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Original article

Total and partial ossiculoplasty in children: Audiological results and predictive factors

J. Dumont [a,*], M. Abouzayd [a], A. Le Louarn [b], S. Pondaven [a], D. Bakhos [a,c], E. Lescanne [a,c,**]

[a] Service d'ORL et de chirurgie cervico-faciale, CHRU Bretonneau, faculté de médecine, université de Tours, 2, boulevard Tonnellé, 37000 Tours, France
[b] Service d'information médicale, épidémiologie et économie de la santé, CHRU Bretonneau, 2, boulevard Tonnellé, 37000 Tours, France
[c] Inserm U930 "Imagerie et Cerveau", faculté de médecine, 10 Bd Tonnellé, 37000 Tours, France

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ABSTRACT

Objective: To assess ossiculoplasty results in children and screen for predictive factors of efficacy.
Patients and methods: Seventy five children undergoing ossiculoplasty between 2001 and 2014 in a pediatric ENT department were included. The following data were collected and analyzed: demographic data, surgical indication, history of tympanoplasty, contralateral ear status (healthy, affected), preoperative hearing thresholds, surgical technique, intraoperative findings, and ossicular chain status at eardrum opening. Audiological results were reported according to American Academy of Otolaryngology-Head and Neck Surgery guidelines.
Results: Forty eight patients were included in the total ossicular reconstruction prosthesis (TORP) group. Mean age at surgery was 9.9 years. Mean follow up was 2.7 years. Mean air-bone gap (ABG) closure to within 20 dB was achieved in 40% of cases at medium term (12 to 18 months after surgery). Air conduction (AC) threshold $\leq$ 30 dB was achieved in 68% of cases. AC threshold improved by 14.6 dB and 8.7 dB at medium and long-term follow-up, respectively. A significant correlation was found between success rate and absence of history of tympanoplasty. The success rate was higher for primary than for revision procedures. Twenty seven children were included in the partial ossicular reconstruction prosthesis (PORP) group. Mean age was 9.5 years, and mean follow-up 2.6 years. Mean air-bone gap (ABG) closure to within 20 dB was achieved in 75% of cases at medium term. AC threshold $\leq$ 30 dB was achieved in 75% of cases AC threshold improved by 9.3 dB and 5 dB at medium and long-term follow-up, respectively. No predictive factors for success were found in the PORP group.
Conclusion: The present study suggested that total ossiculoplasty leads to better results when performed in first-line. It also confirmed that functional outcome is better in partial than total ossicular reconstruction prosthesis.

1. Introduction

Unilateral hearing loss affects language development, cognition and learning [1,2]. Auditory rehabilitation is therefore essential in children, to ensure optimal development. Unilateral conduction hearing loss is mainly secondary to chronic otitis media, with or without cholesteatoma [3]. Ossicular chain involvement is found in more than 80% of cases of chronic otitis with cholesteatoma. The incus is usually involved, and in almost half of cases more than one ossicle is affected [4–6].

Current ossiculoplasty techniques to restore sound-wave transmission use biocompatible materials. Titanium is the most widely used, being light-weight and perfectly tolerated [7]. Efficacy studies in childhood ossiculoplasty report very variable success rates, from 19% [8] to 80% [9]. The explanatory or predictive factors are unclear.

The present study of titanium implant ossiculoplasty analyzed audiometric results in a pediatric series to screen for predictive factors for efficacy.

2. Patients and method

To assess ossiculoplasty results in a pediatric population, a retrospective study was conducted on files of patients operated on in the pediatric ENT department of our University Hospital Center. The list of patients was taken from the implanted medical

* Corresponding author.
** Co-corresponding author.
E-mail addresses: juliedumont18@hotmail.fr (J. Dumont), lescanne@univ-tours.fr (E. Lescanne).

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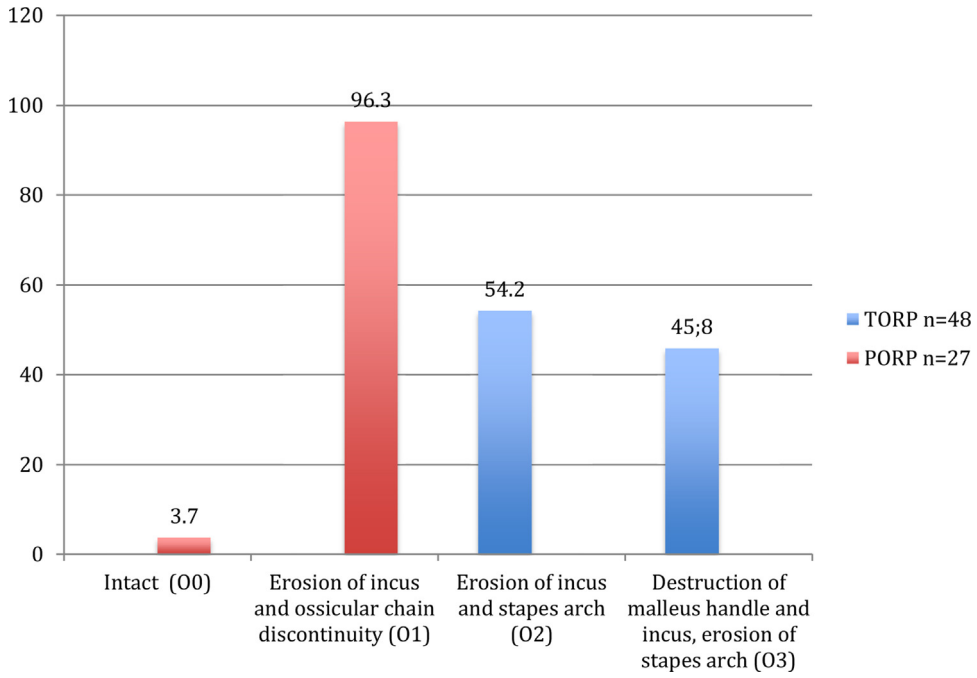

Fig. 1. Distribution between TORP ($n = 48$) and PORP groups ($n = 27$) according to ossicular chain involvement on the Saleh-Mills classification.

device registry of the hospital pharmacy for the period November 2001 through December 2014, during which 100 patients underwent ossiculoplasty. Patients were aged < 17 years at surgery, with tympanoplasty performed by a senior otologist. All had ossicular reconstruction using a partial (PORP) or total (TORP) Kurz TTP Variac ossicular reconstruction prosthesis. Patients with history of ossiculoplasty were excluded; 25 patients were also excluded at the initial phase for lack of any postoperative audiogram in the file.

The tympanic membrane was repaired by cartilage graft. In chronic otitis, ossicles were removed according to the requirements for lesion resection. The modeling cartilage technique was used, following Gaillardin et al. [10]. Ossicular reconstruction used PORP when the stapes was intact and TORP if the superstructure was damaged. In posterior tympanotomy, implant positioning was adjusted via the facial recess [11] on our routine technique [12]. Postoperative follow-up was in the pediatric ENT unit. Otoscopy assessed the anatomic result of the tympanoplasty and screened for ossicular prosthesis extrusion. Hearing was assessed in a soundproof booth, under the same conditions as for the preoperative work-up.

The following data were analyzed: demographic data, surgical indication, history of tympanoplasty, contralateral ear status (healthy, affected), preoperative hearing thresholds, surgical technique, intraoperative revelation of cholesteatoma, and ossicular chain status at eardrum opening on the Saleh-Mills classification [13]. Auditory results were reported according to the AAO-HNS (American Academy of Otolaryngology-Head and Neck Surgery) criteria [14] within 6 months (short term), at 12–18 months (medium term) and later than 18 months (long term). Air and bone-conduction thresholds were measured at 500, 1000, 2000 and 4000 Hz. Functional success was defined as air-bone gap (ABG) ≤ 20 dB (main endpoint). The secondary endpoint was achievement of an air-conduction (AC) threshold ≤ 30 dB. AC gain was also assessed. Sensorineural hearing loss was defined by ≥ 20 dB gain in bone-conduction (BC) threshold at 4 kHz [15]. In case of functional failure, prosthesis displacement was screened for on CT scan. In case of revision surgery, post-revision audiograms were not analyzed.

Two groups were distinguished according to type of prosthesis, and predictive factors for success were analyzed according to group. Significant correlations were sought between candidate factors and ABG ≤ 20 dB. Qualitative variables were assessed on chi^2 test, or Kruskal-Wallis test in case of insufficient numbers. The significance threshold was set at 5%; correlations were interpreted on odds ratio (OR) and 95% confidence intervals (95% CI). Before/after comparison of hearing thresholds and analysis of other quantitative variables used Student t test, or Fisher test in case of insufficient numbers. Data were entered in Microsoft Excel™ spreadsheets and analyzed on Epi-Info™ software.

3. Results

Seventy five patients were included: 48 TORP and 27 PORP.

In the TORP group, the male-to-female sex ratio was 1.66. Mean age was 9.9 ± 3.6 years. Median follow-up was 2.7 years. The left ear was operated on in 20 cases (41.7%). Initial diagnosis was chronic otitis media (cholesteatoma, atelectasis, retraction pocket) in 46 cases (95.8%), traumatic ossicular injury in 1, and minor aplasia in 1. Fifteen children (15.3%) had no history of tympanoplasty, 23 (47.9%) had undergone 1 procedure, and 10 (20.8%) had undergone 2 or more. The contralateral ear was healthy in 20 cases.

Tympanoplasty involved cholesteatoma resection in 31 cases (64.6%), with associated posterior tympanotomy in 29 (60.4%). In 3 cases (6.2%), open surgery was performed. Fig. 1 shows ossicular chain injury on the Saleh-Mills classification. During follow-up, there were 2 cases of prosthetic extrusion: 1 at medium term, 1 at long term. There were 6 cases of prosthetic dislocation, revealed on temporal CT or at revision surgery. There were 5 cases of recurrence of cholesteatoma and 8 of residual cholesteatoma.

Audiograms were unavailable for 4 patients at short-term, 19 at medium-term and 11 at long-term follow-up. Four patients had undergone revision surgery by medium-term and 7 by long-term follow-up.

Audiometry found normal preoperative hearing in 2 cases (4.2%). Hearing loss was mild in 15 cases (31.3%), moderate in 30 and severe in 1 (2.1%). Tables 1 and 2 show postoperative thresholds and ABGs. In the medium term, ABG ≤ 20 dB was achieved in 40% of cases (Table 3). AC was ≤ 30 dB in 68%. Mean AC gain was 12.6 dB, 14.6 dB and 8.7 dB at short-, medium- and long-term assessment,

Table 1
Mean air conduction thresholds (dB) at various post-ossiculoplasty time points according to type of prosthesis ($n = 75$).

Time point	n	Mean	Standard deviation	Range
Total prosthesis (TORP)	48			
Preoperative	48	45.2	12.8	13.7–72.5
M3-M6	44	32.6	15.6	8.7–72.5
M12-M18	25	30.6	14.4	8.7–67.5
Long term	30	36.5	18.1	15–82.5
Partial prosthesis (PORP)	27			
Preoperative	27	33.9	16.7	6.2–76.2
M3-M6	23	24.6	15.5	5.0–75.0
M12-M18	20	24.6	16.7	5.0–67.5
Long term	11	28.9	21.4	5.0–85.0

Table 2
Mean air-bone gap (dB) at various post-ossiculoplasty time points. ($n = 75$).

Time point	n	Mean	Standard deviation	Range
Total prosthesis (TORP)	48			
Preoperative	48	38.2	11.4	13.7–58.7
M3–M6	44	25.5	12.6	8.7–67.5
M12–M18	25	25.9	14.1	8.7–61.2
Long term	30	27.3	14.8	8.7–63.7
Partial prosthesis (PORP)	27			
Preoperative	27	25.8	10.7	6.2–45.0
M3-M6	23	17.1	10.4	0–46.2
M12-M18	20	15.1	9.3	1.2–36.2
Long term	11	18.1	13.5	5.0–45.0

Table 3
Percentage of patients with air-bone gap ≤ 20 dB and air conduction threshold ≤ 30 dB at various post-ossiculoplasty time points.

Time point	n	ABG ≤ 20 dB			AC threshold ≤ 30 dB		
		n	%	95% CI	n	%	95% CI
Total prosthesis (TORP)	48						
Preoperative	48	3	6.3	0.0–13.2	5	10.4	1.8–19.0
M3-M6	44	19	43.2	28.6–57.8	27	61.4	47.0–75.8
M12-M18	25	10	40.0	20.8–59.2	17	68.0	49.7–86.3
Long term	30	12	40.0	22.5–57.5	12	40.0	22.5–57.5
Partial prosthesis (PORP)	27						
Preoperative	27	7	25.9	9.4–42.4	11	40.7	22.2–59.2
M3-M6	23	17	73.9	56.0–91.8	18	78.3	61.5–95.1
M12-M18	20	15	75.0	56.0–94.0	15	75.0	56.0–94.0
Long term	11	8	72.7	46.4–99.0	7	63.6	46.4–99.0

respectively, with no significant differences. There were 2 cases of sensorineural hearing loss.

Age, gender, side, technique, operated or contralateral ear status and ossicular chain status did not affect functional outcome in TORP.

The number of previous tympanoplasties, on the other hand, did affect functional results, with a significant correlation between absence and short-term success: OR, 5.8 (95% CI, 1.4–2.6; $P = 0.01$. This was confirmed at long-term assessment: OR, 4.9 (95% CI, 0.99–24.2; $P = 0.049$. Short-term success was significantly greater for primary than for revision surgery: respectively 71.4% and 30% ($P = 0.01$ in 44 children). Long-term success rate was 63.6% for primary versus 26.3% for revision surgery ($P = 0.05$ in 30 children).

Preoperative hearing threshold influenced functional outcome. Short-term success was achieved in 73.3% of children with normal hearing or only mild hearing loss, versus 27.6% in case of moderate or severe hearing loss: OR, 7.2; 95% CI, 1.8–29.4; $P = 0.004$. This predictive factor for success was maintained at long-term: 72.7% versus 21.0%; $P = 0.008$.

In the PORP group, the male-to-female sex ratio was 1.2. Mean age was 9.5 ± 3.5 years. Median follow-up was 2.6 years. The left ear was operated on in 16 cases. Initial diagnosis was chronic otitis media (cholesteatoma, atelectasis, retraction pocket) in 23 cases (85.2%), and traumatic ossicular injury in 4. Eighteen children (66.7%) had no history of tympanoplasty, 6 (22.2%) had undergone 1 procedure, and 3 (11.1%) had undergone 2 or more. The contralateral ear was healthy in 11 cases.

Tympanoplasty involved cholesteatoma resection in 20 cases (74.1%), with associated posterior tympanotomy in 13 (60.4%). No open surgery was performed. Fig. 1 shows ossicular chain injury on the Saleh-Mills classification. During follow-up, there were no cases of prosthetic extrusion or dislocation. There was 1 case of recurrence of cholesteatoma and 2 of residual cholesteatoma.

Audiograms were unavailable for 4 patients at short-term, 5 at medium-term and 16 at long-term follow-up. Two patients had undergone revision surgery by medium-term.

Audiometry found normal preoperative hearing in 5 cases (18.5%). Hearing loss was mild in 15 cases (55.6%), moderate in 5 (18.5%) and severe in 2 (7.4%). Tables 1 and 2 show postoperative thresholds and ABGs. In the medium term, ABG ≤ 20 dB was achieved in 75% of cases (Table 3). AC was ≤ 30 dB in 75%. Mean AC gain was 9.3 dB, 9.3 dB and 5 dB at short-, medium- and long-term assessment, respectively, with no significant differences. There were no cases of sensorineural hearing loss.

Age, gender, side, technique, operated or contralateral ear status and ossicular chain status did not affect functional outcome in PORP.

Number of previous tympanoplasties or preoperative hearing threshold did not affect functional results.

4. Discussion

The aim of ossiculoplasty in tympanoplasty is to conserve hearing threshold when normal or improve it in case of conduction hearing loss.

The ideal prosthesis should be biocompatible, stable, and easy to manipulate during surgery [16]. The minimum requirement for good quality ossiculoplasty is the presence of a mobile stapes footplate [17].

The literature reports variable results in childhood ossiculoplasty. In the present series of 75 patients, analyzing results only of primary procedures, PORP achieved both success criteria in 75% of cases in the medium term: hearing threshold ≤ 30 dB and ABG ≤ 20 dB. In TORP, the main endpoint was achieved in 40% of cases and the secondary endpoint in 68%. The usual superiority of PORP was thus confirmed, showing more stable reconstruction when the stapes is intact and mobile [8,15].

In the absence of consensual guidelines, ossiculoplasty results are reported inconsistently, as can be seen in the reports by Nevoux et al. [15], Quesnel et al. [18], Wolter et al. [19], Murphy et al. [8] and Michael et al. [9]. Revision surgery for recurrent or residual cholesteatoma is sometimes included, leading to bias: when the prosthesis has been repositioned, it is no longer the results of the initial ossiculoplasty that are being presented. To avoid this, we halted audiometric follow-up before any revision procedure.

Choice of audiometric parameters, duration of follow-up, patient age, inclusion of adults and children and surgeon experience can all affect functional results. To limit the last of these biases, we included only procedures performed by two senior surgeons. Audiometry rarely measured thresholds at 3000 Hz, as recommended by the AAO-HNS [14], but only at 4 frequencies: 500, 1000, 2000 and 4000 Hz. The subjective nature of audiometry is a further source of bias; it is difficult to execute in children, and requires specific expertise. Patient age moreover progresses over the data collection period. All of this impacts data reliability and reproducibility in pediatric audiometry.

The retrospective study by Nevoux et al. [15] reported results for TORP in 116 children with a mean follow-up of 34 months.

TORP was performed in revision. The rate of ABG ≤ 20 dB was 56%. Prostheses dislocations were not included, as these were treated separately. This methodological difference may explain the difference in results with respect to the present series. Quesnel et al. [18] reported a 51% rate of ABG ≤ 20 dB, at a mean 30 months in a series of 47 TORPs, including 5 revision procedures for prosthesis dislocation. In the present series, TORP results deteriorated over follow-up. Wolter et al. [19] likewise reported long-term deterioration in a series of 71 cases: 40% showed AC ≤ 30 dB at 32 months, compared to 60% at 2 months.

Functional results in PORP were stable over the long term in the present series, like for Murphy et al. [8]. In their series of 28 PORPs in 55 children, ABG was ≤ 20 dB in 43% of cases at 1 year. Quesnel et al. [18] had the same finding in 54% of children, at a longer term (30 months). Michael et al. [9] had better results in a prospective series of 9 children: 78% ABG ≤ 20 dB at 1 year. The superior efficacy of PORP [8,9,18] is due to conservation of the superstructure maintaining the prosthesis and stabilizing the assembly [7,15,20].

Among the predictive factors assessed here, absence of surgery prior to TORP emerged as associated with significantly greater success. This may be due to absence of fibro-inflammatory remodeling, facilitating implantation. The finding is in agreement with Mishiro et al. [21], reporting a cohort of 269 patients. Other series [7,8,15], however, failed to confirm this predictive factor. According to Quesnel et al. [18], functional results are better in second-look than in first-line ossiculoplasty: the prosthesis is more stable, as the cartilage has already been incorporated into the tympanic membrane; discovery of cholesteatoma during revision does not affect results, but initial hearing threshold is a factor for success. Like Murphy et al. [8] and Quesnel et al. [18], we found better TORP results when preoperative hearing was normal or hearing loss was merely mild. Intact malleus handle was often reported to be an factor for success in adult ossiculoplasty [22–26], optimizing assembly stability by maintaining the cartilage and preventing extrusion [16,17].

5. Conclusion

In the present study, ossiculoplasty improved hearing, with a success rate of 75% for PORP and 68% for TORP at 12–18 months. These rates corresponded to the percentage of patients with AC threshold ≤ 30 dB: i.e., with limited or no impairment. Close attention to TORP positioning from the outset is to be recommended, as success in revision is not guaranteed.

Disclosure of interest

The authors declare that they have no competing interest.

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