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Malleostapedotomy for otosclerosis, our experience of nitinol piston on twelve patients

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ABSTRACT

Objective: Malleostapedotomy allows to completely by-pass the incus in otosclerosis surgery. Recently its use has been rivaled by hydroxyapatite cement for cases of mild and moderate necrosis of the incus. However, it remains gold standard for cases of extensive necrosis, incus dislocation, or epitympanic fixation. Modern heat-crimping pistons make surgery easier and safer. This study focuses on our experience with this technique.

Methods: Retrospective analysis of patient's files and pre- and post-operative audiograms, for cases of surgically treated otosclerosis with malleostapedotomy.

Results: Twelve patients underwent malleostapedotomy for otosclerosis between 2011 and 2019. Amongst them there were 10 revision surgeries and 2 primary cases. 75% had incus long-process necrosis, 17% had epitympanic fixation and one had a history of incus transposition. Nine patients (75%) had closure of air-bone gap (ABG) of <10 dB ($p < 0.001$) and 11 (92%) had a threshold of 20 dB ($p < 0.001$). Mean pre-operative ABG was 31 dB (15 dB–55 dB), and mean post-operative ABG was 7 dB (0 dB–21 dB; $p < 0.001$). There was no sensorineural hearing loss nor any other post-operative complication.

Conclusions: Malleostapedotomy is a safe and reliable technique, allowing an ABG closure comparable to conventional incus to vestibule prosthesis. It remains the preferred technique whenever the incus cannot be used.

1. Introduction

Malleostapedotomy, or malleovestibulopexy, is a stapes surgery technique, which objective is to fasten a piston directly on the malleus handle instead of the incus. This technique allows to completely by-pass the incus. (Rambousek et al., 2012) It is mainly used as a revision technique for otosclerosis, when the incus cannot be used (erosion, dislocation, epitympanic fixation). It was also described as an alternative to total ossicular replacement prosthesis in chronic otitis media (Chen et al., 2014; Gluth et al., 2011).

One of the main obstacles to its use is its technical difficulty: inserting the piston shaft into the stapedotomy hole with the correct angle and crimping the loop on the malleus is more difficult than in the classical incus-to-vestibule technique. However, new types of pistons have been developed in the past decades and are easier to set up, increasing the rates of surgical success and reducing the risk for the inner ear. (Burggraaf et al., 2018; Kohan and Sorin, 2003) The use of Nitinol piston tightened by laser heat allows an easy and reliable grip on the malleus.(Babighian et al., 2007)

Recently, hydroxyapatite cement has been increasingly used for mild and moderate incus long-process necrosis, (Pitiot et al., 2016; Van Rompaey et al., 2011) and has even been described in the case of a more extensive erosion.

Nevertheless, malleostapedotomy remains the gold standard for extensive long-process necrosis, dislocated incus, or epitympanic fixation of malleus and incus. (Pitiot et al., 2016)

The present study addresses our experience with malleostapedotomy and Smart Malleus pistons (Nitinol/Fluoroplastic), their indications and the results of their use.

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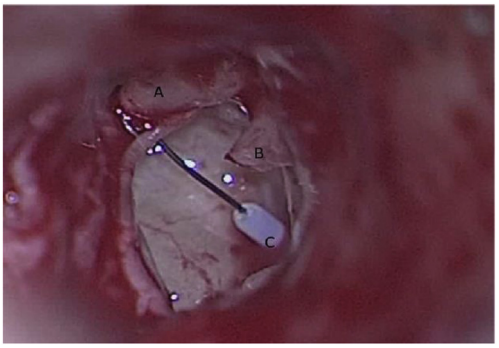

Fig. 1. Intra-operative view of the Nitinol Piston: A: Malleus (piston is placed on the handle, below the lateral process); B: Incus long-process (eroded); C: Platinotomy.

2. Materials and methods

In this monocentric retrospective study, data of patients who underwent malleostapedotomy were extracted from the local database, and included information about the clinical context, surgical technique, and the pre- and post-operative audiograms.

2.1. Ethical concerns

All procedures performed in this study were in accordance with the ethical standards of our institutional research committee (CE_201910129_6_MDL) and with the 1964 Helsinki declaration and its later amendments. Informed consent was obtained from all participants included in this study.

2.2. Patient selection

Patients surgically treated for otosclerosis with malleostapedotomy between May 2011 and March 2019 were identified in the implantable medical device local database of a tertiary care hospital.

2.3. Data collection

Demographics, surgical history, clinical context, and pre- and post-operative audiograms were extracted from patients' records.

2.4. Surgical technique

Under general anesthesia, an endaural incision was carried out, and a tympanomeatal flap was elevated. When necessary, the posterior tympanic spine was removed in order to obtain a correct exposure of the oval window niche, the pyramidal process, and the facial nerve canal. The mobility of the ossicular chain was assessed. The previous piston was removed as well as the remaining incus, whenever necessary. Shrapnel's membrane was elevated from the proximal part of the handle of the malleus. In case of epitympanic fixation of the malleus, the neck and the anterior process were excised and the malleus head was removed. Platinotomy was readjusted with manual perforators to obtain a 0,8 mm opening. The distance between the neck of the malleus and the footplate was estimated using a caliper. The Nitinol piston (SMart Malleus to footplate piston) was inserted and its shaft was angulated so that it would lie perpendicular to the stapes footplate. The piston loop was attached to the malleus handle, just below the lateral process then the shaft was inserted through the platinotomy hole (Fig. 1). The length of shaft penetrating the vestibule was visually checked and adjusted by bending the shaft as needed. The loop was crimped around the malleus with heat from a diode laser (Handylase laser, 3W, pulsed mode, 365µ fiber), allowing an easy and efficient crimping. The laser effect was limited to the loop where the heat was applied, sparing the rest of the prosthesis, especially the bent shaft. The length, axis and mobility of the prosthesis were checked again and the shaft was bent again if necessary. The length, axis and mobility of the prosthesis were checked again. No material was used to seal around the piston.

The metallic loop of the piston was covered with a thin cartilage graft in order to prevent any extrusion.

The tympanomeatal flap was replaced, and a non-resorbable ear wick was inserted for 10 days.

2.5. Outcomes and statistical analysis

Audiometry was analyzed following the American Academy of Otolaryngology-Head and Neck Surgery guidelines. ("Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. American Academy of Otolaryngology-Head and Neck Surgery foundation, Inc," 1995) Air and bone conduction were measured and Pure Tone Average was calculated (PTA, average of 0.5, 1, 2, and 3 or 4 kHz if 3 kHz not available)), pre-operatively and post-operatively at day 1 (only bone-conduction), 6 weeks post-operatively and 3–6 months after surgery. The Air-bone gap (ABG) was then calculated for pre-operative and post-operative audiograms. The latter were performed in soundproof cabins with Madsen Astera (Otometrics) audiometers, and strict cross-hearing prevention was undertaken by masking proportionately to the contralateral ear's thresholds. Eustachian tube function was routinely checked by tympanometry.

The main outcome was the percentage of patients whose Air-bone gap (ABG) at the 6-week audiogram was within 10 dB. Secondary outcomes were the advent of complications (e.g. sensorineural hearing loss, vertigo...), mean ABG closure (comparing mean pre-operative and post-operative ABG), mean air-conduction pre-operatively and at 6 weeks post-operatively, and the percentage of patients with an ABG within 20 dB at 6 weeks post-operatively. Those measures were then also extracted from the 3–6 months audiometry.

The main outcome was analyzed with a Fischer's exact test while a variance analysis was used for quantitative variables. P-values <0.005 were regarded as statistically significant.

3. Results

Between May 2011 and March 2019, 12 patients underwent malleostapedotomy. Amongst whom 10 were revision surgeries and 2 were primary otosclerosis surgeries (the first one because the long process was eroded, and the second because the patient had a history of middle ear trauma with incus transposition surgery). Indications for malleostapedotomy were an incus long-process erosion in 75% of cases, epitympanic fixation of the incus and malleus in two cases (17%), and the absence of incus in one case due to a previous incus transposition (8%). Individual pre- and intra-operative findings are shown in Table 1.

The patient's ages ranged from 33 to 75 years, with an average of 53 years. Mean time since the last middle-ear surgery was 10.8 years (3 months–44 years).

Detailed audiometric results are shown in Table 2. Nine patients (75%) had an ABG within 10 dB at 1 month and 3–6 months post-surgery, and 11 had an ABG within 20 dB (92%) (Fig. 2). Mean pre-operative PTA (AC) was 58.5 dB (33.75 dB–86.5 dB), and mean post-operative PTA (AC) was 28.54 dB (10 dB–60 dB; $p < 0.001$). Tympanometry showed type A tympanogram for all patients.

There was no sensorineural hearing loss or any other post-

Table 1
Individual patients characteristics.

Patient N°	Age at surgery	ear	History of stapes surgery	Time since last middle-ear surgery (years)	Pre-operative ABG[a]	Surgery motivation	Intraoperative findings
1	63	Left	2	16	20	Vertigo + secondary ABG degradation	Incus erosion, shaft in vestibule
2	75	Left	2	44	32.5	Instability + secondary degradation ABG	Incus erosion, shaft dislocated from vestibule
3	41	Right	2	3	20	Persistent ABG	Epitympanic fixation
4	51	Right	3	15	43.75	ABG secondary degradation	Incus erosion, shaft in vestibule
5	56	Right	1	5	15	Mixed secondary hearing loss	Incus erosion and fracture, shaft in vestibule
6	46	Left	0	2	20	Otosclerosis after incus transposition for trauma	Removal of incus necessary
7	48	Right	0	0	40	Primary surgery	Incus erosion
8	52	Right	1	1	28.75	Persistent ABG	Incus erosion, shaft in vestibule
9	54	Right	2	1	31.25	Vertigo + secondary ABG degradation	Incus erosion, shaft in vestibule
10	54	Left	1	11	30	1-month post-operative secondary ABG degradation	Epitympanic fixation
11	63	Left	1	21	41.25	ABG secondary degradation	Incus erosion, shaft in vestibule
12	33	Right	2	2	55	ABG secondary degradation	Incus erosion, shaft dislocated from vestibule

[a] ABG: Air-bone gap.

Table 2
Audiometric results.

	Preoperative	Postoperative	p-value ‡
Mean PTA: AC (dB)	58.5 (33–86)	28.54 (10–60)	<0.001
Mean PTA: BC (dB)	27 (6–54)	21 (7–48)	0.23
Mean ABG (dB)	31.4 (15–55)	7.45 (0–21)	<0.001
ABG < 10 dB (patients)	0	9	<0.001
ABG < 20 dB (patients)	1	11	<0.001

PTA: Pure Tone Average, ABG: Air Bone Gap, AC = Air conduction. Range in brackets.
‡ p-value, calculated from comparing pre-operative and post-operative audiometric results with a variance analysis.

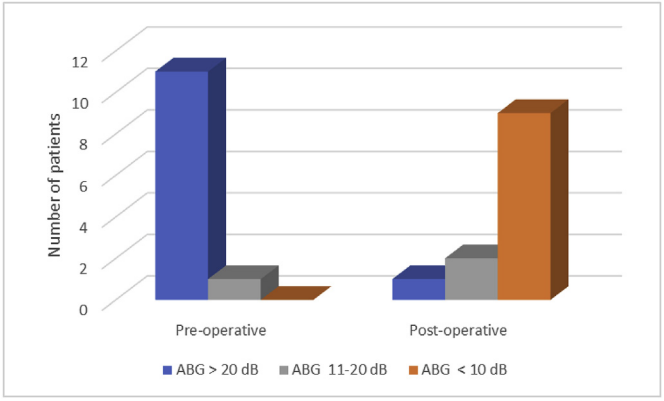

Fig. 2. Pre-operative and post-operative air-bone gap (ABG): number of patients with ABG > 20 dB, ABG between 11 and 20 dB, and ABG < 10 dB, on pre-operative and post-operative audiograms.

operative complications. Vestibular symptoms improved for the three patients that initially presented with vertigo and instability.

Prosthesis were Nitinol SMart Malleus 0.6 × 6 mm in 8 cases, 0.6 × 6.5 mm in 4 cases.

4. Discussion

Out of the 12 patients who underwent malleostapedotomy for primary or revision surgery for otosclerosis, ABG closure within 10 dB was obtained in 75% of cases, and within 20 dB in 92% of cases. There were no complications, such as sensorineural hearing loss, vertigo or dysgeusia.

4.1. Comparison with other studies

By way of comparison, Rambousek and al (Rambousek et al., 2012) studied 60 patients who underwent malleostapedotomy with titanium pistons, 32 of whom were primary surgeries. They obtained air-bone gap closures beneath 20 dB in 100% of primary surgeries, and 82% of revision surgeries.

Burggraaf et al. (2018) used a self-fixing articulated titanium piston in 16 surgeries, and obtained air–bone gap closures ≤ 10 dB in 56% of ears and within ≤20 dB in 81%.

Technical improvement, particularly in terms of the use of Nitinol pistons, could explain the satisfactory results of recent publications, as the classical titanium piston's crimping around the malleus with forceps was likely to be less precise and homogenous than heat-crimping. (Babighian et al., 2007). When reviewing the literature, we did not find any studies comparing the different types of malleus-to-vestibule pistons while several have been published on nitinol incus-to-vestibule stapes surgery pistons. Indeed, Reis and al's meta-analysis (Reis et al., 2018) on Nitinol (heat-crimping) versus conventional prosthesis, showed a better and significant efficiency of Nitinol prosthesis for stapes surgery. Nitinol pistons have also been used concomitantly with cement repair for optimizing the stability of revision surgery for incus erosion, with satisfactory results (Rouhani and Lavy, 2019). Direct comparison with malleovestibular prosthesis is not possible, but it is likely that in the case of malleostapedotomy, an easier technique would lead to better and more stable results.

4.2. Comparison to hydroxyapatite cement

Its place in surgical strategy is rivaled by cement reconstruction, particularly in cases of mild and moderate erosion.(Ghonim et al., 2017; Hudson et al., 2014) However, certain authors published satisfactory results, comparable to malleostapedotomy, for cases of extensive long-process necrosis at 1 and 3 months.(Van Rompaey et al., 2011) (Rouhani and Lavy, 2019).

Pitiot and al (Pitiot et al., 2016) separated in 3 arms 31 patients who underwent revision stapes surgeries for long-process necrosis: ABG closure beneath 10 dB was achieved in 45% of the cases with cement, in 60% with malleostapedotomy and in 10% with a total ossicular replacement prosthesis (TORP). The difference between the 3 arms was not statistically significant.

Moreover, there is some proof in favor of the long-term stability of hydroxyapatite cement, as present series have 5-yearfollow-up thresholds (Demir et al., 2019), but it is still questionable whether the cement remains stable over decades.

On an economic aspect, a vial of hydroxyapatite cement costs around 30% more than a nitinol piston.

4.3. Other clinical applications

Malleostapedotomy with titanium piston has also been described as an ossiculoplasty technique in quiescent chronic otitis media, and was compared to a TORP. (Chen et al., 2014; Gluth et al., 2011) However, using a technique relying on opening the inner ear raises the question of infectious hazard and delayed mobilization of the prosthesis due to a persistent retraction phenomenon. Either of these complications can lead to sensorineural hearing loss, yet, none of them occurred in those series.

Chen and al (Chen et al., 2014) compared 13 patients who underwent malleostapedotomy with 14 patient who underwent TORP ossiculoplasty, for quiescent chronic otitis media. Although statistical significance wasn't achieved, ABG closure was within 10 dB in 22% malleostapedotomy patients, and in 7% for TORP patients. Closure within 20 dB was obtained for 46% of malleostapedotomy patients vs 35% for TORP patients.

Gluth and al (Gluth et al., 2011) used malleostapedotomy in 7 chronic quiescent otitis media patients and obtained ABG closure within 10 dB in 43% and within 20 dB in 71% of patients. Thus, malleostapedotomy can be used in case of quiescent chronic otitis media but with poorer results than in otosclerosis.

Endoscopic malleostapedotomy has also been described and was shown to reduce the morbidity of an endaural or retroauricular approach. (Iannella et al., 2018)

5. Conclusion

Malleostapedotomy is a reliable technique for stapes surgery whenever the incus cannot be used. It allows an ABG closure comparable to conventional incus-to-vestibule prosthesis for otosclerosis. It remains the technique of choice in case of extensive necrosis, dislocated incus or epitympanic fixation of the malleus and incus.

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Ethics approval

Institutional research committee (CE_201910129_6_MDL).

Availability of data and material

Data is available at address https://www.openicpsr.org/openicpsr/project/118321/version/V1/view/

Declaration of competing interest

None.

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