Chapter 2

Stapes Surgery for Otosclerosis in the Academic Medical Center, University of Amsterdam.
Chapter 2

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 “Schwartz 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 Audimetric 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.

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 audiomeric 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 70293, 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 kHz4 Although it is more appropriate to use the term “Carhart effect” to define the alterations in BC thresholds5, 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 Valvassori6, 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.

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, \(r = 0.23, p < 0.0001\)).
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 commer-
cially 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.\textsuperscript{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.\textsuperscript{8,9} The first stapedectomy procedures were performed in 1958, shortly after Shea introduced this technique in 1956.\textsuperscript{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.

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

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.\textsuperscript{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.\textsuperscript{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\textsuperscript{®}, 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.\textsuperscript{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 post-operative 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\textsuperscript{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. 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.

REFERENCES