

**ASSESSMENT OF OUTCOMES OF HEARING AND SPEECH IN
COCHLEAR IMPLANT RECIPIENTS**

A Dissertation Submitted to

**THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY,
CHENNAI - 600032**

In Partial Fulfillment of the Regulations for the Award of the Degree of
M.S. IN OTO-RHINO-LARYNGOLOGY

DONE BY

Dr. JERIL

REG NUMBER: 221914402



**DEPARTMENT OF OTORHINOLARYNGOLOGY
PSG INSTITUTE OF MEDICAL SCIENCE AND RESEARCH**

**THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY,
CHENNAI, TAMILNADU**

2019-2022

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2019-2022

CERTIFICATE

This is to certify that the thesis entitled “**ASSESSMENT OF OUTCOMES OF HEARING AND SPEECH IN COCHLEAR IMPLANT RECIPIENTS**” is a bonafide work of **Dr. JERIL** done under the direct guidance and supervision of **Dr. A. DAYANAND, MBBS, DLO, DNB**, in the department of Otorhinolaryngology, PSG Institute of Medical Sciences and Research, Coimbatore in fulfilment of the regulations of **The Tamil Nadu Dr.MGR Medical University, Chennai** for the award of M.S. degree in ENT.

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I solemnly declare that this dissertation “**ASSESSMENT OF OUTCOMES OF HEARING AND SPEECH IN COCHLEAR IMPLANT RECIPIENTS**” was prepared by me at PSG Institute of Medical Sciences and Research, Coimbatore, under the guidance and supervision of **Dr. A. DAYANAND, MBBS, DLO, DNB (ENT),** Associate Professor, Department of Otorhinolaryngology, PSG Institute of Medical Sciences and Research, Coimbatore. This dissertation is submitted to **The Tamil Nadu Dr. M.G.R. Medical University, Chennai** in partial fulfillment of the University regulations for the award of M.S. Degree in ENT.

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ETHICS COMMITTEE APPROVAL



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Ref. No.: PSG/IHEC/2020/Appr/Exp/053

February 13, 2020

To
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Postgraduate
Department of ENT
Guide: Dr Dayanand A
PSG IMS & R
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Ref: Project No. 20/006

Dear Dr Jeril,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 09.01.2020 to conduct the research study entitled "Assessment of outcomes of hearing and speech in cochlear implant recipients" during the IHEC meeting held on 17.01.2020.

The following documents were reviewed and approved:

1. Project submission form
2. Study protocol (Version 1 dated 09.01.2020)
3. Application for waiver of consent
4. Confidentiality statement
5. Data collection tool (Version 1 dated 09.01.2020)
6. Current CVs of Principal investigator, Co-investigator
7. Budget

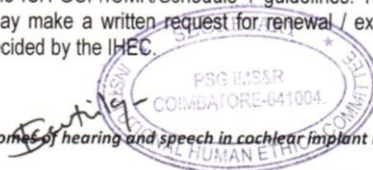
The following members of the Institutional Human Ethics Committee (IHEC) were present at the expedited review meeting held on 17.01.2020 between 10.00 am and 11.00 am:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Dr Rajani Sundar (Chairperson, IHEC)	MD, DA	Clinician	Female	No	Yes
2	Dr S Karthikeyan (Member - Secretary, IHEC)	MD	Epidemiologist, Ethicist	Male	Yes	Yes
3	Dr A Jayavardhana	MD	Clinician, Paediatrics	Male	Yes	Yes
4	Mrs M Nirmala (Alt. member-Secretary, IHEC)	M Sc	Nursing	Female	Yes	Yes

The study is approved in its presented form for the stated sample size. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

Proposal No. 20/006 dt. 13.02.2020, Title: Assessment of outcomes of hearing and speech in cochlear implant recipients

Page 1 of 2





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Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
 - a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
 - b. Variation in the proposed sample size
 - c. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
 - d. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
 - e. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
 - f. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented
 - g. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review
7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,

Dr S Karthikeyan
Member-Secretary
Institutional Human Ethics Committee



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INTRODUCTION

Communication is greatly important in everyday life for us in the world where we live in, so as to satisfy the needs of every individual and it is true that the society at large as well exchange information among and within through communication only. Communication basically helps to inform or exchange messages and information. This is done using the process of speaking or writing or exchanging ideas or many other means. Accordingly, it's considered as a method of creating and sharing and spreading ideas, information, facts, and feelings within individuals and a group or large mass in such a way to reach to a point of a common understanding. Remunerations and the earning acquired through employment are the basis and it is the fundamental need for people to manage their livelihood. In this context, the communication skills are considered to be one of the most important basic requisite for securing employment for which learning processes the fundamental being first and foremost. According to internet data and information, an international statistics indicates that employment is offered to 71% men and 91% women on the basis of the communication skill of the individuals. From the foregoing, it is to be taken into account that communication is very essential for human for their living and survival. Communication plays a very vital role in the life of all living things in the world, more predominantly speaking skills for the human by all means.

In human being, communication ability is developed from childhood stage itself. In general, childhood speech and linguistic development is a multifactorial process. This depends upon many factors, which includes age of the child, ethnic background and also

the process of verbal communication followed at home, originated from the parents. Hearing impairment can impede normal speech development at large. For children to develop speaking skills, hearing ability of the children is the most important aspect. Due to which, it is indeed an essential need to be placed on top most priority for identifying such hearing deficiency at early age of childhood stage and appropriately setting it right at childhood stage itself assumes importance, helping proper child development with adequate hearing ability.

In modern world, audiological, medical, educational intervention are the ones which can help for early identification of such hearing impairment. This helps to maximize the potential of the children by aiding hearing and thereby facilitating speech development at the early childhood stage. Identifying and comprehending the repercussions of hearing impairments, as well as the related medical conditions, is a challenge. At the same time, it is also critical to provide the best opportunity for the child and parents to make well informed and educated decisions and to involve them in a proper decision making in terms of plans for the future of their children.

Given the above context, the subject study and this thesis definitely sheds more light on the subject matter in correlation with the most recently available information along with modern options available for the parents to choose to provide adequate and necessary care on the hearing ability of their children. With the back drop of this scenario, this project paves a way forward on the strategy as to how and what more that

can be done for the betterment and normal growth of the children focusing more on their hearing ability facilitating its associated self-development.

AIMS AND OBJECTIVES

AIM

This project is aimed at focusing on evaluating the post-operative outcomes of the children in speech and hearing capability of the Cochlear implant recipients.

The level of improvement in terms of speech and hearing aspects are assessed to correlate as to how the Cochlear implant can stimulate the speech capability of the impaired children, while detailing the historical development of the Cochlear implants and its successful applications of the modern medical aid and technique.

OBJECTIVE

The objective is to undertake data analysis pertaining to hearing aid implant done for the children and detailed study evaluating the post-operative outcomes of the children in speech and hearing in Cochlear implant recipients on the basis of the primary data sourced from the health records from the hospital and subsequent evaluation and analysis with appropriate interpretations thereon.

REVIEW OF LITERATURE

OVERVIEW OF HEARING IMPAIRMENT AND HEARING LOSS

Hearing loss in children is stated to be very common occurrence and all across the world almost 1 in every 5 children suffers the same. It is to be noted that hearing loss is the most important factor that can cause detrimental effects on the speech, language, education, and intellectual outcomes in children.

Though the Hearing loss in children is caused by many reasons and conditions, the most predominant and prevalent factors, reasons and causes are tabulated here below with their corresponding percentage attributed by these factors within the affected population from the world wide statistical references.

**TABLE-1: CAUSES AND DISTRIBUTION OF CONGENITAL HEARING LOSS
IN CHILDREN**

Sl. No.	Factors and Causes for Hearing Loss in Children	Affected population (on the basis of worldwide statistics)
1	Genetic Reasons / Causes	50 to 60% of the Children
2	Maternal infection during pregnancy and complications after birth	25% of the Babies

In addition to the above, there are several other things that can cause hearing loss in children. Unfortunately there are no proven statistical references as to what percentage of children are affected due to this. However, it is well recognized that the environment attributes significantly toward hearing loss in children.

On the basis of the etiology of hearing loss, the hearing loss can be classified according to the details described here under:

THE ETIOLOGY OF HEARING LOSS AND ITS CLASSIFICATIONS

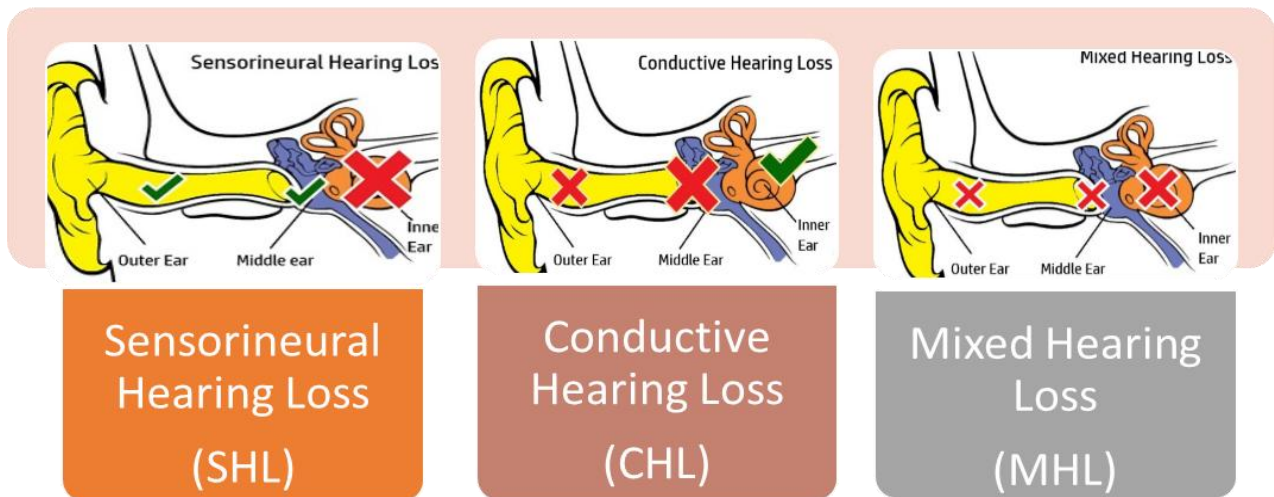


FIGURE-1: TYPES OF HEARING LOSS

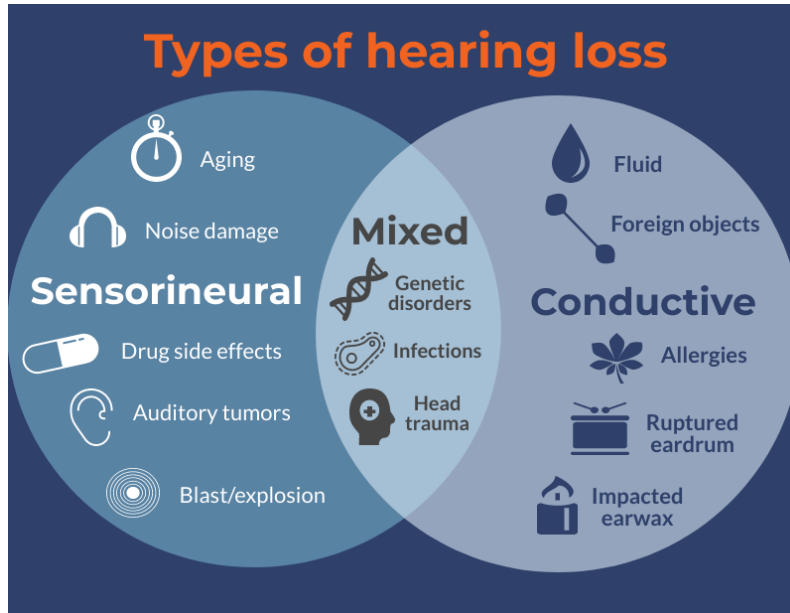


FIGURE-2: CAUSES OF HEARING LOSS

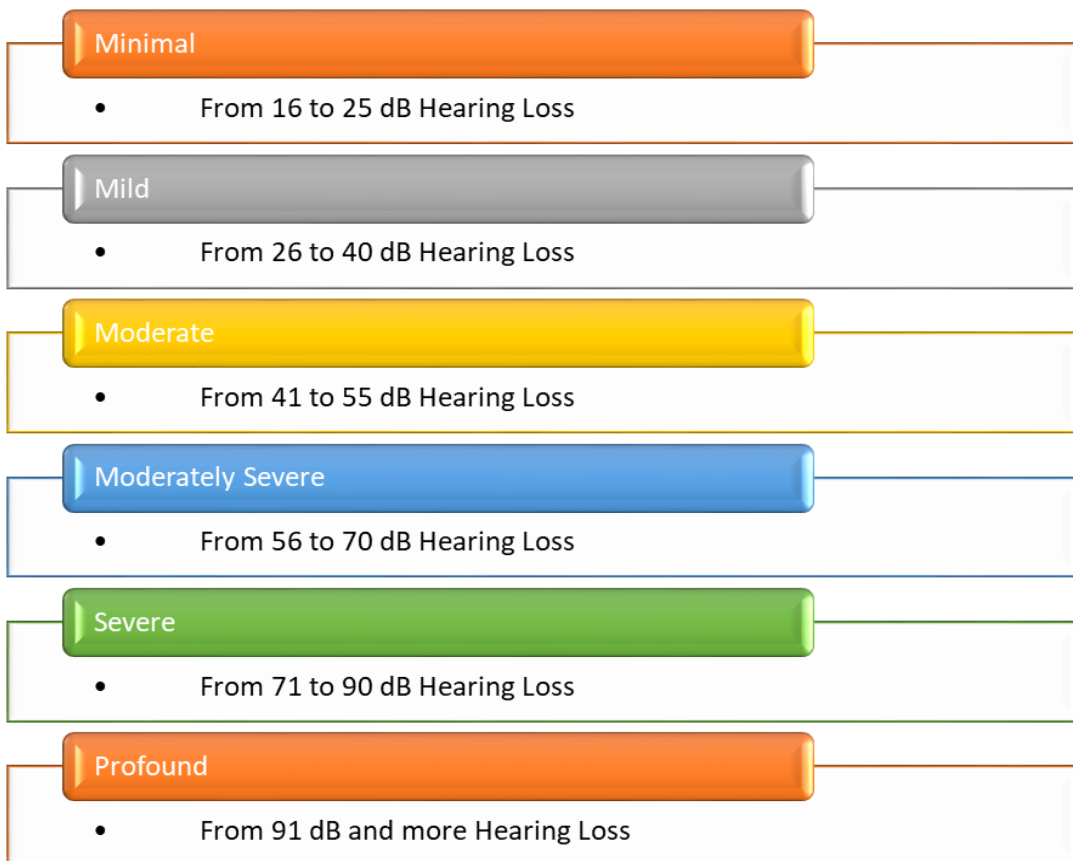


FIGURE-3: GRADING OF HEARING LOSS

The diagnosed type in terms of unilateral or bilateral, the severity and the age are the basis of deciding the management of hearing loss and done accordingly. If hearing loss is shown up and picked up at early age, all such kind of severe to profound bilateral SHL can be managed by Cochlear implantation for either unilateral or bilateral conditions. Conventional hearing aids are considered best suited and easy to manage mild to moderate bilateral SHL. CHL has less impact on the speech development of the child as compared to SHL deafness. Such cases are generally managed by rectifying the underlying etiology for example: otitis media with effusion, sometimes surgical procedures, external ear atresia and/or ossicular malformations.

Unilateral SHL does not have any impact on the language development of children and due to which it may be passed undiagnosed until preschool-ages. The Newborn Hearing Screening Program at national level has helped to improve the management of such affected children. Rehabilitating these children at their early stages paves way and helps for normal speech and development. Different diagnostic and therapeutic approaches are adopted for deaf children after assessing the causes of pediatric hearing loss.

COCHLEAR IMPLANT

Cochlear implant is a tiny, compact, electronic device helps provide the sense of sound to the person with profound deafness. These device consists electrode array. Such electrodes are implanted into the cochlea through a professional surgery. Using electric

current, these electrodes are made functional and operated, which is then used in turn to stimulate the auditory nerve fibers ²⁵ (Wilson, 2000). The Cochlear implant has an external part that is fitted behind the ear whereas the other part is surgically placed/implanted.

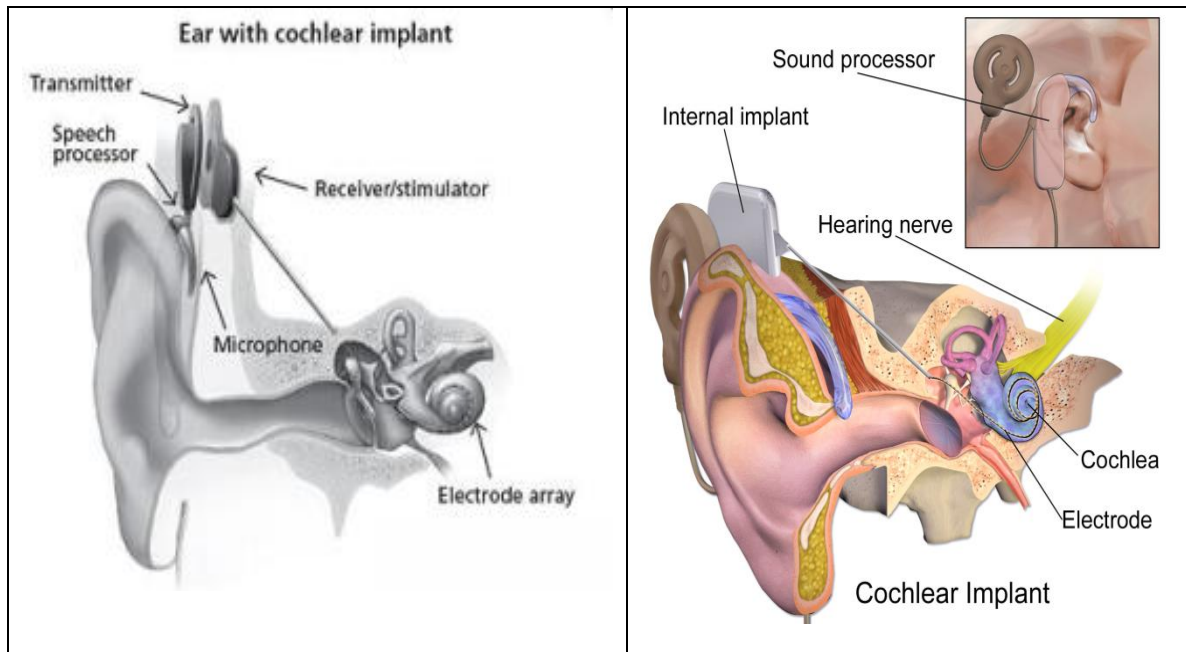


FIGURE-4: COCHLEAR IMPLANT SYSTEM

It comprises of the following:

- A microphone
- A Speech processor
- A transmitter and stimulator
- An electrode array

The sound is picked up by the microphone from the environment around. The sound thus picked up by the microphone from the surrounding is then arranged in the speech processor. The speech processor converts the signals from the transmitter and receiver/stimulator into electrical impulses. All the impulses from the stimulator are collected by a group of electrodes and sends them to various regions of the auditory nerve.

It is to be noted that an implant does not restore normal hearing. However, it provides a useful representation of sounds of the environment to the deaf person helping them to understand speech.

HOW DOES A CI WORK?

A Cochlear Implant(CI)can never be considered as a hearing aid, because the function of hearing aids is just amplifying sounds, in order that the sound can be detected by damaged ears. Whereas, the Cochlear Implants directly stimulate the auditory nerve, bypassing all the damaged portions of the ear.CI generates signals and sent to the brain through the auditory nerve. Then these electrical signals are recognized as sound. Hearing using Cochlear implant will not be similar to normal hearing. It may take time to recognize and to learn and understand. CI now facilitates many people and aids them now to interpret sounds from the environment, and also to hear speech of other persons and also through and over the phone. All such wonders are directly attributed to the modern world Cochlear Implant Systems.

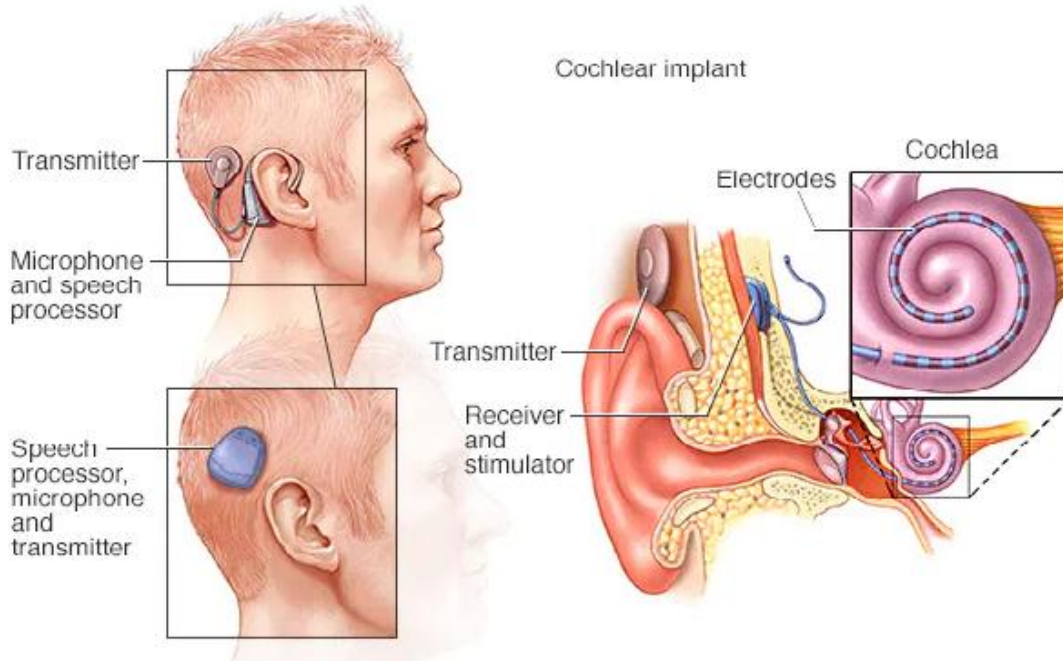


FIGURE-5: COCHLEAR IMPLANT INSTALLATION

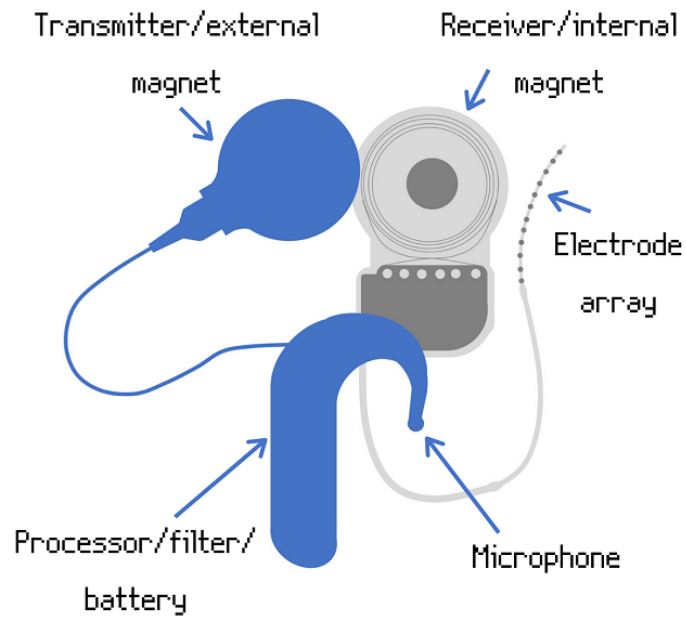


FIGURE-6: PARTS OF COCHLEAR IMPLANT SCHEMATIC-1

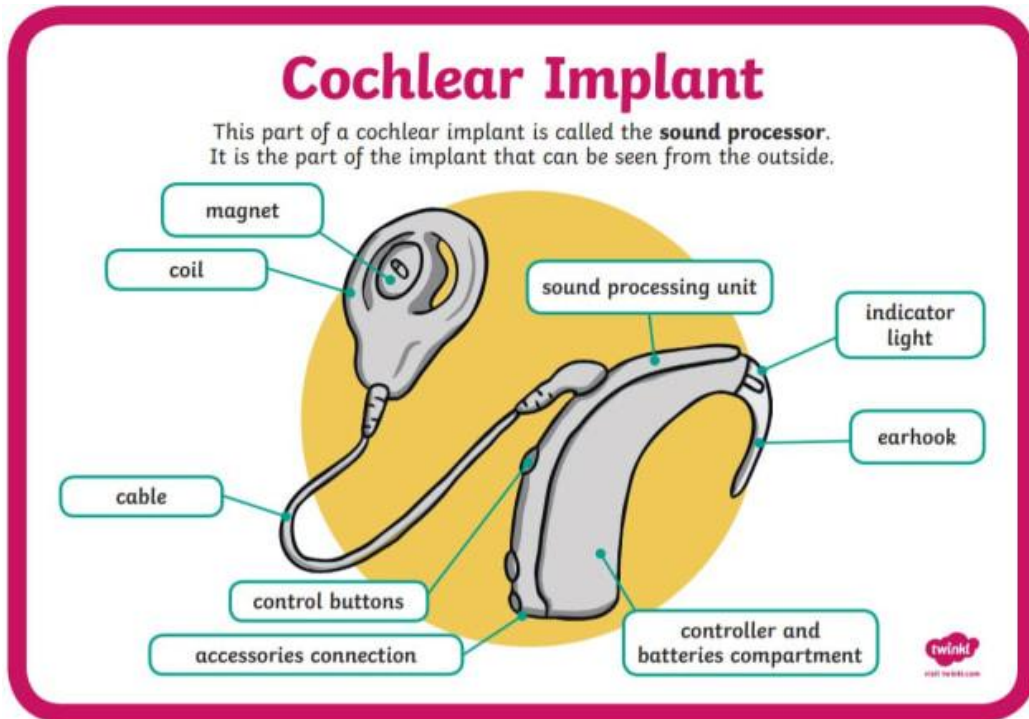


FIGURE-7: PARTS OF COCHLEAR IMPLANT SCHEMATIC-2

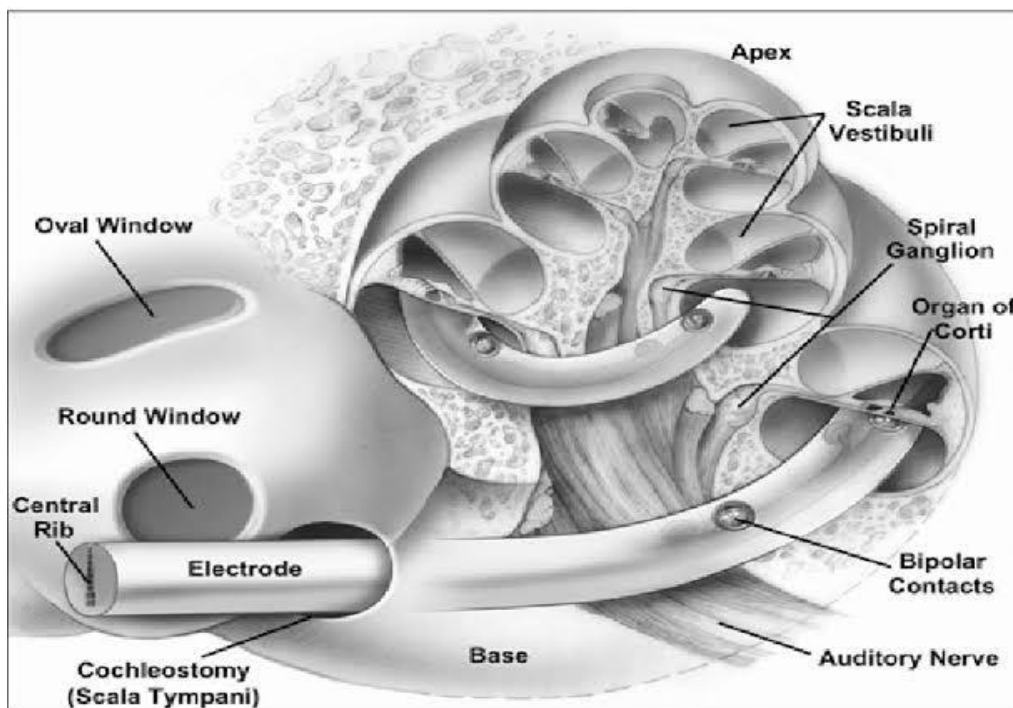


FIGURE-8: ELECTRODE ARRAY PLACEMENT IN INNER EAR

Outer components of the auditory system are responsible for hearing sound, accordingly there used to be movements in the cochlea hair cells. Owing to the above as a result, the hair cells do release potassium ions as a response corresponding to the movement of the hair cells. This potassium then stimulates the hair cells to release neurotransmitters, like glutamate. This activates the Cochlear nerve sending signals to the brain experiencing sound. This is how the normal sound perception is heard by normally hearing individuals.

The CI device is used to pick up the sounds and thereafter digitize. Such digitized sounds are then converted into electrical signals. These signals are then transmitted to the electrodes embedded within the cochlea. These electrodes then electrically stimulate the Cochlear nerve sending signals to the brain.

The historical development of the Cochlear implants with reference to the respective sections of the study results, literatures and the theory based educational materials are also picked up from different sources and are compiled here for providing an overview and overall concepts on the subject matter.

However, the following are further supplementary information added on to the previous sections as a matter of facts collated as a result of review of the literatures pertaining to the subject matter.

In a Study of assessment of outcomes in hearings and speech rehabilitation in children published in Journal of otology Volume 14, Issue 2, Ninety-eight patients with

bilateral severe-to-profound sensorineural deafness who received unilateral Cochlear implantation at Yijisan Hospital of Wanan Medical College from July 2013 to October 2015 were included in this study. All patients were diagnosed with bilateral severe-to-profound sensorineural deafness through preoperative experimental examinations, middle ear mastoid process CT, head MRI and inner ear three-dimensional imaging, brainstem evoked potential, hearing tests and acoustic impedance examinations. Among them 51 were male and 47 were female. Seventeen of the patients had pre-lingual deafness, and 81 patients had post-lingual deafness. Two of the patients received Cochlear implantation on the left side and 96 cases received implantation on the right side; the youngest patient was 1 year old and the oldest was aged 16, with an average age at implantation of 8.86 ± 3.66 years. Group A included 10 patients under 3 years of age, group B included 26 patients aged between 4 and 7 years, and group C included 62 patients aged between 8 and 16 years. All subjects received hearing and speech rehabilitation training at various hearing rehabilitation centres in Anhui Province for 1 year after Cochlear implantation. The study was reviewed and approved by the Ethical Committee of Yijishan Hospital.

All patients had bilateral severe-to-profound sensorineural deafness and met the requirements set out in the guidelines for Cochlear implantation (2013) (*Editorial board of Chinese Journal of Otorhinolaryngology Head and Neck Surgery et al., 2014*). The Hiskey-Nebraska Test of Learning Aptitude was used to test the patients over 3 years of age, and the Griffith Psychological Development and Behaviour Scale was used to test the patients under 3 years of age.

Review of the literatures shed more light on the methodology and the evolution phases of the Cochlear implant and its derived benefits.

OVERVIEW ON SENSORINEURAL DEAFNESS

Sensorineural deafness is one of the key factors affecting the health and quality of life of human beings. Following pictorial representations are added to explain the Sensorineural hearing loss and deafness.

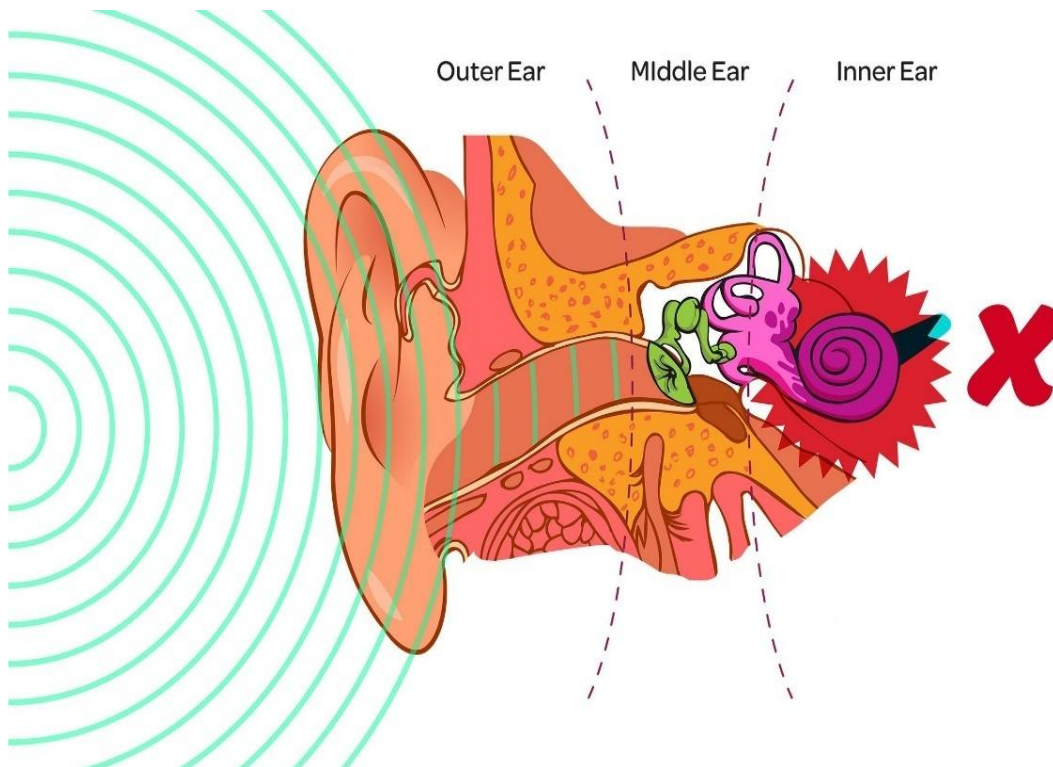
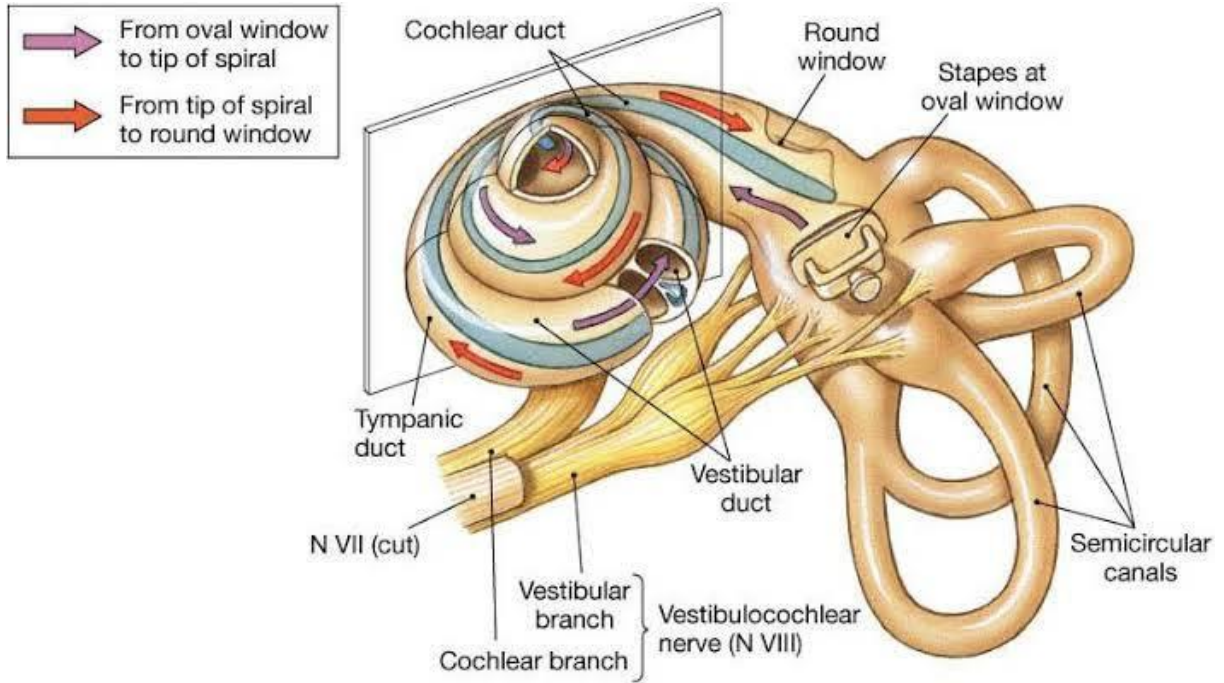


FIGURE-9: SENSORINEURAL DEAFNESS



(a) Structure and orientation of the cochlea

FIGURE-10: INNER EAR ANATOMY

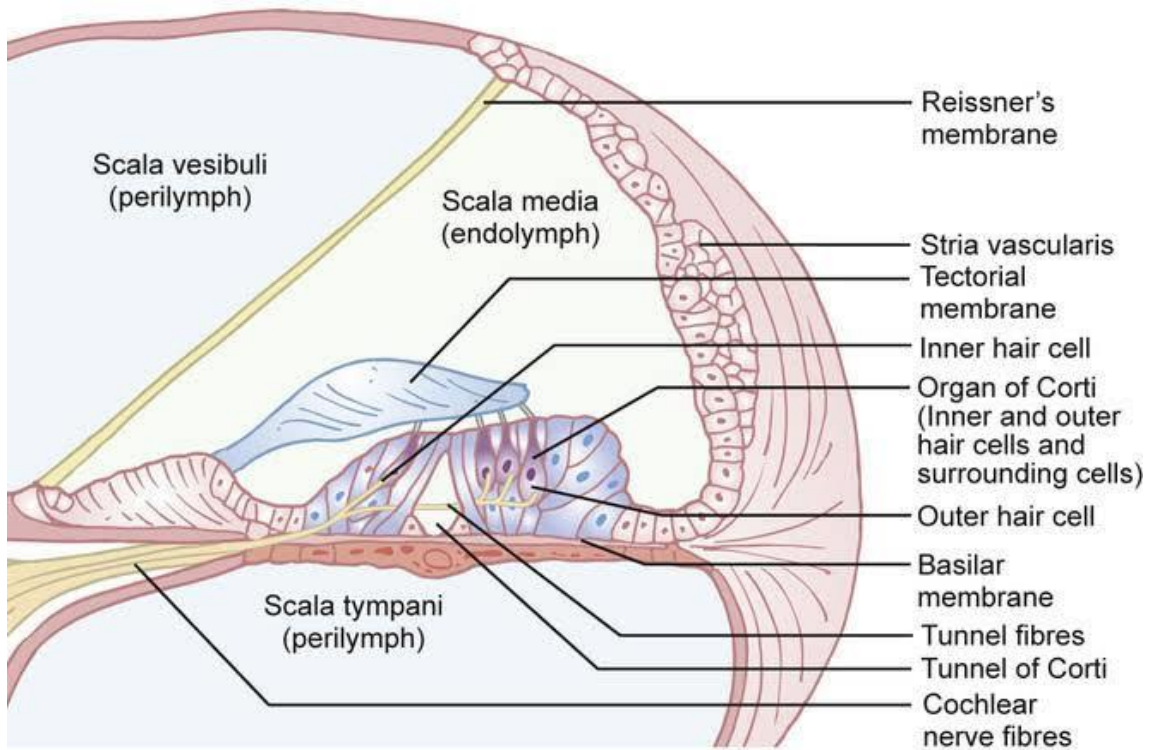


FIGURE-11: ORGAN OF CORTI- END ORGAN OF HEARING

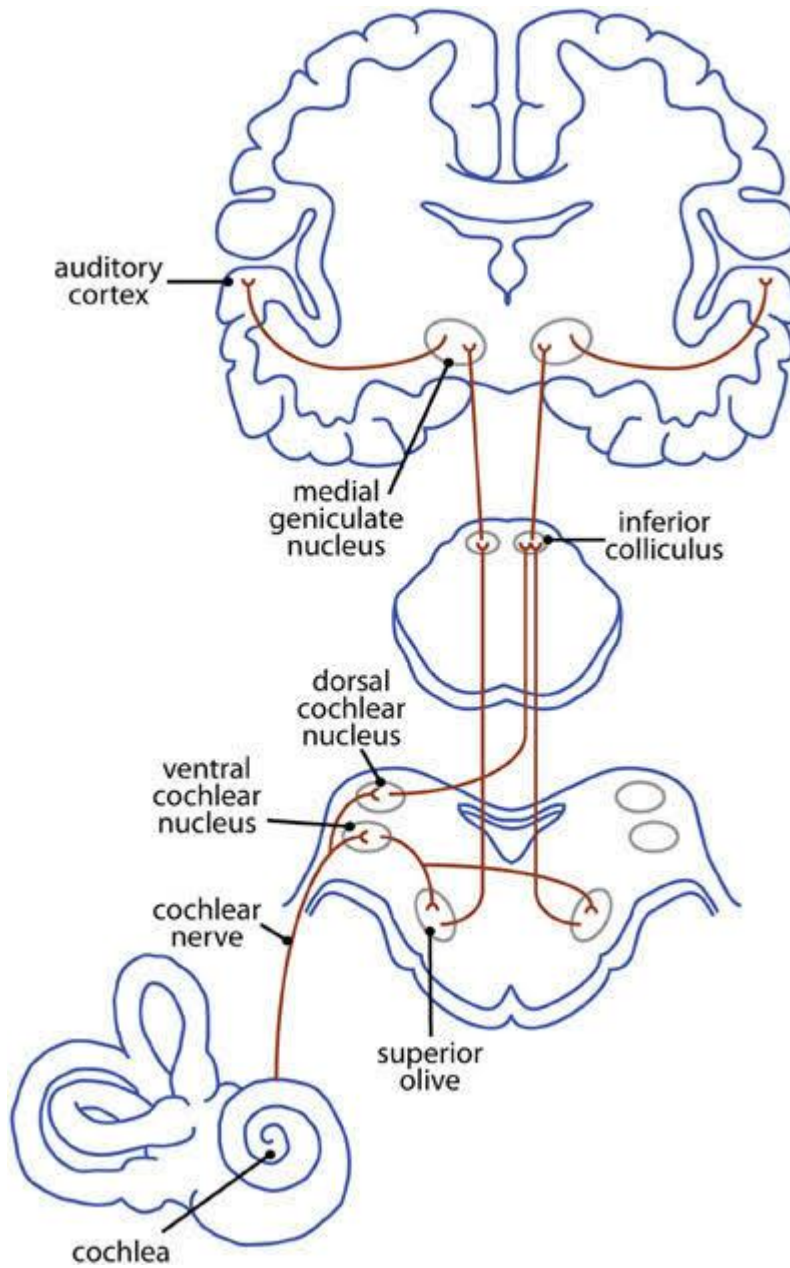


FIGURE-12: AUDITORY PATHWAY

A recent survey indicated that compared with people with normal hearing, the mortality risk of people with moderate and mild hearing loss was increased by 39% and 21%, respectively²³(*Contrera K.J., Betz J., Genter D.J 2015*). In addition, hearing loss negatively impacts patients' cognitive, psychological and physiological function to some extent²³(*Contrera K.J., Betz J., Genter D.J 2015*). A Cochlear implant (CI) is a special electronic device that can convert acoustic energy into electric energy. The external acoustical signal is converted and processed into electrical stimulation signals, which can replace the function of the damaged hair cells of the inner ear to stimulate the auditory nerve and finally produce auditory signals. Cochlear implantation is considered as one of the best options to restore the hearing of patients with severe-to-profound deafness and to help them return to the world of sound²⁴(*Russell et al., 2013*).

HISTORICAL OVERVIEW OF COCHLEAR IMPLANT

The following section provides an overview of the history of Cochlear implantation. The Cochlear implant technologies, and outcomes, are continuously evolving, however, the history has been compiled here on the basis of the currently available information worldwide.

CI is used since the 1980s for providing treatment for the patients with profound, sensorineural hearing loss. At the beginning of CI era, the first CI units and devices were made of single-channel based. Now a days, as technology improves, further more technological developments are in place thereby multichannel CI systems are now made

available in the market. Of course, in the past couple of decades, further more technological advancements in CI designs have taken place and which now brings out considerable improvements in the new designs of the multichannel Cochlear implant bringing more benefits in terms of spoken word recognition. At first, the adults with post lingual profound SHL were the only considered suitable. Now, audiometric thresholds are not considered anymore as a key predictor for Cochlear implant candidacy selection. Whereas, congenitally deaf children, were not thought to be good candidates for multichannel Cochlear implantation. Initially, when implantation of children was first permitted globally, only children aged 2 and up were taken up for surgery, but nowadays, multichannel Cochlear implants can be used in pre-lingually deafened children even from the early stage starting from 12 months. In addition, implants were performed for even the infants younger than 12 months. This was done off protocol.

Since 1980, the commercial Cochlear implant systems are in the available in the market and is being used. There developed the idea of using electrical stimulation in addition to the then existing acoustic auditory system stimulation for aiding and supporting those with profound sensorineural hearing loss. Alessandro Volta in the year 1800 by placing metal rods in his ear canal surprised to perceive aural sensations caused by electrical stimulation. As a result, he proclaimed the sensation by describing it as "A boom within the head". Djourno and Eyries inserted a wire on the auditory nerve of a patient having surgery in 1957. By using a direct electrical current wire cable, the auditory nerve was stimulated directly. The recipient confirmed a distinct hearing

perception. This finding paved further way forward for a treatment of patients with profound deafness. Further study and research were on going. As part of this, in year 1961, House and Doyle came out publically with the information and data of two adults with profound deafness treated with the electrodes placed in the inner year. Here in this case, an electrode was placed into the scala tympani of inner ear of the patient. This electrode was used to electronically stimulate the auditory nerves, which reported significant improvement in hearing. These two patients reported presence of auditory perception. They discovered that the loudness of the stimulus varied depending on the level of stimulation. Besides this, it was also observed that the changing pace of stimulation resulted in changes in the pitch of the stimulus concurrently. Subsequently, an electrode was directly implanted in the modiolus of the cochlea through the promontory into the vestibule by Simmons in 1964. These patients were also found to have better results. They also reported confirming that they were able to recognise differences in duration and sense of tone. These findings were the basis for further perseverance and trails towards the desire for the development of permanently functioning CI systems.

It was in 1972, the first single-channel Cochlear implant was introduced. From then onwards up until 1972 the mid-1980s, over 1000 persons were recipients of CI, which includes hundreds of children also. The 3M/House Cochlear implant¹ (Fretz and Fravel, 1985) was an early single-channel device that was well tolerated by users and delivered significant speech reading augmentation to many users.

The first multi-channel Cochlear implant technology was introduced by Cochlear Corporation in 1984. The Nucleus 22 was a device featuring an implanted receiver/stimulator and a 22-banded electrode array intra Cochlear electrode array. A headband was employed in the first version in order to keep the transmission coil with the reception coil of the implant. The radio frequency pulses generated thereupon are the source utilised to power the implant and its electronics parts and to control them. Accordingly, the stimulations were produced. Magnets were utilised in the later versions of the Nucleus device to ensure keeping the transmitting and receiving coils intact together with.

In Utah, the next level of multichannel Cochlear implant technology was developed thereafter, which was known as Ineraid device. In this, there were six intra cochlear electrodes connected to the speech processor by a permanent connection and placed externally. This system has a microphone with analogue electronic circuit, which regulates the maximum output of the individual electrodes. Also, the system has got four bandpass filters together with this.

The performance among the previous systems were very similar. Consequently, there were large scale clinical trials conducted and it revealed that a multichannel Cochlear implant is much better than a single channel device for post-lingually deafened people.² (*Gantz, B., Tyler, R. S., Abbas, P. J., Tye-Murray, N., Knutson, J. F., McCabe, B. F., Lansing, C., Brown, C. J., Woodworth, G., Hinrichs, J., &Kuk, F. K. 1988*).

Since then, scientists have been working to improve processing algorithms and miniaturising both external and internal hardware. In the United States, three FDA-approved multichannel CI systems are now available. Cochlear Corporation's Nucleus Cochlear Implant System, Advanced Bionics Corporation's Clarion device, and Medical Electronics Corporation's Med-El device are all examples of these. Transcutaneous transmission systems are used in all three implant systems to connect external hardware to the implanted receiver/stimulator. All three systems have seen considerable improvements in performance during the last decade. Regardless of technology, the greatest Cochlear implant users currently attain sound only word recognition scores of 80% or above.

DEVICE SELECTION

The device chosen for a specific patient is determined by a number of factors, including the hospital where the patient is treated, clinical trials of the proposed device, and the surgeon's and recipient's preferences. Some hospitals provide Cochlear Implant candidates with a variety of devices from different manufacturers. The majority of the time, the patient chooses the device after consultation with the surgeon. Within any group of people who use a device, there is a wide range of patient outcomes. Some people get significant auditory-only speech understanding with each device, while others use their Cochlear implant as a speech reading assistance.

In order to get the overall comparison between different manufacturers of Cochlear implants currently available in the market is listed below for your reference. This can also provide fair idea on, as to how one can choose the best adopted implant.

TABLE-2: COCHLEAR IMPLANT - COMPARISON CHART

	ADVANCED BIONICS	COCHLEAR	MED-EL
ESTABLISHED, LOCATION	AB: 1993 California, USA Sonova: 1947 Switzerland	1981 Australia	1990 Austria
CURRENT IMPLANTS	HiRes Ultra 3D HiRes Ultra HiRes 90K Advantage HiRes 90k	CI632 Slim Modiolar CI622 Slim Straight CI612 Contour Advance CI532 Slim Modiolar CI512 Contour Advance CI522 Slim Straight CI422 Slim Straight CI24RE Contour Advance (CA)	SYNCHRONY 2 SYNCHRONY CONCERT SONATA

		or Full-Band Straight (ST) 3	
MAXIMUM STIMULATION RATE	83,000 PPS	32,000 PPS	51,000 PPS
ELECTRODES	16	22	UPTO 24
ACTIVE LENGTH OF ELECTRODE ARRAYS	HiFocus Mid-Scala: 15.0 SlimJ: 20.0 1J: 17.0 Helix: 13.25	CI632/622: 14.0/19.1 CI612: 14.25 CI532: 14.0 CI512: 14.25 CI522: 19.1 CI422: 20.0 CI24RE (CA): 15.0 CI24RE (ST): 16.4	FLEX Series FLEXSOFT: 26.4 FLEX28: 23.1 FLEX26: 20.9 FLEX24: 20.9 FLEX20: 15.4 FORM Series FORM24: 18.7 FORM19: 14.3 CLASSIC Series STANDARD: 26.4 MEDIUM: 20.9 COMPRESSED: 12.1
WARRANTY	10YRS	10YRS	10YRS

COCHLEAR IMPLANT STAFF AND THEIR RESPONSIBILITIES

A Cochlear implant team's responsibilities include determining the candidacy for Cochlear implantation, assisting prospective recipients in making their own decision on their choice and desire towards Cochlear implant surgery and device options and selection including the available options of medical care, the method of surgical implantation, and also giving more information with regard to the post-implant device setting, care and monitoring with a view to get the maximum benefit to the implant recipient. The surgeon (otologist/otolaryngologist) and the audiologist are the team of medical experts to perform the above tasks as per the protocol. Prior to implant, the focus is to assess the medical and audiological condition and suitability of the patient / recipient for Cochlear implant surgery. This also includes the role managing the patient in terms of controlling any medical issues that would complicate the surgery. The focus moves from largely medical to primarily audiological management following Cochlear implant surgery and post-implant recovery.

In delivering services to Cochlear implant applicants and recipients, the surgeon and audiologist play the most important responsibilities. The team may identify the need for additional medical consultations, such as developmental paediatricians, speech and language evaluations, long-term rehabilitation, educational programme evaluations, or family counselling. The age and nature of the population, as well as the team's experience, all influence the delivery of CI services.

In addition to the above, Speech-language pathologist, Audiologists and educators are also involved as a key role players for the pre-implant evaluation and/or post-implant management of children with Cochlear implants.

Adults can also benefit from the services of several specialists listed above, both before and after receiving a Cochlear implant. Adults with post-lingual deafness do not normally require major hearing rehabilitation or speech and language therapy after Cochlear implantation, but they may require further therapy to make use of the sound they hear.

FAMILY SUPPORT AND ITS SIGNIFICANCE

Family members and/or close friends also expected to do some of the essential roles in the Cochlear implant and post-implant including rehabilitation process. The Cochlear implant candidates are also to be provided with necessary emotional support when they get prepared for implant and even the post-implant stage also. This is basically to enable family and friends help to the implant recipient to develop realistic expectations. Of course the support of the surgeon and audiologist is also the most important factor for achieving desired results in the implant recipients. Family and friends can provide moral support and guidance and help to the user, ensuring that the device is used on regular basis in a consistent manner, and also for the rehabilitative activities. Similar kind of support even more than this is required when a child has a Cochlear implant is done. Such support will help the child to develop spoken language at

a fast rate so that listening and speaking in daily activities will be further more practiced yielding better results in an optimal time period. The implant expert also needs valuable contribution by providing information regarding the Cochlear implant users' performance.

CI TEAM'S PROFESSIONAL CAPABILITY AND TRAINING NEEDS

Cochlear implantation training is a series of rigorous courses offered by each implant manufacturer that provide a solid foundation of knowledge. Surgical procedure, device settings, and device programming are frequently covered in these courses. Also, knowledge can be acquired through different professional and scientific conferences on Cochlear implantation being hosted at different levels by different forum and also, by way of informal communications between the Cochlear implant surgeons. Cochlear implant teams are advised to first acquire experience operating and rehabilitating the post-lingually deafened population before working with pre-lingually deafened children. Furthermore, paediatric Cochlear implant teams should be familiar with paediatric audiologic testing and treatment approaches. The technology of Cochlear implants is always improving and fine tuning, both in terms of physical and processing properties. Hence, all the team members must prioritise continuing education and must be informed of all the latest technological improvements.

CI CANDIDACY SELECTION

Candidacy criteria for Cochlear implants have altered over time as breakthroughs in Cochlear implant technology have resulted in improved performance outcomes. Candidacy, on the other hand, hinges around three key questions:

- Examining the medical condition of the patient and to determine physical implantation of the device is possible and/or advisable
- Assessing the individual to conclude whether the individual will receive more benefit of Speech and hearing from a Cochlear implant than from a hearing aid.
- Providing the psychological, emotional, educational that is needed for adequate Cochlear implant post operative rehabilitative support.

Most of the times the evaluation is done in accordance with the above, and on the basis of the clinical investigation and the safety and efficacy of the CI. Over the course of time, these guidelines are being updated with the addition of new requirements as deemed important. in the 1980's only for post-linguistically deafened adults with hearing losses greater than 100 dB with no noticeable benefit using hearing aid were considered and recommended for Cochlear implants³ (*Berliner, K. I. 1985*).

The age for implant had been lowered to 12 months by the year 2000. Cochlear implantation is now performed in patients aged 2 and up who have severe-to-profound deafness, as well as children aged 12 to 23 months who have profound deafness. The

parameters for determining the degree of hearing loss and effectiveness with a hearing aid are evolving as Cochlear implant technologies improve.

MEDICAL EVALUATION OF PROSPECTIVE CI RECIPIENT

In medical examination, patient's overall health, hearing loss history and cause, and the physical condition of the ear and cochlea is evaluated. The general health of the patient is most important criteria for preparing the patient for implant. This includes consideration in terms of fitness for general anaesthesia and surgery, and also ability and patient's health condition and response to complete the necessary post-operative programming of the device. All of these are likely to affect the timing of implantation.

The cause and history of a patient's hearing loss affects how well they do with a Cochlear implant. Cochlear ossification, which might obstruct the implantation of the electrode array, is frequent in those who suffer deafness after meningitis. Implant performance is also impacted and dependent on the degree of Cochlear ossification and thus will have impact on the occurrence of facial nerve stimulation. As long as a sufficient number of electrodes are triggered even individuals with partial electrode array insertion function almost similarly to those with complete insertion. ⁴(*Kemink, Zimmerman-Phillips, Kileny, Firszt, and Novak, 1992*).

Individuals with complete Cochlear ossification, do not have the same level of auditory perception as those with partial Cochlear ossification. They're also more likely to experience issues from facial nerve stimulation and pain, post implant activation⁵

(Rauch, Hermann, B., Davis, L., & Nadol J 1997). This can cause complications of facial nerve stimulation and pain associated with implant ⁶ (Niparko, Oviatt, Coker, Sutton, Waltzman, and Cohen, 1991).

HISTORY OF HEARING LOSS

Adults who are post-lingually deaf for short period are provided to have greater speech perception scores in comparison with the one deaf for a long time period, prior to implantation⁷ (Blamey, Arndt, Bergeron, Bredberg, Briamacombe, Facer, Larky, Linstrom, J., Peterson, Shipp, Staller, and Whitford, 1996). Poor candidates for Cochlear implantation are adults with pre-lingual hearing loss, especially if they have had no previous mode of communication either oral/aural communication.

RADIOLOGICAL EXAMINATION:

Determining the cochlea's patency and identifying aberrant anatomical variations are the prerequisite for implant decision, as these could interfere with electrode insertion. Therefore, High-resolution imaging (Computerized Tomography, CT, or Magnetic Resonance Imaging, MRI) is used for radiological examination as part of evaluation. Although certain obstructions blocking electrode placement may be missed by imaging, this is rare⁸ (Jackler, Luxford, Schindler, and McKerrow, 1987). On the basis of the clinical history of hearing loss and subsequent evaluation, there is a possibility of predicting some obstructions. It is to be noted that, otosclerosis or meningitis can be the causes of Cochlear ossification.

AUDIOLOGICAL EVALUATION OF PROSPECTIVE CI RECIPIENT

The audiological evaluation is normally performed to define the preoperative hearing ability, communicative ability, and also prosthetic device usage. Comparison is done on the current communication status and level to the expected and projected outcome after Cochlear implant. The results are also useful as pre-outcome metrics to assess the Cochlear implant's benefit following implantation. A pure-tone audiogram with air and bone-conducted thresholds is also done for evaluation. Also, speech perception test like word and sentence recognition, evaluation of current amplification, including a trial use of amplification are all consider part of the audiologic evaluation. Speech perception tests are the most important in deciding whether Cochlear implantation is appropriate. Candidates should be considered for implantation if their open-set word or phrase recognition performance is 53 percent lower than the baseline for Cochlear implant recipients.

An assessment is also done to find out the candidate's current amplification and history of hearing aid use as part of the audiological test. If a patient has never worn adequate amplification before, a three- to six-month trial period is recommended.

The auditory stimulus for each ear can be documented using a candidate's hearing aid history. When a person has been deaf for a long time, one ear may have received more help than the other. Ears that have had more constant auditory stimulation over a long period of time may function better with Cochlear implants than ears that have had

no auditory stimulation for a long period of time, and may be a better choice for the implantation ear.

The ear's sensitivity to sound is assessed, and if possible, using tests of auditory perception are included in the audiological screening of young children for Cochlear implantation. Visual reinforcement audiometry and auditory evoked response audiometry are also the additional means and ways of further evaluating hearing sensitivity as the age of implantation lowers. The age and language aptitude of the child are factors in speech/auditory perception testing. Parental reporting scales of auditory listening behaviour, in terms of the method called Infant-Toddler Meaningful Auditory Integration Scale⁹ (Zimmerman-Phillips, Robbins, & Osberger, 2000), are generally used to assess auditory skill levels and development in the youngest children. One can scale a child's abilities on continual basis and record a child's progress over time by employing tests suited for the child's age and language level. The auditory perception tests are used to assess tone sensitivity and progress in developing auditory skills with a hearing aid for the child.

Candidacy criteria at younger ages are often noticed and decided by the parents as they find a lack of speech progress over a specific period of time, generally three to six months.

PSYCHOLOGICAL/REHABILITATION EVALUATION

The examination of the patient to decide the candidature for implant goes with the intention and commitment of the patient to accommodate and to use of a Cochlear implant. The prospect of Cochlear implant surgery, as well as the desire for a positive outcome, adds stress to the candidate and his or her family's lives. Any potential personal and social issues from using a Cochlear implant should be identified by a social worker or psychologist. By proactively addressing areas of concern, potential problems can be averted. These issues could vary from complex social and mental issues including the issue of getting the patient to the clinic whenever required. An assessment of a patient's expectations for life following implantation can help to manage unreasonable expectations and anticipate alternative paths if post implant performance falls short of expectations.

The psychosocial evaluation of children is more comprehensive. This includes many factors, like developmental and educational assessments and also family assessments. The decision on the paediatric Cochlear implant is dependent on the deaf child's and family's preference for spoken language as their form of communication. Establishing a rehabilitation and education plan before implantation allows for a smoother integration of the implant and lowers the likelihood of poor follow-up or gaps in rehabilitative services impeding development.

COUNSELLING AND EXPECTATIONS OF CI RECIPIENTS

Candidates for Cochlear implantation have varying levels of awareness regarding the devices. Therefore, it is necessary to make the implant recipient informed about the dangers and benefits of Cochlear implantation along with the impact of the implant in their life style. The surgical technique and the hazards associated shall also be discussed along with physical description, a demonstration of the device's internal and external components. The candidate should also be shown and explained about the different types and models of Cochlear implant systems available for the specific patient condition and their commitment to post-surgical programming. In addition, Cochlear implant candidates should be aware of what life with the device requires on a day-to-day basis. Contacting other Cochlear implant users and their families is the greatest way to do this. Furthermore, makers of Cochlear implant systems use their websites and other social media platforms to stimulate user discussions, references of which are: (www.medel.com; www.Cochlearimplant.com; www.Cochlear.com).

The most crucial, but sometimes challenging, component of patient counselling is establishing reasonable expectations for the implant's effectiveness. Almost all of the candidates (or their families) desire that the implant help them hear and interpret speech better. During the candidacy examination, reviewing the performance for a predetermined period of time and addressing post-implant plans. This is basically, if in case performance with an implant is less than expected, then it can help those patients who receive minimal post-implant benefit in order to ramp up the performance.

COCHLEAR IMPLANT SURGERY

It is all dependent on the surgeons where they use different approaches and also they do have different perspectives and ideas about Cochlear implant surgery, which is no different from other surgical procedures. All Cochlear implant surgical techniques, however, are guided by some fundamental principles. The following are the main objectives:

- a) to introduce the electrode array into the scala tympani atraumatically,
- b) to position the device on the side of the head in the most trauma-protective position, and
- c) to make sure the electrode array and device are secured to avoid movement and dislodgement.

The goal is to achieve these objectives without causing damage to the surrounding tissue, device, or electrode array, as well as an acceptable cosmetic result. The physical and structural features of a device often determine surgical procedure modifications.

In general, the surgical method is usually the same for children and adults. Few minor adjustments are required due to the size of the head. Meanwhile, the surgical risks or consequences so far reported in young children up to the age set of 12 months are not very serious and are also not in increased order¹⁰ (Cohen, 2000). However, some cases like Mondini deformity (malformed cochlea) or hearing loss caused by meningitis and

ossification, may necessitate changes and/or revisions to the surgical approach. Depending on the degree of ossification, the surgeon can use a variety of techniques to complete electrode array insertion or may opt to use special design electrode array for the cases of strongly ossified cochleas¹¹ (Balkany, Hodges, and Luntz, 1996).

Cochlear implant surgery usually takes two to four hours and is conducted under general anaesthesia. The surgery is usually followed by a one-night stay in the hospital.

SETTING THE COCHLEAR IMPLANT SPEECH PROCESSOR

Recipients are advised to visit the Cochlear implant centre three to five weeks post-surgery to receive their external equipment and thereafter to have their speech processor programmed. The process of device programming includes selecting and customising the speech processing method that will suit the condition of the patient.

After programming, the processing techniques of the device is activated, which is then used to convert the incoming acoustic signals into electrical pulses thereby exciting the auditory nerve fibres. Diverse speech encoding algorithms are applied in various Cochlear prosthesis. However, the basic programming are not device or strategy dependent. The audiologist can collect the basic psychophysical data from all electrodes including its corresponding thresholds and comfort levels also.

For all types of CIs, the basic parameters are the same, the techniques used to obtain these measures are dependent on individual characteristics. This may be such as, age, cognitive abilities, length of deafness, and other potential factors influencing the

same. Subjective and objective techniques are used to obtain these data/information. The subjective method can be set even at the lowest level where the patient response is measured at 100% of the time. Users of the implant can also report the loudness of the stimuli at which they are most comfortable. After all of the electrodes' thresholds and comfort levels have been determined, the computer replicates the data. This gets converted as an operational programme that is sent to the speech processor which produces a live voice stimulation.

Many factors can be identified to improve the quality of sound and to promote open-set speech understanding for any given patient, including loudness, frequency allocation to electrodes, and transmission speed, to mention a few. The qualities can be adjusted precisely by the speech processing approach for any given Cochlear implant device.

Electrical thresholds and comfort levels are key factors to postoperative performance, whether the patient is a child or an adult. As a result, establishing a comprehensive schedule of programming sessions is critical. The number of visits necessary to properly programme and maintain the speech processor is determined by several factors, including the patient's age, past auditory experience, and capacity to actively participate in device programming chores. Long-term audiological follow-up is also essential because the responses to auditory input from a Cochlear implant may change over a period of time. Cochlear implant recipients should contact their Cochlear implant centre for speech processor programming if they fall in auditory

responsiveness, perception, discrimination, speech production, or a change in voice quality.

In order to deliver the highest quality treatment to the patient, audiologists involved in device programming must be well aware of the particular device. Continuing education is required as Cochlear implant speech processor technology and speech programming software are continually evolving and getting developed.

THE USE OF OBJECTIVE MEASURES IN SPEECH PROCESSOR PROGRAMMING

There has been a tendency toward implanting children at younger and younger ages during the last decade. While the FDA has allowed Cochlear implantation for children as young as 12 months old, many children younger than that have already had one. This occurs when waiting is medically impossible or when the physician believes the kid would benefit considerably from very early implantation. Furthermore, several Cochlear implant facilities are implanting more children with major physical and/or developmental disabilities than in the past. If the receiver is very young or has limited response abilities, programming the speech processor of the Cochlear implant can be difficult. In such circumstances, programming strategies that are less dependent on the child's capacity to respond behaviourally can be beneficial.

This section discusses the many programming options that can be used to train the speech processor of a Cochlear implant for users who are unable to respond to

stimulation through the device with a conditioned response. These strategies can also be used to speed up the programming of a Cochlear implant in a child with a short attention span. Information gathered through non-behavioural approaches can also be utilised to evaluate the accuracy of behaviourally derived programming levels.

While there are several different types of electrically evoked potentials that could be used to aid device programming, the electrically evoked auditory brainstem response (EABR), the electrically evoked compound action potential (ECAP), and the electrically evoked acoustic reflex threshold have received the most attention in the literature (EART). All three measurements have acoustic analogues, have been thoroughly researched, and can be recorded in children. The sections that follow go through how these elicited responses can be used in the fitting process. When Cochlear implant users are able to actively participate in the speech processor programming process, these strategies do not often provide speech processor programmes that are superior to those created using classic behavioural programming techniques.

Furthermore, only a few clinics will use these instruments on a regular basis. When the audiologist has cause to doubt the validity of the behavioural measurements obtained, they are usually incorporated into therapeutic practise. However, as the average age of implantation decreases and our knowledge of how these tools might be employed in the clinical treatment of Cochlear implant recipients grows, the need for additional, non-behaviourally based markers of sensitivity to electrical stimulation becomes more apparent.

OUTCOMES OF COCHLEAR IMPLANTATION IN CHILDREN

Improved speech perception and spoken word recognition are the key benefits of Cochlear implant use for persons with profound post-lingual deafness. In children with congenital or pre-lingual deafness, however, Cochlear implantation may have a significant impact on all elements of communication, and the assessment battery used for children should be comprehensive enough to capture these changes. As a result, clinical researchers need access to a diverse set of age-appropriate outcome measures that allow them to focus on various elements of communication development.¹³ (*Kirk, 2000; Kirk, J. K. Niparko, K. I. Kirk, N. K. Mellon, A. M. Robbins, D. L. Tucci, & B. S. Wilson*).

SINGLE-CHANNEL COCHLEAR IMPLANT SYSTEMS

In 1980, the 3M/House single-channel Cochlear implant was first given to children, and by 1984, 164 children had been implanted. The performance of the auditory system was comparable to that of adults¹⁴ (Thielemeir, Tonokawa, Petersen, and Eisenberg, 1985).

MULTIPLE-CHANNEL COCHLEAR IMPLANT SYSTEMS

The Nucleus 22 device was the first multichannel Cochlear implant system for children. Children who employed the Nucleus 22 Cochlear implant with a feature-extraction speech processing technique improved significantly in closed-set word identification but had limited open-set word recognition in early studies¹⁵ (Miyamoto, Osberger, Robbins, Renshaw, Myres, Kessler, and Pope, 1989). When auditory and

visual signals were integrated, the majority of children using the early Nucleus device showed considerable improvement in spoken word recognition.

The Nucleus devices, manufactured by Cochlear Corporation, the Clarion devices, created by Advanced Bionics Corporation, and the Med-El devices, manufactured by Medical Electronics, are the three multichannel Cochlear implant systems now available for use in children. Each company is constantly improving their electrode designs as well as the speech processing algorithms that are offered with their systems. Each generation of processing procedures has resulted in enhanced speech perception benefits in children that are comparable to adults. With today's Cochlear implant systems, the majority of children achieve moderate or better open-set word recognition. For example, Cohen, Waltzman, Roland, Staller, and Hoffman (1999) reported word recognition scores ranging from 4% to 76 percent correct for a group of 19 children, with a mean of 44 percent correct. Similarly, on a more harder measure of monosyllabic word recognition given to children, Osberger and her colleagues obtained average scores ranging from 22% to 36%.

One of the most constant findings is that children with Cochlear implants improvement in their speech perception abilities as their device experience grew. Children with Cochlear implants have average spoken language processing skills that do not plateau after five or more years of device use. In contrast, word recognition skills in postlingually deafened people with Cochlear implants often plateau during the first few

months of device use¹⁶ (Papsin, B. K., Gysin, C., Picton, N., Nedzelski, J., & Harrison, R. V. 2000).

To learn a spoken language, children must make use of the sound they receive through a Cochlear implant. As Cochlear implant technology advances and children are implanted at a younger age, the rate of development of children's auditory skills appears to be improving. It should be noted, however, that a child's auditory development is linked with his or her verbal ability.

RECOGNITION OF SPOKEN WORDS BY COCHLEAR IMPLANT RECIPIENTS

The performance of children with Cochlear implants has been demonstrated to be influenced by a number of demographic characteristics. Early findings revealed that children who were deafened at a younger age had greater speech perception and a shorter time of deafness¹⁷ (Fryauf-Bertschy, Tyler, Kelsay, and Gantz, 1992).

Age at onset of hearing loss was no longer a significant predictor when only children with pre-lingual deafness (i.e., deafness acquired before the age of three years) were evaluated. It is undeniable that earlier Cochlear implant implantation results in better Cochlear implant performance in youngsters. Although the optimal age for implantation in congenitally or pre-lingually deaf children has yet to be found, preliminary evidence suggests that implantation before the age of two or three years may improve outcomes.

SPEECH AND LANGUAGE DEVELOPMENT IN CHILDREN WITH COCHLEAR IMPLANTS

Because Cochlear implants are considered auditory prosthesis, the principal anticipated benefits have been improvements in hearing. Due to the importance of audition in the learning of spoken language, the scope of the advantages is far greater when these devices are used with children who are deafened early in life. Even with significant speech and language therapy, children with severe to profound hearing loss sometimes find it difficult to learn spoken language. Research on the language development of children with severe to profound hearing loss has indicated that children with more hearing had better speech and language results. In light of this, the additional auditory information offered by Cochlear implants should result in enhanced speech and language for CI recipient children. Some, on the other hand, have expressed concern that the auditory information provided by a Cochlear implant would be insufficient to support speech and language development, and thus that this promise would be unmet, and that children receiving these devices would be denied the opportunity to learn sign language systems that would allow them to participate successfully in the Deaf community¹⁸ (Lane and Bahan, 1998).

Since the first Cochlear implants were implanted in children, much of the research has focused on recording the degree and extent of speech and language improvement offered by these devices, as well as assessing factors that account for individual variances in outcomes.

Over the last 15 years, there has been a significant increase in study on the speech and language development of children who have received Cochlear implants. In 1985, the first publication on speech and language in children with single channel Cochlear implants was published (Kirk and Hill-Brown, 1985).

In the following five years, a modest number of studies were published, although the most of them were case studies of children using single-channel devices. Papers describing preliminary findings of speech and language development in youngsters utilising multichannel devices began to appear in the early 1990s. By 1995, researchers had expanded their interest in implant users' communication abilities by looking into language development in children who used multichannel devices; this was accompanied by an increase in the number of studies reporting on speech and language outcomes.

As the scope and amount of study into speech and language grew, so did the nature of devices and the practise of implantation. More advanced processing algorithms and internal hardware were being deployed all the time, and the average age of implantation dropped drastically. As a result, while basic generalisations can be drawn about speech and language results, long-term longitudinal studies of newly implanted children are needed to assess the outcomes that can be predicted given current technology and clinical practise. The results of this literature will be discussed in the sections below, starting with those that concern speech and language outcomes in general, and then moving on to those elements that have been investigated as potentially affecting individual differences in speech and language outcomes.

MATERIALS AND METHODS

STUDY DESIGN

More than 150 pediatric patients with bilateral severe-to-profound sensorineural deafness who received Cochlear implantation were evaluated for speech and hearing improvement by audiovisual team with regular monthly assessment of improvement. All patients were followed up for a period of one year for hearing and speech performance after the surgery. The CAP and SIR hearing and speech assessments and rating materials were used for assessment after surgery on a monthly basis after implant activation.

CATEGORIES OF AUDITORY PERFORMANCE AND SPEECH INTELLIGIBILITY RATING

The University of Nottingham developed the Categories of Auditory Performance (CAP) and the Speech Intelligibility Rating (SIR) for assessing children's daily auditory and speech ability (Han et al., 2007), which have been widely used in the evaluation of the effect of speech rehabilitation after Cochlear implantation in young children (Li et al., 2014; Archbold et al., 1998; Nikolopoulos et al., 2005).

The CAP and SIR criteria is shown in tables 3 and 4 respectively.

TABLE-3: REVISED CAP

(CATEGORIES OF AUDITORY PERCEPTION) SCALE 1995

LEVEL 0	Unaware of environmental sounds
LEVEL 1	Detects some Environmental sounds
LEVEL 2	Responds to some speech sounds
LEVEL 3	Can identify some Environmental Sounds
LEVEL 4	Understands some spoken words with additional performatives. Eg., Where is the duck that says Quack Quack?; Give me the car brmmbrmmm.
LEVEL 5	Understands common phrases.
LEVEL 6	Understands some spoken words without performatives. Eg., Give me the duck. Go get the car.
LEVEL 7	Responds appropriately to simple questions. Eg., What is it?
LEVEL 8	Understands conversation with familiar speakers.
LEVEL 9	Understands conversation with unfamiliar speakers.
LEVEL 10	Follows recorded stories.
LEVEL 11	Uses the telephone with familiar speakers.
LEVEL 12	Uses phone with unfamiliar speakers.

TABLE -4: SPEECH INTELLIGIBILITY RATING

CATEGORY 1	Pre-recognizable words in spoken language. The child's primary mode of communication might be manual
CATEGORY 2	Connected speech is unintelligible. Intelligible speech is developing in single words when context and lip reading cues are available.
CATEGORY 3	Connected speech is intelligible to a listener who concentrates and lip reads within a known context.
CATEGORY 4	Connected speech is intelligible to a listener who has little experience of deaf person speech. The listener does not need to concentrate unduly.
CATEGORY 5	Connected speech is intelligible to all listeners. The child is understood easily in everyday context.

STUDY TYPE

This study is conducted on the basis of the historical real data collected from the primary source and hence it is a Retrospective Study. The information collected and compiled are discussed in detail in the following sections of this report.

STUDY PERIOD

For the purpose of this study, a reasonable quantum of data pertaining to a group of over 150 patients (Cochlear recipients) were collected and correlated for the analysis. Accordingly, the study period has been chosen the data from December 2017 to December 2019. This is considered as a practically reasonable time period that can be well analyzed for correlating the end results and to record the conclusions thereupon.

STUDY SETTINGS

Study has been conducted in the following institute with the official permission for accessing the data for the intended purpose.

Department of Otorhinolaryngology, Department of Audiology, and Department of Speech Therapy, PSGIMSR

STUDY POPULATION

This research study has been done for the children below 6 years and this covers both boy and girl children within this specified age group. Accordingly the research study has been oriented to focus more on the said age group, emphasizing all Children <6yrs with pre-lingual hearing loss. The sample size of the population is 156 children of both sexes. Pictorial representation of the population distribution based on sex and age are represented here below.

SAMPLE SIZE BASED POPULATION

PICTORIAL REPRESENTATIONS

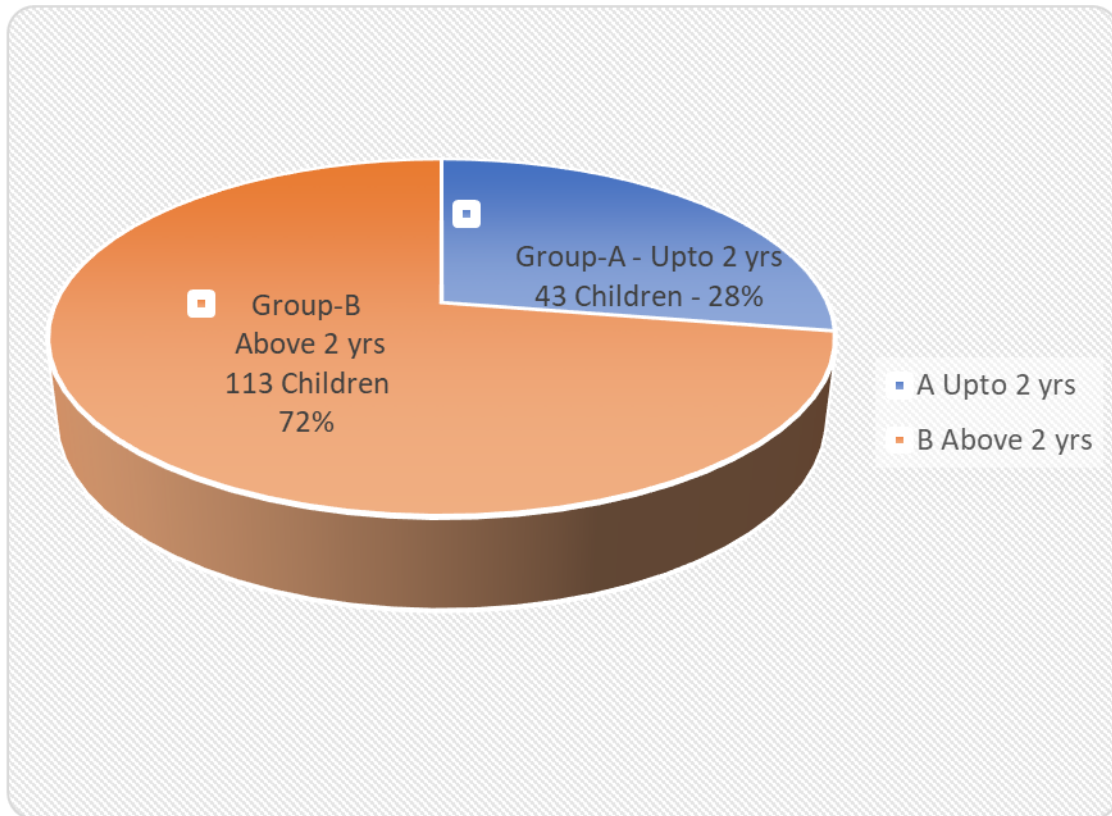
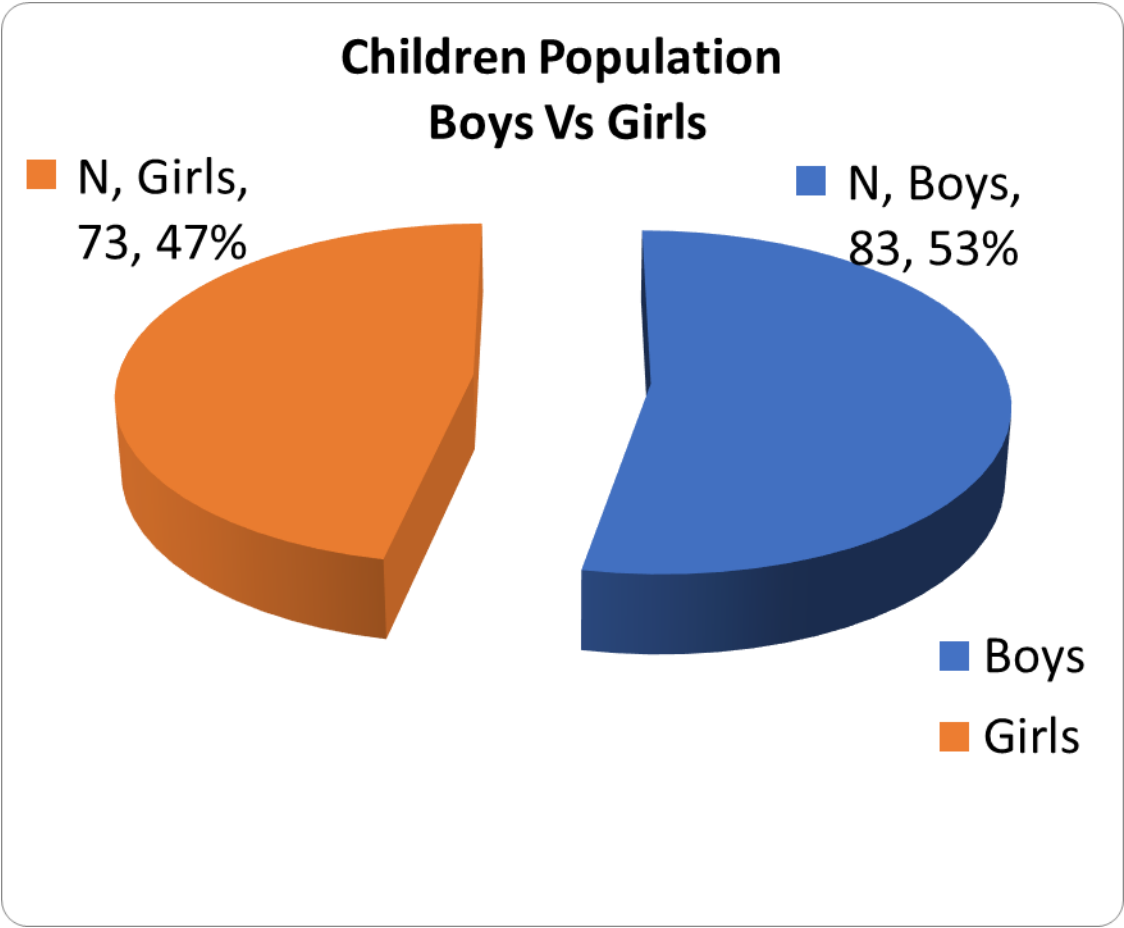


FIGURE-13: CHILDREN POPULATION

(SAMPLE SIZE) GROUP-A Vs GROUP-B

Among the study population, 28 percent of children belonged to Group A (upto 2 yrs) and 72 percent of the children belong to Group B (above 2 yrs) as shown in the above pie chart.



**FIGURE- 14: CHILDREN POPULATION
BOYS Vs GIRLS**

Among the entire study population, 47 percent (73) were girls and the rest 53 percent (83) were boys.

MINIMUM SAMPLE SIZE DESIGN / CALCULATION

The sample size for the subject study has been very carefully decided to get enough data representing the normal distribution of the population to bring out the near realistic findings which can add on to the statistical information data base to benefit the study and analysis in this regard.

Considering the above requirement, the minimum sample size calculation has been done complying with the standard statistical practices. Accordingly, the calculated sample size and its numerical calculations are given hereunder:

$$N = 4 \times SD^2 / d^2$$

SD is given as 10.07 for group A in my parent article and

d is taken as 3

$$SD = 10.07$$

$$d = 3$$

$$N = 4 \times (10.07^2 / 3^2)$$

$$= 4 \times (101.4049/9)$$

$$= 45.0688 \sim 45$$

Non responders taken as 20%

20% of 45 is,

$$20/100 \times 45 = 9$$

$$N = 45 + 9 = 54$$

N = 55 rounding off

As calculated above, the minimum sample size required for the subject research is 55 only.

SAMPLE SIZE CONSIDERED FOR THE STUDY AND JUSTIFICATION

Though the minimum sample size required is only 55 as explained in the previous section. This number and the sample size is good enough for bringing out a fair analysis and an acceptable interpretation on the basis of the statistical findings to conclude the results. However, the sample size considered and taken into account for analysis and statistical interpretations is 156 active cases, eliminating 2 cases of Cochlear explants.

From the foregoing, it is very evident and proved that the sample size taken into consideration for this research study is, therefore, justified, as explained and depicted above. Since it's a retrospective study all the cases which came in the study period (one year and more) are all considered and collected, compiled and analyzed for the study. This is quite a good and reasonable level of sample size and hence it is well justified for conduction the subject study to find out and to conclude on fair results.

JUSTIFICATION FOR STUDY

Within the population considered under this thesis, there is no previous study which looks into the postoperative assessment in Cochlear implant solely for pre-lingual deafness. In this study detailed post op speech therapy pathologist follow up and post operative outcome is analysed with special emphasis on the failure cases.

The improvement in hearing and speech in Cochlear implant recipients is measured subjectively using CAP and SIR categories which are sequentially monitored monthly for a total period of 1 year post operatively.

STUDY CRITERIA - INCLUSION CRITERIA

Inclusion criteria for the study is briefly described here below:

All children with bilateral severe to profound sensorineural hearing loss who met the requirements set out in guidelines of Cochlear implantation for pre-lingual deafness of less than 6yrs of age are included in the study criteria under this project.

EXCLUSION CRITERIA

Exclusion criteria for the study is briefly described here below:

Children/adults with post lingual deafness and Children >6yrs with pre-lingual deafness are excluded in this study.

METHODOLOGY DESCRIPTION

After Ethical Committee approval, a comprehensive preoperative assessment protocol is followed for all patients. The details of the operative record is obtained. Post-operative recovery is followed up weekly for a period of 12 months, with CAP and SIR scoring recorded at the end of every month. Speech pathologist notes and post-operative assessment investigations are followed up and analyzed.

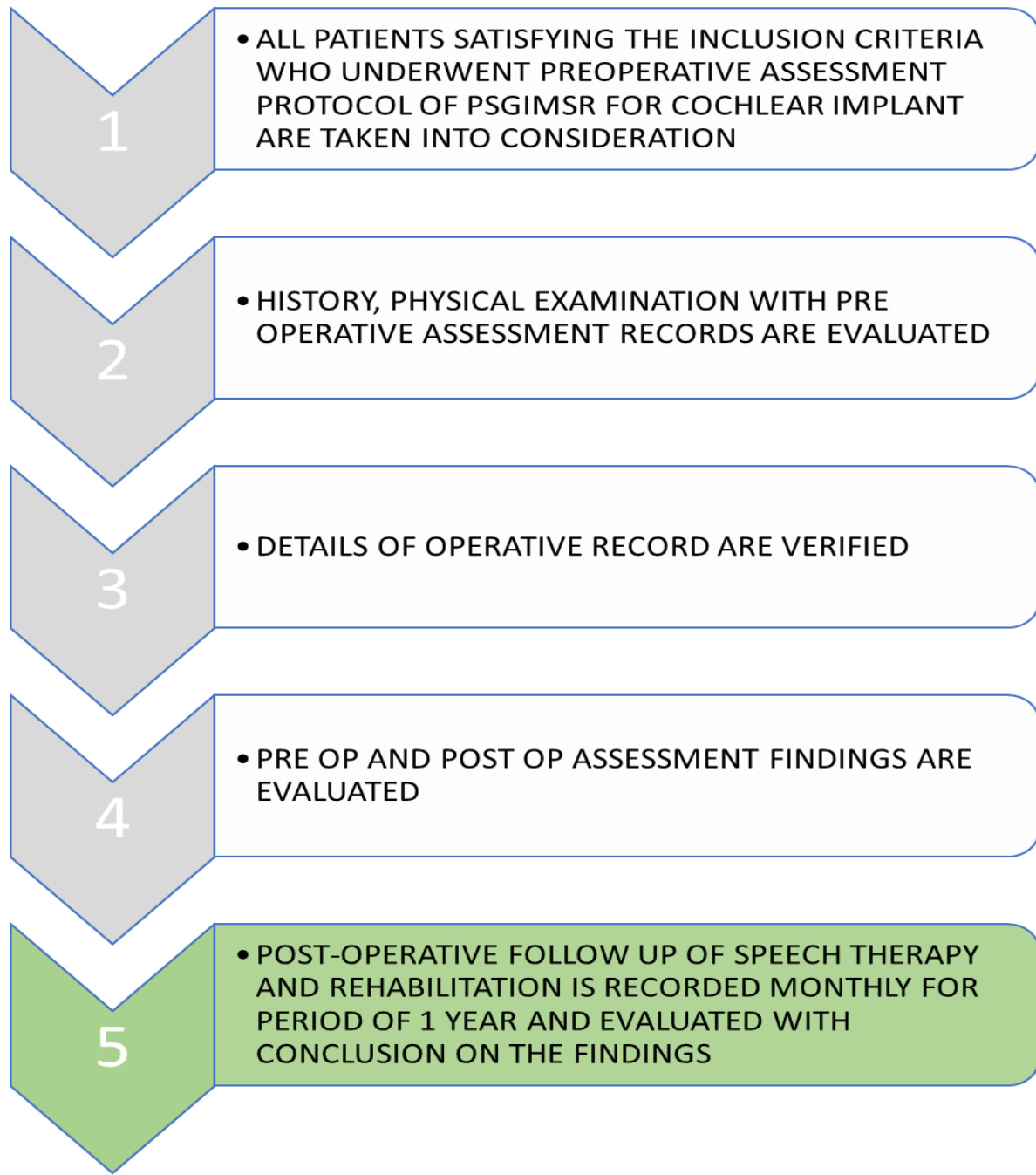
METHODOLOGY - FLOW-CHART

The flow chart depicting the methodology adopted for this study has been appended here below, detailing the steps involved in the process of this study, which shows 5 steps as appended below. The first 4 steps are pre implant stages / process and the fifth stage/process is the post implant assessment, which is the focus of this study and therefore, the fifth process is highlighted with green colour for easy identification and to correlate and understand the subsequent sections of this study report.

As a prerequisite, all patients satisfying the inclusion criteria who underwent preoperative assessment protocol for Cochlear implant are taken into consideration. Their medical and health history, physical examination with pre-operative assessment records are evaluated. Also, their details of operative record are verified along with pre op and post op assessment findings. Final stage is the post-operative follow up of speech therapy and rehabilitation. SIR and CAP data are recorded monthly for period of 1 year and

evaluated to arrive at a conclusion based on the factual findings, which are further described and detailed in the following sections.

FLOW CART REPRESENTATION



PERFORMA USED FOR DATA COLLECTION

Following is the Performa used for collection of data about the Cochlear implant recipients post implant.

This medical and health information is used to do medical assessment of the recipient to ensure that the recipient is healthy as far as his medical conditions are concerned so that further evaluation is undertaken in terms of the effectiveness and measurable improvements of the Cochlear implant under the post implant condition, which will be a true state of reflection of the effectiveness post implant and also to ensure that the patient's health is not impacting on the hearing ability at the post implant condition, as such condition can lead to a wrong interpretation otherwise.

The Data Performa also includes sets of medical examinations and investigations as deemed required, as listed in seriatim in the format given below. The investigation includes certain routine and some specific examinations as well. This will also give a confirmation about the patients health status so that SIR and CAP evaluation and recording can be done without any concerns. Accordingly, the data collection has been done and recorded in the Performa and used for further evaluation.

PREOPERATIVE WORKUP PROFORMA			
NAME		DATE OF BIRTH	CMCHIS CARD NUMBER
		DD/MM/YY YY	DD/MM/YY YY
INVESTIGATIONS			
SL. NO.	TYPE OF TEST	OBSERVATION / FINDINGS / RESULTS	
1.	BLOOD ROUTINE COUNTS		
2.	URINE ROUTINE		
3.	X-RAY CHEST		
4.	X-RAY NASOPHARYNX		
5.	BEHAVIOURAL OBSERVATION AUDIOMETRY		
6.	IMPEDENCE AUDIOMETRY		

7.	OTO-ACOUSTIC EMISSION TESTING	
8.	BRAINSTEM EVOKED RESPONSE AUDIOMETRY (BERA)	
9.	ECG	
10.	PEDIATRIC/ CARDIAC /OPHTHALMOLOGY/PSYCHOLOGIST OPINION	
11.	HEARING AID TRIAL	
12.	CT SCAN	
13.	MRI SCAN	
14.	CERTIFICATE FROM PARENTS/ GUARDIAN WILLINGNESS TO PARTICIPATE FOR 1YR REHABILITATION	

ITEMIZED BUDGET

As a matter of corporate social responsibility, the State governments have initiated child welfare programme under which all Cochlear implants (<6yrs of age) are completely government funded, including the post op 1yr of rehabilitation.

If all tests prove the child is profoundly deaf then it is listed as a candidate for Cochlear implant. The State government decided to offer Cochlear implants under the Chief Minister's health insurance scheme and many children have got benefited and received Cochlear implant. The State government has categorically declared that the Children requiring the implant must undergo surgery before they turn six years of age to achieve the best results as per the experts' advice and projections. The Tamil Nadu Chief Minister's Comprehensive Cochlear Implant Scheme, stands as one of the pioneering programmes with more than 3,500 Cochlear implantations having been done free of cost for poor and needy children below the age of six years, who make up nearly 40 million of the population of rural Tamil Nadu.

As the subject study is done on the basis of real data and is focussed towards data based research and analysis, no budget requirement is envisaged and no expenditure is also incurred.

COST / BENEFIT OF COCHLEAR IMPLANTATION

The consequences of profound deafness differ depending on the age at which it occurs. Adults with post-lingually acquired severe-to-profound deafness have communication problems, which might limit their career prospects and make them feel socially isolated. The impact on children who are pre-lingually deaf is substantially larger. Many children who are pre-lingually deaf show significant language and academic difficulties.

The cost-effectiveness of Cochlear implantation has been studied by a number of researchers. Niparko and his co-workers presented an outstanding description of the assessment techniques and results. In general, these studies have found that severe-to-profound deafness in adults has a measurable impact on quality of life; as a result, Cochlear implantation is linked to significant improvements in recipients' identity, quality of life and appears to be a cost-effective use of health-care resources.

The cost-effectiveness of Cochlear implantation, according to these authors, should be evaluated not only using traditional measures of auditory and speech performance (such as speech perception, intelligibility, and language outcome measures), but also using measures of 1) academic performance, 2) use of special educational and rehabilitative resources, and 3) changes in quality of life. Children with Cochlear implants were mainstreamed earlier (i.e., placed in classrooms with their normal hearing peers) and required fewer special education support services than children with hearing

impairment who were not implanted²²(Koch, Wyatt, Francis, and Niparko, 1997)reported that children with Cochlear implants were mainstreamed earlier (i.e., placed in classrooms with their normal hearing peers) and required fewer special education support services than children with hearing impairment who were not The scientists also did cost-benefit analyses based on the trend they saw after Cochlear implantation toward higher educational independence.

They concluded that Cochlear implantation could result in substantial savings in educational expenses. Irrespective of the direct cost benefits that are associated with the Cochlear implantation, as explained above, the intangible benefits derived in terms of the remarkable positive changes in the quality of life of the recipient is the most considered valuable benefit.

STORAGE & DISPOSAL PROCEDURES OF BIOLOGICAL / HAZARDOUS MATERIAL

This project is study in nature and is done exclusively using the real data collected from the hospital. Therefore, this study did not handle any biological and/or hazardous material for the intended purpose of this study. Also, this study did not generate any waste, which requires careful disposal complying with the applicable norms. Since, there are no waste was produced as a result of this study, no requirements is identified under this section for compliance.

RESEARCH DATA CONSIDERED FOR THE STUDY

As explained in this study report the children details and their post Cochlear implant visit and the CAP and SIR data pertaining to each patient for their each visit has been obtained from the primary source and those data are tabulated hereunder. Though more than 150 patients' data have been collected and collated for the analysis. However, the detailed table and the statistical analysis are appended in the report in its entirety, which can be referred for further details.

DATA ACQUISITION AND ANALYSIS

As described in the flow chart and its subsequent sections, data pertaining to the Cochlear recipients are collected as explained in the following section. Such data processing is done applying statistical analysis for further evaluation and for interpretation of the results.

When we perform statistical analysis, the most suited statistical approach for the given data shall be considered. Such selection of statistical application tool, alone, can reveal the underlying facts and will provide reality-based interpretations for the future application and usages, which could give a good amount of lead for further development on the same area of expertise works.

Considering this aspect, non-parametric test method is adopted for this research data analysis, as data collected are not expected to be normally distributed. These type of data and the associated statistical analysis are also referred to as distribution-free tests.

The advantage of non-parametric statistical analysis is that, they do not require a distribution to meet the required assumptions to be analysed, more specifically where the data is not normally distributed. Accordingly, the statistical analysis has been performed.

The process, programme and application software used for analysis of the data are briefly listed as shown below:

- The collected data were analysed with IBM SPSS Statistics for Windows, Version 23.0.(Armonk, NY: IBM Corp).
- To describe about the data descriptive statistics the mean & S.D were used.
- To find the significant difference between the bi-variate samples in Independent groups the Mann-Whitney U test was used.
- In the above statistical tool the p value 0.05 is considered as significant level.

Further details and the interpretations of the findings and the conclusion thereupon are discussed in the following sections.

POST IMPLANT DATA ACQUISITION

Typically, patients with Cochlear implants had their devices activated approximately 1 month after the surgery, and the first post-operative follow up is done a week after surgery and thereafter they were followed up monthly, for a period of one year following device activation.

All Cochlear implant recipients received postoperative rehabilitation and speech training at PSGIMSR Audiology and Speech therapy department. CAP and SIR were used to assess and record the auditory and speech performance of patients post Cochlear implantation every month for a period of one year after the device activation. These data are collated and compiled and subjected to further statistical analysis.

The data collected as above are screened through and found that these do not form prescribed models that can be attributable and be determined by a small number of parameters like normal distribution model or linear regression model. Hence these data are all of non-parametric data type and therefore, non-parametric statistical analysis was carried out, as explained in the previous section.

RESULTS

Based on the materials and methodology explained above, the data grouping and the data analysis including Statistical Analysis has been performed. The step by step sequencing of the analysis with reference to the interpretations and results are mentioned here below.

DATA GROUPING AND ANALYSIS

By taking into account of speech development, paediatric growth, and the best period for hearing restoration, this study divided the patients into two groups based on age: i.e., ≤ 2 years and $2 < \text{age} \leq 6$.

In order to derive specific outcomes and conclusion, the statistical analysis was done categorizing the data into 2 groups for better narrowed down observations. Accordingly, following two groups are formulated and the collated:

- Group A (Children - Babies upto 2 Year),
- Group B (Children - above 2 Year to 6 Years)

STATISTICAL METHODOLOGY & CONSIDERATIONS AND ANALYSIS

DATA TYPE AND SOURCE OF DATA

- Data Type: Post Cochlear implant CAP and SIR data pertaining to the Children - upto 5 Year
- Monthly review based CAP and SIR data for the period of 12 months post implant

DATA GROUPING AND COMPILATION

- Group A means (Children - Babies upto 2 Year)
- Group B (Children - above 2 Year to 5 Years)

DESIGN BASIS OF DATA ANALYSIS

- The collected data were analysed with IBM SPSS Statistics for Windows, Version 23.0.(Armonk, NY: IBM Corp).
- To describe about the data descriptive statistics the mean & S.D were used.
- To find the significant difference between the bivariate samples in Independent groups the Mann-Whitney U test was used.
- In the above statistical tool the probability value 0.05 is considered as significant level.

STATISTICAL ANALYSIS : NPAR TESTS AND OUTCOME

p - Value	** Highly Significant at $p < 0.01$
p - Value	* Significant at $0.01 \leq p \leq 0.050$
p - Value	# No Significant at $p > 0.050$

NPar Test and its analysis and its outcomes are reproduced here.

CAP DATA ANALYSIS:

- *Data Type = CAP*
- *Mann-Whitney Test*

TABLE- 5: CAP RANKS

Age Group		Group	N	Mean Rank	Sum of Ranks
M 1	Upto 2 yrs	A	43	70.22	3020
	Above 2 yrs	B	113	81.65	9227
	Total		156		
M 12	Upto 2 yrs	A	43	96.63	4155
	Above 2 yrs	B	113	71.6	8091
	Total		156		

TABLE-6: CAP GROUP A Vs GROUP B MEAN, SD COMPARISON

Age Group		Group	N	Mean	SD
M 1	Upto 2 yrs	A	43	1.07	0.55
	Above 2 yrs	B	113	1.27	0.69
M 12	Upto 2 yrs	A	43	6.81	2.99
	Above 2 yrs	B	113	5.25	2.21

Following is the Bar Chart showing the Mean data at 1 month post-implant and also at 12 month post-implant, indicating substantial and significant improvement post-implant of Cochlear on the basis of CAP data.

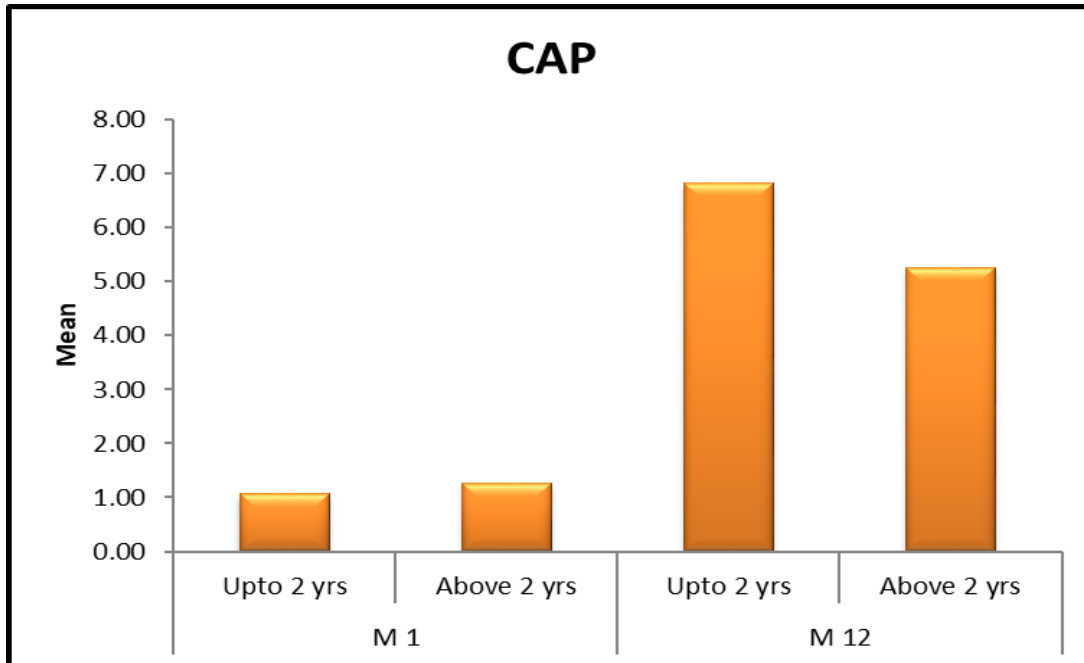


FIGURE-15: CAP GROUP A Vs GROUP B COMPARISON HISTOGRAM

TABLE-7: CAP GROUP A Vs GROUP B P VALUE COMPARISON

	Mann-Whitney U	Group	Z	p-value
M 1	2073.500	A	-1.879	0.060
M 12	1650.000	B	-3.117	0.002

- **Type = CAP**
- **Grouping Variable: Age Group**

**TABLE-8: MONTHLY CAP MEAN AND SD COMPARISON GROUP A Vs
GROUP B**

	Upto 2 yrs		Above 2 yrs	
	Mean	SD	Mean	SD
M 1	1.1	0.6	1.3	0.7
M 2	1.8	1.3	2.1	1.1
M 3	2.7	1.8	2.6	1.4
M 4	3.3	2.1	3.0	1.4
M 5	3.7	1.9	3.3	1.5
M 6	4.1	1.9	3.7	1.5
M 7	4.4	2.2	3.9	1.6
M 8	4.9	2.4	4.2	1.7
M 9	5.3	2.7	4.4	1.8
M 10	5.9	2.7	4.7	1.9
M 11	6.5	2.9	5.0	2.0
M 12	6.8	3.0	5.2	2.2

SIR DATA ANALYSIS:

- *Type = SIR*
- *Mann-Whitney Test*

TABLE-9: SIR RANKS

Age Group		N	Mean Rank	Sum of Ranks
M 1	Upto 2 yrs	44	73.18	3220.00
	Above 2 yrs	104	75.06	7806.00
	Total	148		
M 12	Upto 2 yrs	44	87.69	3858.50
	Above 2 yrs	104	68.92	7167.50
	Total	148		

TABLE-10: SIR GROUP A Vs GROUP B MEAN, SD COMPARISON

Age Group		N	Mean	SD
M 1	Upto 2 yrs	44	.91	.56
	Above 2 yrs	104	.94	.57
M 12	Upto 2 yrs	44	3.43	1.72
	Above 2 yrs	104	2.78	1.47

a. Type = SIR

Following is the Bar Chart showing the Mean data at 1month post-implant and also at 12 month post-implant, indicating substantial and significant improvement post-implant of Cochlear on the basis of SIR data.

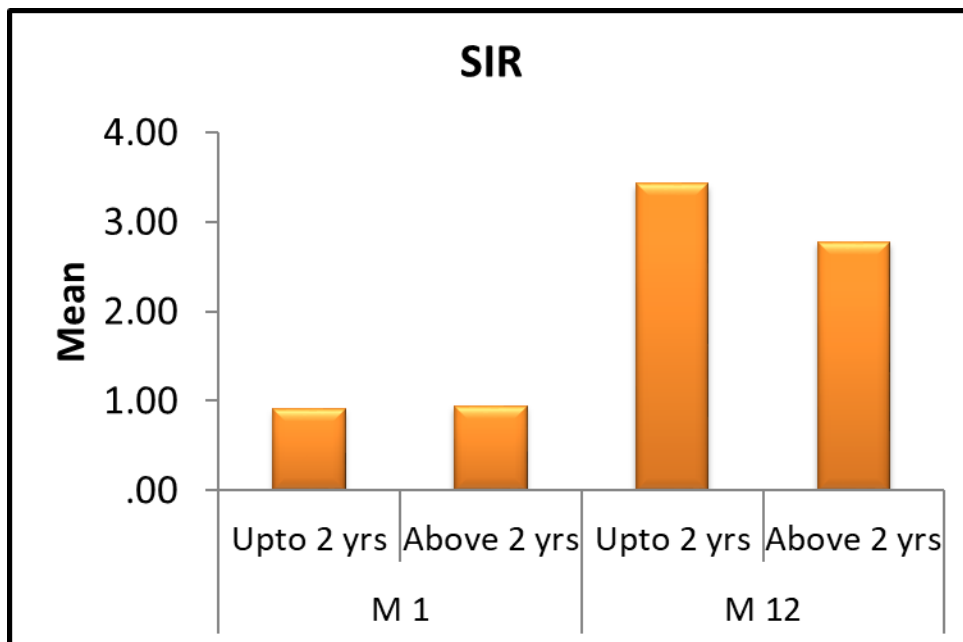


FIGURE-16: SIR GROUP A Vs GROUP B COMPARISON HISTOGRAM

TABLE-11: SIR GROUP A Vs GROUP B P VALUE COMPARISON

	Mann-Whitney U	Z	p-value
M 1	2230.000	-.332	.740
M 12	1707.500	-2.531	.011

- **Type = SIR**
- **Grouping Variable: Age Group**

**TABLE-12:MONTHLY SIR MEAN AND SD COMPARISON GROUP A Vs
GROUP B**

	Upto 2 yrs		Above 2 yrs	
	Mean	SD	Mean	SD
M 1	.9	.6	.9	.6
M 2	1.4	.9	1.3	.7
M 3	1.6	1.2	1.6	.9
M 4	1.7	1.3	1.8	1.0
M 5	2.0	1.4	1.9	1.1
M 6	2.1	1.3	2.1	1.1
M 7	2.2	1.4	2.2	1.2
M 8	2.	1.4	2.4	1.3
M 9	2.7	1.4	2.5	1.3
M 10	2.9	1.5	2.6	1.4
M 11	3.3	1.6	2.7	1.5
M 12	3.4	1.7	2.8	1.5

TABLE-13: LEGENDS AND ABBREVIATIONS USED FOR STATISTICAL ANALYSIS

➤ <i>Npar Test: It is a nonparametric statistical analysis</i>
➤ <i>CAP: Categories of Auditory Performance</i>
➤ <i>SIR: Speech Intelligibility Rate</i>
➤ <i>SD: Standard Deviation, how much the sample in a group differ from the mean value for the group</i>
➤ <i>N: Sample size, the number of patients under each group</i>
➤ <i>Mean Rank: average of the ranks for all observations within each sample.</i>
➤ <i>M1: Post implant Month-1</i>
➤ <i>M12: Post implant Month-12</i>

DISCUSSION

AGE EFFECT ON POST COCHLEAR IMPLANTATION HEARING AND SPEECH

Sharma and colleagues (Sharma et al., 2002, 2009) thought that the ideal age to restore hearing is when a child is under the age of six. The ability to restore hearing declines with age, especially beyond the age of seven. In many countries, the age for implantation for pre-linguistic deaf patients is currently suggested to be 1–6 years in the Guideline for Cochlear Implants (Editorial Board of Chines, 2013; Bradham and Jones, 2008). The better the effect, the younger the age of implantation. Early implantation aids patients in regaining their hearing and receiving speech therapy (Leigh et al., 2016; Mikic et al., 2014). Children of various ages, on the other hand, have varied characteristics in terms of speech development. Voice finalisation occurs between the ages of 2 and 12. Children above the age of six can still learn to speak with the help of speech therapy. In clinical practise, Cochlear implantation is the best option for children over the age of 6 who have severe to profound sensorineural deafness and are unable to hear with hearing aids. After Cochlear implantation, quality of life and speech recognition were reported to increase dramatically in older pre-lingual children (Clinkard et al., 2015; Straatman et al., 2014; Watson et al., 2016). To evaluate the influence of Cochlear implants on auditory outcomes in older children, more research is needed.

COMPARISON OF HEARING AND SPEECH ABILITY IN COCHLEAR IMPLANT RECIPIENTS

COMPARISON OF POSTOPERATIVE CAP SCORES OF PATIENTS AMONG THE 2 GROUPS

The differences in CAP scores of group A (1.07 ± 0.55), group B (1.27 ± 0.69) at 1 month after implant activation were not statistically significant ($Z = -1.879$, $P = 0.060$). Similarly, the differences in CAP scores of patients of both age groups at 12 months ($Z = 7.6$, $P < 0.01$) after the implantation were of statistical significance. The differences in CAP scores were also observed at 12 months after the implantation. These results indicated that the younger the age at Cochlear implantation, the better the postoperative auditory and speech rehabilitation.

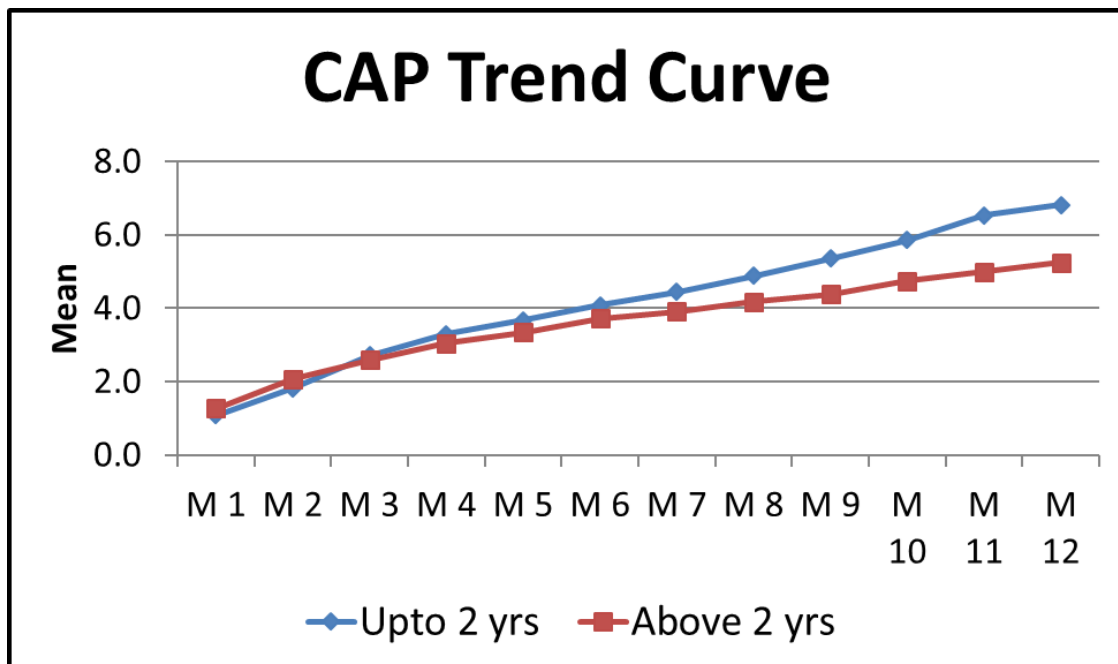


FIGURE-17: CAP TREND CURVE

COMPARISON OF POSTOPERATIVE SIR SCORES OF PATIENTS AMONG THE 2 GROUPS

The differences in SIR scores of group A (0.91 ± 0.56), group B (0.94 ± 0.56) at 1 month after implant activation were not statistically significant ($Z = -0.332$, $P = 0.740$). The SIR scores at 12 months post – operatively Group A (3.43 ± 1.72) and Group B (2.78 ± 1.47). The differences in SIR scores of patients of both age groups at 12 months ($Z = -2.531$, $P = 0.011$) after the implantation were of statistical significance.

These results coincided with findings of CAP and hence younger the age, better the outcome.

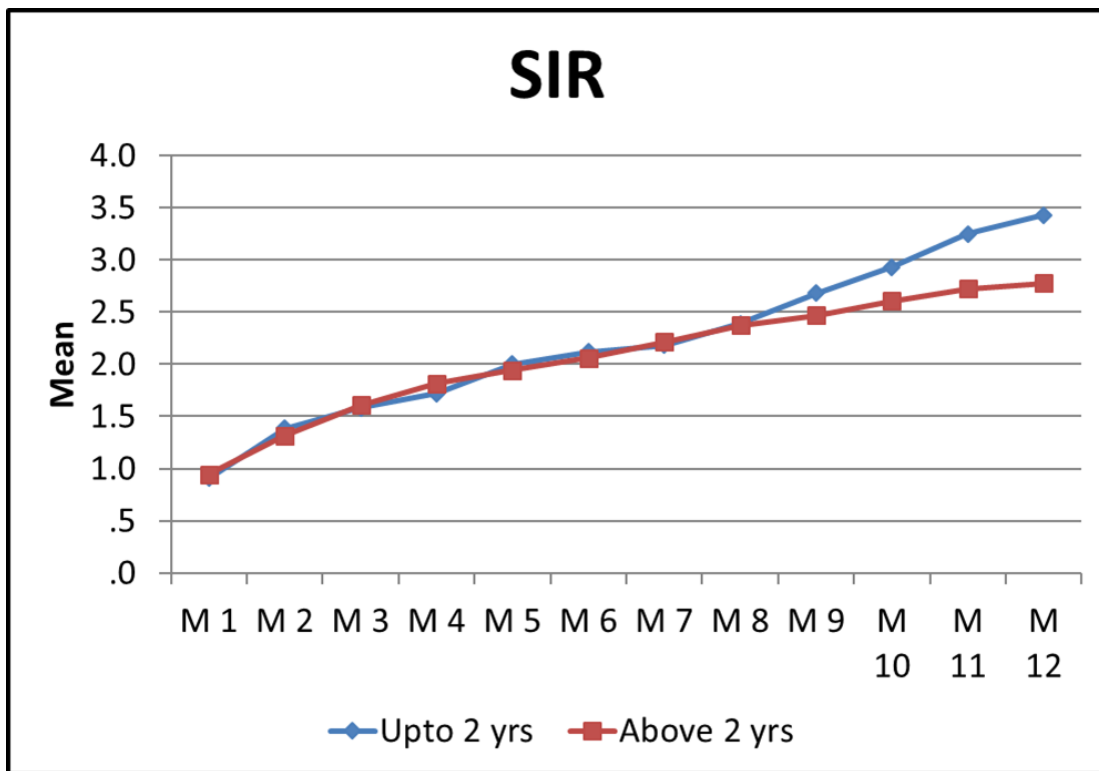


FIGURE-18: SIR TREND CURVE

EFFECT OF COCHLEAR IMPLANTATION ON OPEN-SPEECH SCORES

The scores of the open-set speech assessment for groups A and B after the surgery were recorded. The results indicated that Cochlear implantation significantly improved the open-set speech level of each group and the improvement was enhanced as the rehabilitation time increased .

EFFECT OF COCHLEAR IMPLANTATION ON SCORES OF AUDITORY PERCEPTION

In all age group of patients, the score of the Categories of Auditory Perception was significantly higher after Cochlear implants. Moreover, for each age group, the score increased as the time of rehabilitation extended.

POST OPERATIVE CAP AND SIR RATING OF EACH GROUP

The **Npar Test** was used to examine the CAP and SIR results of each group after the surgery. The differences among groups were not statistically significant at first month after the device activation. Twelve months after activation, the CAP and SIR scores started to show significant differences among groups. These results were consistent with the results of the open-set speech assessment and auditory perception assessment which all showed improvements in scores over time. Therefore, 12 months after the activation, **IBM SPSS Statistics for Windows, Version 23.0.(Armonk, NY: IBM Corp**)assessment software was used for hearing and speech assessment for each age group.

The test of open-set speech assessment and Categories of auditory perception assessment further indicated the difference in the effects in different age groups.

SPEECH ASSESSMENT AFTER COCHLEAR IMPLANTATION

In this study, CAP and SIR assessments techniques were adopted, and it is found that in all age groups the scores at 1 month following Cochlear implantation did not differ significantly from that before the surgery. But significant differences started to appear 4 months after the implantation in terms of CAP values Group A (3.3 ± 2.1) Group B (3.0 ± 1.4) whereas SIR mean scores started to rise in Group A (2.7 ± 1.4) compared to Group B (2.5 ± 1.3) by around the 9th month and thereafter has a steady increase subsequently. Different age groups showed different auditory performance. Therefore, combined use of these methods helps more accurately and reliably evaluate the postoperative auditory and speech performance for paediatric Cochlear implant recipients.

EFFECT OF REHABILITATION TIME ON HEARING AND SPEECH OUTCOMES

In this study, approximately around 150 plus patients with Cochlear implants received hearing and speech assessments before the surgery and at every month after the device activation for a period of 1 year post implantation. The results of CAP and SIR indicated that both the hearing and speech abilities improved over time after implantation, and the differences were statistically significant. CAP and SIR scores showed no obvious improvement at 1 month following the implant activation. While at

12 months, the scores have significantly improved. And, within one year of follow-up, the auditory and speech performance improved over time. Long-term follow-up is needed due to the child's growth and development. In long-term follow-up after Cochlear implantation, extra attention must be made to the child's abilities for interaction among peers and adaption to social life, as hearing and speech develop gradually.

The auditory perception evaluation score was greater than the open-set speech test results, showing that Cochlear implantation can effectively increase the patient's hearing ability, but speech training is required to improve postoperative speech ability. Although the patient's hearing and speech abilities improved over time, we noticed variances in age groups and individual differences. This could be because the patients came from different parts of the country and underwent rehabilitation training in local rehabilitation schools near their homes rather than at the same rehabilitation centre. Different rehabilitation centres featured different hearing and speech training modalities, personnel, and teaching equipment, all of which could have influenced the findings. Furthermore, especially in the open-set speech exam, the patients' home context and educational backgrounds may have an impact on the outcomes.

CI FAILURE CASES AND EXPLANATION

In this study there were 2 cases of failures out of 158. Both children received Advanced Bionics implant and the reason for CI failure was flap necrosis, mainly due to poor wound care after discharge. Both these implants were explanted.

Previous literature review of a retrospective study done in Samsung Medical centre, among the 925 CI recipients, 496 (53.6%) were female and 429 (46.4%) were male. At the time of implantation, the average age was 14.3 years (range: 0-90). The majority of the instances (723 [78.2 percent]) included paediatric patients who had implants before the age of 20; the remaining 202 (21.8 percent) were adults. In 519 patients, Cochlear implants were placed unilaterally, and in 203 patients, they were placed bilaterally. 506 devices were Cochlear (54.7 percent), 270 (29.2%) Med-El, 146 (15.8%) Advanced Bionics, and three (0.3 percent) Oticon.

A total of 43 (4.6%) of the 925 people who had CIs had to undergo revision surgery. The average time between the first operation and the first revision procedure was 878.67 days (2.4 years; range, 1-5234 days). The aetiology of hearing loss was congenital in 31 patients (72%), and acquired in 12 patients who underwent revision surgery (28 percent). The most common cause of acquired hearing loss was idiopathic sudden hearing loss (n = 5), followed by meningitis (n = 2), immunisation (n = 1), chronic otitis media (n = 1), high fever (n = 2), and chemotherapy (n = 1). In addition, 14 of the revision patients (33%) had an inner ear anomaly. CSF leakage occurred in 5 of the 12 people who had CI revisions, and the electrode was partially implanted in three of them (7 percent). In the operation room, the NRT/ART responses were noticed.

36 patients (84 percent) of those who underwent revision surgery had good results, 6 (14 percent) had partial results, and one patient (2 percent) had no reaction.

We also determined manufacturer-specific revision rates (Table 2). The revision rate for Advanced Bionics was the highest (9 of 146 patients [6.2 percent]). Cochlear and Med-El devices had revision rates of 5.3 percent (27 of 506 patients) and 2.6 percent (7 of 270 patients), respectively.

Device failure occurred in 28 of 925 patients (3.0%; 28 of 43 revisions [65%]), making it the most common reason for CI surgical revisions overall and by manufacturer. The second most common reason for revision was flap-related complications and migration, which occurred in 4 of 925 patients (0.4 percent; 4 of 43 revisions [9.3 percent]), followed by hematoma in 3 of 925 patients (0.3 percent ; 3 of 43 revisions [7.0 percent]). In two of the 925 patients, both CSF leaking and misinsertion happened (0.2 percent ; 2 of 43 revisions [4.7 percent]). Flap-related complications were found to be more common in those who received Advanced Bionics devices.

Therefore, Advanced Bionics was found to have the highest device failure rate (7 out of 146 [4.8 percent]), followed by Cochlear (17 out of 506 [3.4 percent]) and Med-El (17 out of 506 [3.4 percent]) (4 of 270 [1.5 percent]).²⁵

Similarly in this both the cases of flap necrosis were implanted with Advanced Bionics. The implant manufacturer may not be the sole cause of infection. Most of the CI recipients belong to low socio-economic status. Overcrowding, poor personal hygiene, and lack of attention to wound site post discharge may be some causes.

TABLE-14: STATISTICAL DATA ON REVISION REASONS AND DEVICE SURVIVAL RATES

Device Model	Mean (SD) Follow-up Duration, y	No.							Rate, No./Total No. (%)				Survival, %			
		Device Failure	Flap-Associated Problem	Migration	Hematoma	CSF Leakage	Misinsertion	No. of Revisions	No. of CIs	Revision	Device Failure	Cumulative		Device		
												5-y	10-y	5-y	10-y	
Cochlear																
CI 24R	15.1 (1.1)	0	0	0	0	0	0	0	49	0	0	100	100	100	100	
CI 24RE	10.2 (1.7)	4	1	2	1	0	1	9	159	9/159 (5.7)	4/159 (2.5)	94.34	94.34	97.42	97.42	
CI 422	4.6 (1.9)	4	0	0	0	0	0	4	185	4/185 (2.2)	4/185 (2.2)	NA	NA	NA	NA	
CI 512	7.9 (1.4)	8	0	2	2	0	1	13	66	13/66 (19.7)	8/66 (12.1)	83.33	NA	90.24	NA	
CI 522	1 (0.4)	1	0	0	0	0	0	1	30	1/30 (3.3)	1/30 (3.3)	NA	NA	NA	NA	
CI 532	0.5 (0.2)	0	0	0	0	0	0	0	17	0	0	NA	NA	NA	NA	
Total, No. (%)	7.5 (4.2)	17 (63.0)	1 (3.7)	4 (14.8)	3 (11.1)	0 (0.0)	2 (7.4)	27	506	27/506 (5.3)	17/506 (3.4)	94.95	NA	96.97	NA	
Advanced Bionics																
Clarion CII	15.5 (0.4)	0	0	0	0	0	0	0	4	0	0	100	100	100	100	
HiRes 90K	11.4 (2.2)	7	2	0	0	0	0	9	142	9/143 (6.3)	7/143 (4.9)	94.32	93.60	95.67	94.94	
Total, No. (%)	11.5 (2.2)	7 (77.8)	2 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9	146	9/146 (6.2)	7/146 (4.8)	94.48	NA	95.79	NA	
Med-El																
SONATA1100	6.8 (0.7)	1	0	0	0	1	0	2	60	2/60 (3.3)	1/60 (1.7)	96.67	NA	98.31	NA	
CONCERTO	3.8 (1.3)	2	1	0	0	1	0	4	178	4/178 (2.2)	2/178 (1.1)	97.55	NA	98.77	NA	
PULSAR CI 100	6.5	0	0	0	0	0	0	0	1	0	0	100	NA	100	NA	
Synchrony	0.6 (0.2)	1	0	0	0	0	0	1	31	1/31 (3.2)	1/31 (3.2)	NA	NA	NA	NA	
Total, No. (%)	4.1 (2.1)	4 (57.1)	1 (14.3)	0 (0.0)	0 (0.0)	2 (28.6)	0 (0.0)	7	270	7/270 (2.6)	4/270 (1.5)	96.93	NA	98.15	NA	
Oticon																
Neuro Zti/Total	0.5 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0	3	0	0	NA	NA	NA	NA	
Total patients who had CIs, No. (%)	7.1 (4.2)	28 (65.1)	4 (9.3)	4 (9.3)	3 (7.0)	2 (4.7)	2 (4.7)	43	925	43/925 (4.6)	28/925 (3.0)	NA	NA	NA	NA	
Reason for revision rates, %	NA	3	0.4	0.4	0.3	0.2	0.2	NA	NA	NA	NA	NA	NA	NA	NA	

Abbreviations: CI, cochlear implant; CSF, cerebrospinal fluid; NA, not applicable.

^a Device failure was the most common reason for revision surgery. Among devices, the revision rate and device failure rate were highest with the CI 512. Among manufacturers, they were highest with Advanced Bionics devices.

CHALLENGES, POTENTIAL RISKS & BENEFITS

One of the largest challenges facing Cochlear implant professionals is to find pre-implant predictors of post implant performance. Moreover, finding ways to improve performance for individual Cochlear implant users remains a challenge.

For these individuals, the largest benefit is demonstrated when sound from the Cochlear implant is combined with speechreading cues.

Despite considerable concerns over the potential of Cochlear implants for aiding speech and language development in children who are deaf, the results of studies concerning speech, language, and reading have provided consistent results showing that

children who are implanted during the preschool years or early school years are very likely to benefit from the auditory experience provided by these devices.

Throughout these studies, substantial individual differences were reported and therefore benefit was not universal, but was frequent. Factors influencing the individual differences in outcome have been found to be the age of implantation, with early implantation tending to be associated with better outcomes, and receipt of oral communication training benefiting the development of better speech production. Thus, it would seem that implantation in the early preschool years and possibly in infancy followed by high quality aural rehabilitation and speech training should improve the proportion of children with good speech and language outcomes.

CI Performance has improved significantly over the course of the past decade with different systems available now a days with varying degree of effectiveness and efficiency. The best Cochlear implant users now achieve sound only word recognition scores of 80% or higher regardless of device.

CONCLUSION

Assessment methodology and evaluation techniques based observations and findings are summarised here below to arrive at appropriate and more relevant conclusions on the subject research.

CAP and SIR rating at each time point after surgery was the major parameter and input for the assessment as a whole along with the other medical information of the patient both Group A (Children - Babies upto 2 Year) and Group B (Children - above 2 Year to 6 Years). The Mann – Whitney U test was used to examine the CAP and SIR results of each group after the surgery.

The differences among groups were not statistically significant before the surgery or at 1 month after the device activation. From 4 months after activation, the CAP started to increase and SIR scores started to show significant increase from 9th month post implant among CI recipients younger than 2 yrs of age.

This research findings are further narrowing down the conclusion in terms of the post-implant outcomes for the children patient age groups.

The scores of patients in the open-set speech assessment, CAP and SIR significantly improved after Cochlear implantation as it is evident from this research data and its associated add-on information pertaining to the subject matter.

The overall outcome of the Cochlear implant and its related benefits proven by the statistical analysis under this research is listed below:

a) Outcome of Cochlear Implant with respect to auditory perception scores:

We find comparisons of the Categories of auditory perception scores among two age groups, which indicated that the differences in scores at 1 month after device activation were statistically not significant ($Z = -1.879$, $P = 0.060$). The score of group B (1.27 ± 0.69) was marginally higher than that of group A (1.07 ± 0.55) at the end of month 1 post-op ($Z = -1.879$, $P = 0.060$).

b) Outcome of Cochlear Implant 6 months after implant:

At the end of 6 months Group A had a mean score of (4.1 ± 1.9) which was higher than the mean score of Group B (3.7 ± 1.5).

c) Outcome of Cochlear Implant 12 months after implant:

The score differences among age groups were also observed at 12 months after the surgery showed significant improvement with a mean score of group A (6.81 ± 2.99) and Group B (5.25 ± 2.21). Further comparisons between groups at 12 months showed that the group less than 2yrs of age had much better CAP ($Z = -3.117$, $p = 0.002$) and SIR scores which was statistically significant ($Z = -2.531$, $p = 0.011$).

In addition to the above, based on the statistical analysis, following worth noting points and conclusions are also arrived at:

- 1) The results showed that hearing and speech abilities of Groups A patients (Children - Babies upto2 Year) are significantly better than that of Group B (Children - above 2 Year to 6 Years), indicating that the younger the age at implantation yields better the outcomes. Compared with Group B (Children - above 2 Year to 6 Years), the better performance of Group A (Children - Babies upto2 Year) is contributed by many factors including better cooperation of the parents and their dedicated commitment, cooperation and post implant care of that age group children.
- 2) The younger the age at implantation, the better the results. Moreover, the hearing and speech performance of Cochlear implant recipients gradually improved with the extension of rehabilitation time.
- 3) There is substantial evidence that Cochlear implant is beneficial to children with residual hearing. Preoperative residual hearing is also valuable to predict speech perception outcomes after Cochlear implantation. There is more extensive research being conducted worldwide in order to make recommendations and to set prognosis for Cochlear implants based on children preoperative residual hearing.
- 4) Early implantation has positive effects on hearing capability which in turn results in better speech and language skills development, which is very significant as it is evident from the analysis on the subject.

- 5) Also, the regular CI use, which is defined as using the CI for 8 hours or greater per day, proved higher benefits. It is also worth noting that high rates of regular CI use are sustained after childhood implantation, which is also an encouraging factual to go for Cochlear implant at young childhood age that would be more useful and beneficial by all means.

- 6) As per auditory perception assessment and open speech assessment, suggesting Cochlear implantation can substantially improve children's hearing and speech ability and even improve their speech perception and cognitive abilities, social activities, and therefore have a better quality of life. Cochlear implantation can improve the hearing and speech performance of patients with bilateral severe-to-profound sensorineural deafness.

- 7) Utilizing the opportunities available in the local State in terms of financial aids by the Tamil Nadu State government for Cochlear implant, the parents shall come forward with open mind to avail the opportunity for the betterment of the children with hearing loss to bring them up in the present day competitive environment to succeed in their future at par with their peers having no profound hearing deficiencies.

All the above significant benefits are the outcomes identified through the subject research as a conclusion.

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ANNEXURE

SOP 15-V 1.2 / ANX 01-V1.0

Application form for requesting Waiver of Written Informed Consent/ waiver of consent
(To be filled by PI)

1. Proposal Number :
2. Principal Investigator's name: Dr. Jeril
3. Department: Department of Otorhinolaryngology
4. Title of project: ASSESSMENT OF OUTCOMES OF HEARING AND SPEECH IN COCHLEAR IMPLANT RECIPIENTS

REASONS FOR REQUESTING WAIVER OF INFORMED CONSENT

Please check the reason(s) for requesting waiver

1. Research involves 'less than minimal risk'
2. There is no direct contact between the researcher and participant

I hereby assure that the rights of the participants will not be violated.

Following are the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

1. **Never shall the patient's name/origin/photograph be used during the research process, it shall always remain confidential.**

Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.

Principal Investigator's signature with date:


9/12/19

PROFORMA

PREOPERATIVE WORKUP PROFORMA			
NAME	DATE OF BIRTH	CMCHIS CARD NUMBER	DATE
	DD/MM/YY YY		DD/MM/YY YY
INVESTIGATIONS			
SL. NO.	TYPE OF TEST	OBSERVATION / FINDINGS / RESULTS	
1.	BLOOD ROUTINE COUNTS		
2.	URINE ROUTINE		
3.	X-RAY CHEST		
4.	X-RAY NASOPHARYNX		
5.	BEHAVIOURAL OBSERVATION AUDIOMETRY		

6.	IMPEDENCE AUDIOMETRY	
7.	OTO-ACOUSTIC EMISSION TESTING	
8.	BRAINSTEM EVOKED RESPONSE AUDIOMETRY (BERA)	
9.	ECG	
10.	PEDIATRIC/ CARDIAC /OPHTHALMOLOGY/PSYCHOLO GIST OPINION	
11.	HEARING AID TRIAL	
12.	CT SCAN	
13.	MRI SCAN	
14.	CERTIFICATE FROM PARENTS/ GUARDIAN WILLINGNESS TO PARTICIPATE FOR 1 YR REHABILITATION	

KEYWORDS AND ABBREVIATIONS:

Keywords:

Hearing loss, Sensorineural, Cochlear implant, Rehabilitation, Speech perception, Assessment, Auditory perception, Hearing loss; Language development,

Abbreviations:

CAP	Categories of Auditory Performance
CI	Cochlear implant
SIR	Speech Intelligibility Rate
CSOM	Chronic Suppurative Otitis media
CHL	Conductive Hearing Loss
SNHL	Sensorineural Hearing Loss

SL. NO	NAME	AGE (YRS)	SEX	DEVICE	COCHLEAR IMPLANT DATE	SWITCH ON DATE	AVT DATE	DATA TYPE	M 1	M 2	M 3	M 4	M 5	M 6	M 7	M 8	M 9	M 10	M 11	M 12
54	SAKTHI.J	3	MALE	NUCLEUS	23-07-2018	24-08-2018	12-09-2018	CAP	1	2	5	5	5	6	6	6	7	7	7	8
								SIR	1	1	3	3	3	3	3	3	3	3	3	3
55	ROOPESH	4	MALE	NUCLEUS	30-07-2018	24-08-2018	13-09-2018	CAP	1	1	1	2	2	2	2	2	2	2	2	2
								SIR	1	1	1	2	2	2	2	2	2	2	2	2
56	DHANSHIKA	2	FEMALE	AB	02-08-2018	27-08-2018	10-09-2018	CAP	1	1	1	1	1	1	1	1	1	2	2	2
								SIR	1	1	1	1	1	1	1	1	1	1	2	2
57	GOWTHAM.M	4	MALE	AB	20-08-2018	12-09-2018	22-09-2018	CAP	1	2	2	3	4	4	4	5	5	7	7	8
								SIR	1	2	2	2	2	2	2	2	2	2	2	3
58	MUKESH	3	MALE	NUCLEUS	22-08-2018	17-09-2018	29-09-2018	CAP	1	2	2	3	4	4	4	5	5	7	8	8
								SIR	1	1	1	2	2	2	2	3	3	3	3	3
59	HASHINI	3	FEMALE	NUCLEUS	27-08-2018	19-09-2018	25-09-2018	CAP	1	3	4	4	4	5	5	5	6	6	7	7
								SIR	1	2	2	2	2	2	2	2	2	2	2	2
60	ANSANA	4	FEMALE	AB	21-09-2018	15-10-2018	25-10-2018	CAP	2	2	3	4	4	4	4	4	4	4	5	5
								SIR	1	1	1	1	1	1	1	2	2	2	2	2
61	JAYAHARINI	1	FEMALE	AB	12-10-2018	09-11-2018	20-11-2018	CAP	0	1	1	1	1	2	2	2	3	4	4	
								SIR	1	1	1	1	1	2	2	2	2	3	3	3
62	DHANSIKA. D	5	FEMALE	AB	15-10-2018	12-11-2018	20.11.2018	CAP	1	2	2	2	2	2	4	4	4	4	4	
								SIR	1	1	1	1	1	1	2	2	2	2	2	2
63	SHREE	2	FEMALE	AB	19-10-2018	14-11-2018	23-11-2018	CAP	1	3	3	4	4	4	4	4	4	5	5	
								SIR	1	1	1	1	1	1	2	2	2	2	2	2
64	SHRIMATHI	5	FEMALE	AB	09-11-2018	01-12-2018	14-12-2018	CAP	1	2	3	4	4	4	5	5	5	5	5	
								SIR	1	1	1	1	1	1	2	2	2	2	2	2
65	SHRIANUSHA	2	FEMALE	AB	12-11-2018	10-12-2018	17-12-2018	CAP	1	1	2	2	2	3	4	4	5	5	5	
								SIR	1	1	1	1	1	1	1	1	1	1	2	3
66	GOWTHAM. S	2	MALE	AB	14-11-2018	12-12-2018	17-12-2018	CAP	1	2	3	3	3	4	4	5	5	6	6	
								SIR	1	1	1	1	2	2	2	3	3	3	4	4
67	MITHRADEVI.K	2	FEMALE	AB	15-11-2018	10-12-2018	15-12-2018	CAP	1	1	2	2	2	3	3	4	4	5	5	
								SIR	1	1	1	1	1	2	2	3	3	3	3	3
68	RITHIK.S	5	MALE	AB	16-11-2018	10-12-2018	18-12-2018	CAP	1	1	1	1	1	3	4	4	4	5	5	
								SIR	1	1	1	1	1	1	1	1	1	1	2	1
69	TANUSHREE	3	FEMALE	AB	19-11-2018	14-12-2018	20-12-2018	CAP	1	2	3	3	3	3	4	5	5	5	5	
								SIR	1	1	1	1	1	1	1	1	1	1	1	1
70	SANTHOSH	2	MALE	NUCLEUS	21-11-2018	02-01-2019	20-02-2019	CAP	1	1	1	3	4	4	4	4	4	5	6	
								SIR	1	1	1	1	2	2	2	2	3	3	3	
71	SHABEEL ARSHAD	5	MALE	NUCLEUS	23-11-2018	19-12-2018	01-01-2019	CAP	1	2	2	2	3	3	3	3	4	4		
								SIR	1	1	1	1	1	1	1	1	1	2	2	2
72	SUBHASRI	4	FEMALE	NUCLEUS	07-12-2018	07-01-2019	13-01-2019	CAP	1	1	1	1	1	2	2	2	2	2		
								SIR	1	1	1	1	1	1	1	1	1	1	1	
73	INIYA. S	6	FEMALE	AB	03-01-2019	01-02-2019	21-02-2019	CAP	2	2	2	2	2	4	5	5	5	5		
								SIR	1	1	1	1	1	1	2	2	2	2	3	3
74	VIJAYALAKSHMI.S	5	FEMALE	NUCLEUS	04-01-2019	01-02-2019	21-02-2019	CAP	1	1	1	2	2	3	3	3	3	6	6	
								SIR	1	1	1	1	1	1	1	1	1	1	1	1
75	MUKESHWARAN	3	MALE	AB	14-01-2019	01-02-2019	09-02-2019	CAP	1	2	2	3	4	5	5	6	6	6		
								SIR	1	1	1	1	2	2	2	2	3	2	3	
76	SENTHURMURUGAN	2	MALE	AB	17-01-2019	01-02-2019	09-02-2019	CAP	1	1	2	2	3	4	5	5	5	6		
								SIR	1	1	1	1	1	1	2	2	2	2	2	3
77	SABARI	3	MALE	AB	21-01-2019	11-02-2019	20-02-2019	CAP	1	1	1	2	3	3	3	3	3	4		
								SIR	1	1	1	1	1	1	1	1	1	1	1	
78	MOHAMMED ARIF	5	MALE	AB	24-01-2019	18-02-2019	03-02-2019	CAP	1	1	1	1	2	3	3	3	4	4		
								SIR	1	1	1	1	1	1	1	1	1	1	1	
79	HARISH.S	3	MALE	NUCLEUS	01-02-2019	06-03-2019	16-03-2019	CAP	1	1	1	2	2	2	3	3	4	5		
								CAP	0	0	1	1	1	1	1	1	1	1	1	
80	ARSHAN	4	MALE	NUCLEUS	04-02-2019	02-03-2019	12-03-2019	CAP	1	2	3	2	5	5	5	6	6			

SL. NO	NAME	AGE (YRS)	SEX	DEVICE	COCHLEAR IMPLANT DATE	SWITCH ON DATE	AVT DATE	DATA TYPE	M 1	M 2	M 3	M 4	M 5	M 6	M 7	M 8	M 9	M 10	M 11	M 12
80	BARSHAN	4	MALE	NUCLEUS	04-02-2019	02-03-2019	12-03-2019	SIR	1	1	1	2	2	2	2	2	2	3	3	4
81	SWATHI.R	4	FEMALE	NUCLEUS	06-02-2019	02-03-2019	12-03-2019	CAP	1	1	2	3	4	4	4	4	4	5	5	6
								SIR	0	0	1	1	1	1	1	1	1	1	1	1
82	ARSHITH.S	3	MALE	AB	14-02-2019	08-03-2019	16-03-2019	CAP	1	1	1	2	2	3	3	3	3	4	4	4
								SIR	0	0	1	1	1	2	2	2	2	2	2	2
83	PRANIKA	2	FEMALE	AB	18-02-2019	15-03-2019	27-03-2019	CAP	1	1	1	2	3	3	3	4	4	5	5	8
								SIR	0	0	1	1	1	1	1	2	2	2	2	3
84	KANISHKA.S	2	FEMALE	AB	20-02-2019	18-03-2019	29-03-2019	CAP	1	1	2	2	3	3	3	3	3	3	3	4
								SIR	1	1	1	1	1	1	1	1	1	1	1	1
85	SHAMUL	3	FEMALE	AB	01-03-2019	18-03-2019	28-03-2019	CAP	1	2	2	3	4	4	4	5	5	6	7	8
								SIR	1	1	1	1	2	2	3	3	3	3	3	3
86	ASWIN.K	5	MALE	NUCLEUS	06-03-2019	01-04-2019	09-04-2019	CAP	1	2	2	3	4	4	4	5	5	5	7	8
								SIR	1	1	1	1	1	1	1	1	1	1	2	2
87	DIVYA.S	6	FEMALE	NUCLEUS	11-03-2019	29-03-2019	03-05-2019	CAP	1	2	2	3	4	4	4	5	5	5	6	7
								SIR	1	1	1	1	2	2	2	2	2	2	2	2
88	SARMITHA	5	FEMALE	NUCLEUS	13-03-2019	10/04/2019	20-04-2019	CAP	1	3	3	4	4	5	6	6	6	7	8	8
								SIR	0	2	2	2	2	2	2	2	3	3	3	3
89	DHITSHANYA	3	FEMALE	NUCLEUS	18-03-2019	11-04-2019	25-04-2019	CAP	1	1	3	4	4	4	4	4	4	5	5	5
								SIR	0	1	1	1	1	1	1	1	1	1	1	2
90	KAVIPUGAL	3	MALE	AB	20-03-2019	12-04-2019	23-04-2019	CAP	2	2	3	4	4	4	4	4	4	8	9	9
								SIR	1	1	1	1	1	2	2	2	2	2	2	2
91	VAISHAK. VARISH	2	MALE	NUCLEUS	25-03-2019	19-04-2019	26-04-2019	CAP	1	2	3	4	4	4	5	5	6	6	7	8
								SIR	1	1	1	1	2	2	2	2	2	2	2	3
92	SWATHI.S	4	FEMALE	AB	27-03-2019	19-04-2019	23-04-2019	CAP	2	2	3	4	4	4	5	5	5	5	5	5
								SIR	1	1	1	1	1	1	1	1	2	2	2	2
93	HARIKIRTHANA.P	2	FEMALE	AB	01-04-2019	26-04-2019	09-05-2019	CAP	1	1	3	4	4	4	4	4	5	6	6	7
								SIR	0	1	1	2	2	2	2	2	2	2	3	3
94	JENISHA.C	2	FEMALE	AB	01-04-2019	29-04-2019	08-05-2019	CAP	2	3	4	6	6	6	6	6	6	8	9	9
								SIR	1	1	2	2	2	2	2	2	3	3	3	3
95	ABUTHAHIR	4	MALE	AB	08-04-2019	03-05-2019	15-05-2019	CAP	1	2	3	3	3	3	3	3	3	3	3	4
								SIR	0	1	1	1	1	1	1	1	1	1	1	2
96	DINESH.G	6	MALE	AB	15-04-2019	12-06-2019	17-06-2019	CAP	1	3	3	3	3	4	4	5	5	5	5	5
								SIR	1	1	1	2	2	2	2	2	2	2	2	2
97	INEEYAA	3	FEMALE	AB	17-04-2019	13-05-2019	22-05-2019	CAP	2	4	6	6	6	6	6	7	8	9	9	9
								SIR	1	1	2	2	2	2	3	3	3	3	3	3
98	JOSHIKA DEEPTHI	4	FEMALE	NUCLEUS	29-04-2019	24-05-2019	01-06-2019	CAP	3	6	7	7	7	9	9	9	9	9	9	9
								SIR	2	2	3	3	3	3	3	4	4	4	4	4
99	PRASATH .V	4	MALE	NUCLEUS	20-05-2019	14-06-2019	24-06-2019	CAP	1	2	2	2	2	3	3	3	4	5	5	5
								SIR	0	1	1	1	1	1	1	1	2	2	2	2
100	MONICA. M	4	FEMALE	NUCLEUS	29-05-2019	24-06-2019	31-06-2019	CAP	1	2	3	3	3	3	3	3	3	3	3	3
								SIR	0	1	1	1	1	1	1	1	1	2	2	2
101	RITHIK.D	2	MALE	AB	03-06-2019	28-06-2019	05-07-2019	CAP	1	1	1	2	2	3	3	4	4	5	6	7
								SIR	0	1	1	1	1	2	2	2	2	3	3	3
102	LAKSHANA.R	4	FEMALE	AB	03-06-2019	28-06-2019	18-07-2019	CAP	2	3	3	3	3	4	4	5	6	6	6	6
								SIR	1	1	1	2	2	2	3	3	3	3	3	3
103	JUDITH MARY	2	FEMALE	AB	05-06-2019	01-07-2019	08-07-2019	CAP	1	3	3	3	3	4	4	5	6	7	8	9
								SIR	0	1	1	1	2	2	2	2	3	3	3	3
104	MAHALAKSHMI	2	FEMALE	NUCLEUS	17-06-2019	10-07-2019	22-07-2019	CAP	1	2	2	4	4	5	6	7	8	8	9	9
								SIR	1	1	1	2	2	2	2	3	3	3	4	4
105	KAVYA.M	5	FEMALE	NUCLEUS	19-06-2019	15-07-2019	01-08-2019	CAP	1	2	2	3	4	5	6	7	7	7	7	8
								SIR	1	1	1	2	2	2	2	3	3	3	3	3
106	KISHORE.K	4	MALE	NUCLEUS	24-06-2019	19-07-2019	22-07-2019	CAP	1	2	2	3	3	3	3	3	3	3	3	3
								SIR	1	1	1	1	1	1	1	1	1	2	2	2

