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First 100 stapedotomies of a surgeon: learning curve and functional results

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Abstract. *First 100 stapedotomies of a surgeon: learning curve and functional results. Objective:* Otosclerosis is a common otologic disease that mostly requires surgical treatment. This study aimed to analyse stapedotomy results and establish a learning curve.
Method: This retrospective study analysed the first 100 stapedotomies of a young surgeon. We measured the pre- and post-operative bone conduction (BC), air conduction (AC) threshold, and mean air-bone-gap (ABG) values. The Amsterdam Hearing Evaluation Plots method, proposed previously, was used to represent audiometric results. We also reproduced the learning curve described previously.
Results: We identified 9 cases with post-operative complications. No dead ear outcome occurred. BC deterioration appeared in 5 cases, but they were not related to surgeon experience. A post-operative ABG <20 dB was observed in 81% of the operated ears, consistent with results from previous studies on other young surgeons. The stapes surgery learning curve showed 2 peaks with post-operative ABGs <10 dB. However, these results were not sustainable, probably due to the introduction of new devices and the increasing difficulty of the cases.
Conclusions: Stapes surgery involves surgical skills that are acquired after training. This learning is facilitated by the use of one single device, rather than several devices. Sufficient patient recruitment is required to preserve expertise.

Introduction

Otosclerosis is a common pathology that affects 0.3 to 0.4% of the Caucasian population, and it can cause either conductive or mixed hearing loss.[1] Treatment mostly requires surgery. The first stapedectomy for otosclerosis was performed by John Shea, in 1956.[2] In 1963, Marquet described the stapedotomy technique: he proposed to make a small hole in the stapes footplate, rather than removing it totally or partially.[3] Currently, the total stapedectomy is no longer performed, because this technique carries a 4-fold increased risk of sensorineural hearing loss, and poor audiometric gain at high frequencies (4 and 8 kHz), which are particularly important for good speech understanding.[4] This retrospective study aimed to evaluate the results and complications associated with the first 100 stapedotomies performed by a young surgeon at our institution. We analysed results with the Amsterdam Hearing Evaluation Plots (AHEPs) method. We also analysed his learning curve.[5]

Materials and methods

We collected the audiometric outcomes of the first 100 patients that received stapedotomies performed by a single junior surgeon at the University Hospital Saint-Luc in Brussels, from January 2001 to April 2014. This medical doctor graduated in otorhinolaryngology. He began his surgical activity with tympanoplasties, and after a few months, he achieved his first stapedotomy. A senior surgeon was available, when necessary. The patients presented stapes ankylosis, due to otosclerosis, except for two patients (children) with congenital stapes ankylosis. We excluded all secondary surgeries and all patients without pre- or post-operative audiometric data.

Surgery

Before surgery, a computed tomography scan of the temporal bone was systematically performed to exclude other abnormalities of the middle or inner ear, which might also cause conductive hearing loss.

Surgery was performed under general anaesthesia, with a classical transcanalar approach, a Rosen incision, and preservation of the chorda tympani, when possible. When necessary, the posterior wall of the ear canal was enlarged with a curette to access the stapes footplate. After confirmation of stapes ankylosis, the incus-stapes joint was disarticulated with a microhook or round knife. The tendon of the stapedian muscle and posterior crus of the stapes were sectioned with a diode laser (continuous mode, 1.0 W). The stapes footplate was weakened with the same laser, unless the facial nerve was too close to the target area. A Skeeter micro-drill was used for a calibrated platinotomy. A piston (0.4 to 0.6 mm in diameter) was attached to the long process of the incus. Several types of pistons were used. In most cases, the Fluoroplastic (Teflon) Piston (N=45, Olympus Europa SE & Co. KG, Wendenstrasse 14-18, 20097 Hamburg, Germany) and the Big Easy® Piston (N=28, Medtronic operational headquarters, Medtronic Parkway 710, Minneapolis, MN 55432-5604, USA) were used; in some cases, other types of piston were used, including: the titanium K-Piston (N=10, Heinz Kurz, Medizintechnik, Tübinger Straße 3, 72144 Dusslingen, Germany), the Nitinol SMart® Piston (Olympus Europa SE & Co. KG, Wendenstrasse 14-18, 20097 Hamburg, Germany), and the NitiBOND® prosthesis (N=6, Heinz Kurz, Medizintechnik, Tübinger Straße 3, 72144 Dusslingen, Germany). In three cases, the type of piston was unknown. Patients spent the night after surgery at the hospital. The next day, BC thresholds were systematically measured to rule out inner ear hearing loss.

Outcomes

We investigated post-operative complications. Routinely, we measured bone conduction (BC), air conduction (AC), and we calculated the air-bone gap (ABG) at 0.5, 1, 2, and 4 kHz, before the surgery, and three times after surgery (at 0-6 months, 6-12 months, and >12 months after stapedotomy). All audiometric measurements were performed by graduate audiologists.

We used *Amsterdam Hearing Evaluation Plots* (AHEPs) to evaluate audiometric results between 0 and 6 months.[5] The effect of surgery on BC was evaluated by comparing pre- and post-operative BC thresholds. The degree of surgical success was established by comparing the pre-operative ABG to the post-operative gain in AC. All surgeries with post-operative ABGs <20 dB were considered successful.

We evaluated the surgery learning curve, as proposed by Yung et al.[6] They proposed that stapes surgery was the ideal operation for studying the learning curve of surgery, for two reasons. First, stapes surgery is technically difficult and requires experience to develop the surgical technique. Second, the measurements are readily performed and quantifiable. They used a moving average of the post-operative ABG, with a window of 15 consecutive observations. The end point of the learning curve was defined as 'when the curve reaches its peak and the results are sustainable'.

Statistics

All statistical analyses were performed with the GraphPad Prism 5™ package and Microsoft Excel 2010.

Results

Our population comprised 58 women and 42 men, aged 8 to 68 years (mean age 44.41 years). In most cases (98%), patients were diagnosed with otosclerosis, but two female children, aged 8 and 9 years, underwent stapedotomies for congenital stapes ankylosis. Our young surgeon used mostly fluoroplastic prostheses for the first years of practice, and Big Easy® prostheses after the 7th year. In addition, he also tried three other piston types. This heterogeneity was not an optimal approach, because each piston may require new techniques.

The mean follow-up was 25.97 months (range: 10 days to 109 months). The rate of follow-up decreased to 59% after 6 months and to 42% after 12 months.

Nine cases developed post-operative complications. Three patients complained of dizziness that persisted more than two months after surgery, without BC deterioration. Five cases presented partial sensorineural hearing loss (measured as a deterioration of the BC threshold that exceeded 10 dB) within 24 h after surgery. These five cases were highlighted in the AHEPs (Figure 1, A). None experienced dead ear, and four of the five ears recovered completely in the following months. One other patient developed peripheral facial palsy (House-Brackmann grade V) 8 days post-surgery. The condition was unresponsive to antiviral and corticoid treatment. We performed a post-operative

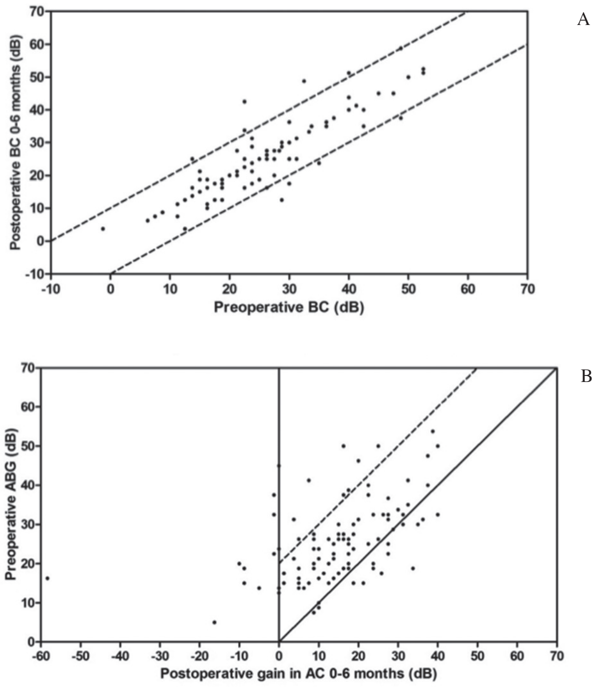

Figure 1
Audiometric results for 100 stapes surgeries, visualized with the AHEP. **A**, Pre- and post-operative BCs are plotted for each ear (each dot represents a single ear). Between the two dotted lines are cases that achieved <10 dB of BC modification after surgery. Above the top line are cases that showed BC deterioration >10 dB. Below the bottom line are cases that showed BC improvements >10 dB. **B**, Post-operative gains in AC are plotted against the pre-operative ABG for each ear. The solid diagonal line indicates cases of total ABG closure. Below the solid diagonal line are cases with overclosure (post-operative AC gain superior to pre-operative ABG, due to Carhart effect). Between the solid and dotted diagonal lines are cases with post-operative ABGs <20 dB, which were considered successful surgeries. Above the dotted line are unsuccessful cases, with post-operative ABGs >20 dB. Patients with AC deterioration are located to the left of the vertical solid line. AHEP: Amsterdam Hearing Evaluation Plot; BC: bone conduction; AC: air conduction; ABG: air-bone gap.

computed tomography scan, but the result was negative. We proposed surgical exploration, but the patient refused. We suspected a viral reactivation of herpes virus, even though the serology remained negative.

Five patients required revision surgery. In one case, revision surgery was performed a few months after the initial stapedotomy, due to the absence of audiometric gain. In that case, the piston proved to be too short, and it was replaced. In another case, the patient reported persistent dizziness and poor audiometric results. The revision surgery revealed a dislocation of the prosthesis with a perilymph fistula at the oval window. In the three other cases, the outcome deteriorated later than one year after surgery, due to fibrous adherences in the middle ear that blocked the ossicles and prosthesis; dislocation of the prosthesis from the incus; and lysis of the long process of the incus.

We used AHEPs to compare the pre- and post-operative BC (Figure 1, A) and to show the ABG change (Figure 1, B). In this study, successful surgery was achieved in 81 cases, and among those, 49 experienced very good results (post-operative ABGs <10 dB). Over time, the post-operative BC thresholds and ABG improvements remained significantly stable (p value <0.0001; Figure 2).

The learning curve (Figure 3) showed that functional outcomes were good at the beginning (post-operative ABGs <20 dB). The post-operative ABGs stabilized to <10 dB between patients #20 and #30 during the 6th year of practice; in that year, the surgeon performed 15 stapedotomies (Table 1). However, from the 7th to 10th year of surgical

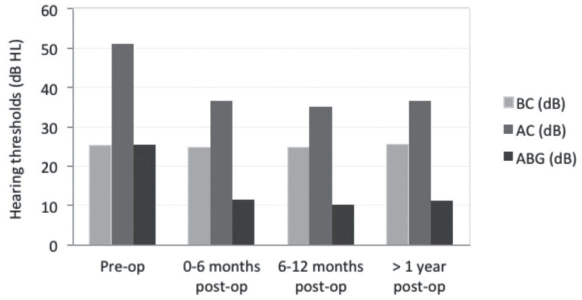

Figure 2
Comparison of BCs, AC thresholds, and ABG values (in dB HL) measured at frequencies of 0.5, 1, 2, and 4 kHz, at different pre- and post-operative time points. BC thresholds remained stable overall, but AC thresholds and the mean ABG decreased after surgery. BC: bone conduction; AC: air conduction; ABG: air-bone gap; HL: hearing loss; pre-op: pre-operative; post-op: postoperative.

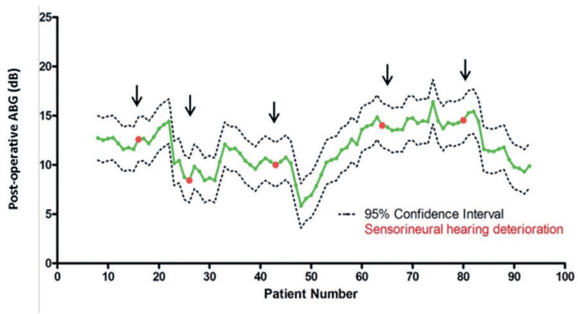

Figure 3
Learning curve shows changes in the average post-operative ABG over time. The two dotted lines represent the 95% confidence interval. Cases of sensorineural hearing deterioration >10 dB are highlighted with red symbols (indicated with arrows). ABG: air-bone gap.

Table 1
Distribution of stapes surgeries performed over the years

Year	Number of cases	Patients numbers [a]
2001	1	Patient 1
2002	0	-
2003	1	Patient 2
2004	15	Patients 3-17
2005	6	Patients 18-23
2006	15	Patients 24-38
2007	5	Patients 39-43
2008	5	Patients 44-48
2009	7	Patients 49-55
2010	6	Patients 56-61
2011	13	Patients 62-74
2012	11	Patients 75-85
2013	10	Patient 86-95
2014	5	Patients 96-100
TOTAL	**100**	

[a] Only 2 patients underwent stapes surgery during the first three years of activity; after 2004, the number of patients increased, followed by a reduction in the number between 2007 and 2010; from 2011 surgeries on more than 10 ears per year were performed.

practice, the surgeon did not perform more than 7 surgeries per year, and the curve displayed relatively worse surgical outcomes (patients #31-45). This period was followed by an improvement in the post-operative ABGs, until patient #50. Then, despite operating on more than 10 ears per year, after the 11th year of practice, the curve continued to trend upward, which indicated worse outcomes. None of those patients experienced post-operative ABG <10 dB.

Discussion

Most stapes surgeons choose one piston and one technique at the beginning of their practice. In the present study, our surgeon chose 5 different piston models, although two were used in more than 70% of the surgical procedures. This heterogeneity may have had a negative impact on the learning curve. Various prosthesis diameters were also used: 0.4-mm for 54 ears, 0.5-mm for 41 ears, and 0.6-mm for 2 ears (missing data in three cases). The effect of the diameter on the results has been discussed in several studies previously. Some studies showed no significant differences between the different diameters, and others demonstrated clinically relevant differences, in favour of the larger-diameter prostheses.[7] A recent prospective study compared pistons of 0.4-mm and 0.6mm diameters. They showed that the 0.6-mm-diameter piston provided a significant improvement in the mean AC gain (+4 dB), compared to the 0.4-mm-diameter piston.[8]

Caldart et al. studied the results of stapes surgeries performed by residents of their hospital. They found a 5.3% BC deterioration, comparable to the rate observed in the present study.[9] We also achieved results similar to those of de Bruijn et al., who reported 97.8% of undamaged BCs, but the rate of improved post-operative BCs was higher (15.1%) than that achieved in the present study.[10] In addition to the inexperience of our young surgeon, another explanation for the lower rate of improved post-operative BCs might be the use of the 0.5 kHz frequency, which contrasted with that used in the de Bruijn et al. study. Indeed, Carhart demonstrated that BC thresholds, which worsened in cases of otosclerosis, tended to improve after stapes surgery, mainly at the frequencies of 1 and 2 kHz (e.g., improvements of 10 and 15 dB, respectively).[11] In their retrospective study on 213 patients, Sabbe et al. highlighted a mean improvement in BC of 1.8 dB at the same frequencies as those used in the present study, with no changes at 0.5 and 4 kHz.[12]

The facial palsy and persistent dizziness rates observed in the present study were similar to those observed by Mahafza et al., who reported complication rates of 1% for dead ear, 1.92% for facial palsy, and 5.76% for persistent dizziness (>7 days).[13] In our study, 5% of patients had to undergo functional revisions, similar to the rate observed by Smith et al.[14]

The results of stapes surgery are closely related to the experience of the surgeon. Backous et al. performed a study on stapedectomies performed by residents, under close supervision by an otologic faculty. That study showed post-operative ABGs <10 dB in 68% of procedures, at frequencies of 0.5, 1, and 2 kHz.[15] Another study described the results of a young otologic surgeon, who performed 31 stapedotomies in 4 years. They reported post-operative results of ABGs <20 dB in 96.4% of patients and ABGs <10 dB in 62% of patients.[16] They used frequencies of 0.25, 0.5, 1, 2, and 4 kHz. Logically, we expect that results from experienced surgeons will be better than results from learning surgeons. Indeed, Somers et al. analyzed 1681 stapes surgeries performed by a single surgeon

(Jean Marquet). They reported good results (post-operative ABG ≤20dB) and very good results (post-operative ABG ≤10 dB) in 94% and 81% of cases, respectively, at frequencies of 0.5, 1, and 2 kHz.[4] Vincent et al. studied the results of 3050 stapedotomies performed by a single surgeon. They reported post-operative ABGs close to 10 dB in 94.2% of cases.[17] de Bruijn et al. reported a successful operation rate of 89.1%, with 21.3% of overclosures, measured at 0.5, 1, 2, and 3 kHz.[5] Overclosure means that the post-operative AC gain is greater than the pre-operative ABG, due to the improvement of both BC and AC thresholds.

However, even when we compared our results to results from other learning surgeons, our success rate was slightly lower. A possible explanation might be that we included the 4 kHz frequency in our measurements, in addition to the traditional frequency combination (0.5, 1, and 2 kHz) studied by, among others, Somers et al. and Backous et al.[4,15] Indeed, de Bruijn et al. previously demonstrated that the auditory results, the rate of BC deterioration, and the rate of overclosure were worse at high frequencies (3 and 4 kHz), compared to those at intermediate frequencies.[10] When, in the present study, we only considered the results at 0.5, 1, and 2 kHz for measuring post-operative ABG, the success rate increased to 89% and 59%, respectively, for good and very good results, and the AC gain reached 17.3 dB, instead of 14.38 dB. However, high frequencies are important for speech intelligibility and for patient satisfaction; therefore, they should be included in audiometric measurements.

We observed no dead ear outcome, but five cases of BC deterioration were found. These cases occurred throughout the studied period, not only at the beginning. This finding suggested that these incidences were not related to surgeon experience. Yung et al. noted that both surgeon had one dead ear in their first 15 cases. In contrast, they observed 3 cases of post-operative BC deterioration, which did not appear exclusively during the first learning phase of performing stapes surgeries (cases 4, 5, and 62).[6]

As described by Yung et al., the outcome of stapes surgery is expected to improve gradually with surgeon experience to the end of the learning curve, which is ′when the curve reaches its peak and the results are sustainable′.[6] They demonstrated that a peak appeared between 60 to 70 cases over a 10-year period. In contrast, the learning curve reported by Oates et al. showed 2 peaks over a 6-year period; the first was around 30 to 40 cases, and the second was around 60 to 70 cases. Hughes reported that 50 stapes surgeries were required over a 9-year period to reach the end of his learning curve, which he defined as a maximum post-operative ABG of 10 dB in 90% of patients.[18] Our learning curve showed two peaks, one around 20 to 30 and the other around 45 to 55 surgeries; but, unlike Yung's results, these very good results were not sustainable. In between patients #30 to #45, we observed a deterioration in the results, which corresponded to a period of reduced activity, with less than 8 surgeries per year (the 7th to 10th years of surgical practice). It is well known that the surgeon's experience dramatically influenced the results in stapes surgery.[19] According to Somers et al., a minimum of 8 stapes surgeries per year was required to maintain competent surgical skills.[4] Manu et al. developed a new quantitative method for estimating the experience needed to achieve competence in medical and surgical procedures. He demonstrated that 15 stapes surgeries were sufficient to attain surgical competence.[20] However, despite the growing experience of our young surgeon, and the performance of more than 10 stapes surgeries per year over this period, we observed a worsening of results after approximately the 55th patient. One reason for these declining results might have been a modification of the surgical technique, as described by Yung and Oates. Similarly, in our case, the surgeon introduced a new piston, the Big Easy® Piston, starting with patient #52 (in 2009), and continuing for most of the following cases. This new piston appeared to cause an interruption of the learning curve. Indeed, compared to other pistons, the Big Easy® Piston produced worse results for our young surgeon. He achieved only 78.57% of good results and 39.28% of very good results with the Big Easy® Piston, compared to, on average, 81% and 49%, respectively, for the entire learning period. We compared those audiometric results to results with the Big Easy® Piston performed by an experienced surgeon in our team. The experienced surgeon achieved post-operative ABGs <20 dB in 90.9% of cases. Therefore, the lower results from the young surgeon were due to his inexperience, rather than the piston type. On the learning curve developed by Yung and Oates, it was not easy to determine the ′end point′; in fact, a true 'end point' might not actually exist. Indeed, results might vary due to the inclusion of complicated cases, due to modifications in the surgical techniques or devices, or due to reductions in the surgical procedures performed per year. Thus, it is probably more relevant to consider the existence of ′landmark points′ across the learning curve, instead of a single ′end point′.[6]

Conclusion

Stapes surgery is the standard treatment for otosclerosis. However, it is a meticulous surgery that requires a trained surgeon. We reported the functional results of surgeries on the first 100 patients of a junior surgeon. We employed the AHEPs method to study the results. This procedure produced interesting visual graphs, which showed results comparable to those of other studies on the learning curves of junior surgeons. We observed some post-operative BC deterioration, which occurred throughout the studied period; therefore, these events did not seem to be related to surgeon experience. The learning curve showed some peaks and troughs, but no clear end point. Indeed, the results improved with experience, but they worsened with difficult cases, with the introduction of new devices or techniques, and when the number of surgical cases per year was insufficient to maintain the required level of surgical skill. Therefore, this analytical procedure should be reserved for studying surgeons that can recruit a sufficient number of patients. To facilitate learning, junior surgeons should limit the number of different devices used at the beginning of surgical practice.

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