AGEWISE OUTCOME OF SPEECH AND HEARING IN PRELINGUALLY DEAF CHILDREN AFTER COCHLEAR IMPLANTATION

Dissertation Submitted in

Partial fulfillment of the regulations required for the award of

M.S. ENT

BRANCH – IV

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

CHENNAI - 600 032

APRIL 2016

CERTIFICATE

This is to certify that this dissertation in **"AGEWISE OUTCOME OF SPEECH AND HEARING IN PRELINGUALLY DEAF CHILDREN AFTER COCHLEAR IMPLANTATION"** is a bonafide research work done by **Dr. RUBINE ZEINUDDEEN C.,** under my guidance during the academic year 2013 to 2016.

This has been submitted in partial fulfillment of the award of **M.S. Degree in ENT (Branch – IV)** by **The Tamil Nadu Dr. M.G.R. Medical University, Chennai- 600 032.**

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DECLARATION

I solemnly declare that this dissertation entitled **"AGEWISE OUTCOME OF SPEECH AND HEARING IN PRELINGUALLY DEAF CHILDREN AFTER COCHLEAR IMPLANTATION"** was done by me at **Coimbatore Medical College and Hospital** during the academic year 2013 to 2016 under the guidance and supervision of **Prof. Dr. V. ARAVINTHAN M.S. ENT, DNB.**

This dissertation is submitted to the **Tamil Nadu Dr. M.G.R. Medical University,** towards the partial fulfillment of requirement for the award of M.S. Degree in ENT (Branch – IV).

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Course : MS ENT

Period of Study : 2013 - 2016

College : Coimbatore Medical college

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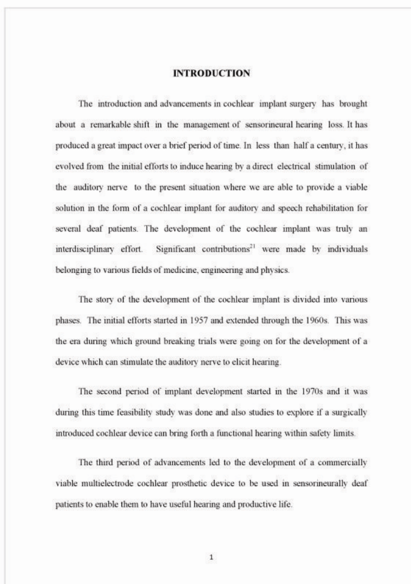

INTRODUCTION

The introduction and advancements in cochlear implant surgery has brought about a remarkable shift in the management of sensorineural hearing loss. It has produced a great impact over a brief period of time. In less than half a century, it has evolved from the initial efforts to induce hearing by a direct electrical stimulation of the auditory nerve to the present situation where we are able to provide a viable solution in the form of a cochlear implant for auditory and speech rehabilitation for several deaf patients. The development of the cochlear implant was truly an interdisciplinary effort. Significant contributions[21] were made by individuals belonging to various fields of medicine, engineering and physics.

The story of the development of the cochlear implant is divided into various phases. The initial efforts started in 1957 and extended through the 1960s. This was the era during which ground breaking trials were going on for the development of a device which can stimulate the auditory nerve to elicit hearing.

The second period of implant development started in the 1970s and it was during this time feasibility study was done and also studies to explore if a surgically introduced cochlear device can bring forth a functional hearing within safety limits.

The third period of advancements led to the development of a commercially viable multielectrode cochlear prosthetic device to be used in sensorineurally deaf patients to enable them to have useful hearing and productive life.

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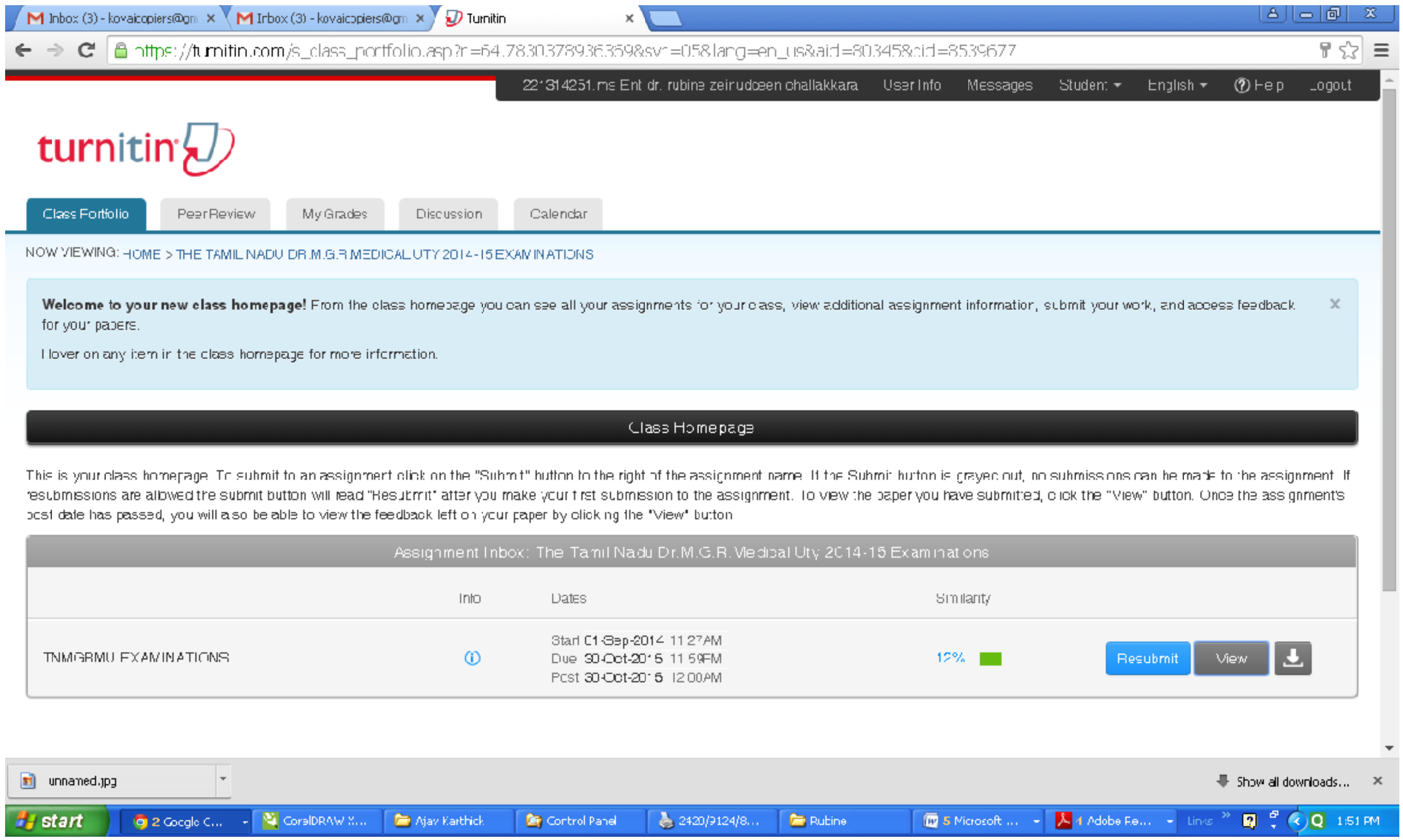
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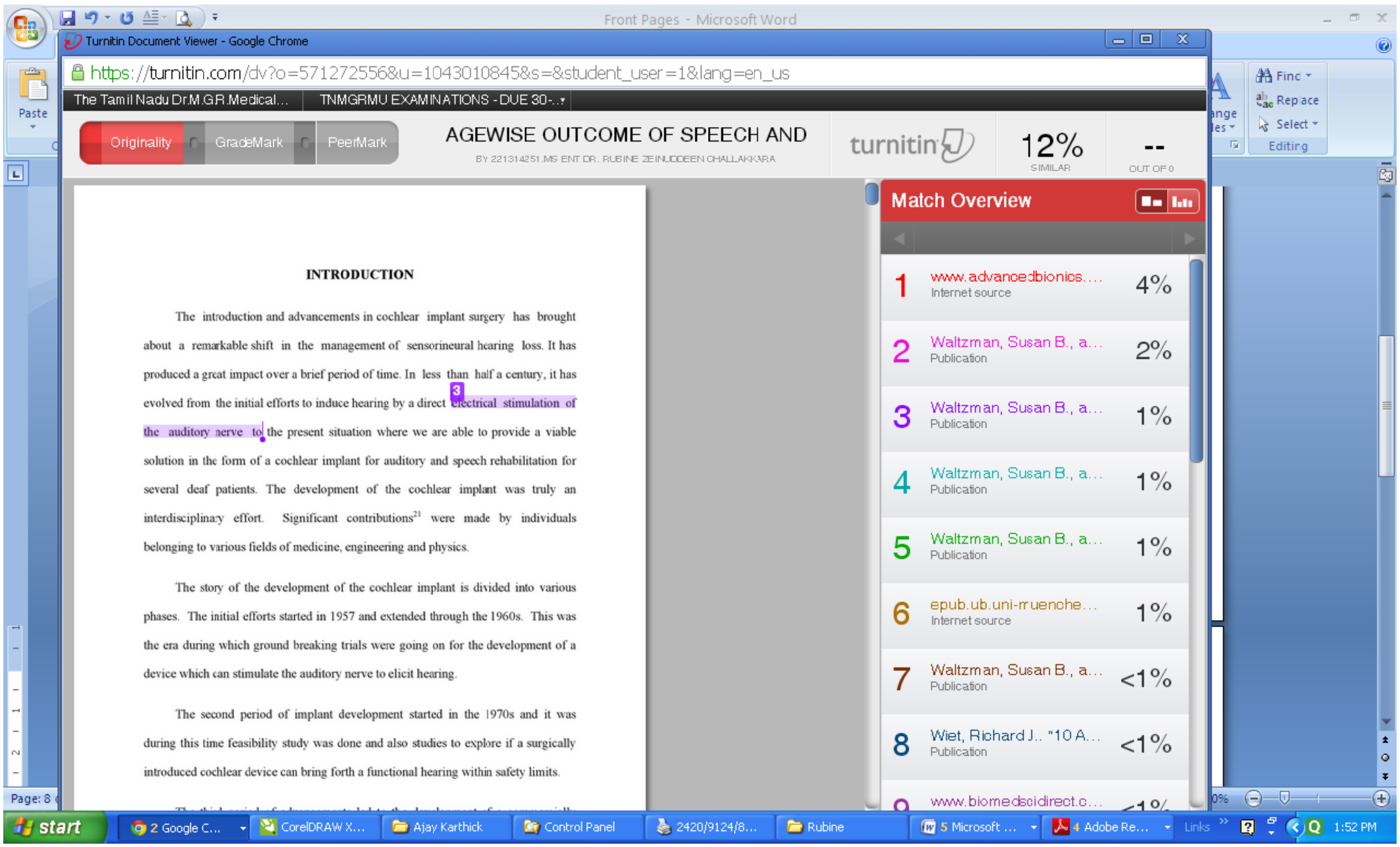
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ACKNOWLEDGEMENT

First of all I would like to express my most sincere and deep gratitude to **Prof. Dr. V. ARAVINTHAN M.S. ENT, DNB,** the Professor and Head of the Department of the ENT department of Coimbatore Medical College, who is also my guide for the thesis. I am grateful and indebted to Sir for entrusting me with the topic of study and for guiding and advising me throughout.

I would like to thank the Dean of Coimbatore Medical College, **Prof. Dr. EDWIN JOE M.D.**,**B.L** for granting permission to conduct my study in Coimbatore Medical College Hospital.

I would also like to wholeheartedly thank **Prof. Dr. A.R. ALI SULTHAN M.S. ENT, DLO,** Professor of ENT in Coimbatore Medical College, whose encouragement and guidance helped me to complete the study.

I am also deeply indebted to **Dr. V. Saravanan M.S. ENT**, Assistant Professor of ENT Department, for providing valuable suggestions and criticisms for the successful outcome of the study.

I also want to express my gratitude to **Dr. M. Nallasivam M.S. ENT, Dr. Sivakumar M.S. ENT, Dr. M. Vasudevan DLO and Dr. R.V. Kuamar M.S. ENT** , Assistant Professors in ENT who patiently encouraged and gave important advise for properly carrying out the study.

I am also extremely thankful to my juniors**, Dr. Anish Karthick** and **Dr. Muralimohan** for their co-operation and help during the period of study.

I also want to thank our audiologist, **Mrs. Kavitha**, who helped me throughout in understanding audiological concepts.

I would also like to take this opportunity to express my gratitude to my parents and my husband for motivating and encouraging me.

I am forever grateful to the Almighty God for helping me in all my endeavors.

Lastly I would like to convey my deepest appreciation and gratitude to the patients and their parents who were the backbone of the study and without whom this would not have been possible.

CONTENTS

ABBREVIATIONS USED

CI	-	cochlear implant
SGN	-	spiral ganglion cells
RW	-	round window
SNHL	-	sensorineural hearing loss
PTA	-	pure tone average
BERA	-	brainstem evoked response audiometry
OAE	-	otoacoustic emission
SRT	-	speech reception threshold
SDT	-	speech detection threshold
ESRT	-	electrical stapedial reflex telemetry
NRT	-	neural response telemetry
T level	-	electric threshold level
C level	-	comfort level
CAP	-	category of auditory perception score
SIR	-	speech intelligibility rating score
MAIS	-	meaningful auditory integration scale
MUSS	-	meaningful use of language scale

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INTRODUCTION

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The incidence congenital severe to profound sensorineural hearing loss which occurs before the formation of language in the child is projected to be around 0.5 to 4 per 1000 births. The cochlear implantation surgery is being applied to provide the ability to hear for the hearing impaired pediatric population children for around thirty years now. Since that time, there have been significant advances being made in both device designs as well as the implantation techniques.

Guidelines for selecting the appropriate candidates for implantation have been formulated by using the data available from the post operative follow up studies conducted in previously implanted children. Over the period of time these guidelines have greatly evolved to encompass a greater group of beneficiaries. Selecting the ideal and deserving patients for implantation has emerged to be a vital step for ensuring a favorable result in the post operative period.

To determine whether a child is suitable for cochlear implantation several criteria have to be necessarily fulfilled. These include first and foremost a confirmatory diagnosis of a profound sensorineural hearing loss not benefited by any other modality of treatment, an absence of medical contraindication to implantation surgical procedure, and the presence of an implantable cochlea without significant anatomical anomalies. Further evaluation of additional factors such as speech and language development of the child, developmental milestones, home environment, educational setting, and the presence or absence of other disabilities facilitates in determining the type and extent of rehabilitation which will be appropriate for the particular implant candidate. Finally, assessment of other additional factors like duration of deafness, age at the onset of deafness, and the speech perception performance of the child preoperatively can give an idea about the probable results for the child. The preoperative evaluation therefore requires a multidisciplinary approach.

Even though the procedure was initially tried for post lingually deaf adults, it has now become a viable mode of intervention for prelingually deaf children and the recommended age of implantation is becoming younger and younger. The cochlear implant surgery is a useful procedure for children with profound SNHL which poses multiple challenges to both beneficiaries as well as the providers of health care. Even though it provides an impressive advantage to the recipients of the procedure, the relative cost for the device, and the follow up rehabilitation maybe high. So the question arises whether the cochlear implantation surgery is beneficial enough and gainful to rationalize an expensive operation in the pediatric age group. Several long term follow up studies across the world conducted in children who underwent implantation under the age of 2 years definitely suggests that cochlear implantation is a valuable procedure for the treatment of the hearing impaired. However the number of cochlear implant surgeries done in most centers is not of significant numbers and the definite benefits and results cannot be determined from any single institution. The study is conducted to illustrate the benefits of implantation in our set up and provide evidence to demonstrate the advantages of earliest possible intervention at a young age.

AIM OF THE STUDY

- To assess the hearing and speech outcome of prelingually deaf children who underwent cochlear implantation surgery over study period of one year.
- To evaluate the outcome cochlear implantation in prelingually deaf children.
- To identify the ideal age for cochlear implantation in terms of best outcome.
- To assess the benefit of cochlear implantation in older children.

REVIEW OF LITERATURE

The procedure of cochlear implantation provides the necessary acoustic signals which are needed for hearing sounds and understanding speech in hearing impaired patients. Since the 1980s several thousands of children and adults all over the world have been beneficiaries of this procedure. However, scientifically conducted studies have proven that the post operative results of the implanted candidates are not uniform, there being great variations in the outcome.

The cochlea[38]

- The spiral ganglion neurons (SGNs) have the soma located in the Rosenthal's canal and they are the targeted neurons for cochlear implantation. In the presence of the cochlear implant the SGNs are electrically depolarized via an electrode array located in the scala tympani, initiating the generation of action potentials. After the initiation of the action potential the implant has no further role in the propagation of the action potential along the auditory pathway.
- The integrity of the organ of Corti determines the survival of these neurons. They are prone for degenerative and atrophic changes secondary to SNHL[37]. Even though the minimum number of SGNs needed to acquire an adequate outcome with CI is not sufficiently proven with studies, it is expected that the presence of a greater amount of functioning spiral ganglion cells present to receive the neural impulses will provide a better post operative outcome.

Cochlear pathology

- The organ of Corti sensory epithelium is susceptible several types of pathological changes caused by factors such as age, toxins, injury and prenatal damage. They do not have the ability to undergo spontaneous regeneration and thus any hair cell damage results in perpetual SNHL. The loss of the hair cells results in a retrograde damage to the spiral ganglion cells. Initially there occurs a widespread and fast damage of the unmyelinated axons followed by the slow atrophy of the myelinated part in the bony spiral lamina and then the soma in the Rosenthal's canal. Eventually there is shrinking of the remaining soma of the spiral ganglion cells. It is a continuous mechanism finally resulting in very few viable neurons. Nadol and colleagues[1] conducted a study in sixty six patients with profoundly severe SNHL and came to the conclusion that the average number of spiral ganglion cells in them was almost half of those in normal individuals but the standard deviation was large. It was also found that the number of spiral ganglion cells lost was more in elderly than the young candidates and that there is more loss associated with a greater period of hearing impairment. The most important factor determining the spiral ganglion cell damage was the cause of deafness with severe loss being associated with viral labrynthitis, congenital or genetic deafness, or bacterial meningitis; that is etiological processes which directly damage the spiral ganglion cells and prolonged periods of hearing impairment. Deafness caused by aminoglycoside antibiotics or sudden idiopathic SNHL showed the least number of spiral ganglion cell damage.

- According to studies in congenitally deaf children two important difference is observed; 1) there was no indication of any continuous spiral ganglion cell damage between 0 - 9 ages, 2) the arrangement of the spiral ganglion cells was more uniform in the cochleae[2]. These conclusions provide encouragement in the field of cochlear implantation for children indicating that there is no significant long term deterioration in the function with the implant.

Physiological effects in SGN

- Inspite of the widespread pathological damage to the spiral ganglion cells due to deafness, they retain the ability to initiate and propagate an action potential in response to an electric impulse even after prolonged periods of deafness with a viable nerve population less than 5% of normal[3]. Even then there are fine differences in the neurological characteristics of a cochlea exposed to prolonged duration of hearing loss; this can result in a diminishing of the perception of sound using an implant. The loss of cells causes a raise in the threshold and the demyelination results in an increase in membrane capacitance decreasing the effectiveness of a nerve in the initiation and propagation of action potentials following an electric impulse. The auditory system shows a decrease in temporal resolution and a considerable prolongation of the refractoriness the eighth nerve fibers and features suggestive of conduction block.

Cochlear nucleus

- Clinical observations related to congenital deafness suggest that the best candidates for cochlear implant are very young children, and that with increasing age the outcomes become less optimal.[4] The implication is that sensory stimulation, whether natural or prosthetic, is necessary during early life to ensure the normal development of the central auditory system.
- In the early childhood period there is a time limit beyond which the auditory system development is affected if there is deficit in the auditory input by means of sound stimuli. This negatively affects the normal progression in the acquisition of language and speech and after this period, the damage cannot be corrected even if there is restoration of the hearing ability. So there is a critical period during which sound impulses are essential for the proper maturation of the hearing apparatus[23]. Hence it is of vital importance to identify profound SNHL as early as possible and provide intervention in the form of cochlear implantation at the earliest for the proper development of language and speech.

Auditory cortex

- In 1942 Woolsey and Walzl[5] reported the first cortical response to electrical stimulation of the auditory nerve in normal hearing cats. The effects of a sensorineural hearing loss on the auditory cortex depends on several variables which includes how severe the hearing loss is, if it affects one ear or both ears and the period of development when the child is afflicted with sensorineural hearing loss. A part of these effects are reversible with establishment of a functional hearing giving impulses to the auditory cortex. It is this aspect of the auditory cortex which causes an ongoing betterment in the functioning of hearing in cochlear implant users[6].

- Lack of hearing causes a decreased level of activity in the auditory cortex, however, after implantation a return of activity can be seen via imaging techniques. After prolonged implant use, the cortical evoked response in children implanted early are found to be almost similar to that of normal hearing children, indicating a maturing of the cortex due to continuous input being received. There is a positive correlation between speech perception and low resting activity in the auditory cortex prior to cochlear implant procedure in prelingually hearing impaired children. This indicates that even though there is a plasticity of the cortex the most favorable results will be obtained when CI is done when the cortex is in early stage of maturation[36].
- Acoustic input is necessary for the proper organization of the auditory pathway determined by genetic factors. The consequence of a deficiency in this input during the developmental period results is the presence of a rudimentary pathway; even this appears adequate in order to give temporal and spatial impulses needed for the awareness of speech perception in children with implantation. The plasticity of the auditory pathway is an important feature which is responsible for the successful post operative results.

The device

- The early implants developed were single channel gadgets which revealed the potential for the activation of the auditory nerve using electric impulses[35]. Patients implanted with this device had the advantage of perception of sound but could not understand speech. Further advancements in the implant technology resulted in the development of a multi channel product[7]. Initially it was attempted to obtain speech by giving auditory impulses. It was shown that interleaved peak-picking strategies are giving better outcome with regard to speech. This is presently used in the Med-El "*n*-of-*m*" strategy[8]. The main disadvantage is that the patients cannot differentiate speech in noise, and musical melodies. This is probably due to the inability of the sound processors to transmit sufficient spectral resolution and temporal fine structure. High resolution processors proved to have better discrimination of speech in noisy background. It has been demonstrated that a combination of auditory and electric impulse will be more beneficial in candidates with some amount of residual hearing.

Selection of cochlear implant candidates

Preoperative evaluation

- This is of extreme importance in the work up towards cochlear implantation in a child. First of all the audiological necessity for implantation has to be established. Then it is necessary to see whether the patient has the medical fitness for surgery.

Medical evaluation

- A thorough medical history is taken and physical evaluation done. The etiology for deafness is evaluated and it is determined if a cochlear implantation is necessary and feasible. Any medical contraindication for surgery is ruled out.

Cochlear imaging

- High Resolution Computerized Tomography or Magnetic Resonance Imaging of the temporal bone is done. This helps to rule out abnormalities of the cochlea and provides an image of the cochlea and surrounding structure. This helps in deciding the suitable ear to be operated and the approach. Abnormalities in the cochlear structure or ossificans influence the type of device to be used, extent to which inserted and positioning of the electrode group.

Audiological evaluation

- This is mainly done to identify the "type and severity of hearing loss". The tests carried out are unaided air and bone conduction thresholds, unaided speech discrimination, speech reception threshold (SRT), speech detection threshold (SDT), otoacoustic emissions, and immittance testing including tympanometry and acoustic reflex.
- Criteria generally accepted for considering a patient for implantation includes bilateral profound sensorineural hearing loss with a pure tone average (PTA) greater than or equal to 90dB. Auditory brainstem evoked response (BERA) confirm the audiological report and also is instrumental in identifying

individuals with auditory neuropathy aswell as excludes “functional deafness”. BERA also helps in determining the electric impulse induced excitability of the auditory nerve.

Hearing aid evaluation

- The main intent of this test is to assess the child’s response to sound amplifiers. It includes testing of aided detection thresholds at 250Hz, 500Hz, 1000Hz, 2000Hz, 3000Hz, and 4000 Hz. Separate testing of each side is done followed by simultaneous evaluation. After the results are attained it is compared with the expected outcome with implantation to assess and confirm that the implant will provide a useful betterment in the hearing skill.

Speech and language evaluation

- The aim of preoperatively evaluating the speech and language is to identify any disorder in language development or articulation and to assess the expected improvements in speech and language after the surgery.

Psychological evaluation

- It is performed mainly in pediatric patients and consists of evaluation of cognitive skills of the child to understand and identify if there are additional aspects impairing the normal development of the child. Also if the child is intellectually challenged it affects his/her potential to utilize the implantation device to full benefit. Thus this assessment helps to counsel the child’s guardians about the expectations for the patient. The results of such evaluation also helps in determining whether the child can utilize acoustic input provided by the procedure, thus helps in deciding to proceed with implantation or not.

Surgical technique

- The aim of the surgery is to completely insert the electrode into the cochlea without any trauma to surrounding structures. This is possible in almost all implantation unless there is the presence of an "obstructed or malformed cochlea". Even though finer details of the surgery may vary in different settings, inserting the electrode is the most important stage. Proper placing of the electrodes ensures the best outcome. If the electrode insertion is sub optimal or if there is kinking or damage of the electrode, this will be reflected as an inferior performance post operatively.

Position and anesthesia

- The child is positioned on the "operating table" supine with face away from the surgical site[9]. Ideally facial nerve monitoring is done by placing electrodes near the mouth and eye; this is especially needed when surgery is done in case of anomalies of the temporal bone.
- Hair is shaved away from behind the ear to accommodate the incision.

Incision

- The site of incision is important, care should be taken so that the implant will not hitch against the speech processor. The implant should rest on a flat portion of the skull. Incision must permit a safe insertion of device and the flap to be raised determined by the incision site should be having enough blood supply to avoid necrosis and breakdown. Blood loss during initial incision can be minimized by infiltrating with dilute adrenaline and using monopolar cauterization.

- ❖ The flap should be raised with care. Dissection should be carried out in the avascular plane deep to the scalp taking care to avoid the flap becoming dry and undue retraction. The incision starts at the mastoid tip and goes up just behind the post aural fold upto the superior attachment of the pinna, barbless fish hooks provide adequate retraction. Next, a sufficient anterior based Palva flap is elevated, to bare the region for the mastoidectomy and the well.

The well or recess

- ❖ The well can be drilled before or after the mastoidectomy. In small children, it has to be drilled up to the dura to avoid the implant producing a bulge over the skin surface. Alternately cutting and diamond burrs are used to prevent dural injury, in case of injury it repaired fascia sutured over the area.

The mastoidectomy

- ❖ A simple mastoidectomy is done the superior and posterior cortex need not be saucerized. The overhang creates an edge, for the placement of the proximal electrode. The short process of incus and the lateral semicircular canal have to be visualized as well the posterior external canal wall is thinned out, in order to identify the facial nerve and approach the facial recess. Drilling of a connecting groove is done between the well and the mastoid cavity, so that the electrode lies at a depth from the surface devoid of angulations or kinking.

The facial recess (posterior tympanotomy)

- Entering the facial recess via a posterior tympanotomy should be done carefully because there is risk of injury the VIIth nerve, posterior meatal wall and the tympanic annulus. In case of a narrow recess, the facial nerve should be definitely identified without exposing it and sacrificing the chorda tympani may be required. If there is an inadvertent baring of the facial nerve all steps should be taken to prevent instrumentation damage as well as heat damage due to drilling. In case the facial recess entry by posterior tympanotomy is not possible, it can be approached by taking out the incus.
- The opening of the facial recess has to be adequately large to easily identify the round window area, promontory and stapedius tendon.

The cochleostomy

- Before exposing the scala tympani all bone dust should be completely washed away. The cochleostomy is done on a position of the promontory anteriorly to the middle and lower 1/3rd of the RW membrane. It ensures entry of the electrodes into the scala tympani without damaging the basilar membrane. A 1.5mm diamond burr[20] is used and drilled upto the endosteum. Adequate water should be used to prevent thermal injury to the inner ear. The entry is completed using a 1.0mm diamond burr. The endosteum is opened using a needle carefully preventing any suctioning of the endolymph.

Device placement

- The receiver of the implant is kept in the well initially drilled and suturing done using nonabsorbable material.

Electrode insertion

- The electrode end is targeted to the center of the scala tympani to prevent injuring the basilar membrane, striae vascularis and is completely inserted.

Electrophysiological testing

- Electrode impedances are checked. One or two electrodes with high impedance could be due to air or N_2O bubbles, so it is temporary and does not need any management. But if there are several electrodes with increased impedence it should be investigated. Other tests done are acoustic reflex telemetry (ART), and electrical stapedial reflex telemetry (ESRT) to check the on table response and success.

Packing the cochleostomy

- Packing if needed is done using soft tissue like fascia to surround the electrode at its entrance. It helps in avoiding a perilymph leak and post op meningeal infection.

Closure

- Closure of the Palva flap is done over the implant, this procedure encloses the proximal part of the electrode array in the osseous canal drilled earlier and provides a soft tissue protection to the implant. Any bleeding should be controlled using bipolar cauterization as the monopolar should not be used after placing the device. Skin is closed in layers using Vicryl.

Dressing

- A mastoid dressing is done. It must not be excessively tight since it can cause flap necrosis.

X-ray

- A post operative check X ray is taken to ascertain the correct positioning of the electrodes, extent to which inserted, or presence of kinking[10].

Special cases

Dysplastic cochlea

- Before operating on a case of dysplastic cochlea a complete work up and preparation is necessary because there is more chance of perilymph fistula, VIIth nerve injury, incomplete placement of electrodes, and poorer outcome in terms of clinical gain. In case of Mondini dysplasia there is a danger of encountering a gushing of the perilymph when the scala tympani is entered but the post operative auditory benefits are good in such children. Greater anomalies result in greater complications and lesser outcome. In case of a common cavity there may occur a CSF leak. But inspite of all these, even in cases of incompletely inserted electrodes, the patient is significantly benefited.

Obliterated cochlea

- Also known as labyrinthitis ossificans is commonly seen as sequelae of meningeal infection. Hence in case of hearing loss after a meningeal infection, a complete assessment including imaging have to be done and implantation operation done at the earliest to prevent bone formation. For completely inserting the electrodes any granulations and un ossified tissue should be taken out.

ELECTRODE INSERTION

General principles of electrode insertion

- The receiver of the implant should be first placed before inserting the electrodes. Adjustments after inserting can cause displacement of the electrode.
- For accurately inserting the electrodes a good a comprehension of how the cochlea is oriented is necessary. The direction of the basal turn is almost parallel to the outer canal wall. So insertion is directed down the center of the basal turn careful to avoid the basilar membrane. Undue pressure should not be employed for insertion. The electrode has to be completely advanced or stopped once there is any obstruction to further advancement. Numerous instruments are available for facilitating easy insertion such as claws and forceps exist.

- Packing around the electrode insertion point promotes scarring and healing, and also minimizes post op giddiness due to leakage, meningeal infections and device displacement.
- In case of cochlear anomalies fluoroscopic imaging is useful in aiding insertion and even though there is radiation exposure, it is justified by the results[11].

Device programming

- The target is to set the implant to efficiently transform auditory cues to compatible electric impulses for every electrode activated. Programming is usually done around 3 weeks to 1 month after the surgery. The results of the audiological assessments done during surgery are also made available to the audiometrician because it helps them to know how many electrodes are within the cochlea and its integrity. This is necessary because if the electrodes outside the cochlea are stimulated there can be adverse effects. Initially two measures[12] need to be obtained: electrical thresholds (T levels), which is "the softest sound that can be identified by the patient 100% of the time", and the most comfortable levels (C/M levels), which is "the loudest sound which can be listened to comfortably for a sustained period of time". They have to be obtained for electrode activation.
- After this the volume matching of neighboring electrodes at 100% and 50% of the dynamic limits is carried out. Equivalent volumes along the electrode array are necessary for acquiring the best speech comprehension and production.
- Next a program is made. This gives the child their first exposure to speech stimuli. Depending on the initial response. Based on the individual's initial

reaction, several manipulations are carried out obtain a comfortable and efficient signal.

Pre programming

- This prepares the candidate for the first activation. It is carried out by teaching auditory concepts in those with a minimal exposure to sound. This is to be done by the speech therapist, audiologist and the parents. Use of a proper sensory aid is an important part of pre programming.

Intra operative monitoring

- It includes several tests done by the audiometrician during the surgery. This includes impedance telemetry, electric stapedial reflex thresholds, and neural response telemetry. It provides data about the electric output of the implant the child's auditory system reaction to activation. It provides a preliminary measure in addition to programming.

Initial stimulation

- Providing a relaxing atmosphere is vital for a successful programming. Toys should be made available as an aid for training. Basic and advanced programming methods are needed to obtain an adequate outcome with device use. The preliminary activation is planned over a 2-3 days. The duration may change depending on the candidate. Mainly 2 tasks have to be achieved. (1) psychophysics- obtaining the T and C levels (i.e. device tuning) and; (2) familiarizing the candidate and care taker with the device. Ascertaining the T and C levels in the pediatric population be both demanding and taxing. Several adjustments have to be made to the initially obtained values over time. As the child becomes more familiar with the auditory impulse the C levels usually increases. Alterations in threshold levels are also seen due to a better physiological conditioning of the auditory system as a result of persistent stimulation. Precise T and C levels, gives a superior outcome.

- A portion of the time is also spent to train about the daily care and maintenance of the device and teaches how to troubleshoot the external equipment.
- Usual complains by the patient is dealt by manipulating the Threshold and Comfort levels. Counseling should be a part of the program.
- Another issue which arises is that a child comes to a performance plateau. No further improvement in the child's auditory development is seen. This usually indicates the need for more aggressive parameter alteration. Another common issue is the candidate's inability to adequately adjust and comprehend the various volume and sensitivity controls.

Objective programming techniques

- Since the guidelines for selecting patients for CI has broadened to include very young individuals and individuals with developmental disabilities, the application of objective electrophysiological measures[13] to aid in device programming has become more necessary. They are used pre operatively, intra operatively and post operatively. They are used pre operatively as a predictor of post operative performance and for ear selection, intra operatively to assess whether the implant is functional and nerve stimulation, and post operatively, to assess the device integrity and to program the device.

Evoked auditory brainstem response

- According to several studies it has been shown that there is a positive correlation between BERA results and behavioral Threshold and Comfort levels in cases where BERA thresholds are within the behavioral dynamic limits. Hence inferred BERA can be used as a conditioning tool in the difficult to program child.

Elicited acoustic reflex threshold

- Jerger et al (1986)[14] demonstrated that stapedial reflex can be obtained by electric stimulation in candidates with a multi channel cochlear implant. In further follow up studies it was seen that the behavioral Comfort levels were approximate to the reflex threshold.

Follow up

- Precise estimations of electrical T and C are an important factor determining the post operative outcome. According to studies conducted it has been shown that these levels can vary greatly following the preliminary activation during the first year necessitating the requirement of a comprehensive programming plan to guarantee the greatest gain it from the implant.
- The recommended program after preliminary activation for first year is as follows: at 1-2 weeks, 4-5 weeks, 3 months, 4-5 months, 6 months, two time

between 6-12 months, and at 12 months. After that sessions are done every 3 monthly. Additional sittings are planned if there are some changes in the candidate's auditory response or speech production.

Speech perception

- Several advancements in the diagnosis of profound deafness, technologies related to implantation, surgical technique, and rehabilitation process which emerged over the last few decades have shown that it is a safe and successful intervention option for individuals with sensorineural hearing loss.

Factors affecting speech perception[26, 27] in the pediatric group after implantation

1. Implant technology
2. Surviving neural population
3. Auditory (sensory) deprivation
4. Auditory pathway development
5. Plasticity of the auditory system
6. Length of deafness
7. Age at the time of implantation
8. Etiology of deafness
9. Preoperative selection criterion
10. Preoperative hearing level
11. Preoperative auditory speech perception
12. Measures of speech perception (preoperative and post operative)
13. Preoperative linguistic level; spoken language or manual language

14. Other handicaps
15. Surgical issues
16. Device programming
17. Device / equipment malfunction
18. Mode of communication
19. Auditory input
20. Frequency / type of training
21. (Pre) school environment / education setting
22. Parental / family motivation, social issues

"Implant technology"

- ❖ Currently multichannel / multielectrode devices are used with a straight or precoiled electrode array and transcutaneous transmission. The parameter influencing outcome is the processing strategy, which decides the nature of the stimulation of the electrodes.

"Surviving neural population, Auditory deprivation, Auditory pathway development, Plasticity of the auditory system, Length of deafness, and Age at the time of implantation."

- ❖ This involves the physiological manifestations of the results of the deprivation of acoustic impulse to the auditory pathway for prolonged periods. Studies have revealed prolonged chronic electric activations caused the SGNs to be preserved and in the absence of it, they undergo degeneration.

- The effects of hearing deprivation and plasticity are related to the duration of deafness and age at implantation[24, 25] and their consequence on outcome with an implantation. Fryauf-Bertschy et al (1997)[15] showed that kids implanted at less than 5 years had a better outcome in "open-set recognition tasks" than those who underwent surgery after 5 years. Other research done by Waltzman and Cohen (1998)[16, 17] and Miyamoto et al (1993)[18] showed there was a better outcome with regard to hearing and speech in lesser age group children.
- Universal newborn screening for hearing has allowed an earlier diagnosis of severe to profound deafness and hence earlier intervention in the form of implantation.
- This does not mean that the older group does not have benefit. It has been shown that there is a significant improvement in their auditory and speech skills following implantation.

"Preoperative hearing level and Preoperative auditory speech perception"

- Studies have proved that individuals with a better residual hearing before surgery had a better outcome comparing those with more severe degrees of deafness.

"Additional handicaps"

- Deafness is occasionally a part of a syndrome or etiology, which can influence the benefits obtained from implantation surgery. The preoperative implant counseling sessions should address this issue and how it can negatively affect the capability of the patient to utilize the auditory inputs obtained from the device

“Surgical issues”

- The electrode insertion may be difficult or hindered by several causes including Mondini dysplasia, labyrinthitis ossificans, problems with the electrodes, and surgical experience. Complications like kinking or damage of the electrodes, facial nerve injury, and postoperative flap problems like necrosis or infection may occur.

“Device programming”

- Programming of the speech processor has a crucial effect on the outcome. Precise estimations of the T and C levels are necessary in order for the candidate to utilize the device adequately and with ease. Skinner et al (1997) outlined specific subjective procedures and periodic programming sessions in an attempt to reduce the problems of programming. Several researchers have advised objective techniques including evoked stapedial reflex (ESRT) and neural response telemetry (NRT) to establish device threshold and assist in programming as the age of implanted patients have deceased over time. Ideally behavioral programming techniques along with objective techniques should be used.

"Mode of communication, Auditory input, Frequency/ type of training, Educational setting, Goals and expectations"

- ❖ Various research has proven that "oral only intervention and oral education" resulted in a better outcome. However, even candidates who use "total communication" receive good results and may eventually become "oral communicators" with implant use[29].

Language development children with cochlear implants

- ❖ Early onset profound hearing loss has a devastating consequence on language development. The most important time for language formation falls between birth to seven years. Those with normal hearing acquire all the necessary parameters needed for communication during this period. The presence of hearing impairment becomes a disadvantage as they cannot receive the environmental signals for language development. Usually cognition and language develops simultaneously, in hearing impaired kids cognition is normal but do not acquire language known as the "cognitive-linguistic gap". So these children can use their cognitive abilities to enhance their language acquisition if they are able to receive auditory input. Intervention by cochlear implantation provides these necessary auditory inputs to develop language to prelingually deaf children.

Measuring language benefit

- ❖ Language a complex entity and it mainly has two parameters - comprehension and formation of "meaningful words and sentences". Depending on the parameter evaluated children with implants perform comparable to normal hearing individuals. Earlier the age of implantation, superior the language benefits, furthermore, they have a better outcome than those who use hearing aids.

- The use of a cochlear implant gives the child access to the spoken language code, helps the child to use audition to monitor ones environment and gives potential for "incidental language" of learning which is how a child with normal hearing acquires language[19].
- Several tests are available to assess the language skills acquired after implantation. "Receptive and expressive language" is assessed separately rather than one being inferred from the other[30].

"Red flags" which signify poor progress

- Full time implant use not seen even one month following the preliminary stimulation
- No change in quality or quantity of vocalization after three months of implantation
- No spontaneous alerting to own name 25% of time after 3 months of implantation
- No spontaneous alerting to own name 50% of time after 6 months of implantation
- No spontaneous alerting to some environmental sounds 6 months after implantation

- Skills from audiological testing not seen in everyday settings after 9 months of implantation
- No evidence of meaning being derived from sound after 1 year of implantation
- Significant improvement in language not observed after 1 year of implantation

How it works

- ❖ The cochlear implant device consists of an external component and internal component.
- ❖ The external part consists of a microphone, speech processor and transmitter.
- ❖ The internal component includes a receiver and electrode array.
- ❖ The microphone picks up the environmental sounds and sends it to the speech processor which contains the necessary software to analyze and digitalize the sound signal and then send it to the transmitter which worn on the head behind the ear.
- ❖ The placement of the transmitter on the skin is such that it directly overlies the receiver of the internal device under the scalp skin. The transmitter sends the digital sound signals to the receiver. It takes the coded electrical signals and delivers it to the electrode array which has been surgically inserted into the cochlea. This creates an action potential in the spiral ganglion cells and hence the auditory nerve and sound signals are perceived.

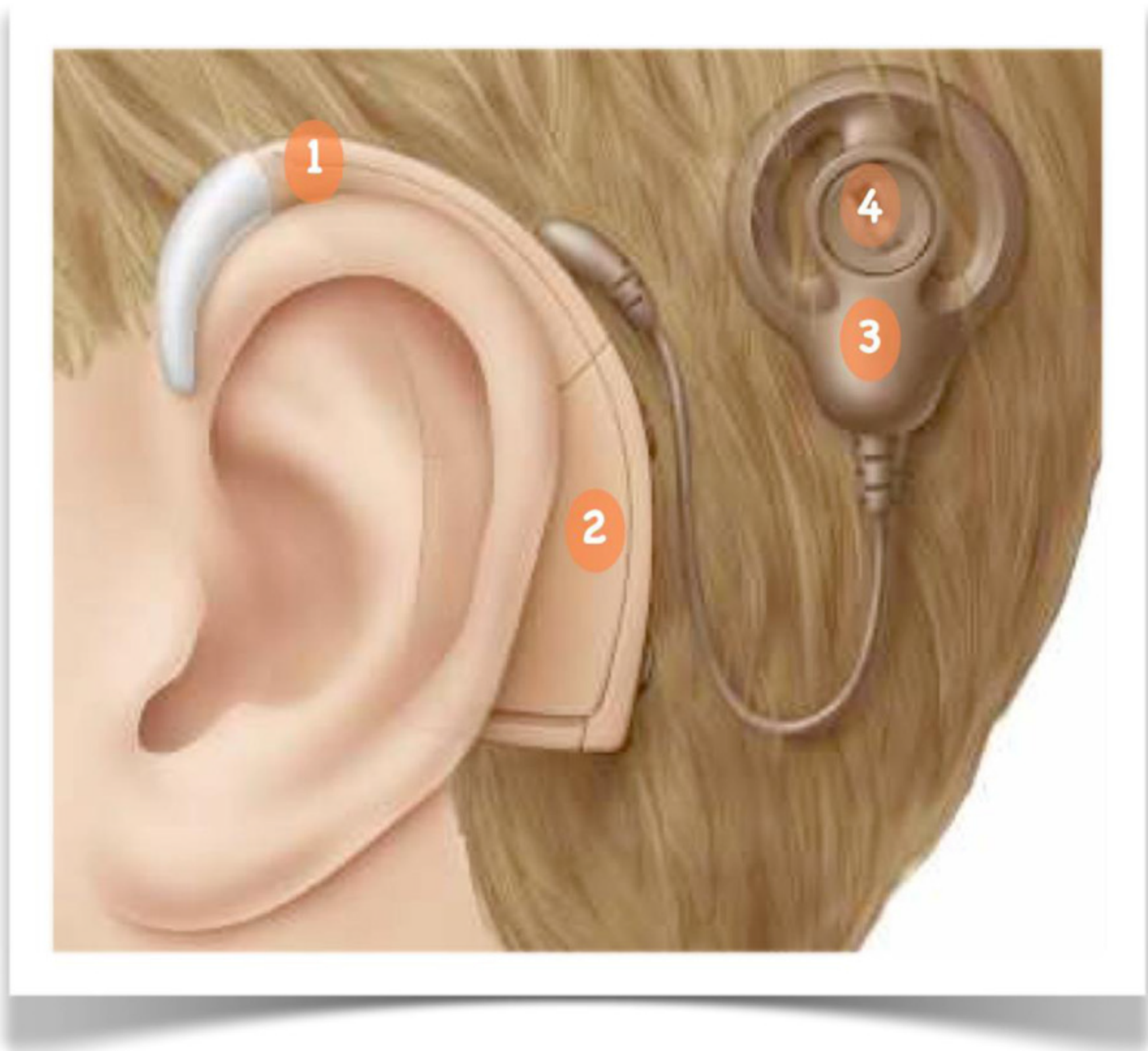


Figure 1 : Parts of Implant

1. **Microphone**
2. **Speech processor**
3. **External antenna**
4. **Transmitter with Magnet**

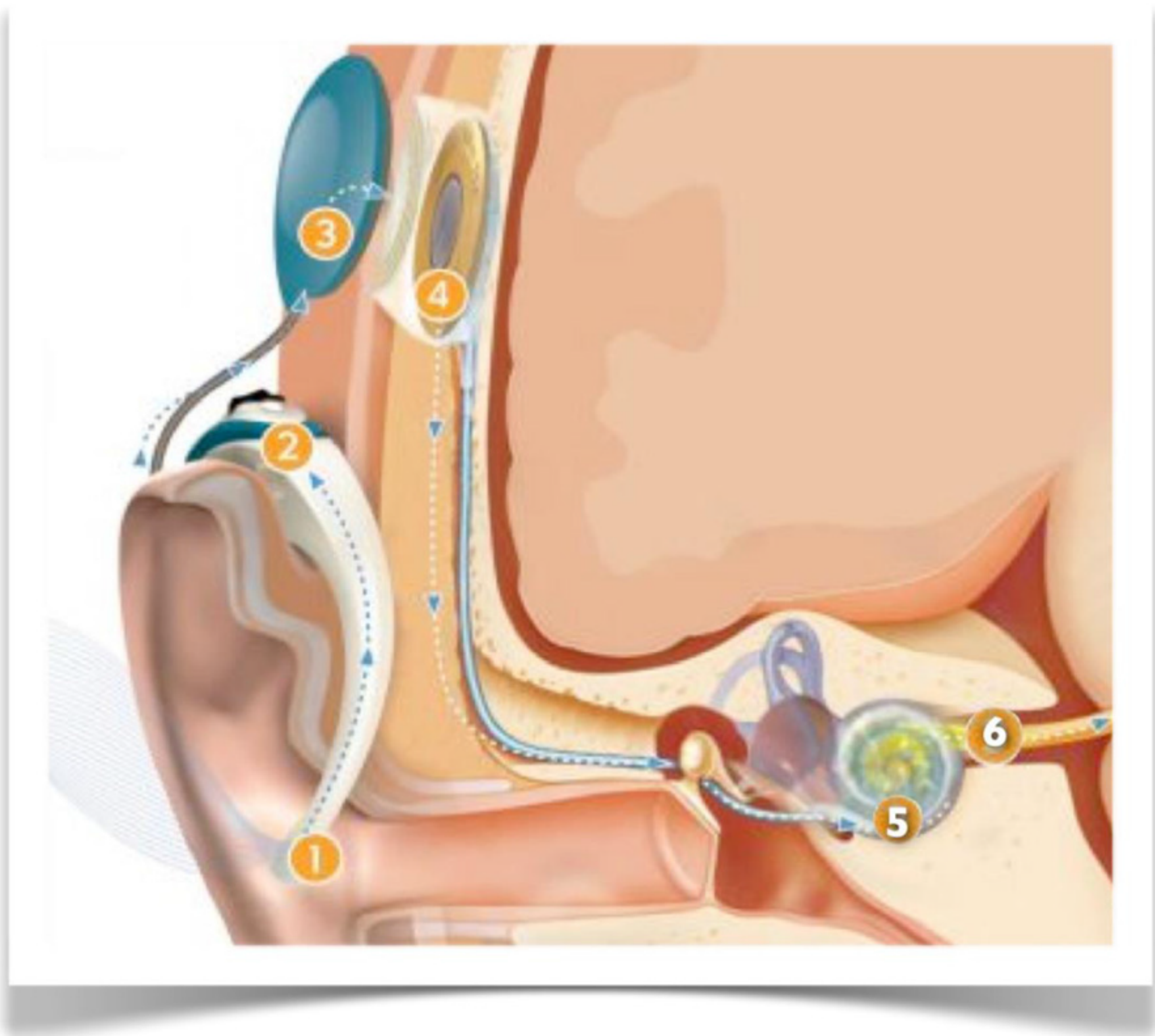


Figure 2 : Mechanism of Action

The microphone (1) receives the sound stimulus. The speech processor (2) analyses and converts it into a digital code. The magnetic transmitter (3) transfers the coded signal to the internal device. The receiver (4) then sends the data to the surgically inserted electrode array (5) which stimulates the nerve fibres (6).

The surgical procedure

Figure 3 : Incision

Figure 4 : Mastoidectomy

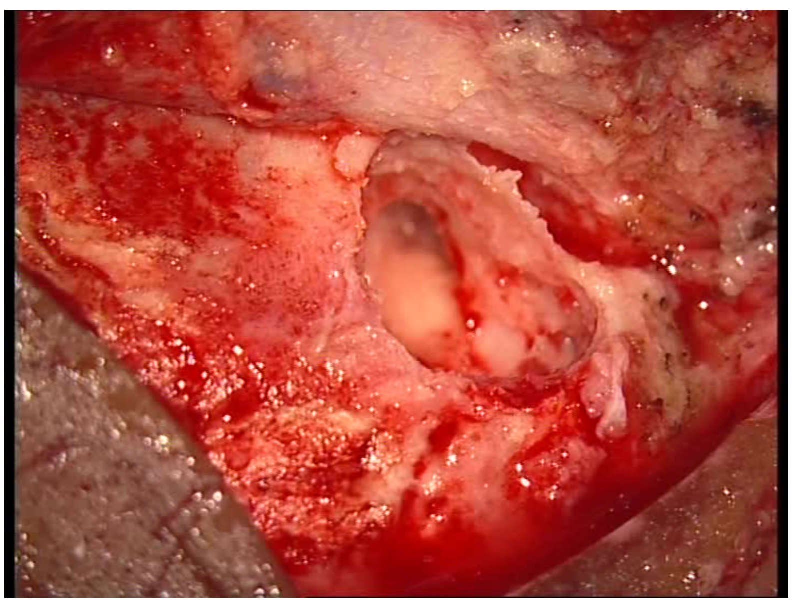


Figure 5 : Facial recess entry via posterior tympanotomy

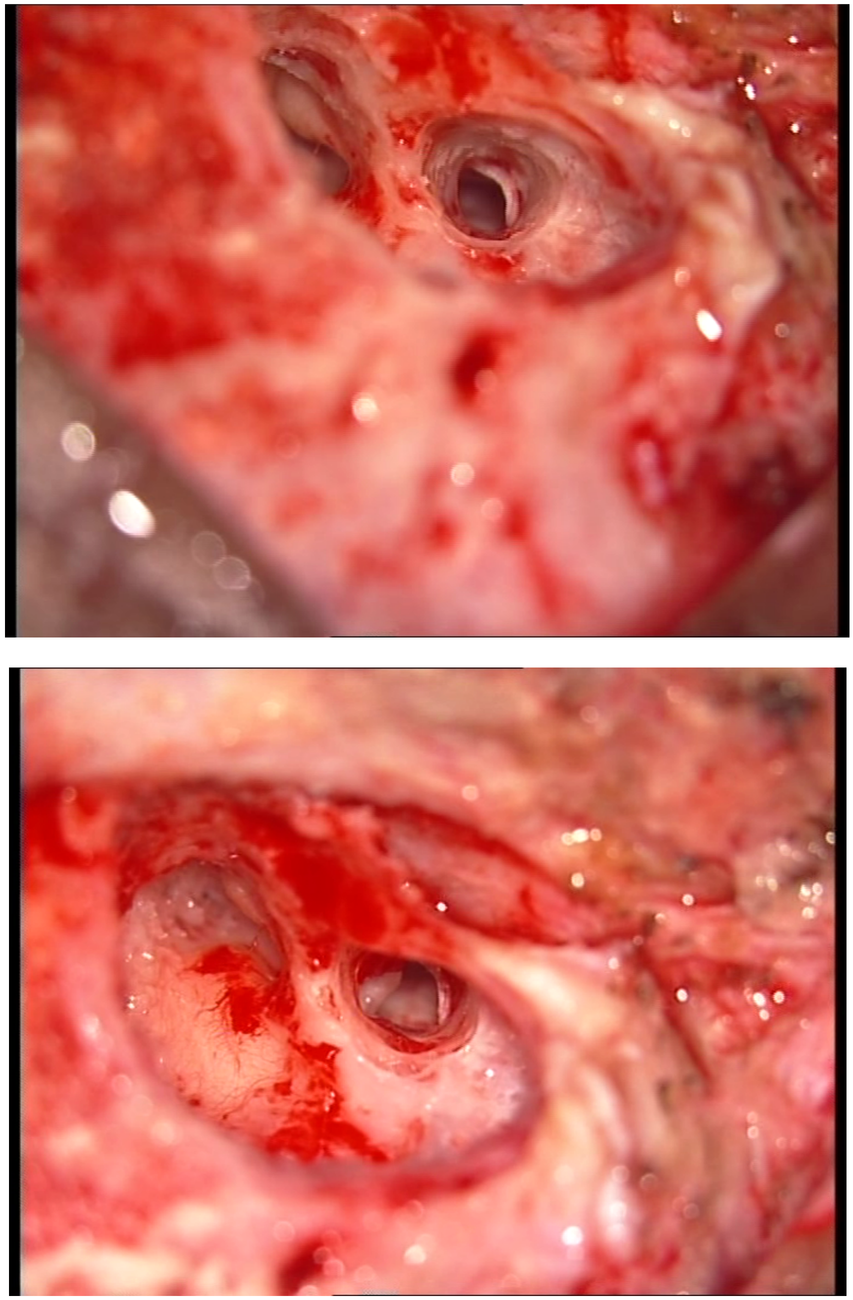


Figure 6 : Cochleostomy

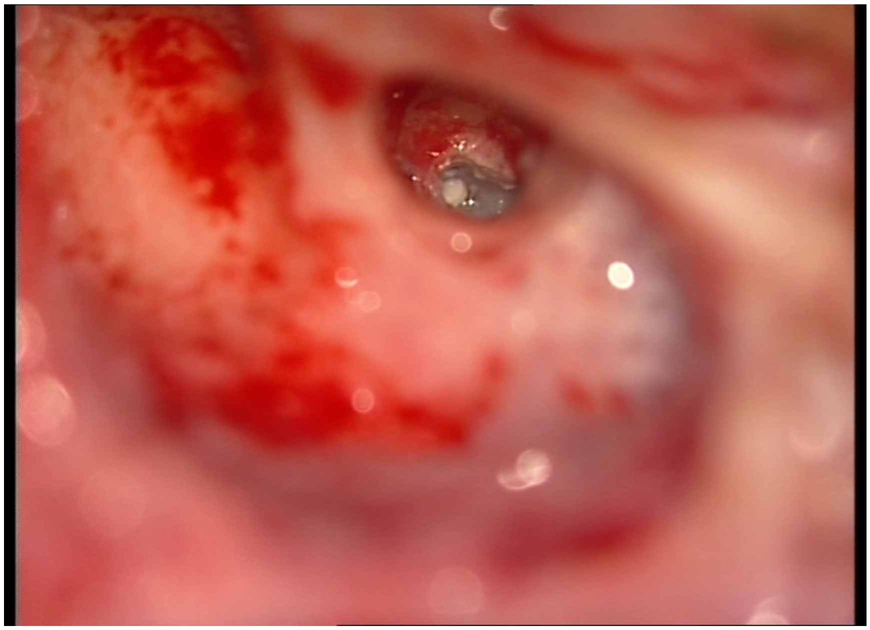


Figure 7 : Bed for the implant

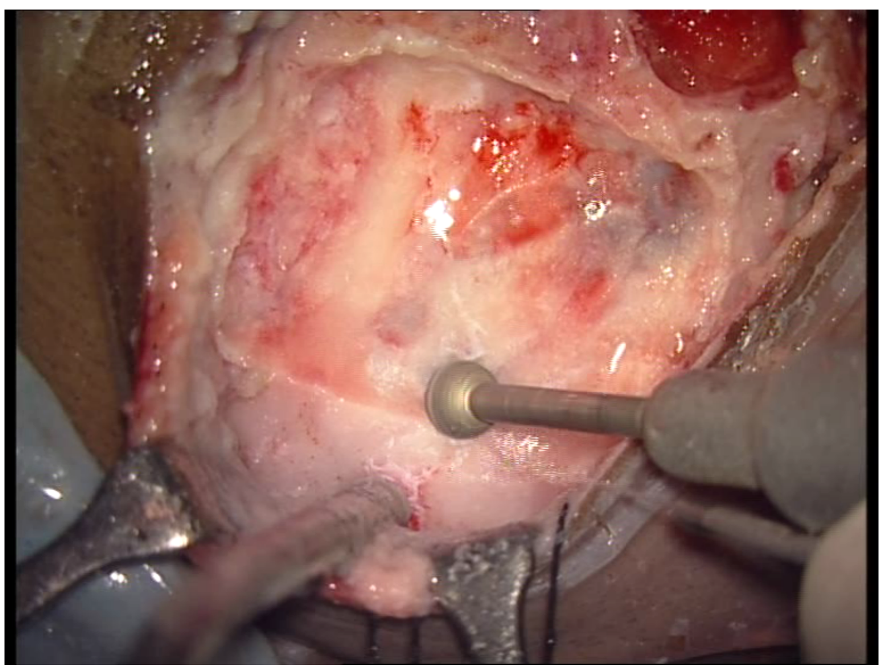


Figure 8 : Placement of implant and fixing by cross sutures

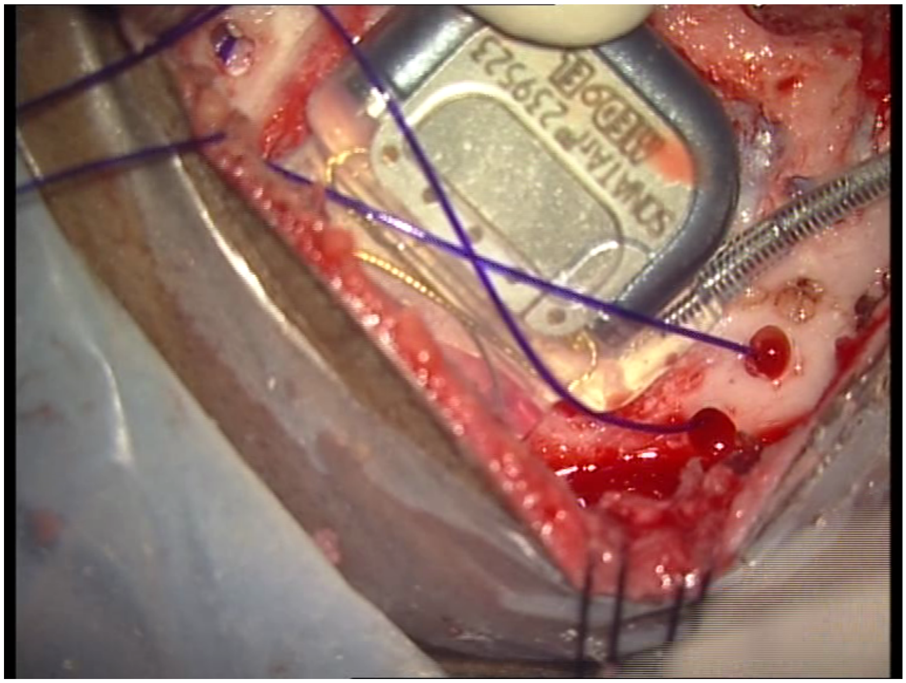


Figure 9 : Electrode insertion

Figure 10 : Post op X ray

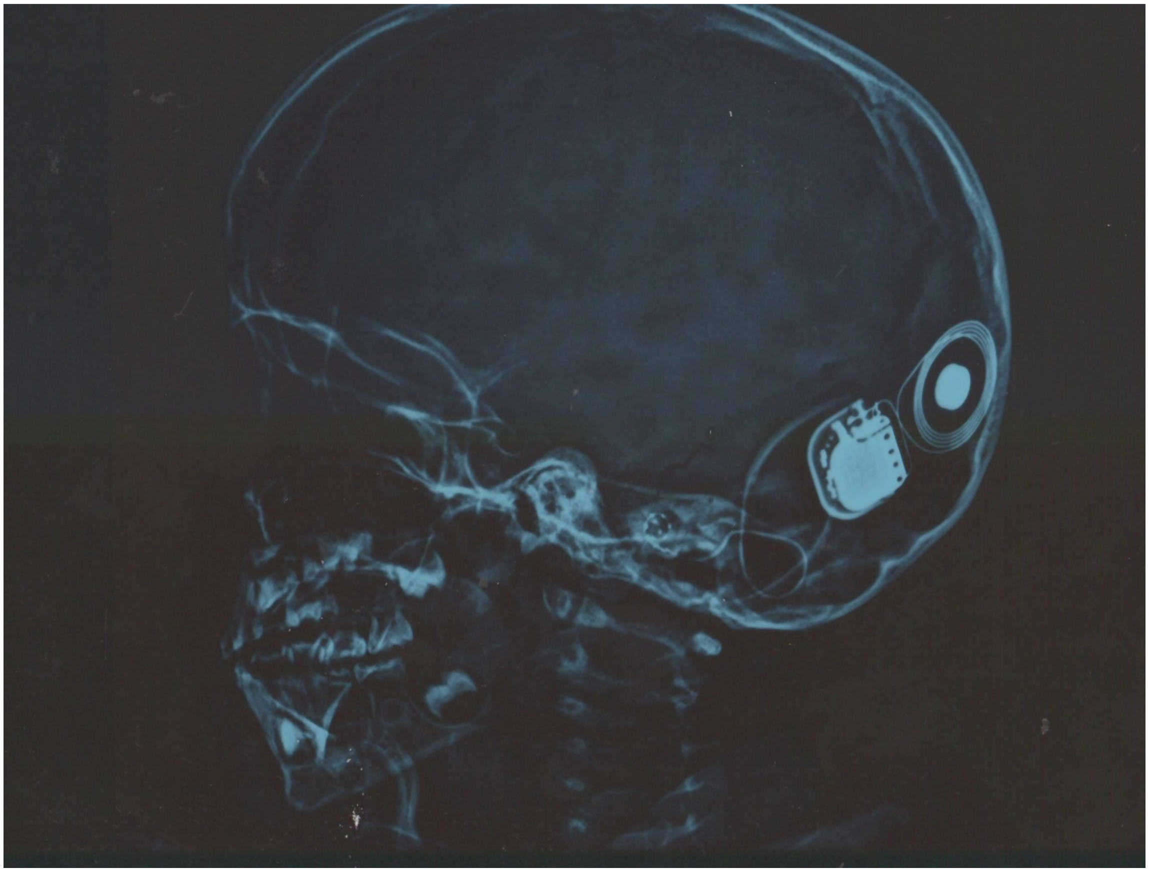


Figure 11 : Child using the implant

MATERIALS AND METHODS

Type of study: Prospective study

Study period: 12 months from July 2014 to June 2015

Number of cases: 50

Source of Data:

Bilaterally prelingually deaf children of age group 1 to 6 years with no benefit with hearing aid, who has undergone cochlear implantation surgery at Government Medical College Hospital, Coimbatore.

INCLUSION CRITERIA

All bilaterally prelingually deaf children of ages ranging from 1 year to 6 years under going cochlear implantation surgery at Government Medical College Hospital, Coimbatore.

EXCLUSION CRITERIA

1. Postlingually deaf children
2. Children with neurological defects
3. Syndromic children
4. Children with anatomic defects of the middle ear, inner ear or eighth nerve
5. Children already using hearing aids with benefit

METHODOLOGY

- Children suspected of having hearing loss undergo a preliminary auditory evaluation. These children include those routinely attending our OP department brought by their parents, those referred from other hospitals, and those children picked up on routine neonatal screening of high risk babies sent from our pediatrics department.
- They are first subjected to OAE and if found absent they undergo BERA and behavioral audiometry to confirm the presence of bilateral severe to profound SNHL of <90dB. A hearing aid trial is given and aided response recorded. The parents are then counseled regarding the prognosis of hearing in the child and about the need for cochlear implantation in such children.
- They then undergo a series of tests and investigations necessary for the preoperative evaluation of the audiological status as well as the general medical condition of the child and to rule out other anomalies in the child. These include:

Audiological evaluations

- Otoacoustic Emission (OAE)
- Brainstem Evoked Response Audiometry (BERA)
- Impedance Audiometry
- Behavioral Observational Audiometry
- Hearing aid Trial
- Speech Reception Threshold

Imaging

- High Resolution CT scan of the temporal bone with MRI of the inner ear

Other investigations

- Complete blood hemogram with bleeding time and clotting time
- Urine routine and microscopy
- Random blood sugar estimation
- Renal function test
- ECG
- Chest X ray
- Echocardiography
- Pre operative psychological evaluation of the child is done to estimate the IQ of the child. Ophthalmologist, pediatrician, and cardiological consultations are done to rule out other anomalies, syndromes and for the general medical fitness of the child to undergo surgery under general anaesthesia. The child is then sent for a pre anaesthetic check up by the anaesthesiologist.

Surgery:

- The ear to be operated is selected on the basis of audiological and imaging studies. The children are advised to continue on hearing aids till the day of surgery. From imaging studies any anatomical variation is noted, thickness of the cochlear nerve is assessed by means of MRI, this gives an idea regarding the number of viable residual neurons. In the absence of any other anatomical abnormalities of the cochlea or vestibular aqueduct, the side with the thicker cochlear nerve is chosen for implantation.
- Surgery is done under general anaesthesia.
- Child is placed on the operating table in supine position facing away from the side of surgery.
- After sterile draping, the incision site is marked in the post aural region and local anaesthetic infiltration (2%lignocaine with adrenaline) is given.
- A 'lazy S' shaped incision is made.
- Skin flap is elevated posteriorly.
- Anterior based periosteal flap is elevated.
- Mastoid bone is exposed in the region of McEwen's triangle and drilled parallel to the posterior wall of external auditory canal.
- Antrum is entered, the aditus, lateral semicircular canal and short process of incus are identified.

- Posterior tympanotomy is done and the middle ear entered in the region of facial recess.
- Promontory, stapedius tendon, incudostapedial joint and round window niche are identified.
- A Cochleostomy is done using skeeter drill and the scala tympani entered.
- Bed is created for the implant in the squamous part of the temporal bone.
- The implant receiver is placed in the bed and fixed using prolene cross sutures.
- Electrodes of the implant are advanced through the cochleostomy completely up to the hub. In cases with a normal anatomy of the cochlea with normal number of turns a Standard Med- El electrode of length 31mm is used. In doubtful cases regarding the dimensions of the cochlea an insertion test device (ITD) is introduced initially to determine the length to be inserted and accordingly the appropriate electrode is chosen. Other electrodes available- medium length compressed 24mm, short electrode- 15mm, flexisoft.
- After the electrode placement, with the help of the audiologist present, on table impedance audiometry, Electrical Stapedial Reflex Telemetry (ESRT), and Neural Response Telemetry (NRT) is done to ensure the proper placement and working of the device.

- Flap is closed over the implant by a 2 layer technique and mastoid dressing applied.
- A check X ray is taken during the post operative period to ensure the proper insertion of the electrodes and placement of the receiver.
- The placement of the external device consisting of the microphone, speech processor and transmitter and the initial activation or "switching on" of the device is done 3 weeks after the surgery.

Rehabilitation and training

- ❖ After the initial activation of the device, a training program is planned out for the child, incorporating both Ausplan and St. Gabriel's curriculum for training of pediatric population with cochlear implants. The number of classes is fixed over a one year period and days convenient for both the parents and therapist is chosen.
- ❖ Ausplan is actually an abbreviation meaning Auditory, Speech, and Language. It consists of strategies laid down by qualified cochlear implant audiologists and speech therapists based at Children's Hospital Oakland. It is instrumental comprehending the tedious process of language development in children and by using it parents along with the therapist can establish the required time needed by the child to achieve targeted goals in terms of speech and language development. The children are categorized into three groups as A, B, or C depending on various criteria pre operative variables such as auditory program, age of implantation, total communication or oral communication, medical condition. They are then followed up for their results. There are three

categories to be assessed including Auditory, Speech / Articulation, and Language, each of which has timeline specific targets that has to be achieved. The therapist and parent can categorize a child, and then based on the timeline specific goals know what the child is expected to achieve for example, at six months post-implant, twelve months post-implant etc. Teaching programs and exercises are listed for all three tracks, which the therapist as well as the parents should follow. Hence it is manual which helps to train a hearing impaired child to hear, speak, and converse fluently. It is a well inclusive program which comprises segments for auditory, speech and language objectives, all of which are essential for the development for proper communication skills in implanted children.

Auditory goals

Five levels with therapeutic objectives to be attained at each level have been identified. These include:

Level 1: Awareness, expected time of achievement 1–4 weeks after implant

- Awareness of voice in voice
- Awareness of environmental sounds
- Awareness of Ling Six sounds
- Distraction

Level 2: Suprasegmental-Discrimination/Association, expected time of achievement 2–5 months after implant

- Vocal length
- Onomatopoeic content
- Word length
- Sentence length
- Intensity pitch
- Oral/nasal resonance rhythm
- Prosody/stress difference intonation

Level 3: Segmental-Association/Identification, expected time of achievement 6–9 months after implant

- Consonant and vowel difference in monosyllable/trochee/three-syllable words

Level 4: Identification, expected time of achievement 9–12 months after implant

- One key word in context with/without suprasegmentals
- Two key words in context
- Three key words in context
- Four-plus key words in context

Level 5: Processing/Comprehension, expected time of achievement 15+ months after implant

- Advanced vocabulary development
- Increase auditory word-play association
- Answer simple questions
- Understand increasingly complex sentences containing three or more key elements
- Listen to short paragraph and answer simple questions
- Answer complex questions with/without visual support
- Listen to longer paragraphs and answer complex questions
- Sequence
- Increase cognitive language skills
- Follow conversation ending with familiar topic
- Follow open conversation

Therapy objectives are outlined parallel to the natural auditory progression phases. By providing the therapy it ensures a more focused auditory stimulation at each level.

Speech Goals[28]

Stage 1: Pre-Speech. Vocal control. In this stage the child learns to use voice voluntarily. The child is also learning to imitate different lengths of open vowels sounds. This is the beginning of breath control and voicing.

Stage 2: Isolation. Child learns placement of the sound.

Stage 3: Sound Sequences. The child learns to blend two or more sounds together. The goal is sound flow and not separation of sounds.

Stage 4: Words. The child first imitates, and then spontaneously produces words that contain the targeted Speech Level Sounds.

Stage 5: Phrase. A phrase is defined as a two-to-four-word utterance that does not necessarily conform to grammatical rules. Intelligibility is the goal.

Stage 6: Sentences. A sentence is defined as any utterance five words or more in length, regardless of grammar. Maintaining intelligibility is the goal.

Language Goals

Level 1: Word approximation. The child is learning to use his/her voice to gain attention. The child is also learning that vocalization is associated with meaning.

Level 2: Word production. Spontaneous true word productions. At this level, the child is learning to spontaneously use true words to convey meaning.

Level 3: Connected utterances that include phrases and basic sentences. This level consists of connected words and basic sentences that do not contain grammatical markers.

Level 4: Simple sentences that include grammatical structure development. At this level, the child is learning to use simple grammatical markers. Sentences are generally four to six words in length.

Level 5: Expanded sentences that include interrogatives and expanded sentences. At this level, the child is learning to use question formats and sentences that contain appropriate word order and grammatical structures. Sentences are generally at least six words in length.

Level 6: Complex sentences that include conjoining, complex sentences, and discourse. At this level, the child is learning to use advanced sentence structures appropriate to his/her normal hearing peer group. The child is also learning to exchange ideas verbally using intricate language. This is an ongoing level of language learning that extends from childhood through adulthood.

Evaluation

- ❖ Throughout the training program there is also a continuous evaluation of the child's performance at regular intervals to assess the outcome and provide more intense training if needed.

- The evaluation process covers 4 areas of development: Audition, Speech, Language and cognition. The final evaluation is done at the end of one year training program and these results have been used for the study.

AUDITION

- The auditory evaluation is done using the "Categories of Auditory Performance" (CAP) [22]scale and Meaningful Auditory Integration Scale (MAIS). CAP consists of a set of 8 accomplishment scales with regard to hearing awareness. There is hierarchal arrangement of increasing difficulty. It is widely used for conducting prospective studies on children with cochlear implants and is a practical to use device for evaluating the improvement. MAIS was developed at Indiana University School of Medicine. It consists of 10 questions with scores ranging from 0-4. The scoring is done by the parents in the home environment. A total score out of 40 is calculated by adding the individual scores.

Categories of Auditory Performance (CAP)

SCORE	DESCRIPTION	PRE OP	3 months	6 months	12 months
0	Displays no awareness to environmental sounds				
1	Awareness of environmental sounds				
2	Responds to speech sounds				
3	Recognizes environmental sounds				
4	Discriminates at least 2 speech sounds				
5	Understands common phrases without lip reading				
6	Understands conversations without lip reading in a familiar talker				
7	Can use the telephone with a familiar talker				

Meaningful Auditory Integration Scale (MAIS)

No.	Question	Score 0-4
1	Is the child wearing the device at all awake hours without any resistance?	
2	Is the child reporting or appear to be upset if the device is not functioning?	
3	Is the child responding spontaneously when his name is called in quiet environment without any visual cues?	
4	Is the child responding spontaneously when his name is called in the presence of background noise without visual cues?	
5	Is the child spontaneously becoming alert to environmental sounds (doorbell, telephone) at home?	
6	Is the child alert to auditory signals spontaneously when in new environments?	
7	Is the child spontaneously recognizing auditory signals that are part of his/her school or home routine?	
8	Is the child able to discriminate spontaneously between two speakers, using audition alone?	
9	Is the child spontaneously able to know the difference between speech and non speech stimuli by listening alone?	
10	Is the child spontaneously associating vocal tone with its meaning by hearing alone?	
	Total	

Scoring

0 = never

1 = rarely

2 = occasionally

3 = frequently

4 = always

SPEECH

- Speech is evaluated using several scales[23] including: Speech Intelligibility Rating Scale (SIR), Meaningful Use of Speech Scale (MUSS), Monosyllabic Trochee Polysyllabic (MTP), Common Object Token Test (COT), and Glendonald Auditory Screening Procedure (GASP)[31].

- The SIR scale is a reliable and practical clinical measure to evaluate the precision of speech. It is a scaling system which includes 5 levels of progression in the acquisition of speech. It helps in monitoring changes in speech over time. MUSS was developed at Indiana University School of Medicine. It consists of 10 questions with scores ranging from 0-4. The scoring is done by the parents in the home environment. A total score out of 40 is calculated by adding the individual scores. MTP measures the ability of the child to identify different syllable patterns; based on the child's age, different sets of words are used (3, 6 or 12 items). COT assesses the ability of the implanted child in the area of complex closed-set speech awareness, integration of the auditory cues with motor skills and auditory memory. GASP measures the ability of the child to understand simple sentences, i.e. ten routine queries are asked and a score out of 10 is given.

Speech Intelligibility Rating Scale (SIR)

SCORE	DESCRIPTION	PRE OP	3 months	6 months	12 months
1	Pre recognizable words in spoken language, primary mode of communication is manual				
2	Connected speech is unintelligible but intelligible speech is developing in single words when lip reading cues are available				
3	Connected speech is intelligible to a listener who concentrates and lip reads within a known context				
4	Connected speech is intelligible to a listener who has little experience of a deaf person's speech and the listener does not need to concentrate unduly				
5	Connected speech is intelligible to all listeners and the child is easily understood in everyday contexts				

Meaningful Use of Speech (MUSS)

No.	Question	Score 0-4
1	Using vocalization to attract others attention?	
2	Vocalizing during communicative interactions	
3	Vocalizations varying with content and message	
4	Spontaneously using speech alone to communicate with parents or siblings when the topic is a known or familiar one?	
5	Using speech alone to communicate with parents or siblings when the topic is not a familiar one?	
6	Using speech spontaneously during social exchanges with hearing persons?	
7	Using speech alone to communicate with unfamiliar people to get something s/he wants?	
8	Child's speech being understood by others who are not familiar with him?	
9	Using appropriate oral repair and clarification strategies when speech is not understood by people familiar with him/her.	
10	Using appropriate oral repair and clarification strategies when speech is not understood by people unfamiliar with him/her.	
	Total	

Scoring

0 = never

1 = rarely

2 = occasionally

3 = frequently

4 = always

LANGUAGE

- ❖ In the process of learning language, comprehending the language which is perceived, that is, the receptive language always comes before the development vocalization of the same that is the expressive language. A child with hearing impairment after implantation will also go through the same pattern of language progression but requires a more intense contact to spoken language as early as possible.

Statistical method

- ❖ The present study undertakes the evaluation of audition and speech in implanted children based on the age at which they have undergone the procedure. The variables and scoring systems included are Categories of Auditory Performance scale (CAP), Speech Intelligibility Rating scale (SIR), Meaningful Auditory Integration Scale (MAIS), and Meaningful Use of Speech Scale (MUSS). The study group is divided into two categories of 0-3 years and 3-6 years and these variables are compared. All the variables required were collected and entered in the Master Chart. The data is reported as the mean +/- SD or the median depending on their distribution. The differences between quantitative variables between groups were assessed by using unpaired t test. Comparison between groups was made by the non parametric Mann- Whitney test. A Chi square test was done to assess differences between categorical variables between groups. All data were analysed using a statistical software package (SPSS version 16.0 for windows).

Concept of p value

- If the p value is between 0.000 to 0.010 it is significant at level 1 (highly significant)
- If the p value is between 0.011 to 0.050 it is significant at level 5 (significant)
- If the p value is between 0.051 to 1.000 it is insignificant at level 5 (not significant)

OBSERVATION AND ANALYSIS

Table 1

AGE DISTRIBUTION

		GENDER		**TOTAL**	**PERCENTAGE**
		MALE	**FEMALE**		
AGE GROUP	<3YEARS	**16**	**8**	**24**	**48%**
	3-6YEARS	13	13	26	52%
TOTAL		29	21	50	

Chart 1

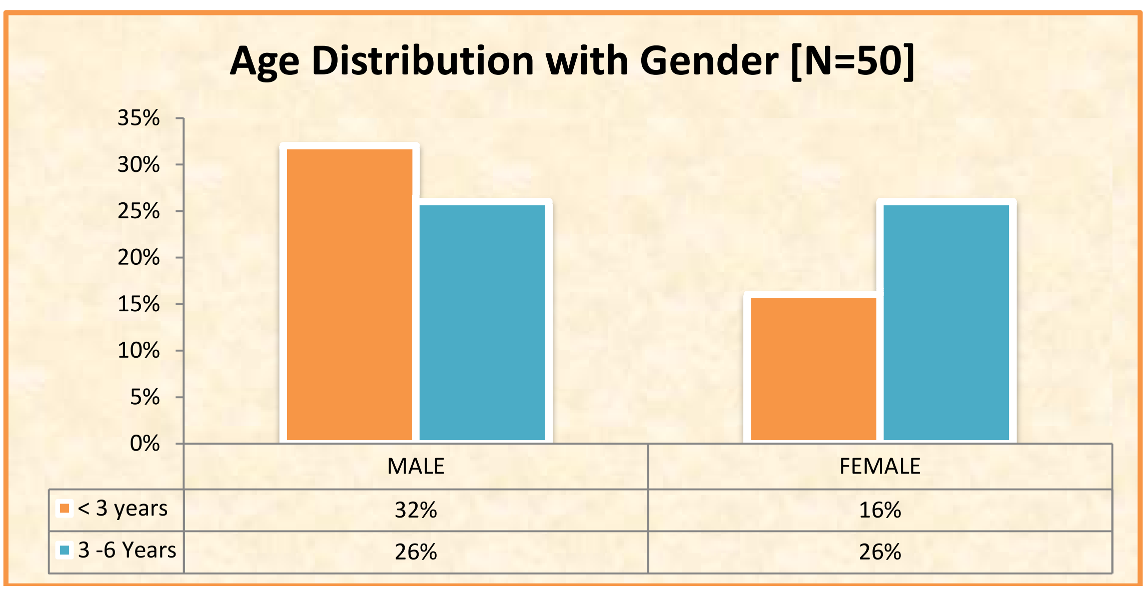


Chart 2

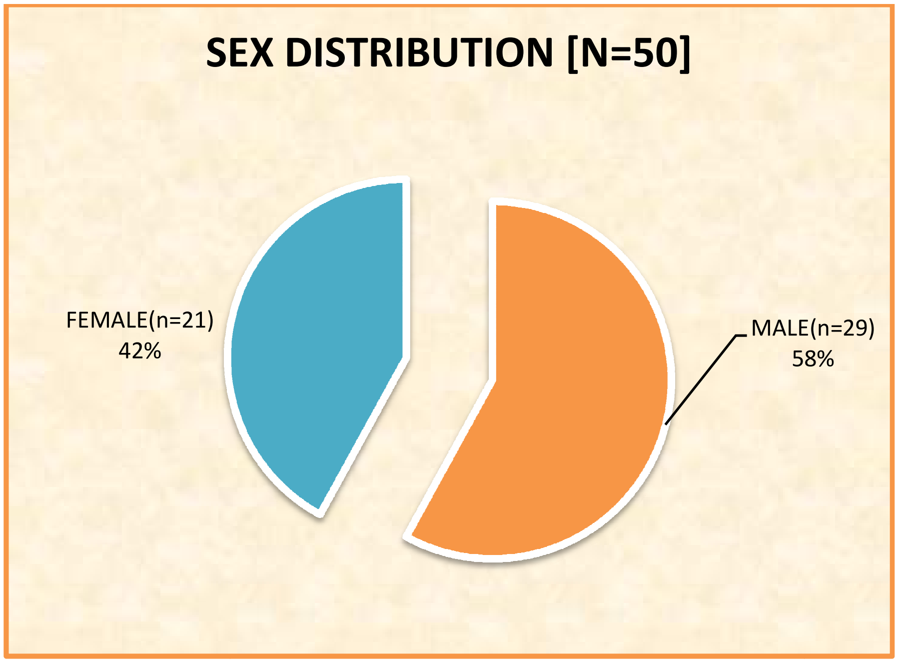


Table 2: CAP SCORE

CAP SCORE	NUMBER	PERCENTAGE
0	0	0%
1	1	2%
2	1	2%
3	10	20%
4	13	26%
5	17	34%
6	8	16%
7	0	0%

Chart 3

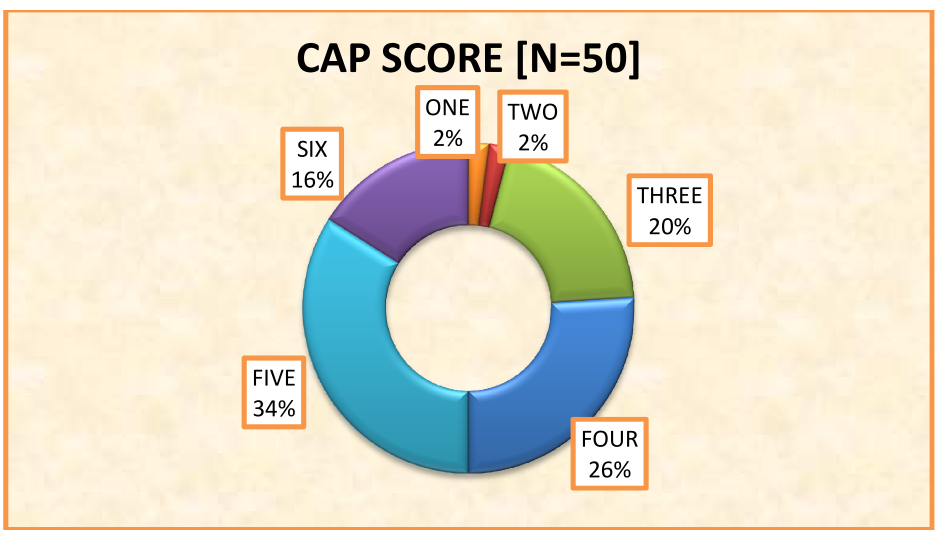


Table 3: SIR SCORE

SIR SCORE	NUMBER	PECENTAGE
1	5	5%
2	12	24%
3	11	22%
4	17	34%
5	5	10%

Chart 4

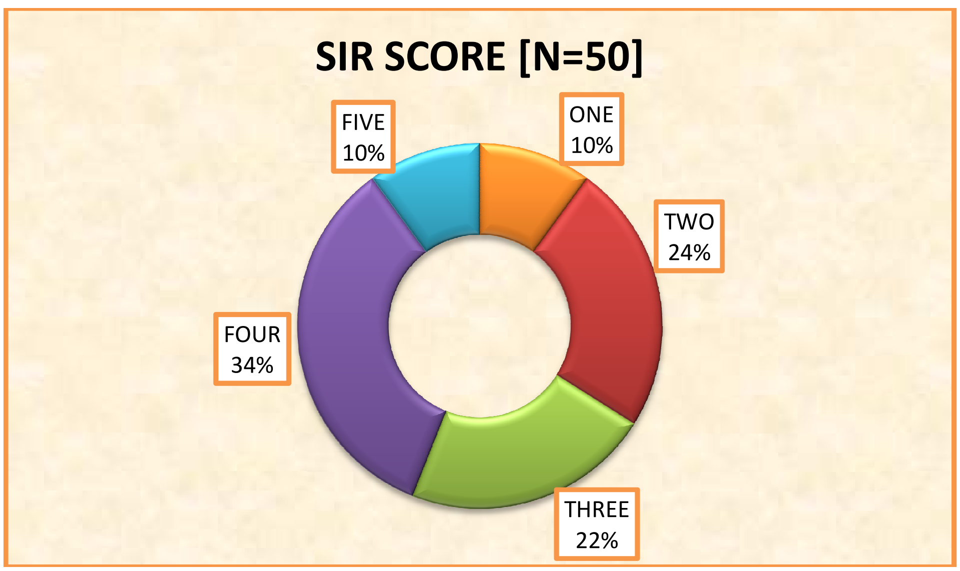


Table 4: MAIS SCORE

MAIS SCORE	NUMBER	PERCENTAGE
0-10	1	2%
11-20	3	6%
21-30	17	34%
31-40	29	58%

Chart 5

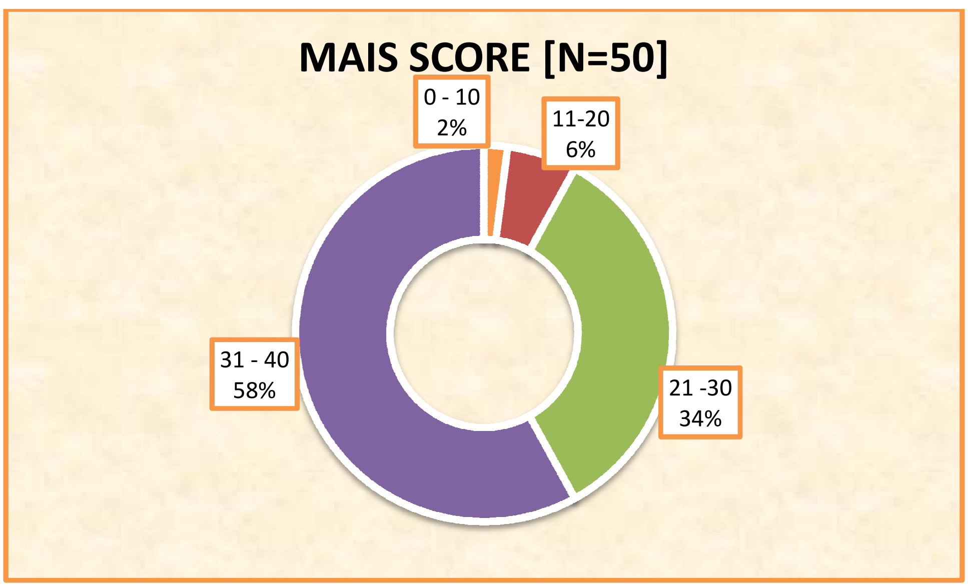


Table 5: MUSS SCORE

MUSS SCORE	NUMBER	PERCENTAGE
0-10	1	2%
11-20	8	16%
21-30	19	38%
31-40	22	44%

Chart 6

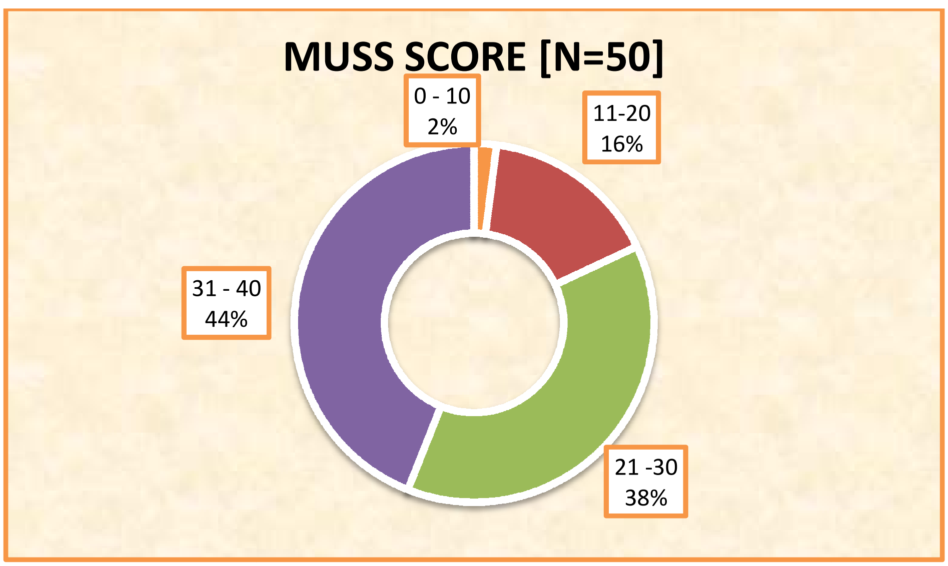


Table 6: Association of CAP score with age distribution

CAP SCORE	Age groups		TOTAL	%
	0-3YRS	3-6YRS		
0	0	0	0	0
1	0	1	1	2
2	0	1	1	2
3	0	10	10	20
4	4	9	13	26
5	12	5	17	34
6	8	0	8	16
7	0	0	0	0

Chart: 7

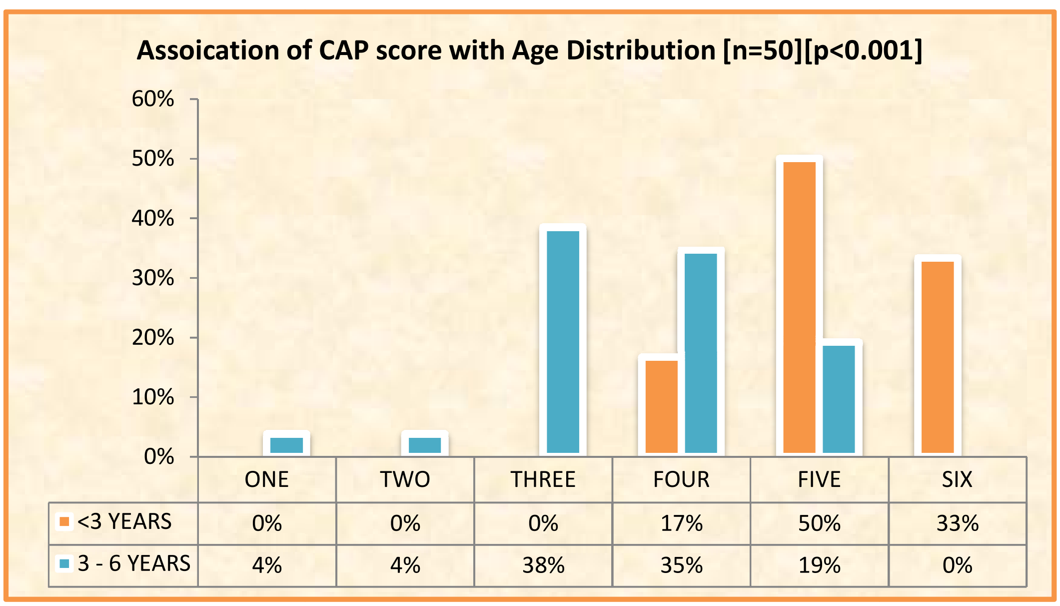


Table 7: Association between CAP score and gender

CAP SCORE	GENDER		TOTAL	percentage
	MALE	FEMALE		
0	0	0	0	0
1	1	0	1	2
2	1	0	1	2
3	5	5	10	20
4	7	6	13	26
5	9	8	17	34
6	6	2	8	16
7	0	0	0	0

Chart: 8

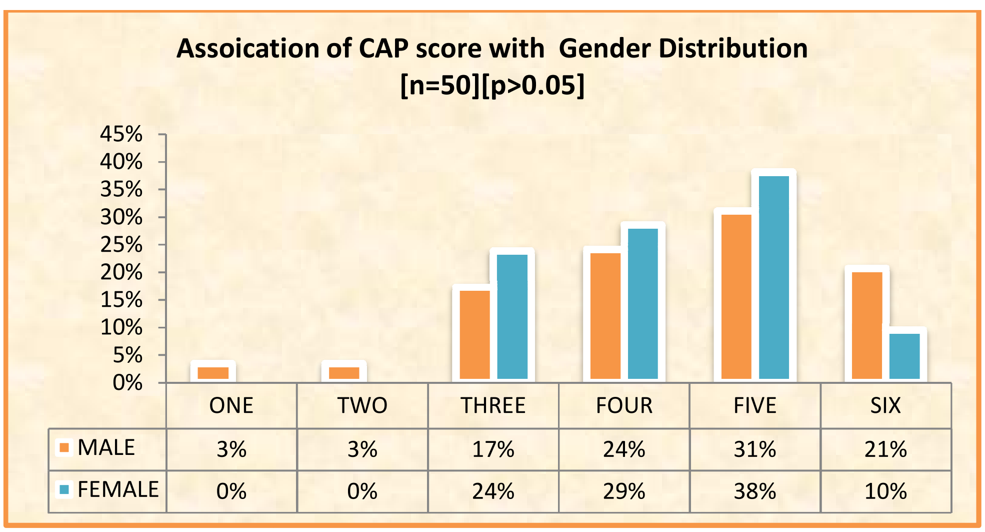


Table 8: Association of SIR score with age

SIR SCORE	AGE DISTRIBUTION		TOTAL	percentage
	< 3	3- 6		
1	0	5	5	10%
2	0	12	12	24%
3	4	7	11	22%
4	15	2	17	34%
5	5	0	5	10%

Chart 9

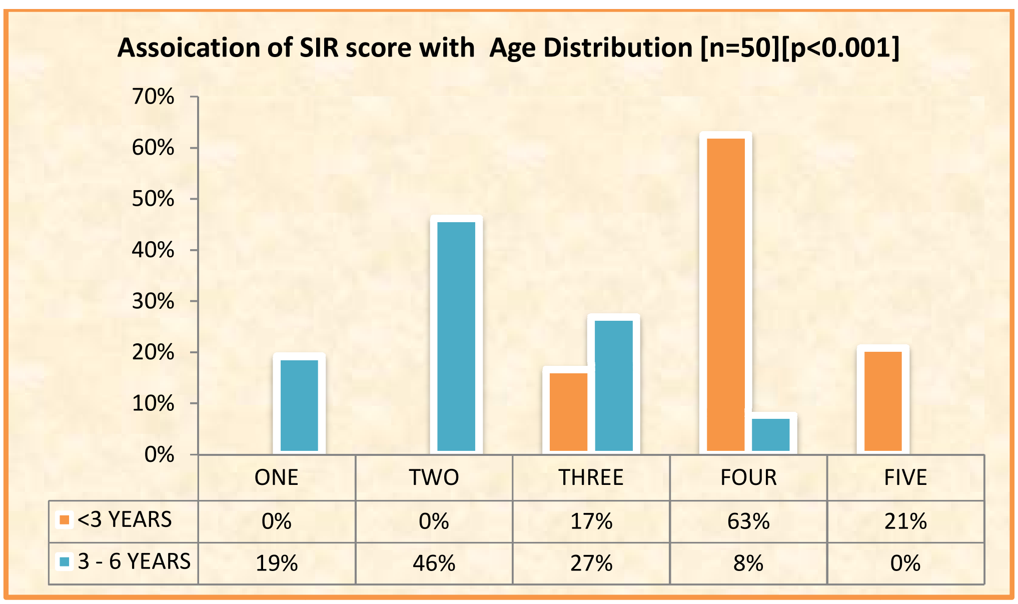


Table 9: Association of SIR score with gender

SIR SCORE	GENDER		TOTAL	Percentage
	MALE	FEMALE		
1	4	1	5	10%
2	5	7	12	24%
3	6	5	11	22%
4	10	7	17	34%
5	4	1	5	10%

Chart 10

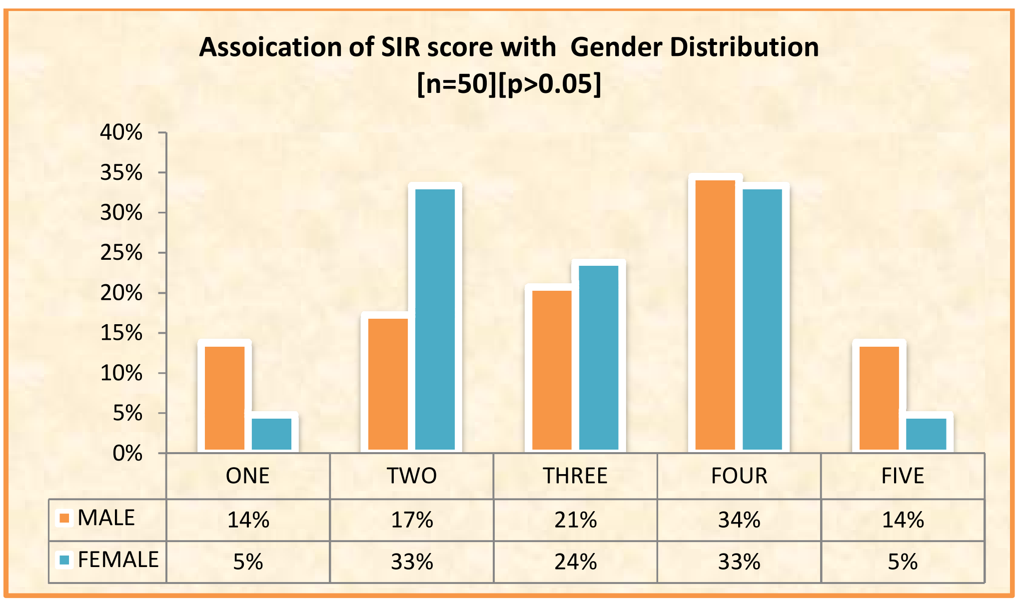


Table 10: Association of MAIS score with age

MAIS SCORE	AGE GROUP		TOTAL	Percentage
	< 3 years	3-6 years		
0 - 10	0	1	1	2%
11 - 20	0	3	3	6%
21 -30	3	14	17	34%
31 - 40	21	8	29	58%

Chart 11

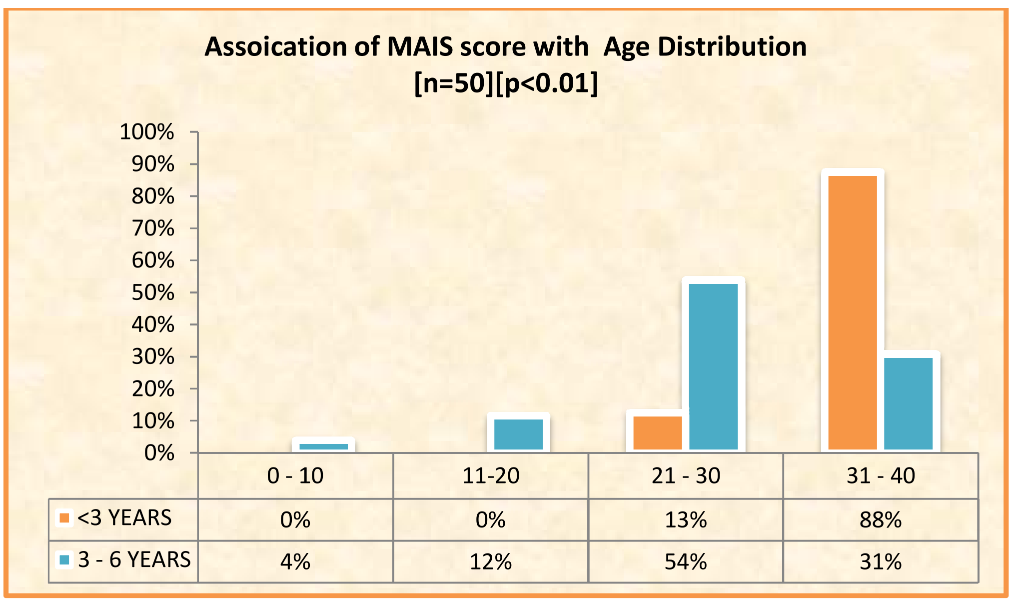


Table 11: Association of MAIS with gender

MAIS SCORE	GENDER		TOTAL	Percentage
	MALE	FEMALE		
0 - 10	0	1	1	2%
11 - 20	1	2	3	6%
21 - 30	10	7	17	34%
31 - 40	18	11	29	58%

Chart 12

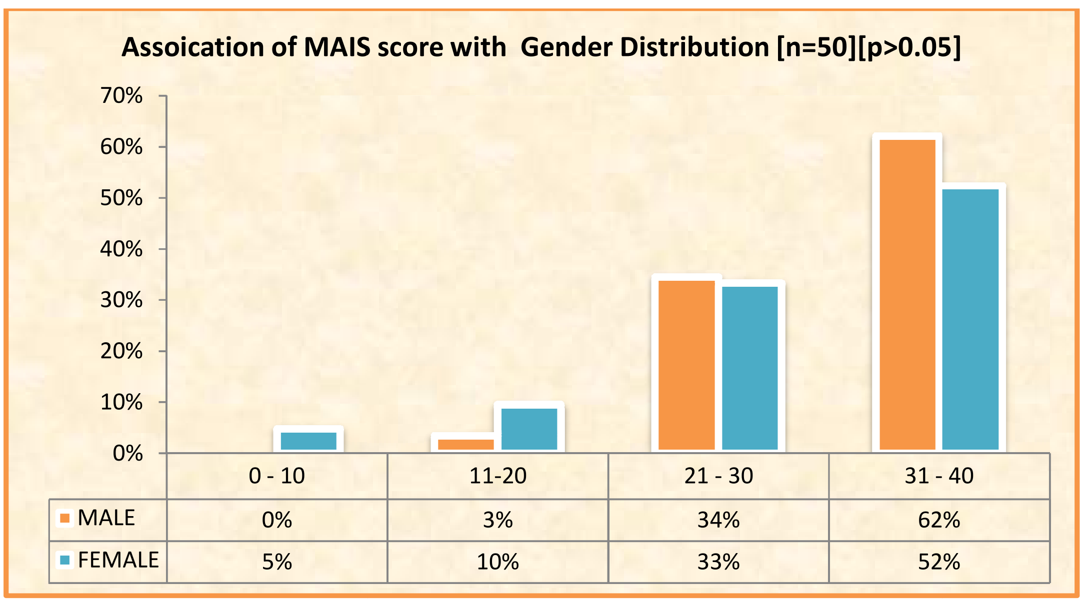


Table 12: Association of MUSS score with age at implantation

MUSS SCORE	AGE GROUP		TOTAL	Percentage
	< 3	3-6		
0-10	0	1	1	2%
11-20	0	8	8	16%
21-30	4	15	19	38%
31-40	20	2	22	44%

Chart 13

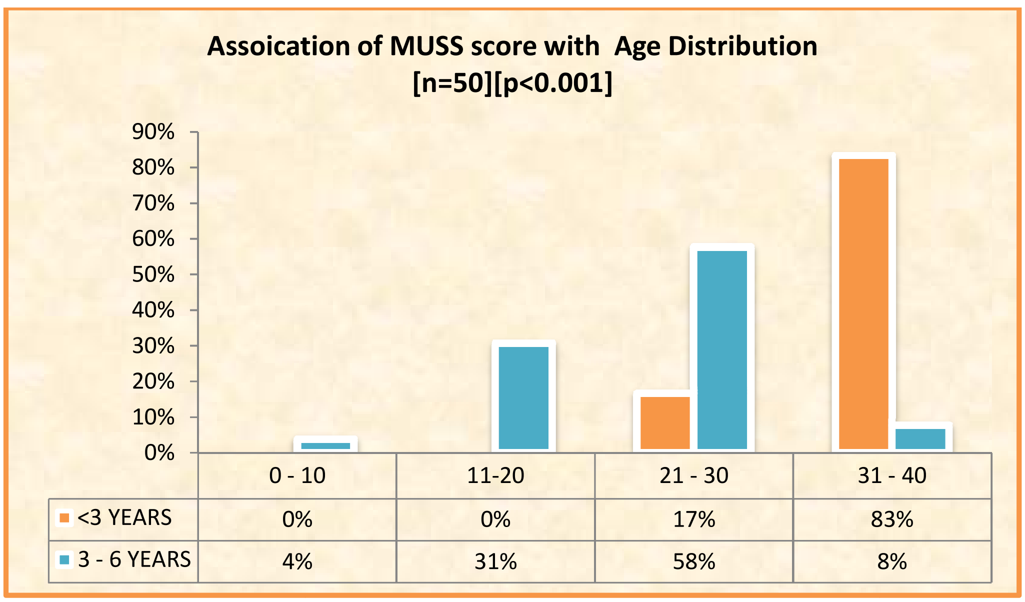


Table 13: Association of MUSS score with gender

MUSS SCORE	GENDER		TOTAL	Percentage
	MALE	FEMALE		
0-10	1	0	1	2%
11-20	6	2	8	16%
21-30	8	11	19	38%
31-40	14	8	22	44%

Chart 14

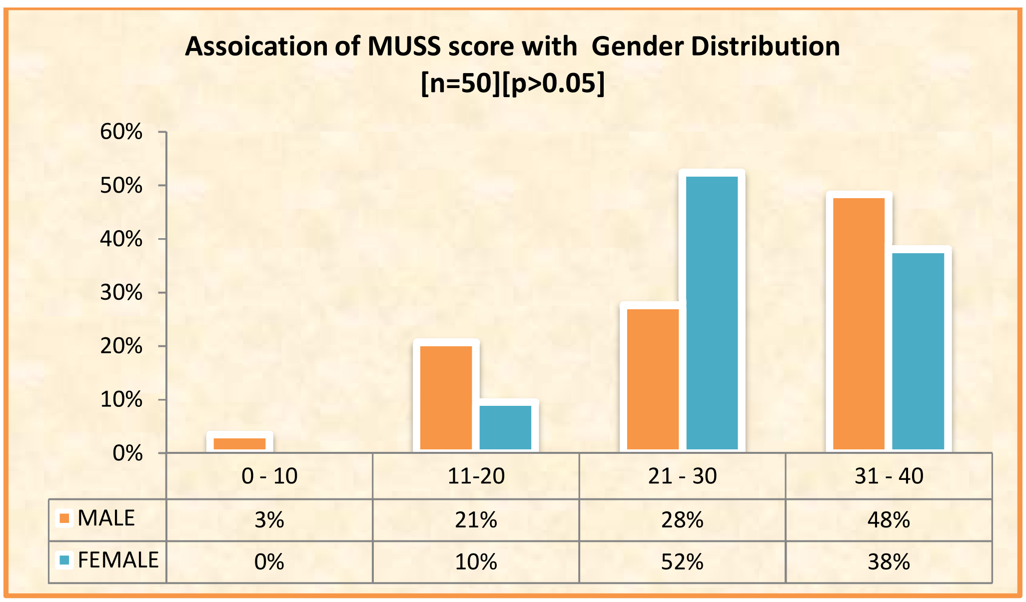
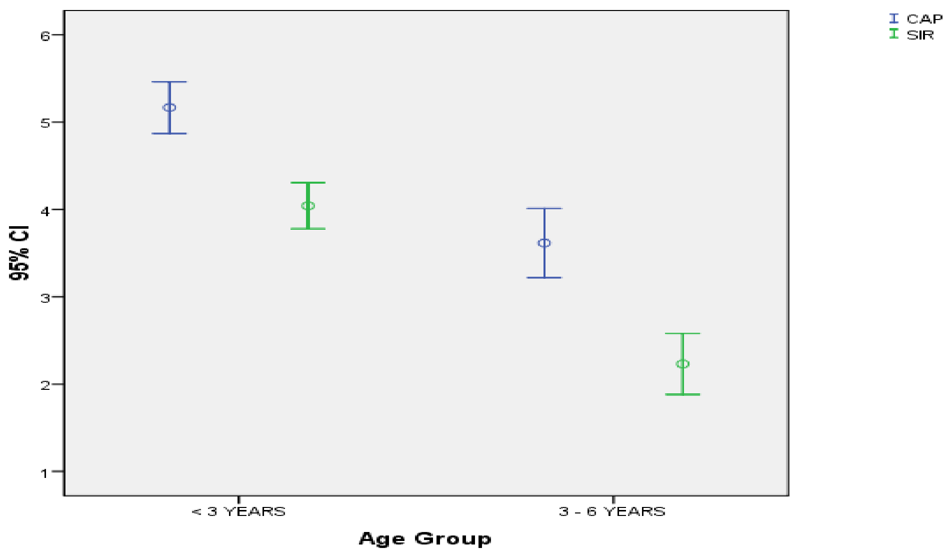


Table 14: Mean scores of clinical variables with age

Mean score of clinical Variables with Age at implantation								
Variables	Age Group	Mean	SD	95% CI for Mean		Minimum	Maximum	P value
				Lower	Upper			
CAP	< 3 YEARS	5.17	0.702	4.87	5.46	4	6	
	3 – 6	3.62	0.983	3.22	4.01	1	5	<0.001
	Total	4.36	1.156	4.03	4.69	1	6	
SIR	< 3 YEARS	4.04	0.624	3.78	4.31	3	5	
	3 – 6	2.23	0.863	1.88	2.58	1	4	<0.001
	Total	3.1	1.182	2.76	3.44	1	5	
MAIS	< 3 YEARS	34.88	2.309	33.9	35.85	30	39	
	3 – 6	27.38	6.268	24.85	29.92	10	37	<0.001
	Total	30.98	6.069	29.26	32.7	10	39	
MUSS	< 3 YEARS	32.79	2.604	31.69	33.89	28	40	
	3 – 6	23.96	6.206	21.45	26.47	8	34	<0.001
	Total	28.2	6.534	26.34	30.06	8	40	

Chart : 15


CAP
SIR
95% CI
6
5
4
3
2
1
< 3 YEARS
3 - 6 YEARS
Age Group

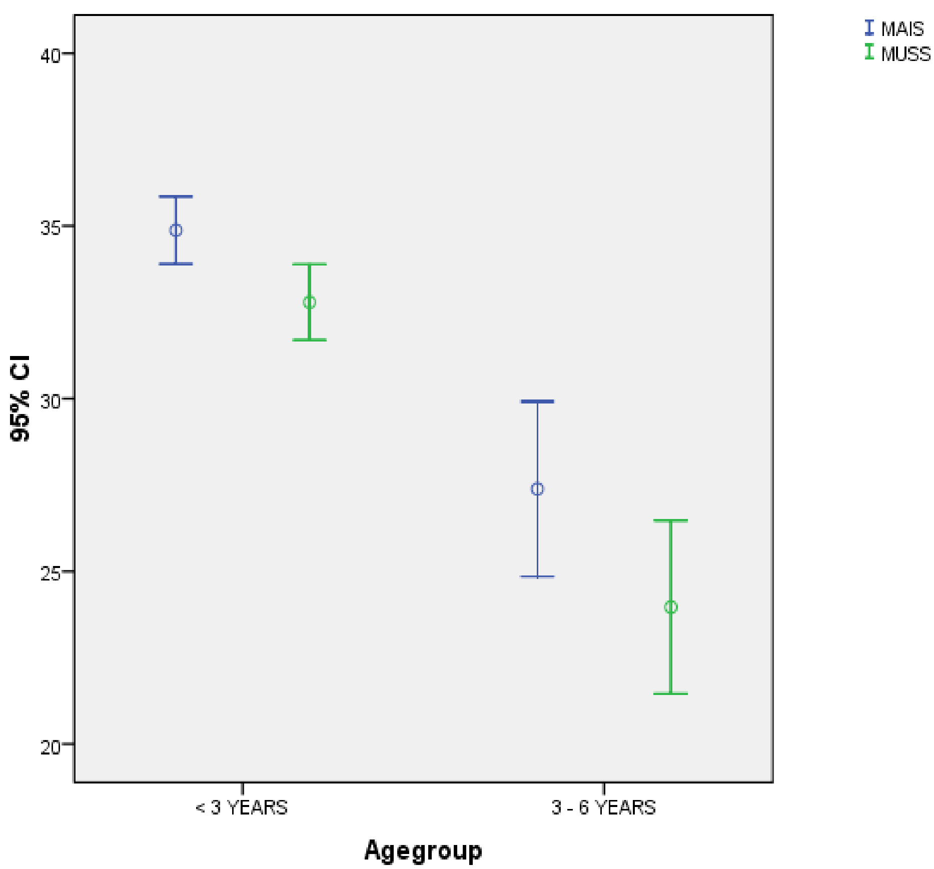
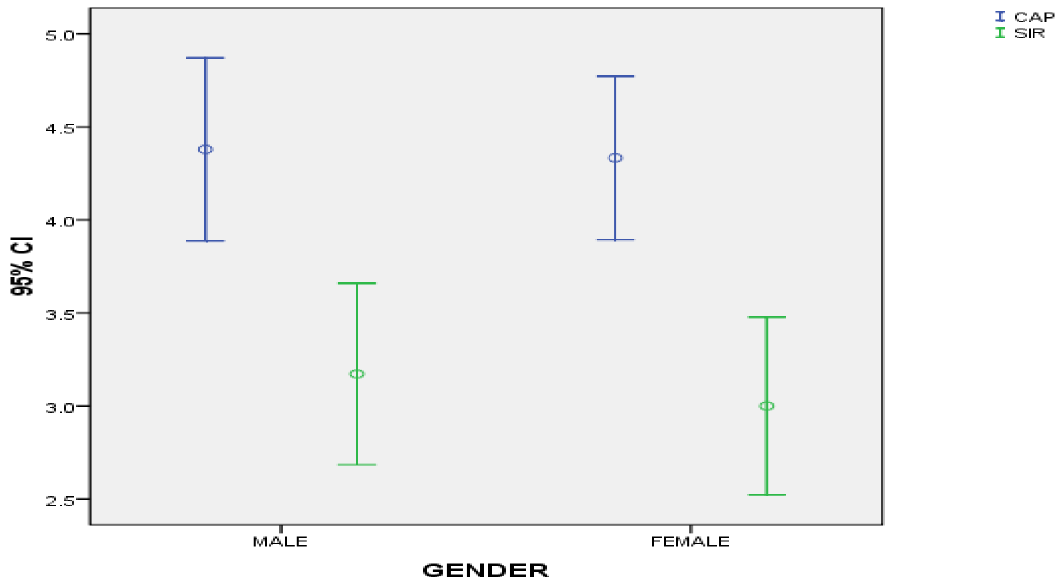
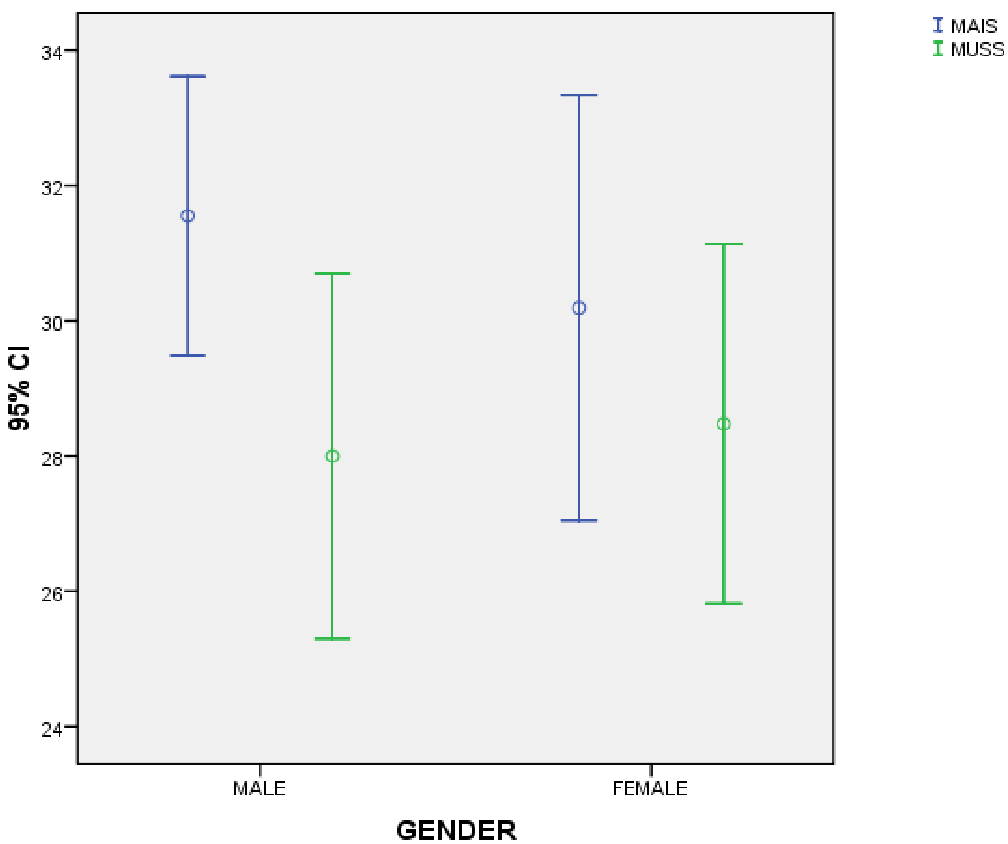

MAIS
MUSS
95% CI
40
35
30
25
20
< 3 YEARS
3 - 6 YEARS
Agegroup

Table 15

Mean score of clinical Variables with Gender								
Variables	Gender Group	Mean	SD	95% CI for Mean		Minimum	Maximum	P value
				Lower	Upper			
CAP	MALE	4.38	1.293	3.89	4.87	1	6	
	FEMALE	4.33	0.966	3.89	4.77	3	6	>0.05
	Total	4.36	1.156	4.03	4.69	1	6	
SIR	MALE	3.17	1.284	2.68	3.66	1	5	
	FEMALE	3	1.049	2.52	3.48	1	5	>0.05
	Total	3.1	1.182	2.76	3.44	1	5	
MAIS	MALE	31.55	5.429	29.49	33.62	20	39	
	FEMALE	30.19	6.918	27.04	33.34	10	37	>0.05
	Total	30.98	6.069	29.26	32.7	10	39	
MUSS	MALE	28	7.091	25.3	30.7	8	40	
	FEMALE	28.48	5.836	25.82	31.13	11	37	>0.05
	Total	28.2	6.534	26.34	30.06	8	40	

Chart : 16


CAP
SIR
5.0
4.5
4.0
3.5
3.0
2.5
95% CI
MALE
FEMALE
GENDER


MAIS
MUSS
34
32
30
28
26
24
95% CI
MALE
FEMALE
GENDER

DISCUSSION

- The study was conducted to evaluate the difference in outcome of hearing and speech in prelingually deaf children after cochlear implantation, based on the age at which implantation is done and hence find out if earlier implantation is more beneficial to the child.
- The present study was a prospective study.
- Fifty children who underwent cochlear implant surgeries were divided into two groups based on the age at which they underwent the surgery, that is, less than 3years and 3 – 6 years. Twenty four children (48%) belonged to less than 3years group and 26 children (52%) to 3 – 6 years group. Out of these fifty children 29 (58%) were male children and 21 (42%) female. Comparison of scores of evaluation was done between the groups.

Average scores	< 3 years	3-6 years	P value
Average CAP score	5.17 ±0.702	3.62 ± 0.983	P < 0.001
Average SIR score	4.04 ± 0.624	2.23± 0.863	P < 0.001
Average MAIS score	34.88±2.309	27.38±6.268	P < 0.001
Average MUSS score	32.79±2.604	23.96±6.206	P < 0.001

- From the above analysis we can come to the following analysis. While observing the CAP score it is seen that there is an improvement in the CAP score in all children at the end of 1 year after implantation. Based on the observation from our study it is seen that the average CAP score in children implanted below 3 years is 5.17 with a standard deviation of ±0.702 whereas in case of the 3 – 6 year age group it is 3.62 ± 0.983. The difference was statistically highly significant. So on an average child implanted before 3 years is able to "understand phrases without lip reading" whereas those implanted after 3 years are only able to "discriminate between speech sounds" at the end of 1 year after rehabilitation.

- Based on the observation of the average SIR score it is seen that the average SIR score in those implanted at an age < 3 years is 4.04 ± 0.624 and in those implanted between the ages of 3 and 6 years is2.23± 0.863. So it can be inferred that a child implanted before 3 years of age are able to produce speech which "is intelligible to a listener who has little experience of deaf persons speech and the listener need not concentrate unduly" whereas in those implanted between 3 – 6 years showed a SIR score corresponding to a speech "intelligible to listener who concentrates and lip reads within a known context" at the end of 1 year training program. The difference in terms of statistical analyses was highly significant.
- The average Meaningful Auditory Integration Scale in children implanted before the age of 3 years was 34.88 with a standard deviation of ±2.309 and in children whose age at the time of implantation was 3 – 6 years showed an average score of 27.38 with a standard deviation of ±6.268. This was statistically highly significant.

- The average Meaningful Use of Speech Scale was compared between the two groups and it was observed that the average value in the earlier implanted group in our study was 32.79±2.604 and those who received implantation between 3 – 6 years of age was 23.96±6.206. The difference in observation is found to be highly significant.
- When comparing the scores based on the gender groups average CAP score in males was found to be 4.38 ± 1.293 and in females it was 4.33 ± 0.966. The average SIR score in males was 3.17 ± 1.284 and in females it was 3 ± 1.049. The average MAIS was 31.55 ± 5.429 in males and 30.19 ± 6.918 in females. The average MUSS was 28 ± 7.091 in males and 28.48 ± 5.836 in females. The difference between these were found to be of no significance (p value >0.05).
- On comparing the present study to studies done by other researchers, it shows a correlation to the results obtained by **Yang et al**[32]**,** who compared the CAP and SIR score between 3 groups of children based on the age at the time of implantation; 1.3 – 2.9 years (12 children), 3 – 4.9 (17 children) and 5 – 7.9 (26 children). It was shown that 1 year after implantation CAP and SIR score in the age group of 1.3 to 2.9 years was significantly higher than the other two groups. There was not much difference in the scores between 3 – 4.9 and 5 – 7.9 years groups.
- In another study done by **Tajudeen et al**[34] showed that children implanted at 6 – 12 months of age showed at a significant better response compared to those implanted at 25- 36 months of age, and also performed better than

those implanted between 13 – 24 months of age. Also the 13 – 24 month group did much better than the 25 – 36 months group. The comparisons were done at 3, 4, 5, and 6 years of age.

- In a separate study done by **Fang et al**[33]**,** CAP and SIR scores were studied in children implanted before 5 years of age. It was shown that those implanted before 3 years of age had significantly better scoring than those who underwent implantation after 3 years of age.

Limitations of the study

In our study only age is taken as a parameter for the follow up of outcome in the implanted children. But apart from age of the child at implantation, a wide spectrum of variables can affect the post implantation performance. This includes the cause of deafness, surviving spiral ganglion cell population, and the social and educational status of the parents. All these factors have to be considered during the rehabilitation and follow up of cochlear implant children.

SUMMARY

- The present study was a prospective study which analyzed the correlation between the age of a child at the time of cochlear implantation surgery and the clinical outcome in terms of hearing and speech.
- The study was conducted during one year period from July 2014 to June 2015 and it involved 50 children who had undergone cochlear implantation surgery at Coimbatore Medical College Hospital.
- All children had undergone a thorough preoperative evaluation of general health and audiological parameters.
- Post operatively the variables recorded during the follow up for the purpose of our study included Category of Auditory performance scale (CAP), Speech Intelligibility Rating scale (SIR), Meaningful Auditory Integration Scale (MAIS), and Meaningful Use of Speech Scale (MUSS). The children were evaluated on the basis of these scoring systems at the end of one year.
- Among the 50 patients 24 children were below 3 years and 26 children between 3 – 6 years. And of the 50, 29 male and 21 female children were present.
- Maximum number of children (12) below 3 years at the time implantation showed a CAP score of 5 at the end of 1 year where as those between 3 – 6 years at the time of implantation most (10) had a score of 3. The average CAP score in the <3 year group was 5.17 ±0.702 and in the 3-6 year group it was 3.62 ± 0.983. The difference was found to be statistically significant.

- In terms SIR score most (15) of children in the earlier age group obtained a score of 4 and in the older group the maximum patients (12) obtained a score of 2. The average SIR score of the <3 year group was 4.04 ± 0.624 and in the 3 – 6 year group was 2.23± 0.863. The difference was statistically highly significant.
- The MAIS and MUSS grading and scoring of the children also showed highly significant difference between children implanted at age <3 years and between 3 – 6years with the earlier implanted children showing better response.
- Based on the gender of the child undergoing implantation the difference in the hearing and speech parameters between male and female children was found to be of no statistical significance (p value > 0.05).

CONCLUSION

- On the basis of the present study it was found that there is a definite improvement in the parameters used to assess hearing and speech at the end of 1 year, across all ages ranging from 1 to 6 years at the time of implantation.
- Even though there is hearing and speech benefit in all children implanted it is observed that earlier the age of the child, that is less than 3 years of age at time of implantation, better the response in the child in terms of hearing and speech.
- So it is inevitable that children should be screened for hearing impairment to diagnose severe to profound hearing loss as early as possible and intervention in the form of cochlear implantation provided at the earliest for the best outcome.
- Children implanted after 3 years of age will need a prolonged duration of rehabilitation and the parents of these children should be motivated further to provide the adequate home environment and training for getting the maximum benefit with device.

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CONSENT FORM

Your child, Sri/ Kum. ________________________, aged ____ years, S/o / D/o __________________________, residing at ________________ ______________________________________ is requested to be a participant in the research study titled "*To assess the hearing and speech outcome of prelingually deaf children who underwent cochlear implantation surgery over a period of 1 year*" conducted by Dr. Rubine Zeinuddeen C. one of the post graduate trainees in the Department of ENT, Goverment Coimbatore Medical College and Hospital, Coimbatore. He/she is eligible for the study as per the inclusion criteria. You can ask her any question or seek from her any clarifications about the study which you may have before agreeing to participate in the study.

TOPIC OF THE RESEARCH

Age wise outcome of speech and hearing outcome in prelingually deaf children after cochlear implantation

PURPOSE OF RESEARCH

To assess the hearing and speech outcome of prelingually deaf children who underwent cochlear implantation over a period of 1 year

To evaluate the outcome of cochlear implantation in prelingually deaf children.

To identify the ideal age for cochlear implantation in terms of best outcome

To assess the benefit of cochlear implantation in older children

PROCEDURES INVOLVED IN THE STUDY

Prelingually deaf children with no benefit with hearing aid who underwent cochlear implant will be followed up over a period of 1 year and their progress monitored based on the age of the child.

DECLINING FROM PARTICIPATION

You are hereby made aware that participation in this study is purely voluntary and honorary, and that you have all the rights to decline from participating in it.

PRIVACY AND CONFIDENTIALITY

You are hereby assured that your privacy is respected. Any information about you or provided by you during the study will be kept strictly confidential.

AUTHORIZATION TO PUBLISH RESULTS

Results of the study may be published for scientific purposes and/or presented to scientific groups. In any case, neither will your identity be revealed nor will your privacy be breached.

STATEMENT OF CONSENT

I, ____________________, do hereby volunteer and consent to my child participating in this study being conducted by Dr. Rubine Zeinuddeen C. I have read and understood the consent form (or) it has been read and explained to me thoroughly. I am fully aware of the study details as well as aware that I may ask questions to her at any time.

Signature / Left Thumb Impression of the parent/guardian

Station: Coimbatore

Date:

Signature / Left Thumb Impression and Name of the witness

Station: Coimbatore

Date:

ஒப்புதல் படிவம்

பெயர் :

வயது :

பாலினம் :

முகவரி :

அரசு கோவை மருத்துவக் கல்லூரியில் காது, மூக்கு, தொண்டை மருத்துவ துறையில் பட்ட மேற்படிப்பு பயிலும் மாணவி **ரூபின் ஜேனுதீன்** அவர்கள் மேற்கொள்ளும் **காக்ளியர் இம்ப்ளாண்ட் அறுவை சிகிச்சைக்குப் பின் பேச்சு மற்றும் செவித்திறன் ஆராய்தல்** பற்றிய ஆய்வியல் செய்முறை மற்றும் அனைத்து விளக்கங்களையும் கேட்டுக் கொண்டு எனது சந்தேகங்களை தெளிவுபடுத்திக் கொண்டேன் என்பதை தெரிவித்துக் கொள்கிறேன்.

இந்த ஆய்வில் எனது மகன் / மகள் ஈடுபடுவதற்கு எனக்கு முழு சம்மதம்.

இந்த ஆய்வில் எனது மகன் / மகள் பற்றிய அனைத்து விவரங்கள் பாதுகாக்கப்படுவதுடன் இதன் முடிவுகள் ஆய்விதழில் வெளியிடப்படுவதில் ஆட்சேபனை இல்லை என்பதை தெரிவித்துக் கொள்கிறேன். எந்த நேரத்திலும் இந்த ஆய்வில் இருந்து நான் விலகிக் கொள்ள எனக்கு உரிமை உண்டு என்பதையும் அறிவேன்.

இடம் :

தேதி :

கையொப்பம் / ரேகை

PROFORMA

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Pre op

CASE NO. I.P. NO.

NAME:

AGE/SEX:

NAME OF PARENT/ GUARDIAN:

ADDRESS:

PRESENTING COMPLAINTS:

PAST HISTORY:

BIRTH HISTORY:

GENERAL EXAMINATION:

VITAL SIGNS:

ENT EXAMINATION:

EAR:

NOSE

THROAT:

OTHER SYSTEMS:

INVESTIGATIONS:

Complete hemogram

Urine routine examination

Bleeding time / clotting time

Renal function tests

ECG

Chest X ray

AUDIOLOGICAL EVALUATION

OAE

BERA

Audiogram

Hearing aid trial

Impedance audiogram

IMAGING

HRCT temporal bone / MRI

Pediatrician opinion

Ophthalmologist opinion

Cardiologist opinion

Psychological evaluation

Anaesthetic assessment

Follow up

Date of surgery

Date of switch on

Score	3 months	6 months	12 months
CAP			
SIR			
MAIS			
MUSS			

KEY TO MASTER CHART

CAP score	:	Category of Auditory Perception
SIR score	:	Speech Intelligibility Rating score
MAIS	:	Meaningful Auditory Integration Scale
MUSS	:	Meaningful Use of Speech Scale

MASTER CHART

SL NO.	NAME	AGE	SEX	CAP	SIR	MAIS	MUSS
1	sruthi	1y11m	female	5	4	33	30
2	parthasarathy	1y11m	male	4	3	34	32
3	mukesh	1y11m	male	5	4	35	31
4	elavarasan	1y11m	male	5	4	37	36
5	diyash	1y9m	male	6	5	36	35
6	ramyadevi	1y9m	female	5	3	35	34
7	kavinraj	2y	male	6	5	35	32
8	samsulreshma	2y	female	6	4	35	37
9	hubaibafathima	2y	male	5	4	37	32
10	meena	2y	female	5	4	36	34
11	devasri	2y1m	female	4	4	35	32
12	yamini	2y1m	female	5	4	36	32
13	akash	2y11m	male	6	4	34	30
14	nandhabalan	2y11m	male	5	4	38	34
15	vishnu	2y11m	male	6	5	39	40
16	akil mohammed	2y4m	male	4	3	30	30
17	balakrishnan	2y6m	male	5	4	35	32
18	mohammed ilyas	2y6m	male	4	3	30	28
19	prabhakaran	2y6m	male	5	4	35	32
20	dikananth	2y6m	male	6	5	36	35
21	rajalakshmi	2y7m	female	6	5	37	34
22	kalaivanan	2y8m	male	5	4	34	31
23	anadakumar	2y8m	male	5	4	30	31
24	kavibharathi	2y8m	male	6	4	35	33
25	subash	3y11m	male	4	2	21	24
26	srihariharan	3y6m	male	3	2	21	18
27	muthugowtham	4y1m	female	5	3	37	29
28	nandhini	4y1m	male	3	2	20	30
29	poomarisri	4y1m	female	4	3	33	25
30	pavithra	4y11m	female	3	2	24	22

31	santhanalakshmi	4y11m	female	4	2	27	19
32	poorani	4y11m	female	5	3	30	27
33	ummuhaniya	4y3m	female	3	2	34	26
34	krithika	4y3m	female	4	2	30	32
35	sivakumar	4y8m	male	5	3	20	24
36	subhalaksmi	4y8m	female	5	3	30	27
37	saravanasanthosh	4y8m	male	4	1	34	20
38	kanishka	5y11m	female	4	4	27	28
39	dilip	5y2m	male	3	1	28	18
40	hariharasudhan	5y3m	male	3	4	34	34
41	loganathan	5y4m	male	3	2	24	20
42	sivaneshan	5y5m	male	4	3	32	28
43	yuvanchakravarthy	5y5m	male	4	2	31	8
44	mohammed haq	5y8m	male	1	1	28	19
45	swetha	5y9m	female	4	2	10	11
46	muthamilselvan	5y9m	male	3	2	30	28
47	sanjayram	6y	male	2	1	22	20
48	lekhasree	6y	female	5	3	35	28
49	renugadevi	6y	female	3	2	30	28
50	tharasri	6y	female	3	1	20	30