The Journal of
Laryngology and Otology
(*Founded in* 1887 *by* MORELL MACKENZIE *and* NORRIS WOLFENDEN)
August 1976

Tympanic reconstruction*

Fifteen year report on tympanoplasty
Part II

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Introduction

MUCH of the author's early efforts in tymanoplasty involved the use of methods and materials which can now safely be designated as obsolete, thus this report does not concern any operations in which plastic ossicular replacements or skin grafts were used. Rather, this investigation is confined to the behaviour of the natural materials—bone cartilage and connective tissue.

Tympanic reconstruction comprises both repair of the tympanic membrane (or myringoplasty) and restoration of the ossicular chain (or ossiculoplasty). In analysing the results, it is convenient to separate myringoplasty from ossiculoplasty. Although we are primarily concerned with results, it is necessary to define the techniques which were used in the present study.

Tympanic membrane repair

Early experience with Thiersch graft, postaural and meatal skin encouraged the author to change to underlaid vein graft when it was introduced by Shea in 1960. The superiority of connective tissue for drum repair was quickly recognized in most otologic centres, and practically every type of this tissue has been reported on at some stage since then.

Autologous temporalis fascia (Örtegren, 1959; Heerman, 1960) soon

* Much of this material was contained in the Yearsley Memorial Lecture given at the Royal Society of Medicine on 7 March 1975.

https://doi.org/10.1017/S0022215100082633 Published online by Cambridge University Press

emerged as a reliable, easily available material, and the author has used it almost exclusively between 1964 and 1972.

Experience with tympanic membrane homograft (TMH) (Marquet, 1966; 1973; Perkins, 1970) did nothing to seduce the author from temporalis fascia, but a desire to streamline transcanal operations led to clinical trials with homologous temporalis fascia (HTF) in 1972 and homologous dura mater (HD) in 1973. Homologous temporalis fascia (HTF) had previously been used clinically by Plester (1970) with some success, as had homologous dura by Albrite and Leigh (1966) and Preobrazhenski and Rugov (1965). Personal interest in the possibility of using these materials had been heightened by the author's experimental experience with homologous dura and fascia to repair total tympanic membrane perforations in the cat.

Thus, four materials have been evaluated for this report—ATF in 1,487; TMH in 41; HF in 128; and HD in 209 ears.

For clinical use, TMH, HTF and HD were obtained under as near sterile conditions as possible from refrigerated cadavers within 12 hours of death, having established with reasonable certainty, that the donor had not suffered from malignant disease, lues, tuberculosis or viral hepatitis. The material was placed in 1/5000 Cialit solution and stored at 4 °C. All these materials were used onwards from 48 hours after harvesting, having been washed for one hour before use in normal saline.

Over the years, the author has used two basic grafting techniques in which the graft was placed either under or over the fibrous tissue remnant of the tympanic membrane. It appeared to be more anatomically correct to form a pocket for the graft between the fibrous tissue and the squamous epithelial elements of the tympanic membrane so that the graft would act as a scaffolding for the growth of mucosa on its deep surface and skin over its superficial surface.

However, encouraged by the continued success of underlaid grafts in the hands of, for example, Hough (1970) and Austin and Shea (1961), and having become aware of the technical advantages with this technique, the author has used an underlay technique in almost every case during the past five years.

Although there were some complications in the overlaid technique such as anterior blunting, lateralization and the formation of epithelial pearls, the main factor in deciding to use the underlaid technique was that it was much faster and easier to perform and less susceptible to complications.

The results of myringoplasty and ossiculoplasty have been assessed in identical fashion. All preoperative, operative and postoperative data have been recorded on a pre-punched IBM card which was a modified form of that originally designed by Austin in 1961. Preoperative data include age, laterality, air and bone conduction, pure tone thresholds and speech

https://doi.org/10.1017/S0022215100082633 Published online by Cambridge University Press

discrimination scores. Operation data classified the tymanoplasty type, ossicular reconstruction, the type of disease, the state of middle ear mucosa, the character of middle ear secretion, the state of the mastoid air cell system, the size of tympanic membrane perforation and the state of the ossicular chain at the conclusion of the operation. Postoperative airbone gap, change in air conduction and bone conduction and the level of speech discrimination have been recorded first at six-monthly and yearly, and subsequently at two-yearly intervals. The types of tympanic membrane and ossicular graft have been recorded for each operation.

In addition, the duration of follow-up, the percentage of possible follow-up and the duration of maintenance of the one-year hearing gain have been recorded.

When Revision operations have been performed, the numbers of these operations, the type of reconstruction which failed, the main problem at each operation and the procedure at each Revision operation—with its hearing result—have been recorded at six months, yearly, and then two-yearly postoperatively. Finally, the numbers of Staged operations, why they were performed and the findings at the second stage are documented along with the type of ossicular reconstruction used at the second stage operation and the results achieved, again on a six-month, one-year and recurrent two-yearly basis.

Separate cards have been used to record the data on Revised and Staged operations, and additional files have been used to document the various categories of failure and all cases of special interest.

These data have been analyzed as required by means of the ICL.1906S computer.

The otologic literature is replete with articles in which conclusions are drawn without any attempt to ascertain the true meaning of the data. Such reporting is worthless. This view is well supported by Austin who wrote: 'Simple statements regarding "success rate" or "percentage of patients reaching social adequacy" do not define the data or permit drawing statistically valid conclusions. The figures cannot and do not speak for themselves and since, in the absence of some statement regarding the possibility that the figures represent a pure chance occurrence, one can only guess if there is a chance that the results are meaningful" (Austin, 1971); and again: 'If no figures estimating error or significances are to be found, better give the whole thing a big glassy stare. If they are there, take them to heart. You may avoid learning a remarkable lot that is not so' (Austin *et al.*, 1974). No conclusions have been drawn from the statistics in this report without prior evaluation of their significance.

Myringoplasty results

1. *Autologous temporalis fascia* was used and assessed between two and eight years after operation in 1,487 ears. The overall analysis shows a

https://doi.org/10.1017/S0022215100082633 Published online by Cambridge University Press

failure rate of 4·8 per cent. Cross-tabulation of the proportions of failure to success in the three basic operation types against the size of perforation is shown in Table VII. Perforation size is designated arbitrarily as attic,

TABLE VII.

EFFECT OF INFECTION ON OVERALL FAIL RATES OF AUTOLOGOUS TF GRAFTS

TCT			CAT		MO	
Small	Large	Attic	Small	Large	Small	Large
13/412	21/257	33/33	5/252	20/315	5/94	6/124
3·1%	8·2%	0	2·0%	6·3%	5·3%	4·9%
P<0·01			P<0·05		NS	

small (half or less of the membrana tensa) and large (larger than half the membrana tensa).

It comes as no surprise that failure occurs more frequently in larger perforations in both TCT (P<0·01) and CAT operations (P<0·05). The difference in take rates for mastoid obliteration (MO) operations is not significant.

When cross-tabulation of the small perforation cases for operation type against the presence or absence of middle ear secretion at the time of operation is made (Table VIII) a significantly greater fail rate in moist

TABLE VIII.

EFFECT OF INFECTION ON TAKE RATE OF AUTOLOGOUS TF GRAFTS IN SMALL PERFORATIONS

TCT		CAT		MO	
Wet	Dry	Wet	Dry	Wet	Dry
11/188	2/224	2/209	0/46	5/83	0/10
6·3%	0·9%	0·9%	0	6·0%	0
P<0·01		NS		NS	

ears is found only in TCT operations (P<0·01). At the time of operation the middle ear was categorized as being either (1) dry or having (2) mucoid or (3) purulent secretion. In the present analysis only the extremes of the range were compared in order to exclude an ill-defined portion of the group (mucoid secretion) which might equally indicate an infected or non-infected state. The better opportunity to control mastoid disease with the

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wider exposure of CAT and MO, might be the reason for this difference On the contrary, with large perforations (Table IX), the fail rate was not significantly influenced by the presence of discharge in any operation type.

TABLE IX.

EFFECT OF INFECTION ON TAKE RATE OF AUTOLOGOUS TF GRAFTS IN LARGE PERFORATIONS

TCT		CAT		MO	
Wet	Dry	Wet	Dry	Wet	Dry
13/166	8/91	19/291	1/24	5/113	1/11
7·8%	8·8%	6·5%	4·1%	4·4%	9·0%
NS		NS		NS	

2. *Homologous fascia.* This material, which was used both in the fresh state (obtained on the same day from another patient) in 128 patients and also from a cadaver preserved in Cialit solution in 100 patients, provided results which are indistinguishable from those obtained with ATF. These statistics are the subject of an earlier communication (Smyth *et al.*, 1975).

3. *Tympanic membrane homograft.* Unacceptable results were reported previously with two series comprising 41 operations in which the take rate was no better than 65 per cent (Smyth and Kerr, 1969; Smyth *et al.*, 1971).

4. *Homologous dura.* The results of tympanic membrane repair with HD were assessed in 209 ears with a postoperative follow-up between 3 and 18 months. There was failure to take in five ears. Thus, there was a fail rate of just over 2 per cent with this material.

Cross-tabulation of the proportions of failure to success in the three basic operation types against the size of the perforation is shown in Table X. The number of failed cases is insufficient for any useful conclusions on the influence of preoperative infection. Thus, the relevance of infection to the overall outcome with HD grafts cannot be assessed.

TABLE X.

OVERALL FAIL RATES WITH HOMOLOGOUS DURAL GRAFTS

TCT		CAT		MO	
Small	Large	Small	Large	Small	Large
2/99	1/19	0/31	0/27	1/15	0/17

https://doi.org/10.1017/S0022215100082633 Published online by Cambridge University Press

Because four of the five HD graft failures occurred in infected TCT operations—the other was in an infected MO case—these cases were looked at separately and a comparison was made between, (1) the proportions of success and failure obtained with ATF and HD in TCT operations on infected ears, regardless of perforation size, and (2) the results in infected ears with small perforations. In neither case was the difference significant.

The most interesting statistic from the results with HD comes from a comparison of overall results with ATF and HD (Table XI) which shows

TABLE XI.

COMPARISON OF FAILURES IN TAKE RATE BETWEEN AUTOLOGOUS FASCIA AND HOMOLOGOUS DURA

	AF	HD
	70 / 1454	5 / 209
	4·8%	2·4%
SD	3·7–5·9	0·3–4·5

95% confidence intervals NS

a respective fail rate of 4·8 and 2·4 per cent respectively. At first glance this would appear to be a real difference in favour of HD. However, when account is taken of the respective standard error, there is an overlap of the distribution curves at 95 per cent confidence intervals. Thus, the difference in percentage is not significant.

Obviously the take rate for any graft is a highly relevant factor in the choice of material, but a complete evaluation also demands knowledge of its functional capacity. The average airbone gap at six months postoperatively in 72 HD grafts was compared with the same statistic from 866 ATF operations where the ossicular chain was intact. The difference of success in terms of closure of airbone gap to 10 dB or less was not significant ($(\chi^2=2\cdot65)$. Furthermore, the presence of infection at the time of operation was not found to affect the success rates in terms of hearing in TCT and CAT operations, one, four or six years postoperatively. Additional further support for the use of both materials was available from a small group of measurements of tympanic membrane complicance in patients who had closure of the airbone gap to 5 dB or less following myringoplasty with ATF and HD.

Discussion

It is probable all these materials act as a scaffolding for the migration of skin and mucosa. Szilagy's (1970) observation that the inherent me-

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chanical strength of arterial implants is the most relevant factor in success, should apply equally to the problems of reconstructive middle ear surgery.

The longer the graft resists lysis the better the chances of healing. However, ATF, HTF and HD appear to be highly resilient and the damaging influence of infection on autologous fascia is only apparent in one category, i.e. in infected ears with small perforations.

The rationale of placing the graft medial to the mucosal surface on a bed of gelatin sponge still seems questionable. One would expect that the layers would maintain this relationship and that there would be mucosal regeneration *lateral* to the graft, with its eventual disappearance and the formation of a two layer tympanic membrane. The author's attempts to elucidate the problem experimentally came to naught because of problems inherent in cat middle ear surgery. Much work elsewhere has been unhelpful and even misleading—extrapolation from animal experiments using healthy ears with surgically produced partial defects of the tympanic membrane cannot necessarily be completely relevant to the human problem.

The overall conclusion in regard to materials for tympanic membrane repair must be that although ATF has served extremely well, HD has proved equally successful and, in addition, most importantly, it is much easier to handle and very much more convenient in transcanal procedures where its use avoids a scalp incision. The author has no hesitation in recommending HD and intends to continue using it, and, indeed, doubts if there will be any better material for tympanic membrane repair in the foreseeable future.

Meanwhile alongside the developments in myringoplasty, there were equally exciting advances in ossiculoplasty.

Progress, away from the five standard types of middle ear reconstruction (advocated by Zollner, 1960), began with the recognition that a fundamental cause of failure had been obliteration of the shallow mesotympanum in Type III and Type IV operations. Cortical bone grafts placed on the stapes head to lateralize the grafted drum and increase the depth of the middle ear failed to improve the end result not only because, as we now know, cancellous bone makes a poor graft (Smith and Abramson, 1974), but also because there were several other unsolved problems in the West German surgical blue-print. But from this time on, increasing attention was paid to the desirability of achieving an air-containing middle ear space. Materials to control mucosal healing were introduced—the wax of Rambo (1965) and the silastic sheeting of House and Sheehy (1963).

The importance of reforming the tympanic membrane in its correct anatomical position and the necessity to restore mucosal function, were widely recognized as indispensable to successful tympanoplasty. Thus was born combined approach tympanoplasty (Jansen, 1958; Smyth, 1962).

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Meanwhile, stapedectomy, now nearing its zenith, provided two important spin-off effects which influenced the development of reconstructive chronic ear surgery.

Stapes replacement, by polythene, and later, teflon pistons, had been introduced by Shea in 1958. Austin and Shea (1961) working in Memphis, realized the possible application of prostheses made from these materials to tympanoplasty, both as a means of increasing the height of the stapes and as incus replacements. Various surgeons, including Harrison (1960), House and Sheehy (1963), Smyth (1964) and others, introduced their own modifications. The initial results were extremely encouraging—the finale almost universally unsatisfactory. Teflon and stainless steel, effective in the otosclerotic ear, caused hyperkeratosis and cholesteatoma when placed against the deep surface of the tympanic membrane and necrosis when they exerted pressure against the malleus handle.

As enthusiasm for plastic and steel ossicular replacement subsided, a further influence from stapedectomy acquired increasing relevance.

Hall and Rytzner had introduced their method of replacing the otosclerotic stapes with the patient's incus in 1957. The application of this method to tympanoplasty proved attractive and during the early 1960's a number of surgeons, especially Farrior (1960), Guilford (1965), Sheehy (1965) and Austin (1971), advocated the incus repositioning technique (IR) as a standard method of ossicular reconstruction. Furthermore, for patients in whom the incus was unsuitable or absent, the use of homograft incudes was introduced by House *et al.* in 1966, and since then, techniques with homologous and autologous ossicular grafts have enjoyed increasing popularity in reconstructive chronic middle ear surgery. With experience, fears over graft rejection have receded. The need to improve functional results led Armstrong (1969) and Austin (1971) to propose technical modifications of the original Farrior technique aimed at achieving greater stability of the ossicular graft. Thus, stapedectomy influenced the course of tympanoplasty both by providing synthetic materials which unfortunately failed to fulfil their early promise, and also by drawing attention to ossicular grafts, which have proven much more useful. It is interesting to observe that the reverse process has occurred with cartilage grafts in the middle ear. In 1956, Jansen (1961) began to use first auricular, and later, nasal septal cartilage to reconstruct chronically infected ears without a stapes superstructure. Subsequently, Utech (1959) and Pfaltz and Piffko (1968) reported the use of cartilage in stapedectomy. Quite soon, Brockman (1965), Harris and Goodhill (1967) and eventually Pulec and Sheehy (1973) have paid tribute to the qualities of auricular cartilage in tympanoplasty. However, although ossicular bone and cartilage have been in widespread use since 1965, there is still a paucity of reports which would engender complete confidence in the long-term reliability of these materials.

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Tympanic reconstruction

Ossicular reconstruction

Before proceeding to an analysis of the clinical results in ossiculoplasty, the techniques concerned must briefly be defined.

After the removal of all irreversibly diseased tissue, we are routinely confronted with four situations which require solution:

1. The malleus and stapes are present; the incus is absent.
2. The stapes is present; the incus and the malleus are absent.
3. The stapes arch, the incus and the malleus are absent: the stapes footplate is mobile.
4. As in (3), but the stapes footplate is fixed.

In the first situation during the early part of this series, an incus was placed on the stapes head and in loose contact with the malleus, incus transposition (IT), but since 1968 the malleus-stapes assembly modification (MSA) of Armstrong and Austin has been routine. In this, a piece of the patient's own or a preserved malleus head, or incus, is sculptured with small burs to fit the interval between the stapes head and the malleus handle.

In the second situation most frequently an incus graft is placed as a columella between the stapes head and the grafted tympanic membrane—'Slipper' interposition (SI), so named because of its shape and appearance. In a smaller number of early cases an interposition was made with a small piece of nasal cartilage—short cartilage 'L' (SCL). A wedge-shaped strut was cut from nasal septal cartilage previously preserved in 70 per cent alcohol at 5 °C and washed for one hour prior to use in normal saline.

In the third situation a long 'L-shaped' strut made from preserved nasal cartilage (LCL) strengthened by stainless steel wire has been used routinely. This is placed to bridge the gap between the mobile stapes footplate and the undersurface of the tympanic membrane. Two pieces of No. 38 French gauge stainless steel wire, sharpened by cutting obliquely with scissors, are inserted at an angle of about 75° into a piece of cartilage measuring about 6 mm square. Using a fresh No. 11 blade, the strut is then cut so that the medial limb which will contact the footplate is about 5 mm. and the lateral limb usually about 4·75 mm. in length, the exact measurements being varied to suit the individual ear.

This type of reconstruction was designed to incorporate a lever with its lateral limb well applied to the tympanic membrane over a sufficient area to act as an efficient sound-energy coupler between the wide surface area of the tympanic membrane, large relative to that of the oval window, and thus preserve the important factor of areal ratio in middle ear sound transmission.

Alternatively in the third situation, early in this series, an incus body and short process was interposed between the malleus handle and stapes footplate in a small number of operations. This type of reconstruction has been described as malleus footplate assembly (MFPA) by Austin (1971).

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In the fourth situation, if the stapes footplate is fixed either by otosclerosis or tympanosclerosis, the procedure *must* be Staged so that three months elapse between the primary operation, to eradicate the inflammatory disease process, and repair the tympanic membrane defect, and the second operation in which the stapes footplate is divided and removed atraumatically. Having covered the oval window with a piece of autologous vein or fascia, an LCL strut is then placed between it and the undersurface of the healed tympanic membrane.

Hearing results

There are three main categories of operation:

1. First operations.
2. Staged operations.
3. Revised operations.

1. *First operations*. These are 1,433 in which no Staging was performed. Many of the failures in this group subsequently had further operations and thus are also included in the Revised operations group. The general statistics can be summarized as follows:

The initial diagnosis was almost equally divided between chronic suppurative otitis and cholesteatoma. Tympanosclerosis occurred in only 6 per cent. Although the extent of the disease process was limited (over half were TCT) there was infected middle ear secretion in half of the total at operation. In an overall analysis of hearing levels, 62 per cent had closure of the airbone gap to 10 db or less at the most recent hearing test. Seventy-six per cent achieved maximum possible follow-up and 68 per cent were followed-up for five years.

2. *Staged operations* in which, for reasons of prudence, usually to avoid cochlear damage or the risks of Residual disease, ossicular reconstruction was postponed for three to six months. The principal reasons for Staging were:

(a) Cholesteatoma associated with the stapes.
(b) Granulations obscuring the anatomy of the oval window.
(c) Tympanosclerotic fixation of the stapes footplate.

There were 192 once Staged operations, as well as 13 twice and one thrice Staged. In addition, there were 15 more once Staged operations in whom subsequent problems necessitated an unplanned Revision operation. Thus, 14 per cent of all the operations analyzed in this report have been Staged. The general statistics for this group are as follows:

Both ears were similarly affected in exactly half of the patients.

The type and extent of the disease process was more often serious in this group than the once-only group in that the initial diagnosis was cholesteatoma in two-thirds, and CAT was performed in two-thirds.

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In over two-thirds, infected middle ear secretion was present at the time of operation.

In an overall analysis 81 per cent had closure of the airbone gap to 10 db. or less at the most recent hearing test.

25 per cent showed postoperative bone conduction levels elevated by 10 db or more.

3 per cent showed cochlear depression of 10 db or more which includes two dead ears.

80 per cent achieved maximum possible follow-up.

86 per cent achieved 75 per cent possible follow-up.

92 per cent achieved 50 per cent possible follow-up.

117/223, i.e. 52 per cent, were followed-up for five years.

Of the 185 who had a satisfactory hearing gain at one year, this was maintained in 178 with developing airbone gaps of greater than 10 db in five after one year and one patient each at two and three years (95 per cent).

3. The *Revised operations* category consists of 279 in which the First Operation failed to achieve the desired result. These First Operations are obviously all in the 'failed' category (i.e. postoperative airbone gap >10 db) and their data make an important contribution to the various total fail rates in the First Operation group. Revision operations constitute 17 per cent of the total number of operations in this report. Two hundred and seven (three-quarters) were single and the remainder spreading with diminishing frequency to one ear revised seven times.

The general statistics for this group are as follows:

The age distribution is the same as for Staged operations with the maximum incidence in the fifth decade.

Just over 50 per cent had bilateral disease.

The predominant initial diagnosis was cholesteatoma, and practically 50 per cent were treated initially by CAT, and in just over half, infected secretion was present at the original operation.

64 per cent *eventually* reached airbone gap closure of less than 11 db. at the most recent hearing test.

46 ears, i.e. 16·5 per cent, showed improvements of 10 db. or more in bone conduction but there were six dead ears (2 per cent).

86 per cent achieved maximum possible follow-up and 80 per cent were followed-up for five years.

Satisfactory hearing gains (10 db. airbone gap) at one year were maintained in 96 per cent.

Data analysis

Part A

During the past decade it has been the author's practice in tympanoplasty to use the method of analysis for hearing results recommended by

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the Committee on Nomenclature in Chronic Ear Disease and the Otosclerosis Study Group of the American Academy of Otolaryngology and Ophthalmology. This method uses preoperative bone conduction and postoperative air conduction to compute the postoperative airbone gap. In the present series, closure of the airbone gap to 10 db. or less has been designated as 'success'.

In order to simplify the results of this continued analysis, the data have been summarized in four tables.

1. In Table XII the numbers of operations (in brackets) and the

TABLE XII.

HEARING RESULTS IN REGARD TO OSSICULOPLASTY TYPE

No. 1,231

	TCT	CAT	MO
IT	(39) 50***	(71) 54***	(13) 61
MSA	(100) 83	(89) 88	(9) 66
MFPA	(7) 100	(6) 33	(1) 100
SI	(35) 71	(31) 74	(18) 72
SCL	(7) 47	(10) 40	(5) 40
LCL	(118) 65	(214) 54 *	(74) 70

P<0·05* P<0·001***

percentage of success for each of the main reconstructive techniques in the three basic operation types are shown in vertical columns.

Tests of significance have been carried out for differences between the success rates with each reconstructive technique in the three operations (in vertical columns), and for the differences between the success rates for each operation type with every type of ossicular reconstruction (in horizontal columns). The significant differences and their P values are indicated by arrowed bars and asterisks as appropriate.

Thus, MSA proved more efficient than IT for both TCT and CAT operations, and the LCL prosthesis was more effective in MO operations than in CAT.

2. In Table XIII the influence of infection in all First Operations (TCT, CAT and MO combined) was evaluated for the larger groups of ossicular reconstruction technique. The total numbers of operations (in brackets) and the percentage of success are tabulated for dry (D) ears and those with purulent secretion (P) at the time of operation. In no category are the differences significant.

3. A comparison was made between the results obtained for the main categories of reconstruction in the three main groups of operation and

https://doi.org/10.1017/S0022215100082633 Published online by Cambridge University Press

the figures tabulated in Table XIV. In the vertical column the MSA technique was better for both First and Revised operations than the IT technique; whereas the LCL technique proved superior to the MFPA technique. In First operations, while SI proved superior to SCL, LCL was less successful than MSA.

TABLE XIII.

RELATIONSHIPS BETWEEN PREOPERATIVE INFECTION AND FINAL HEARING RESULT

	TCT				CAT				MO			
	D		P		D		P		D		P	
IT	(10)	80	(9)	33	(4)	0	(40)	65	(2)	50	(11)	65
MSA	(46)	83	(23)	83	(9)	100	(48)	85	(1)	100	(5)	60
SI	(8)	85	(7)	86	(4)	50	(10)	80	(1)	100	(7)	57
LCL	(58)	64	(21)	62	(20)	50	(97)	39	(10)	60	(46)	69

D = Dry ears. P = Purulent secretion.

TABLE XIV.

COMPARISON OF HEARING RESULTS IN FIRST, REVISED AND STAGED OPERATIONS

	First		Revised	Staged
IT	(98)	53***	(17) 50*	(8) 87
MSA	(148) ***	82*	(31) 84	(22) 100
MFPA	(6)	33	(5) 80	(3) 66
SI	(49)	65	** (13) 69	(25) 84
SCL	(11)	9	* * ←(6)—66——→(5)→80	
LCL	(276)	52	*** * ←(132)—62——→(112)→82 **	

* $P<0.05$ ** $P<0.01$ *** $P<0.001$

In the horizontal columns, MSA was more effective in Staged as compared to the First operation. This superiority between Staged and First operations applied also to SCL and LCL reconstructions. In addition, SCL reconstructions were more successful in Revised as compared to First and LCL reconstructions more successful in Staged than Revised operations.

4. Finally, the possibility that one disease type was more likely than another to necessitate one or more Revised operations was examined (Table XV). When the distributions of the types of chronic otitis media

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TABLE XV.

RELATIONSHIP BETWEEN DISEASE TYPES AND NUMBERS OF OPERATIONS

	First		Revised		
Suppurative	(543)	88	(73)	12	*
Cholesteatomatous	(494)	74	(172)	26	*
Tympanosclerotic	(85)	72	(33)	28	*

*P<0·001

(suppurative, cholesteatomatous and tympanosclerotic) within the First and Revised groups were analysed, it was found that when cholesteatoma or tympanosclerosis was the preoperative diagnosis, the incidence of Revised operations was significantly greater than it was for ears diagnosed as uncomplicated chronic otitis media (P<0·001 in each instance).

Part B

For the purposes of this report, the hearing results were analysed by comparing changes in air conduction as advocated by Austin (1971) using mean and variance to analyse some of the differences in results by t-tests (McNemar 1969).

The mean air conduction changes obtained with the principal reconstructive techniques in First, Staged and Revised operations were compared, in a series of analyses, whose results are summarized in Tables XVI-XIX.

TABLE XVI.

EFFECT OF PREOPERATIVE INFECTION ON AIR CONDUCTION CHANGE

		Dry			Purulent		
		Mean	SD	No.	Mean	SD	No.
Staged	LCL	14·1	19·6	17	24·1*	12·3	82
Revised	LCL	17·3	18·9	26	15·5	13·0	93
First	LCL	18·7	14·5	59	14·1	16·0	130
First	IT	12·9	17·2	26	14·1	10·6	38
First	MSA	16·6	17·7	50	15·6	17·2	100

* P<0·05

1. In Table XV the air conduction changes achieved by the principal types of reconstructive technique in First, Staged and Revized operations (sub-divisions into TCT, CAT and MO being disregarded), in relation to the presence of infection, are cross-tabulated. (Other reconstructive techniques are excluded because of small numbers.) The only significant difference in outcome occurs with Staged LCL reconstructions which produced greater improvements in air conduction thresholds when

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performed on ears infected at the original operation. The explanation for this may be quite simply that in these ears there was a much greater capacity for improvement.

2. A comparison was made between the results for the main categories of reconstruction in First, Staged and Revised operations and the results are tabulated in Table XVII. The significant differences are as follows:

TABLE XVII.

COMPARISON OF AIR CONDUCTION CHANGES IN STAGED, REVISED AND FIRST OPERATIONS

		Staged	Revised	First
IT	Mean	30·0	11·8	12·8
	SD	12·5	19·2	15·3
	No.	8	17	83
MSA	Mean	25·0	17·1	16·6
	SD	8·6	14·9	17·0
	No.	22	31	172
SI	Mean	16·9	20·3	Insufficient numbers
	SD	16·1	13·6	
	No.	24	15	
LCL	Mean	22·2	16·0	15·4
	SD	14·1	13·7	15·4
	No.	112	143	203

* $P<0·05$ *** $P<0·001$

(a) In Staged operations, both IT and MSA techniques gave better results than the SI method.

(b) The IT, MSA and LCL techniques were all more successful in Staged operations than in Revised and First operations.

(c) The differences in result between the Revised and First operations were not significant with any of the reconstructive techniques.

3. An analysis of LCL reconstruction in Staged, Revised and First CAT and MO operations showed no significant differences in the results obtained (Table XVIII).

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TABLE XVIII.

COMPARISON OF RESULTS WITH LONG CARTILAGE STRUTS IN CAT AND MO OPERATIONS

		MO			CAT		
		Mean	SD	No.	Mean	SD	No.
Staged	LCL	24·6	11·6	12	21·7	12·7	80
Revised	LCL	12·7	13·6	22	16·1	31·2	79
First	LCL	11·1	20·8	44	15·2	14·1	87
		NS			NS		

4. Finally, the effect of the passage of time on successful results was examined. A comparison of the mean air conduction changes at fixed intervals postoperatively in First operations with closure of the airbone gap to <11 db. ('successes') (Table XIX) provided no evidence that

TABLE XIX.

DURABILITY OF AIR CONDUCTION IMPROVEMENTS

	IT			MSA			LCL		
	Mean	SD	No.	Mean	SD	No.	Mean	SD	No.
6 months	13·9	14·9	70	17·2	14·9	181	20·3	14·7	183
1 year	14·0	16·3	65	17·6	16·0	168	19·9	15·8	170
2 years	14·4	16·3	59	17·5	17·5	153	18·7	17·0	143
4 years	14·6	16·7	55	17·0	15·9	115	18·7	17·9	103
6 years	14·4	15·1	33	18·2	14·3	58	22·4	12·8	44
8 years	12·9	16·9	24	14·0	17·6	24	19·8	14·6	20
	NS			NS			NS		

initially successful results in the three principal reconstruction categories subsequently suffered significant deterioration.

Discussion of hearing results

Unfortunately from the data provided, many significant problems cannot be resolved because, when subjected to statistical analysis, the differences in success rate are not sufficiently large to be considered other than the result of chance. The data in this report have been analysed under two headings:

1. Evaluation of closure of the airbone gap to 10 db. or less (ABG). (This can only be an arbitrary assessment of technical success.)
2. Evaluation of air conduction change (ACC). (Indicating actual improvement in hearing level.)

Austin (1971) argues that even allowing for the lesser stringency of ACC analysis and acknowledging that some of the surgical techniques employed are less successful than one would wish; nonetheless a comparative analysis suggests that these techniques have value which is not to be

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dismissed. An additional advantage of the ACC method would be the ability to compare statistics from different centres.

In the author's experience, the ACC method of analysis does *not* produce significant additional information to that which the ABG method has already provided, but each has contributed to corroborating specific and general conclusions.

Specific conclusions

1. MSA has proved to be superior to IT in practically every type of operation. It was more successful in both TCT and CAT operations and in all First and Revised operations (the difference in Staged operations was not significant).

2. Although there was little to choose between SI and SCL reconstructions in the three basic operations (TCT, CAT and MO), the difference was significant in First operations in which cartilage grafts did less well overall. Therefore, it could be inferred that cartilage grafts fare less well than osseous grafts in the more hostile environment of the First operation as compared with the less severe middle ear conditions of the Staged and Revised operations. This inference is not, however, borne out by the general findings on the influence of infection.

3. Cartilage struts of both types did significantly less well in First operations than in Staged and Revised operations. Since a comparison of success in infected and non-infected ears in each type of operation and in each type of reconstruction failed to show significance, it can be assumed that there must be factors other than freedom from infection which explain the greater success of LCL in Staged operations.

The most obvious explanations of the success rate are:

(a) the ability to fit a flexible cartilage strut tautly between the footplate and the healed tympanic membrane, the position and character of which are now stabilized; and

(b) the healed state of the mucosa and the aeration of the tympanic space at the second Stage operation.

4. LCL is statistically superior to MFPA using an incus graft because the graft was sculptured in a bulky way and likely to become adherent to the promontory or the horizontal facial canal.

General conclusions

1. Overall, the significant superiority of the results of the Staged, as opposed to First and Revised operations, underlies the difficulty of obtaining satisfactory results in pathological conditions because, not unexpectedly, results *are* better when, (a) mucosal healing leads to aeration of the middle ear space, and (b) the position of configuration of the tympanic membrane retains or achieves relative normality or stability. The contention that the outcome is better is illustrated by the better

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results with both IT and MSA as compared to SI in Staged operations. With Staged IT, healing of the middle ear being far advanced, lateralization of the tympanic membrane has largely ceased and in Staged MSA the presence of the malleus handle is a continually stabilizing influence on the tympanic membrane.

2. In spite of the ability to recognize the cause (or causes) of failure at the second operation, less satisfactory results are recorded for Revision operations than for the Staged. Persistent problems with mucosal healing and tympanic membrane stability continue to interfere with a satisfactory outcome.

3. The absence of stapes crura still constitutes a significantly more difficult reconstruction problem.

4. It could be argued that all tympanic reconstructions should be carried out according to the Staging method if statistical results were to be interpreted at their face value.

The Staging method could be accepted provided that:

1. The pathology of the ears throughout the series was the same. Only then would a two-stage procedure be likely to provide a final result predictably better than a First operation, allowing even for one or more Revisions.

2. That the surgeon be prepared to subject the patient to these procedures knowing that he might well respond to a First operation. However, this point is largely theoretical because the patients in this series have been selected for Staging for reasons related to cochlear safety rather than potential enhancement of middle ear function.

The ACC statistics of this series were compared with those previously reported by Austin (1971) for a similar group of reconstruction operations. Analysis by t-test indicated only two actual differences (Table XX).

TABLE XX.

COMPARISON OF OSSICULOPLASTY RESULTS OBTAINED BY AUSTIN AND SMYTH

			Mean ACC
IT	Austin	Staged	12·8
	Smyth	Staged	30·0 } t=3·23**
		Revised	11·8
		First	−t <1 NS.
			12·8
SI	Austin	Staged	28·7
	Smyth	Staged	16·9 } t=2·21*
		Revised	20·3 −t=1·54 NS.
		First	Insufficient numbers

* P<0·05 ** P<0·01

(a) In the author's series, Staged IT operations resulted in better hearing than that obtained by Austin with a First operation (P<0·01)—further evidence of the value of Staging when necessary.

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(b) The SI reconstruction on the other hand produced less improvement in hearing even in Staged operations than the same reconstruction procedure (tympanic strut) in Austin's series ($P<0{\cdot}05$). The explanation for this difference is not clear.

Operative findings at revision operations

Data from the ears which had Revision operations should be a fruitful source of information about causes of failure in ossicular reconstruction in particular and tympanoplasty in general and serve as guidance in future developments. These data have been looked at from two aspects:

A. The operative findings at all Revision operations.

B. The histological findings from material removed at many Revision operations.

A. Data from operative findings

1. *Ossicular problems*

Although the operative findings can often clearly explain lack of success with the initial operation as, for example, where there is a perforation of the tympanic membrane or Residual or Recurrent diease, frequently there is difficulty in allocating primary and secondary responsibility when more than one problem is detected. The primary findings at all the First Revision operations are tabulated with the original reconstructive procedures in Table XXI.

TABLE XXI.

CAUSES OF FUNCTIONAL FAILURE FOUND AT FIRST REVISION OPERATION

	IT	MSA	MFPA	SI	SCL	LCL
Perforation	3	2	1	2	0	3
Perf.+ossic. problem	1	3	0	0	0	8
Blunting, etc.	2	0	0	2	0	4
LCL off FP	1	0	1	0	0	34
LCL incomplete	0	0	0	0	0	17
Fibrous union	24	11	2	5	4	2
Ossic. stiff	1	4	0	0	1	6
Collagen	2	0	0	2	3	14
Residual	0	0	0	1	0	2
Recurrent	2	0	0	1	1	11

The most frequent problem to be found with all incus grafts was lateral movement of the graft with resultant fibrous union between the graft and the stapes head, accounting for two-thirds of the IR failures, and similarly half of the MSA, half of the MFPA and half of the STI failures.

The main finding to account for failure with long cartilage struts was lateral displacement of the medial limb of the strut off the footplate in just over one-third. Adhesions immobilized the strut in one out of every six which failed, a problem which is the result of incomplete control of mucosal healing.

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In addition, out of a total of 563 LCL procedures there were 17 (3 per cent) in which, at Revision, part of the medial limb of the strut was found to be incomplete. In eight of these there was evidence of middle ear infection, and in a further three there was associated Residual, and in one Recurrent disease. In five others without any history suggesting infection, the strut was found to be notched exactly at the level of the perforation in the silastic sheeting where it overlay the stapes footplate. At operation, the close physical relationship between the notch in the cartilage and the edge of the silastic sheeting was striking.

2. *Multiple operations*

The difficulty in identifying the cause of failure is compounded where there have been multiple operations. In general, the original problem persists although in some ears the persistence of disease was complicated by the development of additional and different problems. An exhaustive analysis of the findings at all Revision operations was undertaken to attempt to isolate the main causes of failure in this series, but it has not been possible to assign significance to much of the data (Table XXI). For example, neither the age of the patient nor the presence or absence of infection at the time of operation could be related to the frequency of Revision operations. However, the following observations appear to be relevant:

(a) The frequency of lateral displacement of the long cartilage strut with disruption of its connection with the stapes footplate, emphasizes the unsatisfactory nature of this reconstructive procedure. Once this problem has occurred it is extremely difficult to correct.

(b) There appear to be two quite different types of Eustachian tube problem in the patients of this group.

In Type A the Eustachian dysfunction of *acute* onset leads to a retraction pocket and later a cholesteatoma. Meanwhile, during childhood the diameter of the tube enlarges with growth and when later the appropriate medical and surgical treatments are given, the tube becomes functional once more. The evidence for this view is that although some retraction pockets have occurred following the first tympanoplasty, *none* has required any more than one Revision.

In Type B, Eustachian tube dysfunction of *subacute* onset leads to generalized granular mucosal disease of the middle ear and mastoid cell system. This condition appears to be analogous to the catarrhal otitis (glue ear) of children without the tendency to retraction pocket formation.

The question arises as to whether there is an unusual susceptibility to infection in these patients or whether the organisms are endowed with exceptional virulence. Certainly ears affected by generalized and recurrent granular mucosal disease constitute a particularly difficult problem. Typically three months after as complete clearance of mucosa as possible

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from the middle ear and mastoid cells, the findings at Revision are identical to those at the previous operation. Most of these patients have gradually improved with repeated operations, but in three ears after multiple biopsies a diagnosis of tubercle bacillus infection was eventually established. This experience emphasizes the importance of a routine search for evidence of this organism in the granulations from all chronically infected middle ears in this era of changing population.

B. **Histological data from animal experiments and revision operations**

Major questions remain about the long-term effectiveness of cartilage and bone grafts and there are further queries, possibly of less urgency, regarding methods of tissue preservation and the comparative efficacy of autologous and homologous tissue.

1. *Animal research*

To some extent, the answers may be found through animal experimentation. This brings us into confrontation with the basic problem of current otologic research, namely, what reliance can be placed on extrapolation from animal experiments to the human condition. Can our experience with incus grafts in the healthy feline middle ear be grounds for any useful prediction on the performance of a homologous ossicle in the chronically infected, poorly aerated, human middle ear?

The lack of unanimity of opinion on the behaviour of ossicular bone grafts between researchers such as Wilson *et al.* (1966), van den Broek (1967) and ourselves (Smyth and Kerr, 1967) serves to emphasize this difficulty. Nevertheless, to guard as far as possible against the possibility of avoidable disaster, we attempted to evaluate several natural materials experimentally for tympanoplastic reconstruction during the early 1960's. It was concluded that in the experimental animal,

(a) both autologous and homologous cartilage struts would act as useful ossicular replacements,
(b) the general shape and appearance of the cartilage struts remained unaltered and there was no evidence of resorption or foreign body reaction, and
(c) both autologous and homologous ossicular bone graft became reossified, but that this process was retarded by infection.

2. *Human histological findings*

To date, 35 human ossicular grafts, which include 28 incudes (15 homologous and 13 autologous) and seven mallei (five homologous and two autologous), have been studied (Smyth and Kerr 1975).

In every transplanted ossicle the gross structure was maintained without evidence of erosion visible to the naked eye. Histologically, every specimen showed some revascularization of the Haversian canals and

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marrow spaces accompanied by mesenchymal cells. Such soft tissue revascularization was widespread in all but three specimens. These exceptions were one two-month and two three-month homografts, and there is little doubt that in these cases also the process was under way and, given time, would have been completed.

Plasma cells were seen in most specimens. Although their numbers varied from case to case, with large numbers in some autologous ossicles and none at all in some homologous ossicles, the overall tendency was for greater numbers to be present in the homografts. Plasma cells also were seen in control incudes taken at primary surgery in chronically infected ears. Above all, the finding of most importance was the deposition of living new bone. High-power views of some regions of new bone show the presence of active osteoblasts, which indicate the laying down of bone and give conclusive evidence of the vitality of the graft.

Fifty-nine cartilage struts have also been examined (Smyth *et al.*, 1673). Histologically they have persisted as non-viable but functioning struts. There was no evidence of fibrous tissue replacement in 48 specimens that had been less than two years in the middle ear. In addition, 11 homologous cartilage grafts which had been in the middle ear for over two years, have been the subject of detailed examination by light microscopy. Our findings with this material have led us to modify the rather optimistic views we expressed previously. In two of these 11 struts there was evidence that the alteration in the cartilage played a part in loss of sound conduction function. In all the other nine, the loss of function was due to some other obvious mechanical factor such as lateral healing of the drum causing the strut to lift off the footplate, or adhesions angulating or displacing the strut; but it should be noted that in two of these nine, there was some erosion of the cartilage or fibrous replacement or both, but insufficient to prejudice function.

Thus, while four of these 11 long-term specimens show fibrous tissue replacement or erosion, this represents a small proportion of the total number of cases. Although it is disappointing to find any abnormality in these grafts, it is not felt that these findings are sufficient to cause disquiet or to change current practice. It is concluded, therefore, that in the healthy, aerated middle ear, a goal generally achieved in tympanoplastic surgery, homologous cartilage grafts can be expected to remain as functional and efficient components of the sound transformer mechanism.

Complications of tympanic reconstruction

The most sinister of these is postoperative deterioration in cochlear function and it is the principal reason for insistence that patients in the author's unit receive and read a written statement about all the possible outcomes of their operation. The patient must understand the risk of a dead ear from even the most apparently straightforward myringoplasty.

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Tympanic reconstruction

No form of middle ear operation, including myringoplasty, is now performed on the only hearing ear. As much time as is necessary is spent on tuning fork, pure tone and speech discrimination tests before the decision to operate is made. The reasons are clearly shown in Table XXII. In

TABLE XXII.

POSTOPERATIVE COCHLEAR LOSS

	Number	Incidence
TCT	782	1·5% (12 ears)
CAT	633	3·0% (19 ears)
Myringoplasty	227	1·8% (4 ears)

the author's hands, there is an overall risk, slightly in excess of 2 per cent, that a significant hearing loss will follow any tympanoplasty operation. (In myringoplasty the incidence was 1 per cent.)

In TCT, the tympanosclerotic ear was formerly very much at risk. This risk is less now since the dangers of a hydraulic effect on the cochlea, from excessive excursions of the stapes footplate, have been recognized (Smyth, 1972). Nevertheless, there appears to be an inherent risk to the cochlea whenever the labyrinth is fistulized, as in removal of the footplate, in a previously infected ear, no matter how long since the original infection. That the cause is something more than infection is suggested by the extremely high incidence of cochlear deficit whenever, without creating a fistula, footplate manipulation of only moderate degree is carried out (Smyth, 1972). The reports of Rauch (1965) and Paparella *et al.* (1972) on the pathology of sensorineural hearing loss in otitis media may well provide the explanation.

In CAT a risk arises from contact between the rotating toothed bur and any part of the intact ossicular chain. In addition, fistulization of the oval window while removing disease from the footplate and excessive manipulation of the chain when removing cholesteatoma from the malleus appear to have contributed to the total or irreversibly damaged cochleas.

Follow-up in tympanic reconstruction

It is often stated that the weakness in most reports on tympanoplasty results lies in their lack of follow-up. The numbers of cases seen on follow-up are undeniably important, but the duration of follow-up may be less important than the proportion of those reattending. Obviously, if large numbers of patients do not reattend they could be receiving treatment in another clinic for Recurrent disease.

The statistics on follow-up have been scrutinized in detail, particularly in regard to the Revised cases where real problems are more likely to occur. The conclusions drawn in this report are valid for three reasons:

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1. The proportion of possible follow-up is high: 85·7 per cent of Revision cases maintained their follow-up from operation until the present time, and 95·7 per cent did so for at least half of that time (Table XXIII).

TABLE XXIII.
FOLLOW-UP IN 279 REVISED CASES

Possible follow-up	Number	Percentage of cases		
0%	1	0·4		
25%	11	3·9		
50%	12	4·3		
75%	16	5·7	91·4	95·7
100%	239	85·7		

2. In a small community with considerable centralization of the chronic ear service, the problem cases are usually referred back to the surgeon who performed the first operation.

3. The annual success rates in the cases attending for follow-up do not vary significantly from year to year and there is no evidence of serious deterioration in the results in the larger part of the patient community which attends for regular check-up (Table XXIV).

TABLE XXIV.
MAINTENANCE OF SUCCESS IN OSSICULOPLASTY

Years	Numbers	Percentage
1	27/39	69
2	27/36	75
3	16/23	69
4	22/35	63
5	28/43	65
6	9/14	64
7	12/16	75
8	6/10	60
9	8/15	54
$\chi^2=3·58$	df=8	P<0·80 NS.

Conclusion

In conclusion, what needs to be done? The obvious problem for tympanoplasty surgeons concerns the numerous failures to restore hearing for which at present there are no real answers. The solution of these problems is particularly urgent for patients, about half in this series, who have a bilateral hearing problem.

On the positive side, the efficacy of homologous dural grafts for repair of the tympanic membrane has been confirmed. We are learning how to avoid injury to the cochlea and Staging the operation certainly assists the functional outcome in many patients. In addition, the replacement of the incus transposition technique by malleus stapes assembly has im-

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proved the results significantly when the stapes superstructure and malleus handle are available. Our hopes for improvements with adhesives have not been realized and, in fact, these substances have proved ototoxic (Kerr and Smyth, 1970). The main problem with the ear which lacks a stapes superstructure lies in establishing a permanent connection between the ossicular replacement and the stapes footplate. The long cartilage prosthesis has a large area of contact and thus adhesion to the tympanic membrane but only a very small area of contact with the stapes footplate. This limited area of contact is not in favour of strong union. Histological examination of cartilage struts removed at Revision operations illustrates the problem. The amount of connective tissue on the surface of the cartilage is not likely to provide a connection strong enough medially to withstand traction arising from lateralization of the tympanic membrane which occurs in many ears where the malleus is absent.

It may be that one of the recently introduced plastic materials with an interconnected porous structure and minimal reactivity which have proved successful in orthopaedic and neurological replacement problems will provide the answer. The physical character of these materials allows a structural union between bone and implant which hopefully will be sufficient for adequate sound transmission (Janeke *et al.*, 1974). However, previous experience with plastic materials in reconstructive middle ear surgery demands a most cautious clinical approach with adequate experimental support if such a solution is to be achieved. Meanwhile, the ear which lacks a malleus handle, incus and stapes arch will continue to present the major challenge in reconstructive middle ear surgery.

Summary

This survey was carried out to evaluate techniques in current use for the treatment of chronic suppurative otitis media.

Part I concerns the incidence of cholesteatomatous complications following combined approach tympanoplasty (CAT). Residual and Recurrent cholesteatoma occurred much more frequently than had been expected or reported elsewhere.

Although the incidence of Recurrent cholesteatoma has been markedly reduced by technical modifications, Residual cholesteatoma was discovered inadvertently in one out of every seven previously cholesteatomatous ears in which a second operation for ossicular reconstruction was performed. In at least one-third the disease had been left in the epitympanum.

Although many cholesteatomatous cysts might lie dormant for years, and possibly never give rise to serious consequences, it can no longer be claimed that CAT provides a satisfactory means of eradicating cholesteatoma unless re-exploration operations were continued until eventually the tubotympanic cleft could be shown free of cholesteatoma.

https://doi.org/10.1017/S0022215100082633 Published online by Cambridge University Press

Because of this high incidence of Residual disease in cholesteatomatous ears an alternative method for the standard treatment of cholesteatoma is advocated. This comprises mastoidectomy with removal of the canal wall, tympanic reconstruction and filling the mastoid segment with a postaurally based soft tissue graft. Experience has shown that this technique provided rapid healing and facilitates the management of epitympanic Residual disease.

Part II concerns some methods of tympanic reconstruction which have been used since 1965. Lack of stability in grafted bone and cartilage and infection were the main causes of failure. Planned Staging has provided the best results.

Acknowledgements

Those who read this report will realize how much it owes to the help I have received from the staff of the Eye and Ear Clinic of the Royal Victoria Hospital, Belfast.

Most especially, I wish to acknowledge my sincere appreciation of the unreserved support which my senior colleagues, the late Mr. Kennedy Hunter, FRCS, and Mr. Robert McCrea, FRCS, gave to a concept which was so widely criticized elsewhere at the time of its conception. This faith has not been wasted, although, as this research has shown, combined approach tympanoplasty, as it was originally conceived, does not appear to have provided the final solution for cholesteatomatous middle ear disease. Nevertheless, with certain modifications this operation has been shown to have a most important place in the treatment of this prevalent cause of deafness and ill health.

I owe much to Dr. D. R. Austin, MD, FACS, Professor of Otolaryngology, The University of Illinois, Chicago, U.S.A., who taught me the basic arts of otologic microsurgery and the absolute necessity for uncompromising self-criticism;

to Dr. Claus Jansen, MD, Gummersbach, Cologne, West Germany, who inaugurated the combined approach technique and who has assisted this work by his continued encouragement and the provision of historical data;

to Jacob Sade, MD, of Afula, Israel, for his criticisms and contributions to the basic theory of chronic middle ear disease; and to my colleague, Mr Alan Kerr, FRCS, for his histological analysis of much pathological material, and for his helpful encouragement at all times.

I acknowledge with gratitude, the daily care and management of so many patients whose success owes much to the loyalty and wisdom of my Senior Registrars, Mr. Rodney England, FRCS, Mr. Roy Gibson, FRCS, Mr. Terence Stewart, FRCS, Mr. John Byrne, FRCS, Miss Kathleen Law, FRCS, and Dr. Victor Jansen, MD.

In particular, I wish to express my thanks to Dr. Kenneth MacRae,

https://doi.org/10.1017/S0022215100082633 Published online by Cambridge University Press

PhD, for his help and advice in analysing the statistics; to Mrs. Mary Carmichael for her tireless assistance with the collection of data; and to Miss May Weller for her painstaking care of the manuscript.

Mr. James Gillespie and Mr. James Easton carried out some thousands of audiometric tests with rigorous impartiality.

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https://doi.org/10.1017/S0022215100082633 Published online by Cambridge University Press