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Otology

Cartilage ossiculoplasty in cholesteatoma surgery: hearing results and prognostic factors

Risultati uditivi e fattori prognostici nell'ossiculoplastica con cartilagine in pazienti affetti da otite cronica colesteatomatosa

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SUMMARY

Cartilage tympanoplasty is an established procedure for tympanic membrane and attic reconstruction. Cartilage has been used as an ossiculoplasty material for many years. The aim of this study was to evaluate hearing results of costal cartilage prostheses in ossicular chain reconstruction procedures in subjects operated on for middle ear cholesteatoma and to determine the presence of prognostic factors. Candidates for this study were patients affected by middle ear cholesteatoma whose ossicular chain was reconstructed with a chondroprosthesis. 67 cases of ossiculoplasty with total (TORP) or partial (PORP) chondroprosthesis were performed between January 2011 and December 2013. 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 were followed and pure-tone average (PTA) was calculated as the mean of 0.5, 1, 2 and 4 kHz thresholds. Statistical analysis was performed with ANOVA tests and regression models. Average air-bone gap (ABG) significantly improved from 39.2 dB HL (SD 9.1 dB HL) to 25.4 dB HL (SD 11 dB HL) ($p < 0.001$). Linear regression analysis showed that the only prognostic factor was the type of operation ($p = 0.02$). In fact, patients submitted to ICWT presented better post-operative ABG compared to CWDT. None of the other variables influenced the results. The present study proposes costal cartilage as material of choice when autologous ossicles are not available. The maintenance of the posterior canal wall was the only prognostic factor identified.

KEY WORDS: Ossiculoplasty • Cholesteatoma • Ossicular Prosthesis • Surgery

RIASSUNTO

La cartilagine è comunemente utilizzata per la ricostruzione della membrana timpanica e dell'attico in corso di timpanoplastica. Nella nostra esperienza la cartilagine costale omologa è stata utilizzata per molti anni per la creazione di protesi ossiculari. Scopo di questo studio è stato quello di valutare i risultati funzionali dell'ossiculoplastica con condroprotesi e di identificare fattori prognostici. Abbiamo valutato pazienti affetti da otite media cronica colesteatomatosa la cui catena ossiculare è stata ricostruita mediante condroprotesi. 67 soggetti sono stati sottoposti a ossiculoplastica totale (TORP) o parziale (PORP) tra gennaio 2011 e dicembre 2013. Per la valutazione dei risultati uditivi sono state utilizzate le Linee Guida della "Committee on Hearing and Equilibrium" dell'American Academy of Otolaryngology Head and Neck. L'analisi statistica dei risultati è stata eseguita con test ANOVA e modelli di regressione lineare. Il gap via aerea-via ossea (ABG) migliorava significativamente dopo ossiculoplastica da 39,2 dB HL (DS 9,1 dB HL) a 25,4 dB HL (DS 11 dB HL) ($p < 0,001$). L'analisi statistica ha dimostrato che l'unico fattore prognostico è stato il tipo di tecnica chirurgica utilizzata. Infatti, i pazienti sottoposti a timpanoplastica chiusa hanno presentato miglior ABG postoperatorio rispetto alla timpanoplastica aperta ($p = 0,02$). Tutte le altre variabili analizzate non hanno influenzato i risultati uditivi. La cartilagine costale è il nostro materiale scelta per la creazione di protesi ossiculari quando gli ossicini autologhi non sono disponibili. La tecnica chirurgica (timpanoplastica chiusa) si è dimostrata quale unico fattore prognostico positivo.

PAROLE CHIAVE: *Ossiculoplastica • Colesteatoma • Protesi Ossiculare • Chirurgia*

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Introduction

The reconstruction of the ossicular chain was first described by Zöllner [1] in 1955, since then several attempts have been made and several materials, biologic and synthetic, have been proposed for ossiculoplasty. The use of synthetic prosthesis in ossiculoplasty procedures is related to the fact that in cholesteatoma surgery autologous ossicles are rarely available for the reconstruction of the ossicular chain. Recently, Albera et al. [2] reported that 82% of patients affected by cholesteatoma present resorbed ossicles during surgery. Although ossicles can be safely utilised without the risk of cholesteatoma recurrence [3], in our experience they can rarely be used to sculpt valid ossicular prostheses.

Among synthetic materials, titanium has been used in os-

siculoplasty, and the results obtained with partial and total titanium prosthesis in intact canal wall tympanoplasty (ICWT) have been recently reported by our group. At 2 years follow-up, mean postoperative air-bone gap (ABG) was 24.1 dB HL in partial chondroprosthesis (PORP) and 27.2 dB HL in total chondroprosthesis (TORP), 5.1% of the prosthesis extruded and 10.5% of the patients required revision ossiculoplasty [4].

The most frequent problem encountered with titanium prostheses is the risk of extrusion. Recently, Pringle et al. [5] reported an extrusion rate of 6,8%, while Yung and Smith [6] reported that 8 of 38 titanium prostheses extruded at 24 months even with cartilage interposition.

As a biological alternative to ossicles, cartilage has been extensively used in tympanoplasty and ossiculoplasty [7]. Autologous tragal and/or conchal cartilage are, however, not always suitable for ossicular chain reconstruction, especially in cases where the stapes arch is missing since they do not have the required mass, stiffness and thickness. Ossicular prostheses made from blocks of homologous costal cartilage were introduced in ear surgery by Carlo Zini in 1984 (personal communication). In 2000, the long-term results obtained with homologous costal cartilage prostheses in subjects affected by cholesteatoma undergoing ICWT were reported by Quaranta et al. [8]. The authors reported no extrusion at 10 years follow-up with stable functional results over the years.

The aim of this study is to evaluate the factors influencing hearing results when cartilage prostheses were used for ossicular chain reconstruction in a group of patients affected by middle ear and mastoid cholesteatoma and operated by the same surgeon.

Materials and methods

Between January 2011 and December 2013, 67 ossiculoplasty procedures were performed in our department. Candidates for this study were patients affected by middle ear and mastoid cholesteatoma (both primary and recurrent) whose ossicular chain was reconstructed with homologous costal cartilage.

The study group consisted of 67 patients. Mean patient age was 45 years (range 7-79 years); 34 were males and 33 females. The ossiculoplasty was performed during the first or the second stage of tympanoplasty in 41 patients undergoing primary surgery, during revision ossiculoplasty in 13 patients and during the first or the second stage of revision tympanoplasty in 13 patients affected by recurrent cholesteatoma. The ossicular chain was reconstructed with a PORP when the stapes arch was present or with a TORP when the stapes arch 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 [9] were followed and pure-tone average (PTA) was calculated as the mean of 0.5, 1, 2 and 4 kHz thresholds. 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 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. Minimum follow-up was 6 months. All patients signed an informed consent form and the work was performed in accordance with the principles of the 1983 Declaration of Helsinki.

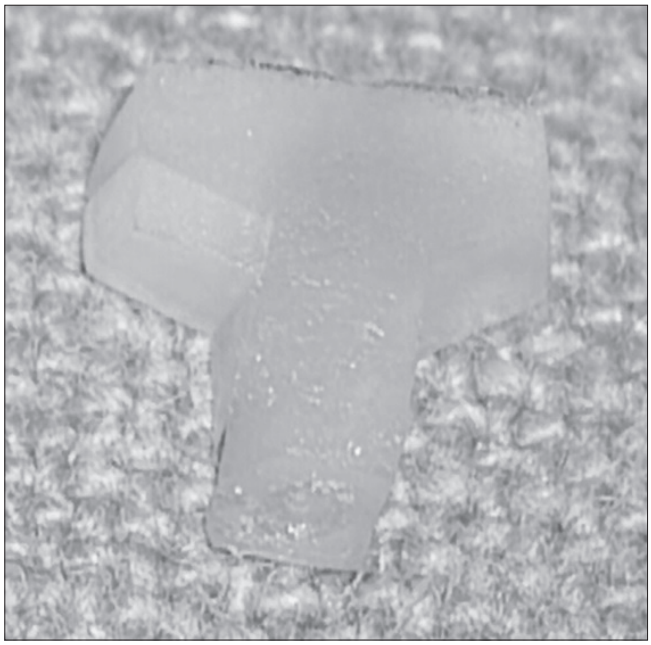

Fig. 1. T-shaped partial ossicular replacement prostheses.

Surgical technique

1 × 1 cm costal cartilage blocks were obtained by the "Banca del Tessuto Muscolo-Scheletrico" of the Istituto Ortopedico Rizzoli, Bologna, Italy. The prosthesis is sculpted from the cartilage block as previously described [8]. Briefly, after the exact distance between the tympanic membrane (TM) and the stapes or the footplate has been determined, a T shaped chondroprosthesis is prepared (Fig. 1). When the stapes is present and mobile, a PORP is sculpted with a small indentation for stapes capitulum (1 mm wide and 0.5-1 mm in depth) at the end of the shaft. When the stapes superstructure is absent, a TORP is prepared. 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 (Fig. 2). When the prosthesis is in its appropriate position, it can be stabilised with fibrin glue or a gelatin sponge. In the present series, in all cases the prostheses was placed under the malleus handle, but always parallel to it when it was present.

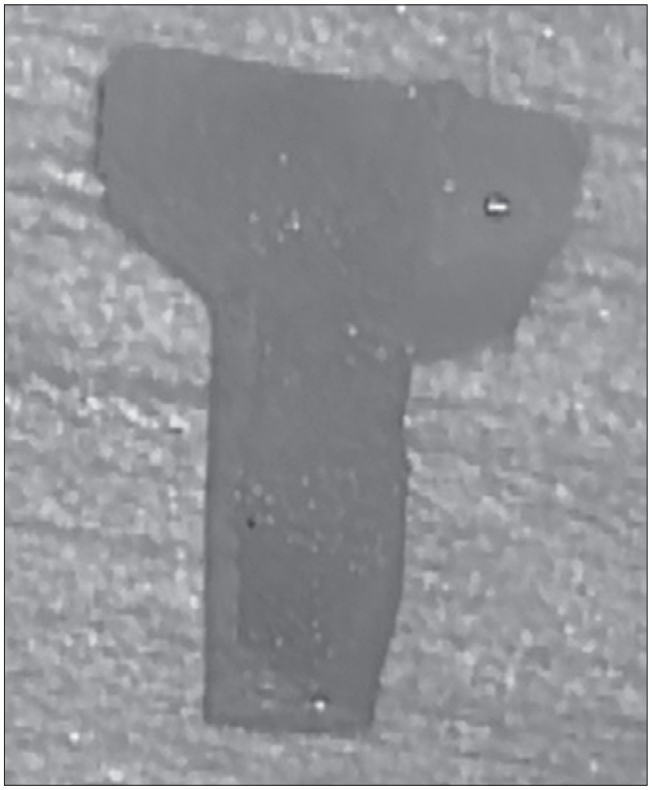

Fig. 2. T-shaped total ossicular replacement prostheses.

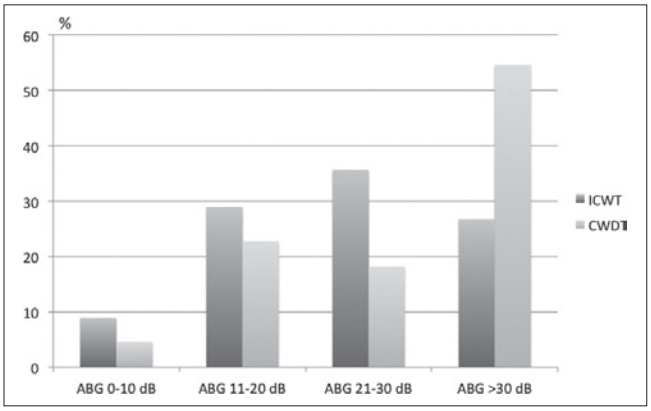

Fig. 3. Percentage of patients with different air-bone gap according to the technique used. CWDT: canal wall down tympanoplasty; ICWT: intact canal wall tympanoplasty.

Table I. Regression analysis of the factors influencing post-operative air bone gap.

Independent variable	p value
Type of tympanoplasty (ICWT *vs* canal wall down-CWDT)	0.02
Type of prosthesis (PORP *vs* TORP)	> 0.05
Pre-operative ABG	> 0.05
Type of surgery (primary *vs* revision)	> 0.05
Staging (yes *vs* no)	> 0.05
Side (right *vs* left)	> 0.05
Age (< 60 yr *vs* > 60 yr)	> 0.05
Sex (male *vs* female)	> 0.05

Statistical analysis

Multiple linear regression analysis was performed on the entire group. Post-operative ABG was considered the dependent variable, while independent variable were: type of surgery (primary *vs* revision); type of tympanoplasty (ICWT *vs* canal wall down-CWDT), staging (yes *vs* no), pre-operative ABG; type of prosthesis (PORP *vs* TORP), side (right *vs* left), age (< 60 yr *vs* > 60 yr), sex (male *vs* female). In addition, patients were split in three groups according to the type of surgery. The ANOVA test was used to compare the three groups and paired t-test was used to evaluate the significance of post-operative hearing change. Statistical software (Statistica 8.0) was used for analysis.

Results

In the entire group, average ABG significantly improved from 39.2 dB HL (SD 9.1 dB HL) to 25.4 dB HL (SD 11 dB HL) ($p < 0.001$). Linear regression analysis showed that the only prognostic factor was the type of surgery ($p = 0.02$). In fact, patients submitted to ICWT presented better post-operative ABG than CWDT. The pre-operative ABG was 37.9 dB HL (SD 8.9 dB HL) in patients submitted to ICWT and 38.6 dB HL (SD 9.4 dB HL) in patients submitted to CWDT. The mean postoperative ABG was, respectively, 23.3 dB HL (SD 10 dB HL) and 29.6 dB HL (SD 12 dB HL). Chi-square analysis showed that the number of patients submitted to ICWT with a post-operative ABG 0-20 dB was significantly higher than patients submitted to CWDT ($p = 0.02$) (Fig. 3). None of the other variables influenced post-operative ABG in regression analysis (Table I). Statistical analysis showed a significant improvement of the hearing in both groups ($p < 0.001$) and no effect of the type of prosthesis on post-operative hearing results.

Postoperative bone conduction change

The average postoperative high frequency bone conduction change in all ossiculoplasty procedures was 3.1 dB HL (SD 7.8 dB HL). In 7 cases (10.4%), the average bone conduction threshold decreased by more than 10 dB HL, in 2 cases (2.9%) by more than 20 dB and in 58 cases (85.5%) remained stable or improved. No post-operative dead ears were encountered.

Failures after the second stage operation

At short-term follow-up, no cases of extrusion or anatomical failures were recorded.

Discussion

Our results show that in patients affected by middle ear and mastoid cholesteatoma the use of homologous costal cartilage prosthesis is associated with a significant improvement of postoperative hearing and a low incidence of failures. Goode and Nishihara [10] reported that the "ideal" ossiculoplasty should have the following characteristics: (a) prostheses mass < 40 mg; (b) proper tension of the prostheses; (c) angle between TM and the stapes < 45°; (d) prostheses with a head angulated at about 30° to increase the surface area connected to the TM. As previously reported [8], costal cartilage prostheses allows ossicular chain reconstruction procedures that fulfil all these requirements. T shaped cartilage prostheses, in fact, have a weight that does not exceed 40 mg and can be sculptured in the required shape and length with extreme ease according to the intra-operative findings. The angle with the stapes footplate or superstructure often approximate 0° when the head of the prostheses is placed under the TM, and the angle between the head and the shaft can be varied according to the intraoperative findings. Finally, the proper tension of the prostheses is obtained by trimming the shaft.

In this study, we have also evaluated the presence of prognostic factors in cartilage ossiculoplasty in a homogeneous population of patients affected by middle ear and mastoid cholesteatoma. Multiple linear regression showed that maintenance of the posterior canal wall was the only prognostic factor. Several authors have reported better hearing results in ICWT than in CWDT [11-13], while others have reported similar results in both techniques when the ossicular chain was reconstructed [14-16.] Recently, Fayad et al. [17] showed that in the absence of the stapes superstructure the presence of a "cavity" was associated with poorer hearing results. In the present series, although most of the patients submitted to CWDT were affected by recurrent cholesteatoma, statistical analysis showed that the average hearing results in primary and revision surgery were not significantly different, and therefore the surgical technique was the only prognostic factor. The difference between ICWT and CWDT has been often ascribed to poorer eustachian tube function and greater severity of disease in cases requiring a CWD procedures [17]. We think that considering these reasons, the anatomy of a small middle ear cleft renders the prosthesis less effective, especially when the stapes superstructure is absent.

In the present series, the presence of the stapes superstructure did not influence post-operative hearing. The presence of the stapes superstructure has been proposed as a significant predictor by some authors [18-20], while other authors did not find a significant correlation with hearing outcome [21 22]. In our experience, the presence of the stapes does not influence short- or long-term hearing results [8]. Although the presence of the malleus handle has been reported to be the most important determinant in ossiculoplasty success [18 21-23], in the present series we could not evaluate this factor since the prosthesis we use is placed parallel to the malleus handle and not under the handle. In addition, all subjects were affected by cholesteatoma, and the handle was missing in most cases.

The rate of complications described in this series was very low. No cases of dead ear, probably due to the elasticity of the cartilage that rarely traumatises the inner ear, and no cases of extrusions were encountered. The extrusion rate of titanium prosthesis has been reported to be between 5% and 20% [4-6]. Chole [24], in a series of 187 ossiculoplasties performed with cartilage prosthesis, reported no extrusions. We have previously reported no cases of extrusion at long-term (10 years) follow-up [8]. Unlike ossicles, that do not extrude, cartilage does not fix the scutum, the promontory, or the facial nerve with subsequent worsening of hearing [25].

The safety of ossicular homografts has been questioned, especially concerning the transmission of acquired immunodeficiency syndrome and the Creutzfeld-Jakob Disease [26]. The cartilages we use are provided by a tissue bank approved by the Italian Ministry of Health that meet all the required regulations for infectious disease prevention.

Conclusions

The present study proposes costal cartilage as the material of choice when autologous ossicles are not available. In terms of hearing improvement, the maintenance of the posterior canal wall was the only prognostic factor identified.

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