Chapter XII

Long term results of ossiculoplasty **:**

Reasons for Surgical Failure

It is generally accepted that the long-term outcome of ossiculoplasty is not as good as the short- or medium-term results(Yung MW,2006).

This may be attributable to a variety of reasons:

Some prosthetic ossicles take time to become extruded or absorbed (Grote J.,1984). Residual disease such as cholesteatoma may take up to several years to manifest itself. In ears with persistent eustachian tube dysfunction, it will take time for the disease to redevelop after tympanoplasty. There are several difficulties hindering surgeons from conducting long-term follow-up studies in tympanoplasty (Yung MW,2006).

A high proportion of patients may have moved out of the area, particularly among the urban population. Hospital-based specialists are constantly under pressure from the management to see more new patients and perform fewer follow-up reviews. Patients themselves may not be motivated to keep returning to their surgeon for long-term reviews. The surgeons themselves may not be given time or resources in their busy clinic to see patients for the purpose of audit. In some countries, the referring otolaryngologists may wish to provide the follow-up care themselves rather than sending them back to the original surgeon for review (Yung MW,2006).

In a previous report on Ceravital, the mean time for complications to become apparent was 6 years for absorption and 3 years for extrusion (Brewis C,et al.,2003).

Chapter XII

Recognizing the importance of the follow-up period in reporting the results of ossiculoplasty, Kartush proposed that follow-up time be classified as preliminary (<1 yr), short-term (1–5 yr), or long-term (>5 yr) (Kartush JM.,1994).

Hughes also defined long-term results as 5 years or beyond in his literature review on ossiculoplasty. In the present series, the overall success rate (postoperative ABG of 20 dB or better) of ossiculoplasty dropped from 64.2% at 6 months to 50.0% at 5 years (Hughes G.,1987).

There was no obvious difference between the pediatric and adult populations, or between cholesteatomatous and noncholesteatomatous ears. Most published reports on ossiculoplasty have been based on short- or medium-term study (Glasscock ME. 1976; Wehrs RE,1978; Jackson CG, et al. 1983; Mann W and Hoffmann R,1988; Gersdorff M, et al.,1989; Mills RP 1993; Farrior JB and Nichols SW,1996; Schwetschenau EL and Isaacson G.,1999 ; House JW and Teufert KB,2001; Iurato S, et al.,2001; Vercruysse J-P, et al. ,2002).

In a literature search , Yung could only identify a relatively small number of publications reporting the long-term results of ossiculoplasty (Tables 7,8). In these reports, the number of patients available for long-term review was often a fraction of the original cohort. Table 6 is a list of publications reporting on the 5-year outcome after ossiculoplasty, together with the percentage of patients available for 5-year review (Reck R, 1983 ; Goldenberg RA and Driver M2000 ; Chiossone E,1987 ; Farrior JB and Nichols SW., 1996 ; Shinohara T, 2000 ; Ojala K,et al.,1983 ; Shinohara T, 2000 ; Colletti V and Fiorino FG. 1999 ; Symth GDL and TORPs,1983 ; Donaldson I, Snow DG. ,1992 ; Vartiainen E, Nuutinen J. 1992).

In all but two reports, the attendance rate at 5 years was below 70%, with many even below 30%. Reports based on such low follow-up rates may not truly reflect the actual long-term outcome. On the basis of a 10% attendance rate at 5 years, Reck et al. reported a longterm success rate of 76% in partial ossicular reconstruction using Ceravital (Reck R.,1983).

It is interesting that Ceravital was subsequently withdrawn from the market because of concerns over absorption. An alternative to a regular review of patients after ossiculoplasty is to recall the patients on a one-off basis to look at the long-term outcome. However, the outcome will then be a collection of results with different followup periods (Brewis C,et al.,2003).

Table (8) is a list of publications reporting on the long-term outcome of ossiculoplasty based on a mixture of results with different follow-up periods (Cody DTR and Taylor WF ,1973 ; Tos M. 1974 ; Pennington CL, 1973 ; Portmann M et al.,1984 ; Rust KR, et al.,1996 ; Slater PW ,et al.,1997 ; Mangham CA and Lindeman RC,1999 ; Siddiq MA).

The patient attendance rates in most of these publications were slightly higher than those listed in Table 1. Tos achieved an attendance rate of 86% in his patient recall, but the follow-up periods ranged from 2 to 10 years (Tos M.,1974).

Donaldson and Snow prospectively studied the long-term hearing results of patients undergoing incus interposition as a second stage in ossicular reconstruction. The percentage of ears with ABG below 15 dB at 3 years and 5 years was 65% and 56%, respectively, indicating that the results of ossiculoplasty continued to deteriorate even after 3 years (Donaldson I and Snow DG.,1992).

A postoperative ABG of 20 dB or better was regarded by many authors as ‘‘success’’ in ossiculoplasty. Such a soft criterion of success can sometimes lead to an operation being labeled as a failure in one period and then a success in another period. The main reason was the lack of consistency in measuring the masked bone conduction thresholds in the operated ear over such a long period (Hughes G.,1987).

The only report on the 5-year outcome based on a high attendance rate was from Vartiainen and Nuutinen. They examined the long-term results of single-stage ossiculoplasty and reported 58% of PORs and 30% of TORs had an ABG of 20 dB or better (Vartiainen E and Nuutinen J.,1992)

Shinohara et al. also reported on the outcome of ossiculoplasty with a 50% attendance rate at 5 years. Using a postoperative ABG of 20 dB or less as one of the criteria of success, they reported 60% success for POR and 34% success for TOR (Shinohara T,et al.,2000).

Using the guidelines from the Committee on Hearing and Equilibrium, Siddiq and East reported that 71% of PORs have an ABG of 20 dB or better after 4 to 17 years (Siddiq MA, East DM.,2004). These results seem to be consistent with the results in the present series. Therefore, the author estimates that the likely 5-year success rate for POR and TOR is around two-thirds and one-third, respectively (Siddiq MA, East DM.,2004).

Table (7) List of publications that provide the 5-year results after ossiculoplasty (Yung M.,2006).

Author(year)	Size of cohort	5-yr follow-up rate	Mean frequency (kHz)	Resuls of POR	Results of TOR	Other observations
Farrior et al. (1996)	115	29%	0.5, 1, 2	50% ≤15 dB	28% ≤20 dB	--------
Shinohara et al(2000)	159	67%	0.5, 1, 2	60% = good	34% = good	Good = hearing gain >15 dB or AC<40 dB or postoperative ABG ≤20 dB
Chissone (1987)	411	68%	--------	----------	----------	Homograft ossicles; 2.5% extruded;2.5 %
Reck et al. (1988)	973	10%	----------	76% ≤20 dB	61% ≤20 dB	----------
Ojala(1983)	--------	n = 164	0.5, 1, 2	Mean ABG = 28.6 dB	Mean ABG = 30.4 dB	----------
Colletti (1999)	290	28%	0.5, 1, 2, 3	Performed malleus-to-footplate interposition in all ossiculoplasties, even when stapes present; Malleus present, 71%≤20 dB; malleus absent, 60% ≤20 dB		
Symth (1983)	213	35%	0.5, 1, 2	-------	Cartilage: 52% success; Plastipore: 25% success	Success defined as postoperative ABG ≤10 dB
Donaldson et al(1992)	71	93%	-------	56% ≤15 dB	---------	Only studied second-stage

						ossiculoplasty with good BC thresholds
Goldenberg et al. (2000)	233	33%	0.5, 1, 2, 3	Overall, 56.8% with postoperative ABG ≤20 dB		---------
Vartiainen et al. (1992)	277	92%	0.5, 1, 2, 3	59% ≤20 dB	30% ≤20 dB	Only studied single-stage tympanoplasty

Chapter XII

Table (8) List of publications giving a mixture of results of different follow-up periods (Yung M.,2006).

Author	Size of cohort	Follow-up period (yr)	Follow-up rate	Results of POR	Results of TOR	Other observations
Emmett et al. (1986)	461	0–8	4–8 yr; 41%	Dry ear: 85% PORP ≤20 dB; 80% TORP ≤20 dB Wet ear: 46% PORP ≤20 dB; 27% TORP ≤20 dB (mean frequency not given)		
Cody et al. (1973)	-------	1.5–8	% Unknown (186 ears)	32% ≤15 dB	21% ≤15 dB	Mean frequency, 0.5, 1, 2 kHz
Tos(1974)	690	1–10	2–10 yr; 86%	Wet ear: overall 41% ≤15 dB Dry ear: overall 67% ≤15 dB (mean frequency, 0.5, 1, 2 kHz; 7% failure excluded)		
Pennington (1973)	216	1–5	-------	----------	----------	Mixture results 1–6 yr; overall 69% #15 dB (mean frequency, 0.5, 1, 2 kHz)
Yamamoto (1988)	220	3–5	34%	66% ≤20 dB	53% ≤20 dB	Mean frequency not given
Mangham et al. (1990)	112	3	71%	58% ≤20 dB	27% ≤20 dB	Mean frequency, 0.5, 1, 2kHz
Rust (1996)	37	0–10	2+ yr; 57%	80%≤20 dB	50% ≤20 dB	Mean frequency, 0.5, 1, 2kHz
Slater et al. (1997)	250	0–4+	4+ yr; 8%	80% ≤20 dB	44% ≤20 dB	Mean frequency, 0.5, 1, 2kHz
Siddiq et	48	4–17	4+ yr;	71% ≤20	-------	Mean

al. (2004)			50%	dB		frequency,0.5, 1, 2, 3 kHz

POR, partial ossicular reconstruction; TOR, total ossicular reconstruction; PORP, partial ossicular replacement prosthesis; TORP, total ossicular replacement prosthesis;-----, data not available; ABG, air-bone gap (Yung MW,2006).

Most publications on ossiculoplasty have been reports on the surgical outcome of a particular surgical technique or ossicular prosthesis. One problem in presenting the long-term results in ossiculoplasty is that the surgeon may change the surgical technique or the prosthesis during the study period. One can argue that the results in the present series would improve if the subset of ears with Ceravital implants were excluded from the final analysis (Yung MW,2006).

It has been recognized that the outcome of ossiculoplasty is influenced by many other risk factors, such as the degree of ossicular damage, otorrhea, condition of the middle ear mucosa, status of the tympanic membrane, and so forth (3,35–38). Rather than looking at individual risk factors (Yung MW,2006).

Yung performed a retrospective analysis on ossiculoplasty cases in a county hospital. Individual patient case records were reviewed in all cases of surgical failure. All patients who had ossiculoplasty were routinely followed-up in a dedicated ear audit clinic on a yearly basis. Even with the benefit of a dedicated audit clinic and a stable population, only 74.4% of ears had a known outcome at 5 years after ossiculoplasty. In his present series, 61.1% of partial and 37.6% of total ossicular reconstructions have an air-bone gap of 20 dB or better at 5 years. Of 83 identifiable late failures , 47 were caused by persistent or recurrent abnormalities within the middle ear and only 36 were thought to be caused by prosthesis-related or surgeon-related problems (Yung MW,2006).

Yung tried to group his surgical failures into three different groups, disease-related, prosthesis related, and surgeon-related . It is accepted that there will be controversy regarding some of the criteria in each group. For example, one can argue that reinforcing the tympanic membrane with cartilage palisades may reduce late perforation or atelectasis. Thus, late perforation or atelectasis may be considered to be surgeon related (Yung MW,2006).

In cholesteatoma ears, again one can argue that the rate of residual or recurrent cholesteatoma was related to the skill of the surgeon. In a previous long-term study by the author on cholesteatoma surgery (median follow-up period, 6.5 yr), the rate of residual cholesteatoma was less than 10% (Yung MW.,2001).

Many cases of migration and extrusion of the prostheses were the consequence of recollapse of the tympanic membrane. There was also evidence of persistent or recurrent otitis media in some cases, causing obliteration of the middle ear space by effusion, granulation tissue, cholesterol granuloma, or fibrous tissue obliterating the middle ear space. Vartiainen and Nuutinen also reported that the main reason for their surgical failures in ossiculoplasty was adhesive changes in the middle ear (Vartiainen E and Nuutinen J.,1992).

In the prosthesis-related failure group, Ceravital was the main culprit. Of 25 Ceravital prostheses, 4 were absorbed and 2 were extruded at 5 years. Five of 35 hydroxylapatite prostheses (14%) were extruded. None of the 34 autologous ossicles was extruded, although 1 resulted in bony ankylosis with the bony canal [tab 9] (Yung MW,2006).

Table (9) Materials used for ossicular reconstruction between 1988 and 1999 (Yung MW ,2006).

Ossiculoplasty material	No.
Cartilage interposition between drum and capitulum of stapes	74
Hydroxylapatite	64
Autologous ossicles	29
Ceravital	18
Titanium	10

In the surgeon-related failure group, the main problem was migration of the prosthesis. This applied to the autologous ossicles, hydroxylapatite (Fig.83), titanium, and the Ceravital prostheses. It was particularly difficult to anchor the prosthesis when the malleus and the stapes suprastructure were absent. It is beyond the scope of the present chapter to analyze specific surgical techniques or prostheses. Overall, the findings indicate that most surgical failures were related to persistent disease within the middle ear (Yung MW,2006).

Yung concluded that in the past 40 years, there have been many technological developments in medical lasers and biomaterials. However, there is no evidence that the overall results of ossiculoplasty have improved greatly during this period (Yung MW ,2003). Unless there is a breakthrough in the understanding and management of the underlying chronic otitis media, the long-term outcome of ossiculoplasty is unlikely to improve dramatically in the future (Yung MW ,2003).

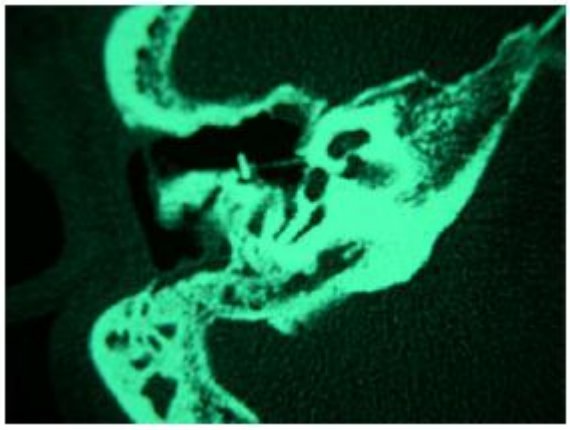

Figure (83). Nonenhanced axial CT scan of a right ear in a patient who noted only short-term improvement in hearing after placement of a total ossicular reconstruction prosthesis. Note the malposition of the prosthesis shaft in relation to the footplate (Ravi N.,et al., 2006).