Chapter 34

Functional orthogonal cholesteatoma surgery

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1. Introduction

The challenge of cholesteatoma surgery is to remove the cholesteatoma permanently and retain or reconstruct the normal functions of the structures housed within the temporal bone. These aims are conflicting. In order that the quality of surgery be measured, it is useful to restate the general objectives of cholesteatoma surgery as four dichotomous and auditable aims.

The problem of residual cholesteatoma is not necessarily an indication of failure of individual effort. The properties of conventional instruments are sometimes the factor limiting the excellence of cholesteatoma surgery. By contrast, the properties of a fibre-guided laser congruently match the problems which beset the complete removal of cholesteatoma. Use of the laser is no substitute for well-honed conventional otological skills, which are necessary to protect the integrity of the facial nerve. The laser reduces the rate of residual cholesteatoma in intact canal wall surgery by a whole order of magnitude. It can be used to remove cholesteatoma from the intact ossicular chain without causing cochlear injury.

A new 'orthogonal' approach is required to remove cholesteatoma from the medial surface of the intact ossicular chain. A combined lateral and orthogonal approach turns out to be the minimum necessary to systematically preserve the ossicular chain during cholesteatoma surgery. The ancillary use of an otological mirror improves cholesteatoma removal from the sinus tympani and anterior epitympanum.

Preservation of the intact ossicular chain not only provides better conductive hearing on average than dismantling and reconstruction, it is also more consistent as it removes the risk of failure of reconstruction. Even a small average improvement in middle ear function results in a large increase in the rate of patient satisfaction, so ossicular chain *preservation* results in significantly higher rates of patient satisfaction than ossicular *reconstruction*.

Surgery for cholesteatoma which preserves the ear canal wall and the intact ossicular chain results from new instrumentation, which has given rise to new concepts, new techniques, new orthogonal approach and new terminology. As a consequence of this innovation, it justifies a name to distinguish it from previous operations. It is termed Functional Orthogonal Cholesteatoma Surgery (FOCS).

Based on the specific auditable outcomes of cholesteatoma surgery, FOCS is more effective than conventional operations for cholesteatoma surgery.

2. Why laser

Evidence presented in the past decade has defined an important role for the fibre-guided laser in cholesteatoma surgery. The laser has been shown to provide a formidable impact on the main aim of cholesteatoma surgery: reducing the rate of residual cholesteatoma. It has also been shown to bestow a powerful effect on preserving useful hearing in the operated ear. No other technology has been shown to improve the main outcomes of cholesteatoma surgery.

In order to understand why the laser is uniquely suited to cholesteatoma surgery, and how it is best applied, it is important to understand the context

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within which it is used. This chapter therefore begins with a description of the nature of cholesteatoma, its effects on the patient and the problems these effects present to conventional surgery. The main body of the chapter relates the author's personal experience of a novel approach to these problems and presents evidence to quantify the benefits and risks associated with the use of lasers in cholesteatoma surgery.

3. The nature of cholesteatoma

Cholesteatoma is an invasive, destructive and progressive disorder of the temporal bone. On the histological scale, it comprises a surface of keratinising squamous epithelium, often associated with inflammatory tissue. On a more macroscopic scale, the epithelial membrane forms an almost closed sheet enveloping a lumen filled with keratin debris. This matrix in this location results in local bone reaction, causing both bone resorption and osteoneogenesis (Friedman, 1956) It gradually expands through the temporal bone by enveloping, adhering to, and eroding those structures it encounters. The only way to actively treat an abnormal physical structure such as cholesteatoma is to remove it.

4. The nature of the temporal bone

The temporal bone forms the major part of the lateral skull base. Most of the interior of the temporal bone is occupied by the adnexal structures of the cochlea: the middle ear space which includes the mastoid air cell complex; the tympanic membrane and ossicles and the external ear canal. Other important structures within its walls are the labyrinth and its sensory nerves, the facial nerve, the major blood vessels to and from the brain and the lowest four cranial nerves.

The anatomy of the temporal bone is manifestly highly complicated and this may influence surgical strategy. On the one hand, the preservation of each of the anatomical structures is desirable since the functional impact of removal of any of these is significant and may be catastrophic. On the other hand, each retained structure acts as a barrier behind which cholesteatoma may shield, thereby hampering its complete removal.

5. General objectives of cholesteatoma surgery

The challenge of cholesteatoma surgery is to remove the cholesteatoma permanently whilst retaining or reconstructing the normal functions of the structures housed within the temporal bone. This general objective of cholesteatoma surgery has two parts: It is directed both against the underlying pathology, and towards maintaining the normal structures and functions of the temporal bone. These aims are conflicting and make cholesteatoma surgery extremely challenging.

6. Specific aims of cholesteatoma surgery

In order that the quality of surgery be measured, it is useful to restate the general objectives of cholesteatoma surgery as four specific auditable aims:

- There should be no residual cholesteatoma within the middle ear after surgery is completed;
- There should be no growth of new cholesteatoma after surgery;
- The ear should be robustly dry after surgery;
- The ear should provide socially useful hearing after surgery.

These aims are auditable as follows: Residual cholesteatoma is determined by a second-look procedure, a delayed postoperative digitally weighted magnetic resonance (DW-MR) scan or prolonged follow up (five years). Growth of new cholesteatoma occurs as retraction of the reconstructed tympanic membrane and is time-dependent and requires long-term (five years) follow up of the patient after surgery. To be robustly dry means that the ear should be able to tolerate exposure to water without resulting infection. The hearing function of the operated ear should satisfy the Belfast Rules of Thumb.

The Belfast Rules of Thumb are calculated using two audiometrical criteria, which have been found to correlate well with the patient's satisfaction with hearing in the operated ear. The two criteria are:

- Air conduction threshold of 30dB HL or less in the operated ear;
- Air conduction threshold within 15 dB of the non-operated ear.

The ear is deemed to satisfy the Belfast Rules of Thumb if the air conduction threshold in the operated ear satisfies at least one of these criteria.

The first two aims reflect the intention to completely and permanently remove cholesteatoma from the middle ear. This requires not just that the middle ear be cleared of cholesteatoma, but also that no subsequent new growth of cholesteatoma occurs.

The second pair of aims reflects the intention to restore the normal functions of the temporal bone. A comprehensive list of all of the functions of the structures within the temporal bone could be tabulated. Fortunately, most of these are rarely affected by cholesteatoma. When establishing a list of auditable functional outcomes, it is practical and efficient to keep to the main symptoms which affect the patient. These are ear discharge and hearing loss, which affect 98% of ears with cholesteatoma.

Note that each of these four outcomes is a simple dichotomous (yes or no) measure.

7. Summary of contextual options in cholesteatoma surgery

The intention to extract, with minimum morbidity, a disease with pervasive and destructive properties from the complex anatomy of the temporal bone cannot be undertaken without consideration that this process necessarily consists of conflicting pathological and functional aims. Any improvement in the treatment of cholesteatoma needs to recognise and resolve this conflict. The true worth of any proposed treatment can be measured using the specific aims tabulated in paragraph 6.

8. The problem of residual disease in cholesteatoma surgery

No surgeon, no matter how skilled, how experienced or how assiduous, has been able to remove all cholesteatoma in all operations in one attempt. In fact, the majority of surgeons do not get anywhere close to removing all disease in all cases. Renowned and dedicated surgeons who have audited and published their work generally record residual cholesteatoma rates of 15-30% (Sheehy, 1977; Sanna, 1984; Haginimoro, 2008).

It is evident that the problem of residual disease is not an indication of failure of individual effort. The corollary is to question why no amount of ‘trying harder’ is likely to improve the clearance of cholesteatoma. The author’s thesis is that the conventional instruments are not sufficiently suited to the task, thus limiting complete clearance of cholesteatoma.

9. Risk factors for residual cholesteatoma

Five factors have been identified statistically using multivariate analysis to be features which increase the likelihood that cholesteatoma will be incompletely cleared from the temporal bone at the completion of surgery (Gristwood, 1990; Rosenfeld, 1992; Roger, 1996; Iino, 2000). These risk factors are:

- The presence of barriers to visual inspection of cholesteatoma;
- The association of cholesteatoma with bleeding;
- Adherence of the cholesteatoma to the temporal bone tissues;
- Concerns about moving the ossicular chain;
- Inexperience of the surgeon.

It hardly needs to be mentioned that cholesteatoma is more difficult to remove when it cannot be seen directly. Unfortunately the anatomy of the temporal bone means that recesses into which the surgeon cannot directly peer exist. When cholesteatoma occupies these sites it may be difficult to remove it, especially when more of these risk factors are also present.

The association of cholesteatoma with bleeding reduces the surgeon’s ability to see the cholesteatoma during dissection. This particular problem is worsened if the cholesteatoma is also hidden from direct view.

Adherence of the cholesteatoma to the temporal bone tissues means that it does not dissect free easily. This is a particular problem if the cholesteatoma is also friable. If the cholesteatoma is hidden from sight, the surgeon may not notice that cholesteatoma has been left.

Concerns about moving the ossicular chain may hinder the surgeon for fear of transmitting destructive amounts of energy into the cochlea because of movement caused by the surgical instruments.

The solution to the problem of residual cholesteatoma is a surgical instrument which has characteristics that remedy as many of the above problems as possible.

10. Technological solutions to the problem of complete cholesteatoma removal

Otological mirrors and endoscopes have solved the problem of inspection of cholesteatoma hidden behind the ossicles and intact ear canal or any other temporal bone obstruction. However, they do not solve any of the other problems of cholesteatoma surgery, as these relate directly to the act of dissection. The fibre-guided laser is the only device with the appropriate properties:

- Pathological tissue is removed *without movement* of the target;
- The laser is easier to use than conventional instruments;
- The laser energy can be directed around corners;
- Otological surgery with an appropriate laser can be bloodless.

11. The properties of the fibre-guided laser

Lasers generate intense electromagnetic radiation. In surgical applications, this radiation is guided from the laser and applied to tissue as intense heat. In this way the pathological tissue can be vaporised, a process which requires no movement of the affected structure. Laser offers a number of advantages.

In the middle of the operative field lies the ossicular chain, linked to the cochlea. The latter is readily damaged by the movement that is an integral part of the elevation of disease by conventional instruments. The key advantage of treatment by surgical lasers of cholesteatoma is that the pathological tissue is removed without movement of the target. No other instrument can offer this property.

Surgical laser energy is directed at the tissue to be ablated and the laser shutter is opened, usually by means of a pedal. This 'point and shoot' property of laser surgery requires much less dexterity than the manipulation of conventional otological dissection instruments.

An essential requirement for an instrument used in the complex three-dimensional temporal bone is that it should be able to be operated around obstacles which prevent direct view. From the perspective of cholesteatoma surgery, the most useful lasers are those whose radiation can be guided around corners within a fibre. Moreover, visible laser light can be bounced off appropriate mirrors. This means that hidden cholesteatoma can be indirectly viewed and removed with the combination of a laser and a mirror.

Cholesteatoma is associated with chronic inflammation and is therefore frequently associated with granulation tissue. Operating with conventional instruments causes bleeding which hinders the identification of cholesteatoma. By contrast, laser dissection can be haemostatic as the wavelength of the laser can be selected to match one of the absorption peaks of haemoglobin in the visible light range.

The properties of a fibre-guided laser congruently mirror the problems which beset the complete removal of cholesteatoma. It is therefore reasonable to regard the fibre-guided laser as a rational solution to the problems which hinder the removal of cholesteatoma.

12. Commercially available fibre-guided lasers

A variety of fibre-guided lasers are commercially available. Lasers for use with fibres have been, until recently, constructed to generate electromagnetic energy within the visible light spectrum. Laser radiation that has a wavelength in the visible light spectrum will have the familiar properties of visible light; the most important of these is the phenomenon of total internal reflection within glass, as this means that the laser radiation can be transmitted along an optical glass fibre. The first surgical laser to exploit the optical fibres for the transmission of light energy was the Argon laser forty years ago, emitting at 490 nm wavelength light. A second visible light laser, Potassium Titanyl Phosphate (KTP) crystal was introduced for ear surgery in 1980 by halving the wavelength of radiation from a Neodymium-Yttrium Aluminium Garnet (Nd:YAG) laser. The later introduction of rare earth metal diodes has now led to the development of many visible light wavelength lasers.

Glass is not sufficiently anhydrous for optical fibres to be used with infra-red wavelength lasers. The delivery of CO_2 laser energy by a fibre was delayed until a hollow waveguide with an appropriately reflective inner surface was developed (Devaiah, 2005). At the time of writing, the expense of these fibres continues to disadvantage the CO_2 lase in otology.

Otological laser fibres need to be very fine so that they can be used around the ossicular chain. A 200 µm fibre is much easier to use than a 300-400µm fibre. The author prefers to use a visible light KTP laser, delivered via 200 µm fibre. At 532 nm emission, it is strongly absorbed by haemoglobin, and thus, is haemostatic.

Standard vaporisation of diseased tissue can be achieved using a 200 µm fibre with the power set at 1 W. Delicate work on the stapes requires less rapid delivery of energy. This is achieved by reducing the power of the laser, to 0.5 W and by shortening the duration of the radiation pulse, to 0.1 s. Note that laser radiation emanating from a fibre is not collimated but diverges as it emerges at the tip of the fibre. A lower rate of energy delivery can therefore also be achieved by holding the fibre tip further away from the target. However, the fibre is usually held with the tip almost in contact with the target to achieve a precise effect.

13. Safety and the fibre-guided laser: general principles

Before using a laser as a surgical instrument, the surgeon needs to be aware of the harm the laser can cause if used without care or expertise. The KTP laser has the potential to interact with any tissue which contains blood vessels. It has the potential to interact with, and therefore vaporise, any structure within the temporal bone. The use of a laser in cholesteatoma surgery is no substitute for adequate knowledge of temporal bone anatomy and surgical dissection skills. Without these, a surgeon with a laser is a danger to the patient.

13.1. Guidelines for safe use of the laser near the facial nerve

Laser energy should not be directed at the facial nerve. Whatever the physical characteristics of the fibre guided laser, the facial nerve is at risk of injury if it absorbs laser energy. The guidelines that should be strictly observed for the preservation of facial nerve integrity when using a laser during cholesteatoma surgery are:

- The surgeon must have the skill to define the course of the facial nerve in the temporal bone before planning to undertake cholesteatoma surgery with a laser;
- The surgeon should define the course of the facial nerve in every case of cholesteatoma before the laser is switched on;
- The laser should not be used to remove cholesteatoma until the relationship of the target to the facial nerve has been established;
- The laser should not be used to remove cholesteatoma from the facial nerve or from bone covering the facial nerve. The surgeon should not attempt to substitute the use of a facial nerve monitor in place of these guidelines.

13.2. Guidelines for safe use of the laser near the open labyrinth

The open labyrinth is encountered most commonly in cholesteatoma surgery as a fistula of the lateral semicircular canal. The surgeon should be forewarned about this circumstance by a pre-operative CT. The surgeon should not use the laser to remove cholesteatoma from the fistula. Laser energy should not be directed into the open labyrinth. Visible light is transmitted with minimal attenuation by the clear labyrinthine fluids. Directing visible light laser energy into the open labyrinth will put the delicate membranous structures at risk of injury. Infra-red laser energy is absorbed by water. Directing energy of this wavelength into the perilymph may cause the fluid to heat in an explosive manner. This may cause acoustic trauma or injury through loss of perilymph.

13.3. Guidelines for safe use of the laser on the ossicles

The stapes superstructure is extremely delicate. Fibre-guided lasers are used to remove the stapes superstructure in stapes surgery. Any attempt to remove cholesteatoma from the superstructure of the stapes requires great care.

The long process of the incus is normally a more stout structure than the stapes arch. Sometimes, however, the long process is attenuated by disease, in which case the laser must be used with caution.

On the stapes arch and the attenuated long process, it is preferable to use a technique in which the cholesteatoma is dissected by strikes tangential to the surface of the ossicle.

Elsewhere on the ossicles the cholesteatoma can be vaporised directly from the surface of the bone.

13.4. Guidelines for safe use of the laser near the dura and great vessels

In general, the laser should not be used to ablate tissue from the exposed dura, sigmoid sinus, jugular bulb or internal carotid artery. These caveats notwithstanding, the laser offers an entirely new means of removing cholesteatoma.

14. The impact of the laser on complete clearance of cholesteatoma

The properties of an ideal device for the removal of cholesteatoma exactly match the properties of the fibre guided laser. No instrument is better suited than a laser to removing an adherent disease from an inflamed and intricate three-dimensional space that contains an organ complex, which is damaged by movement. The rational basis for using the fibre-guided laser in cholesteatoma surgery is strong and justifies further investigation by clinical trial.

Accordingly, the author undertook a prospective, two-centre trial to compare two independent groups of patients undergoing primary intact canal wall cholesteatoma surgery at two different hospitals (Hamilton, 2005); a fibre-guided laser was available at only one of the two hospitals. This design surrendered the scientific power of a randomised trial in order to maintain the ethical integrity that each group was receiving the best possible treatment that their hospital could provide. The design of the study was organised carefully to minimise bias:

- Apart from the laser, the equipment and treatment in the two centres was identical;
- The same surgeon undertook all of the surgery;
- The outcome was a simple and unequivocal dichotomous measure, which was witnessed by the theatre staff: either there was residual disease at a second look operation, or there was not;
- Important baseline features were also prospectively recorded;
- Patients were recruited over nearly three years, and all patients undergoing this surgery were included except for those who deliberately did not undergo a second look operation, either because the cholesteatoma sac was removed without rupture at the first operation or because the canal wall was removed to gain access to the disease. As a coda to the main study this small group of patients were followed up for over five years to check for residual disease;
- KTP laser was used in 36 patients who entered into the laser wing of the trial, whilst 33 without a laser were included (Fig. 1). Only one patient, included in the main trial failed to attend for second-look surgery, despite reminders by mail and telephone.

The group who received treatment with the laser consisted of 35 individuals. One patient had residual disease.The group who received treatment without the laser comprised 33 individuals. Ten patients had residual disease. All patients were assessed at second stage surgery:

- Of the 35 laser patients' outcomes recorded, only one had residual cholesteatoma;

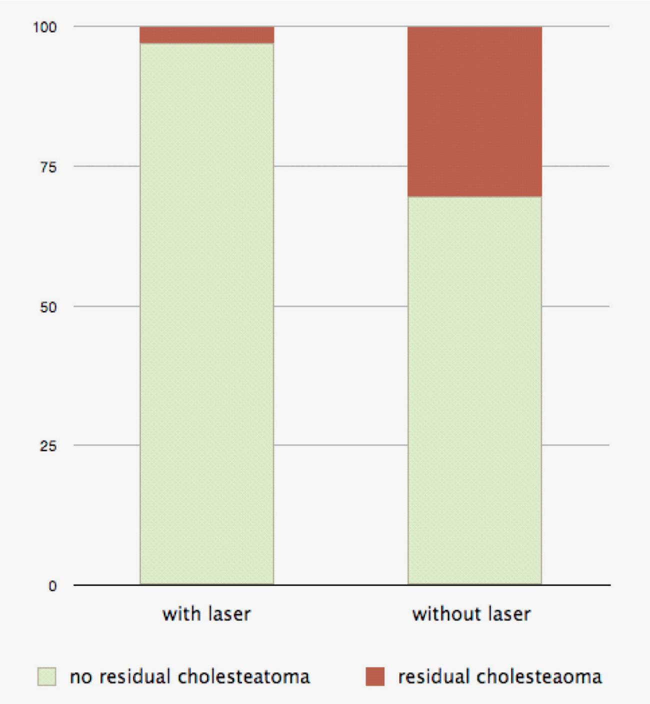

Fig 1. Effect of fibre-guided laser on complete clearance of cholesteatoma.

- Of 33 patients treated without a laser, ten had residual cholesteatoma;
- Multiple regression analysis confirmed that the only factor significantly associated with the outcome was the use of the laser.

The treatment effect is truly formidable: the number need to treat (NNT) was 3.7, which indicates a very powerful effect. This study provided empirical evidence to support the theoretical suitability of the fibre-guided KTP laser for cholesteatoma surgery. Moreover, it has provided a measure of the benefit of using this type of laser in cholesteatoma surgery. The treatment effect is huge and use of the laser reduces the rate of residual disease by a whole order of magnitude. Having confirmed this advantage to using the laser, it was then possible to seek secondary benefits from this approach to cholesteatoma surgery:

- It may permit more frequent preservation of the intact ossicular chain;
- It may allow second look procedures to be directed at ossicular reconstruction;
- It may permit more cases of cholesteatoma surgery to be performed as a single-stage operation.

15. Treatment of the ossicles in conventional cholesteatoma surgery

The ossicular chain is disrupted in most cases of cholesteatoma. In all of these cases restoration of hearing, if feasible, will require an ossiculoplasty. Approximately two out of every seven cholesteatoma cases (28%) present with an ossicular chain which remains in continuity. However, even in this circumstance, there are strong arguments for dismantling the chain:

- The ossicles may act as a barrier to complete removal of cholesteatoma. The surgeon may feel that, in order to remove the cholesteatoma completely, the barrier concealing it needs to be removed (Fig. 2).
- Three problems confront the surgeon intending to preserve the ossicular chain in the presence of cholesteatoma:
  1. Removal of cholesteatoma from behind the barrier caused by preservation of the ossicular chain;
  2. Removal of cholesteatoma from the anterior epitympanum in front of the intact malleus head;
  3. Removal of cholesteatoma from the medial side of the ossicular chain, especially from over the facial nerve in the epitympanic gutter.

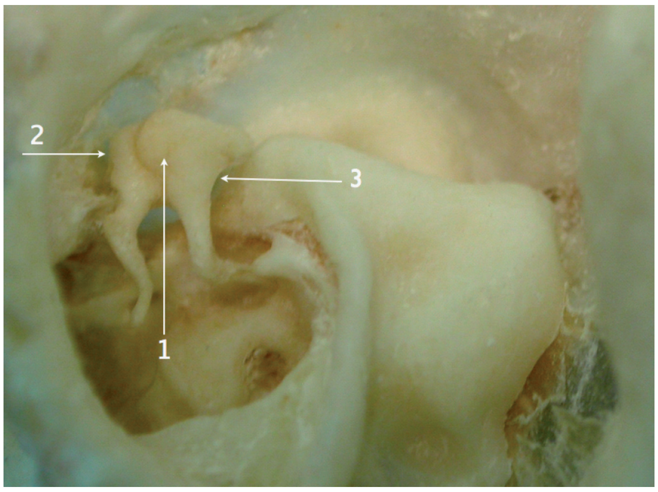

Fig. 2. Problems caused by the preservation of the ossicular chain in the presence of cholesteatoma:
1.Removal of adherent cholesteatoma, particularly from behind the barrier caused by preservation of the ossicular chain without causing cochlear damage;
2.Removal of cholesteatoma from the anterior epitympanum in front of the intact malleus head;
3.Removal of cholesteatoma from the medial side of the ossicular chain, especially from over the facial nerve in the epitympanic gutter.

- When cholesteatoma involves the ossicles, and cannot be easily removed, many surgeons remove the ossicle rather than risk injuring the cochlea by aggressive dissection of the adherent disease, even if the ossicular chain is intact.
- Ruedi (1959) presented evidence implicating epitympanic granulation tissue as a cause of attic cholesteatoma in an animal model. In keeping with this pathology, he advocated that the epitympanum should be cleared during cholesteatoma surgery in order to clear all infected and potentially infected tissue from this area. The procedure necessitates the removal of the head of the malleus and the incus as part of this epitympanectomy. This advice is widely followed.

There is, therefore, a well-established body of opinion which suggests that, to dismantle the ossicular chain and subsequently rebuild it, is a good option in cholesteatoma surgery. However, the observed results of ossicular reconstruction do not present such a positive picture.

A series of long-term hearing results after cholesteatoma surgery was presented in 1999 (Hamilton, 2000). The hearing in each operated ear was categorised dichotomously as good or poor; depending on whether the Belfast Rules of Thumb (Smyth, 1985) were met, as this measure accords well with patient satisfaction after the procedure. The results were also classified on the basis of the procedure undertaken. The proportion of ears with good hearing after ossiculoplasty onto the stapes head, mainly following malleus to stapes assembly during cholesteatoma surgery was 0.535. The proportion of patients with good hearing after ossiculoplasty onto the malleus footplate was 0.495. Clearly, these results left room for improvement.

An obvious solution to this problem was to find methods which would improve the results of ossiculoplasty. A great deal of progress in this regard has been achieved in the last decade. This has been consequent upon advances in middle ear modelling using the finite element method (Koike, 2000), and advances in the observation of middle ear function using laser Doppler vibrometry (Morris, 2004). Excellent work in this field has emphasised the need to minimise tension within the ossicular reconstruction. Stability of the reconstruction, therefore, no longer relies on the tension caused by the elastic recoil of the ossicles, which was formerly deliberately encouraged by placing a prosthesis which was fractionally too long for the interval between the recipient ossicles. Stability in ossicular reconstruction is now achieved by using prostheses which are congruent to the recipient ossicles and which lock onto the ossicles without displacing them.

16. Technique for the systematic preservation of the ossicular chain in cholesteatoma surgery

An alternative and less obvious approach to the problem has been provided by the laser. Since the laser removes disease by vaporisation, without movement, it is reasonable to suppose that this property would allow a laser based surgical technique to overcome concerns about cochlear damage whilst removing cholesteatoma from the ossicles. Starting in 1999, the author gradually developed techniques to remove cholesteatoma from the surface of the ossicles. The problems raised by the ossicles with regard to the removal of cholesteatoma were:

- How to remove firmly adherent cholesteatoma from the surface of the ossicles;
- How to remove cholesteatoma concealed by the ossicles (see Fig. 2).

Cholesteatoma is removed from the body of the incus and the malleus head simply by vaporising the disease. The relatively massive bone of the body of the incus and all parts of the malleus tolerates the energy densities used in cholesteatoma surgery (25 Wmm^{-2}) and does not suffer clinically significant necrosis. The healthy long process of the incus will also tolerate this laser energy density if used in pulses of less than a second.

The finer bone of the stapes superstructure and also of the disease-eroded long process is less robust and is at risk of vaporisation at the energy density levels required to vaporise cholesteatoma. In order to minimise the risk of necrosis of these delicate structures, a dissection-style removal of cholesteatoma, using the laser at a tangent to the surface of the bone, is still preferable on these surfaces. The dissection technique, in which the already elevated cholesteatoma is held taut using a micro-sucker whilst the interface between the still adherent cholesteatoma and the ossicle was divided using the laser, results in a small amount of ossicular movement due to traction on the ossicle by the micro-sucker through the taut sheet of cholesteatoma.

There are two main areas which cause a problem for removal of cholesteatoma from behind the barrier formed by the ossicular chain. These are:

- The anteromedial surface of the malleus head and neck;
- The interval deep to the ossicles and lateral to the facial nerve.

The region from which the removal of cholesteatoma is most hindered by the anatomy, is the space anterior to the malleus head. In an ear with a well pneumatised epitympanum, it may be possible to view this area indirectly using an otological mirror. Using one of the unique properties of the laser, it could be possible to remove disease in this area by bouncing the laser beam off the otological mirror. However, in an ear with a more compact epitympanum, there will not be adequate space to safely insert an otological mirror past the ossicular chain, and so a direct approach by removal of the bone shielding this area is necessary. This can be performed either by undertaking an anterior epitympanotomy or by mobilising the posterior canal wall in this area. This is a labour-intensive technique in either case, not just because of the resection but also because the resulting defect needs to be reconstructed.

The other space from which removal of cholesteatoma is difficult is the interval deep to the ossicles and lateral to the facial nerve. Not only is this area hidden from sight but the presence of the facial nerve appears, at first sight, to rule out the use of the laser in this region.

The solution to working in this area comes from the anatomy of the ossicular chain: the orientation of the chain, as indicated by a vertical plane through the short process of incus and the anterior process of the malleus, lies at approximately 45° to the lateral surface of the skull. This means that a line of sight sufficiently posterior to the ossicles will provide a direct view of the medial surface of the incus and the malleus head. This viewpoint is achieved by carefully dissecting out the pneumatised temporal bone until a pronounced sino-dural angle has been formed. Access to the critical area is improved further by widening the posterior tympanotomy onto the skeletonised facial nerve and up to the blue-lined lateral semicircular canal. When approached and exposed in this way, the space medial to the ossicular chain and lateral to the facial nerve and lateral semicircular canal is directly visible as a deep and steep sided channel, referred to as the ‘para-ossicular epitympanic fossa’, or ‘epitympanic gutter’ (Fig. 3). This perspective on the disease medial to the ossicular chain within the epitympanic gutter is termed the ‘orthogonal’ view.

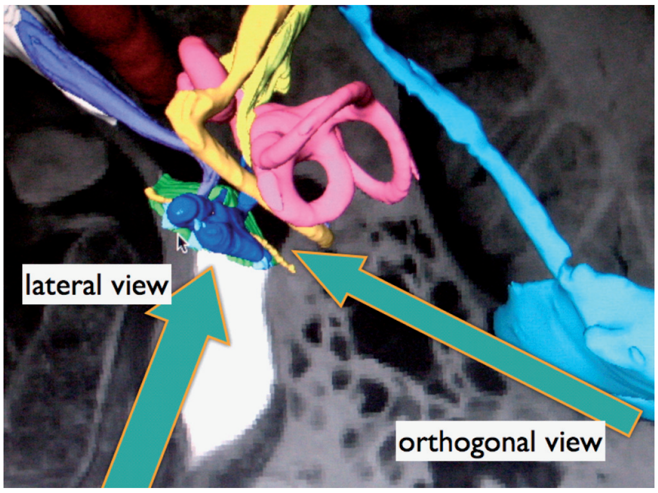

Fig. 3. The orthogonal view.

In order to systematically retain the ossicular chain in cholesteatoma surgery, it is essential to obtain a direct view of the medial surface of the ossicles and the tympanic segment of the facial nerve. A purely lateral approach cannot achieve this. The view obtained by maximally opening the sinodural angle and the posterior tympanotomy can achieve this. The author has termed the latter projection as the 'orthogonal' view.

Surgery limited to a 'lateral' approach alone, such as practiced during atticotomy or permeatal endoscopic surgery, requires the ossicular chain to be dismantled in order to remove cholesteatoma completely deep to the malleus head and incus (Marchioni, 2011). The view through the sino-dural angle and extended posterior tympanotomy, the 'orthogonal' approach, provides extra information which cannot be obtained through the lateral view and which is needed to remove disease safely without removing the ossicular chain.

Having gained access to the epitympanic gutter, the surgeon is faced with the task of removing inflamed and adherent disease from this space. This task is affected safely if the following three rules are borne in mind at all times:

- Use the laser in preference to steel instruments on the ossicles (Fig 4);
- Never use the laser on the facial nerve;
- Always work where you can see what you are doing (i.e., on the nearest disease first).

The space between the medial surface of the ossicular chain and the facial nerve has been termed the epitympanic gutter by the author. The space is best approached through the sinodural angle and posterior tympanotomy (termed the 'orthogonal' approach by the author). The facial nerve can be identified in the pyramidal region and traced forward exclusively using conventional instruments. The medial surface of the ossicles can be directly viewed and disease removed from this side of the fossa exclusively with the laser. The tip of the laser fibre can be placed beyond the facial nerve so that all times the laser is pointed away from the nerve. Conventional instruments are used to remove the cholesteatoma from the facial nerve as necessary.

By working from near to far, the surgeon can minimise the effect of bleeding on the surgical field and can be confident about the anatomical structures he or she is revealing and manipulating as the cholesteatoma is removed. The surgeon will in this way be able to identify the facial nerve as the cholesteatoma is steadily and progressively elevated from this surface. The surgeon can be confident about identifying any dehiscence of the nerve. Similarly, the ossicles will be progressively identified as the cholesteatoma is vaporised from their surface.

By using this technique and the orthogonal view, cholesteatoma can usually be removed from the short process of incus, the medial surface of the incus, the long process of the incus, the posteromedial surface of the malleus head, the capitulum, the processus cochleariformis and the facial nerve. The superior part of the epitympanum also can be cleared comparatively easily.

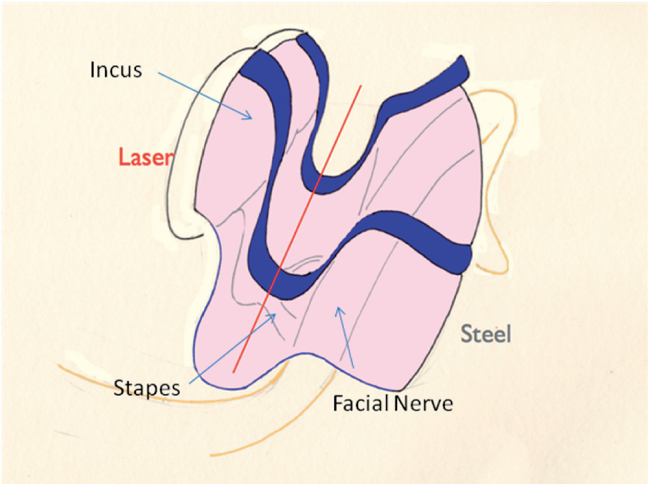

Fig. 4. The paraossicular epitympanic fossa (epitympanic gutter). The ossicular chain, facial nerve and cholesteatoma sac as viewed from the orthogonal approach.

17. Use of the otological mirror during cholesteatoma surgery

It is characteristically difficult to obtain a direct view of the sinus tympani and that part of the epitympanum which is anteromedial to the malleus head and neck. These regions can be inspected with an endoscope, but directing a laser beam off a mirror is the most effective means of removing cholesteatoma from these regions. This technique requires great concentration and no impediment to the surgeon's view. The surgeon must ensure that the mirror is in perfect condition and that the surgical view is not hampered by bleeding or laser smoke:

- It must be ensured that the mirror has no scratches on its surface. The effect on the surgeon's perception of the reflected surgical field is diminished out of all proportion to the minor physical damage sustained when the mirror is first scratched.
- Without good haemostasis there is insufficient time to carefully insert the otological mirror and line up the target, mirror, laser and surgeon's view. If the mirror is moistened by blood, it must be removed from the ear and cleaned, or else the laser light will be absorbed by the blood on the surface of the mirror. The target will not be affected and the blood will be carbonised on the mirror. Hypotensive anaesthesia is valuable and, in addition, topical adrenaline may be required to obtain a sufficiently dry field for this technique.
- To insert a laser fibre, a mirror and an otological micro-sucker clearly requires more hands than the surgeon can offer. Although it is possible to use a combined fibre-guide and suction device, these are usually too bulky for the demanding work in the epitympanum. It is preferable and perfectly adequate for an assistant to hold a large otological sucker no deeper than the entrance to the mastoid cavity and out of the surgeon's line of sight.
- Great care is then required to insert and remove the mirror without knocking the ossicular chain. Once inserted, the mirror and laser are held so that the laser beam is aligned with the surgeons view. Even if there were no guide beam, the surgeon will then be able to see in the mirror the area which the reflected laser beam will affect. In fact, the reflection of the laser guide beam on the target area will be readily visible in the mirror.

18. Auditory assessment of the systematic preservation of the ossicular chain

The fibre-guided laser promises an entirely new way to maintain hearing in cholesteatoma surgery: by removing cholesteatoma from the intact ossicular chain, instead of dismantling the chain and subsequently reconstructing it. In order to test whether this new style of surgery was a benefit to patients a second trial was conducted (Hamilton, 2010).

Two trial groups were compared: in both groups only patients undergoing canal wall up surgery were included.

- In the first group, cholesteatoma was removed from the intact chain and the chain was preserved at the end of surgery;
- In the second group, the chain was dismantled and reconstructed by an ossiculoplasty on to the capitulum of the intact stapes. Both malleus to capitulum assembly and tympanic membrane to capitulum assemblies were included in the latter group.

Ears in which the chain was dismantled and the tympanic membrane draped over the capitulum were not included.

Since the intact chain acts as an extra barrier to removal of disease, the trial also investigated whether the new procedure increased any risks of surgery: the rate of residual disease, injury to the facial nerve and injury to the cochlea were all measured in both groups.

The trial also compared the hearing outcomes in the two groups. This was performed using two outcome measures derived from the postoperative audiological assessment: the conductive hearing loss, which is a useful assessment of the function of the middle ear reconstruction; and the Belfast Rules of Thumb, which is strongly correlated and therefore a useful approximation to the patient's subjective evaluation of the benefit of the intervention. The audiological assessments were undertaken one year after surgery. Consecutive patients were included from 1999 to 2007. The same surgeon supervised or undertook all of the surgery. None of the risks of surgery were increased by the new approach to ossicular preservation. The conductive hearing loss differed between the two groups in two ways:

- The median conductive hearing loss for the intact chain was 4 dB less than the reconstructed group;
- The reconstructed group contained two subgroups with different distributions. The better subgroup

had a similar distribution to the intact chain group and probably represents the spread of results obtained when the middle ear is adequately reconstructed. The worse subgroup was markedly different. It is probable that this latter subgroup represents ossiculoplasties which are technical failures and which have not adequately restored the structure of the middle ear.

This means that preservation of the intact ossicular chain not only provides better conductive hearing than reconstruction in general; it also removes the risk of failure of reconstruction.

Analysis using the patient-related outcome identified a further benefit of ossicular preservation: the rate of patients experiencing benefit is critically sensitive to the improvement in middle ear function. Hitherto, there has been limited understanding of the sensitive dependence of patient benefit on small changes in middle ear function. Even a small average improvement in middle ear function results in a large increase in the rate of patient satisfaction (Fig. 5). This is reflected in the odds ratio for success with intact surgery compared with ossicular reconstruction. In this trial the odds ratio was 2.73, which indicates a powerful effect.

The parameters which most influence patient benefit were revealed by multivariate analysis to be the baseline cochlear function and the type of middle ear reconstruction. In other words, the stringent requirements of patient satisfaction are further limited by the preoperative cochlear function. This finding stresses that the surgical technique should not cause extra cochlear damage. ‘No movement’ vaporisation of cholesteatoma facilitates this.

Patients undergoing surgery with the laser had preservation of the ossicular chain and this group had an 87.5% useful hearing rate. The other group underwent dismantling of the chain and subsequent reconstruction onto the stapes superstructure. The success rate in this group was 66.6%.

This trial suggests that systematic use of the fibre-guided laser in cholesteatoma surgery enables the surgeon to perform new procedures which provide outcomes that cannot be matched by conventional techniques. The patient’s experience is powerfully enhanced by an operation that not only provides critically better hearing, but also a more consistent result than conventional surgery.

19. Conclusions

The two studies detailed in this chapter indicate that the introduction of the fibre-guided laser is an important advance in cholesteatoma surgery. They provide plausible evidence that the fibre-guided laser not only enables the surgeon to achieve better results in pursuit of the primary aim of cholesteatoma surgery: total removal of cholesteatoma. It also addresses patients’ main concern, obtaining improved hearing.

The original proposition upon which this work is based was that *conventional instruments are a factor limiting the results of cholesteatoma surgery.* This premise was based on the author’s belief that the properties of these instruments were incompatible with the challenges of balancing the functional and pathological needs of excellent cholesteatoma surgery. The properties of the fibre-guided laser, by contrast, suit these requirements very well.

The large improvement in the complete clearance of cholesteatoma obtained by using the laser substantiated this thesis. In this early work the laser was merely an ancillary tool, the properties of which, it had become clear, could be put to more complete use around the ossicular chain. In the past, the surgeon removed structures which impeded the difficult process of removing cholesteatoma and then

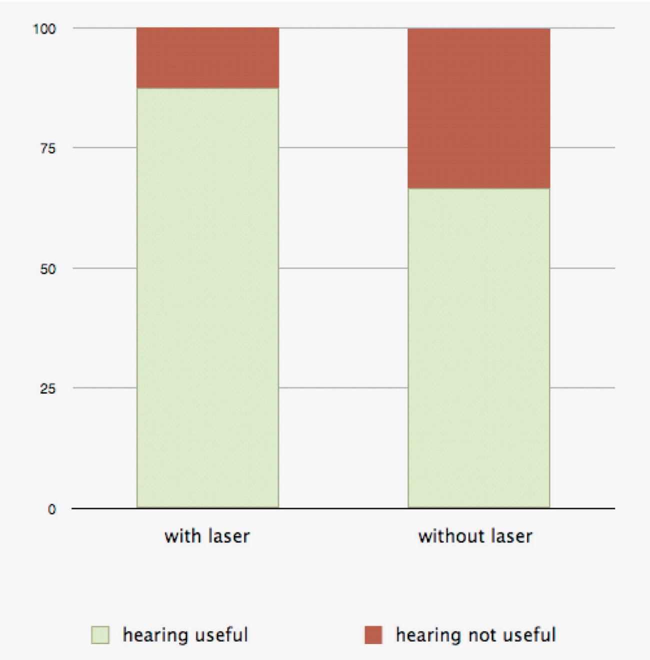

Fig. 5. Assessment of hearing after cholesteatoma surgery using a patient-related outcome measure.

considered reconstructing these at a later stage. With the laser it is now possible for highly conservative surgery to be performed. All the normal structures of the ear can be preserved, as the laser removes the cholesteatoma from their surfaces as part of this new functional cholesteatoma surgery: *the Orthogonal approach.*

To systematically preserve the ossicular chain during cholesteatoma surgery, it is necessary to have an extra approach which circumvents the rampart presented by the ossicles and provides access to the medial surface of the ossicles and the epitympanic gutter. Because this second viewpoint provides information which cannot be gained from the lateral approach, the author has termed it the 'orthogonal' approach. The term 'orthogonal' is appropriated from mathematics where it is used to describe an independent and mutually exclusive point of reference. In geometry it describes a set of perpendicular axes. A combined lateral and orthogonal approach turns out to be the *minimum* necessary. The two-dimensional 'atticotomy' or 'front to back', purely lateral approach, which has been a reasonable technique when the ossicular chain has been dismantled, is inadequate for this type of *functional* surgery.

The laser-assisted combined lateral and orthogonal approach with preservation of the ossicular chain simultaneously enables both the more effective removal of cholesteatoma and the more effective preservation of the function of the ear, thereby achieving the fulfilment of the original inspiration. This Functional Orthogonal Cholesteatoma Surgery (FOCS) is a stepwise improvement in the treatment of cholesteatoma resulting from new concepts, new instrumentation, new techniques, new orthogonal approach and new terminology.

20. The future

At present the second stage operation remains the gold standard assessment of the presence of residual cholesteatoma. The development of non-echo-planar imaging (non-EPI)-based diffusion-weighted (DW) magnetic resonance imaging (MRI) has introduced a technology which may make the systematic second stage operation obsolete (De Foer, 2008). If the potential of the radiological investigation is confirmed, the need to maximise the likelihood of disease removal means that the preferred treatment pathway will become a laser assisted single procedure with an interval MR scan to seek residual disease. It is difficult to imagine how the drive to achieve single stage intact canal surgery could possibly succeed if the use of a laser were not part of the surgical strategy.

21. Envoi

The properties of the laser have generated a new type of surgery for cholesteatoma, known as *FOCS*. The important structures of the ear are retained whilst the disease is cleared more effectively. This procedure restores an ear with normal resilience to infection. The odds ratio for preserving or restoring useful hearing is three times higher than the best conventional surgery. The rate of residual disease is an order of magnitude lower than conventional canal wall up surgery.

The introduction of the laser as a key component in cholesteatoma surgery already has improved outcomes so much that a senior commentator has questioned whether it is reasonable to offer treatment without the use of a laser (Browning, 2005).

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