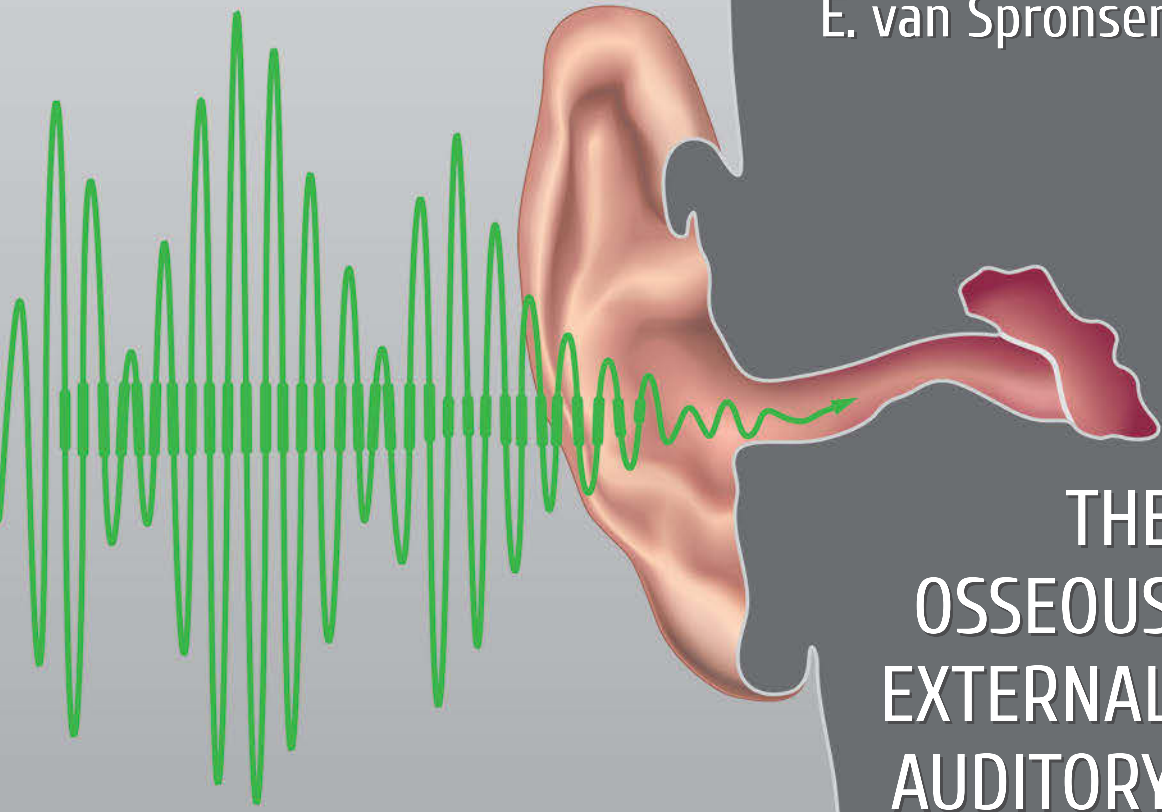
E. van Spronsen



THE OSSEOUS EXTERNAL AUDITORY CANAL:
Surgery, Shape & Sound

THE OSSEOUS EXTERNAL AUDITORY CANAL: SURGERY, SHAPE, AND SOUND

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I CAN'T CHANGE THE DIRECTION OF THE WIND, BUT I CAN ADJUST MY SAILS TO ALWAYS REACH MY DESTINATION

Jimmy Dean

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ABBREVIATIONS

ABG: air bone gap
ACPTR: anterior curvature of the pretympanic recess
AMCF: acquired medial canal fibrosis
(A)OE: (Acute) otitis externa
CI: cochlear implant
(C)OE: (chronic) otitis externa
CT: computed tomography
DPTR: depth of the pretympanic recess
ENT: ear nose throat
EPOS: European position paper on sinusitis and nasal polyps
(O)EAC: (osseous) external auditory canal
(P)OE: persistent otitis externa
HU: Housefield units
ORN: Osteoradionecrosis
PTA: pure tone audiometry
PTR: pre-tympanic recess
QoL: Quality of Life
REUG: real ear unaided gain
REUR: real ear unaided response
SNHL: sensorineural hearing loss
TMP: tympanic membrane perforation
TMJ: temporomandibular joint
VAS: visual analogue scale

General introduction and outline of thesis

1

INTRODUCTION

The external auditory canal (EAC) and its diseases have received relatively little attention when regarding the amount of research done within the field of otology. Still, acquired ear canal pathology affects the patient in many ways. Common symptoms include otalgia, discharge, itch and hearing loss. These symptoms can substantially impair daily functioning and therefore resolving them will greatly improve the quality of life.

Overview of surgical techniques addressing the external ear canal and its acquired diseases has been done thoroughly and complete but no outcome measures are given to compare the advocated techniques (1). A remarkable variety of surgical approach/techniques, with seemingly contradictory rationales, exists. Currently personal preference seems to prevail in which technique is used. Therefore evidence regarding the rationale of each used technique is needed in order to define the most effective and safe technique. Surgery will inevitably alter the shape of the canal and its acoustic properties. Unfortunately the effects of these changes, both beneficial and detrimental, are largely unknown.

NORMAL ANATOMY AND (PATHO)PHYSIOLOGY OF THE EAC

The external ear consists of the auricle (pinna) and external auditory canal. The EAC commonly has a length of 2.5 cm (2,3) and its medial ending is defined by the tympanic membrane. In a 'normal' anatomical situation the EAC is comprised of a lateral fibrocartilaginous part and a larger medial osseous part. The EAC is known to have a complex anatomy with a large inter and intra-individual variability (4). Although many shapes are shown in anatomy books varying from almost completely cylindrical (5) to highly curved shapes with several isthmus (6) no uniform shape or classification of shapes have been described. Two isthmus have been described in the axial plane, the first in the cartilaginous part at the meatal introitus and the second located in the osseous part of the EAC where the mandibular joint bulge is present. In the coronal plane usually only one isthmus is defined which is located in the osseous external auditory canal (OEAC) and is the result of the bulging of the inferior part of the tympanic bone (4,6). Many authors describe that the OEAC has an ascending lateral part which is followed by a descending part in this plane [figure 1] (7-13). This rounding is due to the shape of the tympanic part of the temporal bone. The shape results in a recess just lateral of the tympanic membrane which has been given several different names. We refer to this region as the pre-tympanic recess (PTR) (14). Other names given are pretympanic sulcus (7-9), tympanic sulcus (10), pretympanic sinus (11,12) and inferior tympanic recess(13). The PTR can be formed in such a manner that direct otoscopic examination of this region is limited and clinical cleaning of this area is hampered.

The epithelial lining of the EAC has unique characteristics [figure 1]. The skin of the cartilaginous part consists of sebaceous and apocrine glands and hair (15,16). These glands produce ear wax covering the lateral part of the EAC and forming a protective lipid layer with a pH of 6.1(17). It protects the EAC against micro-organisms (18-20). The skin of the OEAC lacks subcutaneous tissue and adheres directly to the periost of the external auditory canal.

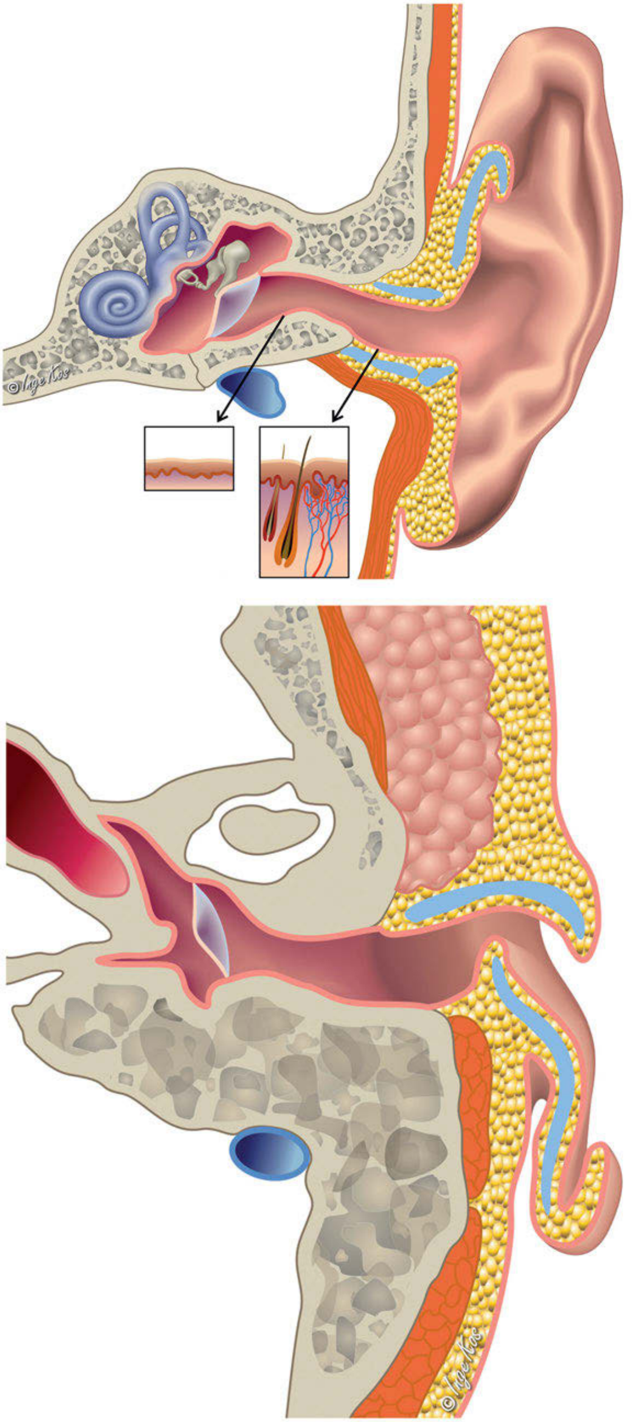

Figure 1. Anatomy of the external auditory canal in coronal and axial plane

These two factors make the skin of the bony external auditory canal extremely vulnerable and hard to replace. No ear wax is produced in this part and it is self-cleansing by lateral epithelial migration towards the external environment (21). The features of the epithelial lining mentioned above enable the external auditory canal to fight water-borne pathogens (thus reducing the risk of infection) and to prevent accumulation of debris. In acquired pathology of the EAC these functions are affected and a disbalance in the natural homeostasis will be the result (17,22).

THE ROLE OF THE EAC

The function of the EAC is to enable the transfer of sound from the concha to the tympanic membrane and to act as a resonant tube (23). The frequencies that are influenced by this resonance function are those who are important in speech perception. Another possible function of the EAC is the protection of the delicate middle and inner ear structures from the external environment (water resistance, trauma) by enabling the inner ear to be located deeper in the temporal bone (24). Furthermore the aforementioned ear wax production has protective abilities against infections and needs an anatomical location before the ear drum.

The EAC also plays a role in the diagnosis and treatment of middle ear pathology. It allows otoscopic evaluation of the tympanic membrane and can offer a window in the surgical approach of the middle ear.

EAC ACOUSTICS AND ITS RELEVANCE

It is known that sound exceeding 200 Hz undergo pressure transformation between the free field and the ear drum (25). This change can be attributed to several factors like the scattering due to the head, the pinna and the resonant effects of the concha bowl and external ear canal (24). Sound transmission in the human ear canal can be regarded as a rigid cylindrical pipe with one open ending and one closed. This meaning the ear drum and middle ear structures can be modelled as a hard-wall termination (26). However, evidence suggests this model to disregard the visco-thermal losses of the ear canal skin and middle ear condition which were seen to affect the ear canal acoustics as well (27). Several manuscripts have reported a change in resonance acoustics when the osseous external auditory canal (OEAC) is modified surgically (28-31). The creation of a wide OEAC (as is the case with a radical cavity) was shown to decrease the resonant frequency substantially and increase the peak amplitude significantly (32). Although these changes have been reported several times in the past, we were not able to find literature concerning the relationships between objective measurements of the resonances and the subjective sound quality of the resulting sound.

POSITION OF SURGERY IN ACQUIRED PATHOLOGY OF THE EAC

In 1950, Work was the first to classify various lesions of the external auditory canal (33). He classified the various conditions of the external auditory canal into three main groups: 1. Lesions arising directly in the external auditory canal 2. Lesions or external mechanical forces that involve the external auditory canal secondarily by extension, encroachment or contact 3. Lesions due to developmental disturbances. Tos pointed out that this classification leads to confusion during the following decades and proposed a new classification (1). In his classification a clear distinction is made between acquired versus congenital aetiology. In this thesis, we focus on acquired disease, excluding congenital atresia or stenosis. In the following paragraphs we will briefly outline acquired EAC diseases/conditions and discuss their definition and treatment. The relevance of surgical intervention will be discussed.

Otitis externa (OE)

Definitions of otitis externa are very difficult to find in the international literature. A definition found in the literature is: Otitis externa is a broad term used to describe an inflammatory condition affecting the ear canal, with or without infection. The inflammation is usually generalized throughout the ear canal and can affect the outer ear (34). The symptoms and signs are easily identifiable. Otalgia, itching, aural fullness with or without conductive hearing loss and jaw pain. Signs of such inflammation are tenderness of the tragus and pinna with or without drainage of the affected ear and oedema or erythema of the ear canal and regional lymphadenitis (35). In clinical guidelines OE is categorized based on the duration and onset of the disease into acute and chronic (35,36,37). In general acute is defined as a duration of less than 3 weeks and chronic as a duration longer than 3 months (35,36,37). In the Dutch guidelines persistent otitis externa (POE) is defined as a OE of more than 3 weeks but less than 3 months (37). Acute otitis externa (AOE) can be secondary to acute otitis media: mucopurulent exudate from the middle ear flowing through an acute tympanic membrane perforation can infect the tissues of the ear canal, creating a secondary otitis externa (35). All clinical guidelines and reviews exclude secondary otitis externa (i.e. being the result of middle ear pathology (cholesteatoma), tympanic membrane perforation, benign and malignant tumors of the external ear canal and radiation induced osteoradionecrosis (ORN)) and the more aggressive necrotizing (malignant) otitis externa (35,36,37).

Moreover, in the literature a distinction is made between diffuse and local forms of AOE (38). Diffuse AOE is a common disease, with a reported incidence in the Dutch population of 12,5 per 1000 patient years and with a slight increase with age (39). Common pathogens of diffuse AOE are *Pseudomonas aeruginosa* and *Staphylococcus aureus* but many others have been identified (40,41). Treatment of AOE is conservative (adequate cleaning of the ear canal and topical treatment) and no surgical intervention is indicated (42,43). Eighty percent of patients with AOE has a reported clinical resolution within 3 weeks when treated adequately (38).

Although literature concerning the development of COE is inconclusive in general it is postulated that COE develops from AOE. Many etiological factors have been identified/suggested promoting chronicity in OE. Increased humidity, excessive sweating in warmer climate, water quality and exposure when swimming, alkaline soap usage, trauma from self-cleaning, occlusion due to hearing aid wearing, allergy, stress, genetic predisposition, debris accumulation, dermatological disease and anatomical shape of the ear canal all have been suggested to play a role in COE (22,44-49). In chronic and recurrent otitis externa swelling and hypertrophy of the skin of the ear canal are persisting and topical treatment becomes ineffective. In these cases surgical management is indicated (37). Many observational studies have shown that surgery leads to high success rates in these cases (50-54). It has been postulated that in COE the skin lining has been subject to hypertrophy and swelling making topical treatment ineffective (1). The principle of surgery therefore is to create a wide and patent ear canal (55). In general two different surgical techniques are described in the treatment of COE: the meatoplasty and the canal(o)plasty. These can be stand-alone, staged or combined procedures. A meatoplasty is performed when a narrowing occurs at the lateral part of the outer ear canal or the introitus (56). A canalplasty, with enlarging of the OEAC, is performed when the medial canal is involved (57). The literature is inconclusive regarding what can be seen as a sufficiently wide ear canal and which determinants contribute to a patent ear canal. It has been recommended to regard surgery as a primary choice in COE (37).

One of of the most radical changes that can be iatrogenically inflicted on the OEAC is radical surgery of the mastoid. Open cavity mastoidectomy is a commonly performed operation for chronic otitis media with or without cholesteatoma (58). Cavities result in clinician dependence as the self-cleansing mechanism of the osseous external auditory canal (OEAC) is disrupted (59) and often they become troublesome (60). Although a troublesome cavity is strictly speaking not a disease of the external ear, it can be regarded as an iatrogenic COE as many presenting symptoms are the same. It has a multifactorial etiology comprising a deep mastoid tip, high facial ridge, open tubal orifice, remaining air cell tracts, inadequate meatoplasty and an inadequate canalplasty (61). Revision surgery is indicated in these troublesome cavities addressing all the aforementioned factors, if applicable.

The following paragraphs will discuss diseases and conditions that present themselves with similar symptoms as OE. These conditions are to be excluded before one can state that a genuine COE is present (37).

Necrotizing (malignant) otitis externa

This condition is defined as an OE with severe osteitis and abscess formation combined with a progression toward the skull base (osteomyelitis of the skull base) (62). It has been recognized as a distinct clinical entity of OE. *Pseudomonas aeruginosa* is the bacterial procreator. Other important eatiological factors include immune suppression and raised blood glucose. These characteristics make it often an unresponsive pseudomonal infection of the external ear canal found in elderly diabetic patients. The presenting symptoms are those of an OE but with a more pronouced severe pain (62). The standard of care is not surgical but prolonged use of antibiotics (primarly parental), tight glycemic control and local debridement. Despite this treatment fatalities are still encountered with mortality rates described up to 10% (63). Facial nerve palsy, positive fungul culture, relapse in disease or radiological signs (tegmen, infratemporal fossa or temporomandibular joint erosion) are signs of more severe disease and additional surgery is advised (63). This surgery comprises of a full mastoidectomy, lowering inflammatory load, and never is limited to only a canalplasty (1).

Osteoradionecrosis (ORN)

This disease It is actually a complication following radiation therapy of head and neck malignancies. Defined as is a slowly progressive, aseptic, avascular necrosis of bone tissue (64). The ear canal is more susceptible for ORN as it has an unfavorable vascularization and thin epithelial lining of the bone (65). Due to the avascular necrosis the ear canal is more susceptible to an OE. Therefore patients often present themselves with all symptoms similar to a regular OE (64). If one wants to treat the infection in this condition it is neccesary to define whether a localized or diffuse form is present as was described by Ramsden (66). A treatment algorithm was supplied by our group, indicating that surgery is only advised in diffuse ORN (67). In such cases a canalplasty is combined with reconstruction of the EAC or obliteration of the mastoid cavity. Diseased bone is removed until living bone is reached. In cases of non functional hearing a subtotal petrosectomy is advised with complete removal of the EAC (67).

Exostosis and osteomata

As exostoses and osteomata are sometimes difficult to differentiate in clinical practice we will describe them together. Exostosis are broad based bony elevations located in the external auditory canal. An osteoma is a solitary, pedunculated bony outgrowth, usually occurring along the tympanomastoid suture. Exostosis are regarded as localized hyperplasias or outgrowths of the compact bone which is in contrast to osteomas which are true tumours (1). Regarding the etiology it has been hypothesized that in exostosis a predisposition (intrinsic factor) is present in patients which is 'excited' by mechanical, chemical or thermal factors (extrinsic factors) (68,69). An association is present between frequent watersports (mainly surfing) and the presence of exostosis (47). The etiology of osteomas remains unknown (70).

Both conditions are often asymptomatic and are usually an accidental finding during ENT examination (70). Exostosis almost always present themselves bilaterally, and more or less symmetrical between both ears whereas osteoma are almost always unilateral. Both conditions are painless but due their slow growth can give rise to an obstruction of the canal and subsequently result in conductive hearing loss (due to ear wax accumulation) and recurrent or chronic OE. Osteoma, if large enough, could give rise to a pressure feeling and in rare cases temporal pain by a presumable interference with the temporomandibular nerve (71). The accumulation of debris could lead to bony erosion mimicking an external ear canal cholesteatoma (68).

If asymptomatic no treatment is necessary . If symptomatic due to obstruction regular cleaning by a professional is often satisfactory (72). If (recurrent) OE is present conservative treatment often fails and these conditions should be addressed surgically (1). Many observational studies have been conducted in which both conditions are 'pooled' and high success rates are reported with varying techniques (72-77). Solitary lesions are often removed with minimally invasive techniques, not always addressing the entire ear canal, and sometimes a chisel is even sufficient. In more extensive lesions the entire OEAC is addressed. The principle of these surgical interventions is simple. Sufficient removal should be achieved to enable normal physiology to return after healing (1). To which extent removal is necessary to achieve this is up to personal preference as no evidence is present regarding this topic.

External auditory canal cholesteatoma (EACC)

An EACC is a rare benign disease characterized by the erosion of the bony external auditory canal through proliferation of the adjacent squamous tissue (78,79). Secondary to this erosion large plaques of desquamated keratin accumulates. A distinction can be made between an iatrogenic, post traumatic and idiopathic etiology (78). It has an unclear etiology and pathogenesis (80). It can be debated whether nomenclature is adequate and if an EACC is a true 'cholesteatoma' of the external ear canal or a separate entity. Symptoms are otorrhea and a chronic, dull pain due to the local invasion of squamous tissue into the bony EAC (81). Conservative treatment has been proposed by removal of keratin and subsequently applying a gauze with salicylate and cortisone ointment (82). This treatment is effective in alleviating symptoms but does not 'heal' the condition. True disease resolution is reached in a similar way as that of middle ear cholesteatoma and surgical treatment is necessary for achieving complete removal of diseased epithelium (1). If the disease is solely located in the OAEC a limited canalplasty will often suffice. If extension into the mastoid air cell tracts occurs, reconstruction of the ear canal is needed with or without obliteration or a modified radical cavity (1). The bony erosion is addressed by equalizing it with surrounding bone and the diseased skin should be removed. If more than 50% of the epithelium is involved grafting can be considered (55).

Keratosis obturans

Keratosis obturans has some similarities with the ear canal cholesteatoma, but is now recognized as a distinct clinical and pathological entity. The accumulation of large plaques of desquamated keratin in the ear canal in keratosis obturans doesn't arise secondary to bone erosion (78). Bony 'remodeling' is possible but only due to prolonged disease without regular cleaning. In cholesteatoma the skin does lead to primary erosion and not to 'remodeling'. It also has an unknown etiology. Presenting symptoms are different to EAC cholesteatoma as well. Conductive hearing loss and feeling of pressure are the symptoms if no infection is present (83). Conservative treatment is propagated with regular removal of the keratin plug. Surgery has shown to only alleviate some obstructing symptoms and to enlarge the period between clinical visits but is not effective in truly treating the disease (83). Complete removal of skin and subsequent grafting did show to have good results but has a risk of stenosis and the need for clinical cleaning after such procedures is still necessary (57). Surgery should not be considered as a preferred treatment (1).

Malignant tumors of the external ear canal

Although rare in occurrence both benign and malignant tumors can be found in the external ear canal. The origin of these tumors can be epithelial (squamous cell carcinoma or papilloma, basal cell carcinoma, ceruminous adenocarcinoma) or soft tissue (fibrosarcoma, hemangioma, neurofibroma) or arising from bone and cartilage (chondroma, osteoma, osteosarcoma)(1). If surgery is indicated the oncological principles apply. Radical removal with a considerable margin is propagated (84). Canalplasty alone does not achieve this goal and therefore is deemed insufficient. The treatment of choice is a (sub)total petrosectomy will be performed with or without subsequent radiotherapy (85).

Acquired stenosis of the EAC.

A stenosis is a narrowing of the canal of varying severity and aetiology. Tos divided the acquired stenosis in four aetiological groups: 1. Postinflammatory. 2. Posttraumatic 3. Postoperative and 4. Neoplastic. (1). Stenosis can be located medially or laterally, can be web shaped or diffuse, and can be circumferential or non-circumferential. Slight stenosis are clinically unimportant. If diffusely present most clinicians regard this entity as a narrow ear canal and often don't refer to it as a disease at all. A stenosis can lead to symptoms, as it can interfere with normal physiology of the EAC and can result in a chronic refractory otitis externa (86). Web shaped stenosis can be seen after surgery and inflammation and is commonly regarded as a undesired situation. Although such small stenosis seldom lead to problems when regular clinical cleaning is performed. Conservative treatment will normally suffice but in the more severe cases surgery is the only real problem solving option. In these cases a canalplasty is necessary (1).

Acquired atresia of the EAC.

Defined by Tos as an intraluminal sequelae of either intra- or extraluminal processes of varying aetiology (1), nomenclature regarding this disease is as varied as its aetiologies. Post-traumatic, post inflammatory and iatrogenic atresia are several entities that have close resemblance to one another without any clear distinguishing parameters. A distinction is made within the acquired atresia group between solid and membranous acquired atresia but these can present themselves in all etiological subgroups. As membranous atresia is very rare (1) we will discuss only the more common disease of a solid acquired atresia. This condition is most commonly referred to as Acquired Medial Canal Fibrosis (AMCF). Iatrogenic blunting of the tympanic annulus region could be regarded as the mildest form of this entity. Giving rise to conductive hearing loss and a feeling of fullness surgical solutions have been described for this condition. Some older reports have described modified radical cavity surgery as a solution (87,88). Current surgical principle is the complete removal of the fibrous plug by elevating it from the bony ear canal, annulus fibrosis and the lamina propria of the ear drum (1). The usage of skin grafts and flaps have been propagated and many advise to enlarge the bony ear as well (a complete canalplasty) (73,89-91).

Surgical management of the OAEC has a clear role in treatment of varying diseases of the external ear canal. But not much evidence is currently present regarding the topic. More research therefore is warranted.

AIM AND BRIEF OUTLINE OF THIS THESIS

The main goal of this thesis is to investigate three aspects of the OEAC in the treatment of COE: surgery, shape and (the effects on) sound. Currently insight is lacking regarding which surgical technique/approach is most safe and effective. Furthermore, the knowledge to which extent the shape needs to be altered during surgery is insufficient. Also, the alteration of shape of the OEAC after sugery will affect the resonance function of the OEAC and therefore the perceived sound quality. More data regarding the effects of these alterations on perceived sound quality will improve pre-operative counselling and minimise patient discomfort.

We asked ourselves whether surgery is a safe and effective way of addressing pathology of the OEAC. Furthermore we wanted to know which techniques can be advocated. We reviewed the literature and identified manuscripts regarding surgery of acquired diseases of the OEAC in order to answer these questions (Chapter 2.1). We report on the retrospective analysis of the results of the canalplasty technique used in our centre to evaluate its effectiveness and safety (Chapter 2.2). This technique enables adequate widening of the bony ear canal due to the creation of a pedunculated skin flap (resulting in a maximisation of exposure and maximal preservation of skin and eliminating the need for grafting). As this technique cannot be used in revision radical cavity surgery (due to the extensive alterations of the OEAC making) we propose a novel canalplasty technique in such cases and the results are shown in Chapter 2.3.

Next we will focus on the shape of the OEAC. Which aspects of the shape are relevant in acquired inflammatory disease of the OEAC? To our knowledge there are no standardised and validated classifications regarding the shape of the OEAC. We therefore suggest a novel method of objectively determining the dimensions of the pre- tympanic recess (PTR) using CT scans (Chapter 3.1) and evaluate whether the PTR plays a role in chronic otitis externa (COE) and troublesome radical cavities. (Chapter 3.1 and 3.2)

The third part of the thesis focusses on the perceived sound quality when the shape of the OEAC has been surgically altered. In order to investigate whether surgically altering the shape has a perceivable effect at all a proof of concept study was performed. We describe a way of filtering sound to simulate a real ear condition. Using this technique we evaluated several conditions of normal and altered ear canals (radical cavities) (Chapter 4.1). Finally we used pre and postoperative conditions of our canalplasty and posterior wall reconstruction in radical cavities techniques (described in Chapters 2.2 and 2.3) to evaluate if and how the perceived sound quality is affected (Chapter 4.2).

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2

Surgery of the OEAC

Canalplasty: systematic review of literature

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Submitted

2.1

ABSTRACT

2.1

Objective

A wide variety of canalplasty procedures have been described in order to treat acquired diseases of the osseous external auditory canal (OEAC). We aimed to systematically investigate the effectiveness and safety of canalplasty and the surgical aspects that may influence the outcome.

Data sources

We searched OVID MEDLINE and EMBASE from inception to 2017 July 10th without restriction on language, date or study design and cross-checked references of relevant articles.

Review Methods

We followed the PRISMA statement for reporting systematic reviews and meta-analyses. An exhaustive search was performed to identify relevant studies. Main outcomes were: resolution of disease, complications, hearing outcomes, the need for revision surgery, and recurrence of primary disease. Two independent reviewers assessed the quality of the manuscripts using the methodological index for non-randomised studies (MINORS).

Results

A total of 872 unique articles were identified. Thirty-seven studies met inclusion criteria for qualitative analysis. The review found an overall effectiveness of 87% of disease resolution with a relatively high overall complication rate of 17%. The rate of major complications was less than 5%. The effects of grafting, approach, usage of burr or chisel and post-operative stenting were analysed.

Conclusion

We supply currently present evidence, showing that canalplasty is a safe and effective procedure in treating acquired diseases of the OAEC. In regard to the various aspects of the procedure, some cautious conclusions with low quality evidence are made. It was demonstrated that underlying pathology dictated type of surgery.

INTRODUCTION

Inflammatory and acquired diseases of the outer ear canal are commonly treated conservatively. Topical application of antibiotics, antifungals, corticosteroids and astringents are preferred treatments. If such treatment fails, surgery is another treatment modality. Both meatoplasty (surgical reconfiguring of the cartilaginous auditory canal (1) and canal(o)plasty (surgical alteration of the osseous external auditory canal (OEAC) (2) are accepted surgical treatment modalities in these acquired refractory cases. Both procedures aim to provide a dry, self-cleaning ear by sufficiently enlarging the auditory canal, enabling better or adequate ventilation and reducing conditions favorable for microbial growth, debris accumulation and recurrent disease (1,2). Whether or not to combine these procedures is dependent on the area of narrowing (3). As conductive hearing loss is often present another aim of a canalplasty procedure could be improvement of hearing. This manuscript focusses on canalplasty in patients with acquired ear canal disease in an anatomically "normal" external auditory canal. The creation of an entirely new ear canal (congenital bony atresia) or reconstruction of the posterior wall in case of prior surgery (modified radical cavity) are not reviewed.

Effectiveness and safety of canalplasty techniques have been described in literature but only within the treatment of one specific disease entity (4-6). To our knowledge, the effectiveness and safety of a canalplasty as a general procedure has currently not been demonstrated.

Based on the same general principle, several canalplasty techniques have been developed using their own surgical 'philosophy'. This resulted in some distinct differences between the various canalplasty procedures: surgical approach, handling of the epithelial lining, post-operative care and the use of surgical tools. Subsequently, this has led to some points of debate about which technique is preferred.

The use of a retro-auricular approach for canalplasty has been advocated because of practical reasons (better exposure of landmarks, possibility to harvest temporalis fascia etc.), and has been suggested to lead to better outcomes (6-8). Endaural and transcanal approaches have been suggested to be less invasive and lead to faster healing as well as having a reduction in operating time (9-11). The introduction of endoscopic ear surgery might be another new approach in acquired diseases of the OAEC and its potential benefits such as superior visibility (due to high resolution, magnification and wide angle view) and eliminating the need for approaches with higher alleged morbidity, have been advocated (12).

As widening of the ear canal will inevitably lead to areas of denuded bone, which lack protective abilities against microorganisms and disrupt normal migratory patterns of the epithelial lining of the OAEC, a potential risk of infection is introduced. Different solutions to this problem have been formulated. Skin preservation by using meatal flaps or by protection with silastic sheets or bone wax, with subsequent secondary healing of the ear canal have been suggested (6,9,13). Covering the denuded bone with fascia, skin grafts and/or pedunculated skin flaps is another possibility. Arguments in favour of grafting are that healing could be faster and recurrence rates are lower (14-16). Full thickness skin grafts (FTSG) or split thickness skin grafts (STSG) have all been used with satisfactory results (7,14). However, the unique properties of the skin of the OEAC are essential for its normal homeostasis and replacement with other skin can lead to higher risk of inflammation and clinical dependence for cleaning (2).

It has been suggested that post-operative ear mould stenting limits the risk of restenosis in some acquired diseases (17) but this has yet not been implemented on a large scale. The widening of the OAEC can be performed with burrs, chisels and piezoelectric devices. Those in favour of chisels mention reduced risk of sensorineural hearing loss (SNHL) and limited damage to the ear canal due to the natural cleavage plates in the bone (10,18,19). Those in favour of using burrs argue that there is a greater ability to tackle more extensive disease, the possibility of more precise removal of bone and the reduced risk of facial nerve and temporomandibular joint (TMJ) complications (6,18). With the introduction of new tools such as the piezoelectric devices, it has been suggested that they could have added benefit within canalplasty procedures. It would limit the risk of mobilising the OEAC and its ability to smooth out bony surfaces with preservation of the adjacent soft tissues (20).

The aim of this systematic review is to supply the available evidence regarding the effectiveness and safety of a canalplasty procedure in treating acquired chronic OEAC disease and to determine whether certain surgical techniques and philosophies can be recommended when performing such surgery.

MATERIAL AND METHODS

Search strategy

This systematic review followed the PRISMA statement for reporting systematic reviews and meta-analyses (21). A medical information specialist [JL] performed a systematic search in OVID MEDLINE and OVID EMBASE from inception to July 10th, 2017 without restriction on language, date or study design. The search strategy consisted of controlled vocabulary (i.e. MeSH) and free text words. To ensure a sensitive search, we didn't only search for canal(o)plasty (as a text word), but also for specific surgical procedures in combination with specific OAEC-diseases [see Fig 1 for the entire MEDLINE search]. We cross-checked the reference lists and the cited articles of the identified relevant papers for additional references. The bibliographic records retrieved were imported and de-duplicated in ENDNOTE.

Titles and abstracts of all identified articles were independently screened for eligibility by two reviewers [ES and MW]. Any discrepancies were resolved by discussion or if required consultation with a third reviewer. We included randomized controlled trails, case control, case series with chart review and a minimal sample size of ten patients, and prospective cohorts. If studies reported serial data and/or overlapping data, only the most recent study providing the longest available follow-up was used. All forms of acquired primary ear canal disease were included, except "malignant external otitis", "osteoradionecrosis" and "malignancy of the ear canal". We included all interventions that widened the osseous ear canal. Full text screening was done by both reviewers simultaneously. Authors were contacted to ensure maximum effort in retrieving all full texts. If the language was non-English a translation was made or

#	Searches	Results
1	(canalplast* or meat*canalplast*).tw,ot,kf,hw.	78
2	(canaloplast* or (canal adj2 plast*)).tw,ot,kf. and ((audito* or ear or ears or otol* or otorhin* or otos* or otiti*).mp,jw. or exp Otorhinolaryngologic Diseases/ or exp ear/)	71
3	1 or 2 [A = CANALPLASTY NARROW]	148
4	su.fs.	1818858
5	reconstructive surgical procedures/ or Surgical Flaps/ or skin transplantation/ or transplantation, autologous/ or Surgery, Plastic/ or otologic surgical procedures/ or Surgical Procedures, Operative/ or reoperation/ or postoperative complication/	577252
6	(graft* or flap or flaps or (skin adj2 (transplant* or split)) or otoplast* or plastic surg* or debrid* or drill* or surgery or surgic* or operative or operate* or operation* or microsurg* or excision* or otosurg* or osteotom*).tw,ot,kf.	2414913
7	or/4-6 [SURGERY]	3279866
8	ear canal/	5130
9	(ear canal* or outer ear).kw.	163
10	(ear*1 adj3 (canal* or meatus or outer)).tw,ot.	4354
11	(auditory meatus or auditory canal*).tw,ot,kw.	6701
12	((meatal or meatus) adj3 (external or outer)).tw,ot,kf.	1446
13	(surfer* adj2 ear*1).tw,ot,kf.	15
14	or/8-13 [AUDITORY EAR CANAL]	12900
15	ear, external/	11530
16	(external adj1 ear*1).tw,ot,kf.	4071
17	14 or 15 or 16 [EXTERNAL EAR]	24130
18	((chronic or refractory or recur*) and otiti* and extern*).ti,ot.	124
19	((obliterati* or postinflam* or post-inflam* or fibro*ing) adj3 otiti*).tw,ot,kf.	19
20	((meatal or canal or EAC or EACs) adj (fibroti* or fibros* or fibrous)).tw,ot,kf.	33
21	or/18-20	167
22	21 and 7 [B]	89
23	(otiti* or atres* or atret* or fibros* or fibrotic or stenos* or stenot* or stricture* or constrict* or cholesteat*).mp.	533086
24	(split adj2 (skin adj (graft* or tranpslant*))).tw,ot,kf.	3446
25	23 and 24	154
26	Fibrosis/su	292
27	Ear Deformities, Acquired/	1061
28	((canal or canals or auditory or aural or outer ear* or EAC or EACs) adj4 (acquired or cholesteat*)).tw,ot,kf.	780
29	(EACC or EACCs).tw,kf.	80
30	Constriction, Pathologic/	28350
31	((fibroti* or fibros* or fibrous) adj3 (atresi* or atretic or stenos* or stenot* or stricture* or constrict* or cholesteat*)).tw,ot,kf.	1238
32	exostoses/ or exostoses, multiple hereditary/ or hyperostosis/ or exp osteoma/	9647
33	(exostos* or exocytos* or hyperostos* or osteoma*).tw,ot,kf.	33088
34	((surfer* or swimmer*) adj2 ear*1).tw,ot,kf.	54
35	((canal or canals or auditory or aural or outer ear* or EAC or EACs) adj5 (exostos* or exocytos* or hyperostos* or osteoma or osteomata or osteomateus or osteomas or osteome)).tw,ot,kf.	314
36	(acquired adj5 (atresi* or atretic or stenos* or stenot* or stricture* or constrict* or cholesteat*)).tw,ot,kf.	1588
37	or/25-36	69282
38	37 and 7 and 14 [C]	615
39	otitis externa/ or otitis media, suppurative/ or otitis media/ or otitis media with effusion/	25158
40	otiti*.tw,ot,kf.	25909
41	or/39-40	33129
42	Fibrosis/	24578
43	(fibros* or fibrot* or fibro-osseous or stenoti* or stenos* or atresi* or atret*).tw,ot,kf.	360500
44	or/42-43	366211
45	41 and 44	518
46	(benign adj5 (osteit* or otit*)).tw,ot,kf.	38
47	BNOE.tw,ot,kf.	5
48	or/45-47	557
49	48 and 7 and 17 [D]	102
50	3 or 22 or 38 or 49 [A B C D]	813
51	exp neoplasms, nerve tissue/ or (neuroma* or schwannom* or astrocytom* or paragangl* or ependymom* or h?emangiom* or meningiom* or malign* or cancer* or carcinom* or adenom* or congenit* or malformat* or microtia).ti,ot.	1746057
52	((animals/ or animal*.ti,ot.) not humans/) or (dog or dogs or cats or hamster* or rabbit* or gerbil* or pig or pigs).ti,ot.	4474797
53	51 or 52 [exclusion animals and neoplastic disease]	6152865
54	50 not 53	659
55	remove duplicates from 54	634

Figure 1. OVID MEDLINE search strategy as was performed. Database(s): Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to 2017-07-10.

a native speaker was contacted to supply the information needed. Studies that did not describe the surgical intervention in sufficient detail or studies in which different interventions were described without clear description of results per intervention, were excluded.

Qualitative synthesis

A qualitative synthesis was performed using the Methodological Index of Non-Randomized Studies (MINORS) (22). In the MINORS, a maximum of 16 (non-comparative) or 24 points (comparative studies) can be achieved.The level of evidence and the risk of bias was assessed at study level (21).

Study characteristics

The following study characteristics were analysed. Cohort size, follow up time (FU), study design and the underlying pathology treated. In order to enable better comparison, several indication categories were defined: [1] *Acquired Medial Canal Fibrosis* (AMCF) comprising all acquired stenosis/atresia, [2] *Chronic otitis externa* (COE), [3] *Exostosis* comprising all exostosis and osteomata, [4] *Ear canal cholesteatoma* (ECC) and [5] *Mixed* comprising multiple indications with a pooled analysis.

Surgical aspects

The surgical approach, use of skin grafting and type of graft used (if applicable), post-operative stenting and the use of surgical tools were all parameters of our analysis. If protective measures were taken to protect the epithelial lining, we regarded it to be a skin preserving technique. If no description of specific post-operative care was given, we presumed that no use of post-operative ear mould stenting was applied.

Outcomes

Outcomes analysed were disease resolution (dry ear rate, symptom free ear, persistence and recurrence of disease), hearing results, time to heal, complications and revision cases. Percentages of surgical complications were derived from the texts, excluding unwanted or undesired results not directly related to the surgical intervention. If no specific details were supplied regarding complications, we did not derive a percentage. We excluded recurrences or late stage stenosis as complications and noted those separately. We specifically noted if SNHL and/or facial nerve paresis (or paralysis) were described in the manuscripts. Because hearing results were given in a number of different ways, we dichomatised hearing results into sufficient hearing improvement or insufficient hearing improvement. Sufficient hearing was defined by a post-operative objective improvement of hearing in more than 80% of the cases, a post-operative ABG closure within 20 dB in more than 80% of the cases, a mean post-operative ABG of less than 20 dB and a mean post-operative PTA of less than 20 dB. If it was impossible to derive the aforementioned parameters from the available data we did not include the study in the dichomatisation.

Data analysis

Information regarding demographic data, surgical technique and outcome parameters were collected and summarized in a tabular format to facilitate identification of trends and patterns in results and descriptions across studies. Fisher's exact test was used in order to evaluate whether distribution of complications was distributed differently over the groups. If the groups became too large a chi-square analysis was performed with Yates' correction for continuity.

RESULTS

The literature search identified 872 unique publications, of which183 were deemed potentially eligible and retrieved for full text review. A total of 37 case series were included in the systematic review [Figure 2]. No randomized controlled trails, case control, and prospective cohort studies were found.

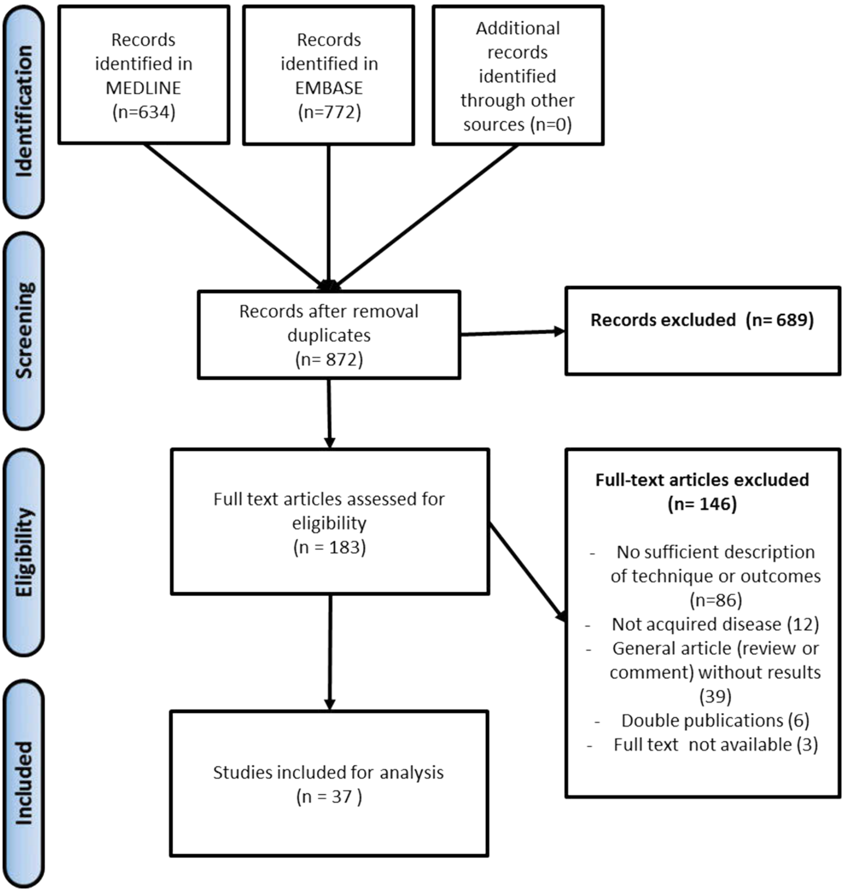

Figure 2. Diagram of literature selection process.

Overall quality of included studies

All of the included studies were retrospective case series. The results of the MINORS evaluation of the included studies are shown in [Table 1]. The scores of included studies did not exceed 9 points (Median: 7, Range 0-9) in the non-comparative studies and 11 points (Median: 11, Range 10-11) in the comparative studies.

Study characteristics

The characteristics of the studies are depicted in [Table 1]. A total sum of 1901 operated ears were identified. Varying cohort sizes were presented with a median of 25 operated ears (11 – 256, mean 49). Mean FU time was mentioned in 23 out of the 37 studies and was very variable median 37 months (range 1,5 – 61,5 months), with three studies having a minimal FU time of more than one year for all participants (14,26,27).

Most studies reported their results for groups of patients suffering from the same pathology. Four studies reported the results of their technique with a mixed group of indications (8,13,35,36).

Surgical aspects data

[Table 3] shows the surgical aspects of the included studies. In 54% of all studies, solely the post-auricular approach was used. Endaural (solely used in 19%) and transmeatal (solely used in 14%) approaches were sometimes used solely or in combination with the post-auricular approach (in 11%). In total, 51% of the studies advocated skin preservation and 59% propagated the use of skin grafts usually (73%) STSG. If skin grafting is performed, the usage of a STSG seems to be predominant (80% of all cases). Post-operative stenting was advocated in one paper (17).

All studies used burrs, chisels or a combination of the two to widen the OEAC , except one in which a combination of chisel and piezoelectric device was used (20).

Outcome data

All outcome data we identified are shown in [Table 3]. Several categories of outcome measures were used in the various manuscripts. Sixteen studies reported their effectiveness in achieving a disease free and symptom free status as a primary outcome measure. The studies had a median overall resolution of disease of 88,5% (range 54-100%). Most articles (27 studies, 73%) used hearing results as their primary or secondary outcome measure (either descriptive or objective, using Pure Tone audiometry (PTA) or air bone gap (ABG) closure). A sufficient hearing improvement (see definition in the methods) was seen in 11 studies. Ten studies demonstrated insufficient hearing improvement. Healing (time of complete epithelisation) was used as an outcome measure in 8 articles. The definition of a normal healing period was variable and ranged between 4-12 weeks. Within 6 weeks, 90% of the ears had healed. All these studies were performed without grafting, with the exception of 8 selected cases out of 193 operated ears (13). Healing was usually not reported in the studies using grafts. One manuscript used quality of life as primary outcome measure, with positive mean scores on all Glasgow Benefit Inventory subsections (4).

Table 1. Study characteristics of selected studies.

Lead author year	MINORS score	Cohort size ears (patients)	FU months (mean)	FU range months	indication category	Study Design
Anthony 1982 [23]	0	12 (10)	26	4-102	ECC	case series
Barrett 2014 [18] #	10	21(?)	-	-	Exostosis	case series
		38(?)	-	-	Exostosis	
		33(?)	-	-	Exostosis	
Beales 1974 [17]	3	22 (?)	-	-	CEO	case series
Becker 1998 [24]	5	53(47)	60	4-156	AMCF	case series
Birman 1996 [25]	3	12(11)	-	5 - 29	CEO	case series
Cremers 1993 [7]	5	17 (15)	12	3 - 54	AMCF	case series
Crosbie 2013 [4]	9	20(16)	-	-	CEO	case series
Dhooge 2014 [5]	8	17(14)	61	-	AMCF	case series
Droessaert 2016 [14]	8	27(27)	24	18 - 30	AMCF	case series
el-Sayed 1998 [26]	4	12 (10)	30	12 - 60	AMCF	case series
Frese 1999 [19]	4	59 (48)	-	-	Exostosis	case series
Ghani 2013 [27]	8	14 (12)	67	21 - 108	AMCF	case series
Ghavami 2016 [28]	7	138 (106)	1,5	1,5	Exostosis	case series
Grinblat 2016 [29]	9	256(217)	20,4	6-180	Exostosis	case series
Haidar 2016 [20]	11	11(10) *	-	-	Exostosis	case series
Hetzler 2007 [10]	8	220(140)	-	-	Exostosis	case series
Ho 2017 [30]	7	30(27)	61,5	8-131	ECC	case series
Keller 2017 [31]	7	21(16)	45,5	-	AMCF	case series
Lavy 2001 [8]	0	100 (86)	-	-	Mixed	case series
Lin 2005 [32]	8	26(21)	52.5	3 - 83	AMCF	case series
Magliulo 2009 [33]	8	25 (23)	-	-	AMCF	case series
Mariezkurrena 2006 [34]	8	52 (45)	53	1 - 76	Exostosis	case series
McCary 1995 [35]	4	18(16)	39	2 - 9	Mixed	case series
McDonald 1986 [36]	5	22 (20)	40	-	Mixed	case series
Moss 2015 [9]	9	41 (34)	35	3 - 271	Exostosis	case series
Nogueira 2014 [37]	5	18 (13)	38	6 - 56	CEO	case series
Paparella 1981 [15]	4	24 (?)	36	6 - 120	CEO	case series
Portmann 1991 [38]	8	25(22)	-	3-120	Exostosis	case series
Potter 2012 [39]	6	16 (14)	35	3 - 84	AMCF	case series
Sanna 2004 [6]	8	65 (57)	34	8 - 120	Exostosis	case series
Sharp 2003 [40]	6	18 (15)	15	2 - 27	CEO	case series
Sheehy 1982 [41]	4	100(83)	-	-	Exostosis	case series
Stougaard 1999 [42]	7	24 (19)	-	-	Exostosis	case series
Strohm 2002 [43]	5	52(46)	-	-	AMCF	case series
Tos 1986 [44]	8	22(19)	60	3 - 156	AMCF	case series
van Spronsen 2013 [13]	9	193 (174)	45	2-100	Mixed	case series
Whitaker 1998 [11]	7	27(18)	-	-	Exostosis	case series

MINORS: Methodological Index of Non-Randomized Studies, FU: follow up, ECC: external canal cholesteatoma, CEO: chronic otitis externa, AMCF: acquired medial canal fibrosis, -: no data/unknown, #: This was a comparative study in which three separate groups could be identified regarding used techniques and their respective outcomes. *: Only patients treated with sonopet were included as the control group was an overlapping cohort.

Table 2. Surgical aspects described in the selected studies.

Lead author year	Burr	Chisel	Approach	Skin preservation	Skin grafting	Type of graft	Use of temporal fascia
Anthony 1982 [23]	Yes	No	-	No	Yes	Free graft	Yes (7 cases)
Barrett 2014 [18] #	Yes	No	Endaural	Yes	No	N/A	No
	Yes	Yes	Endaural	Yes	No	N/A	No
	No	Yes	Endaural	Yes	No	N/A	No
Beales 1974 [17]	Yes	No	-	No	No	N/A	No
Becker 1998 [24]	-	-	Transcanal	No	Yes	STSG (origin unknown)	No
Birman 1996 [25]	-	-	Post-auricular	No	Yes	STSG (upper arm)	No
Cremers 1993 [7]	Yes	No	Post-auricular	No	Yes	STSG (origin unknown)	No
Crosbie 2013 [4]	Yes	-	Post-auricular	No	No	N/A	Yes
Dhooge 2014 [5]	Yes	No	Post-auricular	No	Yes	FTSG (retroauricular)	No
Droessaert 2016 [14]	yes	no	Endaural/post-auricular	Yes	Yes	STSG (retroauricular)	No
el-Sayed 1998 [26]	-	-	Post-auricular	No	Yes	STSG (upper arm)	No
Frese 1999 [19]	Yes	Yes	3 post-auricular /endaural	Yes	No	N/A	No
Ghani 2013 [27]	-	-	Post-auricular	No	Yes	STSG (retroauricular, thigh)	Yes
Ghavami 2016 [28]	4 cases	Yes	Endaural	Yes	No	N/A	Yes (? cases)
Grinblat 2016 [29]	Yes	No	Post-auricular (endaural selected cases)	Yes	No	N/A	Yes
Haidar 2016 [20]	No	Yes combined with sonopet	Endaural	No	No	N/A	No
Hetzler 2007 [10]	30 cases	Yes	Transmeatal	Yes	No	N/A	No
Ho 2017 [30]	Yes	No	Post-auricular	No	Yes	FTSG (pedunculated flap)	Yes
Keller 2017 [31]	-	-	Post-auricular	No	Yes	STSG (upper arm)	no
Lavy 2001 [8]	Yes	No	Post-auricular	Yes	Yes (? Cases)	-	No
Lin 2005 [32]	Yes	No	Endaural	No	Yes	STSG (upper arm)	No
Magliulo 2009 [33]	-	-	Endaural/ Post-oauricular	No	Yes	STSG (retroauricular)	No
Mariezkurrena 2006 [34]	Yes	No	Post-auricular	Yes	No	N/A	No
McCary 1995 [35]	-	-	-	No	Yes	STSG (origin unknown)	No

Table 2. (continued)

Lead author year	Burr	Chisel	Approach	Skin preservation	Skin grafting	Type of graft	Use of temporal fascia
McDonald 1986 [36]	Yes	No	Post-auricular	No	Yes	STSG (upper arm/thigh/lower abdominal wall)	No
Moss 2015 [9]	Yes	No	Post-auricular	Yes	No	N/A	Yes
Nogueira 2014 [37]	Yes	No	Post-auricular	No	Yes	FTSG (retroauricular pedunculated flap)	No
Paparella 1981 [15]	Yes	No	Post-auricular	No	Yes	STSG (upper arm)	No
Portmann 1991 [38]	Yes	No	Post-auricular	Yes	Yes (6 cases)	STSG (retroauricular (3), peduncalated flap (3))	Yes(2)
Potter 2012 [39]	Yes	No	Post-auricular	No	Yes	STSG (upper arm)	Yes
Sanna 2004 [6]	Yes	No	Post-auricular	Yes	No	N/A	Yes
Sharp 2003 [40]	Yes	No	Endaural	Yes	No	N/A	No
Sheehy 1982 [41]	Yes	No	Transmeatal	Yes	No	N/A	Yes (8 cases)
Stougaard 1999 [42]	Yes	No	Post-auricular	Yes	No	N/A	No
Strohm 2002 [43]	Yes	No	Post-auricular	Yes	Yes	STSG (retroauricular)	Yes (? Cases)
Tos 1986 [44]	-	-	Transmeatal	No	Yes	-	No
van Spronsen 2013 [13]	Yes	No	Post-auricular	Yes	Yes (8 cases)	STSG (retroauricular)	No
Whitaker 1998 [11]	2 cases	Yes	Transmeatal	Yes	No	N/A	No

STSG: split thickness skin graft FTSG: full thickness skin graft, N/A: not applicable, -: no data/unknown, #: This was a comparative study in which three separate groups could be identified regarding used techniques and their respective outcomes.

Table 3. Outcomes described in the selected studies.

Lead author year	Disease resolution (dry, symptomfree)	Hearing results	Sufficient hearing improvement
Anthony 1982 [23]	100%	-	-
Barrett 2014 [18] #	-	1 SNHL	-
	-	-	-
	-	-	-
Beales 1974 [17]	73%	15 patients improved, 7 not improved	No
Becker 1998 [24]	93%	ABG: 90% within 20 dB	Yes
Birman 1996 [25]	75%	9 cases improved 20 dB AVG	No
Cremers 1993 [7]	82%	ABG: 88% within 20 dB	Yes
Crosbie 2013 [4]	-	Mean PTA improvement 9 dB, 82% improved	Yes
Dhooge 2014 [5]	59%	ABG: mean 30dB to 9 dB	Yes
Droessaert 2016 [14]	89%	Mean PTA improvement 25 dB, 65% improved	No
el-Sayed 1998 [26]	-	AVG improvement of 20 dB, 83% improved	Yes
Frese 1999 [19]	93%	4 SNHL, **Subjective** improvement in 93%	-
Ghani 2013 [27]	64%	ABG: mean 30 dB to 12dB 58% achieved social hearing	Yes
Ghavami 2016 [28]	-	98% improvement conductive HL	Yes
Grinblat 2016 [29]	-	ABG: mean improvement 2,2 dB, 19 SNHL	-
Haidar 2016 [20]	-	AVG PTA improvement of 4 dB	-
Hetzler 2007 [10]	-	3 SNHL	-
Ho 2017 [30]	-	Hearing unchanged in selected cases	-
Keller 2017 [31]	-	ABG: long term improved 60%, 74% improved	No
Lavy 2001 [8]	-	-	-
Lin 2005 [32]	88%	Mean PTA improvement 17 dB, 70% improved	No
Magliulo 2009 [33]	-	ABG: 66% within 20 dB	No
Mariezkurrena 2006 [34]	-	100 % normalised, 8 of 8	Yes
McCary 1995 [35]	-	ABG: improved25 dB, 9 of 12 ABG within 20 dB	No
McDonald 1986 [36]	81%	68% improvement of hearing	No
Moss 2015 [9]	-	ABG: mean 8 dB to 3 dB, 3 SNHL	Yes
Nogueira 2014 [37]	100%	Air conduction improvement of 14.3 dB	-
Paparella 1981 [15]	-	-	-
Portmann 1991 [38]	-	17 no change, 5 better, 2 worsened , 2 SNHL	No
Potter 2012 [39]	-	ABG: 100% < 20 dB	Yes
Sanna 2004 [6]	-	20 dB improvement conductive HL, 1 SNHL	-
Sharp 2003 [40]	-	-	-
Sheehy 1982 [41]	100%	-	-
Stougaard 1999 [42]	100%	1 SNHL	-
Strohm 2002 [43]	54%	20 improved, 9 unchanged	No
Tos 1986 [44]	-	ABG: 80% within 20 dB	Yes
van Spronsen 2013 [13]	95%	improvement air conduction levels,1SNHL	-
Whitaker 1998 [11]	-	All conductive loss were improved	-

PTA: pure tone threshold, ABG: Air bone gap, AVG: average, SNHL: sensorineural hearing loss, HL: hearing loss, -: no data/unknown, #: This was a comparative study in which three separate groups could be identified regarding used techniques and their respective outcomes.

time to heal (weeks)	range (weeks)	Extrapolated complications n (%)	SNHL	Revision surgery n (%)
Median 6.4	4 - 8	2 (17%)	-	0 (0%)
-	-	7 (33%)	Yes	-
-	-	4 (11%)	No	-
-	-	3 (9%)	No	-
-	-	-	-	-
-	-	12 (23%)	-	5 (9%)
-	-	2 (17%)	-	-
-	-	3 (18%)	-	1 (6%)
-	-	-	-	-
-	-	4 (23%)	-	1 (6%)
-	-	-	-	0 (0%)
-	-	-	No	2 (17%)
-	-	13 (22%)	Yes	4 (7%)
-	-	-	-	-
99% in 6	-	12 (9%)	No	-
Median 6,35	-	20 (8%)	Yes	8 (3%)
100% in 6	-	0 (0%)	No	0 (0%)
3.5	2 - 8	40 (18%)	Yes	-
-	-	-	-	-
-	-	-	-	2 (10%)
-	6 - 26	36 (36%)	-	-
-	-	7 (27%)	-	-
-	-	11 (44%)	No	5 (20%)
-	-	8 (15%)	No	-
-	-	0 (0%)	-	1 (6%)
-	-	-	No	-
-	-	10 (25%)	Yes	0 (0%)
-	-	-	-	0 (0%)
-	-	-	-	5 (21%)
-	-	4 (16%)	Yes	-
-	-	-	-	1 (6%)
-	-	4 (6%)	Yes	3 (5%)
-	-	1 (6%)	-	0 (0%)
Osteomata: 85% in 3 Exostosis: 75% in 6 100% in 12	-	12 (12%)	-	0 (0%)
-	-	4 (17%)	Yes	0 (0%)
-	-	5 (10%)	No	6 (12%)
-	-	4 (18%)	-	-
Median 6.3	3 - 20	54 (28%)	Yes	8 (4%)
100% in 6	-	7 (26%)	-	-

COMPLICATIONS.

Complications are reported in [Table 4]. We analysed whether complications could be attributed the surgical aspects of the included studies. Complications are significantly less reported for the endaural approach then for the the transmeatal and post-auricular approaches ($p<0.001$).

No differences are reported in complication rate between between STSG and FTSG ($p= 0.24$). For the difference between burrs and chisels only studies on exostosis could be meaningfully compared. We derived a complication rate of 16% when solely burr was used compared to 11% if only a chisel was used ($p=0.07$).

Subanalysis of indication categories

We tabulated the results for different disease categories in [Table 4]. All AMCF cases were treated with grafting, whereas almost all exostosis cases were not. Also, the use of the chisel was only reported for exostosis treatment. Although not tabulated, we found that the post-auricular approach was used for all indication categories. The more limited endaural and transmeatal approach was used predominantly for exostosis and some cases of AMCF. The exostosis category had a very high rate of disease resolution (98%) when compared to AMCF (76%). No clear distinguishable differences were seen in regard to the distribution of the hearing results over the different indication categories. With regard to post-operative stenosis and/or atresia, we found low percentages in ECC (0%), exostosis (2%) and CEO (6%) in comparison to AMCF (23%). In total, 35 cases of SNHL (1,8%), 2 cases of transient palsy (0,1%) (8) and no permanent facial nerve paralysis (0%) were identified in all manuscripts. Revision surgery was needed in 5% of all cases (52 of 1079).

DISCUSSION

This paper systematically reports the effectiveness and safety of canalplasty and the surgical aspects that may influence the outcome. We acknowledge that comparing surgical techniques is difficult, as there are many potential biases. The experience of the surgeon performing the procedure, the degree of disease and patient comorbidity are expected to influence outcome significantly. Also, publication bias will potentially be present. We included all studies that we could evaluate because sufficient detail regarding the used surgical technique was reported. Unfortunately many studies had to be excluded. Our review could have been stronger if uniform outcome measures and uniform definitions of complications would have been used in all articles.

Although, with a median overall resolution of disease of 88,5% (range 54-100%), canalplasty can be considered to be very effective in treating acquired OAEC disease. However, for now, we lack high level evidence. Unfortunately, based on the MINORS scores, the quality of the available case series can still improve. Recently, the PROCESS guidelines have been published, which are intended to increase the reporting quality of surgical case series (45). We strongly recommend that future studies use these guidelines.

Table 4. Results for different disease categories.

	Exostosis	AMCF	CEO	ECC	Mixed	Total	
Operated ears	1110	302	114	42	333	1901	
Burr usage	590 (53%)	155 (51%)	102 (89%)	42 (100%)	315 (95%)	1204	63%
Chisel usage	203 (18%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	203	11%
Combined	317 (29%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	317	17%
ND	0 (0%)	147 (49%)	12 (11%)	0 (0%)	18 (5%)	177	9%
No skin grafting	1104 (99,5%)	0 (0%)	60 (53%)	12 (29%)	285 (86%)	1461	
Skin grafting	6 (0,5%)	302 (100%)	54 (47%)	30 (71%)	48 (14%)	440	30%
STSG	6 (100%)	263 (87%)	36 (67%)	0 (0%)	48 (100%)	353	80%
FTSG	0 (0%)	17 (6%)	18 (33%)	30 (100%)	0 (0%)	65	15%
ND	0 (0%)	22 (7%)	0 (0%)	0 (0%)	0 (0%)	22	5%
Disease resolution							
Total eligible ears	183	206	52	12	215	668	
ears disease free	179 (98%)	156 (76%)	43 (83%)	12 (100%)	189 (88%)	579	87%
Studies with sufficient hearing improvement	3	5	2	0	0	11	
Studies with insufficient hearing improvement	1	5	2	0	2	10	
Complications							
Total eligible ears	1110	203	50	12	311	1686	
SNHL	34 (3%)	0 of 89 (0%)	0 of 0 (0%)	0 of 0 (0%)	1 of 215 (5%)	35 of 1414	2%
Facial nerve palsy	0 of 885 (0%)	0 (0%)	0 (0%)	0 of 0 (0%)	2 of 100 (2%)	2 of 985	0,2%
% complications	166 (15%)	45 (22%)	11 (23%)	2 (17%)	65 (21%)	289	17%
Revision surgery	15 of 556 (3%)	23 of 240 (10%)	5 of 60 (8%)	0 of 12 (0%)	9 of 211 (4%)	52 of 1079	5%
Stenosis/atresia	17 of 856 (2%)	37 of 159 (23%)	3 of 48 (6%)	0 of 0 (0%)	16 of 333 (5%)	73 of 1396	5%

ECC: external canal cholesteatoma, CEO: chronic otitis externa, AMCF: acquired medial canal fibrosis, SNHL: sensorineural hearing loss

We demonstrated that for the AMCF category, with a resolution of 76%, a canalplasty is less effective than the median of 88,5% for the whole group, but still satisfactory. As we found no studies comparing surgical versus conservative treatment or studies that describe resolution percentages of these diseases with conservative treatment, we are unable to conclusively state that surgery should be the first choice treatment modality. In spite of this, we think that a canalplasty can be considered to be the primary treatment modality in these diseases because of the high proven rate of disease resolution after previous (non-effective) conservative (medical) treatment.

Clearly defined outcome measures are paramount if future comparisons are to be more conclusive. We therefore propose that resolution of symptoms, time to heal, major complications and complication rate should be mentioned in all articles describing outcomes of canalplasty. Other parameters could be: (conductive) hearing results (46), water resistance, ability to wear hearing aids, Quality of Life (QoL), successful closure of a tympanic membrane perforation, presence of a self-cleansing ear and/or disease recurrence. The median follow-up time was 36 months. We think that the surgical outcome can be sufficiently assessed within a one year FU although some studies advocate a FU of two years (31,44). This period was proposed because final results for hearing and restenosis rates could not be evaluated after one year. It is, however, unclear whether these results are can be contributed to the surgical technique or to the underlying disease.

Ideally, a multifactorial analysis including at least disease category, disease resolution, conductive hearing results, healing time, revision surgery and complications should be done to draw conclusions of superiority. However, the quality of the reported data was insufficient to allow for such an analysis. In spite of the abovementioned consideration, we can draw some cautious conclusions from the presented data.

We found a significant difference between the endaural approach and the other approaches, when regarding the complication rate. In light of these results we could advise that an endaural approach should be considered in all limited exostosis and osteomata cases. However, this result is highly likely biased by the underlying disease and severity of disease, as mainly limited exostosis are treated with this endaural approach (6). Furthermore, this approach may result in lower complication rates, but its effects on other outcomes is still unknown.

This review is not able to conclude on the usefulness of using grafts. Although from a theoretical points of view one might expect healing time to be faster, the healing time was not mentioned in the studies where grafts were used. Furthermore, the amount of graft related complications (amount of epithelial healing failures, flap necrosis or loss of grafts, inclusion cholesteatoma and post-operative stenosis and atresia) were not described. Clinician dependence for regular cleaning of the ear canal after using grafts was mentioned by one author (5) and could be deduced in another article (14). One study demonstrated that up to 50% of the surface area of skin of the OAEC can regenerate without the use of skin grafts (2). We therefore advise that grafts are only used if larger areas of bone (>50%) are denuded (as is often the case in AMCF), as transplanted skin lacks the unique qualities of the OEAC skin. No conclusive remarks can be made about whether STSG's are better or worse in comparison with FTSG's. They may not significantly differ in complication rate, but it remains unknown if they differ in regard to healing time or disease resolution.

Post-operative stenting seems not to be necessary as its added benefit has only been described in one article that does not have better outcomes than the literature in general (17).

The use of a chisel is limited to exostosis and osteomata treatment and therefore not a universally applicable tool in all acquired diseases of the OAEC. No significant difference was found in regard to complications between the burr and chisel. With only one report regarding 'newer' tools, there is a need for more studies regarding their use before any conclusions can be made.

The overall complication rate of 17% in this review is in concordance with the literature. This percentage may even be higher as what is considered to be a complication does not appear to be clearly defined in the canalplasty literature. For example, some authors describe TMJ pain or discomfort as a complication (11,13,32), whereas others clearly state that this discomfort is universal and therefore should not be regarded as a complication (8). In spite of the high rates described, we would still consider a canalplasty procedure to be safe, as both major complications (including the occurrence of lasting disability) and the need for revision surgery are equal to or below 5% (SNHL was present in 2% and revision surgery was needed in 5% of the procedures).

When reviewing the literature, most articles warn for facial nerve complications. It was postulated that this risk is present due to the near proximity of the nerve to the canal wall (47). Our review, however, did not identify any lasting facial paralysis, suggesting that this risk is negligible (less than 1 promile).

A universal definition of relevant complications should be used in future studies regarding canalplasty in order to strengthen conclusions regarding the safety of this procedure. The definitions and classification of adverse events and complications supplied by others (48,49) can be applied and adopted to canalplasty. We would suggest to report using the following categorisation:

Grade A: Adverse events: would be transient with spontaneous resolution and without the need for revision surgery. Examples of these are TMJ pain/discomfort, wound infection, post-operative bleeding/heamatoma, delayed wound healing due to infection or graft necrosis (without need for revision surgery), transient facial nerve palsy, and/or asymptomatic post-operative stenosis or atresia.

Grade B: Minor complications would be permanent without long term disability and without the need for revision surgery. Examples of these are unintended opening of mastoid air cells, exposure of TMJ or mobilisation of the posterior TMJ wall.

Grade C: Major complications would be permanent with lasting disability or whenever revision surgery is deemed necessary. Some examples of such a circumstance could be a novel tympanic membrane perforation (TMP), non-closure of epithelial defects needing revision surgery, SNHL, facial nerve paralysis, inclusion cholesteatoma, iatrogenic symptomatic atresia or stenosis.

If the surgical procedure is not causative for non-responding or recurrent disease, we propose that these should not be reported as complications, but as outcome parameters. This would be in concordance with the advice of reporting sequelae and failures, as they are outcomes of treatment resulting in inconvenience for the patient (49). Some examples of non-responding or recurrent disease which are not surgical complications may be restenosis, recurrent atresia after one year FU, non-closure of a pre-existing TMP or persistent or recurrent COE despite normal healing.

CONCLUSION

This systematic literature review revealed variations in the surgical techniques for canalplasty and non-uniform presentation of results. We conclude that a canalplasty procedure is effective and safe when treating acquired diseases of the OAEC. Current literature does not supply evidence of an adequate level for strong conclusions and recommendations regarding possible superiority of surgical aspects of a canalplasty procedure. We propose a more uniform reporting of surgical procedures and surgical outcomes (preferably using the PROCESS guidelines) in order to enable surgical technique comparison in the future.

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Canalplasty: the technique and the analysis of its results

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2.2

ABSTRACT

Objective

To describe the technique for canalplasty as performed in the Academic Medical Center, Amsterdam, the Netherlands and to present the results of this technique.

Study design

Retrospective chart analysis.

Subjects and methods

Charts of patients who underwent a canalplasty prodedure between 2001 and 2010 were reviewed for indication for surgery, side of surgery, age at the time of surgery, gender, smoking habits, surgical outcome, results of pure tone audiometry pre-and post-operatively and the occurrence of complications.

Results

193 canalplasty procedures with or without more extensive otosurgery in 174 patients were performed for various indications in the Academic Medical Center, Amsterdam, the Netherlands between 2001 and 2010. Complete re-epithelialization took approximately 6.7 weeks and was influenced by smoking and the surface needed to re-epithelialize. Complications occurred in 28.0% of cases, of which most (98%) could be regarded as transient. No significant changes in pure tone bone conduction levels at 1, 2 and 4 kHz were observed.

Conclusion

This retrospective study shows that technique for canalplasty as used in the Academic Medical Center, Amsterdam, the Netherlands can be used for a wide variety of indications, highlighting its added value in otosurgery.

INTRODUCTION

Widening of the bony ear canal (i.e. canalplasty) is an established technique for the treatment of several diseases of the osseous external auditory canal (OEAC). Several techniques to widen the OEAC have been advocated in literature, all based on the same principle (i.e. creating a sufficiently wide, disease free and self cleansing ear canal) (1-5). Next to sufficient width, the quality of epithelial lining of the OEAC plays a pivotal role in the outcome of canalplasty. A healthy, dry and water resistant bony ear canal is completely lined with keratinizing squamous epithelium with normal migratory characteristics and the capacity of producing cerumen (2). These features enable the external auditory canal to fight water-borne pathogens (thus reducing the risk of infection) and prevent accumulation of debris. The skin of the ear canal is unique as it lacks subcutaneous tissue and adheres directly to the periost of the external auditory canal. These two factors make the skin of the bony external auditory canal extremely vulnerable and hard to replace (6). A canalplasty can be a standalone procedure or can be part of more complex otosurgery. Performing a canalplasty has been shown to be both an effective and usefull tool in otosurgery to optimize surgical view of the middle ear and the treatment of primary OEAC disease (1). This manuscript focuses on interventions in which an existing external auditory canal is present. The creation of an entirely new ear canal (as is the case in congenital aural atresia) will not be discussed. The technique for canalplasty as performed in the Academic Medical Center, Amsterdam, the Netherlands is described, results of this technique are presented and suggestions are made on how to handle skin deficits.

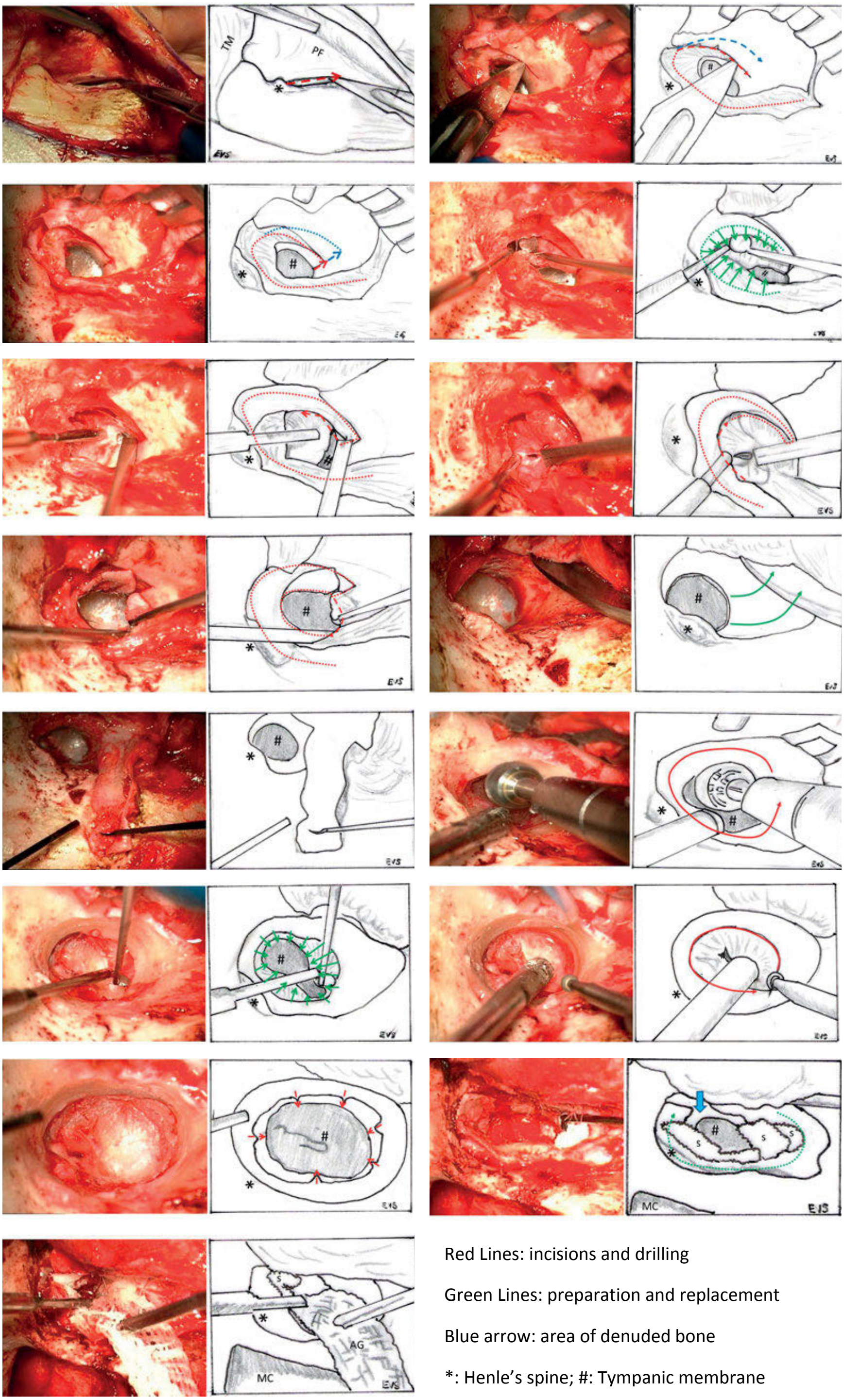
PATIENTS AND METHODS

Patients

A retrospective chart analysis was performed identifying 225 individuals who underwent a canalplasty procedure in one or two ears between September 2001 and May 2010 in the Academic Medical Center, Amsterdam, the Netherlands, a tertiary center for otorhinolaryngology. Of these 225 individuals, canalplasty was part of revision radical cavity surgery in 51 cases. These cases were excluded because of enormous abnormalities in shape of the OEAC. In the remaining 174 patients, 193 canalplasty procedures were performed by either the first or the third author of this manuscript. All charts were reviewed for indication for surgery, side of surgery, age at the time of surgery, gender, smoking habits, surgical outcome (i.e. complete epithelialization of the external auditory canal alias time to heal), results of pure tone audiometry pre-and post-operatively and the occurrence of complications.

Surgical technique

The surgical technique for canalplasty as used in the Academic Medical Center, Amsterdam, the Netherlands is a slight modification of the technique as described by Prof. U. Fisch in 1994 (7) Figure 1 is a representation of all steps of the procedure as are performed in our center.



Red Lines: incisions and drilling

Green Lines: preparation and replacement

Blue arrow: area of denuded bone

*: Henle's spine; #: Tympanic membrane

Figure 1. Used Canalplasty technique – step by step

All steps are described as if a right ear is involved. Briefly, one starts with a post-aural incision and the creation of a periosteal flap, thus allowing adequate exposure of the bony external auditory canal. Once the periostial flap is created, the external auditory canal is opened at the level of the transition between the bony and cartilaginous external auditory canal [1]. This incision is extended forward along the anterior wall to the 3 o'clock position [2]. At the 3 o'clock position, a second incision is made starting as close as possible to the tympanic annulus and reaching laterally to connect with the first incision at the level of the transition of the bony and cartilaginous external auditory canal [3]. If an inadequate amount of meatal skin is expected (as is the case in acquired medial canal fibrosis, AMCF), the technique as described above can be modified. This modification is a 'lateral steal' of skin covering the cartilaginous auditory canal using sharp dissection [3; blue lines]. Upon the first en second incision, the skin covering the bony external auditory canal is elevated starting at the 3 o'clock position in a counter clock wise manner until the 5 o'clock position is reached [4]. The skin should be elevated as medial as possible leaving only a small skin cuff near the tympanic annulus. Following elevation of this skin flap, the skin covering the external auditory canal is circularly cut using micro-scissors just medial to the bony overhang until the tympanosquamous suture is reached (anterior limb) [5]. The posterior limb of the circular incision is initiated by cutting through the elevated meatal skin [6]. The posterior and anterior limbs of the circular incision are connected along the superior canal wall. The circular incision is completed inferiorly [7]. Once the third incision is completed, one can elevate the antero-inferior pedicled skin flap out of the bony external auditory canal using a Rosen microraspatory and Williger raspatory [8], thus revealing the entire meatal skin flap [9]. One can fixate this meatal skin flap outside the operation field using spreaders. If necessary, the flap can be thinned sparing the epithelial layer. Next, the external bony canal is enlarged exposing the entire tympanic annulus using sharp and diamond burrs, eliminating all bony overhangs, particularly anterior and inferior using the tympanic annulus as a margin [10]. One should take care not to open any of the mastoid air cells or temporo-mandibular joint. When a bluish hue is observed, the bone overlying the temporo-mandibular joint is maximally thinned. Care should be taken not to damage the skin cuff near the tympanic annulus [11][12].

At the end of the procedure both skin flaps are repositioned. To allow adequate alignment of skin within the new bony ear canal, the most medial skin flap (the skin cuff near the tympanic annulus) is incised partially at several locations [13]. The lateral skin flap is repositioned in a clockwise manner. One should make sure that the epithelial side of the skin flap is facing the lumen of the OEAC. Part of the OEAC canal will not be covered by skin as a result of its increased diameter [14]. After repositioning both skin flaps, antibiotic gauzes are applied for fixation [15].

Postoperatively, special care should be taken not to displace the skin flaps as antibiotic gauzes are changed every other week until complete re-epithelisation of the OEAC has occurred.

Statistical analysis

Statistical analysis was carried out using SPSS 16.0.2 (Chicago, IL, USA). Data are expressed as number (%) and mean (SD). Paired-samples T-tests and one-way ANOVA tests were performed to check for significant changes from baseline in pure tone audiometry (both air and bone conduction thresholds, at 1,2 and 4 kHz), the occurrence of a dry ear post-operatively, time to heal (i.e. time to complete re-epithelialization) and the influence of smoking. *P* values of less than 0.05 were considered statistically significant.

RESULTS

Patients

Based on our retrospective chart analysis, 193 ears of 174 individuals (87 females and 87 males) were included. The average age at the time of surgery was 34.5 years (range 3-79). Of the included individuals, forty-one patients (46 ears) smoked at the time of surgery (23.6%) and seven (9 ears) patients (4.0%) stopped smoking recently (table 1). Although most procedures were performed unilaterally (153 procedures), some canalplasty procedures were performed bilaterally (20 cases, 40 ears). Ninety-four procedures were performed on the right ear, 99 procedures on the left ear. Follow-up of individuals ranged from 2 to 100 months with a mean of 45 months. In 78 cases (41.4%), prior otosurgery (not being canalplasty) was performed on the side of intervention. In 47 cases (24.4%), canalplasty was performed as a standalone procedure, in 146 cases (75.6%), canalplasty was performed as part of more extensive otosurgery (myringoplasty, middle ear inspection with or without ossicular chain reconstruction, cholesteatoma surgery).

Indications for surgery

Indications for surgery are shown in table 1. The most common indication for surgery was exposure of the tympanic membrane (130 cases, 67.4%, a.o. in cholesteatoma surgery, myringoplasty and middle ear inspection). Chronic external otitis in patients with or without exostoses, not responding to conservative treatment, were the second (34 ears, 17.6%) and third (15 ears, 7.8%) largest groups of indications. In these cases, as well as in those individuals suffering from acquired medical canal fibrosis (13 ears, 6.7%), canalplasty was performed as a standalone procedure.

Presenting symptoms

Retrospective chart analysis showed hearing loss (174 ears, 90.2%) to be the main pre-operative symptom closely followed by a draining ear (139, 72.0%). Lack of resistance to water was another important symptom.

Complications

Complications occurred in 54 (28.0%) of 193 interventions. In 10 individuals (5.2%) two separate side effects occurred and in 5 individuals (2.6%) three separate side effects occurred. The complications are shown in table 2. Temporomandibular pain, post-operative bleeding and/or hematoma and post-operative wound infection were regarded as transient and minor unwanted side effects and occurred 24 times (32.4% of all unwanted side effects, 12.4% of all cases). All of these unwanted side effects resolved within 6 months with adequate care. Rarely complications were persistent. In some patients, a perforation of the tympanic membrane (8

Table 1. Baseline characteristics of all operated ears (n = 193)

Baseline characteristics	
Male gender, n (%)	94 (48.7%)
Right ear, n (%)	94 (48.7%)
Age (y), mean (SD)	34.4 (19.0)
Indications for surgery, n (%):	
exposure of tympanic membrane	130 (67.4%)
chronic external otitis	34 (17.6%)
exostoses	15 (7.8%)
acquired external auditory canal stenosis	13 (6.7%)
cholesteatoma of the external auditory canal	1 (0.5%)
Type of surgery, n (%)	
canalplasty ± meatoplasty	47 (24.4%)
canalplasty + myringoplasty ± meatoplasty	41 (21.2%)
canalplasty + mastoid surgery ± meatoplasty	25 (13.0%)
canalplasty + mastoid surgery + myringoplasty ± meatoplasty	80 (41.5%)
Time to heal (wk), mean (SD)	6.7 (3.3)
Smoking habits, n (%):	
never smoked	122 (63.2%)
history of smoking	9 (4.7%)
current smoker	46 (23.8%)
unknown	16 (8.3%)
Pre-operative pure tone bone conduction levels, mean (SD):	
1 kHz	9.0 (14.5)
2 kHz	18.4 (16.3)
4 kHz	19.4 (18.4)
Post-operative pure tone bone conduction levels, mean (SD):	
1 kHz	6.9 (14.3)
2 kHz	17.1 (17.6)
4 kHz	20.6 (19.3)
Pre-operative pure tone air conduction levels, mean (SD):	
1 kHz	38.7 (22.8)
2 kHz	37.3 (22.9)
4 kHz	46.3 (25.1)
Post-operative pure tone air conduction levels, mean (SD):	
1 kHz	33.4 (23.0)
2 kHz	31.8 (24.1)
4 kHz	49.0 (24.1)
Occurrence of unwanted side effects/complications	54 (28.0%)

Table 2. complications and persistence of complaints in the operated ears (n = 70)

Persistance of complaints and/or complications (n = 70)	**n**
Persistance of complaints:	
recurrent external otitis	10
persistent perforation of tympanic membrane	6
Minor complications:	
post-operative wound infection	12
temporomandibular dysfunction complaints	9
post-operative bleeding and/or hematoma	3
Major complications:	
(partial) stenosis of external auditory canal	7
exposure of temporomandibular joint	6
partial necrosis of skin flap	4
cholesteatoma of the external auditory canal	3
exposure of mastoid air cells	3
non-closure of skin defect	2
free-floating meatal skin flap	2
perforation of tympanic membrane	2
sensorineural hearing loss	1

times of which 6 times a persistent perforation after myringoplasty), exposure of mastoid air cells (3 times), exposure of the temporomandibular joint (6 times) and/or sensorineural hearing loss (defined as a decrease of PTA (bone conduction) of more than 10 dB) (1 time) occurred, all complications that should have been avoided. Fortunately, no long-term sequelae of most of these complications were observed except the one case in which sensorineural hearing loss was demonstrated. Therefore, this complications should be considered a major complication. Recurrence or persistence of symptoms was observed as well. Persistence of recurrent external otitis was observed in 10 individuals. In only one patient (2 ears) of these 10 individuals, the original severity of the complaints persisted post-surgery. One case with recurrent external otitis had a partial stenosis as well. Four cases had cholesteatoma surgery and the recurrence of otitis was due to recurrence of cholesteatoma.

Revision canalplasty

Revision canalplasty was needed in eight cases (4.1%). Revision surgery for reasons other than canalplasty (for example planned second look operations after cholesteatoma surgery) are not considered in this manuscript.

Hearing results

The wide range in pre-operative pure tone audiometry results, which is caused by the nature of the underlying disease and which determined the primary indication for surgery, makes sensible comparison on the basis of pure tone audiometry difficult. Despite this wide range, a few general findings can be mentioned. Complete audiometric follow-up was available in 76.7% of all cases (n = 148). Except for a significant improvement (p = 0.015) in pure tone bone conduction levels at 1 kHz (mean 1.8 dB, SD 9.3 dB), no significant changes in pure tone bone conduction levels were observed (table 1). Although pure tone air conduction levels are more difficult to interpret, a significant improvement (p = 0.000) in pure tone air conduction levels were observed at 1 kHz (mean 6.5 dB, SD 17.4 dB) and 2 kHz (mean 7.0 dB, SD 18.8 dB). At 4 kHz a slight, non-significant deterioration in pure tone air conduction levels was observed (mean 2.2 dB, SD 19.9 dB).

Dry ear

Prior to surgery, otorrhea was observed in 139 ears (73.5%). Post- surgery, recurrent external otitis (6 ears) or otorrhea for other reasons (4 ears) was observed in 10 ears (5.2%) only (p = 0.000).

Re-epithelialization of the external auditory canal

Complete re-epithelisation of the external auditory canal took approximately 6.7 weeks (range 3 to 20 weeks). Within 8 weeks, complete re-epithelisation was observed in 83.7% of cases. This percentage rose to 94.2% within 12 weeks. In smokers complete re-epithelialization of the external auditory canal took approximately 7.2 weeks (range 3 to 20 weeks), a non-significant increase in time to heal when compared to non-smokers (approximately 6.5 weeks).

Mini-Thiersch grafts were used in eight cases, all in patients with acquired medical canal fibrosis (absence of medial meatal skin flap). In this group of patients, complete re-epithelialization of the external auditory canal took 10.9 weeks (range 7 to 20 weeks) on average.

DISCUSSION

We advocate the use of the technique for canalplasty as described in this manuscript as it allows one to exploit an almost standard surgical solution to a wide variety of pathology of the OEAC. Such standardisation will, to our opinion, result in optimal outcomes for patients as it results in steep learning curves. As the surgical technique was similar in all of our patients, we feel that an overall analysis of our technique is allowed despite the heterogeneity in indications involved. The use of our technique allows maximal preservation of the delicate epithelial lining of the OEAC, rendering the use of skin grafts less likely or not necessary at all, a feature that is regarded as very important by many authors (8). Similar to our results, Parisier et al (6) demonstrated that up to 50% of the surface area of skin of the external auditory canal can regenerate without the use of skin grafts. We found that grafts were only necessary if the medial skin flap was absent, as is often the case in AMCF. Another advantage of our technique is the ease with which subcutaneous fibrosis of the skin flap (which is normally present in prolonged inflamed ears) can be removed if necessary. As our technique allows drilling movements to be made in a circular fashion without exerting direct lateral to medial force, a smooth external auditory canal can be created. At the same time, the chance of manipulating the ear drum and/or ossicular chain is lowered as one can work from lateral to medial, thus exposing the ear drum in a gradual manner. Additional protection of the ear drum and/or ossicular chain is provided by the medial skin flap, which is positioned on the ear drum during the procedure as is described elsewhere in this manuscript.

Clearly, the indication for canalplasty should not be regarded lightly as complication rates up to 36% have been reported (5) Fortunately, most complications can be considered as minor, requiring no revision surgery and/or leaving no residual disability. Complications occurred in 28.0% of our cases. Some remarks should be made. First, a considerable proportion of our patients had prior surgery on the affected side. It is generally accepted that these patients are more prone to complications due to altered anatomy and/or extensive fibrosis. Second, canalplasty was performed as a part of more extensive surgery in quite some cases, possibly resulting in contamination of complication rates due to the more extensive nature of the entire intervention. Third, complication rates are disease dependant (e.g. comparing complications rates in AMCF patients (31%) with exostosis patients (13%) clearly favours the exostosis group. We decided to mention recurrence of complaints when discussing our complication rate, but one can debate whether recurrence of complaints is a complication indeed. Although an important outcome measure, we feel that recurrence of complaints is not a true complication.

Hearing levels are commonly reported as the primary outcome measure in most studies. Unfortunately, a great variety of methods for describing hearing results is used. In our series, a possible improvement in pure tone audiometry (PTA) for some indications is confounded by the heterogeneity of indications included in this study, rendering a viable comparison difficult. But importantly, we did not observe a worsening in bone conduction levels except in one patient. And, in contrary to Vasama (9) and Sanna (1), we did not observe a deterioration in PTA in general. Comparison of our results to those of authors who describe their hearing results in air bone gap (ABG) closure (5;10;11) is difficult due to the aforementioned reasons.

We feel that time to complete re-epithelisation and the occurrence of a dry ear post-operatively should be primary outcome measures of a canalplasty procedure. As discussed previously, we stress the importance of very meticulous post-operative care as re-epithelization is paramount for adequate healing. In our series, the time needed for complete re-epithelisation was 6.7 weeks on average. This time is comparable with three other reports (all without grafting) mentioning healing time (8;12-15) Considering subgroups, we can state that the inflammatory status of the external auditory canal does not seem to influence healing time as healing times are similar in several subgroups of patients (e.g. myringoplasty, chronic external otitis etc.). Perhaps parameters such as smoking and the amount of surface needed to re-epithelialize (as is the case in AMCF) are of more influence. We also showed the significant reduction of otorrhoea which resulted in symptom free ears.

Our study is retrospective in nature and therefore subject to various limitations. First of all, some data were missing resulting in the loss of valid entries. Second, no control group was included. Thus, the added value of canalplasty over, for example, pharmaceutical therapy was not possible. Third, follow-up in some patients (n = 12, 5%) was very short (less than 6 months), perhaps creating a slight positive bias. And finally, as most patients suffered from prolonged disease and were often operated prior to our intervention, a negative selection bias may be present. Although the heterogeneity of indications for canalplasty may conceal some disease specific results, we still feel that the results we describe are representative for the technique we used.

CONCLUSION

The presented technique and proposed variations enables one to use our surgical technique for canalplasty for a wide variety of indications thereby demonstrating its added value in otosurgery. We showed that skin grafts are rarely necessary and that, by using our technique, the epithelial lining is maximally preserved. This retrospective study shows that the canalplasty technique used in our centre is safe and has favourable results.

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Canalplasty in revision radical cavity surgery using a meatal t- skin flap technique

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2.3

ABSTRACT

Background

In literature no technique of canalplasty in revision radical cavity surgery has been reported. Yet, inadequate canalplasty is a known contributing factor in troublesome cavities and should be addressed when necessary.

Methods

Retrospective cohort analysis of patients undergoing revision radical cavity surgery in which a canalplasty was indicated. All received a canalplasty using a skin flap technique which enables maximal preservation of the delicate epithelial lining of the osseous external auditory canal (OEAC).

Results

The described canalplasty technique resulted in quick re-epithelialization (median 8.9 weeks) and dry ears. Only one minor complication was seen.

Conclusions

We describe a canalplasty technique that can be used in revision radical cavity surgery and show it is safe and effective. This technique can easily be combined with radical cavity obliteration.

INTRODUCTION

Open cavity mastoidectomy is a commonly performed operation for chronic otitis media with or without cholesteatoma. Radical cavities , however regularly remain troublesome cavities (1) resulting in clinician dependence as the self cleansing mechanism of the osseous external auditory canal (OEAC) is disrupted (2,3). A multifactorial etiology for these troublesome cavities has been mentioned by many authors and revision surgery has been shown to be very effective (4-7).

Well known etiologies of troublesome cavities inlcude a high facial ridge, an inadequate meatoplasty and persistent cell tracts. Less frequently, an inadequate canalplasty is mentioned. Bercin et al demonstrated that an inadequate canalpasty is present in 67% of their troublesome cavities (6). When adequate, a canalplasty succesfully removes the excess of bone of the tympanic bone segment of the OEAC resulting in a straight and wide OEAC, thereby facilitating the postoperative care and the self cleansing property of the OEAC (7). Maximal preservation of the epithelial lining of the OEAC will facilitate fast healing. In addition, the unique properties of the epithelium of the OEAC will be preserved (8). In radical cavities, three regions of the OEAC which should be considered for revision surgery can be identified (see figure 1E, hatched area): the anterior curvature, the pretympanic recess and the epitympanic remnant of the posterior OEAC. In this paper, we propose a novel and simple method for canalplasty in revision radical cavity surgery using a T-flap meatal skin flap. The procedure in our series was performed during reconstructive surgery of the posterior canal wall and subsequent obliteration of the mastoid.

MATERIALS AND METHODS

Patients and statistics

We retrospectively analyzed the medical records of 46 consecutive individuals with a draining radical cavity undergoing revision surgery including a canalplasty procedure. All operations were performed by the first author of the manuscript in the Academic Medical Center, Amsterdam, the Netherlands, a tertiary center for otorhinolaryngology. Patient characteristics, time tot heal (i.e. time to complete epithelialization), complication rate, type of complications and success rate (i.e. a dry and waterresistant ear) were recorded. *Mann-Whitney U tests* were performed to check for significant changes from baseline in time to heal in relation to smoking habits and the frequency of prior surgery. We decided to use a non-parametric test as sub analysis of data was performed on unequal size low sample groups. P values of less than 0.05 were considered statistically significant. As this study was a retrospective cohort analysis of regular care no IRB was necessary as in the Netherlands such research does not need ethical committee review by Dutch law as long as the presented data is not reducible to patients. Informed consent was obtained in all cases.

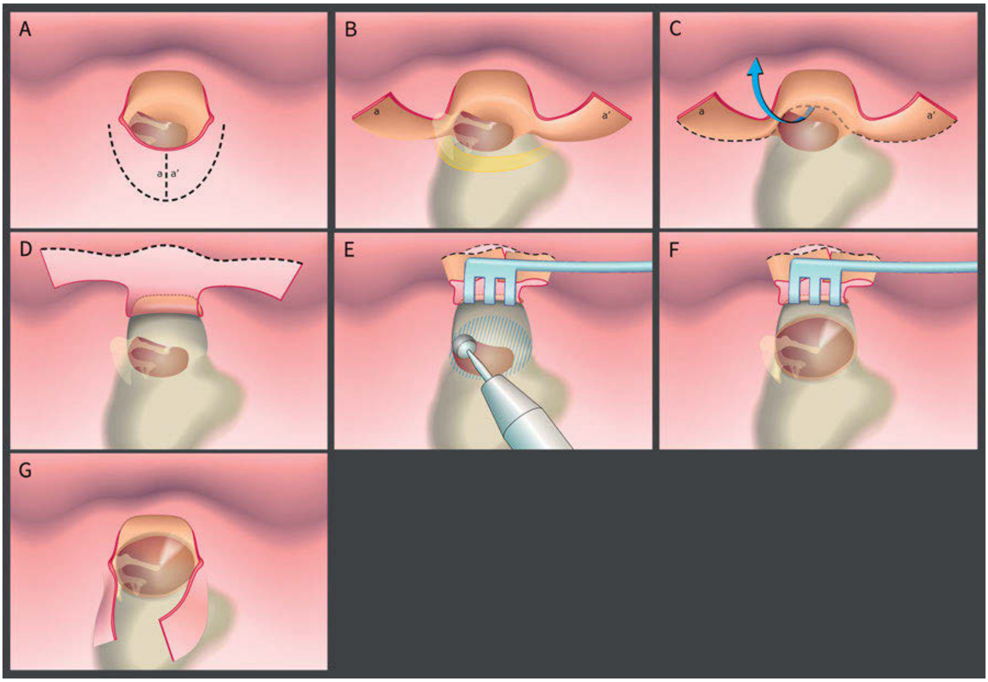

Figure 1. T-Flap technique, step by step. A: Canal exposure via a lateral incision. The incision between a and a' allows inspection of the epithelial lining of the cavity and the preparation of two skin flaps. B: Preparation of skin flap a and a'. C: A third – anterior – incision, just lateral to the tympanic membrane defines the medial border of the T-flap. D: Using sharp and blunt dissection, the flap is created over the mastoid cavity and the entire tympanic bone, revealing the T-shape. E and F: A medial circular skin flap is created, allowing the removal of bone excess in all problem areas (hatched area). G: The medial skin flap is repositioned, thereby allowing adequate alignment of skin within the newly formed bony ear canal or newly formed cavity.

Surgical technique

All canalplasty procedures were performed in combination with the obliteration of the mastoid bowl and reconstruction of the posterior canal wall using cartilage, hydroxyapatite and a midtemporal flap (which is a slightly modified technique as was described earlier by Yung et al (9)). All steps are described as if a right ear is involved.

Briefly, one starts with a post-aural incision and the creation of a periosteal flap, thus allowing external auditory canal exposure via a lateral incision [A]. Another incision allows inspection of the epithelial lining of the cavity and the preparation of two skin flaps [A]. The quality of the skin in a radical cavity is variable. If the cavity is mainly mucosal, inevitably the skin flaps will become shorter as one should take care not to include the mucosal lining in the skin flaps. Next, one could chose to remove all remaining cell tracts of the mastoid first or one could decide to proceed directly with a third incision which is positioned anteriorly and just lateral of the tympanic membrane remnant and facial nerve and defines the medial border of the T-flap [C]. Preferably, good exposure of and direct view on the remnant of the tympanic membrane and the suspected position of the facial nerve is realised. Using sharp dissection, flaps are created in area's where the skin is not in direct contact with bone. Blunt dissection is easily performed in areas where skin is in direct contact with a bony surface. Both inferior and superior sides of the flap are prepared [B]. Then, using Rosen and Williger raspatories, the anterior section of the flap is prepared until the entire tympanic bone is exposed and the T-shape is revealed [D]. Next, this anteriorly peduncalated flap is fixated outside the operation field, thereby achieving maximum skin preservation [E]. Finally, a medial circular skin flap is created using a Rosen raspatory. Now, one can remove the excess of bone in all problem areas (hatched area) using the burr in a circular fashion [F]. One should take care not to open the mandibular joint and to sufficiently lower the ear canal to expose the entire tympanic annulus. After enlargment of the OEAC, the medial skin flap is repositioned, thereby allowing adequate alignment of skin within the new bony ear canal [G]. Several partial incisions can be made or in some cases the tympanic membrane can be reconstructed using fascia.

Although in our case series, the canalplasty procedure as described above was performed in combination with reconstruction of the posterior wall with cartilage and a midtemporal flap and obliteration of the mastoid cavity with hydroxyapatite, one can use the technique in combination with many other procedures such as partial obliteration of a radical cavity with a Palva flap or bone pate or revision radical cavity surgery. Whichever procedure is chosen, after completing the work in the mastoid cavity, the T-flap is to be repositioned [G]. Using sponges and gauzes, its delicate skin is kept in place. Sometimes it is needed to excise excess skin as the resulting cavity (i.e. canal) may be much smaller in size. Postoperatively, special care should be taken not to displace the skin flaps as antibiotic gauzes are changed every fortnight until complete re-epithelization of the OEAC has occurred.

RESULTS

Between 2008 and 2013, 46 patients (17 females and 29 males; mean age 48,1 years), a revision radical cavity surgery procedure was performed in combination with a canalplasty procedure. Table 1 gives a comprehensive overview of baseline characteristics. Of these individuals, 12 patients smoked at the time of surgery (26%) and 1 patient suffered from diabetes (2%). In 12 cases (26%), prior revision radical cavity surgery had been performed on the side of intervention not resulting in a dry cavity. In 3 of these 12 cases (7%), only a meatoplasty procedure was performed. On the affected side, prior otologic surgery was performed once in 18 cases (39% primary radical cavity), twice in 10 cases ,three times in 4 cases, four times in 7 cases and five, six and seven times in 2 cases each. In 59% of the cases, radicalization was secondary to multiple canal wall up attempts. Follow-up of individuals ranged from 3 to 56 months with a mean of 18 months. Median re-epithelialization of the OEAC lasted 8.9 weeks (range 3.6 to 25.6 weeks). Smoking had no significant effect (p=0,11) on the time to complete re-epithelialization. No

Table 1. Baseline characteristics of all operated patients (n = 46)

Baseline characteristics			
Male gender, n (%)	29 (63%)		
Smokers, n (%)	12 (26%)		
Diabetes	1(2%)		
	Mean	**SD**	**Range**
Age (y)	48,1	17,7	13,6 - 86,1
Time to heal (wk)	8,6	4,6	3,6 - 25,6
amount of prior operations	2	2	1 - 9
Follow up (mos)	17,9	12,9	3 - 56

significant difference in healing time was observed between those individuals who underwent prior revision radical cavity surgery and those undergoing a first attempt (*p*=0,29).

In our series, only one complication related to the T-flap (formation of granulation tissue) was seen in the healing period. This complication was succesfully treated with local removal and application of polycresulen. Five patients in our series underwent revision surgery afterwards, all related to middle ear problems: a protruding prothesis (one case), disappointing hearing result (three cases) and a persistent tympanic membrane perforation (one case). A dry, waterresistant ear was reached in all cases (in the aforementioned five cases not primarily, but after revision surgery).

DISCUSSION

Inadequate canalplasty during a canal wall down procedure has been shown to contribute to a draining cavity. Yet, to our knowledge, only few reports and no description of the surgical technique and its results have been published. We suggest the evaluation of the shape of the OEAC when contemplating revision radical cavity surgery and advocate its use in revision surgery as it allows the complete exposure of the entire OEAC, thereby facilitating the creation of a smooth OEAC as drilling movements can be made in a circular fashion without exerting direct lateral to medial force. Furthermore maximal preservation of the delicate epithelial lining of the OEAC is allowed, rendering the use of skin grafts less likely or not necessary at all. Another advantage is the ease with which subcutaneous fibrosis (which is regularly present in prolonged inflamed ears) can be removed if necessary.

Complete re-epithelization lasted approximately two months, a result comparable to another report studying revision radical cavity surgery (10). When compared to regular canalplasty, the time to complete re-epithelialisation is however prolonged (8). In concordance with our earlier report on canalplasty (8) smoking did not significantly influence the time to heal. The number of prior procedures did not influence results.

Complications related to the canalplasty procedure occurred in 2% of cases. Revison surgery was indicated in 11% of cases however. One could argue that in these 11% of cases, a complication occurred as revision surgery was indicated. The need for revision surgery was however not related to the canalplasty procedure in only one case. In all other cases, the epithelial lining healed without problems.

2.3

In all cases a dry ear and water resistent was attained Although the results of this study do not directly proof that an adequately performed canalplasty would result in a dry ear, at least it describes a surgical technique that provides good accessibility of an area that is thought to be involved with ongoing infection in chronically discharging ears (pretympanic sulcus) and that enhances easier cleaning in outpatient setting. If the cause of chronic discharge is thought to be located in the radical mastoid cavity itself, obliteration of the cavity is a wise surgical step in many cases. Different obliteration and canal wall reconstruction techniques are available and discussion of the pros and cons each single technique are outside the scope of this article. Reconstructing the posterior canal wall without adequate canalplasty however, may result in an undesirably narrow canal, thereby exchanging one problem for another. This surgical technique should therefore be thought of whilst performing a reconstruction of the canal wall. Our study is retrospective and therefore subject to limitations. First, no control group was included. Thus, the added value of canalplasty over, for example, revision radical cavity surgery without canalplasty was not possible. Second, follow-up in some patients (n=5) was very short (less than 6 months), perhaps creating a slight positive bias. Even so, the represented results do show the added value of a canalplasty with a T-flap meatal skin flap in revision radical cavity surgery.

CONCLUSION

This retrospective series shows that the described technique for canalplasty using a T-flap in revision radical surgery is of added value and contributes to favourable end results in otosurgery.

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3

Shape of the OEAC

The shape of the osseous external auditory canal and its relationship to chronic external otitis

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3.1

ABSTRACT

Background

In literature and based on clinical observations, the shape of the osseous external auditory canal (OEAC) has often been suggested to be an etiological factor in chronic otitis externa (COE). However, to date no evidence has been presented to confirm this correlation. The aim of this study was to see whether evidence of such a correlation exists and if so, what shape of the OEAC is related to COE.

Methods

Using CT scans of two groups of patients (with and without COE), a novel and easy to use method was introduced to measure two dimensions of the OEAC: the pretympanic recess (the depth,(DPTR) and anterior curvature (ACPTR)). In addition, a descriptive classification of the entire OAEC was introduced.

Results

The proposed method was demonstrated to be useful as excellent inter-observer agreements were found (r=0,89). No significant differences in the descriptive classifications of the OEAC were observed between COE and the non-COE patients. The DPTR was significantly deeper in COE patients. For the ACPTR, no significant differences were observed.

Conclusions

Based on a new method of determining the DPTR, we demonstrate that the DPTR is significantly deeper in COE patients and that the shape of the OEAC is thus of importance in the pathogenesis of COE.

INTRODUCTION

Otitis externa (OE), or swimmer's ear, is very common. In some individuals, the acute form of OE leads to chronic otitis externa (COE). This form is defined as a single episode lasting longer than four weeks or more than four episodes of OE in one year (1). It is estimated to affect 3% of the population (2,3) and has a proven negative impact on the quality of life of those inflicted (4). The shape of the osseous external auditory canal (OEAC) has often been suggested in literature to be an etiological factor in (C)OE (3,5-9). Although several classifications of the shape of the OEAC have been proposed (10,11) no attempt to correlate a certain classification to pathology has been published to date. Clinical observations suggest that certain shapes are likely to be involved in the development of a chronic inflammation as they hamper proper cleaning of the OEAC. We propose that the curvature of the OEAC, both anteriorly and inferiorly , are possible causes of this inability of (self) cleansing. Another hypothesis could be that both anterior and inferior curvatures lead to intertriginous eczema as sharper angles enable skin-to-skin contact when inflamed, thus perpetuating the inflammation and leading to chronic disease. The region of the anterior and inferior curvatures of the OEAC is called the pretympanic recess (PTR) and is located just before the tympanic membrane [Figure 1]. In literature, the nomenclature of this area varies and may bear names such as pretympanic sulcus (12-14), tympanic sulcus (15), pretympanic sinus (16-18) and inferior tympanic recess (19) Although the shape of the OEAC has been investigated before, no attempt was made to correlate the shape of the OEAC to pathology. The objective of this study was therefore twofold. First, we wanted to develop an 'easy to use' method in order to determine the dimensions of the PTR. Second, we wanted to investigate if and how the shape of the OEAC is related to COE.

MATERIAL AND METHODS

Participants

Retrospective analysis of high-resolution temporal bone CT images of two cohorts of adult ENT patients was performed. One cohort consisted of 42 patients (81 ears; 3 ears were excluded because of prior radicalisation) with COE with an indication for canalplasty and a second, control group consisted of 100 randomly selected patients (200 ears) who had received a cochlear implant (CI) in our centre and had no indication for canalplasty. Within our centre all COE cases are primarily treated conservatively. If conservative treatment fails all these cases are indicated for surgery regardless of the shape of the OEAC. Prior to canalplasty or CI-surgery, all patients underwent a high-resolution temporal bone CT scan as part of their pre-operative work-up. Before inclusion in this study, all patients in the CI group were checked for prior symptoms of (chronic) ear disease. If present, individuals were excluded from this study.

Figure 1. The dimensions of the pretympanic recess (Depth and Anterior Curvature) depicted in coronal and axial plane. The DPTR is measured in the axial plane and the ACPTR is measured in the coronal plane. First slide is determined by the first contact made of the bony OEAC (*) and the last slide where the space of the PTR is totally closed (#) (arrowhead: area in front of drum). TM: tympanic membrane MJ: mandibular joint

Imaging of the osseous external auditory canal

All CT-scans were obtained using 125 mAs and 120 kV multi-detector row CT scanners (Philips Mx8000 and Philips Brilliance 64). Images were taken parallel to the orbitomeatal line. The thickness of the slides was 0.55 mm. and the interval thickness was 0 mm. The window level was 600 HU and the window width was 3200 HU.

Measurement of the PTR dimensions

The depth of the PTR (DPTR) was measured in the axial plane. First, the first slide in which the inferior part of the OEAC was entirely visible was identified. Next, the number of slides inferiorly of this point was counted until the PTR was not visible anymore (i.e. a complete closure of the area in front of the tympanic membrane, [Figure 1]). Then, the number of slides was multiplied by 0.55 mm (thickness of one slide), resulting in the DPTR.

The anterior curvature of the PTR (ACPTR) was measured in the coronal plane and was determinded in an almost similar way to the DPTR. Using the first slide in which the anterior part of the OEAC was completely visible, the starting point of the ACPTR was determined. Next, the number of slides was counted until the most anterior point next to the drum was reached [Figure 1]. Finally, the number of slides was multiplied by 0.55 mm, resulting in the ACPTR.

Data were evaluated in two separate ways. First, both ears of our patients were evaluated as belonging either to the normal group or to the COE group. Left and right ears were evaluated separately. Secondly, only affected ears of the COE group were studied. In bilateral cases, one of two the two COE ears (e.g. left or right) was used. In these cases, the ears were randomised based on the date of birth (1-15 left ear and 16-31 right ear). A similar way of randomisation was performed in the control group.

Validation of the measurement method

In order to assess and evaluate the method of measuring the DPTR and ACPTR, measurements of the DPTR and ACPTR were performed by two independent observers. In this validation session, only CT scans of the CI (control) group were used. In this way, the interobserver agreement of this technique could be determined, thus enabling us to identify whether the suggested technique produced reliable results.

Descriptive evaluation of the shape of the OE AC

In addition to the DPTR and the ACPTR, we evaluated various shapes of the OEAC shapes using a descriptive method developed by Virapongse et al. These shapes are determined in the axial plane (20). Using forced choice, the shape of the OEAC was determined after reviewing all CT images. The various shapes of the OEAC were numbered: 1: uniform, 2: slight flaring, 3: narrowing from posterior wall, 4: uniform convex, 5 narrowing of both walls lateral to drum, 6: narrowing at drum 7: uniform angulated and 8: uniform convex angulated.

Statistical analysis

Statistical analysis was carried out using SPSS 16.0.2 (Chicago, IL, USA). Data are expressed as number (%) and mean (SD). A Pearson product-moment correlation coefficient was computed to assess the inter-observer agreement between the two independent observers regarding DPTR and the ACPTR measurements. A Bland-Altmann plot was made to investigate the existence of a fixed inter-observer bias or systematic error between our measurements. A Pearson product-moment correlation coefficient was determined to assess a possible association between DPTR and ACPTR and the left and right ear of the participants. Rho values were interpreted using the arbitrary but common scale of inter class comparisons values: 0.00 = no agreement, 0.01 to 0.20 = slight agreement, 0.21 to 0.40 = fair agreement, 0.41 to 0.60 = moderate agreement, 0.61 to 0.80 = substantial agreement, 0.81 to 0.99 = excellent agreement and 1.00 = perfect agreement. Independent T-tests were performed to check for significant changes between DPTR and the ACPTR of the OEAC between males and females and control patients and COE patients. Crosstabs and a Chi-square analyses were used to identify differences in the distribution of the various Virapongse shapes classified. *P* values of less than 0.05 were considered statistically significant.

RESULTS

Study population

Patient characteristics are depicted in [Table 1]. The mean age of the participants was 52.7 years (range 18 – 85 years, 41% males) in the COE group and 57.6 years (range 18- 82, 48% males) in the control group. In seven patients in the COE group exostoses were observed. In one of these seven patients, bilateral COE was present. In 9 cases bilateral COE was present. Of the included CT-scans, both ears of the patient were examined. In the COE-group, 3 right ears and 1 left ear were excluded because of prior surgery (considerably changing the anatomy of the OEAC of these ears). As no CT scans were excluded in the control group, a total of 281 ears were evaluated.

Table 1. Characteristics of the participants.

	Normal	COE
N=	100	42
Age (median)	57.6	52.7
Female-male ratio	59:41	22:20
Right sided disease	-	13
Left sided disease	-	21
Both sided disease	-	9
Exostosis	-	7 (1 bilat)

Validation of the measurements

An excellent agreement between the independent observers regarding both DPTR (r= 0,89, p < 0.001) and the ACPTR (r = 0.89, p < 0.001) was observed. Results are summarized in scatterplots [Figure 2ab]. Regarding the accuracy of our measurements, an exact inter-observer agreement was present in 25% of our measurements. Additional analysis, using a Bland Altman plot, demonstrated a systematic error between both observers of approximately one slide . Deducting 1 slide from one of the observers, a perfect inter-observer agreement of 42% was observed.

3.1

A clear correlation between left and right ears was observed in most of the participants regarding DPTR (r= 0,60, p < 0.001) and ACPTR (r= 0.72 , p< 0.001). No correlation was seen between the DPTR and the ACPTR (r= 0,17, p= 0.02).

Difference in DPTR and ACPTR between normal and COE groups

The DPTR ranged between 0.55 and 6.6 mm in the COE group. In the control group, values ranged between 0 and 6.05 mm. The DPTR in the COE group was 3.06 ± 1.37 mm for the right

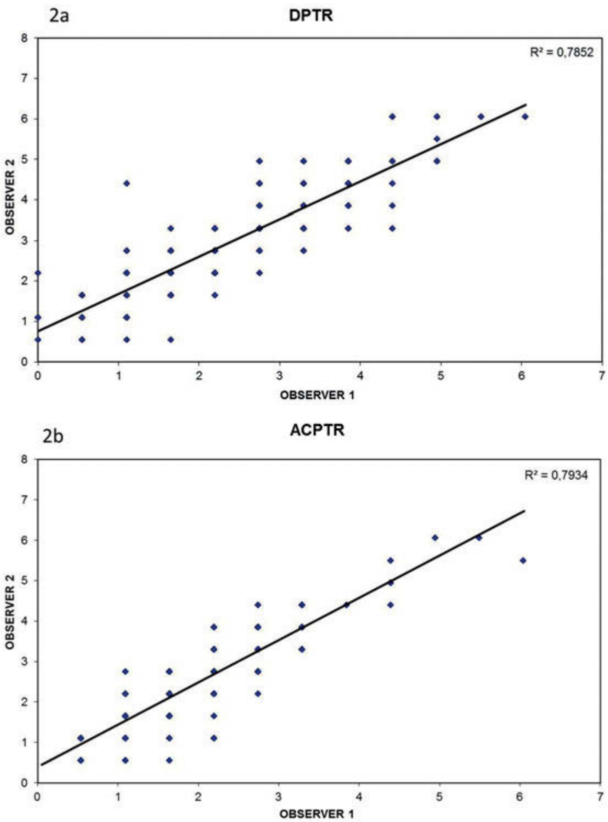

Figure 2. Interobserver agreement of DPTR and ACPTR measurements.

and 3.25 ± 1.36 mm for the left ear. In the control group, it was 2.32 ± 1.22 mm for the right and 2.35 ± 1.31 mm for the left ear [Figure 3A]. There was a significant difference (AD p=0.002, AS p=0.000) in DPTR between the two groups.

The ACPTR was found not to be significantly different between both groups (AD p=0.743, AS p=0.954). In the COE-group it was 2.20 ± 0.88 mm for the right and 2.17 ± 1.04 mm for the left ear. In the control group, the ACPTR was 2.15 ± 0.91 mm for the right and 2.18 ± 0.93 mm for the left ear. In [Figure 3A], the mean of the DPTR and ACPTR of both ears is depicted for both groups of patients. No significant differences between male and female participants were observed, both overall and in subgroup analysis (p values all > 0,3),

Using only affected ears in comparison to control ears as discussed above, similar results were observed [Figure 3B]. Ranges in both groups were similar. No significant changes in average and standard deviation of DPTR and ACPTR were observed using this approach. Significant differences remained present between the COE and control group regarding DPTR (p=0.002) . No significant differences were observed regarding the ACPTR (p=0.93).

Descriptive evaluation of the OEAC shape

The distribution of the various shapes of the OEAC is shown in [Figure 4]. Shapes 1 and 7 were found to be most common (about 50% of all ears). Shapes 4 and 6 seem to be not or hardly present at all. No significant differences in the distribution of the various shapes of the OEAC were observed using chi-square analysis (p all > 0,2).

DISCUSSION

In this study we confirm, as was previously suggested by many authors (3;5-9), that the shape of the external auditory canal (OEAC) is an important contributing factor in the development of COE. It has been proposed (8) that the entire shape of the OEAC plays a role within COE. We have showed that depth of the pretympanic recess (DPTR) is of relevance. Yet, the ACPTR was not found to be relevant suggesting that the hypothesis that the entire shape is relevant is not fully supported. Still other dimensions could also be of relevance within COE but these are beyond the scope of this study. In this study we tried to identify the ideal descriptive technique of evaluating the shape of the OEAC in literature. We felt that the technique and shapes described by Virapongse were best as this method is applicable in daily practice. Using a forced choice method, two independent evaluators showed a reasonable level of consistency in the evaluation of the OEAC shapes. Unfortunately none of the shapes correlated with the development of COE.

Our hypothesis, that the PTR is the most important area of the OEAC in relationship to the presence of absence of COE, required a novel method of determining the dimensions of this area. Our clinical impression was that both depth (DPTR) and anterior curvature (ACPTR) were of importance. The fact that the ACPTR is not significantly different between COE patients and controls was unexpected, as this curvature is likely to impede proper cleaning of the OEAC by ENT surgeons. Apparently though, it does not impede the cleaning of the OEAC itself. The only

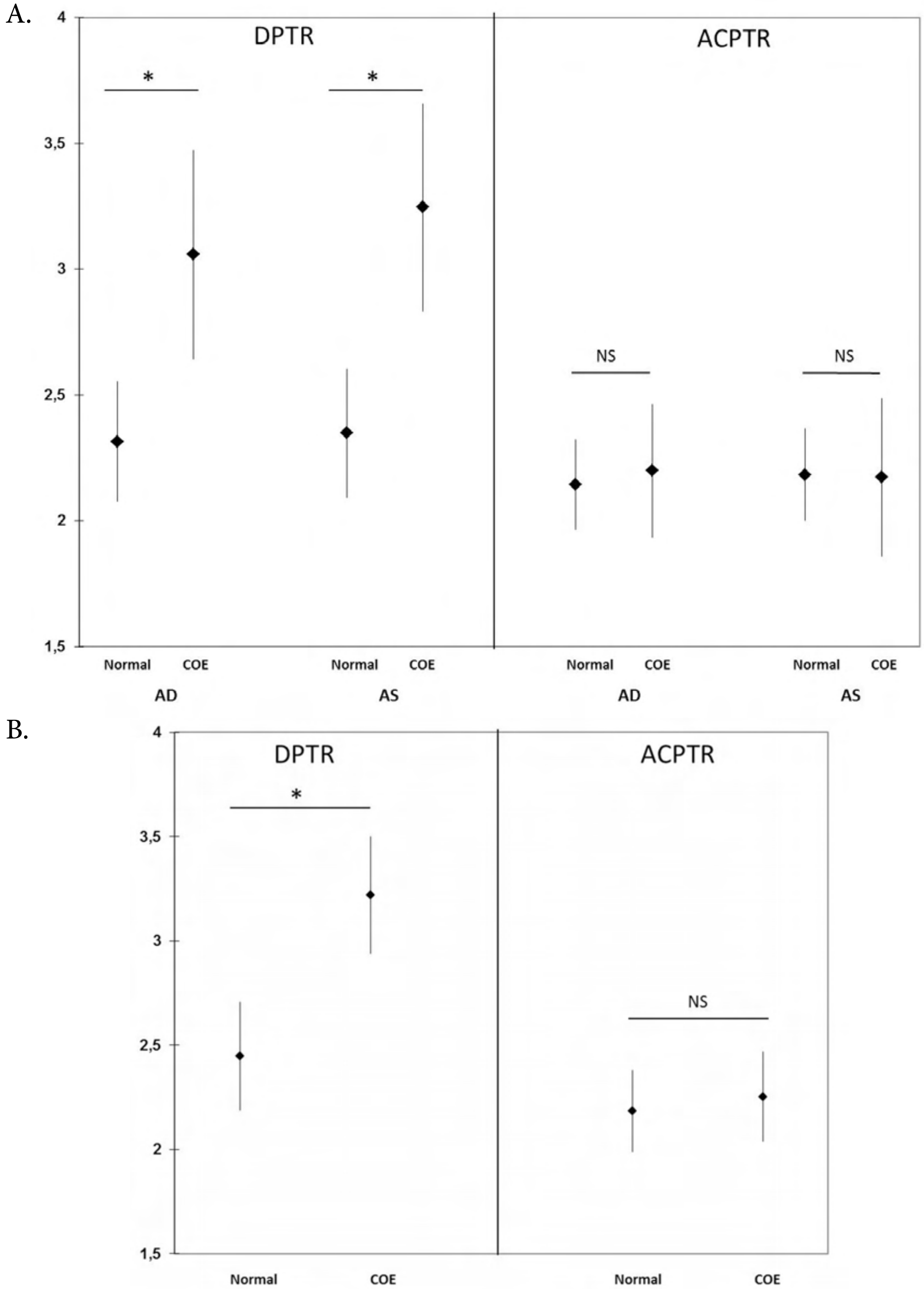

Figure 3. A. Both averages of DPTR and ACPTR compared between normal and COE group. Left (AS) and right (AD) ears. 95% Confidence interval is depicted. (*: significant difference, p<0.05; NS: no significant difference). B. Both DPTR and ACPTR compared between normal and COE group. Only affected ears and randomised normal ears. 95% Confidence interval is depicted. (*: significant difference, p<0.05; NS: no significant difference)

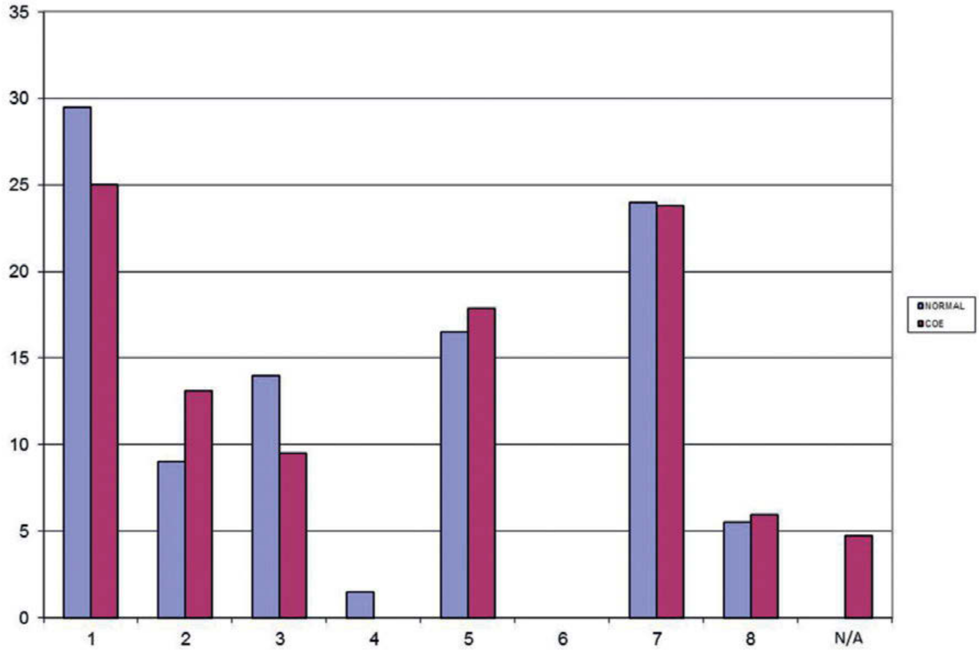

Figure 4. Distribution of the various descriptive shapes in the normal and COE group. (Y-axis: percentage X-axis: Shape type).

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relevant measurement in our study was the DPTR. Although our data show overlapping ranges of DPTR between both groups, our 95% confidence interval, however, does not, suggesting that a DPTR of less than 2,6 mm is 'protective' against the development of COE.

We suggest an 'easy to use' method which allows independent observers to determine the dimensions of the PTR with excellent agreement, although a systematic error was found to be present. This error was only one slide and may be the result of a different interpretation of when to start counting slides.

Because ears of one subject are paired observations and thus correlated, we first compared all left and all right ears between both groups. This enabled us to include all affected ears. This method is only valid if one assumes that the DPTR acts as a maintenance or perpetuating factor within a multifactorial disease. One could then state that the non- affected side within the COE group is more prone to COE but lacks the initiating infection. As our data does not give certainty that in the control group and non-affected side of the COE group never a transient episode of OE was observed, one could debate if such an assumption is valid. We therefore decided to analyse only the affected ears and compare the affected ears to those in the control group. We could not include all affected ears as bilateral cases would force us to use paired observations in non-paired analyses. This was also the case with the control group. To solve this problem we randomised sides of the bilateral cases and ears in the control group using the date of birth. This allowed us to do a non-paired analysis between affected and non-affected ears. A significant difference in DPTR remained present. Using the non-affected side as a control group did not show significant differences in DPTR and ACPTR. This was expected as left and right ears are correlated. Yet, if our abovementioned assumption is valid using the non-affected side as a control is not necessary as these ears could be regarded as being more prone to COE as well.

One could argue that we should have excluded patients with exostoses as they may belong to a group of patients suffering from a different disease entity. In our subgroup analyses, we showed that the presence or absence of exostoses did not influence outcome.

It would be interesting to evaluate how the PTR develops during childhood as children rarely develop COE (21). As our study is limited by its restrospective nature one would suggest a prospective study is warranted to strengthen the conclusions made in this manuscript. More dimensions could be included and perhaps volume and humidity could be assessed as well. In addition, future investigations should focus on the clinical implications of our findings. For example, one may hypothesize that patients with COE and a deep PTR are likely to have a better clinical outcome after adjusting the shape of the OEAC by means of a canalplasty than those patients that do not have a deep PTR and that in those individuals, preferably, the DPTR is reduced to less than 2.6 mm.

CONCLUSION

To our knowledge we are the first to provide evidence that the shape of the OEAC is associated with COE. We demonstrate that the DPTR is significantly associated with the presence of COE. We supply an 'easy to use' method of determining the DPTR using CT scans with an excellent inter-observer agreement. Treatment of COE should take into account these findings. We suggest that a reduction in the DPTR may result in better clinical outcomes in patients with COE.

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Shape of the osseous external auditory canal and its relationship to troublesome cavities

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3.2

ABSTRACT

Background

On the basis of clinical observations, the shape of the osseous external auditory canal (OEAC) has often been seen as an aetiological factor in troublesome cavities after modified radical mastoidectomy.

Methods

To assess the role of the shape of the OEAC in troublesome modified radical cavities using computed tomography (CT) scans of three groups of patients (without pathology and with or without draining cavities), we determined the depth of the pretympanic recess (DPTR) and its anterior curvature (ACPTR). In addition to looking at the shape of the OEAC, we also studied the role of any remaining mastoid air cells in relation to troublesome radical cavities, as well as the consultation frequency.

Results

The DPTR was significantly deeper in draining cavities than in ears without pathology and dry cavities. No difference in the ACPTR was observed. The presence of remaining mastoid air cells is significantly associated with the presence of a troublesome radical cavity.

Conclusion

The shape of the OEAC – in other words, the depth of the pretympanic recess (DPTR) – is a contributory factor to the drainage of modified radical cavities.

Level of evidence: 4

Keywords

Ear canal, Ear disease, Radical Cavity, tomography X-ray computed

INTRODUCTION

Open-cavity mastoidectomy is a common procedure for chronic otitis media (COM) with or without cholesteatoma. However, the resulting radical cavities can be troublesome (1). Self-cleansing mechanisms of the osseous external auditory canal (OEAC) are disrupted, leading to frequent consultations with otorhinolaryngologists (2,3). A multifactorial aetiology has been proposed and revision surgery has proven to be very effective (4-7). Well-known aetiologies of troublesome cavities include a high facial ridge, inadequate meatoplasty, a deep mastoid tip, persistent mastoid air cell tracts and inadequate canalplasty,(6)) the latter being the focus of this manuscript.

3.2

In some series, up to 67% of troublesome cavities are linked to inadequate canalpasty (6) Certain OEAC shapes seem to be involved more frequently than others in the development of chronically inflamed radical cavities. In our opinion and on the basis of clinical observations, it is the variation in the anterior and inferior curvature of the most medial part of the OEAC that explains why some radical cavities develop into troublesome radical cavities [Figure 1]. In the literature, the nomenclature for this area varies from pretympanic sulcus and recess, to tympanic sulcus, pretympanic sinus and inferior tympanic recess. The aim of this study was to examine the role of various pretympanic recess (PTR) dimensions in the development of troublesome radical cavities.

MATERIAL AND METHODS

Participants

We retrospectively identified 107 patients with draining modified radical cavities that were eligible for revision surgery (draining cavity group). Of these 107 patients, 70 were included in the study after the exclusion of patients with bilateral disease (which would have precluded any comparison with the contra-lateral 'normal' side), children (patients < 18 years of age) and patients without adequate CT scans (CT scans performed with the wrong protocol). CT scans were performed as part of regular pre-operative work-up as all patients were scheduled for revision surgery in our tertiary otology referral centre.

Our first control group consisted of CT images of the OEACs of 38 adult patients without a draining modified radical cavity (non-draining cavity group). We identified 76 patients with non-draining modified radical cavities in regular outpatient clinical care over a period of one year. Twenty-four of these 76 patients did not undergo a post-surgery CT scan and, in 9 cases, the CT scan available was not performed using our hospital protocol. Another 5 patients suffered from bilateral disease, leaving us with 38 eligible subjects. All our participants with a cavity had undergone a prior surgery in which the middle ear space was present and the tympanic membrane was reconstructed (modified radical cavity).

The second control group consisted of CT images of the OEACs of 100 randomly selected adult patients (200 ears) scheduled for cochlear implantation ('normal' group). None of

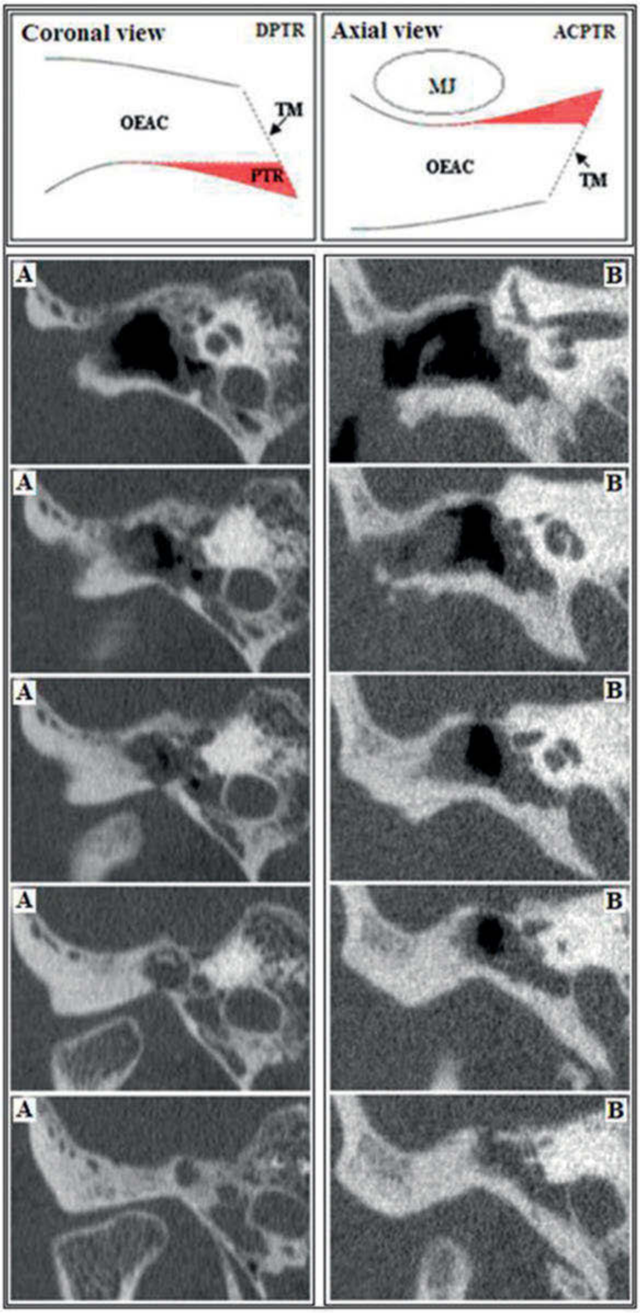

Figure 1. Dimensions of the pretympanic recess (PTR) in different planes (top row). CT images show two series (A and B) illustrating difficult ACPTR measurements in radical cavities (all in coronal view). First slide: When the bony anterior wall is complete (series A) or when the anterior bone is level with the umbo (series B; dotted line). Second slide: when the bony annulus is not present (arrow)(not zygomatic (#), epitympanal(*) or hypotympanal/tubal (+) cell tracts).

the patients in the cochlear implantation group had a history of prior ear disease except for their sensorineural hearing loss.

Imaging of the osseous external auditory canal

All CT scans were obtained using 125 mAs and 120 kV with multi-detector row CT scanners (Philips Mx8000 and Philips Brilliance 64). Images were taken parallel to the orbitomeatal line and slide thickness varied slightly between 0.5 mm and 0.6 mm. The thickness interval was 0 mm. The window level was 600 HU and the window width was 3200 HU.

Measurement of the PTR dimensions

The dimensions of the pretympanic recess (PTR) in both ears were assessed as described earlier by our group (8) in all three patient groups. The depth of the PTR (DPTR) was measured in the axial plane. The slide was identified where the inferior part of the OEAC was first entirely visible. The number of slides were counted inferiorly until the PTR was not visible anymore, i.e. complete closure of the area in front of the tympanic membrane. The anterior curvature of the PTR (ACPTR) was measured in the coronal plane and was performed almost similar to the measurement of the depth of the PTR. Using the first slide where the anterior part of the OEAC was completely visible as starting point. The number of slides was counted until the most anterior point next to the drum was reached. Both the depth (DPTR) and anterior curvature (ACPTR) of the PTR of all radical cavity patients were determined 'blind'. Cavity patients were randomly presented to an observer who did not know whether the cavity was either draining or dry. In radical cavity patients with zygomatic (epitympanic) cell tracts extending a long way in the anterior direction, the starting point of the ACPTR was marked by the first slide, in which the osseous canal extended in a more superior direction than the presumed umbo. In all cases, the bony annulus was used to define the location of the tympanic membrane [Figure 1].

Classification of clinical status and remaining air cell tracts

The frequency of clinical consultation in each year was retrospectively determined for all cavity patients by reviewing the last three years and taking the average number of visits per year. Cavities were classified using the Merchant classification (9). [Table 1] shows this classification. All patients in the draining radical cavity group were Merchant types 2 or 3; all patients in the non-draining radical cavity group were Merchant types 0 or 1. In addition to the Merchant classification, the remaining air cell tracts were scored in all radical cavity patients using CT images. Three areas were defined for the remaining air cell tracts: (1) mastoid air cell tracts (2) supralabyrinthine air cell tracts and (3) the sinodural angle. All areas were scored separately.

Statistical analysis

Statistical analysis was carried out using SPSS 16.0.2 (Chicago, IL, USA). The data were expressed as numbers (%) and means (SD). Normality was checked using the Shapiro-Wilk test. One-way

Table 1. Merchant classification (9)

Grade 0
No episode of otorrhea, AND no pus or granulation tissue on otologic exam.
Grade 1
One episode of otorrhea of <2 weeks' duration in 3-month period OR no otorrhea but a subjective feeling of wetness in the ear.
Grade 2
More than one episode of otorrhea in 3 month period, OR an episode of otorrhea lasting more than 2 weeks, OR otologic exam showing localized granulation tissue/pus that was promptly cured with antibiotic drops, curettage, or silver nitrate cautery.
Grade 3
Constant purulent otorrhea on a daily basis, OR otologic exam showing extensive granulation tissue, OR need for a revision procedure to control infection.

ANOVA and independent T-tests were performed to check for significant changes between DPTR, the ACPTR of the OEAC, age and clinical visits per year of the participants in the three different groups. Affected and non-affected sides were analysed independently. The left ear in the cochlear implantation group was used as the control group for the affected side and the right ear in the cochlear implantation group was used as the control group for the non-affected side. Chi-square analyses were used to identify differences in the distribution of remaining air cell tracts (location and number) by comparison with the Merchant classification and cavity type (non-draining and draining cavity). In addition, gender distribution between the three groups was evaluated using chi-square testing. Additionally we assessed the difference in ACPTR and DPTR between the condition groups correcting for differences in presence of remaining air cell tracts by multivariable logistic regression. *P* values of less than 0.05 were considered statistically significant.

RESULTS

Study population

Patient characteristics are listed in [Table 2]. The mean age of the participants was 60 years of age in the control (cochlear implantation) group (range 25 – 88 years, female percentage 41%), 55 years of age in the non-draining cavity group (range 29 – 95 years, female percentage 47%) and 48 years of age in the draining cavity group (range 22 – 80 years). A slight female predominance was observed in the control group (59% females). By contrast, a slight male predominance was observed in both radical cavity groups (53% males in the non-draining cavity group and 63% males in the draining cavity group). This observed difference was statistically significant ($p = 0.02$). A significant difference in age was seen between patients in the 'normal' group and patients in the draining radical cavity group ($p < 0.01$) but all other differences in age were non-significant ($p > 0.05$).

Table 2. Patient characteristics

	Normal	Wet cavity N (%)	Dry cavity N (%)	P-value t-test or chi-square (Anova)
N =	100	70	38	
Median age (y)	60	48	55	<0.01 (<0.001)
Male:female	41 : 59	44 : 26	20 : 18	0.02 (0.01)
Number of clinical visits/year	N/A	3	2	<0.001 (N/A)
Remaining air cell tracts	N/A	65	15	<0.001 (N/A)
Regions affected				
sinodural angle	N/A	40	6	0.54 (N/A)
mastoid tip	N/A	61	9	0.54 (N/A)
supralabyrinthine area	N/A	46	11	0.54 (N/A)
Regions involved				
0	N/A	5	23	<0.001 (N/A)
1	N/A	18	7	<0.001 (N/A)
2	N/A	12	5	<0.001 (N/A)
3	N/A	35	3	<0.001 (N/A)

3.2

The non-draining cavity group included 31 patients with a Merchant type 0 cavity and 7 patients with a Merchant type 1 cavity. The draining cavity group included 21 patients with a Merchant type 2 cavity and 49 patients with a Merchant type 3 cavity.

As for the frequency of clinical consultation, an additional 26 patients in the draining radical cavity group and 3 patients in the non-draining radical cavity group were excluded from analysis because of insufficient data about follow-up and/or insufficient time prior to operation (because of direct referral for surgery). In the draining cavity group, an average of 4 (median 3) visits per year (range 1 to 12 visits per year) was observed. In the non-draining cavity group, an average of 1 (median 2) visit per year (range 1 to 5 visits per year) was observed. This difference was statistically significant ($p < 0.001$).

3.2

Differences in DPTR and ACPTR between the groups

As for the dimensions of the pretympanic recess, the DPTR was found to range between 0 and 6 mm in the control (cochlear implantation – 'normal') group. In the non-draining and draining radical cavity groups the DPTR ranged from 0 to 6 mm and 0 to 8.3 mm respectively. The average DPTR in the control group was 2.2 ± 1.4 mm. In the non-draining radical cavity group it was 2.1 ± 1.8 mm. A DPTR of 2.9 ± 1.7 mm was observed in the draining radical cavity group [Figure 2]. The difference in DPTR between draining radical cavities and non-draining radical cavities was statistically significant (p = 0.04). The same holds true for the comparison between draining radical cavities and the 'normal' control ears (p = 0.005). The significant difference between the DPTR of patients with draining and non-draining radical cavity groups disappeared when the comparison was made with the non-affected side (p = 0.18). When comparing the non-affected side of patients with a draining radical cavity with 'normal' control ears, however, we still observed a significant difference in DPTR (p = 0.03).

In the 'normal' control ears, the average ACPTR was 2.2 ± 0.9 mm (range 0 to 5.0 mm). In non-draining radical cavities, the ACPTR was 2.4 ± 1.1 mm (range 0 to 4.2 mm). In draining radical cavities, on the other hand, the ACPTR was 2.2 ± 0.9 mm (range 0 to 4.4 mm) [Figure 2]. No significant difference in the ACPTR was observed when the affected ears were compared (all p > 0.3). Nevertheless, a significant difference was seen in the non-affected ears of the two radical cavity groups. In these groups, the ACPTR in non-affected ears was significantly more pronounced than in 'normal' controls (p = 0.03 and p < 0.01 respectively). No significant difference was observed when these two groups were compared (p = 0.53).

Differences in remaining air cell tracts between the groups

We observed remaining air cell tracts in 15/38 patients (39.5%) in the non-draining radical cavity group. Remaining air cell tracts were observed in one area in 7 of these 15 patients (47%), in two regions in 5/15 cases (33%) and in all three areas in 3/15 patients (20%). Eleven of these 15 patients (73%) had remaining air cell tracts in the supralabyrinthine area, 9/15 (60%) in the mastoid tip area and 6/15 (40%) in the sinodural angle.

In the draining radical cavity group, remaining air cells tracts were found in 65/70 patients (93%). Eighteen of these 65 patients had remaining air cell tracts located in one area (28%), 12/65 in two areas (18%) and 35/65 in all three areas (54%). The difference between the two radical cavity groups in terms of remaining air cell tracts was statistically significant (p<0.001). Sixty-one of 70 patients (94%) in the draining radical cavity group had remaining air cell tracts in the sinodural angle area. There was involvement of the supralabyrinthine air cell tracts in 46/70 patients (71%) and involvement of cells in the sinodural angle area in 40/70 patients (62%). The difference in the affected remaining air cell tracts between the two radical cavity groups was not statistically significant (p = 0.54). Similar results were observed when the Merchant classification was compared with the presence or absence of remaining air cell tracts in the two groups.

The multivariable logistic regression showed no significant association between ACPTR and the cavity condition corrected for the presence of remaining air cell tracts (OR 0,75; 95

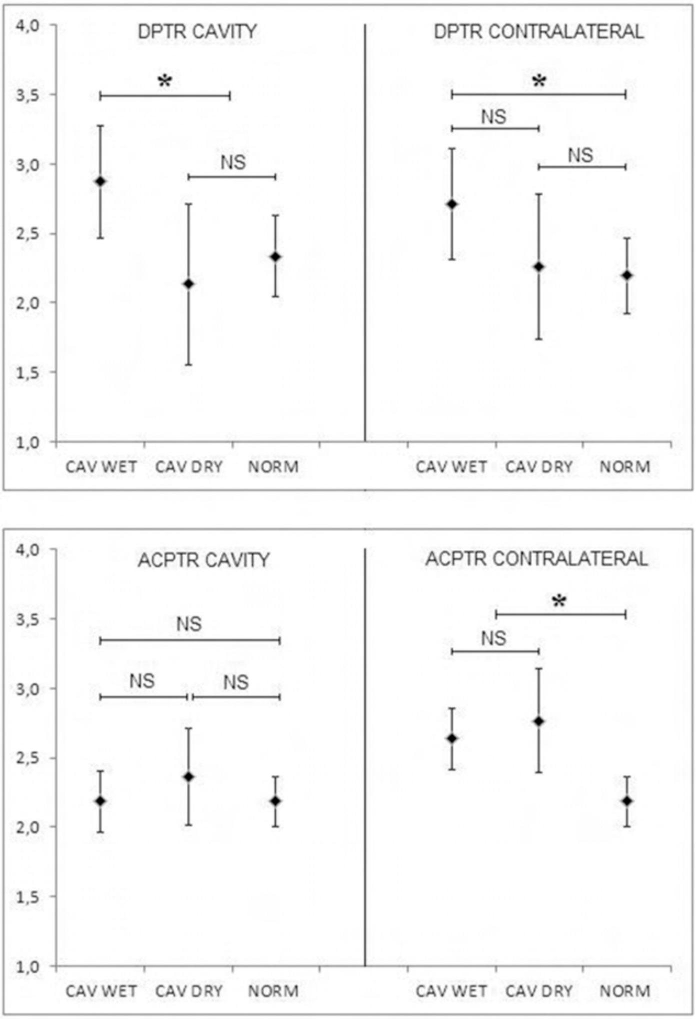

Figure 2. Averages and 95% confidence interval of DPTR and ACPTR compared between normal, dry cavity and draining cavity groups are depicted. Both affected and contralateral ear are shown separately. (*: significant difference, $p<0.05$; NS: no significant difference)

CI 0.46 to 1.23; p=0.26). The association between DPTR and the cavity condition corrected for the presence of remaining air cell tracts was statistically significant (OR 1,47; 95% CI 1,08 to 2,02; p=0.02). This result implicates that with each 1 mm increase in DPTR, the odds that a cavity will become a draining cavity instead of a dry cavity is about 1,5 times higher.

DISCUSSION

This study demonstrates that the shape of the osseous external auditory canal (OEAC) is a contributory factor to a draining radical cavity. Our hypothesis that the PTR is an important area of the OEAC and is therefore involved in the development of a draining radical cavity is strengthened. This result suggests that the pathophysiology of the chronically draining cavity may resemble the pathophysiology of chronic OE in some patients since a previous study by our group demonstrated that an increased DPTR is also correlated with therapy-resistant otitis externa (OE) (8). We postulate that regular clinical cleaning and the self-cleansing ability of the cavity is hampered by a deep PTR. Another possibility could be that intertriginous eczema can arise as sharper angles enable skin-to-skin contact when inflamed, thus perpetuating the inflammation and leading to chronic disease. As the 95% confidence intervals for the DPTR in all three groups (control group of cochlear implant patients, non-draining radical cavity patients and draining radical cavity patients) overlap, we cannot state with certainty that a certain depth of the DPTR is predictive for the development of a draining radical cavity, but a depth exceeding 2.7 mm is certainly not beneficial (this number exceeds the 95% confidence interval for non-draining radical cavities). The fact that no significant difference in ACPTR was observed concurred with the results of the above OE study (8).

In addition to the shape of the pretympanic recess, this study confirms that the presence of remaining air cell tracts is another important contributory factor in the development of a draining cavity. Other well-known contributory factors - an inadequate meatoplasty and/or high facial ridge, for example - were not studied since there are no objective and adequate measurement techniques. Although our multivariable logistic regression showed that the DPTR is a contributing factor regardless of the remaining air cell tracts these other etiologies should be considered as well.

Patients with draining cavities need more frequent clinical consultations (in other words, several appointments every year) than patients with non-draining cavities. This result is in line with the patient perception of the burden associated with a draining cavity. Nevertheless, no hard conclusions can be drawn about these results given the inclusion bias resulting from the selection of draining cavities for operation and the short follow-up period. In addition, gaps in the data undermine these results.

This study included only patients with a unilateral cavity. As a result, we were able to use the contra-lateral non-affected ear as the possible 'pre-operative' condition since individual's ears are intra-individually correlated (8). Unexpectedly, a significantly different ACPTR was observed in the contra-lateral non-affected ear in the two cavity groups and in the control (cochlear implantation) group. One could speculate that the presence of a more pronounced ACPTR is associated with the development of pathology (cholesteatoma) or that a cavity was drilled because of limited visibility in the anterior direction (in other words, a canal wall up procedure may suffice in patients with cholesteatoma with smaller ACPTR).

The inclusion of unilateral cases only in this study was intended to simplify the evaluation of our data since including both ears would have precluded a non-paired analysis given the fact that including both ears of single individuals results in paired observations.

Due to the limited number of participants in some groups, meaningful sub-analyses of cavities with and without remaining air cell tracts in both non-draining and draining cavity groups was not feasible. An analysis of this kind would be desirable in order to show whether the localisation of the remaining air cell tracts play a role at all.

As the analysis of data based on the groups defined as wet and dry cavities on the one hand, and the individual grades of Merchant groups on the other, did not produce different results, we feel confident in stating that combining types 0 and 1 and types 2 and 3 is reasonable and that a combination approach of this kind could be adopted in future research.

Our study was retrospective in nature and so conclusions will always be subject to bias. To exclude bias as much as possible, CT scans were blinded before the dimensions of the PTR were assessed.

One could argue that we should have included children in our study as the presence of cavities is not limited to the adult population. However, because it is still not known how PTRs develop during childhood, we decided to exclude all children from the present study. Future studies should look to study the development of PTRs during childhood and to determine whether the shape of the PTR is involved in draining cavities in children as well.

Studies in the future should focus on the clinical implications of our current findings. A better clinical outcome could be possible in patients with deep PTRs and draining cavities after OEAC shape has been adjusted with a canalplasty. In that case, the OEAC should be reduced to an extent that is adequate to offset the deep DPTR (that is to say, to less than 2.7 mm). If correcting the depth of the DPTR leads to better results, this would further support our hypothesis, and also justify the conclusion that the treatment (revision surgery, for example) of troublesome cavities should take both the depth of the pretympanic recess and remaining air cell tracts into account.

CONCLUSION

To our knowledge, this is the first paper to supply evidence that the shape of the osseous external auditory canal is significantly associated with the presence of a draining modified radical cavity. PTR depth is particularly important. Although it is more pronounced in the non-affected ears of all radical cavity patients, the ACPTR seems not to be involved in the development of draining modified radical cavities. Remaining air cell tracts were present significantly more often in draining modified radical cavities than in non-draining radical cavities. Further research to determine the importance of this association in the multi-aetiological problem of the troublesome cavity is warranted.

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Sound of the OAEC

4

The effects of alterations in the osseous external auditory canal on perceived sound quality

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4.1

ABSTRACT

Objective

To evaluate the perceptual effect of the altered shape of the osseous external auditory canal (OEAC) on sound quality.

Study design

Prospective study

4.1

Subjects and methods

Twenty subjects with normal hearing were presented with six simulated sound conditions representing the acoustic properties of six different ear canals (3 normal ears, and 3 cavities). The six different real ear unaided responses (REURs) of these ear canals were used to filter Dutch sentences, resulting in six simulated sound conditions. A seventh unfiltered 'reference' condition was used for comparison. Sound quality was evaluated using paired comparison ratings and a Visual Analogue Scale (VAS).

Results

Significant differences in sound quality were found between the 'normal' and cavity conditions (all $p<0.001$) using both the seven-point paired comparison rating and the VAS. No significant differences were found between the reference and 'normal' conditions. Sound quality deteriorates when the OEAC is altered into a cavity.

Conclusion

This proof of concept study shows that the altered acoustic quality of the OEAC after radical cavity surgery may lead to a clearly perceived deterioration in sound quality. Nevertheless, some questions remain about the extent to which these changes are affected by habituation, and by other changes in middle ear anatomy and functionality.

INTRODUCTION

The external auditory canal is known to have a complex anatomy with considerable inter- and intra-individual variability (1). The auditory canal plays a role in the transfer of sound from the concha to the tympanic membrane and acts as a resonant tube (2). Several manuscripts have reported a change in resonance acoustics when the osseous external auditory canal (OEAC) is modified surgically (3-6). The creation of a wide OEAC (as is the case with a radical cavity) was shown to decrease the resonant frequency substantially and alter the peak amplitude significantly (3). Although these changes have been reported several times in the past, it seems that no attempt has been made to correlate objective measurements with the subjective sound quality of this altered sound. As suggested by Satar et al., an evaluation of the perceptual consequences could be interesting (7). The fact that some of our patients reported changes in hearing after surgery even when the audiometric evaluation of both speech intelligibility or pure tone sensitivity remained the same makes the evaluation of this possible explanation even more worthwhile. As these effects may affect 'everyday' sound perception in patients, it is important to determine whether these changes are clinically relevant. If changes in sound perception are significant, otologists should be aware of these effects when planning therapeutic interventions or, alternatively, disregard them if there is no significant change in sound quality.

The purpose of this study was to test whether and to what extent sound quality is affected by changes in the acoustics of the external auditory canal and whether these changes explain our clinical observations and are therefore clinically relevant.

PARTICIPANTS AND METHODS

Subjects

Twenty individuals with normal hearing were selected. The group was comprised of 14 (70%) female and 6 (30%) male participants with an average age of 36.8 years (median 32.3, range 21.4 to 61.8 years). Their hearing thresholds were 20 dB HL or better at 0.25, 0.5, 1, 2, 4 and 8 kHz. All participants were healthy and had no history of ear disease. No CT scans were made as there was no clinical need to do so. Three patients (1 female, 2 males) who had undergone a canal wall down procedure 15 years or more prior to this study due to cholesteatoma agreed to participate in this study. The cavities were all dry (Merchant grade 0)(8) and had been properly cleaned before measurements were performed. CT images of these cavities were acquired during regular clinical care. Three other volunteers (1 female, 2 males) with no history of ear disease and normal ear canals determined by regular otoscopy agreed to participate as normal controls.

Simulation of the acoustic properties of six individual ear canals

The acoustic properties of the ear canal can be characterised by measuring the real ear unaided response (REUR) (9). This response is measured with a probe microphone inserted into the external auditory canal and it shows the sound pressure level at the eardrum after the presentation of a well-defined broadband sound stimulus. Differences between individual REURs therefore represent differences in the acoustic properties of individual ear canals. For instance, the acoustic effect of an ear canal of a radical cavity can be simulated in a normal ear canal by filtering the incoming sound stimulus using the difference between the REUR of a normal ear and the REUR of a cavity ear. In a normal ear, this filtering results in the same distribution of sound pressure at the eardrum as in the original radical cavity.

We made recordings of Dutch speech (two male-spoken and two female-spoken sentences based on the VU98 sentence material (Versfeld et al. (9)), filtered to simulate the acoustic properties of three normal ear canals and three radical cavity ear canals. The REURs of the three 'normal' ear canals and the three radical cavities were measured in the non-participating volunteers using the REM module of the Affinity 2.0 Hearing Aid Analyzer platform (Interacoustics, Denmark). [Figure 1] shows the REUR results for three healthy individuals with normal ear canals and three patients with a radical cavity. The results are presented as real ear unaided gain (REUG: the difference between the incoming broadband stimulus and the REUR). In addition, CT images are shown of the three cavities at the level of the oval niche.

Six filters (simulated conditions) were built on the basis of the differences between these six REUGs and the average REUG of a normal adult ear canal (see Table 4.6 in Dillon H, page 110 (10)). The seventh 'reference' condition consisted of the unfiltered speech material.

Perceptual evaluation

The perceptual evaluation experiment was performed with a paired comparison category rating with two fragments ('A' and 'B') in accordance with ITU-T 1996. Participants were asked to use a seven-point scale to indicate which fragment sounded more natural. These fragments consisted of the six conditions (three 'normal' ears and three cavities) and each filtered condition was compared with the unfiltered reference condition. All conditions were presented using two male-spoken and two female-spoken sentences. Each condition was measured twice: once with the filtered sentence as 'A' and the reference sentence as 'B', and once in the reverse order. These 48 paired comparisons, together with 4 control comparisons in which the seventh unfiltered condition was compared with itself, resulted in a total of 52 paired comparisons being presented in random order.

The paired comparison category rating was followed by VAS scoring to evaluate the 'overall' sound quality of the seven conditions, with 0 being the worst possible outcome and 100 the best. Once again, the seven conditions were presented in random order by playing four different Dutch sentences.

All the speech material was presented in free field at a level of 65 dB(A) using a loudspeaker in front of the listener (0^0 angle).

Statistical analysis

Statistical analysis was conducted using SPSS 16.0.2 (Chicago, IL, USA). Data are expressed as numbers. The paired comparison rating results are stated on a seven-point scale ranging

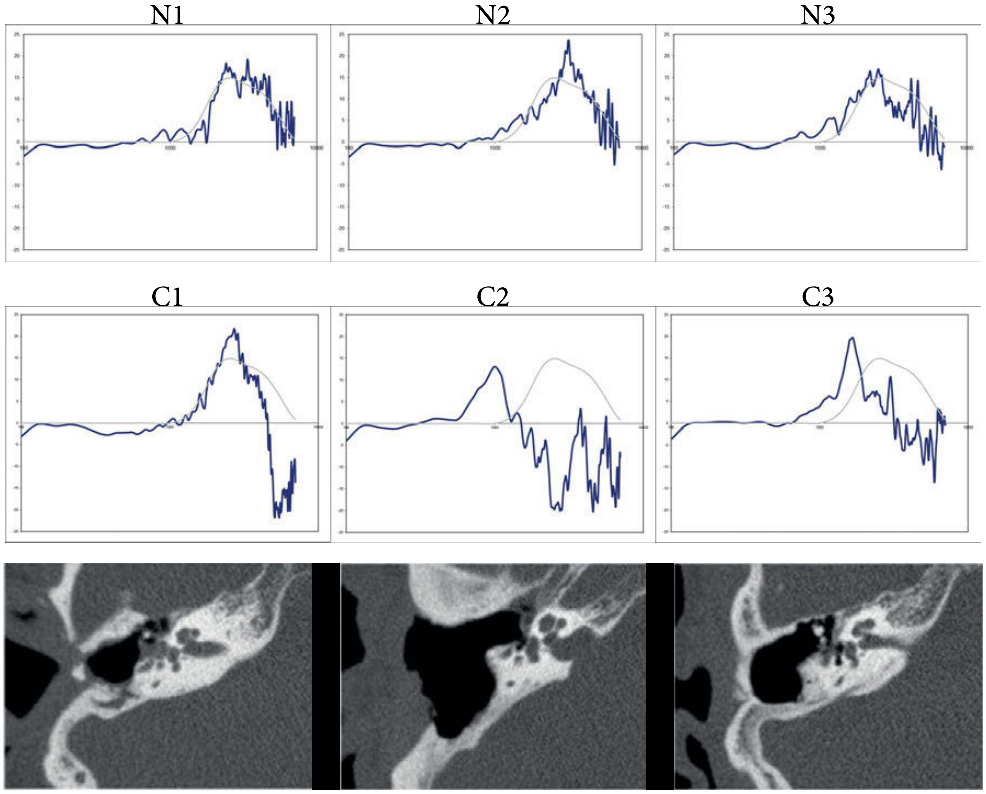

Figure 1. Measured Real Ear Unaided Gain (REUG) of all conditions: three normal ear canals (N1, N2 and N3) and three ear canals with a radical cavity (C1, C2 and C3, dark lines). In each window the average adult REUG ia also depicted (Dillon) (light line). The REUG data are depicted on the same scale from 100 Hz to 7000 Hz on the frequency x-axis, and -25 to 25 dB(gain) on the y axis. The cavity conditions are shown with the according CT scan image in the axial plane using the oval window niche as reference point.

from +3 (the simulated ear canal, or filtered, signal sounds are much more natural than the reference, or unfiltered, condition) to -3 (the reference condition sounds much more natural than the simulated ear canal). A score of 0 means that no noticeable difference in naturalness was perceived between the two conditions. Mann-Whitney U testing was performed to check for significant changes from baseline in the VAS scores. ANOVA multivariate analysis was used to determine the effects of subject, condition, and gender of the speaker on the results. A Bonferroni correction was applied to account for multiple comparisons. *P* values of less than 0.05 were considered statistically significant.

RESULTS

Paired comparison ratings

The ANOVA analysis did not identify a significant difference in perceived sound quality between the male and female speakers (p=0.19). However, the different conditions significantly affected outcome, as can be seen in [figure 2]. When the various conditions were compared pairwise with the reference condition, all the cavity conditions were perceived to be significantly less natural. No significant difference was seen between the three normal conditions and the reference condition since their rating scores were not significantly different from 0. In a pairwise comparison, all cavity conditions were found to be significantly less natural than the normal conditions (all p<0.001). The second cavity condition (C2) was rated as being significantly less natural than all other conditions (all p<0.001).

4.1

VAS scores

The seven conditions presented are shown in [figure 3]. No significant difference in VAS scores was observed between the reference and normal conditions (all p>0.1). However, there were

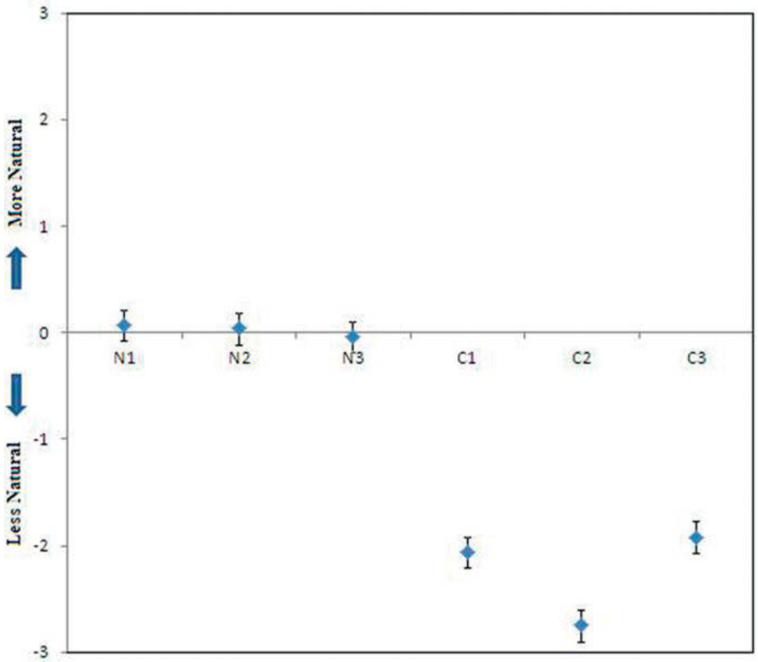

Figure 2. Results of the paired comparison ratings. Scores range from 3 to -3 on a seven point scale. A score of 3 means that the simulated ear canal acoustic c.q. filtered signal sounds much more natural than the reference c.q. unfiltered signal. A score of -3 denotes a clear preference in naturalness for the unfiltered signal. A score of 0 means that there is no noticeable difference in naturalness between the two signals. Bars denote de 95% confidence interval for the mean.

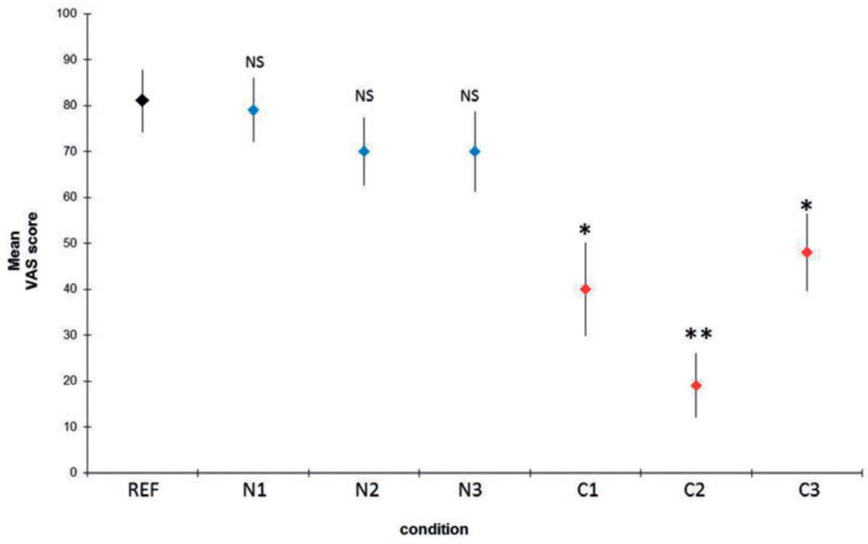

Figure 3. VAS evaluation of the percepted quality of the presented sound per condition. REF (black colour): reference N1-3 (Blue colour): 'Normal ear conditions' C1-3(Red colour): Cavity conditions. NS: not significant compared to reference, * significant difference with reference and normal conditions ($p<0.01$), ** significant difference with all conditions ($p<0.01$)

4.1

significant differences between both the reference and normal conditions and those of the cavities (all $p<0.001$). The condition represented by C2 was found to be significantly different from all other conditions (even relative to the other cavities) (all $p<0.001$).

DISCUSSION

The clear, significant effects between normal conditions and cavity conditions strongly support the hypothesis that alteration of the OEAC can result in a clinically relevant distortion of sound quality, which may be less natural or of poorer quality. This supports our hypothesis that this phenomenon is the cause of our clinical observations. The cavity conditions were found to generate poorer overall quality as compared with normal conditions and were perceived to be less natural. An unexpected, interesting finding was that significant differences were also found in the cavity conditions. These differences could possibly be explained by the shape of the cavities: the volume of the bowl or the size of the meatoplasty could cause this wide variance in the alteration of the acoustic properties. Further research to determine the cause could be useful in evaluating which properties could be beneficially altered (in other words, the properties that have a minor impact on perceived sound quality). As the field of otology is moving towards the usage of obliteration techniques and Satar (7) has shown that obliterated cavities can achieve near-normal resonance frequencies, this could also be a condition that requires further evaluation.

Intelligibility of speech is not affected. Although there were clearly audible differences in sound quality, the content of all the sentences was easily understood. This is in line with earlier work in the field of audiology as it is known that the speech spectrum can be altered quite extensively before intelligibility is affected. One could debate whether a 'distortion' of sound without any loss of speech intelligibility is clinically relevant. Nevertheless, our clinical observations do suggest that this phenomenon is indeed clinically relevant.

We only explored the most 'radical' alterations resulting from changes in the shape of the OEAC using radical cavities in our study design. Nevertheless, other surgical alterations to the OEAC (and subsequently the changes in resonant frequency) such as canalplasty, meatoplasty and reconstruction of the OEAC in revision radical cavity surgery can elicit similar significant effects on sound. Further research in this field is therefore advisable.

The VAS score and paired comparison scoring for the assessment of the overall quality of sound could be seen as crude instruments since sound quality can be broken down into many subcategories (such as loudness or sharpness). Even so, we feel that this is a valid approach to relevant testing in outpatient clinic practice on a regular basis because the answers to general questions of this kind are important as primary outcome parameters for clinical success. Both five-point Likert scales and VAS scores are regularly used for subjective measurements of complaints.

A possible limitation of this study could be that we looked at more female than male subjects. Even so, we believe that this gender discrepancy has not had a significant impact on the outcome of our study. Using normal-hearing subjects does give rise to some points of discussion. We know that the alteration of external ear acoustics is not the only effect that surgery can have. It has been argued that a change in middle ear volume in canal wall down procedures and the type of tympanoplasties/ossicular chain reconstruction performed could also play an important role in perceptual hearing (3,11,12). However, our study did not consider these possible mechanisms since we wished to focus exclusively on the changes in perceived sound quality resulting from the changes in the shape of the OEAC.

It is possible that using radical cavity patients as their own control could reveal whether sound quality is influenced by habituation in patients. Our study design did not look at possible habituation. Even so, if there is habituation, this could render our findings less useful since adaptation to 'poorer' sound quality could mean that differences experienced at the outset will no longer be clinically relevant in the long term, even when patients perceive clinically relevant primary deterioration. Further research looking at habituation effects would therefore seem to be necessary.

CONCLUSION

Our proof of concept study shows that changing the shape of the OEAC not only has an impact on sound quality but that it also leads to poorer perceived sound quality when a cavity is drilled. The changes in resonant frequency will elicit a clinically-relevant, perceptual 'distortion' of sound and this should therefore be considered when altering the shape of the OEAC. Since some aspects are still unclear, further research is needed to make these findings more applicable in current clinical practice.

4.1

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The effects of a Canalplasty and a Canal wall reconstruction on perceived sound quality; preliminary results

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4.2

ABSTRACT

Objective

To evaluate the perceptual effect of the acoustic properties before and after canalplasty and a reconstruction of the posterior canal wall in revision modified radical cavity surgery.

Study design

Prospective study.

Subjects and methods

Twenty normal hearing subjects were presented six simulated sound conditions representing the acoustic properties of six different ear canals (2 normal ears, and 2 pre- and postoperative conditions). The six different real ear unaided responses (REURs) of these ear canals were used to filter Dutch sentences, resulting in six simulated sound conditions. A seventh unfiltered 'reference' condition was used for comparison. Sound quality was evaluated using a seven-point paired comparison rating and a Visual Analogue Scale (VAS).

Results

Significant differences in sound quality were found between all conditions and the pre-operative cavity condition (all $p<0.001$) using both the paired comparison rating and VAS. No significant differences in VAS were found comparing the other conditions with each other. But when using the paired comparison rating, the post-operative canalplasty condition and both the pre and post-operative cavity conditions differed significantly from the other conditions.

Conclusion

This explorative study shows that altering the acoustics of the OEAC after a canalplasty and a reconstruction of the ear canal in revision modified radical cavity surgery results in perceivable changes in sound quality. It is likely that these change are primarily due to volume changes. To which extend these changes are of clinical importance remains to be determined.

INTRODUCTION

It is well known that the external auditory ear canal plays a role in the transfer of sound from the concha to the tympanic membrane. It acts as a resonant tube (1). Several manuscripts have reported a change in resonance acoustics when the osseous external auditory canal (OEAC) is modified surgically (2-5). Our group frequently encountered patients reporting a post-operative improvement or deterioration of sound quality while pure tone audiometry (PTA) showed no relevant changes at all. This could be explained by the abovementioned literature findings. Surgical alteration of the OEAC was shown to alter the resonant frequency substantially and the peak amplitude significantly (2,6). An evaluation of the perceptual consequences of the largest surgical alteration (drilling a modified radical cavity) has shown significant effects (6) on perceived sound quality. Although some questions still remain regarding possible habituation and its relevance in regular clinical care, these effects cannot be disregarded. Beside drilling a modified radical cavity, various other surgical alterations of the OAEC can be performed. A canalplasty procedure can be performed to widen the OAEC, in order to create a self-cleansing and patent external auditory canal. Is it possible that such a procedure leads to similar acoustic effects? And, does reconstruction of the posterior canal wall after prior radicalisation, thereby restoring more 'normal' dimensions of the OAEC, lead to a significant effect in perceived sound quality?

The purpose of this study was to test whether and to which extent sound quality is affected by surgical changes in the shape of the external auditory canal in one individual patient. For this purpose we compared the acoustic effects pre- and post-operatively in patients undergoing a canalplasty procedure and a revision radical cavity surgery with reconstruction of the posterior canal wall.

PARTICIPANTS AND METHODS

Subjects

For the listening experiments, twenty individuals with normal hearing were included. This group was comprised of 14 (70%) female and 6 (30%) male participants with an average age of 32,9 year (median 29,0 ranging from 22 to 60,6 years). Their hearing thresholds were 20 dB HL or better at 0.25, 0.5, 1, 2, 4 and 8 kHz. All participants were healthy and had no history of ear disease. All participants underwent otoscopy showing no pathology (except a few cases of minor myringosclerosis). Informed consent was obtained from all individual participants included in the study. IRB was acquired and given by the ethical committee review board to perform this study.

Sound recordings

Two patients agreed to participate in this study. One patient suffered from chronic external otitis due to extensive exostosis formation. A canalplasty procedure was indicated and performed as was described by our group in an earlier manuscript (7). Very briefly, this technique uses a skin flap that allows complete circular drilling and limites potential skin loss. No grafts are used as the skin is spared and healing is secondary. Two REURs were obtained, one pre-operatively and one after successful healing. The other patient was indicated for revision modified radical cavity surgery due to a troublesome cavity. During this procedure a partial obliteration using hydroxyl-apatite granules of the mastoid bowl was performed and a new posterior canal wall was reconstructed with cartilage and a midtemporal flap. This procedure was a slight modification of the technique described by Yung et al (8). The modification being that the inferiorly based flap is not used in our series as the midtemporal flap alone suffices. Again, two REURs were obtained, one pre-operatively and one after successful healing (this being approximately three months post-operatively). Two other (non-participating) volunteers with no history of ear disease and having normal ear canals determined by regular otoscopy agreed to participate as normal controls. In both these volunteers, a REUR was obtained from one ear.

Simulation of the acoustic properties of six individual ear canals

The acoustic properties of the ear canal can be characterized by measuring the real ear unaided response (REUR) (6). This response is measured with a probe microphone inserted into the external auditory canal and shows the sound pressure level at the eardrum after the presentation of a well-defined broadband sound stimulus. Differences between individual REURs therefore represent differences in acoustic properties of individual ear canals. For instance, the acoustic effect of an ear canal with a radical cavity can be simulated in a normal ear canal by filtering the incoming sound stimulus using the difference of the REUR of a normal ear and the REUR of a cavity ear. The filtered sound stimuli, presented to a normal ear, should result in the same distribution of sound pressure at the eardrum as in the original radical cavity (6).

We used Dutch speech recordings (two male and two female speaker sentences based on the VU98 sentence material (9), filtered to simulate the acoustic properties of six ear canal conditions: two normal ear canals, two pre-operative conditions (ear canal with exostosis and radical cavity), and two post-operative conditions (canalplasty and revision radical cavity surgery with reconstruction of the posterior ear canal wall). The REUR of these six conditions were measured using the REM module of the Affinity 2.0 Hearing Aid Analyzer platform (Interacoustics, Denmark). [Figure 1] shows the REUR results of the six conditions, presented as a real ear unaided gain (REUG, being the difference between the incoming broadband stimulus and the REUR). Six filters c.q. simulated conditions were built based on the differences between these six REUGs and the average REUG of a normal adult ear canal (see Table 4.6 in Dillon H (8), page 110 (10)) The seventh 'reference' condition consisted of the unfiltered speech material. We included sound samples, using English sentences but the same filters, comparable to those who were presented to the participants in the sound files.

Perceptual evaluation

The perceptual evaluation experiment was performed with a paired comparison category rating between two fragments ('A' and 'B'), according to ITU-T 1996. Participants were asked which

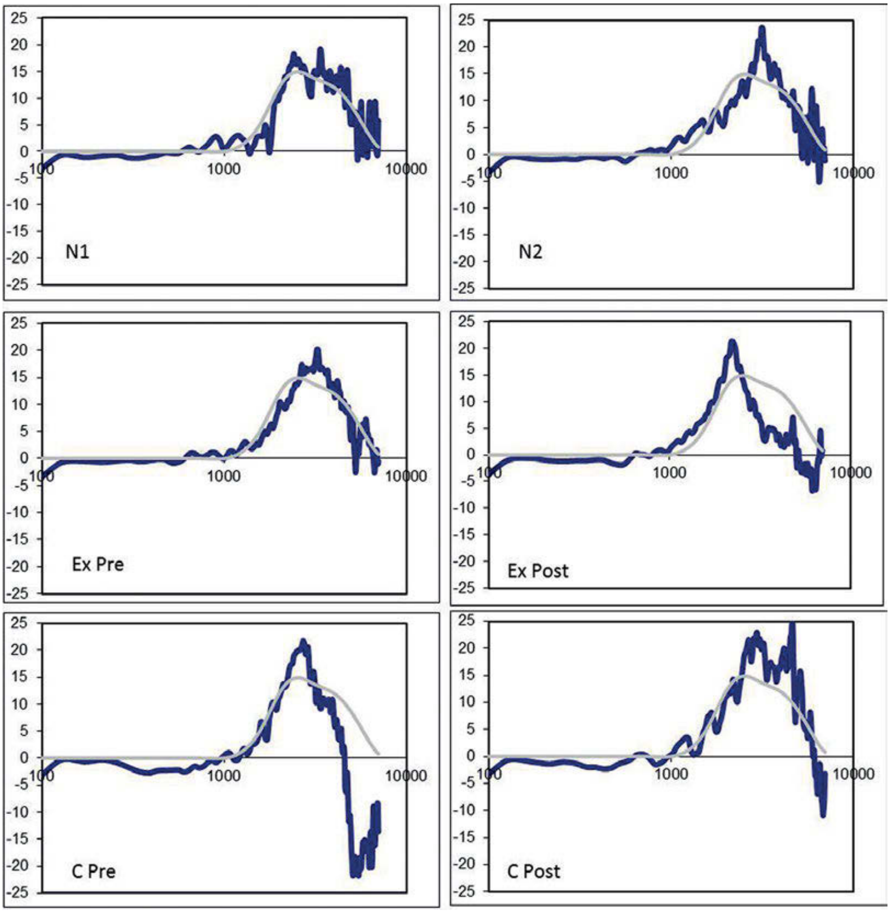

Figure 1. Measured Real Ear Unaided Gain (REUG) of all conditions: two 'normal' ear canals (N1 and N2), a pre and postoperative condition of a patient with exostosis who underwent canalplasty (Ex Pre and Ex Post) and a pre and postoperative condition of a patient with a radical cavity who underwent a revision surgery with cartilage reconstruction of the posterior ear canal (C Pre and C post) (dark lines). In each window the average adult REUG is also depicted (Dillon) (light line). The REUG data are depicted on the same scale from 100 Hz to 7000 Hz on the frequency x-axis, and -25 to 25 dB(gain) on the y axis.

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fragment sounded more natural using a 7 point comparison rating scale . The paired comparison rating results are denoted on a 7 point scale from 3 (the simulated ear canal c.q. filtered signal sounds much more natural than the reference c.q. unfiltered condition) to -3 (the reference condition sounds much more natural than the simulated ear canal). A score of 0 means that there is no noticeable difference perceived in naturalness between the two conditions. These fragments were comprised of the 6 conditions and each filtered condition was compared to the unfiltered reference condition. All conditions were presented with two male and two female speaker sentences and were measured twice: one time with the filtered sentence as 'A' and the reference sentence as 'B', and vice versa. With these 48 paired comparisons, together with 4 control comparisons in which the seventh unfiltered condition was compared with itself, a total of 52 paired comparisons were presented in random order.

The paired comparison category rating task was followed by a Visual Analogue Scale (VAS) score task, evaluating the 'overall' sound quality of the 7 conditions, 0 being the worst possible outcome and 100 the best. Again, the 7 conditions were presented in random order by playing four different Dutch sentences.

All of the speech material was presented in free field at a level of 65 dB(A), using a loudspeaker in front of the listener (0^0 angle).

Statistical analysis

Statistical analysis was conducted using SPSS 16.0.2 (Chicago, IL, USA). Data are expressed as numbers. Mann-Whitney-U test were performed to check for significant changes from baseline in the VAS scores. ANOVA multivariate analysis was used to determine the effects of subject, condition, and gender of the speaker on the results. The Bonferroni correction was applied to account for multiple comparisons. *P* values of less than 0.05 were considered statistically significant.

RESULTS

Paired comparison ratings

The ANOVA (mixed model) analysis showed no significant effect of the four different sentences used in the experiment. A second ANOVA analysis, with the gender of the speaker as a fixed effect, showed a small but significant effect of gender on perceived sound quality (p=0.028). The mean rating score was 0.17 less natural for the male speaker, as opposed to the female speaker. More importantly, the different conditions significantly influenced outcome as can be seen in [figure 2]. When comparing the various conditions pairwise with the reference condition, there was no significant difference in naturalness between the two normal conditions (N1 and N2) and the pre-op exostosis condition (EXpre) , since their rating scores were not significantly different from 0. In a pairwise comparison, all other conditions were perceived as significantly less natural (all p<0.001). The pre-op cavity condition (Cpre) scored significantly less natural than all other conditions (all p<0.001).

VAS-scores

The 7 conditions presented are depicted in [figure 3]. No significant difference in VAS scores were observed between the reference condition and all other conditions (all p>0.1), except the pre-operative radical cavity condition (p<0.01).

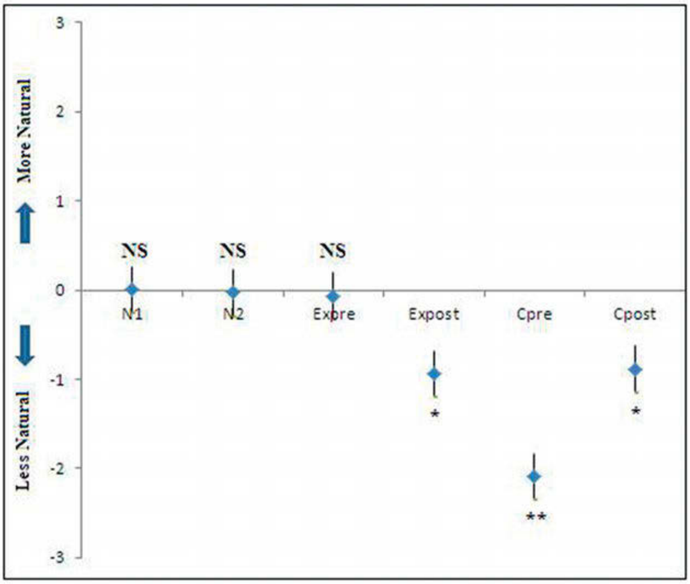

Figure 2. Results of the paired comparison ratings. Scores range from 3 to -3 on a seven point scale. A score of 3 means that the simulated ear canal acoustic c.q. filtered signal sounds much more natural than the reference c.q. unfiltered signal. A score of -3 denotes a clear preference in naturalness for the unfiltered signal. A score of 0 means that there is no noticeable difference in naturalness between the two signals. Bars denote de 95% confidence interval for the mean. * significant difference with 'normal' conditions and Expre condition (p<0.01), ** significant difference with all other conditions (p<0.01)

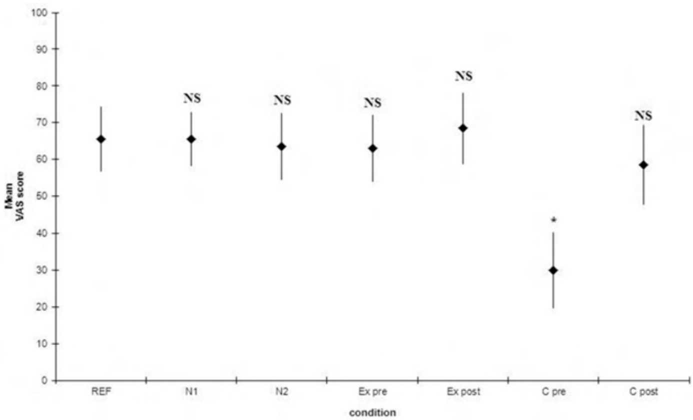

Figure 3. VAS evaluation of the percepted quality of the presented sound per condition. REF: reference, N1-2: 'Normal ear conditions', Ex pre and Ex post: Exostosis condition pre and postoperative, Cpre and Cpost: Cavity condition pre and postoperative. NS: not significant compared to reference, * significant difference with reference and other conditions (p<0.01). Bars denote de 95% confidence interval for the mean.

4.2

DISCUSSION

Our data show that surgery on the osseous external auditory canal may result in clinically relevant changes in sound quality. This is in agreement with our prior work showing that extensive alterations have distinct and clear effects. The current study shows that less extensive changes also lead to distortions, albeit more subtle. This study clearly is an expansion of our earlier work as we used alterations of the osseous external auditory canal within one individual patient instead of multiple individuals. If one evaluates changes within one individual possible effects of the meatal entrance are eliminated. As shown in the present study, a canalplasty can result in a small deterioration in perceived quality of sound whereas a revision radical cavity with reconstruction of the posterior wall can result in a significant improvement. This suggests a volume related change. We hypothesize that a greater ear canal volume results in a deterioration of perceived sound quality. Yet it seems unlikely that ear canal volume is the sole contributor to this effect as both postoperative conditions were quite comparable, while the REURs differed considerably. It would seem that the REUR is also affected by the material of which the external auditory canal is constructed. As the field of otology is moving towards advocating obliteration techniques it is very interesting to determine how critical resonance effects are dependent on the material used for reconstructing the external auditory canal. Satar (11) has shown that obliterated cavities can achieve near normal resonance frequencies if residual volumes were in the normal range. As we still observed some difference in the resonance frequency in obliterated cavities, this may be explained by the materials used for reconstruction. Also, it could be that the normal mastoid cavity with its air cell tracts has a function in resonance, yielding a difference in resonance after obliteration of the entire mastoid cavity. This would be a novel function of the mastoid cavity as its aeration could be a part of how our hearing is influenced. Future studies are necessary to confirm this hypothesis.

We were surprised to find that a small, but significant, effect was found between male and female speech and we did not find a clear explanation. This finding suggests that spectral differences between male and female speech may have their effect on the sensitivity to perceive relatively subtle changes between conditions

Although a significant change was observed between the reference and the post-operative conditions using the paired comparison technique this did not result in different VAS scores. Obviously, it is more difficult to determine the effect of the change without a clear comparison. This indicates that in future research both methods should be used as slight differences are found when comparison techniques are used. In unilateral cases this would be a comparison between the affected and non-affected ear if hearing levels in the audiogram would be preserved. Still, overall quality is a very subjective measurement and made without comparison and therefore it may well be that the VAS could is a better representative for everyday functioning of the patient.

As sound quality can be divided in many subcategories (i.e. loudness, sharpness) one could debate whether our approach is too simple to evaluate the entire scope of 'quality' of perceived sound. We still feel that both tests provide valid and relevant data as these patient reported outcomes reflect daily practice. Therefore they can be regarded as the primary outcome of a surgical intervention.

Using normal hearing subjects does give rise to some points of discussion. We know that the alteration of the acoustics of the external auditory canal is not the only effect surgery will elicit. Two other mechanisms suggested by Evans (5) are eliminated in our study design. First a conductive hearing loss of varying degree for different frequencies will be present, influencing overall sound quality. Yet our study design was aimed at exploring the isolated effect of the change in external ear acoustics on sound quality. Second, the change in middle ear volume in a canal wall down procedure and the type of tympanoplasty performed may also play an important role (2,12,13).

As our study did not consider these possible mechanisms for the abovementioned reasons, the study should be regarded as explorative and its usefulness in clinical practice remains to be proven. Other effects (for instance habituation and the interaction with the post-surgical hearing levels and hearing rehabilitation) have not been investigated and are open for future work. However, this study has strengthened our hypothesis that surgical procedures that alter the shape of the OEAC do effect overall quality of perceived sound. This would explain our clinical observations that some patients claim to have better or worse hearing without any change in post-operative audiogram. Also this effect should be considered in post-operative hearing aid fitting if hearing rehabilitation is (still) needed

CONCLUSION

This explorative study shows that commonly performed surgical procedures changing the shape of the OEAC do affect the resonance function and the perception of sound quality. These results seem to be influenced primarily by volume changes. In this study a canalplasty led to a small deterioration and an obliteration of a mastoid bowl in revision modified radical cavity surgery led to a significant improvement of perceived sound quality. To which extent these changes are important clinically (either in pre-operative counselling or post-operative hearing rehabilitation) remains to be determined.

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General discussion and conclusions

5

INTRODUCTION

This thesis focused on three themes:

1. Surgical treatment of acquired diseases of the OEAC. In order to define the optimal treatment we deemed it necessary to have a better understanding to which extent surgery is effective in alleviating the disease. Furthermore we investigated which aspects are relevant to address during surgery in order to be successful.
2. Shape of the OEAC. Although many authors have suggested that the shape of the OEAC can be a contributing factor in many cases of refractory inflammatory disease and in troublesome cavities we tried to supply clinical evidence for this prior unsubstantiated statement . We investigated the pretympanic recess area as we hypothesize this region to be an important factor for chronicity.
3. Perceived sound quality after surgery addressing the OEAC. When altering the shape of the OEAC it stands to reason that the resonance function will change. Although this phenomenon has been described in the literature, it remains unknown to which extent this change in resonance function is perceived and whether it is clinically relevant. We investigated this phenomenon with more detail.

SURGICAL CONSIDERATIONS.

When extensive conservative therapy of acquired inflammatory disease of the OEAC is exhausted and a state of refractory pathology has arisen surgical intervention is indicated (1). Although Proud (2) recommended to resort to surgery after failure of three weeks of conservative treatment for external otitis, personal experience and experiences described in literature (3) show that many cases have a duration of many years prior to surgical intervention. The optimal moment of surgical intervention is unknown. Perhaps the lack of a clear consensus how to define when a refractory state is present is responsible for such delay? Or could it be that conservative treatment is continued for a longer period due to patient and doctor related reluctance towards surgical intervention?

Varying intervals have been described ranging from 72 hours (4), 2 weeks (5), 3 months (6) to as much as at least one year (7) before one states a chronic or refractory state is present. The Dutch national guideline (8) classifies otitis externa to be persistent after 3 weeks but chronic after 3 months. It states that for chronic otitis externa surgery is the primary treatment. This definition does not cover recurrent otitis externa which could be regarded as a type of refractory state as well.

Although for some diseases (for instance otitis externa) various definitions have been proposed to determine chronicity (see above) it has proven to be very difficult to implement them. This is due to the multi-aetiological origin and varying clinical presentation of these diagnoses. For instance, if a temporal resolution of the inflammation is achieved when does one regard a recurrence or exacerbation to be therapy resistant or chronic. If the middle ear is affected as well or a tympanic membrane perforation is present one cannot define the disease as being solely located in the OEAC and a different strategy must be followed and therefore should not be seen as a sole otitis externa

We would suggest to define acute otitis externa to have an acute start and a resolution within three weeks (with adequate treatment) and without a recurrence within one year. No concomitant ear disease such as tympanic membrane perforation, granular myringitis or middle ear effusion or infection should be present. Chronic otitis externa could therefore be defined to have a duration longer than three weeks or exacerbations and remissions within a one year period. Such a definition would mirror the definition of acute and chronic rhinosinusitis as was described in the european position paper on sinusitis and nasal polyps (EPOS document) (9).

Beside the abovementioned problems of disease definition and disease complexity one could argue that an increased reluctance towards a surgical therapy is present as one can assume it to be accompanied by more risks than the conservative therapy. We meticulously described adverse events and or complications when analyzing our results (Chapter 2,2; 2,3) in order to give insight into which sequelae are related to surgery of the OEAC (safety-aspect). The literature review (Chapter 2.1) and our own series (Chapter 2.2) show that complication rates vary but are a definite factor to consider when proposing surgery and that transient problems occur in a relatively high percentage of patients. This shows that surgery indeed is accompanied with a significant burden to the patient (10). Yet, when considering long term complications, unwanted and adverse effects, this percentage decreases significantly. (Chapter 2.1;2.3) and the balance shifts in favour of surgical intervention if one assumes that no single form of conservative therapy actually will resolve the refractory OEAC disease (11). As the large majority does not suffer major and/or persistent sequelae of surgical intervention one could postulate that the risks of surgical interventions does not weigh up to its potential benefit.

Still some other considerations against surgical treatment can be taken into consideration. First surgical intervention has shown to vary in efficacy between different diseases of the OEAC (Chapter 2.1). For instance we showed (Chapter 2,2) that AMCF has less favorable surgical results compared to COE, exostosis and troublesome cavity groups. This group has a higher recurrence rate and therefore a surgical treatment of AMCF should be deemed less effective. Moreover, if a dry symptom free blind sac is present and only hearing is impaired one could argue that if hearing rehabilitation is successful (either with bone conduction devises or regular hearing aids) no indication remains for surgery at all.

An important aspect is the perceived burden of the disease by the patient. If a patient subjectively experiences limited burden of the disease and if he/she is satisfied with a conservative therapy one could argue that continuation of that treatment is preferred.

In conclusion, the literature review (in Chapter 2.1) and our own data (Chapters 2.2 and 2.3) show that surgery of the OEAC would lead to very high percentages of disease resolvement in a wide variety of ear canal related diseases (including non-inflammatory diseases). Considering all above mentioned arguments and contemplations it seems that with current knowledge one could conclude surgical treatment to be the primary treatment for acquired chronic symptomatic OEAC disease and should be propagated as such.

We are not aware of studies in the literature comparing surgical and conservative treatment in patients with OEAC disease. We are in need of multicenter randomized clinical trials including sufficiently high patient numbers to enable multivariate analysis. Because of the patient number limitations, a careful consideration of the relevant determinants seems mandatory.

As second best a well described case series including all potentially relevant determinants could be used to strengthen recommendations regarding the indications of surgical intervention in acquired OEAC diseases.

When one has decided to perform surgery some practical considerations arise regarding the procedure to perform. The literature review (Chapter 2.1) showed that a wide variety of surgical techniques and underlying philosophies are currently propagated.

Regarding the epithelial lining, two possible contradictory philosophies can be distinguished. One advocating the use of skin grafts and another using secondary healing of the epithelial lining. Although evidence is lacking regarding both positions those in favour of grafting state that faster healing, the need for complete removal of diseased skin and lesser risk of restenosis are acquired when grafts are used. Those in favour of secondary healing state that the unique properties of the skin lining of the OAEC (migratory epithelium, wax production, the absence of subcutaneous tissue and direct adherence to the periosteum) are essential for a normal ear environment and that grafting introduces the need for life-long clinical cleansing and a higher recurrence rate. Further randomized prospective studies could be conducted comparing healing and functional results between a graft and secondary healing group.

Our techniques of canalplasty minimizes skin loss and showed that skin grafting is not obligatory which is in concordance with other observations (1, 12) (Chapter 2.2 and 2.3). Still we have used grafts in revision surgery and in cases of extensive shortage of epithelial lining. We found that these ears healed satisfactory but indeed needed life-long clinical cleansing as migratory properties were no longer present. We therefore think that secondary healing should be preferred and grafting only used in selected cases. We have been very reluctant to use the epithelial lining of the non-affected ear as a possible graft as this could potentially lead to bilateral problems if healing fails.

A promising development has been described regarding in vitro ear canal tissue growth (13). Although no clinical results have been described for the usage of such grafts it could potentially have the benefits of both philosophies. Functional epithelium could be used as a 'transplant' in order to prevent denuded bone surfaces. This would hypothetically lead to faster healing, less intensive post-operative care and possibly minimize 'blunting' of the OEAC while not compromising the unique properties of the skin of the OEAC.

Also, when considering which area to adress and amount of bone to remove during surgery no consensus is currently present. The reviewed techniques (Chapter 2.1) showed that some advocate minimal bone removal of the posterior canal wall while others advocate extensive circular removal of bone especially of the anterior wall. No rationale is given for such decision. We will describe the role of the shape of the OEAC more extensively in the following paragraph but our work has shown that certain areas should be addressed in certain diseases. How much bone has to be removed to acquire a patent and disease free ear canal is completely unknown at the moment. Such knowledge will make surgical intervention even more successful and safe as minimal removal of bone limits potential complications and healing time. This knowledge should be expanded with future research.

A canalplasty only addresses the OEAC and therefore is insufficient when the cartilaginous EAC is involved as well. Some of the techniques described in Chapter 2.1 do not enable a simultaneous meatoplasty as the skinflaps do not leave any space for suturing in a 'pessimistic' flap management strategy (14) or because the lack of exposition of the subcutaneaous layers due to the approach (15) or the need for post-operative use of stents (16,17). This results in a forced staging of surgery, even when one could foresee a meatoplasty to be needed. One can combine our described canalplasty technique with a myringoplasty, meatoplasty, mastoidectomy, and reconstruction of the posterior canal wall (Chapters 2.2 and 2.3) making the technique very versatile. At the moment personal preference or experience is used to decide if a simultaneous meatoplasty is necessary as no evidence based recommendations are present. Future research regarding the interaction between OEAC and the cartilaginous EAC is needed to base the choice of surgical intervention and the type of surgical intervention on clearly defined evidence based parameters such as described below.

THE IMPLICATIONS OF THE SHAPE OF THE OEAC.

We showed that the shape of the OEAC, especially the DPTR plays a role in chronic inflammatory OEAC disease (chapter 3.1 and 3.2).. We mainly evaluated the bony aspects of the ear canal but we do realize that the cartilaginous part may play and important role that remains under exposed in this work. Although we know that a meatoplasty can influence chronic inflammatory OEAC disease significantly(18), we are in need of better methods to quantify the cartilaginous part of the EAC (CEAC) as it remains unknown which aspects of the shape of the CEAC contribute to the effect of a meatoplasty. Evaluation of our surgical cases suggests that the amount of occlusion due to the isthmus of this CEAC might be a crucial factor. Analysis of several dimensions, for instance the distance between conchal cartilage and tragal cartilage or the percentual difference in the cartilaginous circumference in regard to the OEAC circumference, could be used as parameters to investigate the relationship and to formulate a hypothesis that can be tested.

Although we showed that the pretympanic recess plays a role, in COE and draining cavities, we cannot disregard the fact that not all dimensions of this three dimensional complex anatomical shape have been investigated. We had no need to evaluate these parameters in order to investigate our primary hypothesis (being that the PTR was an important part in the chronic inflammatory EAC) and therefore did not include them. Furthermore the factor volume (a better quantifiable factor through tympanometry) is very interesting but unfortunately this information was lacking in our retrospective cohort. So further research could include aspects like the length, width, volume and their mutual relationships as contributing factors. Furthermore a classification should be based on evidence supporting its definition of subsets. With so little evidence presently available (i.e. only the DPTR for COE and draining cavities at the moment) and so many unknown determinants it is crucial that further research defines the relevant factors before constructing a classification for inflammatory ear canal disease.

Based on theoretical grounds, we argued that the DPTR plays a role in the chronicity of inflammatory disease due to the inability of adequate (self) cleansing of the ear canal. Furthermore we postulated that a possible intertriginous eczema would occur due to a smaller angle in case of deeper PTR, allowing easier skin-to-skin contact (Chapter 3.1). This assumption provides a logical explanation for the fact that (at least a part of) the shape of the OEAC is a contributing factor to chronic inflammatory ear canal disease. Perhaps the OEAC shape influences other aspects like humidity and pH values in the external ear canal as well. Martinez Devesa (19) showed that also the pH is correlated with possible chronicity but immediately stated that more research was needed for conclusive statements. Gray (20) found similar results regarding humidity. A 'smaller' ear canal volume could give rise to an increased humidity and disruption of ear wax homeostasis due to accumulation, which could alter pH values significantly. A multifactorial analysis including shape, pH, humidity, volume and disease occurrence could elucidate the pathogenesis of chronic inflammatory disease of the ear canal. Such further knowledge will facilitate the development of precision medicine in the treatment of OEAC.

We have demonstrated that the shape plays a role in inflammatory disease (Chapters 3.1 and 3.2). Some other acquired diseases of the OEAC (such as AMCF, Canal stenosis, troublesome cavities and to some extent exostosis) could be regarded as closely related to inflammatory processes. Yet other acquired diseases (such as malignancies, benign tumors, cholesteatoma, exostosis and osteomata) are not associated with inflammation. Although it is more difficult to hypothesize how the shape would be a part of the pathogenesis of such diseases perhaps the shape would influence treatment outcome or affect symptoms. Further research regarding the non-inflammatory diseases and their relation to the shape could be interesting and useful.

Although not within the scope of this thesis the shape of the OEAC would logically play a role in treatment of other ear diseases as well. As the ear canal is an easy approach to the tympanic membrane, the middle ear and the cochlea it is reasonable to assume that surgical treatment outcomes of diseases of the middle ear and tympanic membrane will be influenced by the shape due to the amount of surgical exposure. Currently an interesting field of endoscopic ear surgery is developed in which the ear canal is used in treating a wide variety of middle ear disease (21). One could easily postulate that outcome of such surgery is related to ear canal shape.

Unpublished clinical observations made by our group suggest that the shape of the OEAC influences the width of the facial recess making a pre-operative assessment of the surgical approach possible, for instance in case of a cochlear implantation. One could decide whether a transmastoid posterior tympanotomy drilling of the cochleotomy (or drilling of the crista ante fenestram in a round window implantation) is preferred or that a transcanal drilling would be easier. As results have shown to be similar (22) one could choose for an approach that minimizes risks for chorda tympani and facial nerve and maximizes exposure of the target organ.

We also suspect that some radical cavities are the result of lowering the posterior border of the ear canal in order to optimize exposure of the anterior part of the middle ear space. This would not be necessary if a canalplasty is performed or if an endoscope is used. One could pre-operatively asses the problem of limited visibility as it is directly related to a larger ACPTR. Our findings (Chapter 3.2) show that this abovementioned suspicion is definitely a possible factor in choosing for a radical cavity. An approach to further research this hypothesis is to prospectively asses the ACPTR and investigate whether a conversion to a conservative radical mastoidectomy was needed / deemed necessary (with the assumption that a CWU approach is indicated beforehand). Or if an endoscope was used to assess the anterior middle ear space.

We feel that the success rate of tympanic membrane closure (especially in anterior and (sub) total perforations) increases if more exposure is present. It is commonly accepted that the residual disease rate of cholesteatoma (especially tympanic cholesteatoma) is lower when the ear canal shape allows more exposure (23). The drop in residual cholesteatoma when an endoscope is used to inspect the difficult regions of the middle ear cavity also strengthens this statement (24).

Another aspect in the treatment decision process of patients with acquired OEAC disease, but also in the treatment of hearing loss in general is hearing aid rehabilitation. We know that some patients do not tolerate the occlusion of the OEAC due to wearing acoustical hearing aids. Some even develop OE which in turn can become chronic. Although sound presentation via other modalities as vibration through Bone-Conduction Devices (BCD) has shown to be very effective in hearing rehabilitation in such cases (25,26), it has been generally accepted that acoustical hearing aids have distinct advantages like a higher maximum output and more effective gain than BCD's. Consequently, acoustical hearing aids are the preferred option when tolerated.

Some of our study cohort patients had COE due to occlusion and the results of canalplasty are partly comprised with patients wearing conventional hearing aids (Chapter 2.2). It would be very interesting to perform sub analysis whether a canalplasty was successful in altering the shape in such a manner that hearing aids could be tolerated better post-operatively. Special attention is required in case of troublesome cavities. As hearing results are generally poorer in cavities (27) and mixed hearing loss is often present with a contralateral better hearing ear, conventional hearing aids are often a better choice than the abovementioned alternative of BCD's. Unfortunately most cavities do not respond well to occlusion and often hearing aids are not tolerated (28). Clearly further research, preferably in a prospective randomized manner, is warranted to determine whether and to which extent a canalplasty can increase the tolerance for acoustic hearing aids in complicated cases. Multifactorial analysis in individuals that had unsuccessful hearing aid rehabilitation due to radical cavity, excessive sweating, aural fullness, sound distortion and inflammatory response could elucidate to which extent anatomical dimensions, and the humidity and pH play a role.

An anatomical model that allows us to alter the shape factor independently while leaving other factors unchanged could supply even more insight how altering the shape influences the final outcome. The predictions of such a model should be tested in clinical studies to evaluate them. These results could lead to a better prognosis of the post-operative results and to an improved evaluation of operative techniques.

PERCEIVED SOUND QUALITY CHANGES AND ITS IMPLICATIONS

We have shown that we can measure and simulate at least some of the alterations that are the result of the shape of the OEAC (Chapter 4.1). Significant effects can be achieved in perceived sound quality with surgery altering the shape of the OEAC (Chapter 4.2). Further studies are necessary to implement this knowledge in daily clinical practice and in pre-operative counseling when considering a canalplasty or canal reconstruction. We still face an extensive lack of knowledge, so these studies should at least include whether habituation/acclimatization takes place. Certain aspects of the sound perceived as more or less distorted and hearing rehabilitation can be used to compensate this perceived effect.

Acclimatization can be investigated by using patients as their own controls. Do patients still regard the simulated cavity condition presented to their normal ear to have a poorer sound quality? And can we reach better perception if we present 'normal' resonance conditions to the cavity ear? If acclimatization does not occur one can imagine that the altered resonance state can be compensated using hearing aids using filtering that takes into account the acoustical effects of the surgical interventions. If this is a viable alternative remains to be investigated. If similar results in perceived sound could be attained with hearing aids this could reduce the need for surgical intervention.

We showed how the real ear unaided response curves differed from the normal reference curve for several conditions (Chapter 4.1 and 4.2). Not very surprisingly we observed a less 'natural' sound or poorer 'quality' when these curves were more deviant from "normal". This raises the question whether this difference could be used as an objective measure for subjectively perceived sound quality. Another question would be which aspect of the real ear unaided response is the most critical factor for the subjective sound quality? Is the gain loss more important when present in certain frequencies? Does an increase in gain lead to more or lesser distortion when evaluated subjectively? Further research should be performed to answer these questions. Such knowledge can be used in research regarding surgical changes made to the OEAC eliminating the need for normal hearing cohort analysis of outcomes. Perhaps mathematical models can be used to predict which adjustment of real ear gain would lead to positive of negative subjective effects. And the usage of the real ear unaided response and gain could be used to predict pre-operatively which effect can be achieved when certain types of surgical interventions are performed

For the field of hearing rehabilitation, it will be important to understand how the resonance function leads to a perceptible effect. In children hearing aid rehabilitation often takes such effects into account (29) as the OEAC is not yet full grown. Yet when cavities or post-operative changes are present such effects are often ignored when applying a hearing aid. Whether hearing rehabilitation will improve when taking in account the effects of the alterations in shape of the OEAC after surgery can easily be explored in a randomized prospective trail using subjective outcome tools as primary outcome measurements.

Apart from our primary interest in OEAC we appreciate that other factors are important in patients undergoing ear surgery. Ideally, acoustic modeling including middle ear function (or dysfunction) and cochlear function could pre-operatively evaluate the acoustical effects for a broad scope of otological intervention. In addition to modeling we are in need of further developed patient reported outcome measures that can be used to personalize treatment counseling.

THE CONTRIBUTION OF THIS WORK.

This thesis indicated that an evidence-based approach was lacking in OEAC surgery. The work in this thesis tried to supply evidence and specify the rationale used regarding the indication and technique for OEAC surgery. Also we indicated areas where additional research is needed. Our proposal to standardize reporting of surgical outcome will hopefully lead to better comparisons between the techniques and to the identification of the key elements of surgery that influence outcome. We supplied evidence for the benefit of the canalplasty techniques we used in acquired OEAC disease and radical cavities. Because enlarging or widening the OAEC leads to a deterioration of perceived sound quality, we advocate a more individually tailored approach to OEAC surgery based on a systematic analysis of the contributing components. We showed the reduction of the depth of the pre-tympanic recess is an important component in OAEC surgery while the anterior curvature can be left untouched. Less extensive surgery can also lead to faster healing, less pain and to better care. We also suggest to perform earlier surgery in persistent otitis externa (duration of more than 3 weeks) especially when the DPTR is larger than 2,7 mm and other diagnoses have been considered. In conclusion this thesis has increased our understanding and knowledge regarding the surgical approach an d the effects of shape and sound of the OEAC. The ultimate aim is to enable evidence based surgery. Further research as indicated in this discussion will help us to reach that goal.

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Appendix

Summary
Dutch summary, Nederlandse samenvatting
About the Author
Publications
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Dankwoord

SUMMARY

This thesis describes three aspects of the osseous external auditory canal which are related to each other.

Chapter 1

A review of normal anatomy and pathophysiology of the OEAC is given and the acquired diseases of the OEAC and their treatment are described. In the final paragraph the relation between surgery of the OEAC, the shape of the OEAC and the perceived sound quality due to the resonance function of the OEAC are discussed when outlining the aim of this thesis.

Chapter 2

This chapter focuses on several aspects of surgical intervention in acquired disease of the OEAC and presents techniques that allow one to perform a standardized canalplasty. An extensive review of literature is presented in chapter 2.1. A wide variety of surgical techniques/approaches have been described. Unfortunately the lack of well-defined outcome parameters, no comparability of patient groups, overall quality of series description make meta-analysis of and meaningful conclusions regarding these data very difficult. It does provide a comprehensive overview of all techniques that are described with results. We describe the results of our own canalplasty technique in chapter 2.2. The technique is described in a comprehensive way and its results regarding healing time, hearing results, adverse events, complications are discussed. We debate the need of preservation of epithelial lining and share our philosophy of maximizing exposure in order to enable adequate bone removal in all directions. We show that our used technique is effective and safe when surgically addressing almost all acquired diseases of the OEAC. However when regarding troublesome modified radical cavities (an iatrogenic acquired problem of the OEAC) the extensive change in anatomy makes the described technique impossible. We describe a different technique in chapter 2.3 that does enable one to perform a canalplasty with the same advantages and philosophy regarding skin preservation and maximal exposure in a troublesome cavity. We show that this technique leads to very satisfactory results.

Chapter 3

The shape of the OEAC is the main focus in this chapter. Many authors have referred to this shape as a contributing factor in many acquired diseases of the OEAC. No specifics were given and no useful classification is mentioned of this shape. In chapter 3.1 we describe our effort to quantify, classify and objectify the shape of the OEAC. We use a descriptive technique of the overall shape and we propose a method of measuring two dimensions of the pretympanic recess. The depth of this recess (DPTR) and the anterior curvature (ACPTR) as we hypothesize that the ability of (self)cleansing of the OEAC is hampered by these two dimensions. As we propose a novel measurement technique we investigated if this technique was viable using interobserver agreement. An excellent agreement was observed demonstrating our method

to be reproducible. In order to determine if the shape was related to chronic otitis externa (COE) we compared two groups with each other using all the above mentioned parameters. One group consisted of patients with COE and we used cochlear implant patients with no otologic disease as our controls. Using the descriptive technique no overall form could be defined that was more dominant or significantly more present comparing the groups. We did find a significant difference between both groups when assessing the DPTR. We found that a deeper pretympanic recess is present in the COE group when compared to our control group. Using the 95% confidence intervals we postulated that a depth of less than 2.6 mm could be seen as a 'protective' factor in COE. No significant difference in ACPTR was observed. This is the first evidence that the shape of the OEAC is indeed a factor in COE. It supports our hypothesis of the importance of the pretympanic recess in chronic inflammatory disease. In chapter 3.2 we decided to investigate whether the shape of the OEAC was a contributing factor in draining (troublesome) cavities as well as one could suggest that this is a form of chronic inflammation. As it is well known that draining cavities (troublesome) have multifactorial causes we regarded these as well. The amount of remaining air cell tracts is easily quantifiable but other factors (such as height of facial ridge, adequate meatoplasty, CSF leakage) are not. We compared the DPTR and ACPTR of three groups (one comprised of troublesome cavities, one comprised of troublefree cavities and a control group of cochlear implant users). Significant differences were found between the cavity groups regarding amount of remaining air cell tracts. A significant difference was also present between the troublesome cavity group and the other two groups in DPTR. The DPTR was significantly greater and more air cell tracts remained in the troublesome group in comparison to the other groups. Using multivariable logistic regression the difference in DPTR remained significant between cavity groups when corrected for remaining air cell tracts. Using the 95% confidence intervals we showed that a depth of less than 2.7 mm could be regarded as being 'protective' in case of cavities becoming draining or not. Although ACPTR did show a remarkable significant difference in the non-affected ears when comparing cavities with controls it wasn't found to be significantly different in the affected ears. This would suggest that the DPTR is the most important quantifiable factor in chronic inflammation of the OEAC leading to symptoms such as otorrhoea.

Chapter 4

As the OEAC plays a role as resonance tube it would be logical to presume that perceived sound will alter when surgically altering the shape of the OEAC. In this chapter we aim to elucidate if and to which extent the presumed effect is perceivable.

In order to do so we describe a method which enables us to present conditions that represent the sound perceived at the level of the ear drum using a filter that can be made using real air unaided response (REUR) of different ear canals. These filtered conditions can be presented to normal hearing subjects to determine the true effect of the change in resonance function (regardless of conductive hearing loss, middle ear mechanisms and possible habituation). A proof of concept study is described in chapter 4.1 using the extremes (normal ear canals and modified radical cavities). We presented these conditions to 20 normal hearing subjects and using a VAS scale and paired comparison ratings in order to determine the overall perceived 'quality' and whether the sound was perceived to be more 'natural' in comparison with a reference (unfiltered) condition. Very clear significant results were found using both methods showing a perceived 'worsening' of the sound qualities tested in all cavity conditions in regard to the normal conditions. These results show that changes in shape of the OEAC will lead to perceivable sound changes and therefore are of importance. Although we acknowledge more research should be done in regard to habituation. Also these results are not directly translational into clinical practice. In chapter 4.2 we wanted to see whether less extreme changes in shape would be perceivable as well. We were also interested if our method could demonstrate changes within patients who undergo surgery. We used both canalplasty techniques as were described in chapter 2 in two different patients. One patient suffered from COE due to exostoses and the other had a troublesome cavity which was revised using a canalplasty technique combined with a partial obliteration of the mastoid cavity. We measured pre and postoperative REUR after complete healing. When 20 normal hearing subjects evaluated the conditions using a VAS score the pre-operative cavity condition was significantly different from all other conditions. Yet, all other conditions did not differ significantly suggesting that the effect of a canalplasty is not noticeable as a deterioration of sound quality in case of an increase in OEAC volume (removing exostoses) but a clear improvement is present when the volume is decreased. Using a paired comparison method we did find significant differences between the post-operative conditions when compared with the reference condition but the difference was determined to be a slightly less 'natural' compared to the reference condition. This suggests that a perceivable difference is present without major effects on sound quality when the ear canal is enlarged in comparison with a normal ear volume. One can conclude that the effects of a canalplasty with enlargement of the OEAC will be perceived but minimally. The effect of canalplasty and obliteration (volume decrease) will lead to a more 'natural' sound and better sound quality than a radical cavity.

Chapter 5

In this chapter the obtained results of this thesis are discussed in general. We show how the various aspects investigated in this thesis are intertwined with each other and overall conclusions are drawn.

DUTCH SUMMARY, NEDERLANDSE SAMENVATTING VAN HET PROEFSCHRIFT

Dit proefschrift beschrijft drie aspecten van de benige externe gehoorgang (BEG) die aan elkaar zijn gerelateerd namelijk de chirurgie, vorm en resonantierol ervan.

Hoofdstuk 1 beschrijft een overzicht van de normale anatomie en pathofysiologie van de BEG. Verder worden de verworven ziekten van het BEG en de behandeling ervan beschreven. In de laatste paragraaf worden de relaties tussen de chirurgie, de vorm van de BEG en de waargenomen geluidskwaliteit als gevolg van de resonantie-functie van de BEG besproken. Daarmee wordt ook het doel van dit proefschrift verhelderd.

Hoofdstuk 2 richt zich op de verschillende aspecten van chirurgische interventie van de BEG bij een verworven ziekte van de gehoorgang. Een tweetal technieken van een gestandaardiseerde gehoorgangplastiek worden gepresenteerd. Hiernaast wordt een uitgebreid overzicht van de literatuur gepresenteerd ten aanzien van alle verschillende gehoorgangplastieken (hoofdstuk 2.1). Dit overzicht laat zien dat er een grote verscheidenheid van chirurgische technieken/methoden is beschreven. Door het gebrek aan duidelijk gedefinieerde uitkomst parameters en vergelijkbare patiëntengroepen was de wetenschappelijke kwaliteit van de gevonden literatuur zo laag dat er geen meta-analyse mogelijk was. Daardoor was het moeilijk om tot zinvolle conclusies te komen ten aanzien van de verschillende gehoorgangplastieken. Wij beschrijven de resultaten van onze gehoorgangplastiek techniek in hoofdstuk 2.2. In onze beschrijving van deze techniek hebben wij geprobeerd om alle relevante resultaten(genezingstijd, hoor resultaten, bijwerkingen en complicaties) mee te nemen. Wij beschrijven onze visie ten aanzien van de maximalisatie van chirurgisch zicht en de werkruimte, met behoud van de epitheliale bekleding van de gehoorgang, met als doel om voldoende bot te kunnen verwijderen met minimale effecten op de functie van de BEG. We tonen aan dat onze gepresenteerde techniek van gehoorgangplastiek effectief en veilig is en toepasbaar in de chirurgische behandeling van alle verworven BEG ziekten. Echter in het geval van een gemodificeerde radicaalholte (een iatrogeen verworven probleem van de BEG) is door de uitgebreide verandering van de anatomie deze techniek niet mogelijk en vandaar dat we ook een andere techniek hebben beschreven (hoofdstuk 2.3). Met deze techniek is het mogelijk om een gehoorgangplastiek te verrichten, met gelijke filosofie als de eerder beschreven techniek ten aanzien van expositie en behoud van epitheliale bekleding van de BEG,. We laten zien dat deze techniek ook tot zeer bevredigende resultaten leidt.

In hoofdstuk 3 ligt de focus op de vorm van de BEG. Alhoewel veel auteurs de vorm van de BEG vaak beschrijven als etiologische factor in verworven ziekten van het BEG worden hiervan geen nadere specificaties gegeven. Er ontbreekt een beschrijving welke vorm (of onderdeel van de vorm) dan bijdragend zou zijn en er ontbreekt een nuttige classificatie van de vorm van de BEG. In hoofdstuk 3.1 beschrijven wij onze inspanning om de vorm van de BEG te objectiveren door goed te kwantificeren en een poging te doen om te classificeren. Wij gebruiken een beschrijvende techniek van de gehele vorm van de BEG en beschrijven een methode voor het meten van de twee dimensies van de pretympanische ruimte. De diepte van deze uitsparing (DPTR) en de anterieure kromming (ACPTR) lijken ons van belang. Dit vanuit de veronderstelling dat deze dimensies het zelfreinigend vermogen van de BEG kunnen belemmeren. Deze nieuwe meettechniek liet een voortreffelijke overeenstemming tussen beoordelaars zien (´inter-observer´ overeenkomst) waardoor het een goed bruikbare en reproduceerbare methode blijkt te zijn. Om te bepalen of de vorm van de BEG was gerelateerd aan chronische otitis externa (COE) vergeleken wij twee groepen met elkaar met behulp van al de hierboven genoemde dimensies. Eén groep bestond uit patiënten met COE en de controlegroep bestond uit patiënten met een blanco otologische voorgeschiedenis die een cochleair implantaat gingen krijgen. Met behulp van een beschrijvende techniek van de gehele vorm van de BEG kon geen vorm worden geïdentificeerd die verschillend of oververtegenwoordigd was tussen beide groepen. Een significant verschil werd gevonden tussen beide groepen in de DPTR. Wij vonden dat een diepere pretympanische ruimte aanwezig was in de COE groep in vergelijking met de controlegroep. Met behulp van het 95%-betrouwbaarheidsinterval konden wij stellen dat een diepte van minder dan 2,6 mm kan worden gezien als een 'beschermende' factor tegen COE. Geen significant verschil in de ACPTR werd waargenomen. Dit is het eerste bewijs dat de vorm van de BEG inderdaad een factor in COE is. Het ondersteunt onze hypothese van het belang van deze pretympanische ruimte in chronische ontstekingsziekten van de BEG. In hoofdstuk 3.2 hebben wij onderzocht of de vorm van de BEG een bijdragende factor in problematische radicaalholten zou zijn, aangezien dit ook een chronische ontsteking betreft. Aangezien het algemeen bekend is dat problematische radicaalholten een multifactoriële etiologie kennen probeerden wij deze ook mee te nemen bij het evalueren van deze conditie. Eén ervan, namelijk de hoeveelheid resterende celtracti, is gemakkelijk meetbaar, maar andere factoren (zoals bijvoorbeeld de hoogte van het facialisspoor, een niet adequate meatusplastiek, liqourlekkage) zijn dit helaas niet. We vergeleken de DPTR, ACPTR en de hoeveelheid restcellen van drie verschillende groepen (één met problematische radicaalholten, één met rustige radicaalholten en een controlegroep met cochleair implantaatkandidaten). Een significant verschil werd gevonden binnen beide radicaalholte groepen in de hoeveelheid restcellen. Een significant verschil was ook aanwezig tussen de problematische radicaalholte groep en de andere twee groepen in DPTR. De DPTR was beduidend dieper ten opzichte van de andere twee groepen. Met behulp van multivariabele logistische regressie bleef het significante verschil in DPTR aanwezig tussen beide radicaalholte groepen, ook na een correctie op aanwezigheid van restcellen. Met behulp van het 95%-betrouwbaarheidsinterval stelden wij vast dat een diepte van minder dan 2,7 mm, van de DPTR, kan worden beschouwd als potentieel beschermend tegen het ontstaan van een problematische radicaalholte. Alhoewel de ACPTR een opmerkelijk significant verschil liet zien tussen de niet aangedane oren van de radicaalholte groepen in vergelijking met de controlegroep werd dit niet gevonden tussen de radicaalholtezijde met de controlegroep. Al deze resultaten suggereren dat momenteel de DPTR de belangrijkste kwantificeerbare factor is bij een chronische ontsteking van de BEG.

Hoofdstuk 4 is gericht op de perceptieve effecten. Aangezien de BEG als een resonerende buis werkt en hiermee een rol speelt in het horen is het logisch te veronderstellen dat de geluidswaarneming zal veranderen wanneer er chirurgisch wordt ingegrepen in de vorm van de BEG. In dit hoofdstuk wilden wij vaststellen of en in welke mate dit verondersteld effect aanwezig is. Om dit te bewerkstelligen beschreven wij een methode die ons in staat stelde om het geluid van verschillende gehoorgangvormen te simuleren, zoals deze wordt waargenomen op het niveau van het trommelvlies. Hierbij werd een filter gemaakt voor geluid, gebruik makend van de 'real ear unaided response' (REUR) gemeten in verschillende gehoorgangen. Deze gefilterde condities werden vervolgens aan normaalhorenden gepresenteerd teneinde een subjectieve beoordeling te krijgen van het effect van de verandering in resonantiefrequentie van de gehoorgangconditie. Deze methode is geheel gericht op de resonanties in de gehoorgang en laat andere effecten (zoals bijvoorbeeld een aanwezig geleidings gehoorverlies, middenoorpathologie en een mogelijke habituatie) buiten beschouwing. In hoofdstuk 4.1 wordt een conceptuele studie beschreven waarbij, met behulp van extreme BEG condities (normale gehoorgangen en gemodificeerde radicaalholten), gekeken is naar de waarneembaarheid van de verschillen. Door 20 normaal horenden gevraagd werd de klank van de verschillende condities beoordeeld op een visuele analoge schaal (VAS) ten aanzien van de kwaliteit van het gepresenteerde geluid. Ook werd gevraagd om aan te geven hoe 'natuurlijk' het geluid klonk en dit werd geëvalueerd met de waardering van gekoppelde vergelijkingen (paired-comparison) waarbij elke conditie werd vergeleken met een ongefilterde referentie conditie. Met beide methoden werden evident significante verschillen gevonden. Er was sprake van een waargenomen 'verslechtering' van kwaliteit en natuurlijkheid van het geluid in alle radicaalholte condities versus de normale condities. Deze resultaten tonen aan dat veranderingen in de vorm van de BEG tot een waarneembaar geluidsdistorsie zal leiden en dus relevant zijn. Dit zijn belangwekkende bevindingen, al onderkennen wij dat meer onderzoek nodig is naar de invloed van de andere factoren, zoals bijvoorbeeld habituatie, voordat sterke conclusies getrokken kunnen worden. Ook zijn deze resultaten (nog) niet direct bruikbaar binnen de kliniek. In hoofdstuk 4.2 was de vraagstelling of minder extreme veranderingen in vorm ook waarneembaar zouden zijn. Hiernaast waren wij ook geïnteresseerd of onze methode binnen een patiënt veranderingen kon aantonen tussen een preoperatieve en postoperatieve toestand van de BEG na een vormverandering hiervan. Om dit te bewerkstelligen werden er condities gesimuleerd van twee patiënten die beide gehoorgangplastieken ondergingen, zoals beschreven in hoofdstuk 2. Het betrof een casus van een patiënt met COE op basis van exostosen en een casus van een patiënt met een problematische radicaalholte die werd gereviseerd met een gehoorgangplastiek. Bij de laatste werd de achterwand gereconstrueerd en de mastoidholte werd partieel geoblitereerd. Een REUR werd gemeten preoperatief en postoperatief nadat er een volledige genezing was opgetreden. Na evaluatie door 20 normaalhorenden van de condities met behulp van een VAS score werd de preoperatieve radicaalholte als significant slechter beoordeeld ten opzichte van alle andere condities. Alle andere condities lieten echter geen significante verschillen zien en dit resultaat suggereert dat het effect van een gehoorgangplastiek zoals beschreven in hoofdstuk 2.2 geen merkbare verslechtering van de geluidskwaliteit geeft. Men kan dan ook met enige voorzichtigheid stellen dat de toename van het volume van de BEG bij de gehoorgangplastiek voor exostosen geen verschil geeft maar dat er wel een duidelijke verbetering aanwezig is wanneer het volume wordt verkleind (zoals het geval bij de gehoorgangreconstructie en partiele obliteratie van de mastoidholte). Met behulp van de methode met gekoppelde vergelijkingen vonden wij, naast een evident significant verschil tussen de radicaalholteconditie en de referentieconditie, ook significante verschillen tussen beide postoperatieve condities ten opzichte van de referentieconditie. Dit verschil werd echter als 'iets onnatuurlijker' ten opzichte van de referentieconditie vastgesteld. Dit suggereert dat er wel een waarneembaar verschil aanwezig is, maar zonder grote gevolgen voor de geluidskwaliteit, wanneer er een verandering van de BEG plaatsvindt. Geconcludeerd kan worden dat de geluidsdistorsie van een gehoorgangplastiek (met een toename van BEG volume) zal worden opgemerkt maar met minimale effecten op geluidskwaliteit. Het effect van een gehoorgangreconstructie en partiele obliteratie van de mastoidholte zal leiden tot een sterk waarneembare verandering met een meer natuurlijk geluid en betere geluidskwaliteit dan in de situatie met een radicaalholte.

In hoofdstuk 5 worden de beschreven resultaten van dit proefschrift in het algemeen besproken. Wij laten zien hoe de verschillende aspecten van de BEG, onderzocht in dit proefschrift, met elkaar zijn vervlochten en wij komen tot het formuleren van algemene conclusies.

ABOUT THE AUTHOR

Erik van Spronsen was born 23th of May 1975 in Leiden. After attending primary schools in several countries. He received secondary education (atheneum) at the Rijnlands Lyceum Sassenheim from which he graduated in 1993. From 1993 until 2001 he studied Biomedical sciences at the Leiden University which was successfully completed in 2001 and simultaneously starting his medical training at Leiden University from 1995 until 2000. He received his medical degree in 2000. Following the medical training he started the ORL specialization at the Radboud university Nijmegen which was successfully completed in 2006. He demonstrated his otologic interest by winning three consecutive Dutch petrous bone dissection prizes (twice second place and once fifth place). After his residency he obtained a position as an otorhinolaryngologist at the Academic Medical Centre, Amsterdam subspecialized in Otology and Neurotology. With the help of his fellow otologists he organized an advanced otology course for over 8 years now. From 2010 to 2016 he participated as a part of the management team of the ORL department of the AMC. He supervised multiple bachelor theses. He finished several courses within the field of teaching and management. He is married to Marieke van Weel and has three daughters (Mylène, Veerle and Alyse).

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PHD PORTFOLIO

Name PhD student: E. van Spronsen
Name PhD supervisors: Prof. dr. W.J. Fokkens and Prof. dr. ir. W.A. Dreschler
Name PhD cosupervisor: Dr. F.A. Ebbens

Invited lectures

2014 Flaps and Materials in Mastoid Obliteration, Belgian Ent Society congress, Brugge, Belgium (ECTS 1)

2016 Surgery, Shape and Sound of the osseous external auditory canal, CHUV, Lausanne, Switzerland (ECTS 1)

&

Other lectures

2003 Patiëntenvoordracht “een dwarse leasie”, Dutch ENT society congress (ECTS 0.5)

2005 Sublinguale immunotherapie bij graspollenallergie, studieopzet, Dutch ENT society congress (ECTS 0.5)

2011 10 jaar gehoorgangplastieken, Flemish Dutch Otologic Society (ECTS 0.5)

2013 Retrospectieve analyse van revisie radicaalholte chirurgie met partiele obliteratie, Flemish Dutch Otologic Society (ECTS 0.5)

2014 Akoestiek van de veranderde gehoorgang, Flemish Dutch Otologic Society (ECTS 0.5)

2016 Groeisnelheid van Cholesteatomen, Flemish Dutch Otologic Society (ECTS 0.5)

2017 Behandeling van binnenoorfistels door cholesteatoom, Flemish Dutch Otologic Society (ECTS 0.5)

Honours and awards

2003 Second place, the Dutch national temporal bone dissection prize

2004 Fifth place, the Dutch national temporal bone dissection prize

2005 Second place, the Dutch national temporal bone dissection prize

Teaching

2014 Basis Kwalificatie Onderwijs (Qualified Educator) (ECTS 2)

MD –Bachelor Theses supervised:

2010 Cathelijne van Wettum – 'Retrospective analysis of canalplasty in the AMC' (ECTS 1)

2011 Zainab Baksoellah - 'Subjective or objective measurements'. (ECTS 1)

2013 Simon Geerse - 'The shape of the osseous external auditory canal and its relationship to chronic otitis externa' (ECTS 1)

2015 Joris Logher - 'Residual cholesteatoma in subtotal petrosectomy; measuring growth and the implications' (ECTS 1)

Otology education

Course Director of the Amsterdam Course on Mastoid Obliteration and Surgery of the external Auditory Canal. (ECTS 1)

Faculty member of Dutch endoscopic ear surgery course. (ECTS 1)

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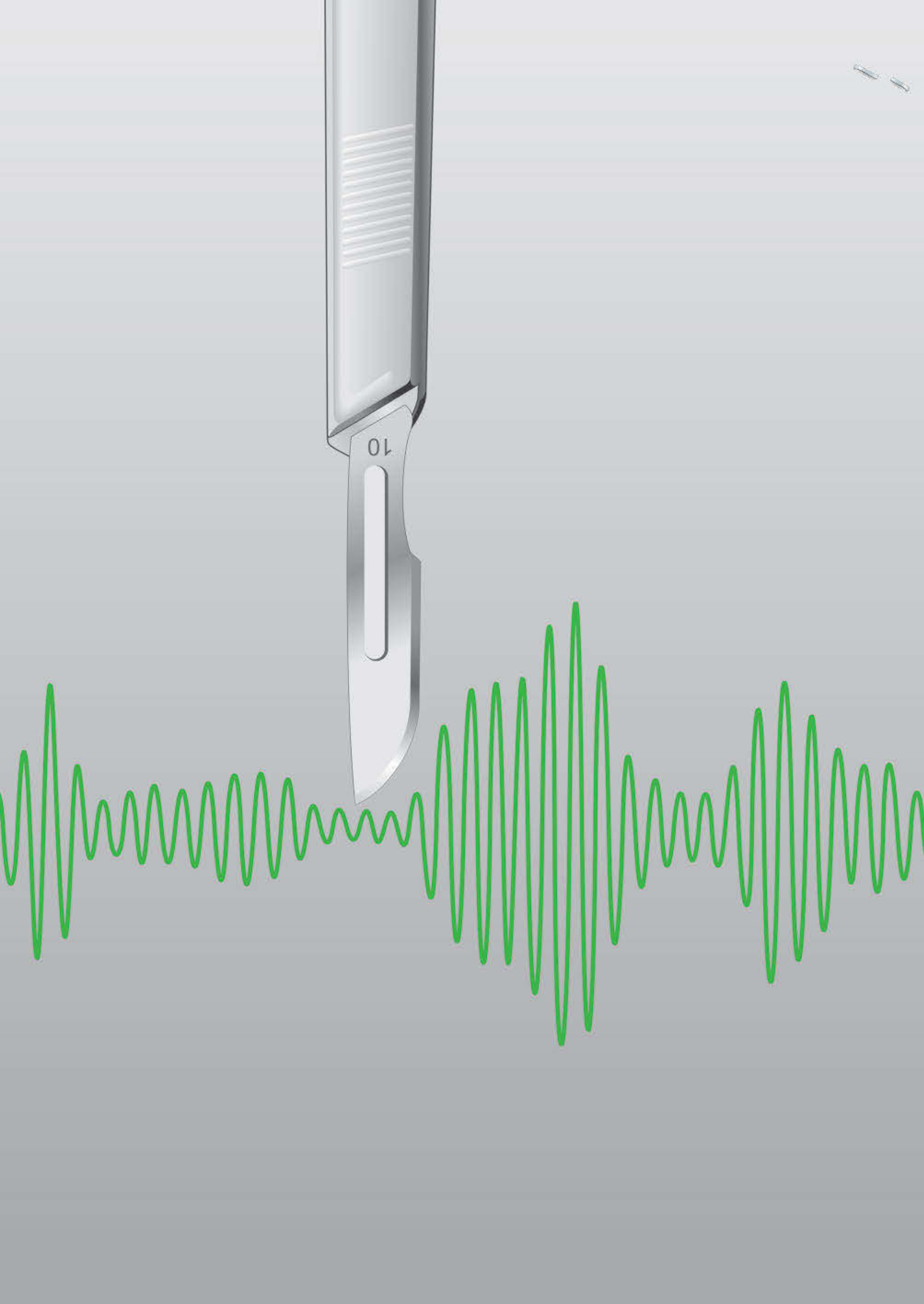
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