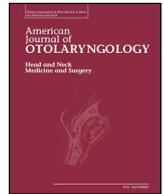




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Endoscopic approach in second stage ossicular chain reconstruction

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ABSTRACT

Purpose: Today limited studies regarding surgical and hearing outcomes in patients undergoing the totally endoscopic ossicular chain reconstruction has been published. The aim of this study is to show the different materials and endoscopic technique used in our experience to perform a second stage endoscopic ossiculoplasty.

Materials and methods: Patients underwent to second stage endoscopic ossiculoplasty has been enrolled in the study. According to the ossicular defect the endoscopic surgical procedures of ossicular chain reconstruction used in our clinical practice were: ossicular chain reconstruction using PORP (13 cases); ossicular chain reconstruction using TORP (11 cases); incus interposition ossiculoplasty (6 cases); cartilage ossiculoplasty (10 cases). Intraoperative and postoperative complications were analyzed. Final hearing recovery at 6 months follow-up was used to evaluate audiological outcomes.

Results: None of the patients developed intraoperative complications. Postoperative TM complications emerged in 5% of cases: one patient (2.5%) presented TM perforation and prosthesis extrusion (TORP) after 3 months follow up.

A significative difference between preoperative and postoperative values of AC-PTA, ABG and WRS ($p < 0.05$ in each case) emerged.

Conclusions: Different materials and methods can be used for performing an endoscopic ossicular chain reconstruction in order to obtain optimal clinical-audiological outcomes. Endoscopic surgery can be considered a valid alternative technique to traditional microscopic surgery for ossiculoplasty surgery.

1. Introduction

Nowadays, the endoscope is becoming more frequently used in middle ear surgery and the number of papers dealing with endoscopic ear surgery have been increasing over the last years [1–6]. This surgical technique is suitable for chronic otitis media, cholesteatoma, otosclerosis, and other middle ear diseases [6–13].

An increasing number of ear-surgeons consider middle ear pathologies suitable for totally endoscopic ear surgery (TEES) due to the fact that the endoscopic approach offers excellent visualization of middle ear structures and recesses, mainly the oval window niche, stapes anterior crus and its suprastructure [6–11]. Nevertheless, ossiculoplasty surgery is still mainly performed via the transcanal approach under an operating microscope [14–17].

The reasons for the marginal role that endoscopes play in the ossiculoplasty surgery include: instrument limitation, single-handed work,

the lack of a stereoscopic view and, last but not least, a potentially long surgeon learning curve [10–14,18,19].

At present there is limited evidence regarding the influence of TEES on surgical and hearing outcomes in patients undergoing ossicular chain reconstruction (OCR): consequently, due to the limited number of papers analyzing the outcome of endoscopic ossiculoplasty surgery, several aspects remain unclear [10,14,15]. Only Yawn et al. [14] reported audiometric outcomes following endoscopic ossicular chain reconstruction. Thirty-one ears (50.0%) underwent endoscopic OCR compared with 31 (50.0%) ears that were reconstructed microscopically. There were no significant postoperative differences in bone PTA, air PTA, and ABG between microscopic and endoscopic approach.

The aim of this study is to show the different materials and endoscopic technique used in our experience to perform a second stage endoscopic ossicular chain reconstruction. Surgical and audiological outcomes of second stage ossiculoplasty performed using TEES are also reported.

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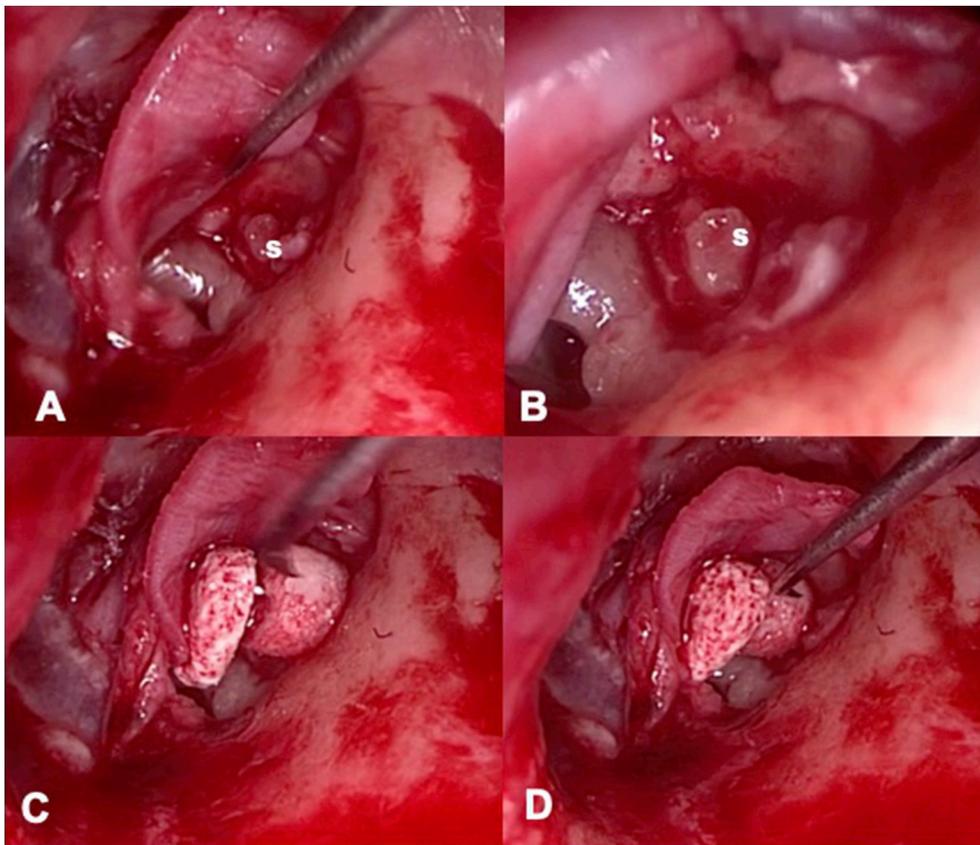


Fig. 1. Ossicular chain reconstruction using PORP: **A, B;** endoscopic access to the middle ear. Stapes superstructures evaluation **C;** with a small hook and gentle movements the prosthesis is first placed with the hollow portion on the stapes head. **D;** the prosthesis is rotated and positioned under the MT in the correct position. Stapes superstructures (s).

Advantages and disadvantages of the different types of reconstruction as well as the use of endoscope in this type of surgery are discussed.

2. Materials and methods

2.1. Patient enrollment

Second stage endoscopic ossiculoplasty performed at the ENT division of Sapienza University between October 2015 and December 2018 has been initially reviewed. Fifty-six patients were surgically treated with TEES ossiculoplasty over this period of time.

Patients in whom follow-up was too brief or absent were excluded from the study.

Forty patients (23 females and 17 males) who underwent a second stage ossiculoplasty for transmissive hearing loss were enrolled in the study.

The endoscopic approach was performed in all cases as a secondary stage.

At the time of surgery the patients ranged in age from 18 to 63 years (mean: 41.3 years). Surgery was done on the right and left ears in 18 and 22 patients, respectively. The postoperative follow-up period ranged from 12 to 36 months (mean: 25.6 months).

All surgical procedures were performed by one of authors (G.M.) at the 'Sensory Organs' Department of the 'Sapienza' University of Rome. Endoscopic surgery was introduced in our Otolaryngology division 18 months before the enrollment of the first patients.

2.2. Instruments

For endoscopic stapes surgery, rigid endoscopes at 0- and 30-degree angled with a length of 14-cm and an outer diameter of 3 mm and 4 mm (Storz, Germany) were used, connected to a camera head (Storz, Germany) and a high definition monitor. The monitor was positioned in front of the surgeon and standard instruments for middle ear surgery were utilized.

Images of each surgical procedure were recorded and reviewed.

2.3. Surgical procedures

Patients of the studies underwent second stage ossiculoplasty for conductive hearing loss treatment. All patients had undergone a previous endoscopic or microscopic tympanoplasty due to middle ear cholesteatomas/chronic otitis media/atelectasis.

According to the ossicular defect the endoscopic surgical procedures of ossicular chain reconstruction used in our clinical practice were [16,17,20,21]:

- GROUP 1 - Ossicular chain reconstruction using PORP (13 cases)
- GROUP 2 - Ossicular chain reconstruction using TORP (11 cases)
- GROUP 3 - Incus interposition ossiculoplasty (6 cases)
- GROUP 4 - Cartilage Ossiculoplasty (10 cases)

Hydroxyapatite bone cement was not used in our experience for ossicular chain reconstruction after tympanoplasty.

2.4. Surgical steps

The first two surgical steps were common to all procedures. These were creation of the tympanomeatal flap in the posterosuperior part of the external auditory canal. Access to the middle ear. Investigation of possible cholesteatoma recurrence. Evaluation of the ossicular chain defects especially presence or absence of the stapes superstructures.

- GROUP 1 - Ossicular chain reconstruction using PORP - Fig. 1

Group 1 consists of 13 patients who underwent repair of the incudo-stapedial defect by using a PORP alloplastic prosthesis. PORP was used when the stapes superstructures were intact and the footplate was present and mobile (Fig. 1A,B).

In all cases a model of (PAP 0738 Audio®) prosthesis was used. This consists of a flat part that rests beneath the MT and a hollow portion that is still at the head of the stapes. The distance between the head of the stapes and the tympanic membrane was measured and the prosthesis was sized so that it just met the TM. Under the endoscopic view with a small hook and gentle movements the prosthesis was first placed with the hollow portion on the stapes head (Fig. 1C) and then rotated and positioned under the MT in the correct position (Fig. 1D). In no case was the procedure converted into a microscopic approach because of difficult insertion in the head of stapes due to one-handed surgery.

Cartilage or Fascia can be interposed between the head plate of the titanium prosthesis and the TM to reinforce the TM and prevent prosthesis extrusion. Gelfoam is placed in the middle ear to stabilize the prosthesis. When the handle of the malleus was present, the head of the prosthesis was usually positioned posterior to it.

- GROUP 2 - Ossicular chain reconstruction using TORP

Eleven patients performed ossiculoplasty using a TORP. In all patients the same model of prosthesis (TAP 0735 Audio®) was used. This consists of a flat part that rests beneath the MT and a stem that is positioned in contact with the stapes footplate.

In eight patients the prosthesis was interposed between the stapes footplate (absent stapes superstructure) and the TM and further stabilized with pieces of cartilage (Fig. 2A–C). Under the endoscopic view the prosthesis was first placed in the middle ear (Fig. 2A), then rotated towards the footplate and embedded on it. Subsequently, using a small hook, it was rotated and positioned under the TM (Fig. 2B). At the end a small piece of cartilage is interposed between the prosthesis and the TM (Fig. 2C).

In three cases the stapes was intact and leaning against the promontory: in accordance with the technique described by Fisch [22], the prosthesis was placed on the stapes footplate between the stapes crura and the TM, resulting in stable positioning (Fig. 2D).

- GROUP 3 – Incus interposition ossiculoplasty

Six patients underwent repair of the incudo-stapedial defect using a “remodelling incus” technique. In this surgical procedure it is possible to use the incus preserved from previous surgery or remnant incus. In all cases the incus is first remodelled and replaced to bridge the ossicular gap: the incus is fashioned to an appropriate shape and size by drilling. A hole is drilled into the base of the long process of incus, and the short process is drilled off (Fig. 3A–B). Under endoscopic view a gentle force is applied to fit the head of the stapes into the drilled hole on the incus (Fig. 3C–D).

- GROUP 4 – Cartilage ossiculoplasty (10 cases)

8 patients with only incus absence performed a cartilage ossiculoplasty using heterologous cartilage (R 23.01H Audio®). In these cases, under an endoscopic view, a square-shape cartilage block was used to connect the head of the stapes with the malleus. A hole corresponding to the size of the head of the stapes was previously created on one side of the cartilage. Its thickness was modelled according to the distance between the head of the stapes and the malleus (Fig. 4A–B). Under endoscopic view the cartilage block is gently positioned on the stapes with its hollow portion and gently rotated under the TM (Fig. 4B–C). The possibility of obtaining an angled view with the endoscope is helpful in encasement of the cartilage on the stapes head. Other pieces of cartilage can be used to strengthen the TM (Fig. 4D).

Two patients with absence of the stapes superstructure underwent a cartilage ossiculoplasty according to the L' shape technique which makes it possible to obtain a graft with an ‘inverted L’ shape cartilage placed between the stapes footplate and the TM [23] (Fig. 4E–F).

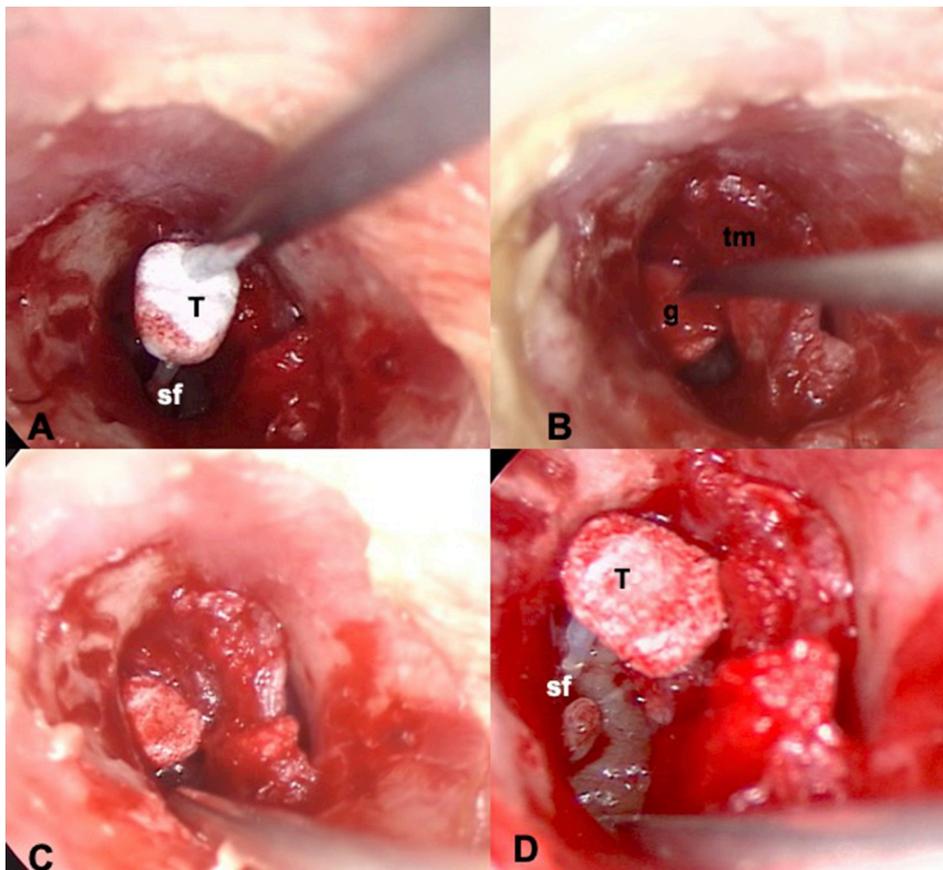


Fig. 2. Ossicular chain reconstruction using TORP: A; under the endoscopic view the prosthesis is first placed in the middle ear. B; the prosthesis is rotated towards the footplate and embedded on it. C; using a small hook, it is rotated and positioned under the tympanic membrane. D; intact stapes superstructures. The prosthesis is placed on the stapes footplate between the stapes crura and the TM, resulting in stable positioning. TORP (T), stapes footplate (sf), tympanic membrane (tm), gelfoam (g).

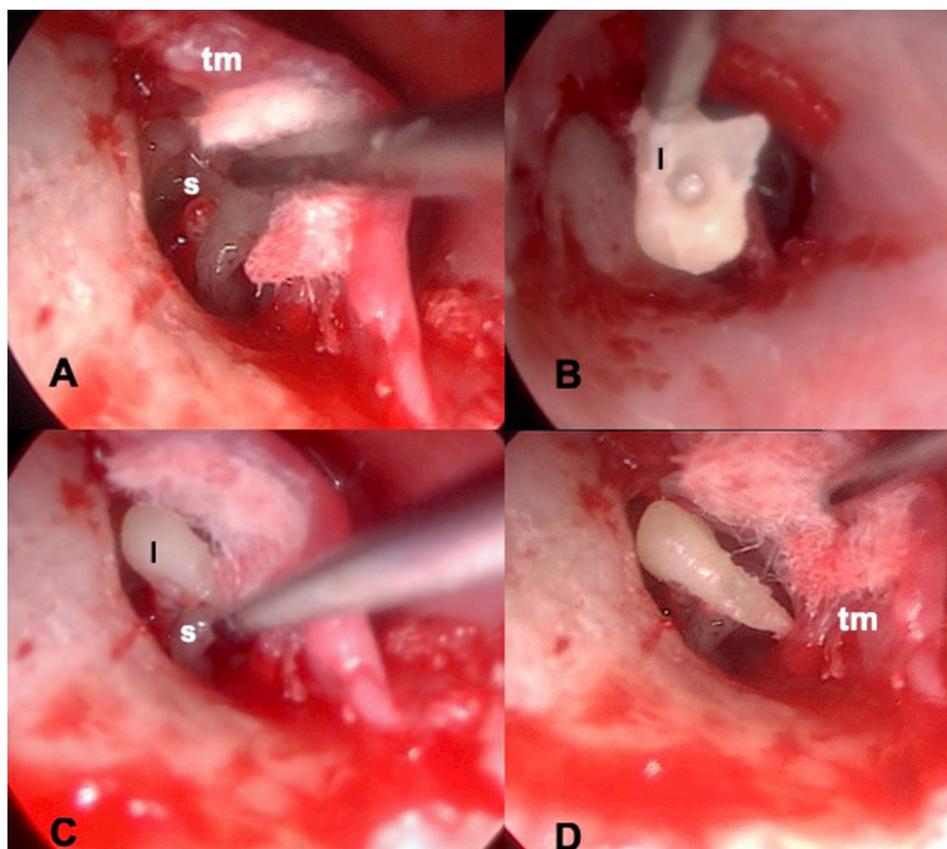


Fig. 3. Incus interposition ossiculoplasty: **A;** middle ear access, intact stapes. **B;** the incus is fashioned to an appropriate shape and size by drilling. A hole is drilled into the base of the long process of incus, and the short process is drilled off. **C;** under endoscopic view a gentle force is applied to fit the head of the stapes into the drilled hole on the incus. **D;** the incus is gently positioned under the tympanic membrane.

Stapes (s), tympanic membrane (tm), incus (RI).

2.5. Parameters investigated

The severity of postoperative pain was recorded using three grades: almost no pain, mild pain requiring no analgesics, and pain requiring analgesics. When present, postoperative dizziness was reported as the number of days duration.

Intraoperative and postoperative complications, such as facial paralysis, abnormal taste sensation, persistent vertigo or tinnitus were analyzed.

Postoperative TM complications and/or prosthesis extrusion/dislocation were investigated at the clinical follow-up.

Hearing was assessed preoperatively and at 1, 3, and 6 months after surgery in all patients. Final hearing recovery at 6 months follow-up was used to evaluate audiological outcomes [24].

2.6. Statistical analysis

For comparison of data changes between preoperative and postoperative outcomes, the Student's *t*-test was used by SAS, JMP8 version (SAS Institute, Cary, NC). A *p* value of < 0.05 was taken as the threshold of statistical significance. If no statistical significance between the two groups was estimated the definition *p* > 0.05 was adopted in the text.

This research study was performed in accordance with the principles of the Declaration of Helsinki and approved by the local Ethics Committee of the University “Sapienza” of Rome.

3. Results

3.1. Patient population and endoscopic ossicular chain reconstruction

All patients underwent an exclusive endoscopic ossiculoplasty at secondary stage surgery.

The characteristics of patients surgically treated with a TEES ossiculoplasty, enrolled in the study, is reported in Table 1. Most of the patients (60%) were previously treated for a middle ear cholesteatoma. Canal wall up tympanoplasty was the most common surgical procedure performed in all the patients reviewed (55%); previous endoscopic tympanoplasty was performed in 25% of cases.

The average time between the first surgery and the ossicular chain reconstruction was calculated as 9.2 months. During the endoscopic ossiculoplasty, cholesteatoma recurrence/residual emerged in 7.5% of patients, whereas 29.5% of patients showed inflammatory or granulation tissue. In all cases cholesteatoma pearls and inflammatory/granulation tissue were totally removed before performing the ossicular chain reconstruction.

An ossicular chain reconstruction with the use of PORP was the most frequent ossiculoplasty which emerged in the study (32.5%); TORP were employed in 27.5% of cases, remodelling of incus and cartilage in 15% and 25% respectively. Different types of TEES ossicular chain reconstruction performed are reported in Table 1.

3.2. Postoperative sequelae and complications

Postoperative sequelae and complications are reported in Table 1. None of the patients developed intraoperative complications. Postoperative TM complications emerged in 5% of cases: one patient (2.5%) presented TM perforation and prosthesis extrusion (TORP) after 3 months follow up. Another patient (2.5%) treated with a PORP ossiculoplasty, had a TM lateralization and prosthesis dislocation after 6 months follow-up.

Postoperative sensorineural hearing loss emerged in one patient (2.5%) who underwent a PORP ossicular chain reconstruction. No cases of postoperative facial palsy, persistent vertigo or persistent tinnitus emerged. No differences emerged between the different types of ossiculoplasty and postoperative complications (*p* > 0.05 in each cases).

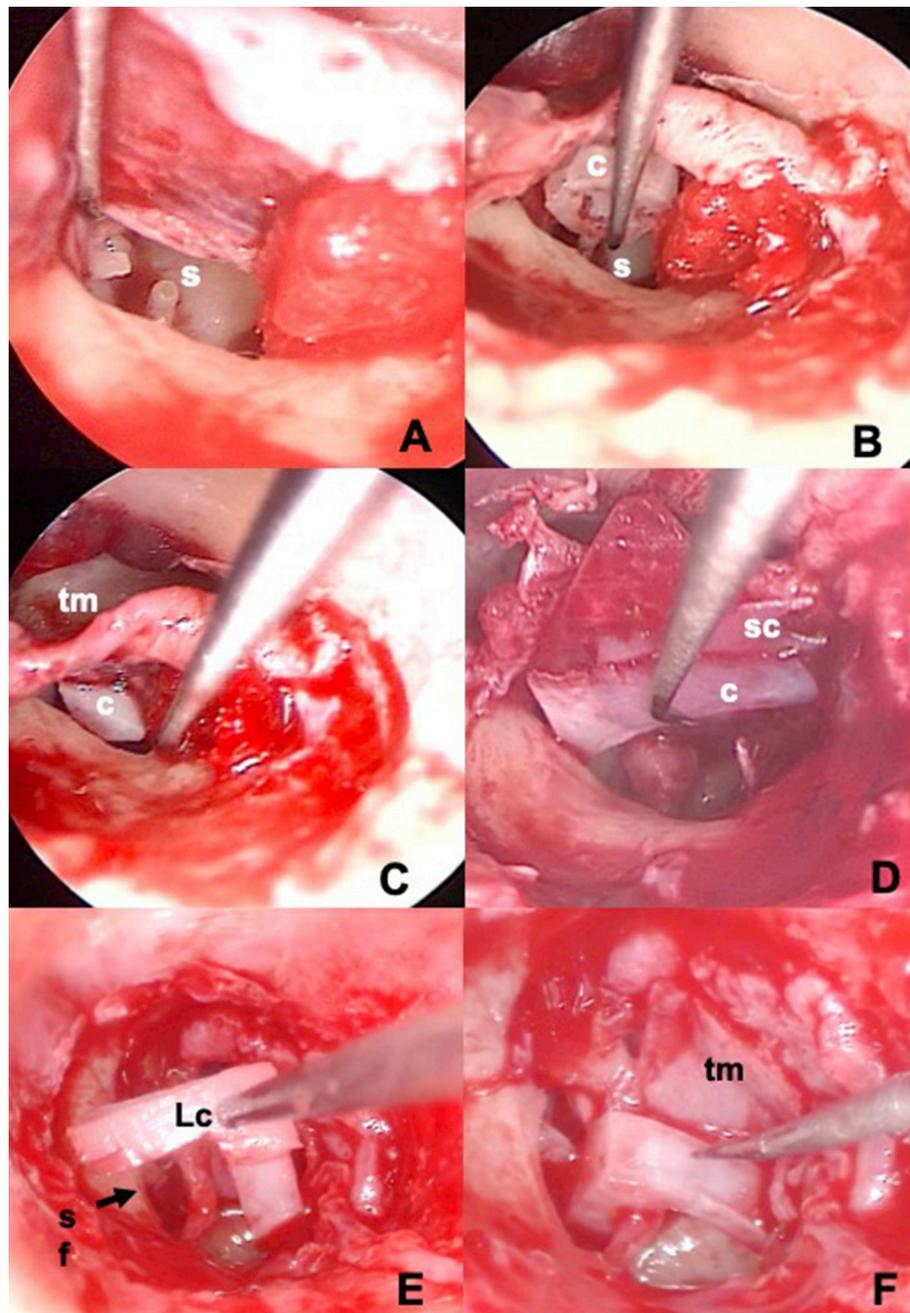


Fig. 4. Cartilage ossiculoplasty: **A**; middle ear access, intact stapes. **B**; a hole corresponding to the size of the head of the stapes was previously created on one side of the cartilage. **C**; under endoscopic view the cartilage block is gently positioned on the stapes with its hollow portion and gently rotated under the TM. **D**; other pieces of cartilage can be used to strengthen the TM. **E**; cartilage is molded in the L shape. **F**; the L shape cartilage is positioned between the stapes footplate and the TM. Stapes (s), cartilage (c), tympanic membrane (tm), sheet of cartilage (sc), stapes footplate (sf), L shape cartilage (Lc).

3.3. Audiological outcomes (Table 2)

The mean postoperative Air-bone gap (ABG) of all the patients enrolled in the study was 49.1 dB; it went down after surgery to a mean value of 28.2 dB, with an evident statistical difference ($p = 0.0001$). Preoperative ABG showed a mean value of 33.8 dB that went down after surgery to a mean value of 11.7 ($p = 0.0001$). Similarly, a significant difference emerged between preoperative and postoperative WRS (word recognition score) emerged ($p = 0.02$).

Preoperative and postoperative audiological outcomes for the different ossiculoplasty procedures performed is reported in Table 2. A significant difference between preoperative and postoperative values of AC-PTA (air conduction- pre tone audiometry), ABG and WRS

($p < 0.05$ in each case) emerged for the different procedures. Only in the PORP group the difference between preoperative and postoperative WRS did not show statistical significance. However, it should be considered that the patients with severe postoperative sensorineural hearing loss belonged to this group of patients.

No statistical differences in hearing recovery emerged between the different endoscopic ossiculoplasty approaches ($p < 0.05$ in each case).

4. Discussion

Achieving optimal ossicular chain reconstruction results depends on several factors; the major factors include the biomechanical properties

Table 1
Characteristics, postoperative sequelae and complications of patients surgical treated with a total endoscopic ossicular chain reconstruction.

Middle age (years)	41.3 (Range 18 to 63)
Sex	23 Females and 17 males
Previous middle ear pathology	
Cholesteatoma	24 (60%)
Chronic otitis media	9 (22.5%)
Atelectasis	7 (17.5%)
Previous surgery	
Canal Wall Down (microscopic approach)	8 (20%)
Canal Wall Up (microscopic approach)	22 (55%)
Endoscopic Tympanoplasty	10 (25%)
Time after previous surgery (mean time)	9.2 months
Intraoperative recurrence of pathology	
No recurrence	25 (62.5%)
Cholesteatoma pearl	3 (7.5%)
Granulation tissue	5 (12%)
Inflammatory/adhesion tissue	7 (17.5%)
Different types of secondary TEES ossiculoplasty	
Group 1 PORP 13 cases (32.5%)	- 13 (100%) Prosthesis between stapes superstructures and TM
Group 2 TORP 11 (27.5%)	- 8 (72.2%) Cases - Classical technique: prosthesis between stapes footplate and TM - 3 (27.2%) Cases - TORP positioned on the stapes footplate between the stapes cruras and the TM
Group 3 Incus interposition ossiculoplasty 6 cases (15%)	- 6 (100%) Remodelled incus between stapes superstructures and residue of the malleus
Group 4 Cartilage 10 cases (25%)	- 8 (80%) Square-shape cartilage block used to connect the head of the stapes with the TM - 2 (20%) L shape cartilage between the stapes footplate and the TM
Postoperative pain	
Almost no pain	28 (70%)
Mild pain requiring no analgesics	11 (27.5%)
Pain requiring analgesics	1 (2.5%)
Postoperative dizziness	
No dizziness	29 (72.5%)
One day (day of surgery)	9 (22.5%)
Two days	2 (5%)
More of 2 days	–
Postoperative facial palsy	–
Postoperative persistent vertigo	–
Postoperative persistent tinnitus	–
Postoperative abnormal taste sensation	3 (7.5%)
Postoperative TM complications	
Perforation (TORP patient)	1 (2.5%)
TM lateralization (PORP patient)	1 (2.5%)
Postoperative sensorineural hearing loss (PORP patient)	1 (2.5%)
Postoperative prosthesis extrusion/dislocation	7.5%
PORP ^a	–
TORP ^b	1 (2.5%)
Remodelling incus	1 (2.5%)
Cartilage ^c	–1 (2.5%)

^a The same patient presenting lateralization of the TM.
^b The same patient presenting perforation of the TM.
^c New ossiculoplasty performed 6 months later the first OCR surgery.

of the prosthesis, techniques of reconstruction, and the severity of the middle ear disease. Certain variables such as middle ear fibrosis, adhesive otitis, and significant Eustachian tube dysfunction are not easily controlled by the otologist. In contrast, the variables that may be controlled by the surgeon are the type of prosthesis used and the surgical technique applied [20–22].

In this paper we have described the different materials and methods used in our clinical practice to perform a second stage endoscopic OCR. Despite the expanding popularity and interest in TEES, to the authors' knowledge, this is the first study reporting different approaches in endoscopic secondary staged endoscopic ossiculoplasty, also investigating the surgical and audiological outcomes of this approach [10,14,15].

Table 2
Preoperative and postoperative audiological outcomes of total endoscopic ossicular chain reconstruction and divided for the different type of ossiculoplasty.

	Preoperative AC-PTA (mean value)	Postoperative AC-PTA (mean value)	p-Value	Preoperative ABG (mean value)	Postoperative ABG (mean value)	p-Value	Preoperative WRS (mean value)	Postoperative WRS (mean value)	p-Value
Total group (40pts)	49.1	28.2	0.0001	33.8	11.7	0.0001	90.6	97.7	0.02
PORP (13pts)	47.4	30.8	0.002	31	11.3	0.0001	93.7	92.9	0.9^a
TORP (11pts)	51.1	25.3	0.0001	36.8	11.8	0.0001	93.8	100	0.03
Incus (6pts)	49.3	29.4	0.008	34.6	14.7	0.004	93.5	99.6	0.04
Cartilage (10pts)	49	27.1	0.0001	33.7	11.3	0.0001	90	99.2	0.04

AC-PTA (air conduction- pre tone audiometry), WRS (word recognition score), ABG (Air-bone gap).

Statistical significant values has been reported in bold.

^a Considering the patient with postoperative sensorineural hearing loss.

The first group of endoscopic OCR analyzed in this study (13 patients) underwent an endoscopic ossiculoplasty using a PORP prosthesis. PORP was used primarily when the stapes superstructures were intact and the footplate was present and mobile without the need to remodel the patient's incus [16,21]. This prosthesis has the advantage of being readily available, but stability problems and extrusion may also occur when placed under endoscopic view [14]. One patient of our study treated with a PORP ossiculoplasty had a TM lateralization and prosthesis dislocation after 6 months follow-up.

Endoscopic TORP ossiculoplasty has been performed in 11 patients. In our experience in these cases the endoscopic view allowed a precise view of the stapes platina and prosthesis location under the TM. Also in these cases prosthesis extrusion is possible (2.5% of cases).

When autologous materials as incus is available, it can be easily remodelled to join the stapes to the long process of the malleus [25]. We have shown that incus remodelled ossiculoplasty can be easily performed under endoscopic approach. Although well tolerated by the body, these grafts can partially necrotize and develop ossifying bridges, or become displaced. However, no postoperative necrosis or displacement appeared in our series.

Finally, in our experience heterologous cartilage was used to perform an endoscopic OCR in 10 cases. When stapes superstructures are present a squared-shape cartilage block can be used to connect the head of the stapes with the malleus. Differently when the stapes superstructure was absent we performed an endoscopic ossiculoplasty according to the L shape technique which makes it possible to obtain a graft between the stapes footplate and the TM.

A mean postoperative ABG of 11.7 emerged in our study, with a reduction of the ABG from 33.8 to 11.7. These results appeared similar to the audiological outcomes described in the study of Yawn et al. [14] which reported a mean postoperative ABG of 13.8 dB and 15.9 dB in the PORP and TORP groups of patients, respectively. Similarly, in our study good audiological results with PORP and TORP emerged ($p < 0.05$ in each case). In addition to the data reported in the literature we have shown that it is also possible to perform endoscopic OCR using a remodelled incus and/or heterologous cartilage obtaining similar audiological results of endoscopic PORP and TORP ossiculoplasty.

The possible advantages and disadvantages of endoscopic OCR should be borne in mind. Different authors concord that endoscopic ear surgery (EES) offers the advantage of an excellent visualization of middle ear structures and recesses, mainly the oval window niche, stapes anterior crus and its suprastructure. In our opinion this aspect is important in a precision surgical procedure such as OCR; an accurate visualization of the middle ear site/structures where the prosthesis will be placed (presence of stapes superstructure and its mobility, presence and integrity of the long limb of the incus, distance between stapes or round window and the TM), allows precise positioning of the prosthesis in a correct site [3,12,26,27].

The disadvantages of endoscopic OCR exist and are the same as those of endoscopic ear surgery: single-handed work, the lack of a stereoscopic view and, last but not the least, a potentially long surgeon learning curve [12,26–28].

In our experience, after adequate EES training, single-handed work should not be considered as a major limitation to this approach. No difficulty in performing single-handed work procedures emerged [12,26]; moreover, none of the endoscopic OCR procedures reported in this study were intraoperatively converted to a microscopic approach. Besides, with the introduction of 3D-endoscopic surgery it is possible to overcome the problem of the absence of a stereoscopic view [29].

In this study we have shown that it is possible to perform all types of OCR generally performed by a microscopic approach, using exclusive endoscopic surgery. The otologic surgeon with adequate knowledge of the anatomy of the middle ear and expertise in one-handed surgery can adopt for different materials and methods to reconstruct the ossicular chain with similar clinical and audiological results [14].

The choice of the surgical approach must be made by each surgeon

in accordance with the middle ear characteristics, prosthesis availability, costs, depth of field and, last but not least, his/her surgical skills. Obviously, a long training period in endoscopic ear surgery is essential in order to improve the surgeon's ability to perform one-handed ear surgery before performing any type of endoscopic OCR [27,28].

The main limitation of this study is that clinical and audiological outcomes were not compared with those of patients who underwent microscopic OCR.

Another study comparing intraoperative, postoperative and audiological outcomes of microscopic and endoscopic procedures is under way in order to confirm the preliminary results of this study.

5. Conclusions

Different materials and methods can be used for performing an endoscopic ossicular chain reconstruction obtaining optimal clinical-audiological outcomes.

Compliance with ethical standards

No grant or other source of funding.

Authors declare that they have no conflict of interest.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent was obtained from all individual participants included in the study.

Declaration of Competing Interest

None.

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