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Joubert, Wynand

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Surgery performed for Chronic Otitis Media at Chris Hani Baragwanath Academic Hospital: an 18-month retrospective clinical audit

Candidate:
Dr Wynand Joubert
Student No: 0617912K

Supervisor:
Adjunct Professor PC Modi

A Research Report (NEUS 7009) submitted to the Faculty of Health Sciences, University of Witwatersrand in partial fulfillment of the requirements for the degree of Master of Medicine in Otorhinolaryngology (MMC022)

September 2012

I, Wynand Joubert declare that this dissertation is my own work. It is submitted in part requirement towards the degree of Master of Medicine (Otorhinolaryngology) at the University of Witwatersrand, Johannesburg. This report has not been submitted for any other degree or examination at this or any other University.

_____

Dr Wynand Joubert (Wits Student No: 0617912K)

DECLARATION BY SUPERVISOR

This dissertation is for marking /acceptance by an External Examination towards the degree of Master of Medicine (ORL) with my approval as University Supervisor.

_____

Adjunct Professor Pradip C Modi (Supervisor)

Dedication

This dissertation is dedicated

To

My fiancée, **Leori Hoare,**

And **family**

for all the help and assistance during the writing of this

research report

Summary

The surgical management of chronic otitis media is ever evolving. This is also the case at the Chris Hani Baragwanath Academic Hospital where in recent times, certain new techniques were adopted and other older ones revisited. This changed surgical approach was deemed to be necessary not only in view of the limited resources available to deal with a large patient load, but also to improve surgical outcomes in the local environment. The focus was mainly on the implementation of internationally accepted surgical techniques that have been shown to not only be effective and safe, but also simple and time-saving. Changes were mostly seen in the management of patients presenting with *simple perforations* and *cholesteatoma*. It is the objective of this study to formally assess the outcome and feasibility of this changed surgical approach, as well as to assess the outcomes of surgery as a whole.

A retrospective clinical chart review was undertaken over an eighteen-month period from July 2009 to December 2010. All patients undergoing single stage surgery for chronic otitis media in this period were included, and grouped in terms of procedure performed, viz. Tympanoplasty, Tympanomastoidectomy and Canal wall down CWD mastoidectomy. All data were collected from an otological database, each case independently evaluated in terms of surgical and audiological outcomes after at least a 2 month follow up period. Only data acquired at the latest follow-up date were used. The follow up period ranged from 2 to 18 months.

The Butterfly Cartilage Inlay Graft (BCIG) tympanoplasty technique was the predominant technique used for simple perforations of any size and location, and showed superior surgical outcomes to the more traditional Fascia underlay graft (FUG) technique. Surgical success (i.e. healed / intact tympanic membrane) in the FUG tympanoplasty group was 75%, compared to 93% in the BCIG group. One hundred percent of cases subjected to BCIG tympanoplasty achieved sociable hearing (ACT< 30dB) in the early post-operative period. We found the hearing

improvement post-surgery to be directly related to the size of perforation (p= 0, 0195), and pre-operative hearing loss (p= 0, 0001 r= 0.93). None of the other variables studied influenced the audiological outcome achieved.

In the study period, surgical techniques used for more severe Non-cholesteatomatous chronic otitis media (NCCOM) were little changed from before. An evaluation of these cases focused on those with actively discharging ears to assess the outcome of Tympanomastoidectomy to achieve not only a dry ear, but also an intact tympanic membrane (TM) and hearing improvement (HI). Eighty-six percent of patients with discharging ears had dry ears post-operatively, 50% of which achieved an intact tympanic membrane and sociable hearing (ACT< 30dB). Graft failures in the tympanomastoidectomy group as a whole were mostly related to size of perforation (p= 0,047) and to the presence of discharge pre-operatively (p= 0,012).

In the CWD mastoidectomy group, although evaluating both the large (completely exenterated mastoid)- and small cavity techniques, the focus was on the latter. With this technique, disease is surgically approached from its site of origin, and followed into the attic and mastoid. The resultant defect in the medial canal wall and mastoid is kept as small as possible, to avoid obliteration and the morbidity of an unnecessarily large cavity. Dry ears were achieved in 93% of patients. In cases where the TM was grafted, an intact tympanic membrane was achieved in 85% of patients. Significant hearing improvement (>10dB in two consecutive frequencies) was achieved in 33% of patients who had the tympanic membrane grafted to an intact stapes suprastructure (Type 3 tympanoplasty with or without a cartilage columella). These results compared favourably to the large cavity CWD technique in this series where obliteration and middle ear grafting were not performed on a regular basis. In this group, only 16% of patients had an intact tympanic membrane post-operatively, and 63% of ears were dry at latest follow up. Although statistical analysis did not show one technique to be superior to the other in achieving a dry ear post-operatively (p= 0,39), the results with the small cavity technique were very encouraging. Hearing improvement in both groups were variable and hearing

preservation rather than augmentation was achieved in most. The lack of hearing improvement may not only have been related to the extensive disease encountered (80% extending beyond attic, 50 % stapes suprastructure erosion), but also to inadequate and infrequent reconstruction of the middle ear.

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List of acronyms

ABG	Air- Bone Gap
ACT	Air Conduction Threshold
BCIG	Butterfly Cartilage Inlay Graft
CCOM	Cholesteatomatous Chronic Otitis Media
CHBAH	Chris Hani Baragwanath Academic Hospital
COM	Chronic Otitis Media
CSOM	Chronic Suppurative Otitis Media
CWD	Canal Wall Down
CWU	Canal Wall Up
dB	Decibel
ENT	Ear Nose and Throat
FUG	Fascia Underlay Graft
HI	Hearing Improvement
HIV	Human Immunodeficiency Virus
Hz	Hertz
IgA	Immunoglobulin A
IgG	Immunoglobulin G
ISJ	Incudo-Stapedial Joint
LA	Local Anesthetic
MERI	Middle Ear Risk Index
N/A	Not available
NCCOM	Non-Cholesteatomatous Chronic Otitis Media
OOPS	Ossiculoplasty Outcomes Parameter Staging index
OME	Otitis Media with Effusion
STSG	Split Thickness Skin Graft
PTA	Pure Tone Average
TM	Tympanic Membrane
TORP	Total Ossicular Reconstruction Prosthesis

1. INTRODUCTION

Perforation of the tympanic membrane, with or without a chronic aural discharge is a common presenting problem at Ear, Nose and Throat (ENT) clinics in Johannesburg's public hospitals. In the developing world, in addition to it being a leading cause of progressive hearing impairment, it is also associated with considerable potential morbidity. Surgery plays an important role to reverse the chronic infectious process in the middle ear and mastoid, and to rehabilitate hearing.

The literature frequently classifies the chronic infectious disease processes in the middle ear and/or mastoid into Non-Cholesteatomatous Chronic Otitis Media (NCCOM) and Cholesteatomatous Chronic Otitis Media (CCOM). NCCOM refers to the presence of a perforated tympanic membrane, with or without a discharge, in the absence of keratin in the middle ear and mastoid. CCOM refers to the situation where keratinizing squamous epithelium has migrated to or appeared in the middle ear, mastoid and/or other parts of the temporal bone.

Management of these two clinical entities is constantly evolving and is frequently tailored to the capabilities of an institution and to the patients' expectations. In this respect, not only does the availability of resources and surgical expertise play a critical role, but also the patients' reliability to follow up.

2. STUDY OBJECTIVES

The aim of this study was to assess the outcomes of surgery for both NCCOM and CCOM at the Chris Hani Baragwanath Academic Hospital.

It specifically aimed to assess the following:

- Surgical and audiological outcomes of the BCIG tympanoplasty compared to the traditional FUG tympanoplasty.
- Effectiveness of Tympanomastoidectomy in severe CCOM to:
    - Eliminate a discharge (if present),
    - Achieve an intact TM post-operatively, and
    - Improve hearing.
- Effectiveness of the small cavity CWD mastoidectomy in achieving the goals of cholesteatoma surgery (see literature review).
- The effect that certain variables may have on the outcomes of the above-mentioned procedures (see Methodology section).

It is hoped that the outcomes of this study will further guide the management of these prevalent and important conditions to ensure an optimal outcome for patients.

3. A REVIEW OF THE LITERATURE ON THE MANAGEMENT OF CHRONIC OTITIS MEDIA

In this chapter, COM is discussed in terms of the pathogenesis and management of the disease processes involved. The chapter will make a clear distinction between cholesteatomatous and non-cholesteatomatous disease and will focus on certain aspects of surgery performed for these processes that is relevant to this study and our institution.

The review of the literature aimed to flow in a natural manner, starting with a general overview of the subject, progressing to the general surgical considerations and further onto the aims of surgery and the relevant techniques to achieve the objectives of surgery.

3.1. NCCOM (NON-CHOLESTEATOMATOUS CHRONIC OTITIS MEDIA)

3.1.1. Definition and pathogenesis

Acute otitis media is a common occurrence in any population. It occurs in most instances when an episode of Eustachian tube dysfunction leads to acute infection in the middle ear. Ongoing Eustachian tube dysfunction or non-resolution of infectious process in the middle ear or mastoid may result in the acute episode of otitis media becoming chronic. This in turn will result in the tympanic membrane to lose its elasticity, atrophy and to perforate without healing. [(1)]

A perforated tympanic membrane exposes the middle ear to possible colonization by organisms from the external ear canal, and frequently results in a recurrent or continuous discharge from the middle ear. [(2)] Although opinions vary regarding the definition of chronic otitis media, most consider middle ear disease to be chronic if present for longer than 6 weeks. [(2)]

3.1.2 Classification

According to the status of the middle ear, NCCOM may be *Active, Inactive or Healed.* [3]

Active disease, when associated with a frank discharge from the middle ear, is also frequently referred to as chronic suppurative otitis media (CSOM). [2] In cases where signs of infection of inflammation (wet middle ear, mucosal edema) are present, but without a clear discharge, some prefer the term quiescent chronic otitis media to describe the condition of the middle ear. [4, 5]

Theoretically, many systemic and upper respiratory tract conditions may cause or contribute to a discharge from the middle ear. Some of which include the following:

- Regional pathology (upper respiratory tract), of which acute or chronic air-borne allergies, chronic laryngo-pharyngeal reflux, post nasal space-adenoidal hypertrophy and tumors are the most common conditions.
- Systemic pathology (patient immunity), of which host immune suppression (HIV, poorly controlled Diabetes Mellitus, chronic anti-inflammatory medications etc.) is most important.

Although a direct relationship between the mentioned factors and chronic otitis media has not been established, [2] it is common practice to treat positive regional and/or systemic findings as part of a comprehensive management protocol. This is especially the case in the pediatric population where the Eustachian tube is anatomically and functionally immature in its development, and where systemic and local immunity (IgA and IgG) are not fully developed. In these cases, CSOM can easily become a prevalent problem when poor socio economic circumstances and overcrowding prevail as well. [2]

Inactive disease refers to a persistently perforated tympanic membrane, but with no discharge or evidence of bacterial infection or inflammation. This situation suggests the possibility that previous causes of COM have resolved, or did not contribute to the disease process. [3]

Healed chronic otitis media refers to a tympanic membrane that has healed either with the formation of excessive amounts of fibrosis and calcifications, or by the formation of a thin dimetric tympanic membrane where the middle fibrous layer is absent. The patient in such cases may still have variable levels of conductive hearing loss and is vulnerable to the development of retraction pockets or re-perforation. [3]

3.1.3 Management

The management of NCCOM includes both *medical* and *surgical* treatment:

3.1.3.1 Medical management

Medical management is usually implemented in active NCCOM to resolve the middle ear and/or mastoid focus of infection/inflammation. It entails both topical- and systemic treatment, which may include the following:

- Intensive and repeated aural toilet (debridement),
- Short term topical antibiotics (with or without steroids), and
- Treatment of the mentioned factors that affect Eustachian tube function and patient immunity.

It has been shown that the combination of aural toilet and topical antibiotics are more effective than either alone in achieving a dry middle ear, and that this combination is superior to systemic antibiotics alone. [2] Topical quinolones were shown to be superior to non-quinolone eardrops in the same study. If successful, medical management will result in a healthy middle ear that will facilitate reconstructive surgery of the tympanic membrane and/or ossicles.

The duration given for medical treatment to take effect varies and is dependent on certain disease- and patient specific factors. Long periods of treatment, although possibly effective, [6] are frequently avoided though, as evidence exists that ongoing middle ear disease may result in further damage to the middle ear structures and possibly the inner ear. [2]

3.1.3.2 Surgical management

a) General surgical considerations

Certain aspects of the surgical management of NCCOM may influence the outcome achieved. In the literature, the most commonly disputed areas of discussion include the questions of timing of the procedure, the need for mastoid air cell exenteration (mastoidectomy), and the effect that certain disease specific variables may have on the outcome of surgery.

i. Timing of the procedure

It is the opinion of some that a "dry ear" for a period of at least one month [7] is required to have a reasonable degree of certainty that the infectious process in the middle ear and/or mastoid is under control. All however do not share this thinking, and some believe that good results with TM reconstruction alone is possible as long as the ear is dry at the time of surgery. [8]

In the pediatric age group however, a dry ear, even for the mentioned period above, may not lead to a good long-term surgical outcome. The effect that recurrent ear infections or Eustachian tube dysfunction may have on tympanic membrane perforation repair, is frequently the subject of discussion in the literature. Some believe that the procedure should be delayed as long as possible to allow for innate immunity and Eustachian tube function to mature, while others believe that surgery should be performed as soon as possible. Proponents of the latter approach are of the opinion that a delayed tactic may risk worsening of the ossicular defect and that an early repair, irrespective of age, will result in good long term outcomes as long as upper respiratory tract conditions are under control at the time of surgery. [8]

ii. Role of mastoidectomy in the management of NCCOM

In cases of an **actively discharging ear** (with granulation tissue and polypoid mucosa formation), it has been shown that mastoid exenteration frequently, but not always results in disease resolution. [6, 9] A number of patients however will need intensive aural toilet and topical antibiotics post-operatively to finally achieve the goal of a dry ear. Repeat operations may also be necessary to address residual perforations. [6]

In the case of only minor changes in the middle ear mucosa (**quiescent chronic otitis media)** studies have shown that good outcomes are possible, irrespective of whether mastoidectomy was added to tympanoplasty or not. [4, 5, 8] It is believed in such cases, that the secretory diseased mucosa will normalize spontaneously once the tympanic membrane perforation has been repaired, and that any residual mucous will be of low viscosity that can easily be cleared into the nasopharynx via the Eustachian tube. [8]v

More severe disease (as indicated by the presence of polypoid mucosa or granulation tissue) however may warrant the addition of a mastoidectomy, the reason for its consideration being twofold. Firstly, disease in the mastoid reflects that of the middle ear and a failure to address this mastoid extension of disease is likely to increase the risk of early failure. [5, 10] Secondly, mucosal damage in such cases may be of such an extent that its normalization post grafting is unlikely. Surgical excision of this permanently damaged, fibrotic mucosa from the mastoid may be indicated to prevent late graft failures or recurrent perforations after healing has occurred. [11]

Evidence also exist however that the presence of granulation tissue in the middle ear and mastoid, in fact does not compromise graft survival. Studies have shown that tympanic membrane grafting without mastoidectomy in such ears, may result in similar success rates and that hearing improvements will be equivalent to cases where a mastoidectomy was added. [12, 13]

The surgery required for **inactive NCCOM** may also include a mastoidectomy in addition to the grafting of the tympanic membrane. [12] The theory is that fluctuating middle ear pressures can be buffered by the surgical creation of a mastoid "air reservoir", and that long-term graft success rates are improved by doing so. [10] Many challenge this opinion though, stating that mastoidectomy has no advantage over grafting alone in such cases. [5, 14] Some in fact believe that the removal of non-diseased air cells, may negatively affect success rates in such ears. [12] Although clinical support for the latter theory is lacking, [15] it is plausible that a reduction in the true surface area of the mastoid may reduce its middle ear pressure buffering capacity, [10] and result in future atelectasis, retraction pockets and cholesteatoma formation.

In view of the above, contrasting evidence exists regarding the approach to a failed tympanic membrane repair. In such cases, some have shown the benefit of adding a mastoidectomy, [10] while others have shown that a mastoidectomy may still be avoided as long as a more resilient grafting material is used. [16] In this respect, cartilage has been shown to be particularly useful, especially when Eustachian tube dysfunction is suspected, and recurrent ear infections are expected in future.

iii. Effect that patient variables may have on the outcome of surgery

The status of the **contra-lateral ear** may reflect Eustachian tube function and therefore may influence surgical outcomes. Studies however are contradictory on its role in the determination of success, as some have shown no correlation between this variable and success rates, [7,17,18] while others have shown it to be an independent variable determining outcomes in pediatric patients. [19]

Age has been shown to negatively affect surgical success rates over the longer term (2-5 years) but only in younger children (< 6 y of age). [18] As mentioned, immunity problems and recurrent Eustachian tube dysfunction are the possible reasons given for failures in this age group. In adults, although graft success rates

have not been shown to be related to age, it is known that late audiometric outcomes are frequently worse than earlier recorded ones [8]

Size of perforation may influence graft success rates based on graft instability and difficulties experienced in the repair of large or subtotal perforations. [20] The instability of certain grafting materials (i.e. fascia) may not allow for healing by secondary intention to occur in such large perforations [18] resulting in residual perforations or retraction pocket formation in the anterior segment of the tympanic membrane [21]. Size of perforation may affect hearing outcome, as hearing improvement post repair, in most cases, will be directly proportional to the size of the perforation pre-operatively. [22]

Before performing surgery, one assumes that the original insult responsible for the sequelae of perforation and the subsequent reasons for its persistence have been resolved. In many cases, this assumption will prove to be correct; but in some, persistence of causative factors may remain undetected and undefined with consequent late failure of the procedure. **Follow-up period** thus may play a role in reported outcomes as well. [23]

Surgical technical issues may affect outcomes as well. Whereas such issues may not be a factor in the outcome of surgery for central or small perforation, [18, 22] it may play a significant role when dealing with subtotal- [20] or anteriorly located perforations. [7, 22]

b) Theory behind surgical hearing rehabilitation

For optimal conduction of sound from the tympanic membrane to the inner ear, the main requirements include the following [24]:

i. An intact tympanic membrane and ossicular chain

Sound transmission from the tympanic membrane to the oval window requires an intact ossicular chain. Ossicular coupling is the sound pressure gain that occurs through the tympanic membrane and ossicular chain and is a factor of the

effective vibrating area of the tympanic membrane to the area of the stapes footplate.

ii. Aeration of the middle ear cavity

Air reduces the pressure difference between the external ear canal and the middle ear, allowing the tympanic membrane and ossicular chain to move. In addition, it reduces the resistance to the flow of acoustic energy through the cochlear fluids from the stapes footplate to the round window membrane. At least 0.5ml of air in the middle ear is required to maintain hearing within 10 decibel (dB) of normal.

iii. Normal stapes to cochlear impedance

An impediment to the movement of the stapes or round window membrane, such as pathologic changes in the annular ligament of the stapes or fibrous tissue in the round window niche, may contribute to a conductive hearing loss.

iv. Minimal acoustic coupling (Phase protection)

Sound pressure that acts directly on the oval and round window simultaneously (e.g. ossicular interruption behind an intact tympanic membrane or a total absence of the tympanic membrane) will reduce the hearing gain through the middle ear. It is therefore imperative to channel most of the sound pressure directly to the oval window to have optimal sound transmission through the cochlea.

In most cases of NCCOM, the perforated tympanic membrane is the main cause of the hearing loss, which when repaired, will improve the patient's hearing. Closure of the tympanic membrane defect will have a maximum effect on hearing in the 500Hz-, 1000Hz- and 2000Hz frequencies, [25] which when averaged, can be expressed as the pure tone average (PTA) or air conduction threshold (ACT).

Because hearing improvements in the higher frequencies (3000-4000Hz) is important for speech discrimination in noisy environments, either of these frequencies may be included in the PTA as well. [25] Controversy exists however,

as to whether its inclusion will materially affect the measured post-operative PTA, and many continue to only use a 3-frequency average to report results. [25]

Because sociable hearing lies in the range of 20 to 40dB, surgery should aim to improve or maintain hearing in this range. Many would consider the surgical procedure successful, if the patient's speech reception threshold can be improved to, or maintained at a level better than 30dB. [8] It has been shown in a large meta-analysis that these hearing levels can be achieved in 88% of patients with simple tympanic membrane perforations. [18]

In the absence of obvious ossicular discontinuity, many cases may still have sub optimal hearing improvement post successful perforation repair. It is important in such cases to consider other adverse conditions in the middle ear that may have been present or occurred after surgery. Conditions that may affect outcomes include middle ear space reduction secondary to fluid accumulation, granulation or fibrous tissue formation, and retraction of the tympanic membrane. Subtle or undiagnosed ossicular chain abnormalities may also be responsible for unexpected hearing deficits post surgery. It is important not only to manage these conditions if present in the middle ear, but also where possible, to prevent it from occurring post operatively.

In the case of suspected ossicular pathology in addition to a perforated tympanic membrane, the reconstructive effort may include the repair of both the ossicular chain and the TM perforation in the same setting (**non-staged ossiculoplasty**), or the TM perforation can be repaired and the ossicular reconstruction deferred to a later stage (**staged ossiculoplasty**). The decision as to which approach to follow, is mostly made intra-operatively and is dependent on the extent of adverse middle ear conditions present in the middle ear. To prognosticate the outcome of surgery when such adverse conditions are present in the middle ear, a risk index can be used to determine the feasibility of non-staged surgery. One such risk index, the middle ear risk index (MERI), [26] includes the following variables:

- Extent of ossicular defect post disease clearance,
- Status of tympanic membrane (perforated or intact), and
- Presence of middle ear infection.

Although this index may be helpful in determining whether a staged or non-staged approach is appropriate, these variables, alone or in combination, may not be as accurate a predictor of surgical outcome as was previously thought. [26] In addition, the impact that certain surgical and anatomical factors may have on the outcome of ossiculoplasty, are not included in this risk index system. The Ossiculoplasty outcome parameter-staging index (OOPS), may more accurately predict hearing outcome post ossiculoplasty in a variety of circumstances. [26]

Even though a range of ossicular and anatomical defects may be present post disease clearance, the most common isolated ossicular defect remains the defective incus. [27] In such cases it has been shown that the ABG can be closed to within 20dB in more than 80% of cases, and that these hearing levels can be maintained over the longer term (2-5 years), irrespective of technique used or whether the surgery was staged or not.[27]. Type of ossicular reconstruction prosthesis may also not affect outcomes in such cases when the suprastructure is present. The use of autologous (cartilage, ossicles)-, and allogenic (artificial prosthesis) grafts have all shown good results, even over the long term. [27]

c) Tympanoplasty classification

In order to simplify the description of the procedure performed to repair a defective middle ear sound conduction mechanism, many use the tympanoplasty classification system described first by Zollner and Wullstein. [28] This system, albeit very useful, is also very basic, and certain modifications have been added to more accurately describe the reconstructive procedure performed. A discussion and illustration (Figure 1) of the classically described procedures, as well as some of the modifications, will follow below.

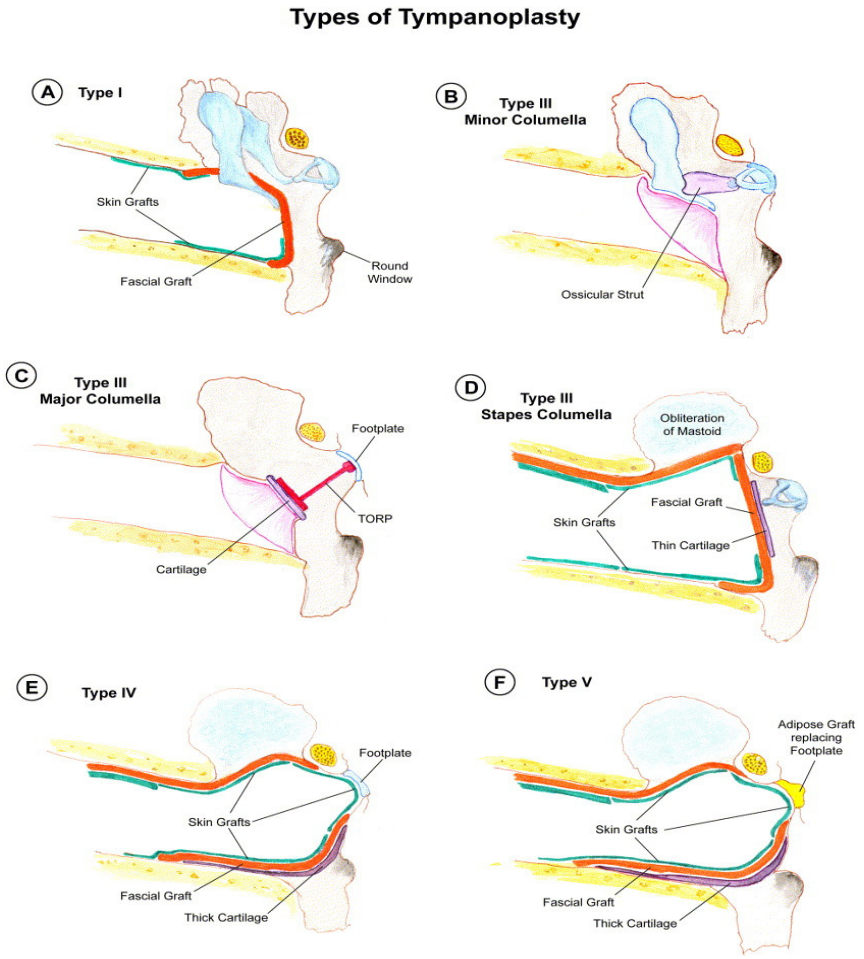


Figure 1: Wullstein classification of tympanoplasties with modifications. [28]

i. Type 1 tympanoplasty

The procedure implies an intact ossicular chain and includes the surgical removal of middle ear pathology (e.g. granulation tissue), inspection of the ossicular chain and/or the lifting of a tympanomeatal flap to gain access to the middle ear. Although frequently used interchangeably with type 1 tympanoplasty, the procedure of repairing a tympanic membrane perforation without the lifting of a tympanomeatal flap or of the addressing of middle ear pathology, according to original descriptions, may also be termed **myringoplasty.** [20]

ii. Type 2 tympanoplasty

Type 2 tympanoplasty classically describes the procedure performed for a defective malleus, where grafting is to an intact mobile incus. Because the original description of the procedure implied that the "lever" mechanism of sound transmission to the inner ear is maintained, one may consider the repair of a defective incudo-stapedial joint as a type 2 tympanoplasty as well. [29] Such a repair may include the use of ionomeric cement, [29] allogenic prosthesis [30], or cartilage. [31]

iii. Type 3 tympanoplasty [32]

The original description of a type 3 tympanoplasty implies a defective incus with or without malleus erosion where grafting is to an intact mobile stapes suprastructure. If grafting is *directly* to an intact suprastructure, the terms tympano-stapediopexy [32] or simple [33] type 3 tympanoplasty may be used to describe the procedure. In many instances however, the procedure involves the placement of a columella (prosthesis) between the suprastructure and tympanic membrane/malleus or graft. By doing so, the middle ear cavity can be maintained and the hearing gain enhanced. Even in the absence of the "lever" mechanism of sound conduction, sociable hearing is still possible in the majority of intact suprastructure type 3 tympanoplasties. [1]

With the expansion of ossiculoplasty techniques, a modification to the originally described procedure have come to the fore (see figure 1). According to such a modification, type 3 tympanoplasty is further classified in terms of the columella (prosthesis) used for reconstruction (see figure 1) and includes cases where the suprastructure is absent. [28]

iv. Type 4 tympanoplasty

Type 4 tympanoplasty describes the situation of an absent stapes suprastructure and the grafting of the tympanic membrane directly to the promontory, leaving the mobile stapes footplate exposed. The procedure, also termed "sonic shielding

of the round window membrane", will eliminate the effect that phase cancellation might have on hearing. [34] Hearing gains, albeit limited, can be enhanced if cartilage is used to reinforce the aerated area over the round window membrane. [34]

v. Type 5 tympanoplasty

This procedure classically describes tympanic membrane grafting to a newly created inner ear window in the lateral semicircular canal. [34] In the presence of a fixed stapes footplate, the procedure will allow for the propagation of sound waves to the inner ear. The grafting to an open vestibule (absent footplate) post disease clearance, also constitutes a type 5 tympanoplasty. [28]

d) Type 1 tympanoplasty techniques

As discussed, the surgical closure of tympanic membrane perforations has been the subject of intense debate since the first successful skin graft closure of a perforation in 1878. [20] Not only are the indications and contra- indications of this procedure controversial, but the many described techniques are adding to the difficulties of formulating a management plan for many such cases.

Over time, many different tympanoplasty techniques have been developed to address the inadequacies or difficulties of previously described operations. Among others, the most frequently used ones include the STSG overlay- (Wullstein 1950), vein underlay- (Shea 1957), temporalis fascia underlay- (Storrs 1961), "sandwich"- (Karlan 1979), swinging door- (Schwaber 1986) and "crowncork"- (Hartwein 1992) tympanoplasties. [20]

Minimally invasive techniques also have a long history. First described in 1877, was the use of a paper patch for small perforations. More recently, the use of lobule fat grafts and self-stabilizing tympanic membrane patches have shown promise as minimally invasive procedures. [20]

The temporalis fascia graft used in an underlay fashion, is currently the most popular technique to repair the majority of tympanic membrane perforations. The graft is considered ideal for tympanic membrane grafting, as it is thin, durable, easy to harvest, abundant, and in the incision site used for exposure to the middle ear. Considering its mentioned drawbacks (see section 3.1.3.2 a iii) and the many (sometimes complex) grafting techniques developed to address these, [20] cartilage as grafting material has gained popularity.

Previously, the use of cartilage grafts were limited to attic and posterior canal wall reconstructions. It is considered ideal in these circumstances, as its rigidity will prevent retraction pockets to form, especially in cases where middle ear aeration capabilities are questionable. [35] A gradual expansion of its use in middle ear surgery, and specifically tympanic membrane grafting, occurred however once perceptions regarding its negative impact on hearing was shown to be incorrect. [21, 35] The development of numerous cartilage-grafting techniques since, [36] has lead to its frequent use in revision surgery and large or peripherally located perforations.

In 1998, its possible value as grafting material as part of a minimally invasive technique was realized when a novel grafting technique termed the cartilage butterfly technique was described. [37] The original technique, described for pediatric patients with small, easy accessible perforations, was used with perichondrium intact on both sides, in combination with a STSG. Subsequent expansions have lead to its use in larger perforations, [38-40] and as part of formal tympanoplasty techniques. [41] In adults, the technique gained favour as it could be performed under local anesthesia and on an outpatient basis [42].

Other benefits of the BCIG technique include the following [42, 43]:

- Reduced theater time as compared to the fascia underlay technique, especially if performed under local anesthesia (LA).

- Reduced cost for the hospital (or patient), as the procedure can be performed as a day case procedure and post-operative analgesic requirements are minimal.
- Enhanced post-operative patient comfort, as in most instances no external ear incisions are required.

The technique entails the harvesting of a tragal- or conchal composite cartilage-perichondrial graft as described, shaping it to the size and shape of the perforation and scoring its edge circumferentially between the two layers of perichondrium. [37] The graft is then "laid into" the fistularized perforation, the scored edges on either side of the tympanic membrane remnant (Figure 2).

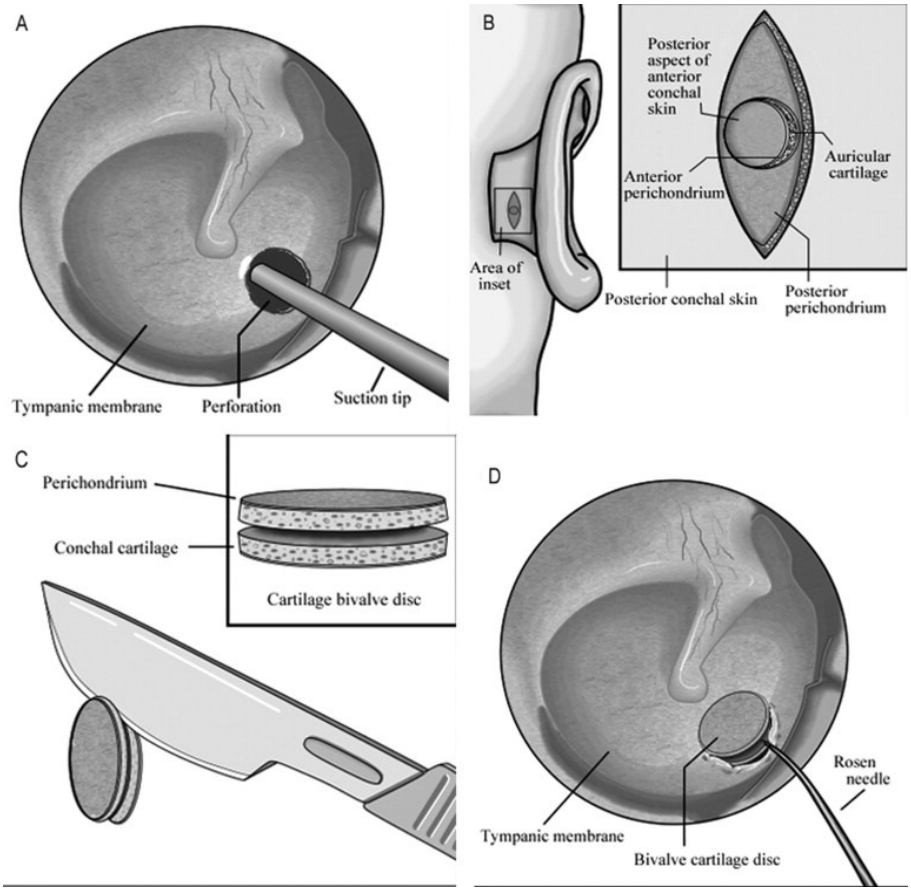


Figure 2: Illustration of cartilage preparation and placement with BCIG technique. [39]

The procedure may be technically difficult to perform if the entire perforation is not seen through the canal with the patient's head and microscope in one position. Large perforations may thus be particularly troublesome to repair using a trans-canal approach, and residual perforations may occur because of inadequate exposure. [39] In the pediatric age group, cartilage, and more specifically the BCIG technique, may be particularly useful as grafting material because of the increased possibility of recurrent Eustachian tube dysfunction. [38]

3.2 CCOM (CHRONIC CHOLESTEATOMATOUS OTITIS MEDIA)

3.2.1 Pathogenesis and classification

The migration of keratinized epithelium into the middle ear and the formation of cholesteatoma sacs remains and enigmatic pathological mechanism. Although various theories are forwarded to explain these processes, [44] a classification based on its site of origin is more practical, as not only does it improve the understanding of the disease process, but it also contributes a great deal to surgical decision making.

Cholesteatoma can be classified into two groups according to the suspected pathogenesis viz. Congenital and Acquired. [45]

3.2.1.1 Congenital Cholesteatoma

Congenital Cholesteatoma is generally believed to originate from keratinizing epithelial deposits in the anterior tympanic cavity that occur during embryogenesis of the middle ear. By definition, there should be no history of middle ear infection or surgery and no perforation of the tympanic membrane. In advanced cases however, the distinction between congenital- and acquired cholesteatoma is not clear, as the one type may resemble the other. Up to a third of pediatric cases however may be of congenital origin. [45]

3.2.1.2 Acquired Cholesteatoma

Acquired Cholesteatoma is a disorder of the epithelial junction characterized by the medial displacement of the epithelial-mucosal boundary. [46] It can further be classified as being primarily- or secondarily acquired. [44]

a) Primary Acquired Cholesteatoma (Attic cholesteatoma [47])

Eustachian tube dysfunction and the action that the resultant negative middle ear pressure has on the naturally weakened pars flacida (Shrapnel's membrane) may be responsible for this type of cholesteatoma. [44]

The tympanic membrane retraction that forms because of the negative pressure in the middle ear, may progress into the attic and epitympanum, and cause epithelial debris and keratin to accumulate in the formed pocket. The cholesteatoma that has now formed, gradually expands, its growth accelerated by an intense inflammatory reaction that frequently ensues. [44] This type of cholesteatoma typically progress lateral to the ossicles (incus), and frequently results in medial canal wall (scutum) erosion. [48]

Pediatric cases of cholesteatoma are often primary acquired. It may be that recurrent middle ear infections or OME predispose this age group to the formation of this type of cholesteatoma by not allowing for the development of the normal mastoid to middle ear air cell tracts [48] and/or by weakening the pars flacida. [44] The combination of a large mastoid antrum, deep air cell tracts, poor Eustachian tube function and an increased growth potential of tissues, frequently result in cholesteatoma to be larger and more extensive in the pediatric population. [46, 48]

b) Secondarily Acquired Cholesteatoma

In this type of cholesteatoma, epithelium gains access to the middle ear by a way other than via the pars flacida. The cholesteatoma may originate either through a marginal postero- superior perforation or retraction (*sinus cholesteatoma*), or may occur as a result of the entire tympanic membrane being retracted (*pars tensa cholesteatoma*). [49] The latter type may also form secondary to an epithelial invasion of the entire middle ear. Chronic inflammation and granulation tissue formation predisposes the middle ear for this process to occur. [46] Cholesteatoma normally propagates medial to the incus and malleus, over the stapedial niche and into the attic. [47] Scutum erosion is typically absent in these cases.

Although the above classifications of cholesteatoma is helpful in the planning of surgery and reporting of outcomes, [47] frequently the distinction between the different types are not possible. This is particularly evident in advanced cases of cholesteatoma. [46]

3.2.2 Management

Before sophisticated instruments and microscopes were available, performing destructive radical mastoidectomies were common practice in the management of cholesteatoma (and even NCCOM). [50] With the development of microscopic equipment and an improved understanding of the disease process, innovative surgical techniques developed with subsequent reductions in patient morbidity. [50]

In general terms, in order to achieve an acceptable surgical outcome, certain goals have been described in the management of cholesteatoma. These can be summarized into the following [51]:

- Complete clearance of disease and the creation of anatomic conditions that prevents recurrence.
- Hearing preservation

3.2.2.1 Clearance of disease

The aim of disease clearance without considering disease recurrence is likely to lead to the ultimate failure of the procedure. Surgeons aiming to address both these aspects of surgery have to consider the options of disease clearance whilst preserving normal anatomy and clearance by sacrificing normal anatomy. In this respect, many follow either approach on an individualized basis, using certain cholesteatoma- and patient characteristics to decide on the appropriate course of action. [46, 47, 49]

The two basic techniques to address disease include [48]:

- Canal wall up mastoidectomy (CWU)
- Canal wall down mastoidectomy (CWD)

a) CWU Mastoidectomy [52]

With CWU mastoidectomy, the aim is to maintain normal anatomy as far as possible whilst still removing all cholesteatomatous disease. It involves a posterior tympanotomy and an extended facial recess approach, combined with a

thorough cortical mastoidectomy of all diseased air cells (healthy air cells are left *in situ* to facilitate mucosalization of the created cavity). Although the aim is to leave the external canal wall intact, often the medial canal wall is defective post disease clearance and then may require reinforcement with a rigid material such as cartilage to prevent recurrent retraction pocket and cholesteatoma formation. [46]

Although considerable controversy exists as to the indications for the procedure, arguably the technique is ideally suited for patients with limited attic (primary acquired) cholesteatoma. [46, 49] In pediatric cases presenting specifically with such cholesteatomas, the presence of a large aerated antrum may not only allow for the safe and complete removal of disease with reduced incidences of recurrence, [45] but CWU surgery will also avoid the morbidity associated with a large exenterated mastoid cavity. [46]

In extensive pars tensa cholesteatoma (requiring mastoidectomy for removal [53]), the technique may be inadequate in achieving the goals of CWU surgery, mainly for the following reasons:

- Considerable difficulty may be encountered in the complete removal of disease from the middle ear. Poor exposure offered by the technique in the facial recess and sinus tympani may lead to residual macroscopic disease, which when combined with the fact that even innocent looking mucosa may contain microscopic squamous epithelium, [47] will lead to a high incidence of *residual* disease.
- Significant mucosal sacrifice in the removal of the disease frequently results in a mostly adhesive TM with very little if any hearing improvement post operatively. [46, 49]

The problem of cholesteatoma *recurrence* is particularly troublesome with the CWU technique. Frequently the inherent inability of a cholesteatoma ear to maintain middle ear pressures and the negative pressure created in the large

mastoid cavity combine to cause such a recurrence. [51, 53] Young pediatric cases (<9 years of age) are particularly prone in this respect. [46]

Although many recurrences with the CWU technique will occur in the first year post surgery, these may increase almost linearly over time. Recurrences can occur up to 10 years post-surgery and up to 60% of ears will have had a recurrence after this period. [53] Long term surveillance is therefore particularly important with this technique, and many will advocate routine second relook operations/procedures, either to exclude residual disease, or to manage recurrent retraction pockets and/or cholesteatoma formation. [54] In cases where cholesteatoma was confined to the attic and middle ear, and no mastoidectomy was needed in its removal, the suggestion is that pathologically significant recurrences will be evident on routine clinical examination, and that surveillance by way of close outpatient observation is appropriate. [49] Radiological surveillance may also be useful to avoid unnecessary second look procedures. [55]

Presuming that most cases of cholesteatoma recurrence are secondary to factors other than the completeness of the surgical procedure itself, some authors believe that the single most important reason for the notoriously high recurrence rates may be poor surgical decision making. Their opinion is that recurrence rates below 10% are possible over the long term (10 years) in carefully selected patients. [49]

Besides the problem of recurrence, other problems with the technique include the following:

- Significant surgical skill and experience required in its safe performance. [52]
- Financial constraints and patients' reluctance or inability to commit to a strict follow up schedule and planned relook operations, may compromise the safety of the procedure. [46,51,54]

- Atrophy of the thinned posterior canal wall that may result in an irregular cavity that is inferior to a surgically created one. [53]
- Hearing gains that can be less than expected and comparable to the CWD technique. [51,56]

b) CWD Mastoidectomy

In complicated cases of cholesteatoma (*only hearing ear, septic intra- cranial complications, high anesthetic risk, facial nerve paralysis, sensori- neural hearing loss*), and in cases where safe removal of the cholesteatoma matrix is not possible, CWD mastoidectomy is generally accepted by most to be the safest and most appropriate procedure.

The reasons proposed for taking the canal wall down in uncomplicated cases include the following:

- Disease clearance is simpler, as exposure in difficult to access areas in the middle ear and mastoid is increased. [51, 57] This is especially the case in the severely sclerotic and contracted mastoid with extensive middle ear disease.
- Postoperative safety of the procedure is improved, especially in cases where follow up may be troublesome. Possible disease recurrence is likely to progress externally rather than intracranially in such cases. [50]
- Outpatient follow up is possible, most of the time negating the need for a planned relook procedure. This is a very important benefit where theatre time- and financial constraints prevail. Second look surgery however may still be necessary to exclude recurrences in the mastoid bowl after cavity obliteration or in the middle ear after tympanic membrane reconstruction. [58] These recurrences however, assuming complete macroscopic clearance, are rare, even over the long term. [33, 51, 53 and 57]

In the literature two differing CWD techniques are commonly used, namely the *large cavity*- or *"Fisch"* technique, [33, 51, 53] and the *small cavity*- or *inside out* technique. [48, 50, 56-60]

i. The "Fisch-", or large cavity technique [51]

This approach entails the complete exenteration of all mastoid air cells, and the removal of the cholesteatoma with or without mastoid tip amputation. Because the technique frequently results in the creation of sumps and/or crevices, obliteration is a necessary part of the procedure to minimize the collection of keratin debris and to reduce cavity size. A third important step of the procedure entails the placement of a graft to the middle ear. Although neo-tympanic membrane formation occurs in up to 50% of cases, grafting of the middle ear will increase the number of closed middle ears. [59] It has been shown that a successful TM reconstruction will result in a dry cavity more often, as not only are the exposed middle ear mucosa and Eustachian tube separated from the mastoid bowl, but crevices in the middle ear are also eliminated, preventing the possible accumulation of keratin debris. [50] The performance of a meatoplasty that matches the size of the cavity completes the procedure. The aeration provided by a large meatus will further decrease the likelihood of a discharge in future.

The <u>disadvantages</u> to this approach include the following:

- Impaired sound dynamics and hearing outcomes secondary to the abnormal anatomy post-operatively. [33]
- Problematic hearing aid (behind the ear hearing aid) fitting, because of a large meatus and absent external ear canal.
- Undetected cholesteatoma recurrence secondary to an obliterated cavity. [53] Failed obliterations (recurrence, wet ear, and residual disease) may occur in up to 23% of cases. [59]
- Significant morbidity because of a large meatus and cavity- patients may complain of intermittent discharge, vertigo, pain and cosmetic issues. [51, 53]

ii. The small cavity- or *"inside-out" technique* [56, 60]

This technique involves the removal of cholesteatoma from the canal outwards to the mastoid. The aim is to match the size of the cavity to the size of the cholesteatoma to avoid the morbidity of an unnecessarily large cavity. Uninvolved, sclerotic bone is left *in situ* as far as possible.

Small cholesteatoma involving the attic can be excised with the canal left intact and, depending on middle ear conditions, the middle ear is reconstructed to maintain near normal anatomy post operatively. [49, 57] Larger cholesteatoma involving the antrum can be removed and the cavity exteriorized. A cartilage–perichondrial graft can be used to reduce the cavity size and prevent the formation of a retraction pocket into the remaining mastoid. [56]

Advanced cholesteatoma (deep into the mastoid) is managed by taking the canal wall down to the level of the facial nerve. This should be done as far distally as the floor of the external ear canal to expose the sumps and crevices in the supralabyrinthine area and mastoid tip. Focus in such cases should still be on retaining uninvolved mastoid bone as far as possible, but also to create a rounded smooth cavity by placing a graft to the middle ear and supralabyrinthine area where possible. [60]

In most cases, obliteration of the cavity is not necessary, as it is likely to be small enough to avoid the morbidity associated with a large cavity. In fact, the cavity performed in this way may even resemble a normal, albeit widened external auditory canal post operatively. [50]

The **disadvantages** of this approach include the following:

- Surgical control may be suboptimal when drilling in a long narrow space. To enhance exposure, a canaloplasty (widening of the canal) at the beginning of the procedure is frequently required. [50]

- A continuous discharge post-operatively secondary to retained diseased mucosa and osteomyelitic bone. The reported incidence of dry ears post-operatively however, appears to be similar between the small and large cavity mastoidectomy techniques.
- Risk of Cholesterol Granuloma formation in sealed off retained mastoid air cells. Because the reported incidence of this phenomenon is low, it is possible that these air cells acquire ventilation somehow. A possible explanation is that air from the middle ear reaches the retained air cells via the retro facial air cell tracts. [56]

3.2.2.2 Hearing rehabilitation

Besides the avoidance of cavity problems, some CWU technique proponents have shown hearing outcomes to be superior to the CWD technique. [46, 49] Criticism to these results however relates to the fact that frequently the technique would not only be employed in cases with less severe disease, but also that these superior hearing gains frequently deteriorate over time to ultimately result in hearing outcomes equivalent to that of the CWD technique. [47] Long-term studies have shown that hearing outcomes are independent of technique, with only a third experiencing significant hearing improvement (>10dB). It further showed that hearing will remain unchanged in one third, and worsen in one third. [47]

Because of these generally perceived poor outcomes, certain CWD mastoidectomy proponents consider hearing reconstruction in only a minority of their patients. [51] Some of the reasons given include the following:

- Middle ear and mastoid aeration is poor in most cases of cholesteatoma (sclerotic mastoid and shallow middle ear cleft) and therefore do not allow for effective middle ear reconstruction. [56]
- Large cavities may have adverse effects on the transmission of sound to the middle ear, and therefore may attenuate hearing gains achieved from an attempted reconstruction. [33]

- Although considered significant to the surgeon, small hearing increments, especially in cases with uni-lateral disease, may be of no benefit to the patient. [51]

Not all however agree that most patients with cholesteatoma will at best have limited and short lived hearing improvement post operatively. [57, 61-63] In order to achieve significant and meaningful hearing improvements however, it is necessary to take cognisance of, or address certain identified variables that may affect the outcome of surgery. These include the following:

a) Status of stapes suprastructure

Many have showed that grafting to an intact suprastructure results in better hearing outcomes than when it is absent. [45, 46, 57, 64 and 65] Although others have shown that this variable does not affect audiometric outcomes, [61] its presence in a well-aerated middle ear should encourage middle ear reconstruction, as hearing outcomes are likely to be good in such cases.

b) Status of the contra-lateral ear

Although the primary objective should be on the creation of a safe and care-free ear, in bilateral cholesteatomatous disease an attempt should be made to improve the hearing in the first operated ear. [46] In addition to the fact that patients with bilateral disease will appreciate any hearing improvement, even if limited, it may also be important to improve the worse hearing ear's thresholds (ACT's) to a level better than the better hearing ear's. If successful, one can avoid the difficulties associated with operating on a better hearing ear in future, as the (initial) better ear will then be worse.

c) The depth of the middle ear after surgery (amount of air in the middle ear)

Granulation tissue in the middle ear, adhesive otitis media and adhesions post operatively, all contribute to a shallow cavity and poor hearing post-surgery.

Steps to deepen the middle ear cleft, such as the cartilage ring tympanoplasty [61] may improve outcomes. Similarly, the placement of silastic sheets or chromic catgut suture material in the middle ear may help to maintain this space by preventing adhesions to form. [50, 52]

d) The size of the marsupialized cavity after the operation

As discussed, the small cavity technique frequently results in a cavity resembling a widened external ear canal and therefore may limit the adverse acoustics effects of a large fully exenterated cavity. It has been shown that tympanoplasty in such ears frequently result in significant hearing improvements. [61] In case a hearing aid is needed for hearing augmentation, the small cavity may also lend itself to easier fitment and use of standard behind the ear hearing aids.

With the large cavity technique, some authors may attempt to reconstruct the posterior canal wall [61] or to obliterate the mastoid cavity completely. [53] In doing so, not only does it facilitate ossicular reconstruction it also eliminates the acoustic effects of an open cavity. As mentioned though, the risk of undetected recurrence is increased. [53]

3.2.3 Pediatric cholesteatoma and the small cavity technique

Regardless of the fact that pediatric cases of cholesteatoma usually exhibit a more aggressive form of the disease, [45, 48, 53] some surgeons still place emphasis on initial functionality (normal anatomy and hearing improvement) rather than on the safety of a canal wall down procedure. [45, 46] The reasons mentioned is that in addition to allowing for normal speech and social development in this critical period to occur, the long term morbidity associated with a CWD procedure can be avoided.

In experienced hands and in carefully selected patients, the CWU technique often results in good early surgical outcomes with more than 50% of cases achieving sociable hearing (ACT<30dB). [45, 49, 54] The difficulties associated with the CWU technique however, and the development of equally effective, more dynamic

CWD approaches are playing a role in some surgeons previously employing the CWU technique, to now favour the small cavity CWD technique. [60] This technique has shown promise in this population as near normal anatomy and hearing can be achieved with small cholesteatoma resections, while safety can be established in larger ones as the canal wall is taken down completely. [58] Providing middle ear conditions are favourable, surgery performed in this way may allow for the reconstruction of the medial canal wall if cholesteatoma is limited to the attic. [58] In such cases, the result will then be similar to that of the CWU technique, except for the possibility that recurrences will be less. The elimination of the negative pressure created by a large exenterated mastoid cavity is likely to prevent recurrent retraction pocket formation. [58]

4. OBSERVATIONS AND HYPOTHESIS

4.1 OBSERVATIONS

The motivation for this study came from some important observations made in the study period regarding changing trends in the surgical management of chronic otitis media. It allowed a hypothesis to be formulated according to anecdotal reports on the outcomes of surgery. This chapter will briefly discuss these observations and hypothesis.

4.1.1. Surgical management of NCCOM

In the past, FUG tympanoplasty was the preferred procedure at the CHBAH in the surgical management of simple dry perforations. Results were not formally studied but were deemed to be satisfactory at the time. The major problem with this technique though is that it is time consuming. Limited theatre time and patient load were major factors leading to the research of other less invasive techniques to manage simple dry tympanic membrane perforations. Literature reports on BCIG tympanoplasty have shown it to be a simple, quick and very effective technique. In cases of small simple perforations, the good initial results achieved with the technique, led to its use on an increasingly regular basis, and for more complex cases of NCCOM.

4.1.2. Surgical management of CCOM

It is the opinion of regional colleagues that CCOM managed in the local setting reflects that that is prevalent in the third world economic setting (generally advanced). This fact, as well as significant follow up issues and patient compliance problems has led many surgeons to opt for safety in surgical management rather than optimal functional outcomes. The retro auricular approach, with full mastoid air cell exenteration without obliteration or tympanic membrane reconstruction was previously the preferred approach in the surgical management of patients with cholesteatoma. In fear of undetected cholesteatoma recurrence, this approach was believed to be appropriate in most cases.

In the last few years, our surgical approach to cholesteatoma has changed. The literature evidence supporting the effectiveness of less radical procedures in cholesteatoma surgery, combined with perceived improvements in the socio-economic conditions of the local population, allowed for the implementation of surgical techniques to reduce morbidity. The small cavity technique was found to be particularly useful in this respect, as early reports showed the technique to more often result in a dry, self-cleaning cavity.

4.2. HYPOTHESES

- Recent outcomes of surgery for NCCOM at Chris Hani Baragwanath Academic Hospital generally reflect those reported in international literature.
- Butterfly cartilage inlay tympanoplasty in our setting, is as successful as the reported success rates for fascia underlay graft tympanoplasty.
- Tympanomastoidectomy for discharging ears is effective to clear the discharge but not as effective in achieving an intact tympanic membrane post operatively.
- The small cavity technique in cholesteatoma surgery, with tympanic membrane reconstruction, is superior to the large cavity technique without reconstruction, in creating a dry care free cavity

5. METHODOLOGY

In this chapter, an approach to the research is presented. Patients were grouped in terms of the surgical procedure performed. Although the inclusion and exclusion criteria were uniform for all three groups, outcome measures and variables studied differed as the aim of surgery in the three groups differed as well. The chapter will end with a detailed description of the statistical analysis performed.

5.1 STUDY POPULATION AND LOCATION

The study population included all patients that had surgery performed for Chronic Otitis Media at the Chris Hani Baragwanath Academic Hospital (CHBAH) from July 2009 to December 2010 (i.e. 18 months).

5.2 STUDY DESIGN

A retrospective clinical chart review.

5.3 DATA COLLECTION

Data was collected from the otological database in the outpatient department at the CHBAH, and grouped according to surgical procedure performed. These groups were:

- Tympanoplasty,
- Tympanomastoidectomy, and
- Canal wall down mastoidectomy.

In all three groups of patients, the clinical and audiological data acquired at the last (latest) follow up visit were used. Only data that were collected more than two months post operatively were included for study purposes. The follow up period varied from 2 to 18 months post operatively.

Except for the CWD mastoidectomy group of patients, audiological data were collected only on patients with an intact tympanic membrane post operatively. An effort was made to collect all post operative data post CWD surgery as the hearing

may have deteriorated post surgery because of the destructive nature of the procedure.

5.3.1 Inclusion criteria

- Patients who had more than one procedure performed on the same or contra lateral ear. Each operation was documented on an individualized basis.
- Patients with pre- and post-operative audiograms. In cases where graft failure has occurred, a post-operative audiogram was not a pre-requisite for inclusion.

5.3.2 Exclusion criteria

- All patients who did not fulfill the above inclusion criteria.
- Patients subjected to ear surgery for reasons other than COM.
- Cases of staged operations where the middle ear was explored after complete healing of the tympanic membrane has occurred. These cases were excluded from the study because of the frequent unavailability of information about the initial surgical procedures performed.
- All cholesteatoma patients that had a procedure other that a CWD mastoidectomy performed or where the procedure could not be classified as being a small- or large cavity technique. The aim of this arm of the study was to assess the effectiveness of the small cavity technique in relation to the large cavity technique.

5.3.3 Outcome measures

5.3.3.1 Tympanoplasty

Tympanoplasty patients were divided into FUG- and BCIG tympanoplasties and evaluated independently. **Surgical success** was defined as a stable, healed, and clinically intact tympanic membrane. Improvements in patients' hearing in the speech frequencies (500, 1000 and 2000Hz) were used to report **audiological outcome**. The decibel (dB) measure of hearing in these frequencies were averaged and documented pre- and post-operatively.

5.3.3.2 Tympanomastoidectomy

Patients is this group were divided into those, where a discharge was present pre-operatively and those where the ear was reported to be dry. These were independently evaluated post-operatively in terms of dryness of the ear (discharging ears), intactness of the tympanic membrane and hearing improvement achieved.

5.3.3.3 Canal wall down mastoidectomy

CWD mastoidectomy patients were divided into small- and large cavity groups, and also independently evaluated in terms of dryness of the ear post-operatively. In cases where tympanoplasty was performed after disease clearance, intactness of the tympanic membrane was documented post-operatively. In cases with an *intact* stapes suprastructure pre- operatively and an intact tympanic membrane post operatively, audiological outcomes were studied as well to assess the efficacy of the reconstructive effort. Audiological data for cases other than the afore-mentioned (perforated tympanic membrane or absent supra structure) was collected to assess for possible hearing deterioration.

5.3.4 Variables

5.3.4.1 Tympanoplasty patients

- Pre-operative hearing loss.
- Perforation size.
- Age.
- Sex.
- Status of contra lateral ear.

5.3.4.2 Tympanomastoidectomy patients

- Age.
- Pre operative hearing loss.
- Perforation size.

5.3.4.3 CWD mastoidectomy patients

- Age.
- Status of contra lateral ear.
- Extent of disease.
- Status of Stapes suprastructure.

Some important variables frequently studied have been excluded in this study because it is not routinely documented in patients' files. These include:

- Whether the ear was quiescent or intermittently discharging pre-operatively.
- Whether radiological assessment was used to assess the mastoid bone prior to surgery.
- The status of the middle ear and type of cholesteatoma managed.
- Surgical experience and grade.

5.3.5 Data analysis

A descriptive analysis in terms of surgical and audiological success was conducted to produce frequency tables and cross tabulations. It was used specifically to:

- Describe the baseline clinical characteristics of the patient population.
- Determine both surgical and audiological outcomes of surgery within our institution.
- Determine the association between the variables studied and surgical/audiological outcome.

Data from the otological database was coded and captured onto an Excel spreadsheet and transferred to a Statistica version 12 programme for analysis. Normally distributed continuous variables (age, hearing loss and hearing improvement post-operatively) were analyzed across the two outcome groups using the Students't-test. Categorical variables (perforation size, extent of disease [CWD mastoidectomy], status of stapes suprastructure [CWD mastoidectomy]

and status of contra lateral ear [CWD mastoidectomy and Tympanoplasty]) were compared across the two outcome groups using the Pearson's Chi Square test. The Fischer's Exact test was performed when expected cell frequencies were < five observations. The correlation co-efficient was used when testing for a linear relationship between two continuous variables.

6. RESULTS

In this chapter the results of surgery will be presented separately for the three groups mentioned, both in terms of pre-operative patient profile and post-operative surgical and audiological outcomes. Important findings will be elaborated on in terms of statistical analysis of results and the drawing of graphs for illustration. Although the outcomes of all the surgery performed for COM is presented, the focus will be on the parts relevant to the objectives of the study set out in section 2.

6.1 TYMPANOPLASTY

6.1.1 Surgical and audiological outcomes

In the study period, 43 tympanoplasties were performed. Table 1 describes the population in terms of pre-operative hearing loss and type of procedure performed.

Table 1: Tympanoplasty: Type of procedure versus pre-operative hearing loss

Hearing loss	Tympanoplasty Type 1 (BCIG)	Tympanoplasty Type 1 (FUG)	Tympanoplasty Type 2/3 (BCIG+ FUG)	Total
ACT <30dB	16	3	0	**19**
ACT 30- 50dB	10	3	6	**17**
ACT >50dB	2	2	1	**7**
Total	**28**	**8**	**7**	**43**

ACT= Air conduction threshold, dB= Decibel, BCIG= Butterfly cartilage inlay graft, FUG= Fascia underlay graft

Most patients had a hearing loss less than 50dB (36/43) and most (27/43) had a type 1 BCIG tympanoplasty. The hearing loss pre-operatively in the FUG Tympanoplasty group was generally worse than the BCIG group.

In cases where Type 1 tympanoplasty was performed, the outcome of surgery in terms of surgical procedure (FUG or BCIG) is described in Table 2.

Table 2: Tympanoplasty Type 1: Post-operative outcome.

Hearing loss	BCIG		FUG		Total
	P	I	P	I	
ACT <30dB	1	23	2	4	**30**
ACT 30- 50dB	0	0	0	0	**0**
ACT >50dB	0	0	0	0	**0**
Total	**1**	**23**	**2**	**4**	**30**

ACT= Air conduction threshold, dB= Decibel, BCIG= Butterfly cartilage inlay graft, FUG= Fascia underlay graft, P= Perforated tympanic membrane, I= Intact tympanic membrane

23/24 (96%) patients in the BCIG group achieved an intact tympanic membrane compared to 4/6 (67%) in the FUG group. In cases with an intact TM, an ACT of <30dB post-operatively occurred in 23/23 (100 %) of patients in the BCIG group and in 4/6 (67%) patients in the FUG group.

The graph below (Figure 3) compares hearing improvement between the FUG and BCIG expressed in percentage terms.

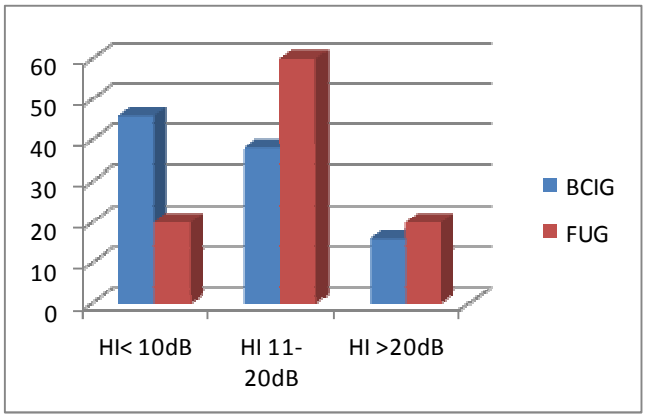


Figure 3: Type 1 Tympanoplasty: Hearing improvement comparison: BCIG versus FUG

Most patients in the BCIG group had less than 10dB improvement (46% of cases). 3/4 patients (75% of cases) in the FUG group had 11- 20dB improvement in hearing. Statistical analysis was not possible, due mainly to a large discrepancy in patient numbers.

6.1.2 VARIABLES

In this series, initial healing of the tympanic membrane (2 months post-operatively) was uniformly good. The post-operative finding of a high percentage of patients with an intact tympanic membrane (91%), made the role that certain variables might have had on surgical outcome irrelevant. The relationship between the mentioned variables and hearing outcome was studied rather, as it was deemed likely that adverse middle ear conditions (adhesions, fluid accumulation or retraction of the TM) will manifested as a hearing loss post-operatively.

6.1.2.1 Age

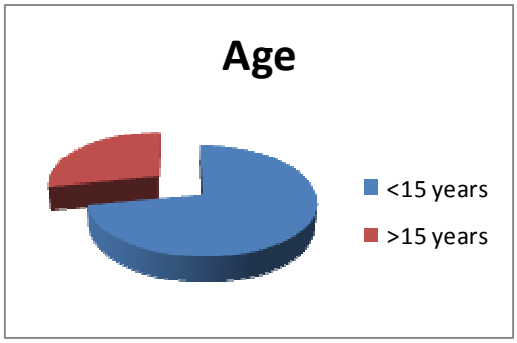


Figure 4: Tympanoplasty: age distribution.

The mean age in the tympanoplasty arm of the study was 17 (youngest 6, oldest 48)

The scatter graph below (Figure 5), age on the X-axis and HI on the Y-axis, illustrates the age distribution in terms of the hearing improvements (in dB) achieved.

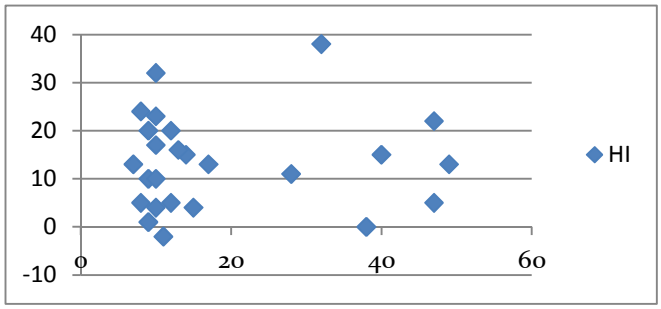


Figure 5: Type 1 tympanoplasty: Hearing improvement versus age

Although most patients were in the younger age group, HI was not shown to be related to age (p = 0,935, r- correlation= 0,017).

6.1.2.2 Size of perforation

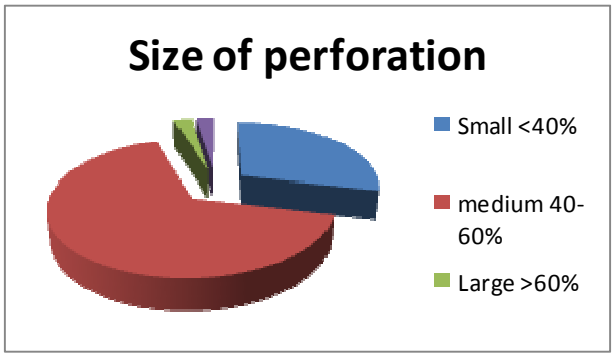


Figure 6: Tympanoplasty: Pie chart classifying patients in terms of the size of perforation.

Most patients had medium sized perforations. The average HI in medium and large perforations was 16,7dB compared to 6,14dB in small perforations. Audiological outcome in relation to perforation size is shown in Figure 7. (Y-Axis= percentage of patients, X- Axis= HI bins):

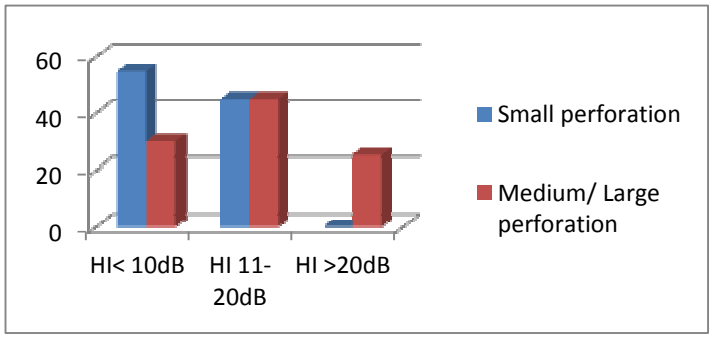


Figure 7: Type 1 tympanoplasty: Hearing improvement in terms of size of perforation

Hearing improvement in patients with small perforations was limited; most (55%) had improvements of less than 10dB, where as hearing improvement more than 10dB was achieved in 70% of patients with medium to large perforations. This relationship between perforation size and HI is statistically significant. (p= 0, 0195)

6.1.2.3 Pre-operative hearing loss

In patients with a pure conductive hearing loss, with no identified ossicular pathology, the association between pre-operative hearing loss and HI are demonstrated in the scatter graph below (Figure 8).

Pre-operative hearing loss is documented on the X- axis and HI on the Y- axis.

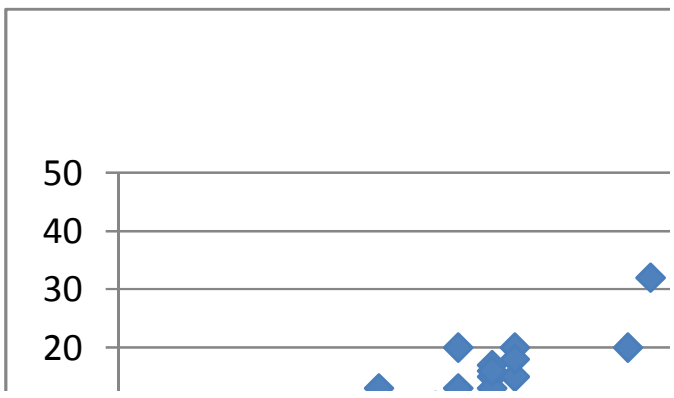


Figure 8: Type 1 tympanoplasty: Relationship between pre-operative hearing loss and hearing improvement post-operatively.

A paired T-test was performed on the above data and a statistically, highly significant direct relationship was found between pre-operative hearing loss and hearing improvement. (p= 0, 0001, r- value= 0,901)

6.1.2.4 Other variables

No statistically significant relationship was found between sex and hearing improvement post operatively (p=0, 77). Whether disease was uni- or bilateral, also had no impact on hearing improvement post-operatively (p= 0, 34).

6.1.3 Type 2/3 tympanoplasty

Seven patients had an ossiculoplasty as a non-staged procedure, of which one was lost to follow up. Table 3 below describes the type of ossiculoplasty performed and outcomes achieved.

Table 3: Type 2/3 tympanoplasty: Outcomes

Reconstructive technique	TM intact and HI> 10dB	Graft failure	Audiological failure (no HI)
PORP Prosthesis (n=3)	0	1	1
Cartilage (S-I) (n=3)	2	1	0
Cartilage (S-M/TM) (n=1)	0	0	1

Porp= Partial ossicular reconstruction prosthesis, TM= Tympanic membrane, HI= Hearing improvement, S-I= Stapes to Incus, S-M= Stapes to malleus.

Only 2/6 patients (33%) had significant hearing improvement (>10dB) post ossiculoplasty. Both of these cases had minimal ossicular abnormalities (ISJ dislocation/fibrous union), and repair was performed by placing a cartilage auto graft between the incus and stapes.

6.2 TYMPANOMASTOIDECTOMY

6.2.1 Surgical and audiological outcomes

In the study period, 33 procedures were performed.

In Table 4, ears are grouped as being dry or discharging, and described in terms of pre- operative hearing loss and type of procedure performed.

Table 4: Tympanomastoidectomy: Pre operative characteristics

Hearing loss	**Tympanoplasty + Mastoidectomy**		**Mastoidectomy only**	**Total**
	Type 1	Type 3		
Dry ears				
ACT <30dB	0	0	0	**0**
ACT 30- 50dB	2	1	0	**3**
ACT >50dB	4	3	0	**7**
Sub Total	**6**	**4**	**0**	**10**
Discharging ears				
No Audio	1	0	1	**2**
ACT <30dB	0	0	0	**0**
ACT 30- 50dB	6	0	0	**6**
ACT >50dB	9	1	5	**15**
Sub Total	**16**	**1**	**6**	**23**
Total	**22**	**5**	**6**	**33**

BCIG= Butterfly cartilage inlay graft, FUG= Fascia underlay graft, ACT= Air conduction threshold, dB= Decibel.

Most patients had a severe hearing loss (22/33) (67%) and an actively discharging ear (23/33) (69%) pre-operatively. All but six patients had reconstruction of the tympanic membrane (Tympanomastoidectomy).

The seventeen tympanomastoidectomy patients presenting with a discharging ear pre- operatively, all had fascia underlay graft tympanoplasties. Ten patients had a dry ear pre-operatively. All ten patients had ACT's worse than 30dB and four had an ossiculoplasty in the non-staged setting.

Table 5 grouped Tympanomastoidectomy patients post-operatively as dry or discharging and in terms of the status of the tympanic membrane and hearing.

Table 5: Tympanomastoidectomy: Post-operative outcome.

Hearing loss	**Status of tympanic membrane**		**Mastoidectomy only**	**Total**
	Intact	Perforated		
Lost to f/u				**3**
Dry ears				
No audio	0	1	1	**2**
ACT <30dB	9	0	0	**9**
ACT 30- 50dB	5	1	0	**6**
ACT >50dB	3	3	2	**8**
Sub Total	17	5	3	**25**
Discharging ears				
No audio	0	1	0	1
ACT <30dB	0	0	0	**0**
ACT 30- 50dB	0	0	0	**0**
ACT >50dB	0	1	3	**4**
Sub Total	0	2	3	**5**
Total	**17**	**7**	**6**	**33**

ACT= Air conduction threshold, dB= Decibel

Dry ears improved from 10/33 (30%) pre-operatively to 25/30 (83%) post-operatively.

In patients who had tympanoplasty in addition to mastoidectomy (Tympanomastoidectomy), the results were as follow:

- 18/24 patients had an intact tympanic membrane post- operatively, 10/10 (100%) dry ears and 7/14 (50%) discharging ears. This difference in surgical outcome (Intact TM) between dry and discharging ears was statistically significant (p= 0,012).
- Patients with an ACT of <30dB improved from 0/18 pre-operatively to 9/18 post- operatively.
- The average HI in the dry ear group was 20dB as compared to 12dB in the discharging group, the difference being statistically significant. (p= 0,02)

In order to study the impact that Tympanomastoidectomy had on discharging ears, the following outcomes where studied and illustrated in Figure 9 below:

- Dry ears achieved,
- Intact tympanic membrane achieved, and
- Hearing improvement >10dB.

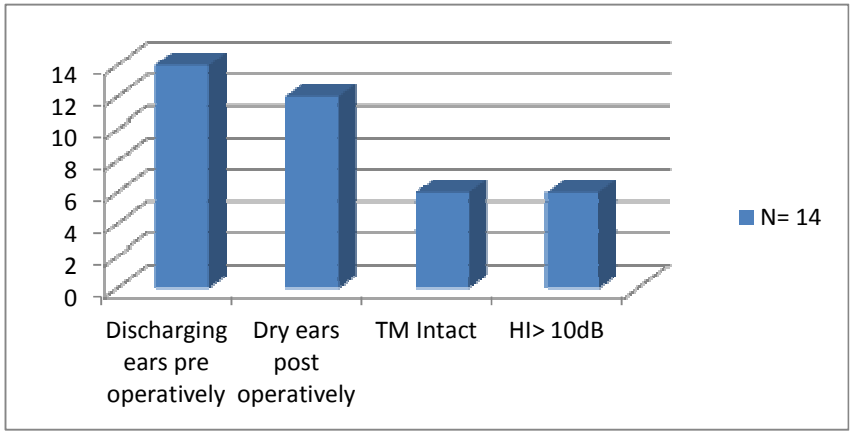


Figure 9: Tympanomastoidectomy: Outcome in discharging ears.

Only 50% of discharging ears in this series achieved an intact tympanic membrane post- operatively. Significant hearing improvement (10dB) was achieved in all seven patients who had an intact tympanic membrane post-operatively.

6.2.2 Variables

6.2.2.1 Age

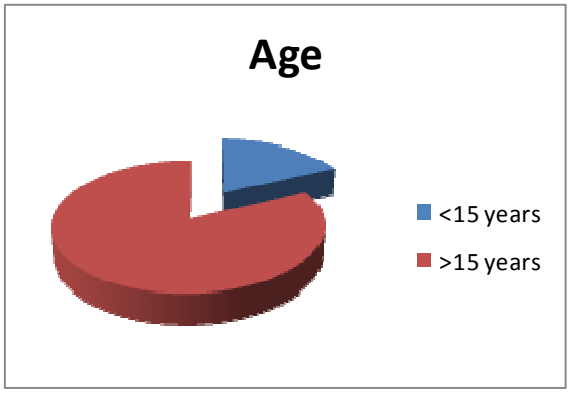


Figure 10: Tympanomastoidectomy: Age distribution.

The majority of patients subjected to Tympanomastoidectomy were in an older age group (>15 years of age). No statistical significant relationship was found between age and graft success rates (p= 0, 18).

6.2.2.2 Perforation size

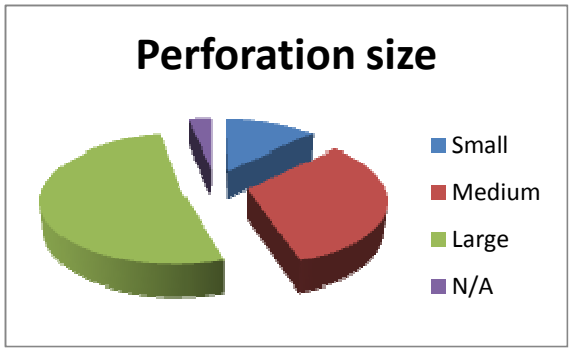


Figure 11: Tympanomastoidectomy: Distribution of patients in terms of perforation size.

Perforation size as a variable was studied to determine whether it had an impact on tympanic membrane closure post-operatively. In contrast to the tympanoplasty group of patients, the majority of patients in this group had large perforations (16/32). 7/15 patients with a large perforation had an intact TM post-operatively,

compared to 10/12 patients who had small or medium sized perforations. The difference in success rates was statistically significant (p= 0,047).

6.2.2.3 Pre-operative hearing loss

Figure 12 below illustrates the surgical outcome (Status of tympanic membrane) of tympanomastoidectomy in discharging ears in terms of pre-operative hearing loss.

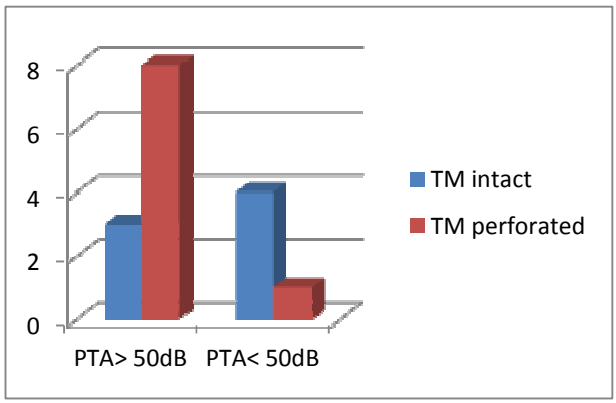


Figure 12: Tympanomastoidectomy: Surgical outcome for discharging ears.

Only 37% of cases with a hearing loss more than 50dB had an intact TM post-operatively, compared to 80% when the hearing loss was <50dB. These results were not statistically significant (p= 0,13).

6.3 CANAL WALL DOWN MASTOIDECTOMY

6.3.1 Surgical and audiological outcomes

In this series, 14 patients had a small cavity- and 19 a large cavity procedure. Table 6 describes the procedure performed in terms of the hearing loss pre-operatively, as well as whether a tympanoplasty was performed in the same setting or not.

Table 6: CWD mastoidectomy: Hearing loss and surgical technique.

Hearing loss	Small cavity		Large cavity		Total
	Tymp	No Tymp	Tymp	No Tymp	
No audiogram				3	**3**
ACT <30dB	0	0	1	1	**2**
ACT 30- 50dB	4	0	0	4	**8**
ACT >50dB	10	0	3	7	**20**
Total	**14**	0	**4**	15	**33**

Tymp= Tympanoplasty performed, No Tymp= No tympanoplasty performed, ACT= Air Conduction Threshold

Hearing loss was generally in the moderate to severe range (>50dB) pre-operatively.

20/30 (67%) had ACT's worse than 50dB pre-operatively. Only 4/19 patients in the large cavity group had reconstruction of the tympanic membrane, where as all the patients in the small cavity group had a fascia graft to the middle ear.

Table 7 describes the outcome for CWD mastoidectomy, in terms of whether the ear was dry or discharging and whether the TM was intact post-operatively. Patients are grouped in terms of their post-operative hearing loss.

Table 7: CWD mastoidectomy: Surgical and Audiological outcome.

Hearing loss	Small cavity				Large cavity				Total
	ID	IDc	PD	PDc	ID	IDc	PD	PDc	
No audiogram	0	0	0	0	0	0	3	1	**4**
ACT <30dB	3	0	0	0	0	0	0	0	**3**
ACT 30- 50dB	4	0	0	0	1	0	3	0	**8**
ACT >50dB	5	1	0	1	2	0	3	6	**18**
Total	**12**	**1**	**0**	**1**	**3**	**0**	**9**	**7**	**33**

ID= Intact tympanic membrane and dry, IDc= Intact tympanic membrane but discharge present, PD= Perforated TM and dry, PDc= Perforated TM and discharging, ACT= Air conduction threshold, dB= Decibel.

In the small cavity group, 12/14 patients (86%) achieved both an intact tympanic membrane and dry cavity post-operatively, compared to only 3/19 (16%) in the large cavity group. However, 12/19 (63%) in the large cavity group, still had a dry cavity post-operatively. Even though the small cavity group had more dry ears post-operatively as compared to the large cavity group, this was not statistically significant (p= 0,39). Overall, audiological evaluation revealed no significant difference between pre- and post-operative values (p= 0, 31). Three patients that had a tympanoplasty performed after a CWD mastoidectomy had hearing improvement with an ACT within 30dB post-operatively. Two patients who had pre-operative ACT's <30dB in the large cavity group with no middle ear reconstruction, had documented worsening of the hearing to the 30-50dB range.

Table 8 indicates the hearing outcome post CWD mastoidectomy where the stapes suprastructure was intact pre-operatively and the tympanic membrane intact post-operatively.

Table 8: CWD mastoidectomy: Hearing outcome where stapes suprastructure and tympanic membrane intact post-operatively (Type 3 Tympanoplasty).

Reconstructive procedure	Hearing worse/Unchanged/ <10dB improvement	10-20 dB HI	>20dB HI	Total
Fascia graft only	6	0	1	**7**
Fascia graft+ Columella (cartilage or incus)	2	1	2	**5**
Total	**8**	**1**	**3**	**12**

3/12 patients had more than 20dB improvement and 1/12 had 10-20dB improvement. Overall, post operative ACT's were significantly better in ears with an intact suprastructure as compared to those without (p= 0,004).

6.3.2 Variables

6.3.2.1 Age

Age as a variable was studied to determine if it was related to the extent of the cholesteatoma or not. In this series, cholesteatoma was evenly distributed over all ages. (Figure 13)

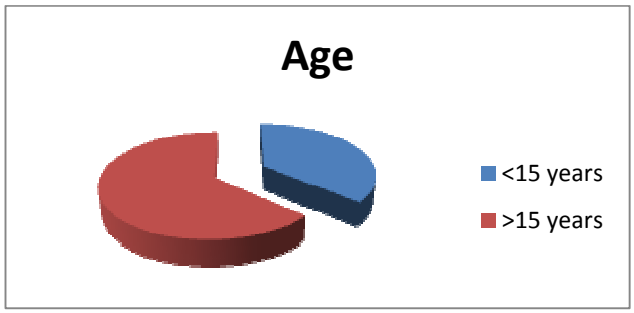


Figure 13: CWD Mastoidectomy: Age distribution

No statistically significant relationship existed between Age and Extent of disease (p= 0, 84)

6.3.2.2 Status of contra lateral ear

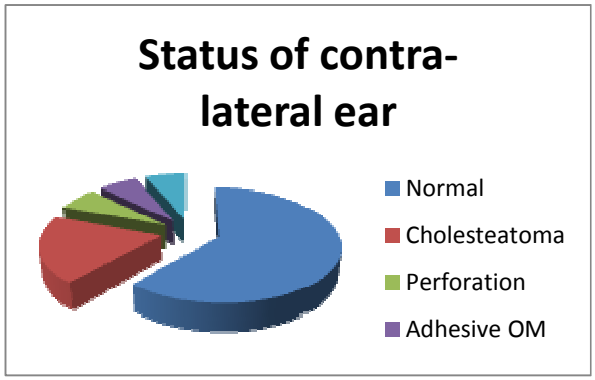


Figure 14: CWD mastoidectomy: Pathology opposite ear

The status of the contra-lateral ear in this series of cholesteatoma showed that the majority had unilateral disease with a normal contra-lateral ear. The majority of the pathology in patients with bilateral disease presented with cholesteatoma in the opposite ear as well.

6.3.2.3 Extent of disease

Cholesteatoma extension to the mastoid region was encountered in 12 of 29 patients. Only 6 of 29 patients presented with small attic cholesteatoma (Figure 15).

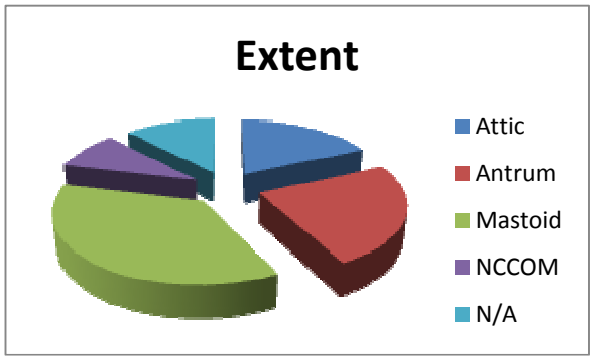


Figure 15: CWD mastoidectomy: Cholesteatoma extent.

No statistically significant relationship was found between extent of disease and the outcome of surgery (discharging or dry, post-operatively) (p= 0, 63).

6.3.2.4 Status of the stapes suprastructure

The status of the suprastructure was studied as a variable, as hearing outcome is thought to be related to this variable.

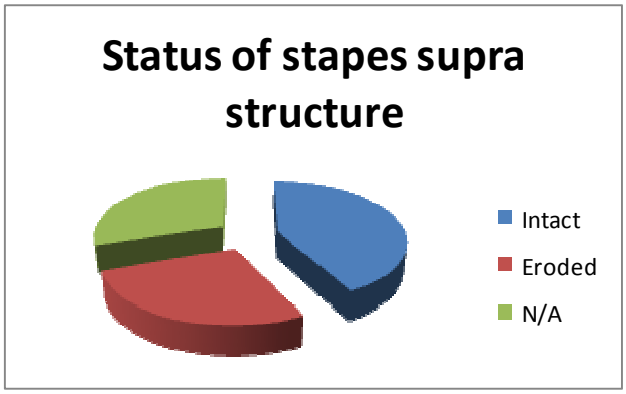


Figure 16: CWD mastoidectomy: Status of the stapes suprastructure.

A large number of patients had stapes erosion (9/23). 14/23 patients had an intact suprastructure. In 10/33 patients, the status of the suprastructure was not commented on.

No patients in this study had hearing improvement in the absence of a suprastructure. In cases with an intact suprastructure, hearing outcome is shown in Table 7.

7. DISCUSSION

A discussion of the most important findings of this study will follow in this chapter. Again, the three groups of patients will be discussed separately, both in terms of the surgical, and audiological outcomes achieved. Where appropriate, these outcomes will be discussed in relation to those reported in the literature, after which possible explanations will be forwarded as to the results achieved in this study. Recommendations may then be made regarding the future surgical management of patients in our setting.

The focus of the discussion will be on the areas mentioned in section 2, which include the following:

- BCIG tympanoplasty for simple perforations.
- Tympanomastoidectomy for actively discharging ears.
- Small cavity canal wall down mastoidectomy for advanced cholesteatoma.

7.1 TYMPANOPLASTY

Tympanoplasty techniques and grafting materials have evolved over time to a point currently where the FUG is the gold standard. [24] Fascia is effective and appropriate for the majority of patients with tympanic membrane perforations, and has been the choice grafting material for more than 60 years.

Cartilage on the other hand, also used in middle ear surgery for a very long time, has only recently become a regular choice of tympanic membrane grafting material in some centres. [41] Its previously perceived inferior, sound conducting properties contributed to many avoiding it as grafting material. Audiological outcomes, shown to be equivalent to FUG tympanoplasty however, led many to use it on an increasingly regular basis for simple perforations. In this regard, the BCIG technique, being simple and effective proved to be particularly useful. In addition, its rigidity and resilience in a hostile middle ear environment presents significant advantages over fascia as grafting material.

7.1.1 Surgical and audiological outcomes

In the literature, numerous studies have been published regarding the BCIG technique, since it was first described in 1998. Its initial description for pediatric patients was extended to adults where the procedure was performed as a minimally invasive procedure under LA and on an outpatient basis. [39, 42, 43]

The outcomes of studies regarding the BCIG technique are summarized in Table 9.

Table 9: BCIG tympanoplasty outcomes (Literature review)

Study	Graft success	Audiological success	
		Pre operative	Post operative
Present study (n= 30)	93%	PTA <30 dB 53% PTA 30- 50dB 40% PTA >50dB 7%	PTA< 30 dB 100%
Wang et al. (n= 28) [43]	85%		Change in ABG < 10dB 71% 11-20dB 25% >20dB 3.6%
Coulognier et al.(n=49) [38]	71%		ABG within 20dB 92%
Monfared et al. (n=145) [39]	67%	Average PTA 37dB	Average PTA 28dB
Anand et al. (n=20) [66]	90%	PTA <30 dB 50% PTA 30- 50dB 50%	PTA< 30dB 100%
Lin et al. (n=71) [40]	87%		ABG closure index(pre op ABG-post op ABG/Pre op ABG) <0% 20%, 0-25% 15%, 25-50% 25%, 50-75% 15%, 75- 100% 25%
Ghanem et al. (n=99) [41]	92%	ABG <20dB 43% ABG 20-40dB 45% ABG> 40dB 11%	ABG <20dB 51% ABG 20- 40dB 38% >40dB 10%
Mauri et al. (n=34) [42]	85%	ABG <20dB 56% ABG 20-40dB 44% ABG> 40dB 0%	ABG <20dB 94% ABG 20- 40dB 6% >40dB 0%

PTA= Pure tone average, ABG= Air-Bone-Gap, dB= Decibel

From the above-mentioned studies, the BCIG technique for centrally located small to medium sized perforations (<4mm), has proved to be very effective both in terms of surgical and audiological outcomes. Its role in large perforations however is still uncertain, as mixed results have been reported. The following paragraphs will focus on its use in larger and peripherally located perforations.

Controversies exist regarding the outcome of tympanoplasty for large perforations in general. Although many studies have shown no difference in closure rates between small and large- or anterior located perforations [7,17,20,22], a recently published large retrospective power analysis of more than 400 cases found surgical success rates in 74% of small perforations and 56% of large perforations (FUG technique). [67] These authors concluded that most studies reporting equivalent results between large and small perforations, either were of a non-controlled nature or included too few patients to make a conclusion.

The numerous cartilage-grafting techniques [36] have shown promise in the reconstruction of large- or anteriorly located tympanic membrane perforations as well, as its rigidity proved particularly useful in such ears. Unfortunately, most of these techniques require significant surgical skill, experience and time to perform well.

As mentioned, because of the effectiveness of the BCIG technique for small simple perforations, an expansion of indications occurred to include more challenging perforations and pathology. With regards to larger perforations, some authors found surgical success to be higher in smaller perforations than larger ones, [38, 39] while others have shown no difference in success rates when this variable was studied. [40, 41]

Both the authors who related success rate to size of perforation, concluded that the technique as originally described should be used with caution in large perforations. One of these two studies included 145 patients where the procedure was performed under LA in an office setting. They concluded that residual perforations were frequent in perforations larger than 4mm in diameter, and increased almost linearly with size of perforations. Perforations larger than 6mm had only a 44% success rate in their series. Although the authors did not mention possible theories as to why these perforations occurred, they did state that the

procedure in their opinion is contra indicated when the perimeter of the perforation can not be inspected adequately. [39]

In our experience with the technique, a possible explanation for residual perforations in large defects, as described by the authors of the above study, is the inadequate exposure offered by an operating microscope in a trans canal approach. The difficulty associated with the procedure in such cases is likely to result in inaccurate placement of the graft with subsequent failure.

The other study relating success to perforation size was performed for pediatric patients with simple perforations. In this study of 57 patients, all perforations included were those that were non-marginal where a clear view of the entire perforation perimeter was possible with a single trans canal view. Size of perforations was not a criterion for inclusion. They reported that most of their failures, albeit few, occurred after closure of larger perforations and that these perforations were recurrent rather than residual ones. They explained this finding by speculating that the process of epithelization over perichondrium is generally slow, and that the prolonged absence of epithelial covering over some of the perichondrium resulted in parts of the graft to necrose and perforate. To this extent, the authors suggested that a STSG is necessary in such cases, to facilitate the epithelisation process. [38]

Although a limited population size, the complications of myringitis and recurrent perforations in the closure of large perforations were absent in the present series. A possible explanation for this finding may be the routine and prolonged use of topical antibiotics in the post-operative period. We believe that this practice, in addition to preventing infection and necrosis of the cartilage graft, will also facilitate epithelisation by keeping the graft moist until complete healing has occurred.

In addition to the risk of recurrent or residual perforations with the BCIG technique, the theoretical risk of cholesteatoma formation by epithelial entrapment remains a danger of this technique, especially in marginal perforations. [39] Although none of the three studies with adequate long term follow up (2 years on average) reported any cases of cholesteatoma formation, [38-40] at our institution we tend to err on the side of caution when addressing large or marginal perforations.

It is our policy to anchor the graft on the bony annulus when the perforation approaches the annulus. The fibrous annulus is lifted out of its sulcus and draped back over the graft post placement, resulting in what can be described as a combination of an inlay and underlay technique. Performing the procedure in this way may reduce the chances of epithelial entrapment at the margins of the perforation. We consider the afore- mentioned technique particularly important when dealing with large or subtotal perforations as post-operative middle ear surveillance for cholesteatoma formation may be difficult with a large opaque graft *in situ*. [41]

Only one study to date has explored the use of the BCIG as part of a formal tympanoplasty technique. [41] The authors of this study included 99 patients with large perforations, the bulk of which (70%) needed a canal wall up mastoidectomy, and a retro auricular approach to the middle ear. Half the patients in this particular study presented with cholesteatoma. They achieved a perforation closure rate of more than 90% in spite of the fact that most patients had extensive middle ear disease. The authors mentioned that in most cases, the graft needed anchoring on annular bone and that because of the size of the perforation, also required a STSG to cover the graft. They reported no retraction pocket formation or graft dislodgement in the post-operative period. In their conclusion, the authors mentioned that a comparative study with fascia was not possible as, because of BCIG being the preferred technique, they performed too few such tympanoplasties in the study period.

The outcomes of the above study confirms our observation that exposure with the BCIG technique, as is the case with all types of ear surgery, plays a critical role in the achievement of consistently good results. This is especially the case when dealing with large or marginal perforations.

In addition to the observations made above, we identified some additional points regarding the BCIG technique itself that may increase the safety and/or the graft success rates in challenging perforations:

- A retro-auricular approach and canaloplasty may improve exposure, especially in the anterior portion of the TM, but we have found that the use of an endoscope (0- or 30- degree) result in superior exposure and more accurate placement in this difficult to access area. In addition, inspection of the perforation rim is optimized and the risk of epithelial entrapment minimized.
- The scissor harvesting of large pieces of cartilage (especially tragal), may result in a fractured graft with poor stability. Performing sharp dissection rather, may more often result in a cartilage graft that maintains its rigidity and that locks into position more securely.
- When dealing with large perforations, literature suggests the leaving of perichondrium on one side of the graft only, [36] as this may minimize the adverse effects that a very thick graft may have on sound conduction. In this series and others, [38, 39, 67] cartilage with the perichondrium left intact on both surfaces was used when repairing such perforations. Besides not affecting sound conduction negatively, it also seems to allow the cartilage to maintain its original shape and rigidity.
- Post-operative dislodgement or residual perforations may result from an inaccurately prepared graft. A saline flush to the placed graft under direct endoscopic vision, may help to detect residual perforations or unstable areas that may lead to dislodgement post-operatively. One can then either "patch" such defects with additional cartilage, or one can harvest a new graft to repair the original defect.

As mentioned, comparative studies have shown that similar hearing improvements are possible between cartilage and fascia, independent of graft size. [35] This is also the suggestion from this series, as sociable hearing (ACT< 30dB) was achieved in all patients subjected to a type 1 BCIG tympanoplasty. This finding is in accordance with the available literature on BCIG specifically (see Table 9) and suggests that factors other than grafting material determine hearing outcome in most patients.

We postulate that the good hearing outcomes with the BCIG technique are due to a combination of factors, which may include the avoidance of middle ear packing, and the maintenance of the TM in its anatomical position. Both these factors will facilitate unrestricted ossicular movement in a large middle ear space free of adhesions.

7.1.2 Variables

As mentioned, the size of the perforation and cartilage graft did not negatively affect hearing gains in the present study. In fact it was found that hearing improvement was directly related to the size of the perforation in that the larger the perforation the more the hearing gain (p= 0, 0195). One study observed similar findings and postulated that the significant hearing improvements seen with large BCIG's, are due to the cartilage graft contacting the malleus directly, resulting in a phenomenon they call the "4th ossicle effect". [40]

Following on from the above finding, is the observation of a direct linear relationship between pre-operative hearing loss and hearing improvement post operatively (r= 0,901). Statistical analysis further revealed these results to be strongly significant (p<0, 0001), confirming the fact that hearing gains are independent of grafting material. No studies in the researched literature investigated this relationship to identify factors that may affect outcomes. It may have been interesting if this relationship was studied for Type 1 FUG tympanoplasty. In such cases, the entering and packing of the middle ear may

result in adhesions to form, effectively reducing the middle ear space and attenuating hearing gains post-operatively.

Debate exists as to the outcome of tympanoplasty in the longer term. In pediatric cases, contradictory findings exist, as some report no deterioration over the longer term, [8] whereas others found hearing to deteriorate frequently, secondary to recurrent OME and perforations. [17] Age in the pediatric population specifically, may be important in this respect, as some have found that older children (10-14 years) have better long term hearing outcomes than younger ones (2-10 years). [18]

In the present series most patients were in the pediatric age group (<15 years of age) and follow up periods were short (<1 year). Accepting that at least some patients will develop recurrent middle ear disease and hearing deterioration in the future, it is our belief that overall patient management has not been compromised. With the BCIG technique, redo surgery is likely to be uncomplicated, as the absence of external ear incisions and an undisturbed external ear canal, will simplify any further surgery. Furthermore, unnecessary entrance into, and packing of the middle ear is avoided, resulting in most patients having an undisturbed middle ear cleft that may facilitate a possible future tympanotomy and/or ossiculoplasty.

7.1.3 Type 2/3 tympanoplasty

7.1.3.1 Limited lenticular process erosion

As mentioned, to repair this type of ossicular defect (Type 2 tympanoplasty), a variety of materials may be used. In the present series, cartilage was used to repair two cases presenting with ISJ erosion. A satisfactory outcome (ACT<30dB) was achieved in both. Although most authors prefer the use of allogenic prosthesis' or cement to repair such defects, cartilage is readily available, easy to sculpture and shown to result in equally good hearing outcomes. [31]

7.1.3.2 Extensive ossicular erosion

In the absence of active middle ear infection or Eustachian tube dysfunction, according to the MERI system, outcomes of ossiculoplasty are dependent on extent of ossicular erosion and the presence of a perforation. In the case of a perforation with both an intact malleus long process and stapes suprastructure present, most will prefer one-stage surgery to repair the defect.

Frequently however, the perforation may be large, the malleus handle medialized/eroded, and the stapes suprastructure absent. Although not seemingly affecting results in the literature [1, 70] these factors may have been a major factor to account for the poor outcomes in this series. In this respect, a change in approach may be necessary to improve outcomes. As was the findings in some studies, [68] staged surgery in our setting may yield superior results as one can then avoid the additional difficulties associated with prosthesis placement and TM grafting in a compromised middle ear cavity. In this respect, although our experience with ossiculoplasty as part of a BCIG tympanoplasty is limited, we believe that it can potentially be superior to the FUG tympanoplasty in such a staged setting. In at least some of such cases, the intact cartilage graft on the lateral aspect of the prosthesis will help with initial stabilization and prevent later extrusion. [28] The absence of adhesions will further facilitate placement of the prosthesis.

Only one study reported outcomes of ossiculoplasty combined with a BCIG technique. They reported good surgical and audiological outcomes in such cases, but unfortunately did not mention whether surgery was staged or not. Neither extent of ossicular pathology nor the techniques or materials used to repair it were mentioned either. [41]

7.2 TYMPANOMASTOIDECTOMY

7.2.1 Surgical outcomes

Even though no scientific evidence exists for the exenteration of mastoid air cells to improve *all* tympanoplasty outcomes, this is still common practice. [12] If one considers literature evidence on the subject, it is clear that although mastoidectomy will be beneficial in certain cases of tympanoplasty, a subgroup of patients exists where its role remains uncertain.

The following discussion will focus on the outcomes of tympanomastoidectomy in different clinical situations.

7.2.1.1 Actively discharging ears

In actively discharging ears with gross disease in the middle ear (granulation tissue, muco-purulent pus), except for one researched article, [12] most authors have shown that a mastoidectomy is necessary to achieve the goal of a dry ear [5, 6, 9, 10], both in the early and late post operative period. [9] This was also the finding in the current series where dry ears were achieved within 2 months of surgery in the majority of such cases (10/12 patients).

Concerning graft take rates however, in contrast to most studies that report very good outcomes (see Table 9), [9, 10] an intact TM was achieved in only 50% of discharging ears in this series. Some of the reasons that may explain these results are discussed below.

Table 10: Summary of studies that describe outcomes in dry and discharging ears post tympanomastoidectomy.

Study	Active NCCOM		Inactive NCCOM	
	Graft success	Audiological success (ACT< 30dB/ ABG <20dB	Graft Success	Audiological success (ACT<30dB / ABG<20dB)
Present study (n= 22)	50%	50%	100%	80%
Krishnan et al. (n=76) [5]	80%	75%	100%	80%
McGrew et al. (n=131) [15]			92%	80%
Mishiro et al. (n=147) [12]	90%	82%	91%	82%
Balyan et al. (n=28) [13]	85%	Ave ABG 20dB		
Ruhl et al. (n=47) [10]	90%	81%		

ACT= Air Conduction Threshold, ABG= Air-Bone-Gap, dB= Decibel

Firstly, certain clinical parameters indicate that the severity of disease managed in the current series may have been more severe than that of the mentioned studies. Considering pre-operative hearing loss in this respect, an interesting finding may explain at least some of the outcomes. It is evident from this series that surgery resulted in an intact TM in only 37% of cases presenting with a severe hearing loss (ACT >50dB). These results, compared with cases where a mild or moderate hearing loss (ACT 30- 50dB) were present (80% achieving an intact TM), although not statistically significant (p= 0, 13), may support the possibility that disease severity affected outcomes and that it may have been worse than in the studies mentioned in Table 10.

A second reason may relate to the inadequacy of surgery in our setting. Two of the studies that reported very good results with standard fascia underlay grafting (>80% graft take rate), performed a complete air cell exenteration and posterior tympanotomy to clear disease [9, 11]. In the present study, even though attempts were made to remove all obvious granulation tissue in the mastoid and to establish attic patency, most cases had neither a full mastoid air cell exenteration nor a posterior tympanotomy performed. It may thus be, that retained diseased air cells and persistent poor mastoid to middle ear drainage resulted in at least some of the grafts to fail.

A third possible reason that may explain the poor graft survival rates in this series relate to certain patient specific factors. The role that systemic and regional factors may play on the outcome of surgery is illustrated by a large study on the long-term outcome of tympanomastoidectomy in the pediatric population. [6] The authors of this study also found high rates of residual perforations and concluded that in their series, tympanomastoidectomy did not cure the actively discharging ear completely. The developing immunity and challenging anatomic conditions in the postnasal space of pediatric patients may not only have explained their results, but may also point to the role that similar conditions may play in our patient population. Poor socio-economic conditions and high sub-clinical HIV infection rates may also have played a role in the outcome of surgery in this series.

7.2.1.2 Dry and quiescent ears

Existing evidence that mastoidectomy in dry and quiescent ears does not influence outcomes, may be true in selected ears only. From the literature and this series on NCCOM, little doubt exists that an expertly performed tympanoplasty for a simple tympanic perforation (no discharge, middle ear disease and ossicular pathology) of any size, with or without mastoidectomy, [15] can be expected to result in a healthy and intact tympanic membrane post- operatively.

Many ears however have some degree of tympanic membrane retraction, atelectasis, quiescent middle ear changes and/or disproportionate hearing loss that complicates decision making as to the appropriate surgical procedure. Although many studies in the past attempted to establish the role of mastoidectomy in dry or quiescent ears, none controlled for all the above variables and therefore are difficult to interpret.

In the present study also, no conclusion could be drawn as to the role of mastoidectomy to improve tympanoplasty outcomes. Some of the reasons include following:

- Many surgeons are involved in the surgical assessment and treatment of patients with COM in our institution. The different opinions regarding the management of patients frequently result for instance in one patient to be subjected to a tympanomastoidectomy, while another with similar pathology, receives a tympanoplasty alone after assessment by a different surgeon.
- Incomplete and/or inaccurate pre- operative details regarding the status of the middle ear were frequent and did not allow for outcomes to be compared post operatively.

7.2.2 Audiological outcomes

7.2.2.1 Type 1 Tympanomastoidectomy- dry ears

The audiological outcome post Type 1 Tympanoplasty in dry or quiescent ears (as discussed in section 7.1.3), is not only a factor of disease extent and the management thereof, but is also related to the aeration of the middle ear post surgery. A mastoidectomy to improve middle ear aeration may be effective to keep hearing stable over the longer term, [15] but studies have shown no difference in hearing outcome between tympanomastoidectomy and tympanoplasty alone in the early post-operative period. [12] In cases with an intact tympanic membrane post-operatively then, one can expect similar hearing outcomes in these two groups of patients. [12, 13] The addition of a mastoidectomy to the tympanoplasty procedure is unlikely to benefit the patient if the sole purpose is to augment the hearing gain achieved.

Unfortunately, a direct comparison between the audiological outcomes in dry ears for the Tympanoplasty- (30 patients, average HI 12,5dB) and Tympanomastoidectomy (4 patients, average HI 23dB) groups of patients in this series was not possible because of the following reasons:

- Large discrepancy in patient numbers,
- Pre operative hearing loss and perforation size not controlled for

7.2.2.2 Type 3 Tympanomastoidectomy-discharging ears

In contrast to the above, controversy arises in the management of cases where ossicular chain abnormalities exist in active COM. Not only may the diagnosis of ossicular pathology be compromised in these circumstances, but also the repair and surgical outcomes. [28]

Staged surgery plays an important role in these circumstances as it is hoped to result in a healthy, closed and well-aerated middle ear that will facilitate reconstruction in future. Frequently however, especially in severely diseased middle ears, it may also result in shallow middle ear clefts with adhesions [52] and residual perforations that may negatively affect the outcome of a staged ossiculoplasty. In addition, one may then be committed to the use of allogenic materials, as often the incus may have been sacrificed in the process of establishing attic patency.

These observations, as well as the fact that most patients prefer a single operation, have led many to perform non-staged surgery even in active COM. [27] In the literature, results for non-staged surgery in such cases vary, as some report very good outcomes, [27] while others mention that staged surgery, especially in pediatric patients, [68] will result in superior audiological outcomes.

At CHBAH, staged surgery is frequently the preferred approach (the outcomes of which is not included in this study), non-staged surgery being performed very infrequently (only one patient in current series). Of the eight patients planned for staged ossiculoplasty post tympanomastoidectomy, only 3 (37%) achieved an intact tympanic membrane post operatively.

In view of the above-mentioned arguments and results that suggest that residual perforations and adhesions indeed frequently complicates staged ossiculoplasties, the best management in our setting may be one that incorporates *both* approaches.

In future, outcomes may be improved if the choice between staged and non-staged surgery is individualized and based on *disease extent, the availability of autologous grafting materials (e.g. incus), and surgical capabilities*. As mentioned, the use of the BCIG tympanoplasty to reconstruct the tympanic membrane may be particularly beneficial to improve graft take rates and outcomes achieved in staged surgery. (See section 7.1.3.2)

7.2.3 Variables

Because extent or severity of disease is difficult to define, one aim of this study was to find measurable variables that may mirror extent of disease and therefore may predict outcome. **Advancing age, pre operative hearing loss and size of perforation** were postulated to affect surgical outcome by virtue of the likelihood of severe middle ear disease being present in such ears.

In the present series, although significance could not be established (p= 0, 13), the results indicated a possible relationship between pre-operative hearing loss and surgical success (graft take rates) in discharging ears but not in dry ears. As mentioned, in the discharge group, it was found that ACT's worse than 50dB resulted in more surgical failures as compared to cases were ACT was better than 50dB (37% vs. 80% respectively). An explanation for this finding may be the possibility that at least some patients experiencing a failed procedure, suffered from "end stage COM pathology" where permanent damage to the middle ear mucosa and/or mastoid resulted in poor healing post-operatively. In the literature, multiple failed tympanoplasties or adhesive otitis media are often attributed to end stage COM. [(28)] In our setting, it may be that improved patient selection will improve surgical outcomes in future.

In the case of age as a possible predictor of surgical outcome, we could find no statistical significance linking age and graft success rates (p= 0, 18). This was also the finding in the studied literature.

Although size of perforation was not found to influence success rates in the tympanoplasty arm of the study, a statistically significant relationship was found in the tympanomastoidectomy arm of the study (p= 0,047). It may be that size of perforation mirrors pre-operative hearing loss and that the two variables may combine to indicate severe middle ear disease and predict a poor surgical outcome.

7.3 CANAL WALL DOWN MASTOIDECTOMY

7.3.1 Motivation for small cavity technique

CCOM is a destructive disease process that frequently results in a severe hearing loss and considerable morbidity. In addition, life-threatening complications may occur in untreated disease. Surgery therefore plays a very important role, not only to reverse the ongoing destructive process, but *also* to improve patients' quality of life. During cholesteatoma surgery, although disease eradication and complication prevention (creation of a safe ear) should be the focus of attention, significant morbidity reduction and hearing improvement are possible as well. Even in the presence of advanced disease, the many described surgical options available to the surgeon should allow for the creation of a carefree ear and hearing improvement in the majority of patients.

In our setting, these surgical options however, are subject to many variables that may influence the outcome of surgery. Of these, poor patient compliance and limited resources may have been factors in the past that played a central role in the perceived poor outcomes of surgery for cholesteatoma. Although resources (equipment, theatre time and staff) are considered adequate at present, patient compliance in the current setting is still uncertain over the long term. The introduction of expansive surgical and reconstructive techniques (i.e. CWU surgery) to reduce morbidity is therefore difficult to implement as not only may it compromise the safety of the procedure, but inadequate follow up will also hamper surgical progress. In order to improve morbidity and surgical outcomes therefore, an improvement in CWD surgery technique is more appropriate.

Approaching disease through the mastoid cortex in a back to front fashion and removing the canal wall at the end, although providing the best exposure to the epitympanum for safe cholesteatoma removal, also results in a cavity that has little chance of being dry and self-cleansing. [59] As acknowledged in the literature, obliteration of the cavity is a vital step to improve outcomes of surgery performed in this way. [47, 51, 53] Since obliteration is seldom a consideration in our

setting, the small cavity technique may effectively address the shortcomings of the large cavity technique.

In advanced cholesteatoma, drilling is limited to the size of the cholesteatoma, and early identification of important facial nerve landmarks results in safe facial nerve skeletonization and lowering of the facial ridge. This provide for accurate and complete middle ear cholesteatoma removal, which in turn allows for grafting of the tympanic membrane in almost all the procedures performed in this way. These steps combine to create a carefree cavity post-operatively in most cases.

In limited cholesteatoma, its similarities to the CWU technique are obvious, except for the fact that a full mastoidectomy is not performed and disease is exteriorized. [57, 58] Both of these factors combine to reduce recurrence rates, improve safety and negate the need for planned relook procedures.

7.3.2 Surgical outcomes

In the literature, comparing results between the large- and small cavity techniques is difficult as the extent of disease managed frequently differs between these two groups of patients. Except for a few, [33, 51] proponents of the large cavity technique, utilize the procedure mostly in advanced cholesteatoma [47, 54, 63] and reserve a CWU technique for patients with limited disease. Proponents of the small cavity technique mostly employ the procedure in all cases of cholesteatoma managed.

Although literature suggests that similarly good surgical results are achievable regardless of CWD mastoidectomy technique used (see Tables 11 and 12), the extent of surgery required, differs greatly between techniques. For instance, smaller cholesteatomas managed with a small cavity CWD technique are far less demanding than managing an acutely infected, extensive cholesteatoma with a large cavity technique.

Table 11: Summary of studies mentioning outcomes for CWD Tympanoplasty with complete air cell exenteration and obliteration with temporalis muscle flap (Large cavity or "Fisch technique")

Study	Dry ear	Stapes eroded	Graft success	Audiological success	
				ABG< 20dB	Mean PTA improvement(dB)
Present study (n=15)	66%	50%	16%	0%	N/A
De Zinis et al. (n= 189) [51]	95%	57%	N/A	44%	N/A
Nyrop et al. (n=27) [54]	89%	52%	N/A	N/A	12,5
Kos et al. (n=259) [33]	95%	30%	94%	31%	N/A
Berenholz et al. (n=33) [63]	N/A	45%	N/A	63%	12,3
Vertiainen et al. (n= 297) [47]	N/A	25%	N/A	44%	6
Lau et al. (n=64) [49]	81%	63%	8%	24%	N/A

dB= Decibel, ABG= Air Bone Gap, N/A= Not available

Table 12: Summary of studies mentioning outcomes for CWD mastoidectomy using "small cavity" technique

Study	Dry ear	Stapes eroded	Graft success	Audiological success	
				ABG< 20dB	Mean PTA improvement(dB)
Present study (n=18)	87%	50%	92%	21%	N/A
Roth et al. (n=604) [57]	93%	25%	97%	N/A	12
Grewal et al. (n=600) [50]	91%	30%	91%	N/A	>10dB PTA improvement 70%
De Corso et al. (n=142) [61]	N/A	31%	N/A	69%	12,4
Shrestha et al. (n= 77) [32]	N/A	0%	94%	65%	N/A

dB= Decibel, ABG= Air Bone Gap, N/A= Not available

This was indeed the case in some of the small cavity CWD mastoidectomy studies, where the bulk of the patients had limited disease with relatively small cavities and well preserved middle ears post-operatively. [57, 61] Comparing results of these studies with those of certain large cavity technique studies [47, 51] will not give a true reflection of the superiority of one technique over the other.

One study however described their experience with the small cavity procedure in patients with mostly extensive cholesteatoma and reported equally good results to those achieved by proponents of the large cavity technique. [50] They included 600 patients in their study and reported dry and trouble free ears in over 90% of patients. Recurrence rates were low and comparative to the number frequently quoted in the literature for the large cavity technique (5-10%).

Most of the ears in the small cavity arm of this study also had advanced cholesteatoma (79%), which required a complete CWD (facial ridge taken down in its entire length in the mastoid) procedure with cavity saucerisation. Performing this surgery in a front to back fashion, we found that the deliberate retention of non-diseased or sclerotic air cells in the sino-dural angle and mastoid tip, kept the cavity small and cylindrical. By removing the cortical bone around the meatus sparingly, the meatus could be kept small enough to avoid the morbidity of an excessively large one, but large enough to provide adequate aeration and surveillance of the created cavity.

Our results for the small cavity technique for advanced cases as described above, reflects those reported by others where a similar technique was used (see Tables 11 and 12) and was far superior to the large cavity technique in this series. Accepting that most of the large cavity technique patients had surgery that can be considered incomplete (no cavity obliteration or tympanic membrane reconstruction), from this study, at least in the short term, the small cavity technique is a valuable alternative for patients with advanced cholesteatoma. Although the long-term safety of the procedure is still uncertain in our setting, literature evidence exists that recurrence rates will mirror that of the large cavity technique. [50] The exteriorization of disease in all cases will likely prevent serious complications should follow up issues occur.

7.3.3 Audiological outcome

When evaluating and comparing audiological outcomes between studies on CWD surgery, the consideration of some disease- and surgical factors are important. From the studies mentioned in the above two tables (Tables 11 and 12), it is clear that mainly two factors need consideration.

Firstly, one needs to consider the prevalence of the stapes suprastructure in the particular study and the reconstructive techniques employed to repair the ossicular defect. From the literature, an intact suprastructure is particularly important.

Performing even a simple type 3 tympanoplasty [32, 33] in such cases may result in significant hearing gains. Adding a cartilage columella graft, these gains can be enhanced, in most cases to a level where sociable hearing is possible. This fact is illustrated in a study on the subject where the latter group of patients was found to have significantly more hearing improvement than the former. The authors concluded that the superior audiological outcomes achieved with cartilage augmentation, are secondary to the increase in the effective vibrating area of the TM that a cartilage plate provides. [28]

In the absence of a suprastructure however, with some exceptions, [28] results seem to be heavily dependent on reconstructive techniques. With exceptions, studies that employed a high percentage of Type 4 tympanoplasty [47, 49, and 51] in such cases seem to achieve worse results as when major columellas (TORP's) were used liberally. [57, 61, 63]

One exception to the above is a study that included 40 patients with stapes suprastructure erosion subjected to a CWD mastoidectomy. They found no difference in audiological outcomes, irrespective of whether a type 4- or major columella tympanoplasty was performed. [28] They mentioned that a major columella (TORP) is preferred when the oval window niche is deep, as opposed to a Type 4 tympanoplasty when the footplate lies shallow in the niche.

A second factor for consideration when evaluating audiological outcomes is the extent of cholesteatoma and middle ear mucosal disease dealt with. Post-operative scarring in severely affected middle ears frequently results in poorly aerated shallow middle ear clefts that in turn negatively affect sound transmission to the inner ear. [51] Authors who reserve CWD mastoidectomy for cases with extensive ossicular defects (eroded stapes suprastructure) and poor middle ear conditions, [45, 49] naturally have poorer outcomes, as compared to studies where a CWD technique was the only technique used, irrespective of middle ear conditions. [57, 58, 61]

In the latter group of studies, limited disease that allows for small cavity creation or medial canal wall reconstruction may have further enhanced audiological outcomes. In such cases, a more effective middle ear reconstruction is likely, with a more acoustically efficient transfer of vibrations to the inner ear.

One exception to the above generalization however, was the findings of a study that dealt with extensive middle ear disease and a high percentage of patients with an absent stapes suprastructure. [63] The authors mentioned that their main indication for performing a CWD mastoidectomy is cholesteatoma with extensive middle ear involvement and stapes erosion. In such cases, they normally perform a two-stage procedure where they manage not only residual cholesteatoma pearls and adhesive otitis media, but also focus on hearing improvement by way of ossiculoplasty. They use silastic sheets in the middle ear at the first operation to maintain the middle ear space, and remove it at the second stage to allow for a TORP reconstruction. Even though hearing deterioration did occur post reconstruction, on average about 1dB per year, they reported exceptionally good results (ABG<20dB in 69% of cases).

The audiological outcomes in the present study on CWD surgery was generally poor, more so in cases where the stapes suprastructure was absent. A possible reason for this lack of hearing improvement in cases presenting with an eroded suprastructure may be related to the tympanoplasty technique itself. Whenever a graft was placed in the middle ears of such cases, fascia was used to cover the entire promontory including the mobile footplate. Leaving the stapes footplate open or placing a STSG over it (as classically described), [28, 34] may have improved the outcomes achieved.

The poor results achieved in cases with less severe disease and no stapes erosion however (see Table 8), is largely unexplained. In these cases, the possibility exists that middle ear aeration instead of being poor, was very good, and that the reconstructed tympanic membrane have lost contact with the stapes suprastructure

post healing. In such cases the more frequent use of a columella that slightly overestimates the distance between the stapes and the tympanic membrane, may have resulted in better outcomes.

7.3.4 Variables

Certain variables in the CWD mastoidectomy group of patients were studied to determine whether disease is more advanced in the local population, and whether it may have influenced the results achieved.

7.3.4.1 Status of contra lateral ear

Only two papers in the studied literature reported on the status of the opposite ear. Both of these showed a large percentage of patients presenting with uni-lateral disease (90%). [51, 57] The status of the contra lateral ear in this series of cholesteatoma showed that a large percentage of patients (38%) presented with bilateral COM, the majority of disease in the opposite ear also being CCOM. The reason for this finding is not clear, but suggests that the patients in this series experienced more morbidity and hearing disability from the disease compared to those in the literature. Hearing rehabilitation by way of middle ear reconstruction may thus be particularly beneficial in our population.

7.3.4.2 Extent of disease

Cholesteatoma extension to the mastoid region was encountered in 12 of 29 patients, only 6/29 (20%) patients presenting with small attic cholesteatomas. Eighty percent of cholesteatoma thus were extensive and needed mastoidectomy for complete disease eradication. Literature from developed countries frequently report extensive cholesteatoma in less than 50% of cases. [47, 57, 61]

The effect that this seemingly more extensive disease may have had on the outcome of surgery needs to be seen in the context of the predetermined goals of surgery. If the goal is to achieve a dry and safe ear, in this series, extent did not play a role in the outcome of surgery (p= 0, 63). In terms of morbidity reduction

(self cleansing ability and hearing improvement), although not formally studied, advanced disease may have played a role in outcomes as cavity sizes may have been bigger and middle ear conditions poorer.

7.3.4.3 Status of stapes suprastructure

As discussed the status of the stapes suprastructure *per se* does not give an indication of advance disease, but relates more to the type of cholesteatoma managed, viz. tensa- vs. attic cholesteatoma. [47] In the present series, this observation is also evident as the advanced disease seen in the pediatric age group was seldom associated with stapes erosion. In total, stapes erosion occurred in 50% of assessable cases. The high percentage of patients where this structure was eroded or could not be assessed (secondary to severe middle ear disease) (60% of cases), is not only testament to the extensive middle ear disease frequently dealt with, but also explains in part the poor audiological outcomes achieved.

In the literature, reported incidences of stapes erosion vary widely (between 20 and 70 percent), most reporting erosion in around 30 % of cases. [45, 47, 50, 53, 61] No studies reported cases where the stapes could not be assessed though, possibly confirming the suspicion of a more extensive nature of disease dealt with in our setting. The effect that this variable may have had on audiological outcomes has been discussed.

7.3.4.4 Age

The age distribution of patients in this study reflects that in the literature, with a large percentage of patients (33%) falling in the pediatric age group, [53, 54, 57] the youngest of which was 6 years of age. The belief that pediatric patients present with more advanced and aggressive disease, are frequently mentioned in studies. The most popular opinion is that this observation may relate to the anatomic conditions present in these cases, rather than the cholesteatoma behaving differently as compared to adults. [48]

In this respect, it is interesting to note that none of the studied literature on pediatric cholesteatoma actually described their study populations to be of a more advanced nature than that reported by studies including all age groups. It may be that, although some cases of cholesteatoma in pediatric patients, especially the very young, do have relatively well-aerated mastoids and large cholesteatomas, older ones may not. In these older children, the percentage of sclerosed mastoids and limited cholesteatomas is likely to mirror that of adults. Unfortunately, none of the studied literature specifically looked into the possible relationship between age and advanced disease.

In the present study, advanced disease was seen in the majority of pediatric patients. Ninety percent of patients had disease extending to at least the antrum, and 3/12 patients presented with a complication of cholesteatoma. Possible reasons for this discrepancy between our findings and that described in the literature, may be related to poor socio- economic conditions in the local population, where access to antibiotics may be limited and time to referral for specialist opinion are prolonged. These delays and lack of treatment may allow the cholesteatoma to spread deep into an expected well-aerated mastoid.

Five out of thirteen (38%) pediatric cases had a *small cavity* technique performed with tympanic membrane reconstruction, and even though hearing improvement was negligible in all but one patient, hearing preservation was possible in all. In addition, a dry carefree cavity with an intact tympanic membrane was achieved in all five cases.

Although literature reports indicate similarly high surgical success rates, a significant percentage of patients did experience worsening of their hearing (13-30% of cases). [45, 47] A likely explanation for this finding lies in the differences in disease extent dealt with. Frequently in the removal of cholesteatoma, especially if limited, the ossicular chain may have been intact. The subsequent removal of the disease may require disruption and reconstruction of the ossicular chain, resulting in audiological outcomes that may be inferior to those present pre-

operatively. The lack of additional hearing loss in the post-operative period in the present series is likely to be a result of a maximal conductive hearing loss that was present even before surgery.

The finding of a dry ear in the eight cases subjected to an *incomplete large cavity* technique was largely unexpected. These patients, in the face of advanced disease and acutely infected mastoid and middle ears, had incomplete facial ridge removal in most cases, no tympanic membrane grafting and often a meatus smaller than the cavity created.

The reason for these relatively good results is unclear. Local opinion is that because most cases of pediatric cholesteatoma may be of the pars flacida or attic type, [45] complete cholesteatoma removal may have been possible, as disease was either absent or limited in the middle ear. The resultant exteriorized mastoid cavity and possible neo-tympanic membrane formation [59] may have accounted for the high percentage of dry ears post-operatively.

8. CONCLUSION

This study was conducted in a retrospective way to determine the outcome of surgery for COM at our institution. It was done in view of a changed approach to certain important aspects of the surgery frequently performed at our institution.

In terms of the study objectives set out in section 2 of this dissertation, we have found some important improvements in outcomes related to this changed approach, but have also identified areas where more improvements are needed. In addition, certain areas have been identified where an expansion of the indications of certain surgical techniques might improve outcomes further.

We have found the BCIG technique effective for the majority of simple tympanic membrane perforations. The procedure resulted in graft success rates reflecting that reported in international literature, and produced sociable hearing (ACT< 30dB) in all such patients. Hearing improvement, even in cases with large perforations, was not negatively affected by the thickness or rigidity of the graft. Rather it was found that the hearing improvement was directly related to the size of the perforation in that the larger the perforation the bigger the gain.

Regarding the surgical technique itself, we found that the use of an endoscope allowed us to avoid external ear incisions in the majority of patients, improving patient comfort post-operatively and reducing theatre time.

Unfortunately, a comparison with the more traditional FUG tympanoplasty was not possible as the patient numbers in the two study groups differed significantly. This was because the positive outcomes of the technique were of such significance that it became the choice method for the grafting of simple tympanic membrane perforations of any size and location at our institution.

In the Tympanomastoidectomy group of patients, we found the procedure to be inadequate in actively discharging ears presenting with a severe hearing loss. Graft success rates in patients with a limited hearing loss were significantly better than in this group of patients. Better patient selection and a more extensive exenteration of mastoid air cells may improve outcomes in future.

The management of CCOM in our setting has changed as well as a move towards less destructive procedures was undertaken to reduce morbidity and theatre time. Regarding CWD surgery, the small cavity technique has proven to be relatively simple with a marked reduction in morbidity as compared to the large cavity technique. Although significant challenges remain regarding hearing outcomes achieved and follow up in future, the keeping and regular auditing of an otological database will go a long way in addressing these problems. The "feedback" that one gets from such a database will allow for ongoing improvement of surgical techniques.

Important limitations of this study as a whole, included not only the fact that it was of a non-controlled nature, but also its small sample size and short follow up periods. In this respect, it is the author's opinion that the establishment of a dedicated otology team and clinic will address these shortfalls in future, and clarify at least some of the controversies in the surgical management of COM.
Future work regarding surgery itself should focus on,

- the possible benefits that the BCIG technique might have on the outcome of staged ossiculoplasty in active NCCOM,
- and whether an improvement in tympanoplasty techniques will materially affect audiological outcomes post small cavity CWD surgery.

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10. APPENDIX

TYMPANOPLASTY DATA TABLE

	Age	Sex	Bil/Uni	Perforation size	PTA	MATERIAL	TYPE	TM post operative	PPTA	HI
1	14	F	U	S	33	F	I	IN	18	15
2	46	F	U	S	65	F	I	IN	60	5
3	40	M	U	M	35	C	I (RM)	IN	20	15
4	14	M	-	S	15	C	I	IN	10	5
5	9	F	-	S	9	C	I	IN	8	1
6	9	F	U	M	28	C	I	IN	18	10
7	11	F	B	M	60	C	I	IN	60	0
8	10	F	U	M	30	C	I	IN	20	10
9	38	M	U	S	20	C	I	IN	20	0
10	27	F	U	M	48	F	III PORP	IN	50	-2
11	13	M	U	M	45	C	I	IN	25	20
12	8	M	U	M	25	C	I	IN	20	5
13	16	M	U	M	70	F	III PORP	P	75	-5
14	**8**	**M**	**U**	**M**	**25**	**C**	**I**	**IN**	**20**	**5**
15	12	M	B	L	45	F	II CAR	IN	10	35
16	NA	M	U	M	33	C	I	IN	16	17
17	27	M	U	S	20	F	I	P	28	-8
18	34	M	U	M	82	F	I	IN	82	0
19	10	F	B	M	53	F	I	IN	30	23
20	48	M	U	M	33	C	I	IN	20	13
21	8	F	U	M	50	C	I	IN	16	34
22	13	F	B	M	33	C	I	IN	17	16

	Age	Sex	Bil/uni	Perforation size	Pta	Material	Type	Tm post operative	Ppta	Hi
23	9	F	B	M	35	F	I	IN	15	20
24	9	F	B	M	30	F	I	IN	10	20
25	16	F	U	S	23	C	I	IN	10	13
26	16	F	B	M	38	C	II CAR	IN	13	25
27	46	F	U	M	50	C	I	IN	28	22
28	10	M	B	M	47	C	I	IN	15	32
29	44	F	U	S	25	C	I	IN	-	
30	6	M	U	M	30	C	I	IN	17	13
31	35	M	U	S	25	C	I	IN	-	
32	10	F	U	M	35	C	I	IN	17	18
33	32	M	U	M	53	C	I	IN	15	38
34	35	F	U	S	45	C	II CAR	P	-	
35	9	F	U	M	50	F	III PORP	-	-	
36	14	F	-	-	Na	C	I	IN	-	
37	**22**	**F**	**U**	**NIL**	**50**	**F**	**III CAR(RM)**	**IN**	**50**	**0**
38	25	M	U	M	23	C	I	P	23	0
39	27	F	U	M	20	F	I(RT)	P	26	-6
40	27	F	U	S	26	C	I	IN	15	11
41	11	F	U	S	23	C	I	IN	25	-2
42	33	M	U	S	45	C	I	IN	-	
43	10	M	U	M	20	C	I	IN	16	4
44	15	M	B	M	20	C	I	IN	16	4

F= Female, M= Male, U= Unilateral, B= Bilateral,- = Not Available ,S= Small perforation, M=Medium size perforation, L= Large perforation, NIL= No perforation, C= Cartilage Tympanic membrane reconstruction, F= Fascia underlay tympanic membrane reconstruction ,II= Type 2 Tympanoplasty, III= Type 3 Tympanoplasty PORP= Partial ossicular replacement prosthesis,, CAR= Cartilage Columella, RM= Redo Post Tympanomastoidectomy, RT= Redo Post Tympanoplasty, IN= Intact, P= Perforated, PTA= Pre operative Pure Tone average, PPTA= Post operative Pure Tone Average, HI= Hearing Improvement.

TYMPANOMASTOIDECTOMY DATA TABLE

	Age	Sex	Bil/Uni	Perforation size	Active/inactive	PTA	Material	Type	TM post operative	Dry or dc	PPTA	HI
1	34	F	U	M	D	45	C	I	IN	D	30	15
2	47	F	U	L	Dc	67	F	I	IN	D	28	39
3	11	M	U	L	Dc	-	F	I	P	Dc	-	-
4	16	F	B	M	D	35	F	III PORP	IN	D	18	17
5	14	F	B	L	Dc	50	F	I	P	D	50	0
6	50	F	U	Ad	Dc	80	-	MAST	P	Dc	80	0
7	26	F	U	L	Dc	40	F	I	IN	D	30	10
8	17	M	U	M	Dc	40	F	I	IN	D	21	19
9	15	F	B	L	D	35	F	I	IN	D	10	25
10	20	F	U	S	Dc	48	F	I	IN	D	28	20
11	22	F	U	S	Dc	65	-	MAST	P	D	65	0
12	44	M	U	M	Dc	50	F	I	IN	D	35	15
13	12	M	B	L	D	70	F	I	IN	D	70	0
14	**12**	**M**	**U**	**Ad**	**Dc**	**66**	**F**	**I**	**IN**	**D**	**73**	**-7**
15	45	M	B	L	Dc	66	F	I	P	D	66	0
16	39	F	U	M	D	48	F	I	IN	D	25	23
17	62	M	B	M	Dc	80	F	I	IN	D	80	0
18	48	F	-	L	Dc	63	F	I	P	D	63	0
19	10	M	-	L	Dc	55	F	III CAR	-	-	-	-
20	43	M	B	L	Dc	80	-	MAST	P	D	80	0
21	35	F	B	L	D	70	C	III INC	IN	D	40	30
22	50	F	U	L	D	95	C	I	IN	D	95	0
23	39	M	-	-	Dc	56	F	I	P	Dc	56	0
24	23	F	B	L	D	70	F	III CAR	IN	D	25	45

	Age	Sex	Bil/Uni	Perforation size	Active/inactive	PTA	Material	Type	TM post operative	Dry or dc	PPTA	HI
25	68	F	U	S	Dc	83		MAST	P	Dc	83	0
26	41	F	U	L	D	64	F	I	IN	D	32	32
27	9	F	U	M	D	60	F	III INC	IN	D	32	28
28	48	F	U	L	Dc	80		MAST	P	Dc	80	0
29	47	F	U	M	Dc	56	F	I	IN	D	37	19
30	54	M	U	S	Dc	-		MAST	IN	D	-	-
31	36	M	B	M	Dc	33	F	I	-	-	-	-
32	17	M	B	L	Dc	53	F	I	P	D	-	-
33	37	M	U	M	Dc	66	F	I	-	-	-	-

F= Female, M= Male, U= Unilateral, B= Bilateral,- = Not Available ,S= Small perforation, M=Medium size perforation, L= Large perforation, Ad= Adhesive otitis media, C= Cartilage Tympanic membrane reconstruction, F= Fascia underlay tympanic membrane reconstruction , III= Type 3 Tympanoplasty, MAST= Mastoidectomy only, INC= Incus Columella, CAR= Cartilage Columella,, IN= Intact, P= Perforated, Dc= Discharge present, D= Dry ear, PTA= Pre operative Pure Tone average, PPTA= Post operative Pure Tone Average, HI= Hearing Improvement.

CANAL WALL DOWN MASTOIDECTOMY

	Age	Sex	Bil/Uni	Extend	Stapes	PTA	TECHNIQUE	Type	TM postoperative	Ear site	PPTA	EMER/ELEC
1	45	M	B	Ant	A	65	LC	-	P	Dc crev rec small	65	
2	42	F	B	Na	Na	50	LC	-	P	Dc rec	53	
3	20	F	B a	Ant	P	80	SC	III CLAS	I	Dry	80	
4	10	F	U n	Ant	Na	46	LC	-	P	Dry crev	43	E spa
5	20	F	B p	At	Na	55	LC	-	P	Dc	57	
6	60	F	B c	At	Na	70	LC	-	I	Dry	60	
7	31	M	Na	Mast	Na	Na	LC	-	P	Dry small	Na	E spa
8	6	F	U n	Na	Na	Na	LC	-	P	Dc crev rec small	Na	E spa
9	19	M	B c	Ant	A	60	LC	-	P	Dry crev small	60	
10	20	M	B c	At	A	65	LC	-	P	Dry crev	83	
11	12	F	B p	Mast	Na	43	LC		P	Dry crev	45	
12	12	M	Na	Na	A	65	LC	-	P	Dry crev	75	
13	13	M	U n	Mast	P	45	SC	III INC	I	Dry	53	
14	**39**	**F**	**U n**	**Na**	**P**	**53**	**SC**	**III CLAS**	**I**	**Dry**	**53**	
15	14	F	U n	Mast	P	55	SC	III CLAS	I	Dc gran bowl	58	
16	12	F	U n	Mast	Na	35	LC	-	P	Dry	40	
17	45	F	U n	Mast	P	70	SC	III CAR	I	Dry	30	
18	47	F	B c	Mast	P	43	SC	III CAR	I	Dry	30	
19	47	F	B c	Mast	A	50	SC	IV	I	Dry	50	
20	43	F	B a	Mast	A	80	SC	IV	I	Dry	80	
21	10	M	U n	Mast	P	43	SC	III CLAS	I	Dry	43	
22	34	F	U n	Mast	P	55	SC	III CLAS	P	Dc gran bowl	55	
23	30	M	U n	Com	P	60	SC	III CLAS	P	Dc gran bowl	60	

	Age	Sex	Bil/Uni	Extend	Stapes	PTA	TECHNIQUE	Type	TM postoperative	Ear site	PPTA	EMER/ELEC
24	18	M	U n	At	P	40	SC	III INC	I	Dry small	12	
25	20	M	U n	Mast	A	80	SC	IV	I	Dry	80	E spa
26	50	M	U n	Com	P	60	SC	III CLAS	P	Dc gran small	60	
27	15	M	U n	At	P	65	SC	III CLAS	I	Dry	40	
28	18	M	B c	At	A	52	SC	IV	I	Dry	52	
29	15	F	U n	Ant	P	28	SC	III CLAS	I	Dry small	32	
30	20	F	U n	Ant	A	65	LC	-	P	Dc gran bowl rec	65	
31	58	F	U n	Com	P	63	SC	III CAR	I	Dry	63	
32	8	F	U n	Ant	Na	20	LC	-	P	Dry	Na	
33	15	M	U n	Ant	Na	Na	LC	-	P	Dry small	Na	E spa

F= Femal, M= Male, Un= Unilateral, Bc= Bilateral Cholesteatoma opposite ear, Bp= Bilateral Perforation opposite ear, Na= Not Available, Ba= Bilateral Adhesive otitis media opposite ear, At= Attic, Ant= Antrum, Mast= Matoid, P= Present, A= Absent, LC= Large Cavity technique, SC= Small Cavity technique, III= Type 3 Tympanoplasty, CLAS= Classical, INC= Incus Collumella, CAR= Cartilage Columella, IV= Type 4 Tympanoplasty, IN= Intact, PE= Perforated, Dc= Discharge, gran= granulation tissue in mastoid bowl, crev= Crevices in mastoid cavity, E spa= Emergency procedure presenting with Sub periosteal Abcess, Small= Small meatus, PTA= Pre operative Pure Tone average, PPTA= Post operative Pure Tone Average.