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Clinical and Audiological Aspects of Stapes Surgery in Otosclerosis

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Aan Hedwig, aan mijn ouders

Contents

Abbreviations

ABG	Air-Bone Gap
AC	Air Conduction
AHEPs	Amsterdam Hearing Evaluation Plots
AMA	American Medical Association
BC	Bone Conduction
BHI	Binaural Hearing Impairment
dB	Decibel
DSHL	Decibel Sum of the Hearing thresholds Levels
GBP	Glasgow Benefit Plot
HL	Hearing Level
IWP	Impairment of the Whole Person
MDSHL	Modified Decibel Sum of the Hearing thresholds Levels
MSDS	Maximum Speech Discrimination Score
PTA	Pure-Tone Average
SD	Standard Deviation
SDS	Speech Discrimination Score
SNHL	Sensorineural Hearing Loss
SRC	Speech Reception Curve
SRT	Speech Reception Threshold

Chapter 1

General Introduction.

1. OTOSCLEROSIS

1.1 Definition

Otosclerosis is a term used to describe a localised disease of the bone derived from the otic capsule and characterised by alternating phases of bone resorption and formation. Mature lammelar bone is removed by osteoclasts and replaced by osteoblasts into bone of a greater thickness, cellularity and vascularity. The characteristic lesion is a deposit of new bone with a different fibrillar and cellular pattern which is laid down at certain sites in the temporal bone. The site of predilection of otosclerotic foci is the region of the otic capsule, located between the cochlea and vestibule and just anterior to the footplate of the stapes. This region is associated with the globuli interossei or so-called embryonic rests.[1]

The term "otosclerosis" , introduced by Politzer in 1894[2], refers to the final inactive stage of the process where the bone is sclerotic or hardened. The term "otospongiosis", first used by Siebenmann in 1912[3], refers to the active and vascular stage of the process and is more accurate from a pathological point of view as it indicates that an active lesion may be present. The term "otospongiosis" was initially widely used in Europe. However, the term "otosclerosis" was used in the UK and in North America and is at present adopted in the English language world literature to define the pathological changes.

1.2 History

It has been credited to Vasalva who, in 1741, has been the first to report a description of ankylosis of the stapes revealed during autopsy on the body of a patient who was believed to be deaf.[4] In his textbook of 1868, Toynbee confirmed the link between unilateral deafness and ankylosis of the stapes in his pioneering studies of the ear when he found 136 specimens of ankylosis of the stapes footplate out of a total 1149 dissections of diseased ears.[5] Politzer gave the first account of the histopathology of the condition in 1894.[2] In his temporal bone sections through the stapes and oval window niche and adjacent labyrinthine wall, he showed that clinical otosclerosis did not present a diseased condition of the mucosa of the tympanic cavity, as had been previously held, but was a primary disease of the labyrinthine capsule with circumscribed bony deposits and tissue changes, leading to a progressive ankylosis of the stapes in the oval window niche and a progressive conductive deafness. Politzer's work was of fundamental importance as he demonstrated, for the first time, that the stapedial ankylosis was not secondary to "chronic middle ear catarrh", but was the result of a primary disease of the labyrinthine capsule.[2]

As Politzer, Siebenmann did also a lot of work on temporal bone sections, which led him to realise that the underlying pathological condition of stapes ankylosis is not a sclerosis but a growth process of the labyrinthine bone. Therefore, instead of otosclerosis, he proposed the name otospongiosis in 1912, which referred to the active and vascular stage of the process.[3,7]

However, it was not until 30 years later, when the fenestration operations were performed on a wider scale allowing direct inspection of the oval window in the living patient, that the concept of a "chronic catarrhal condition", causing secondary fixation of the stapes footplate, was finally abandoned.

1.3 Aetiology

Many theories about the aetiology have been postulated. However, despite intensive research, the true nature about the origin of otosclerosis remains unclear. The theories that are currently considered as relevant, are concerned to more than one cause but it is not fully understood how they are related with each other. Several of these aetiological theories are related to the presence of the numerous embryonic cartilaginous rests (globuli interossei) scattered through the enchondral layer of the otic capsule.[1]

Causse[8,9], Chevance[10] and their co-workers suggested that an auto-immune response forms a trigger for otospongiotic changes by enzymatic processes in these embryonic rests of cartilage. According to this theory, also named the enzymatic concept, a disequilibrium between certain enzymes and anti-enzymes in the microfoci of otosclerosis gives rise to variable clinical features. Conductive hearing loss occurs when the focus has a localisation in the region of the stapes footplate. When proteolytic enzymes reach the inner ear, sensorineural hearing loss may develop, and even vertigo may occur.

Causative factors from auto-immune responses are supported by studies which find elevated antibody levels to type II collagen (present in the embryonic cartilage rests) in patients with otosclerosis.[11–13] Elevated levels of antibodies to type II collagen were also found in perilymfe.[14]

Another indication for an auto-immune process being a factor in the aetiology of otosclerosis, is that certain human leucocyte antigen (HLA) determinants are more frequently found in patients with otosclerosis. The HLA is that region in the chromosomal system which plays an important role in the immunological response. It is well known that an association exists between the presence of certain HLA genotypes and certain autoimmune diseases. Several studies have shown different HLA antigens in a higher or lower frequency in patients with otosclerosis compared to normal individuals.[15–18] However, despite these findings, there are also studies showing no relation between otosclerosis and HLA antigens.[19–21]

A genetic component in the aetiology has been found by several studies, and, at present time, there is more or less consensus about the way otosclerosis is inherited; autosomal dominant with incomplete penetrance.[22–24] At present, efforts are made with genetic linkage to find the gene on which otosclerosis is located. Tomek et al.[25] studied a multi generational family and completed a genetic analysis. The results indicate strong evidence that chromosome 15q is involved in the development of otosclerosis.

Several studies found a relation between the onset or progression of conductive hearing loss and pregnancy.[26,27] Therefore, endocrine factors have been suggested to play a role in the acceleration of the pathological changes and in the preponderance of females over males in clinical otosclerosis.

A viral participation in the aetiology of otosclerosis has been suggested by several investigators who found a possible relationship between prior infection with the measles virus and subsequently the development of clinical otosclerosis.[28–31] With the more recently introduced, sensitive technique of polymerase chain reaction (PCR), Niedermeyer and Arnold[30] found evidence for viral measles RNA sequences in active otosclerotic foci.

Furthermore, IgG anti-measles virus antibodies were detected in the perilymph of otosclerotic subjects supporting the hypothesis that a local immune response within the inner ear would be provoked by these viruses.

1.4 Epidemiology

In describing the prevalence of otosclerosis a distinction has to be made between clinical (with symptoms) and non-clinical otosclerosis, or histological otosclerosis. The latter form is a common condition in white adults and occurs in about 5 to 12 % [32–36] Clinical otosclerosis is less common than the asymptomatic histologic form. Several studies are undertaken in the past to obtain prevalence and incidence figures. Altmann et al.[37] combined the data of Engström[38] and Guild[32] which showed that 6 out of 601 white individuals of 10 years and older whose temporal bones had been obtained at autopsy had stapedial ankylosis from otosclerosis. This prevalence of stapes fixation of 1 % has generally been accepted as the prevalence of clinical otosclerosis among those of white European population.[39] Hinchcliffe[40] found a prevalence of 1.1 % on the basis of otological and audiometric examination in 2 random samples of the British population. More recently, a large population study of adults in the UK reported a prevalence for presumptive clinical otosclerosis of 2.1 %.[41] Presumptive clinical otosclerosis in this study was defined as an ear with a normal appearance of the ear drum and with an air-bone gap (ABG) of 15 dB or greater over 0.5, 1, and 2 kHz. Several other prevalence studies showed lower figures. Gristwood and Venables[39] found an overall prevalence of 4.70/1000 in the age category 30-49 years and a figure of 6.89/1000 in the age category 50-69 years among whites in South Australia. These prevalence figures are in agreement with the prevalence figures among Caucasoids in the USA found by Pearson et al.[42] who reported a prevalence of 3.44/1000 and 7.70/1000 in the age groups of 30-49 and 50-69 years, respectively. Recently, Sakihara and Parving[43] found an overall prevalence of 1.41/1000 in Denmark with an increase in the prevalence as a function of age from 0.22/1000 to 3.53/1000 in the eldery. However, it should be noted that these prevalence figures must be considered as underestimates of the true prevalence, as not all clinical otosclerosis in the area was included.

In clinical practice, otosclerosis is seen more often in women than men, and a sex ratio of 2;1 has been noted by many authorities.[39,41,42] It has been suggested that the prevalence is probably the same in both sexes, although, due to hormonal influences, otosclerosis is likely to advance more rapidly in women. This is confirmed in histological reports where bilateral otosclerosis is more frequent in women and in clinical population reports where the incidence was similar but women were three times more likely to have an ABG of 30 dB or greater.[34,41]

There is general agreement that the prevalence of otosclerosis varies enormously in different racial groups and populations. Otosclerosis is most frequently encountered in the Caucasian races. It appears to be uncommon among Mongoloid races[44,45] and extremely rare in Negroid races.[37,46]

1.5 Clinical features

The typical clinical features of otosclerosis are gradually increasing hearing losses at both sites, most frequently occurring between the third and fifth decade, and often associated with the presence of paracusis and tinnitus. Although usually both ears are affected by otosclerosis, often there is an asymmetry in hearing loss with one ear showing a greater conductive hearing impairment, and this ratio is usually maintained. Unilateral otosclerosis occurs in approximately 15 to 30 % of patients.[47] The deafness can remain confined to one ear, or the second ear may become affected later. Tinnitus is a common symptom which may disappear spontaneously. However, in many cases it continues unabated and may become louder as the hearing loss progresses. The origin of tinnitus is not clear but it may be the result of cochlear degeneration or an abnormal degree of vascularity within the labyrinthine capsule.[47] Vertigo is not a prominent feature although some patients may experience a slight and transitory giddiness. Causse suggested that they are possibly the result of the action of toxic enzymes, which are liberated by the lesion, on the vestibular labyrinth.[8,9]

The typical appearance during otoscopic examination is that of an intact ear drum. The "flamingo flush", or "Schwartze sign" is the result of vascular bone on the promontory, or prominent blood vessels in the submucosal layer of the mucous membrane of the promontory. It is an uncommon phenomenon, but when it is seen, it may indicate active disease which might progress rapidly.[48]

Tuning fork tests are of help in establishing the type of hearing loss. However, audiometric testing is the most important method for hearing evaluation. Basic audiologic tests include the determination of pure tone thresholds for air-conduction (AC) and bone-conduction (BC), the assessment of the speech reception threshold (SRT) and the maximum speech discrimination score (MSDS) for a list of phonetically balanced words. The hearing thresholds measured with pure-tone audiometry depends on the stage of the otosclerotic changes. In the earliest stages, stiffness of the annular ligament produces a low frequency conductive hearing loss with normal BC thresholds. The AC curve shows a stiffness tilt sloping upward to the higher frequencies, and there is a minor ABG in the lowest frequencies. As stapedial fixation develops the ABG becomes more pronounced, the AC being elevated over all frequencies to produce a flat curve at about 50 to 60 dB. The BC curve no longer accurately depicts the level of cochlear reserve but suffers a mechanical distortion known as the Carhart notch, which was first reported by Carhart in 1950.[49] Gatehouse and Browning[50] define this phenomenon as "an alteration in BC thresholds due to a decrease in the external and middle ear components of BC transmission leading to a depression of BC thresholds". The depression of BC thresholds is maximal at 2 kHz, and has therefore conventionally been labelled as "Carhart notch". However, because the phenomenon occurs over the whole frequency range from 0.5 to 2 kHz, Gatehouse and Browning[50] consider the term "Carhart effect" as more appropriate.

In many cases of stapedial otosclerosis, a sensorineural hearing loss (SNHL) increases gradually, develops coincidentally with, or develops after the conductive hearing loss. A mixed or combined hearing impairment develops with elevation of both AC and BC thresholds, the AC curve more than the BC, so that the BC curve of the patient lies between the AC curve

and the normal threshold level. The AC curve represents the sum of the hearing losses produced independent by the stapedial fixation and by the cochlear lesion.
Acoustic impedance measurements using an electroacoustic impedance meter can provide valuable clinical information including assessment of middle ear pressure, shape and height of the tympanogram, and middle ear muscle reflexes. The typical shape of a tympanogram in an ear with otosclerosis is that of a normal ear type A configuration but with a reduced maximum compliance within the normal middle ear pressures of between -100 mmH2O and + 50 mmH2O (type As). Stapedial reflex measurements show the absence of ipsilateral and contralateral reflexes for measurements with the probe in the otosclerotic ear.[51]
High resolution computerized tomography (CT-scan) has proved its value by establishing the so-called cochlear otosclerosis.[52,53] Fenestral otosclerosis is essentially a clinical diagnosis and only when it is severe, with complete obliteration of the oval window niche, it may be visible on CT-scans.
The differential diagnosis includes conditions having a normal or near normal tympanic membrane in association with a conductive or mixed hearing impairment. This includes congenital stapedial fixation, stapedial fixation from tympanosclerosis, osteogenesis imperfecta and Paget's disease, traumatic ossicular discontinuity, the fixed malleus-incus syndrome and congenital cholesteatoma.[48]

1.6 Non-surgical treatment of otosclerosis

1.6.1 Hearing aids

Although nowadays the choice of treatment in cases of otosclerotic deafness is stapes surgery, there are circumstances that surgery is not desirable or possible and sometimes patients do not give informed consent for surgical treatment. In those cases the prescription of a hearing aid forms a good alternative. In the majority of patients with conductive or mixed hearing losses due to otosclerosis, the modern hearing aid, currently also available with digital technique, gives good results. The profoundly deaf may be assisted by high-powered bone conductors or vibrotactile devices that provide additional clues for speech reading. In those cases in which normal rehabilitation with hearing aids is not possible due to recurrent otitis externa, and also in the rare cases of bilateral fenestration cavities, a bone anchored hearing aid (BAHA) can be considered.[54]
Although a more natural hearing can be obtained after stapes surgery, the advantages of surgery always have to be related to the disadvantages, and especially in bilateral cases the risk of severe SNHL, which can occur many years after surgery, has to be taken into consideration.

1.6.2 Treatment with sodium fluoride

The thought that sodium fluoride, given in moderate to high dosis, might influence favourably the otosclerostic bone lesions, was first presented by Shambaugh and Scott in 1964.[55] The idea was that sodium fluoride might promote the change of actively expanding otosclerotic lesions to more dense, inactive lesions. This stimulation of the natural tendency of otosclerotic lesions to become recalcified and inactive would result in a stabilisation of the progressive sensorineural deafness, a reduction of tinnitus and an improvement of mild vestibular symptoms.[55]

Several concepts are published in the last 35 years about the mode of action of sodium fluoride. In animal experimental studies, Petrovic and Shambaugh[56] demonstrated the influence of sodium fluoride on bone metabolism, reducing osteoclastic bone resorption as its major effect, and at the same time promoting osteoblastic bone formation. Bretlau et al.[57] reported on an evaluation of sodium fluoride treatment using scanning transmission electron microscopy (STEM) together with an energy dispersive x-ray element analyser. The results showed that using the calcium/phosphorus ratio as an indication for bone maturity, sodium fluoride could stabilise otosclerotic lesions, particularly the spongiotic type with unstable mineralisation, in retaining calcium relative to phosphorus. The results supported the view that sodium fluoride promotes recalcification and reduces the activity of otospongiotic bone.

Causse and co-workers suggested an antienzymatic action of sodium fluoride.[58,59] When the balance between trypsin and α_1-antitrypsin is disturbed in favour of trypsin, this results in an increase of trypsin values that damage the hair cells, leading to cochlear deterioration. It was shown that sodium fluoride can act directly on trypsin and reduces the levels of protease inhibitors, such as α_1-antitrypsin and α_2-macroglobulin. Causse et al.[59]stated that the overall reduction of enzymatic rates by inhibition favours the stabilisation of the otosclerotic process and consequently arrest or slowing down the cochlear deterioration caused by an alteration of Corti cells attributable to active proteases. These findings were supported by other authors.[60] In a clinical report on a large series of over 5000 patients treated with sodium fluoride, Causse et al.[58] found that medical treatment with sodium fluoride results in a stabilisation of cochlear deterioration in the majority of cases having a progressive cochlear component. Only a few patients showed an improvement in sensorineural hearing. Furthermore, it was found that sodium fluoride seems to slow conductive hearing loss by stapedial fixation but cannot release stapedial fixation.

Despite these findings, the administration of sodium fluoride remains a matter of controversy, partly due to the unknown toxic effect of long-term medication with sodium fluoride.[61] Furthermore, most studies showing favourable results are not randomised and only a few studies are carried out as double-blind randomised, placebo-controlled trials.[62,63]

2. Stapes surgery for otosclerosis

2.1 Evolution of otosclerosis surgery

2.1.1 The first stapes surgery era (1876–1900)

The historical development of surgery for conductive hearing losses due to otosclerosis is fascinating. The first attempts to correct hearing losses have to be interpreted in relation with the limited and confused knowledge the pioneers had of the physiology and pathology of the ear. There was no accurate way to measure hearing loss or to examine the ear adequately before, during, and after operation. The diseases of the ear, especially chronic otitis media and otosclerosis, were not well understood.[64]

It was Professor Kessel of Jena who was one of the first otologists to use animal experimentation to gain information to guide treatment in humans in the mid 1800's. In 1876, Kessel mobilised the stapes in a young woman with inactive chronic suppurative otitis media with no drum, malleus, and incus. There was some immediate hearing improvement. Subsequently, Kessel removed the stapes in humans, with, according to him, "some improvement in hearing and no serious complications".[65] The first mobilisations of the stapes and stapedectomy operations by Kessel were soon followed by other leading otologists of those days.
Despite the initial enthusiasm and advances in stapes surgery, the inevitable happened. Because of the many failures, together with some serious complications, like meningitis, and even death, leading otologists of those days, like Politzer and Siebenmann, condemned stapes surgery for otosclerosis as useless and dangerous. Professor Kessel, nowadays contemplated as the father of stapes surgery, had fallen into disrepute and in 1900 he was publicly censured for unscrupulousness.

2.1.2 The fenestration era (1910–1960)

The fenestration era began as conditions started to improve for otologic microsurgery. The pathology of otosclerosis was better understood by the establishment of temporal bone pathology laboratories in otologic centres in Europe and the United States. Progress was made with the magnification and electrical illumination of the operation field .
The term "fenestration" was used by Jenkins in 1913.[66] He suggested that it would be better to detour the sound vibrations around the obstruction in the oval window by making an opening in the bony lateral semicircular canal and covering it with a skin flap from the ear canal. Initially, Holmgren from Sweden gave great impulse to the fenestration technique by introducing the operation microscope.[67] He continued with the closed fenestration technique of Jenkins but he covered the fenestra with mucoperiosteum.[68] Sourdille, a French student of Holmgren, developed the three-stage procedure named "tympano-labyrinthopexy".[64,69] At the first stage a mastoidectomy was performed, at the second stage an external ear canal skin flap was created and at the third stage a fistula was made in the horizontal canal which was subsequently covered with the canal skin flap. This alteration of technique was an important improvement over the closed fenestration operation of Jenkins and Holmgren as sound could enter the perilymph space directly without the obstruction of the ear drum and bony canal wall.
It was Lempert who modified the three stage technique into a one stage technique, and who performed the operation with the electric drill rather than hammer and chisel. He published his results in 1938 in a famous paper entitled "Improvement in Hearing in Cases of Otosclerosis: A New One Stage Surgical Technic".[70] Later, Shambaugh Jr., the first pupil of Lempert, published his results with the fenestration operation.[71] Soon the procedure gained world wide acceptance. The results with the Lempert modification of the fenestration operation were better, with a lasting hearing improvement to the 20 to 25 dB level in approximately 50 % of the patients in expert hands.[64]

2.1.3 *The second stapes surgery era (1952 – present)*

In 1952 Rosen[72] published a preliminary report to describe a simple method of palpation of the stapes to determine whether it was partially or completely fixed. Rosen found that rocking palpation of a fixed stapes rendered the footplate more mobile with improvement of hearing. Sequentially, Rosen developed a procedure based on the premise that ankylosis was not necessarily permanent or irreversible. His relatively simple procedure, which resulted in better maintained hearing, could easily be followed by fenestration, should success not be achieved by stapes mobilisation. In 1953 Rosen[73] published his results in a series of patients, on whom he performed mobilisation of the stapes, with improved hearing. After some time, the mobilisation technique became generally accepted and the fenestration became reserved, more or less, for those in whom mobilisation has failed.[74,75]

In 1954, the first bypass procedures were begun. This type of surgery for otosclerosis was based on the concept that the otosclerotic focus of bone might be bypassed entirely, rather than being mobilised and left free to reankylose. It was Shea Jr. who rediscovered the stapedectomy procedure and reconstructed the transmission system with a prosthesis. In 1956 he did his first stapedectomy operation with insertion of a prosthesis with the same shape and size of a normal human stapes.[64] This stapes replica was made out of a newly discovered material named tetraflur ethylene or Teflon which was believed to be inert in the body. Shea used this Teflon prosthesis over a vein graft in a 54 year-old woman with extensive oval window otosclerosis. The woman's hearing immediately improved.

Shea's contribution to otosclerosis surgery soon proved to be a start of a new revolution in the surgical treatment of otosclerosis, much as Lempert's fenestration has done many years before. Numerous modifications in the stapedectomy technique have been made over the years by numerous contributors. Furthermore the era of pistons had arrived, and soon many surgeons modified their techniques from total stapedectomy to partial stapedectomy and to stapedotomy using a wide range of different prostheses.

2.2 Current techniques of stapes surgery

Currently stapes surgery consists of the traditional stapedectomy in which the footplate is totally or near-totally removed, and stapedotomy in which a small fenestra is made through the central portion of the footplate. Another technique is to remove a part of the footplate which is also called partial stapedectomy[76] or partial platinectomy.[77] Some surgeons use a soft tissue graft, like vein, perichondrium or fascia, to cover or fill the oval window in order to limit the loss of perilymph and prevent subsequent fistula formation. Either operation can be performed under general or local anaesthesia, depending on availability and the surgeon's choice. An increasing number of surgeons prefer local anaesthesia supplemented by intravenous sedation because, with the patient awake, immediate hearing improvement can be noted intraoperatively as well as vestibular and other pathology reflected by complains of dizziness.

The standard approach for surgery is endaural. More exposure can be obtained by an endaural incision. After a tympanomeatal flap is created the middle ear can be exposed. In most cases bone from the posterior-superior scutum has to be removed, until the oval window can be inspected with the facial nerve superiorly and the pyramidal process posteriorly. After the ankylosis of the stapes is confirmed, one of the three above mentioned techniques can be applied. Many surgeons believe that a small hole (the so called safety hole) should be placed in the centre of the footplate prior to removal of the suprastructure to avoid a negative suction effect on the vestibule if the footplate is removed with the suprastructure. Furthermore, if a stapes gusher is encountered, the preserved suprastructure can help support connective tissue over the central hole.

With regard to the indication for surgery, many surgeons feel that the ABG should be at least 15 dB and there should be a SDS of 60% or more for a good hearing improvement. Previously, there was some concern regarding the performance of stapes surgery in children. It is clear now that stapes surgery in children can be accomplished quite safely.[78,79]

2.3 Stapes replacement prostheses

A variety of different prostheses are available today for reconstruction, although a few surgeons prefer to use autolog material for reconstruction, like the posterior crus over a tissue sealed oval window after total removal of the footplate. All prostheses differ in size, shape and weight.[80] The mass of the implant is important, because it will affect the transmission of lower and higher frequencies. Most of the prostheses consists of a piston or cylinder that projects into the oval window. The main difference in the design of stapes replacement prostheses are at the point of connection with the incus. The attachment to the incus consists of either a loop that surrounds the incus or a cup into which the lenticular process fits. Most loops are made of thin stainless steel or platinum ribbon that hooks onto the incus. Some prostheses have a ring composed of Teflon that require opening the ring prior to placement. Most prostheses are available in a variety of different lengths. Some prostheses are manufactured at a standard length and require the surgeon to trim them to the desired length. The shaft diameter of most prostheses ranges from 0.3 to 0.8 mm at the attachment of the oval window.

A stapes replacement prostheses must be composed of a biomaterial which is well tolerated by the middle ear with no reactions at both the oval window and the incus. The biomaterials currently most often used are a Teflon type polymer, stainless steel, and platinum.[81] Some prostheses contains a combination of materials, like the combination of a Teflon piston shaft with a stainless steel loop in the Fisch piston or Schuknecht piston or the combination of a platinum shaft and a stainless steel loop in the McGee piston.[80]

If the incus is not available for reconstruction, an incus replacement prosthesis can be used like the Shea malleus handle prosthesis.[82,83]

3. Evaluation of hearing results

3.1 History of assessing hearing

In the days of the first stapes surgery era (1876-1900) mechanical acoumeters were developed to produce controlled quantifiable stimuli in order to establish hearing in a more reliable way before and after surgery. Of these the best known were those of Itard (1821) and of Politzer

(1877).[84] The first electrical audiometers stemmed from the invention of the telephone by Alexander Graham Bell in 1876, which opened the way for the development of sound generators with variable output intensities.[85] Of the first electrical audiometers there were two which have attracted most attention; that of Hartmann (1878) and that of Hughes (1879).[84] The latter was the first who made the audiometer commercially available.[86] However, despite the technical improvements in establishing the amount of hearing loss, initially the first electrical audiometers were not well adopted in the relatively new speciality of otology which was more concerned with the more urgent and widespread problems of ear infections and their often fatal consequences.[87]

After World War I, the invention of electronic valves was the next major advance in the development of electrical audiometers. During the late 1920s a lot of work had been conducted on BC vibrators by a variety of researchers, and from the early 1930s most audiometers were fitted with both AC and BC transducers.[88] These modifications helped to facilitate the acceptance among otologists. From that time the basis principles, embodied in the new design of the standard clinical audiometer, have remained essentially unchanged to the present day.

At the time that the fenestration procedure was promoted by Lempert, the three frequencies of 0.5, 1, and 2 kHz were selected for hearing evaluation because they were the prime frequencies involved in hearing conversational speech. In those days, BC measurement above 2 kHz was unreliable due to technical limitations of the audiometers; therefore, higher frequencies could not be used in computing the ABG. Subsequently, when speech audiometry was developed, it was found that these pure tones correlated well with SRTs.

Later, in the 1950s the electronic valves were replaced by transistors and integrated circuits in audiometers were widely used in the 1970s. In the late 1970s the microprocessor was introduced in the audiometry devices and it has evolved to the present state of audiometry with the fully computer controlled audiometer.

3.2 Methods for hearing evaluation

How should hearing results be reported following stapes surgery? This is a question that every author who wants to report about hearing outcome after this type of surgery has to deal with. By reviewing the literature, a wide diversity of methods, criteria and parameters can be found used in the reports to summarise the audiologic results as well as many different statistical tests for their analysis. What method to be used depends on the primary purpose of the study. If technical factors are being evaluated, such as surgical procedure, type of prosthesis, use of a specific biomaterial, or surgical skill, closure of the ABG is probably most important. The comparison of pre- and postoperative BC, including higher frequencies, allows postoperative cochlear damage to be assessed. In addition speech discrimination tests are also good indicators of cochlear reserve.[89] If the interest is in absolute hearing function, AC threshold levels are critical, although they will depend upon patient selection as much as technical skill. In general, pure-tone AC thresholds at speech frequencies correlate well with the SRT assessed by speech audiometry.[89]

In reporting the hearing results also other factors have to be taken into account with regard to the patient's perspective as the aim of stapes surgery is to reduce auditory disability. In general, the degree of disability is determined by the status of the better hearing ear. The ideal of bilateral normal hearing is not always attainable, and so, in advising patients regarding surgery for hearing gain, it is important not forget the contribution of the other ear.

Smyth and Patterson assessed the requirements for patient's benefit by drafting the "Belfast Rule of Thumb".[90] They concluded that for significant benefit to be achieved the postoperative AC average over the speech frequencies must be close to 30 dB or the interaural difference reduced to less than 15 dB. The "Glasgow Benefit Plot" devised by Browning et al.[91] is a valuable elaboration of the forenamed requirements. The degree of auditory disability can be assessed with the criteria of the American Medical Association.[92]

3.3 Standardisation in reporting hearing results

At the time that stapes surgery was performed on a larger scale, many otologists realised that they needed generally accepted recommendations in order to report audiologic data in a more uniform way. Why is standardisation in the reporting of hearing results so important? Shea[93] summarised the problem when he discussed 30 years of stapes surgery. He noted that "the diversity of techniques and lack of uniformity of reporting results make it difficult to agree on the best method to reconstruct the sound conducting mechanism after the stapes has been removed. Technique, materials, patient selection, type of procedure, type of prosthesis, and pathological condition are all factors that may affect results of middle ear reconstruction, but particularly the lack of standardisation in reporting hearing results has made comparison across studies difficult in the past."

Initially, the standard classification system, developed by a committee of the American Academy of Ophthalmology and Otolaryngology[94] for surgery of chronic ear infection in 1965, was embedded for the evaluation of hearing results after stapes surgery.[89] It required an observation period for at least 1 year and thresholds at the speech frequencies 0.5, 1, and 2 kHz were involved in computing ABG. Although it was not clearly stated in the classification system, it was a common use at that time to calculate the postoperative ABG by taking the difference between the postoperative AC and preoperative BC. This method of computing postoperative ABG was also recommended by The Committee on Nomenclature in Chronic ear Disease and the Otosclerosis Study Group in 1971.[95]

Independently from the American otological working groups, the Committee of Nomenclature of the Japan Society of Clinical Otology developed there own guidelines in 1987.[96] According to these guidelines the average should be taken over the frequencies at 0.5, 1, and 2 kHz either by the "dividing by three method" or the "dividing by four method". In the former method the hearing level at each frequency is counted equally, while in the latter method the hearing level at 1 kHz is counted twice to stress the importance of this frequency in speech recognition. The observation period should be at least 6 months and a successful result was obtained if one of the following was achieved: (1) an ABG closure of 20 dB or less, (2) a postoperative AC threshold within 40 dB, or (3) a gain in AC of more than 15 dB. The guidelines of the Japan Society of Clinical Otology (currently The Otological Society of Japan) did not give definite recommendations about how to establish postoperative ABG either with preop-

erative BC or postoperative BC.
More recently, the Committee on Hearing and Equilibrium of the American Academy of Otolarygology - Head and Neck Surgery[97] published guidelines to evaluate hearing results after ossiculoplasty and stapes surgery. The guidelines have been established for two levels: level 1 provides for the uniform reporting of summary data and level 2 provides for the uniform reporting of raw data. The Committee encourages to report raw data from each individual case to enable more detailed analytical studies and meta-analyses in the future. With regard to level 1, the Committee recommended guidelines that had and still have an important impact in many otological societies. One of the major change in the recommendations is that the mean of thresholds at the frequencies 0.5, 1, 2, and 3 kHz should be used to form a four-frequency PTA in stead of the traditionally three-frequency PTA at 0.5, 1, and 2 kHz. Another important change is that the Committee advises to compute postoperative ABG by the method of taking the postoperative AC and BC thresholds instead of the traditionally method by taking the postoperative AC and preoperative BC. The latter method commonly results in a higher success rate after stapes surgery because ABG overclosure due to the Carhart effect is taken into account.[98] In this study we will evaluate different methods for hearing evaluation for a large set of clinical data.

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Chapter 2

Stapes Surgery for Otosclerosis in the Academic Medical Center, University of Amsterdam.

1. PATIENTS

1.1 Data collection

This thesis describes data retrieved from patients who were subjects to stapes surgery for clinically confirmed otosclerosis during the period from 1983 to 1998. During this period 576 stapes operations were performed by one surgeon (R.A. Tange, MD, PhD) in the Academic Medical Center, University of Amsterdam. Relevant data with reference to preoperative symptoms, clinical findings, intraoperative findings, complications, and follow-up were recorded. Eventually, data were stored in a data base by making use of a card system. Later, data were collected in a computer database. Since 1987 data from audiological tests were stored automatically in a hospital computer system directly after testing.

Of the total amount of operated ears there were 5 cases (0.9 %) in which we did not succeeded to trace the clinical data. The remaining 572 cases concerned 515 patients. In 42 patients stapes surgery was performed on both sides at separate surgical settings. There were 76 patients who received revision surgery; 11 patients had their initial surgery performed by Dr. Tange, while 65 patients were referred from other physicians. Of the revision cases who had their primary operation performed by Dr. Tange, there was 1 patient who needed a second revision and in another patient it was necessary to do a third revision. In the group of 65 patients with primary surgery performed by another surgeon, there was one patient who received revision surgery at both sides.

In the whole group of patients there were 340 females and 175 males. Figure 1 shows the age distribution for males and females in 10 years intervals. The average age for the whole group of patients was 40.4 years (range 12 - 74, SD ± 11.5) There were 5 patients below the age of 15 and there was one female patient of 74 years of age. None of the patients had an age below 10 years. The distribution between left and right ears was approximately even; 292 right ears and 280 left ears.

1.2 Symptoms and clinical findings

For describing the symptoms and clinical findings, only the 386 ears were taken into account that received primary stapes surgery during the period from 1987 to 1997 and in which we had complete clinical and audiological data. These ears concerned 346 patients; in 40 patients surgery was done on both sides.

All patients suffered from hearing loss in the affected ear and the presence of otosclerosis was confirmed during surgery. In the female patient group 7 % (17/244) indicated that the hearing was deteriorated during pregnancy. A hearing aid was used by 2.3 % (8/346) of the patients before surgery. Mild tinnitus was a preoperative symptom in 6.9 % (24/346) at the side with otosclerosis, and it was indicated as severe in 1.4 % (5/346) of the patients. Attacks of mild vertigo occurred in 3.8 % (13/346) of the patients. Both tinnitus and mild vertigo were present in 0.6 % (2/346). There were two patients who had complaints of ipsilateral otalgia before surgery. However, ear pain in these patients were most likely due to Costen's syndrome.

During otological examination an intact eardrum was present in 98.4 % (380/386) of the cases. One ear (0.3 %) had a small perforation in the anterior part of the pars tensa and 5 ears (1.3 %) showed an atrophic tympanic membrane. Small plaques of tympanic membrane calcifications were revealed in 2 % (8/386). A small retraction pocket in the pars flaccida, without any signs of cholesteatoma, was found in 1 % (4/386). The "Schwartze sign" was present in 3.9 % (15/386) of the cases.

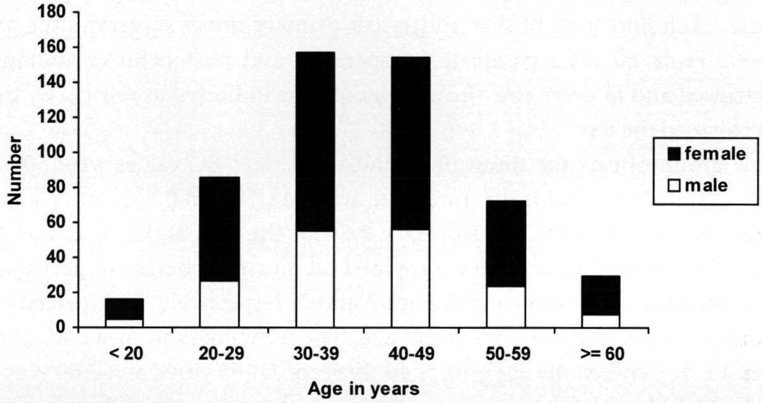

Fig. 1. *Age distribution of males and females in 10 years intervals.*

1.3 Audiological findings

1.3.1 Audiometric testing and analyses

All patients who were considered for surgery had complete audiological examination at least one week before surgery. Postoperative audiological testing is performed 2 to 3 months after surgery in all cases and about 1 year after surgery in the majority of cases. Audiometric testing include the determination of pure-tone thresholds for air-conduction (AC) and bone-conduction (BC), and the assessment of speech reception threshold (SRT) and the maximum speech discrimination score (SDS) for a list of phonetically balanced CVC-words.[1]

In our clinic the AC thresholds are routinely measured at the octave intervals from 0.125 to 8 kHz and the BC thresholds at the octave intervals from 0.25 to 4 kHz with adequate masking. For most subjects who were considered for analysis both AC and BC thresholds at the above mentioned frequency ranges were available before and after surgery. However, in some subjects the hearing loss was very severe resulting in hearing thresholds which were beyond the maximum output of the audiometer. In these cases the pure tone thresholds at certain frequencies were impossible to determine and this is marked in the audiogram with an arrow pointing down. It is important to consider these limitations of the capacity of the audiometer, because pre- or postoperative data of unmeasurable hearing thresholds could wrongly be excluded from analysis. Severe postoperative hearing loss as a consequence of an unfavourable operation would then not be taken into account. Conversely, ears with unmeasurable hearing thresholds before operation as a consequence of severe hearing loss but with measurable hearing thresholds after operation could also be rejected. To avoid this problem in these cases thresholds were assumed to be just beyond the audiometer limits. If AC or BC was not measurable at a certain frequency a value of 10 dB above the limit for that frequency was given. All audiograms were performed by classified personnel according to the ISO-389 (1975) standard.[1]

1.3.2 Hearing loss due to otosclerosis

For describing the hearing loss caused by otosclerosis in our patient group, again only the 386 ears were taken into account that underwent primary stapes surgery in the period from 1987 to 1997. From all cases complete preoperative and postoperative audiometric data could be retrieved and in every case the audiogram was indicated as reliable by the audiologist who performed the test.

In the whole group of ears the mean preoperative AC and BC values were 50.6 dB (SD ± 13.2) and 20.6 dB (SD ± 9.3) for the pure-tone average (PTA) at 0.5, 1, and 2 kHz, and they were 50.0 dB (SD ± 13.9) and 21.9 dB (SD ± 9.6) for the PTA at 0.5, 1, 2, and 4 kHz. The mean AC and BC thresholds for each octave interval measured before surgery and classified according to age groups are shown in figures 2 and 3, respectively. As expected the AC and BC thresholds deteriorated with increasing age. The differences in mean AC thresholds at 0.5, 1, 2, and 4 kHz between the age groups 40-49 years, 50-59 years, and ≥ 60 years are statistically significant (Mann Whitney test, $p < 0.05$). Furthermore, the differences in mean BC thresholds at 0.5, 1, 2, and 4 kHz between each age group are statistically significant (Mann Whitney test, $p < 0.01$), except for the difference between the age group 20-29 years and 30-39 years. However, when the influence of normal physiological ageing on cochlear function is corrected using correction figures from the International Standard ISO 7029[3], only the difference in mean preoperative BC levels at 0.5, 1, 2, and 4 kHz between the age group < 20 year and 20-29 year is statistically significant (Mann Whitney test, $p < 0.001$). Correlation analysis shows that, although there is a significant correlation between age and the BC thresholds corrected for age, this correlation is weak (Spearman $r = 0.169$, $p < 0.0001$). The mean BC thresholds corrected for age are shown for the different age groups in figure 4.

The "Carhart notch" caused by otosclerosis is a depression of BC thresholds due to the reduced transmission function of the middle ear and is maximal at 2 kHz[4] Although it is more appropriate to use the term "Carhart effect" to define the alterations in BC thresholds[5], this effect can only be assessed appropriately when pre- and postoperative BC thresholds are compared for several frequencies. Because this section is meant to describe the (preoperative) audiological findings caused by otosclerosis, only the notch values at 2 kHz are analysed in relation to the BC values at 1 and 4 kHz. To define the Carhart notch at 2 kHz we used the method described by Naunton and Valvassori[6], who calculated the notch values by taking the difference between the BC thresholds at 2 kHz and the average losses at 1 and 4 kHz. This calculation may be expressed as follows:

"Carhart Notch Value = BC at 2 kHz - [(BC at 1 kHz + BC at 4 kHz) / 2] dB".

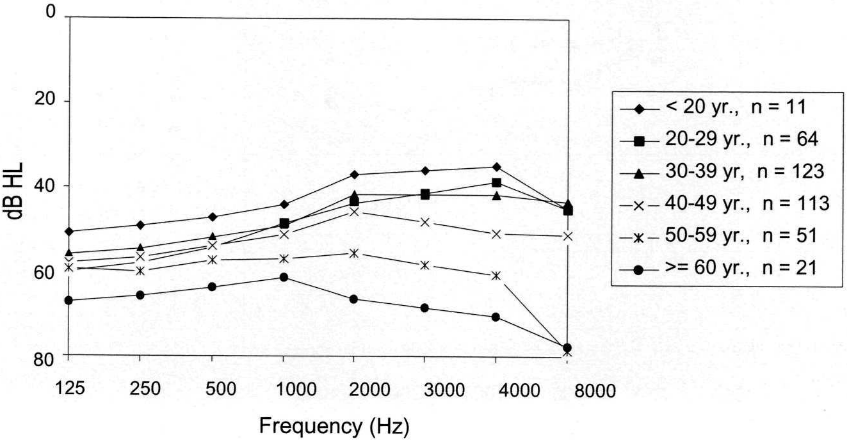

Fig. 2. *Mean preoperative air-conduction (AC) thresholds classified by age groups.*

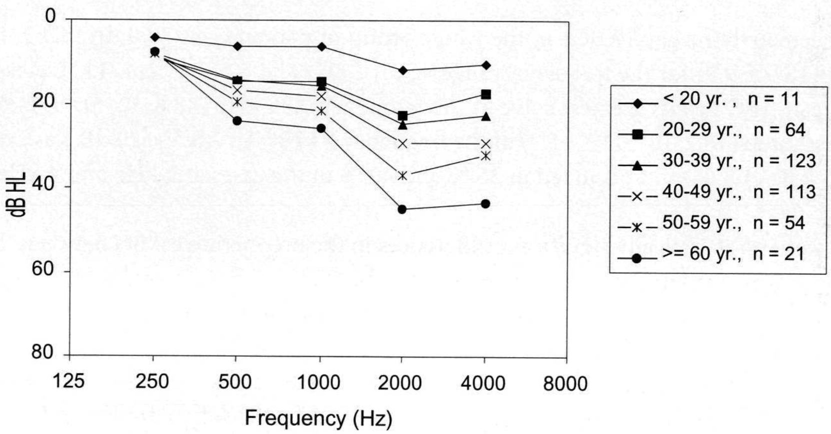

Fig. 3. *Mean preoperative bone-conduction (BC) thresholds classified by age groups.*

Carhart notch values were calculated in the whole group of ears for the BC thresholds not corrected for age and corrected for age (ISO 7029)[3] showing average notch values of 6.6 dB (SD ± 8.3, n 386) and 7.5 dB (SD ± 8.4, n 386), respectively. In the whole group of ears, 66.3 % (256/386) had a notch value ≥ 5 dB, and 39.6 % (153/386) had a notch value of ≥ 10 dB with BC thresholds not corrected for age. When the BC thresholds were corrected for age, these percentages were 67.9 (262/386) and 40.9 158/386), respectively. The notch values with BC corrected for age were weakly but statistically significant correlated with age (Spearman correlation test, $r = 0.23$, $p < 0.0001$).

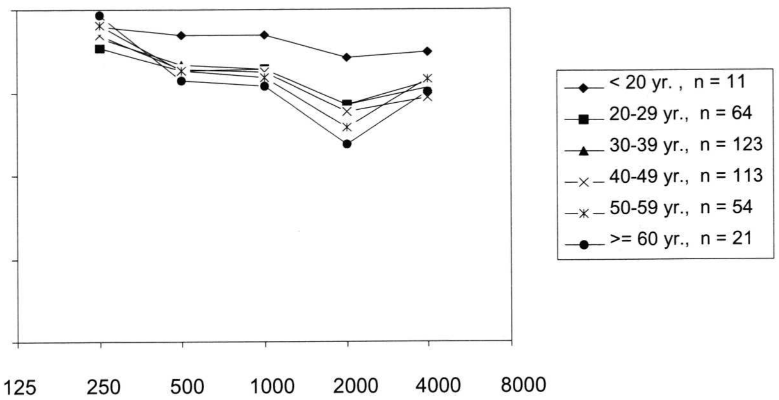

Fig. 4. *Mean preoperative bone-conduction (BC) thresholds classified by age groups and corrected for age using the ISO 7029 standards.*

The mean air-bone gap (ABG) in the whole group of patients was 30.0 dB (SD ± 10.4) and 28.0 dB (SD ± 9.9) for the frequency range 0.5, 1, 2 kHz and 0.5, 1, 2, and 4 kHz, respectively. The mean ABG has its greatest value at the frequency 0.25 kHz (48.8 dB, SD ± 14.5) and its smallest value (18.2 dB, SD ± 11.2) at the frequency 2 kHz. An ABG < 20 dB was exceptional at 0.25 kHz (1.3 %) but occurred in 36 % and 40 % of the cases at 2 kHz and 4 kHz, respectively.

There were no statistically significant differences in the preoperative ABG between the different age groups for separate frequencies and for the PTA at 0.5, 1, 2, and 4 kHz. The correlation between the Carhart notch values and the ABG for the PTA 0.5 and 1 kHz was analysed and this shows no significant correlation (Spearman correlation test). The ABG value at 2 kHz was not included in this analysis because the notch values and ABGs are based on the same BC values for this frequency (cq. notch values and ABG values are not independent for this frequency).

2 SURGICAL APPROACH

2.1 Development of stapes surgery

Data about the type and number of operations performed in the University Hospital of Amsterdam for otosclerosis are known from 1950. Figure 2 shows the type and number of operations for each 5-years period from 1950 to 1999. Unfortunately data of the years 1975 to 1978 are missing. In the early fifties the fenestration technique, modified by Lempert, was mainly done in cases with hearing loss due to otosclerosis. Later this technique was changed by the relatively simple mobilisation procedure according to Rosen. An important improvement in the surgery for otosclerosis was when the Zeiss-Opton microscope became commercially available in 1953. This microscope was especially developed for surgery purposes and was able to reach a magnification power of x 63 which was far more than previous models of microscopes.[7] Professor Jongkees, at that time head of the Department of Otorhinolaryngology, University Hospital of Amsterdam (in those days named "Wilhelmina Gasthuis"), was the first who used this microscope for ear surgery in the Netherlands and gave great impulse to the further expansion of this indispensable instrument within and even outside the Netherlands.[8,9] The first stapedectomy procedures were performed in 1958, shortly after Shea introduced this technique in 1956.[10] In 1982 the first small fenestra stapedotomy procedures were done and this technique is today the surgical treatment of first choice for otosclerosis in our hospital.

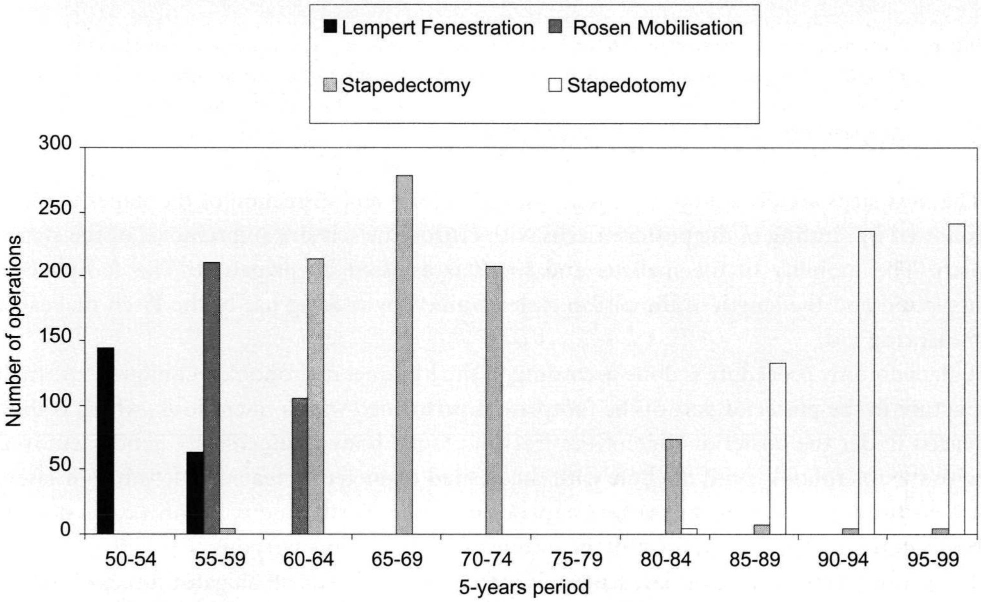

Fig. 5. *Type and number of operations performed in the University Hospital of Amsterdam for otosclerosis in 5-years periods from 1950 to 1999. Data from the years 1975-1978 are missing.*

2.2 Current standard surgical technique

Although stapes surgery can be performed well either under general or local anaesthesia, the policy in our clinic is to do stapes surgery under general anaesthesia. Both methods have advantages and disadvantages as already mentioned in Chapter 1. Oral antibiotics is given perioperatively (Doxycyclin). The surgical approach to the middle ear is transcanal. To gain more exposure, an intercartilaginous incision similar to the Heermann A incision is carried out. After this procedure, two retractors can be put in place. After preparation and elevation of a tympanomeatal flap, the incudostapedial joint is visualised. The chorda tympani is separated from the incus and sometimes slightly stretched. The bone of the superoposterior bony annulus is removed using Heermann chisels and a curette, until the whole oval window region can be inspected and the presence of otosclerotic lesions can be noticed. The extension of otosclerosis is estimated using the classification system according to Portmann.[11]

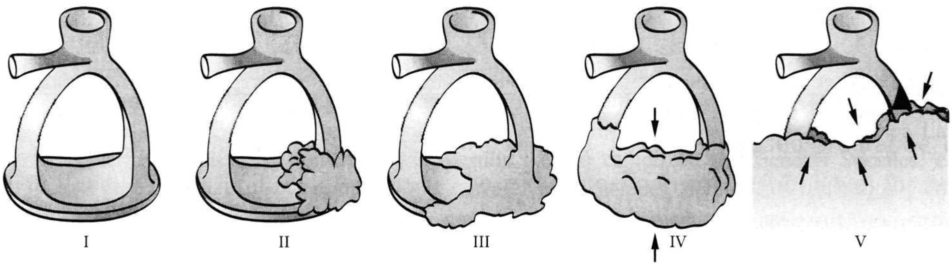

Fig. 6. *Classification of otosclerotic lesions according to Portmann. Type I: normal aspect (ankylosis of annular ligament); Type II: focus involves the anterior quarter of the footplate; Type III: focus involves the anterior half of the footplate; Type IV: focus involves the entire footplate; Type V: complete obliteration of the oval window niche.*

The next steps are division of the incudostapedial joint and dissection of the stapes tendon, followed by cutting of the posterior crus with crurotomy scissors and removal of the stapes arch. The mobility of the malleus and incus is assessed by palpation. The footplate is inspected and the length of the piston is determined by making use of the Fisch malleable measuring rod.

A stapedotomy procedure is done according to the Marquet microhook technique.[12] A small fracture in the posterior part of the footplate is performed with a microhook, which is then placed under the posterior edge of the fracture. Small bony fragments are gently removed with the microhook, until the hole with the desired diameter is created. Microdrill or lasers are not used in our clinic to create a stapedotomy hole. Furthermore, in most cases no soft tissue grafts are used to cover or fill the oval window for sealing purpose.

The piston, with the appropriate length, is introduced with a small alligator forceps holding the loop. In the same action the distal end of the shaft is put into the footplate opening and the loop of the piston is placed onto the incus. In the case of a gold piston or wire piston, the loop is crimped to the long process of the incus, using a large alligator forceps. After checking the mobility and position of the piston, sometimes small pieces of gelfoam are placed onto the footplate. Finally the tympanomeatal flap is replaced, and the endaural incision is closed. Small pledgets of gelfoam are used to cover the tympanic membrane. The external ear canal is packed with a strip of gauze impregnated with antibiotic ointment (Terracortril®, Pfizer, New York). This procedure is repeated one week after surgery. After the operation patients remain hospitalised for three days with a careful mobilisation schedule. Water in the external ear canal must be avoided.

3 AIM OF THIS THESIS

At present time, there is general agreement that stapes surgery is the treatment of first choice in patients with a conductive hearing loss due to otosclerosis. As elaborated in Chapter 1, there unfortunately exists a lack of uniformity with regard to the reporting of hearing results, despite the guidelines drafted by several otologic working groups.[13,14,15] Uniformity is necessary to make comparison of studies in the literature possible.

This thesis is concerned with the efficacy of using different methods, criteria and parameters in the evaluation of hearing results after stapes surgery. Furthermore, this thesis goes into the findings and results of revision stapes surgery and the comparison of two different prosthesis used in stapes surgery.

In chapter 3 the hearing results of 451 stapes operations were analysed in order to get a better understanding to what extent the use of different audiologic criteria affects success rates in our material. The influence of choice of frequencies in accounting PTAs is described with reference to the impact on success rates. In addition, these results are related to the results obtained with speech audiometry. Furthermore, the differences in ABG reduction are described by the use of postoperative and preoperative BC in computing postoperative ABG. In this chapter we also analysed to what degree success rate is affected by the choice of success criteria.

In chapter 4 a new method is described in which the effects of stapes surgery on hearing can be deduced for each operated ear individually using two plots, which we named the "Amsterdam Hearing Evaluation Plots" (AHEPs). In evaluating hearing results most often the mean values of specific audiologic parameters are considered. However, for a good impression of differences between patient groups or between certain surgical techniques, it is illustrative to present results of each operated ear separately. The audiometric results of the same stapes operations from chapter 3 are used to demonstrate the AHEPs.

In chapter 5 the audiologic results of a Teflon piston (type Causse) and of a gold piston (K-piston), both with a shaft diameter of 0.4 mm, are compared. An important difference between both prostheses is the difference in mass: the gold piston is three times heavier than the Teflon piston. For data analysis the mean values of several audiologic parameters are taken into account as well as the hearing results of each ear individually in separate analyses (with the AHEPs) for the ears that received a gold piston or a Teflon piston.

In chapter 6 the effects of stapes surgery on several parameters retrieved from speech audiometry are evaluated with special reference to factors involved when either an increase or decrease in speech discrimination occurs after surgery. Therefore, several data from speech audiometry were related to pure-tone audiometric data in order to examine whether postoperative loss in speech discrimination can be predicted from the shapes of pure-tone audiograms.

In chapter 7 the results are reported of stapes surgery in patients with bilateral otosclerosis with regard to auditory disability. In this approach the criteria of the American Medical Association in the Guides to the Evaluation of Permanent Impairment[16] were used in order to assess the decrease of hearing handicap after subsequently first and second ear stapes surgery.

In chapter 8 the benefit of second ear stapes surgery is assessed by making use of the Glasgow Benefit Plot.[17] This way of analysing audiometric data is a method to evaluate hearing results of each individual ear after stapes surgery in a more functional way rather than from a technical standpoint.

In chapter 9 the intraoperative findings and causes of failure revealed during revision stapes surgery, together with the audiometric results are reported. Furthermore, a review of the literature was performed to compare the findings and results with those of other reports.

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Chapter 3

Efficacy of Evaluation of Audiometric Results after Stapes Surgery in Otosclerosis. Part I: The Effects of Using Different Audiological Parameters and Criteria on Success Rates.

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Otolaryngology- Head and Neck Surgery, in press

Abstract

The Committee on Hearing and Equilibrium of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) proposed guidelines to provide more uniformity in reporting hearing results after middle ear surgery. One of the proposals was to include the hearing thresholds at 0.5, 1, 2, and 3 kHz in a four-frequency pure-tone average (PTA) and to use postoperative bone-conduction (BC) levels rather than preoperative BC levels in describing postoperative air-bone gap (ABG). The hearing results of 451 stapes operations were evaluated to analyse to what extent the choice of different audiological criteria affects success rates. It appeared that choice of PTA significantly affects postoperative gain in air-conduction (AC) thresholds and ABG levels. If one takes the improvement in speech reception threshold (SRT) as "the golden standard", the gain in AC correlates best with the gain in SRT if a higher frequency, like 3 or 4 kHz, is included in a four-frequency PTA. Also choice of preoperative BC or postoperative BC in computing postoperative ABG had a significant effect on the mean postoperative ABG levels showing more favourable results with the use of preoperative BC thresholds.

Introduction

In the last four decades the surgical treatment for hearing losses caused by otosclerosis has evolved extensively and it has, according to many prominent otologists, obtained a position as treatment of first choice. The surgical techniques have been refined and still new developments are going on, especially in the field of stapes replacement prostheses. In this respect, it is a necessity that uniformity exists in reporting hearing results after stapes surgery for a fair comparison between several surgical techniques or between various patient populations.

During review of the literature on stapes surgery it appears unfortunately that a great variation exists in audiologic parameters and criteria used to establish success rates. Often the consequences of using different audiologic criteria on hearing outcome are underestimated and therefore it is difficult to make an accurate comparison of results reported in the literature. Furthermore, it appears that the results from speech audiometry are seldom taken into consideration, whereas one of the most important goals of stapes surgery is improvement of speech reception. Several efforts have been made in the past to advance more uniformity in reporting hearing results. In many proposals for guidelines the pure-tone average (PTA) at 0.5, 1, and 2 kHz was the most important because these frequencies are involved in speech reception. However, in 1994 the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS)[1] proposed guidelines in which the Committee recommended the use of mean of thresholds at frequencies 0.5, 1, 2 and 3 kHz to form a four frequency PTA in reporting results from stapes surgery or ossiculoplasty. Berliner et al.[2] showed in their material that including a higher frequency, like the 3 or 4 kHz, in a four frequency PTA had a substantial influence on success rate in stapes surgery. Another guideline from the Committee was to use postoperative bone-conduction (BC) rather than preoperative BC in computing postoperative air-bone gap (ABG). With respect to this point, Berliner et al.[2] found that the use of postoperative BC instead of preoperative BC in computing ABG after surgery had an unfavourable influence on success rates.

The purpose of this study was to get a better understanding to what extent the use of different audiologic criteria affects success rates after stapes surgery in our material in which hearing results of 451 stapes operations were analysed. Our study focuses on the following questions: (1) Does choice of frequencies in accounting PTAs influence reported success rates? (2) How do these results relate to results from speech audiometry? (3) To what extent is ABG reduction affected by the use of postoperative instead of preoperative BC thresholds? (4) To what degree is success rate affected by the choice of success criteria?

Patients and Methods

Data were retrieved from every consecutive patient who underwent stapes surgery for otosclerosis during an eleven year period from January 1987 to December 1997. During this period 473 stapes operations were performed by the second author. Of the total amount of patients we had to exclude 22 cases (4.7 %) from analysis; in 18 cases data were incomplete, in 3 cases the audiologist had indicated that the test was not reliable and in 1 case there was a dead ear caused by an infection two weeks postoperatively. The remaining 451 cases that were considered for analysis concerned 397 patients. In 40 patients the operation was performed on both sides at separate surgical settings. There were 61 patients who underwent revision surgery; 10 patients had their initial surgery performed by the second author, while 51 patients were referred from other physicians. Of the revision cases who had their primary operation performed by the second author, there was 1 patient who needed a second revision operation, while in another patient it was necessary to do a third revision. In the group of 51 patients with primary surgery performed by another surgeon, there was one patient who needed revision surgery at both sides. Furthermore, there were 3 cases who already had one revision operation, 4 cases who had a revision operation twice and there was 1 patient who had a revision operation for the third time prior to surgery in our clinic. The intraoperative findings revealed during revision as well as the postoperative hearing results are described in another study.[3]

The patient group consisted of 261 women and 136 men with a mean age of 39.9 years (range 12 – 74) at the time of their operation in our hospital. The distribution between left and right ears was approximately even.

In the majority of patients a small fenestra stapedotomy was performed (98.4 %) and in only a few cases a stapedectomy technique was used (1.6 %). A variety of stapes replacement prostheses was implanted. The most frequently used prostheses were the Causse® Teflon piston (63 %), the gold K®-piston (19 %) and the Cawthorne® Teflon piston (12 %). Several other prostheses were used in a minority of the patients. Although the diversity of prostheses is an influential factor in hearing outcome, we did not subdivide the population on the basis of implanted prostheses, because this study concerns only with the relative differences in

methods of reporting results.
In our clinic the air-conduction (AC) thresholds are routinely measured at the octave intervals from 0.125 to 8 kHz and the BC thresholds at the octave intervals from 0.25 to 4 kHz with adequate masking. For most subjects who were considered for analysis both AC and BC thresholds at the above mentioned frequency ranges were available before and after surgery. However, in some subjects the hearing loss was very severe resulting in hearing thresholds which were beyond the maximum output of the audiometer. In these cases the pure tone thresholds at certain frequencies were impossible to determine and this is marked in the audiogram with an arrow pointing down. It is important to consider these limitations of the capacity of the audiometer, because data of pre- or postoperatively unmeasurable hearing thresholds could wrongly be excluded from analysis. Severe postoperative hearing loss as a consequence of an unfavourable operation would then not be taken into account. Conversely, ears with unmeasurable hearing thresholds before operation as a consequence of severe hearing loss but with measurable hearing thresholds after operation could also be rejected. To avoid this problem in these cases thresholds were assumed to be just beyond the audiometer limitations. If AC or BC was not measurable at a certain frequency a value of 10 dB above the limit for that frequency was given.
The AC and BC thresholds at 3 kHz are not routinely measured in the Dutch audiological centres. To obtain values for the four frequency PTA at 0.5, 1, 2 and 3 kHz, a fictive hearing level at 3 kHz was interpolated by taking the average of the thresholds measured at 2 and 4 kHz.
In 93.8 % (n = 423) of the cases speech audiometry was available before and after surgery. For each subject complete speech audiometry was carried out at different levels, using lists of phonetically-balanced CVC-words.[4] From these tests the pre- and postoperative SRTs could be derived. All audiograms were performed by classified personnel according to the ISO-389 (1975) standard. The mean time of audiometric testing after surgery was 2.1 months (range 0.6-12.1; SD ± 2.4). Ninety-four percent of the subjects had postoperative audiometric testing within 3 months.
All data were entered into a computer database and analysed with a spreadsheet program. In analysing our data the postoperative results are presented using four different PTA combinations at 0.5, 1, and 2 kHz, at 0.5, 1, 2, and 3 kHz, at 0.5, 1, 2, and 4 kHz and at 1, 2 and 4 kHz. The last named frequency combination was also analysed because it is has been suggested to be a sensitive measure of overclosure or cochlear damage to hearing.[1] ABG closure data are reported using postoperative BC thresholds as well as preoperative BC thresholds for the four different PTA combinations in computing postoperative ABG. For speech audiometry, data are presented with regard to improvement in speech reception thresholds (SRTs).
Audiometric data in this study did not show a normal distribution established with normality tests. Therefore nonparametric statistical analyses were performed (GraphPad Prism®). The Wilcoxon signed rank test was used for independent data, whereas the Spearman test was used for correlation analysis. Our criterion for statistical significance was set at *p*-values of less than 0.05 (two-tailed).

RESULTS

Table 1 shows data with regard to mean pre- and postoperative AC and BC levels (with standard deviations). A statistically significant improvement in AC is reached for every frequency, except at 8 kHz. Postoperatively there was an improvement in the mean BC levels at all frequencies. The most obvious improvement was achieved at 2 kHz which was 6.1 dB. The differences between pre- and postoperative BC thresholds were statistically significant for the individual frequencies at 0.5, 1, and 2 kHz. At 4 kHz there is only a small improvement and it was not statistically significant.

Influence choice of frequencies in computing PTA

Figure 1 shows graphically the gain in AC, BC and ABG for the four PTA combinations. For reasons of comparison also the mean gain in SRT has been reported. Choice of frequencies in computing PTA has a relatively small influence on improvement in BC. However, PTA frequency combination does have a significant ($p < 0.001$) influence on improvements in AC and ABG. The differences between the traditional three-frequency (0.5, 1, 2 kHz) and high-frequency (1, 2, 4 kHz) PTA were the largest being 4.9 dB and 4.5 dB for the gains in AC and ABG, respectively. The high frequency PTA combination gives overall a smaller gain in AC and ABG. The gain in AC for the frequency combination 0.5, 1, 2 and 4 kHz is 21.2 dB (SD ± 12.2) and corresponds on average best with the gain in SRT which is 20.2 dB (SD ± 12.1).

Choice of PTA frequency combination has some influence on the preoperative ABG (Fig. 2). Postoperatively it has little influence on the remaining ABG computed either with pre- or with postoperative BC. These differences are not statistically significant. In addition, Figure 3 shows that PTA frequency combination has also little influence on the percentage ABG closures ≤ 10 and higher categories when using either postoperative BC or preoperative BC. The relations between postoperative improvement in SRT at one side and improvements in AC and ABG for the four different PTA combinations at the other side were explored by correlation analysis (Table 2). As expected a stronger correlation exists between gain in AC and gain in SRT in comparison with gain in ABG and gain in SRT. Furthermore, choice of frequencies in computing PTA does have influence on correlation coefficients. In this respect gain in AC for the two four-frequency combinations at 0.5, 1, 2, and 3 kHz and at 0.5, 1, 2, and 4 kHz correlates better with gain in SRT in comparison with the traditional three-frequency or high-frequency combination.

Influence choice of pre- or postoperative BC in computing postoperative ABG

Figure 2 shows that the overall results with regard to postoperative ABG are more favourable using preoperative BC. The differences are 3.5 dB, 3.4 dB, 2.5 dB and 3.0 dB for the PTA combinations at 0.5, 1, 2 kHz, at 0.5, 1, 2, 3 kHz, at 0.5, 1, 2, 4 kHz and at 1, 2, 4 kHz, respectively. These differences are statistically significant ($p < 0.001$) for all four PTA combinations. Using preoperative BC gives also more favourable results with regard to percentage ABG closures ≤ 10 dB (Fig. 3). In this respect the largest differences are 6.6 %, 4.9 % and 3.4 % for the PTA combinations 0.5, 1, 2 kHz , 0.5, 1, 2, 3 kHz and 1, 2, 4 kHz respectively, but only 1.5

% for the PTA combination 0.5, 1, 2, 4 kHz. Using pre- or postoperative BC does not substantially affect the results on percentage ABG closures for the higher categories.

Table 1. Pre- and postoperative air-conduction and bone-conduction thresholds.

Frequency (kHz)	Preop	SD	Postop	SD	Difference	SD	Statistical sign.
Air-conduction							
0.125	58.7	14.9	31.8	13.5	26.9	16.6	$p < 0.0001$
0.25	57.5	15.2	30.0	13.0	27.5	16.4	$p < 0.0001$
0.5	54.4	14.1	27.4	13.5	27.0	14.9	$p < 0.0001$
1	51.3	14.3	25.4	13.6	25.9	14.4	$p < 0.0001$
2	47.2	15.9	27.0	15.5	20.2	12.3	$p < 0.0001$
3*	48.3	17.1	32.1	16.9	16.2	12.8	$p < 0.0001$
4	49.5	21.1	37.2	20.8	12.3	15.4	$p < 0.0001$
8	54.9	50.6	53.0	25.3	1.9	46.2	NS
Bone-conduction							
0.25	8.6	9.0	8.1	9.1	0.5	8.1	NS
0.5	16.5	10.7	15.3	11.3	1.3	9.4	$p = 0.001$
1	17.3	10.4	14.3	11.6	3.0	9.5	$p < 0.0001$
2	28.5	12.9	22.4	14.4	6.1	10.3	$p < 0.0001$
3*	27.5	13.0	24.4	14.4	3.1	8.0	$p < 0.0001$
4	26.4	15.8	26.3	16.9	0.1	9.7	NS

For each frequency the preoperative (preop) and postoperative (postop) air-conduction (AC) and bone-conduction (BC) thresholds with standard deviations (SD) are shown. Statistical significance (Wilcoxon test) of the reduction of AC and BC levels are indicated in the right column.

* The hearing level at 3 kHz is an interpolated value by taking the average of the hearing thresholds measured at 2 and 4 kHz.

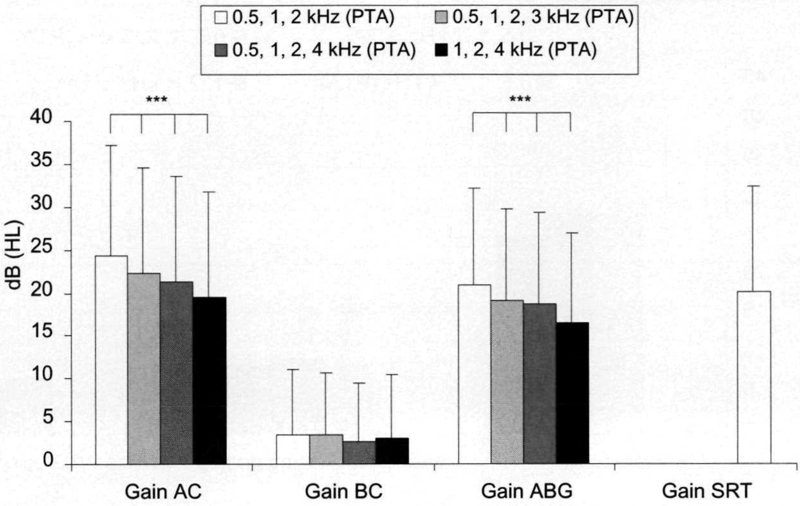

Fig. 1. *Mean gain in air-conduction (AC), bone-conduction (BC) and air-bone gap (ABG) are shown for four different pure-tone average (PTA) combinations. Values for ABG improvement were based on postoperative ABG computed with postoperative BC. For comparison the mean gain in speech reception threshold (SRT) is given as the "golden standard".*
**** The brackets indicate that for AC and ABG all PTA combinations yield significantly different results (Wilcoxon test, p < 0,001).*

Table 2. Correlation analysis with gain in speech reception as the "golden standard".

	Gain in AC			
	0.5, 1, 2 kHz	0.5, 1, 2, 3 kHz	0.5, 1, 2, 4 kHz	1, 2, 4 kHz
Gain in SRT	R = 0.808; $p < 0.001$	R = 0.888; $p < 0.001$	R = 0.884; $p < 0.001$	R = 0.796; $p < 0.001$
	Gain in ABG[#]			
	0.5, 1, 2 kHz	0.5, 1, 2, 3 kHz	0.5, 1, 2, 4 kHz	1, 2, 4 kHz
Gain in SRT	R = 0.608; $p < 0.001$	R = 0.637; $p < 0.001$	R = 0.653; $p < 0.001$	R = 0.642; $p < 0.001$

Gain in speech reception threshold (SRT) vs. gain in air-conduction (AC) and air-bone gap (ABG) explored by correlation analysis (Spearman test) for four different frequency combinations.
[#]Values based on postoperative air-bone gap computed with postoperative bone-conduction.

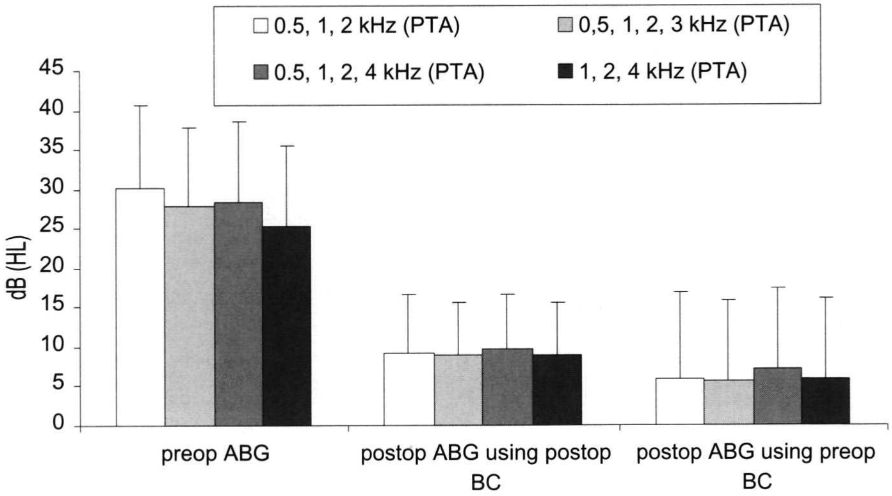

Fig. 2. *Preoperative mean air-bone gap (preop ABG) and postoperative mean air-bone gap (postop ABG) are shown for four different pure-tone average (PTA) combinations. Postoperative BC (postop BC) values and preoperative BC (preop BC) values are used in accounting postoperative air-bone gap.*

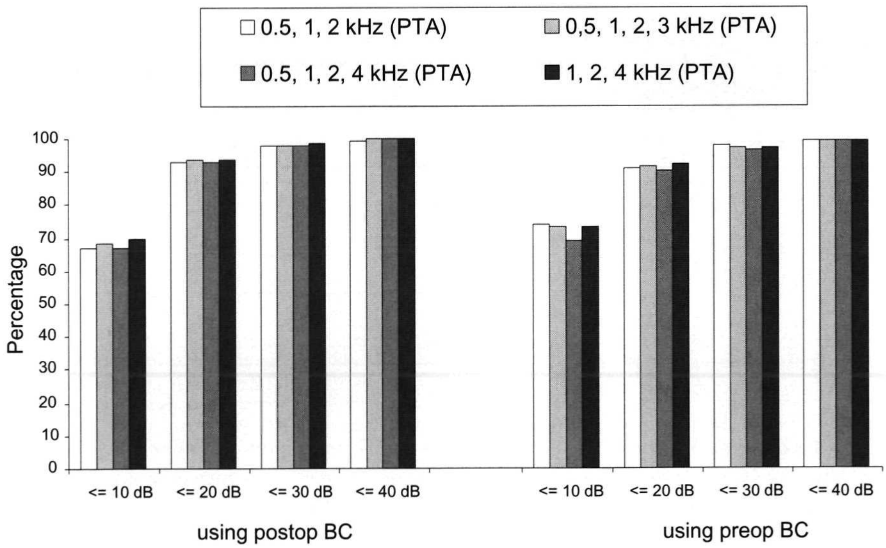

Fig. 3. *Cumulative percentage of postoperative air-bone gap (ABG) for four different pure-tone average (PTA) combinations. Postoperative bone-conduction (postop BC) values and preoperative bone-conduction (preop BC) values are used in accounting postoperative ABG.*

Influence choice of success criteria

Figure 4 shows graphically the success-rates according to different success-criteria. The percentages AC thresholds and the percentages ABG closures within several levels are calculated for the four different PTA combinations. Postoperative ABG has been computed with postoperative BC. Also the percentages of ears with SRTs within several levels are presented. The curve from AC thresholds for the traditional three-frequency PTA at 0.5, 1, and 2 kHz corresponds best with the curve from SRTs. Fig. 4 shows clearly the effect of the choice of PTA on success rate with regard to percentages ears with AC levels within different categories. If normal hearing, defined as an AC threshold ≤ 20 dB, is taken as a measure of success, the success rate will be ~ 8 % higher for the traditional three-frequency PTA at 0.5, 1, and 2 kHz than for the four-frequency PTA at 0.5, 1, 2 and 4 kHz. This difference will be even more (~ 10 %) if one defines success as "socially acceptable" hearing with an AC level ≤ 30 dB.

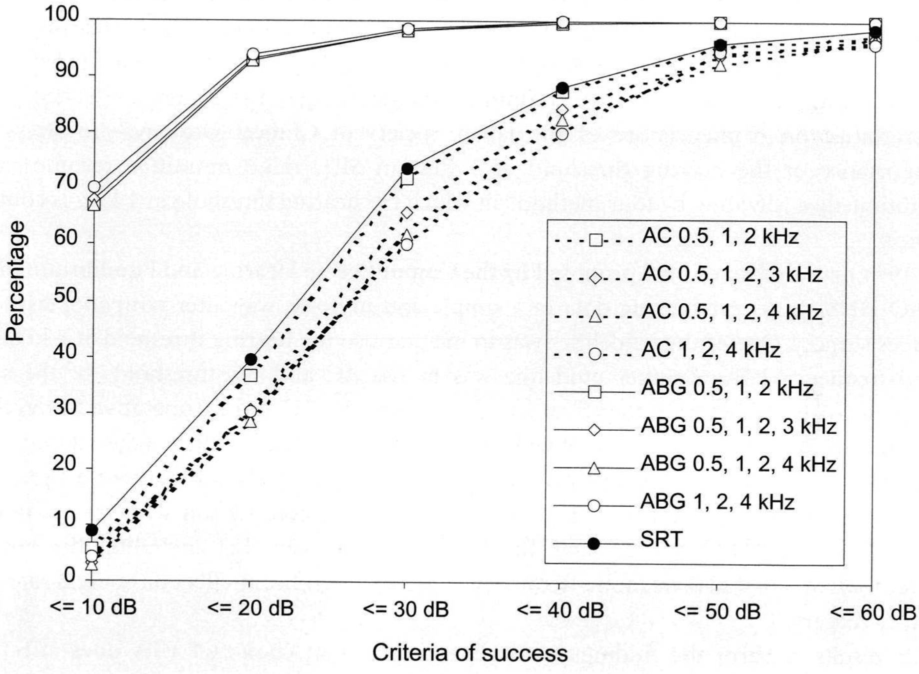

Fig. 4. *Success rates are shown for air-conduction (AC) thresholds and air-bone gap (ABG) values within several categories for four different pure-tone average (PTA) combinations. Postoperative ABG was computed with postoperative bone-conduction. In addition, success rates are shown for speech reception threshold (SRT) levels within several categories.*

The most important differences are between the percentages ABG closures and AC or SRT levels within certain criteria. A much higher success rate (~ 30 %) will be achieved if one considers the percentage of ears with ABG closure ≤ 10 dB as criterion for success in stead of the percentage of normal hearing ears with AC or SRT levels ≤ 20 dB. However, less striking differences will be obtained if one compares ABG closure ≤ 10 dB with AC or SRT levels ≤ 30 dB as criteria for "socially acceptable" hearing.

Discussion

In the evolution of surgical treatment of hearing loss caused by otosclerosis initially the frequencies 0.5, 1, and 2 kHz were considered for accounting PTAs in evaluation of hearing results, because they were mostly involved with conversational speech reception.[5] During development of speech audiometry it appeared that the traditional three-frequency PTA (the so called "Fletcherian index") for AC thresholds correlate well with SRTs. Also later, after introduction of the stapedectomy technique by Shea,[6] the hearing thresholds at 0.5, 1, and 2 kHz remained the most important in evaluation of hearing results. Hearing levels at the same frequencies were also recommended in the guidelines of reporting hearing results after surgery of chronical ear infections by the Committee on Conservation of Hearing of the American Academy of Ophthalmology and Otolaryngology in 1965.[7] More recently the above mentioned frequencies were recommended according to the guidelines drafted by the Committee on Nomenclature of the Japan Society of Clinical Otology.[8] To stress the importance of the hearing threshold at 1 kHz in SRT, this Committee recommended additionally a "dividing by four method" in which the hearing threshold at 1 kHz is counted twice.

In 1994 new guidelines were proposed by the Committee on Hearing and Equilibrium of the AAO-HNS[1] to report hearing data in a simple and uniform way after tympanoplasty and stapes surgery. One of the guidelines was to include also the hearing threshold at 3 kHz in a four-frequency PTA. Another guideline was to use AC and BC thresholds of the same postoperative audiogram rather than using postoperative AC and preoperative BC levels in computing postoperative ABG. Goldenberg and Berliner[5] found in their material that when a higher frequency (3 or 4 kHz) was used in a four-frequency PTA, it had not a significant influence on success rate after tympanoplasty surgery in comparison with the traditional three-frequency PTA. A year later Berliner et al.[2] showed that including the hearing thresholds at 3 or 4 kHz in a four-frequency PTA had a significant effect on success rate after stapes surgery.

Our results confirm the findings of Berliner et al.[2] that choice of PTA does affect the percentage of normal hearing ears with AC levels ≤ 20 dB; in this study the differences were 6.0 % and 8.0 % in the advantage of the traditional three-frequency PTA at 0.5, 1, and 2 kHz in comparison with the four-frequency PTAs at 0.5, 1, 2, 3 kHz and 0.5, 1, 2, 4 kHz, respectively. Choice of PTA had little effect on postoperative ABG levels (Fig. 2) which is also in agreement with the findings of Berliner et al.[2] Furthermore, it appeared that it had also little effect on the percentage of ears with ABG closure ≤ 10 dB or higher categories (Figs. 3 and 4).

The most important goal of stapes surgery is improvement of hearing and consequently improvement of the ability for reception of conversational speech. In this perspective we also analysed the improvements in SRTs and used it as the "golden standard" for comparison with gains in AC and ABG for the four different PTAs examined (Fig. 1). It appeared that the mean postoperative gain in SRT corresponds on average best with the mean gain in AC for the PTA combination 0.5, 1, 2, and 4 kHz, although there are no significant differences with the other PTA combinations after correlation analysis (Table 2). To our surprise, it appeared that after comparison between the percentages ears with a SRT within a certain level (for example 20 dB or 30 dB) and the percentages ears with an AC threshold within a certain level, these success percentages are best in agreement with the traditional PTA combination at 0.5, 1, and 2 kHz (Fig. 4). This may be caused by the fact that SRTs have been measured in quiet and not with background noise. For speech reception in noise the higher frequencies have been shown to be more important.

It is logical that in many studies the surgical success is related to the improvement of ABG, because it is supposed that gap reduction represents repair of the conductive system of the middle ear which shows the technical success of surgery. In establishing postoperative ABG often studies[9,10] are using the method by taking the differences between postoperative AC and preoperative BC levels while more recently published studies[3,11] are using the method in which the differences between postoperative AC and BC thresholds are taken into account. In some studies[12,13] it is not possible to trace which method has been used. Occasionally, postoperative ABG is computed by taking the best BC level.[14,15]

Initially, the first mentioned method by using preoperative BC levels was, according to the literature, used more often and an ABG closure within 10 dB was considered as a technical success. This method of computing postoperative ABG was also recommended by the Committee on Nomenclature in Chronic Ear Disease and the Otosclerosis Study Group[15] in 1971. It is however well known that BC thresholds can substantially improve after surgery as already described after fenestration surgery by Carhart in 1950 and is known as the Carhart effect.[16] Postoperatively the inertial component of bone conducted sound transmission is restored and therefore postoperative BC thresholds may correspond better with the true function of the cochlea. This supports the use of postoperative BC thresholds for computing postoperative ABG. Harder[17] found in his study that the gap between postoperative AC and preoperative BC was dependent on the level of preoperative BC thresholds but the gap to postoperative BC seemed to be independent of the preoperative BC thresholds level. Furthermore, he found that gaps to postoperative BC showed less variation than the gaps to preoperative BC and it was stated that postoperative BC thresholds may serve as a more stable and natural reference when calculating postoperative ABG.

In our results choice of preoperative or postoperative BC most obviously affected the mean postoperative ABG levels for all four PTAs with larger improvements relative to preoperative BC (Fig. 2). It had also an effect on the percentage ABG closure $\leq$ 10 dB with the largest difference for the PTA combination 0.5, 1, and 2 kHz which was 6.6 % more favourable when using preoperative BC. The use of pre- or postoperative BC did not have a substantial influence on the percentage ABG closure $\leq$ 20 dB or higher levels for all four PTAs (Fig. 3). Berliner et al.[2] did not find large differences in percentages ABG closures $\leq$ 10 dB and several higher levels by using preoperative or postoperative BC in computing postoperative ABG.

During review of the literature, it appears that several criteria are used to establish success. Studies which report results with regard to improvement of AC thresholds, often take the traditional speech frequencies (PTA 0.5, 1, 2 kHz) into account,[18,19] although sometimes the gain for individual frequencies are reported as well.[19,20] Less often results with regard to improvement of AC thresholds are reported with four-frequency PTAs as recommended by the AAO-HNS.[1] Sometimes authors[12] are relating surgical success with the percentage ears with AC thresholds within a certain level like 20 dB or 30 dB. Only a few studies[12,19] have analysed speech audiograms and report results with regard to improvement in SRTs. Just because a variety of success criteria are being used in the literature, it is difficult to compare studies with regard to hearing improvement after surgery. In our material it makes, as expected, a big difference when taking the percentages of ears with ABG closure within a certain level as a measure of success, or when taking the percentages of ears with an AC threshold within a certain level. If one takes the percentage of ears in which normal hearing was obtained after surgery, defined as an AC threshold ≤ 20 dB as a measure of success, there will be a difference of ~35 % from the percentage of ears with an ABG closure ≤ 10 dB postoperatively. The difference will be less when success is defined as the percentage of ears with "socially acceptable" hearing (AC threshold ≤ 30 dB). The effects of choice of PTA on the extent of this difference has been clearly illustrated in this study (Fig. 4).
Although it was not strictly necessary for this study to subdivide the cases with primary surgery from revision surgery, it is well known from the literature[3] that revision surgery yields less favourable results with regard to hearing improvement as is the case in this study: success rates, defined as an ABG closure ≤ 10 dB (postoperative ABG computed with postoperative BC for the four-frequency PTA at 0.5, 1, 2, and 4 kHz), was 71 % for the primary cases while it was 58 % for the revision group.

Conclusions

The aim of this study was to establish to what extent choice of different audiological criteria affects success rates following stapes surgery. This study provides the following answers to the questions mentioned in the introduction:

1. Choice of PTA significantly affects postoperative gain in AC thresholds and ABG levels (Fig. 2). It has however little influence on the remaining postoperative ABG and on the percentage of ears with ABG closures ≤ 10 dB or higher categories.
2. If the improvement in SRT is regarded as the "golden standard", the gain in AC does correlate best with the gain in SRT if a higher frequency, like the 3 or 4 kHz, is included in a four frequency PTA.
3. Choice of pre- or postoperative BC in computing postoperative ABG had a significant effect on the mean postoperative ABG levels showing more favourable results when preoperative BC thresholds were used. In our results using preoperative BC levels gives also more favourable results with regard to ABG closure ≤ 10 dB with the largest difference for the PTA combination 0.5, 1, and 2 kHz which was 6.6 %. It has less effect on the percentage of ears with an ABG closure to higher categories.

4. Success rate is mainly dependent on definition and criteria as a measure of success (Fig. 4). In this perspective, the percentage ears with "socially adequate" hearing, defined as an AC threshold ≤ 30 dB, does compare best with the percentage ears with ABG closure ≤ 10 dB. In our opinion the achievement of "socially adequate" hearing is a more realistic measure of success than the achievement of "normal" hearing defined as an AC level ≤ 20 dB.

On the basis of our results we agree with the conclusions of Berliner et al.[2] and the AAO-HNS recommendations[1] to use AC and BC levels from the same audiogram in computing ABG. Because in many audiology departments in Europe the 3 kHz is not routinely measured, a four-frequency PTA will be an average at 0.5, 1, 2 and 4 kHz in most situations and is preferred for reporting results after stapes surgery with regard to mean values of audiological parameters.

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Chapter 4

Efficacy of Evaluation of Audiometric Results after Stapes Surgery in Otosclerosis. Part II: A Method for Reporting Results From Individual Cases.

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Otolaryngology- Head and Neck Surgery, in press

Abstract

To standardise the reporting of hearing results after middle ear surgery, the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology–Head and Neck Surgery proposed two levels of guidelines. Level 1 for reporting *summary* data and level 2 for reporting *raw* data. The Committee encourages to report raw data from each individual case. However, in studies where the examined population is too large this can yield difficulties. With respect to this point we designed a method for a simple visual presentation of hearing results in an attempt to provide data from each individually operated ear in a patient group. In this method (1) the relation between the pre- and postoperative bone conduction levels is evaluated to assess overclosure and iatrogenic cochlear damage and (2) the relation between postoperative gain in air-conduction and the preoperative air-bone gap is evaluated as a measure of technical success rate. This results in two plots, which we named the "Amsterdam Hearing Evaluation Plots" (AHEPs). Audiometric data from 451 stapes operations were used to demonstrate the use of the AHEPs.

Introduction

In evaluating the effect of different surgical techniques on hearing, or to compare hearing results from various patient populations, most often the *mean* values of specific audiologic parameters are considered. Less often the hearing results in each *individually* operated ear are surveyed. However, for a good impression of differences between patient groups or between certain surgical techniques, it is illustrative to present results of each operated ear separately. Although reporting raw data from individual cases is also encouraged by the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS),[1] often the number of operated ears is too high to report all data from each individually operated ear. In an attempt to accommodate with this problem we developed a new method of data analysis in which the effects of operation on hearing can be deduced for each individual ear using two plots, which we named the "Amsterdam Hearing Evaluation Plots" (AHEPs). In the first plot the results with regard to postoperative bone-conduction (BC) thresholds are related to preoperative BC thresholds to evaluate the effect of surgery on bone conduction. In the second plot the preoperative air-bone gap (ABG) levels are related to postoperative gain in air-conduction (AC) to establish the degree of success with regard to restoration of middle ear hearing transmission function. One of the great advantages of reporting data with these plots is that favourable and unfavourable results with regard to technical success can easily be identified and in addition ears with cochlear damage due to surgery can be recognised.

The aim of this study was to report audiometric results of 451 stapes operations with the AHEPs as an attempt to present operation results of individual ears in a simple but clarifying way.

Patients and Methods

Amsterdam Hearing Evaluation Plots (AHEPs)

The purpose of these plots is to give a visual representation of hearing results of each individual ear after middle ear surgery. In this study we applied the AHEPs on the audiometric results of stapes surgery, although this method of analysing data could easily be used in other middle ear interventions. One of the potential risks in the case of stapes surgery is sensorineural hearing loss and especially hearing sensitivity at the higher frequencies are at risk. On the other hand it is known that in some ears the BC improves due to the Carhart effect.[2] To visualise the effect of surgery on BC the pre- and postoperative BC thresholds are plotted in the first graph (Fig. 1A). The gain in AC after surgery is largely dependent upon the preoperative gap between AC and BC levels: the greater the ABG the more gain one may expect in AC after a technically successful operation. To show the relationship between these two parameters the second graph was designed in which the postoperative gain in AC is plotted against the preoperative ABG of each individually operated ear (Fig. 1B).

In the first graph (Fig. 1A), the two dotted diagonal lines enclose the area within BC did not changed over more than 10 dB. Iatrogenic cochlear damage was defined as a postoperative decrease of BC threshold of more than 10 dB and it is indicated by every point above the upper dotted diagonal line, while every point below the lower dotted diagonal line can be considered as an improvement of the BC due to the Carhart effect.

In the second graph (Fig. 1B), the horizontal axis represents the postoperative change in AC and the vertical axis represents the preoperative ABG. The solid diagonal line indicates total closure of the gap between preoperative AC and BC. Consequently, every point below the solid diagonal line indicates a gain in AC which is larger than one may expect from preoperative ABG and such a result can be regarded as a "successful result with overclosure". We defined an unsuccessful operation result as a negative change in AC threshold or a change in AC which was not enough to close the gap between postoperative AC and preoperative BC to 20 dB or less. Every point above the dotted diagonal line in Figure 1B indicates such an "unsuccessful result". In contrast, every point below the dotted diagonal line can be considered as a "successful result".

For reporting the AC, BC and ABG values several PTA combinations as well as individual frequencies can be used. To demonstrate the AHEPs a few examples are given which have been listed in Table 1 and have been visualised in Figures 1A and 1B.

In the first graph (Fig. 1A), the two dotted diagonal lines enclose the area within BC did not changed over more than 10 dB. Iatrogenic cochlear damage was defined as a postoperative decrease of BC threshold of more than 10 dB and it is indicated by every point above the upper dotted diagonal line, while every point below the lower dotted diagonal line can be considered as an improvement of the BC due to the Carhart effect.

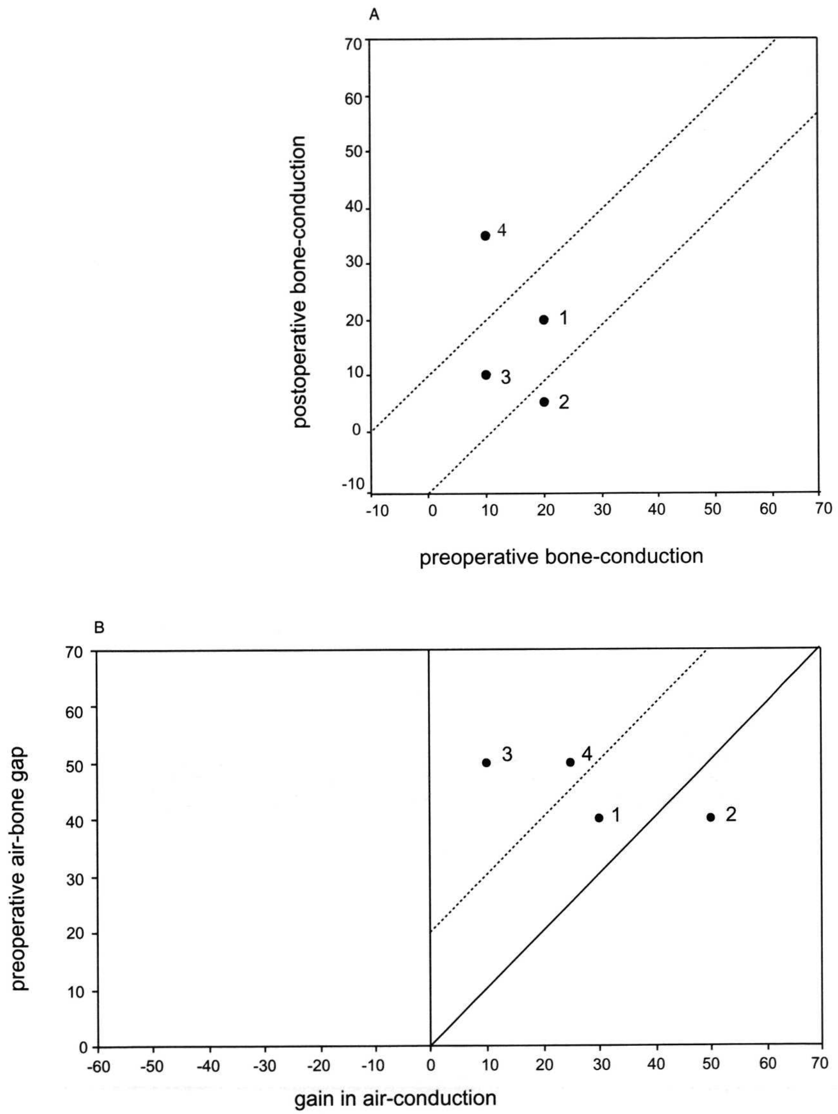

Fig.1. *The "Amsterdam Hearing Evaluation Plots" (AHEPs). A, Preoperative bone-conduction plotted against postoperative bone-conduction for each operated ear. The two diagonal lines enclose the area within bone-conduction did not changed over more than 10 dB. B, Postoperative gain in air-conduction plotted against the preoperative air-bone gap for each operated ear. The solid diagonal line indicates total closure of the gap between preoperative air-conduction and bone-conduction. Every point below this line is defined as overclosure. An unsuccessful operation result with regard to air-conduction is defined as a negative change in air-conduction or a change in air-conduction which was not enough to close the gap between postoperative air-conduction and preoperative bone-conduction to 20 dB or less. This is indicated by the dotted diagonal line.*

In the second graph (Fig. 1B), the horizontal axis represents the postoperative change in AC and the vertical axis represents the preoperative ABG. The solid diagonal line indicates total closure of the gap between preoperative AC and BC. Consequently, every point below the solid diagonal line indicates a gain in AC which is larger than one may expect from preoperative ABG and such a result can be regarded as a "successful result with overclosure". We defined an unsuccessful operation result as a negative change in AC threshold or a change in AC which was not enough to close the gap between postoperative AC and preoperative BC to 20 dB or less. Every point above the dotted diagonal line in Figure 1B indicates such an "unsuccessful result". In contrast, every point below the dotted diagonal line can be considered as a "successful result".

Table 1. Examples to demonstrate the use of the AHEPs.

Example 1:		Successful result	
	Pre AC 60	Post AC 30	Gain AC 30
	Pre BC 20	Post BC 20	Gain BC 0
	Pre ABG 40	Post ABG 10	Gain ABG 30
Example 2:		Successful result with overclosure	
	Pre AC 60	Post AC 10	Gain AC 50
	Pre BC 20	Post BC 5	Gain BC 15
	Pre ABG 40	Post ABG 5	Gain ABG 35
Example 3:		Unsuccessful result	
	Pre AC 60	Post AC 50	Gain AC 10
	Pre BC 10	Post BC 10	Gain BC 0
	Pre ABG 50	Post ABG 40	Gain ABG 10
Example 4:		Unsuccessful result	
	Pre AC 60	Post AC 35	Gain AC 25
	Pre BC 10	Post BC 35	Gain BC –25
	Pre ABG 50	Post ABG 0	Gain ABG 50

For reporting the AC, BC and ABG values several PTA combinations as well as individual frequencies can be used. To demonstrate the AHEPs a few examples are given which have been listed in Table 1 and have been visualised in Figures 1A and 1B.

Example 1: "Successful result". Point (1) in Figures 1A and 1B is a fictitious ear with an AC threshold of 60 dB and a BC threshold of 20 dB before operation. Postoperatively the AC improved to a threshold of 30 dB while the BC remained at 20 dB. It is clear that such an outcome can be considered as successful.

Example 2: "Successful result with overclosure". Point (2) in Figures 1A and 1B is a fictitious ear with preoperatively the same AC and BC values as in example 1. However this time the AC improved to a threshold of 10 dB while the BC improved to 5 dB. Such a result can be regarded as an "overclosure" of the ABG as the BC improved with 15 dB.

Example 3: "Unsuccessful result". Point (3) in Figures 1A and 1B is a fictitious ear with preoperatively an AC threshold of 60 dB and a BC threshold of 10 dB. Postoperatively the AC improved only with 10 dB while the BC did not changed. An unsuccessful result can be caused by two reasons: it did not succeed in restoring middle ear transmission function as is the case in this example and/or cochlear damage occurred due to surgery. The last named situation is demonstrated in the next example.
Example 4: "Unsuccessful result". Point (4) in Figures 1A and B is a fictitious ear with the same AC and BC values as in example 3 before operation. After surgery the AC improved with 25 dB while the BC deteriorated with 25 dB. If postoperative ABG is conducted with postoperative BC, the ABG after surgery would be 0 dB and could wrongly be interpreted as successful.

Subjects and Materials

To demonstrate the use of the AHEPs in reporting audiometric results after stapes surgery, the same set of data were used as described in Chapter 3 concerning 451 operations in 374 patients.[3]

Results

In Figure 2A the preoperative BC thresholds have been plotted against the postoperative BC thresholds while in Figure 2B the postoperative hearing gains in AC are plotted against the preoperative ABGs for every single ear that underwent stapes surgery. For reporting AC and ABG levels in Figure 2B a four frequency average at 0.5, 1, 2, and 3 kHz was used as recommended by the Committee on Hearing and Equilibrium of the AAO-HNS.[1] Because it has been stated by the Committee that the preoperative minus the postoperative BC levels for the pure-tone high frequency combination at 1, 2, and 4 kHz is a sensitive measure of overclosure or cochlear damage to hearing, the BC levels in Figure 2A have been calculated for the high frequency PTA. As explained in "Patients and Methods" every point above the upper dotted diagonal line in Figure 2A was regarded as a cochlear damage ≥ 10 dB due to surgery and every point below the lower dotted diagonal line indicates a postoperative gain in BC ≥ 10 dB. From the total group of ears in Figure 2A 373 (82.7 %) had postoperative BC thresholds which are ± 10 dB from preoperative BC levels. The number of ears in Figure 2A with an improvement of BC threshold ≥ 10 dB was 68 (15.1 %).
In Figure 2B every point below the solid diagonal line indicates "overclosure" and every point above the dotted diagonal line indicates an "unsuccessful" result. According to the AHEPs, the number of successfully operated ears with regard to AC is 402 (89.1 %). From this total group of ears 306 ears had a "successful result without overclosure" while 96 ears had a "successful result with overclosure" (Fig. 2B). All ten ears (2.2 %) with cochlear damage ≥ 10 dB in Figure 2A could also be defined as an "unsuccessful result" in Figure 2B. Of all ears in Figure 2B 311 (68.9 %) had postoperative AC thresholds which were ± 10 dB from preoperative BC levels.

From Figure 2B 49 (10.9 %) cases could be defined as an "unsuccessful" result with regard to AC. In this failure group the amount of revision surgeries was relatively high; from the whole group of revision cases (n=65) eleven had an "unsuccessful" hearing result. Figures 2A and B visualise one failure with extreme values regarding to the gain in AC and the postoperative BC.

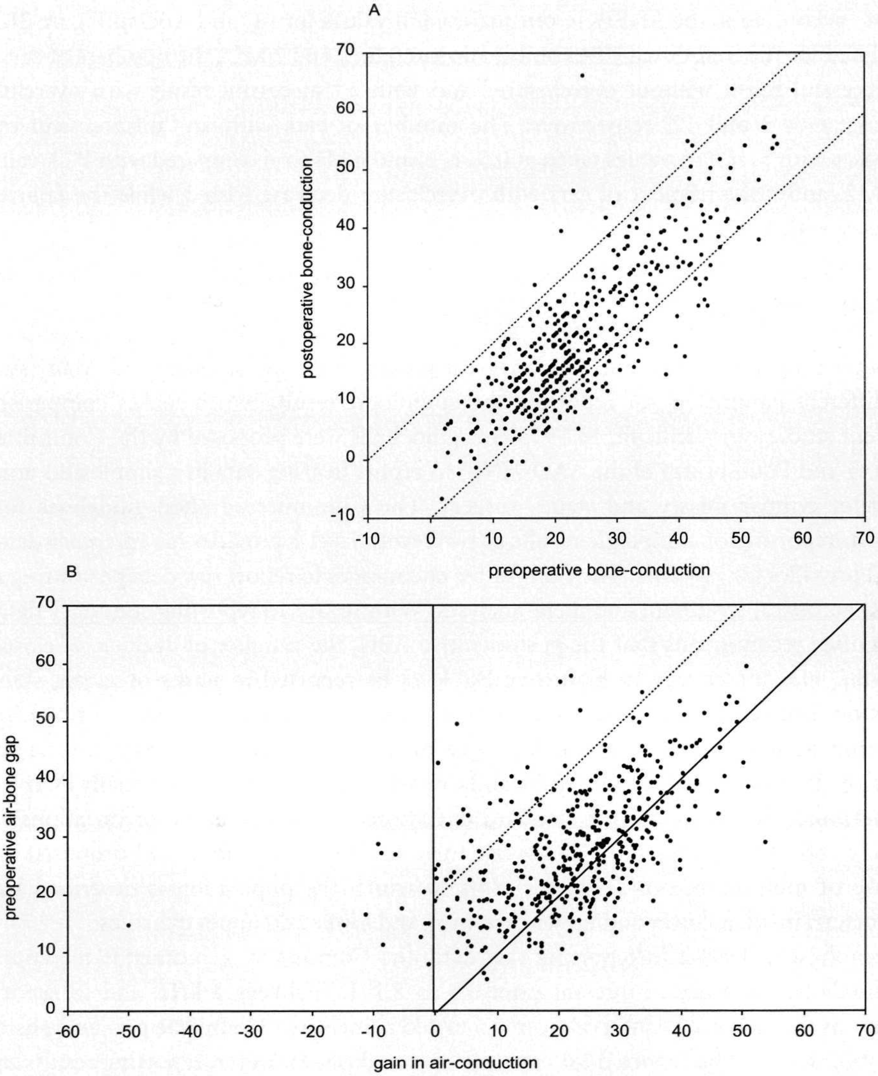

Fig. 2. *Audiometric results of 451 stapes operations visualized with the Amsterdam Hearing Evaluation Plots (AHEPs). A, Preoperative bone-conduction and postoperative bone-conduction plotted for individual ears. Pure-tone average (PTA) was calculated for the high frequency combination at 1, 2, and 4 kHz. B, Postoperative gain in air-conduction plotted against preoperative air-bone gap for individual ears. PTA was calculated for the frequency combination at 0.5, 1, 2, and 3 kHz.*

This is an ear with a preoperative BC value of 20 dB and a postoperative BC value of 65 dB (Fig. 2A) while the gain in AC value was – 50 dB and the preoperative ABG value was 15 dB (Fig. 2B). This patient had revision surgery for the second time.
Part I of this study showed that choice of PTA significantly affects postoperative gain in AC thresholds and ABG levels after stapes surgery. Choice of PTA has also some effect on the numbers of "successful results", "successful results with overclosure", and "unsuccessful results" according to the AHEPs in our material. If values for AC and ABG in Figure 2B were calculated for the traditional PTA combination at 0.5, 1, and 2 kHz, the numbers of ears with a "successful result without overclosure" and with a "successful result with overclosure" increase with 9 and 12, respectively. The number of ears with an "unsuccessful result" decreases with 8. If PTA values taken at 0.5, 1, 2, and 4 kHz are compared with PTA values at 0.5, 1, 2, and 3 the number of ears with overclosure decrease with 3 while the failure rate increases with 4 ears.

Discussion

The reporting of hearing results in middle ear surgery is not yet standardised. Many authors use different parameters for reporting the audiologic results which makes comparison of different studies very difficult. In 1995 new guidelines were proposed by the Committee on Hearing and Equilibrium of the AAO-HNS[1] to report hearing data in a simple and uniform way after tympanoplasty and stapes surgery. The Committee drafted guidelines for the uniform reporting of audiologic results at two levels: level 1 provides for *summary* data and level 2 provides for *raw* data. The Committee encourages to report raw data permitting more precise statistical treatment and meta-analyses. With regard to reporting summary data, the Committee recommends that the postoperative ABG, the number of decibels of closure of the ABG, and the change in high-tone BC level be reported in terms of mean, standard deviation, and range. However, Govaerts et al.[4] has already mentioned the shortcomings of reporting results in this way because choice of mean and standard deviations suggests a normally distributed population, while audiometric data are often not normally distributed. Furthermore, the mean and the standard deviations are very sensitive to variations at the extreme end of the population. To obviate these criticism Govaerts et al.[4] proposed to add the use of multiple box and whisker plots in which the population is described by five parameters: median, lower and upper extremes, and lower and upper quartiles.
To comply with level 2 in reporting raw data, the Committee recommends to report AC thresholds for each octave interval from 0.5 to 8 kHz inclusive 3 kHz, and to report BC thresholds for each octave interval from 0.5 to 4 kHz inclusive 3 kHz. The pre- and postoperative values should be reported for each ear operated on. However, reporting results in this way could enhance difficulties when the population examined is too large to show all data. For this reason we designed the AHEPs in an attempt to give a visual presentation of audiometric results after middle ear surgery. Although data are not represented according to level 2 of the guidelines, we feel that this way of analysing data can add valuable information to the evaluation of audiometric results in a larger population when it is desired to report data from

each case. The plots show the individual results and visualise the amount of "overclosures" (Fig. 2B) which is especially of interest in reporting results of stapes surgery. In addition the unfavourable hearing results can easily be recognised with regard to cochlear damage (Fig. 2A) and residual conductive hearing loss (Fig. 2B).

Although definitions of good, moderate or unfavourable outcome are arbitrary issues, we choose to define an "unsuccessful result" as a negative change in AC threshold or a remaining gap of more than 20 dB between postoperative AC and preoperative BC levels and this was indicated by the dotted diagonal line in Figure 2B. Actually, this is the same measure for success rate as when success is defined as an ABG closure to 20 dB or less used in Part I of this study provided that postoperative ABG is conducted with preoperative BC for the PTA combination 0.5, 1, 2, and 3 kHz. According to this criterion 89.1 % of the cases in our stapes surgery series had a "successful result". This percentage is more favourable when compared to other criteria as measures of success like for instance ABG closure ≤ 10 dB or postoperative AC level ≤ 30 dB as shown in Part I of this study. In this perspective criteria for success can easily be changed in the AHEPs if necessary.

We have evaluated the "unsuccessful results" in our material separately in an attempt to get a better understanding of the reasons why those surgical performances had failed. It appeared that every ear with a postoperative deterioration of BC level of more than 10 dB in Figure 2A, defined as an iatrogenic cochlear damage, could also be identified as an "unsuccessful result" in Figure 2B. Furthermore, the percentage of revision cases in the unsuccessful group was relatively high (11/49) underlining that revision surgery is an unfavourable factor with regard to hearing results which is well known from the literature.[5, 6]

As shown in part I of this study it appeared that choice of PTA significantly affects postoperative gain in AC thresholds and ABG levels after stapes surgery. In demonstrating the AHEPs with the audiometric results of stapes surgery we have chosen to use two different PTA combinations as recommended by the Committee of the AAO-HNS.[1] Choice of PTA has also some effect on the amount of "successful results" and "unsuccessful results" according to the AHEPs in our material with more favourable results using the traditional three-frequency PTA at 0.5, 1, and 2 kHz.

Evaluation of hearing results with the AHEPs is a refined method to determine technical success after surgery and to compare the spread in individual results for different populations. However, it must be emphasised that it is not a method to obtain an impression of the benefit a patient derives from surgery as patient's disability is also dependent on the hearing thresholds of the not operated ear. More disability-oriented methods of data analysis are described by Smyth et al.[7] and Browning et al.[8] as well as by de Bruijn et al.[9, 10]

Conclusion

The AHEPs form an easily understood visual presentation of audiometric results of each individual case after stapes surgery or other middle ear interventions. In our opinion the use of the AHEPs would gain additional information when it is combined with the guidelines of the Committee on Hearing and Equilibrium of the AAO-HNS in reports of audiometric results. Another advantage of presenting data with the AHEPs is that outliners with extreme values of audiometric results are visualised clearly. These values would influence summary statistics but are not always recognisable when presenting summary data with means and standard deviations.

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Chapter 5

Comparison of Stapes Prostheses. A Retrospective Analysis of Individual Audiometric Results Obtained After Stapedotomy by Implantation of a Gold and a Teflon Piston.

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Abstract

This study evaluates the hearing results after implantation of a Teflon piston (type Causse; Xomed Surgical Products, Jacksonville, FL, USA) and of a pure gold piston (K-piston; Heinz Kurz GmbH Medizintechnik, Dußlingen, Germany), both with a shaft diameter of 0.4 mm in cases of otosclerosis requiring stapedotomy. An important difference between both prostheses is the difference in mass: the gold piston is three times heavier than the Teflon piston. Retrospective analyses were carried out of the presurgery and postsurgery audiologic results obtained after primary stapedotomy by implantation of 62 Teflon pistons and 66 gold pistons. The results were compared according to mean values of several audiometric parameters. Furthermore, individual audiometric results have been evaluated with the "Amsterdam Hearing Evaluation Plots" (AHEPs) as a method for visual presentation of hearing results from each operated ear. With this method "unsuccessfully" and "successfully" inserted prostheses can be recognised easily and a more realistic comparison between prostheses is possible.

It was found that in the overall group the heavier gold prosthesis gives a significantly larger gain in air-conductive hearing at 2 kHz ($p < 0.05$) and in the speech frequency range 0.5 to 2 kHz ($p < 0.05$). There were no significant intergroup differences with regard to change in bone-conduction and air-bone gaps. Analysis of the hearing results of the subgroup that included only the "successfully" implanted prostheses according to the criteria of the AHEPs had mainly consequences for improvement of air-conduction thresholds: none of the intergroup differences were statistically significant.

This study concluded that for a fair comparison between prostheses, it is necessary to take only the prostheses into account that are inserted properly and that are functioning under normal conditions with regard to transmission of sound vibrations. After analysis of the hearing results of these "successfully" implanted prostheses, a trend was noticed that the heavier gold piston gives more gain in the low- and mid- frequency range and the light-weighted Teflon piston gives more gain in the high- frequency range, although none of the differences were significant.

Introduction

During the evolution of otosclerosis surgery many stapes replacement prostheses have been developed. All these implants differ in size, shape, and weight. Various materials have been used for composing the prostheses. The available prostheses are most commonly composed of three materials: fluoroplastic (Teflon-type polymer), stainless steel, or platinum.[1] Of these materials, Teflon remains the most frequently used material placed into the oval window as a stapes prosthesis. Teflon is well-tolerated in the middle ear because it is not reactive with tissue.

Recently, a new prosthesis composed of gold became available on the market. Gold has the same advantage of being unreactive with tissue. One of the most important differences between Teflon and gold is the specific gravity of the material. The difference in mass of the implants is important because it will affect the transmission of lower and higher frequencies in a different way.

In our clinic, the Teflon piston has been used most frequently. However, since the golden piston became available in 1995, the second author started to use this prosthesis for implantation and the first results with this prosthesis were promising.[2]

The purpose of this study is to analyse retrospectively the audiologic results of the heavier gold piston in comparison with the lighter Teflon piston. For data analysis, most often mean values of several audiologic parameters are taken into account, and we analysed our results in this way as well. However, it is also illustrative to evaluate the hearing results of each individual ear in separate analyses for the ears that received a gold piston or a Teflon piston. Therefore, we used the "Amsterdam Hearing Evaluation Plots" (AHEPs)[3] as a method for a simple visual representation of audiometric results from each individually operated ear. In this method, the relation between the preoperative and postoperative bone conduction (BC) levels is evaluated in the first plot to assess overclosure and iatrogenic cochlear damage, whereas in the second plot the relation between postoperative gain in air-conduction (AC) and the preoperative air-bone gap (ABG) is evaluated as a measure of technical success rate. Presenting results with the AHEPs opens the possibility to interpret and analyse audiometric data in any desirable way.

Subjects and Methods

In the 2-year period from January 1994 to December 1995, a Teflon stapes replacement prosthesis was the first choice to be used in primary stapes surgery. In the next 2-year period from January 1996 to December 1997, a gold stapes replacement prosthesis was the first choice to be used. To prevent selection bias, 14 ears that received a Teflon piston in the second period and 2 ears that received a gold piston in the first period were excluded from analysis. All operations were done by one experienced surgeon (second author) who had performed more than 500 stapes operations before the period enclosed by this study. Therefore, selection bias caused by a learning curve resulting from the surgeon being more experienced during the second set of surgeries, may be expected to play no significant role.

Every ear that underwent revision stapes surgery and received a Teflon piston (n = 10) or gold piston (n = 9) were excluded from analysis. Eventually, the stapes replacement prostheses that were considered for further analysis consisted of the remaining 62 Teflon pistons that were implanted in 60 patients in the period from January 1994 to December 1995 and 66 gold pistons that were implanted in 65 patients in the period from January 1996 to December 1997. One patient received at both sides a gold piston and two patients received a Teflon piston at both sides. Two patients received at one side a Teflon piston and at the other side a gold piston. The patients who received a Teflon piston included 21 men and 39 women with a median age of 40.7 years (range 16-68; SD ± 12.0) at the time of surgery. The patients who received a gold piston included 25 men and 40 women with a median age of 43.9 years (range 21-74; SD ± 10.9) at the time of their operation.

The surgical approach to the middle ear was in all cases transcanal. In all cases the micro-pick technique described by Marquet[4] was used to create a small fenestra in the stapes footplate. The pistons were inserted directly into the opening of the stapes footplate. No soft tissue grafts have been used to cover or fill the oval window for sealing purpose. Oral antibiotic prophylaxis was given during surgery in all cases.
Figure 1 shows the gold and Teflon pistons that have been implanted. Table 1 gives the data concerning several properties of both prostheses. The weight of the pistons was measured with a Mettler Toledo MT5 microbalans (accuracy 1 μgr). The length of both prostheses was depended on the distance between the long process of the incus and stapes footplate.

Table 1. Data of both prosthese.

	Gold piston (n = 66)	Teflon piston (n = 62)
Alternative name	K-piston	Causse piston*
Material	pure gold (99,9%)	fluoroplastic
Shaft diameter (mm)	0.4	0.4
Weight (μg)	10192.0#	3199.0#
Attachment to incus	loop	ring

* Designed for Jean Bernard Causse, MD, Béziers, France.
\# Weight of piston both with a length of 5.0 mm.

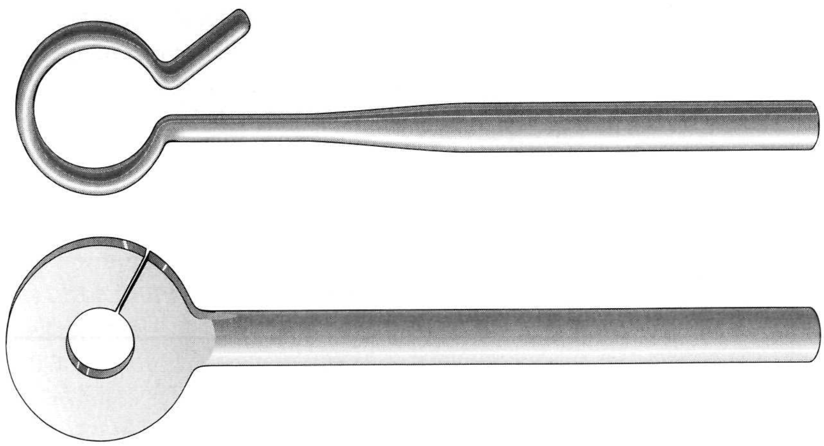

Fig. 1. *The prostheses to be compared in this study. Above the gold K-piston and below the Causse Teflon piston.*

Every patient had audiometric testing of both AC thresholds (0.125-8 kHz) and BC thresholds (0.5-4 kHz) before and after operation. The mean time of audiometric testing after surgery was 1.8 months (range 0.6-3.4; SD ± 0.5) in the gold piston group and 1.7 months (range 0.8-12.0; SD ± 1.4) in the Teflon piston group. All audiograms were performed by

classified personnel according to the ISO-389 (1975) standard. The mean follow-up time after surgery was 16.2 months (range 5-27; SD ± 7.8) in the gold piston group and 22.4 months (range 10-42, SD ± 9.4) in the Teflon piston group.
Different studies[5,6] have shown that the inclusion of 4 kHz in establishing the AC and BC pure-tone average (PTA) influences the success rate for hearing outcome. To allow comparisons with other studies, we present our results by accounting the three frequency PTA (0.5, 1, 2 kHz) and the four frequency PTA (0.5, 1, 2, 4 kHz). To analyse the influence of both prostheses on the BC thresholds, a third PTA combination was computed by using 1, 2 and 4 kHz because the difference in preoperative versus postoperative values of this particular frequency combination has been suggested as a sensitive measure of overclosure or cochlear damage to hearing.[5] For evaluation of effects on ABG, we used the AC and BC of the same test session (i.e. postoperative audiogram) in computing the postoperative ABG as recommended by the AAO-HNS.[5]
All data were entered into a computer database and analysed with a spreadsheet program. Inferential statistics (paired *t*-tests) were used to study hearing changes per group. To test the intergroup differences, a repeated measures analysis of variance was used to test and estimate frequency-specific differences in AC, BC and ABG with respect to changes in preoperative and postoperative hearing. The model assumptions used for statistical analysis were checked by normal probability between and within patient residuals and by comparing frequency-specific standard deviations. P-values for effects with >1 numerator degree of freedom were based on the Huynh-Feldt corrections for nonsphericity. Our criterion for statistical significance was set at p-values ≤ 0.05.

Results

Results are presented with regard to mean postoperative changes in BC, ABG and AC. Furthermore, hearing results of each ear were analysed for the gold piston group and Teflon piston group separately.

Bone-conduction
Preoperatively, there were no clear differences in BC thresholds between both groups. Postoperatively, there was an average improvement in the mean BC levels at every frequency for both prostheses with exception at 0.25 kHz for the Teflon piston. The most obvious improvements in mean BC thresholds were at 2 kHz being 8.4 dB (SD ± 10.1) for the gold piston and 7.4 dB (SD ± 9.1) for the Teflon piston (Table 2).
In the gold piston group, the mean improvements in BC hearing were statistically significant (paired *t*-test) for the individual frequencies in the range from 0.5 to 2 kHz and for all three PTA combinations, whereas the mean improvement in the Teflon piston group was statistically significant (paired *t*-test) for the frequency 2 kHz and for the PTA combinations 0.5, 1, 2 and 1, 2, 4 kHz (Table 2). However, none of the inter-group differences according to the repeated measures analysis of variance were statistically significant for each of the frequencies or frequency combination.

Air-bone gap

The mean postoperative reduction of ABG for each single frequency and for the three frequency PTA (0.5, 1, 2 kHz) and four frequency PTA (0.5, 1, 2, 4 kHz) are presented in Figure 2. Before surgery, the mean ABG for the three frequency PTA was 31.2 dB (SD ± 9.5) in the gold piston group and 29.3 dB (SD ± 11.2) in the Teflon piston group. Postoperatively, these values were 6.8 dB (SD ± 4.7) and 7.6 dB (SD ± 5.9), respectively. Including 4 kHz in computing a four frequency PTA, the mean preoperative ABG was 28.1 dB (SD ± 9.3) in the gold piston group and 26.5 dB (SD ± 10.3) in the Teflon piston group, which reduced postoperatively to 7.7 dB (SD ± 5.1) and 7.1 dB (SD ± 5.6), respectively. After a repeated measures analysis of variance, there was no evidence of a significantly better ABG reduction between both prostheses groups.

Table 2. Postoperative gains averages and standard deviation in bone-conduction thresholds of the gold piston in comparison with the Teflon piston for each individual frequency and three different PTA frequency combinations.

	Gold piston (n = 66)			Teflon piston (n = 62)			Intergroup diff. St. sign
Frequency (kHz)	mean gain (dB)	SD	St. sign.	mean gain (dB)	SD	St. sign.	
0.25	1.4	7.0	NS	-0.4	6.2	NS	NS
0.5	3.4	9.0	$p = 0.023$	1.2	8.1	NS	NS
1	3.8	8.2	$p = 0.020$	2.7	8.2	NS	NS
2	8.4	10.1	$p < 0.001$	7.4	9.1	$p = 0.001$	NS
4	1.9	8.4	NS	1.0	8.7	NS	NS
0.5, 1, 2	5.2	7.1	$p = 0.001$	3.8	6.4	$p = 0.014$	NS
0.5, 1, 2, 4	4.4	6.3	$p = 0.006$	3.1	6.0	NS	NS
1, 2, 4	4.7	6.6	$p = 0.011$	3.7	6.4	$p = 0.046$	NS

St. sign. = statistical significance; NS = not significant; inferential statistics (paired t-test) was used for statistical significance within the gold and Teflon piston group; repeated measured analyses of variance was used for statistical significance for inter- group differences (Intergroup diff.).

Table 3 presents data of postoperative ABG closures for both PTA combinations against the cumulative percentages of subjects in 10 dB increments. Taking ABG closure within 10 dB as a measure of success, the gold piston has a small advantage for the three frequency PTA; the intergroup difference was 4% (Table 3). However, there was practically no difference in ABG closure within 10 dB for the four frequency PTA.

Table 3. Postoperative air-bone gap (ABG) computed with postoperative bone-conduction levels for two different PTA combinations against cumulative percentage of patients in 10 dB increments.

	0.5, 1, 2 kHz (PTA)		0.5, 1, 2, 4 kHz (PTA)	
	Gold (n = 66)	Teflon (n = 62)	Gold (n = 66)	Teflon (n = 62)
ABG	% (n)	% (n)	% (n)	% (n)
≤ 10 dB	86.3 (57)	82.3 (51)	80.3 (53)	79.0 (49)
≤ 20 dB	98.5 (65)	96.8 (60)	95.4 (63)	98.4 (61)
≤ 30 dB	100 (66)	100 (62)	98.5 (65)	100 (62)
≤ 40 dB	100 (66)	100 (62)	100 (66)	100 (62)

Air-conduction

Before operation there were no clear differences in the mean AC thresholds between both groups. Postoperatively, there were statistically significant ($p < 0.001$; paired t-test) improvements of AC thresholds at each frequency for both prostheses except at 8 kHz. The mean preoperative AC hearing loss for the three frequency PTA in the gold piston group was 52.1 dB (SD ± 11.1) and in the Teflon piston group this was 49.0 dB (SD ± 12.6). This improved after the operation to 22.1 dB (SD ± 9.2) in the gold piston group and to 23.5 dB (SD ± 9.4) in the Teflon piston group. The mean preoperative AC levels for the four frequency PTA were 51.9 dB (SD ± 11.9) in the gold piston group and 48.0 dB (SD ± 12.6) in the Teflon piston group. Postoperatively, this improved to 26.1 dB (SD ± 10.6) in the gold piston group and to 25.6 dB (SD ± 10.7) in the Teflon piston group.

After repeated measures analysis of variance the intergroup differences between both prostheses were statistically significant for 2 kHz and for the PTA combination 0.5, 1 and 2 kHz (Table 4).

Analysis hearing results for each individual ear

We used the AHEPs[3] as a method for visual presentation in reporting hearing results from each individually operated ear which received a gold and a Teflon piston. To visualise the effect of surgery on BC, the pre- and postoperative BC thresholds for the PTA combination 1, 2, and 4 kHz are plotted in Figures 2A and 3A for the gold and Teflon piston, respectively. In these graphs the two dotted diagonal lines enclose the area within BC did not change more than 10 dB. Iatrogenic cochlear damage was defined as a postoperative decrease of BC thresholds of more than 10 dB and it is indicated by every point above the upper dotted diagonal line, whereas every point below the lower dotted diagonal line can be considered as an improvement of the BC due to the Carhart effect. In the gold piston group, 21.2 % (14/66) showed 10 dB or more improvement of BC thresholds (Fig. 2A) against 17.7 % (11/62) in the Teflon piston group (Fig. 3A). A deterioration of BC thresholds of more than 10 dB was not found in the Teflon piston group (Fig. 3A), whereas one patient in the gold piston group showed a deterioration of 13 dB (Fig. 2A).

Table 4. Postoperative gains averages and standard deviations in air-conduction thresholds of the gold piston in comparison with the Teflon piston for each individual frequency and two PTA frequency combinations.

	Gold piston (n = 66)			Teflon piston (n = 62)			Intergroup diff.
Frequency (kHz)	mean gain (dB)	SD	St. sign.	mean gain (dB)	SD	St. sign.	St. sign
0.125	33.0	13.8	$p < 0.001$	28.5	16.0	$p < 0.001$	NS
0.25	33.0	13.5	$p < 0.001$	30.5	17.2	$p < 0.001$	NS
0.5	32.9	12.3	$p < 0.001$	28.5	16.4	$p < 0.001$	NS
1	31.5	11.3	$p < 0.001$	27.6	12.7	$p < 0.001$	NS
2	25.5	11.3	$p < 0.001$	20.4	13.3	$p < 0.001$	$p = 0.020$
4	13.3	15.2	$p < 0.001$	13.3	14.6	$p < 0.001$	NS
8	-3.9	16.4	NS	-0.3	17.2	NS	NS
0.5, 1, 2	30.0	10.2	$p < 0.001$	25.5	12.8	$p < 0.001$	$p = 0.034$
0.5, 1, 2, 4	25.8	10.2	$p < 0.001$	22.4	12.4	$p < 0.001$	NS

St. sign. = statistical significance; NS = not significant; inferential statistics (paired *t*-test) was used for statistical significance within the gold and Teflon piston group; repeated measures analyses of variance was used for statistical significance for intergroup differences (Intergroup diff.).

The gain in AC after surgery largely depends on the preoperative gap between AC and BC levels: the greater the ABG the more gain one may expect in AC after a technically successful operation. To show the relation between these two parameters, the AC for the PTA combination 0.5, 1, 2, and 4 kHz is plotted against the preoperative ABG of each operated ear in Figures 2B and 3B for the gold and Teflon piston, respectively. In these graphs the solid diagonal line indicates total closure of the gap between preoperative AC and BC. Consequently, every point below the solid diagonal line indicates a gain in AC that is larger than one may expect from preoperative ABG and such a result can be regarded as overclosure. The number of overclosures can be seen easily from the plots being 25 (37.9%) in the gold piston group (Fig. 2B) and 16 (25.8%) in the Teflon piston group (Fig. 3B). All ears that were considered as a technically "successful" operation (i.e., all points below the dotted diagonal line) had ABG closure to 20 dB or less between postoperative AC and preoperative BC levels but also between postoperative AC and postoperative BC thresholds. We defined an "unsuccessful" operation result as a negative change in AC threshold or a change in AC that was not enough to close the gap between postoperative AC and preoperative BC to 20 dB or less. Every point above the dotted diagonal line in Figures 2B and 3B indicate such an "unsuccessful result" (marked by ▲-symbol and Arabic numeral). There was one "unsuccessful" operation result in the gold piston group (Fig. 2B) against four in the Teflon piston group (Fig. 3B).

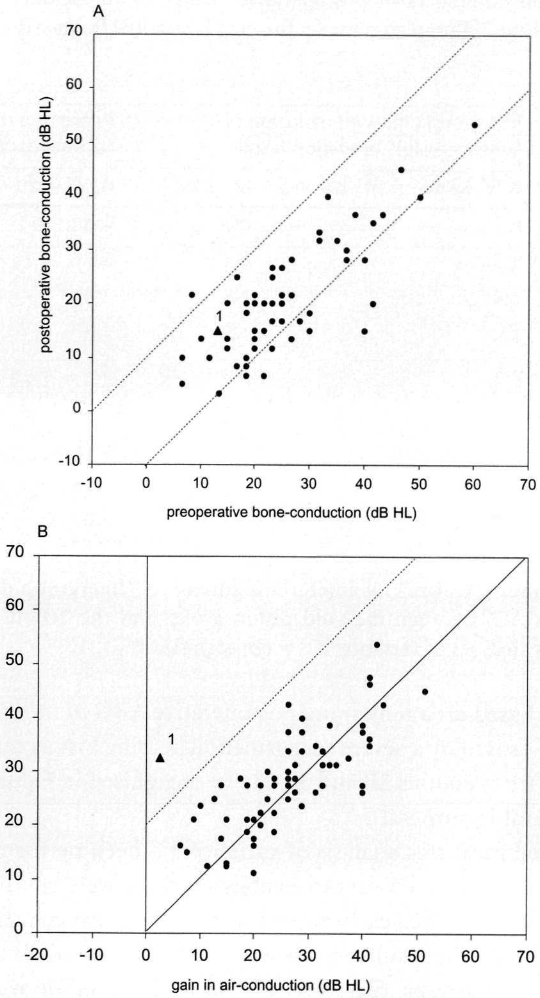

Fig. 2. *Audiometric results after implantation of 66 gold pistons visualized with the "Amsterdam Hearing Evaluation Plots" (AHEPs). A: Preoperative bone-conduction and postoperative bone-conduction plotted for individual ears. Pure-tone average (PTA) was calculated for the high frequency combination at 1, 2, and 4 kHz. The two diagonal lines enclose the area within the bone-conduction did not change over more than 10 dB. B: Postoperative gain in air-conduction plotted against preoperative air-bone gap for individual ears. PTA was calculated for the frequency combination at 0.5, 1, 2, and 4 kHz. The solid diagonal line indicates total closure of the gap between preoperative air-conduction and bone-conduction. Every point below this line is defined as overclosure. An unsuccessful operation result with regard to air-conduction (marked by ▲-symbol) is defined as a negative change in air-conduction (indicated by the dotted vertical line at 0 dB gain in air-conduction) or a change in air-conduction that was not enough to close the gap between postoperative air-conduction and preoperative bone-conduction to 20 dB or less (indicated by the dotted diagonal line). Each unsuccessful operation result from Figure 2B is also marked by a ▲-symbol in Figure 2A, and each failure-case can be identified by the same Arabic numeral. Some points in the graph may coincide when they have the same audiometric values.*

Table 5. Inter-group differences of postoperative change in air-conduction between the gold piston group and the Teflon piston group for each individual frequency and two frequency combinations.

	Intergroup diff. with inclusion of "unsuccessful" operation results		Intergroup diff. with exclusion of "unsuccessful" operation results	
Frequency (kHz)	Δ AC Gold - Δ AC Teflon	St. sign.	Δ AC Gold - Δ AC Teflon	St. sign.
0.125	4.5	NS	2.8	NS
0.25	2.5	NS	2.3	NS
0.5	4.4	NS	2.5	NS
1	3.9	NS	2.8	NS
2	5.1	$p = 0.020$	4.1	NS
4	0	NS	-1.2	NS
8	-3.6	NS	-5.4	NS
0.5, 1, 2	4.5	$p = 0.034$	3.1	NS
0.5, 1, 2, 4	3.4	NS	2.0	NS

Statistical significance (St. sign.) for intergroup differences (Intergroup diff.) of postoperative gain in air-conduction (Δ AC) between the gold piston group and the Teflon piston group was based on repeated measures analyses of variance; NS = not-significant.

All failures were based on a remaining postoperative ABG of more than 20 dB while none of the failures were caused by a severe sensorineural hearing loss as can be seen from Figures 2A and 3A (failures from Figures 2B and 3B can be recognised in Figures 2A and 3A by the same ▲-symbol and Arabic numeral).

A second repeated measures analysis of variance has been performed on the hearing results of the "successfully" operated ears to establish if there were significant differences between both prostheses groups after exclusion of technically "unsuccessful" results identified with the AHEPs. Analysing the results in this way did not substantially affect improvement in BC nor in ABG for both groups; there was still no evidence of an overall intergroup difference for both audiological parameters. However, such an analysis had consequences on the gain in AC as shown in Table 5.

In the frequency range 0.125 to 2 kHz the gold piston gives better hearing improvement and for the frequencies 4 and 8 kHz the Teflon piston shows an advantage. However, the differences are small and none of the intergroup differences were statistically significant for all individual frequencies nor for both frequency combinations.

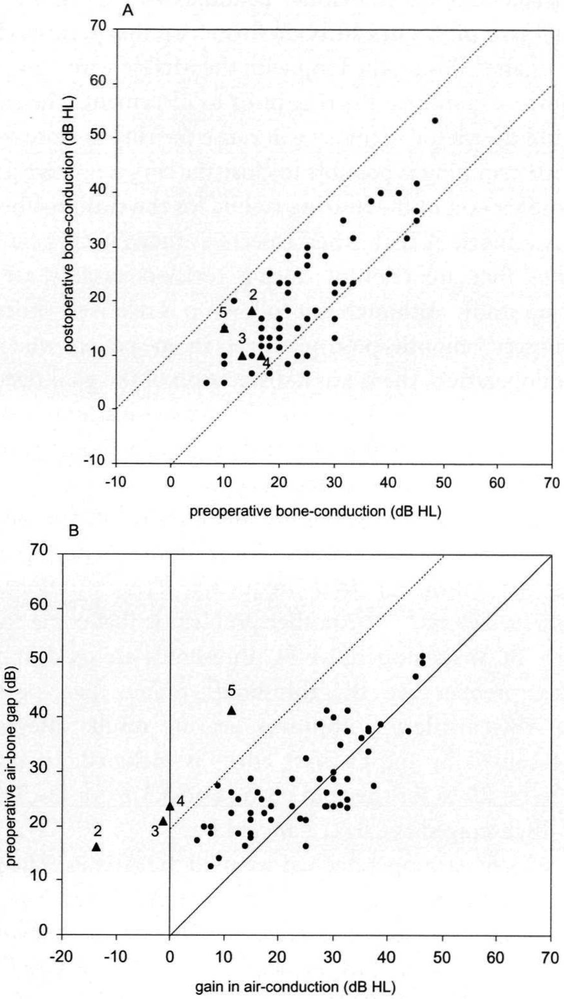

Fig. 3. *AHEPs as in Figure 2, but for 62 Teflon pistons.*

DISCUSSION

Since Shea[7] demonstrated in 1956 that removing the stapes, opening the inner ear, and replacing the stapes with a prosthesis could be performed safely and with immediate improvement of hearing, the search for the ideal stapes replacement prosthesis began. The ideal prosthesis has to meet several requirements. It must be biocompatible, it must be easy to manipulate, and it must fit securely on the incus to transmit the vibrations towards the oval window. Teflon and gold have the qualities of being nonreactive with host tissue, but they differ in weight. Gold has the advantage of being soft and malleable and thus the

prosthesis can easily be shaped to the individual conditions in the middle ear. For the attachment to the incus, the gold piston has a ribbon form loop that permits close contact to the long process of the incus after closing the loop with the McGee wire crimper. The Teflon piston has a loop that requires expanding the ring prior to placement. The ring will remain open for several minutes and the plastic memory will cause the ring to close securely around the incus. If necessary, gentle crimping is possible to close the ring more tightly.
Our study focused on a comparison of the hearing results for the two prostheses in a short-term follow-up study. It is important that other aspects as incus necrosis and other prosthesis-related complications that are relevant during revision surgery are examined in another long-term follow-up study. Although our follow-up is relatively short, it was necessary to perform revision surgery 7 months postoperatively in one patient who received a gold piston. During the revision operation, there was a dislocation of the gold piston that apparently was bent because of many adhesions in an ear with active otosclerosis. A Teflon piston could be placed with success. In the patient group that received a Teflon piston, we did not perform revision surgery within the follow-up interval covered by this study.
Comparison of stapes replacement prostheses in the literature is difficult because different audiological criteria are used to establish success. Some studies report preoperative and postoperative AC results with three or four frequency PTAs.[8,9] Other studies used postoperative ABG to evaluate success.[10-12] Another problem is that some studies[12] do not mention if the preoperative BC or postoperative BC thresholds are used in composing the postoperative ABG. Using preoperative BC thresholds rather than postoperative BC thresholds in computing ABG artificially improves hearing results after stapes surgery because ABG overclosure caused by the Carhart effect is included. In our results, this improvement turned out to be 4.5 % for the gold piston and 3.3 % for the Teflon piston for the closure rate within 10 dB, averaged at 0.5, 1, 2 and 4 kHz.
To evaluate the hearing results in each operated ear we used the AHEPs. The plots show the individual results and visualise the amount of overclosures (Figs. 2B and 3B), which is especially of interest in reporting results of stapes surgery. In addition, the unfavourable hearing results can be recognised easily with regard to cochlear damage (Figs. 2A and 3A) and residual conductive hearing loss (Figs. 2B and 3B).
In comparing audiometric results after implanting different prostheses and especially in examining the effects of differences in weight, it is important to take only the prostheses into account that are functioning normally with regard to sound transmission function. Not excluding "unsuccessfully" performed operations (i.e., all points above the dotted diagonal line in Figures 2B and 3B) could easily lead to misleading results as these pistons do not transmit sound vibrations under normal conditions. In these cases the pistons were incorrectly inserted, became dislocated some time after surgery, or there were other reasons resulting in a remaining conductive hearing loss. The reason why a substantial ABG still exists postoperatively can only be detected by performing revision surgery. Although definitions of good, moderate or unsuccessful results are arbitrary issues, we choose to define an "unsuccessful" result as a negative change in AC threshold or a remaining gap of more than 20 dB between postoperative AC and preoperative BC levels.

In our opinion, analysing audiometric data with the AHEPs forms a valuable complementary method to determine technical success after surgery and offers the possibility to compare the spread in individual results for different populations. However, the AHEPs do not give an impression of the benefit a patient derives from surgery as patient's disability is also determined by the hearing thresholds of the nonoperated ear. More disability-oriented methods of data analysis are described by Browning et al.[13] and de Bruijn et al..[14]

Which influence upon hearing can be expected from the differences in weight between both prostheses? From a theoretical point of view one may expect a difference in hearing improvement on the basis of the "Impedance Formula" as already described by Johansen[15] in 1948. The impedance is defined by the following equation:

$$I = \sqrt{[r^2 + (m \cdot f - {}^{s}/_{f})^2]}$$

where r, s and m indicate friction, stiffness and mass, respectively. If it is taken for granted that the sound conduction system of an ear may be equalised to a simple vibrating system, the proportion between force and rate can be expressed by an impedance or resistance. The higher the impedance, the more difficult it will be for the vibrations striking the tympanic membrane to be transmitted to the sensory epithelium, and this means a decrease in hearing. From the "Impedance Formula" it can be converted that increased mass of the vibrating system will increase the impedance for higher frequencies. The converse effect will happen for the lower frequencies. Thus, from a theoretical point of view one may expect that the lighter Teflon piston will give more hearing gain in the higher frequencies and the heavier gold piston will give more gain in the lower frequencies, although some precautions have to be made with this theoretical approach because it was assumed that difference in stiffness and friction would not be influential factors. The approach, however, is in agreement with our findings after performing a second analysis on hearing results in which we took only the pistons into account that were implanted "successfully" according to the AHEPs. Although differences were small and not statistically significant, it appeared that the heavier gold piston showed a larger gain in hearing for the lower and mid frequencies, while the lighter Teflon piston showed an advantage in the higher frequencies (Table 5).

Some experiments have been done on the effects of mass on middle ear function. Brenkman et al.[16] found in human temporal bones that loading the stapes with a magnet with a weight of 3.66 mg affected stapes amplitude measured with a SQUID magnetometer method. A higher amplitude was reached in the lower frequencies and a lower amplitude in the higher frequencies. The crossover frequency was between 3 and 4 kHz. However, this effect was only evident if the mass was large enough; loading the stapes with magnets with a lower mass (1.05, 1.5, 2.16 mg) did not have a substantial effect on stapes amplitude. These results from experimental studies are to a certain extent in agreement with our findings. The gold piston is approximately three times heavier than the Teflon piston, whereas the weight of the Teflon piston is about the same as the weight of an average human stapes (3.02 mg)[17] Thus, one may expect that the mass added on the vibrating system of the middle ear after insertion of a gold piston is enough to have an effect on amplitude. The increased mass will give a higher amplitude in the low frequencies and a lower amplitude in the high frequencies.

Consequently, one may expect that increased mass will give more gain in hearing for the lower frequencies and less gain in hearing for the higher frequencies with the crossover frequency between 3 and 4 kHz as is the case in our results.
Loading experiments in animals were done by Cottle and Tonndorf.[18] They put drops of mercury on the stapes footplate of cats and measured the cochlear microphonics. It was found that if 1.14 mg of mercury was loaded on the stapes footplate, the cochlear microphonic response increased with about 3 to 4 dB at 1 kHz, but a loss occurred at the higher frequencies. In this case the stapes mass in the cat (normal weight 0.58 mg) was increased with a factor of approximately three.
Robinson[12] performed a clinical comparative study between two prostheses with a difference in weight. He compared the hearing results obtained after stapedectomy by implantation of the Robinson stainless steel prosthesis (weight 12.5 mg) and the Robinson Teflon prosthesis (weight 3.3 mg). Better hearing results were obtained with the heavier stainless steel prosthesis in the low frequency ranges and in the high frequency ranges. Furthermore, he found that the rate of overclosures was much higher with the heavier stainless steel prosthesis. In our results there was also a higher overclosure rate with the heavier gold piston (37.3 %) in comparison with the lighter Teflon piston (25.8%). However, if the criterion ABG closure to within 10 dB is taken as a measure of success, the success rates do not differ much between both prostheses and are in agreement with other studies dealing with hearing results after implantation of stapes replacement prostheses.[10,19,20]
Although changing the weight of the prosthesis in stapes surgery may have only a relatively small effect on the final hearing result, this effect may be significant if it contributes to approximately 5 dB more gain over other prostheses. It can be an influential factor in detrmining the type of prosthesis to be used in patients with mixed hearing losses because such a gain can be critical in changing the result from a non-serviceable hearing level to a serviceable hearing level. In our results, the mean hearing gain in the speech frequencies at 0.5, 1 and 2 kHz (PTA) differs 4.5 dB in favour of the gold piston and was statistically significant in the whole group of "successfully and "unsuccessfully" implanted prostheses after repeated measured analysis of variance. However, analysing the results after exclusion of "unsuccessful" operations identified with the AHEPs, the intergroup difference was 3.1 dB and not statistically significant (Table 5).
In this study we were mainly interested in the differences of the hearing results after operation. Although the overall hearing results were in favour of the gold piston, it must be stated that our follow-up is relatively short; therefore, it is necessary to perform a reevaluation in the future to establish the differences in long-term hearing.

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Chapter 6

Effects of Stapes Surgery on Speech Reception.

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Submitted

Abstract

A retrospective, nonrandomized review of 363 cases undergoing primary stapes surgery for otosclerosis was undertaken to evaluate the effects of surgery on several parameters obtained by pre- and postoperative speech audiometry in quiet. Therefore, the change in speech reception thresholds (SRT), the maximum speech discrimination score (MSDS), the slope of the speech reception curve (SRC), and the occurrence of a slope decay of the SRC were analysed. Several data from speech audiometry were related to pure-tone audiometric data in order to examine whether postoperative loss in speech discrimination can be predicted from the shapes of pure-tone curves.

It appeared that stapes surgery had neither significant effect on the slope of the SRC, nor on the slope decay. Phonemic regression (slope decay > 0.5 %/dB) was not found before surgery, but occurred in 15 cases after surgery. In 96 % of the cases the SRT improved and correlation analysis showed that the change in SRT correlates well with the change in AC levels for the pure-tone average at 0.5, 1, 2, and 4 kHz.

A postoperative loss in MSDS ≥ 10 % occurred in 8 cases, while 13 cases showed an improvement ≥ 10 % in MSDS. Factors involved with an increase or a decrease in MSDS were elaborated. On the basis of the results it was concluded that loss in speech discrimination can not be predicted from the shape of the curves from preoperative pure-tone audiometry as either a Carhart effect or cochlear damage can occur. Cochlear damage resulting in sensorineural hearing loss is often associated with a reduction in speech discrimination. When the preoperative pure-tone hearing loss is severe and there is a preoperative loss in discrimination, there is a chance that speech discrimination improves in those cases having a successful closure of the air-bone gap and an obvious increase in bone conductive hearing due to the Carhart effect.

Introduction

Since the introduction of the stapedectomy technique for restoring impaired middle ear transmission function due to otosclerosis, many reports are published dealing with the benefits of this type of surgery. Most reports are establishing postoperative hearing results by making use of parameters retrieved from pure tone audiometry. However, the most important purpose of stapes surgery is to improve speech reception. In this respect, it is especially important to be informed about the effect of stapes surgery on speech discrimination. A good technical result (gap-closure ≤ 10) is only relative when at the same time a deterioration in speech discrimination occurs after surgery. A few articles have reported such reductions of speech discrimination which were found after successful closure of the air-bone gap (ABG).[1,2,3] Nevertheless, on the whole only sporadically postoperative outcome is described in terms of speech audiometric parameters.[4]

One of the mechanisms of a decrease in speech discrimination after successful stapes surgery is a masking effect of high frequency features of speech by the low frequency components. This phenomenon has been studied by Huizing[5], who related loss in speech discrimination to an increase in the steepness of the air-conduction (AC) threshold after stapes surgery. Such a decline of the AC curve can occur postoperatively in those patients showing a mixed type of hearing loss which is not an infrequent occurrence in otosclerosis, and, due to physiological ageing on cochlear function, it is often seen in middle aged and elderly patients. The hearing loss in these patients is usually made up of a high tone sensorineural hearing loss (SNHL) and a conductive loss that mainly concerns the lower and middle frequencies. Successful stapes surgery in these situations leads to a low and middle-frequency hearing gain. As a consequence the original horizontal or slightly declining AC threshold is transformed into a more or less steeply declining curve. The decline of the curve can be even more obvious when at the same time SNHL occurs in the higher frequencies due to cochlear damage, which is a well known risk factor of stapes surgery. Huizing[5] observed a loss in speech discrimination when the postoperative pure tone audiogram showed a decline of the AC curve within defined criteria.

Another factor which has an effect on postoperative speech discrimination is that in the surgical treatment of otosclerosis often the stapedius tendon is sectioned and not reconstructed. This consequently results in a loss of the attenuation of middle-ear sound transmission at higher intensities by stapedius muscle contraction. This attenuation of sound transmission is termed stapedial reflex, or acoustic reflex, and is thought to be protective to the cochlea when loud sounds are presented.[6] Furthermore, the stapedial reflex plays an important role in improving the intelligibility of speech at higher sound intensities.[7,8] An intact stapedial reflex attenuates sound energy in the low frequency portion of the speech spectrum. It therefore reduces the undesirable upward spread of masking of low frequency sounds and preserves the transmission of information for higher frequencies. In this respect, we may expect in our patients an effect after stapes surgery on speech discrimination with increasing sound intensities as the standard surgical technique in our hospital is to sacrifice the stapedius tendon without reconstruction. This negative effect of sectioning the stapedius tendon on speech discrimination is found by several authors.[9,10]

The purpose of this study is to evaluate the effects of stapes surgery on several parameters obtained by speech audiometry with special reference to the following questions: (1) Which factors are involved when either a substantial deterioration or improvement in speech discrimination occurs after stapes surgery? (2) Is it possible to identify patients before surgery who are at risk for loss in speech discrimination after surgery?

Patients and Methods

Data were retrieved from every consecutive patient who underwent primary stapes surgery for otosclerosis during an eleven years period from January 1987 to December 1997. During this period 386 primary stapes operations were performed by the second author. Pre- and postoperative speech audiometry was available in 363 cases (94.0 %) These cases were considered for further analysis and concerned 323 patients; 40 patients had surgery at both sides. The patient group consisted of 230 women and 93 men with a mean age of 40.7 years (range 12 - 74, SD ± 11.2) at the time of their operation in our hospital. The distribution between

left and right ears was approximately even.
In the majority of patients a small fenestra stapedotomy was performed (98.9 %) and in only a few cases a stapedectomy technique was used (1.1 %). A variety of stapes replacement prostheses was implanted. The most frequently used prostheses were the Causse® Teflon piston (64 %), the gold K®-piston (26 %) and the Cawthorne® Teflon piston (9 %). Several other prostheses were used in a minority of the patients.
In our clinic the AC thresholds are routinely measured at the octave intervals from 0.125 to 8 kHz and the BC thresholds at the octave intervals from 0.25 to 4 kHz with adequate masking. For each subject complete speech audiometry was carried out at different levels, using lists of phonetically-balanced CVC-words.[11] All audiograms were performed by classified personnel according to the ISO-389 (1975) standard. The mean time of audiometric testing after surgery was 2.1 months (range 0.6-12.1; SD ± 2.4). Ninety-four percent of the subjects had postoperative audiometric testing within 3 months.
All data were entered into a computer database and analysed with a spreadsheet program. In analysing our data from pure tone audiometry, the pure tone average (PTA) at 0.5, 1, 2, and 4 kHz were taken for AC and BC levels. As a measure of overclosure or SNHL due to cochlear damage the change in BC was used for the PTA at 1, 2, and 4 kHz. ABG closure data are reported using postoperative ABG computed with AC and BC from the same postoperative audiogram.
Data retrieved from speech audiometry were analysed with Matlab®. In all patients the pre- and postoperative speech reception threshold (SRT) could be derived as well as the maximum speech discrimination score (MSDS). Furthermore, the pre- and postoperative maximum slope and slope decay of the speech reception curve (SRC) were analysed, both expressed in %/dB. The maximum slope is the maximum steepness of the curve in its ascending part. The slope decay is the average steepness of the curve in its descending part after it has reached maximum speech discrimination (Fig. 1). Phonemic regression is defined as a slope decay > 0.5 %/dB.
For statistical analysis nonparametric tests were used for independent variables (Graphpad Prism®). The Wilcoxon signed rank test was performed for paired data, whereas the Mann-Whitney test was used for unpaired data. Correlation analysis was done with the Spearman test. Our criterion for statistical significance was set at p-values < 0.05 (two-tailed).

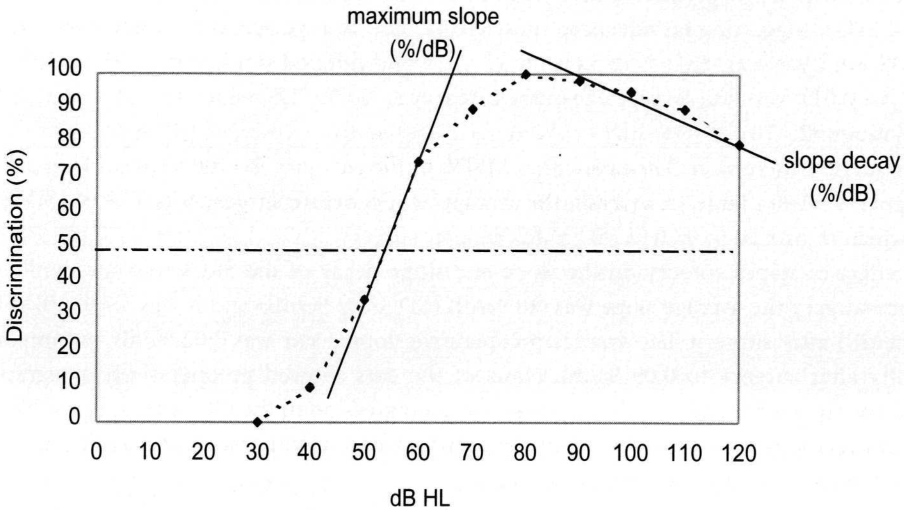

Fig. 1. *Analysis of maximum slope and slope decay of a speech reception curve (SRC). The maximum slope represents the maximum steepness of the SRC in its ascending part and is expressed in %/dB. The slope decay is the average steepness of the SRC in its descending part after it has obtained its maximum speech discrimination score, and is also expressed in %/dB.*

RESULTS

Overall effects of stapes surgery upon speech reception

In the whole group of patients the average SRT before surgery was 68.8 dB (SD ± 13.1 dB) which improved to 48.8 (SD ± 12.3 dB) after surgery. Ninety-six percent of the ears showed an improvement in SRT. Figure 2 shows the change in SRT as a function of the change in AC for the PTA at 0.5, 1, 2, and 4 kHz. The change in SRT correlates well with the change in AC for this frequency combination (Spearman r = 0.89, $p < 0.0001$).

Table 1 presents the number of ears with MSDS within certain categories before and after surgery. Before operation there were 342 ears within the category 91-100 %, while 21 ears had a score of ≤ 90 %. Analysis of the slopes of the preoperative AC for these 21 ears revealed that only 3 cases showed a rather steep pure-tone audiogram: two ears with an average audiometric slope ≥ 20 dB/octave in the frequency range 0.5 - 8 kHz with a cut-off frequency of 1 kHz and one ear with an average slope decay ≥ 10 dB/octave in the frequency range 0.5 - 8 kHz with a cut-off frequency of 0.5 kHz. The average preoperative AC threshold (PTA at 0.5, 1, 2, and 4 kHz) in the group of ears with a preoperative MSDS ≤ 90 % differed highly significant from the group of ears with MSDS > 90 % (Mann Whitney test, $p < 0.0001$): in the category ≤ 90 % MSDS the mean preoperative AC value was 71.3 dB (SD ± 15.5 dB) and in the category 91-100 % MSDS it was 48.2 dB (SD ± 12.0 dB). Furthermore, also the difference in average BC values was highly significant (Mann Whitney test, $p < 0.001$) between these two categories with values of 34.1 dB (SD ± 10.1) and 21.1 dB (SD ± 8.7 dB), respectively. The three ears with a preoperative MSDS ≤ 80 % had AC values exceeding 90 dB (PTA at 0.5, 1, 2, and 4 kHz), suggesting far advanced otosclerosis. The average age in the category 91-100 % MSDS was 39.6 years (SD ± 10.5, range 12 - 67) and differed significantly (Mann Whitney test, $p < 0.01$) from the average age in the category ≤ 90 % SDS, which was 54.1 years (SD ± 12.8, range 32 - 70).

After surgery there were 349 ears with a MSDS in the category 91-100 % and 14 ears in the category ≤ 90 % (Table 1). Overall, the average MSDS before surgery was 97.9 % (SD ± 4.5 %) which improved to 98.6 % (SD ± 4.2 %) after surgery.

The effect of stapes surgery on the slope and slope decay of the SRCs was not significant. Before surgery the average slope was 6.0 %/dB (SD ± 1.5 %/dB) and it was 5.7 %/dB (SD ± 1.6 %/dB) after surgery. The average preoperative slope decay was 0.02 %/dB and impaired slightly after surgery to 0.09 %/dB. None of the ears showed preoperatively a regression (slope decay > 0.5 %/dB), while 15 ears showed a regression of the SRC after surgery. No significant relations were found between the occurrence of postoperative phonemic regression and either postoperative change in BC or age.

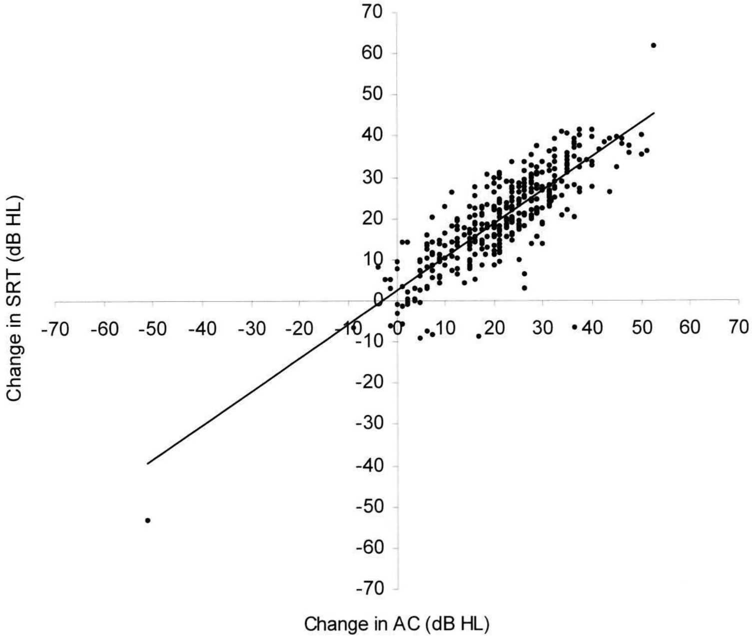

Fig. 2. *Change in speech reception threshold (SRT) as a function of the change in air-conduction (AC) for the pure-tone average (PTA) at 0.5, 1, 2, and 4 kHz. The change in SRT correlates well with the change in AC for this frequency combination (Spearman r = 0.89, p < 0.0001) as is also shown by the regression line.*

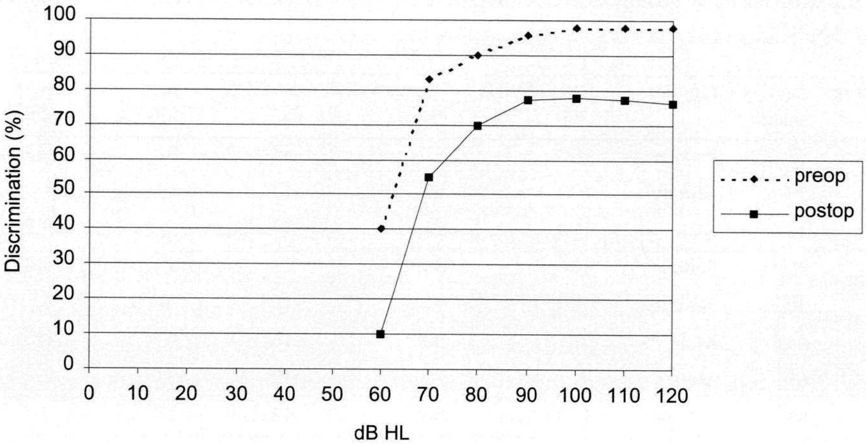

Fig. 3. *Preoperative (preop) and postoperative (postop) median speech reception curve for the 8 ears with a decrease ≥ 10 % in maximum speech discrimination score.*

Table 1. Number of ears categorised by maximum speech discrimination scores (MSDS) before and after surgery.

Preoperative MSDS (%)		Postoperative MSDS (%)			
	N	91-100	81-90	71-80	≤ 70
91-100	342	332	6	2	2
81-90	18	15	2	1	-
71-80	1	1	-	-	-
≤ 70	2	1	1	-	-

Factors involved when loss in discrimination occurred

Because we were interested in identifying the patients who had postoperatively a MSDS that was markedly lower compared to the preoperative percentage, we analysed the findings for the 8 patients who had a reduction ≥ 10 % in MSDS after surgery. Table 2 shows the age, gender, the pre-and postoperative MSDS, and the postoperative change in MSDS, AC and BC for these 8 patients. The mean age in this group of patients was 48.9 years and differs not significantly from the rest of the population. The average loss in MSDS for this group of patients was 20.1 % (SD ± 12.2 %). Figure 3 shows the median pre- and postoperative SRC for this group of patients. For each of the 8 ears, there were no significant changes in the pre- and postoperative maximum slope of the SRCs and phonemic regression did not occur.
It was found that before surgery a great variety existed in the AC and BC values (PTA at 0.5, 1, 2, and 4 kHz) in this group of patients. However, statistical analysis revealed that the average preoperative AC and BC levels (PTA at 0.5, 1, 2, and 4 kHz) in this group of patients do not significantly differ from the average levels in the rest of the population. The values were 52.6 dB (SD ± 20.2 dB) and 24.1 dB (SD ± 14.0 dB), respectively.

Table 2. Patients with a postoperative reduction ≥ 10 % in maximum speech discrimination score (MSDS).

Patient nr.	Age (years)	Gender	Preop MSDS (%)	Postop MSDS (%)	Δ MSDS (%)	Δ AC (dB HL)	Δ BC (dB HL)
1	57	Female	100	67	-33	5	-23
2	59	Female	100	88	-12	14	3
3	36	Male	100	53	-47	-51	-42
4	38	Female	100	83	-17	3	-27
5	30	Female	100	90	-10	-4	3
6	44	Male	96	80	-16	6	-15
7	65	Male	91	79	-12	31	2
8	62	Female	100	86	-14	23	3

Δ MSDS = postoperative change in maximum speech discrimination score.
Δ AC = postoperative change in air-conduction calculated for the PTA at 0.5, 1, 2, and 4 kHz.
Δ BC = postoperative change in bone-conduction calculated for the PTA at 1, 2, and 4 kHz.

In three ears a good improvement in AC was achieved (patient 2, 7, and 8; Table 2). The preoperative BC curves in these ears were steep with a slope decay ≥ 15 dB/octave in the frequency range 0.5 - 4 kHz (Fig. 4. B). Because of the good technical result with gap closure ≤ 10 dB, the AC thresholds in these ears turned into rather steep curves (Fig. 4. A). Patient 7 and 8 had an average slope decay ≥ 10 dB/octave in the frequency range 0.5 - 8 kHz, while patient 2 had an average slope decay ≥ 20 dB/octave in the frequency range 1 - 8 kHz. In these three ears the possible explanation of a reduction in MSDS could be in fact a masking effect of the higher frequency elements of speech by low frequency elements, due to the increased steepness of the AC curves as mentioned in the Introduction.
In 4 ears (patient 1, 3, 4, and 6; Table 2) SNHL occurred with a decrease in BC level > 10 dB in the high-frequency PTA at 1, 2, and 4 kHz. The preoperative AC curves in these ears showed a flat configuration which did not change after surgery (average slope decay < 10 dB/octave in the frequency range 0.5 - 8 kHz). In none of these cases closure of the ABG ≤ 10 dB was achieved and the operations performed in these cases can be considered as technical failures without repair of transmission function but with the occurrence of cochlear damage.
In one ear (patient 5; Table 2) it was not succeeded to restore transmission function, while no substantial change in the postoperative BC threshold was observed. However, MSDS showed a reduction of 10 % after surgery for which we have no explanation. Test error could be a possibility.

Factors involved when gain in discrimination occurred

There were 13 ears (3.6 %) with an increase ≥ 10 % in MSDS after surgery. For each of these patients the age, gender, pre-and postoperative MSDS, as well as the change in MSDS, AC, and BC are shown in Table 3. The average age in this group of patients was 52.2 years and was significantly higher compared to the population who showed no change in MSDS ≥ 10 %

(Mann Whitney test, $p < 0.01$). A Carhart effect, defined as an improvement in BC > 10 dB for the PTA at 1, 2, and 4 kHz, was noticed in 7 ears (Table 3). Figure 5 shows the median pre- and postoperative SRC for this group of patients. The mean improvement in MSDS for this group of patients was 14.5 % (SD ± 4.0 %). For each of the 13 ears, there were no significant changes in the pre- and postoperative maximum slope of the SRCs and phonemic regression did not occur.

Before surgery the average preoperative AC and BC thresholds (PTA at 0.5, 1, 2, and 4 kHz) in this group were 73.4 dB (SD ± 18.3) and 34.9 dB (SD ± 12.4), respectively. These values are significantly worse than the average preoperative AC and BC thresholds in the rest of the population (Mann Whitney test, $p < 0.0001$ for AC; $p < 0.01$ for BC). Only one ear had an AC threshold that was above the average threshold of the total population.

In the group of 13 ears with improvement in MSDS ≥ 10 % both the AC and BC levels (PTA 0.5, 1, 2, and 4 kHz) improved significantly (Wilcoxon test, $p < 0.0001$ for AC, $p < 0.001$ for BC) after surgery with values of 36.8 dB (SD ± 7.5) and 8.3 dB (SD ± 6.2), respectively. These values are also significantly larger compared to the average gain in AC and BC for the rest of the population (Mann Whitney test, $p < 0.0001$ for AC, $p < 0.01$ for BC).

Analysis of the steepness of the pre- and postoperative BC and AC curves showed that before surgery 2 ears (patient 5 and 9; Table 3) had a steep BC curve with an average audiometric slope ≥ 15 dB/octave in the frequency range 0.5 - 4 kHz. After surgery, both ears showed an improvement in BC for the PTA at 1, 2, and 4 kHz and the BC curves turned into rather flat curves with average audiometric slopes not exceeding 10 dB/octave. In the whole group of 13 ears none of the cases had an AC curve with an average slope decay ≥ 15 dB/octave in the frequency range 0.5 - 8 kHz before and after surgery.

Discussion

The aim of this study is to evaluate the effect of stapes surgery on several parameters derived from speech audiometry in quiet. Therefore, the change in SRT, the slope of the SRC, the MSDS and the presence of regression were analysed. We were especially interested in factors related with the occurrence of a deterioration or improvement in speech discrimination after surgery.

The occurrence of a substantial decrease in speech discrimination after surgery is a serious matter. Several factors can be related to a decrease in postoperative MSDS. One of the factors is that after successful stapes surgery the steepness of the AC curve increases when preoperatively there exists a rather steep BC curve. This leads to a masking effect of the low frequency on the high frequency components of speech as already mentioned in the Introduction. The amount of acoustic energy contained in the frequencies below 1 kHz is much greater than the energy contained in the frequencies above 1kHz for a speech signal at a given decibel level. However, more of the key-information necessary for the understanding of speech is contained in the frequencies above 1 kHz.[12]

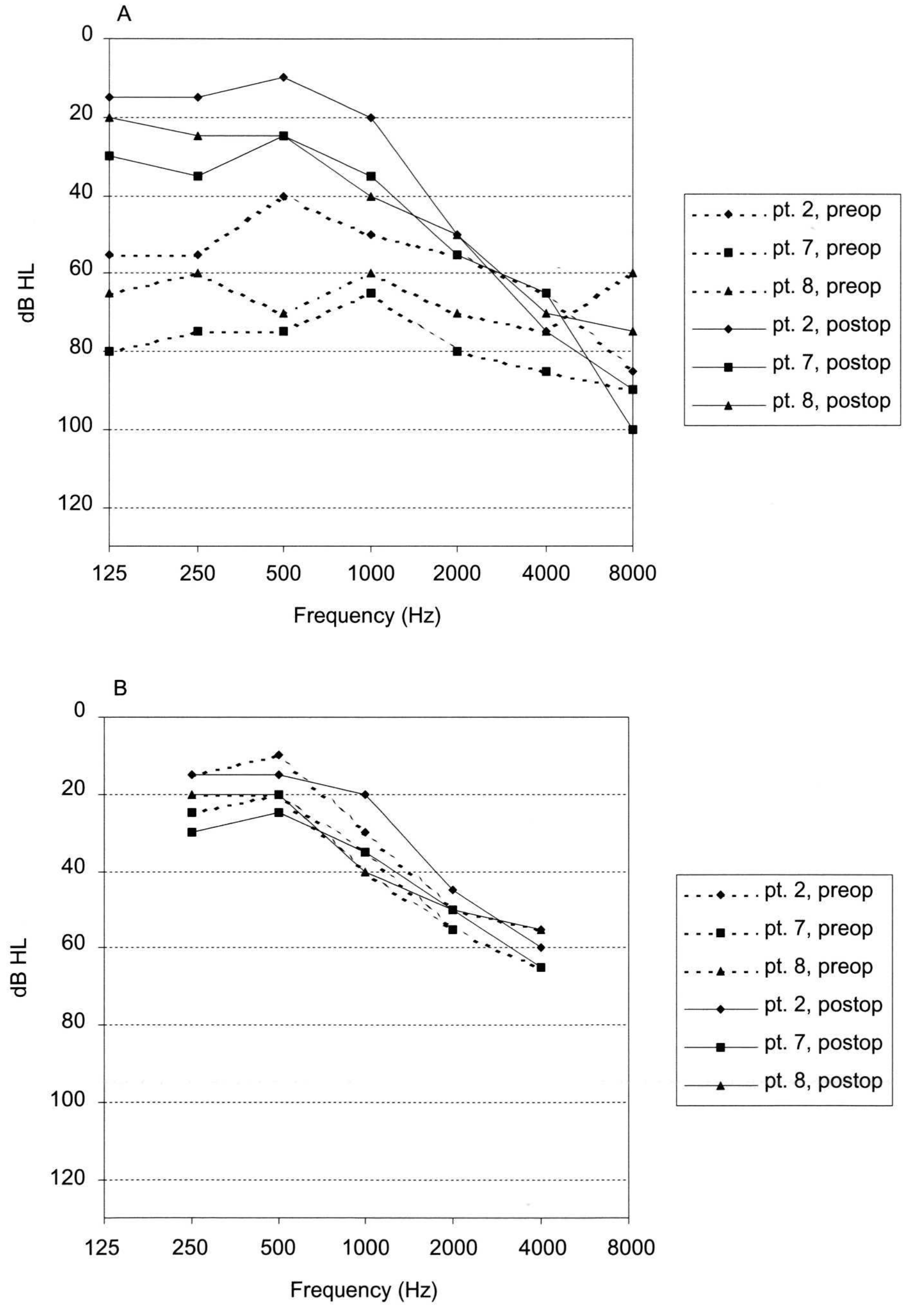

Fig. 4. *Preoperative (Preop) and postoperative (Postop) pure tone air-conduction thresholds (**A**) and bone-conduction thresholds (**B**) for 3 ears with postoperatively a good improvement in air-conductive hearing but with a postoperative reduction ≥ 10 % in speech discrimination score (SDS).*

Table 3. Patients with a postoperative improvement ≥ 10 % in maximum speech discrimination score (MSDS).

Patient nr.	Age (years)	Gender	Preop MSDS (%)	Postop MSDS (%)	Δ MSDS (%)	Δ AC (dB HL)	Δ BC (dB HL)
1	49	Male	70	95	25	24	5
2	32	Male	83	100	17	35	12
3	70	Female	70	82	12	26	-3
4	57	Female	83	100	17	51	7
5	56	Female	88	100	12	33	12
6	59	Female	82	100	18	33	11
7	50	Female	90	100	10	46	-3
8	35	Male	88	100	12	40	15
9	68	Female	82	94	12	35	15
10	57	Female	83	100	17	44	15
11	37	Female	88	100	12	31	13
12	69	Male	90	100	10	38	7
13	40	Male	79	94	15	43	2

Δ MSDS = postoperative change in maximum speech discrimination score.
Δ AC = postoperative change in air-conduction calculated for the PTA at 0.5, 1, 2, and 4 kHz.
Δ BC = postoperative change in bone-conduction calculated for the PTA at 1, 2, and 4 kHz.

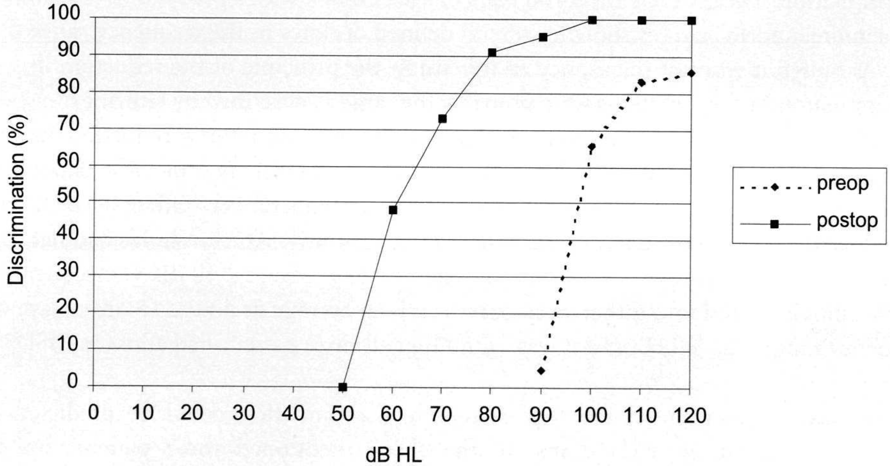

Fig. 5. *Preoperative (preop) and postoperative (postop) median speech reception curve for the 13 ears with an improvement ≥ 10 % in maximum speech discrimination score.*

This masking effect resulting in loss in speech discrimination has been studied by Huizing.[5] He related the maximum speech discrimination obtained by speech audiometry in quiet to the shape of the postoperative AC pure-tone thresholds of patients who had successful gap closure after stapes surgery for otosclerosis.

A loss in speech discrimination was observed when the postoperative pure-tone audiogram showed either an AC curve with a cut-off frequency of about 1 kHz and a slope that exceeded 20 dB per octave, or an AC curve with a cut-off frequency of about 0.5 kHz and a slope that amounted to 10 dB per octave or more. The loss in discrimination was more severe if the cut-off frequencies were more in the range of 0.5 kHz and the slope showed a sharp decline. In the same study, comparable results were found in young persons with normal hearing and otologically normal ears in whom speech discrimination was established with high-frequency filtered speech as a function of various combinations of cut-off frequencies and slopes. The results of this study pretend to give a general indication as to when a post-operative speech discrimination loss is to be expected if stapes surgery increases the slope of the audiogram.

In another study, carried out by Owens et al.[3], the speech discriminations obtained by speech audiometry in quiet were also related to the postoperative AC configurations in patients with otosclerosis who had gap closures <= 10 dB after stapes surgery. In this study it was found that loss in discrimination occurred when the postoperative AC curve showed a decline of > 15 dB/octave. On the basis of the preoperative pure-tone audiogram several declines in BC were defined which were typically associated with reductions in speech discrimination after surgery. Owens et al.[3] could identify a group of patients who were at risk for loss in speech discrimination. These were patients 60 years of age or older, with a preoperative BC loss of 25 dB or more, and BC curves showing several defined declines in the frequency range 0.5 - 2 kHz. Although it was not mentioned in this study, the principle of the reduction in speech discrimination in these patients were probably the same as described by Huizing.[5]

In our population a masking effect was probably the reason for a reduction in speech discrimination in three patients (Patients 2, 7, and 8; Table 2). Two of these patients were indeed over 60 years of age and all three ears showed preoperatively rather steep BC curves with slope decays ≥ 15 dB/octave (Fig. 3. B). The preoperative AC thresholds had flat configurations (Fig. 3.A) and each patient had a successful gap closure ≤ 10 dB. Consequently, the AC thresholds turned into rather steep curves with an average decline ≥ 15 dB/ octave in the frequency range 0.5 - 8 kHz and it was found that all three patient had a loss in MSDS ≥ 10 %.

The question rises whether the loss in speech discrimination could be predicted from preoperative pure-tone audiograms. In the above mentioned three patients we could retrospectively presume that a loss in speech discrimination could occur when a good technical result was obtained without substantial change of the BC level. However, the slope of the postoperative AC threshold is not always to be predicted from the preoperative BC thresholds, even when technical success is achieved with ABG closure ≤ 10 dB. The reason is that after surgery there is a chance that either a SNHL due to cochlear damage or a Carhart effect occurs. A SNHL will mainly impair hearing in the higher frequencies and consequently the steepness of the AC curve will increase in most cases. The Carhart effect results in an improvement of the BC and is most pronounced at 2 kHz in the majority of cases but can improve the BC levels in the whole frequency range 0.5 - 4 kHz.[13] Most of the patients in our study who improved in speech discrimination ≥ 10 % showed a Carhart effect with a markedly improvement in BC for the PTA at 1, 2, and 4 kHz (Table 3). We could identify two patients (patient 5 and 11; Table 3) who had preoperatively rather steep BC curves with a decay ≥ 15 dB/octave. When the BC levels in these patients would not have changed after surgery, this could lead to steep AC curves after surgery and consequently a masking effect could occur with a possible reduction in MSDS. However, the BC levels in these two patients showed a Carhart effect and BC curves turned into rather flat curves (average slope decay < 10 dB/octave in the frequency range 0.5 - 4 kHz). Speech discrimination improved in both patients and we presume this is possibly related to the good technical result with overclosure of the ABG and a markedly improvement in air-conductive hearing. The improvement in speech discrimination in these two ears demonstrates that either improvement or deterioration of speech discrimination can not always be predicted from the shapes of the preoperative pure-tone thresholds. This is also supported by the finding that in the whole population of 386 ears we could identify 7 ears having BC curves with an average slope decay ≥ 15 dB/octave in the frequency range 0.5 - 2 kHz. Six of them had gap closure ≤ 10 dB and showed postoperatively an increase in the steepness of the AC curve (average decline ≥ 10 dB in the frequency range 0.5 – 8 kHz). Only three ears (patient 2, 7, and 8; Table 2) showed a reduction in discrimination. The other 3 patients had a MSDS of 100 % which did not change after surgery. Furthermore, in four cases (patient 1, 3, 4, and 6; Table 2) a reduction in speech discrimination was found which was related to technical failure with cochlear damage.

Another factor which plays a role in the reduction of speech discrimination is the absence of the stapedial reflex when sectioning the stapedius tendon without reconstruction. An intact stapedial reflex attenuates sound energy in the low frequency portion of the speech spectrum. It therefore reduces the undesirable upward spread of masking of low frequency sounds and preserve the transmission of information with higher frequencies. The absence of the stapedial reflex results in phonemic regression, also called "roll-over", and is best examined with speech audiometry in noise.[10,12] However, the consequences of an absent stapedial reflex have also been demonstrated clearly in patients with Bell's palsy and a paralysed stapedius muscle using speech audiometry in quiet.[15] The effects of an absent stapedius reflex on speech discrimination have led to a change of the stapes surgery technique with reconstruction of the stapes tendon by several authors.[9,10,16]

In this study we defined "phonemic regression" as a slope decay > 0.5 %/dB of the SRC after MSDS has been obtained with increasing sound intensity. With this definition we found only 15 ears (3.9 %) with regression after surgery, while none of the ears showed regression before the operation. This low occurrence of postoperative regression is most likely due to the test circumstances in quiet. Probably we would find a higher incidence of postoperative regression when speech audiometry is done in noise.

CONCLUSIONS

In general, the overall results of primary surgery were good in the ears included in this study. An ABG closure ≤ 10 dB was obtained in 76 %, while in 93 % it was closed to ≤ 20 dB. On average the conductive hearing improved with 21.6 dB (SD ± 11.7 dB), and, as expected, the change in AC threshold (PTA 0.5, 1, 2, 4 kHz) correlates well with the change in the SRT (Fig. 2) which was also found in a previous study.[17] Stapes surgery has little effect on the slope of the SRC; no significant postoperative changes were found, neither in the general population nor in the group of ears with a either a deterioration or improvement in MSDS ≥ 10 %.
From the results in this study it appears that we could not identify a group of patients who is at risk for loss in speech discrimination because it is not possible to predict the shape of the postoperative pure-tone curves as either a Carhart effect or cochlear damage can occur. Severe SNHL (deterioration in bone conductive hearing > 10 dB) is often associated with discrimination loss. On the other hand, when before surgery a loss in discrimination exists with AC and BC levels showing markedly impaired hearing, there is a chance that speech discrimination improves in those cases having a successful closure of the ABG and with an obvious increase in bone conductive hearing due to the Carhart effect.

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Chapter 7

Bilateral Stapedotomy in Patients with Otosclerosis: A Disability-Orientated Evaluation of the Benefit of Second Ear Surgery.

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Abstract

This study reports the evaluation of the results of 80 stapedotomies in patients with bilateral otosclerosis. All preoperative and postoperative audiologic data, together with all relevant information of the operations, were stored in a database and analysed retrospectively. A new approach has been developed in order to evaluate the benefit of second ear stapes surgery in a more disability-orientated way using the criteria of the American Medical Association (AMA) in the Guides to the Evaluation of Permanent Impairment. In all patients the percentage of Binaural Hearing Impairment (BHI) and the percentage of Impairment of the Whole Person (IWP) were determined according to the AMA-criteria. In patients who had both operations at the Academic Medical Center it was found after the first operation that there was an important decrease for the BHI-percentage (from 26% to 10%) as well as for the IWP-percentage (from 9% to 4%). In addition, the percentages dropped significantly after the second operation (from 11% to 7% and from 4% to 2%, respectively). During follow-up there were no serious complications. It is concluded that bilateral stapedotomy is a safe procedure with good results.

Introduction

There is still controversy regarding the decision to perform bilateral stapes surgery in patients with significant bilateral conductive hearing losses due to otosclerosis. There is, of course, a risk of immediate or delayed sensorineural hearing loss (SNHL) which can, very rarely, be bilateral. This problem can occur even many years after the operation. The policy of the Academic Medical Center is to offer a second operation on the contralateral side to patients who had a good result after the first stapes operation without any specific technical problems. Patients are fully counselled about the potential risks of bilateral surgery.

Usually the surgical success has been described with reference to the improvement in air-conduction (AC) thresholds, closure of the air-bone gap (ABG) and achieving socially acceptable hearing in the operated ear. It is well recognised that the patient's disability is mainly determined by the hearing thresholds in the better hearing ear. However, the patient's disability is also influenced in a positive way by an improvement of the hearing in the poorer hearing ear after a second stapes operation. To gain a better understanding of the benefits of a second stapes operation the authors determined the percentage of Binaural Hearing Impairment (BHI) and the percentage Impairment of the Whole Person (IWP) according to the international AMA-criteria[1] in order to study the impairment of binaural hearing and the degree of disability caused by the hearing loss before and after stapes surgery. In this way the authors hope to achieve a more disability-orientated method to evaluate the benefit of second side surgery.

Subjects and Methods

From 1983 to 1996 80 operations were performed in 44 patients with bilateral otosclerosis at the Academic Medical Center by the second author. Of these 44 patients, 8 had their first stapes operation at another hospital. All clinical information from these first operations was traced. The patient group consisted of 17 men and 27 women with a median age of 33 years (range 12-65) at the time of their first operation. The surgical approach to the middle ear was in all cases transcanal. In all cases the micro-pick technique described by Marquet[2] was used to create a small fenestra in the stapes footplate. During the operation the clinical otosclerosis grade was estimated by the surgeon (according to the grade system of M. Portmann & Y. Guerrier[3]) and a choice was made of different prostheses depending on the anatomical situation and grade of otosclerosis. Oral antibiotic prophylaxis was given during surgery to all patients.

Conventional air-bone pure tone and speech audiometry was performed before every operation and 2 to 3 months after the operation in all patients who underwent surgery in our hospital. In some patients additional audiological data were available 12 months or more after the second operation. All audiograms were performed by classified personnel according to the ISO 1975 standard.

In order to analyse the percentage BHI according to the Guides to the Evaluation of Permanent Impairment[1] a modification was applied to determine the "Decibel Sum of the Hearing thresholds Levels (DSHL)". Originally the DSHL was determined by totalling the decibel hearing levels at the following frequencies: 0.5, 1, 2 and 3 kHz. Because the AC threshold at 3 kHz is not routinely measured in The Netherlands, we interpolated between 2 kHz and 4 kHz. In this way the MDSHL (Modified DSHL) was determined by totalling the AC thresholds at 0.5, 1, 2 and the mean thresholds at 2 and 4 kHz. The same guide lines from the AMA were used to determine the percentage of monaural hearing loss. To determine the percentage BHI the following formula was used:

$$\text{binaural hearing loss (\%)} = \big((5 \times \%\text{ hearing loss better ear}) + \%\text{ hearing loss worse ear}\big) / 6.$$

According to the AMA-criteria the IWP index can be derived as different categories of percentage of BHI are corresponding to a certain percentage of IWP. In this way an impairment percentage is intended to represent an informed estimate of the degree to which an individual's capacity to carry out daily activities has been diminished.

All data were stored into a database (Microsoft Access®). These data, together with the audiological data, were further analysed using a spreadsheet program (Microsoft Excel®).

For statistical analysis the Student *t*-test for independent variables was used as well as analysis of variance tests. All tests carried out were two-tailed. *P*-values of less than 0,05 were considered as statistically significant.

RESULTS

For analysis of the results the patient population was divided into two cohorts of patients: (1) group A: those who had both operations at the Academic Medical Center (n = 36) ; and (2) group B: those who had the first operation in another clinic but the second operation in our institution (n=8).

Table 1 shows the data regarding the number of right and left ears, the degree of otosclerosis, the type of prosthesis that has been used, and the mean, minimum, and maximum duration of follow-up in months. The mean time between the operation on the first side and the second side was 27 months (range 7-123) in group A and 34 months (range 11-96) in group B. In group A there were five revision operations in patients who had the first operation elsewhere. Of these five patients three had a poorly fitting prosthesis and this had to be replaced by a new prosthesis. In one patient who was operated elsewhere the attempt to insert a prosthesis was not successful because of a protruding facial nerve. In another patient a mobilisation of the incus/stapes joint was performed without inserting a prosthesis. In both these patients a prosthesis could be placed successfully. In group B there were two patients who had an operation on both ears elsewhere. In one of these two patients a dislocation was found of the prosthesis in one of the ears, while in another patient a prosthesis could not be placed because of unknown technical reasons. A new prosthesis was also placed successfully in these two patients.

Table 1. Data of patient population.

	First side* (n = 36)	Second side* (n = 36)	Second side** (n = 8)
Affected side			
Left ear	20	16	3
Right ear	16	20	5
Degree of otosclerosis			
Grade 1	7	5	-
Grade 2	12	17	4
Grade 3	14	13	3
Grade 4	1	1	-
Unknown	2	-	1
Type prosthesis			
Teflon loop 0.4 mm	25	25	3
Teflon loop 0.3 mm	4	3	2
Teflon loop 0,6 mm	3	-	-
K-piston	1	8	3
Shea cup small	3	-	-
Follow-up in months			
Mean	52	28	34
Minimum	15	6	6
Maximum	147	99	63

* = Group A patients (who had both operations at our institution; ** = Group B patients (who had their first operation elsewhere).

In the group of patients who had both operations in our clinic (group A) the state of otosclerosis was known for both operations. There were no clear differences in the grade of otosclerosis between the first and the second operation. First operation: average grade 2,26; SD 0,8; second operation: average grade 2,27; SD 0,7 (grade 2: small focus of ankylosis; grade 3: large focus of ankylosis, ≥ 50% of footplate).

Of all the evaluated patients it was necessary to perform revision surgery 7 months after the operation on the second side in one patient from group A because of persistent conductive hearing loss which occurred 5 months after operation. During the revision operation there was a dislocation of a golden K-piston which apparently was bent due to many adhesions in an ear with active otosclerosis. A 0,4 mm Teflon piston was placed successfully and this resulted in a clear improvement in hearing. During evaluation of the audiological data for this patient only the pre- and postoperative audiograms from the second operation in which a golden K-piston was placed were taken into account and not the pre- and postoperative audiograms of the revision operation.

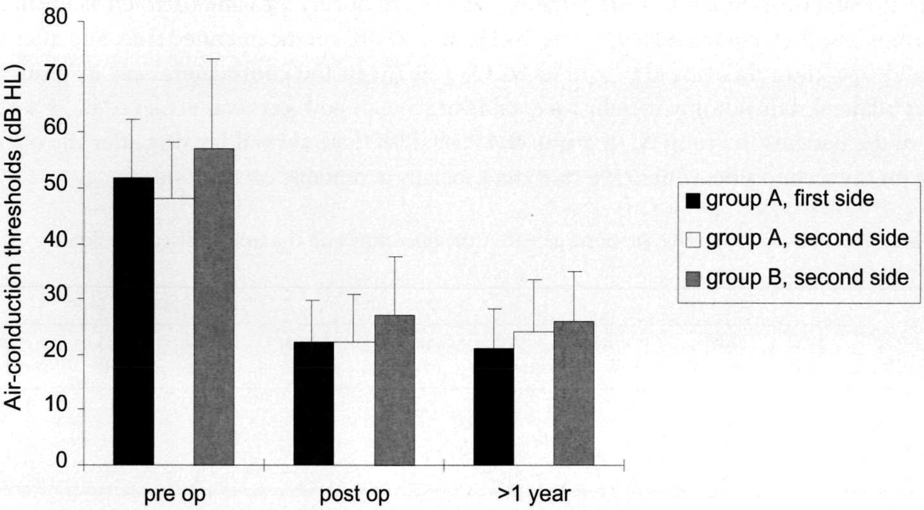

Fig. 1. *Mean air-conduction thresholds at frequencies 0.5, 1, and 2 kHz (PTA) preoperatively and postoperatively and more than 1 year after stapedotomy.*

For evaluation of the audiological data the hearing losses were averaged. In patients from group B, who had their first operation elsewhere, the pre- and postoperative audiograms were not complete. All patients in group A had an audiogram more than 1 year after the operation on the first side (often this was the preoperative audiogram of the operation on the second side), while in 11 patients audiological data were present more than 1 year after the operation on the second side. The mean time of these audiograms after the first and second operation in group A was 38 months (range 12-144) and 21 months (range 12-82), respectively. In group B there were 6 patients whose audiological data was available more than 1 year after the operation on the second side. The mean time of these audiograms after the second operation was 23 months (range 14-63).

Figure 1 gives the results of the mean AC thresholds at 0.5, 1 and 2 kHz (PTA) pre- and postoperatively and at least 1 year after the operation on the second side. There was no serious SNHL (dead ear) in either group A or group B and there was no decline in speech discrimination. However, in one of the patients in group A, there was a SNHL of 25 dB directly after the revision operation. Postoperatively the ABG was closed from 42 to 5 dB and the mean AC thresholds at 0.5, 1, and 2 kHz (PTA) in this patient improved from 55 to 42 dB. No patients suffered from persistent vertigo.

Table 2 shows the results with regard to the ABG closure. In group A a closed ABG (conductive component of less than 10 dB) was achieved in 86,1% (31/36) after the first operation and in 80,5% (29/36) after the second operation. In group B this result was achieved in 62,5% (5/8). After more than 1 year of follow-up a closed ABG was retained in 83,3% (30/36) after the first operation and in 72,7% (8/11) after the second operation in group A, while in group B this was in 66,6% (4/6).

After the first operation 80,5% of patients (29/36) had normal hearing (defined as mean AC thresholds at the frequencies 0.5, 1, and 2 kHz of ≤ 30 dB) on the operated side, and after the second operation this was also true of 80,5% (29/36) in the contralateral ear in group A. After bilateral stapedotomy socially acceptable hearing in both ears was achieved in 75% (27/36) of the patients in group A. In group B, 87,5% (7/8) had normal hearing after the operation on the second side, while 75% (6/8) had socially acceptable on both sides.

Table 2. Pre- and postoperative air-bone gap after the operations on the first and second side.

	First side*			Second side*			Second side**		
Air-bone gap (dB)	pre (n=36)	post (n=36)	>1 year (n=36)	pre (n=36)	post (n=36)	>1 year (n=11)	pre (n=8)	post (n=8)	>1 year (n=6)
0-10	-	31	30	-	29	8	-	5	4
11-20	4	4	6	7	6	3	-	3	2
21-30	14	1	-	13	1	-	4	-	-
31-40	12	-	-	10	-	-	2	-	-
41-50	5	-	-	6	-	-	1	-	-
51-60	1	-	-	-	-	-	1	-	-

* = Group A patients (who had both operations at our institution); ** = Group B patients (who had their first operation elsewhere).

In all patients the percentage BHI and the percentage IWP according to the AMA criteria could be determined before and after the operation. Figure 2 shows the reduction of the mean percentages of BHI and IWP at different times during follow-up. There was an obvious reduction in both BHI and IWP after the first operation in group A (from 26% to 10% and from 9% to 3%, respectively). These differences were highly significant ($p < 0,001$ for BHI and $p < 0,01$ for IWP; 2-tailed Student *t*-test). Between the first and second operations the

BHI and IWP increased slightly (differences were not significant). After the second operation there was a further decline in both BHI and IWP (from 11% to 5% and from 4% to 2%, respectively). These differences were also significant for both parameters ($p < 0,05$). The same percentages increased slightly at the time of audiometry more than 12 months after the second operation in group A (differences not significant). Also in group B there was a clear reduction of both BHI and IWP after the second operation (from 17% to 9% and from 6% to 3%, respectively). These differences were, however, not significant.

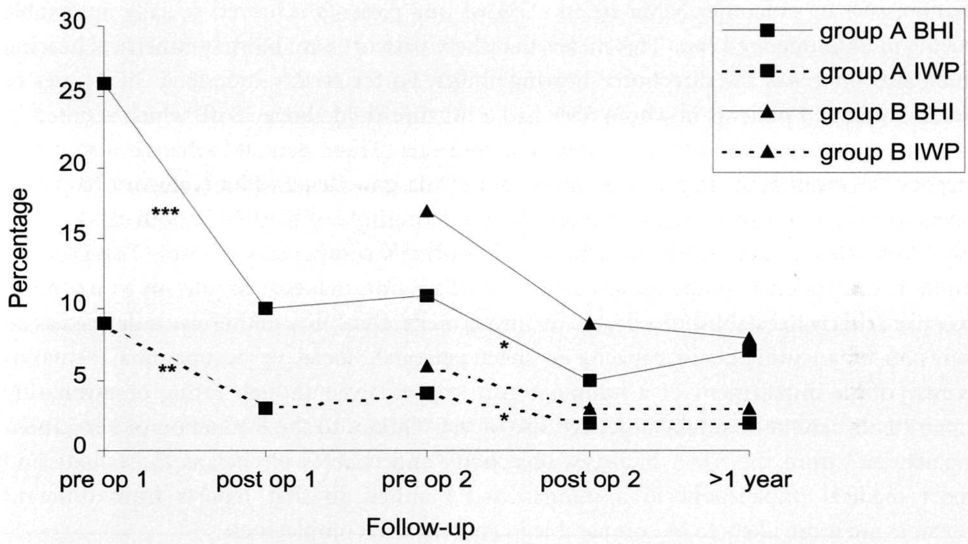

Fig. 2. *Percentages Binaural Hearing Impairment (BHI) and Impairment of the Whole Person (IWP) according to the AMA criteria.*
**** = $p < 0,001$; ** = $p < 0,01$; * = $p < 0,05$ (two-tailed Student t-test).*

Discussion

It is important that the surgeon be aware of his individual results so that he can obtain truly informed consent to the patient especially when he considers a procedure in which serious complications can occur. The purpose of this study was the evaluation of the results in patients after bilateral stapes surgery. On both sides there was an obvious hearing improvement in every frequency except 8000 Hz. This improvement of the hearing was also measured greater than one year postoperatively for the same frequencies in both ears.

Whether one should offer a second operation to patients with bilateral otosclerosis remains a point of discussion. There is a risk of immediate or delayed SNHL, which in the case of bilateral surgery can occur at both sides. Vestibular damage can also occur with permanent loss of balance. The advantages of bilateral stapes surgery, if it is successful, are the improvement of binaural hearing and consequently the ability to localise the direction from which sound is coming. Different publications on this subject are in favour of[7,11,12] or against[8,9] the policy of performing a second stapes operation. Zeittoun et al.[4] established by a questionnaire that 41 % of British consultants perform bilateral stapes operations, while 58% do not. Many surgeons, especially those who do not specialise in the surgical treatment of otosclerosis, feel that the patient should be allowed the safeguard of being able to wear a hearing aid in the second ear if necessary.[10]

Socially acceptable hearing after stapes surgery depends of course on the preoperative cochlear hearing loss which can be severe in otosclerosis. It is therefore clear that in these cases of severe cochlear hearing loss even a technically perfect operation can appear unimpressive in outcome. Nevertheless 75% of our patients achieved socially acceptable hearing in both operated ears. This means that these patients have more symmetrical hearing which also improves the directional hearing ability. Porter et al.[12] described in a series of bilateral operated patients in whom 35% had a BC threshold above 30 dB which resulted in 65% socially acceptable hearing in both operated ears. These patients achieved a so-called category "a" result according to the criteria of the Glasgow Benefit Plot (category "a" result means socially acceptable hearing defined as an AC threshold of $\leq$ 30 dB in both ears).

The AMA-criteria[1] are widely used by law in worker's compensation cases. The growing emphasis on worker's compensation claims and litigation makes it important to use more objective criteria to establish the degree of impairment. Disability in this way is defined as an alteration of an individual's capacity to meet personal, social or occupational demands because of an impairment of a human organ system. Even though rating or estimating impairments cannot be totally objective, use of the "Guides to the Evaluation of Permanent Impairment" from the AMA increases objectivity and enables physicians to evaluate and report medical impairment in a standardised manner, so that reports from different observers are more likely to be comparable in content and completeness.

The BHI and the degree of disability due to the hearing loss (IWP) declined significantly after the first operation in patients who had both operations in our hospital. The benefit of a second stapes operation appears from a further statistical significant decline of both the BHI and the degree of disability. Because it was not possible to determine the DSHL in all patients a modified DSHL (MDSHL) was calculated as an alternative by taking the mean AC thresholds at the frequencies 2000 and 4000 Hz in to account instead of the threshold at 3000 Hz. There were no statistical differences (2 tailed Student-t test) if the AC threshold at 4000 Hz had been taken into account to determine the MDSHL in stead of the mean thresholds at 2000 and 4000 Hz at any measured point during follow-up in figure 2. Our approach of data analysis is a useful method to gain a better impression of the patients benefit after such a procedure of bilateral surgery.

During the follow-up period it was necessary to do revision surgery in one patient out of a total of eighty operations and it appeared that there was a dislocated prosthesis which had to be replaced (see results). During the same follow-up period there were no perilymph fistulas or serious SNHL (dead ears).

The results from this study justify our policy of offering a second operation to patients with bilateral otosclerosis. It appears that this procedure improves the chance of achieving normal and symmetrical hearing and that patients who had a good result from the first operation almost always may expect a good result from their second operation. An important factor in achieving good results is extensive surgical experience in performing stapes surgery and therefore we think that some centralisation of these operations is appropriate.

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Chapter 8

Evaluation of Second-Ear Stapedotomy with the Glasgow Benefit Plot.

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ABSTRACT

This study reports the evaluation of the results after 72 stapedotomies in patients with bilateral otosclerosis. All pre- and postoperative audiological data, together with all relevant information of the operations, were stored in a data base and analysed retrospectively. The Glasgow Benefit Plot is a useful method to evaluate the hearing results of each individual ear after stapes surgery in a more functional way rather than from a technical standpoint. Therefore, it has been used to assess the benefit obtained after second-ear stapedotomy. From the results it appears that a second operation on the contralateral side increases the chances of achieving at least one "normal"-hearing ear, and it makes symmetrical "normal" hearing possible in the majority of the cases.

INTRODUCTION

The decision to perform second-ear stapes surgery in patients with significant bilateral conductive hearing losses due to otosclerosis is still controversial. There is a risk of immediate or delayed sensorineural hearing loss (SNHL), and patients operated on both sides are exposed to the risk twice. The policy of our institution is to offer a second operation on the contralateral side to patients who had a good result after the first stapes operation without any specific technical problems which might increase the risk of immediate or delayed complications. Patients are fully counselled about the potential risks of bilateral surgery.

Most often evaluations of the hearing results after stapes surgery have been described with reference to improvement in air-conduction (AC) thresholds, closure of air-bone gap (ABG) and achieving socially acceptable hearing in the operated ear. These methods are relevant in that they assess the technical success of the operation, but they do not take account of the hearing in the contralateral ear and, therefore, do not necessarily assess the functional benefit the patient obtains from the surgical procedure.

Recently, de Bruijn et al.[1] have published a more disability-oriented method of evaluating the benefits of second-side stapes surgery using American Medical Association-criteria.[2] It was shown that the percentage of binaural hearing impairment and the percentage of impairment of the whole person declined significantly after the first-ear operation. The benefit of a second-ear stapes operation appeared from a further statistically significant decline of both the binaural hearing impairment and the degree of disability.

The reported results in the above-mentioned study were *mean* values of several audiological parameters including binaural hearing impairment and impairment of the whole person. It is, however, also illustrative to report the hearing results of each *individual* ear after the first- and second-side surgery. Browning et al.[3] introduced in 1991 the Glasgow Benefit Plot (GBP) which provides an analysis of hearing results of each ear separately. This method takes also the hearing in the nonoperated ear into consideration which makes it a useful instrument for assessing functional benefit a patient can achieve after surgery.

The aim of this study was to obtain impression of the benefit of second-ear stapedotomy of each *individual* ear by plotting the AC thresholds of each patient after their first-ear and next after their second-ear stapes operation according to the criteria of the GBP.

Patients and Methods

For this retrospective study, all important data from 72 operations in 36 patients were stored in a data base. We took the same patients into account as previously reported[1] who had both operations in our hospital. All these patients were operated by the second author. The patient group consisted of 14 men and 22 women with a median age of 34 (range 12 - 65) years at the time of their first-ear operation. The surgical approach to the middle ear was in all cases transcanal. In all cases the micro-pick technique described by Marquet[4] was used to create a small fenestra in the stapes footplate.

Conventional pure-tone audiograms were available before every operation and 2-3 months after the operation in all patients. All audiograms were performed by qualified personnel according to the ISO 1975 standard. From the audiograms the mean AC thresholds were taken over 0.5, 1 and 2 kHz. Also the mean bone-conduction (BC) thresholds over the same frequencies were calculated.

In our study we used the GBP as described in 1997.[5] In this plot the vertical axis represents the mean AC threshold in the ear to be operated on, and the horizontal axis represents the mean AC threshold in the nonoperated ear (Fig. 1). Thus for each patient there is a vector joining the pre- and postoperative co-ordinates. "Normal hearing" has been defined as an AC threshold of $\leq$ 30 dB, and for the GBP this definition is represented graphically by the vertical and horizontal lines. "Symmetrical hearing" has been defined as an intra-aural difference in AC of $\leq$ 20 dB, and the two diagonal lines in the GBP enclose the area within which the hearing is regarded as symmetric.

The concept of the GBP is to group patients into different pre- and postoperative categories, as the potential benefits from stapes surgery are not the same in each group. Browning distinguishes six categories: category 1: bilateral "normal" hearing; categories 2 and 3: unilateral "normal" hearing; categories 4 and 6: bilateral hearing impairment with asymmetric thresholds; category 5: bilateral hearing impairment with symmetric thresholds.

Figure 2 illustrates the seven different audiometric changes of categories after surgery. To prevent overcrowded and unclear plots, we choose to make a plot for each category after the first operation and next to make a second plot to evaluate to what postoperative categories the hearing of the same patients changed after the operation at the second side.

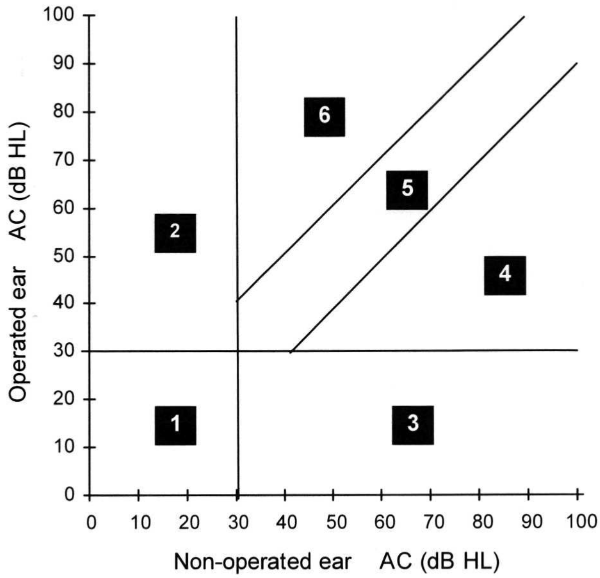


Fig. 1. *GBP with six different pre-/postoperative categories. Category 1 = bilateral "normal" hearing; categories 2 and 3 = unilateral "normal" hearing; categories 4 and 6 = bilateral hearing impairment with asymmetric thresholds; category 5 = bilateral hearing impairment with symmetric thresholds. AC = Air conduction.*

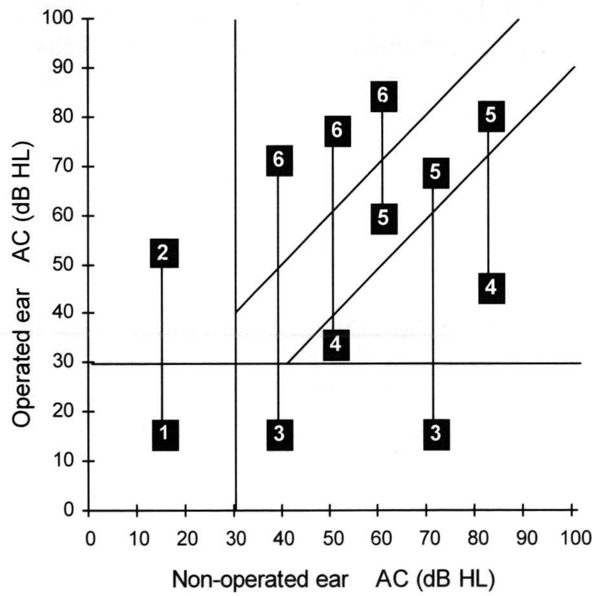


Fig. 2. *GBP with the seven possible postoperative changes into different categories. Each patient is categorised according to the situation before surgery. The change in hearing of every patient is indicated by a vector joining the pre- and postoperative co-ordinates. AC = Air conduction.*

Results

In reporting our data, the starting point is the hearing level prior to the operation at the first side, and we could group patients either into category 6, 5, or 4. From each category the pre- and postoperative hearing thresholds after the first and second operation are shown in figures 3-5, respectively. Table 1 shows the results with regard to the number of patients in each preoperative category prior to the first-ear operation against the number of patients who changed into each potential postoperative category after the first- and second-ear operation. The mean time between the operation at the first side and the second side was 27 (range 7-123) months. There were 5 cases of revision surgery in patients who already had a stapes operation before in another hospital. These are patient "7" in figure 3, patients "1", "14" and "17" in figure 4 and patient "4" in figure 5; all these patients had revision surgery on the side operated first.

Of the twelve patients in preoperative category 6, ten patients changed into category 3 after the operation on the first side (Fig. 3a). Bilateral "normal" hearing (category 1) was achieved in nine patients after the second-ear operation (Fig. 3b). The mean hearing improvement in all twelve patients was 35.7 dB (SD ± 9.5) after the first-ear operation and 21.0 dB (SD ± 6.8) after the second-ear operation.

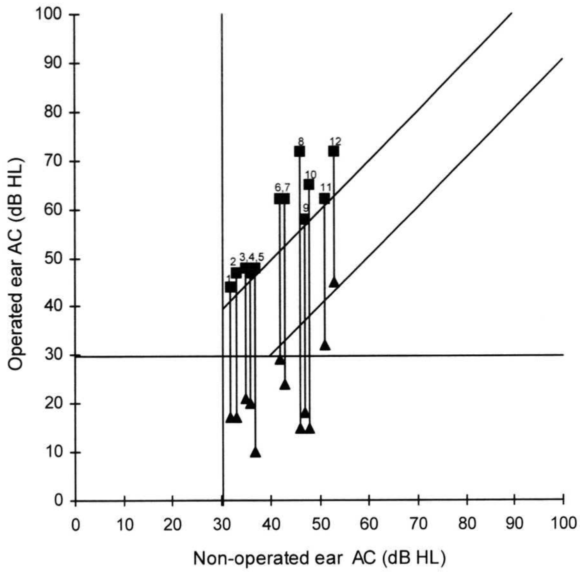
Before the first-ear operation, there were twenty patients in category 5 with bilaterally impaired but symmetrical thresholds, and sixteen patients changed into category 3 after first-side surgery (Fig. 4a). Eventually fifteen patients achieved a category 1 result after their second-side operation (Fig. 4b). The mean gain in hearing was 28.0 dB (SD ± 13.4) after the first-side and 27.3 dB (SD ± 10.3) after the second-side operation in all twenty patients.

Four patients were grouped in category 4 who had their first operation at the best-hearing ear. After the operation on the first side three patients changed into category 3 (Fig. 5a), and the same three patients obtained bilateral "normal" hearing levels after second-ear surgery (Fig. 5b). The hearing improved with 24.5 dB (SD ± 5.4) after the first-ear operation and with 39.0 dB (SD ± 9.4) after the second-ear operation.

Patient "12" in figure 3, patients "18" and "20" in figure 4 and patient "4" in figure 5 are patients who had mixed impairments with BC thresholds >30 dB, and it was, therefore, not possible to achieve socially acceptable hearing without overclosure of the ABG. All of these patients had a closure of the ABG within 10 dB both in the first and second operated ear.

Patient "17" in figure 4 had a SNHL of 25 dB directly after the operation on the first side. This patient had been operated before on this side in another hospital and was considered for revision surgery because of a poorly fitting prosthesis. Postoperatively the ABG was reduced from 42 to 5 dB, while the mean AC thresholds at 500, 1000 and 2000 Hz (PTA) in this patient improved from 55 to 42 dB. In our series there were no other patients with SNHL exceeding 10 dB. None of the patients complained of persistent vertigo.

A



B

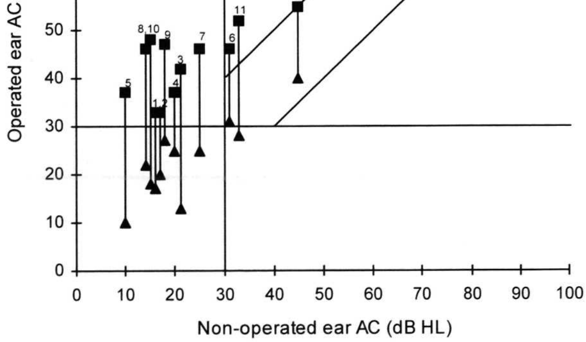
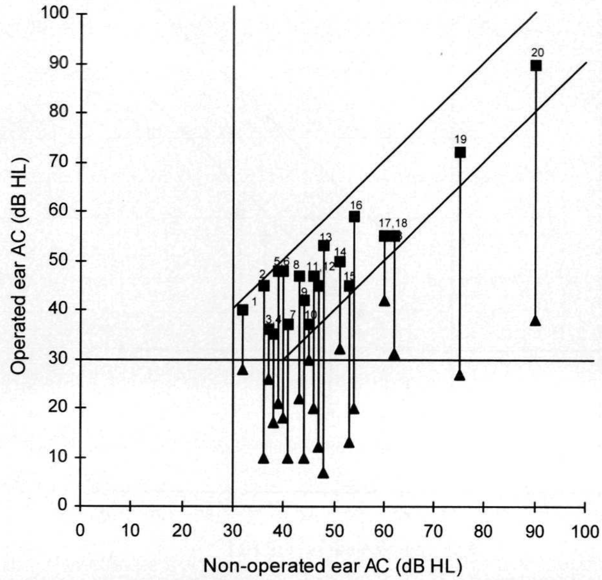


Fig. 3. *Pre- (■) and postoperative (▲) AC thresholds for every patient grouped into preoperative category 6 before first-side surgery. Each patient is indicated by an Arabic numeral. A, Results after stapedotomy on the first side. B, Results after stapedotomy on the second side.*

A



B

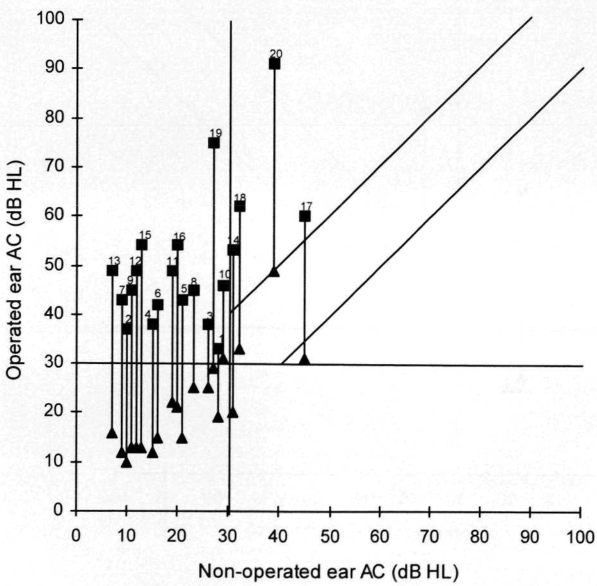


Fig. 4. *Pre- (■) and postoperative (▲) AC thresholds for every patient grouped into preoperative category 5 before first-side surgery. Each patient is indicated by an Arabic numeral. A, Results after stapedotomy on the first side. B, Results after stapedotomy on the second side.*

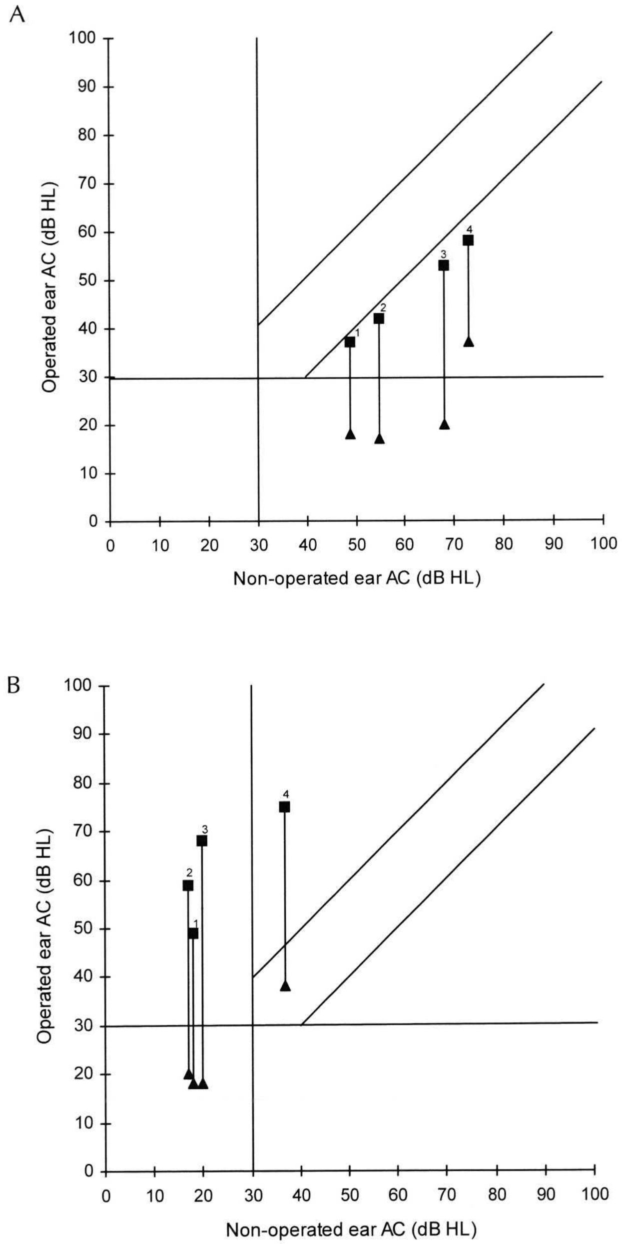


Fig. 5. *Pre- (■) and postoperative (▲) AC thresholds for every patient grouped into preoperative category 4 before first-side surgery. Each patient is indicated by an Arabic numeral. A, Results after stapedotomy on the first side. B, Results after stapedotomy on the second side.*

Table 1. Number of patients in each preoperative category against the number of patients who changed into each potential postoperative category after operation on the first and second side.

		Postoperative Category									
		First Side					Second Side				
Pre-operative Category	No. of Patients	1	2	3	4	5	1	2	3	4	5
6	12	-	-	10	1	1	9	-	1	-	2
5	20	-	-	16	4	-	15	1	1	1	2
4	4	-	-	3	1	-	3	-	-	-	1

Discussion

Otosclerosis is characterised by a slowly progressive hearing loss which initially affects one ear, but later affects both ears in most patients. Nowadays stapes surgery has established its position as the primary treatment of conductive hearing losses in otosclerosis.[6] The patient who has had a successful stapes surgery with hearing improvement on one side will often ask the surgeon to perform an operation in the second ear. The low risk of delayed SNHL after stapedotomy appears to support the policy of performing a second-ear operation for optimum auditory rehabilitation.[7-10]

Conventionally, the results of stapes surgery are reported in terms of improvement in AC thresholds and postoperative closure of the ABG. These methods are appropriate for the purpose of assessing the surgical success. It is, however, also important to be aware of the benefit a patient will obtain after stapes surgery, especially when considering second-ear surgery. In this respect the GBP can be a useful instrument because it allows a prediction of the potential functional gain a patient will obtain from surgery. In doing so, it is important to establish the preoperative category of every patient because the benefit will be different for each category. The maximal feasible result can be derived from the preoperatively measured BC threshold in the ear to be operated on. Thus, it is possible to predict into which postoperative category the patient will change after a technically successful operation.

It was originally stated that if an ear shows sensorineural hearing with a threshold above the "normal" border of 30 dB, it is questionable whether an operation should be performed in such a case.[3] This certainly applies to patients who have normal hearing in the first operated ear and who are under consideration for a second operation in an ear with a BC threshold of >30 dB. The hearing would stay impaired in the second operated ear, possibly necessitating a hearing aid. On the other hand, it is known that stapes surgery can substantially improve the BC threshold due to the Carhart effect[11], and in these cases an overclosure can be achieved resulting in "normal" hearing.

Because the GBP is a valuable method to evaluate the benefit a patient derives from stapes

surgery, we used this method for our bilaterally operated patients to judge if it was worthwhile to perform second-ear surgery, and consequently expose patients to potential surgical risks for a second time as mentioned in the Introduction.
After the operation on the first side 80.5 % (29/36) changed to category 3 and had "normal" hearing in the operated ear. Prior to second-ear surgery, these patients were grouped into preoperative category 2, and in only one patient (indicated as patient "10" in figure 4) it was not succeeded to achieve bilaterally "normal" hearing. Postoperatively this patient had an AC threshold of 32 dB in the second operated ear, while the ABG was closed to within 10 dB. The hearing was practically symmetrical in this patient, and he was not dependent on a hearing aid. In the total group of patients, "normal" hearing in both ears was achieved in 75 % (27/36) after bilateral surgery. Of the bilaterally operated patients reported by Porter et al.[12], 35 % had a BC threshold above 30 dB, and eventually 65 % achieved "normal" hearing. Also in this study the GBP was used to assess the benefit of bilateral stapes surgery.
It is important to realise that a good result in the opinion of the surgeon with regard to benefit is not always a good result in view of the patient, as Browning[5] has shown in his recent study. In this study the opinion of the patient about benefit was compared with that of the surgeon after unilateral surgical procedures with the aim to improve hearing. It was found that patient's benefit is related to the magnitude of improvement in the AC threshold, and in addition the preoperative category was more important than the achievement of "normal" hearing with a threshold of <30 dB. Consequently, Browning[5] adjusted the GBP by removing the horizontal 30-dBHL line and retaining the vertical 30-dBHL line for preoperative categorisation purposes.
Another finding of Browning's study was that in the patients' opinion benefit after unilateral surgery is twice as great in those with bilateral hearing impairment as those with unilateral hearing impairment, provided that the operated ear is made the better hearing ear. This suggests that in our series the majority of the bilaterally operated patients experienced more benefit from their first-ear operation than from their second-ear operation. The GBP keeps his value especially for identifying bilaterally impaired patients in whom it is not possible to make the operated ear the better-hearing ear because the preoperative BC thresholds are no better than the AC thresholds in the nonoperated ear. In our series we had a patient (indicated as patient "12" in figure 3) who had a category 5 result after the first-side operation; the hearing in the operated ear was not substantially improved in comparison with the contralateral ear, although the ABG was reduced to <10 dB. Also a second-ear stapedotomy in this patient was less beneficial. There was a technical good result of the operation (ABG closure within 10 dB), but this patient remained in category 5. In retrospective, it is questionable whether it was worthwhile to perform a second-ear stapedotomy in this patient.
In our opinion, it is important to relate improvement of hearing after stapes surgery to the possibilities of hearing aid fitting, as the latter can profit from the gain in sensitivity due to stapedotomy. Postoperatively, we can use less powerful hearing aids (e.g. in-the-ear aids), and the problems of acoustical feedback will be reduced. In the case of patient "20" in figure 4 a technically successful second ear stapedotomy (the ABG was closed to within 10 dB) had changed this patient into postoperative category 5. So, in this situation stereophonic fitting

of hearing aids is possible, and we may expect that this will result in improved hearing in background noise and less hindrance of reverberation. A second-ear stapedotomy in the case of patient "12" in figure 3 was also less beneficial with regard to hearing rehabilitation, because this patient remained in postoperative category 5 which indicates not a substantial improvement of stereophonic fitting of hearing aids.

The functional benefit of stapes surgery is more complicated than we initially thought of, and evaluation of the benefit of second ear stapes surgery makes it not easier. However, using the GBP helps one to identify the patients who will have less benefit of stapes surgery and particularly of second-ear stapes surgery. In some cases the effects of wearing a hearing aid should be included in the decision to perform stapes surgery. From the results of this study it was concluded that a second-ear stapedotomy improves the chance of achieving "normal" and symmetrical hearing and that patients who had a good result from the first-ear operation may expect a good result from their second-ear operation.

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Chapter 9

Evaluation of Revision Stapes Surgery in Otosclerosis and Review of the Literature.

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R.A. Tange
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Submitted

ABSTRACT

A retrospective, nonrandomized chart review of 79 cases undergoing revision stapes surgery was undertaken to identify causes of failure after prior otosclerosis surgery, to assess whether these are different based on source of initial surgery, and to evaluate results with regard to hearing outcome. Preoperative symptoms, intraoperative findings, causes of failure, surgical techniques, complications, and repeated revisions were recorded. Pre- and postoperative audiometric data from pure-tone and speech audiometry were analysed and related to several operative findings and techniques. Most common causes of previous stapes surgery failure included dislocated prosthesis (27 %), incus erosion (13 %), inadequate prosthesis length (11 %), and fibrous adhesions (10 %). Postoperative air-bone gaps were computed using the conventional method (i.e. postoperative air conduction minus preoperative bone conduction) as well as using the guidelines from the American Academy of Otolaryngology - Head and Neck Surgery (postoperative air conduction minus postoperative bone conduction), with success rates of air-bone gap closure to within 10 dB after revision surgery of 64 % and 60 %, respectively. Sensorineural hearing loss (decline of more than 10 dB in bone pure-tone average) occurred in 1.3 %. Hearing results were analysed for subgroups showing no statistical differences with regard to number of revisions and the absence of a usable incus for reconstruction. Revision surgery for persistent conductive hearing loss after initial surgery had a less beneficial hearing outcome compared to surgery for those cases that initially improved, then developed recurrent conductive losses. Findings and results in this study are discussed and related to the findings and results from other studies revealed in literature review.

INTRODUCTION

In spite of many improvements and refinements that have been accomplished in stapes surgery over the past four decades, there continues to be short-term and long-term failures. A wide range of causes can be identified in the failure of primary stapes cases for otosclerosis, and even in the hands of the most experienced otologic surgeons, a stapes operation can result in a less satisfactory outcome. According to the literature, frequently mentioned causes of failure with respect to the restoration of conductive hearing loss, are prosthesis malfunction, long process resorption and fibrous adhesions.[1-20] In many cases multiple factors are involved in the recurrence of hearing loss. Also the occurrence of perilymph fistulae, leading to symptoms like vertigo and sensorineural hearing loss (SNHL), are reasons to consider a revision procedure.[1-20] It is well recognised that, overall, postoperative hearing results after revision surgery are not as good as in the primary cases, and furthermore, due to inner ear trauma, SNHL is more likely to occur. In the literature, successful results, defined as a postoperative air-bone gap (ABG) closure to within 10 dB, have been reported in 17 % to 80 % of cases, with a mean of approximately 50 % in most series.[1-20] In the same series, the postoperative SNHL, defined as a decline in bone conduction threshold of more than 10 dB, was found in the range of 0 % to 12 % of cases.

Reports dealing with revision stapes surgery are valuable for the otologic surgeon, as they can lead to adaptations of the techniques to perform otosclerosis surgery. Sheehy and House were the first to report about failures in stapes surgery and the need for revision surgery.[21] The most common cause of their series was a displaced polyethyleen strut. Slippage of the strut into the vestibule were associated with SNHL and vertigo. These complications were also frequently reported in later published series which led to the virtual abandonment of the polyethyleen strut.[3] Later, the wire Gelfoam prosthesis was abandoned because of the reported association with fistula of the oval window.[3] An adaptation introduced in the eighties and nineties is the use of laser surgery in revision cases.[8,12,16]
To highlight the problems encountered in revision stapes surgery, as well as to allow us to better counsel our revision candidates with respect to the potential risks and rewards of revision surgery, a retrospective study was undertaken of our revision operation files. The present study reports the type of the initial procedure used, the alleged cause of failure, the applied surgical solutions and the audiometric results. Furthermore, a review of the literature was performed to compare our findings and results with those of other reports.

Materials and Methods

Data were retrieved from every consecutive patient who underwent revision stapes surgery for otosclerosis during a twelve years period from January 1987 to December 1998. During this period 80 revision operations were performed by the second author. Of the total amount of patients we had to exclude one case from analysis because data were missing. The remaining 79 cases which were considered for analysis concerned 75 patients. In one patient revision surgery was done at both sides. Two patients needed a second revision operation, of whom one patient needed revision surgery for the third time. The patient group consisted of 48 women and 27 men with a mean age of 39.9 years (range 13-76) at the time of their operation in our hospital. The distribution between left and right ears was approximately even.
All revision procedures were performed under general anaesthesia via a standard transcanal approach. Detailed intraoperative findings and surgical techniques were recorded as operative notes as well as postoperative diagrams.
Preoperative audiometric data were obtained from the most recent audiogram prior to surgery which was within 3 months of the operation in every case. In 85% the audiograms of more than 1 year postoperatively were available. The average postoperative time was 16.2 (range 12-72) months and audiometric data of these audiograms were used for analysis. In the other 15 % audiometric data were used from the audiograms between 6 weeks and 6 months following revision surgery with an average postoperative time of 2.8 (range 1.8-5.2) months. All audiograms were performed by classified personnel according to the ISO-389 (1975) standard.
The guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery[22] advocates the use of a four frequency pure-tone average (PTA) at 0.5, 1, 2, and 3 kHz for evaluation of hearing results. However, in our clinic the air-conduction (AC) thresholds are routinely measured at the octave intervals from 0.125

to 8 kHz and the bone-conduction (BC) thresholds at the octave intervals from 0.25 to 4 kHz with adequate masking. The PTA at 3 kHz is measured only when the difference between the thresholds at 2 kHz and 4 kHz exceeds 20 dB. Therefore, the threshold at 4 kHz was used instead of at 3 kHz to calculate PTA in this study. In reporting our audiometric data we used the method by taking the difference of the AC and BC thresholds of the same postoperative audiogram for accounting postoperative ABG as recommended by the Committee on Hearing and Equilibrium.[22] To make comparison with other studies possible we also report the results using the former practice of comparing the postoperative AC thresholds with preoperative BC thresholds for the frequency range 0.5, 1, and 2 kHz. Postoperative overclosure or SNHL was calculated by subtracting preoperative from postoperative high pure-tone BC average at 1, 2, and 4 kHz. Overclosure is defined as an improvement of more than 10 dB in BC while SNHL is defined as a decline of more than 10 dB in BC.

For most subjects who were considered for analysis both AC and BC thresholds at the above mentioned frequency ranges were available before and after surgery. However, in some subjects the hearing loss was very severe resulting in hearing thresholds which were beyond the maximum output of the audiometer. In these cases the pure-tone thresholds at certain frequencies were impossible to determine and this is marked in the audiogram with an arrow pointing down. It is important to consider these limitations of audiometer capacity, because data of pre- or postoperatively unmeasurable hearing thresholds could wrongly be excluded from analysis. Severe postoperative hearing loss as a consequence of an unfavourable operation would then not be taken into account. Conversely, preoperatively severe hearing with measurable hearing thresholds after operation would also be rejected. To avoid this problem in these cases, thresholds were assumed to be just beyond the audiometer limitations. If AC or BC was not measurable at a certain frequency a value of 10 dB above the limit for that frequency was given.

In 92.4 % (n = 73) of the cases speech audiometry was available before and after surgery. For each subject complete speech audiometry was carried out at different levels, using lists of phonetically-balanced CVC-words. From these tests the pre- and postoperative speech reception threshold (SRT) as well as the speech discrimination score (SDS) could be derived .

Demographic data, otologic history, intraoperative findings, details of procedure, complications, and audiometric data were entered into a computer database and analysed with a spreadsheet program.

For statistical analysis nonparametric tests were used for independent variables (GraphPad Prism®). The Wilcoxon signed rank test was performed for paired data, whereas the Mann-Whitney test was used for unpaired data. Our criterion for statistical significance was set at *p*-values of less than 0.05 (two-tailed).

RESULTS

Of the 79 cases reviewed, 13 had their initial surgery performed by the second author, and 66 were referred from other physicians. Of the revision cases who had their primary operation performed by the second author, there was one patient who needed a second revision operation, while in another patient it was necessary to do a third revision. In the group of 66 cases with primary surgery performed by another surgeon, there were 5 cases who already had one revision operation, 4 cases who had a revision operation twice and there was 1 patient who had a revision operation for the third time prior to surgery in our clinic. Time from previous to revision surgery ranged from 2 weeks to 35 years with an average of 5.4 years. Nineteen percent had revision surgery within 1 year after their initial surgery, while 64 percent had their revision surgery within 5 years.

Indications for revision surgery included recurrent conductive hearing loss in 62 cases (78.5 %) and persistent conductive hearing loss in 11 cases (13.9 %). In 6 cases (7.6 %) a revision operation was performed because of the suspicion of a perilymph fistula: two patients had a SNHL with vertigo and tinnitus within the period of three months following previous surgery, three patients complained primarily of postoperative vertigo, and one patient experienced severe tinnitus with vertigo in an ear which was already deaf for several years as a complication that occurred a few months after previous primary surgery in another clinic. The follow-up periods ranged from 6 weeks to 122 months with an average of 18.8 months. Eighty-four percent had a follow-up period of more than 1 year.

Intraoperative findings and causes of failure.

The intraoperative findings at the time of revision surgery are summarised in Table 1. In some cases more than one finding was identified that could have lead to the failure of the previous operation. In such cases we selected the factor that in our opinion was the most likely cause of failure. For example in an ear with many adhesions but also with necrosis of the long process of the incus, we selected the incus necrosis as the major factor for recurrence of conductive hearing loss.

Problems with the prosthesis were the most common cause of failure in 41.8 %. Table 2 summarises the variety of prostheses found during revision in relation to the time of revision surgery, to the cause of failure, to the condition of the incus, and to the number of replaced prostheses. Full Teflon pistons, Teflon-wire pistons and metal wire pistons were the most frequently detected prostheses. Dislocation occurred in 11 cases at the level of the oval window, in 4 cases at the long process of the incus and in another 6 cases both at the incus and oval window (Table 1). An inappropriate prosthesis length was the cause of failure in 9 cases. A prosthesis that was too loose was found in 3 cases.

Another important cause of failure is a severe erosion of the long process of the incus in 12.7 % of the revision cases (Table 1). This problem occurred most frequently between 1 and 10 years after insertion of a metal wire prosthesis and a Teflon wire prosthesis in 2 and 8 cases, respectively (Table 2). Incus necrosis was also more frequently seen in multiple revision cases; 4 ears had previously one or more revisions.

Table 1. Intraoperative findings of revision surgery.

	N	%
Condition cavum tympani & tympanic membrane (n = 79)		
Fibrous adhesions in middle ear cavity	43	54.4
Tympanic membrane perforation	1	1.3
Tympanic membrane retraction	2	2.5
Chlolesteatoma	2	2.5
Anatomical obstacles (n= 79)		
Facial nerve overhang	2	2.5
Massive oval window otosclerosis	1	1.3
Condition chorda tympani (n = 79)		
Intact	66	83.5
Not intact	13	16.5
After revision surgery intact	62	78.5
After revision surgery not intact	17	21.5
Condition of incus (n = 79)		
Intact	61	77.2
Necrosis of long process	10	12.7
Subluxation	1	1.3
Fixed	4	5.1
Missing	3	3.8
Prosthesis related problems (n = 79)		
No prosthesis present	15	19.0
Displaced at incus	4	5.1
No attachment to incus because of necrosis long process	10	12.7
Displaced at oval window	11	13.9
Displaced at incus and oval window	6	7.6
Too short	9	11.4
Loose	3	3.8
Fixed	6	7.6
Condition of oval window and footplate (n = 79)		
Intact stapes but fixed after previous mobilisation	6	7.6
Reobliteration of otosclerosis in oval window	5	6.3
Fibrous tissue in oval window	17	21.5
Granuloma tissue in oval window	5	6.3
Inadequate removal of footplate/Inadequate hole	7	8.9
Depressed footplate in vestibule	1	1.3
Perilymph fistula/leak	3	3.8

Table 2. Initial prostheses, timing to revision, cause of failure, and eventual prostheses replacement.

Initial Prosthesis	No	Time to Revision < 1 year	1-10 years	> 10 years	Prosthesis problems DP	SP	Loo	Incus erosion	Prothesis replaced
Full Teflon piston	20	5	14	1	4	4	1	-	16
Gold piston	3	1	2	-	2	-	-	-	2
Platinum piston	1	-	1	-	-	-	-	-	1
Teflon Cup piston	4	1	1	2	3	1	-	-	4
Teflon-Wire piston	18	2	14	2	3	1	2	8	17
Metal wire piston	13	2	6	5	4	2	-	2	13
Fat-wire piston	1	1	-	-	1	-	-	-	1
Stainless steel piston	3	-	3	-	2	1	-	-	3
Polyethyleen tube	1	-	-	1	1	-	-	-	1
Totals	64	12	41	11	21	9	3	10	58

DP = displaced prosthesis, SP = short prosthesis, Loo = loose prosthesis.

Adhesions in the middle ear cavity were a common finding in 54.4 % of the cases. However, in only 8 cases (10.1 %) it was considered as the main cause of failure because many dens fibrous adhesions were adherent to the prostheses which lead apparently to a fixation of the prosthesis in 6 cases and to a displacement in 2 cases. Cholesteatoma was found in the middle ear cavity of two ears, and was the main cause of failure in one case. One ear showed a small tympanic membrane perforation, while in two cases a severe retraction of the tympanic membrane was present. An intact chorda tympani was identified in 66 ears and it remained intact in 62 cases after revision surgery.

In 2 cases an extreme facial nerve overhang appeared as an anatomical obstacle, restraining the previous surgeon to insert a prosthesis. In one case the previous surgeon caused a subluxation of the incus which was the reason for not inserting a prosthesis at that moment. Previously unidentified epitympanic fixation of the incus and malleus was encountered in 4 cases.

During revision surgery the oval window region was thoroughly examined. An intact but fixed stapes was found in the 6 ears that previously underwent a mobilisation procedure of the stapes. An intact oval window niche without markedly pathology was found in 29 cases: 14 with the prosthesis in the right position and 15 with a displaced prosthesis at the oval window. A profuse reobliteration of the oval window region was seen in 5 cases and it was considered as the main cause of failure in 2 cases. In one case the overgrowth of otosclerotic foci was extremely severe causing an anatomical obstacle for making a fenestra in the stapes footplate by the previous surgeon. Fibrous tissue covering the oval window niche was a common finding (21.6 %) but in itself would not cause conductive hearing loss. Granuloma tissue in the oval window niche was seen in 5 cases. In 3 cases an inadequate hole in the stapes footplate was encountered which precluded a satisfactory hearing improvement. In one case a depressed footplate in the vestibule was identified. In the group of 5 patients who were considered for revision because of the suspicion of a perilymph fistula, there were three cases with a leakage of perilymph through the fenestra in the footplate while in 2 cases a leakage could not be detected.

Operative solutions.
Several operative techniques were used to restore the transmission function of the middle ear depending on the situation found during revision surgery. When present, middle ear adhesions were lysed carefully with microscissors. The initial stapes prosthesis was carefully examined and the displaced or malfunctioning prosthesis was removed. The mobility of the malleus and incus was assessed by palpation. The oval window niche was explored and the previous fenestra in the stapes footplate inspected. Fibrous tissue in the oval window niche was carefully removed with conventional instruments. Laser surgery was not performed in this series. If necessary, the fenestra in the stapes footplate were enlarged or a new hole was created. If a perilymph fistula was revealed, it was covered with fat tissue and fibrin glue to stop the leakage.
In the group of 64 ears with a prosthesis present during revision, the prosthesis was replaced by a new one in 58 cases. When the incus was usable for repair, the prostheses used for reconstruction were a full Teflon piston (type Causse® in 44 cases and type Cawthorne® in 4 cases), or a pure gold piston (K-piston® in 15 cases) and a Teflon-wire prosthesis (type Schuknecht® in 1 case) . In the 15 cases with a severe erosion of the incus, a malleus handle attachment piston (type Shea®) has been inserted.[23] Prosthesis size ranged from 4 to 6 mm in length and 0.3 to 0.6 mm in diameter.
In one case with a severe erosion of the long proces of the incus, ionomer bone cement has been used to enlarge the eroded inadequate incus to allow placement of a new Teflon piston as previously described by Tange.[24]

Hearing results.
In the whole group of 79 patients there were two cases with severe vertigo and tinnitus without any hearing perception before revision surgery. After the revision operation the complaints of vertigo and tinnitus declined, although the hearing did not improve. Because these two cases were considered as dead ears preoperatively, they were excluded from analysis of audiometric data. In the remaining group of 77 ears, 92.2 % had an improvement in hearing. The mean AC for the PTA at 0.5, 1, 2, and 4 kHz was preoperatively 55.9 dB (SD ± 14.0 dB) which improved to 33.3 dB (SD ± 15.0 dB) after surgery. The preoperative ABG for the same frequency range was on average 31.4 dB (SD ± 11.8 dB) and postoperatively improved to 11.8 dB (SD ± 8.5 dB).
Table 3 shows the number of cases with ABG values within different categories, calculated for the method recommended by the Committee on Hearing and Equilibrium[22] as well as for the traditional method to make comparison with other studies possible. Using the new method (i.e. taking the difference of postoperative AC and BC values), 46 ears (59.7%) had ABG closure to within 10 dB. A postoperative ABG within 20 dB was obtained in 65 cases (84.4 %). In two cases, postoperative ABG was greater than 30 dB (incidence, 2.6 %). Using

the traditional method for accounting postoperative ABG (i.e. substracting preoperative BC from postoperative AC) an ABG closure to 10 dB or less was obtained in 49 ears (63.6 %), and it was closed to within 20 dB in 64 ears (83.1 %). In our study the difference between the two methods with regard to mean postoperative ABG was statistically significant (Wilcoxon-test, $p < 0.001$).

Table 3. Postoperative air-bone gap (ABG) using the revised and traditional calculation methods.

Hearing level (dB)	0.5, 1, 2, 4 kHz*		0.5, 1, 2 kHz#	
	n	%	n	%
≤ 10 dB	46	59.7	49	63.3
11-20 dB	19	24.7	15	19.5
21-30 dB	10	13	8	10.4
> 30 dB	2	2.6	5	6.5

* Postoperative ABG computed with postoperative AC and postoperative BC.
\# Postoperative ABG computed with postoperative AC and preoperative BC.

In 80.5 % of the revision cases the BC threshold (1, 2, 4 kHz PTA) did not change more than 10 dB. Overclosure was obtained in 18 cases (23.4 %) while serious SNHL occurred in one ear (1.3 %) that underwent revision surgery for the first time. The decline of 11.7 dB for BC in this ear, however, did not affect SDS which remained at 100 %. Overall, the mean improvement in BC was statistically significant (Wilcoxon-test, $p < 0.001$) being 3.5 dB (SD ± 6.9 dB, n = 77).

Postoperative SRT and SDS were available in 73 patients for comparison to preoperative scores. Before revision the hearing measured by SRT on average was 74.9 dB (SD ± 13.8 dB) and after revision the average was 54.3 dB (SD ± 16.0 dB) showing an average improvement of 20.6 dB (SD ± 16.8 dB). This value is in agreement with the mean improvement in AC for the frequency range 0.5-4 kHz, which is 22.6 dB (SD ± 15.9 dB). The average SDS preoperatively was 97 % (SD ± 7.6 %) which improved after revision to the average of 98.3 % (SD ± 5.2 %) for the same ears. SDS did not changed over more than 10 % in most of the revision cases. One ear developed a dramatic improvement of its SDS; there was an increase from 42 % preoperatively to 79 % postoperatively. A decline in SDS of more than 10 % occurred in 2 cases (2.7%). One ear with a decline of 17 % in SDS had revision surgery for the fourth time, and postoperatively a decrease of 5.0 dB in BC occurred while the ABG improved to 16.3 dB. The other case, who had revision surgery for the first time, showed a decline of 15 % in its SDS, with a decrease of 8.3 dB in BC and a remaining ABG of 30 dB. Overall, the changes in SDS were not statistically significant.

We have analysed the audiometric results also for subgroups. The mean postoperative ABG in the first revision group was 11.4 dB (SD ± 8.8, n = 65) and not statistically different (Mann-Whitney test, $p = 0.199$) from the mean postoperative ABG of 13.6 dB (SD ± 6.9, n = 12) in the multiple revision group with one or more prior revisions. The percentages of ears with ABG closure to within 10 dB are comparable for first and second revisions which were

55.4 % and 57.1 %, respectively (Table 4). However, none of the ears that underwent revision for the third or fourth time had ABG closure to within 10 dB.

Table 4. Number of revisions and postoperative hearing results*.

Hearing level (dB)	First revision		Second revision		Third revision or more	
	n	%	n	%	n	%
≤ 10 dB	41	55.4	4	57.1	-	-
11-20 dB	14	29.2	3	42.9	3	60.0
21-30 dB	8	13.8	-	-	2	40.0
> 30 dB	2	1.5	-	-	-	-

* Postoperative ABG computed with postoperative AC and BC averaged at 0.5, 1, 2, and 4 kHz.

The ability to obtain ABG closure was in some extent dependent on the availability of a usable incus. When the incus is usable for repair, a Teflon piston or gold piston was inserted, and in those cases an ABG closure to within 10 dB was achieved in 61.0 %. No significant differences were present between the Teflon and gold pistons. If the incus was not usable for repair, a malleus attachment prosthesis was used for repair, and an ABG closure to within 10 dB was seen in only 46.7 % (Table 5), while in 26.6 % it was not possible to close the gap to within 20 dB. The remaining ABG in the group with a not usable incus was on average 11.2 dB (SD ± 7.6), which is not significantly (Mann-Whitney test, $p = 0.136$) lower than the average value of 15.5 dB (SD ± 11.6, n = 15) in the group with a usable incus.

Table 5. Type of prosthesis and hearing results*.

Hearing level (dB)	Teflon piston (n = 47)		Gold piston (n = 15)		Malleus handle piston (n = 15)	
	n	%	n	%	n	%
≤ 10 dB	31	66.0	8	53.3	7	46.7
11-20 dB	9	19.1	6	40.0	4	26.7
21-30 dB	7	14.9	1	6.7	2	13.3
> 30 dB	-	-	-	-	2	13.3

* Postoperative ABG computed with postoperative AC and BC averaged at 0.5, 1, 2, and 4 kHz.

Hearing results were also analysed with regard to the primary indication for revision. In the subgroup of ears with recurrent conductive hearing loss and persistent conductive hearing loss as the indications for revision, the postoperative ABG was on average 11.0 dB (SD ± 7.8 dB, n = 62) and 18.2 dB (SD ± 18.2 dB, n = 11), respectively. This difference is statistically significant (Mann-Whitney test, $p = 0.035$). Furthermore, only 36.4 % of the cases with persistent hearing loss had ABG closure to within 10 dB (Table 6). The postoperative ABG in the group with vertigo as the operative indication was on average 6.3 dB (SD ± 3.8, n = 3). However, the number of cases with vertigo was too small for statistical comparison.

Table 6. Indication for revision surgery and postoperative hearing results*.

Hearing level (dB)	Recurrent chronic hearing loss		Persistent chronic hearing loss		Vertigo	
	n	%	n	%	n	%
≤ 10 dB	38	61.3	4	36.4	2	66.7
11-20 dB	17	27.4	2	18.2	1	33.3
21-30 dB	6	9.7	4	36.4	-	-
> 30 dB	1	1.6	1	9.1	-	-

* Postoperative ABG computed with postoperative AC and BC averaged at 0.5, 1, 2, and 4 kHz.

Discussion

Although many articles have been written about primary stapes surgery, publications dealing with revision stapes surgery are less numerous. From 1980 to 1998 about 20 articles evaluating revision surgery have been appeared in the English language literature. An important review of the literature was provided by Han et al.[17] For the present study more detailed data about intraoperative findings have been collected and the review was updated with the reports that appeared in 1997 and 1998. The most common intraoperative findings from these reports are summarised in Table 8. The number of reviewed revision operations varies between the studies from 35 to 337 cases. The incidence of the findings encountered in this study were comparable to this series.[1-20] Some reports have stressed a single major cause of failure, while others have recognised that several factors may contribute to deterioration of hearing or to vestibular symptoms.

Since revision surgery presents more pathological variables, the surgeon must master less stereotyped surgery as the method of repair is almost always dictated by the pathological findings at the time of the revision. Therefore, revision stapes surgery is more technically challenging in comparison with primary stapes surgery. Consequently, hearing results of revision stapes procedures are less predictable compared with those of primary surgery. Factors which may interfere with successful results include the initial cause of failure leading to revision, revision number, the type of prosthesis previously used and the presence of a usable incus for repair. Audiometric outcomes of the reviewed studies are summarised in Table 7.

In most reports a dislocated prosthesis is the most common cause of failure with an incidence ranging from 4.8 % to 82 %, which encompasses our incidence of 26.6 %.[1-20] The most common type of displacement is a dislocation from oval window area, followed by a detachment from the incus in combination with a dislocation from the oval window. Prosthesis displacement probably was not related to prosthesis type, since there was an equivalent incidence of this complication for the various prosthesis types. The rate of extrusion or displacement for each type of prosthesis is difficult to determine from previously published series. We could confirm the finding of Somers et al.[19] that a dislocation at the oval window is more frequently seen after a previous total stapedectomy than after small fenestra stapedotomy technique. In our series a dislocation of the prosthesis at the oval window occurred in 46 % (6/13) after previous total stapedectomy while it was encountered in 29 % (15/51) of the stapedotomy revisions. Probably this difference can be explained by the fact that after total removal of the footplate, the lower end of the prosthesis is not restrained by the rim of the fenestra created in the footplate as is the case after stapedotomy procedures.

Long process resorption was reported in every series, with an incidence ranging from 4.4 % to 41 % of cases.[1-20] It occurred in various degree of severity in 12.7 % of the revision cases in present study and was more often associated with multiple revisions. In every case with incus erosion, it was found after insertion of a wire-type prosthesis. Incus necrosis is most probably to be ascribed to devascularization of the mucosa over the lenticular process by the repetitive movements of the prosthesis wire, a more likely event if the crimp is not perfect. A greater risk of incus erosion with a wire-type prosthesis was also found in other reports.[9,17] The ear with a severe erosion of the long proces that was reconstructed with ionomer bone cement to allow placement of a new Teflon piston (see Results), had a good short term postoperative hearing result with ABG closure within 10 dB.[24] However, it unfortunately appeared that a recurrence of conductive hearing loss occurred after 3 years without extrusion of the prosthesis.

The presence of fibrous adhesions is a common finding during revision but it could be identified as the main cause of failure in only 8.9 % in this study. Adhesion fixing the ossicles and prosthesis have also been reported in previous series.[2-4,7,14,16,17,19,20] Our approach to this problem is conventional by cutting away the adhesions with microscissors and, if necessary, replacing the prosthesis. To avoid new adhesions the surgical procedure must be performed with the least trauma possible.

The most common oval window finding was a fibrous tissue obliterating the oval window niche, present in 21.5 % of our cases. However, in none of the cases it was identified as the main cause of precluding a satisfactory result. Several studies advocate the use of laser surgery with KTP, CO2, or argon lasers, by vaporizing fibrous tissue obliterating the oval window to minimize the risk of trauma to the inner ear.[8,12,16] In our experience, fibrous tissue covering the oval window can be carefully and safely removed with conventional instruments and the low incidence in our series of severe SNHL (1.3 %) did not motivate us for changing our conventional policy.

Bony regrowth was encountered in 6.3 % of our cases but was recognised as the main factor of failure in only two cases (incidence 2.6 %). This prevalence is lower than in other reported series.[1-20] When re-fixation of the stapes after a previous mobilization procedures is included, the incidence would be 14 % which is in the median of the reported range of 1.2 % to 24.3 % by the previous reports. Perilymphatic fistula was discovered in 3.8 % of patients, which is on the lower side of the reported range of 1.6 % to 12.5 %. Perilymphatic fistula have been associated with postoperative hearing loss as was the case in two patients in our series.

Table 7. Review of the literature: intraoperative findings.

Author (year)	n	Host response		Oval window			Prosthesis problems			
		FA (%)	IE (%)	PF (%)	BR (%)	FT (%)	DP (%)	SP (%)	Loo (%)	Lon (%)
Crabtree et al.[1] (1980)	35	-	17.1	8.6	11.4	-	45.7	-	14.3	-
Lippy et al.[2] (1980)	63	4.8	31.7	1.6	3.2	-	4.8	7.9	-	1.6
Sheehy et al.[3] (1981)	258	3	5	9	9	-	41	9	-	-
Pearman et al.[4] (1982)	95	7.4	25.3	3.2	5.3	6.3	32.6	4.2	3.2	-
Derlacki[5] (1985)	217	-	30.0	9.7	9.7	2.3	82.0	-	-	-
Glasscock et al.[6] (1987)	79	-	19	9	8	6	30	8	-	2.5
Bhardwaj et al.[7] (1988)	120	18.3	5.0	1.6	14.1	-	30.8	6.6	6.6	11.6
Lesinski et al.[8] (1989)	59	-	16.9	11.9	-	-	62.7	13.6	3.4	-
Farrior et al.[9] (1991)	109	-	27.5	11.9	8.3	-	43.1	-	-	-
Vartiainen et al.[10] (1992)	45	-	4.4	-	13.3	-	13.3	-	-	-
Prasad et al.[11] (1993)	66	-	31.8	-	21.2	-	59.1	-	-	-
McGee et al.[12] (1993)	77	-	11.7	-	14.3	20.8	42.9	5.2	-	-
Langman et al.[13] (1993)	66	-	40.9	6.1	9.1	-	48.5	-	-	-
Pedersen[14] (1994)	186	28.0	11.3	3.2	16.1	-	28.5	9.1	7.0	2.2
Cokkeser et al.[15] (1994)	56	-	17.9	3.6	14.3	23.2	32.1	8.9	-	3.6
Silverstein et al.[16] (1994)	72	29.2ϕ	29.2	12.5	12.5	8.3	52.8	5.6	8.3	4.2
Han et al.[17] (1997)	74	-	43.2	5.4	24.3	44.6	58.1	-	9.5	1.4
Magliulo et al.[18] (1997)	63	-	14.6	5.6	6.7	15.7	28.0	10.1	-	7.9
Somers et al.[19] (1997)	226	12.8	28.3	6.6	4.9	-	9.7	2.7	16.4	4.0
Hammerschlag et al.[20] (1998)	250	13.6	14.0	2.0	1.2	-	24.4	14	-	0.8
Present series	79	8.9ϕ	12.7	3.4	6.3	21.5	26.6	11.4	3.8	0

ϕ Adhesions fixing the prosthesis or ossicles.
n = number of cases the calculation was based on; FA = fibrous adhesions; IE = incus erosion; PF = perilymph fistula; BR = bony regrowth; FT = fibrous tissue; DP = displaced prosthesis; SP = too short prosthesis; Loo = loose prosthesis; Lon = too long prosthesis.

The general consensus from reports dealing with revision stapes operations is that the audiometric outcome after revision is less successful than after primary surgery. A successful result is defined as closure of the ABG to within 10 dB and in the previously reported series, this was achieved in 18% to 80% of the cases.[1-20] Our success rate of 64 % is quite favourable compared to other series. The postoperative hearing was considered to be improved when the ABG is closed to within 20 dB. This was reported in the range of 54% to 92% by various authors.[1-20] In our series this was achieved in 83 % of the cases. When postoperative ABG is computed with AC and BC thresholds of the same postoperative audiogram (as recommended by the Committee on Hearing and Equilibrium[22]) using a four frequency PTA at 0.5, 1, 2, and 4 kHz, the success rate is somewhat poorer: 60 % for successful result. However, improved hearing was still obtained in 84 % of the cases .

Table 8. Review of the litarature: hearing results*.

			Air-bone gap closure		SNHL	Dead ear
Author (year)	N	n	≤ 10 dB	≤ 20 dB	(%)	(%)
Crabtree et al.[1] (1980)	35	35	46	-	-	14.3
Lippy et al.[2] (1980)	92	63	49	54	-	-
Sheehy et al.[3] (1981)	258	214	44δ	71δ	7	3.3
Pearman et al.[4] (1982)	95	83	53	-	2.4	-
Derlacki[5] (1985)	217	217	60	72	4.1	1.4
Glasscock et al.[6] (1987)	82	79	39	64	2.5	1.3
Bhardwaj et al.[7] (1988)	120	100	44φ	-	12.0	2.0
Lesinski et al.[8] (1989)	59	59	66μ	89μ	0	0
Farrior et al.[9] (1991)	109	102	57	84	-	-
Vartiainen et al.[10] (1992)	45	44	46	70	4.4	2.2
Prasad et al.[11] (1993)	66	41	46μ	78μ	7.6	0
McGee et al.[12] (1993)	185	77	81	92	2.6§	0
Langman et al.[13] (1993)	66	62	61δ	84δ	3.2	0
Pedersen[14] (1994)	186	163	-	-	1.2	1.6
Cokkeser et al.[15] (1994)	56	49	17π	60π	10.2	4.1
Silverstein et al.[16] (1994)	72	61	46	62	10	1.6
Han et al.[17] (1997)	74	60	52	82	4.1	1.3‡
Magliulo et al.[18] (1997)	63	63	24π	59π	-	3.2
Somers et al.[19] (1997)	332	232	40	64	1.3	0
Hammerschlag et al.[20] (1998)	337	250	80λ	85λ	0.8†	0
Present series	79	77	64	83	1.3	0

* Using postoperative AC minus preoperative BC average at 0.5, 1, 2 kHz, unless otherwise noted.
δ Using best BC threshold for accounting postoperative ABG.
φ ABG closure to within 15 dB.
μ Using a four frequency PTA at .5, 1, 2, and 3 kHz.
π Using a four frequency PTA at .5, 1, 2, and 4 kHz.
λUsing postoperative AC and BC for accounting postoperative ABG.
‡ Delayed sudden SNHL after 13 months of hearing improvement.
† SNHS defined as a drop in SDS of more than 25 %.
§ SNHL defined as drop in AC of 10 dB or more at 4 kHz.
N = total number of cases in the study; n = number of cases the calculation was based on

The wide range of successful outcomes in the literature must be interpreted as a result of the large variation of the studied population and surgical techniques. These are depending on the primary surgical technique, the selection criteria for revision, the relative number of cases with primary surgery performed by another surgeon and the relative number of second or more revisions. Therefore, some caution is necessary for direct comparison of the percentages of successful results in different studies. In this context, another influencing factor is that only recently published articles reviewing revision surgery have analysed their results using the guidelines of the Committee on Hearing and Equilibrium[22], while the other studies were published before calculating method for hearing results was standardised. In this study the difference with regard to mean postoperative ABG computed with the two methods was statistically significant. In another study we have analysed our audiometric data of 451 stapes operations (primary and revision cases) revealing that choice of pre- or postoperative BC in computing postoperative ABG had a significant effect on the mean postoperative ABG levels, showing more favourable results when preoperative BC thresholds were used. However, choice of PTA (0.5, 1, 2 kHz vs. 0.5, 1, 2, 4 kHz) has no significant influence on the remaining postoperative ABG, and on the percentage of ears with ABG closures to within 10 dB.[25]

Reviewing the literature several factors have been reported associated with a less beneficial result with regard to hearing improvement. In this study we could confirm the findings of Han et al.[17] that when revision is performed for cases with a lack of hearing improvement after primary surgery, a significant poorer outcome was obtained compared to cases with a recurrent conductive hearing loss. Multiple revisions were not significantly associated with a poorer hearing outcome compared to first revisions in the present study, which is in agreement with other reports.[17,20] Several authors report less satisfactory hearing results in revision surgery in cases with incus necrosis.[13,19] When the incus is not available, several incus bypass techniques can be considered for reconstruction. We used a malleus Teflon piston prosthesis resulting in a success rate of 46.7 %. When the incus was usable for repair, a full Teflon piston or pure gold piston was inserted and a successful result was obtained in 61 % of the cases. This is significantly lower than when a Causse Teflon piston or a gold piston is used in primary operations; ABG is closed to within 10 dB in 80.3 % and 79 %, respectively.[26] Overall, in this study we could not find significant differences in hearing outcome between the presence or absence of a usable incus with regard to the mean postoperative ABG.

The incidence of SNHL varies between 0 % to 12.0 % in the literature.[1-20] However, SNHL is not always defined in the same manner. In some studies a significant drop in SDS was considered as SNHL[12,15], while in other studies the percentage with worse postoperative hearing is reported without specification of the ears with a decline in BC.[1,2,9] In our study, one patient (1.3 %) had postoperative decrease in the BC PTA of more than 10 dB. This was a patient referred from another hospital who previously underwent total stapedectomy. During revision it was found that the prosthesis was too short. After removing the prosthesis, a profuse perilymph leakage occurred necessitating some suction in the oval window niche which was probably related to the postoperative drop in BC of 11.7 dB. A complete loss of hearing following revision surgery was not observed in the ears of this series. It occurred in 0 % to 14.3 % in the reviewed studies.[1-20]

Conclusion

As in the reviewed series, we found the most common causes for recurrent or persistent conductive hearing loss to be prosthesis displacement, inadequate prosthesis length, incus erosion, and fibrous adhesions. Multiple revisions and the absence of a usable incus for restoration did not correlate with poorer hearing results. Revision surgery for recurrent hearing loss had significantly better results than surgery for ears that demonstrated a lack of improvement at the primary operation. Overall, success rates of post-revision stapes surgery, expressed as an ABG closure to within 10 dB and 20 dB, were 60 % and 84 %, respectively, using postoperative AC and postoperative BC PTA's. SNHS occurred in 1.3 % of the cases, whereas none of the ears showed a total loss of hearing. There is general consensus that revision stapes surgery is more technically challenging and less likely to achieve optimal postoperative hearing results. Therefore, we have the opinion that centralisation of these operations should be aimed at to guarantee the best results.

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Chapter 10

Summary and Conclusions.

Summary

This thesis concerns the clinical and audiological aspects of stapes surgery performed in patients with clinically confirmed otosclerosis. The procedures were done at the Department of Otorhinolaryngology – Head and Neck Surgery, Academic Medical Center, University of Amsterdam, in the period from 1983 to 1998.

In **chapter 1** a general introduction is presented. Firstly the definitions and several historical facts of the disease "otosclerosis" are reviewed. Subsequently aetiology, epidemiology, clinical features, and the non-surgical treatment are discussed. More extensively the fascinating history of the surgical treatment of hearing losses due to otosclerosis is described, and a short review of the current surgical techniques with the application of several prostheses is described.
Furthermore, this chapter goes into the several aspects related to the evaluation of the hearing results after stapes surgery. Reviewing the literature about stapes surgery, it appears that there exists a considerable diversity in the use of audiological parameters and criteria to establish success rates. This renders the comparison of different studies very difficult. In this context several guidelines have been drafted by various committees in order to make the reporting of hearing results more standardised.

In **chapter 2** the patient group with otosclerosis is presented who had a surgical treatment in our clinic. The acquisition of data is briefly reviewed, and subsequently the symptoms and clinical findings are discussed of the patient group who underwent primary stapes surgery. Audiometric testing of patients and analysis of audiometric data are described. Several aspects considering the hearing loss caused by clinically confirmed otosclerosis are discussed for the patient group who had primary surgery in our hospital. It appears that when the influence of physiological ageing on cochlear function is corrected according to the ISO 7029 standards, there exists a weak but significant correlation between age and the degree of BC hearing loss. When the bone-conduction (BC) thresholds are not corrected for age, a Carhart notch ≥ 5 dB was found in 66.3 % and a notch value ≥ 10 dB was found in 39.6 % of the cases. The air-bone gap (ABG) has its maximum value at 0.25 kHz (48.8 dB, SD ± 14.5) and its minimum value at 2 kHz (18.2 dB, SD ± 11.2).
After a short review of the development of surgical treatment of otosclerosis in the past 50 years at the Academic Medical Center, University of Amsterdam (previously "Wilhelmina Gasthuis"), the standard surgical technique is described which is applied in our hospital at present.
Additionally the aims of this thesis are discussed in this chapter. The main purpose of this retrospective study is to evaluate clinical and audiological results in a large series of patients with special reference to several methods of analysing audiometric data.

In **chapter 3** the consequences of choice in using several audiological parameters and criteria to establish success rates are discussed. It appears that choice of different frequencies in the pure-tone average (PTA) results in important differences in the evaluation of hearing results after stapes surgery. When the traditional three frequency PTA at 0.5, 1, and 2 kHz (so called Fletcherian index) is compared with a four frequency combination in which a higher frequency, like the 3 or 4 kHz, is included, significant differences were found in the postoperative improvement of the mean air-conduction (AC) level and ABG. Furthermore, it appears that the postoperative change in AC, calculated for a four frequency combination with a higher frequency, correlates best with the change in speech reception threshold (SRT). Because the improvement in speech perception is the most important goal in stapes surgery, the change in SRT is taken as the gold standard. Also choice of using pre- or postoperative BC in computing postoperative ABG results in significant differences when analysing the mean postoperative ABG values. Using preoperative BC results in better overall ABG values as ABG overclosure due to the Carhart effect is included. However, because the inertial component of bone conducted sound transmission is restored after surgery, the postoperative BC level corresponds better with the true cochlear function and should therefore be preferred to be used in computing postoperative ABG. Finally, the success rates are dependent on how to define success. In this perspective, the percentage of ears with a postoperative AC threshold ≤ 30 dB, also called "socially acceptable hearing", does compare best with the percentage of ears with an ABG closure ≤ 10 dB, and is a more realistic measure of success than the achievement of "normal hearing" defined as an AC threshold ≤ 20 dB.

In **chapter 4** a method is presented in which the individual results can be deduced from two plots, which we have named the "Amsterdam Hearing Evaluation Plots" (AHEPs). The first plot provides information for the effect of surgery on cochlear function, which is of special interest in reporting results after stapes surgery. A Carhart effect can occur resulting in an improvement in BC. However, because the inner ear is opened during surgery, there is also a chance of iatrogenic cochlear damage resulting in a postoperative deterioration of BC. The second plot gives information on the change in AC related to the preoperative ABG. In this perspective, a few definitions are drafted with reference to a "successful result", a "successful result with overclosure", and a "not-successful result". The number of ears with one of these three possible results can easily be deduced from the second plot.
In our opinion, the AHEPs form an easily understood visual presentation of audiometric results of individual cases and would gain additional information when it is combined with the guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology - Head and Neck Surgery. Another advantage of using the AHEPs is that hearing results with extreme audiometric values are visualised clearly. These values would influence summary statistics but are not always recognisable when presenting data with means and standard deviations.

In **chapter 5** two different stapes replacement prostheses are compared: a Teflon piston (type Causse; Xomed Surgical Products, Jacksonville, FL, USA) and a gold piston (K-piston; Heinz

Kurz GmbH Medizintechnik, Dußlingen, Germany). Both pistons have the same shaft diameter of 0.4 mm. An important difference between prostheses is the difference in weight: the gold piston is three times heavier that the Teflon piston. In this chapter it is emphasised that for a fair comparison of the transmission function of prostheses, it is important to take only the prostheses into account that are functioning normally with regard to sound transmission function. To identify the normal functioning prostheses, the "Amsterdam Hearing Evaluation Plots" can be of help. In a retrospective analysis of audiometric results obtained after implantation of 62 Teflon pistons and 66 gold pistons, it appeared that in the whole group of ears the gold piston gives a significant larger gain in AC for the frequency combination 0.5, 1, and 2 kHz and for the individual frequency at 2 kHz. However, there were no significant inter-group differences with regard to the change in BC and ABG.
When an analysis is done for the "normally" functioning prostheses, identified with the AHEPs, a trend was noticed that the heavier gold piston gives more gain in the lower frequencies and the lighter Teflon piston gives more gain in the higher frequencies. On theoretical grounds (e.g. Impedance formula) one would expect this trend.

In **chapter 6** pre- and postoperative data from speech audiometry were analysed of ears receiving primary stapes surgery, in order to evaluate the effect of surgery on speech reception. Therefore, the change in SRT, the maximum speech discrimination score (MSDS), the slope of the speech reception curve (SRC), and the occurrence of a slope decay of the SRC were examined.
It appeared that stapes surgery had no significant effect on the slope, nor on the slope decay of the SRC after MSDS has been achieved. Phonemic regression (slope decay > 0.5 %/dB) was not found before surgery, but occurred in 15 cases after surgery. This low incidence of postoperative regression was probably related to the test circumstances in quiet. In 96 % of the cases the SRT improved and correlation analysis showed that the change in SRT correlates well with the change in AC levels for the PTA at 0.5, 1, 2, and 4 kHz.
A postoperative reduction in MSDS ≥ 10 % occurred in 8 cases, while 13 cases showed an improvement ≥ 10 % in MSDS. Factors involved with the occurrence of a deterioration or improvement in speech discrimination were further elaborated. Therefore, the change in speech discrimination were related to the slopes of the preoperative pure-tone thresholds in order to examine whether postoperative loss in speech discrimination can be predicted from the configurations of preoperative pure-tone curves. In three cases a reduction in postoperative speech discrimination was thought to be related to a masking effect of the high frequencies by the low frequency elements of speech, due to an increase of the steepness of the AC curve. The increase in the steepness of the AC curve could retrospectively be predicted from the steepness of the preoperative BC curve. However, it was found that the slope of the postoperative AC threshold is not always to be predicted from the preoperative BC curve, even when technical success is achieved with gap-closure ≤ 10 dB. The reason is that either a Carhart effect or cochlear damage can occur. Therefore, it is not possible to predict a reduction in speech discrimination from the shape of the preoperative pure-tone thresholds.

In **chapter 7** results of bilaterally performed stapes surgeries are evaluated with the criteria of the "Guides to the Evaluation of Permanent Impairment" of the American Medical Association (AMA). On the basis of these criteria the degree of auditive impairment and the degree of general impairment in all patients with bilateral otosclerosis were established. Analysing results in this way gives a more disability-orientated approach, rather than a technical evaluation of results.
In order to establish the degree of auditive impairment, expressed in the percentage "Binaural Hearing Impairment" (BHI), a modification was applied to determine the "Decibel Sum of the Hearing threshold Levels" (DSHL). The "Modified DSHL" (MDSHL) was determined by totalling the AC thresholds at 0.5, 1, 2 and the mean thresholds at 2 and 4 kHz. According to the AMA criteria the general impairment, expressed in the percentage "Impairment of the Whole Person", can be derived as different categories of percentage of BHI are corresponding to certain percentages of IWP.
Analysing the pre- and postoperative values, either the BHI percentage and the IWP percentage showed an important decrease after the first operation. The justification to offer second-side surgery to patients with bilateral otosclerosis appears from a further significant decline in both the percentages BHI and IWP after the second operation. During follow-up there were no serious complications and it was concluded that bilateral stapedotomy is a safe procedure which improves the chance of achieving normal and symmetrical hearing.

In establishing the indication to perform stapes surgery, it is important to realise that a good result from a technical point of view is not always a good result in the opinion of the patient. The Glasgow Benefit Plot, designed by Browning et all, can be a valuable instrument to determine the potential functional benefit a patient can achieve from hearing improvement surgery. In doing so, the Glasgow Benefit Plot takes the hearing at both sides into consideration. In **chapter 8** we used the Glasgow Benefit Plot to judge retrospectively if it was worthwhile to perform stapes surgery in patients with bilateral otosclerosis, and particularly if it was worthwhile to do second-ear surgery at the contralateral side and consequently expose patients to the potential risk related to this type of surgery for a second time. From analysis of the bilaterally operated patient group it appears that the GBP is a valuable instrument to identify those patients in whom it is not possible to make the operated ear the better-hearing ear, because the preoperative BC thresholds are no better than the AC thresholds in the contralateral ear. In these situations the functional gain of a (n) (second) operation will be less beneficial.

In **chapter 9** a retrospective study on 79 revision stapes operations is presented. The preoperative symptoms, intraoperative findings, and surgical techniques as well as the occurrence of eventual complications are discussed. Most common causes of failures of previous stapes surgery were a dislocated prosthesis, incus erosion, inadequate prosthesis length, and fibrous adhesions. Several surgical solutions are described. The hearing results were established by computing postoperative ABG with the conventional method (postoperative AC minus preoperative BC) and with the method according to the guidelines of the American Academy of

Otolaryngology – Head and Neck Surgery (postoperative AC minus postoperative BC). The overall hearing results were favourable with an ABG closure ≤ 10 dB in 64 % and in 60 % for the first and second method, respectively. Iatrogenic sensorineural hearing loss occurred in 1.3 % of the cases. In this chapter the intraoperative findings as well as the hearing results were compared with those found in the literature.

Conclusions

Based on the results of this study, the following can be concluded.

1. The overall results of stapes surgery in the Academic Medical Center, University of Amsterdam are comparable with the results reported by other authors in the literature. The use of different parameters and criteria in the evaluation of hearing results after stapes surgery can result in significant differences and should therefore not be underestimated. In this respect it is to be recommended to calculate PTAs for four-frequency combinations at 0.5, 1, 2, and 3 or 4 kHz. For computing postoperative ABG it is to be recommended to use postoperative BC, as the postoperative BC threshold represents the true cochlear function. For the definition of success rate, the percentage of ears with ABG closure ≤ 10 dB appears to be a good measure of technical success.
2. The application of the "Amsterdam Hearing Evaluation Plots" (AHEPs) in the evaluation of hearing results, gives an easily understood visual presentation of the technical result of each ear operated on. The plots can be used for stapes surgery, but likewise for other types of hearing improvement surgery.
3. Implantation of the Teflon piston (type Causse) and the gold piston (K-piston) gives comparable good results. The use of the heavier gold piston tends to give better sound transmission in the lower frequencies and on the other hand insertion of the lighter Teflon piston tends to result in a better transmission function in the higher frequencies, with the cross-over frequency between 3 and 4 kHz.
4. Speech audiometry should be involved more frequently in the evaluation of hearing results after stapes surgery. It is especially important to be informed about the change in maximum speech discrimination. From our study it appears that preoperatively it is not possible to identify a group of patients who are at risk for a loss in speech discrimination after surgery.
5. To obtain a more handicap orientated evaluation of hearing results after stapes surgery, the application of the criteria of the American Medical Association (AMA) forms a useful method. The AMA-criteria are internationally used to establish auditive handicap and this is expressed in a percentage.
6. The use of the Glasgow Benefit Plot forms a useful method to establish patient's benefit of stapes surgery. Therefore, it can be of value to establish the indication for stapes surgery and particularly in establishing the indication for second-ear surgery in the contralateral ear in cases of bilateral hearing losses due to otosclerosis.
7. Revision surgery goes along with more pathological variables, and, therefore, a greater expertise of the surgeon is necessary. The results of revision stapes surgery in our clinic

are in agreement with the results of other experienced surgeons, although less good compared to primary surgery. They give support to continue the policy to offer revision surgery to patients, even when previous revision surgeries have been performed.

Samenvatting

In dit proefschrift worden klinische en audiologische aspecten beschreven van stapes chirurgie uitgevoerd bij patiënten met klinisch bewezen otosclerose. De ingrepen werden uitgevoerd in de periode van 1983 tot 1998 op de afdeling Keel-, Neus- en Oorheelkunde / Heelkunde van het Hoofd-Halsgebied van het Academisch Medisch Centrum, Universiteit van Amsterdam.

In **hoofdstuk 1** wordt een algemene inleiding gegeven. Allereerst wordt ingegaan op de definitie en enkele historische feiten met betrekking tot de aandoening otosclerose. Vervolgens worden achtereenvolgens de etiologie, de epidemiologie, de klinische kenmerken en de niet chirurgische behandeling van otosclerose beschreven. Uitgebreider wordt ingegaan op de fascinerende geschiedenis van de chirurgische behandeling van gehoorverliezen door otosclerose, waarbij tevens een kort overzicht wordt gegeven van de huidige chirurgische technieken met gebruik van verschillende prothesen.
Verder wordt in dit hoofdstuk ingegaan op de verschillende aspecten gerelateerd aan het evalueren van gehoorresultaten na stapes chirurgie. Bij het doornemen van de literatuur over stapes chirurgie blijkt dat er een aanzienlijke diversiteit bestaat in het gebruik van audiologische parameters en criteria voor het analyseren van de succespercentages, waardoor het zeer moeilijk wordt om de verschillende studies met elkaar te vergelijken. In dit verband zijn er in het verleden verschillende richtlijnen opgesteld door diverse commissies met als doel om tot een meer gestandaardiseerde rapportage te komen van gehoorresultaten.

Hoofdstuk 2 beschrijft de patiëntengroep met otosclerose die een chirurgische behandeling hebben ondergaan in onze kliniek. Kort wordt ingegaan op de wijze van data acquisitie en vervolgens worden de symptomen en klinische bevindingen van de patiëntengroep beschreven die een primaire stapes operatie hebben ondergaan. Het audiometrisch testen van de patiënten en het analyseren van de audiologische data worden behandeld. Verschillende aspecten m.b.t. het gehoorverlies veroorzaakt door klinisch bewezen otosclerose worden beschreven voor de patiëntengroep die een primaire stapes operatie hebben ondergaan in onze kliniek. Daarbij blijkt dat wanneer de invloed van de fysiologische veroudering op de functie van de cochlea wordt gecorrigeerd volgens de ISO 7029 standaarden, een zwakke maar significante correlatie bestaat tussen de leeftijd en de beengeleidingsdrempels. Indien de beengeleidingsdrempels niet worden gecorrigeerd voor de leeftijd, wordt een Carhart notch van $\geq$ 5 dB gevonden in 66.3 % en een Carhart notch van $\geq$ 10 dB in 39.6 %. De air-bone gap heeft zijn grootste waarde bij 0.25 kHz (48.8 dB, SD $\pm$ 14.5) en zijn kleinste waarde bij 2 kHz (18.2 dB, SD $\pm$ 11.2).
Na een kort overzicht van de ontwikkelingen van de chirurgische behandeling van otosclersose in de afgelopen 50 jaar in het Academisch Medisch Centrum, Universiteit van Amsterdam (voorheen "Wilhelmina Gasthuis"), wordt vervolgens de huidige standaard techniek beschreven zoals die tegenwoordig in onze kliniek wordt toegepast.

Tot slot worden in dit hoofdstuk de doelen beschreven van dit proefschrift. Over het geheel is het doel van deze retrospectieve studie de klinische en audiologische resultaten te evalueren in een grote groep patiënten met speciale aandacht voor verschillende methoden voor het analyseren van audiometrische data.

In **hoofdstuk 3** worden de consequenties van de keuze van het gebruik van verschillende audiologische parameters en criteria op succespercentages geëvalueerd. Het blijkt dat de keuze van verschillende frequenties in de pure-tone average (PTA) belangrijke verschillen kunnen opleveren bij de beoordeling van de verbetering van het gehoor na stapes chirurgie. Indien de traditionele frequentiecombinatie bij 0.5, 1 en 2 kHz (zogenaamde Fletcher-index) wordt vergeleken met een frequentiecombinatie waarbij een hogere frequentie, zoals de 3 of 4 kHz, is inbegrepen, levert dat significante verschillen op voor het berekenen van de verbetering in de luchtgeleiding en air-bone gap. Verder blijkt dat de verbetering in luchtgeleiding, berekend voor een vier-frequentiecombinatie waarin de 3 of 4 kHz is inbegrepen, het beste correleert met de verbetering in de speech reception threshold (SRT). Aangezien de verbetering in spraakverstaan het belangrijkste doel is van stapes chirurgie, wordt de verbetering in de SRT beschouwd als de gouden standaard. Ook de keuze van de pre- of postoperatieve beengeleiding in het berekenen van de postoperatieve air-bone gap levert een significant verschil op bij het analyseren van de postoperatieve gemiddelde air-bone gap waarden. Het gebruik van de preoperatieve beengeleiding resulteert over het algemeen in betere air-bone gap waarden, omdat oversluiting van de air-bone gap door het Carhart effect wordt meegeteld. Echter, omdat na chirurgie de inertiële component van geluidstransmissie via de beengeleiding is hersteld, correspondeert de postoperatieve beengeleiding beter met de werkelijke functie van de cochlea en is daarom te prefereren bij het berekenen van de postoperatieve air-bone gap. Tot slot is het succespercentage afhankelijk van hoe men succes definieert. In dit opzicht komt het percentage oren met een postoperatieve luchtgeleidingsdrempel ≤ 30 dB, ook wel "sociaal aanvaardbaar gehoor" genoemd, het meeste overeen met het percentage oren met een air-bone gap sluiting ≤ 10 dB en is dit een meer realistische maat voor succes dan het bereiken van een "normaal gehoor" met een luchtgeleidingsdrempel ≤ 20 dB.

In **hoofdstuk 4** wordt een methode beschreven waarbij de individuele gehoorresultaten kunnen worden herleid vanuit een tweetal plots, die wij de "Amsterdam Hearing Evaluation Plots" (AHEPs) hebben genoemd. Daarbij geeft de eerste plot informatie over de invloed van chirurgie op de cochleaire functie, wat met name bij stapes chirurgie van belang is. Een Carhart effect kan optreden, zich uitend in een verbeterde beengeleidingsdrempel. Echter, doordat tijdens de ingreep het binnenoor wordt geopend, bestaat er ook een kans op iatrogene cochleaire schade, zich uitend in een verslechterde beengeleidingsdrempel na de ingreep. De tweede plot geeft informatie over de verandering in de luchtgeleidingsdrempel in relatie met de preoperatieve air-bone gap. Hierbij zijn een aantal definities opgesteld die betrekking hebben op een "succesvol resultaat", een "succesvol resultaat met oversluiting van de air-bone gap" en een "niet succesvol resultaat". Het aantal oren met een van deze drie resultaten kan makkelijk worden herleid uit de tweede plot.

In onze opinie resulteert het gebruik van de AHEPs in een inzichtelijke en eenvoudig te begrijpen grafische weergave van de individuele gehoorresultaten, die, indien gecombineerd met de richtlijnen van de "Committee of Hearing and Equilibrium" van de American Academy of Otolaryngology – Head and Neck Surgery, veel additionele informatie kunnen verschaffen. Een ander voordeel van het gebruik van de AHEPs is dat gehoorresultaten met extreme audiometrische waarden duidelijk worden gevisualiseerd. Deze resultaten hebben invloed op de statistiek, maar zouden minder duidelijk aan het licht komen indien data worden gepresenteerd met behulp van gemiddelden en standaard deviaties.

In **hoofdstuk** 5 worden twee verschillende stapes vervangingsprothesen met elkaar vergeleken, namelijk een Teflon piston (type Causse; Xomed Surgical Products, Jacksonville, FL, USA) en een gouden piston (K-piston; Heinz Kurz GmbH Medizintechnik, Dußlingen, Germany). Beide pistons hebben een schachtdiameter van 0.4 mm. Een belangrijk verschil tussen beide prothesen is het verschil in gewicht: de gouden piston is drie keer zwaarder dan de Teflon piston. In het hoofdstuk wordt benadrukt dat wanneer men een eerlijke vergelijking wil uitvoeren naar de transmissiefunctie van prothesen, het belangrijk is om alleen de prothesen in de analyse te betrekken die op normale wijze functioneren met betrekking tot de transmissie van geluidstrillingen. Voor het bepalen van de "normaal" functionerende prothesen kunnen de AHEPs van dienst zijn. Bij retrospectieve analyse van de audiometrische resultaten verkregen na het implanteren van 62 Teflon pistons en 66 gouden pistons, bleek dat in de gehele groep van oren de gouden piston een significant grotere winst geeft in luchtgeleiding voor de frequentiecombinatie 0.5, 1 en 2 kHz en voor de individuele frequentie bij 2 kHz. Er werden echter geen significante inter-groep verschillen gevonden met betrekking tot de verandering in de beengeleiding en air-bone gap.
Wanneer een analyse wordt uitgevoerd bij de "normaal" functionerende prothesen, geïdentificeerd m.b.v. de AHEPs, blijkt een trend waarneembaar waarbij de zwaardere gouden piston meer winst geeft in de lagere frequenties en de lichtere Teflon piston meer winst geeft in de hogere frequenties. Op theoretische gronden (o.a. de Impedantieformule) zou men deze trend ook kunnen verwachten.

In **hoofdstuk 6** worden de pre- en postoperatieve data van spraakaudiometrie geanalyseerd bij oren die een primaire stapes operatie voor otosclerose hadden ondergaan, om zo de invloed van stapes chirurgie op spraakverstaan te evalueren. Daartoe werden de veranderingen in de speech reception threshold (SRT), de maximale spraakdiscriminatie score, en de steilheid van de spraakverstaan curve onderzocht, alsmede het optreden van een afname van de spraakverstaan curve bij toenemende geluidsintensiteit.
Het bleek dat stapes chirurgie geen significante invloed had op de steilheid van de spraakverstaan curve, alsook niet op de afname van de spraakverstaan curve nadat maximaal spraakverstaan was bereikt. Fonemische regressie (afname van de curve > 0.5 %/dB) werd in geen van de gevallen gevonden voorafgaand aan de operaties, maar kwam bij 15 oren voor na chirurgie. Deze lage postoperatieve incidentie van regressie was waarschijnlijk gerelateerd aan het feit dat spraakaudiometrie in stilte werd uitgevoerd. In 96 % trad er een verbetering op

van de SRT en uit correlatie analyse bleek dat deze verandering goed correleert met de verandering in de luchtgeleidingsdrempel voor de frequentiecombinatie 0.5, 1, 2 en 4 kHz. Een postoperatieve afname in maximale spraakdiscriminatie ≥ 10 % trad op bij 8 oren, terwijl 13 oren een toename ≥ 10 % lieten zien. Factoren die mogelijk een rol spelen bij het optreden van een verlies of winst in de maximale spraakdiscriminatie werden nader onderzocht. De verandering in de maximale spraakdiscriminatie werd gerelateerd aan de steilheid van de afname van de preoperatieve drempels van toonaudiometrie als een functie van de frequentie. Op deze wijze werd onderzocht of het optreden van discriminatieverlies kan worden voorspeld op grond van de vorm van deze toonaudiometrie drempels. In drie gevallen werd een afname in spraakdiscriminatie verweten aan het maskeringseffect van lagere frequentie op hogere frequenties in het spraaksignaal. Dit zou kunnen zijn ontstaan doordat de steilheid van de luchtgeleidingsdrempel is toegenomen na de ingrepen. Deze toename van de steilheid kon in retrospectie worden voorspeld op grond van de steilheid van de preoperatieve beengeleidingsdrempel. Echter, uit de resultaten van de studie bleek dat de vorm van de postoperatieve luchtgeleidingsdrempel niet altijd kan worden voorspeld vanuit de vorm van de preoperatieve beengeleidingsdrempel, ook niet wanneer een technisch goed resultaat wordt verkregen met sluiting van de air-bone gap ≤ 10 dB. Dit komt omdat een Carhart effect danwel cochleaire schade kan optreden. Het is daarom niet mogelijk om een verlies in spraakdiscriminatie te voorspellen op grond van de vorm van de preoperatieve drempels bij toonaudiometrie.

In **hoofdstuk 7** worden de resultaten beoordeeld van dubbelzijdig uitgevoerde stapedotomieën met behulp van de criteria van de “Guides to the Evaluation of Permanent Impairment” van de American Medical Association (AMA). Op basis van deze criteria werden bij alle patiënten het percentage van de auditieve invaliditeit, alsmede het percentage algemene invaliditeit bepaald. Het op deze wijze analyseren van resultaten geeft een meer handicap georiënteerde benadering in plaats van een technische benadering van de gehoorresultaten.
Om de mate van auditieve invaliditeit, uitgedrukt in het percentage “Binaural Hearing Impairment” (BHI), te bepalen werd er een modificatie toegepast om de “Decibel Sum of the Hearing threshold Levels” (DSHL) te berekenen. De “Modified DSHL” (MDSHL) wordt daarbij berekend door de luchtgeleidingsdrempels bij 0.5, 1, 2 en de gemiddelde waarde bij 2 en 4 kHz te totaliseren. De algemene invaliditeit, uitgedrukt in het percentage "Impairment of the Whole Person (IWP), kan volgens de AMA criteria worden herleid doordat verschillende categorieën percentages van de BHI overeenkomen met verschillende percentages van de IWP.
Uit analyse van de pre- en postoperatieve waarden bleek dat zowel het BHI percentage als het IWP percentage belangrijk afnamen na de eerste operatie. De rechtvaardiging van het aanbieden van een tweede operatie aan de contralaterale zijde bij patiënten met bilaterale otosclerose, bleek uit verdere significante afnamen van beide percentages na de tweede operatie. Er traden gedurende de follow-up geen serieuze complicaties op en er werd geconcludeerd dat een bilateraal uitgevoerde stapedotomie een veilige procedure is welke de kans op het bereiken van een normaal en symmetrisch gehoor vergroot.

Bij het vaststellen van de indicatie tot uitvoeren van een stapes operatie is het van belang te beseffen dat een goed resultaat vanuit chirurgisch standpunt niet altijd hoeft te betekenen dat het resultaat gunstig is vanuit de optiek van de patiënt. De Glasgow Benefit Plot, ontworpen door Browning et al., kan een waardevol hulpmiddel zijn bij het beoordelen van de potentiële functionele winst die een patiënt kan verkrijgen na een gehoorverbeterende operatie. De Glasgow Benefit Plot houdt daarbij rekening met het gehoor aan beide zijden. In **hoofdstuk 8** hebben we gebruik gemaakt van de Glasgow Benefit Plot om retrospectief te beoordelen of het waardevol was om een stapes operatie uit te voeren bij patiënten met bilaterale otosclerose en in het bijzonder of het waardevol was om een tweede stapes operatie uit te voeren aan de contralaterale zijde met als consequentie dat de patiënt voor een tweede keer wordt bloot gesteld aan de potentiële risico's die zijn verbonden aan deze vorm van chirurgie. Uit de evaluatie van de bilateraal geopereerde patiëntengroep blijkt dat de Glasgow Benefit Plot een belangrijk hulpmiddel kan zijn bij het identificeren van patiënten met een gehoorsvermindering bij wie het niet mogelijk is om van het te opereren slechthorende oor het beter horende oor te maken, omdat de preoperatieve beengeleiding van dit oor niet beter is dan de luchtgeleidingsdrempel van het contralaterale oor. In zulke situaties zal de functionele winst van een (tweede) operatie voor de patiënt niet groot zijn.

In **hoofdstuk 9** wordt een retrospectieve studie uitgevoerd van 79 revisie stapes operaties. Daarbij worden de preoperatieve symptomen, de intraoperatieve bevindingen en de chirurgische technieken, alsmede het optreden van eventuele complicaties beschreven. De meest voorkomende oorzaken voor het falen van de eerder verrichte stapes operatie waren een gedisloceerde prothese, erosie van de incus, een inadequate lengte van de prothese en fibreuze adhaesies. Verschillende chirurgisch technische oplossingen worden beschreven. De gehoorresultaten werden beoordeeld waarbij de postoperatieve air-bone gap wordt berekend volgens de conventionele methode (postoperatieve luchtgeleiding min preoperatieve beengeleiding) en de methode volgens de richtlijnen van de American Academy of Otolaryngology – Head and Neck Surgery (postoperatieve luchtgeleiding min postoperatieve beengeleiding). De overall gehoorresultaten waren gunstig met een air-bone gap sluiting ≤ 10 dB van 64 % en 60 % voor respectievelijk de eerste methode en de tweede methode. Een iatrogene cochleaire gehoorverlies trad op in 1.3 % van de gevallen. In dit hoofdstuk worden de intraoperatieve bevindingen alsook de gehoorresultaten vergeleken met die van de literatuur.

Conclusies

Op basis van de resultaten van deze studie kan het volgende worden geconcludeerd.

1. De overall resultaten van stapes chirurgie in het Academisch Medisch Centrum, Universiteit van Amsterdam zijn overeenkomstig met andere gerapporteerde resultaten in de literatuur.
2. Het toepassen van verschillende parameters en criteria bij het evalueren van gehoorresultaten na stapes chirurgie kan belangrijke verschillen opleveren en moet derhalve niet worden onderschat. Daarbij is het aan te bevelen om voor het berekenen van het gemid-

delde toonaudiometrisch verlies een vier-frequentie combinatie te nemen bestaande uit de 0.5, 1, 2, en de 3 of 4 kHz. Voor het berekenen van de postoperatieve air-bone gap is het aan te bevelen om de postoperatieve beengeleiding te nemen, omdat de postoperatieve beengeleidingsdrempel de beste schatting geeft van de ware cochleaire functie. Voor het definiëren van succes blijkt het percentage oren met een air-bone gap sluiting ≤ 10 dB een goede maat voor technisch succes.

3. Het gebruik van de "Amsterdam Hearing Evaluation Plots" (AHEPs) bij het evalueren van gehoorresultaten resulteert in een inzichtelijke visuele presentatie van het technische resultaat van ieder afzonderlijk geopereerde oor. De plots kunnen worden gebruikt bij stapes chirurgie maar ook bij andere typen gehoorverbeterende operaties.
4. Implantatie van de Teflon piston (type Causse) en de gouden piston (K-piston) levert vergelijkbaar goede resultaten op. Het gebruik van de zwaardere gouden piston lijkt te resulteren in een betere geluidstransmissie van de lagere frequenties en daarentegen lijkt toepassing van de lichtere Teflon piston een betere transmissie in de hogere frequenties te geven, waarbij het omslagpunt zich tussen de 3 en 4 kHz bevindt.
5. Spraakaudiometrie zou vaker moeten worden betrokken bij het evalueren van gehoorresultaten na stapes chirurgie, waarbij vooral van belang is om geïnformeerd te worden over de verandering in de maximale spraakdiscriminatie. Uit onze studie bleek dat het niet mogelijk is om preoperatief een risicogroep te identificeren die meer kans heeft op verlies van spraakdiscriminatie na de ingreep.
6. Voor een meer handicap-georiënteerde evaluatie van gehoorresultaten na stapes chirurgie vormen de criteria van de American Medical Association (AMA) een geschikte methode. De AMA-criteria worden internationaal gebruikt voor het vaststellen van de auditieve handicap en deze wordt uitgedrukt in een percentage.
7. Toepassing van de Glasgow Benefit Plot vormt een geschikte methode om de baten van stapes chirurgie voor de patiënt vast te stellen. Derhalve kan het van waarde zijn bij het stellen van de indicatie voor stapes chirurgie en in het bijzonder voor het stellen van de indicatie voor het uitvoeren van een tweede operatie aan het contralaterale oor bij dubbelzijdige gehoorverliezen door otosclerose.
8. Revisie stapes chirurgie gaat gepaard met meer gevarieerde pathologie en vereist derhalve een grotere expertise van de operateur. De resultaten van revisie stapes chirurgie in onze kliniek zijn in overeenstemming met andere resultaten van ervaren operateurs, hoewel minder goed in vergelijking met die van primaire chirurgie. Ze geven ondersteuning om het beleid te continueren revisie chirurgie aan te bieden aan patiënten, ook als reeds eerdere revisie operaties zijn uitgevoerd.

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Curriculum Vitae

The author of this thesis, Arthur J.G. de Bruijn, was born on Oktober 10th, 1966 in Utrecht, the Netherlands. In the year 1985 he passed the atheneum-ß examination at the "Niels Stensen College" in Utrecht. In that year he also started the medical study at the Free University of Amsterdam and he graduated in 1990. He obtained the Medical Doctor degree in 1993 at the University of Utrecht. For a period of one year he worked as a resident at the Department of General Surgery of the "Oudenrijn Ziekenhuis" in Utrecht. In April 1994 he started his residency at the Department of Otorhinolaryngology – Head and Neck Surgery of the Academic Medical Center, University of Amsterdam (Head: Prof. P.F. Schouwenburg, M.D., Ph.D.). During the residency he started this research project in January 1997, which has resulted in the work presented in this thesis. After his certification as an Otorhinolaryngologist in December 1999, he became a staff-member at the Department of Otorhinolaryngology – Head and Neck Surgery of the Academic Medical Center, University of Amsterdam. He is married to Hedwig P.A.H. de Bruijn – van Gennip and they have one daughter, Laura Anna.

De auteur van dit proefschrift, Arthur J.G. de Bruijn, werd op 10 oktober 1966 geboren te Utrecht. In 1985 behaalde hij zijn atheneum-ß diploma aan het Niels Stensen College te Utrecht. In dat zelfde jaar werd aangevangen met de studie Geneeskunde aan de Vrije Universiteit te Amsterdam, welke in 1990 werd afgerond. In 1993 behaalde hij zijn arts-diploma aan de Rijks Universiteit Utrecht. Voor een periode van één jaar werkte hij als arts-assistent chirurgie in het Oudenrijn Ziekenhuis te Utrecht. Sinds 1994 is hij werkzaam op de afdeling Keel-, Neus- en Oorheelkunde / Heelkunde van het Hoofd-Halsgebied in het Academisch Medisch Centrum, Universiteit van Amsterdam (Hoofd: prof. dr. P.F. Schouwenburg). Tijdens de opleiding tot Keel-, Neus- en Oorarts werd in januari 1997 gestart met onderhavig research project, welke resulteerde in dit proefschrift. Sinds de voltooiing van de opleiding in december 1999, is hij werkzaam als staflid op de afdeling Keel-, Neus- en Oorheelkunde / Heelkunde van het Hoofd-Halsgebied in het Academisch Medisch Centrum, Universiteit van Amsterdam. Hij is getrouwd met Hedwig P.A.H. de Bruijn – van Gennip en zij hebben één dochter, Laura Anna.

STELLINGEN

behorend bij het academisch proefschrift

Clinical and Audiological Aspects of Stapes Surgery in Otosclerosis

in het openbaar te verdedigen
op woensdag 29 november 2000 des namiddags te 14.00 uur

door

Arthur Jacobus Gerardus de Bruijn

1. Bij het beschrijven van de gehoorresultaten na stapes chirurgie is het aan te bevelen om voor het berekenen van het gemiddelde toonaudiometrische verlies een vier-frequentie combinatie te nemen bestaande uit de 0.5, 1, 2, en de 3 of 4 kHz.

2. Bij stapes chirurgie geeft de postoperatieve beengeleiding de beste schatting van de ware cochleaire functie. Derhalve is het aan te bevelen om bij het beschrijven van de gehoorresultaten, de postoperatieve air-bone gap te berekenen door het verschil te nemen tussen de postoperatieve luchtgeleiding en de postoperatieve beengeleiding.

3. Het evalueren van gehoorresultaten met behulp van de "Amsterdam Hearing Evaluation Plots" (AHEPs) is een verfijnde methode om het chirurgische succes te bepalen en om de spreiding van individuele resultaten van verschillende populaties met elkaar te vergelijken.

4. Bij het vaststellen van de indicatie tot uitvoeren van een stapes operatie is het van belang te beseffen dat een goed resultaat vanuit chirurgisch oogpunt niet hoeft te betekenen dat het resultaat goed is vanuit de optiek van de patiënt.

5. Wil men de invloed van gewicht of andere eigenschappen van stapes vervangingsprothesen met betrekking tot de transmissiefunctie onderzoeken, dan is het van belang dat de prothesen optimaal zijn gepositioneerd.

6. Spraak audiometrie zou vaker moeten worden betrokken bij het evalueren van gehoorresultaten na stapes chirurgie.

7. Communicatie heeft niet genoeg aan woorden, het verdient verklankt te worden. Die klank *hoort* opgevangen te worden en te worden geïnterpreteerd. (W.A. Dreschler, Zoals het hoort, Oratie, 1995).

8. Aangaande reconstructieve oorchirurgie: het is wenselijk om naast het beste resultaat ook het gemiddelde maar vooral ook het slechtste resultaat te publiceren.

9. Bij het verrichten van wetenschappelijk onderzoek naast de opleiding tot medisch specialist, is het niet zo dat je de draad weer oppakt daar waar het de vorige keer geëindigd is. Vaak ben je tijden bezig dit stukje draad weer te vinden.

10. Een patiënt met een rhinophyma neem je snel bij de neus.

11. Een hedendaags zorgwekkend probleem in de zorgsector is dat de duur betaalde bestuurder voor die ene daadwerkelijke beslissing per jaar waarvoor hij is aangenomen een nog duurder betaalde consultant inhuurt van een organisatie- en adviesbureau.

12. Dat we tweemaal zo lang leven als een eeuw geleden, is niet aan de dokter maar aan de loodgieter te danken. (Midas Dekker, De Vergankelijkheid)