Efficacy of minimally invasive endoscopic ear surgery procedures

Developing new therapeutic options for diseases affecting the middle and inner ear

DOCTORAL (Ph. D.) THESES

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1 Introduction

1.1 Function and anatomy of the middle ear

The middle ear is an impedance transducer, its main function is acoustic impedance matching, i.e. the transfer of longitudinal sound waves from the air to the fluid space of the perilymph, which, in turn, causes the Corti organ to begin the process called hearing.

In terms of sound wave propagation, we can draw the medial and lateral boundaries of the middle ear by defining the lateral boundary as the eardrum and the medial boundary as the oval window. The tympanic membrane forms the boundary between the outer and middle ear, and the oval window provides the connection between the middle and inner ear. The three auditory bones, the hammer, the anvil and the stirrup, mediate between them. The handle of the hammer rests against the eardrum, while the base of the anvil covers the oval window. The hammer and the stirrup are connected by the anvil. This is how the transmission of the stimulus from the outside world to the inner ear is established.

1.2 Tympanoplasty

Tympanoplasty is a modern ear surgery solution for chronic otitis media and its residual conditions, creating a closed, air-retaining tympanic cavity. The creation of a ventilated tympanic cavity creates the possibility of correcting conductive hearing loss.

Tympanoplasty consists of two phases: a rehabilitation phase and a reconstruction phase**.**

The sanation phase of tympanoplasty is the removal of abnormalities in the tympanic cavity(e.g. cholesteatoma, damaged auditory bone, sarcoid tissue, tympanic cavity polyps and scars). The reconstructive phase of tympanoplasty is the reconstruction of the damaged, or inadequately functioning tympanic membrane and ossicular chain.

In 1956, *H. Wullstein* created the 5-element classification of tympanoplasty.

The term myringoplasty was introduced by *Berthold E. et al. in* 1878. Professor *A. Mudry* proposed the clarification of the terms type I tympanoplasty and myringoplasty in 2008. Considering that this thesis will deal with Type I tympanoplasty later in this paper, I consider it important to clarify here the difference between the two procedures.

The difference is that while myringoplasty involves manipulation of the tympanic membrane or the eardrum alone, type I tympanoplasty involves also manipulation of the

annulus, which means that a tympanomeatal flap is created. Importantly, the ossicular chain is not affected.

1.3 Chronic suppurative otitis media

The main features of chronic otitis media are intermittent discharge from the ears, perforation of the eardrum and conductive hearing loss. These symptoms persist for months, rarely years.

The two subtypes are the mesotympanic and the cholesteatoma form. The former has an intact, round, central true perforation of the eardrum, the latter classically has a sac growing towards the tympanic cavity, immitates a perforation at the edge of the eardrum, destroying the eardrum and the ossicular chain. Typically, the epithelium lined sacc starts from the upper, and less often the lower back quadrant, of the eardrum and grows towards the cavity of the middle ear. It is worth noting, however, that recent publications on the definition, classification and staging of cholesteatomas describe a cholesteatoma as a space occupating tumor. It is composed of the squamous epithelium (matrix) in the area of the tympanic cavity and/or mastoidal cell system, the subepithelial connective tissue (perimatrix) and the keratin mass produced. This may be accompanied (but is not obligatory) by inflammation of the surrounding tissue. According to the most recent classification, cholesteatoma can be congenital, acquired and unclassifiable. A relatively recent theory that presents a completely different view of the development of cholesteatoma is the so-called mucosal traction theory.

The treatment is always tympanoplasty, which involves, if necessary, repair of the suppurative process, closure of the perforation of the eardrum and restoration of the ossicular chain.

1.4 Minimally invasive endoscopic ear surgery

The endoscopic anatomy of the structures of the middle ear was first described by *Mer and colleagues in the* 1960s. The advantages of the endoscope in functional sinus surgery and anterior skull base surgery have been well known for decades. In otolaryngology, however, the inadequate diameter and length of the optics, the poor resolution of the previous endoscopic cameras and the difficulties of the technique have meant that the introduction of endoscopic techniques in this field has been delayed until now. Today, ear surgery is almost exclusively performed using a microscope. The increasing number of publications on this

subject over the last 5 to 10 years is proof of the growing importance of otoendoscopy. This technique has made it possible to gain a better understanding of the anatomy of the middle ear, a difficult and constricted area, and has greatly facilitated the understanding of the pathophysiology of certain ear diseases.

Although the endoscope has been a tool in sinus surgery for decades, it has only occasionally been used in middle ear surgery as an adjunct to microscopic ear surgery, most often as a final step to exclude residual cholesteatoma. However, the current endoscopic surgical technique has evolved considerably beyond its initial use, as the endoscope is used not only for insight but also for exploration, dissection and reconstruction. The endoscope offers the possibility of avoiding retroauricular incision and canaloplasty, which are often unavoidable steps in microscopic surgery. Under endoscopic control, the ear surgery technique performed through the external auditory canal is known internationally as *"Transcanal Endoscopic Ear Surgery (TEES)"*.

1.4.1 Endoscope versus microscope

The endoscope and the microscope are instruments based on different technological backgrounds, which, apart from their advantages and disadvantages, differ most significantly in the visualisation field they provide. The lens of the microscope is positioned approximately 250 mm from the surgical site, so that the narrowest point of the external auditory canal is located between the two, limiting the desired view (*Figure 1*). In contrast, the endoscope is generally positioned 10 mm from the surgical site, medial to the narrowest point of the external auditory canal, to provide a wider angle of view. The proximity of the endoscope lens to the surgical site thus provides a more focused magnification and a more detailed image compared to a microscope. The use of different angled endoscopes, while avoiding major bone work, allows insight into the hidden sinuses of the middle ear ("behind the corner"), including the tympanic sinus, a common site of residual cholesteatoma. However, in addition to its advantages, the disadvantages of using an

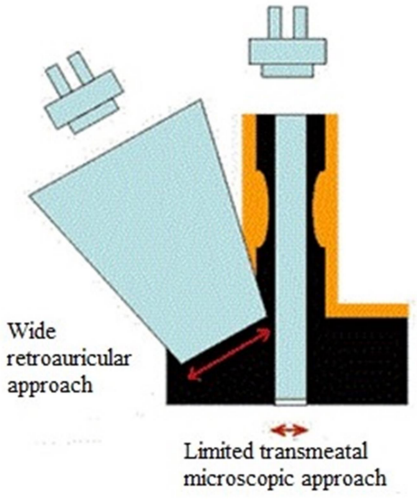
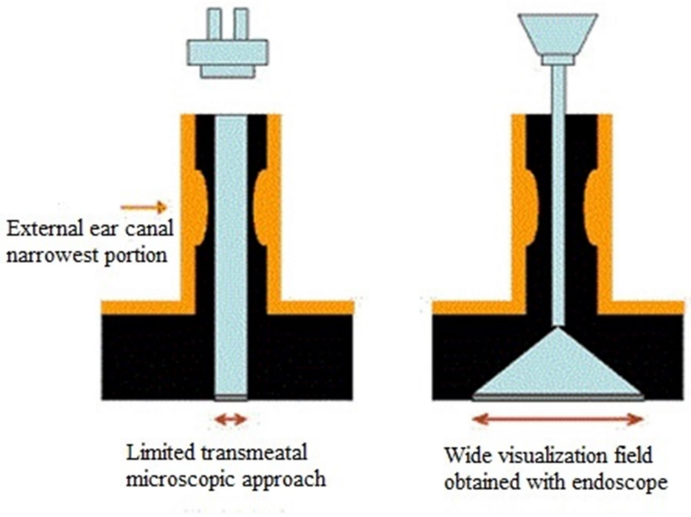


Figure 1 (source: own ed.)

endoscope should also be mentioned. The obvious difficulty is the one-handed dissection, which is the longest part of the learning curve to master. A further disadvantage is the loss of spatial (3D) vision, which can be compensated to a certain extent by the frequent movement of the endoscope, creating a so-called pseudo-3D sensation.

1.4.2 Tympanic cavity versus mastoid cavity system



The professional conception is that the tympanic cavity is the target area for the endoscope, while the mastoid is the microscopes. There are several practical reasons why the advantages of the endoscope cannot be exploited during manipulations in the mastoid cavity.

Figure 2 (own ed.)

The mastoid cavity cannot be approached from the external auditory meatus, unlike the tympanic cavity, and therefore processes involving the mastoid cell system are still achieved by mastoidectomy, which requires more extensive bone work *(Figure 2). The* generally accepted postero-superior limit of dissection in endoscopic middle ear surgery is the antrum. However, with special curved instruments and the use of endoscopes with different angles of view, even cases of small cholesteatoma extending into the antrum can be treated. In the case of processes extending posteriorly from this limit, dissection by microscopic mastoidectomy is more appropriate.

1.5 Quality of life aspects of chronic otitis media and tympanoplasty

The concept of Quality of Life (QoL) first emerged in the 1970s as an important new endpoint to analyse in health care. The World Health Organization (WHO) defines quality of life as the position of an individual in life in the context of the culture and value system in which he or she lives, in relation to his or her goals, expectations, norms and concerns.

The aforementioned forms of chronic suppurative otitis media cause a number of quality of life problems for affected patients, such as a foul-smelling ear discharge, hearing loss and, less commonly, dizziness. Furthermore, affected patients are not allowed to let water in their ears. The procedure itself (tympanoplasty) can also potentially be associated with cosmetic disadvantages, poorly improved hearing and certain surgical complications.

The majority of QoL questionnaires for the patient population with existing ear disease focus on outcomes, regardless of the surgical technique used. In addition, these studies mostly compare a healthy patient population with a group of patients with chronic otitis media.

Questionnaires focusing on postoperative quality of life aspects comparing the outcomes of two surgical techniques are well suited, especially when comparing a new, minimally invasive technique with a traditional, more invasive technique.

It is important to note that, as in any field of surgery, there are limitations to minimally invasive procedures in ear surgery. As a practicing clinician, we often encounter recurrent, difficult to control middle and inner ear diseases, sometimes with active middle ear infections after several surgical failures. In such cases, the principle of minimal invasiveness is pushed into the background and we have to give priority to more radical surgical solutions.

1.6 Subtotal petrosectomy

Subtotal petrosectomy (STP) is the surgical treatment of chronic and recurrent ear diseases affecting the os temporale, excluding the cells of the apex of the petrous bone, and the middle ear cavity. The procedure involves the creation of an extensive surgical cavity and often involves the visualisation and exploration of anatomical structures of vital importance (middle and posterior fossa dura, internal carotid artery, bulbus venae jugularis, facial nerve, internal auditory canal). At the end of the operation, the middle ear and mastoid cavities are obliterated with abdominal fat after closure of the externa auditory canal and the eustachian tube, so that reconstruction of the conductive system is not an option.

Over the last 10-15 years, interest in STP has been renewed and the surgical indication has been expanded with many new elements. In the last decade, this intervention has come to the fore again, due to its many advantages and its ability to be combined with new hearing rehabilitation methods, as a definitive solution to many problematic middle ear disorders.

2 Objectives

To demonstrate with the highest level of evidence, both nationally and internationally, that endoscopic Type I tympanoplasty is as effective as microscopic Type I tympanoplasty, but less invasive.

To be the first in Hungary and in the international literature to create a new questionnaire, supported by statistical analysis, to address quality of life issues after tympanoplasty.

Using the questionnaire above, to be the first study, both nationally and internationally, to investigate the quality of life indicators between microscopic and endoscopic techniques.

In view of the renewed interest in combining subtotal petrosectomy with modern hearing rehabilitation methods in the international literature, we are the first in Hungary to present our results with the above mentioned technique.

3 Investigations

3.1 Comparison of postoperative outcomes of endoscopic and microscopic type I tympanoplasty - a meta-analysis

3.1.1 Methodology

The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines were used to report our results. The protocol of this study was registered with PROSPERO (registration number: CRD42018095616; www.crd.york.ac.uk/PROSPERO).

Selection and exclusion criteria

Following the PICO framework, eligible studies examined patients (P) at various age, suffering from dry, central tympanic membrane perforation, and, who underwent type I tympanoplasty, carried out with either the endoscope (I) or microscope (C), and discussed strategic, postoperative outcomes (O). Patients with sensorineural or mixed hearing loss, discharging ear, cholesteatoma, ossicular chain abnormality, or combating an active ENT infection were excluded.

Randomized and non-randomized studies (nRCT), including conference abstracts, were all included. Case reports, case series, review articles, letters, editorials, and comments were excluded.

3.1.2 Estimating the Risk of Bias (RoB)

RoB in the individual studies was independently assessed by two authors (I.P. and I.T.). Randomized controlled trials were assessed using the Cochrane Risk of Bias Tool, in compliance to the following domains: random sequence generation, allocation concealment, blinding of participants, personnel, and outcome assessment, incomplete outcome data, selective reporting, and other bias. In the case of nRCTs, we used the topic-tailored version of Newcastle-Ottawa Scale (NOS) regarding three domains: selection, comparability, and outcome assessment. If an agreement could not be reached, a third-party arbitration was adopted to settle the dispute (I.Sz.).

3.1.3 The GRADE approach

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) was used for assessing the quality of evidence of critical and important outcomes assessed. The grade of evidence was assessed in support of subgroups of RCTs, if possible.

3.1.4 Results

3.1.4.1 Graft uptake rate:

Endoscopic Type I tympanoplasty performs as well as microscopic Type I tympanoplasty (high level of evidence).

A total of 1179 interventions were found to be eligible for inclusion in the 16 studies reviewed. Based on the pooled results in a homogeneous database, endoscopic type I tympanoplasty was found to be as effective as type I microscopic tympanoplasty, with a graft incorporation rate of 90.5% reported in the endoscopic group and a success rate of 88.3% in the microscopic group (OR: 1.21, CI: 0.82-1.77; I^2 =0.0%, p=0.910). Conducting trial sequential analyses, we conclude that further studies are potentially futile.

3.1.4.2 Postoperative audiological findings:

Endoscopic Type I tympanoplasty performs as well as microscopic Type I tympanoplasty (very low evidence level).

Fifteen authors published data on audiological outcomes. No statistically significant difference was found in the analysis of the postoperative mean air-bone gap (ABG), but a trend in favour of endoscopic exploration was observed (WMD=-1.13; 95% CI: -2.72-0.45; I^2 =78.1%, p<0.001). Regarding the air-bone (ABG) categories, in the group with ABG of 0-10

dB, endoscopic technique was superior to microscopic exploration. Our sensitivity analysis showed that if any of the studies examined were excluded from the analysis, the overall results would not be affected or altered.

3.1.4.3 The need for canaloplasty:

Endoscopic Type I tympanoplasty performs better than microscopic Type I tympanoplasty (high level of evidence).

Six articles examined the rate of canaloplasty, including 594 interventions. The rate of canaloplasty was found to be eight times greater when using the microscope than when using the endoscope (15% vs 0%; OR=7.96; 95% CI: 4.30-14.76; I^2 =0.0%, p=1.000). In sensitivity analysis, if and when any study was excluded from the analysis, the overall results were not affected or altered.

3.1.4.4 Cosmetic results:

Endoscopic Type I tympanoplasty performs better than microscopic Type I tympanoplasty (medium evidence level).

Cosmetic results were reported in 4 studies, for a total of 279 interventions. Microscopic type I tympanoplasty was 19 times more likely to have an unfavourable cosmetic outcome compared to endoscopic exploration (58.3% vs 0%; OR=19.29; 95% CI: 11.37-32.73; I^2 =0.0%, p=0.839). Our sensitivity analysis showed that if any of the studies examined were excluded from the analysis, this fact did not affect or change the overall results.

3.1.4.5 Operation time:

Endoscopic Type I tympanoplasty performs as well as microscopic Type I tympanoplasty (low evidence level).

Twelve studies evaluated data on operating time, but three were excluded due to incomplete data reporting. Of the studies included in the review, 6 were non-randomised controlled trials (nRCT) and another 3 were randomised controlled trials (RCTs). Based on pooled data analysis, there was no statistically significant difference between the two approaches (WMD=-21.11; 95% CI: -42.60-0.38; I^2 =99.3%, p<0.001). Egger's test confirmed that there was no likelihood of publication bias (p=0.902). When subgroup analysis of nRCTs was performed, we found that type I endoscopic tympanoplasty took 31 minutes less on average (WMD=-31.83; 95% CI: -56.72- -6.94; I^2 =99.3%, p<0.001). In the analysis of RCTs, no statistically significant difference was found between the two groups in terms of operative time (WMD=0.30; 95% CI: -32.18-32.79; I^2 =98.0%, p<0.001).

3.2 Quality of life questionnaire after tympanoplasty

3.2.1 The aim of our research

To be the first in Hungary and in the international literature to create a new validated questionnaire addressing quality of life issues after tympanoplasty.

3.2.2 Methodology

3.2.2.1 Ethical considerations

Prior to the conduct of the study, the University of Pécs, Faculty of Medicine, Regional Research Ethics Committee granted ethical approval and the study fully complies with the Helsinki Declaration of Ethical Principles for Medical Research Involving Human Subjects. Ethical approval no. 8107 PTE-2019.

3.2.2.2 Design and structure of the questionnaire

The questionnaire was developed by our working group based on surveys from other ear surgery questionnaires and our own clinical experience. As the survey was conducted in Hungary, the primary language was Hungarian, and later translated into English for validation and international publication.

The questionnaire is accompanied by an informed consent form for the patient, which must be signed by the patient if he or she is selected for the study.

The translation has been certified by the Institute of Health Language and Communication of the University of Pécs University of Medical Sciences (certification code number: 2021.04.11.)

The questionnaire - the exact title of which is "Quality of life questionnaire after tympanoplasty" - contains ten questions, five of which were open-ended, three of which were answered on a visual analogue scale and two of which were provided as supplementary questions. For the questions to be answered and those to be rated on a visual analogue scale, the patient was given the option to write down on paper any details to be highlighted in their own words under the "Comment:" section. Many of the questions have been used in international quality of life studies before, but have not been tested in this form as a single questionnaire.

The two figures below (*Figures 3-4)* show the structure of the questionnaire.

Tympanoplastica utáni, életminőséget felmérő kérdőív

Páciens neve: TAJ:

Születési idő: Operáció időpontja:

Az alábbiakban kérdések következnek. Kérem, hogy a skálán értékelendő kérdéseknél a megadott értékek közül ***egyet*** *legyen kedves* ***aláhúzni/bekarikázni****. Az eldöntendő kérdéseknél az igen-t/nem-et(/egyebet)* ***aláhúzni*** *szíveskedjék. Némely kérdés időintervallumra kérdez, itt az időtartam* ***napokban/hetekben*** *történő megadására törekedjen. Ezen kívül minden kérdésnél lehetősége nyílik a „Megjegyzés:" pontnál egyéb észrevételének írásba foglalására. Kiskorú/cselekvőképtelen páciens esetén kérem, hogy szülője/gondviselője/törvényes képviselője töltse ki a kérdőívet.*

Operációt követően tapasztalt-e fájdalmat az operáció helyén? Amennyiben igen, kérem, értékelje egy 1-10-ig terjedő skálán. Az 1-es az éppen érezhető, legenyhébb fájdalom, a 10-es pedig az élete során érzett legerősebb fájdalom. Fájdalom erőssége:

Nem lépett fel fájdalom. 1 2 3 4 5 6 7 8 9 10

Megjegyzés:

Operációt követően tapasztalt-e fejfájást, amit feltehetően az operáció váltott ki? Amennyiben igen, kérem, értékelje egy 1-10-ig terjedő skálán, az előző kérdésnek megfelelően. Fájdalom erőssége:

Nem lépett fel fájdalom. 1 2 3 4 5 6 7 8 9 10

Megjegyzés:

Operációt követően tapasztalt-e hányingert?

igen / nem

Megjegyzés:

Operációt követően lépett-e fel hányás?

igen / nem

Megjegyzés:

Figure 3.

Operációt követően jelentkezett-e szédülés? *Amennyiben Ön az operáció után legalább 4 hónappal kapja meg a kérdőívet, a kérdés a következőre módosul:*
Az operáció óta gyakrabban lép-e fel szédülés? *Kérem, szíveskedjék kifejteni a szédülés minőségét, kitérve annak jellegére, gyakoriságára, időtartamára!*

igen / nem

Megjegyzés:

Operációt követően tapasztalt-e ízérzészavart? *Amennyiben Ön az operáció után legalább 4 hónappal kapja meg a kérdőívet, a kérdés a következőre módosul:*
Az operáció következményeként tapasztal-e ízérzészavart? *Kérem, szíveskedjék kifejteni az ízérzés változásának minőségét, kitérve annak lokalizációjára (hol?), az ízek érzetére (melyik íz?), a változás irányára (erősödött/gyengült?)!*

igen / nem

Megjegyzés:

Elégedett-e a sebgyógyulást követő kozmetikai eredménnyel? Kérem, értékelje egy 1-10-ig terjedő skálán! Az 1-es érték fejezi ki a sebgyógyulással való teljes elégedetlenséget, míg a 10-es érték (szinte) láthatatlan operációs hegre enged következtetni.

1 2 3 4 5 6 7 8 9 10

Operációt követően hány napot töltött kórházban?

Hány nap után tudott ismét munkába állni? *Amennyiben Ön nem munkavállaló, a kérdés így szól:*
Hány nap után tudta felvenni a szokásos életritmusát?

Operációt követően tapasztalt-e változást a hallásélményben? *Amennyiben Ön az operáció után legalább 4 hónappal kapja meg a kérdőívet, úgy a kérdés a jelen állapotára kérdez rá.*

igen / nem *Változás esetén:* javult / rosszabbodott

Aláírás, dátum:

Figure 4.

3.3 Comparison of quality of life indicators of endoscopic and microscopic type I tympanoplasty

3.3.1 Material and method

All patients included in the study were operated on at the Department of Otolaryngology, Head and Neck Surgery, University of Pécs. Only cases where type I tympanoplasty was performed were included.

In order to exclude as much as possible database heterogeneity due to surgical experience, only patients operated on by surgeons with at least ten years of experience were included.

The study started on 4 April 2017, and the last patient whose data were processed in this study underwent surgery in November 2021.

3.3.1.1 Selection criteria

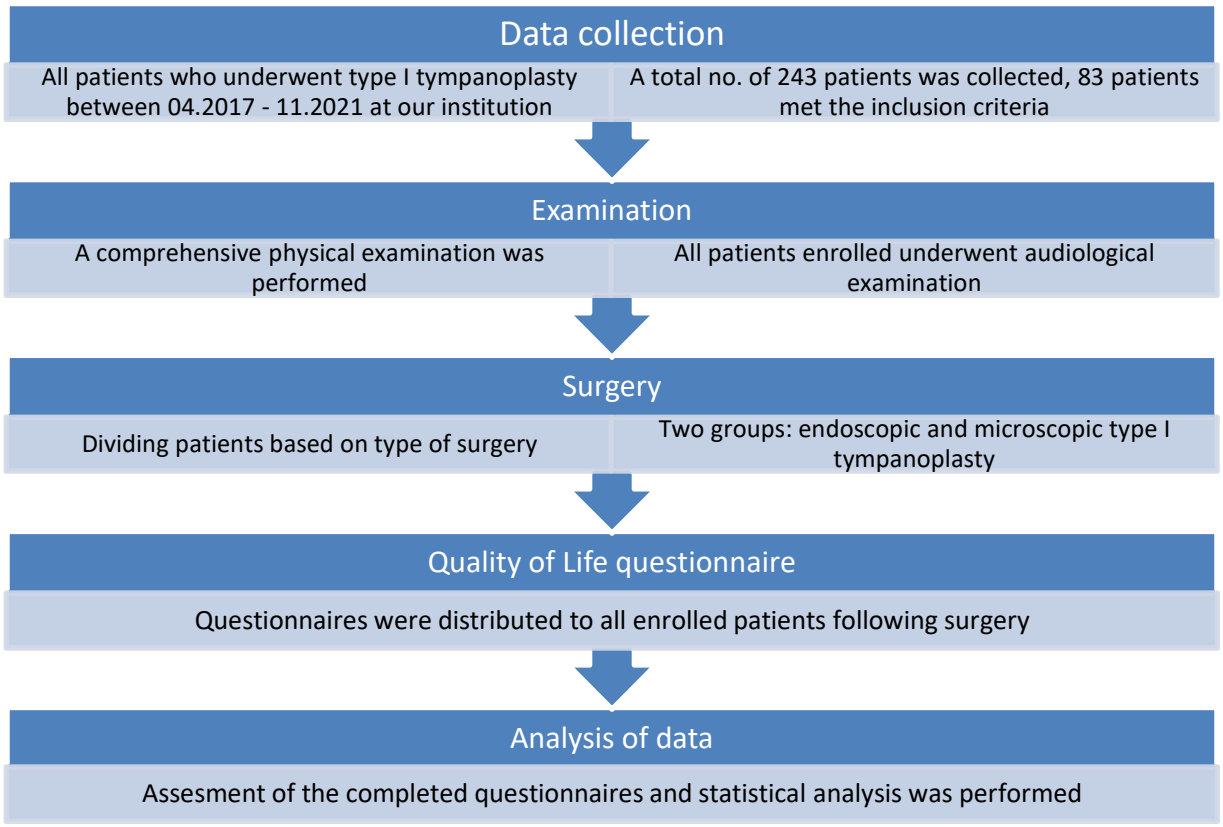
1. Patients with chronic mesotympanic otitis media
2. The affected side must have been dry (inactive) for at least one month before surgery
3. Primary ear surgery

3.3.1.2 Exclusion criteria

1. Patients with chronic cholesteatomas expanding beyond the atticus
2. Patients with active ear discharge
3. Patients with a serious chronic disease (such as diabetes mellitus)
4. Patients who have had previous ear surgery

3.3.1.3 Data collection

The main workflow stations are shown in the following inset diagram.



The study was conducted as a prospective cohort study. The questionnaires were first distributed to patients within the first 24 hours after surgery, in order to capture as accurately as possible the impact of the intervention on the patient's postoperative quality of life. Our minor patients completed the questionnaire with the help of their parents.

In the 4th month postoperatively, we asked our patients again to answer the above questions.

During the follow-up examination, the following complaints were investigated on several occasions: dizziness, loss of taste and hearing loss. At the follow-up examination, the patient was asked to score 0 or 1, depending on whether he or she experienced any of these presenting complaints. The change in hearing had to be similarly indicated as either a change in negative direction (0), stagnation (1) or a change in positive direction (2).

3.3.2 Results

3.3.2.1 Examined outcomes

There was a small, statistically non-significant difference in postoperative pain in favour of the endoscopic group.

No representative differences were found when looking at the rate of postoperative headache.

As endoscopic type I tympanoplasty has been shown to be a less invasive procedure, we focused mainly on the cosmetic results. Here we found a statistically significant difference in favour of the endoscopic group.

In relation to audiological findings, we wanted to know if the patient had experienced any change in hearing after the surgery and if so, in what direction. When analysing our data, we found no statistically significant difference between the two groups.

When analysing the prevalence of postoperative dizziness (p= 0.962) and taste disturbance (p= 0.769), no convincing differences were found between the two interventions. It is worth noting that some patients reported taste changes in the "Note:" section, whereby the perception of sweet taste was significantly increased at the expense of other tastes.

There was no statistically significant difference in the incidence of postoperative nausea (p=0.135), although the endoscopy group had better mean values.

No statistically significant difference was found between the two groups in the presence of postoperative vomiting (p=0.790).

Patients were asked to declare how many days they spent in hospital after surgery. A statistically significant difference was found between the two groups in favour of the endoscopy group.

3.3.2.2 Evaluation of questionnaires completed during follow-up

In this subsection, we compare the endoscopic group scores for the three variables: dizziness, taste disturbance and postoperative hearing.

In the control study, only two patients in the endoscopy group continued to complain of dizziness, and as can be seen, the proportion of patients complaining of dizziness has decreased significantly. This is a statistically significant difference in favour of the endoscopic group (p = 0.025). Five patients who complained of dizziness in the immediate postoperative period were free of complaints at follow-up.

Four patients in the endoscopy group complained of persistent taste disturbances. Overall, we observed an improvement in taste sensation, with a statistically significant difference between early postoperative and late control results at $p = 0.046$.

3.4 Combining subtotal petrosectomy and modern hearing rehabilitation methods, literature review

Subtotal petrosectomy (STP) has been known for decades, but due to its over-radicality and adverse effects on hearing, it has been almost forgotten until recently as a surgery at the border between middle ear and skull-base surgery. Today, STP is the initial step in almost all lateral skull base surgery.

Our study is the first publication in Hungarian otosurgery practice, covering a large number of patients, in which we review the correct indications for STP and the details of the surgical technique. We analyse our own results in the light of the most important publications in the literature to date, combined with modern hearing rehabilitation tools.

3.4.1 Patient selection and methods

In our retrospective clinical study, 45 surgeries of 44 patients who underwent STP at the University of Pécs Clinical Centre, Department of Otolaryngology and Head and Neck Surgery between 1 October 2014 and 1 April 2019 were analysed (one patient had both ears operated on). The four basic criteria for STP at our institution were defined as follows:

1) Turning outwards and closing the meatal skin of the external ear canal ("blind sac closure").
2) Performing a radical mastoidectomy, removing all residual epithelium from the cavity of the middle ear.
3) Exenteration of the cellular system of the middle ear, including perifacial, perisigmoid, perilabyrinth and hypotympanal cells.
4) Obliteration of the surgical cavity with abdominal fat.

The data from following cases where collected, if:

1) The above definition applied.
2) Minimal extension of the original bone work of the STP was required (drilling of any semicircular canal, exposure of the facial nerve and dura, dissection of the internal auditory canal).
3) We combined the surgery with either a simultaneous or sequential modern hearing rehabilitation device.

Criteria for exclusion from the study:

1) If the STP was the initial step of extensive skull-base surgery (transotic, transcochlear, translabyrinth, infratemporal fossa, subtotal temporal bone resection, transtemporal skull-base surgery).
2) If no ear canal skin inversion and closure ("blind sac closure") has been performed.
3) If patient documentation was incomplete (e.g. post-operative audiometric test results were not available, patient compliance was inadequate) or if follow-up was less than 6 months.

3.4.2 Results

Of our forty-four patients, 25 (57%) had at least 2 previous middle ear surgeries. Of our patients who had undergone bilateral surgery, 3 had had 3 previous unsuccessful ear operations in one ear and 4 in the other. One of our patients had previously undergone cochlear implantation. In the other patients, STP was performed as a first intervention (*Table 1*).

Indications for subtotal petrosectomy in our patients	
Indication	**Case number**
"Wreck ear" (numerous unsuccessful middle ear operations, persistent discharge, mixed or conductive hearing loss, possibly deaf ear)	26
Type B3 tympanomastoid paraganglioma	5
Horizontal pyramid fracture	5
Mastoid schwannoma	3
Eosinophilic otitis media	1
Ot. med. supp. chron. mesotymp.	1
Tumour involving the petrous bone	1
Wegener's granulomatosis	1
Saccus endolymphaticus tumor (ELST)	1
C.I. replacement, difficult anatomy ("wreck ear")	1

1. Table

In 6 of the cases, the surgery was performed on deaf ears. Of the other 38 cases, 4 patients could not be convinced to undergo regular hearing tests. The average preoperative air conduction mean (0.5-1-2-4 kHz) of the 34 patients we followed regularly was 90 ± 21 dB, the average bone conduction mean was 62 ± 31.2 dB, and the air-bone gap was 28 ± 20.6 dB. The mean postoperative air conduction, bone conduction and air-bone gap values were 96 ± 6.1 dB, 66 ± 36.8 dB and 33 ± 2 27.5 dB, respectively.

The audiological results of the 14 cochlear implantations performed in 13 patients and the 6 BAHA implantations are summarised in *Table 2.*

How hearing rehabilitation works	Number of cases (pcs)	No (f/n)	Average age (years)	Average functional gain (dB)	Average speech hearing threshold improvement (dB)	Average speech understanding improvement (%)
Cochlear implantation	14	7/7	43,5	62,42	59,58	54,50
BAHA implantation	6	1/5	52	19,50	31,33	40,83

2. *Table*

The values of the two round window VSB surgery patients are shown in *Table 3.* Our first case unfortunately went deaf over time and is currently awaiting cochlear implantation.

Vibrant Soundbridge audiological results										
Name of patient	Age (years)	No (F/N)	Preop. SRT50 (dB)	Preop. WRS65 (%)	Postimpl. (dB)	FG (dB)	Postimpl. SRT50 (dB)	SRT50 Gain (dB)	Postimpl. WRS65 (%)	WRS65 Profit (%)
					free-hangar	500-4000 Hz				
B.K.	54	N	92	0	88	1	74	18	0	0
BM.	64	N	84	0	42	43	45	39	80	80

3. *Table*

4 Discussion

Endoscopic ear surgery (TEES) represents a growing, minimally invasive branch of otologic surgery. There have been quite a few publications on TEES in recent years. This fact has prompted the idea of conducting a study comparing endoscopic and conventional microscopic ear surgery techniques through the most commonly performed so-called type I tympanoplasty and clarifying the controversies surrounding the two approaches. Our study shows that endoscopic tympanoplasty compared with the microscopic technique achieves representative results in terms of graft incorporation and hearing recovery. In terms of cosmetic results, a more favourable outcome was achieved with endoscopic technique and the need for canaloplasty was significantly lower in the endoscopic study group, a clear advantage of the technique.

Thus, our meta-analysis concluded that endoscopic type I tympanoplasty may be a first-line procedure for the treatment of middle ear infections with chronic mesotympanic otitis media.

Both techniques performed well when examining the graft uptake rate. Technical differences between the procedures (e.g. material used for eardrum reconstruction: fascia, perichondrium or cartilage) could have affected the results of the study in terms of clinical heterogeneity, but this was not reflected in statistical heterogeneity (I2 = 0.0%).

One of the primary advantages of Type I endoscopic tympanoplasty was that it did not require canaloplasty. The fact of minimal invasiveness was confirmed in both the RCTs and the nRCTs subgroup studies: in the endoscopic group, no canaloplasty was required on any occasion. In contrast, in the microscopic exploration group, 47 of the 309 procedures (15%) required canaloplasty, which involved the drilling of the medial part of the anterior bony wall of the external auditory canal.

The big difference between the endoscopic and microscopic techniques is that the endoscope lens can be brought within a centimetre of the surgical site, bypassing the narrowest part of the external auditory canal, while the microscope lens is positioned laterally, limiting the full wide view of the surgical site.

However, the effectiveness of TEES is underlined by the fact that retroauricular skin incisions can be completely avoided with the technique, while visible scarring is almost inevitable when using the microscope. The minimal invasiveness reduces the chance of possible postoperative auricular deformity, numbness and pain. Our meta-analysis has shown that the use of an endoscope is definitely preferable in terms of cosmetic results.

Our study is significantly heterogeneous, which may reflect clinical and/or methodological differences between RCTs. The absence of the need for an additional surgical incision may explain the shorter operative time observed with the endoscopic approach.

Our meta-analysis has several strengths. We performed a thorough systematic search and risk of bias estimation using the "Cochrane Risk of Bias Tool" and "NOS".

The "GRADE" approach was used to determine the level of evidence for each claim. After the subgroup analysis was completed, only RCTs were used to determine the evidence levels of the claims.

The Trial Sequential Analysis (TSA) concluded that there was no difference in graft uptake rate between endoscopic type I tympanoplasty and type I microscopic tympanoplasty.

There is a growing demand for the development of questionnaires to help medical research measure the results of certain new surgical techniques. Particular attention is being paid to the effects on quality of life. Questionnaires for this purpose are playing an increasing role in research and are seen as a valid and effective tool for data collection.

However, there are relatively few quality of life questionnaires in the literature that are used to analyse the quality of life of patients with chronic otitis media (COM).

One such questionnaire is the COMQ-12, which was designed to assess the impact of otitis media on quality of life from the patient's perspective. This questionnaire compares a normal, healthy population with patients with chronic otitis media. *Phillips et al.* conclude that the outcome of studies using the COMQ-12 is greatly influenced by how we define the "normal" population.

There is another similar questionnaire, the Chronic Ear Survey (CES), which has been used in many cases in the past. The CES provides information on the patient's overall physical condition, clinical status, and focuses on the patient's symptoms and how much the otitis media is hindering the patient in their daily activities. It also scores the extent to which health resources are used in the patient's care.

Nadol et al. found that the CES scores of 147 patients with chronic otitis media in their prospective, non-randomised study were significantly lower compared to the control group. They also observed, however, that if surgical intervention had been performed, there was a significant improvement in the patient's symptoms, and this was reflected in the questionnaire.

Devi et al. used the Modified Chronic Otitis Media-4 questionnaire in their study. They investigated the impact of Type I tympanoplasty on the quality of life of patients with COM. They looked at the following endpoints: pain, hearing loss, anxiety and limitation in daily activities. It was concluded that Type I tympanoplasty significantly improved patients' quality of life for the above endpoints. However, their study also found statistically significant improvements in audiological outcomes.

From the studies mentioned so far, we can conclude that the use of questionnaires in different languages and translations gives us the opportunity to study different patient populations and cultures. It can provide information on the functioning of different health care systems, help us to understand the importance of a disease and to decide on the appropriate therapeutic approach.

It can be seen that the questionnaires presented above either compare a healthy population sample with patients with COM, or they focus on the impact of the disease on quality of life. It should be stressed that none of the publications and questionnaires mentioned so far have investigated the impact of the type of surgical technique chosen on the patient's quality of life.

The questionnaire developed by our team aims to analyse how the surgical technique chosen affects the patient's postoperative quality of life. We believe it can be used to assess any patient population with COM who have undergone surgery. Our study focused on patients who underwent type I tympanoplasty for chronic mesotympanic otitis media.

Our patient population was divided into two groups: patients undergoing endoscopic type I tympanoplasty and patients undergoing microscopic type I tympanoplasty. We found that there was no statistically significant difference between the two groups in terms of postoperative pain, headache, nausea and vomiting. Nevertheless, our analysis showed a slight advantage in favour of the endoscopic technique. It is worth noting that postoperative nausea was likely to be influenced by the medication administered during anaesthesia, which may have modified the outcome of this study.

For postoperative dizziness and taste disturbance, the questionnaire was completed by patients in the immediate postoperative period and also at least four months after surgery. No statistically significant difference was found between the two groups, but in the late postoperative period the results were in favour of the endoscopic group.

A visual analogue scaling method was used to evaluate the cosmetic results. Our analysis showed a statistically significant result in favour of endoscopic type I tympanoplasty, which is consistent with our previous results found when performing our meta-analysis.

When examining the hospitalisation rate, we also found that the number of days spent in hospital after this type of surgery was statistically significantly lower in the endoscopic group than in the microscopic tympanoplasty group. In our opinion, this is an important finding, given the increasing emphasis on minimally invasive, one-day surgery and its correlation with health economics.

The recovery rate of patients has raised the question of how many days patients need to return to work after surgery. However, we found that these results are not so easy to interpret. Indeed, there are underlying socio-economic factors that may influence a patient's decision on when to return to work. It is uncommon for a patient to be unable to return to work for 90 days due to Type I tympanoplasty, despite the absence of any postoperative complications.

We also analysed our post-operative hearing results. Our questionnaire gave patients the opportunity to say whether their hearing was unchanged, worse or better. We found no statistically significant difference between the two groups, although we did find a slight percentage advantage in the immediate and late postoperative period in favour of the endoscopic group.

One of the complicating factors in endoscopic ear surgery is the one-handed dissection. In our case, the duration of surgery is expected to decrease over time, and the learning curve represents this accordingly.

One limitation of our study is that it was conducted in a single institution, and we therefore encourage a multicentre study in the future. Our long term plans include an international and national collaboration with other institutions to test the questionnaire we have developed.

It is important to note that, as in any field of surgery, there are limitations to minimally invasive procedures in otologic surgery also. There are some difficult to manage middle and inner ear diseases where minimal invasiveness is not an option and the aim is to provide a durable solution with doesnt majorly affects the life quality of the patient. Subtotal petrosectomy (STP) has been known for decades, but due to its over-radicality and adverse

impact on hearing, it has been until recently an almost forgotten surgery at the borderline between otolaryngology and skull-base surgery. Today, STP is the starting point for almost all lateral skull base surgery, and its new success is due to its ability to be combined with modern hearing rehabilitation tools.

The first description resembling STP was given by Rambo, a long-standing and recurrently secreting, chronically suppurating, repeatedly operated cholesteatoma case in wich the cavity was obliterated with a temporalis muscle flap, but initially did not close the external auditory canal. In a later communication he also reported his experience with blind sac closure. He used an endoaural incision, but did not obliterate the eustachian tube. In the 1960s, Fritz and Tschopp reported on their experience of operating on more than 100 patients using a similar technique to Rambo's.

The indications for STP have been previously summarized in *Table 1*. This surgery is therefore considered in cases where a large cavity is created following surgical removal of a limited disease that has destroyed the temporal bone (residual cholesteatoma, tympanomastoideal paraganglioma, radionecrosis, etc.). STP is also recommended in cases of complicated and recurrent disease. It is an extreme and almost unbelievable literature that STP has resulted in a definitive cure in a case where the patient had previously undergone 26 middle ear surgical procedures.

Today, one of the reasons for the rediscovery of STP is that the surgery can be combined with modern hearing rehabilitation methods. The first reports of combining STP and cochlear implantation appeared in the 1990s. Initially, the surgery was performed in two stages: one year after STP, the surgeons performed the implantation in the now inflammation-free cavity after ruling out residual disease. Nowadays, simultaneous STP and implantation is increasingly performed, unless there is doubt about the residual disease. This finding are supported by our own experience.

We have not observed any complications in our own simultaneous cases, so this will continue to be an integral part of our surgical palette. Overall, we are satisfied with the results of BAHA and cochlear implantation. Unfortunately, the first of our 2 VSB implanted patients went deaf over time, probably due to micro-damage of the round window membrane. Subsequently, the patient underwent cochlear implantation. Our second patient is a real success story in terms of hearing rehabilitation.

Following STP, following up patients with radiological methods is an essential aspect. In the past, the combination of CT and MRI was the predominant follow-up modality, but nowadays most authors, including our group, prefer diffusion-weighted MRI. We consider it advisable to follow up patients 6 to 12 months after surgery, and then at least every 2 years until 10 years after surgery. For surgical cavities with implants, we recommend HRCT (High Resolution Computed Tomography) to follow the patient. It is well known that the radiological analysis of a cavity obliterated by fat is a rather difficult task. However, HRCT can detect soft tissue growth or bone erosion, which may reveal a residual cholesteatoma. If HRCT cannot clearly exclude the presence of residual disease, 1.5 T MRI can provide additional information without significant distortion. However, if the distortion is pronounced, the implant magnet may occasionally be removed and the MRI repeated without distortion.

5 Summary, new clinical findings

Based on our results and literature the following establishments can be made:

1. We have demonstrated with the highest level of evidence, both nationally and internationally, that endoscopic Type I tympanoplasty is as effective as microscopic Type I tympanoplasty, but less invasive.
2. Based on the Trial Sequential Analysis (TSA) of the graft uptake rate between the two methods (endoscopic and microscopic), it is clear that there is no need for further randomised controlled trials to support this finding.
3. For the first time in our country and internationally, we have created a questionnaire, supported by a statistical analysis, which is new in the literature, to address quality of life issues after tympanoplasty.
4. Using the questionnaire above, we investigated the quality of life indicators between microscopic and endoscopic techniques as a first national and international study.
5. In view of the renewed interest in combining subtotal petrosectomy with modern hearing rehabilitation methods in the international literature, we were the first in Hungary to present our results with the above mentioned technique.

6 Own publications on the subject of the thesis

1. Pap István ✉ ; Kovács Márton ; Bölcsföldi Barbara ; Szakács Zsolt ; Gerlinger Imre ; Imreh Bence ; Csongor Alexandra ; Warta Vilmos ; Szanyi István - *Quality-of-life outcomes with endoscopic and microscopic type I tympanoplasty-a prospective cohort study* - EUROPEAN ARCHIVES OF OTO-RHINO-LARYNGOLOGY 2023 Oct; 280(10):4401-4408. doi: 10.1007/s00405-023-07938-6.
2. Pap István ✉ ; Tóth István* ✉ ; Gede Noémi ; Hegyi Péter ; Szakács Zsolt ; Koukkoullis Alexandros ; Révész Péter ; Harmat Kinga ; Németh Adrienne ; Lujber László et al. - *Endoscopic Type I Tympanoplasty is as Effective as Microscopic Type I Tympanoplasty but Less Invasive - a Meta-Analysis* - CLINICAL OTOLARYNGOLOGY 44 : 6 pp. 942-953. , 12 p. (2019), https://doi.org/10.1111/coa.13407
3. Gerlinger Imre ; Molnár Krisztián ; Nepp Nelli ; Tóth István ; Tóth Tamás ; Szanyi István ; Bakó Péter ; Pap, István ✉ - *Subtotal petrosectomy - indications, surgical technique, experiences in Pécs* - ORVOSI HETILAP 161 : 14 pp. 544-553., 10 p. (2020) doi: 10.1556/650.2020.31691
4. István Pap, I. Tóth, Z. Szakács, N. Gede, A. Koukkoullis, P. Révész, K. Harmat, A. Németh, L. Lujber, T. Bocskai, P. Hegyi, G. Varga, I. Gerlinger, and I. Szanyi, *"Endoscopic type I tympanoplasty is as effective as microscopic type I tympanoplasty but less invasive - Meta-analysis,"* FÜL-ORR-GÉGEGYÓGYÁSZAT, vol. 67, no. 4, pp. 139-146, 2021.
5. István Pap, A. Burián, I. Szanyi, and I. Gerlinger, *"Initial experience with endoscopic ear surgery at the Department of Otolaryngology, Head and Neck Surgery, PTE University of Tartu,"* EAR, ENT and ENT-GEAR, vol. 64, no. 4, pp. 147-152, 2018.

7 Further publications

1. T. B. Bölcsföldi, I. Pap, T. Tóth, I. Tóth, P. Révész, I. Gerlinger, and I. Szanyi, "*Surgical solution of selective epitympanal dysvalvular syndrome,"* ORVOSI HETILAP, vol. 163, no. 36, pp. 1440-1446, 2022.

2. István Szanyi, I. Pap, T. B. Bölcsföldi, and I. Gerlinger, *"Endoscopic ear surgery - a new surgical procedure in otolaryngology,"* MEDICAL TRIBUNE, vol. 17, no. 7, pp. 14-15, 2019.
3. István Szanyi, T. B. Bölcsföldi, I. Pap, I. Tóth, and I. Gerlinger, *"Selective epitympanic dysvalvular syndrome,"* FÜL-ORR-GEEGYGY, vol. 64, no. 2, pp. 34-38, 2018.
4. M. Kovács, J. Uzsaly, G. Bodzai, I. Pap, B. Lippai, T. Dergez, A. Németh, I. Gerlinger, I. Szanyi, and P. Bakó, *"Efficacy of high dose systemic versus combined (systemic and intratympanic) corticosteroid therapy in idiopathic sudden sensorineural hearing loss : A prospective randomized trial and risk factor analysis,"* AMERICAN JOURNAL OF OTOLARYNGOLOGY, vol. 45, no. 1, 2024.
5. Imre Gerlinger, É. Szabó, I. Szanyi, T. Rostás, I. Pap, P. Révész, and E. Kopjár, *"Bone powder and bioactive glass granules for mastoidobliteration in cholesteatoma surgery,"* ORVOSI HETILAP, vol. 163, no. 21, pp. 838-845, 2022.
6. István Pap, K. Jakab-Péter, J. Uzsaly, I. Tóth, M.-A. Barabás, G. Fábián, and L. Lujber, *"Transorbitomaxillary percutaneous endoscopic gastrostomy,"* ORVOSI HETILAP, vol. 163, no. 3, pp. 116-119, 2022.
7. Imre Gerlinger, I. Végh, N. Nepp, I. Pap, P. Révész, P. Bakó, I. Szanyi, T. Rostás, and I. Tóth, *"Modern treatment of pars petrosa cholesteatomas Pécs experiences,"* ORVOSI HETILAP, vol. 161, no. 43, pp. 1840-1848, 2020.
8. István Tóth, I. Pap, and I. Gerlinger, *"Cholesteatoma update 2019,"* FÜL-ORR-GÉGEGYÓGYÁSÁSÁSZAT, vol. 66, no. 1, pp. 9-18, 2020.
9. T. Bocskai, M. Kovács, Z. Szakács, N. Gede, P. Hegyi, G. Varga, I. Pap, I. Tóth, P. Révész, I. Szanyi, A. Németh, I. Gerlinger, K. Karádi, and L. Lujber, *"Is the bispectral index monitoring protective against postoperative cognitive decline? A systematic review with meta-analysis,"* PLOS ONE, vol. 15, no. 2, 2020.
10. Alexandros Koukkoullis, I. Tóth, N. Gede, Z. Szakács, P. Hegyi, G. Varga, I. Pap, K. Harmat, A. Németh, I. Szanyi, L. Lujber, I. Gerlinger, and P. Révész, *"Endoscopic versus microscopic stapes surgery outcomes : A meta-analysis and systematic review,"* LARYNGOSCOPE, vol. 130, no. 8, pp. 2019-2027, 2020.
11. Imre Gerlinger, I. Pap, and N. Nepp, *"Endoscopic balloon catheter dilatation of the auricle,"* MEDICAL TRIBUNE, vol. 17, no. 7, pp. 12-13, 2019.

12. András Burián, K. Harmat, N. Nepp, I. Tóth, I. Pap, and I. Gerlinger, *"'Power stapes' - A new surgical solution for the treatment of moderate to severe mixed hearing losses associated with stapes fixation,"* ENT ENT ENT, vol. 64, no. 1, pp. 3-10, 2018.

TOTAL IMPACT FACTOR: 16,742

8 List of own scientific presentations

1. 55th Meeting of the Audiology Section of the MFOE (Szeged, 2018) - Treatment options and differential diagnosis of aggressive giant cell lesions of the petrous bone, skull base and external auditory canal. Case presentation.
2. Extended scope MSc in Nursing - Nursing aspects of surgery of the large salivary glands (Pécs, 2018).
3. The XXIIIrd Meeting of the Pediatric Ear, Nose, Throat, Head and Neck Section of the Hungarian Society of Otolaryngology and Head and Neck Surgeons - ENDOSCOPIC MYRINGOPLASTICS - A NEW METHOD FOR THE TREATMENT OF PEDIATRIC CENTRAL DOBHARDY PERFORATIONS (Siófok, 2019)
4. XXIIIrd Meeting of the Hungarian Association of Otolaryngology and Head and Neck Surgeons of the Pediatric Section of Otolaryngology (Szombathely, 2019) - Endoscopic vs. Microscopic Type I Tympanoplasty - meta-analysis
5. Efficacy of minimally invasive endoscopic ear surgery procedures - MFOE Congress (Sopron, 2021)

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