of the middle ear space and the low rate of anatomical failures encountered in this consecutive series contribute to the stability of the prostheses.

In short-term follow-up studies several authors [4, 5, 9, 11, 13, 15, 16, 19, 21, 22, 24, 25] reported that an ABG of < 20 dB HL was reached in from 49 to 100% of ears when a fitted incus or a synthetic partial prosthesis (polyethylene, ceramic or gold) was used and in from 43 to 85% of ears when a total prosthesis was used.

At middle-term follow-up (3–5 years), Smyth [25] reported that with a Plastipore® partial prosthesis 43% of patients had an ABG of < 10 dB HL, and with a total prosthesis 22% had an ABG of < 10 dB HL; Mangham and Lindeman [19] and Grote [15] noticed that with partial synthetic (Plastipore®, Ceravital and hydroxylapatite) prostheses the percentage of ears reaching an ABG of < 20 dB HL ranged from 54% to 100% while with total prostheses the percentage of ears reaching an ABG < 2 dB HL ranged from 25 to 66%.

Farrior and Nichols [10] reported that in their experience with autologous ossicular grafts at 5 years the 57% of cases reconstructed with a total ossicular chain prosthesis had an ABG lower than 15 dB HL while at 10 years only 28% retained the same ABG. At long-term follow-up (10 years) patients with the stapes had a mean ABG of 18.7 dB HL and patients without the stapes had a mean ABG of 28 dB HL. Fifty per cent of the ears reconstructed with a partial prosthesis had an ABG of < 15 dB HL while only the 28% reconstructed with a total prosthesis had an ABG of < 15 dB HL.

Although similar, the results of this study should be only cautiously compared with those reported by other authors because of the wide differences in the analyses of the hearing data and the very few reports of long-term hearing results (> 3 years).

The rate of complications described in this series was very low. No cases of dead ear were encountered, probably because of the elasticity of the cartilage that rarely traumatizes the inner ear, and there were no cases of extrusions. Chole and Kim [7] in a series of 187 ossiculoplasties performed with cartilage prostheses reported no extrusions. The extrusion rate of synthetic materials used for ossicular chain reconstruction is quite variable: high for the Plastipore prostheses [5, 13, 18, 22, 24], lower for the hydroxyapatite, ceramic and composite prostheses [4, 9, 11, 13, 15, 21]. The risk of extrusion is low, as it is for ossicles; however, unlike ossicles, cartilage does not fix the scutum, the promontory or the facial nerve [10].

The safety of ossicular homografts has been questioned, especially concerning transmission of the acquired immunodeficency syndrome (AIDS) and CJD [12]. To our knowledge, although we have used cartilage homografts since 1984, no case of infectious disease has occurred after cartilage transplantation. We believe that the clinical and serological screening to which organ donors are submitted, the treatment of the cartilage with rifampicin and ethanol, and the minimal vascularization of this tissue significantly reduce the risk of infection.

The efficacy of ethanol in killing the human immunodeficency virus has been previously shown [1, 23]; moreover there has been no report of transmission of CJD after tympano-ossicular homografts [6]. To date the best way to protect people from CJD remains clinical and pathological screening [20].

The present study proposes costal cartilage as the material of choice when autologous ossicles are not available. In fact this cartilage has proven to have all the features the ideal prosthesis should have: availability, versatility, biocompatibility and low cost.

References

1. Asselmaier MA, Caspari RB, Bottonfield S (1993) A review of allograft processing and sterilization techniques and their role in transmission of human immunodeficency virus. Am J Sports Med 21:170–175
2. Belal A Jr, Linthicum FH Jr, Odnert S (1981) Fate of cartilage autografts for ossiculoplasty: An electron microscopic study. Clin Otolaryngol 6:231–236
3. Belal A Jr, Sanna M, Gamoletti R (1984) Pathology as it relates to ear surgery. V: Ossiculoplasty. J Laryngol Otol 98:229–240
4. Black B (1991) A universal ossicular replacement prosthesis: Clinical trials of 152 cases. Otolaryngol Head Neck Surg 104: 210–218
5. Brackmann DE, Sheehy JL, Luxford WM (1984) TORPs and PORPs in tympanoplasty: A review of 1042 operations. Otolaryngol Head Neck Surg 92:32–37
6. Brown P, Preece MA, Will RG (1992) "Friendly fire" in medicine: hormones, homografts and Creutzfeld-Jakob disease. Lancet 340:24–27
7. Chole RA, Kim HJ (1996) Ossiculoplasty with presculpted banked cartilage. Oper Tech Otolaryngol-Head Neck Surg 7: 38–44

8. Committee on Hearing and Equilibrium: Guidelines for the evaluation of results of treatment of conductive hearing loss (1995) Otolaryngol Head Neck Surg 113:186–187
9. Dornhoffer JL (1998) Hearing results with the Dornhoffer ossicular replacement prostheses. Laryngoscope 108:531–536
10. Farrior JB, Nichols SW (1996) Long-term results using ossicular grafts. Am J Otol 17:386–392
11. Gjuric M, Schagerl S (1998) Gold prostheses for ossiculoplasty. Am J Otol 19:273–276
12. Glasscock ME, Jackson CG, Knox GW (1988) Can acquired immunodeficency syndrome and Creutzfeld-Jakob disease be transmitted via otologic homografts? Arch Otolaryngol Head Neck Surg 114:1252–1255
13. Goldemberg R (1992) Hydroxylapatite ossicular replacement prostheses: results in 157 consecutive cases. Laryngoscope 102:1091–1096
14. Goode R, Nishihara S (1994) Experimental model of ossiculoplasty. Otolaryngol Clin N Am 27:663–675
15. Grote JJ (1990) Reconstruction of the middle ear with hydroxylapatite implants: long-term results. Ann Otol Rhinol Laryngol 144:12–16
16. Jackson CG, Glasskock ME, Schwaber MK, Nissen AJ, Christiansen SG, Smith PG (1983) Ossicular chain reconstruction: the TORP and PORP in chronic ear disease. Laryngoscope 93:981–988
17. Kerr AG, Byrne JE, Smyth GDL (1973) Cartilage homografts in the middle ear: A long term histological study. J Laryngol Otol 87:1193–9
18. Mair IW, Pedersen S, Laukli E (1989) Audiometric results of TORP and PORP middle ear reconstruction. Ann Otol Rhinol Laryngol 98:429–433
19. Mangham CA, Lindeman RC (1990) Ceravital versus plastipore in tympanoplasty: a randomized prospective trial. Ann Otol Rhinol Laryngol 99:112–116
20. Meylan PRA, Duscher A, Mudry A, Monnier P (1996) Risk of transmission of human immunodeficency viral infection during tympano-ossicular homograft: an experimental study. Laryngoscope 106:334–337
21. Nikolaou A, Bourikas Z, Maltas V, Aidonis A (1992) Ossiculoplasty with the use of autografts and synthetic prosthetic materials: A comparison of results in 165 cases. J Laryngol Otol 106:692–694
22. Sanna M, Gamoletti R, Scandellari R, P. Delogu, Magnani M, Zini C (1985) Autologous fitted incus versus Plastipore™ PORP in ossicular chain reconstruction. J Laryngol Otol 99: 137–141
23. Sattar SA, Springthorpe VS (1991) Survival and disinfectant inactivation of the human immunodeficency virus: a critical review. Rev Infect Dis 13:430–447
24. Silverstein H, McDaniel AB, Lichtenstein R (1986) A comparison of PORP, TORP and incus homograft for ossicular reconstruction in chronic ear surgery. Laryngoscope 96:159–165
25. Smyth GDL (1982) Five-years report on partial ossicular replacement prostheses and total ossicular replacement prostheses. Otolaryngol Head Neck Surg 90:343–346
26. Smyth GDL, Kerr AG, Hassard TH (1977) Homografts materials in tympanoplasty. Otolaryngol Clin N Am 10:563–580
27. Steinbach E, Pulsakar A (1981) Long-term histological fate of cartilage in ossicular reconstruction. J Laryngol Otol 95:1031–1039
28. Yamamoto E, Iwanaga M, Fukumoto M (1988) Histologic study of homograft cartilages implanted in the middle ear. Otolaryngol Head Neck Surg 98:546–551
29. Zini C (1970) Homotransplantation de dent en tympanoplastie. Rev Laryngol 91:258–61
30. Zollner F (1955) The principles of plastic surgery of the sound conducting apparatus. J Laryngol 69:637