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BUTTERFLY CARTILAGE INLAY GRAFT MYRINGOPLASTY AT CHRIS HANI BARAGWANATH HOSPITAL (2009 – 2013)

DR NATASHA MORGADO

BSc (Pret), BSc (Hons) (Wits), MBBCh (Wits), FCORL (SA)

Research Report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirement for the Degree of Masters of Medicine in Otorhinolaryngology

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DEDICATION

To my beautiful daughter, Georgia, for all the sacrifices she has made in order for me to realise my dreams. May your future be bright and successful and may you never stop fighting until your every single goal has been reached.

To my husband, Bruno, for his unwavering support, sacrifices and constant encouragement. Thank you for always believing in me. You are the quintessence of a husband and friend.

To my parents, Néninha and Tobé, for having instilled in me a love for learning and the importance of discipline and perseverance in order to achieve my goals. Your love, support and guidance have proven invaluable in my journey.

To my mother-in-law and father-in-law, Ceu and Gilberto, for your love, support and never-failing assistance.

To my brother, grandparents, sister-in-law's, brother-in-law, nieces, nephews and special friends…. you add colour and joy to my days!

Without you, I would never have been able to realise my dreams.

DECLARATION

CANDIDATE:

This dissertation is my original work and has not been previously presented for a Degree, or other Academic award, at this or any other University or Institution of higher learning.

Signed _____

Date 11.10.2017.

Dr Natasha Morgado

BSc (Pta), BSC Hons (Wits), MBBCh (Wits), FCORL (SA)

SUPERVISOR:

This dissertation is submitted as a final copy with my approval as the University's Academic and Clinical Supervisor.

Signed _____

Date 11/10/2017

Dr Shahpar Motakef

MBBCh, FCORL (SA)

Clinical Head of Department ORL-HNS

Charlotte Maxeke Johannesburg Academic Hospital

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LIST OF ABBREVIATIONS

- **BCIG -** Butterfly cartilage inlay graft
- **ABG -** Air bone gap
- **ENT –** Ear Nose Throat
- **PTA –** Pure Tone Average
- **CI –** Confidence Interval
- **HI –** Hearing Improvement
- **dB –** Decibel
- **Hz –** Hertz
- **SD –** Standard deviation

DEFINITIONS:

- **Myringoplasty:** operative procedure to close/repair a perforation in the tympanic membrane
- **Chronic suppurative otitis media:** persistent inflammation of the middle ear mucosa with associated recurrent discharge/otorrhoea
- **Endaural incision:** incision commencing superior to tragus, extending into skin of the external auditory canal to gain access to middle ear.
- **Post auricular incision:** incision made 0,5 cm – 1 cm posterior to attachment of pinna to skin overlying skull, commencing at attachment of helix down to mastoid tip.
- **Canaloplasty:** procedure performed to widen external auditory canal. May require use of the powered bone drill.

ABSTRACT

AIM: This study aimed to assess the anatomical and functional success rate of Butterfly Cartilage Inlay Graft myringoplasties done at Chris Hani Baragwanath Academic Hospital using an oto-endoscope. Size of perforation was assessed as a possible predictor of success.

METHODS: The study comprised of a retrospective review of all records from the ENT Department at Chris Hani Baragwanath Academic Hospital of all patients who underwent BCIG myringoplasty from January 2009 to December 2013. 85 of the 160 patients who had BCIG's at CHBAH met the inclusion criteria for this study.

Data was collected on a data collection sheet and analysed using standard statistical methods.

RESULTS: 85 patients were included in the study of ages 5 years – 67 years with a mean age (SD) of 19,2 years (16,3). 61% were children (<13 years), 39% adults (14 – 49 years) and only 6% were >50 years. There were 30 (35%) Female patients and 55 (65%) Male patients.

The data presented in this study show an anatomical success rate of 90,6% for Butterfly Cartilage Inlay Grafts at Chris Hani Baragwanath Academic Hospital. The anatomical success rate of this study is equal to the success rates reported in the literature for the same procedure. 87% of patients experienced hearing improvement post operatively. The average hearing improvement in this study post Butterfly Cartilage Inlay Graft is 15dB. Finally, perforation size does not influence both anatomical and functional success rates in this study.

CONCLUSION: Endoscopic BCIGs performed at Chris Hani Baragwanath Academic Hospital, for small, medium and large perforations, show anatomical and functional success rates similar to those reported in the literature, performed with both microscope and endoscope. Size of perforation is not a predictor of anatomical and functional success for this procedure.

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CHAPTER 1 - INTRODUCTION:

1.1 BACKGROUND

Tympanic membrane perforations can occur as a result of chronic suppurative otitis media, acute otitis media or trauma. A perforation of the tympanic membrane causes hearing loss, which is proportional to the size of the perforation. This hearing loss is associated with decreased quality of life. Therefore, it is crucial to rectify tympanic membrane perforations and consequently the hearing loss to improve patient's quality of life.

1.2 TREATMENT

Myringoplasty is the surgical procedure used to repair perforations of the tympanic membrane. This procedure entails using a graft to repair the tympanic membrane perforation without working on the ossicular chain.

There are varying surgical approaches to reconstructive Myringoplasty. The different approaches used for myringoplasty are: transcanal, endaural or postauricular. The choice of approach being dependent on size of the tympanic membrane perforation, location of perforation, accessibility through external auditory canal and surgeon expertise. Graft materials for the procedure have also seen a myriad of items being used and are generally of mesoderm / connective tissue origin. The different tissues being used include free fascia, free fat, vein grafts and now free cartilage.

The traditional method has been the fascia underlay technique using free temporalis fascia as the graft material through a post auricular incision, with the use of a microscope. The graft itself needs to be cleared of attached muscle and connective tissue fibres and thinned and trimmed before use; e.g. using the graft cruncher. The procedure is generally regarded as cumbersome. It may be necessary to remove bone from the external auditory canal to increase visibility. This can be achieved with a bone curette or the bone powered drill may be used. This leads to an increased associated risk to the middle ear structures including the chorda tympani, that is the special sensory nerve responsible for taste, inner ear windows, the ossicles and to the Eustachian tube opening.

Free Cartilage as a graft has gained popularity as graft material in myringoplasty procedures. Cartilage has a low metabolic rate and receives its nutrients through diffusion from neighbouring tissues. Cartilage is a more rigid and resilient tissue compared to other tissues used in myringoplasty in the past. Its ease of handling, even in the less experienced hands of a trainee surgeon, together with the above-mentioned factors make the use of cartilage as a graft material in myringoplasty procedures an attractive alternative to the fascia underlay graft procedure.

CHAPTER 2 – LITERATURE REVIEW

2.1 TECHNIQUE:

Butterfly cartilage inlay graft (BCIG) myringoplasty was first described in 1998 by Roland Eavey and was further modified by Lubianco-Neto to the procedure that is now used.[1,2]

Eavey's technique is done with a microscope and uses a transcanal approach to place a 'butterflied' split piece of tragal cartilage into the perforated tympanic membrane allowing for closure of non-marginal tympanic membrane perforations. Eavey then placed a split thickness skin graft over the perichondrium of the cartilage graft.[1] Lubianco-Neto also performed the procedure with a microscope but modified this technique by excluding the overlying skin graft.[2]

BCIGs have gained popularity internationally for many reasons. The literature shows a 75%-100% success rate with regards to cartilage graft take. [1,2,3,4] This success rate is comparable to the success rate of the more technically demanding fascia underlay graft in experienced hands. [5,6,7] Wang *et al* showed that there is closure of the air bone gap (ABG) to within 20 dB hearing level in 96% of cases receiving a BCIG.[5] This result is repeated in most studies looking at hearing improvement post BCIG. [1,2,3,4,5] Furthermore, the postoperative hearing improvement post BCIG [1,2,3,4] is also comparable to the hearing improvement post fascia underlay graft procedures. [5,6,7] These studies show that BCIG, which is known to be a less invasive technique, has equal success rate and postoperative hearing improvement compared to Fascia underlay grafts.

2.2 BENEFITS:

In addition to the excellent anatomical and functional outcomes, BCIGs have a number of benefits over fascia underlay grafts. This technique has been shown to be less challenging, takes less time to implement and is better tolerated in the immediate postoperative period. It therefore sells itself as economically beneficial as well as being more convenient for patients.

Mauri *et al* reported that BCIGs are associated with less postoperative complaints of ear canal pressure and pain. This is due to the limited skin incisions and dissections and the fact that the ear canal does not need to be packed very firmly postoperatively. The actual operative time is shortened in BCIGs and is therefore economically beneficial.[7, 5] BCIGs can even be done in the office setting for adults - under local or regional anaesthesia.[2,4] Children can undergo this procedure with mask anaesthesia alone.[1]

BCIGs have been shown to have good anatomical and functional outcomes with the added benefit of being more comfortable for the patient and being less expensive. [5,7,8]

2.3 PROGNOSTIC FACTORS:

Several studies have looked at prognostic factors for success rate of BCIG. Size of the perforation has been thought to affect success rates of myringoplasty. Couloigner *et al* showed that large perforations (perforation involving 2 or more quadrants of tympanic membrane) did not influence anatomical and functional results in BCIG procedures.[6] However, Monfared *et al* showed that perforations larger than 5mm were associated with a minimal but significantly higher functional failure rate. [4] Later, in 2011, Lin *et al* showed that, in their study, larger

perforations (>50 % of tympanic membrane) were associated with better air bone gap closure and hence more hearing improvement compared to smaller perforations (<50 % of tympanic membrane). [11] Lack of a universal grading system for size of tympanic membrane perforations makes it difficult to compare these studies. Currently, there is no consensus in the literature if the size of tympanic membrane perforation affects anatomical and functional success rates.

2.4 ENDOSCOPIC OTOLOGIC SURGERY:

The use of endoscopic instrumentation in otological surgery is gaining momentum. Previously, all otologic surgery, transcanal, endaural and post auricular, had been done with the use of a microscope. However, in some instances the canal may be narrow or the canal wall may protrude into the external auditory canal, making it difficult to assess the entire circumference of the rim of the perforation. In these cases, the surgeon would usually convert to an open procedure or at least have to perform a canaloplasty. The oto-endoscope is a minimally invasive instrument that may be used to circumvent this problem. Transcanal endoscopic myringoplasty provides excellent exposure of the entire tympanic membrane even in the presence of external auditory canal bony prominences. The use of oto-endoscope also allows for visualisation of the middle ear structures and the medial surface of the tympanic membrane, especially in patients with large perforations. [9,10] There are a few limitations with the use of oto-endoscope. Firstly, it requires one-handed surgery. [11] This is a skill that is readily acquired. Secondly, the oto-endoscope may injure the external ear canal skin and cause bleeding which may make the surgery more difficult.[9] Once again, with experience; this becomes less of a problem. However, despite these limitations, transcanal endoscopic myringoplasty has been shown to have similar results to myringoplasty performed with the use of a microscope.[9]

2.5 JUSTIFICATION:

Chris Hani Baragwanath Academic Hospital is a tertiary institution in Soweto, Johannesburg, South Africa associated with the University of the Witwatersrand. At the ENT Department at Chris Hani Baragwanath Academic Hospital, the use of BCIGs is routinely practised with the use of an oto-endoscope (not microscope), for non-marginal tympanic membrane perforations. BCIGs are performed on small to large sized tympanic membrane perforations, providing that a rim of tympanic membrane is present circumferentially. The sizes are calculated as percentage of total surface area of tympanic membrane and are characterized as: small <40%, medium 40% - 60% and large >60%.

BCIG's are performed regularly at Chris Hani Baragwanath Academic Hospital. The procedure is usually associated with acceptable results both in anatomical and functional terms. However, despite the number of times the procedure is performed, the results have never been assessed statistically.

Therefore, we propose to assess the anatomic and functional success rates of BCIGs at Chris Hani Baragwanath Academic Hospital. We will also assess which of the different sizes of tympanic membrane perforation is better suited to BCIGs. This information will aid in formulating a protocol on how best to manage tympanic membrane perforations surgically at our Hospital.

CHAPTER 3 - STUDY OBJECTIVES:

This study aimed to assess the success rate of the Butterfly Cartilage Inlay Graft myringoplasties done at Chris Hani Baragwanath Academic Hospital; using a 30 degree endoscope.

3.1 OBJECTIVES:

1) To assess the Anatomical success rate by looking at number of patients who have intact tympanic membranes, post BCIG, at 6 month follow up.
2) To assess Functional success by looking at the amount of hearing improvement, post BCIG, at 6 week follow up.
3) To compare the anatomical and functional success rates of the different perforation sizes (small, medium and large), to determine if the size of perforation influences success rate.

3.2. STUDY DESIGN:

This study is a retrospective review of all records from the ENT Department at Chris Hani Baragwanath Academic Hospital of all patients who underwent BCIG myringoplasty from January 2009 to December 2013.

3.3. STUDY SITE:

Chris Hani Baragwanath Academic Hospital is the third largest hospital in the world, with 3200 beds. The ENT Department at Chris Hani Baragwanath Academic Hospital has 2 sections, the inpatient and outpatient section. The inpatient section has 36 adult beds and 10 paediatric beds. The outpatient department sees, on average, 250-300 patients per week.

3.4. STUDY POPULATION:

160 patients had the BCIG procedure performed at Chris Hani Baragwanath Academic Hospital in the selected time period. Every patient having a BCIG at Chris Hani Baragwanath Academic Hospital gets a discharge summary. A copy of this discharge summary with preoperative, operative and postoperative details is kept in the ENT Outpatient Department for each patient. The data for this study was obtained from these discharge summaries. All records were reviewed. No sampling was done.

In order to be a candidate for BCIG at Chris Hani Baragwanath Academic Hospital, patients had to fulfil the following criteria:

- Absence of otorrhoea for a minimum period of 3 months.
- Preoperative audiogram (not older than 3 months old)
- Have a non-marginal tympanic membrane perforation.
- Have an Air Bone Gap of less than 30 dB (an ABG larger than 30 dB suggests that there may be a ossicular pathology and therefore requires a more invasive procedure).[12]

3.4.1. INCLUSION CRITERIA:

1. Must have preoperative audiogram results documented on discharge summary
2. Must have a postoperative audiogram at 6 weeks with results documented on discharge summary.
3. Must complete 6 months of follow up with results documented on discharge summary.

3.5. OPERATIVE PROCEDURE:

At the ENT Department of Chris Hani Baragwanath Academic Hospital, the Modified Lubianco-Neto technique is used to perform BCIG's. In contrast to the described technique, the 30 degree oto-endoscope is used to assist with the surgery, instead of the operating microscope. All cases are done under general anaesthesia. Ear is lightly packed with gelfoam soaked in Ciloxan drops (Ciprofloxacin). Patients are discharged on day 1 postoperatively unless unforeseen circumstances have arisen.

3.5.1 FOLLOW UP:

All patients' follow up was done at the ENT Outpatient Department 2 weeks postoperatively. At this visit, the small tragal incision wound is assessed. It is often difficult to visualise the tympanic membrane at this point since some of the gelfoam is still in the external auditory canal. Patients book their 6 week audiogram at this visit.

The 6 week follow up appointment is to assess the tympanic membrane and graft and to evaluate and document the postoperative audiogram.

At 6 months, the tympanic membrane is assessed and the status of the graft is documented.

3.6. OUTCOMES:

3.6.1. ANATOMIC SUCCESS:

Graft take was reported as successful if the tympanic membrane is intact on otoscopic examination at 6 months postoperatively.

3.6.2. FUNCTIONAL SUCCESS:

Functional success was assessed using audiometric analysis:

1. Pure Tone Average (PTA) was measured as an average of the air conduction thresholds at 500Hz, 1000Hz and 2000Hz of the operative ear.
2. The ABG was measured as the average gap between air and bone conduction at the same intervals as mentioned above.
3. Hearing improvement was calculated as preoperative PTA minus postoperative PTA.
4. Functional success was taken as any improvement in postoperative PTA

3.6.3. SIZE AS A PREDICTOR OF SUCCESS:

Hearing improvement and anatomical success of different perforation size groups (small <40%, medium 40% - 60%, large >60% of total surface area of tympanic membrane) was compared.

3.7. DATA:

The following information was captured on a Data collection sheet from the patients' discharge summary:

- Age
- Gender
- Size of perforation (measured as percentage of total surface area of tympanic membrane)
- Audiometry:
    - Preoperative PTA
    - Preoperative ABG
    - Postoperative PTA
    - Postoperative ABG
- Graft integrity (intact or not intact) at:
    - 2 weeks
    - 6 weeks
    - 6 months

3.8. DATA COLLECTION:

- Data was collected by the primary researcher.
- All patients were allocated a Study number for confidentiality.
- Data was documented on the data collection sheet attached (Appendix 1)
- Data was then transferred to an Excel spread sheet.

3.9. DATA MANAGEMENT:

- All patients with missing data were excluded from the study.
- Anatomical success:
    - Data was grouped into intact tympanic membrane and perforated tympanic membrane
    - Statistical analysis was performed on data.
- Functional success:
    - Preoperative PTA was subtracted from the Postoperative PTA giving the overall Hearing Improvement for each patient
    - Hearing improvement was grouped into 3 groups:
        - 0-10 dB hearing improvement
        - 10-20 dB hearing improvement
        - >21 dB hearing improvement
    - Statistical analysis was performed on data
- Size of perforation:
    - Perforations was categorised into:
        - Small = perforation size < 40% of total tympanic membrane
        - Medium = perforation size between 40% - 60% of total tympanic membrane
        - Large = perforation size > 60% of total tympanic membrane
    - Statistical analysis was performed on data

3.10. DATA ANALYSIS:

Statistical analysis was performed by the primary researcher with assistance from a statistician employed by the University of Witwatersrand.

Anatomical success rate (intact versus perforated tympanic membrane) and Functional success rate were compared by looking at confidence intervals. Follow up times were analysed using Mann-Whitney test.

Age as a predictor of anatomic success was analysed using the Mann-Whitney test. Age as a predictor of hearing improvement was assessed using Kruskal-Wallis ANOVA.

Preoperative PTA as a predictor of anatomic success was assessed using unpaired t-test and using the one-way ANOVA when assessing preoperative PTA as a predictor of functional success

The ages between the different perforation size groups were analysed using the Kruskal-Wallis test. Perforation size as a predictor of anatomical success rate and functional success rate was analysed using one-way ANOVA.

Statistical analysis is considered significant at $p < 0.01$.

3.11. ETHICS:

This research protocol was presented to the University of Witwatersrand's Ethics committee for ethics approval. Ethics approval was granted (Ethics clearance number: M160514) (Appendix 2)

Approval to access hospital records was granted from the Head of the ENT Department at Chris Hani Baragwanath Academic Hospital and the Chris Hani Baragwanath Academic Hospital CEO and Ethics Committee. (Appendix 3 and 4)

Records indicating patient names and hospital numbers were treated with utmost respect and integrity. All information was kept anonymous and was only available to the primary researcher and supervisor. A study number was allocated to each patient to maintain patient confidentiality.

3.12. FUNDING:

Required funding was for printing and binding of the dissertation.

The researcher incurred these costs.

CHAPTER 4 - RESULTS:

4.1 STUDY SAMPLE:

A total of 160 patients had a BCIG procedure at Chris Hani Baragwanath Academic Hospital from January 2009 – December 2013. Of these, 75 were excluded as they did not have a postoperative audiogram at 6 weeks and/or did not complete a full 6 months of follow up. Therefore, a total of 85 patients were entered into the study.

4.2 DEMOGRAPHIC DATA:

The age of the patients included in the study ranged from 5 to 67 years with a mean age (SD) of 19,2 years (16,3). 61% were children (<13 years), 39% adults (14 – 49 years) and only 6% were >50 years. There were 30 (35%) Female patients and 55 (65%) Male patients.

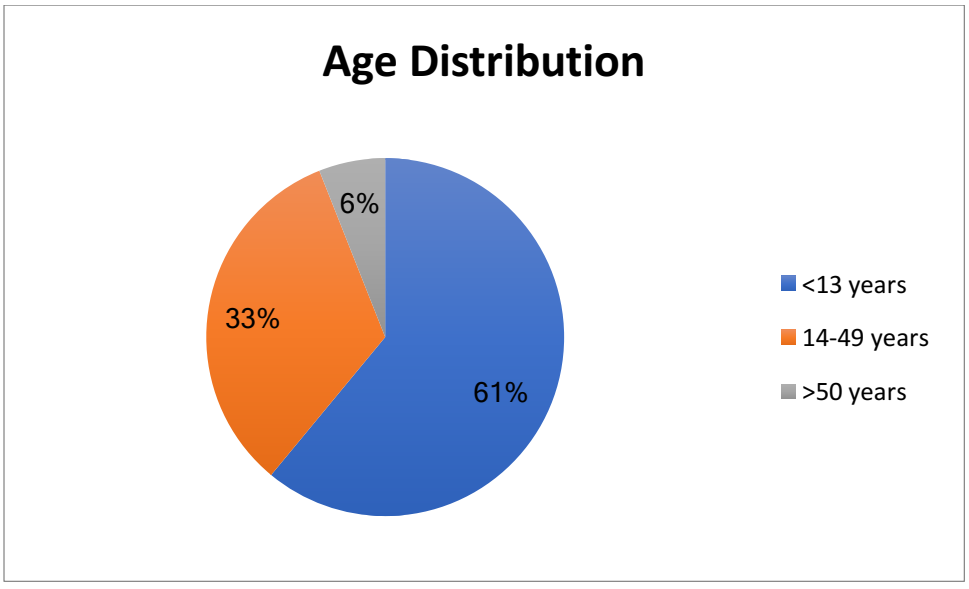

Figure 4.1 Age distribution of study population

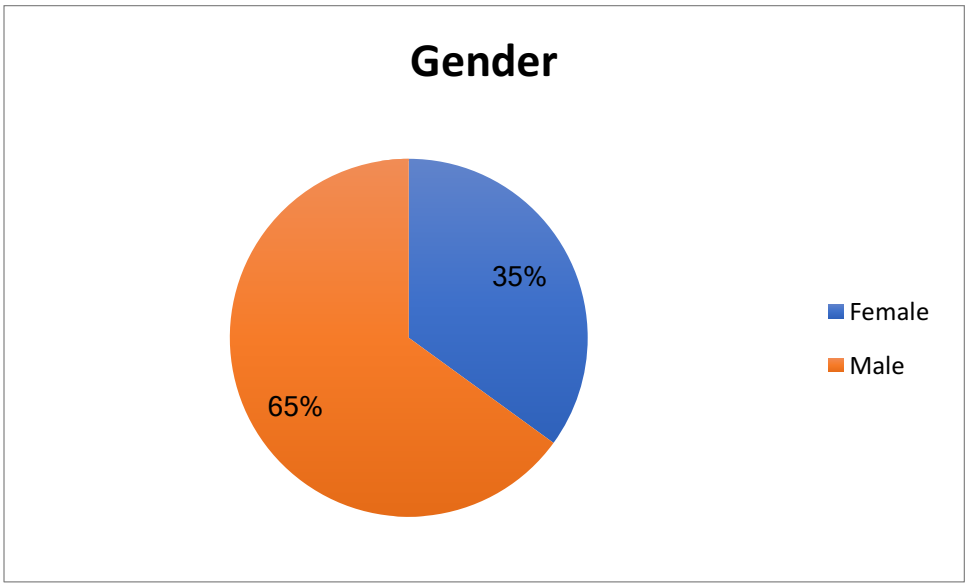

Figure 4.2: Gender of all patients receiving BCIG at Chris Hani Baragwanath Academic Hospital January 2009 - December 2013

4.3 ANATOMICAL SUCCESS:

Of the 85 patients in the study, BCIG surgery was successful in 90.6% (n=77) and failed in 9.4% (n=8) patients (CI 82-95 and CI - 4.8-17 respectively). The confidence intervals do not overlap for the 2 groups. Therefore, it is significantly different.

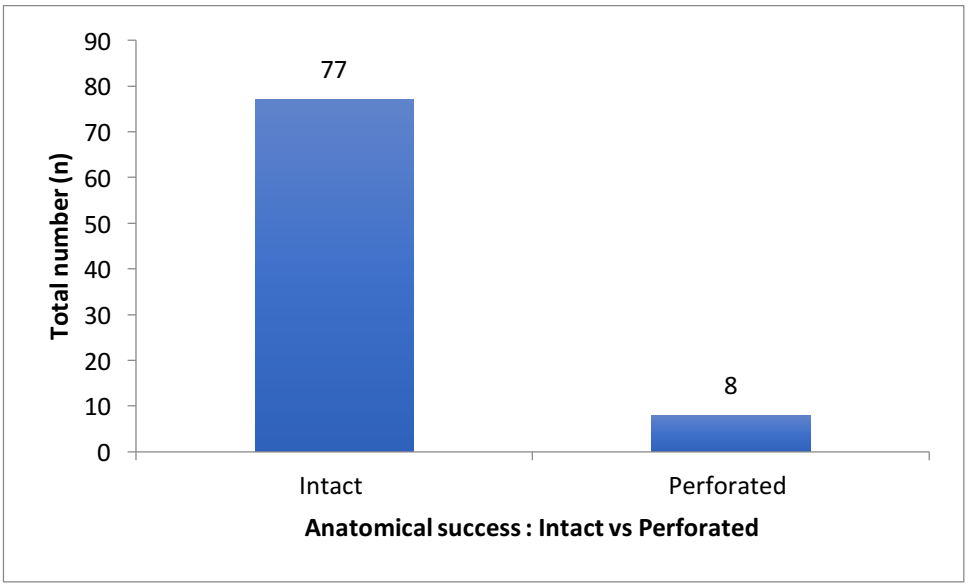

Figure 4.3: Anatomical Success rate (Intact versus Perforated) Confidence Intervals (82-95 and 4.8-17)

4.3.1 FOLLOW UP TIME:

The follow up time between the two groups (intact vs perforated) was not significantly different. Intact group follow up time = 10 months, Perforated group follow up time = 11.2 months. (p = 0.3392)

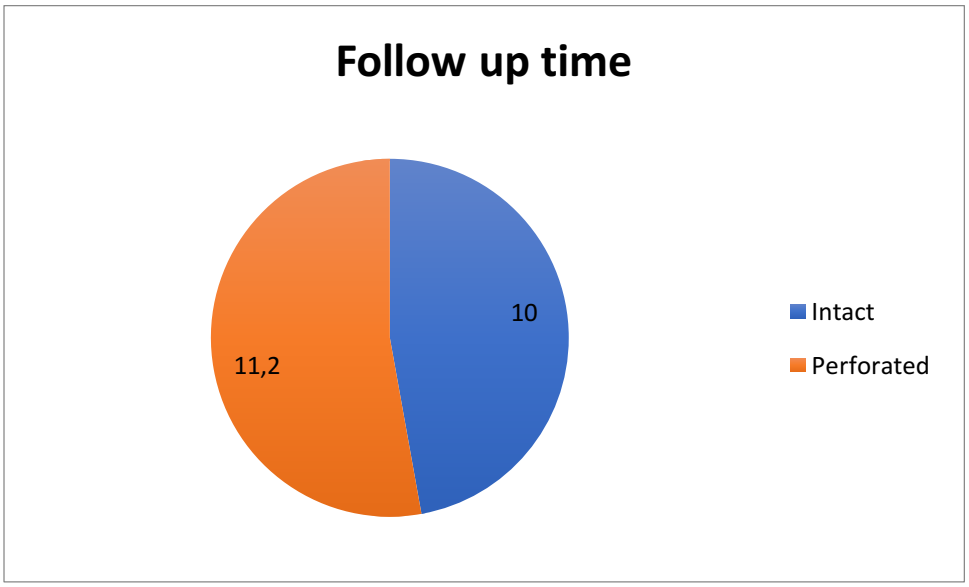

Figure 4.4: Follow up time in relation to Anatomic Success

4.4 HEARING IMPROVEMENT:

87% of patients in this study showed an improvement in hearing, 5% had no change in hearing and 7% had worse hearing.

Hearing improvement was grouped quantitatively into 3 groups namely, <10 dB, 11-20 dB, >21 dB. 32.9% (CI - 28.9-43.5) of patients fell in the <10 dB HI group, 36.5% (CI - 27.0-47.1) fell in the 11-20 dB HI group and 30.6% (CI - 21.8-41.1) fell in the >21 dB HI group. The confidence intervals all overlap meaning that there is no significant difference between the groups.

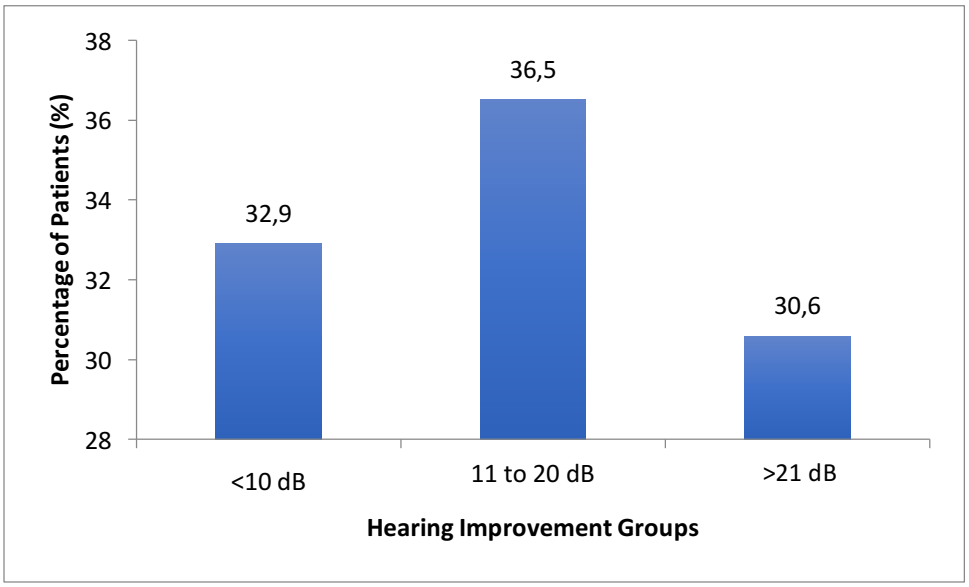

Figure 4.5: Percentage of patients in each Hearing Improvement group

4.4.1. FOLLOW UP TIME

The follow up time was not significantly different between the 3 groups.

In the <10 dB group the mean follow up time was 13,4 months, in the 11 – 20 dB group 11,7 months and in the >21 dB group 13,6 months.

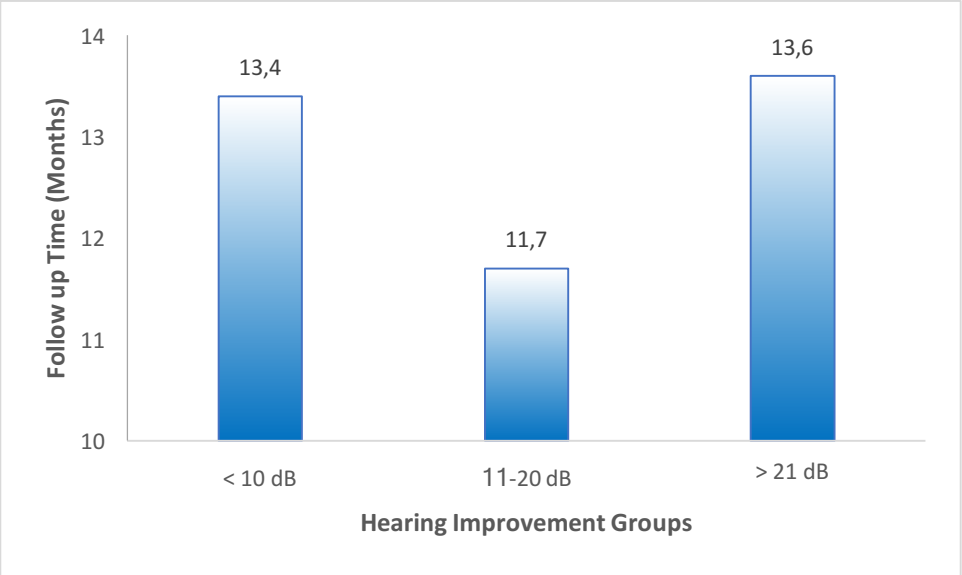

Figure 4.6: Follow up time for the Hearing Improvement groups

4.5 PREDICTORS OF SUCCESS

4.5.1 AGE:

4.5.1.1 AGE VERSUS ANATOMICAL SUCCESS

The age (median range) of patients in the Intact group was 11 years (5 – 67 years) and in the Perforated group was 10 years (7 – 46 years). There was no statistical difference between the two groups (p = 0.9042)

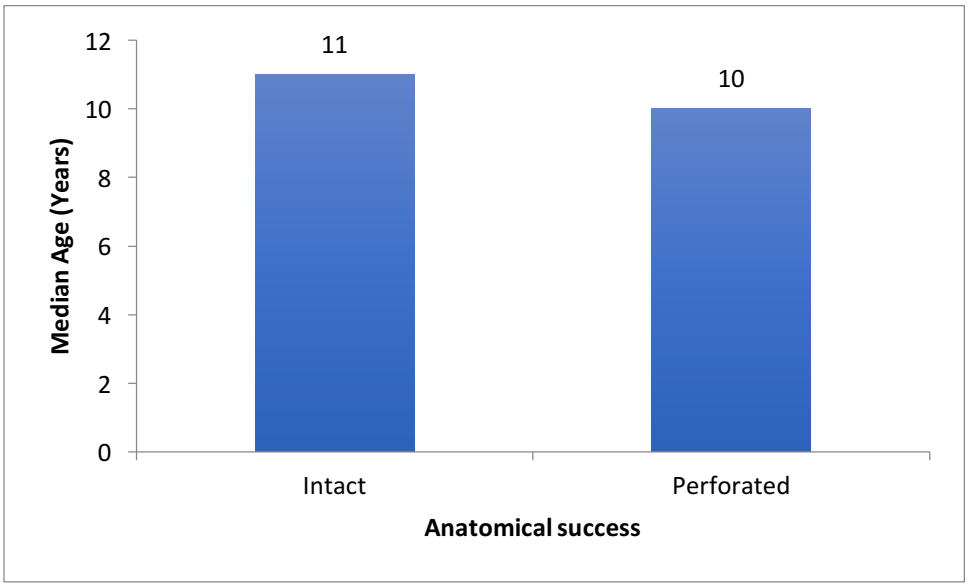

Figure 4.7: Age as a predictor of Anatomical Success (p = 0.9042)

4.5.1.2 AGE VERSUS HEARING IMPROVEMENT

There was no significant difference of age in the 3 groups.

The mean age in the <10 dB group was 10.5 years, in the 11-20 dB group was 12 years and in the >21 dB was 10 years (p = 0.9909).

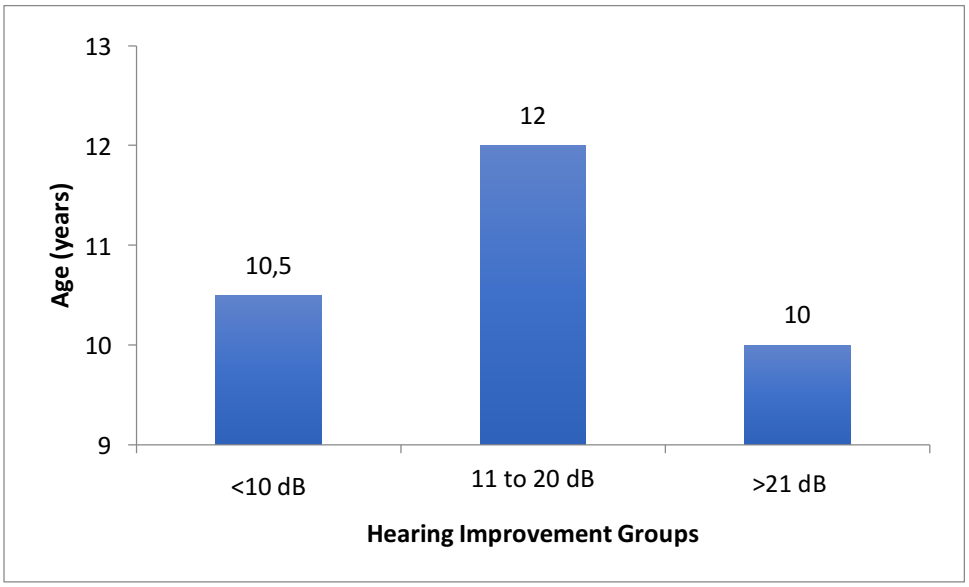

Figure 4.8: Age of Hearing Improvement groups

4.5.2 PREOPERATIVE PTA

4.5.2.1 PREOPERATIVE PTA VERSUS ANATOMICAL SUCCESS

The preoperative PTA of the patients who had Intact tympanic membranes (PTA = 31.6, SD = 12.7) postoperatively versus those with postoperative perforations (PTA = 32.4, SD 8.8) was not significantly different (p=0.8642) Therefore, preoperative PTA is not a predictor of anatomical success in BCIG surgery.

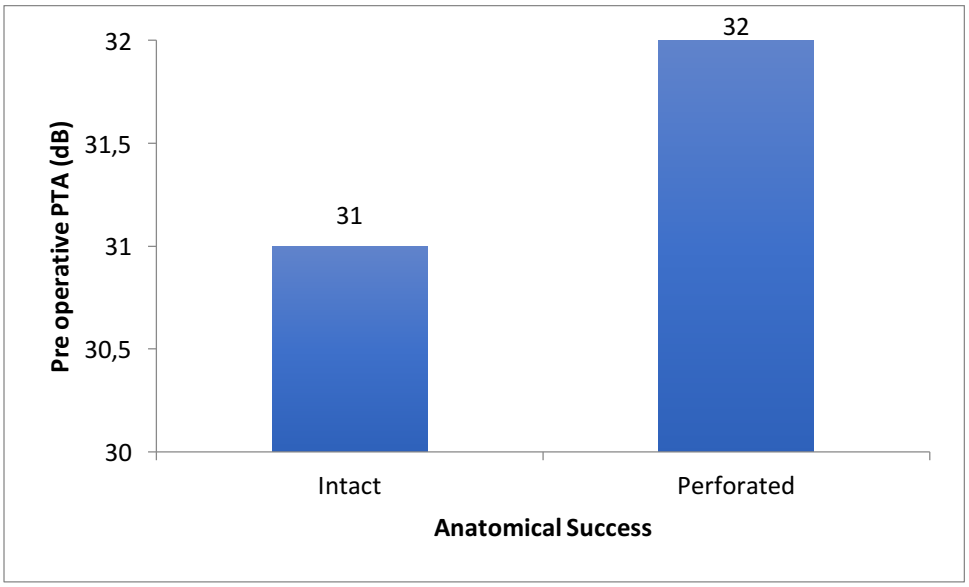

Figure 4.9: Preoperative PTA as a predictor of Anatomical success (p = 0.8642)

4.5.2.2 PREOPERATIVE PTA VERSUS FUNCTIONAL SUCCESS

As expected, the preoperative PTAs were significantly better in the <10 dB and 11-20 dB hearing improvement groups compared to the >21 dB group. (25.3dB, 28.6dB, 42.2dB respectively) ($p < 0.001$)

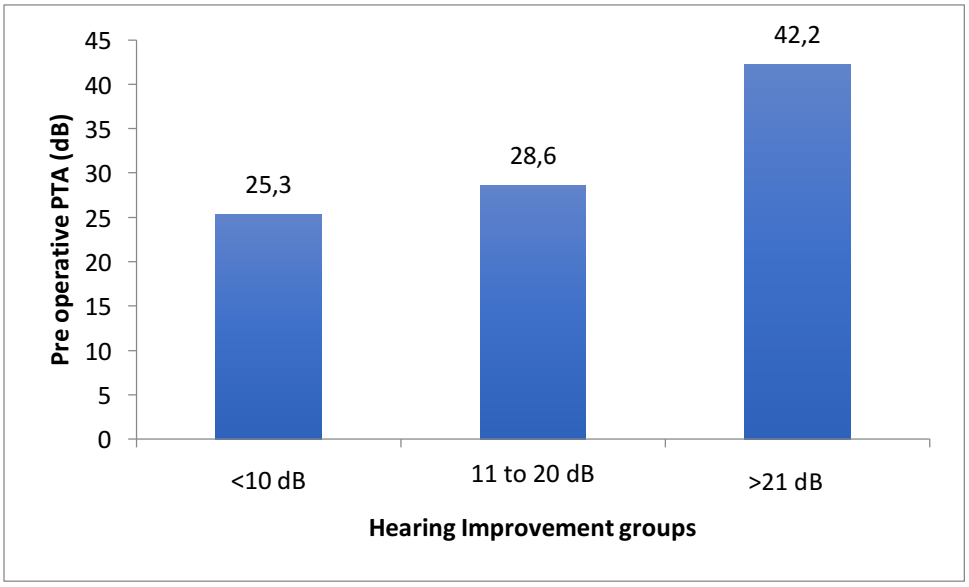

Figure 4.10: Preoperative PTA as a predictor of Hearing Improvement ($p < 0.001$)

4.5.3 PERFORATION SIZE:

Of the 85 patients in this study, 40% had small perforations, 49,4% had medium sized perforations and 10,6% had large perforations.

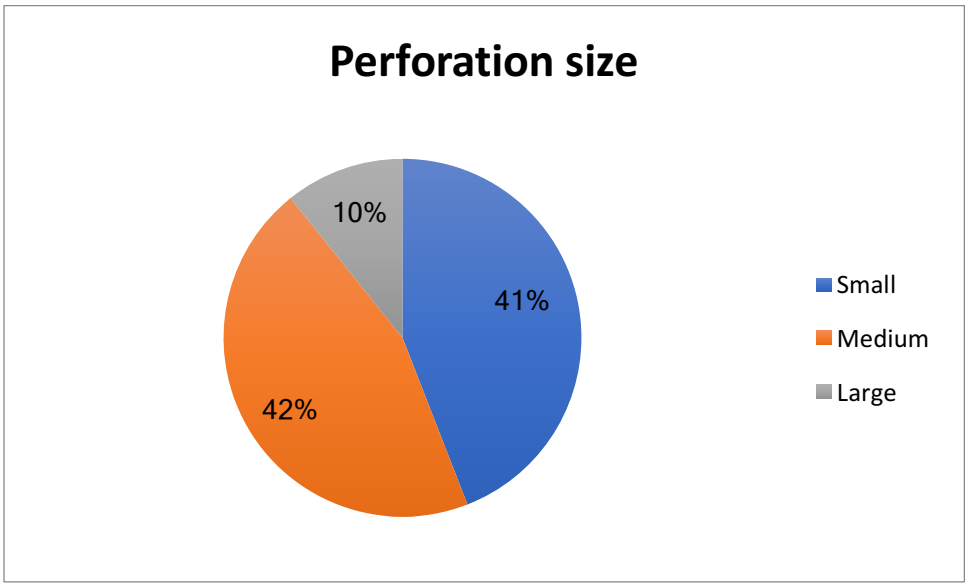

Figure 4.11: Perforation size. Small (0% - 40%), Medium (41% - 60%), Large (>60%)

4.5.3.1 AGE

The age of patients presenting with different perforation sizes is not statistically different. Patients with small perforations presented at the median age of 12,5 (range = 5 – 67), patients presenting with medium size perforations at the median age of 10 (range = 5 – 56) and large perforations at the median age of 10 (range = 6 – 16). (p = 0.2135)

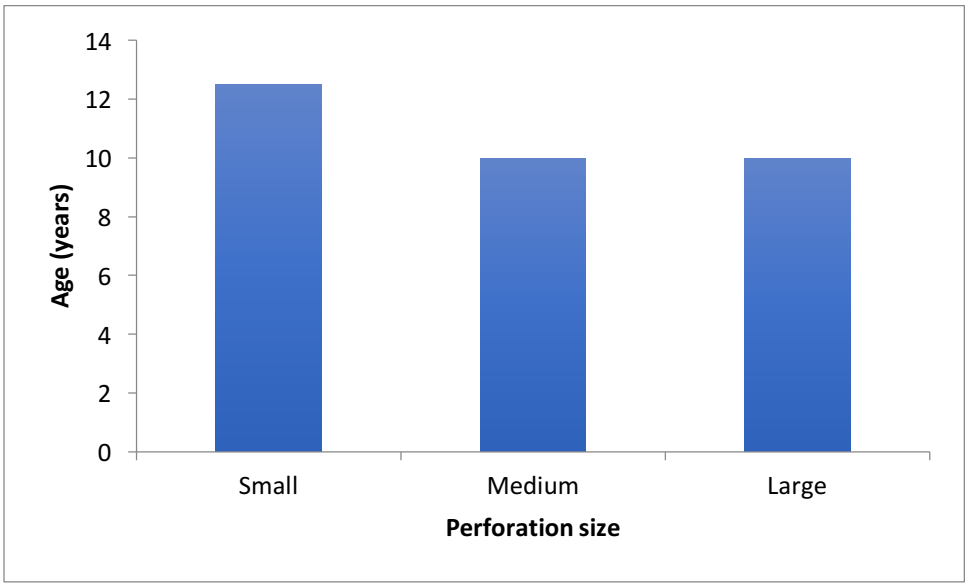

Figure 4.12: The Age of patients presenting with Small, Medium and Large Perforations.

4.5.3.2 PERFORATION SIZE AS A PREDICTOR OF ANATOMICAL SUCCESS

The size of the perforation does not predict if the surgery will be Anatomically successful or not. Anatomical success was equal for all 3 perforation sizes. Small (Intact 91,2%, Perforated 8,8%), Medium (Intact 88,1%, Perforated 11,9%) and Large (Intact 100%, Perforated 0%) (p = 0,5339)

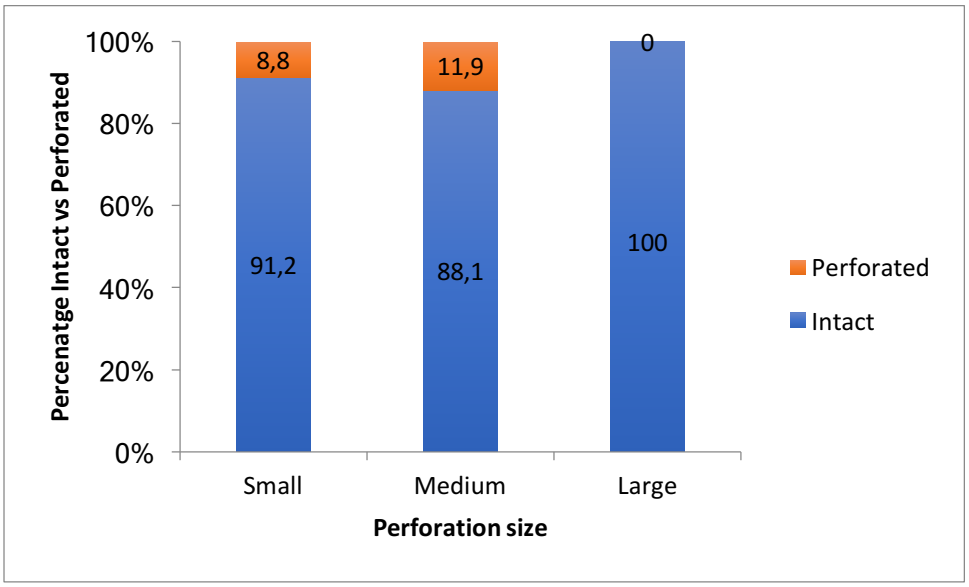

Figure 4.13: Perforation size as a predictor of Anatomical success

4.5.2.3 SIZE OF PERFORATION AS A PREDICTOR OF HEARING IMPROVEMENT

The size of perforation does not predict the amount of hearing improvement post BCIG. The group with small perforations had hearing improvement of 11,9 dB postoperatively, medium sized perforations had hearing improvement of 16,9 dB and large perforations had hearing improvement of 19,0 dB (p = 0,575)

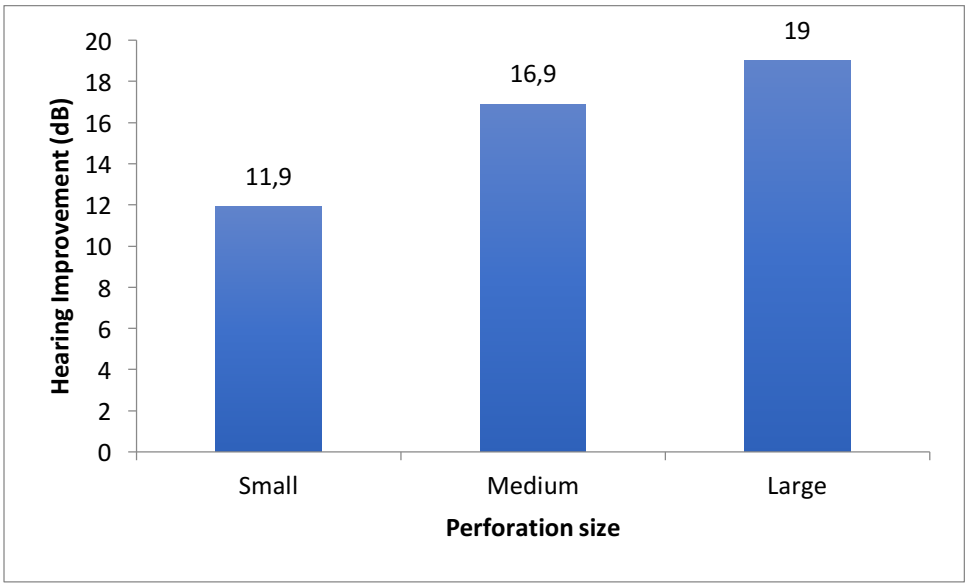

Figure 4.14: Perforation size as a predictor of Hearing Improvement

CHAPTER 5: DISCUSSION

The aims of this study were to assess the anatomical and functional success rates of Butterfly cartilage inlay graft myringoplasties done at Chris Hani Baragwanath Academic Hospital using an oto-endoscope. The size of perforation was then assessed to see if it had any predictive value for anatomical and functional success.

5.1 SUMMARY OF RESULTS

The data presented in this study show an anatomical success rate of 90,6% for Butterfly Cartilage Inlay Grafts at Chris Hani Baragwanath Academic Hospital. The anatomical success rate of this study is equal to the success rates reported in the literature for the same procedure. [1,2,3,4,5,6,7,8,11,13] 87% of patients experienced hearing improvement postoperatively. The average hearing improvement in this study post Butterfly Cartilage Inlay Graft is 15dB. Finally, perforation size does not influence both anatomical and functional success rates in this study.

Of the other predictive factors investigated, age and preoperative PTA are not predictors of success in this study.

5.2 LIMITATIONS

This study included both children and adults. Most studies in the literature either include adults [2,4,5,7,11,14] or children [1,6] as the aetiology of tympanic membrane perforations may be different in the 2 age groups. However, the operation has been found to be equally successful in both ages groups hence the reason that this study, like two others [3,13], grouped both age groups together.

There is no internationally accepted classification for tympanic membrane perforation size. Therefore, studies classify their perforation sizes differently. Some use percentage of total tympanic membrane [11], others number of quadrants involved [2,6,] size in millimetres [3,4,7] and still others classify it into number of thirds involved [1,13,14]. This makes comparing the results of studies difficult.

Similarly, functional success is reported differently in studies. Some look at the change in pure tone average (i.e.: actual hearing improvement) [1,2,3,4,6], while others report on closure of air bone gap. [5,7,11,13,14] Some studies that use change in PTA, use a 3-frequency average (500Hz, 1000Hz and 2000Hz) [1,4], others use a 4-frequency average (500Hz, 1000Hz, 2000Hz and 4000Hz) [6], while others don't report how they measure the PTA [3]. A study by Dawes *et al* found that the 3 and 4 frequency averages are significantly different. The study showed that including the 4000Hz value into the calculation of PTA resulted in fewer patients having a closure in ABG to within 10 dB or 20 dB. [15] Inconsistencies in the method of reporting hearing results in the literature make comparing of results difficult.

5.3 DISCUSSION OF RESULTS

5.3.1 DEMOGRAPHICS

This study included 85 patients, which makes it the second largest study looking at the success of Butterfly Cartilage Inlay graft procedures. Most studies look at smaller population groups. [1,2,3,5,6,7,13,14] The only study with a larger population group of 145 patients is the study by Monfared *et al*. [4]

The majority of the above-mentioned studies investigate BCIGs performed with the use of a microscope.[1,2,3,5,6,7,13,14] The current study investigated the success rate of endoscopic BCIG's.

5.3.2. ANATOMICAL SUCCESS

At the end of the 6 month follow up period, 90,6% of patients who underwent BCIG in this study had an intact tympanic membrane. The failure rate was 9,4%. This compares favourably to the results in the literature. Of the studies in the literature exclusively looking at anatomical success rate of BCIG, the anatomical success rate ranges from 67% to 100%. [1,2,3,4,13,14] The anatomical success rate of studies comparing BCIG and Fascia underlay myringoplasty report anatomical success rates for BCIGs of 82% - 96%. [5,7,6,14]

Interestingly, the Monfared *et al* study, which is the largest study assessing anatomical success rate of BCIG, also has the lowest anatomical success rate (67%). [4] A possible reason for the lower success rate could be that patients who had had previous, failed surgery to the same perforation were included the study. Previous failed surgery to the same ear may indicate poor candidate selection for the BCIG procedure. The reasons for prior failure are not stated in the

study. The author also contributes the fact that they included large perforations (perforations larger than 5mm) in the study and that larger perforations may not be amenable to in-office BCIG under local anaesthetic. [4]

The average follow up time in this study was 12 months (SD 7,2 months). 6 of the 9 studies in the literature had average follow-up times of between 6-12 months. [2,3,4,5,7,14] The remaining 3 studies followed up their patients for 22 – 24 months. [6,11,13] Despite the differences in follow up time; the anatomical success rate is similar between all studies.

5.3.3 FUNCTIONAL SUCCESS

87% of patients in this study showed an improvement in hearing, 5% had no change in hearing and 7% had worse hearing postoperatively. However, there was no significant difference when hearing improvement was grouped quantitatively into groups (<10db improvement, 11-20dB improvement, >21dB improvement).

Most studies in the literature showed some form of hearing improvement in 75% – 96% of patients. [1,2,3,4,5,6,7,11,13,14] As mentioned in the limitations section, it is difficult to compare the study's results, including the current study, since functional success rates were quantified in different ways. However, 7 out of the 9 studies did show hearing improvement in over 90% of patients, which indicates that BCIG's results in hearing improvement in the majority of cases. [1,2,3,4,5,6,7,14] The remaining 2 studies showed a more modest result of 79% and 76% hearing improvement. [11,13] The Lin *et al* study that showed 79% overall hearing improvement further stratified their data and found that 92% patients under the age of 60 years had hearing improvement, compared to 64% of patients over the age of 60 years. Therefore, the inclusion

of older patients into their study resulted in a reduction in overall hearing improvement. [11] The Hod *et al* study, which showed 76% hearing improvement, included 3 patients whose ABG indicated ossicular chain lesions. This could be the reason for the reduced improvement in hearing in this study. [13]

5.3.4. PREDICTORS OF ANATOMICAL AND FUNCTIONAL SUCCESS

5.3.4.1 Age

The median age of patients in this study was 11 years (range: 5 – 67 years). More of the patients in this study were in the paediatric age group (age <13 years, n=52), but adults (age >13 years, n=33) were included as well. As previously discussed in the Limitations section of this thesis, most studies separate the age groups. But since the results for BCIG in children and adults are similar in the literature, the 2 age groups were grouped together in this study.

The results of this study have shown that age is not a predictor of anatomical and functional success in BCIG procedures. This is in keeping with the results in the literature for BCIG procedures. [4,] Furthermore, a review article by Sarkar *et al* showed that age is not a predictor of success in tympanoplasty in the children's age group either. [16]

5.3.4.2 Preoperative PTA

The preoperative PTA was not a predictor of anatomical success in this study. When looking at hearing improvement, patients with lower preoperative PTA showed the least improvement in hearing postoperatively (< 20dB improvement). This makes sense since patients who have

better hearing preoperatively only require a small improvement postoperatively to reach normal hearing limits. Inversely, the larger the tympanic membrane perforation, the worse the preoperative PTA and therefore more room for improvement with a healed tympanic membrane postoperatively.

The only other study that has looked at preoperative PTA as a predictor of success is the study by Monfared *et al.* [4] They showed that a lower preoperative PTA was a predictor of both anatomical and functional success. However, the lower preoperative PTA was attributed to smaller perforations and hence the better outcome. [4]

5.3.4.3 Perforation size

Perforation size was not found to be a predictor of anatomical and functional success in this study. The median age was not significantly different between small, medium and large perforation groups. Hearing improvement was similar between all 3 sizes.

The literature has confounding results in this regard. Monfared *et al* showed that large perforations (>5mm in diameter) are associated with increased failure rate. [4] Whereas, Lin *et al* showed that hearing improvement was better with larger perforations (perforation > 50% of tympanic membrane). However, anatomical success rates were not influenced by perforation size. [11] Hods *et al* results, similar to the current study, showed that the size of perforation did not influence success rates. [13] Furthermore, Dornhoffer, who assessed audiological results in cartilage tympanoplasties, found that hearing improvement in subtotal perforations was equal to those for small perforations. [17] Therefore, the lack of consensus in the literature in this regard as well as a lack of universal scoring system for size of perforation, leaves this point open for debate.

5.4 ENDOSCOPIC BCIG

The overall anatomical and functional success rates of BCIGs at Chris Hani Baragwanath Academic Hospital are similar to results reported in the literature. It is important to highlight that the majority of the previously mentioned studies were performed with the use of a microscope. All the BCIGs in the current study were performed with the use of an oto-endoscope. One study has looked at the success of BCIGs done endoscopically. The study showed that endoscopic BCIGs were as successful as microscopic BCIGs. [18] The current study, together with the Akiyigit *et al* study, prove that endoscopic BCIGs are equally as effective as the initially described BCIG, which is performed with the use of a microscope.

Furukawa *et al* compared the outcomes of myringoplasties performed with a microscope to those performed with an oto-endoscope. He found that the oto-endoscope lent better visualisation of the tympanic membrane and that the surgery was less invasive as tympanomeatal flaps and canaloplasty were often avoided. [9] Since large post auricular and endaural incisions are avoided in Endoscopic ear surgery, there is less pain and bleeding and improved postoperative cosmesis. The oto-endoscope can also be used to enter the middle ear through the perforation for examination of middle ear contents. The limitations of endoscopic ear surgery are that it is a 'one-handed' surgery and may initially take some getting used to. [9,10]

5.5 CONCLUSION

Endoscopic BCIGs performed at Chris Hani Baragwanath Academic Hospital, for small, medium and large perforations, show anatomical and functional success rates similar to those

reported in the literature, performed with both microscope and oto-endoscope. Size of perforation is not a predictor of anatomical and functional success for this procedure.

These results are valuable since oto-endoscopes are far cheaper than microscopes. In settings similar to those of Chris Hani Baragwanath Academic Hospital where resources are scarce, doctors can be trained to do endoscopic ear surgery thereby helping more people.

5.6 RECOMMENDATIONS

HIV is a burden on the South African Health System. HIV positive patients often present to the ENT departments with CSOM. I would recommend assessing BCIGs in the HIV population to assess the practicability of performing BCIGs endoscopically on these patients.

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APPENDIX 1

Butterfly Cartilage Inlay Graft Myringoplasty at Chris Hani Baragwanath Academic Hospital (2009 – 2013)

Data Collection Sheet

Study Number | |

1. Date of surgery: _____
2. Age: _____
3. Sex: _____

4. Size of perforation:

Small (≤40 %)	Medium (41% - 60%)	Large (≥61%)

5. Audiometry (in dB)

Preoperative Pure Tone Average	
Preoperative Air bone gap	
Postoperative Pure Tone Average	
Postoperative Air bone gap	

6. Postoperative findings at follow up: Intact TM = I Residual perforation = P

2 weeks	
6 weeks	
6 months	

APPENDIX 2 – Ethics Clearance certificate

R14/49 Dr Natasha AG Morgado and Prof P Modi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160514

NAME: (Principal Investigator)	Dr Natasha AG Morgado and Prof P Modi
DEPARTMENT:	Neurosciences Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Butterfly Cartilage Inlay Graft Myringoplasty at Chris Hani Baragwanath Hospital (2009 - 2013)
DATE CONSIDERED:	27/05/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr S Motakef
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	15/06/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated,from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review in May and will therefore be due in the month of May each year.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 3 – CHBH ENT Department Ethics Clearance letter

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Chris Hani Baragwanath Academic Hospital
Department of Surgical - ENT
P.O. Bertsham
2013
Tel: +27 11 933 8118

27/04/2016

TO WHOM IT MAY CONCERN

ETHICS COMMITEE

RE: PERMISSION TO DO REASEARCH AT CHRIS HANI BARAGWANATH HOSPITAL, ENT DEPARTMENT

This letter serves to grant permission to Dr Natasha Morgado(MP0679496) to conduct research at Chris Hani Baragwanath Hospital, Department of ENT.

Title of research:
Butterfly Cartilage Inlay Graft Myringoplasty at Chris Hani Baragwanath Hospital (2009 – 2013)

- It is a Retrospective patient record review.
- Patient records are kept in to ENT OPD.
- All patients who had a Butterfly cartilage inlay graft from 1/01/2009 – 31/12/2013 will be included
- The discharge summaries will be reviewed and data taken from the discharge summary
- Variables to be extracted:
  - Pre operative Audiogram findings
  - Post operative Audiogram findings
  - Size of perforation
  - Graft take/failure on follow up

Regards,

.....
DR R. AHMED

APPENDIX 4 – CHBH Ethics Committee clearance certificate

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 11 May 2016

TITLE OF PROJECT: Butterfly cartilage inlay graft myringoplasty at Chris Hani Baragwanath Hospital (2009-2013)

UNIVERSITY: Witwatersrand

Principal Investigator: N Morgado

Department: ENT

Supervisor (If relevant): S Motakef

Permission Head Department (where research conducted): Yes

Date of start of proposed study: May 2016
Date of completion of data collection: Dec 2018

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 11 May 2016

.....
Approved/Not Approved
Hospital Management
Date: 12/05/16

R14/49 Dr Natasha AG Morgado and Prof P Modi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160514

NAME: (Principal Investigator)	Dr Natasha AG Morgado and Prof P Modi
DEPARTMENT:	Neurosciences Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Butterfly Cartilage Inlay Graft Myringoplasty at Chris Hani Baragwanath Hospital (2009 - 2013)
DATE CONSIDERED:	27/05/2016
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CONDITIONS:	
SUPERVISOR:	Dr S Motakef
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	15/06/2016

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Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

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