

# **Audit of outcomes of endoscopic cholesteatoma ear surgery**

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## **Minor Dissertation**

Master of Medicine (MMed) in Otorhinolaryngology

## **University of Cape Town**

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## DECLARATION

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I, Ndivhuwo Diale, declare that this thesis is based on a research study conducted by me, except where I have quoted or referenced the sources. To the best of my knowledge, this work has not been previously submitted for a degree in my university or any other institution, neither has it previously been submitted for publication to another journal.

Signature: ..... 

Signed by candidate
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Date: 08 February 2019

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## CHAPTER 1

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### LITERATURE REVIEW

#### INTRODUCTION

The role of the endoscope as a relatively newer technique in the management of cholesteatoma has sparked relevant debates among ear surgeons. Endoscopic ear surgery might have gained acceptance in its role as a complementary tool to microscopic ear surgery but perhaps not so much as an instrument for exclusive use. To review outcomes of this surgical tool, existing literature on endoscopic cholesteatoma ear surgery was reviewed.

There is a consensus in literature regarding the objective of cholesteatoma surgery, which is complete disease clearance to keep the ear safe and dry<sup>1</sup>.

Researchers have made considerable advances in our understanding of cholesteatoma etiopathogenesis at molecular level; however, a non-surgical treatment capable of completely eradicating cholesteatoma is yet to be developed. Complete disease eradication can only be achieved through surgical techniques; however, proper patient selection is important.

Before the emergence of endoscopes, the microscope was a widely used surgical tool in cholesteatoma surgery. Many otologic surgeons remain accustomed to it. The advantages of the operative microscope still make it invaluable even in the era of this newer technique. To mention a few: good quality view of the middle ear, mastoid and the temporal bone anatomy and pathology adds to its value; and it affords the surgeon the freedom to use both hands during surgery to clear the surgical field for better visualization while clearing the pathology<sup>2</sup>. Its main limitation has been reported as the inability to look around corners, with concerns of possibly missing pathology in the deeper recesses of the middle ear such as the sinus tympani, facial recess and the attic<sup>2,3</sup>. As a result, this necessitates soft tissue retraction and drilling for adequate exposure.

Since the 1990's, operative endoscopy was introduced in ear surgery by Thomassin et al<sup>4</sup>, with the objective of using it as a complementary tool to the microscopes<sup>5</sup>. It has since been believed to improve visualization during cholesteatoma surgery and has been gaining acceptance.

Literature defines "exclusive endoscopic ear surgery" as the sole use of the rigid endoscope to visualize and facilitate middle ear surgery<sup>4</sup>. It is a minimally invasive approach which is indicated for cholesteatoma not extending beyond the confines of the tympanic cavity<sup>5</sup>. There is currently insufficient data on recidivism and hearing outcomes following exclusive endoscopic use in cholesteatoma ear surgery<sup>5</sup>.

Reports have shown the endoscope to be a superior tool for detecting cholesteatoma hotspots without removal of bone and unnecessary soft tissue stripping<sup>3-6</sup>. With endoscopic ear surgery (EES), patient morbidity has been reduced by avoidance of skin incisions, reduced need for drilling, less postoperative pain and reduced hospital stay<sup>4,5</sup>. Its cost effectiveness has been found to be comparable to microscopic uses<sup>5</sup>.

Some pitfalls of EES are well described in literature and include using one hand to hold the scope while the other performs surgery<sup>1</sup> and looking at the screen while operating, which

could result in inability to judge the distance between the scope and the surgical plane<sup>3</sup>. Concerns regarding the safety of the endoscope as a surgical tool have been raised, particularly with regard to possible thermal injury, especially when the xenon light is used. Other concerns like fogging of the scope and ear trauma in case of accidental movement add to the drawbacks of this technique.

In some instances, the use of both the microscope and the endoscope has been advocated when dealing with cholesteatoma near high-risk middle ear structures such as the facial nerve<sup>7</sup>.

Studies looking at outcomes of exclusive endoscopic approach in cholesteatoma surgery are few and long-term follow-up of patients for recidivism is short, particularly when looking at recurrent diseases<sup>8</sup>.

## **LITERATURE SEARCH**

The aim of the research study was to address the hypothesis that “endoscopic ear surgery offers equivalent, if not better surgical outcomes, compared to microscopic ear surgery in the surgical management of cholesteatoma. Journal articles were obtained through the PubMed central library by inserting the search words “endoscopic ear surgery”, “cholesteatoma ear surgery” and “cholesteatoma recidivism”. Articles reporting on outcomes of endoscopic ear surgery, microscopic ear surgery, and combined techniques written in English were selected. Seventeen articles were found to be relevant to this study.

## **SUMMARY AND INTERPRETATION OF LITERATURE**

Endoscopic ear surgery is a newer technique and there is paucity in the literature on outcomes of its exclusive use in cholesteatoma surgery, and as a complementary tool for microscopic approaches. No studies were found comparing recidivism outcomes of all four known surgical techniques described in the literature, namely: exclusive endoscopic surgery (EES), microscopic canal wall up (CWU), microscopic canal wall down (CWD) and combined endoscopic-microscopic techniques.

There is consensus in the literature regarding the objective of cholesteatoma surgery, which is complete disease resection to keep the ear safe and dry<sup>1</sup>. Historically, the management of cholesteatoma was either approached using microscopic canal wall up or microscopic canal wall down techniques. The decision on which approach to use is based on a number of factors which include: the extent of the disease, pneumatisation of the mastoid, aeration of the middle ear and mastoid, reliability of patient follow-up and the surgeon’s preference. It is well known that a canal wall up technique has a much higher recidivism rate compared to a canal wall down technique<sup>1</sup>.

A Canadian study found that 70% of ear surgeons used an endoscope for cholesteatoma surgery<sup>9</sup>, either exclusively or as a complementary tool. Then a systematic review looked at outcomes of 11 EES studies in cholesteatoma surgery<sup>2</sup>. In all of them, the endoscope was found to be useful for visualization and facilitation of cholesteatoma eradication. These studies however had low evidence follow-up data due to short time of follow-up (mean follow-up period of 23 months) and the limited number of patients treated by the authors. In fact, with the exception of Tarabichi<sup>11</sup>, there is no report showing a follow-up period greater than three years. In terms of patient numbers, only Marchioni et al.<sup>8</sup> reported a cohort larger than 100 patients.

Analysing the articles chosen for their review, it can be noted that three authors (Tarabichi, Migirov and Barakate) exclusively performed transcanal endoscopic surgeries, while in the other five reports, a combined technique was also applied if necessary. Overall, exclusive endoscopic management of the pathology was obtained in 293 (57%) cases, while 224 (43%) operations were performed with a combined technique. During the follow-up period, a total of 48 patients showed residual pathology: in particular, 32 patients had residual disease, while 16 patients presented with a recurrence of cholesteatoma. Conversion from endoscopic approach to microscope use in these studies occurred in up to 23% of cases<sup>3</sup>. Marchioni et al.<sup>8</sup> published an article looking at the exclusive endoscopic approach to cholesteatoma in the paediatric population. In this study, 59 cases were included, with 31 endoscopic approaches and 28 patients underwent a combined approach. Their recidivism rate was 13% for the EES group and 17% for the combined group. Of note was that the microscope had missed 17% of residual cholesteatoma. The sites of residual disease are however not stated in their article.

Published data also showed CWU residual rate of 20 % versus 7% in CWD procedures<sup>10</sup>. Gaillardin's study found cholesteatoma residual rates of 25% with CWU procedures over a 4 year follow-up. Mishiro et al.<sup>12</sup> observed higher recidivism of 19.4% after lowering the canal wall, this concurred with a study by Haginomori<sup>13</sup>. Over a follow-up period ranging from 4 to 15 years (mean follow-up of 8 years), de Zinis et al. observed only 4 (2.1%) residual cholesteatomas and no recurrent cholesteatomas among 189 ears treated with a CWD procedure for cholesteatoma of the middle ear. Sanna et al. evaluated 222 cases of cholesteatomas operated with their modified Bondy's technique, they reported a pearl-like residual cholesteatoma in 7.4% of ears, while no recurrences were discovered over a mean follow-up period of 7.8 years (range, 5-16 years).

Mishiro<sup>12</sup> also observed that the methods used for statistical analysis, among other factors, determined recidivism rates, and therefore advocated for the use of Kaplan-Meier survival analysis. In their meta-analysis performed on 13 studies including a total of 4720 patients, Tomlin et al.<sup>14</sup> demonstrated that, when performed as a single-stage surgery, an intact canal wall approach to cholesteatoma treatment had nearly 3 times greater likelihood of recurrence than a canal wall down surgery. In our study there was a 7 times likelihood of recurrence with a CWU procedure. In general, only 2 of the studies reported no significant differences between the two techniques. Regarding the data in their review, the high rate of exclusive endoscopic trans-canal procedures performed (57%), should be noted in comparison with the lower rate of combined approaches requiring mastoidectomy (43%). Another point of interest was the rate of residual disease and recurrences that appear lower compared to data reported in the literature for canal wall up interventions performed exclusively by microscopy. These promising results seemed to confirm the usefulness of the endoscope in terms of outcomes.

A study by Mohammad Ajalloueyan et al.<sup>15</sup> showed that adding the use of an endoscope to any surgical approach in cholesteatoma surgery lowers recidivism and improves hearing results. Similarly, Hamed et al.<sup>16</sup> also found in their study that bringing in an endoscope at the end of a microscopic procedure reduces risk of leaving behind any residual disease.

Finally, a case series by Cohen et al.<sup>17</sup> looked at residual rates in elective second-look operations in children during planned second-look procedures following primary cholesteatoma resection using endoscopic and microscopic operative approaches. Case series looking at outcomes from paediatric patients undergoing cholesteatoma surgery from January 2011 through August 2015 were analysed. Cholesteatoma extent at initial resection was staged, and comparison among endoscopic dissection and microscopic or

endoscopic inspection groups was made. Presence of disease at the time of planned second-look was quantified and a descriptive analysis performed. Fifty-five patients (56 ears) with planned second-look procedures were included and underwent a total of 120 procedures. The median age was 11 years. Endoscopes were used for inspection in 25 (39%) primary resections and for dissection in 39 (61%) primary resections. Extent of the disease at the time of primary resection was similar among groups. Cases where the endoscope was used for inspection only or not at all during primary resection had a 24% rate of residual cholesteatoma at the time of second-look compared with a 23% rate for cases with endoscopic resection. Rate of mastoidectomy significantly decreased from 63% to 33% over the study period ( $P = 0.04$ ), with similar disease extent ( $P = 0.99$ ), but residual cholesteatoma rates during planned second-look procedures were similar between the study groups. Unnecessary mastoidectomies were reduced to over 30% just by bringing in the endoscope.

## **CONCLUSION**

Eradication of cholesteatoma and restoration of hearing function presents unique surgical challenges. Exclusive endoscopic approach for cholesteatoma surgery appears to have recidivism rates that are comparable to classic microscopic CWU approaches, with the added benefit of conservative surgery and possibly a shorter average operating time compared with a traditional postauricular approach.

The exclusive endoscopic approach now represents a feasible, minimally invasive technique for the management of middle ear cholesteatoma. Endoscopes do play a useful role as adjuncts to microsurgery in the visualization of hidden areas and with confirming disease eradication, and an added benefit of a reducing the need for mastoidectomy.

CWD is now reserved for larger cholesteatoma or for unfavourable anatomic conditions. The choice to perform a CWD is often intraoperative and related to anatomical conditions that do not allow safe cholesteatoma removal, i.e. a low-lying middle cranial fossa dura, an anteriorly positioned sigmoid sinus which creates a small mastoid, and limited access into the anterior epitympanum for the presence of a perilymphatic fistula.

Limitations related to the studies analysed are short period of follow-up, small patient numbers and the absence of randomized trials.

## **AREAS FOR FUTURE RESEARCH**

Studies with a long-term follow up and larger cohort studies are necessary to definitively validate the outcomes of the different techniques in cholesteatoma surgery, for a more meaningful conclusion. Studies looking at correct patient selection for the different surgical method would add quality and standardized approaches. None of the papers considered in this study were randomized trials, so there is always room for bias.

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## CHAPTER 2

### PUBLICATION READY MANUSCRIPT

#### TITLE PAGE

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### **TITLE: AUDIT OF OUTCOMES OF ENDOSCOPIC CHOLESTEATOMA EAR SURGERY**

#### **MMed Dissertation in Otorhinolaryngology**

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## ABSTRACT

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**Background:** Endoscopic ear surgery has gained acceptance as a complementary tool to microscopic ear surgery, but perhaps not so much as an instrument for exclusive use. With this approach becoming popular, there is scarce data on cholesteatoma recidivism and hearing outcomes, when exclusively used.

**Objectives:** Auditing outcomes of endoscopic ear surgery for the surgical management of cholesteatoma in the Groote Schuur hospital (above 13 year age group) and the Red Cross War Memorial Children's hospital (below 13 year age group), with a secondary aim of comparing recidivism and hearing outcomes of 4 different surgical techniques for cholesteatoma resection, namely, exclusive endoscopic (EES), microscopic canal wall down (CWD), microscopic canal wall up (CWU) and combined endoscopic-microscopic techniques.

**Methods:** A retrospective chart review was conducted at our two tertiary academic referral hospitals in Cape Town, namely, Red Cross War Memorial Children's Hospital and Groote Schuur Hospital from January 2012 to December 2016.

**Results:** A total of 128 cholesteatoma ear surgeries were done; 110 patients were above the age of 13 years and 18 patients were below the age of 13 years. Eight Red Cross patients underwent EES, 7 had CWU, 2 had CWD and 1 had a combined technique. Overall recidivism rate in this population was 33% (6/18), of which 2 were approached exclusively endoscopically, 2 underwent a microscopic CWU, 1 had a CWD and 1 had combined endoscopic-microscopic approach. The mean postoperative hearing in this group was 40dB compared to a preoperative mean of 50,3 decibels (dB). In the Groote Schuur group, 23 underwent an exclusive endoscopic approach; 42 had a CWU, 40 had a CWD and 5 had a combined endoscopic-microscopic approach. Overall recidivism rate for the above 13 year old group was 17% (19/110). Of those, 7 were from the endoscopic group, 8 from the CWU group, 1 from CWD group and 3 from the combined technique group. Mean postoperative hearing was 47,4dB compared to a preoperative hearing of 48,4dB.

**Conclusions:** The CWD technique demonstrated superior outcomes in both the above and below 13 year age groups. In the above 13 year old group, the EES approach had the same recurrence rate as CWU. While paediatric cholesteatomas have much higher recidivism rates compared to adults, our below 13 year old group was too small to conclude any statistical significant differences between the different approaches, and therefore, further studies are required in this age group. Management of cholesteatoma requires a highly individualized approach that takes into account anatomic, clinical and social factors to determine the most appropriate surgical treatment paradigm.

**Keywords:** Cholesteatoma; endoscopic ear surgery; cholesteatoma surgery; recidivism; outcomes

## **List of abbreviations**

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RCWMH: Red Cross War Memorial Hospital

GSH: Groote Schuur Hospital

ENT: Ear, Nose and Throat

EES: Endoscopic ear surgery

CT: Computerized Tomography

MRI: Magnetic Resonance Imaging

dB: Decibel

AC: Air conduction

BC: Bone conduction

PTA: Pure Tone Average

CWU: Canal wall up

CWD: Canal wall down

## INTRODUCTION

The objective of cholesteatoma surgery is complete disease resection to keep the ear safe and dry<sup>1</sup>.

Before the arrival of endoscopes, the microscope was a widely used surgical tool in cholesteatoma surgery. Many otologic surgeons preferred using it. Certain advantages of the operative microscope still make it invaluable even in the era of the newer endoscopic technique. Amongst other advantages, the microscope is known for its good quality view of the middle ear, mastoid and temporal bone anatomy and pathology; and it affords the surgeon the freedom to use both hands during surgery<sup>2</sup>. Its main limitation is its inability to look around corners, with concerns of possibly missing pathology in the deeper recesses of the middle ear such as the sinus, tympani, facial recess and the attic<sup>2,3</sup>. As a result, this may necessitate soft tissue retraction and drilling for adequate exposure.

Endoscopic ear surgery has gained acceptance in its role as a complementary tool to the microscope, but perhaps not so much as a technique for exclusive use in cholesteatoma surgery. To improve understanding of this technique, existing literature on endoscopic cholesteatoma ear surgery was thoroughly reviewed.

Operative endoscopy was introduced in ear surgery in the 1990's by Thomassin<sup>4</sup>, with the objective of using it as a complementary tool to the microscope<sup>5</sup>. Over the years, this technique has been widely gaining acceptance. Literature defines exclusive endoscopic ear surgery as the sole use of the rigid endoscope to visualize and facilitate middle ear surgery<sup>4</sup>. It is a minimally invasive approach which is indicated for cholesteatoma not extending beyond the confines of the tympanic cavity<sup>5</sup>.

There is currently insufficient data on recidivism and hearing outcomes following exclusive endoscopic use in cholesteatoma ear surgery<sup>5</sup>. It has been reported to improve visualization during cholesteatoma surgery. Reports have shown the endoscope to be a superior tool in detecting cholesteatoma hotspots, without the need to remove excessive bone, and avoiding unnecessary need for soft tissue stripping<sup>3-6</sup>. With EES patient morbidity has been directly reduced by avoiding skin incisions, reduced need for drilling, less postoperative pain and reduced hospital stay<sup>4,5</sup>. Its cost effectiveness has been found to be comparable to the microscope<sup>5</sup>.

Some pitfalls of EES are well described in literature and includes using one hand<sup>1</sup> to hold the scope, while the other performs surgery, and looking at the screen when operating which could result in an inability to judge the distance between the scope and the surgical plane<sup>3</sup>. Concerns regarding safety of the endoscope as a surgical tool have been raised, and this includes possible thermal injury especially when xenon light is used. Fogging of the scope and ear trauma in case of accidental head movement adds to the drawbacks of this technique.

In certain cases, the use of both the microscope and the endoscope is advisable when dealing with cholesteatoma near high-risk middle ear structures such as the facial nerve<sup>7</sup>.

Studies looking at outcomes of cholesteatoma surgery exclusively using the endoscope are few and long-term follow-up was found to be short<sup>8</sup>.

## OBJECTIVES

The objective of this study was to audit outcomes of endoscopic ear surgery for the surgical management of cholesteatoma in the group above 13 years of age and the group less than 13 years of age; with a secondary aim of comparing recidivism and hearing outcomes of 4 different surgical techniques for cholesteatoma, namely, exclusive endoscopic (EES), microscopic canal wall down (CWD), microscopic canal wall up (CWU) and the combined endoscopic-microscopic techniques.

## MATERIALS AND METHODS

### Definitions

- **Cholesteatoma** is a growth of abnormal keratinizing squamous epithelium with accumulation of squamous debris in the middle ear cleft and can be either congenital or acquired<sup>9</sup>.
- **Recurrent cholesteatoma** is defined as a new cholesteatoma developing from a newly formed, non-self-cleaning retraction pocket<sup>10</sup>.
- **Residual cholesteatoma** is defined as cholesteatoma left behind during initial surgery<sup>10</sup>.
- **Recidivism** refers to both residual and recurrent disease.
- **Endoscopic ear surgery** is defined as the use of the rigid endoscope to perform ear surgery<sup>4</sup>.
- **Canal wall up mastoidectomy** refers to exenteration of the mastoid air cells with preservation of the posterior external canal wall <sup>9</sup>.
- **Canal wall down mastoidectomy** refers to the exenteration and exteriorization of the mastoid air cells by removal of the posterior external ear canal wall<sup>9</sup>.
- **Combined endoscopic-microscopic cholesteatoma ear surgery** refers to use of both the microscope and the endoscope for eradication of cholesteatoma. The endoscope may be employed either just for visualization to ensure that the disease has been eradicated after resection has been done microscopically, or the endoscope may be used at the start for resection of cholesteatoma confined to the middle ear and attic but then converted to microscopic approach when the disease extends beyond the posterior limit of the lateral semicircular canal. This is the approach adopted for combined procedures at our institutions

### Study Population

The study was conducted at two tertiary academic hospitals in Cape Town, Red Cross War Memorial Children's Hospital, which is our main referral center for patients under the age of 13 years, and Groote Schuur Hospital, which serves as a major referral hospital for patients above the age of 13 years. For the purpose of this study, the study participants were classified into a category of less than 13 years of age and above 13 years of age.

### Study design

A retrospective chart review was conducted of all patients who underwent primary surgery for cholesteatoma at Red Cross War Memorial Children's Hospital and Groote Schuur Hospital between January 2012 and December 2016. The study's participants, 128 in total, were identified through the theatre booking books over the 5year period. Follow-up for assessing outcome was initially conducted at 3 months, 6 months and 12 months, followed by

6 monthly visits in the first year following surgery. The study population was divided into four groups, namely populations A, B, C and D. Population A comprised of patients presenting with cholesteatoma who underwent primary exclusive endoscopic cholesteatoma surgery, while population B included those who underwent primary microscopic canal wall up procedure. Population C had a primary microscopic canal wall down procedure and Population D underwent a primary combined endoscopic-microscopic approach at initial surgery.

The following data was collected and summarized onto a data collection sheet (see appendices):

- Age
- Sex
- Affected side
- Number of previous cholesteatoma surgeries
- Preoperative otoendoscopic-otomicroscopic findings
- Preoperative CT scan findings: it was a prerequisite for all patients to have preoperative CT scans to determine the appropriate surgical method to use
- Site of cholesteatoma
- Integrity of ossicular chain
- Degree of pneumatization (i.e. sclerotic, moderately well or well pneumatized)
- Extent of opacification
- Hearing outcomes looking at preoperative and postoperative air conduction (AC), bone conduction (BC), air-bone gaps (ABGs) and pure-tone averages (PTA)
- Residual disease
- Disease complications
- Iatrogenic complications
- Presence of otorrhoea

#### **Inclusion criteria**

- All patients who underwent primary surgery endoscopically or microscopically or both combined for cholesteatoma between the time period of January 2012 and December 2016
- High resolution CT scan done pre-operatively

#### **Exclusion criteria**

- Cholesteatoma revision surgery
- Patients without a pre-operative CT scan
- Patients lost to follow-up were excluded, i.e. those who did not arrive for their 3 months, 6 months and 12 months post-operative reviews

#### **STATISTICAL ANALYSIS**

Data was captured on a customized data collection sheet and entered into Microsoft Excel spreadsheet for analysis. Frequencies and proportions were used to describe categorical data. The Pearson chi-square test (or Fisher's exact test where cell values were less than 5) was used to test the differences between groups or categories. All analysis was conducted in Stata version 13 (Stata Corp, College Station, Texas). All p-values <0.05 were considered statistically significant.

## **ETHICAL CONSIDERATIONS**

The study was approved by the University of Cape Town's Departmental Research Committee of the Surgical specialties and ethical approval granted by the Research Ethics Committee, Faculty of Health Sciences, University of Cape Town ( HREC REF: 347/2017).

## **RESULTS**

### **Baseline characteristics of study participants (Table 1.1)**

A total of 128 patients were included in the study of which 110 were from Groote Schuur Hospital and therefore >13 years of age, and 18 were from Red Cross Children's Hospital and <13 years of age (age range for this group was 4 to 13 years). Of the 128 ears, 31 (24%) underwent an exclusive endoscopic surgical technique, 49 (38%) had a microscopic canal wall up procedure, 42 (33%) underwent a canal wall down procedure, with 6 (4%) having undergone a combined endoscopic-microscopic procedure. Twenty-three of 31 (74%) patients >13-year-old group had an exclusive endoscopic procedure, 42 of 49 (86%) had a microscopic canal wall up technique, 40 of 42 (95%) had a canal wall down procedure, and 5 of 6 (83) underwent a combined endoscopic-microscopic procedure. Eight (26%) patients from the <13-year-old group underwent an exclusive endoscopic resection, 7 (14%) had a microscopic canal wall up procedure, 2 (5%) had a canal wall down mastoidectomy and 1 (17%) underwent a combined endoscopic-microscopic procedure. There were 60 (47%) males and 68(53%) females. There was a slight predominance of involvement of 67 (52%) right sided ears and 61 (48%) left sided ears. All were unilateral with no bilateral involvement. The mean follow-up period was 29 months, with a range of 23-36 months.

### **Site of cholesteatoma (Table 1.3)**

In the >13 year old group, the attic was the commonly involved primary site (58%) followed by extension of disease into mastoid in 47%, followed by disease extension into sinus tympani in 25% of cases. Prussak's space was the fourth most frequently involved subsite (18% of cases) followed by extension into the facial recess (15%). Extension of disease into the hypotympanum was the least common (4%).

When findings of the >13 year olds and <13 year olds were combined, the commonest site of cholesteatoma was the attic (66 of 128, which is 51.6%), followed by extension into mastoid (54 of 128, which is 43.2%), subsequently followed by extension into the sinus tympani (33 of 128, which is 25.8%). Extension of disease into the facial recess and Prussak's space had similar proportions (14.8%) and extension of the disease into the hypotympanum was the least common (4 of 128, which is 3.1%). See Figure 1.2.

When looking exclusively at the <13 year old population, the overall distribution was slightly different. The attic and sinus tympani were the commonest sites (each 44.4%), followed by extension into the mastoid (38.9%), the facial recess (22.2%) and lastly Prussak's space (5.6%). There were no lesions in the hypotympanum. Of note was that 60% of ears involved > than 2 sites. See Figure 1.3 and Table 1.4.

## **Outcomes by surgical technique**

In the >13 year old population, the recurrence rate was 17.3% and the proportion of recurrences by intervention mirrored that of the overall population.

The lowest recidivism rate was seen in the canal wall down group (2.5%), with unfavourable outcomes noted in the combined endoscopic-microscopic group. A recidivism rate of 19% was seen in the microscopic CWU and 30% in the EES group. See table 2.1 and figure 2.2. The overall recidivism in the <13 year olds was higher at 33%, compared 17% for >13 year olds. In this group, recidivism was lowest in the exclusive endoscopic group (25%), followed by microscopic CWU with almost similar outcomes (28%). The highest recidivism rate was observed once again in the combined endoscopic-microscopic group (100%), followed by microscopic CWD recidivism (50%). The difference was not statistically significant ( $p=0.11$ ). See table 2.2 and Figure 2.3. In this group however, the numbers were small to make any meaningful comparisons. The overall recurrence rate was 19.5% (25 of 128) when combining both the above and below 13 year old groups. This recurrence rate differed between the four intervention groups and was found to be statistically significant ( $p=0.001$ ). Recurrence was highest after the combined intervention (4 of 6, which is 66.7%) and lowest after CWD intervention (2 of 42, which is 4.8%). See figure 2.1. Overall, the attic was the commonest site of recidivism across the four different interventions (9 of 25, which is 36%) and the hypotympanum was the least affected.

## **Site of recidivism**

The commonest site of recidivism for both groups was the attic and extension of disease into the mastoid, followed by disease extension into sinus tympani and into facial recess. In the <13 year old group, the site of recidivism for microscopic CWU and combined endoscopic-microscopic approaches was confined to the attic, while recidivism in the exclusively endoscopic approach and microscopic CWU approaches extended into the mastoid. In the group >13 years, the site of recidivism for the exclusive endoscopic and microscopic CWU approach was confined to the attic, while disease extension into mastoid was seen with exclusive endoscopic and combined endoscopic-microscopic procedures (Table 2.1).

## **Hearing outcomes**

In the <13 year age group, the mean postoperative hearing was 40dB, compared to a preoperative mean of 50,3dB. The change was much higher than that of the group >13 years of age (48.4dB). The overall hearing improvement post-operatively in the above 13 year olds seemed marginal (47,4dB post-operatively and 48,4 preoperatively) See figure 3.1.

Fifty two (41%) had granulation tissue in the middle ear, while 90% had ossicular involvement, with the long process of incus being the most frequently eroded ossicle (53%), followed by stapes superstructure (24%).

Analysing ossicular chain findings per technique, the endoscopic group had 2 cases of intact ossicles, 12 cases of eroded long processes of the incus, 5 cases of eroded malleus and 3 cases of eroded stapes superstructures. The CWU group had 6 cases of intact ossicles, 19 eroded long processes of incus, 8 eroded malleus and 11 eroded stapes superstructures. In the CWD group, all ossicles were eroded; 13 involved the long process of incus, 9 involved the malleus and 19 involved the stapes superstructure. Lastly for the combined group, 1 had intact ossicles while 3 had erosion of the long process of incus and 1 had an eroded stapes

superstructure. Overall, 47 patients had erosion of long processes of incus, 22 cases had an eroded malleus, 34 had eroded stapes superstructures, while only 9 cases had intact ossicles.

### **Other interesting observations**

One hundred patients (79%) had wet ears at the time of surgery. The chorda tympani nerve was involved by cholesteatoma in 14% of all cases. Of those, 84% were sacrificed, with no recidivism observed for the sacrificed nerves regardless of surgical technique. The remaining 16% of involved chorda tympani had cholesteatoma “peeled off”, with 100% recidivism observed for that group, regardless of surgical technique.

### **DISCUSSION**

Looking at our retrospective study, a total of 128 cholesteatoma ear surgeries were done; 110 patients were above 13 years and 18 children below 13 years. Eight Red Cross patients underwent EES, 7 had CWU, 2 had CWD and 1 had a combined technique. Overall recidivism rate in this population was 33% (6 of 18), of which 2 were approached endoscopically, 2 underwent a microscopic CWU, 1 had a CWD and 1 had combined endoscopic-microscopic approach. The mean postoperative hearing in this group was 40dB compared to a preoperative mean of 50,3 dB. In the Groote Schuur group, 23 underwent endoscopic approaches; 42 had a CWU, 40 had a CWD and 5 had a combined endoscopic-microscopic approach. Overall recidivism rate for the above 13 year old group was 17% (19 of 110). Of those, 7 were from the endoscopic group, 8 from the CWU group, 1 from CWD group and 3 from the combined technique group. Mean postoperative hearing was 47,4dB compared to a preoperative hearing of 48,4dB. The CWD technique demonstrated superior outcomes in both adults and children <13years. In the above 13 year old group, the EES approach had the same recurrence rate as CWU. While paediatric cholesteatomas have much higher recidivism rates compared to adults, our below 13 year old group was small to conclude any statistical difference between the different approaches and further research is required for this age group.

Historically, the management of cholesteatoma was either approached using microscopic canal wall up or microscopic canal wall down techniques. The decision regarding which approach is used is based on a number of factors which includes: the extent of disease, pneumatisation of mastoid, aeration of middle ear and mastoid, reliability of patient to follow-up and surgeon preference<sup>1</sup>. It is well known that a canal wall up technique has a much higher recidivism rate compared to a canal wall down technique<sup>1</sup>.

Recently, endoscopic ear surgeons have been advocating exclusive use of the endoscope in cholesteatoma surgery for disease confined to the middle ear due to lower recidivism rates<sup>5,8,11-17</sup>. In our study, the endoscopic approach for cholesteatoma has comparable results in terms of recidivism with canal wall up mastoidectomy.

A study by Migirov et al.<sup>5</sup> retrospectively looked at recidivism rates in trans-meatal exclusive endoscopic ear surgery (EES). Thirty patients aged 9 to 75 years underwent EES eradication of cholesteatoma between July 2008 and May 2010. The posterior epitympanic space was involved with cholesteatoma in all except one ear. There was no residual disease in 18 patients who were followed-up for >1 year, and the diffusion-weighted sequence MRI was negative in 3 patients. Seven additional patients were scheduled to undergo MRI within the next 2 to 3 months. The other 8 patients were satisfied with their clinical results, declined going for a follow-up MRI scan. Their preliminary results indicate that the minimally

invasive EES allowed complete eradication of cholesteatoma from the middle ear and its extensions, with minimal morbidity and good functional results. The study showed good results. However the follow-up period of 1 year is very short. Their results however, differ significantly from our EES recidivism of 28% and 30% for the < 13 year olds and > 13 year olds respectively, over a follow-up period of 29 months.

Marchioni's results<sup>8</sup> showed a higher recidivism, with a recurrence rate of 12,9% and a residual rate of 19,3% . He had a longer follow up period of 36 months compared to Migirov's study above. Of note, these were all paediatric patients treated with EES approach, between January 2007 and December 2013. Patients presenting with cholesteatoma of the tympanic cavity with no mastoid involvement were included in the first group and underwent EES. Patients with mastoid extension of the pathology were included in the control group and underwent a CWU procedure. Fifty-nine ears of 54 patients were reviewed. Median age was 9.6 years (range 4-16 years). Thirty-one cholesteatomas underwent an EES approach, while 28 underwent a CWU approach. Recurrence rates were 12.9% (4 ears) for the EES group and 17.2%(5 ears) for the CWU approach. Residual disease was present in 26.6%: 19.3%(6 ears) for the EES and 34.4%(10 ears) for the CWU approach. The mean follow up period was 36 months (range 8-88). Kaplan-Meier analysis at 36 months showed a lower recurrence risk for the EES compared with the CWU approach, but this data had no statistical significance (P = 0.58). This is fairly similar to the findings of our <13 year old group. We had a recidivism of 28% for CWU and 25% for EES over a period of 24 to 29 months.

Tarabichi's study<sup>11</sup> evaluated 8 years of experience with trans-canal endoscopic management of limited attic cholesteatoma. He did a case series on seventy-three ears with limited attic cholesteatoma that underwent endoscopic trans-canal tympanotomy and extended atticotomy to access and completely remove the sac. Their mean follow-up was 43 months. Only five ears required revision for recurrent disease (6,8%). The recidivism rate was much lower compared to 29% for our EES overall results . Based on his findings, he concluded that an endoscopic technique allows transcanal, minimally invasive, eradication of limited attic cholesteatoma.

Alicandri-Ciufelli et al<sup>12</sup> analysed only cholesteatoma treated endoscopically (exclusively or combined) with at least 3 years of follow-up; canal wall down procedures were excluded. The final study group included 244 ears in 234 patients. The mean follow-up was 64.3 months. 166 patients (68%) free from disease post-operatively, 29 patients (12%) had recurrence, and 49 patients (20%) had residual disease. 73 patients (30%) had a cholesteatoma limited exclusively to the attic, whereas 44 (18%) had also a mesotympanic extension of the disease, 37 (15%) patients had exclusive involvement of the mesotympanum, 73 (30%) had antral extension, and 17 (7%) had mastoid extension. There were 41 patients (17%) who were aged < 18 years, and 203 (83%) were adults. A recurrence or residual was present in 68 adult patients (33%), and 10 recurrence or residual in 41 patients aged < 18yrs was noted (24%). Of 73 patients with cholesteatoma limited exclusively to the attic, 15 experienced residual disease; of 44 patients who also had a mesotympanic extension, 8 experienced residual pathology at follow-up, and of 37 patients with exclusive mesotympanic involvement, 5 experienced residual disease. Of 73 patients with antral extension, 18 experienced residual pathology, and of 17 patients with mastoid extension, 3 experienced residual pathology. In terms of site of cholesteatoma, their paediatric findings concur with our findings of the attic being the commonest primary site (51%) and commonest site of recurrence (33%). Their

comment was that the endoscopic results were similar to those reported for classic microscopic techniques in terms of recurrences or residual pathology at long-term follow-up.

Presutti et al<sup>13</sup> assessed the result of using an endoscope in cholesteatoma surgery and demonstrated how it reduced the incidence of residual disease prospectively. A total of 53 ears with a primarily acquired cholesteatoma were resected. Twenty were resected using a canal wall up (CWU) technique, 6 using a canal wall down (CWD) technique, and in 27 cases a trans-canal atticotomy was performed. All of the patients underwent explorative and operative endoscopic ear surgery complementary to the operating microscope to uncover and remove residual cholesteatoma. In the primary surgery after completion of microscopic cleaning, the overall incidence of intraoperative residual disease detected with the endoscope was 37.5%, with the sinus tympani being the most common site of intraoperative residuals, followed by the anterior epitympanic recess and protympanum. Out of the 20 CWU cases, 12 second-look endoscopies were performed. Two recurrences were identified, both in the sinus tympani.

Marchioni et al<sup>14</sup> reported results of 146 ears with a mean follow-up of 31.2 months. Of the 146 patients, 4 (2.7%) patients were diagnosed with recurrence, and 7 (4.8%) patients had residual disease. Of 33 patients with cholesteatoma limited *exclusively to the attic, none experienced residual disease*. Fifty-five patients had mesotympanic extension, 2 experienced residual pathologic condition at follow-up. Of 31 patients with antral extension, 2 experienced residual disease, and of 23 patients with mastoid extension, 3 experienced residual disease. When one looks closely at his results for residual disease it would appear that the lowest rate of residual disease is when the cholesteatoma is confined to the attic. As soon the disease is more extensive the risk of leaving behind residual disease appears to be higher. When looking at the sites of involvement in our study, more than 60% of patients in the overall had more than 2 sites involved by cholesteatoma.

Badr-el-Dine et al<sup>6</sup> prospectively assessed the value of ear endoscopy in cholesteatoma surgery and whether it improves surgical outcomes. A total of 92 ears were operated on. Eighty two cases were operated on by using canal wall up (CWU) technique, and 10 underwent canal wall down (CWD) procedures. Endoscopically guided ear surgery was incorporated complementary to the microscope. In the primary surgery after completion of microscopic cleaning, the overall incidence of intraoperative residuals detected with the endoscope was 22.8%. Sinus tympani was the most common site of intraoperative residuals in both CWU and CWD groups, followed by the facial recess and the under surface of the scutum in the CWU cases. Three recurrences (8.6%) were identified with CWU.

Prasad et al<sup>15</sup> did a retrospective study to evaluate the outcomes of the modified Bondy's technique performed at their centre and for limited epitympanic cholesteatomas and to debate the benefits of endoscopic surgery for the same indication. Two hundred and sixty nine ears in 258 patients with a minimum of 5-year follow-up that were operated for limited epitympanic cholesteatoma using the modified Bondy's technique were included in the study. There were no recurrent cholesteatomas in their series. Their conclusion was that the modified Bondy's technique, which provided excellent postoperative outcomes, is the surgery of choice for limited epitympanic cholesteatomas. They also concluded that the endoscope, despite its better visualization of hidden areas did not provide a distinct overall technical advantage or better results than the microscope.

The important question is: which patients are suitable for exclusive endoscopic technique? Following a literature search, there was no clear patient selection criteria proposed. Both Tarabichi et al<sup>16</sup> and Glikson et al<sup>17</sup> recommended endoscopic surgery when the cholesteatoma did not extend posterior to the anterior limb of the lateral semi-circular canal. These are the same criteria we use in both our centres.

When reviewing our CT scans, we paid attention to pneumatization and ventilation of the temporal bones, as we suspect this may affect recurrence rates. Studies have shown higher incidences of squamous disease with sclerotic mastoids and poor tubal function<sup>18</sup>.

Other factors that impact decision making for EES such as patient reliability and preoperative CT scan as a requirement to assess whether disease is confined to middle ear space or extensive, are not adequately addressed in literature.

Comparing recidivism rates between the >13 year old group and <13 year old group, findings in our study show that recidivism rates are higher in the <13 year old population, which concurs with findings in the literature, which shows that children have more aggressive disease caused by continuing eustachian tube dysfunction and hence formation of new retraction pockets<sup>18</sup>. The peaking of recidivism in this group was eleven years. Our study also shows that the exclusive endoscopic approach in paediatrics has a comparable recidivism rate to the microscopic canal wall up procedure. One limitation of our study was that our <13 year old patient numbers were relatively small (n=18). Larger paediatric studies are obviously needed to derive a meaningful conclusion. Previous studies quoted above looking at cholesteatoma surgery in children reported very favourable results for limited disease.

The reported advantages of endoscopy in cholesteatoma surgery is improved visualization of the hidden sites, and this may have an advantage in reducing residual disease especially in those hidden sites, which include the sinus tympani, facial recess and the attic<sup>1</sup>. We analysed a retrospective study by Ayache<sup>4</sup>. The objectives of the study were to evaluate otoendoscopy as a means of identifying residues of lesions after excision of disease under otomicroscopy in the same stage of surgery and its impact on the frequency of residual cholesteatomas at the time of surgical revision. They had 350 patients. The surgical procedures were divided into closed tympanoplasty via the trans-meatal approach, closed tympanoplasty with antroatticomastoidectomy and open tympanoplasty. Eighty patients (34%) who presented with an initial location of the disease at the epitympanum underwent complementary exploration by otovideoendoscopy. In 35 cases (44%), otoendoscopy revealed a residual lesion after an apparently total excision by otomicroscopy during closed tympanoplasty. In 65 cases (76%), a residual lesion was identified by otoendoscopy during the first stage of surgery in the sinus tympani or on the footplate of the stapes, between the crura of the stapes. Analysis using otoendoscopy reduced the incidence of residual cholesteatomas by identifying lesion extensions that are overlooked under otomicroscopy. In this population, the frequency of CWD was also significantly lower.

In our study, the microscopic canal wall down approach remained the most effective single stage procedure with the lowest recidivism, which was statistically significant (p=0.001).

Our research study also shows evidence that the combined microscopic-endoscopic approach is the least favourable option when disease extends beyond confines of the tympanic cavity. Nogueira et al<sup>19</sup> looked at outcomes of combined endoscopic-microscopic approach to cholesteatoma in 112 patients. Their recidivism rate was 6.8%, which is a figure almost

equivalent to quoted CWD surgery outcomes. Their study does not however, specify whether the canal wall was lowered or not.

There has been a paradigm shift in the surgical approach to cholesteatoma with intent to restore the tympanomastoid anatomy and physiology. The endoscope no doubt allows a more conservative approach by providing better visualisation of hidden sites thereby enabling preservation of the canal wall. The aim of cholesteatoma surgery however is not only to eradicate disease but also reduce the risk of recurrence. While the use of the endoscope has been shown to reduce the rate of residual disease more studies are required which have a longer follow-up period to assess the risk of recurrent disease.

## **CONCLUSION**

The key findings of our study were that the CWD technique demonstrated superior outcomes in both adults and children <13years. In the above 13 year old group, the EES approach had the same recurrence rate as CWU. While paediatric cholesteatomas have much higher recidivism rates compared to adults, our below 13 year old group was too small to conclude any statistical difference between the different approaches and further studies are required in this age group.

Based on our data, the choice of appropriate surgical technique should depend on a balance between extent of disease, anatomical favourability, radiological factors and patient reliability. We recommend pre-operative CT scan to assess extent of disease to aid in decision making regarding the most appropriate surgical method to use. To reduce risk factors for recidivism, we advise having a low threshold for taking down the canal wall when disease extends into the mastoid. Although the surgeon's personal preference and experience should also be taken into consideration, an individualized approach must be adopted for all patients.

## **LIMITATIONS**

- In the group below 13 years of age, we had a limited number of patients, statistically, it was not possible to make meaningful conclusions.
- Grouping of participants according to age above or below 13 was due to our two referral hospitals, Red Cross and Groote Schuur, using 13 years as a cut-off age for referring and managing patients. Below 13 year old are seen at Red Cross only, while those above 13 are referred and managed only in Groote Schuur Hospital.
- Disease extension differed across all 4 study groups, meaning cholesteatomas were not confined to the same sites, this was noted as a potential limitation of the study.

## **SUGGESTIONS FOR FURTHER RESEARCH**

Studies with a long-term follow up and larger cohort studies are necessary to definitively validate the outcomes of the different techniques in cholesteatoma surgery, for a more meaningful conclusion. Studies looking at correct patient selection for the different surgical method would add quality and standardized approaches. None of the papers considered in this study were randomized trials, so there is always room for bias.

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## Section 1 Description of all participants (>13 and <13 age groups)

Table 1.1 Baseline Characteristics of the all Study Participants

Characteristic	Endoscopic	CWU	CWD	Combined	Total
Total ears	31 (24.2%)	49 (38.3%)	42 (32.8%)	6 (4.7%)	128
<b>Sex</b>					
Male	15 (48.4%)	19 (38.8%)	21 (50.0%)	5 (83.3%)	60 (46.9%)
Female	16 (51.6%)	30 (61.2%)	21 (50.0%)	1 (16.7%)	68 (53.1%)
<b>Side of ear</b>					
Right	15 (48.4%)	31 (63.3%)	19 (45.2%)	2 (33.3%)	67 (52.3%)
Left	16 (51.6%)	18 (36.7%)	23 (54.8%)	4 (66.7%)	61 (47.7%)
<b>Unilateral/bilateral</b>					
Unilateral	31 (100.0%)	49 (100.0%)	42 (100.0%)	6 (100.0%)	128 (100.0%)
Bilateral	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Numbers per surgical technique</b>					
>13 age group	23 (74.2%)	42 (85.7%)	40 (95.2%)	5 (83.3%)	110 (85.9%)
<13 age group	8 (25.8%)	7 (14.3%)	2 (4.8%)	1 (16.7%)	18 (14.1%)

Table 1.2 Site of Cholesteatoma in combined >13 and <13 age group participants

Site	Endoscopic	CWU	CWD	Combined	Total
Attic	25 (80.6%)	22 (44.9%)	14 (33.3%)	5 (83.3%)	66 (51.6%)
Extension into sinus tympani	12 (38.7%)	13 (26.5%)	7 (16.7%)	1 (16.7%)	33 (25.8%)
Extension into facial recess	7 (22.6%)	7 (14.3%)	4 (9.5%)	1 (16.7%)	19 (14.8%)
Extension into Prussak's space	4 (12.9%)	14 (28.6%)	1 (2.4%)	0 (0.0%)	19 (14.8%)
Extension into hypotympanum	0 (0.0%)	2 (4.1%)	2 (4.8%)	0 (0.0%)	4 (3.1%)
Extension into mastoid	5 (16.1%)	16 (32.7%)	27 (64.3%)	6 (100.0%)	54 (42.2%)

Figure 1.1 Site of cholesteatoma in both >13 and <13 age group participants

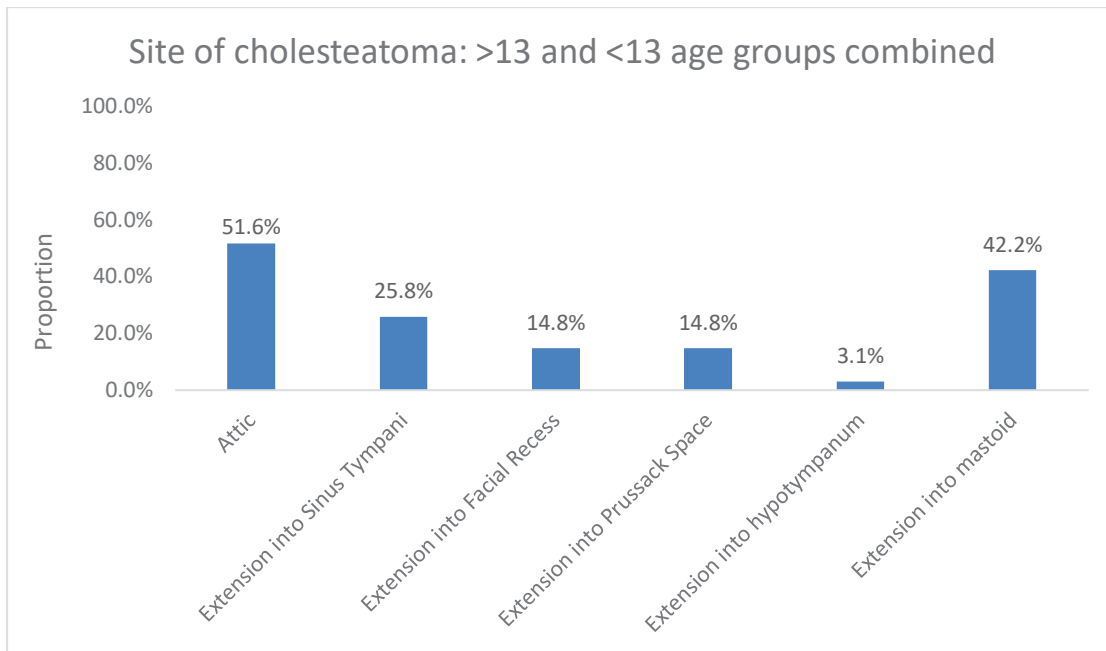


Figure 1.2 Site of cholesteatoma in the participants > 13 years

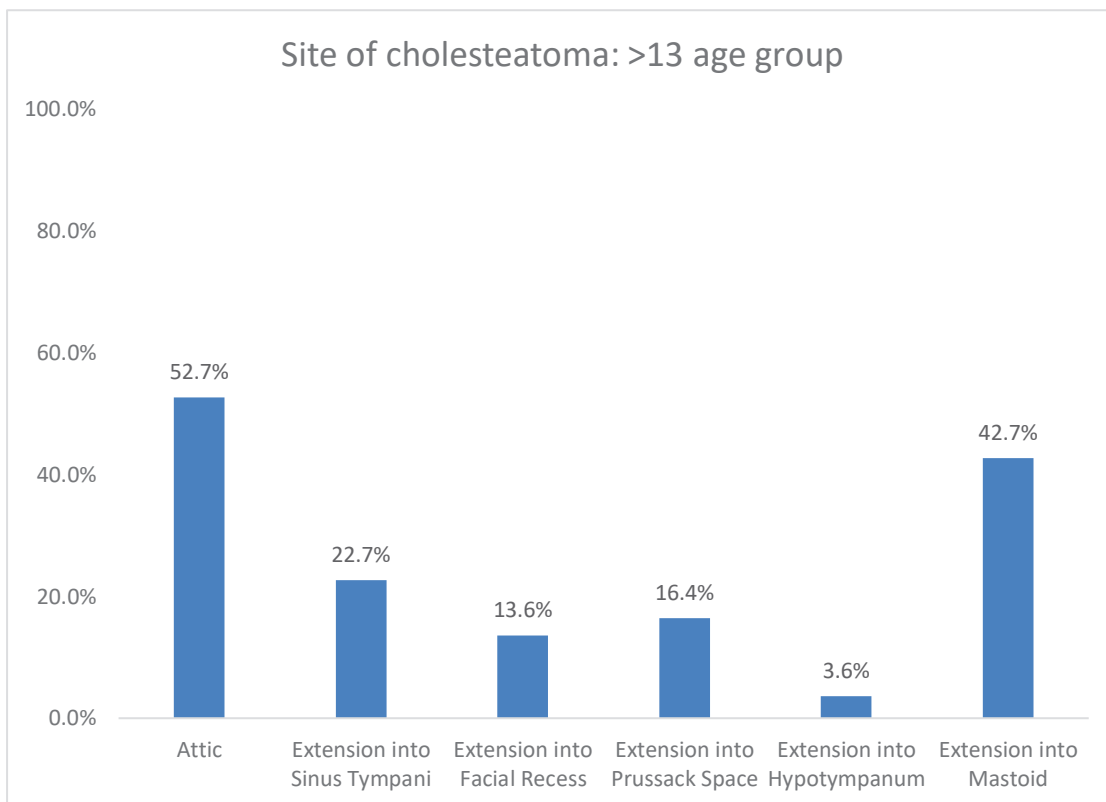


Table 1.3 Site of Cholesteatoma in >13 year age group participants

Site	Endoscopic	CWU	CWD	Combined	Total
Attic	18 (78.3%)	22 (52.4%)	14 (35.0%)	4 (80.0%)	58 (52.7%)
Extension into Sinus Tympani	8 (34.8%)	9 (21.4%)	7 (17.5%)	1 (20.0%)	25 (22.7%)
Extension into Facial Recess	5 (21.7%)	6 (14.3%)	3 (7.5%)	1 (20.0%)	15 (13.6%)
Extension into Prussak's Space	4 (17.4%)	13 (31.0%)	1 (2.5%)	0 (0.0%)	18 (16.4%)
Extension into Hypotympanum	0 (0.0%)	2 (4.8%)	2 (5.0%)	0 (0.0%)	4 (3.6%)
Extension into Mastoid	3 (13.0%)	13 (31.0%)	26 (65.0%)	5 (100.0%)	47 (42.7%)

Figure 1.3 Site of Cholesteatoma in <13 age group participants

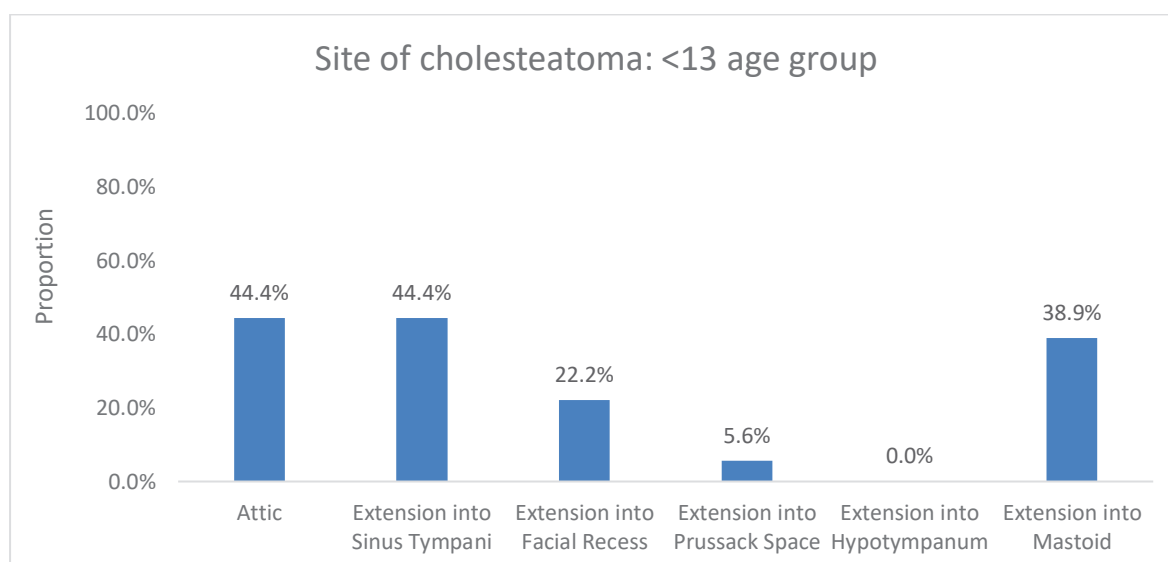


Table 1.4 Site of Cholesteatoma in <13 year age group participants

Site	Endoscopic	CWU	CWD	Combined	Total
Attic	7 (87.5%)	0 (0%)	0 (0%)	1 (100.0%)	8 (44.4%)
Extension into Sinus Tympani	4 (50.0%)	4 (57.1%)	0 (0%)	0 (0%)	8 (44.4%)
Extension into Facial Recess	2 (25.0%)	1 (14.3%)	1 (50.0%)	0 (0%)	4 (22.2%)
Extension into Prussak's Space	0 (0%)	1 (14.3%)	0 (0%)	0 (0%)	1 (5.6%)
Extension into Hypotympanum	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Extension into Mastoid	2 (25.0%)	3 (42.9%)	1 (50.0%)	1 (100.0%)	7 (38.9%)

Section 2 Outcomes (Recidivism rate)

Table 2.1 Outcomes by surgical intervention in combined >13 and <13 age group patients

Site	Endoscopic	CWU	CWD	Combined	Total
<b>Recidivism rate</b>	9 (29.0%)	10 (20.4%)	2 (4.8%)	4 (66.7%)	25 (19.5%)
<b>Site of recidivism</b>					
Attic	3 (33.3%)	4 (40.0%)	1 (50.0%)	1 (25.0%)	9 (36.0%)
Extension Sinus Tympani	2 (22.2%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	4 (16.0%)
Extension into Facial Recess	0 (0.0%)	3 (30.0%)	1 (50.0%)	0 (0.0%)	4 (16.0%)
Extension into Prussak's Space	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
Extension into Hypotympanum	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extension into Mastoid	3 (33.3%)	1 (10.0%)	0 (0.0%)	3 (75.0%)	7 (28.0%)

Figure 2.1 Overall Recurrence rate by surgical technique in >13 and <13 age group participants (Overall rate =19.5%)

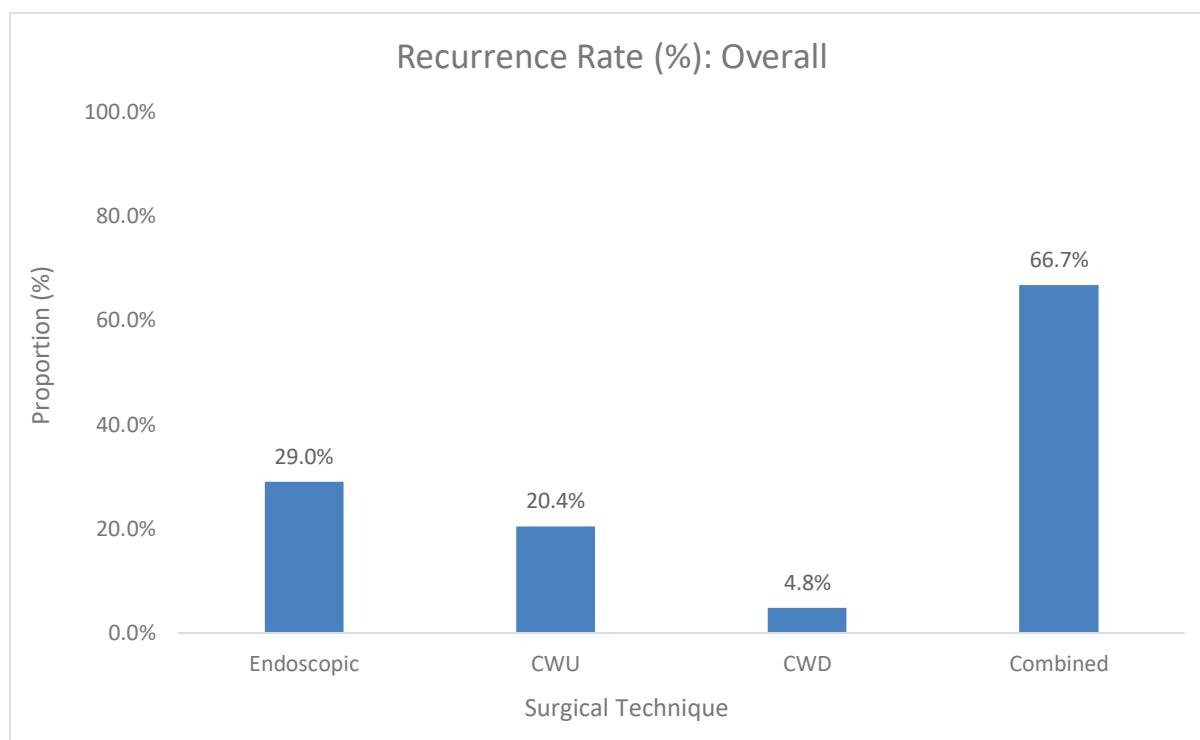


Table 2.2 Outcomes by surgical intervention in >13 age group participants

Site	Endoscopic	CWU	CWD	Combined	Total
Recurrence	7 (30.4%)	8 (19.0%)	1 (2.5%)	3 (60.0%)	19 (17.3%)
Site of recurrence					
Attic	3 (42.9%)	3 (37.5%)	1 (100.0%)	0 (0.0%)	7 (36.8%)
Extension into Sinus Tympani	1 (14.3%)	2 (25.0%)	0 (0.0%)	0 (0.0%)	3 (15.8%)
Extension into Facial Recess	0 (0.0%)	3 (37.5%)	0 (0.0%)	0 (0.0%)	3 (15.8%)
Extension into Prussak's Space	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)
Extension Hypotympanum	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mastoid	2 (28.6%)	0 (0.0%)	0 (0.0%)	3 (100.0%)	5 (26.3%)

Figure 2.2 Overall Recurrence rate in >13 age group participants by surgical technique

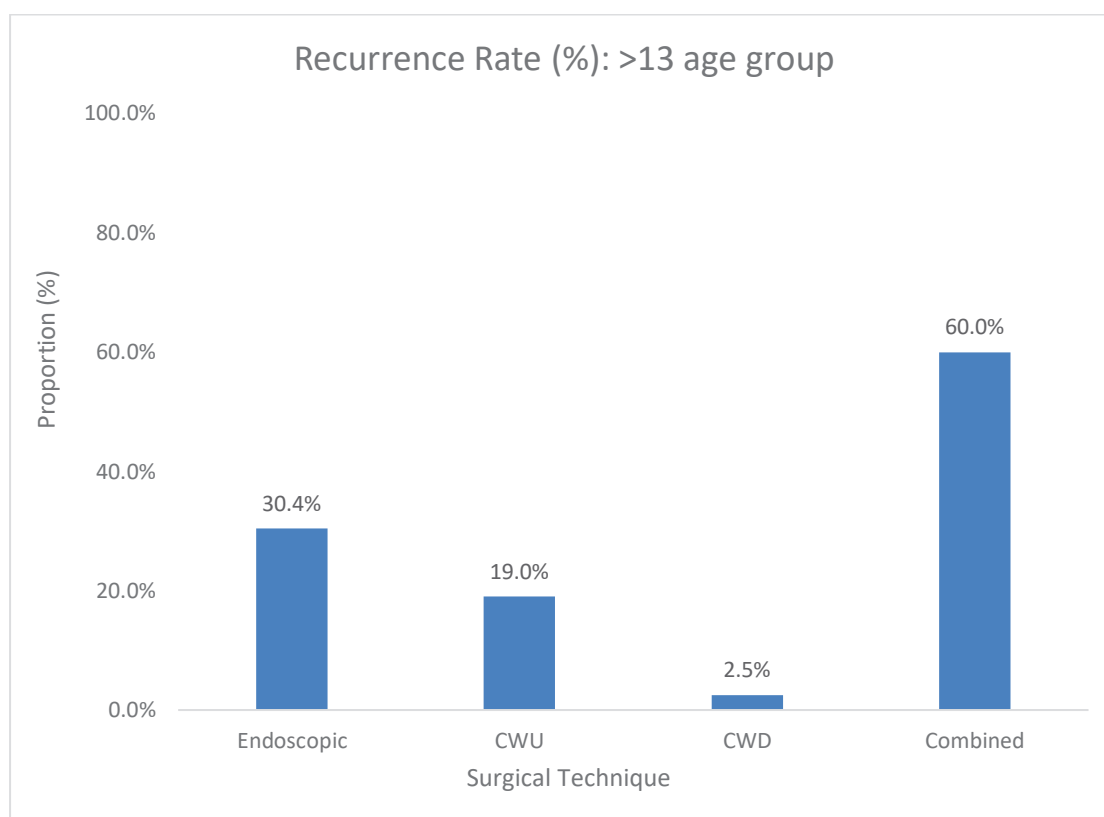
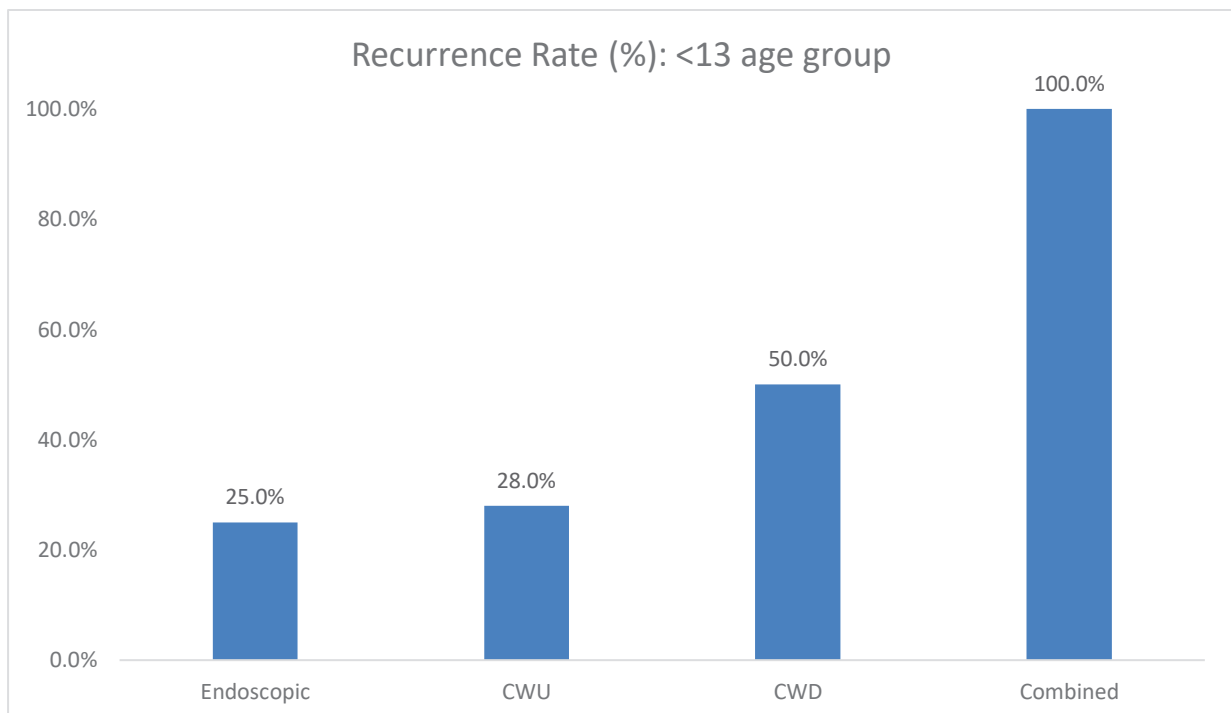


Table 2.3 Outcomes by surgical intervention in <13 age group participants

Site	Endoscopic	CWU	CWD	Combined	Total
Recurrence	2 (25.0%)	2 (28.0%)	1 (50.0%)	1 (100.0%)	6 (33.3%)
Site of recurrence					
Attic	0 (0.0%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	2 (33.0%)
Extension into Sinus Tympani	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
Extension into Facial Recess	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	1 (16.7%)
Extension into Prussak's Space	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extension into Hypotympanum	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extension into mastoid	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	2 (33.0%)

Figure 2.3 Overall Recurrence rate in the <13 age group participants by surgical technique



### Section 3 Hearing Outcomes

Table 3.1 Pre and post-operative hearing outcomes by intervention group

	Mean scores	<b>ENDOSCOPIC</b>	<b>CWU</b>	<b>CWD</b>	<b>COMBINED</b>	<b>TOTAL</b>
>13 group	Pre Op Audio dB	49.0	48.0	45.8	51.0	<b>48.4</b>
	Post Op Audio dB	42.6	43.1	41.6	54.0	<b>47.4</b>
	Delta	<b>6.4</b>	<b>4.9</b>	<b>4.2</b>	<b>-3.0</b>	<b>1.0</b>
Below 13 group	Pre Op Audio dB	46.3	45	60	50	<b>50.3</b>
	Post Op Audio dB	30.6	42	42.5	45	<b>40</b>
	Delta	<b>15.7</b>	<b>3.0</b>	<b>17.5</b>	<b>5.0</b>	<b>10.3</b>

## **APPENDICES**

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### **ACKNOWLEDGEMENTS**

I am grateful to my family for their prayers and support during my post-graduate training and this research project. I would like to thank Dr Tashneem Harris for her invaluable guidance and supervision of from the beginning to the completion of this Masters research study. I thank Dr Estie Meyer for providing access to her endoscopic ear surgery database as well as contributing to the final manuscript. Records department for providing requested patients clinical records for data collection; Dr Simba Takuva for his patient advice on statistical analysis; and to the management at Groote Schuur and Red Cross War Memorial Children's Hospitals for allowing me the opportunity to conduct this research project.

## DEPARTMENTAL RESEARCH COMMITTEE APPROVAL LETTER



UNIVERSITY OF CAPE TOWN



**Department of Surgery**  
**Departmental Research Committee**  
**Dr Timothy Pennel**  
D24 Office, Grootte Schuur Hospital  
Observatory 7925  
South Africa  
**Tel (021) 404 3430**  
**Email: [tim.pennel@uct.ac.za](mailto:tim.pennel@uct.ac.za)**

2 May 2017

Dr N Diale  
Department of Surgery  
University of Cape Town

Dear Dr Diale

RE: Project 2016/101

**PROJECT TITLE: Audit Of Outcomes Of Endoscopic Cholesteatoma Ear Surgery**

The above proposal has been reviewed by the Department of Surgery Research Committee. I am pleased to inform you that the committee approved the scientific merit of the study, and endorse the protocol for submission to the relevant ethics committee.

Please use the above project number in all future correspondence.

Yours sincerely

signature removed to avoid exposure online

DR TIMOTHY PENNEL  
CHAIRMAN: RESEARCH COMMITTEE

"OUR MISSION is to be an outstanding teaching and research university, educating for life and addressing the challenges facing our society."

# HUMAN RESEARCH ETHICS APPROVAL LETTER



UNIVERSITY OF CAPE TOWN  
Faculty of Health Sciences  
Human Research Ethics Committee



Room E53-46 Old Main Building  
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Observatory 7925  
Telephone [021] 406 6626  
Email: [shuretta.thomes@uct.ac.za](mailto:shuretta.thomes@uct.ac.za)  
Website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms)

22 June 2017

**HREC REF: 347/2017**

**Dr T Harris**  
c/o Ndivhuwo Diale  
Division of Otolaryngology  
ENT, H-Floor, OMB

Dear Dr Harris

**PROJECT TITLE: AUDIT OF OUTCOMES OF ENDOSCOPIC CHOLESTEATOMA EAR SURGERY (MMed-candidate- Dr N Diale)**

Thank you for submitting your response to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study subject to adding the HREC contact details to the informed consent form in case they have queries and the investigator's contact details please.

**Approval is granted for one year until the 30 June 2018.**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms))

**Please quote the HREC REF in all your correspondence.**

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

**The HREC acknowledge that the student, Dr Ndivhuwo Diale will also be involved in this study.**

*Yours sincerely*

signature removed to avoid exposure online

**PROFESSOR M. BLOCKMAN**  
**CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE**  
Federal Wide Assurance Number: FWA00001637.

HREC 347/2017

**DATA CAPTURE SHEET**

**RESEARCH STUDY: A RETROSPECTIVE AUDIT OF OUTCOMES OF ENDOSCOPIC CHOLESTEATOMA EAR SURGERY**

<b>DEMOGRAPHICS</b>											
Study number				Folder number							
Date of birth				Gender		Male <input type="checkbox"/>		Female <input type="checkbox"/>			
Total number of cholesteatoma surgeries				1 <input type="checkbox"/>		2 <input type="checkbox"/>		3 <input type="checkbox"/>		4 <input type="checkbox"/>	
Primary Surgery Side operated R <input type="checkbox"/> L <input type="checkbox"/>		Date of operation		Endoscopic <input type="checkbox"/>		Microscopic CWU <input type="checkbox"/> CWD <input type="checkbox"/>		Combined <input type="checkbox"/>		Chorda Tympani involved Yes <input type="checkbox"/> No <input type="checkbox"/> If yes: Preserved <input type="checkbox"/> Sacrificed <input type="checkbox"/>	
1 <sup>st</sup> Revision Side operated R <input type="checkbox"/> L <input type="checkbox"/>		Date of operation		Endoscopic <input type="checkbox"/>		Microscopic CWU <input type="checkbox"/> CWD <input type="checkbox"/>		Combined <input type="checkbox"/>		Chorda Tympani involved Yes <input type="checkbox"/> No <input type="checkbox"/> If yes: Preserved <input type="checkbox"/> Sacrificed <input type="checkbox"/>	
2 <sup>nd</sup> Revision Side operated R <input type="checkbox"/> L <input type="checkbox"/>		Date of operation		Endoscopic <input type="checkbox"/>		Microscopic CWU <input type="checkbox"/> CWD <input type="checkbox"/>		Combined <input type="checkbox"/>		Chorda Tympani involved Yes <input type="checkbox"/> No <input type="checkbox"/> If yes: Preserved <input type="checkbox"/> Sacrificed <input type="checkbox"/>	
3 <sup>rd</sup> Revision Side operated R <input type="checkbox"/> L <input type="checkbox"/>		Date of operation		Endoscopic <input type="checkbox"/>		Microscopic CWU <input type="checkbox"/> CWD <input type="checkbox"/>		Combined <input type="checkbox"/>		Chorda Tympani involved Yes <input type="checkbox"/> No <input type="checkbox"/> If yes: Preserved <input type="checkbox"/> Sacrificed <input type="checkbox"/>	
<b>PREOPERATIVE OTOLOGIC FINDINGS</b>											
Site of cholesteatoma											
State of ear				Wet <input type="checkbox"/>			Dry <input type="checkbox"/>				
Tympanic membrane				Intact <input type="checkbox"/>			Perforated <input type="checkbox"/>				
Ossicular chain				Intact <input type="checkbox"/>			Eroded <input type="checkbox"/>				
State of middle ear mucosa											
Preoperative complications				Non <input type="checkbox"/>		Extratemporal <input type="checkbox"/> State:		Intratemporal <input type="checkbox"/> State:			
<b>AUDIOLOGICAL ASSESSMENT</b>											
Preop Audio		3months Postop audio		6months Postop audio		12months Postop audio		18months Postop audio			
Bone conduction (BC)		BC		BC		BC		BC			
Pure tone average (PTA)		PTA		PTA		PTA		PTA			
Speech reception threshold (SRT)		SRT		SRT		SRT		SRT			
<b>IMAGING</b>											
Preoperative CT temporal bone		Done before primary procedure <input type="checkbox"/>		Postop CT							
		Done before revision surgery <input type="checkbox"/>									
Site of cholesteatoma				Residual disease/ Recurrent disease & site							
Integrity of ossicular chain				Integrity of ossicular chain							
Pneumatization of mastoid				Pneumatization of mastoid							
State of middle ear				State of middle ear							
Ventilation				Ventilation							
Disease complications				Disease complications							
<b>Post primary surgery clinical findings</b>											

Recurrent/ residual disease		Yes <input type="checkbox"/> Site:	No <input type="checkbox"/>	
Tympanic Membrane		Intact <input type="checkbox"/>	Perforation <input type="checkbox"/>	
Cavity	Wet <input type="checkbox"/>	Mucosalized <input type="checkbox"/>	Epithelialized <input type="checkbox"/>	
Iatrogenic complications: Present <input type="checkbox"/> Absent <input type="checkbox"/>		Details		
<b>Post 1st revision surgery clinical findings</b>				
Recurrent/ residual disease		Yes <input type="checkbox"/> Site:	No <input type="checkbox"/>	
Tympanic Membrane		Intact <input type="checkbox"/>	Perforation <input type="checkbox"/>	
Cavity	Wet <input type="checkbox"/>	Mucosalized <input type="checkbox"/>	Epithelialized <input type="checkbox"/>	
Iatrogenic complications: Present <input type="checkbox"/> Absent <input type="checkbox"/>		Details		
<b>Post 2nd revision surgery clinical findings</b>				
Recurrent/ residual disease		Yes <input type="checkbox"/> Site:	No <input type="checkbox"/>	
Tympanic Membrane		Intact <input type="checkbox"/>	Perforation <input type="checkbox"/>	
Cavity	Wet <input type="checkbox"/>	Mucosalized <input type="checkbox"/>	Epithelialized <input type="checkbox"/>	
Iatrogenic complications: Present <input type="checkbox"/> Absent <input type="checkbox"/>		Details		
<b>Post 3rd revision surgery clinical findings</b>				
Recurrent/ residual disease		Yes <input type="checkbox"/> Site:	No <input type="checkbox"/>	
Tympanic Membrane		Intact <input type="checkbox"/>	Perforation <input type="checkbox"/>	
Cavity	Wet <input type="checkbox"/>	Mucosalized <input type="checkbox"/>	Epithelialized <input type="checkbox"/>	
Iatrogenic complications: Present <input type="checkbox"/> Absent <input type="checkbox"/>		Details		



### Submissions

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##### General:

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- The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).
- Please make your article concise, even if it is below the word limit.
- Qualifications, full affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.
- Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
- Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.
- Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).
- Litres is denoted with an uppercase L e.g. 'mL' for millilitres).
- Units should be preceded by a space (except for % and °C), e.g. '40 kg' and '20 cm' but '50%' and '19°C'.
- Please be sure to insert proper symbols e.g.  $\mu$  not u for micro,  $\alpha$  not a for alpha,  $\beta$  not B for beta, etc.
- Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.
- Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.
- If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the only exception. Please DO NOT use fill, format lines and so on.

SAMJ is a generalist medical journal, therefore for articles covering genetics, it is the responsibility of authors to apply the following:

- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.
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**\*\*NB:** Copyeditors cannot be expected to pick up and correct errors ~~wrt~~ the above, although they will raise queries where concerned.

- Define all genes, proteins and related shorthand terms at first mention, e.g. '188del11' can be glossed as 'an 11 bp deletion at nucleotide 188.'

- Use the latest approved gene or protein symbol as appropriate:

Preparation notes by article type

Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text .

Structured abstract

- This should be 250-400 words, with the following recommended headings:
  - Background: why the study is being done and how it relates to other published work.
  - Objectives: what the study intends to find out
  - Methods: must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.
  - Results: first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
  - Conclusion: must be supported by the data, include recommendations for further study/actions.
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All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

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- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc) that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
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- Start with description of the population and sample. Include key characteristics of comparison groups.
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Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

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- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
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This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

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NB: Only complete, correctly formatted reference lists in Vancouver style will be accepted. Reference lists must be generated manually and not with the use of reference manager software. Endnotes must not be used.

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,<sup>[2]</sup> and others.<sup>[3,4-6]</sup>
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- First and last page, in full, should be given e.g.: 1215-1217 not 1215-17.
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  - Click Actions > Cite
  - Alongside 'url =' copy the URL between { }.
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