

STATISTICAL ANALYSIS OF OTOSCLEROSIS SURGERY PERFORMED BY JEAN MARQUET

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The early and long-term hearing results of 1,681 primary otosclerosis operations performed by the same surgeon, Jean Marquet, were reviewed retrospectively and analyzed with very strict statistical standards. Significantly better short- and long-term results were achieved with the stapedotomy technique compared to total stapedectomy, mainly at the higher frequencies (4 and 8 kHz) important for speech discrimination. Whatever technique was used to open the footplate (micropick, microdrill, or laser), no statistical audiometric difference could be found. The results were equal whether or not the stapedial tendon was preserved. Perioperative problems like pronounced oozing, difficult anatomic relationships, and accidental perilymph aspiration could affect hearing at higher frequencies. The calibrated hole technique was equally as good as conventional oval window sealing in sealing of the fenestra to prevent fistula. The stapedotomy technique was found the safest, having fewer complications.

KEY WORDS — otosclerosis, stapedotomy, stapes surgery, total stapedectomy.

INTRODUCTION

Jean Marquet, who died in 1991, was mostly known as a pioneer in tympanoplasty surgery because of his systematic use of tympano-ossicular homografts. In addition, in 1963 Marquet et al¹ introduced the small hole technique, which is a modification of the stapedectomy technique originally described by Shea² in 1958. To date, it is commonly called the stapedotomy technique, and is now widely acknowledged to be the treatment of choice for otosclerosis.^{3,4} The procedure starts with the making of a limited opening of 0.7 mm in the center of the footplate, whereafter a 0.6-mm all-Teflon piston is placed in the vestibule not deeper than 400 μ m, without vein graft interposition. Reducing the caliber of the fenestra in the footplate lowers the risk of immediate and delayed sensorineural deafness for the following reasons.

1. Only a limited part of the vestibule is exposed to possible trauma.
2. The annular ligament is not disrupted.
3. A small physical air-liquid interface is created after opening of the footplate. This meniscus with its surface tension will act as a protective layer to prevent waste particles' falling into the vestibule.⁵ Once covered by a fibrin layer, it will also guide the endothelial repair underneath and around the prosthesis.

Since the introduction of the stapedotomy technique, several authors have reported better results as compared to total stapedectomy, mainly for higher frequencies.^{4,6-11}

After Marquet's untimely death in 1991, the authors, all former trainees of his, decided to perform a thorough statistical analysis of his 30 years of experience with stapedotomy. The present study not only describes the functional results as such, but also analyzes the results in terms of several parameters such as the surgical techniques used (mainly stapedotomy, partial stapedectomy, and total stapedectomy), the methods used to create the hole in the footplate (micropick, microdrill, or laser), the shape of the Teflon prosthesis (normal, bent, or truncated), the fate of the stapedial tendon, and the perioperative problems documented in the surgical records. All cases analyzed were operated on by the same surgeon (Marquet) at the University Department of Otolaryngology of Sint-Augustinus Hospital between 1961 and 1991.

PATIENTS AND METHODS

For the present retrospective study, the patient records were put at the authors' disposal by the Jean Marquet Otological Foundation. The records of patients in whom an exploratory tympanotomy was performed through an endaural incision (Rosen type) were retrieved; they numbered 2,919. These patients

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TABLE 1. FREQUENCY OF TECHNIQUES USED FOR PRIMARY SURGERY IN 1,681 CASES

	Frequency (%)
Stapedotomy	85.0
Partial stapedectomy	5.8
Total stapedectomy	4.1
Polyethylene strut	1.2
Fowler	1.7
Mobilization	2.1
Malleovestibular wire	0.2

presented a conductive hearing loss with a normal or near-normal tympanic membrane. Of these 2,919 tympanotomies, 2,521 cases (86%) were perioperatively diagnosed as having otosclerosis. Of these 2,521 operations, 810 were excluded from the present study because they were considered statistically dependent cases, either because they were revisions (82 of Marquet's personal series and 161 revisions after previous surgery elsewhere) or because the other ear was already enrolled in the present study. In such cases a random choice was made as to which ear to include. Thirty records were excluded because of incomplete data. So 1,681 ears remained for the present statistical study, being the "pure" otosclerosis cases, ie, otosclerosis ears operated on for the first time, by the same surgeon, only one ear per patient being included.

Eleven variables were studied, namely, date of surgery, age, sex, side, whether the contralateral ear was affected by otosclerosis, type of surgery, technique for opening the footplate, shape of the all-Teflon prosthesis, perioperative problems or findings, fate of the stapedial tendon, and major postoperative complications. Whenever available, three full audiograms (bone and air conduction) were analyzed (the preoperative audiogram, the audiogram 6 to 12 months postoperatively, and the latest audiogram), together with the time interval between surgery and audiometry (months).

A lack of response to air-conducted sound was coded as 120 dB, and to bone-conducted sound, 80 dB. Missing values were coded as such. Descriptive statistics were performed on all variables. Counts, percentages, and histograms were used to describe nominal data.

According to the central limit theorem,¹² the distribution of the audiometric results was considered normal if more than 30 cases were studied. Hence, audiometric results (often expressed as Fletcher index, ie, the mean of the hearing threshold at 500, 1,000, and 2,000 Hz) were described by means of nonparametric statistics if subgroups containing fewer than 30 cases were analyzed; otherwise, parametric

statistics was performed. Analytic statistics was performed to study the interdependence of all variables and the dependence of the audiometric results on the different variables.

The null hypothesis of independence was tested for each two separate variables. *T* tests for independent variables, χ^2 tests, and analysis of variance tests were used. All tests were carried out two-tailed.

A global level of significance for the whole study was set at 5%. In consequence, according to the Bonferroni principle, a much more stringent significance level was set for each individual test, and only *p* values of 0.1% were considered significant. *P* values between 0.1% and 0.5% are reported, but should be interpreted with caution. *P* values of more than 0.5% were considered not significant. Taking into account an α error of 0.001 and a β error of 0.20, the present study design was able to demonstrate audiometric differences of approximately 2 dB, 4 dB, and 8 dB for subpopulations of 750, 200, and 50 cases, respectively. All statistics were performed by a computer running CSS/PC software (release 2.1; Statsoft Inc).

RESULTS AND DISCUSSION OF STATISTICAL ANALYSIS

The results of 1,681 cases were analyzed. Short-term evaluation took place after an average of 8 months; long-term evaluation was after an average of 59 months. Our population showed the usual sex distribution for otosclerosis: women about twice more frequently affected than men (64% versus 36%). The youngest patient was 10; the oldest, 86 years of age. The average age at operation was 45 years. In 51% of the cases the operation was performed on the right ear; in 49%, on the left ear. Eighty-five percent of the patients presented otosclerosis in both ears; 35% underwent surgery in both ears.

Influence of Surgical Technique. Table 1 shows the different techniques used for stapes surgery and how often each technique was used. Marquet initially used the first technique described by Shea,² performing a stapedectomy and placing a polyethylene strut between the incus and the venous fenestral seal (1.2%).

In 1963 he started to make a limited opening in the footplate, only as far as necessary to admit a 0.6-mm piston freely. This stapedotomy could be performed in 85% of the 1,681 cases analyzed.

In 5.8% a partial stapedectomy was done because a fracture line reached the annular ligament and a mobile part of the footplate needed to be removed. Depending on the surface to be closed, a vein graft, a mucosal flap rotated from the promontory, or a drop of fibrin glue was used.

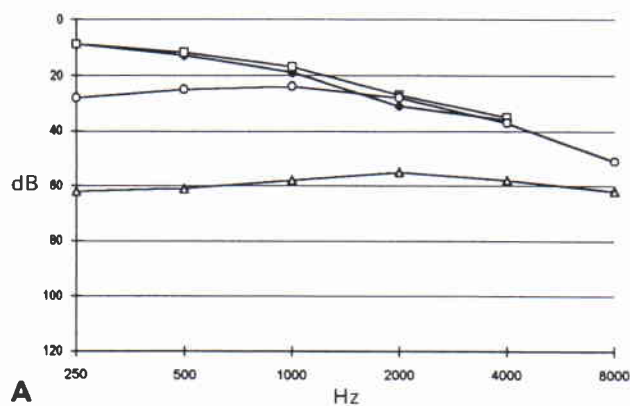
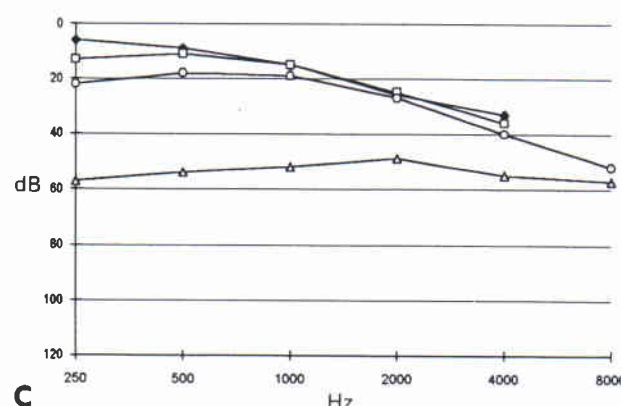
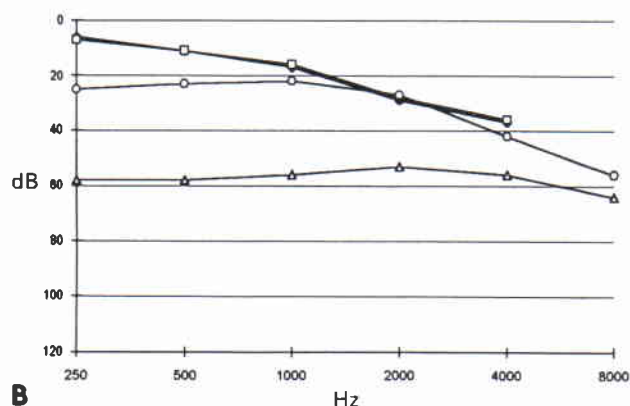


Fig 1. Short-term audiometric results of A) stapedotomy, B) partial stapedectomy, and C) stapedectomy with venous graft interposition. Diamond — preoperative bone conduction, square — postoperative bone conduction, triangle — preoperative air conduction, circle — postoperative air conduction.



A total stapedectomy had to be performed in 4.1%, requiring an oval window seal with a vein graft taken from the dorsum of the hand.

Between 1970 and 1980 Marquet used the intervention known as the Fowler technique (1.7%), consisting of an anterior crurotomy and removal of the anterior third of the stapedial footplate, where the focus is nearly always localized. Because of less satisfactory permanent results due to refixation, this technique was abandoned.

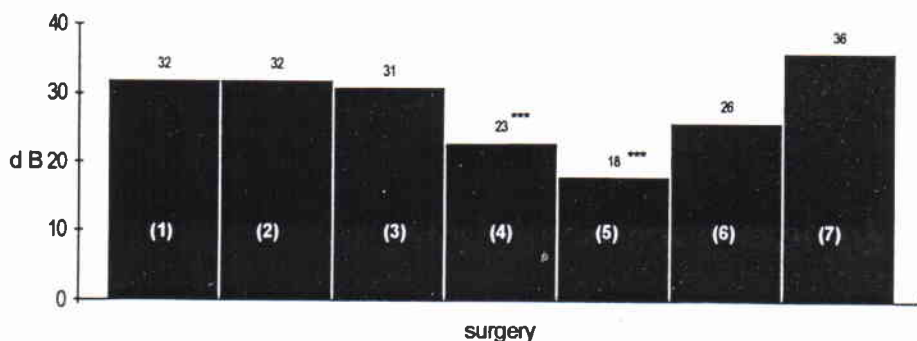
In some ears (2.1%) the intervention was stopped after complete mobilization of the footplate; after refixation a relatively safe stapedotomy could be performed at a later stage. A few of those ears were only-hearing ears (6 cases), in which a limited mobilization was preferred for maximal safety.

The malleovestibular wire proved necessary only in those very rare cases in which otosclerosis was combined with a missing long process of the incus (0.2%).

Whatever technique was used, in the short term the overall closure of the air-bone gap to within 10 dB for the speech frequencies (0.5, 1, and 2 kHz) could be obtained in 81% of the cases. A closure within 20 dB was reached in 94% of the cases. The residual postoperative air-bone gap averaged 5 dB. The average gain in air conduction was 32 dB. A slight overclosure of the bone conduction (2 dB) was found for the speech frequencies. Figure 1 shows the short-term audiometric curves according to the three main techniques.

Figure 2 summarizes the postoperative average

Fig 2. Audiometric gain for air conduction at 6 to 12 months according to type of surgery. 1 — stapedotomy, 2 — partial stapedectomy, 3 — stapedectomy, 4 — Fowler technique, 5 — mobilization, 6 — malleovestibular wire, 7 — polyethylene strut, *** — $p < .001$.



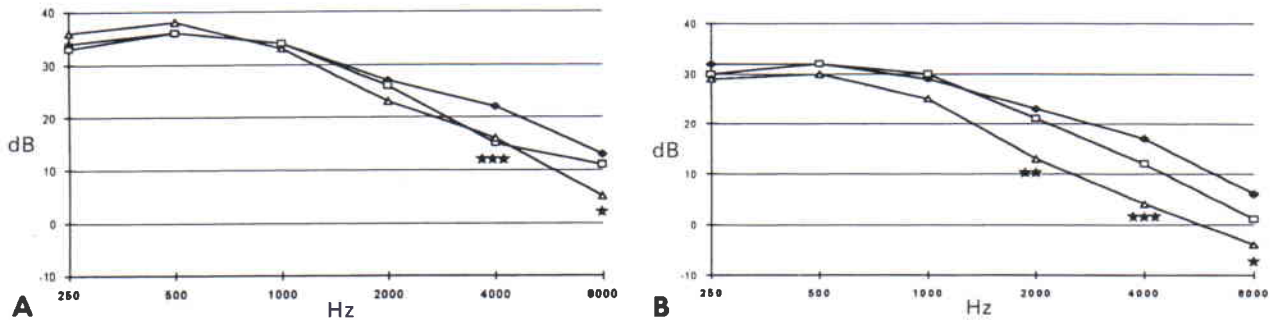


Fig 3. Mean gain in air conduction of speech frequencies at A) 6 to 12 months and B) latest audiometry. Diamond — stapedotomy, square — partial stapedectomy, triangle — stapedectomy with venous graft interposition, * — $p < .01$, ** — $p < .001$, *** — $p < .0001$.

gain at the speech frequencies. No statistically significant difference could be found among the three main techniques (stapedotomy and partial and total stapedectomy) for the speech frequencies. The mobilization and Fowler interventions scored significantly less, because of refixation in many cases.

The better postoperative results after stapedotomy with a polyethylene strut are to be attributed to the larger preoperative air-bone gap in those ears operated on in the early 1960s, when operations were only performed after a marked hearing loss.

Comparing gains for air conduction (Fig 3A), at the higher frequencies (4 and 8 kHz) we found significant differences for the short-term (6 months) postoperative results: stapedotomy scored significantly better at 4 kHz than partial and total stapedectomy, and better at 8 kHz than total stapedectomy. For the lower frequencies, 250 and 500 Hz, stapedotomy seemed to score slightly less well than stapedectomy, but the difference was not statistically significant.

In agreement with Fisch,⁶ we could not confirm the less satisfactory closure of the air-bone gap at the lower frequencies (250 and 500 Hz) after stapedotomy in comparison with stapedectomy as originally mentioned by Marquet et al¹; this incomplete closure is only found during the very early postoperative months.

After a mean follow-up period of 5 years, the differences are even more striking (Fig 3B): stape-

dotomy scored better for all frequencies. The values are statistically highly significant at 2 and 4 kHz, and slightly significant at 8 kHz. The curve of partial stapedectomy shows a tendency to score slightly less than stapedotomy at higher frequencies. The long-term deterioration after stapedectomy, mainly for high tones, is deleterious for speech discrimination.

Influence of Fenestration Technique. The fenestral opening in the footplate was most often (96.3%) made with a micropick and ultrasmall (0.2 mm) microhooks. The microdrill was only used in very thick footplates (2.9%), difficult to pierce with micro-instruments. Marquet used the argon laser (0.8%) in 1979, but abandoned it because he found it too cumbersome and expensive in those early years of laser surgery.

Influence of Shape of Prosthesis. For primary surgery the same all-Teflon piston of 0.6 mm was almost always used because of its nonwetttable properties (allowing the endothelial repair to follow the guide formed by the air-liquid interface),¹ and because the pressure applied over the lenticular process is more diffuse than with a metal wire,¹ as also stated by Perkins and Curto¹³ (Figs 4 and 5). Its normal shape could be preserved in most cases (94.1%). Because of an overhanging fallopian canal or too short a lenticular process, the prosthesis sometimes needed to be bent into a bayonet shape (3.1%). In 2.8% of the cases the tip of the piston needed to be truncated with a surgical blade because of the risk of

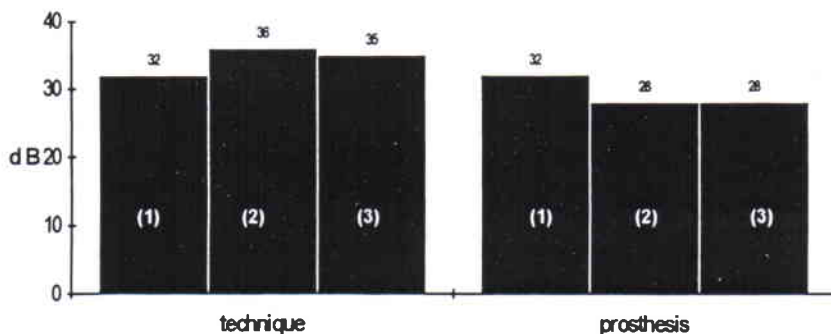
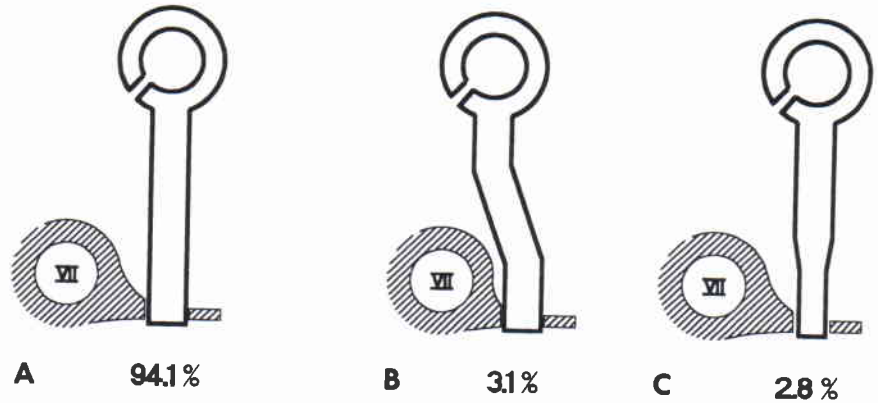


Fig 4. Mean audiometric gain for air conduction of speech frequencies at 6 to 12 months according to technique used to open footplate and type of prosthesis. For technique, 1 — micropick, 2 — drill, 3 — laser. For prosthesis, 1 — normal, 2 — truncated, 3 — bent.

Fig 5. Shape of prosthesis and percentage of cases. A) Normal. B) Bent. C) Truncated.



a floating footplate if the calibrated hole was further enlarged. The slight difference (4 dB) found with these two piston modifications was not statistically significant enough for us to conclude that they give less satisfactory results.

Influence of Perioperative Problems and Gain. No problems were encountered in most of the surgical cases (83.3%; Fig 6). The most important perioperative problems that could have a bearing on the hearing gain were registered and analyzed. These included above-normal bleeding despite hypotension (4.2%), accidental perilymph aspiration (2%), difficult anatomic relationships (2.6%), adhesions in the middle ear (6.9%), tubal dysfunction with middle ear effusion (0.4%), and tympanosclerosis (0.6%). The first three perioperative problems were followed by less satisfactory gains, the average gain at speech frequencies (500, 1,000, and 2,000 Hz) being 30, 27, and 26 dB, respectively, instead of the 32 dB found in uncomplicated cases. These differences are consistent but too small to be detectable with the present study methodology. On the other hand, at 4,000 Hz, above-normal bleeding and accidental perilymph aspiration resulted in larger differences: 14 and 12 dB gain, respectively, compared to 22 dB gain in ears not presenting those problems. These differences were statistically significant ($p < .0001$). This supports our clinical feeling that damage may occur to the sensorineural elements of the basal turn, which is the region closest to the surgical area. Bleeding during

stapes surgery is the surgeon's greatest enemy, because it impairs good visualization of the footplate. Prolonged suctioning in the region of the oval window to aspirate fresh blood can create a continuous and inconspicuous flow of perilymph from the vestibulum to the middle ear. Also, once clotting takes place, there is an increased risk of perilymph aspiration from beneath a coagulum when attempts are made to remove the clot with the suction catheter. These clots, therefore, should always be removed with the forceps.

On the other hand, when the anatomic situation was causing problems, the gain was found to be 25 dB instead of 34 dB at 250 Hz ($p < .0005$). This can be attributed, from a mechanical point of view, to a less than ideal orientation of the prosthesis and to friction forces against the fallopian canal.

The perioperative finding of soft adhesions during primary surgery, surprisingly, does not statistically alter the postoperative results. But the presence of middle ear effusion or tympanosclerosis, each present in only 4 cases, all operated on during the early period of Marquet's career, resulted in a markedly smaller gain for the speech frequencies: only 23 dB and 9 dB, respectively, instead of 32 dB. In cases of temporary tubal dysfunction we, as Marquet advised, would first improve middle ear ventilation by tube insertion and after extrusion wait a long period for observation of the middle ear aeration before making a new attempt to perform the stapes surgery. Also, like other

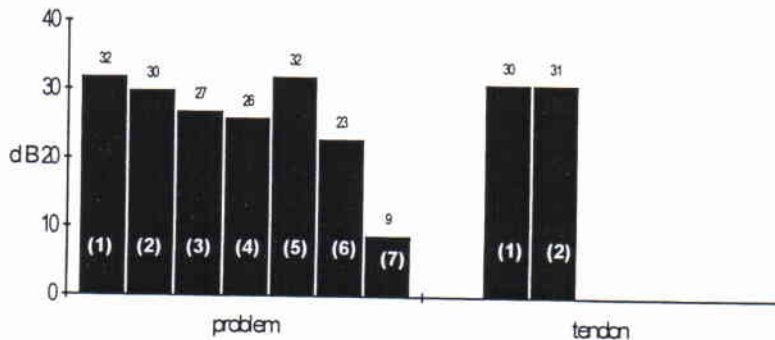


Fig 6. Mean audiometric gain for air conduction of speech frequencies at 6 to 12 months according to perioperative findings and problems and fate of tendon. For problem, 1 — none, 2 — bleeding, 3 — perilymph aspiration, 4 — difficult anatomy, 5 — adhesions, 6 — tubal dysfunction, 7 — tympanosclerosis. For tendon, 1 — saved, 2 — cut.

TABLE 2. INCIDENCE OF MAJOR COMPLICATIONS

Complication	Operation	Incidence (%)
Perilymph fistula	Stapedotomy (5/1,911)	0.26
	Partial stapedectomy (0/140)	0.0
	Total stapedectomy (1/117)	0.85
	Polyethylene strut (1/28)	3.6
Sensorineural loss	Stapedotomy (13/1,911)	0.68
	Partial stapedectomy (1/140)	0.71
	Total stapedectomy (3/117)	2.56
	Polyethylene strut (1/28)	3.6
	Fowler (1/30)	3.3
	Mobilization (1/48)	2.1
	Malleovestibular wire (0/4)	0.0
	Revision surgery (3/243)	1.2
Total (23/2,521)	0.91	

authors,¹⁰ we think that in the presence of tympanosclerosis extreme caution or abstention is imperative.

Influence of Stapedial Tendon. In 56% of the cases the stapedial tendon could be saved (Fig 6). In 44% the tendon was cut, because it was inserting too low or impaired good visualization of the footplate. In many of the cases in which the tendon inserted at the upper third of the posterior stapedial crus, the tendon could be preserved by sharp dissection from below upward along the posterior crus, the tendon being kept in continuity with the mucosa and periosteum of the upper third of the posterior crus and of the lenticular process. No statistically detectable short- or long-term difference could be found for the hearing gain at all frequencies. The same finding has also been reported by other authors. Some of them, also using speech audiometry, noticed better speech understanding in noise.⁹

Interdependence of Different Parameters. The analysis of the correlations between various factors showed some interesting statistical findings. In ears that bled more than normal, the prevalence of partial platinectomies was three times higher than in ears that had trouble-free surgery. The impaired vision did not allow the meticulous opening of the footplate, so a fracture line occurred more easily up to the annular ligament, followed by a partial removal of the foot-

plate.

The same factor, bleeding despite systematic use of hypotension,¹⁴ was also accompanied by a twofold increase in the need to truncate the prosthesis. This troublesome oozing resulting in an 8-dB lower gain at 4 kHz. In surgery under general anesthesia, hypotension is mandatory and does statistically improve the results.

We also found the prevalence of perilymph aspiration to be 4 times higher during total stapedectomy than during stapedotomy. The larger exposure of the vestibule and the maneuvers needed to position the vein graft enhance the risk of an accidental suctioning of the labyrinthine fluids. In consequence, the lower gains in the short and the long term, observed mainly for the higher tones, after total stapedectomy could be partially attributed to the greater risk of perilymph aspiration.

In the presence of difficult anatomic relationships (a deep oval window niche, an overhanging facial nerve, too short a long incudal process), the prosthesis needed to be reshaped into a bayonetlike form. Also, this longer and more difficult procedure increases the risk of perilymph aspiration: we found the prevalence of perilymph suction to be increased fourfold.

Complications. Because of the very low frequency of complications, the statistics on this topic (Table 2) have been done on the totality of the cases operated on for otosclerosis (n = 2,521), including second ears and revision cases.

One of the most feared complications in stapes surgery is perilymph fistula. Among Marquet's global series of total stapedectomies (n = 117), 1 case of perilymph fistula has been found (0.9%). None was found among the 140 partial stapedectomies. Postoperative fistula after stapedotomy without an oval window seal appears also to be extremely rare (0.26%). In Marquet's personal series we could not find 1 case of a perilymph fistula in the first half-year after surgery. All 5 cases (0.2%) occurred after a long delay, the mean delay being 5 years (range, 9 months to 13 years) after primary surgery. We are convinced that a well-calibrated hole technique and preservation of the annular ligament are more important than oval window sealing to prevent perilymph fistula.

A total of 23 ears presented a postoperative early or late sensorineural hearing loss (0.91%). The severity of the hearing loss was mild (less than 60 dB air conduction at last audiogram) in 4 cases (0.16%), severe (60- to 80-dB loss) in 7 cases (0.28%), and total (worse than 80 dB) in 12 cases (0.48%). The

early sensorineural losses during the first year after primary surgery can be ascribed directly to the surgery: this early-onset loss occurred in 9 cases (0.36%), including 2 with gushers. The late-onset sensorineural loss found in 14 cases (0.56%) occurred up to 11 years after surgery: 1 occurred after influenza, 2 after air flight barotrauma, and 1 after acoustic trauma (blast). In 10 cases no reason could be found.

The relative incidence of sensorineural hearing loss according to the different techniques is presented in Table 2. Stapedotomy and partial stapedectomy present a comparable risk, but total stapedectomy is four times more risky than stapedotomy. The incidence after revision surgery was half that seen after total stapes removal.

CONCLUSIONS

This statistical retrospective study on a large number of patients, all operated on by the same surgeon, shows that stapedotomy without interposition of a graft is a safer technique than stapedectomy with interposition and yields better long-term results, mainly at higher frequencies, which are of paramount importance for good speech understanding. Partial stapedectomy remains a valuable alternative when stapedotomy is not feasible. Our study could not disclose a statistical difference in hearing gain according to whether the footplate was opened by micropick, laser, or microdrill, or according to whether or not the tendon of the stapedial muscle was preserved.

This study, to the best of our knowledge the first to analyze in detail the perioperative problems involved

in otosclerosis surgery, reveals factors that may be important in influencing the final results: excessive bleeding, accidental perilymph aspiration, and difficult anatomic situations. These are not always avoidable, but may definitely alter the end results in a significant way.

Slightly less satisfactory results are rarely spotted by the surgeon when he or she contemplates the hearing curve of an individual patient recently operated on. These can only be detected statistically, when larger patient groups are analyzed.

Skill and experience will help the surgeon confront these unexpected situations. Even so, if difficulties arise (excessive bleeding, difficult anatomic relationships, mobile footplate), it might occasionally be better to withdraw and resume surgery under better circumstances (eg, when the footplate is refixated and the ear is dry).

This study also showed that fear of fistula, after stapedotomy without fenestral sealing, is unjustified, since no single case of early-onset fistula was found. This means that the very small (0.1 mm) gap around the prosthesis always closes when the prosthesis is introduced not deeper than 400 μ m into the vestibule. Only a very small proportion of patients (0.26%) developed a fistula after a very long delay (mean, 5 years). Since stapedotomy gives the patient the most satisfying long-term results and is still the safest technique because of the very low incidence of serious complications like fistula and sensorineural loss, we recommend stapedotomy as the treatment of choice for otosclerosis.

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