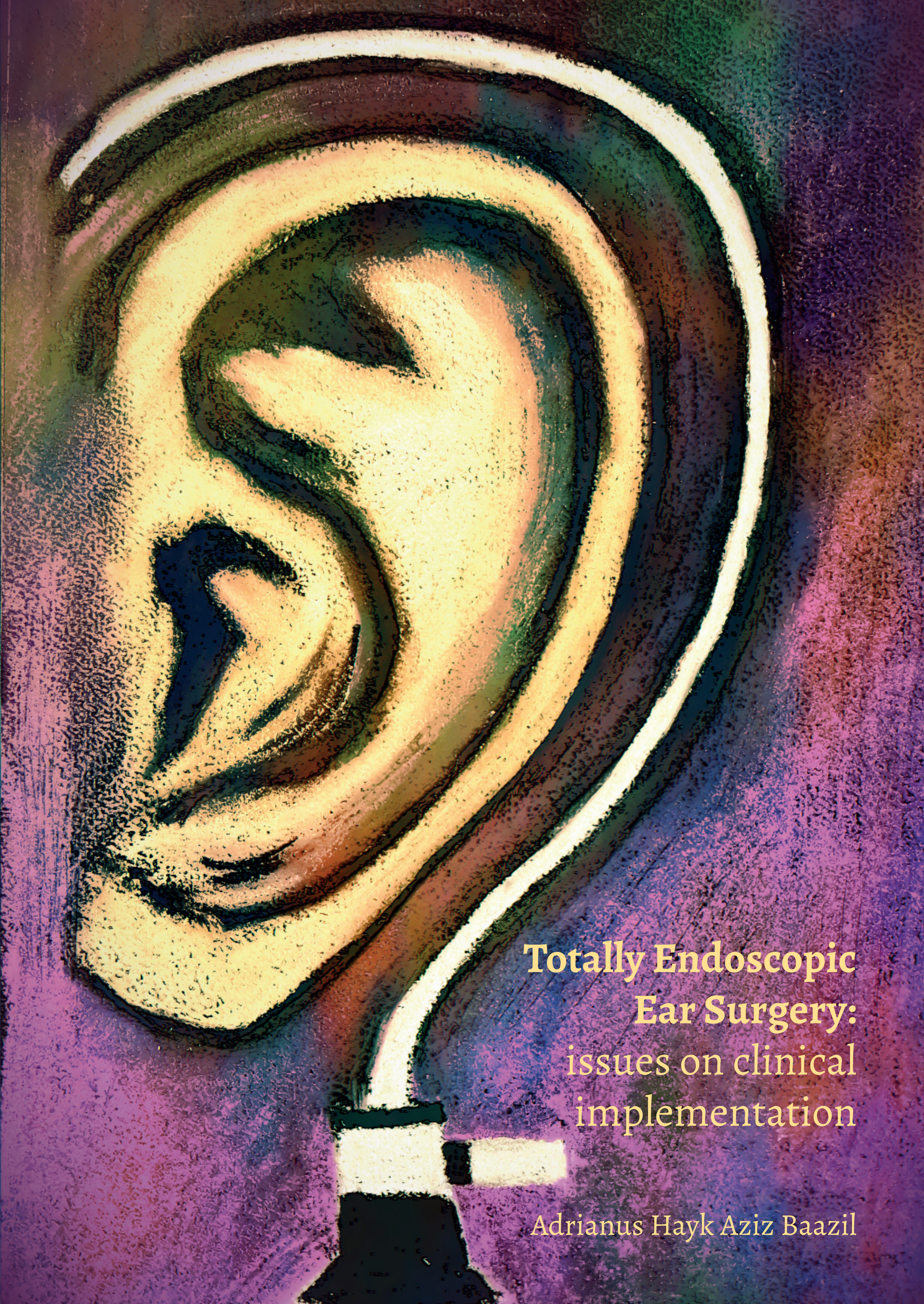

# Totally Endoscopic Ear Surgery: issues on clinical implementation

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# Totally Endoscopic Ear Surgery: issues on clinical implementation

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prof. dr. ir. P.P.C.C. Verbeek
ten overstaan van een door het College voor Promoties ingestelde commissie,
in het openbaar te verdedigen in de Agnietenkapel
op donderdag 28 november 2024, te 13.00 uur

door Adrianus Hayk Aziz Baazil
geboren te Vught

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# Part 1

## General Introduction

## The ear, its pathology and goals of treatment

The ear is the organ of hearing and balance and consists of the outer, middle and inner ear.[1] The outer ear is made up of the pinna and external ear canal. Its function is to gather soundwaves and transmit them through the ear canal. The outer ear is separated from the middle ear by the tympanic membrane. The middle ear consists of the tympanic cavity containing three ossicles (stapes, incus, malleus) and the Eustachian tube. Vibrations from the tympanic membrane are transferred to the inner ear through the ossicles. The cochlea (hearing organ), vestibule and semicircular canals (balance organ) make up the inner ear. Information regarding hearing and balance is sent to the brainstem, cerebellum and brain cortex through the vestibulocochlear nerve. Posterior to the tympanic cavity lies the mastoid cavity. They are interconnected by the aditus ad antrum.

Pathology, such as a chronic infection, usually originates in the ear canal and the middle ear.[1] Symptoms of ear pathology often are diminished hearing and purulent ear discharge (otorrhea). These complaints can impair daily functioning and therefore quality of life.[2,3] When ear pathology is left untreated, local complications such as facial nerve palsy, imbalance or sensorineural hearing loss may occur. Also potential life-threatening complications, such as intracranial extension, may arise.[4] Therefore, adequate treatment of ear pathology is of great importance.

The goal of treatment depends on the nature of the pathology and its potential threats. In case of a dry tympanic membrane perforation with only impaired hearing, one aims at preventing ear infections with a good chance of hearing improvement. In case of a chronic ear infection, the focus primarily lays on treating the infection. In these situations, restoration of hearing is not the intervention’s main purpose. To achieve these goals, otologists need surgical access to the affected areas of the ear; mostly the middle ear, epitympanum and antrum. The anatomy of the ear and its surrounding structures forces the surgeon to a certain surgical approach, either via the external ear canal or through the mastoid. Traditionally, the microscope is the most frequently used instrument to help visualize the ear and its pathology in outpatient clinic or during surgery. In recent years, the endoscope has been used more often in otology.

## Introduction of microscopes in ear surgery

The first descriptions of microscopes are from the 17$^{th}$ century in the Netherlands.[5] In these days, the optical quality was very poor and they were mainly used experimentally by scientists. By adding a screw barrel in the 18$^{th}$ century, focusing was improved. Yet, many problems withheld the use of microscopes in medical practice, such as magnification and illumination of visualized objects. In 1820, the first microscope that allowed different magnifications was presented. It also improved working distance from the visualized object. Still, it took until 1921 for Carl Olof Nylen, a Swedish otologist, to describe the use of a microscope in ear surgery. A monocular microscope was used for inspection in a chronic otitis media case with labyrinthine fistula.[5] As optical quality and magnification was still too limited, the first binocular microscope was developed one year later. These first binocular models had better optical quality and allowed greater magnification, but had an insufficient field of view, short focal distance and poor quality of lighting. Therefore the use of these models was still very unpractical. In 1951, Leitmann and Zeiss created the Opmi 1 model which allowed magnification change without alteration of the focal distance. Also it had good lighting and proper stability and mobility in all axes.[5] The significance of this microscope model was depicted by Wullstein at the 5$^{th}$ Medical Congress in Amsterdam: 'In the era of surgical dissection, microsurgery brought a new dimension into surgery far less reachable by conventional methods. This can only be compared with the radical change that occurred in medicine with the introduction of antisepsis, asepsis and anesthesia'. This powerful statement turned out to be true as the use of the Zeiss Opmi 1 in ear surgery became common practice all over the world. Further progress in the past decades was achieved on areas, such as stability, lighting, mobility and magnification. Yet, in essence, today's microscopes do not differ from the Opmi 1 model.

By using a microscope during surgery, one is able to magnify the surgical field and therefore better distinguish between pathology and healthy structures.[6] It allows more accurate manipulation of tissue, which is essential in ear surgery. As a result, in the second half of the 20$^{th}$ century, otologic surgery as a whole evolved rapidly.[7–9] Many techniques that are currently used for tympanoplasty, mastoidectomy, stapes surgery and cochlear implantation originate from this period. Over the past decades, with the help of microscopic visualization, these techniques have been altered and refined up to today's level. Therefore, one can state that the microscope truly revolutionized otologic surgery.

## Issues regarding the use of microscopes in ear surgery

As mentioned, the great value of microscopes in ear surgery is undeniable. Yet, despite its advantages, there are certain drawbacks in using microscopes. As the microscope is positioned outside of the patient and as it has a straight line of sight, it requires a sufficiently wide exposure to oversee the surgical field.[10,11] In some cases this means that healthy tissue needs to be removed to adequately visualize and treat underlying pathology. Yet, despite having this wide approach, some areas of the middle ear, such as the tympanic sinus and anterior epitympanum, can remain hidden.[11,12] Also, surgeons must frequently interrupt dissecting to reposition the microscope to create or maintain an adequate field of view. Next to these surgery related issues, there is a surgeon related issue in terms of ergonomics. Up to 72% of ENT-surgeons in the Netherlands report musculoskeletal disorders due to microscopic otoscopy.[13]

Due to the abovementioned issues using surgical microscopes, surgeons have always been keeping an eye out for other methods of visualization during surgery. As endoscopes became thinner and more capable of producing images of high quality, this has become an interesting addition and to some extent potential alternative to the microscope.

## Introduction of endoscopes in ear surgery

Endoscopes are tubular instruments which allow visualization inside cavities. The term endoscope is derived from the Greek “*endo*”, meaning “within”, and “*skopein*”, which means “to view” or “observe”. The first design of an endoscope was made more than two centuries ago by an Italian-German physician, Philip Bozzini.[14] He designed a tubular device that used mirrors and candle light to illuminate objects. In the decades to follow, others mainly experimented with different types of light sources[15]. The first major improvement was performed by the German Carl-Friedrich Nitze in 1877, who started using microscope optics.[15] At the beginning of the 20$^{th}$ century, the main components of endoscopes as we know them today were already used: a small diameter endoscope with an electrical light source and different lenses to enable visualization.[15] Yet, improvements were still necessary to improve magnification and lighting, and enlarge the field of view.[15] The latter was taken care of in 1929 by a German gastroenterologist, Heinz Kalk, who designed an endoscope that had a 135° field of view.[15] The magnification and lighting problem would be solved 30 years later by Harold Hopkins, a British scientist, and Karl Storz, a German instrument engineer. They introduced the rod-lens optical system and a fiber optic bundle for cold light illumination.[15] Over the past decades, endoscopes have become thinner and produce high quality images. Also digital video cameras were introduced allowing image visualization on a monitor.[15]

The main advantage of endoscopes is the possibility to advance the tip inside a cavity. This allows visualization from inside a cavity, enabling minimally invasive surgical approaches. In other medical specialties, such as gynecology and abdominal surgery, this is associated with faster healing, better quality of life and comparable surgical results.[16,17] In otorhinolaryngology, the use of endoscopes has become common practice to investigate and treat laryngological and rhinological pathology.[18,19]

The first report of the use of endoscopes in ear surgery dates from 1967 by Mer et al.[20] They used a fiberoptic system to inspect the middle ear through tympanic membrane perforations. From the 1980s, others experimented with transtympanic inspection of the middle ear.[21–23] In the 1990s, otologic surgeons explored the use of endoscopes merely in addition to the microscope in removal of cholesteatoma.[24–29] Later, surgeons began to use the endoscope as the sole optical instrument in surgical treatment of ear pathology.[30] During this period, the endoscope gained popularity in some parts of the world and many started to explore the possibilities for its use in otology. This is reflected in the number of scientific publications that has drastically increased since the 1990s (fig. 1). In the early stages of endoscope implementation, publications could be traced back to a small group of otologic surgeons. At present, endoscopes are used and researched worldwide. Although many feel that the endoscope has made a positive impact in their daily practice, several surgery, patient and surgeon related issues have not yet been fully unraveled.

## Issues regarding the present use of endoscopes in ear surgery

In the past decades, otologists have shown that the endoscope can be used successfully in a multitude of otologic procedures. When used as the sole instrument of visualization during surgery, it is called Totally Endoscopic Ear Surgery (TEES). In this setting, the surgeon holds the endoscope in one hand and visualizes the surgical field by positioning it in the external ear canal and middle ear. The other hand is used for tissue manipulation and blood suction. Generally, the endoscope image is captured by a camera and shown on a screen, positioned in the surgeon's line of sight. The endoscope can also function as an additional visualization tool next to the microscope: endoscope-assisted microscopic surgery (EAMS). In this situation, the procedure is mainly performed under microscopic visualization, allowing the surgeon to use both hands while looking through the microscope binoculars. The way endoscopes are used next to the microscope can vary: for visualization only and/or during dissection. A classification system is described by Lee et al. to rate the endoscope use.[31]

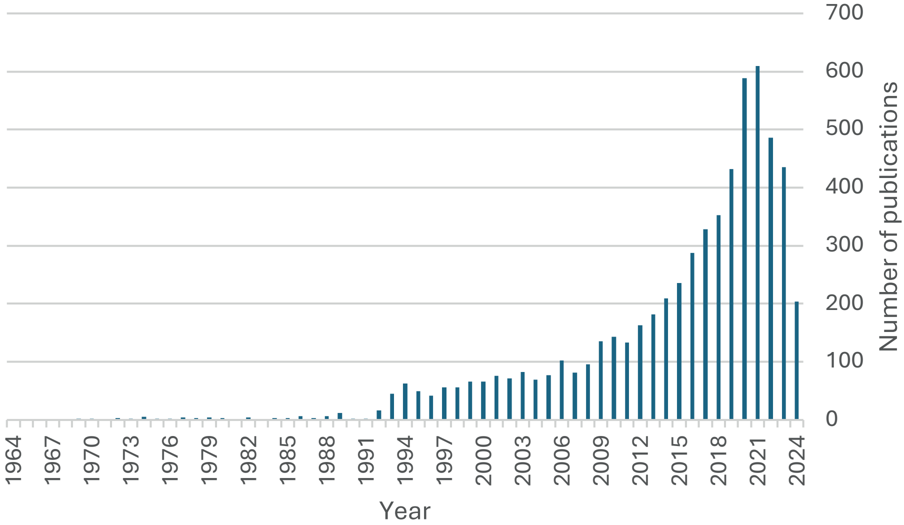


**Fig. 1.** Number of scientific publications regarding endoscopic ear surgery over the past decades. Figure displays situation per June 2024.

Myringoplasty for tympanic membrane perforations might be the most frequently used indication for TEES as the endoscope allows a good transmeatal overview of the complete tympanic membrane.[10] Closure rates and audiological results equal those from microscope-assisted myringoplasty.[32] Meanwhile, the indication for a retroauriculair approach or canalplasty for successful TEES myringoplasty has been practically eliminated.[33–38] In totally endoscopic stapedotomy, audiological results and complication rates, such as dysgeusia, equal results of microscope-assisted stapedotomy.[39–48] The endoscope allows oval window visualization with less or no scutum resection.[49] The scutum is a bony spur of the superior wall of the external ear canal, that often restricts oval window visualization. The chorda tympani, the taste nerve, runs in close contact with the scutum.[1] Despite less scutum bone removal, dysgeusia after totally endoscopic stapedotomy is still a regular complication.[40,43,44,46,48] A few studies have described totally endoscopic total ossiculoplasty, showing comparable hearing results and complication rates to microscope-assisted ossiculoplasty.[50–53] However, more data are needed to strengthen these findings.

In the surgical treatment of chronic otitis media with cholesteatoma, the endoscope can be used for visualization.[54–63] In these cases it is possible to use the endoscope as sole visualization tool (TEES), or additionally to the microscope (EAMS). The endoscope seems to give better view of otherwise hidden areas, such as the tympanic sinus and facial recess.[11,12] These areas are of great importance as residual cholesteatoma is often found in these middle ear areas.[64] In lateral skull base surgery, the endoscope can be a valuable addition to the microscope in visualization of the petrous apex and cerebellopontine angle.[65–73]

## Knowledge gaps of endoscopic ear surgery

As is shown above, the endoscope can be used for many otologic procedures. Yet, this does not necessarily mean it is advantageous over the microscope per se. On many surgery, patient and surgeon related issues, the added value of endoscopes is yet unclear. The following section discusses these issues and points out their knowledge gaps.

## Surgery related issues

Three aspects of the value of endoscopes in surgery related issues will be discussed: Visualization, Depth perception and Lighting modalities and heat production.

### Visualization

In TEES, rigid endoscopes are used. The tip of the endoscope is positioned inside a cavity, such as the ear canal or middle ear, and allows visualization of this area. What can be visualized, depends on the endoscopic field of view and is defined as the angle over which objects are viewed. Endoscopes can be forward viewing (0°) and angled (10°, 30°, 45°, 70°, 120°) (fig. 2). The angled endoscopes allow visualization out of the axis of the endoscope and can be used to increase the field of view by rotating the instrument around its axis. In TEES, 0° and 30° endoscopes with a 3-4 mm outer diameter are most frequently used. Endoscopes with a viewing angle up to 70° can help the surgeon to ‘look around the corner’.

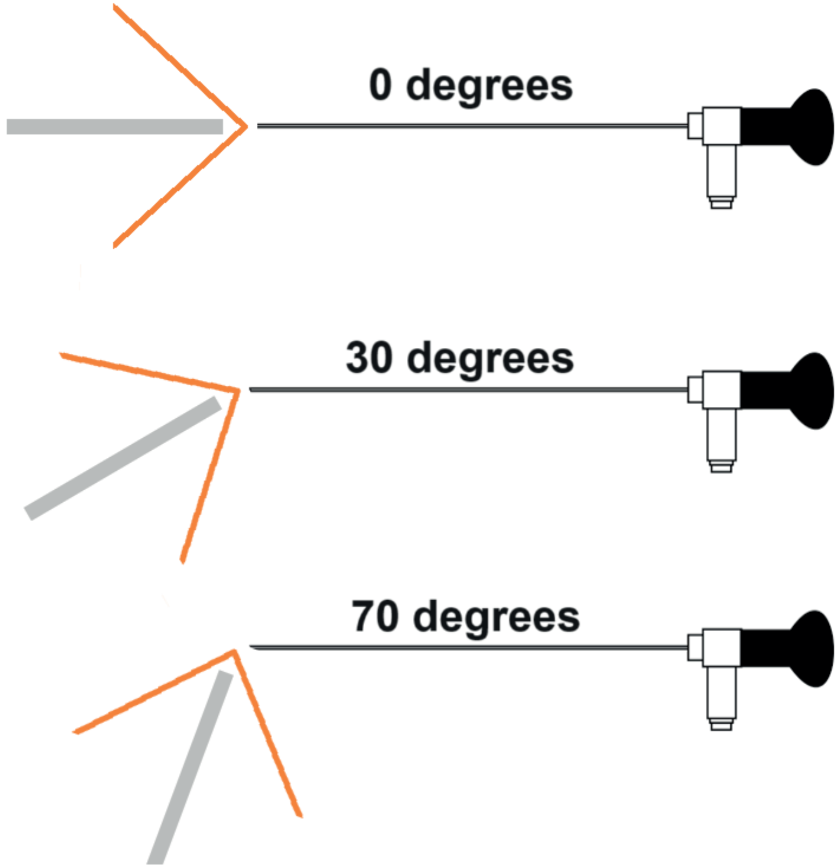


**Fig. 2.** Drawing of a forward viewing endoscope (0°) and endoscopes with a 30° and 70° viewing angle (grey line). The field of view is depicted by the orange lines.

The endoscope offers a better transmeatal overview of the anterior part of the tympanic membrane in comparison to the microscope.[10] Also, in areas of the middle ear that are difficult to visualize, such as the tympanic sinus, endoscopes seem to offer benefits over the microscope.[11,12] The tympanic sinus is a surgically important region as cholesteatoma residuals are often found in this middle ear recess.[64] One group evaluated transmeatal visualization of the tympanic sinus with 30° and 45° endoscopes and compared this to microscopic visualization.[11] Others compared tympanic sinus visualization after canal wall down mastoidectomy with canal wall reconstruction by microscope to a 30° and 45° endoscope.[12] In these studies, endoscopic visualization of the tympanic sinus was rated significantly better than the microscopic overview.

Other areas of importance for complete disease removal in chronic otitis media with cholesteatoma are the epitympanum and antrum. Transmeatal visualization of these areas is restricted by the scutum.[74] Therefore, in case the scutum hasn't already been destructed by pathology, it is often partially resected in transmeatal cholesteatoma surgery. As removal of the scutum seems to be associated with a higher chance of disease recurrence,[75–83] this should be done as minimally as possible.[84] One study described the size of templates used for scutum reconstruction after transmeatal cholesteatoma surgery. In that study, it was stated that an endoscopic approach requires minimal scutum resection.[84] Yet, detailed volumetric data on the size of the resected scutum and a comparison to a transmeatal microscopic approach are lacking.

### Depth perception

A potential disadvantage of using endoscopes is the lack of depth perception. The image provided by the endoscope is displayed on a screen in two dimensions. Yet, due to repeated and continuous movement of the endoscope, surgeons still receive information regarding depth. This continuous movement helps our brain to reconstruct a sense of three dimensions. Also the size and position of anatomic structures and instruments help surgeons to estimate depth during surgery. The lack of depth perception does not seem to result in surgical misjudgment as TEES complication rates are low and comparable to microscope-assisted surgery.[85] In the 1990s, rhinologists had drawn the same conclusion from the transition from traditional endonasal to endoscopic sinus surgery.[86]

### Lighting modalities and heat production

In clinical practice, white light sources, such as LED, Xenon and halogen are used in TEES. The use of other light sources or digital image enhancement could help to improve disease identification and dissection. Narrow Band Imaging (NBI, Olympus®) is such an alternative lighting modality that uses blue and green wavelengths to enhance visualization of blood vessels.[87] Its use in otorhinolaryngology detecting pathology has been proven in laryngology and head & neck surgery.[19,88–90] In otology, investigation on its applicability is limited to a few experimental qualitative studies, visualizing healthy and diseased ears.[91,92] An interesting potential application of NBI could be its use in epithelium identification in cholesteatoma surgery. One could imagine NBI to highlight epithelium in a landscape of mucosal vascular patterns, thus demonstrating presence or absence of cholesteatoma. Other companies have developed alternative visualization systems using digital image enhancement. In digital image enhancement, such as the CLARA and CHROMA application of the SPIES-system (Karl Storz®), a white light source is used and the digital image signal is altered to enhance certain colors and contrast.[93] At present, one study described advantages of digital image enhancement in tissue identification,[94] while another found no difference to white light.[93] Therefore, its clinical value in ear surgery at present is unclear.

Endoscope tips increase in temperature during their use.[95] There has been concern regarding potential middle and inner ear damage due to heat. Several studies have been performed to document the effect of the increase of endoscope tip temperature.[95–97] Multiple surgery related factors play a role in heat generation, such as duration of tip placement in the middle ear, suction, irrigation and endoscope distance to the round window. Also the endoscope diameter and type of light source has an effect on heat generation. Overall, Xenon light sources lead to the highest endoscope tip temperatures.[98] Halogen and LED light sources result in lower temperatures. Up to now, one study evaluated middle ear temperatures *in vivo* during tympanoplasty (LED light source, 0° scope, diameter 2.7mm); peak temperatures of only 37.3°C were measured at the subtympanic recess, inferiorly to the round window.[99] This is significantly lower than previously described in multiple *in vitro* models[98] and does not seem to differ from heat production by microscopic lighting.[100] These findings correspond with equally low rates of sensorineural hearing loss and transient facial nerve palsy after both TEES and microscope-assisted surgery.[85] Heat production does therefore not seem to be a problem in TEES when moderate light intensity settings are applied.

## Patient related issues

Three aspects of the value of endoscopes in patient related issues will be discussed: Postoperative pain and tissue invasiveness, Preservation of functional anatomy and Cosmetics.

### Postoperative pain / tissue invasiveness

In the majority of otological cases, the middle ear is the main area of interest. To reach that area three surgical approaches can be considered, each with their unique tissue invasiveness and surgical exposure: a transmeatal, an endaural and a retroauricular approach. A transmeatal approach is used frequently, just requiring a skin incision in the bony ear canal (Rosen incision).[101] Secondly, an endaural approach with the need of an incision in the cartilaginous part of the ear canal (Lempert incision) can be performed.[101] Finally, a retroauricular approach that requires a skin incision behind the ear and the creation of a periosteal flap can be considered.[101] In general, one can state that the surgical exposure increases with the extent of tissue invasiveness. The access needed for successful treatment depends on the pathology type, location and extension. Also the surgeon's experience and preference should be taken into consideration. Due to the advantageous visualization characteristics of endoscopes, one might be able to visualize and treat pathology more easily through the ear canal with only a Rosen incision, thus requiring minimal tissue damage.

Limited literature is available on pain after ear surgery. One study examined pain after various otologic, rhinologic and laryngologic surgeries using Patient Reported Outcomes Measures (PROMs) and concluded that ear surgery in general is not very painful.[102] A more recent study focused solely on ear surgery and compared TEES and microscope-assisted surgeries. Pain in both groups was minimal with a visual analogue scale (VAS, scale 0-10) of 1.1 for transmeatal TEES and 2.8 for retroauricular microscope-assisted surgery.[103] If minimal tissue invasiveness by TEES results in lower pain perception, is yet to be confirmed.

## Surgical anatomy

As discussed above, the scutum limits visualization of the epitympanum and is often partially resected in transmeatal cholesteatoma surgery. Is seems plausible to assume that the external ear canal plays a role in transmeatal visualization of the middle ear, antrum and epitympanum. Until today, one study has evaluated the ear canal and discussed its effect on the suitability for TEES.[104] This study solely focusses on bony ear canal diameter and does not take in account other geometric characteristics. It is known that the inter- and intraindividual anatomy of the external ear canal varies greatly.[105] Quantification of ear canal geometrics in relation to the amount of scutum removal needed for complete transmeatal visualization of the middle ear, antrum and epitympanum is, until now, lacking. An easy to use planning tool for surgeons to preoperatively evaluate expected scutum resection could be of value in daily clinical practice.

As the endoscope offers good transmeatal overview of the middle ear, one might be able to treat more pathology through the ear canal. This way, a mastoidectomy may be prevented in some cases. The effect on mastoid and middle ear ventilation after surgical treatment of pathology currently remains unclear and will not be further discussed in this thesis.

## Cosmetics

A retroauricular skin incision can lead to changes in the auriculomastoid angle and an altered alignment of the pinna.[106] A comparison of cosmetic results after transmeatal

TEES to retroauricular microscope-assisted surgery showed that over half of patients rate the cosmetic result of microscope-assisted surgery with a retroauricular skin incision lower than TEES.[33,35] This might be an important factor for patients to prefer TEES over microscope-assisted surgical treatment of one's ear pathology.

## Surgeon related issues

Two aspects of the value of endoscopes in surgeon related issues will be discussed: One-handed surgery and its learning curve, and Ergonomics.

### One-handed surgery / learning curve

In microscope-assisted surgery, the surgeon has both hands available. One is used for surgery and has the ability to use suction to control bleeding while dissecting with the other hand. In TEES, suction and dissection have to be done with one hand alone, as the other is needed to hold the endoscope. Therefore, preventive measures to minimize bleeding are essential. One should pay extra attention to pre- and peroperative application of vasoconstrictive solutions. Also blunt dissection using absorbent materials soaked in (nor)adrenaline restrain bleeding and improve exposure. One-handed surgery has been claimed to be the biggest drawback for those learning TEES.[107] Yet, those who are experienced with TEES state that this does not need to pose a drawback. The learning curve of one-handed surgery has been evaluated by multiple groups. They conclude that it takes on average 20 to 60 endoscopic myringoplasty cases to reach optimal results regarding operating time and closure rate.[108–110]

### Ergonomics

In all surgical medical specialties, prolonged periods of suboptimal posture can lead to musculoskeletal disorders.[111] In ear surgery, many have complaints of pain in the upper extremities, back, neck and shoulders.[13] TEES allows 'heads up' surgery, meaning that the surgeon looks at a screen at eye level with their head in a neutral upright position.[112,113] By using a chair with armrests, also the upper extremities can be placed in a neutral ergonomic posture.

## Aim and outline of this thesis

The overall objective of this thesis is to fill some of the knowledge gaps regarding the use of endoscopes in ear surgery.

**Part 2** addresses **surgery related** issues of totally endoscopic ear surgery. The issue of endoscopic visualization of the middle ear is discussed in **chapter 2.1**. The amount of resected scutum for adequate epitympanum and antrum visualization is presented and a comparison between TEES and a transmeatal microscopic approach is made. **Chapter 2.2** focusses on the audiological outcome of totally endoscopic vs microscope-assisted total ossicular chain reconstruction. In **chapter 2.3**, the potential advantage of an alternative endoscopic lighting modality in ear surgery is studied by evaluating the effect of NBI on epithelium identification in cholesteatoma surgery.

**Part 3** discusses two **patient related** issues of TEES. Pain after ear surgery using three different surgical approaches (transmeatal, endaural and retroauricular) is compared in **chapter 3.1**. The limiting factor of the external ear canal in transmeatal endoscopic middle ear visualization is addressed in **chapter 3.2**. In this study, a method to preoperatively predict the necessary iatrogenic scutum defect for adequate visualization is explained. This might become a useful tool for otologic surgeons in choosing the most suitable surgical approach. This thesis does not further address the aforementioned surgeon related issues.

In **part 4** the general discussion is presented, including its consequences for treatment and future research. The summary of this PhD thesis in English and Dutch is provided in **part 5**.

At present, multiple issues regarding the use of endoscopes in ear surgery remain unraveled. Results from this thesis will help otologic surgeons value the potential of endoscopes in ear surgery.

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# Part 2

## Surgery related issues

# Chapter 2.1

## A volumetric three-dimensional evaluation of invasiveness of an endoscopic and microscopic approach for transmeatal visualization of the middle ear

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# Abstract

## Objective.

This study aimed to compare the necessary scutum defect for transmeatal visualization of middle ear landmarks between an endoscopic and microscopic approach.

## Method.

Human cadaveric heads were used. In group 1, middle ear landmarks were visualized by endoscope (group 1 endoscopic approach) and subsequently by microscope (group 1 microscopic approach following endoscopy). In group 2, landmarks were visualized solely microscopically (group 2 microscopic approach). The amount of resected bone was evaluated via computed tomography scans.

## Results.

In the group 1 endoscopic approach, a median of 6.84 $mm^3$ bone was resected. No statistically significant difference (Mann–Whitney U test, $p = 0.163$, $U = 49.000$) was found between the group 1 microscopic approach following endoscopy (median 17.84 $mm^3$) and the group 2 microscopic approach (median 20.08 $mm^3$), so these were combined. The difference between the group 1 endoscopic approach and the group 1 microscopic approach following endoscopy plus group 2 microscopic approach (median 18.16 $mm^3$) was statistically significant (Mann–Whitney U test, $p < 0.001$, $U = 18.000$).

## Conclusion.

This study showed that endoscopic transmeatal visualization of middle ear landmarks preserves more of the bony scutum than a microscopic transmeatal approach.

# Introduction

A transmeatal approach is widely used for the surgical treatment of small epitympanic cholesteatomas. This inevitably makes it necessary to create a defect of the bony scutum to enable sufficient visualization of the epitympanum. Sufficient overview of the surgical field is essential for complete removal of pathology. However, it is also relevant to aim for the smallest defect possible because a scutum defect relates to recurrence of retraction pockets and cholesteatoma.[1–9] To achieve adequate visualization, a given extent of tissue trauma is needed when using linear view modalities, such as the microscope. The wide-angle view of the endoscope on the other hand is potentially less invasive while providing a better overview.[10]

Within the field of otology, a trend towards minimally invasive surgery is present. In other surgical specialties, minimally invasive surgery has been associated with faster healing and better post-operative quality of life.[11,12] Benefits of endoscopic ear surgery that have been postulated are reduction of residual disease in cholesteatoma surgery [13–22], shorter time of surgery [23–25] and better cost effectiveness.[19,26,27] Imai et al. states that the transmeatal endoscopic approach is minimally invasive, given the limited scutum defect for resection of cholesteatoma.[28] However, up to now, no volumetric information is available concerning invasiveness for transmeatal visualization of the middle ear.

In this computed tomography (CT) based study we used advanced three-dimensional (3D) imaging technology to quantify the bony scutum defect needed to visualize a defined area in the epitympanum and attic, using a microscopic and endoscopic transmeatal approach. We hypothesized that an endoscopic approach requires less bone removal compared with a microscopic approach. We expected the area of microscopic resection to overlap the endoscopic resection area. We therefore aimed to compare both methods within the same ear and rule out the effect of inter-ear variability.

# Materials and methods

In this study, human cadaveric heads were used. Specimens with a fracture through the ear canal were excluded.

## Groups and surgery

Two groups were defined to compare the resected amount of bone between the endoscopic and microscopic approach. In group 1, which consisted of 10 heads with 20 ears, middle ear landmarks were visualized endoscopically. Following a baseline CT scan, bone of the scutum and posterior bony ear canal was resected with a curette or drill under endoscopic view (length: 175 mm, outer diameter: 4.0 mm, angle: 0 degrees, Richard Wolf, Knittlingen, Germany). Middle ear landmarks to be visualized were: anteriorly, the anterior and superior border of the malleus head; superiorly, the tegmen; and posteriorly, the antrum or start of mastoidal trabecular air cells and the posterior border of the lateral semicircular canal.

For adequate visualization of these landmarks, the incus was resected. Bone dust was removed by rinsing with water and suctioning. Afterwards a post-endoscopic CT scan was done. To evaluate if more bone resection was needed via the microscopic approach, all endoscopically operated ears in group 1 were subsequently approached by microscope (type: Opmi 9, Carl Zeiss Gmbh, Oberkochen, Germany). This group is identified as the group 1 microscopic approach following endoscopy. Any additional amount of bone was resected transmeatally through an ear speculum (type: Hartman (Olympus, Hamburg, Germany), diameter: 5.0 mm) until all landmarks were visualized. Afterwards, another CT scan was done: the post-microscopy after endoscopy CT scan. The location of resected bone was evaluated visually during the procedure.

In order to establish whether the endoscopic and subsequent microscopic approach removed more bone than a solely microscopic approach, a second group was added. This group, the microscopic group (group 2 microscopic approach), consisted of four heads with eight ears. After a baseline preoperative CT scan, middle ear landmarks were visualized microscopically through an ear speculum similar to that performed in the group 1 microscopic approach following endoscopy group. Following this procedure, a post-microscopy CT scan was done.

**Figure 1** shows a right ear illustration of the transmeatal view of resected regions of the scutum for all (sub-)groups. All surgical steps were performed by the senior author (M de Wolf).

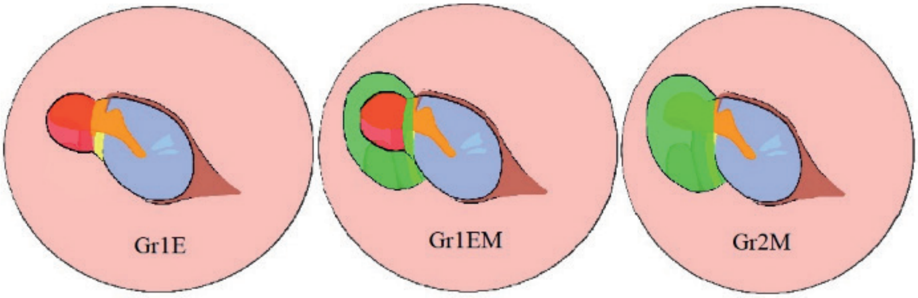


**Fig 1.** Right ear illustration of the transmeatal view of resected regions of the scutum for all (sub-)groups. Gr1E = group 1 endoscopic approach, Gr1EM = group 1 microscopic approach following endoscopy, Gr2M = group 2 microscopic approach

## Quantifying the resected volume

All CT scans were performed on a Siemens Somatom Force CT-scanner (Siemens Gmbh, Erlangen, Germany). Image data were reconstructed into volume images with voxel spacing of 0.45 × 0.45 × 0.45 mm. Differences in the amount of resected bone between the approaches were evaluated using custom-made software.[29] All CT scan images per specimen were aligned by image segmentation and registration. To this end, the available part of the skull in the first image was segmented and registered to the subsequent images, yielding inter-image positioning matrices. The inverse of such matrix was used for image alignment. A 3D image of the resected bone volume was created by subtracting the image intensities on a voxel-by-voxel basis. Three subtraction images were created. Two of these were made by subtracting the post-endoscopy or -microscopy CT scan from their baseline CT scan (group 1 endoscopic approach, group 2 microscopic approach). This subtraction image clearly distinguished the resected incus from the resected bone and allowed manual segmentation of the resected bone voxels in the 3D selection using a painting tool. The third subtraction image was made by subtraction of the post-microscopy after endoscopy CT scan from the post-endoscopy CT scan (group 1 microscopic approach following endoscopy). This image visualized the additional bone resection for subsequent segmentation and volume quantification. An example of a digitally reconstructed radiograph of the baseline, post-endoscopic, post-microscopic and subtraction images of a right ear is shown in Figure 2. The sum of the selected voxels represents the resected volume of bone and was expressed in millimetres cubed. The median of resected bone is reported with its $25^{th}$ and $75^{th}$ percentile.

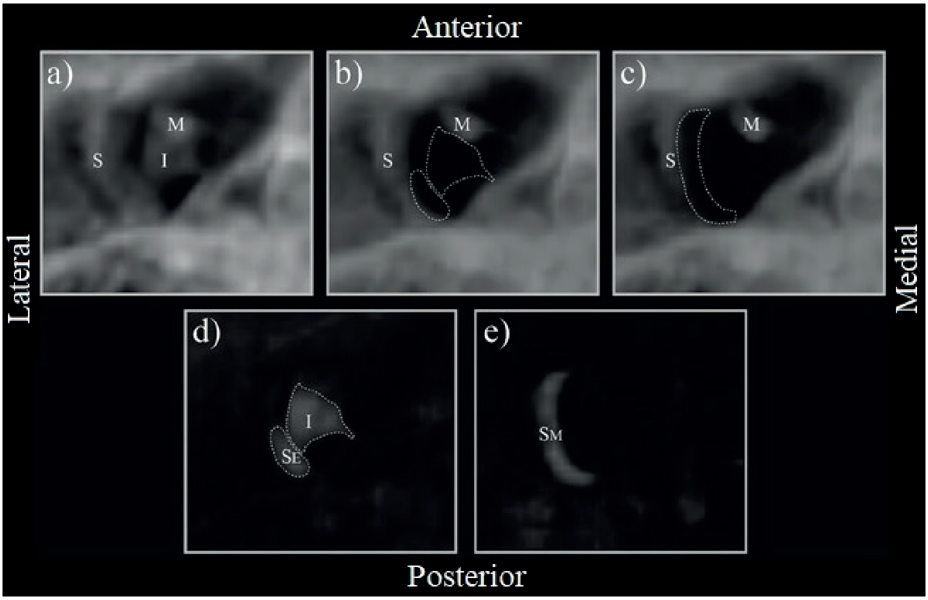


**Fig 2.** Right ear example from group 1 visualized using a digitally reconstructed radiograph of the selected volume of interest (15 × 14 × 14 mm), showing an inferior view of a bony ear canal and middle ear. a) Baseline situation, b) situation after endoscopic visualization with removal of the incus and part of the scutum, c) situation after microscopic visualization with additional removal of the scutum, d) subtracted image (post-endoscopy from baseline) showing the resected incus and part of the scutum and e) subtracted image (post-microscopy from post-endoscopy) showing the additionally resected scutum.
S = scutum, I = incus, M = malleus, SE = endoscopically resected part of scutum, SM = extra microscopically resected scutum.

## Data analysis

Z-values for skewness and kurtosis were evaluated to analyse normality of the data (data were considered normally distributed if $-1.96 < z < 1.96$). To evaluate correlation between the measured volumes of ears within one head, the Spearman's rank correlation coefficient between the left and right ears was determined. Resected volumes of the group 1 endoscopic approach were compared with the group 1 microscopic approach following endoscopy and the group 2 microscopic approach. The amount of resected bone in the group 1 microscopic approach following endoscopy was compared with the group 2 microscopic approach. The resected volume in the group 1 endoscopic approach was expressed as a percentage of the total resected volume after microscopic visualization.

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. Approval from the institutional review board was not necessary.

## Results

One right ear from group 1 was excluded from analysis because noise due to displacement of defrosted water and soft tissue made it impossible to reliably select voxels representing resected bone.

Data were not normally distributed in all groups. The Spearman's rank correlation coefficient between left and right ears showed a low correlation ($r_s = 0.251$; $p = 0.259$; median right ears = 9.88 $mm^3$ and median left ears = 8.28 $mm^3$).

All predetermined landmarks were visualized successfully using the endoscopic and microscopic approach after removal of the incus and sufficient part of the scutum. During the dissection, the endoscopically resected part of the scutum lay inside the area of resected bone for microscopic visualization.

In the group 1 endoscopic approach, a median of 6.84 $mm^3$ (25th percentile: 5.66, 75th percentile: 9.61 $mm^3$) bone was resected. No statistically significant difference (Mann–Whitney U test, $p = 0.163$, $U = 49.000$) of resected bone was found between the group 1 microscopic approach following endoscopy (median 17.84; 25th percentile: 13.78, 75th percentile: 21.47 $mm^3$) and the group 2 microscopic approach (median 20.08; 25th percentile: 15.86, 75th percentile: 29.80 $mm^3$). Since there is no statistically significant difference between these 2 groups, they were combined to form 1 microscopic evaluation group (group 1 microscopic approach following endoscopy + group 2 microscopic approach: median 18.16; 25th percentile: 13.89, 75th percentile: 22.00 $mm^3$).

The difference between the group 1 endoscopic approach and group 1 microscopic approach following endoscopy plus group 2 microscopic approach is statistically significant (Mann–Whitney U test, $p < 0.001$, $U = 18.000$). By using an endoscope, 38 per cent (6.84 / 18.16 $mm^3$) of the amount of bone for microscopic visualization had to be resected.

**Figure 3** shows a boxplot representing resected volumes of bone from the endoscopic and microscopic groups.

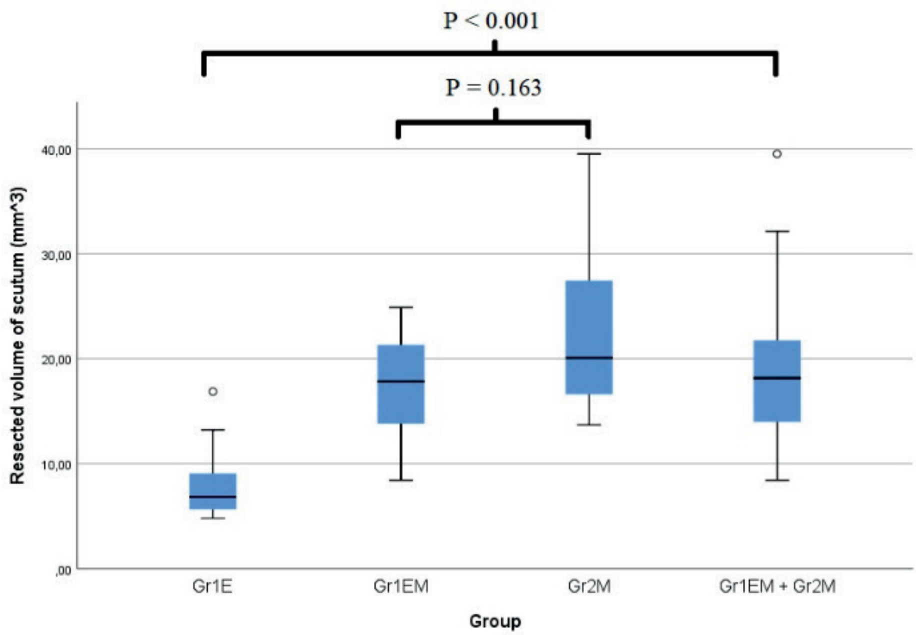


**Fig 3.** Boxplot of resected volumes of bone from the scutum per (sub-)group. Statistical analysis of differences between groups was done by Mann-Whitney U test.

Gr1E = Group 1 endoscopic approach, Gr1EM = Group 1 microscopic approach following endoscopy, Gr2M = Group 2 microscopic approach

# Discussion

This cadaveric study compared volumes of resected bone from the scutum to visualize middle ear landmarks transmeatally by endoscope and microscope. State of the art, custom-made 3D imaging technology was used to evaluate resected volumes of bone in three dimensions.[29] Since there was a low correlation between left and right ears, all ears were interpreted as independent. During the dissection, the endoscopically resected part of the scutum was overlapped by the area of resected bone in the microscopic group. The finding that there was no statistically significant difference between the group 1 microscopic approach following endoscopy and the group 2 microscopic approach confirms this observation. Therefore, both methods were compared within the same ear and the effect of inter-ear variability on resected volumes could be ruled out. However, despite the inter-ear variability, there was no significant difference found between resected volumes in the group 1 microscopic approach following endoscopy and group 2 microscopic approach. So, these groups were combined to create one larger group for comparison with the group 1 endoscopic approach.

A statistically significant difference of resected volumes between the endoscopic and microscopic approach was found. To visualize middle ear landmarks, the endoscopic approach preserves a larger part of the scutum compared with the microscopic approach.

To minimize intra- and inter-observer variability, all procedures, including identifying the middle ear landmarks, were performed by one surgeon. Quantification of resected bone with the 3D-imaging software was done by the first author. This study established that the endoscopic approach is less invasive compared with the microscopic approach despite inter-scan and the aforementioned variabilities. Our results strengthen the conclusion of Imai et al, who state that the endoscopic approach allows minimally invasive transmeatal removal of cholesteatoma. They used two-dimensional imaging technology by measuring templates for reconstruction of the scutum after endoscopic transmeatal resection of cholesteatoma (median 37.3; minimum 14.7; maximum 68.4 $mm^2$).[28] In our study, the aim was to transmeatally visualize predetermined landmarks. Imai et al. performed a retrospective analysis of endoscopically treated cholesteatoma cases. These two studies can therefore not be compared. In the Japanese study there was no microscopic control group. Notably, there is a large difference between the size of the smallest (14.7 $mm^2$) and largest (68.4 $mm^2$) created scutum defect. The authors explained this by pointing out a correlation between the size of the cholesteatoma and the post-surgery scutum defect (correlation coefficient $R^2 = 0.617$). We believe that the position of the external ear canal in relation to the horizontal semicircular canal also plays an important part in posterior visualization. When the external ear canal, in relation to the horizontal semicircular canal, is positioned relatively anteriorly, large parts of the bony ear canal have to be removed for adequate view in the posterior direction. In our study, for three ears, large amounts of bone had to be endoscopically removed (group 1 endoscopic approach) with hardly any additional resection for microscopic visualization (group 1 microscopic approach following endoscopy): 27, 31 and 21 per cent, respectively. In these cases, the endoscopic advantage regarding preservation of the bony scutum is limited. In the study performed by Imai et al., this might also have played a role for cases that required a large scutum defect, next to the size of the cholesteatoma.[28] A future study might investigate the possibility to create a predictive model to select patients who are suitable for an endoscopic transmeatal approach.

Since the 1980s, it has been known that a scutum defect plays a role in the recurrence of retraction pockets after canal wall up mastoidectomy. Additionally, the importance of scutal defect reconstruction to prevent recurrence, has been stressed.[9] Many studies strengthen this statement.[1–8] It is plausible that smaller iatrogenic scutum defects may reduce the risk of recurrence of pathology. To our knowledge, only one study (Bae et al.) has compared results of cholesteatoma surgery after an endoscopic and microscopic transmeatal approach.[30] In the microscopic group, a Lempert incision was made and no mastoidectomy was performed. Neither residual, nor recurrent disease was reported for both groups. Limitations of this study are a short follow-up time (19.75 vs 41.05 months) and small groups (10 vs 10 patients). Whether the reduced invasiveness of the endoscopic transmeatal approach will actually decrease recurrences compared with a microscopic transmeatal approach, has to be evaluated in larger, prospective, long-term follow-up studies.

Multiple studies have compared the outcomes of a transmeatal endoscopic with a retroauricular microscopic approach with mastoidectomy for cholesteatoma cases.[20,21,31,32] Although their results favour the endoscopic transmeatal approach, the studies also have their limitations. Interpretation is difficult due to heterogeneity of the study groups and short follow-up time. Despite the promising usefulness of the endoscope, high-quality studies are needed to evaluate its position in relation to canal wall up mastoidectomy with obliteration as a surgical modality in management of primary cholesteatoma.[33]

## Conclusion

The results of this study show that an endoscopic transmeatal approach preserves more of the bony scutum than a microscopic transmeatal approach to acquire visualization of the same middle ear landmarks and antrum. Long-term follow-up studies of endoscopically treated epitympanic ear pathology will have to show if preservation of larger parts of the scutum plays a role in preventing disease recurrence.

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# Chapter 2.2

## Comparison of long-term microscopic and endoscopic audiologic results following total ossicular replacement prosthesis surgery

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# Abstract

*Objective* To compare short-term and long-term outcomes following transcanal endoscope-assisted with microscope-assisted ossiculoplasty using the Fisch titanium total prosthesis (FTTP).

*Study design* Retrospective chart review.

*Setting* Tertiary referral center.

*Patients* Pediatric (<18 yr of age) and adult patients undergoing ossiculoplasty with the FTTP between January 2016 and December 2019.

*Intervention* Transcanal endoscope-assisted (n = 30) or microscope-assisted (n = 76) ossiculoplasty with the FTTP. In the microscopic group, 48 were performed through the ear canal and 28 by retroauricular approach.

*Main Outcome Measure* Short-term (3 mo) and long-term (average 20.2 mo) $PTA_{0.5\text{-}2kHz}$ air and bone conduction thresholds were evaluated.

*Results* In total, 106 patients were included. Nine of 30 (30.0%) of endoscopic and 15 of 76 (19.7%) of microscopic patients were pediatric. Endoscopic preoperative air conduction $PTA_{0.5\text{-}2kHz}$ was 52.1 ± 15.8 dB and 52.2 ± 17.9 dB for the microscopic group ($p > 0.05$). Three months postoperative endoscopic air conduction $PTA_{0.5\text{-}2kHz}$ was 37.6 ± 17.4 dB (14.5 dB improvement) and 44.6 ± 19.9 dB (7.6 dB improvement) in the microscopic group ($p > 0.05$). Three months postoperative endoscopic $PTA_{0.5\text{-}2kHz}$ ABG was 26.8 ± 16.6 dB and 28.4 ± 14.7 dB in the microscopic group ($p > 0.05$). Latest follow-up endoscopic air conduction $PTA_{0.5\text{-}2kHz}$ audiogram (mean follow-up 20.6 ± 10.4 mo) was 36.1 ± 18.2 dB (16.0 dB improvement) and 40.1 ± 16.8 dB (12.1 dB improvement) in the microscopic group (mean follow-up 19.9 ± 10.3 mo)($p > 0.05$). For endoscopic air conduction $PTA_{0.5\text{-}2kHz}$, between the 3 months and latest follow-up audiogram, 25.0% showed improvement, 50.0% remained stable and 25.0% deteriorated. In the microscopic group, 26.7% improved, 46.6% remained stable and 26.7% deteriorated ($p > 0.05$).

*Conclusion* Our study shows that hearing results with the Fisch titanium total prosthesis are in line with literature. Endoscope-assisted total ossiculoplasty proves to be a suitable technique with comparable results to the microscopic approach.

# Introduction

Total ossicular chain reconstruction is often performed and an important part of otologic surgery. Despite the frequent use of endoscopes in ear surgery, only three studies with a small number of endoscopically treated patients (n < 21) with a follow-up of less than 6 months have evaluated the endoscope's role in total ossiculoplasty. Das et al.[1] described significantly better hearing results 1 month after endoscope-assisted ossiculoplasty in comparison to microscope-assisted ossiculoplasty. At 6 months after surgery both methods were shown to have comparable audiologic outcomes (endoscopic group: n = 14, follow-up 6 months, postoperative air bone gap (ABG) $PTA_{0.5\text{-}3kHz}$ 26.2 dB). Yawn et al.[2] state that audiologic results of endoscope-assisted and microscope-assisted ossiculoplasty are equal (endoscopic group: n = 8, follow-up 6 months, postoperative ABG $PTA_{0.5\text{-}3kHz}$ 15.9 dB). Kwinter et al.[3] found no difference between endoscope-assisted (n = 21) and microscope-assisted (n = 23) total ossiculoplasty results (postoperative air conduction $PTA_{0.5\text{-}4kHz}$ of 29.0 vs 31.5 dB, respectively). One of the postulated advantages of endoscopic ear surgery is the wide field and high-resolution view that may benefit accurate placement of middle ear prostheses. Potential drawbacks of using an endoscope include difficulty clearing secretions due to one-handed surgery and diminished depth perception.[4,5] Because only three studies have been performed evaluating short-term hearing results, more data are needed to confirm these results. Moreover, at present, no data in literature is available on the long-term audiologic results after endoscope-assisted ossiculoplasty.

In 2004, Fisch et al.[6] published their 1 year audiologic results after total microscope-assisted ossiculoplasty using the Fisch titanium total prosthesis (FTTP, Karl Storz, Tuttlingen, Germany). They reported audiologic results with a mean postoperative air conduction and ABG $PTA_{0.5\text{-}2kHz}$ of 43.2 and 21.3 dB, respectively. Fifty-seven percent of patients had a postoperative ABG of <20 dB and 87% <30 dB. These postoperative results are similar or superior to those published in literature for other titanium and nontitanium total prostheses.[7–12] More data should be presented to confirm the results of ossiculoplasty with the FTTP by Fisch et al. It has been stated that ABGs after ossiculoplasty deteriorate upon longer follow-up.[13,14] This is explained by mechanical factors and other persistent problems such as continuing tubal dysfunction, middle ear mucosal status and/or iatrogenic scar tissue formation.[6,15] Fisch et al. advise the use of a cartilage “shoe” to obtain prosthesis stability.[6] It is interesting to evaluate the long-term hearing results after ossiculoplasty with the FTTP with shoe fixation.

The aim of this study is to describe the short-term and long-term hearing results after endoscope-assisted ossiculoplasty and to compare these to endoscopic results from literature. The second aim is to confirm the hearing results of microscope-assisted ossiculoplasty with the FTTP with shoe achieved by Fisch et al. In addition to air conduction and ABG, results are presented by means of the Glasgow Benefit Plot. This plot incorporates the hearing of the contralateral ear and provides important information about postoperative functionality of hearing.

## Material and methods

### Patients

Patients were operated between January 2016 and December 2019. They were reviewed before surgery, 3 months and 1 to 3.5 years after surgery. Of all patients, gender, age, type of surgery, operated side and indication for surgery were recorded.

### Fisch Titanium Total Prosthesis

The Fisch titanium total prosthesis (Karl Storz SE&Co. KG, Tuttlingen, Germany) is a titanium L-shaped prosthesis designed for total reconstruction of the ossicular chain. Due to its L-shape and its flexible connection (0.2 mm thin) between the shaft and the large head (5 mm diameter and 0.1 mm thin), the FTTP can be accommodated under the tympanic membrane without cartilage protection. An additional strength of the FTTP is the alterable length of its shaft. After measuring the necessary prosthesis length with a disposable depth meter, the prosthesis shaft can be precisely cut to the desired length. The 10-mm-long shaft can be cut within 0.1 mm to the desired length.[6] The offset head of the FTTP enables the surgeon to visualize the oval window freely and enables accurate placement of the prosthesis shaft on the stapes footplate.[6]

### Type of Surgery

Cases were divided into categories based on mastoid and canal wall status: transcanal tympanoplasty or atticotomy with intact mastoid and canal wall, canal wall up mastoidectomy (CWU), CWU with obliteration of the epitympanic and mastoid areas (CWUO), canal wall down mastoidectomy (CWD) and CWD with reconstruction of the posterior canal wall and obliteration of the mastoid cavity (CWR). In obliterated ears (both CWUO and CWR), the epitympanum and mastoid are separated from the middle ear by a midtemporal artery flap followed by the obliteration of the mastoid and epitympanum with hydroxyapatite granules.[16] Microscope-assisted ossiculoplasty was performed through the ear canal in cases undergoing second/third/fourth look after CWU(O) and in those having an ossiculoplasty after CWD. In those having a CWU(O) or CWR, it was done by a retroauricular approach. For endoscopically operated cases, the total endoscopic ear surgery (TEES) classification score by Cohen et al.[17] was noted. For all cases, the prosthesis extrusion rate was evaluated. Fixation of the prosthesis in the oval window niche was achieved using various techniques (silastic shoe, cartilage shoe, cartilage wedges, no fixation). Finally, the status of the malleus and its effect on postoperative hearing results was assessed. Status of the malleus was categorized in three groups: intact, only malleus handle present and completely absent. Microscope-assisted ossiculoplasty was performed by all three otologists (F.E., Ev.S., Md.W.). Endoscope-assisted ossiculoplasty was solely done by Md.W.

## Evaluation of Hearing Results

We calculated ABG, air and bone conduction pure-tone averages (PTAs) for 500 Hz, 1 kHz and 2 kHz ($PTA_{0.5\text{-}2kHz}$). Audiologic outcomes 3 months after surgery and at the latest moment of follow-up (>3 months after surgery) were compared with the preoperative situation.

Overclosure was defined as bone conduction improvement >0 dB for $PTA_{0.5\text{-}2kHz}$. Postoperative ABGs for cumulative decibel bins were evaluated. For the calculation of the PTAs and ABGs, air and bone conduction threshold levels obtained simultaneously were used. Stability of hearing was evaluated by comparing audiologic outcomes at the latest moment of follow-up audiograms to audiometric results 3 months after surgery. Results were binned in 3 categories: stable (– 5 < change of air conduction between latest and 3 month audiogram < 5 dB), improvement (change > 5 dB), deterioration (change < - 5 dB). To evaluate the functional benefit of postoperative hearing outcomes, a Glasgow Benefit Plot was made.[18] This plot takes into account preoperative and postoperative air conduction levels of the (to-be-)operated ear and the contralateral ear. We defined socially acceptable hearing as a $PTA_{0.5\text{-}2kHz}$ air conduction threshold of <35 dB.

## Statistics

T-test, Chi square and one way ANOVA were performed to statistically analyze differences. P-values <0.05 were considered as statistically significant.

## Ethics

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. Institutional review board approval was attained (W20_313 # 20.348).

# Results

Complete preoperative audiograms were available for 106 patients. Postoperative audiograms at 3 months were available for 99 of 106 (93.4%) patients, 28 of 30 (93.3%) endoscopic and 71 of 76 (93.4%) microscopic. Fifty-three (50.0% of 106) latest follow-up audiograms were present (mean time to follow-up, 20.2 ± 10.3 mo, range 5.5–42.4 mo), 18 of 30 (60%) endoscopic and 35 of 76 (46.1%) microscopic. Mean follow-up for all endoscopic cases was 13.7 months (range 2.5–39.7 mo) and 10.8 months (range 1.7–42.4 mo) in the microscopic group as a whole. Mean age at surgery in the endoscopic group was 30.4 years (range 8.2 – 68.4 years) and 36.9 years (range 6.6 – 75.3 years) in the endoscopic group. Nine of 30 (30.0%) of endoscopic and 15 of 76 (19.7%) of microscopic patients were younger than 18 years. In the endoscopic group 73.3% and 67.1% of patients in the microscopic group were male. Fifty-four prostheses (50.9%) were placed in right ears and this percentage was comparable for both groups.

One hundred five procedures (99.1%) were performed for chronic otitis media with or without cholesteatoma. In one ear, conductive hearing loss was caused by a congenital absence of the stapes. In all patients, a mobile footplate was present and the stapedial suprastructure was partially or totally absent. All endoscopic cases were TEES Class 4, except for one endoscopically assisted microscopic surgery case, which was TEES class 2. Ten of 30 (33.3%) endoscopic procedures and 22 of 76 (28.9%) microscopic procedures were revision ossiculoplasties. Extrusion of the FTTP was seen in 8 of 106 cases (7.5%). Table 1 summarizes the demographic details of our study population.

## Changes in Air Conduction

Preoperative $PTA_{0.5\text{-}2kH}$ air conduction thresholds and postoperative changes are shown in a scattergram in Table 2. Endoscopic preoperative air conduction $PTA_{0.5\text{-}2kH}$ was 52.1 ± 15.8 dB and 52.2 ± 17.9 dB for the microscopic group ($p > 0.05$). Three months postoperatively (mean 3.1 ± 0.6 mo), endoscopic air conduction $PTA_{0.5\text{-}2kH}$ was 37.6 ± 17.4 dB (14.5 dB improvement) and 44.6 ± 19.9 dB (7.6 dB improvement) in the microscopic group ($p > 0.05$). Latest follow-up endoscopic air conduction $PTA_{0.5\text{-}2kH}$ (mean time to follow-up, 20.6 ± 10.4 mo) was 36.1 ± 18.2 dB (16.0 dB improvement) and 40.1 ± 16.8 dB (12.1 dB improvement) in the microscopic group (mean time to follow-up, 19.9 ± 10.3 mo) ($p > 0.05$).

**Table 1.** Demographic details of a series of 106 patients undergoing ossiculoplasty with the Fisch titanium total prosthesis.

| **Demographic details (n = 106)** | |
|---|---|
| Age (mean, range) | 35.0 (6.6 – 75.3) |
| <18 years old (n) | 24 |
| ≥18 years old (n) | 82 |
| Male sex (n,%) | 73 (68.9%) |
| Right ear (n, %) | 54 (50.9%) |
| Length of FTTP (mean, range) | 4.53 (3.0 – 7.0) |
| Type of FTTP fixation | |
| Silastic shoe (n, %) | 55 (51.9%) |
| Cartilage shoe (n, %) | 26 (24.5%) |
| Cartilage wedges (n, %) | 5 (4.7%) |
| No fixation (n, %) | 7 (6.6%) |
| Unknown (n, %) | 13 (12.3%) |
| Type of surgery | |
| Microscopic CWU(O) (n, %) | 9 (8.5%) |
| Second look with ossiculoplasty after CWU(O) (n, %) | 25 (23.6%) |
| Third look with ossiculoplasty after CWU(O) (n, %) | 5 (4.7%) |
| Fourth look with ossiculoplasty after CWU(O) (n, %) | 2 (1.9) |
| Transmeatal tympanoplasty and ossiculoplasty (n, %) | 13 (12.3%) |
| Primary ossiculoplasty in CWD (n, %) | 3 (2.8%) |
| CWR(n, %) | 19 (17.9%) |
| Endoscopic | |
| Endoscopically assisted microscopic CWU (n, %) | 1 (0.9%) |
| Primary ossiculoplasty after CWU(O) (n, %) | 5 (4.7%) |
| Second look with ossiculoplasty after CWU(O) (n, %) | 15 (14.2%) |
| Transmeatal atticotomy with ossiculoplasty (n, %) | 1 (0.9%) |
| Transmeatal tympanoplasty with ossiculoplasty (n, %) | 4 (3.8%) |
| Primary ossiculoplasty in CWD and CWR (n, %) | 4 (3.8%) |
| Primary indication for surgery | |
| Chronic otitis media with or without cholesteatoma (n, %) | 105 (99.1%) |
| Congenital ossicular chain malformation | 1 (0.9% |
| Time to follow-up in months (mean, range) | 11.7 (1.7 – 42.4) |

CWU: Canal wall up mastoidectomy

CWUO: CWU with obliteration of the epitympanic and mastoid areas

CWD: Canal wall down mastoidectomy

CWR: CWD with reconstruction of the posterior canal wall and obliteration of the mastoid cavity

**Table 2.** Scattergram of preoperative $PTA_{0.5\text{-}2kHz}$ air conduction hearing level and the 3-mo and latest follow-up postoperative change.

Preoperative $PTA_{0.5\text{-}2kHz}$ air conduction hearing level (dB) (n = 106)

| 0-10 | 11-20 | 21-30 | 31-40 | 41-50 | 51-60 | 61-70 | 71-80 | 81-90 | >91 |
|---|---|---|---|---|---|---|---|---|---|
| Endoscopic (n = 30) | | | | | | | | | |
| 0 | 1 | 1 | 8 | 5 | 6 | 4 | 5 | 0 | 0 |
| Microscopic (n = 76) | | | | | | | | | |
| 0 | 0 | 6 | 16 | 19 | 15 | 10 | 6 | 0 | 4 |

Postoperative change of $PTA_{0.5\text{-}2kHz}$ air conduction level: 3 months and latest audiogram

| **Worsened** | | | | | **No change** | **Improved** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| ≥50 | 40 | 30 | 20 | 10 | 0 | 10 | 20 | 30 | 40 | ≥50 |
| **3 month postoperative (n = 99)** | | | | | | | | | | |
| Endoscopic (n = 28) | | | | | | | | | | |
| 0 | 0 | 0 | 1 | 3 | 6 | 7 | 6 | 3 | 1 | 1 |
| Microscopic (n = 71) | | | | | | | | | | |
| 0 | 1 | 0 | 2 | 5 | 36 | 14 | 7 | 5 | 1 | 0 |
| **Latest audiogram (n = 53)** | | | | | | | | | | |
| Endoscopic (n = 18) | | | | | | | | | | |
| 0 | 0 | 0 | 1 | 1 | 5 | 2 | 4 | 3 | 1 | 1 |
| Microscopic (n = 35) | | | | | | | | | | |
| 0 | 0 | 0 | 2 | 3 | 12 | 6 | 6 | 3 | 1 | 2 |

## Changes in Air Bone Gap

The mean endoscopic preoperative ABG for $PTA_{0.5\text{-}2kHz}$ was 39.7 ± 14.0 dB and 36.5 ± 14.2 dB for the microscopic group ($p > 0.05$). The endoscopic 3 month postoperative ABG for $PTA_{0.5\text{-}2kHz}$ was 26.8 ± 16.6 dB and 28.4 ± 14.7 dB in the microscopic group ($p > 0.05$). Latest follow-up endoscopic ABG for $PTA_{0.5\text{-}2kHz}$ was 28.1±17.9 dB and 25.3±17.0 dB for the microscopic group ($p > 0.05$).

For the endoscopic ABG $PTA_{0.5\text{-}2kHz}$ 3 months after surgery, 14.3% of patients demonstrated an ABG within 0 to 10 dB, 42.9% within 0 to 20 dB and 64.3% between 0 and 30 dB. For the microscopic group, this was 12.7%, 31.0% and 60.6%, respectively ($p > 0.05$). At the latest moment of follow-up, for the endoscopic ABG $PTA_{0.5\text{-}2kHz}$, 11.1% had an ABG within 0 to 10 dB, 55.6% between 0 and 20 dB and 61.1% within 0 to 30 dB. For the microscopic group, this was 22.9%, 45.7% and 62.9%, respectively ($p > 0.05$).

Table 3 shows the distribution of postoperative ABGs. No significant differences between the endoscopic and microscopic group at 3 months after surgery were found ($p > 0.05$).

**Table 3.** Endoscopic vs microscopic postoperative $PTA_{0.5\text{-}2kHz}$ air bone gap (ABG) at 3 months after surgery and at latest follow-up. Results from endoscope-assisted and microscope-assisted ossiculoplasty are comparable (Chi square, $p > 0.05$).

| Postoperative $PTA_{0.5\text{-}2kHz}$ ABG | Postoperative 3 months (n =99) | | Latest audiogram (n = 53) | |
|---|---|---|---|---|
| | Endoscopic n (%) | Microscopic n (%) | Endoscopic n (%) | Microscopic n (%) |
| 0-10 | 4 (14.3%) | 9 (12.7%) | 2 (11.1%) | 8 (22.9%) |
| 0-20 | 12 (42.9%) | 22 (31.0%) | 10 (55.6%) | 16 (45.7%) |
| 0-30 | 18 (64.3%) | 43 (60.6%) | 11 (61.1%) | 22 (62.9%) |
| >30 | 10 (35.7%) | 28 (39.4%) | 7 (38.9%) | 13 (37.1%) |
| Total | 28 (100%) | 71 (100%) | 18 (100%) | 35 (100%) |

## Stability of Hearing

Forty-six of 53 patients (16 endoscopic, 30 microscopic) who had a latest follow-up audiogram also had an audiologic evaluation at 3 months after surgery. Change in air conduction was evaluated between these audiograms. For endoscopic air conduction $PTA_{0.5\text{-}2kHz}$, 25.0% showed improvement (change > 5 dB), 50.0% remained stable and 25.0% deteriorated (change < - 5 dB). In the microscopic group, 26.7% improved, 46.6% remained stable and 26.7% deteriorated ($p > 0.05$). Results are summarized in Table 4.

**Table 4.** Endoscopic and microscopic binned air conduction change between latest follow-up and 3 months after surgery for $PTA_{0.5\text{-}2kHz}$. Endoscopic and microscopic results are equal (Chi square, $p > 0.05$). Approximately 50% of endoscopic and microscopic hearing results at 3 months after surgery remain stable at the latest audiogram. Around 25% improve.

| Endoscopic $PTA_{0.5\text{-}2kHz}$ air conduction bins | n | % |
|---|---|---|
| Improvement (> 5 dB) | 4 | 25.0% |
| Stable (-5 < change < 5 dB) | 8 | 50.0% |
| Deterioration (< -5 dB) | 4 | 25.0% |
| Total | 16 | 100% |
| **Microscopic $PTA_{0.5\text{-}2kHz}$ air conduction bins** | | |
| Improvement (> 5 dB) | 8 | 26.7% |
| Stable (-5 < change < 5 dB) | 14 | 46.6% |
| Deterioration (< -5 dB) | 8 | 26.7% |
| Total | 30 | 100% |

## Changes in Bone Conduction

The 3-month postoperative $PTA_{0.5\text{-}2kHz}$ changes in bone conduction are shown in table 5. A deterioration in perception of more than 10 dB was observed in 7 of 99 patients (7.1%), of which 2 of 28 (7.1%) were endoscopic and 5 of 71 (7.0%) microscopic. In these seven patients, the drop in $PTA_{0.5\text{-}2kHz}$ averaged 18.8 dB, showing no difference between both groups ($p > 0.05$). One case of total deafness was observed 3 years after microscopic surgery.

**Table 5.** Postoperative changes in bone conduction.

| | **3 months after surgery (n = 99)** | | **Latest audiogram (n = 53)** | |
|---|---|---|---|---|
| Postoperative bone conduction at latest audiogram | n | % | n | % |
| Overclosure | 44 | 44.4% | 22 | 41.5% |
| No change | 48 | 48.5% | 27 | 50.9% |
| Sensorineural hearing loss > 10 dB | 7 | 7.1% | 3 | 5.7% |
| Dead ear | 0 | 0% | 1 | 1.9% |
| Total | 99 | 100% | 53 | 100% |

Three months after surgery, overclosure was present in 44 of 99 patients (44.4%). A deterioration in perception of more than 10 dB was observed in 7 of 99 patients (7.1%). In these 7 patients, the drop in $PTA_{0.5\text{-}2kHz}$ averaged to 18.8 dB. One case of total deafness was observed 3 years after surgery.

## Ear Status after Previous Surgery

Sixty-two individuals (58.5%) had ossiculoplasty in a closed cavity (CWU, CWUO). Forty-two of those were obliterated (CWUO). In 26 patients (24.5%), ossiculoplasty was performed after CWD or CWR. In 18 ears (17.0 %) the ossicular chain was reconstructed with an intact mastoid and canal wall. No significant difference ($p > 0.05$) was found in 3 months postoperative $PTA_{0.5\text{-}2kHz}$ ABG between CWU, CWD, CWUO, CWR and those with an intact mastoid.

## Prosthesis Length, Fixation Method and Status of Malleus

The average length of the prosthesis shaft for all patients was 4.53 mm (range, 3.0-7.0 mm). In CWU(O) this was 4.59 mm (range, 3.0-6.0 mm), in CWR 4.46 mm (range, 3.0-7.0 mm), in CWD 4.00 mm (range, 3.5-5.0 mm) and in patients with an intact mastoid and ear canal 4.52 mm (range, 4.0-5.50 mm). The average FTTP length was $4.72 \pm 0.72$ mm for endoscope-assisted and $4.45 \pm 0.92$ mm for microscope-assisted ossiculoplasties ($p > 0.05$). The prosthesis length had no influence on ABG improvement ($p > 0.05$).

As over 75% of patients had a shoe-fixated FTTP, this could not be compared with other fixation methods.

The 3-month postoperative ABG $PTA_{0.5\text{-}2kHz}$ was 27.6 ± 17.1 dB for 13 cases with an intact malleus. For 60 with only the malleus handle present it was 25.6 ± 14.8 dB and in 26 with a completely absent malleus it was 33.5 ± 14.3 dB. The differences between these 3 groups were not statistically significant ($p > 0.05$).



## Overall Hearing Outcome

Preoperative and postoperative Glasgow Benefit Plots are shown in figure 1 and table 6. Preoperatively, 77.8% of our patients had a unilateral impairment of >30 dB on the to-be-operated ear. Three months postoperatively, 29.3% of patients had a normal hearing (air conduction threshold < 30 dB) in the operated ear. Of those patients, 24.2% had bilateral normal hearing and in 5.1% unilateral normal hearing (operated ear) was achieved. In another 38.4% of patients, hearing improved after surgery, but mean air conduction threshold levels remained above 30 dB. No improvement was seen in 33.3%. A postoperative deterioration of >10 dB of the mean air conduction threshold was present in 12.1% of patients.

When the mean air conduction threshold level was set to 35 dB, 39.4% achieved socially acceptable hearing on the operated side. In 35.4% of patients bilateral and in 4.0% unilateral (operated ear) socially acceptable hearing was measured. In another 30.3% of patients, hearing in the impaired and operated ear improved, but the mean air conduction threshold levels remained above 35 dB.

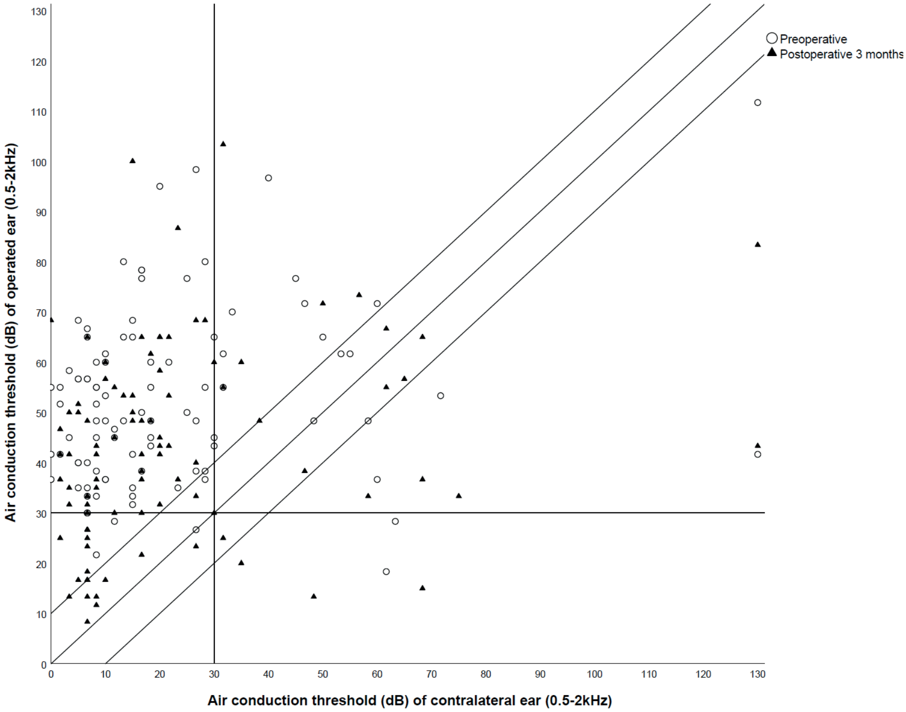


**Figure 1.** Glasgow Benefit Plot, 3 months after surgery (n = 99).

In 24.2% of patients bilateral normal hearing and in 5.1% unilateral normal hearing (operated ear) was measured. In another 38.4% of our patients, hearing in the impaired and operated ear improved, but mean air conduction threshold levels remained above 30 dB.

**Table 6.** Glasgow Benefit Plots, 3 months after surgery.

| **Glasgow Benefit Plot ($PTA_{0.5\text{-}2kHz}$), preoperatively (n = 99)** | **n** | **%** |
|---|---|---|
| Unilateral hearing impairment (operated ear), asymmetric thresholds | 77 | 77.8% |
| Bilateral hearing impairment, asymmetric thresholds | 12 | 12.1% |
| Bilateral hearing impairment, symmetric thresholds | 4 | 4.0% |
| Unilateral hearing impairment (non-operated ear), asymmetric thresholds | 2 | 2.0% |
| Bilateral normal hearing | 4 | 4.0% |
| **Glasgow Benefit Plot ($PTA_{0.5\text{-}2kHz}$), postoperatively (n = 99)** | **n** | **%** |
| Bilateral normal hearing (30 dB as upper margin) | 24 | 24.2% |
| Unilateral normal hearing (operated ear) | 4 | 5.1% |
| Operated ear improves, but is still impaired | 38 | 38.4% |
| Symmetric but impaired thresholds | 6 | 6.1% |
| Operated ear does not improve and is still impaired | 21 | 21.2% |
| Air conduction of operated ear deteriorates > 10 dB | 12 | 12.1% |
| **Glasgow Benefit Plot ($PTA_{0.5\text{-}2kHz}$), postoperatively (n = 99)** | **n** | **%** |
| Bilateral socially acceptable hearing (35 dB as upper margin) | 35 | 35.4% |
| Unilateral normal hearing (operated ear) | 4 | 4.0% |
| Operated ear improves, but is still impaired | 30 | 30.3% |
| Symmetric but impaired thresholds | 6 | 6.1% |
| Operated ear does not improve and is still impaired | 18 | 18.2% |
| Air conduction of operated ear deteriorates > 10 dB | 12 | 12.1% |

At 3 months after surgery, 39.4% had socially acceptable hearing on the operated side (air conduction threshold level of 35 dB).

# Discussion

## Endoscope-Assisted vs. Microscope-Assisted Ossiculoplasty

To our knowledge, our study is the largest to primarily investigate the results of endoscope-assisted total ossiculoplasty. In addition, our follow-up is longer than previously described in literature.[1–3] Das et al.[1] described significantly better hearing results 1 month after endoscope-assisted ossiculoplasty in comparison to microscope-assisted ossiculoplasty. Yet, at 6 months after surgery both methods were shown to have comparable audiologic outcomes. Yawn et al. and Kwinter et al.[2,3] state that audiologic results of endoscope-assisted and microscope-assisted ossiculoplasty are equal. Short-term endoscopic results from our study are comparable to those in literature. Our study does not confirm the postulated advantage of the superior view leading to better hearing results in endoscope-assisted ossiculoplasty as opposed to the microscope. However, this study does show that the endoscopic approach achieves comparable results to a microscopic approach. Drawbacks of endoscopic surgery, such as blood obscuring the view, one-handed surgery and diminished depth perception, do not seem to play a major role in ossiculoplasty.

## Changes in Air Conduction and Air Bone Gap

Audiologic outcomes of FTTP ossiculoplasty in our tertiary referral center are largely comparable to those published by Fisch et al. They reported a mean postoperative air conduction and ABG $PTA_{0.5\text{-}2kHz}$ of 43.2 and 21.3 dB. Postoperative air conduction thresholds by Fisch et al. for $PTA_{0.5\text{-}2kHz}$ do not significantly differ from our results. As they presented no standard deviations for ABG results, this could not be statistically compared to ours. Fisch et al. also describe 57% of patients having a postoperative ABG of <20 dB and 87% <30 dB, which is comparable to our results. These postoperative results are similar or superior to those published in literature for other titanium and nontitanium total prostheses.[7–12] As these results are largely reproducible, the outcome of FTTP ossiculoplasty does not solely depend on surgical skills. In our opinion, the slightly lower improvement in air conduction threshold levels and ABG in comparison to Fisch et al., can be explained by a larger difference in mean preoperative air conduction threshold levels and ABGs. As we showed that conduction can improve from 3 months to latest follow-up (±20 mo), also the timing of audiologic evaluation might have contributed. In our study this was 3 months after surgery and in the study by Fisch et al. 1 year. The prostheses used in CWU(O) were longer in the study by Fisch et al. (mean, 7.9; range, 4-11 mm) when compared with our study (mean, 4.59; range, 3.0-6.0 mm). Although Fisch et al. describe better results in patients treated with longer prostheses, we found no effect of prosthesis length on outcome. As prosthesis length varied little in our study, this might possibly explain the lack of differences. In both studies, middle ear depth was measured before FTTP placement. We therefore have no explanation for the difference in closed cavity prosthesis length between Fisch et al. and our study.

In 8 of 106 cases (7.5%), the FTTP was extruded. This rate is higher than the 0% described by Fisch et al. For other TORPs described in literature, extrusion rates vary from 0%[6,19] to 16.5%.[10] Others found an extrusion rate of 5%[20], 1.1%[21] and 3.8%.[7] For all of these TORPs a cartilage graft was placed between the prosthesis and the tympanic membrane. Despite no cartilage graft is necessary using the FTTP, results are comparable. As we had a longer follow-up period than Fisch et al., this might be an explanation for the difference in extrusion rate.

## Stability of Hearing Outcome

In addition to the 1-year postoperative results by Fisch et al., we described the long-term results of the FTTP. Over a mean follow-up of 2 years, for around 75% of patients hearing remained stable or improved. Twenty-five percent showed deterioration of >5 dB. We suggest that the stability of results is possibly the result of the shoe-fixation of the FTTP in the oval window niche. Also, the ability to fine tune the positioning and angulation of the large flexible FTTP head in direct contact and in alignment with the tympanic membrane may have contributed to its stability.

Long-term audiologic results have been described for different nontitanium TORPs. Coletti et al.[13] demonstrated an ABG increase from 6 months to 5 years after surgery of 17.5 to 24.7 dB. Lesinski[14] also showed a tendency of decreased conduction over time (18% of TORPs ABG <25 dB 4 years after surgery). In achieving better prosthesis stability, the use of a cartilage shoe has been evaluated. In one study by Gostian et al.[22], comparing shoe-fixated with non-shoe-fixated total ossicular chain reconstruction led to a smaller ABG (17.7 vs. 21.6 dB, respectively) at the short-term (<1 yr follow-up). At longer follow-up (>1 yr), results were equal as conduction improved slightly in the non-shoe-fixated group (18.0 vs. 19.3 dB, respectively). Yung and Smith[10] evaluated the Aerial-Total-Dusseldorf total titanium prosthesis with shoe fixation (Aerial-Total-Dusseldorf, Heinz Kurz GmbH Medizintechnik, Dusslingen, Germany). He demonstrated a postoperative ABG of 20.7 dB over a follow up of 24 months (n = 28). Unfortunately, audiologic results 6 and 12 months postoperatively are not presented in the article, rendering it impossible to evaluate the long-term stability of their shoe-fixated titanium TORP. Fayad et al.[23] also evaluated their shoe-fixated long-term titanium TORP hearing outcomes. Their postoperative ABGs were comparable to those described by Yung et al. In addition to hearing outcome, this study described outcome stability comparing short-term (mean follow-up 3.4 mo, n = 134) with long-term (mean follow-up 21.7 mo, n = 63) hearing results[23]. Improvement was found in 23.3% and deterioration in 11.6% of cases. These results by Yung and Fayad et al. are in line with our results, but is impossible to conclude what the role of shoe fixation is in the acquired results as both studies lack a non-shoe-fixated group. In our study, the non-shoe-fixated FTTP ossiculoplasty group was too small for a reliable comparison to those with shoe fixation.

Timing of postoperative audiologic evaluation may influence the final hearing outcome. Internationally, consensus has been reached that an audiogram 3 months after surgery will result in a reliable audiogram as hearing likely has reached its final level.[24] Yet, the results by Fayad et al. and our results do imply that hearing can change even after 3 months; in up to around 25% of patients hearing further improved after 3 months. This means that at 3 months after surgery, hearing outcome would be underestimated and patients should be informed of this possibility. We postulate that, although titanium has good biocompatibility[25], the middle ear mucosa has not settled completely around the titanium prosthesis at 3 months, explaining the further improvement over time. This has probably contributed to the difference in air conduction and ABGs 3 months after surgery between our study and the one by Fisch et al.

### Changes in Bone Conduction

No difference in deterioration in perceptive hearing of more than 10 dB between our study and the study by Fisch et al. was found. Three years after microscopic surgery one of our patients developed a total deafness on the operated ear. A computed tomography showed a normal piston position, and no abnormalities were found on magnetic resonance imaging, deeming a causal relation with the ossiculoplasty unlikely.

### Ear Status after Previous Surgery

No significant difference in hearing outcome was found for patients after a CWU, CWD, CWUO and CWR. This result is in line with data in medical literature.[6,26]

### Overall Hearing Outcome

Postoperative improvement of the air bone gap and air conduction levels are important when evaluating the results of ossiculoplasty. Yet these outcomes do not assess the functional benefit from improved hearing.[18] With the Glasgow Benefit Plot, we demonstrated that in around 40% of cases a socially acceptable air conduction threshold of less than 35 dB on the operated side is achieved. This is an important and useful message for patient counseling as it means that they might no longer need a hearing aid after surgery.

## Conclusion

Our study shows that hearing results with the Fisch titanium total prosthesis are in line with literature. Endoscope-assisted total ossiculoplasty proves to be a suitable technique with comparable results to the microscopic approach.

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# Chapter 2.3

## Identifying epithelial borders in cholesteatoma surgery using narrow band imaging

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# Abstract

## Purpose
To quantify changes in the perceived epithelial border with narrow band imaging (NBI) and white light imaging (WLI) during cholesteatoma surgery and to objectify possible benefits of NBI in otology.

## Methods
Perioperative digital endoscopic images were captured during combined approach tympanoplasty at our tertiary referral center using WLI and NBI (415 nm and 540 nm wavelengths). Sixteen otologic surgeons defined the epithelial borders within 16 identical WLI and NBI photos. Pixels of these selections were calculated to analyze the quantitative difference between WLI and NBI. A questionnaire also analyzed the qualitative differences.

## Results
Sixteen otologic surgeons participated in the study. Stratified per photo, only two photos yielded a significant difference: less pixels were selected with NBI than WLI. A Bland–Altman plot showed no systemic error. Stratified per otologist, four participants selected significantly more pixels with WLI than with NBI. Overall, no significant difference between selected pixels was found. Sub-analyses of surgeons with more than 5 years of experience yielded no additional findings. Despite these results, 60% believed NBI could be advantageous in defining epithelial borders, of which 83% believed NBI could reduce the risk of residual disease.

## Conclusion
There was no objective difference in the identification of epithelial borders with NBI compared to WLI in cholesteatoma surgery. Therefore, we do not expect the use of NBI to evidently decrease the risk of residual cholesteatoma. However, subjective assessment does suggest a possible benefit of lighting techniques in otology.

# Introduction

Narrow band imaging (NBI) is a relatively new modality in the field of otorhinolaryngology. It remains under investigation how useful it will be in specifically otology. To our knowledge only two studies described the possibilities of NBI in otology.[1,2] Both studies concluded that NBI could be of added value, but they lacked objectivation and quantification of the proclaimed advantages. In the first study, the authors qualitatively describe the perioperative images captured with NBI. In the second study, the authors captured images of normal and pathologic tympanic membranes and compared the difference in contrast. Both studies concluded that NBI could be of added value, but they lacked objectivation and quantification of the proclaimed advantages.

One of the advantages hypothesized was the improved accuracy in detection of epithelial borders in cholesteatoma surgery.[1] Narrow band light exists of two wavelengths that penetrate the surface of the tissue (415 nm and 540 nm) and is mainly absorbed by hemoglobin in blood vessels.[3] It has been proven to be a useful endoscopic tool in the diagnosis of benign and malignant mucosal pathology, such as recurrent respiratory papillomatosis and squamous cell carcinoma.[4–9] Theoretically, this characteristic could be utilized to differentiate skin, being an avascular structure, from other vascularized tissues.[1] NBI could, therefore, be beneficial for recognition and removal of epithelium in cholesteatoma surgery. Endoscopes have also been deemed useful in cholesteatoma surgery, due to improved middle ear exposure and movability.[10] Perhaps, a synergetic effect will be achieved when these modalities are combined.

In this study, we aim to quantify changes of the perceived border between epithelium and other tissue with NBI and white light imaging (WLI). We hypothesize that the epithelial border will be perceived differently in comparison to WLI and that NBI will accentuate suspicious lesions which would be missed with WLI.

# Methods

## Photos for evaluation

Perioperative photos were taken during cholesteatoma surgery between July and August 2020. After a retroauricular surgical approach was performed, with subsequent opening of the mastoid cavity and the cholesteatoma sac, keratin was removed from the sac. The epithelial border was identified. The surgical field was maximally cleared of blood by rinsing with water and local application of noradrenaline (1:1000). An Olympus 0-degree rigid laryngoscope of 5 mm in diameter was used, using a 4 K Olympus NBI system (415 nm and 540 nm wavelengths). After applying the auto-focus function to ensure sharp epithelial borders, digital endoscopic images were captured. Two consecutive photos were taken, one with WLI (Fig. 1a) and one with NBI (Fig. 1b).

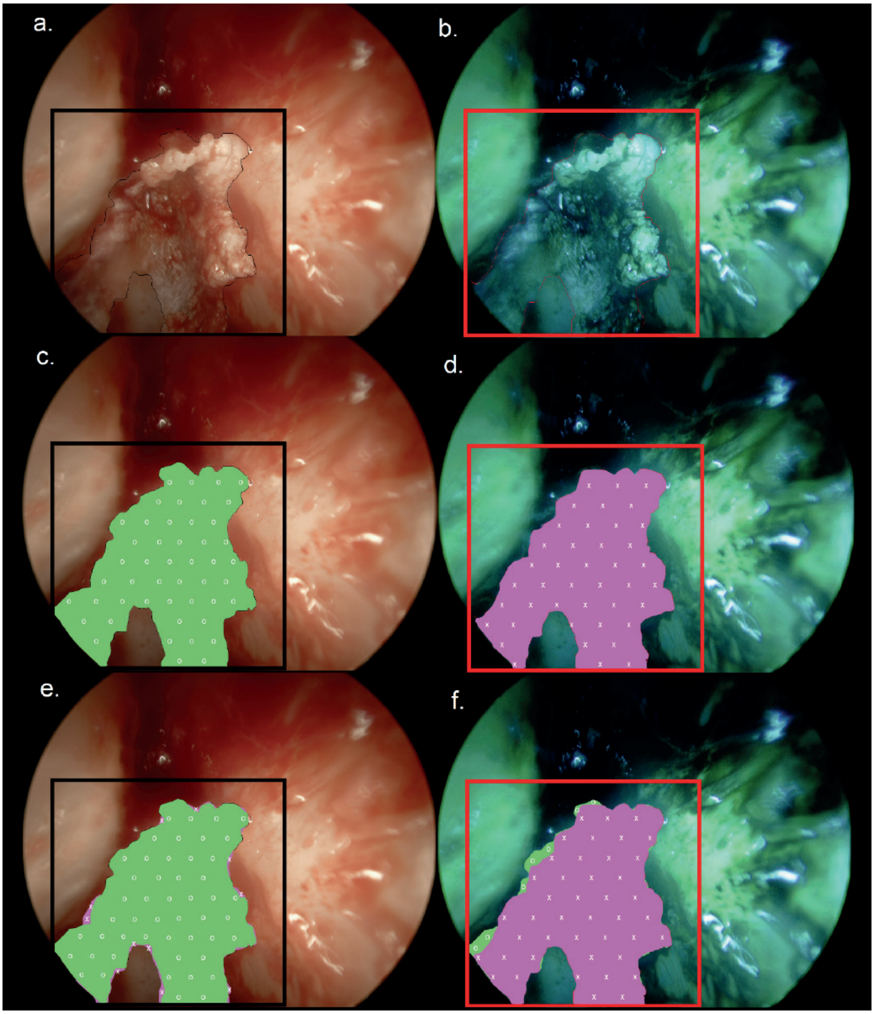


**Figure 1.** Example of white light (WLI) and narrow band imaging (NBI) photos of the left ear during combined approach tympanoplasty. **a, b** shows perioperative WLI and NBI photos of the left antrum during cholesteatoma surgery, with the external ear canal on the left and the tegmen tympani on the right. The box represents the framework in which the epithelial border is drawn by the participant. In **c, d,** the drawn borders are used to make the pixel selection and add a green (o) or purple (x) colored layer with Photoshop. The layers are projected over one another in (**e, f**)

As photos were two dimensional, the center of photos was in focus and the periphery was blurred. A framework was drawn in all photos, with Microsoft Paint, containing only the focused part of the photo, in which the epithelial border was to be defined. A short description of the image was supplied to aid orientation of the surgical situation.

## Participants

Otologic surgeons in the Netherlands were approached to participate in this study. Their otologic experience was noted, according to registration by the Dutch ENT society. The images were sent to the participants digitally and evaluated individually. The participants had no prior training in using NBI and declared to have no conflict of interest in NBI, neither personal nor commercial. Epithelial borders were defined and drawn with the smallest width pencil tool in Microsoft Paint, to ensure precision. In the WLI photos, a black color was used (Fig. 1a), while in the NBI photos a red color was applied (Fig. 1b).



## Data analysis

Photos were divided into two groups. Group 1 consisted of ten WLI and their corresponding NBI photos. The corresponding WLI and NBI photos were subsequently evaluated. Participants were allowed to switch between photos before defining the border. This was done to evaluate if the WLI photo would influence the location of the perceived border with NBI. As participants were not trained in the use of NBI, this would allow them to get accustomed to the visual effect of NBI. In group 2, six WLI and their corresponding NBI photos were presented and evaluated in a random order. In this group it was not permitted to switch between photos before defining the border. Otologic surgeons were asked to analyze all photos in both groups.

With the Magnetic Lasso tool from Adobe Photoshop (version 13.0.1), borders were selected and the perceived area of epithelium encircled. Pixels within the defined area were quantified by the software. For all photos, the total number of pixels was identical. The selected pixels from the WLI photos were colored green (Fig. 1c) and the NBI selection purple (Fig. 1d). As the WLI and NBI photos were identical, selected areas and overlap could be compared to one another. NBI selections were projected over the WLI selection, and vice versa (Fig. 1e, f). NBI pixels which overlapped with WLI pixels were quantified by the software and expressed as a percentage of the total amount of NBI pixels.

### Questionnaire

Participants filled out a questionnaire including three questions. First, participants were asked if NBI was advantageous over WLI in defining the epithelial border. Second, the ability of NBI to reduce residual disease was questioned. If so, the amount of money the otologists were prepared to pay for the NBI system had to be selected (A: €1000, B: €5.000, C: €10.000, D: €50.000 and E: €100.000).

### Statistical analysis

Z values for skewness and kurtosis were evaluated to analyze normality of the data (data were considered normally distributed if $-1.96 < z < 1.96$). Normally distributed data were expressed as mean with its standard deviation. Non-parametric data were expressed as median with its interquartile range. Differences between WLI and NBI selections were assessed with paired samples t test and Wilcoxon signed-rank test. A *p* value less than 0.05 was considered statistically significant. A Bland-Altman plot was made to evaluate a possible systemic error in differences. Linear regression analysis was done to compare participant evaluations.

### Ethics

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. Approval from the institutional review board was not necessary as photos were anonymous and no patients were investigated.

## Results

All photos were acquired in ten different ear operations in which a combined approach tympanoplasty was performed, both primary and revision cholesteatoma surgery. Sixteen photos of the highest quality were selected, corresponding to 16 WLI photos and 16 identical NBI photos.

Sixteen otologic surgeons participated in the study. All otologists were employed at regional hospitals across the country. Of these otologists, 11 had more than 5 years of experience.

### Evaluation by participants stratified per photo

In 2 of the 16 photos, both from group 1, a significant pixel difference was found between the WLI and NBI selection (paired samples *t* test, $p < 0.05$). For these two photos, NBI resulted in a lower number of selected pixels. For the other 14 photos, there was no significant difference. In Table 1, the selected pixels per WLI and NBI photo are shown with corresponding *p* values.

**Table 1.** Selected pixels per photo and modality with the inter-modality *p* values and percentage of narrow band imaging (NBI) pixels overlapping with white light imaging (WLI) pixels.

| Photo No. | Modality | Available photos | Mean (SD) or Median (IQR) pixels in selection | Inter-modality difference of pixels (*p* value) | NBI pixels overlapping with WLI selection (%) |
|---|---|---|---|---|---|
| **Photos in order (group 1)** | | | | | |
| 1 | WLI | 15 | 91 164 (172 231) | 0.015* | |
| | NBI | 15 | 89 095 (40 569) | | 89.8 |
| 2 | WLI | 15 | 55 524 (21 848) | 0.511 | |
| | NBI | 15 | 51 715 (23 675) | | 81.7 |
| 3 | WLI | 15 | 275 931 (44 450) | 0.445 | |
| | NBI | 15 | 268 118 (63 997) | | 92.1 |
| 4 | WLI | 14 | 231 228 (96 375) | 0.097 | |
| | NBI | 14 | 204 521 (125 336) | | 86.6 |
| 5 | WLI | 15 | 302 395 (86 349) | 0.499 | |
| | NBI | 15 | 290 848 (113 931) | | 91.0 |
| 6 | WLI | 14 | 257 333 (78 248) | 0.154 | |
| | NBI | 14 | 241 953 (102 078) | | 86.9 |
| 7 | WLI | 13 | 275 462 (77 120) | 0.728 | |
| | NBI | 13 | 281 019 (97 969) | | 89.5 |
| 8 | WLI | 14 | 58 634 (27 868) | 0.556 | |
| | NBI | 14 | 56 835 (26 981) | | 91.1 |
| 9 | WLI | 14 | 185 050 (70 348) | 0.623 | |
| | NBI | 14 | 182 169 (68 112) | | 93.3 |
| 10 | WLI | 12 | 155 395 (71 226) | 0.027* | |
| | NBI | 13 | 136 666 (68 451) | | 93.8 |
| **Photos in random order (group 2)** | | | | | |
| 11 | WLI | 16 | 88 070 (10 874) | 0.642 | |
| | NBI | 16 | 83 757 (8 775) | | 92.8 |
| 12 | WLI | 16 | 245 134 (36 141) | 0.785 | |
| | NBI | 16 | 242 237 (50 295) | | 91.2 |

**Table 1.** Continued

| Photo No. | Modality | Available photos | Mean (SD) or Median (IQR) pixels in selection | Inter-modality difference of pixels (*p* value) | NBI pixels overlapping with WLI selection (%) |
|---|---|---|---|---|---|
| 13 | WLI | 16 | 210 964 (109 198) | 0.112 | |
| | NBI | 15 | 208 548 (10 860) | | 93.0 |
| 14 | WLI | 16 | 305 836 (60 905) | 0.157 | |
| | NBI | 14 | 333 302 (75 135) | | 82.8 |
| 15 | WLI | 16 | 152 182 (154 801) | 0.109 | |
| | NBI | 16 | 128 295 (70 505) | | 90.6 |
| 16 | WLI | 16 | 347 766 (108 875) | 0.596 | |
| | NBI | 16 | 340 103 (113 468) | | 90.7 |

In total, a median of 93.5% (IQR 10.4%) NBI pixels overlapped with the WLI selection. In group 1, this median was 93.4% (IQR 10.6%) and in group 2, it was 94.1% (IQR 9.5%). The difference between both groups was not statistically significant (Wilcoxon signed-rank test, $p > 0.05$).

**Figure 2a** shows a scatterplot in which the WLI and NBI pixels of individual photos are plotted. Comparison with the drawn y = x line shows that there is a small difference for most photos between the WLI and NBI selection. A Bland-Altman plot (Fig. 2b) shows no systematic error.

## Evaluation by participants stratified per otologic surgeon

When stratifying per otologic surgeon, participant 5, 12, 14 and 15 selected significantly more pixels with WLI than with NBI (paired samples t test, $p < 0.05$). A linear regression line was plotted for all participants and Fig. 3 illustrates most participants do not significantly differ from the y = x line. For 11 participants, the slope was smaller than 1, meaning that for 100 pixels of WLI selection less than 100 NBI pixels were selected. For 5 participants, the slope was larger than 1. Selections of participant 2, 3 and 16 were most divergent from the y = x line and resulted in slopes of, respectively, 0.738, 1.203 and 0.644. For these three participants, there was no significant difference in selected pixels between the two lighting modalities overall (paired samples t test, $p > 0.05$) as WLI pixel selections for some photos were larger than for NBI and vice versa.

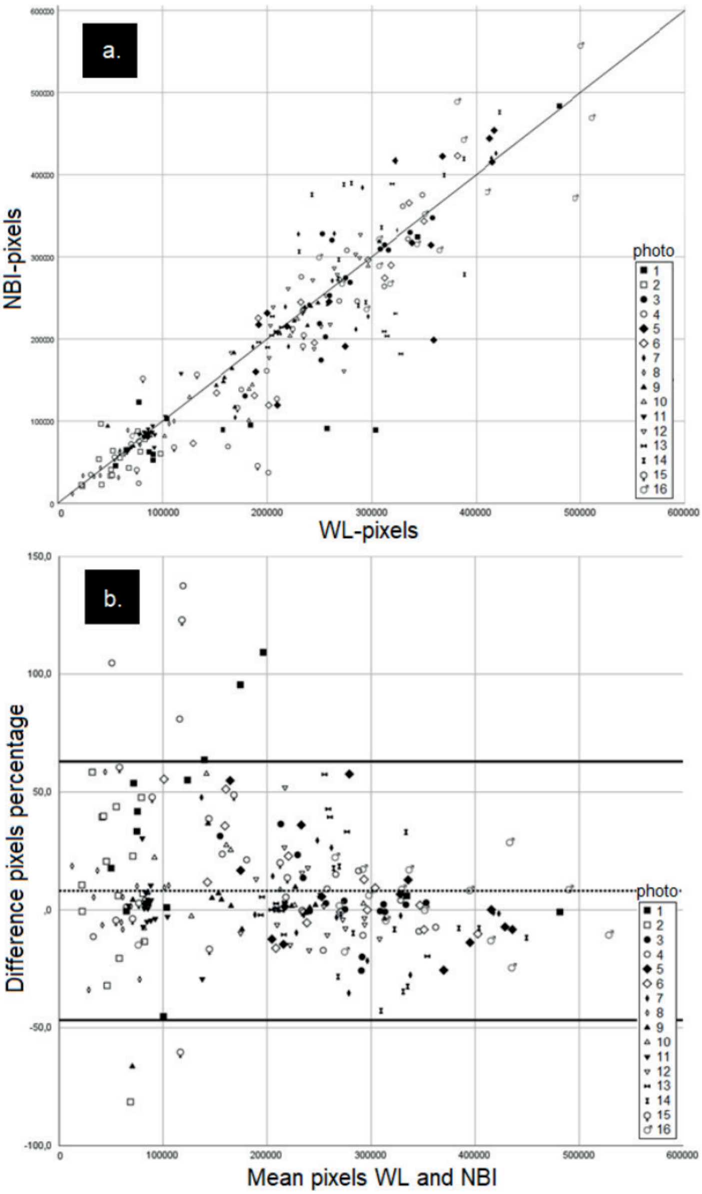


**Fig. 2 a** Scatterplot of white light (WLI) and narrow band imaging (NBI) selected pixels for all photos showing limited differences between the two modalities. Photos 1-10 were evaluated in order (group 1). Photos 11-16 were evaluated in random order (group 2). **b** Bland-Altman plot of the mean and difference between white light (WLI) and narrow band imaging (NBI) pixel selection illustrating no systematic error. Difference is plotted on the y-axis as a percentage of the mean. The dotted line represents the mean difference and the black lines correspond with ± 2 standard deviations. For photo 1 and 10, a mainly positive difference can be seen that leads to a significant difference: WLI > NBI. For all other photos, differences are distributed randomly.

Sub-analyses of the group of otologic surgeons with more than 5 years of experience, compared to surgeons with less seniority, also yielded no significant differences between NBI and WLI or number of pixels selected.

Some otologic surgeons were not able to submit all photos due to technical difficulties; therefore, not all image selections are complete (table 1, 2). Analyses were done with available images.

## Questionnaires

Ten of 16 participants (63%) filled out the questionnaire. Six of them (60%) found NBI advantageous in defining the border of epithelium, of which five (83%) believed NBI could help reduce the risk for residual disease. These five participants were be prepared to invest €5.000 in an NBI system.

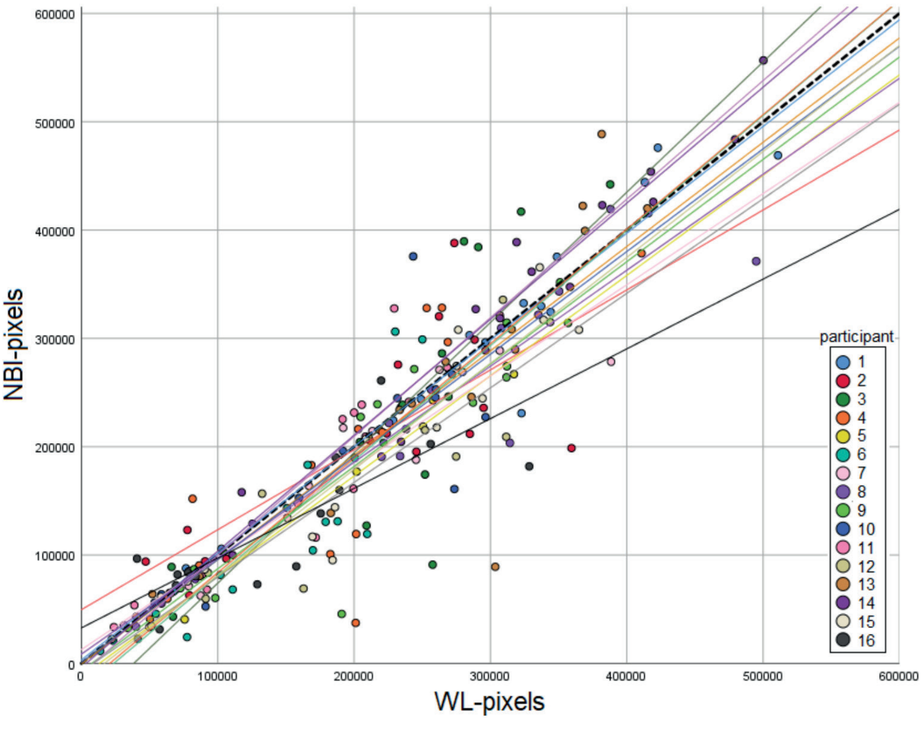


**Fig. 3** A scatterplot of white light (WLI) and narrow band imaging (NBI) pixels of individual participants, with corresponding linear regression lines, demonstrates the small difference between modalities.For 11 participants the slope was smaller than 1, meaning that for 1 pixel of WLI selection corresponded with less than 1 NBI pixel selected. For 5 participants the slope was larger than 1. Slopes generally are close to 1, thus close to the y = x line (dotted line).

**Table 2.** Linear regression analysis and intra-participant *p* values of differences between white light (WLI) and narrow band imaging (NBI). Wilcoxon signed-rank test was used. Statistically significant results are marked with an asterisk ($p < 0.05$).

| Participant No. | Available photos | Linear regression (β) | Intra-participant pixel difference (*p* value) |
|---|---|---|---|
| 1 | 16 | 0.985 | 0.889 |
| 2 | 15 | 0.738 | 0.804 |
| 3 | 16 | 1.203 | 0.979 |
| 4 | 16 | 0.963 | 0.649 |
| 5 | 5 | 0.926 | 0.027* |
| 6 | 16 | 1.062 | 0.137 |
| 7 | 16 | 0.842 | 0.099 |
| 8 | 16 | 0.886 | 0.075 |
| 9 | 15 | 0.945 | 0.115 |
| 10 | 15 | 0.948 | 0.548 |
| 11 | 16 | 1.095 | 0.461 |
| 12 | 11 | 0.873 | 0.031* |
| 13 | 16 | 1.057 | 0.650 |
| 14 | 15 | 1.071 | 0.028* |
| 15 | 15 | 0.978 | 0.030* |
| 16 | 15 | 0.644 | 0.113 |



## Discussion

In this study 2-dimensional photos were used to quantify and compare epithelial borders in cholesteatoma surgery by 16 participating otologic surgeons. This method allows for direct comparison between WLI and NBI in identical perioperative images to evaluate the potential added value of NBI in cholesteatoma surgery. By drawing a framework inside the photo, participants evaluated the area of the photo which was in focus and of highest quality. A potential drawback of this study is that it might not be a perfect representation of reality. First, as static photos were used, sight of depth and the possibility to dynamically visualize borders lack in this method. Second, as NBI colors blood black, hampering view of underlying tissues, it was purposely removed from the surgical field to allow for optimal visualization. It could be questioned whether this method is adequate and time efficient in a real-time surgical setting. Local application of noradrenaline could also influence the appearance of epithelium with NBI due to vasoconstriction. In this study, no correction was done for drawing error. Despite these minor limitations in our study design, we consider it robust enough to draw solid conclusions.

Presently, two studies have been performed that describe the use of NBI in otology.[1,2] Valdez et al. used a modified otoscope to obtain images of normal tympanic membranes, cholesteatoma and acute otitis media.[2] Zhang et al. looked at multiple ear pathologies, including cholesteatoma, with NBI.[1] Both state that NBI has advantages in identification and dissection of cholesteatoma.[1,2] Neither study objectified nor quantified this presumed advantage. Our study provided no significant differences in the amount of selected pixels with NBI in comparison to WLI for most photos when images were examined in both modalities separately and successively. Linear regression analyses illustrated that overall WLI pixel selection was close to NBI pixel selection. Furthermore, differences between WLI and NBI selections within participants were smaller than the variation between participants. This is reflected by the large standard deviation in comparison to the mean of WLI and NBI selections that was found in our study, suggesting a greater influence of participant on amount of pixels selected than lighting modality. Also, for the few photos and participants in which a significant difference was found between NBI and WLI, more pixels were selected with WLI than with NBI. NBI would, therefore, result in a smaller perceived area of epithelium and theoretically less tissue resection. As it has been shown that more tissue resection leads to a lower chance of residual cholesteatoma,[11,12] this could be an evident disadvantage of NBI use. We demonstrated that over 93% of the NBI pixels overlapped with the already selected WLI pixels. As the remaining 7% of NBI pixels were mainly located adjacent to the WLI selections, it revealed no novel areas of epithelium. However, due to the method of the study, no perioperative biopsies could be taken of the areas of difference between WLI and NBI. We thus cannot state with certainty that no additional areas of disease were present. Overall, our findings weaken the previously suggested assumption that NBI could allow for increased accuracy in detection of epithelial borders. We, therefore, do not expect NBI to significantly decrease of the number of cholesteatoma residuals.

Despite the lack of uniform results, a majority of the participants considered NBI to be potentially beneficial in identifying epithelial borders, according to the questionnaires. They also believed NBI to be helpful in lowering cholesteatoma residuals. All of them were prepared to invest € 5.000 in an NBI system. This is in line with the possible benefit found in the literature. Therefore, it is possible that advantages of NBI do exist but were not demonstrated by our study. Lucidi et al.

looked at the use of digital color renderings to enhance the spectral separation of the recorded broad visible spectrum to histologically confirm visual suspicion for cholesteatoma.[13] Digital color rendering was also used by Miwa et al. to grade normal tissue and cholesteatoma based on vascularization pattern and surface irregularity.[14] Digital color rendering is different from NBI as this is done by digital application of color filters during image processing. Lucidi et al. conclude that digital color rendering successfully enhances cholesteatoma tissue and results in high sensitivity and specificity rates.[13] A major drawback of this study was the lack of histological confirmation of visually unsuspicious tissues as WLI was used to declare a lesion unsuspicious of cholesteatoma. Miwa et al. conclude that scores for normal mucosa and cholesteatoma significantly differ.[14] For this study, histological confirmation lacked for suspected normal mucosa and cholesteatoma. Despite drawbacks of both studies, they also suggest that the use of different lighting modalities might be beneficial in cholesteatoma surgery.



The advantages of NBI in diagnosing mucosal pathology are based on better visualization of vascularization patterns and density.[4–9] The avascular structure of cholesteatoma could credibly be the reason no advantages were found in cholesteatoma surgery. Our findings do not suggest that NBI has no benefits in the entire field of otology. It would be interesting to evaluate changes in vascularization during treatment of granulomatous myringitis and evaluation of tympanic membrane vascularization after myringoplasty in relation to closing rates. More research should be done to evaluate these other potential benefits. As an NBI system is costly, a necessary next step would be to perform a cost-benefit analysis. Of course, these costs should be put in to perspective as the system can be of added value to the entire ENT department, especially laryngologists. Also, applicability in day-to-day practice has to be considered. As NBI is a built-in modality of light sources, it can be easily used during endoscopic surgery. At present, operation microscopes include multispectral functionality that enhance contrast, but do not emit true NBI wavelengths. NBI is not (yet) available on microscopic light sources. It would, therefore, be unpractical for perioperative microscopic use.

## Conclusion

Our data show that epithelial borders are not perceived significantly different with NBI to WLI. We, therefore, deem it unlikely that NBI will greatly contribute to complete removal of cholesteatoma. Subjective assessment of NBI does suggest that lighting modalities could still be beneficial in cholesteatoma surgery.

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# Part 3

## Patient related issues

# Chapter 3.1

## Pain After Ear Surgery: A Prospective Evaluation of Endoscopic and Microscopic Approaches

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# Abstract

## Objectives / Hypothesis

Assumed advantages of a minimally invasive endoscopic transmeatal approach in ear surgery are less postoperative pain, faster healing and preservation of functional anatomy. We evaluated pain after ear surgery and compared endoscopic transmeatal, microscopic endaural and retroauricular approaches.

## Study Design

Prospective cohort study

## Methods

A prospective evaluation of pain during 3 weeks after ear surgery was performed. Three groups were defined: endoscopic transmeatal, microscopic endaural, and retroauricular. Data from 20 fully completed questionnaires (Brief Pain Inventory - Short Form) per group were analyzed with Bayesian and frequentist statistics.

## Results

For all approaches, low pain scores were found, not exceeding 4 on a scale of 0 to 10. Analysis of the worst, least, and average pain scores documented per 24 hours showed no statistically significant difference nor equality between groups. With Bayesian statistics, a Bayes factor of 1.07, 0.25, and 0.51 was found, respectively. With frequentist statistics a p value of .092, .783, and 0.291, respectively. Small, but statistically significant, differences were found for sleep, natural sleeping position, normal work and pain medication taken. The location of pain correlates with the incision site.

## Conclusions

The results of this study show that the surgical approach has no clinically relevant influence on postoperative pain after ear surgery. The statistically significant differences on natural sleeping position, sleep, normal work and amount of pain medication taken are small and should be interpreted with caution. Therefore, these should not be decisive factors in the choice of surgical approach in ear surgery.

# Introduction

Several surgical approaches can be used to access the middle ear. These range from the minimally invasive transmeatal, to the more invasive endaural, and most invasive retroauricular approach. Each of these approaches is associated with specific soft and hard tissue trauma. These days, a surgical trend toward minimally invasive surgery is advocated. This has been associated with faster healing, better postoperative quality of life and comparable surgical results.[1,2]

Within the field of otology, this trend has gained traction with the introduction of endoscopic ear surgery. To achieve sufficient view of the operating field, the microscope needs a more traumatic approach. The endoscope hypothetically will achieve the same - or better - surgical view with less trauma needed.[3] It would seem reasonable to assume that the aforementioned benefits would apply to endoscopic ear surgery. Other benefits of endoscopic ear surgery that have been postulated are a reduction of residual disease in cholesteatoma surgery,[4–11] reduction of surgery time,[12–14] preserving functional anatomy,[15–18] and better cost effectiveness.[10,19,20] Comparable results in myringoplasty have been demonstrated, suggesting that the outcome remains equal[21].

Only a few studies have been conducted investigating these benefits. One comparative study was found regarding time needed to heal between microscopic and endoscopic ear surgery.[22] Only two studies compared both types of surgery with respect to postoperative pain.[23,24] To strengthen the claims that endoscopic ear surgery has true benefits over microscopic ear surgery, more comparative studies with high quality are needed.

The aim of our study was to prospectively compare postoperative pain in patients following either endoscopic or microscopic ear surgery. More specifically, we aimed to compare the three mentioned approaches for increasing tissue damage.



# Materials and methods

## Participant Selection

Three groups were defined. The first group was comprised of patients with a transmeatal endoscopic approach, the second group consisted of patients with an endaural approach, and the third group consisted of patients with a retroauricular approach. To be eligible for inclusion, patients had to be older than 18 years and have sufficient understanding of the Dutch language to complete the questionnaire. Patients were excluded if they suffered from chronic pain complaints, migraine or other forms of headache, and if they mentioned the chronic use of painkillers.

No randomization was performed, as inclusion and informed consent was acquired after surgical approach and planning were completed. All consecutive patients listed for an operation and eligible for inclusion were asked to participate until a total of 20 patients in every group were included.

### Pain Assessment

The Brief Pain Inventory - Short Form (BPI-SF) was used to measure postoperative pain.[25–27] BPI-SF is a validated pain questionnaire and uses a scale from 0 (no pain/influence) to 10 (worst pain/influence). Three nonvalidated questions were added separately to specify pain due to the pressure bandage applied in the retroauricular group, influence of pain on normal sleeping position and pain medication used (type, frequency, dose). Relief of pain by medication is measured as a percentage from 0% to 100%. Additionally, a drawing of a human head was added to enable patients to specify areas of paresthesia and/or numbness. A baseline measurement was attained 1 day preoperatively. We repeated the questionnaires daily during the first week and on day 10, 14 and 21 postoperative. Localization and extent of pain were recorded on a drawing of a human head.

### Data Analysis

Repeated-measures analysis of variance (ANOVA) was performed on all 10 time points to evaluate the difference of pain perception and influence of pain on daily life activities among the three groups. These analyses were performed with Bayesian statistics (primary analysis) as well as with frequentist statistics (secondary analysis) using JASP version 0.9.0.1 (https://jasp-stats.org). For the Bayesian analysis, default priors were used.[28]

With Bayesian statistics, smaller datasets can be analyzed without losing power while retaining precision.[29] Such analyses result in Bayes factors (BFs), which express relative support for one model over another model given the data. We used Lee and Wagenmakers' classification scheme for interpretation of the BF.[30] A BF higher than 1 favors the model that allows a difference between groups, whereas a BF lower than 1 favors the model in which there is no difference between groups. A BF between 1 and 0.1 should be interpreted as anecdotal to moderate evidence, whereas a BF smaller than 0.1 can be interpreted as strong evidence for the no-difference model.

A BF between 1 and 10 can be seen as anecdotal to moderate evidence, whereas a BF larger than 10 should be interpreted as strong evidence for the difference model.

To facilitate comparison with literature, we secondarily determined significance with frequentist statistics between groups using JASP. We performed repeated-measures ANOVA to analyze differences of pain perception and influence of pain on daily life activities. Differences in pain medication taken were determined by one-way ANOVA. A p value <.05 was considered statistically significant.

Comparison of the location of pain and paresthesia to the surgical approach was done on the day of worst pain by visual evaluation of the drawing in the questionnaire.



The study was conducted according to the current version of the Declaration of Helsinki (Edinburgh, Scotland, October 2000). Institutional review board approval was attained (W16_283 # 16.333).

## Results

### Participants

Inclusion started March 2017 and was completed in June 2018. Due to dropouts and incomplete questionnaires, a total of 72 eligible participants were asked to participate before all groups were complete. The demographics of the final study groups are shown in Table 1. The endoscopic group consisted of 18 tympanoplasties (86%) and two transmeatal atticotomies (9%) and had a dropout of one tympanoplasty (5%). The endaural microscopic group was comprised of 11 stapedotomies (40%), eight tympanoplasties (30%) and one transmeatal atticotomy (4%). The seven dropouts (26%) were evenly divided: four tympanoplasties, two stapedotomies and one transmeatal atticotomy. The retroauricular group consisted of 15 canal wall up mastoidectomies (63%), four cochlear implants (17%) and one canalplasty (4%). Four canal wall up mastoidectomies dropped out (16%).

### Pain Assessment

The mean scores with its standard deviations of the individual questions of the BPI-SF are shown in Table 2 with their BF and P values. Overall visual analog scale (VAS) scores at all time points did not exceed 4. Additionally, no BF was found to be lower than 0.1 or higher than 10 for all subquestions, which implies that no evidence was found for one of both models. Frequentist statistics, on the other hand, showed that patients from the retroauricular group experienced significantly more impact on their sleep (P = .032) and patients from the endaural group were less impaired in performing normal work (P = .011). The additional questions did result in a BF of more than 10 when asked if pain influenced the normal sleeping position (Table 2). A mean VAS score of 3.83 ± 3.08 was found in the retroauricular group regarding pain by the pressure bandage.

We illustrate how pain is scored over time in Fig. 1. The worst and least pain are distributed just above and below the average pain. A significant (P < .001) increase is present in experienced pain after surgery for the worst and average pain compared to the baseline measurement. Pain levels quickly receded, and after 10 days pain scores were below 2. Analysis of the worst, least, and average pain scores measured per 24 hours showed a BF of 1.07, 0.25 and 0.51, respectively, between groups in the first week and on day 10, 14, and 21 after surgery.

**Table 1.** Patient Demographics and Performed Surgeries.

| | **Study population (n=60)** | **Group 1 transmeatal endoscopic (n=20)** | **Group 2 endaural microscopic (n=20)** | **Group 3 retroauricular microscopic (n=20)** |
|---|---|---|---|---|
| **Gender** | | | | |
| male | 31 | 11 | 9 | 11 |
| female | 29 | 9 | 11 | 9 |
| **Age, yr, mean** | 50 | 39 | 54 | 58 |
| **Surgery (n=60)** | | 18 tympanoplasties<br>2 atticotomies | 8 tympanoplasties<br>1 atticotomy<br>11 stapedotomies | 15 canal wall up mastoidectomies<br>4 cochlear implants<br>1 canalplasty |

**Table 2.** Mean scores of pain and additional questions with their between groups p-value and Bayes factor. Overall scores do not exceed 4. No significance was found between the groups for worst, least and mean pain. Moreover, BF's are between 0.1 and 10. The pressure bandage resulted in a mean score of 3.83 on the first day in the retroauricular group. Sleep was significantly influenced in the retroauricular group (P = .032), whereas the endaural group was less impaired in performing normal work (P = .011). Patients in the retroauricular group experienced more influence on their natural sleeping position (Bayes factor = 25.43 and P = .001).

| | Group 1 Transmeatal Endoscopic (Mean Score ± SD) | Group 2 Endaural Microscopic (Mean Mcore ± SD) | Group 3 Retroauricular Microscopic (Mean Score ± SD) | P value of Between Groups Effect of RM ANOVA | Bayes Factor of Between Groups Effect of RM ANOVA |
|---|---|---|---|---|---|
| **BPI-SF** | | | | | |
| Worst pain | 2.26 ± 2.02 | 1.42 ± 1.72 | 2.72 ± 1.85 | 0.092 | 1.07 |
| Least pain | 0.91 ± 1.30 | 0.91 ± 1.62 | 1.16 ± 0.85 | 0.783 | 0.25 |
| Mean pain | 1.51 ± 1.58 | 1.11 ± 1.68 | 1.87 ± 1.28 | 0.291 | 0.51 |
| General activities | 1.96 ± 2.29 | 0.98 ± 1.25 | 2.00 ± 1.49 | 0.126 | 0.75 |
| Mood | 1.33 ± 1.29 | 0.66 ± 1.27 | 1.53 ± 1.36 | 0.096 | 0.81 |
| Walking ability | 0.82 ± 1.09 | 0.55 ± 0.92 | 0.85 ± 1.07 | 0.629 | 0.18 |
| Normal work | 2.66 ± 2.47 | 1.07 ± 1.54 | 3.17 ± 2.41 | 0.011* | 4.84 |
| Relations with other people | 1.23 ± 1.52 | 0.62 ± 1.22 | 1.14 ± 1.09 | 0.308 | 0.32 |
| Sleep | 1.82 ± 1.62 | 1.29 ± 2.07 | 2.82 ± 1.72 | 0.032* | 2.11 |
| Enjoyment of life | 0.94 ± 0.96 | 0.85 ± 1.75 | 1.49 ± 1.48 | 0.311 | 0.28 |
| **Additional questions** | | | | | |
| Influence on natural sleeping position | 1.95 ± 1.54 | 1.31 ± 1.75 | 3.34 ± 1.80 | 0.001* | 25.43* |
| Pain by pressure bandage | - | - | 3.83 ± 3.08 | - | - |

*Statistically significant value
ANOVA = analysis of variance, BPI-SF = Brief Pain Inventory-Short Form, RM = repeated measures, SD = standard deviation.

3.1

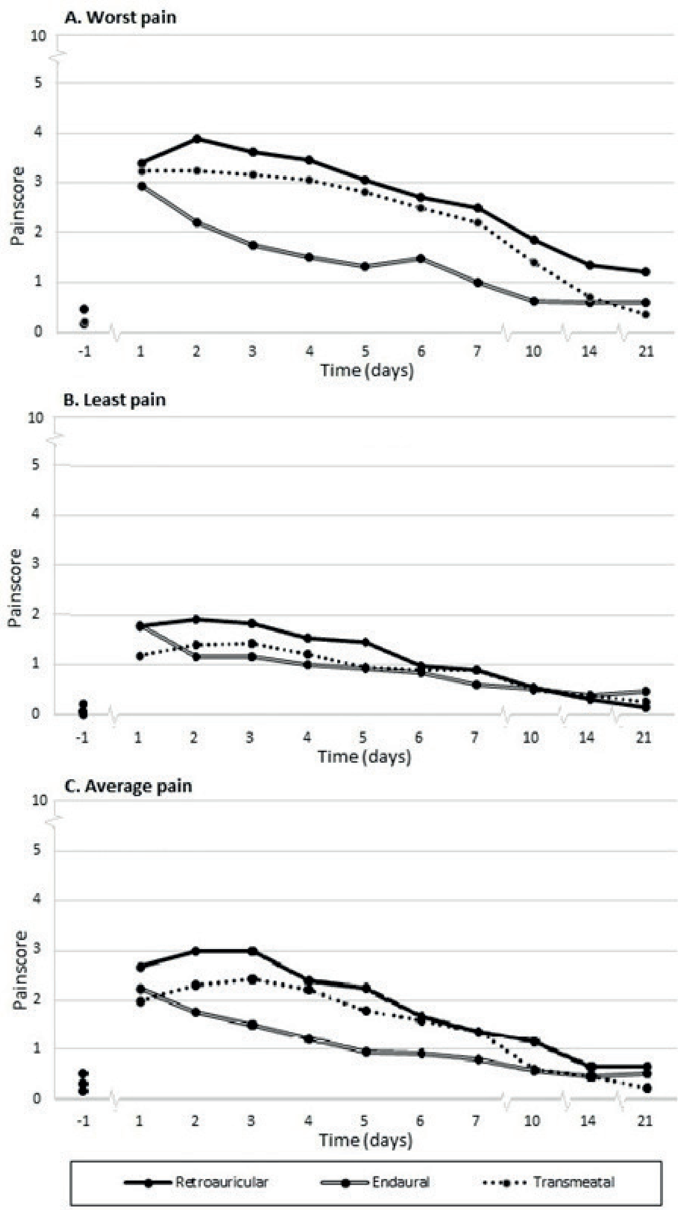


**Fig. 1.** Worst, least and average pain per 24 hours on postoperative days 1-7, 10, 14 and 21 postoperatively per group (endoscopic transmeatal and microscopic retroauricular and endaural).

**A.** Worst pain: Bayes factor of 1.07. This represents anecdotal evidence that there is difference between groups.

**B.** Least pain: Bayes factor of 0.25. This represents mild evidence that there is no difference between groups.

**C.** Average pain: Bayes factor of 0.51. This represents mild evidence that there is no difference between groups.

Approximately twice the amount of pain medication was used in the retroauricular and endoscopic transmeatal group, compared to the endaural group (Table 3). This difference was statistically significant (P < .001). More powerful opioid painkillers were not used in the endoscopic group when compared to the microscopic groups. The number of patients not needing painkillers was evenly distributed over all investigated groups (P = .650). The areas of experienced pain and paresthesia correspond with the incisions of the surgical approaches.

**Table 3.** Average amount of taken pain medication and its mean relief on pain.

| | Group 1 Transmeatal Endoscopic (Average per Patient ± SD) | Group 2 Endaural Microscopic (Average per Patient ± SD) | Group 3 Retroauricular Microscopic (Average per Patient ± SD) |
|---|---|---|---|
| **Paracetamol 1 gram** | 10.1 ± 10.7 | 5.6 ± 9.0 | 11.3 ± 9.6 |
| **NSAID (ibuprofen 400 mg, diclofenac 50 mg, naproxen 250 mg)** | 3.2 ± 8.6 | 0.7 ± 1.56 | 4.6 ± 7.5 |
| **Opioid (tramadol 50 mg, oxycodone 5 mg)** | 0 | 0.7 ± 3.1 | 0.7 ± 2.5 |
| **Mean relief of pain (%)** | 54.5 ± 29.7 | 64.4 ± 26.6 | 67.1 ± 18.3 |

Approximately twice the amount of pain medication per patient was used in the retroauricular and endoscopic transmeatal group, compared to the endaural group. Opioid painkillers were taken in the endaural and retroauricular group (average 0.7 per patient), but not in the endoscopic transmeatal group. Relief of pain was 54.5%, 64.4% and 67.1%, respectively, for the endoscopic transmeatal, endaural and retroauricular group (P = .704).
NSAID = nonsteroidal anti-inflammatory drug, SD = standard deviation

3.1

# Discussion

Overall pain perception in all groups is very low, especially when compared with other pathologies measured with the BPI-SF such as osteoarthritis of the hip and knee or a malignancy with bone metastases.[26,31] Others have also demonstrated that ear surgery in general can be considered to be near to painless.[32] Even the pressure bandage in the retroauricular group did not negatively influence pain scores (mean VAS 3.83 ± 3.08). We used only fully completed questionnaires, because inclusion of pain scores from incomplete questionnaires from dropouts had no influence on results.

Differences between groups are evaluated with Bayesian and frequentist statistics. Bayesian statistics makes it possible to evaluate differences and equality in small groups without losing power while retaining precision.[29] Frequentist statistics solely test differences and cannot determine equality. Bayesian analysis neither showed equality nor difference between the three groups. This says that there is anecdotal evidence or a relationship by chance that the amount of pain is different or equal between groups. Frequentist analysis did not show significant differences in pain. Because differences in pain scores are small, much larger groups would be needed to achieve statistical significance. It is our belief that these large numbers needed to treat do not reflect clinically relevant differences. The statistically significant differences found between groups, such as the small disadvantages for sleep and natural sleeping position in the retroauricular group, should be interpreted with caution. Because these differences are small, the clinical relevance of these differences is questionable. We believe this also applies to the difference of pain scores found by Kakehata et al., which were mean 1.1 ± 0.9 for transmeatal endoscopic versus 2.8 ± 2.6 for retroauricular microscopic approach.[23]

In this study, more dropouts were present in the microscopic group. Additionally, there is a difference in performed surgeries; the amount of tissue damage can be considered to differ among our three groups. Because Kakehate et al. demonstrated that type of surgery did not influence pain within his study population,[23] we believe that groups are comparable. They found that between the endoscopic and microscopic group, the amount of resected bone was not an influence on postoperative pain. Our patient selection minimalized inclusion bias but did not completely eliminate it.

Our study population was not hospitalized for more than 24 hours, which is different from the study conducted in Japan.[23] This could theoretically influence pain perception. Therefore, our study group cannot be considered easily comparable to the Japanese group. Others found no difference in pain measured once 2 weeks postoperatively.[24] Mean pain scores of 3.6 and 4 for respectively endoscopic transmeatal and retroauricular microscopic surgery are relatively high compared to the Japanese group and our results. No information about hospitalization is mentioned.[24]

The role of postoperative pain medication appears to be limited, because few painkillers were taken, and similar relief percentages were reported (P = .704). We have no explanation why patients from the endaural group used half the amount of pain medication compared to the other two groups. Opioid painkillers, although in low amounts (average = 0.7 per patient), were taken in the endaural and retroauricular group. Surprisingly, none were used in the endoscopic group. As expected, areas of pain and paresthesia correspond with the incisions of the surgical approaches. This supports Kakehata's finding that type of surgery has no influence on the level of pain.[23]

## Conclusion

The results of this study show that the surgical approach has no clinically relevant influence on postoperative pain after ear surgery. The statistically significant differences on natural sleeping position, sleep, normal work and amount of pain medication taken are small and should be interpreted with caution. Therefore, these should not be decisive factors in the choice of surgical approach in ear surgery.

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# Chapter 3.2

## External ear canal geometry and its relation to iatrogenic scutum defect for totally endoscopic epitympanum and antrum visualization

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*Submitted*

# Abstract

## Background

To correlate osseous external ear canal (OEEC) geometry and the orientation of the endoscope to the scutum defect for epitympanum and antrum visualization in totally endoscopic ear surgery (TEES). Additionally, a 2D model using regular temporal bone CT scans to assist in surgical planning was created.

## Methods

The endoscopic scutum defect volume (ESD) for complete epitympanal visualization was measured in 10 cadaveric heads. The ESD was correlated with the endoscope orientation angles (EA) in 3D and in all 2D projection planes. ESD was also correlated with the OEEC dimensions (length, diameter). Geometrics were quantified using custom made software. A 2D method using multiplanar reconstructions of temporal bone CT slices was described and its results were correlated with the 3D obtained results.

## Results

Correlations between ESD and EA as observed in 3D and the coronal plane were moderate; $r=-0.448$, $p=0.027$ and $r=-0.455$, $p=0.025$, respectively. Correlation with the sagittal plane EA was weak ($r=-0.396$, $p=0.047$). No statistically significant correlation was found between ESD and the axial plane EA. 2D obtained results showed very strong agreement with the 3D results for all projection planes ($r>0.802$, $p\leq0.001$).

## Conclusion

OEEC geometry plays a role in scutum preservation in TEES. A steep upward ear canal and endoscope angle allows preservation of large parts of the scutum for visualization of the epitympanum and antrum. A planning tool using regular 2D temporal bone CT slices for use in clinical practice is described. 2D obtained endoscope angles showed very strong agreement with results from the 3D model.

# Introduction

During tympanoplasty and cholesteatoma surgery, the endoscope is regularly used for transmeatal visualization of, and dissection in the epitympanum and antrum[1–3]. The scutum, a bony spur of the superior wall of the external ear canal, is restricting visualization of these areas[4,5]. Therefore it often needs partial resection. Preferably it should be performed as minimally as possible, as it has been shown that the removal has a higher cholesteatoma recurrence rate[6–14].

Totally endoscopic ear surgery (TEES) is performed through the external ear canal. It seems reasonable to assume that the ear canal plays a role in the extent of what can be visualized. Up to now, only one study has studied the role of ear canal dimensions in TEES. In that study, Ito et al. recently described the osseous external ear canal (OEEC) diameter as an important parameter for suitability of a transmeatal endoscopic approach[15]. However, factors such as orientation, length and curvature have not been addressed. Others have described the diameter and volume of the OEEC based on CT scans[16–20]. Yet, these studies were done for earplug measurement and did not regard the ear canal's influence on TEES.



The aim of our 3D study is to correlate OEEC geometry (orientation, length and diameter) and the orientation of the endoscope to the scutum defect for epitympanal visualization. In preoperative surgical planning, the use of 3D software is often too complex for daily clinical practice. Therefore, an additional aim was to create an easy to use 2D model using regular temporal bone CT scans to assist in surgical planning. The accuracy of this 2D model will be verified, using the 3D model as reference.

# Material and methods

## Calculating the scutum defect volume for endoscopic epitympanum and antrum visualization

In 10 human cadaveric specimens, epitympanic landmarks and the antrum were visualized transmeatally by endoscope (length: 175 mm, outer diameter: 4.0 mm, angle: 0 degrees, Richard Wolf, Knittlingen, Germany)[4]. Parts of the scutum and the incus were resected until all epitympanic landmarks and the antrum were visualized. These landmarks were; anteriorly: the superior and anterior border of the malleus head; superiorly: the tegmen; posteriorly: the antrum or start of mastoidal trabecular air cells at the posterior border of the horizontal semicircular canal (HSCC). Preoperative and postendoscopy CT scans were performed of all 10 cadaveric ears.

Image data were reconstructed into volume images with voxel spacing 0.45×0.45×0.45 mm. Scutum defect volumes were evaluated using custom made software[21]. The skull was segmented from the preoperative image, and registered to the postendoscopy image to enable alignment of the preoperative and postendoscopy image volumes. Subsequently, the postendoscopy image was subtracted from the preoperative image. The subtraction image clearly distinguished the resected bone and allowed manual segmentation and quantification of its volume.

## 3D quantification of OEEC geometry and endoscope orientation

To assess the osseous external ear canal (OEEC) geometry, a 3D polygon mesh model of the OEEC was reconstructed by a semi-automatic segmentation tool using custom made software[21]. Also both HSCCs were segmented resulting in an additional polygon mesh model (fig. 1). Both models were placed in a 3D local coordinate system (discussed below). The OEEC orientation was quantified in 3D with respect to the line between the HSCCs (discussed below).

**Local coordinate system.** A right handed anatomical 3D coordinate system was automatically computed based on the three axes of inertia of the polygon mesh model representing both HSCCs. The x-axis runs between the centre of masses of the left and right HSCCs. The x- and y-axes are in the same plane as both HSCCs, with the y-axis directing anteriorly and perpendicular to the x-axis. The z-axis points in the cranial direction and is perpendicular to the x- and y-axes (fig. 1).

**OEEC orientation.** The main gravitation axis of the OEEC polygon mesh was determined automatically by the software and is used to determine the orientation of the OEEC (fig. 1). The orientation of the OEEC (Canal angle: CA) was quantified, in 3D, by the software as the angle between its gravitation axis and the x-axis of the local coordinate system.

**Endoscope orientation.** The endoscope was simulated by a cylinder shaped line with a 4.0 mm diameter, which was placed within the boundaries of the OEEC polygon mesh (fig. 1). This enabled digital endoscope placement while taking into account restrictions based on the OEEC dimensions (length, diameter, curvature). The cylinder was placed in the OEEC pointing to the supero-posterior direction; the direction of the antrum. The Endoscope angle (EA) was quantified, in 3D, as the angle between the cylinder centerline and the x-axis of the local coordinate system.

**OEEC dimensions.** OEEC length was measured by drawing a line at the most superior part of the OEEC polygon mesh. The OEEC length was defined by the distance between the two points where the line intersects both OEEC polygon mesh extremities. Measurements were taken automatically by the software. The OEEC polygon mesh volume was calculated automatically by the software and corresponds with the OEEC volume.

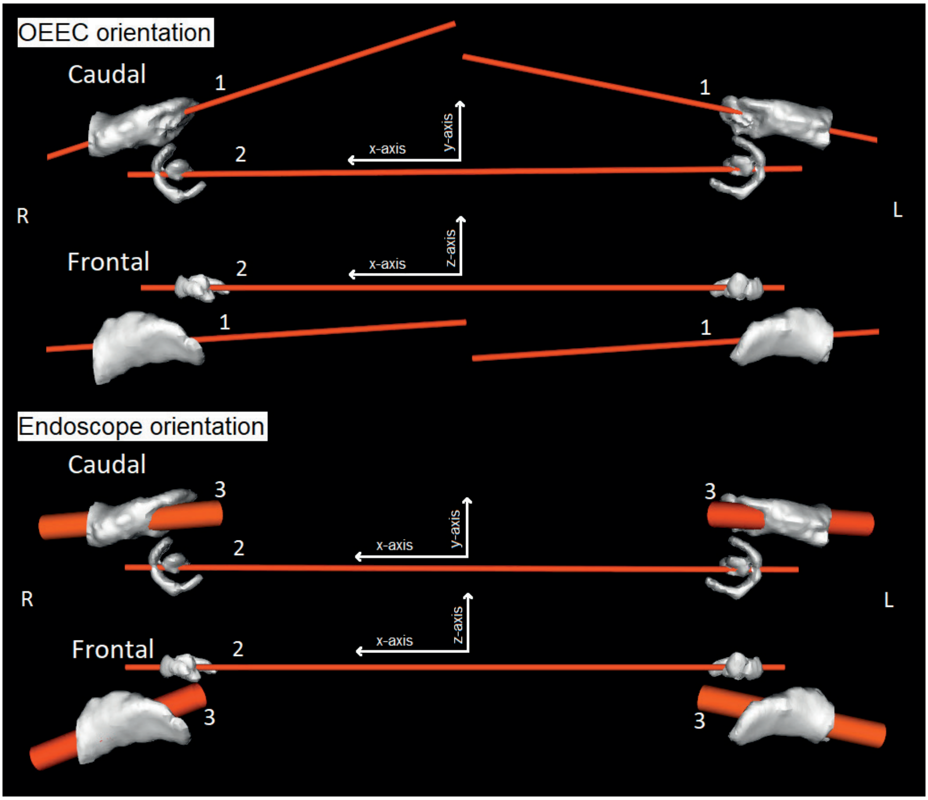


**Figure 1.** Example of segmented polygon mesh models of the osseous external ear canal (OEEC) and horizontal semicircular canals (HSCCs) in caudal and frontal view.

Line 1 represents the OEEC gravitation axis of the polygon mesh. Line 2 is the x-axis of the anatomical coordinate system based on the three axes of inertia of the two HSCC's polygon mesh models. Its y-axis is directed anteriorly and the z-axis cranially. Line 3 represents the endoscope as positioned in the OEEC. The OEEC orientation was quantified as the angle between its gravitation axis (line 1) and the x- and y-axis of the local coordinate system (Canal angle). By enlarging the OEEC line diameter in fig 1 to 4.0 mm it simulates our endoscope (line 3). This enables manual positioning, while respecting the OEEC boundaries (based on volume, diameter and curvature). Its angle to the x- and y-axis of the local coordinate system was quantified (Endoscope angle).

**Axial, coronal and sagittal projection of 3D angles.** To determine the CA and EA in the 2D projection planes, the angle was taken between the projection of lines representing the OEEC and endoscope and:

– the x-axis in the axial plane (xy).
– the x-axis in the coronal plane (xz).
– the y-axis in the sagittal plane (yz).

## Multi-planar reconstruction from standard CT slices

In this section, we describe a method to replace the 3D model by a 2D model to derive axial, coronal and sagittal plane projections of the EA, from standard 2D temporal bone CT slices. Multi-planar reconstructions (MPRs) of the CT scan, showing orthogonal slices in the axial, coronal and sagittal view, were used. In the temporal bone CT scans the head is calibrated in a horizontal position based on both HSCCs. RadiAnt DICOM Viewer, version 2020.2.3 (Medixant, Poznan, Poland) was used. Crosshair lines, interactive vertical and horizontal lines projected in CT slices, are created automatically by the software.

**2D derived axial plane EA.** Measurements were done on the axial CT slice showing the largest OEEC dimensions. In this slice, an axial endoscope line (fig. 2, white line/□) was identified by a line that runs between points halfway on two helplines (fig. 2, red lines/Δ). The first helpline is drawn between the posterior and anterior bony annulus. The second helpline is placed between the bony landmarks identifying the ear canal entrance. The angle in the selected axial plane between the endoscope line and the DICOM viewer crosshair line (x-axis; fig. 2, blue line/○) represents the projection angle that we seek in the axial plane (fig. 2, yellow line/*). This angle can be measured using a standard DICOM drawing tool.

**2D derived coronal plane EA.** Measurements were done on the coronal CT slice visualizing the OEEC with largest dimensions. A coronal endoscope line (fig. 2, white line/□) is created by connecting 2 points on 2 helplines (fig. 2, red lines/Δ). The first point is at 1/3 of the helpline from the scutum to the inferior bony annulus. The second point is found at 2/3 of the helpline between the superior and inferior bony landmarks identifying the ear canal entrance. The angle between the endoscope line and the crosshair line (x-axis; fig. 2, blue line/○) is the projection angle that we seek in the coronal plane (fig. 2, yellow line/*).

**2D derived sagittal plane EA.** The sagittal plane endoscope line (fig. 2, white line/□) was created by connecting two points (fig. 2, red dots/Δ); the OEEC center of the most medial CT slice (fig. 2) with the OEEC center observed in the most lateral CT slice (fig. 2) showing a complete circular bony ear canal. The angle of this line with the horizontal crosshair line (y-axis; fig. 2, blue line/○) represents the intended projection angle (fig. 2, yellow line/*).

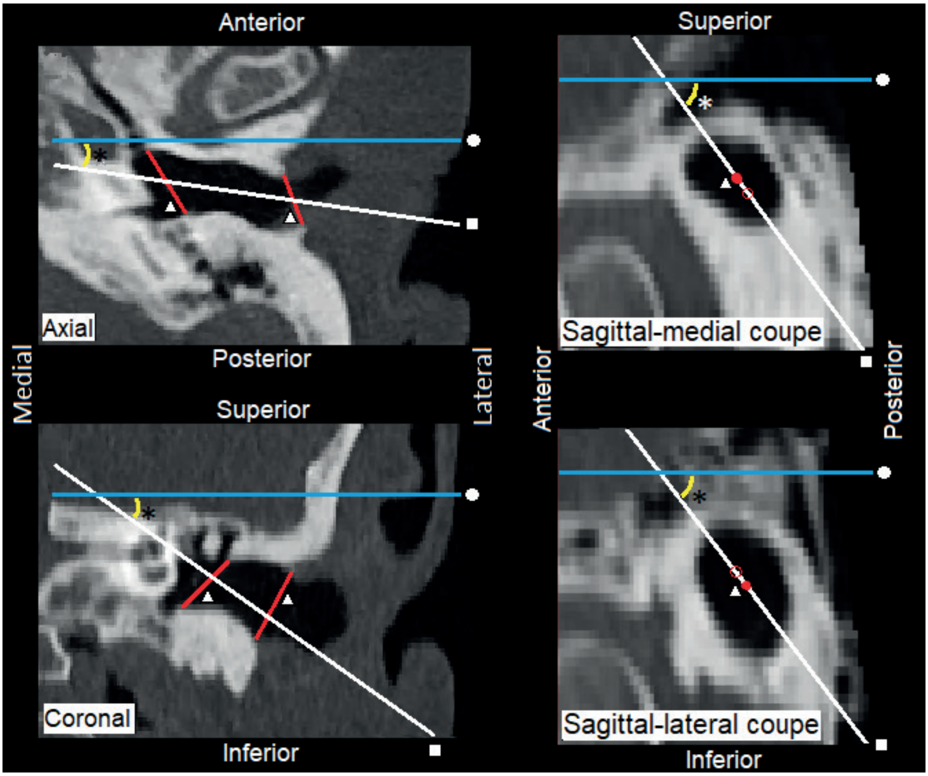


**Figure 2.** Assessment of the endoscope orientation in the osseous external ear canal to view the epitympanum and antrum from a multi-planar reconstruction of a left-ear CT scan.

The white line (□) in the axial and coronal plane represents the endoscope line as drawn by the user based on 2 red helplines (Δ). For evaluation in the sagittal plane the white line is based on the 2 solid red dots (Δ) which represent the ear canal center in a medial and lateral coupe. The red circle in the medial coupe figure represents the ear canal center in the lateral coupe and vice versa. The blue lines (○), the automatically created DICOM viewer crosshair lines, represent corresponding axes of a local coordinate system (x-axis for axial and coronal slices; y-axis for sagittal slices). The projection angles that result from these analyses are measured between the white and blue lines (yellow lines, *).

To evaluate the sensitivity of the above described 2D method, the EAs as measured in the CT slices were compared with the projection angles as found by the 3D evaluation. An intraclass correlation test (absolute agreement) between angles obtained using these two approaches was performed. In addition, the interobserver variation of these two approaches was determined using 3 otorhinolaryngologists.

### Statistical analysis

Statistical analyses were done using SPSS (version 28.0.1.1, SPSS, Chicago, Illinois, USA). The correlation between the OEEC and endoscope orientation and the endoscopic scutum defect volume (ESD) was evaluated by running Spearman's correlation test for CAs and EAs and the ESD. The same was done for the ear canal volume and length.

Z-values for skewness and kurtosis were evaluated to analyze normality of the data (if $-1.96 < z < 1.96$ data were considered normally distributed). Normally distributed data was expressed as mean with its standard deviation. Non-parametric data was expressed by median and 25$^{th}$ ($Q_1$) and 75$^{th}$ ($Q_3$) percentiles. A correlation of 0.2-0.39 was considered weak, 0.4-0.59 moderate, 0.6-0.79 strong and >0.8 very strong. A p-value less than 0.05 was regarded as statistically significant.

### Ethics

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. Approval from the institutional review board was not necessary.

## Results

### OEEC geometry and endoscope orientation obtained from 3D analyses

The 3D derived CAs and EAs, and the OEEC dimensions (volume, length) were normally distributed. The endoscopic scutum defect volume (ESD), was not normally distributed, and correlations were therefore determined using Spearman's test.

**ESD in relation to OEEC orientation.** The mean 3D CA in relation to the x-axis was 22.2 ± 6.6°. The 3D CA projection in the axial, coronal and sagittal planes was 16.2 ± 5.3°, 11.5 ± 12.0° and 36.4 ± 23.4°, respectively (table 1). The median ESD was 6.80 mm$^3$ ($Q_1$ = 5.70 and $Q_3$ = 9.60 mm$^3$). The correlation between ESD and CA in the coronal plane was moderate; $r = -0.477$ ($p = 0.020$). Correlations between the ESD and CA as observed in 3D and in the axial and sagittal plane were weak and not statistically significant ($r < 0.4$, $p > 0.05$) (fig. 3).

**ESD in relation to endoscope orientation.** The mean 3D EA in relation to the x-axis was 22.7 ± 8.8°. The 3D EA projection in the axial, coronal and sagittal planes was 9.0 ± 5.2°, 18.4 ± 12.8° and 57.6 ± 24.2°, respectively (table 1). Correlations between

ESD and EA as observed in 3D and the coronal plane were moderate; r = -0.448, p = 0.027 and r = -0.455, p = 0.025, respectively. The correlation with the sagittal plane EA was weak (r = -0.396, p = 0.047) (fig. 3). No statistically significant correlation was found between ESD and the axial plane EA.

**ESD in relation to OEEC dimensions.** The OEEC length was 11.0 ± 0.9 mm, showing little variation (table 1). The OEEC volume was 543.4 ± 110.0 mm³. No significant correlation was observed between ESD and OEEC length (r = 0.187, p = 0.221), nor between ESD and OEEC volume (r = -0.183, p = 0.227).

**Table 1.** Mean Canal angle, Endoscope angle and ear canal dimensions with their correlation with Endoscopic scutum defect volume.
Statistically significant correlations are marked with an asterisk ($p < 0.05$).

| | Observed in | Mean and SD | Correlation with ESD | p-value |
|---|---|---|---|---|
| **Canal angle (CA)** | 3D | 22.2 ± 6.6° | -0.317 | 0.093 |
| | Axial | 16.2 ± 5.3° | 0.037 | 0.440 |
| | Coronal | 11.5 ± 12.0° | -0.477 | 0.020* |
| | Sagittal | 36.4 ± 23.4° | -0.380 | 0.054 |
| **Endoscope angle (EA)** | 3D | 22.7 ± 8.8° | -0.448 | 0.027* |
| | Axial | 9.0 ± 5.2° | 0.161 | 0.256 |
| | Coronal | 18.4 ± 12.8° | -0.455 | 0.025* |
| | Sagittal | 57.6 ± 24.2° | -0.396 | 0.047* |
| **OEEC dimensions** | Length | 11.0 ± 0.9 mm | 0.187 | 0.221 |
| | Volume | 543.4 ± 110.0 mm³ | -0.183 | 0.227 |

ESD = Endoscopic scutum defect volume
OEEC = Osseous external ear canal
SD = standard deviation

The CA is the angle of orientation of the osseous external ear canal (OEEC) in the axial and coronal plane in relation to the x-axis, a line through both horizontal semicircular canals (HSCCs). In the sagittal plane, it is the angle between the OEEC orientation and the y-axis, an anteriorly directed line perpendicular to the x-axis. The EA is the angle of endoscope orientation in the OEEC in relation to the x- and y-axis, as mentioned above. Correlations were analyzed by Spearman's test. Statistically significant results are marked with an asterisk. The correlation between ESD and CA was moderate in the coronal plane. Moderate correlations with ESD were found for the 3D and coronal plane EA. In the sagittal plane the correlation was statistically significant but weak.

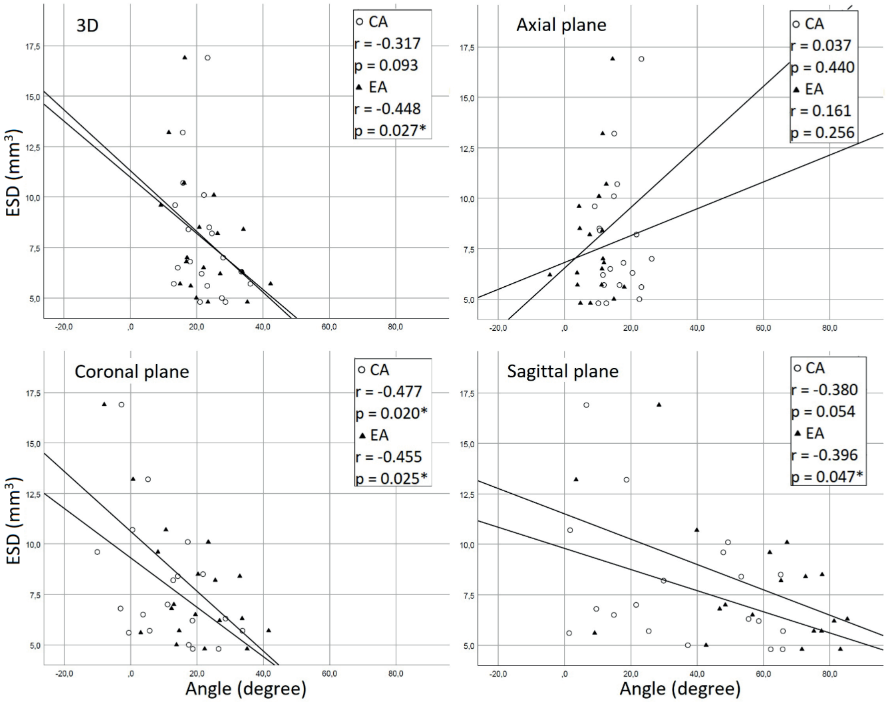


**Figure 3.** Scatterplots showing the relation of the Endoscopic scutum defect volume (ESD) with the Canal angle (CA) and Endoscope angle (EA) in 3D and all projection planes.

CA = Canal angle
EA = Endoscope angle
ESD = Endoscopic scutum defect volume

## Endoscope orientation obtained from standard MPRs of CT slices

The EAs derived with the 2D model from standard MPR slices of a temporal bone CT scan, measured in the axial, coronal and sagittal plane, were normally distributed. The intraclass correlation between these angles and the axial, coronal and sagittal projection of the 3D EA were very strong (absolute agreement; r = 0.802, p = 0.001; r = 0.859, p < 0.001; r = 0.810, p < 0.001, respectively), as shown in figure 4. Little variation between the 2D derived EAs of the 3 observers was found (intraclass correlation test, absolute agreement; r = 0.959, r = 0.908 and r = 0.978; for all p < 0.001).

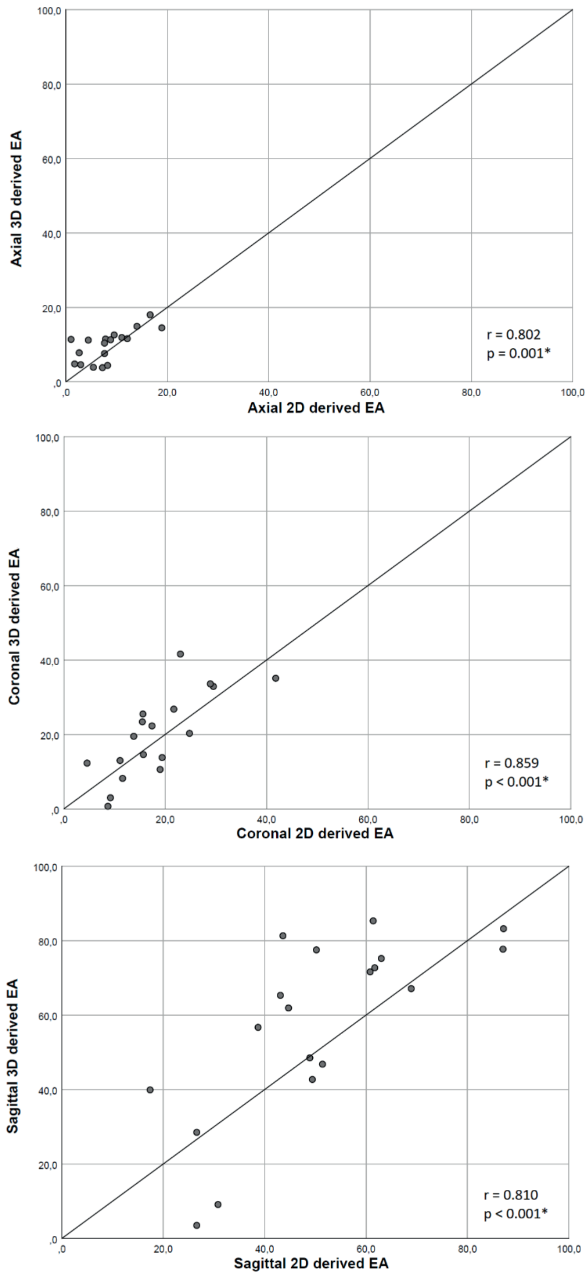


**Figure 4.** Scatterplot of the 3D and 2D derived Endoscope angles in the axial, coronal and sagittal plane. A large and statistically significant correlation was found between the 3D and 2D derived EAs for the axial, coronal and sagittal planes (intraclass correlation test, absolute agreement). Significant p-values are marked with an asterisk.

EA = Endoscope angle

# Discussion

This study is the second to evaluate the role of the external ear canal in TEES. It is the first to study the ear canal's geometry and correlate this to the volume of iatrogenic scutum defects. The complexity and variation of the ear canal anatomy poses a challenge to grasp its effect on visualization and accessibility of the epitympanum and antrum[22]. In this study we used custom made software to evaluate the osseous external ear canal (OEEC) geometry. Our assessment of OEEC dimensions correspond with earlier findings. These findings show that the total ear canal volume is approximately 1.0 $cm^3$, of which half to two-thirds is comprised by the bony ear canal[16–18,20]. Our method however, does not take into account the cartilaginous part of the ear canal. The cartilaginous part of the ear canal is made of soft tissue and cannot be evaluated by our software. Yet, one should question the impact this has on the found Endoscopic scutum defect volume (ESD); the cartilaginous part of the external ear canal is flexible and one can alter its shape by moving and positioning the endoscope during surgery. Therefore, we expect this is to be a minor restrictive factor in endoscope positioning compared to restrictions due to the osseous geometry. We believe it has limited effect on the found ESD. A 4.0 mm endoscope was used to visualize the epitympanum and antrum. In time, the use of a 3.0 mm endoscope became more mainstream. A 3.0 mm endoscope improves movability and might result in smaller ESDs. Also the use of angled scopes might influence the size of the ESD. Yet, this is less relevant for the results of this study as the aim was to correlate the ESD with the ear canal geometry and not to describe absolute ESDs. Despite the minor limitations, we are convinced that our method is an adequate representation of reality and allows us to draw solid conclusions.

**OEEC orientation (CA) and endoscope orientation (EA).** Results show that on average the ESD is smaller when the OEEC is orientated cranially. The same is true for the endoscope orientation, as this depends on the OEEC orientation, dimensions and curvature. Thus, when the endoscope can be positioned steeper in the cranial direction, a larger part of the scutum can be preserved. This corresponds to what one would expect as the antrum and epitympanum are situated superiorly from the OEEC. In practice this might be useful in planning surgery for cholesteatoma which extend posteriorly. These types of cholesteatomas are most difficult to access with TEES[23], particularly when one is eager to preserve as much scutum as possible. In those cases one has to counterweigh the use of a retroauricular transmastoid approach.

**OEEC dimensions.** No significant correlations were found between length and volume of the OEEC and ESD. OEEC length varied little and volume is therefore mainly determined by the OEEC diameter. Ito et al. found that the diameter is the most important parameter in evaluating the difficulty for transmeatal endoscopic ear surgery. This finding is based on measurements of the OEEC diameter on sagittal CT slices with a limited set of parameters studied[15]. Their study did not take into account the orientation, length and curvature of the auditory canal. Our study supports their findings that the OEEC geometry plays a role in TEES suitability, yet it does not confirm the OEEC diameter to be the most important factor per se. In fact, we found that ear canal orientation is more determinative than the diameter, as the ear canal and endoscope orientation show large agreement (table 1).

**Multi-planar reconstruction of CT slices.** In order for our findings to be easily used in clinical practice, we created a 2D model to determine the axial, coronal and sagittal plane projections of the 3D EA, using multi-planar reconstruction (MPR) of the CT scan. This method is easy to perform with regular DICOM viewers. It can be applied on standard temporal bone CT scans, provided that calibration of the head in a horizontal position is based on both HSCCs. Measured angles by this method showed very strong correlation with the 3D derived angles in all projection planes (for all planes, $r > 0.800$ and $p \leq 0.001$). This proves that it is possible to determine the 3D axial, coronal and sagittal plane EA projection from 2D CT slices. As the correlations in the coronal and sagittal plane were strongest, one can best use these for preoperative screening.



**Overall considerations.** The correlations between 3D derived CA/EA and ESD for the whole group were moderate, mainly due to anatomic variation. Our results indicate that the ESD for TEES will likely be smaller when the ear canal and endoscope are orientated in a cranial direction. Our findings could not be accurately used for individual cases. It was therefore not possible to define clear EA cut-off values in relation to expected iatrogenic scutum defects for individual ears. Despite the very strong agreement, the endoscope angles found with the 2D method sometimes differ significantly from results of the 3D model. This adds to the difficulty of using our findings for individual cases. On the other hand, our method using MPR from 2D temporal bone CT slices could give surgeons a general estimate of the expected iatrogenic ESD when performing TEES. It could therefore be useful in estimating the feasibility of totally endoscopic removal of cholesteatoma without excessive scutum destruction. Generally, the transmeatal use of an endoscope contributes to scutum preservation when compared to an endaural microscopic approach[5]. Yet, when a large scutum defect is expected, one should consider using a retroauriculair approach primarily. This approach allows complete antrum and epitympanum overview without the need for scutum resection. Ear canal and endoscope orientation can be a useful parameter to be used to assist in surgical planning for cholesteatoma surgery and patient counselling.

## Conclusion

Osseous external ear canal geometry plays a role in scutum preservation in totally endoscopic ear surgery. A steep upward ear canal and endoscope angle allows preservation of large parts of the scutum for visualization of the epitympanum and antrum. A planning tool using regular 2D temporal bone CT slices for use in clinical practice is described. 2D obtained endoscope angles showed very strong agreement with results from the 3D model.

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# Part 4

## General Discussion

Diseases of the ear, such as a chronic ear infections, are common and can impair one's quality of life (QoL) significantly.[1,2] To remove pathology and to improve hearing, surgery is one of the treatment options. In past decades, the use of an endoscope as a visualization tool has gained popularity worldwide.[3] Despite the increase of knowledge on the use of endoscopes in ear surgery, some issues regarding its clinical applicability remain unraveled. In order to keep improving the quality of otologic care, it is of great importance to evaluate the use of endoscopes in ear surgery. In this thesis, several surgery and patient related issues regarding endoscopic ear surgery are addressed.

## Surgery related issues

In general, adequate visualization of the surgical field is of critical importance in achieving successful treatment.[4,5] For optimal visualization, endoscopes can be a valuable tool, because the endoscope tip is advanced into a body cavity.[6] The wide field of view and viewing angles up to 70°, allow surgeons to gain a wide overview and to 'look around corners'. This is different from visualization by microscope, as a microscope has a straight line of sight and is positioned outside the patient.

In chronic middle ear pathology, the tympanic membrane is often retracted superoposteriorly.[7] Such a retraction pocket can be self-cleaning, yet in case of a cholesteatoma, epithelium stacks up inside the pocket, which can result in inflammation, infection and otorrhea.[8] In complete removal of this pathology, the middle ear, epitympanum and antrum are three of the main areas of interest.[9] To reach these regions, a surgeon can choose a transmeatal, or a transmastoid approach.[10] The less invasive transmeatal approach prevents a retroauricular skin incision and mastoidectomy. However, this approach often necessitates (partial) removal of the scutum (that has not already been destructed by disease) to 'look around the corner' for adequate visualization of the mentioned important areas. There is a downside to having to do this. Literature suggests that the scutum is an important structure in preventing recurrence of retraction pockets.[11,12] Scutum removal can also result in recurrence of cholesteatoma.[13] Therefore, it is advised to preserve the scutum as much as possible and to reconstruct the defect.[11,12,14–20] If the size of the scutum defect has an effect on chances of recurrence, is to be studied. Whether or not the reconstruction method, for example using a cartilage graft instead of epitympanum and mastoid obliteration, might affect recurrences rates, is a topic of debate. In order to facilitate future research, one should gain knowledge on the necessary size of the scutum defect for visualization of the mentioned important areas.

In **chapter 2.1**, the iatrogenic scutum defect volume for transmeatal visualization of the epitympanum and antrum is discussed. It is shown that a complete transmeatal overview of these two areas can be achieved by endoscope with less scutum removal in comparison to a transmeatal microscopic approach. It seems reasonable to assume that when disease has not extended into the mastoid, the endoscope could be a helpful visualization tool in minimally invasive removal of pathology through the ear canal. This is in line with results from a Japanese study from 2017, who measured the size of scutum reconstruction templates after transmeatal removal of cholesteatoma.[21] In 2022, a 3D volumetric evaluation of the resected scutum in stapes surgery was performed.[22] Comparison of a transmeatal endoscopic vs. microscopic approach showed significantly less scutum removal in the endoscopic group. Coulson's group found better transmeatal overview of the tympanic membrane by endoscope in comparison to the microscope.[23] Despite the area of interest differing from our work, these studies strengthen our finding that a transmeatal endoscopic approach allows better visualization 'around a corner'.

Next to maximizing scutum preservation, the reconstruction of the scutum defect is of importance. Previous studies have shown that scutum reconstruction positively influences recurrence rates, when compared to cases without scutum reconstruction.[11,12,14–20] Whether the scutum defect size and the extent of reconstruction affects risk of disease recurrence has not been proven by scientific evidence. Alternatively to Totally Endoscopic Ear Surgery (TEES), one could opt for a transmeatal microscopic approach and therefore accept the need for a larger scutum defect and reconstruction. One could argue that reconstruction of a large defect might result in a less robust reconstruction in comparison to a small defect. But, at present, it is impossible to define a scutum defect size cut-off value to help choose the most appropriate surgical approach.

Another surgical option to maximize scutum preservation is a transmastoid approach, requiring a retroauricular skin incision and canal wall up mastoidectomy, but leaving the scutum largely untouched. All three aforementioned approaches (TEES, microscopic transmeatal or retroauricular transmastoid) can all result in adequate visualization and removal of disease from the areas of interest and differ mainly in tissue invasiveness to achieve this.

In recent years, it has been shown that obliteration of the mastoid cavity and epitympanum reduces the risk of cholesteatoma recurrence.[13] Currently, obliteration is mainly performed through a transmastoid approach. However, transmeatal endoscopic obliteration of the epitympanum and antrum with cartilage graft scutum reconstruction has also been described. This technique combines the advantages of obliteration with minimal scutum removal and reconstruction.[24] At this moment, results in large patient groups with sufficient follow-up of the TEES technique are lacking. Whether the transmeatal endoscopic obliteration technique will be successful and used as widespread as the transmastoid approach, remains to be seen and will mainly depend on its outcome.

In contrast to the abovementioned uncertainties of the endoscope's benefit in chronic ear pathology, literature is quite clear on its advantages in myringoplasty. A retroauricular skin incision with or without a canalplasty is no longer necessary for complete transmeatal visualization and closure of the majority of tympanic membrane perforations.[25–30] Closure rates and audiological outcomes are similar to microscope-assisted myringoplasty.[31] In **chapter 2.2**, the audiological results of totally endoscopic total ossiculoplasty are presented, a topic on which only limited evidence is available in literature. The outcomes in our study are comparable to results of microscope-assisted total ossiculoplasty. Also bone conduction deterioration rates were equally low in both groups. Therefore, TEES seems to be safe and suitable for total ossiculoplasty. This conclusion is strengthened by other studies that reached similar results.[32–35]

Despite depth perception and one-handed surgery not being our primary research goal in chapter 2.2, ossiculoplasty results might indirectly provide us insight on these issues. In performing total ossiculoplasty, one needs to position the prosthesis gently on the stapes footplate. In doing so, one requires an adequate sense of depth. As endoscope- and microscope-assisted surgery resulted in equal audiological results with a comparable complication rate, the use of an endoscope does not seem to have a negative effect. Moreover, otologists who use the endoscope do not experience the 2D image as a large drawback because repeated and continuous movement of the endoscope gives information regarding depth.[36] 3D endoscopes could be an alternative to improve depth perception during TEES in the future.[37] In paranasal sinus surgery, which can be seen as a leading field, 3D endoscopes improve depth perception but result in lower overall picture quality.[38] At present, 3D endoscopes have not been widely adopted in this field.[39]

Even experienced otologists in microscopic ear surgery need to undergo a learning curve before mastering a totally one-handed procedure.[40] In practice, this means that when an otologist decides to start with TEES, one should expect a 'training period' before achieving the results and time efficiency one is used to in microscopic ear surgery. An endoscope holder has been described as possible solution by an Indian group.[41]

This tool fixates the endoscope outside the patient's body, pointing the tip inside the ear canal or middle ear.[42] In this setting, the surgeon has both hands available for tissue manipulation and suctioning. A disadvantage could be the risk for middle and inner ear damage in case of unexpected patient movement during surgery, as the endoscope is fixed to an external system rather than the patient's head. Also, one should be critical on the potential effect on rising of middle and inner ear temperatures when an endoscope is in a fixated position. In one-handed TEES, the surgeon continuously moves the endoscope in and out of the ear canal, allowing temperatures to drop. When using a self-retaining system, it seems wise to frequently suction and apply water.

In TEES, an external light source is necessary. LED is used most often as it has proven to be safest with limited temperature rise in the middle ear.[43] LED is a white-light source and solely illuminates the surgical field. As the endoscope's light source is an external device, alternative lighting modalities can be used in TEES. In **chapter 2.3**, the use of Narrow Band Imaging (NBI, Olympus®, Tokyo, Japan) in visualization of epithelium borders in cholesteatoma surgery is investigated. That study did not find significant differences in epithelium border identification with the NBI modality compared to white light. Yet, a subjective assessment showed that the majority of contributing otologists thought NBI to be useful in the identification of epithelium. The subjective advantage of NBI could also be interpreted as false security for otologists in pursuing correct epithelium identification. Whether NBI could play a role in other otologic pathologies seems doubtful.

In addition to an alternative light source, digital image enhancement can be used during surgery. Storz® (Tuttlingen, Germany) offers systems in which white light is used and the image is digitally altered (Storz Professional Image Enhancement System (SPIES) and IMAGE1). This gives enhancement of contrast and oppression of red colors. The effect of IMAGE1 digital image enhancement on cholesteatoma identification was evaluated.[44] In 11% of cases the digitally enhanced images revealed residual cholesteatoma (histologically confirmed) which was not detected with white light alone. Unfortunately, histological evaluation of visually unsuspected tissues was not performed, meaning that it is impossible to tell what rate of cholesteatoma remains undetected. Also no difference was found in the differentiation between cholesteatoma and granulation tissue with white light only compared to SPIES digitally enhanced white light images.[45] For both NBI and digital image enhancement, blood negatively affects the image quality as it deprives view of underlying tissues. Therefore, extra attention should be paid to minimize the amount of blood in the surgical field. While the advantages of these systems in otology are being studied, their costs may pose an issue. Yet, both NBI and digital image enhancement already have proven benefits in benign and malignant laryngeal pathology. Both systems can therefore be used in several subdisciplines and already be worth the investment.

## Patient related issues

To reach the middle ear, otologists can choose from different surgical approaches. The least invasive of approaches is the transmeatal approach, requiring only a Rosen incision.[10] Alternatively, an incision in the external ear canal to widen the entrance to the ear canal (Lempert incision) is often performed.[10] The most invasive approach requires a retroauricular skin incision with the creation of a periosteal flap after which the auricle is flipped anteriorly.[10] This allows a wide access to the mastoid plane and bony ear canal.[10]

In TEES, only a Rosen incision is needed, therefore being less invasive in comparison to the endaural and retroauricular approach. Whether the surgical approach has an effect on postoperative pain perception, has been described in **chapter 3.1**. This prospective evaluation by Patient Reported Outcome Measures (PROMs) showed that no significant difference was found between all three approaches on ten time points in the first three weeks after surgery. Moreover, pain was low in all groups, with the worst measured pain not exceeding a score of 4/10. One can therefore state that ear surgery in general is not considered very painful. As one may expect, this study showed that a retroauricular skin incision affects sleep in general and sleeping on the operated side significantly. Yet, also in this category, scores did not exceed 4/10. Regarding pain medication usage, significantly more paracetamol and NSAIDs were used in the transmeatal and retroauricular group. Despite the statistically significant result, the amount of pain medication usage in the whole group was low (average per person; 11 tablets paracetamol 1g, 5 tablets diclofenac 50mg). It is therefore that our results should be interpreted with care; the statistically significant results do not necessarily have to be clinically relevant. A lack of clinical relevance seems to be the case for the small differences on pain medication used and effect on sleep.

More recently, several researchers investigated pain after ear surgery. A 2022 systematic review shows that pain scores found in other studies are similar to the absolute pain scores in our study, generally being low for all surgical approaches.[46] In contrast to our study, some groups identified statistically significant differences. It seems that this is mainly due to the effect of having large patient groups, as absolute pain scores differed little between groups. The clinical relevance of these small differences in pain appears to be limited. One could therefore argue that pain should not be a decisive factor in the choice for a surgical approach in ear surgery.

In our study on postoperative pain, both frequentist and Bayesian statistics were applied. Bayesian statistics allows more precise evaluations of small groups, without losing power.[47] In contrast to frequentist statistics, additionally to differences, Bayesian statistics can determine equality between groups as well. Due to these properties, Bayesian statistics seemed better applicable for data from our study. Yet, as this statistical method is lesser known in medical literature, it was decided to present results apart from those from frequentist statistics. As expected, results from both statistical methods were in line with each other, showing no statistical difference in postoperative pain. Bayesian statistics showed no equality between groups. This means that based on pain scores from our study, neither difference, nor equality was found between groups. Due to mentioned advantages of Bayesian statistics, this statistical method can be considered when one is dealing with small groups and when trying to prove equality between groups. In the past two decades, the use of Bayesian statistics has increased tenfold in scientific literature.[48,49] If this trend continues, it might become a widely accepted and well-known alternative to frequentist statistics.



In addition to postoperative pain, the surgical approach can also affect cosmetics. The cosmetic outcome after ear surgery with a retroauricular skin incision appears to be lower than in patients who underwent TEES.[25,27] Despite the difference being small, this might be an important topic for patients as we live in days and ages in which esthetics are of great importance. This is represented in the increasing incidence of body dysmorphic disorders among the adolescent population.[50] When pathology can be treated with different surgical approaches, the cosmetic effect of a surgical technique should be discussed in preoperative patient counselling.

The option for TEES mainly depends on the type and extensiveness of pathology. In literature about endoscopic ear surgery, it is stated that when pathology extends into the aditus ad antrum, TEES is not advised and a transmastoid approach is indicated.[51] The reason for this is that too much of the bony ear canal has to be removed to reach pathology. In current literature, surgeons mainly focus on the pathology and do not take in account a patient's anatomy.[51] Preferably, otologists tailor the surgical approach to the pathology, but also to the individual anatomical characteristics of the patient. In **chapter 3.2**, cadaveric heads were used to correlate the osseous external ear canal (OEEC) geometrics to the scutum defect made for complete visualization of the antrum and epitympanum. The epitympanum and antrum are situated superoposteriorly from the OEEC. As mentioned in chapter 2.1, it is recommended to remove the scutum as little as possible. Chapter 3.2 also discusses the potential to preoperatively predict on CT scans the necessary iatrogenic scutum defect. Multiple geometric parameters were taken into account and the OEEC angle in the coronal plane was found to be the most important factor. Our results show that an upward sloping OEEC was the most important geometric predictor for maximal scutum preservation. This means that when one's OEEC steeply runs upwardly, only a small scutum defect is necessary for adequate visualization of the epitympanum and antrum.

In a study by the group of Kakehata et al.,[52] the OEEC diameter was identified as the most relevant factor to allow TEES as the OEEC diameter determines the endoscope's maneuverability. In that study the minimal and maximal OEEC diameter from CT scans was measured with 3D radiological software. Yet, in contrast to the statement of the OEEC diameter being the most relevant factor for TEES, all patients in that study were successfully treated by TEES and no conversion to a retroauricular approach was necessary. This was true even for cases with the smallest OEEC diameter (3.4 mm at the narrowest point, 2.7 mm diameter endoscope used). It seems that the diameter is an important predictor for endoscope maneuverability, but not a critical factor for TEES suitability. This conclusion is in line with our results as our study showed that the OEEC diameter had no correlation with the scutum defect size. It appears that the diameter and therefore endoscope maneuverability do not seem to affect the iatrogenic scutum defect size for adequate visualization of the epitympanum and antrum.

In our study, a method was presented for OEEC angle measurement on multiplanar reconstructed 2D CT slices. This model can be used to preoperatively quantify the OEEC angle in the coronal plane on regular CT scans and might give the surgeon some information on the expected scutum defect. Our goal was to create an easy-to-use 2D model and this succeeded largely. Still, the right CT slice has to be selected, multiple lines have to be drawn and the angle has to measured manually. The 2D model had good correlation overall to our 3D measurement. But, on a case-to-case level, variation is present, making it difficult to apply it on individuals. The relatively small sample size of cadaveric heads in our study is a drawback. Also, we struggled to project the complex 3D OEEC structure into 2D. With the development of easily accessible 3D planning tools by radiological software companies, individualized surgical approaches might become an important feature in the future. We hope and expect that our attempt will stimulate others to also explore the possibilities of individualized preoperative planning in TEES.

## Concluding remarks / the contribution of this work

This thesis focused on several patient and surgery related issues in implementation of endoscopes in ear surgery. We showed that a surgical endoscope allows transmeatal visualization of the epitympanum and antrum, while preserving large parts of the scutum. This is especially true in ears with an upwards pointing osseous external ear canal (OEEC). A method was presented that allows measurement of the OEEC angle in standard 2D CT slices. For total ossiculoplasty, we have shown that TEES is a safe technique, with the hearing outcome being comparable to the result of microscope-assisted ossiculoplasty. The use of NBI as external lighting method was tested and did not affect the identification of epithelium on surgical images when compared to white light. Finally, we found that a transmeatal TEES surgical approach did not lead to lower pain scores when compared to endaural or retroauricular approaches, respectively.

Although this thesis has clarified some important issues regarding TEES, many other uncertainties remain unraveled. The role of TEES in cholesteatoma surgery is an important point of discussion. Currently there is a lack of studies with sufficiently large groups and adequate follow-up using diffusion-weighted MRI. This knowledge gap should be addressed in future research. Nevertheless, looking at our findings and current literature, TEES appears to be a safe technique for otologic surgery. Advantages of the endoscope are its wide angled view and visualization 'around the corner', as the tip is advanced inside the ear canal and middle ear. Due to these properties, the endoscope can be a valuable addition to the surgical microscope in achieving one's surgical goals. Surgeons do not need to choose between the endoscope and microscope, as they should be regarded as complementary to one another. Yet, to be able to apply TEES, surgeons have to accept a learning curve before mastering this skill as only one hand is available for tissue manipulation. Endoscope Assisted Microscopic Surgery (EAMS) could offer a useful way of implementation of the endoscope in one's otologic practice. This combines the best of both worlds: two-handed surgery by microscope with optimal visualization by alternate use of the endoscope.

TEES is nowadays used worldwide with differing popularity per region. In the Netherlands, many surgeons have already explored the possibilities of endoscopes in otology. For some this has led to a change in their clinical practice. We expect that this thesis offers more insight on the issues in TEES and will stimulate further research on this topic. Moreover, we hope our work will add to the curiosity of otologists to explore the clinical applications of TEES.

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# Part 5

## Appendices

# English summary

Pathology of the ear, such as chronic inflammation, is common and can have a significant impact on one's quality of life. Symptoms that may arise include hearing loss and purulent discharge. If left untreated, this can lead to serious consequences such as facial nerve dysfunction, destruction of the vestibular organ, or intracranial disease expansion. For these reasons, it is crucial to treat ear pathology adequately.

In addition to the use of medication, surgery is a suitable method to address pathology. The goal is the complete removal of disease, as well as the preservation or restoration of hearing and the prevention of complications. To achieve this, good visualization of the surgical field is essential, generally done using an operating microscope. In recent decades, the use of endoscopes as a visualization tool has been increasingly described.

**Part 1** of this thesis provides a brief historical overview of the rise and development of the operating microscope and endoscope in ear surgery. In this first chapter, the advantages and disadvantages of the clinical use of endoscopes are discussed.

**Part 2** addresses some of the **surgery related** knowledge gaps regarding the use of endoscopes in ear surgery. This part is divided into three chapters.

**Chapter 2.1** compares the extent of scutum resection between a totally endoscopic and microscopic transmeatal approach. Scutum resection involves the removal of bone from the superoposterior part of the medial side of the external auditory canal. This is necessary for transmeatal visualization of the antrum and epitympanum. The extent of scutum resection was investigated using digital 3D volumetry based on CT scans of human cadaveric heads. Preservation of as much scutum as possible is important in chronic ear pathology due to its likely favorable role in preventing recurrence of pathology. In this chapter, it is demonstrated that a totally endoscopic transmeatal approach leads to the preservation of larger portions of the scutum compared to a microscopic transmeatal approach (resection of 6.84 $mm^3$ vs. 18.16 $mm^3$ scutum bone).

In **Chapter 2.2**, the hearing of patients who underwent total ossicular chain reconstruction using a middle ear prosthesis, specifically the Fisch Total Titanium Prosthesis (FTTP), is analyzed. This chapter also includes a comparison between endoscope- versus microscope-assisted cases. No statistically significant difference was found in terms of hearing outcome between endoscope- and microscope-assisted

ossicular chain reconstructions (postoperative air conduction threshold after 3 months: 37.6 dB HL in the endoscopic vs. 44.6 dB HL in the microscopic group). This indicates that the results of ossicular chain reconstruction with FTTP are good and comparable to those described in medical literature. No differences were found in surgical complications. These findings suggest that endoscope-assisted ossicular chain reconstruction is successful and can be safely performed.

**Chapter 2.3** describes the use of Narrow Band Imaging (NBI) in identification of epithelium in cholesteatoma surgery. NBI is a lighting technique used in endoscopy where blue and green light are used to accentuate certain tissue aspects, such as the vascular pattern in mucosa. In this chapter, the hypothesis that NBI can contribute to more accurate identification of epithelium, potentially reducing residual pathology, is tested. This is examined through photos taken during ear surgery with standard white light and NBI. These photos were evaluated by sixteen ENT specialists in the Netherlands. On these photos, the perceived epithelial boundaries by the ENT specialists were digitally marked and later analyzed. On average, NBI did not lead to a different assessment of the epithelial borders compared to standard white light. It seems unlikely that NBI will contribute to reducing the chance of residual cholesteatoma.

**Part 3** investigates two **patient related** knowledge gaps.

**Chapter 3.1** describes the outcomes of a prospective analysis of pain in the first three weeks after ear surgery, based on Patient Reported Outcome Measurements (PROMs). A comparison is made between three surgical approaches: a totally endoscopic transmeatal, a microscopic endaural, and a microscopic retroauricular approach. This involves making a Rosen incision, Lempert incision, and retroauricular incision, respectively. This chapter demonstrates that ear surgery is generally perceived as minimally painful, with average pain scores lower than 4/10 (0 no pain, 10 unbearable pain). No differences in pain were found between the three groups. However, a retroauricular approach has a greater impact on sleep position and overall sleep than the other two approaches. An endaural approach poses a smaller hindrance to performing daily activities than the transmeatal and retroauricular approaches. It should be noted that even for these statistically significant differences, the average scores are lower than 4/10.

**Chapter 3.2** builds on Chapter 2.1, where it was demonstrated that a totally transmeatal endoscopic approach leads to the preservation of more scutum than a transmeatal microscopic approach for visualization of the epitympanum. In

Chapter 3.2, a radiological 3D reconstruction of the osseous external ear canal of twenty human ears is made. The relationship of various geometric parameters to the size of the scutum defect is taken into account. It is revealed that the angle of the osseous external ear canal in the coronal plane has the greatest correlation with the size of the scutum defect: an upward sloping ear canal is associated with a small scutum defect. Additionally, a method is presented that allows determination of the orientation of the ear canal in the coronal, axial, and sagittal planes based on slices from standard CT scans. The geometric results derived from this method show a strong correlation with the outcomes based on the 3D reconstruction.

**Part 4** includes the general discussion and a glimpse into the future regarding the use of endoscopes in ear surgery. The expectation is expressed that endoscopes can be successfully and safely used as a visualization method. The wide field of view and the viewing angle of endoscopes allow good visualization of the eardrum and middle ear when endoscopes are introduced through the ear canal. Because endoscopes must be held with one hand, the surgeon needs to undergo a learning curve to perform the procedure one-handedly.

# Nederlandse samenvatting

Pathologie van het oor komt frequent voor en kan van grote invloed zijn op kwaliteit van leven van de patiënt. Klachten die hierdoor kunnen ontstaan zijn gehoorverlies en purulente uitvloed. Indien oorpathologie niet wordt behandeld, kan dit tot ernstige gevolgen leiden, zoals uitval van de functie van de aangezichtszenuw, destructie van het evenwichtsorgaan of intracraniële uitbreiding van ziekte. Om deze redenen is het van groot belang om oorpathologie adequaat te behandelen.

Naast het gebruik van medicatie, is chirurgie een geschikte methode om pathologie aan te pakken. Het doel hiervan is volledige verwijdering van ziekte en tevens behoud, dan wel herstel, van het gehoor, en het voorkomen van complicaties. Om dit te bereiken is goede visualisatie van het operatiegebied van essentieel belang. Dit wordt over het algemeen gedaan met behulp van een operatiemicroscoop. In de afgelopen decennia is het gebruik van de endoscoop als visualisatie-instrument in toenemende mate beschreven.

**Deel 1** geeft een kort historisch overzicht weer van de opkomst en ontwikkeling van de operatiemicroscoop en endoscoop in de oorchirurgie. In dit eerste hoofdstuk wordt dieper ingegaan op de voor- en nadelige aspecten van het klinisch gebruik van een endoscoop.

**Deel 2** gaat in op bestaande **operatiegerelateerde** kennishiaten omtrent het gebruik van endoscopen in de oorchirurgie. Dit deel is opgedeeld in drie hoofdstukken.

In **hoofdstuk 2.1** wordt de mate van scutumresectie vergeleken tussen een volledig endoscopische en microscopische transmeatale benadering. Scutumresectie is verwijdering van bot van het superoposterieure deel van de mediale rand van de uitwendige gehoorgang. Dit is noodzakelijk voor transmeatale visualisatie van het antrum en epitympanum. Bovenstaande is onderzocht met behulp van digitale 3D-volumetrie op basis van CT-scans van hoofden van menselijke kadavers. Behoud van zoveel mogelijk scutum is van belang bij chronische oorpathologie vanwege de waarschijnlijk gunstige rol in het voorkomen van recidief. In dit hoofdstuk tonen we aan dat een volledig endoscopische transmeatale benadering leidt tot behoud van grotere delen van het scutum dan een microscopische transmeatale benadering (resectie van 6,84 $mm^3$ vs. 18,16 $mm^3$ scutumbot).

In **hoofdstuk 2.2** is het gehoor geanalyseerd van patiënten die een totale ketenreconstructie hebben ondergaan met behulp van een middenoorprothese, in dit geval de Fisch Total Titanium Prothese (FTTP). In dit hoofdstuk wordt tevens een vergelijking gemaakt tussen casus die onder endoscopisch dan wel microscopisch zicht zijn behandeld. Hieruit blijkt dat de resultaten van ketenreconstructie met een FTTP goed en vergelijkbaar zijn met resultaten die worden beschreven in medische literatuur. Er is geen statistisch significant verschil gevonden met betrekking tot gehooruitkomst tussen endoscopisch en microscopisch ondersteunde ketenreconstructies (postoperatieve luchtgeleidingsdrempel na 3 maanden: 37,6 dB HL in de endoscopische vs. 44,6 dB HL in de microscopische groep). Op het gebied van operatieve complicaties worden evenmin verschillen gevonden. Hieruit kan worden geconcludeerd dat endoscopisch ondersteunde ketenreconstructie succesvol is en veilig kan worden uitgevoerd.

**Hoofdstuk 2.3** beschrijft het gebruik van Narrow Band Imaging (NBI) in het herkennen van epitheel bij cholesteatoomchirurgie. NBI is een belichtingstechniek die bij endoscopie kan worden toegepast waarbij blauw en groen licht wordt gebruikt om bepaalde aspecten, zoals het vascularisatiepatroon, in slijmvlies te accentueren. In dit hoofdstuk is de hypothese getoetst dat NBI kan bijdragen aan het meer accuraat identificeren van epitheel, wat zou kunnen leiden tot het verminderen van residuale pathologie. Dit is onderzocht aan de hand van foto's, tijdens ooroperaties genomen met standaard wit licht respectievelijk NBI, die door zestien KNO-artsen in Nederland zijn beoordeeld. Op deze foto's zijn de gepercipieerde epitheelgrenzen door de KNO-artsen digitaal ingetekend en nadien geanalyseerd. Gemiddeld genomen leidt belichting met NBI niet tot een andere inschatting van de epitheelgrens vergeleken met standaard wit licht. Het lijkt er dus niet op dat NBI zal bijdragen aan het verlagen van de kans op residuaal cholesteatoom.

In **deel 3** worden twee **patiëntgerelateerde** kennishiaten onderzocht.

**Hoofdstuk 3.1** beschrijft de uitkomsten van een prospectieve analyse van pijn in de eerste drie weken na een ooroperatie. Dit is gedaan aan de hand van patiëntgerapporteerde uitkomstmaten (Patient Related Outcome Measures, PROMs). Hierbij is een vergelijking gemaakt van drie chirurgische benaderingen van het operatiegebied: een volledig endoscopische transmeatale, een microscopische endaurale en een microscopische retroauriculaire benadering. Hiertoe worden respectievelijk een zogenaamde Rosenincisie, Lempertincisie en retroauriculaire incisie gemaakt. Dit hoofdstuk toont aan dat oorchirurgie over het algemeen als weinig pijnlijk wordt ervaren, waarbij de gemiddelde pijnscores lager dan 4/10 liggen (0 geen pijn, 10 ondraaglijke pijn). Er werden geen verschillen in pijnbeleving gevonden tussen de drie groepen. Wel heeft een retroauriculaire benadering een grotere invloed op de slaaphouding en slaap in het algemeen dan de andere twee benaderingen. Een endaurale benadering vormt een kleinere belemmering voor het uitvoeren van dagelijkse werkzaamheden dan de transmeatale en retroauriculaire benadering. Hierbij dient de kanttekening geplaatst te worden dat ook voor deze statistisch significante verschillen de gemiddelde scores lager liggen dan 4/10.

**Hoofdstuk 3.2** borduurt voort op hoofdstuk 2.1, waarin werd aangetoond dat een volledig transmeatale endoscopische benadering leidt tot behoud van meer scutum dan wanneer men een microscoop gebruikt voor visualisatie van het epitympanum. In hoofdstuk 3.2 is een radiologische 3D-reconstructie gemaakt van de benige gehoorgang van twintig menselijke oren. De relatie van verschillende geometrische parameters ten opzichte van de grootte van het scutumdefect zijn hierbij in ogenschouw genomen. Hieruit komt naar voren dat de hoek van de benige gehoorgang in het coronale vlak de grootste correlatie heeft met de grootte van het scutumdefect: een opwaarts georiënteerde gehoorgang hangt samen met een klein scutumdefect. Tevens is in dit hoofdstuk een methode gepresenteerd waarmee op basis van coupes van standaard CT-scans de oriëntatie van de benige gehoorgang in het coronale, axiale en sagittale vlak kan worden bepaald. De geometrische resultaten die voortkomen uit deze methode hebben een sterke correlatie met de uitkomsten op basis van de 3D reconstructie.

**Deel 4** omvat de algemene discussie en een blik op de toekomst omtrent het gebruik van endoscopen bij ooroperaties. Hierbij wordt de verwachting geuit dat endoscopen als visualisatiemethode succesvol en veilig kunnen worden gebruikt. De groothoeklens en de kijkhoek van endoscopen maken het mogelijk om een goed beeld te creëren van het trommelvlies en middenoor wanneer endoscopen via de gehoorgang worden opgevoerd. Omdat endoscopen met één hand moeten worden gepositioneerd, dient de chirurg wel een leercurve door te maken om de ingreep eenhandig uit te voeren.

# Portfolio

PhD student: AHA Baazil
PhD period: 2016 - 2023
PhD supervisor: Prof. Dr. F. G. Dikkers
PhD co-supervisor: Dr. M. J. F. de Wolf

| **Courses** | **Year** | **ECTS** |
|---|---|---|
| Teach the teacher, AMC, Amsterdam | 2016 | 0.25 |
| Mini-endoscopie cursus, UMCG, Groningen | 2017 | 0.5 |
| Epidemiologie cursus, LUMC, Leiden | 2017 | 0.5 |
| Coach de Co cursus, AMC, Amsterdam | 2017 | 0.25 |
| Bijscholing financiën in de zorg, Flevoziekenhuis, Almere | 2017 | 0.25 |
| Intervisie voor AIOS, Flevoziekenhuis, Almere | 2017 | 0.25 |
| Mini-FESS cursus, AMC, Amsterdam | 2018 | 0.5 |
| Omgaan met culturele verschillen in de spreekkamer, OLVG, Amsterdam | 2018 | 0.25 |
| 53rd Nijmegen Ear Surgery Course | 2018 | 2.0 |
| KNO-Radiologie cursus, ZMC, Zaandam | 2019 | 0.5 |
| Bony Obliteration Course, European Institute for ORL, Antwerp, Belgium | 2019 | 0.5 |
| Mondpathologie cursus, VUMC, Amsterdam | 2020 | 0.25 |
| Disciplineoverstijgend onderwijs | 2016-2020 | 2.0 |
| 24e Kliniek van duizeligheid en evenwichtsstoornissen MUMC+, Maastricht | 2020 | 0.5 |
| eBROK ('Basiscursus Regelgeving Klinisch Onderzoek') | 2020 | 1.5 |
| Teach the teacher: effectief gebruik KPB, Amphia, Breda | 2023 | 0.25 |
| Training werkbegeleiding basis, Amphia, Breda | 2023 | 0.25 |
| Training medisch leiderschap, samenwerken in de zorg, financiën in de zorg, 'young talent class 2023' Amphia, Breda | 2023 | 0.5 |
| Symposium duizeligheid 2024, Gelre ziekenhuizen, Apeldoorn | 2024 | 0.25 |

| | | |
|---|---|---|
| **Presentations** | | |
| Presentatie *'Pain after ear surgery; a prospective evaluation of endoscopic and microscopic approaches'*, vergadering KNO-vereniging, Nieuwegein, Nederland | 2019 | 0.5 |
| Presentation *'Pain after ear surgery; a prospective evaluation of endoscopic and microscopic approaches'*, Spring meeting, Belgian ORL society, Brussels, Belgium | 2019 | 0.5 |
| Casus presentatie 'Vibrant Soundbridge in subtotale petrosectomie', refereeravond AMC, Amsterdam | 2019 | 0.5 |
| Presentatie *'A volumetric three-dimensional evaluation of invasiveness of an endoscopic and microscopic approach for transmeatal visualization of the middle ear'*, vergadering KNO-vereniging, Nieuwegein, Nederland | 2020 | 0.5 |
| Presentatie *'Comparison of long-term microscopic and endoscopic audiologic results after total ossicular replacement prosthesis surgery'*, vergadering KNO-vereniging, Nieuwegein, Nederland | 2022 | 0.5 |
| Presentatie auto-immuun oorziekten, refereeravond interne geneeskunde, Amphia, Breda | 2023 | 0.5 |
| Presentatie rol gehoorverlies in dementie, refereeravond geriatrie, Amphia, Breda | 2023 | 0.5 |
| Presentatie gehoorverlies en cognitie, nascholing huisartsen regio Breda, Amphia, Breda | 2024 | 0.5 |
| Presentatie duizeligheid, patiëntenavond Stichting Hoormij, Amphia, Breda | 2024 | 0.5 |
| **(Inter)national conferences** | | |
| Spring meeting, Belgian ORL society, Brussels, Belgium | 2019 | 0.5 |
| Digital meeting European Academy of Otology & Neuro-Otology | 2021 | 1.0 |
| Wetenschappelijke vergadering KNO-vereniging, Nieuwegein, Nederland | 2016-2023 | 6.0 |
| **Supervising/Teaching** | | |
| Teaching on the risks of noise on hearing at junior school, Basisschool de Leydraad, Cromvoirt | 2016 | 0.25 |
| Teaching clinical officers on ear diseases, stichting Eardrop, Mumias, Kenya | 2019 | 1.0 |
| Temporal bone dissection course for Belgian ORL residents, European Institute for ORL, Antwerp, Belgium | 2022 | 0.5 |
| Supervisor R. Verkaik case report *'Conductief gehoorverlies door hamerkop ankylose'*, Amphia, Breda | 2023 | 0.5 |
| **Awards and Prizes** | | |
| First place Dutch temporal bone dissection prize | 2016 | |
| Second place Dutch temporal bone dissection prize | 2019 | |

| **Publications** |
|---|
| Baazil AHA, Dalemans A, De Smet L, Degreef I. Comparison of surgical treatment of mucous cysts of the distal interphalangeal joint. Acta Orthop Belg. 2015; 81(2):213-7 |
| Baazil AHA, Roosendaal SD, Vleming M. Casus traumatische hamersteelfractuur. Ned Tijdschr KNOHeelkd. 2018; 24(2):50-3 |
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# About the author

Adrianus Hayk Aziz Baazil was born on September 1st, 1989, in Cromvoirt, the Netherlands. In 2007 he graduated from Gymnasium Beekvliet Sint-Michielsgestel. After a gap year studying economics, he started medical school at the Catholic University of Leuven, Belgium. In 2015 Hayk graduated from medical school and the same year he started his Otorhinolaryngology residency training at the Acadamic Medical Centre – University of Amsterdam (AMC – UvA) (Prof. Dr. F. G. Dikkers). During this period he started his research projects on totally endoscopic ear surgery, supervised by Dr. M.J.F. de Wolf. In 2020 Hayk successfully completed his residency training. Before starting a one-year fellowship neurotology at the European Institute of Otorhinolaryngology, Antwerp, Belgium (Prof. Dr. Offeciers), he was offered the chance to stay at the department of Otorhinolaryngology at the AMC – UvA as research fellow. For the duration of five months he was able to focus fulltime on his research projects, made possible by a generous gift by the Heinsius Houbolt Foundation. From April 2022 Hayk started as an Otorhinolaryngologist at the Amphia hospital in Breda. He lives in Ulvenhout with his wife Lianne and two sons, Boris and Alec. In his free time Hayk enjoys playing tennis, going for a hike and cooking.