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Original Article

Long-term outcomes for treatment of middle ear cholesteatomas with intact-canal wall and scutum plasty techniques

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Abstract: Objectives: The aim of this study was to assess outcomes for treatment of middle ear cholesteatomas using intact-canal wall and scutum plasty techniques. Methods: A total of 113 patients (124 ears), with posterior canal walls preserved, were included between September 2001 and January 2006. A successful procedure was considered an air-bone gap (ABG) <20 dB or ABG>20 dB + air conduction threshold < 40 dBHL, while an effective result was defined as an ABG<10 dB or ABG>10 dB + decrease >30 dB. Relapse, successful and effective rates, and outcomes during follow-ups were analyzed. Results: The mean follow-up duration was 36.58 ± 20.47 months. Relapse rate was 4.8%, success rate was 85.48%, and effective rate was 47.58%. Twelve patients underwent re-operations. In the six cases of relapse, five ears had hearing loss and one ear had re-perforation of the tympanic membrane. In the 112 patients that underwent a single operation, postoperative ABG was lower than preoperative ABG (13.58 ± 9.27 vs. 33.61 ± 12.35 dB, P<0.01). It was also lower in the 12 ears that underwent re-operations (10.38 ± 8.99 vs. 38.83 ± 12.43 dB, P<0.001). In teenagers, the success rate was 100% and the postoperative ABG was 8.80 ± 5.27 dB. After seven years, 11 ears relapsed (13.7%), corresponding to a success rate of 83.87% and an effective result rate of 38.7%. Conclusion: Short- and long-term outcomes of intact-canal wall and scutum plasty techniques for middle ear cholesteatomas were effective, with low relapse rates.

Keywords: Cholesteatoma, middle ear, otologic surgical procedures, canal up, scutum repair, outcomes

Introduction

Cholesteatoma is a confusing misnomer referring to fatty bile tumors, a serious otolaryngologic condition [1] and benign collection of keratinized squamous epithelium within the middle ear [2].

Surgical management of cholesteatomas remains a controversial issue, as recurrence and hearing loss are major challenges [3]. The intact-canal wall technique has been considered an effective method of protecting hearing. However, several studies have reported that this method could involve a relatively high risk of residual cholesteatoma and recurrence [4-7]. Fortunately, these risks have been effectively decreased with the development of related surgical procedures [8]. Scutum plasty via transcanal and transcortical methods with secondary reconstruction has very low recurrence and provides hearing improvement [4]. Endaural incisions, preserving the posterior canal wall and bone bridge [9], along with harvesting bone chips, are very important. The tympanic nerve elastic press on the ossicular prosthesis, which can also prevent adhesion with hyaluronic acid ester membranes [10-12], offers better outcomes [10-12]. The present study assessed recurrence rates and changes in hearing of patients using these techniques.

Methods

Subjects

A total of 113 patients (60 males and 53 females) with middle ear cholesteatomas were included in the present study, without the mastoid posterior to the lateral semicircular canal involved. The mean age was 42.7 years, ranging from 9 to 74 years. Ten of these patients were

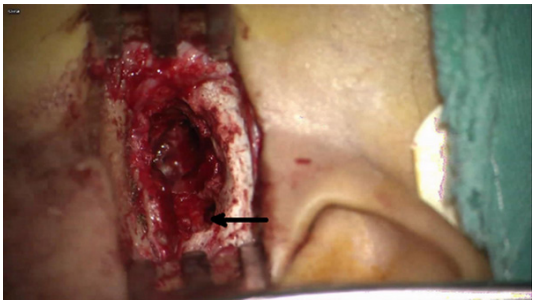

Figure 1. The probe enters the sinus and expands to explore the cholesteatoma cysts completely (Arrow shows the hole in the sieve area entering the sinus).

teenagers of less than 19 years of age. Eleven of the patients had cholesteatomas involving both ears, while only one ear was involved in the remaining 102 patients. All cholesteatomas were confirmed by postoperative pathological examinations. A total of 137 operations were performed for the 124 ears, including 11 ears that had been operated on twice and one ear that had been operated on three times. Among patients with a single operation, the mean air-bone gap (ABG), calculated as the mean value and standard deviation of sound pressure levels, measured at 0.5, 1, and 2 k, was 33.61 ± 12.3 dB before the primary operation. The mean air conduction threshold was 51.32 ± 18.14 dB before the primary operation. In patients that had reoperations, mean ABG and air conduction thresholds before the primary operation were 38.83 ± 12.43 and 59.75 ± 24.4 dB, respectively.

All patients were diagnosed before the operation. Postoperative pathological examinations were performed for the cholesteatomas that had been identified during the operation. Postoperative follow-up studies were performed for all patients, including those with multiple operations. The follow-up period ranged from 12 to 52 months. The mean follow-up period was 36.58 ± 20.47 months for all patients, with a follow-up period greater than 24 months for 73 ears (59%). Patients without cholesteatomas, with a large old radical cavity, without posterior canal walls, or with a follow-up time of fewer than 12 months, were excluded. In the present study, the 124 ears had follow-up periods of no less than 12 months, with a mean follow-up period of 95.34 ± 28.7 months. The present study was approved by the Ethics Committee of the Shanghai No.4 People's Hospital. All patients provided written informed consent.

Surgical procedures

Indications for surgery were cholesteatoma otitis media. Main complications included facial nerve injuries (that may lead to facial paralysis), craniocerebral injuries in the middle ear, brain abscesses or meningitis, total deafness or inner ear injuries, vertigo for a long time, thrombosis (caused by vascular injury of the sigmoid sinus), bacteremia, and septicemia. In the present study, local anesthesia was used for most patients, except for two ears in children and two ears in patients with vertigo before the operation. This may have been caused by a labyrinthine fistula. Endaural incisions were made and a mini air drill (Changyi Company, Tiso, UK) and milling cutter-like drill [10], designed by present researchers, were used to harvest 3-4 arch- (10×8×2-mm) and slice-shaped (8×4×1-mm) bone chips from the opening in the bony auditory canals. Cutting of the bone was stopped at about 1 cm from the perforation edge of the pars flaccida. The ear canal wall (bone bridge) was kept intact. The drill was applied to the superior tympanum and tympanic antrum to expose cavities. The hole was extended for full exposure of the upper wall of the superior tympanum and the posterior edge of the cholesteatoma at the tympanic antrum and mastoid process, as well as the outline of the mastoid process cavity. Cholesteatoma sacs, especially those around the auditory ossicles, were separated completely (**Figure 1**). For cholesteatoma sacs that extended deep into the tissues around the head of the malleus and body of incus (32 ears), a hook was used to separate the sacs from the auditory ossicles before removal of the sacs. Six of these 32 ears had residual cholesteatomas. Erbium-YAG laser ablation was performed to remove a part of the head of the malleus and body of incus to expose and completely remove residual cholesteatomas. The tunnel at the tissues above and posterior to the head of the malleus and body of incus was carefully examined. Laser ablation of the bone at the head of the malleus, body of the incus, and upper wall of the superior tympanum was performed if necessary.

For some patients with only necrosis on the long process of the incus, nested and connect-

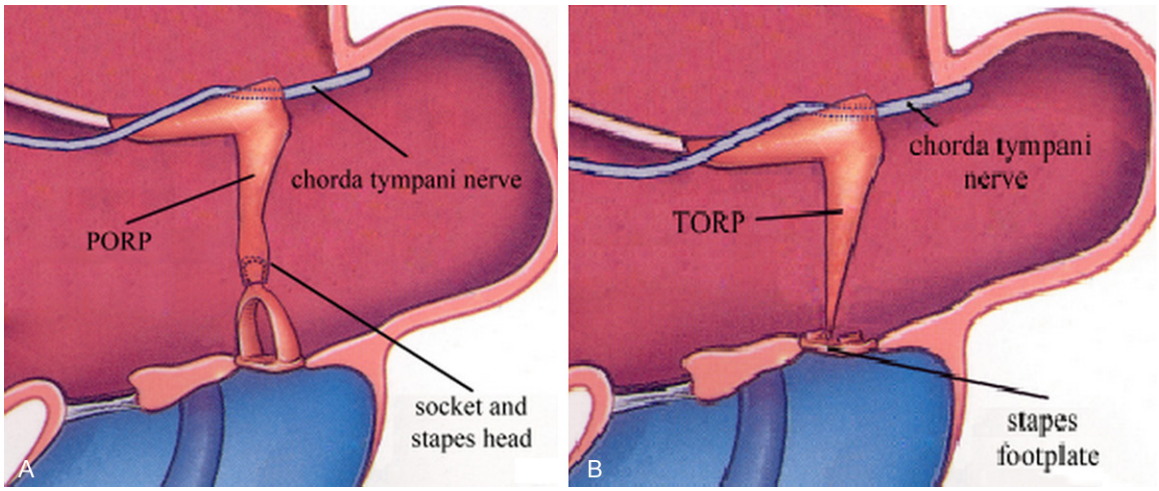

Figure 2. The reconstruction of hearing with (A) or without (B) stapes.

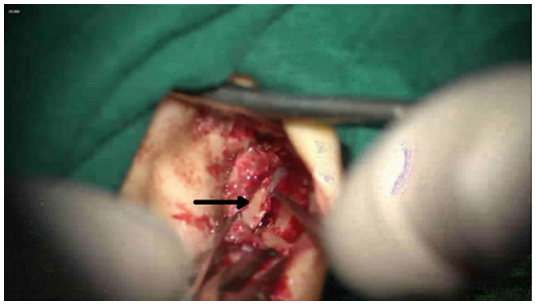

Figure 3. Repair of tympanic membrane defects and cover orifice with the cartilaginous membrane of the ear by interlayer method (arrows show bone plates to repair shield plates).

ed was performed with autologous bone grafts to connect the incus and the stapes (two ears). The incus was removed (for patients without an incus, bone grafts derived from the opening in the bony auditory canals were used) and modified to a bar-shaped bone with mortar to connect with the head of the stapes (59 ears) [13, 14]. Chorda tympani nerve tightening prosthesis was performed for 49 ears, increasing the stability of the auditory ossicles (**Figure 2A**). For patients without an incus and the upper part of the stapes, a gun-shaped bone with a sharp end was used to connect to the footplate (31 ears) [14]. Chorda tympani nerve or residual tympanic membrane press prosthesis [11] was performed in 21 of these patients (**Figure 2B**).

To repair defects of the membranous wall of the tympanum, grooves parallel to the auditory canal axis were made on the posterior and anterior bone-wall of the ear canal. Bone grafts in an arch shape were used to connect the two grooves. Periosteum or perichondrium was used to cover the bone grafts (**Figure 3**). For patients with tympanic membrane perforation, sandwich repair with the tragus perichondrium was also performed. For patients with tympanum fluid (6 ears), a grommet was used until it fell out of the ear spontaneously after the operation. A middle ear inflator was designed for early postoperative ventilation, greatly improving postoperative hearing recovery rates. This inflator was patented (patent approval number ZL2009 20212541.5) and has begun drug authority approval procedures for medical devices. The method was used to extract 2 mm silicone tube from the hole during the operation (**Figure 4**).

Reoperations were performed for cases of relapse. Briefly, incisions and holes that were made in the primary operation were used for the complete removal of cholesteatoma sacs (drilling of the bone was performed for cases with bone graft healing). The origination of the cholesteatoma was also identified and resected along with the adhesion part of the tympanic isthmus. Next, the isthmus that had fused and the tunnel posterior to the malleus were drilled open to examine the invasion and the dislocation of auditory ossicles. Treatment was applied if necessary. Periosteum or perichondrium was used to repair the perforation through which the removal of cholesteatomas was performed. The examination hole and scute were repaired by bone grafts.

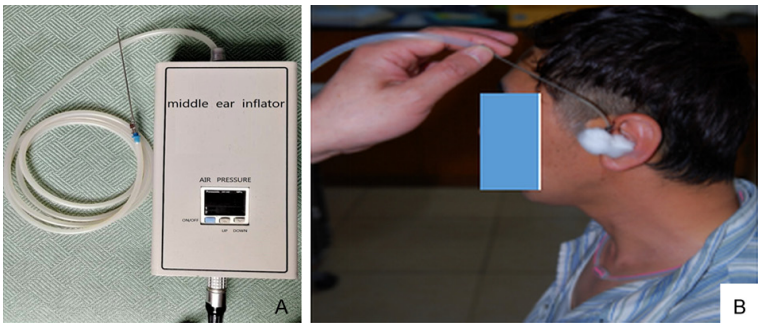

Figure 4. Homemade middle ear inflator (A: Appearance; B: In use).

Follow-up

Pure tone audiometry was performed for all patients at two weeks post-operation. Examinations were performed once every month, at one-month post operation and once every three or six months at three months post-operation. Data collected at the last follow-up was used for analysis. For patients with long-term follow up studies, the last follow-up data, collected after 2007, was used for analysis. Long-term follow-ups are important in confirming surgical outcomes.

Patients were considered successfully treated if: 1) Postoperative ABG was <20 dB; or 2) Postoperative ABG was >20 dB but the air conduction threshold was <40 dB HL. Patients were considered as effectively treated if: 1) Postoperative ABG was <10 dB; or 2) Postoperative was ABG>10 dB, but the difference between the ABGs before and after the operation was more than 30 dB. Those not meeting the above standards were defined as "poor" outcomes.

Statistical analysis

Pre-operation and post-operation ABGs were compared by paired t-tests in single operation and reoperation patients, respectively. Data were analyzed using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp., USA).

Results

There were 118 ears (95.2%) without cholesteatoma relapse before 2007. A total of 112 ears (90.3%) had recovered tympanic membranes and normal ear canals. Six ears had cholesteatoma relapse and were treated with reoperations. The remaining six ears, including five with hearing loss and one with tympanic membrane re-perforation, were also treated with reoperations. One of the ears that received a reoperation had a retraction pocket. It was treated with a third operation. No further cholesteatoma relapses were found in these 12 ears, after more than one year of follow-up.

The mean postoperative ABG of the 112 ears that were operated on only once was 13.58 ± 9.27 dB, with a difference of 20.11 ± 11.5 dB from the preoperative ABG (33.61 ± 12.35 dB). Statistical analysis (paired *t*-test) showed that differences were statistically significant (t = 18.35, P<0.01).

The mean ABG was 10.38 ± 8.99 dB for the 12 ears that had been re-operated before 2007, a difference of 28.25 ± 18.01 dB from the preoperative mean ABG (38.83 ± 12.43 dB). Differences were statistically significant (paired *t*-test, t = 5.38, P<0.01).

One hundred and six ears (85.48%), including 100 ears (89 ears that received a primary operation, six ears that received reoperation for cholesteatoma relapse, and five ears that received reoperation for other reasons) with a postoperative ABG<20 dB and six ears with a postoperative ABG>20 dB and air conduction threshold <40 dB, were treated successfully. The other 59 ears (47.58%) included 50 ears (44 ears that received a primary operation and six ears that received reoperation) with a postoperative ABG<10 dB and nine ears with a postoperative ABG>10 dB. Differences between postoperative and preoperative ABG were >30 dB, indicating effective treatment.

The mean bone conduction threshold was 17.3 ± 13 dB before the operation and 15.15 ± 11.79 dB at the last follow-up, indicating statistically significant differences (paired *t*-test, t = 4.77, P<0.01). The bone conduction threshold increased by 1-9 dB in 21 ears (16.93%), decreased by 1-28 dB in 61 ears (49.49%), and was not substantially changed in 42 ears (33.87%).

Postoperative ABG of the 10 teenagers (less than 19 years of age) in this study was 8.8 ± 5.27 dB, an improvement of 1-18 dB. These

Table 1. Comparisons of the results collected in the long- and short-term follow up studies (124 ears)

	Long-term follow up (dB)	Short-term follow up (dB)	*t*-value	*P*
GAP	15.08 ± 10.12	13.58 ± 10.05	0.076	0.939
AC	33.4 ± 14.66	32.49 ± 14.4	0.135	0.9989
GAP difference	20.37 ± 13.01	20.0 ± 12.72	0.00208	0.998

were considered successful treatments. Two of the teenagers developed cholesteatoma relapse and underwent reoperations. After follow-ups of more than 12 months, the hearing of these teenagers was well-maintained.

Ear canals and tympanic membranes with normal appearances were observed in all patients, except for three ears with grommets.

Until 2013, the mean follow-up time was 95.34 ± 28.7 months for 124 ears. Fifteen ears received reoperations for cholesteatoma relapse (11 ears, 8.87%), effusion (one ear), and conductive hearing loss (three ears). In addition, cholesteatoma relapse was observed in six ears before 2006. Thus, the overall recurrence rate was 13.7% (17/124).

The mean time between the primary operation and cholesteatoma relapse for 11 ears was 67.94 ± 23.14 months, ranging from 26 to 108 months. The mean ABG was 35.90 ± 9.88 dB before the reoperation but improved to 12.73 ± 5.12 dB after reoperation, a statistically significant difference (t = 7.577, P<0.01). The mean GAP of these 11 ears was 13.73 ± 12.11 dB at the last follow-up of the long-term follow-up study. This difference that was not statistically significant, compared to data collected at the last follow-up of the short-term follow-up study (t = 2.28, P>0.05). The hearing of 10 ears (91%) was well-maintained, with four ears (37%) treated effectively.

One of the 11 ears had a retraction pocket of the pars flaccida, associated with hypoventilation around the auditory ossicles of the superior tympanum. Another ear had a retraction pocket of the pars flaccida and effusion of the tympanum, associated with temporary Eustachian tube defects. The other nine ears had epithelial proliferation in the pars flaccida and large granuloma, which may have been residual cholesteatomas or caused by cholesteatoma relapse. As the Eustachian tube catheterization had been performed smoothly, the lesions in these nine ears were not associated with Eustachian tube function.

Difference betweens the long- and short-term follow-up GAP were not statistically significant (15.08 ± 10.12 vs. 13.58 ± 10.05 dB, t = 0.076, P = 0.939).

Similarly, differences in air conduction between long- and short-term follow-ups were not statistically significant (33.4 ± 14.66 vs. 32.49 ± 14.4 dB, t = 0.135, P = 0.9989). GAP changes in long- and short-term follow-up studies did not differ significantly (20.37 ± 13.01 vs. 20.0 ± 12.72 dB, t = 0.00208, P = 0.998) (**Table 1**).

After long-term follow up, 94 ears had a GAP <20 dB and were considered successfully treated. In another 10 ears, the GAP was >20 dB but the air conduction was <40 dB. They were also considered successfully treated. Therefore, the overall success rate was 83.87% (104/124) after long-term follow-up, 1.61% lower than that of short-term follow-up (85.48%). Similarly, the overall effective rate was 8.88% lower after long-term follow-ups (GAP<10 dB in 41 ears, GAP>10 dB but an improvement >30 dB in seven ears), compared to short-term follow-ups (38.7% vs. 47.58%).

Discussion

Patient hearing after cholesteatoma removal

Before the 1950s, the classic surgery for chronic suppurative otitis media was radical or modified radical mastoidectomies to facilitate lesion cleaning [4]. However, protecting and improving hearing by intact-canal wall techniques has now accepted by more clinicians [15], consistent with the Committee on Hearing and Equilibrium [16]. Findings of the present study demonstrate effective and successful treatment in 59 (47.58%) and 106 ears (85.48), respectively. According to the criteria [4], no changes in hearing were found in only nine ears (7.25%) in the present study. The causes of reoperation in the present study were adhesion (four ears), calcification (one ear), and perforation (one ear). Present findings suggest that it is possible to remain or even improve the hearing of most patients after cholesteatoma operations.

Recurrence rates of cholesteatoma

All patients were treated with open mastoidectomies before 1958. This involved a permanent surgical cavity that required life-long medical care [17]. Combined-approach tympanoplasty (CAT) has attracted much attention [18] but has a high recurrence rate (62%) [4]. One of the reasons is the removal of the epithelium, especially that at the anterior part of the superior tympanum, incudal fossa, and sinus tympani, which cannot be successfully performed with CAT [5].

Risk factors, including adhesions between the facial ridge and the tympanic membrane and severe mucosal reactions to the reinforced silastic, could affect the removal of the cholesteatoma. These may lead to the complete blockage of the Eustachian tube [19]. Low relapse rates (2.9%) are related to the surgical procedures described by the authors, including: 1) Harvesting of bone chips from the mastoid wall by mini or bone drills; 2) Preservation of the bone bridge, removal of lesions from back to front, and removal of the incus and the head of the malleus; 3) Endoscopic examination of critical regions, including facial recess and sinus tympani; 4) Reconstruction of the superior tympanum and the outer wall of the sinus tympani with bone chips to maintain atticoantral patency; 5) Bone chips used to connect the manubrium of malleus and the stapes in 31 ears and prosthesis for other patients; and 6) Staging the operation in some cases and preservation of the autologous incus in the mastoid process cavity [4].

Patients with recurrent hearing loss underwent a repeated operation. Cholesteatoma found during surgery was defined as recurrence. In the present study, cholesteatoma relapse was found in only six of the 124 ears. During reoperations, retraction pocket, epithelium proliferation, residual cholesteatomas in the anterior superior quadrant of the tympanum, and residual cholesteatomas deep in the sinus tympani were found in two, two, one, and one ear, respectively. In addition to Reddy's experience, it is believed that the following procedures should be performed: 1) The anterior superior quadrant of the tympanum must be opened and connected to the mesotympanum; 2) Part of the bone at the posterior part of the sinus tympani should be removed to expose the back edge of the cholesteatoma sac; 3) Cholesteatoma removal must be complete and the outer wall of the superior tympanum could be fixed by removing part of the bones to expose the body of the incus, stapes, facial nerve, and posterior tympanum; and 4) Scutum plasty must be carefully performed to ensure the stability of bone grafts. When these procedures are well performed, the relapse rate could be very low. For cases with cholesteatoma relapse, these procedures could also result in good outcomes, demonstrated by the fact that 91% (10/11) of the ears that received reoperations had good hearing at the last follow-up.

Bone conduction threshold after cholesteatoma operation

Linstrom et al. [20] compared the bone conduction threshold before and after the operation at 0.25, 0.5, 1, and 2 kHz, reporting statistically significant improvement of more than 10 dB at least two frequencies after reconstruction of auditory ossicles. In contrast, no improvement was found in patients that did not undergo reconstruction. These findings suggest that successful reconstruction of auditory ossicles could effectively improve bone conduction.

In the present study, the mean bone conduction threshold was 17.3 ± 13 dB before the operation, statistically different from values measured in follow-ups (15.15 ± 11.79 dB). Increased bone conduction threshold was observed in 21 ears (16.93%, an increase of 1-9 dB). As the increase was less than 10 dB, it is believed that no bone conduction damage occurred. In addition, 42 ears (33.87%) had no bone conduction threshold change and 61 ears (49.19%) had a decreased bone conduction threshold (a decrease of 1-28 dB, with 10 ears decreasing by more than 10 dB). These findings suggest that treatment with multiple techniques could effectively improve the bone conduction of patients with auditory ossicle damage, consistent with the findings of Linstrom et al. [20]. Present findings also demonstrate that noise caused by laser and bone drills did not affect the safety of treating cholesteatoma patients. The mechanisms were in accord with improvement of bone conduction after the operation for the otitis media. This may be due to reduced middle ear inflammation, pressure,

and impedance, as well as improved conduction, resulting in relief of the inhibition of bone conduction. It used to emphasize to grind the upper wall until very thin, but if the meninges were very low, the risk of leakage of cerebrospinal fluid was high. During surgery, to expose the lesions of the upper tympanum and retain the wall of the external auditory canal, the outer wall of the external auditory canal was removed and re-positioned to maintain the thickness of the bone and to expose the anterior wall of the tympanum directly. At the same time, since cholesteatomas always penetrate into the upper tympanic chamber. This is the main risk factor of recurrence. Thus, bone repair was used instead of membrane repair, to hold the pressure and prevent recurrence. Maintaining the posterior wall of the external auditory canal during surgery provided an advantage.

Long-term effects of treating middle ear cholesteatoma with multi-techniques

After more than one year of follow-up, the 124 ears treated in the present study had good outcomes. Differences between children and adults may have been due to immediate treatment and reduced inflammation. Further follow-up studies revealed that, after more than seven years, the number of ears with cholesteatoma relapses increased from six (4.8%) to 17 (13.7%). The mean time between relapse and the primary operation was 67.94 ± 23.14 months (ranging from 26 to 108 months), suggesting that cholesteatoma relapse could occur even nine years after the operation. Consistent with present findings, Kuo et al. [7] also reported a mean relapse time of 10.4 years (ranging from 1.9 to 17.2 years) in a 29-year follow-up study of 71 patients, including five ears with relapse times of more than 10 years. Therefore, follow-up times should be more than 10 years for patients undergoing these operations. The success rate in the present study was 83.87% (104/124 ears), including 48 ears (38.7%) with effective results. No relapses were observed in patients that underwent reoperations. Their hearing also improved. No statistical differences between long- and short-term GAP, GAP change, or AC were observed, suggesting that these surgical procedures provide excellent long-term effects.

Conclusion

Results of the present study demonstrate a very low relapse rate for intact-canal wall and scutum plasty techniques in patients with middle ear cholesteatomas. These techniques could also improve hearing and should be recommended for use in clinical settings.

Disclosure of conflict of interest

None.

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