NEW COCHLEAR IMPLANTS- MYTHS AND FACTS

A CIGI INFORMATION DOCUMENT

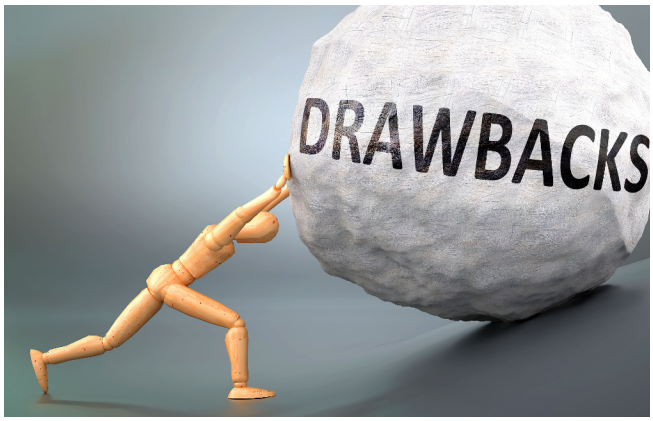
For information of Professionals, Care givers and patients with cochlear implants

CIGI
COCHLEAR IMPLANT GROUP OF INDIA

www.cigi.in

Introduction

We know that over 1 million cochlear implants have been performed worldwide. It has been, by far, the most advanced electro-neural interface known to humans. The safety and efficacy of cochlear implants have been ratified by hundreds of thousands of research papers all over the world. Patients as young as 6 months to as old as 100 years now receive cochlear implants all over the world to enable them to hear sounds hitherto not possible with hearing aids in severe to profound hearing loss. Pushing the boundaries of science, today cochlear implants are being done for people with significant residual hearing, and for those who have hearing loss only in one ear. Governments all over the world, knowing the financial benefit of cochlear implants in the way that they improve the quality of life and increase earning potential, have begun funding cochlear implants in a big way.



Drawbacks of Cochlear implants

While the benefits are immense, there are some issues that we need to address. The cost of cochlear implants, the surgical expenses and their continuous care has been significant and the underprivileged are often at a disadvantage to meet this. After the initial euphoria of improvement has set in, the seemingly never-ending process of spares and upgradation costs has at the very least, frustrated many patients and caregivers, but at the extreme, has made some completely become non-users.

The lack of proper habilitation services, still a major thorn in cochlear implant programs in many countries has led to frustration, poor outcomes and failures that could have been easily avoided. Adding to the problem is the unfortunate fact that diagnosis of hearing loss in the newborn is often delayed and by the time the child is recruited into the program, he or she is often beyond the time when age-appropriate speech and language outcomes can be achieved.

© Cochlear Implant Group of India

The Arrival of "new" Cochlear implants

As in every new technology, the drawbacks garner more interest and publicity than the obvious and proven advantages, the completely avoidable drawbacks of cochlear implants have resulted in certain developments in the market aimed to take advantages of the demerits. The so-called miracles therapies like injection of materials like Platelet reinforced Plasma (PRP), confounding concoctions of vitamins and herbal extracts to improve hearing, alternative medicine solutions guaranteed to reverse hearing loss all have continued to sadly exploit the gullible nature of the population overwhelmed by propaganda.

But while the number of people going for these fake cures are not large in number, and they often realize their mistake and return to mainstream

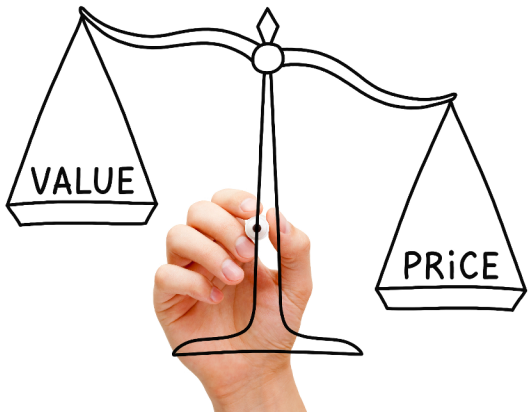
therapy albeit with a little delay, the shady world of unapproved cochlear implant devices are a major threat to the population, as they involve significant costs and it is many years before patients realize that the promised benefits are still far away. This has prompted the Cochlear Implant Group of India (CIGI) to come out with this document, to enable the public and professionals to have a realistic view of the developments and offer solutions.

© Cochlear Implant Group of India

Myths and Facts

Why are cochlear implants so expensive? Why are cochlear implants made only in a few countries worldwide?

Cochlear implants are still handmade and not mass-produced. There is continuous research needed into developing newer, smaller, and more efficient cochlear implants and the funding required for this is immense. The process of manufacture involves meticulous quality control of each component which is supposed to last in the human body for a lifetime and the extreme nature of the body fluid environment. Accelerated ageing processes need to be laboratory replicated and all failures meticulously studied, revised, and corrected. Regulatory process approvals are very expensive and time-consuming. Just for comparison, a company specializing in software which can be used as an add-on to a Bluetooth headset for mild to moderate losses spent 12 years and nearly 11 million Euros for medical



certification in Europe and is still waiting for FDA approval. All these push up the costs of cochlear implants which is not a consumer device that sells millions of products every year. To go through the entire process of developing a new implant from scratch would take too much time and too much money to be financially worthwhile.

© Cochlear Implant Group of India

Why is it not possible to use analogue stimulation in cochlear implants? Is it necessary to have electronics inside the implant itself, for is that not which is prone to failure?

Older cochlear implants developed in the 1970's and earlier, used analog stimulation. Analysis of speech frequencies was not thought about at that time. From the time of Alessandro Volta who stimulated his ear with electric current, the path-breathing discovery of Djourno and Eyries who in 1957 inserted an electrode into an exposed auditory nerve, to the first commercial cochlear single channel implant inserted in 1961 by William House and John Doyle, every implant used only analog stimulation and gave limited speech information. Patients could hear, yes, and they enjoyed the frequency discrimination that the implants gave, but it still did not improve speech understanding. Nevertheless, the discovery of this gave hope to millions of patients who suffered or will suffer from severe to profound hearing loss.

But scientists soon realized that the access speech information through formants,or the concentration of acoustic energy around a particular frequency, the electronic signal given to the internal device of the cochlear implant needs to be "steered' to respective parts of the cochlea. You needed electronics to do this and digital technology to deliver that. So, when the first successful multichannel cochlear implant was performed by Graeme Clark in Melbourne in 1978, this technology of feature-extraction schemes conveyed fundamental frequency information as well as information about the first two formants of speech (F0F2 and F0F1F2). To improve speech understanding, especially in noise, various strategies like CIS, ACE, MPEAK, Hi-res and FSP were developed and significantly improved outcomes. For these new strategies to work, you need electronics inside the implant and digital sound processing. The words of Graeme Clark,"stimulating pulse shape that minimizes the production of toxic substances and loss of metal from the electrodes" continue to drive researchers all over the world today.

You also needed information back from the device to assess its function and interaction with the auditory nerve. This is called "Telemetry" and is used by all modern implant systems to program, adjust and troubleshoot the function of the implant. None of this is possible without electronics and therefore claims that an "electronic free " implant is better and gives a more natural "analogue sound" is clearly against science and all the research and progress made in the last 50-odd years of Cochlear implant technology.

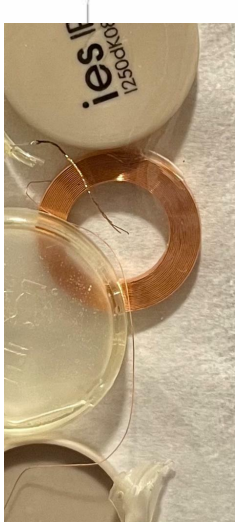
© Cochlear Implant Group of India

Why is there that there are claims that children using these electronic free implants hear sounds and appear to be developing speech skills?

We must never underestimate the power of the brain. Given something, the brain is often able to multiply it, but limitations of what is given also limit the brain. The early single-channel cochlear implants with just a magnet and a coil of wire which led to an electrode that was inserted into the cochlea also provided auditory stimulation, but speech discrimination as opposed to sound and frequency awareness was severely limited. This is why FDA approval of single-channel implants was withdrawn.

The later variations of the House 3M cochlear implant like the IES Korean cochlear implant and the Neubio implants will also similarly provide sound stimulation, but very limited speech discrimination. The IES implant was also received well by some surgeons and patients in 2012, with over 120 patients implanted amidst tall claims, but eventually, all of them became non-users or had to be reimplanted with another device. It is noteworthy to note that the internal components of the IES (I Enjoy Sound) cochlear implant and the Neubio implant are remarkably similar. No surprise because they have both been developed by a person called Jay Chang, who was once associated with the House 3M project.

Neubio exploded view



IES implant explanted view

© Cochlear Implant Group of India

So, how does one choose a cochlear implant?

It is quite easy. One has to do self-research into various publications and internationally approved journals, FDA and MDR (EU) websites to see how the cochlear implant companies stand in quality and performance. One must look at the biggest and most reputed cochlear implant centres worldwide and see what their experience is. Company websites often paint a very rosy picture, even the most reputed ones, and must be taken with great caution

So, given this information, is it dangerous to use the “newer” implants?

It may not be dangerous from a surgical perspective but will seriously affect the acquisition of speech discrimination and language abilities especially in young children and that delay will not be corrected even if you change the implant to a certified one later. There are some implants which have been given transitory FDA approval like the Oticon device (formerly the Neurelec implant) for which many research papers are available and the Chinese Neurotron implant for which FDA approval is awaited. It is quite possible that with proof of efficacy and performance, some of these will find their way into the market. However, it is quite dangerous to sanction an implant with no studies, no research papers from reputed journals and no regulatory approval from the country of origin. This can only be done at a great personal risk

© Cochlear Implant Group of India

THE COCHLEAR IMPLANT GROUP OF INDIA

(Registered under the Karnataka Societies Registration Act 1960, Reg. No728/2003-2004)

President: Dr. Neelam Vaid (Pune)

Secretary: Dr. Mohnish Grover (Jaipur)

President Elect: Dr Manoj Manikoth (Calicut)

Jt.**Secretary:**Ms. Rashmi Deshpande (Bangalore)

Treasurer: Dr. Sumit Mrig (New Delhi)

Executive Council Members:

Dr. Aparna Nandurkar (Mumbai)

Ms Leena Vishwakarma (Ahmedabad)

Ms. Meenakshi Wadhera (New Delhi)

Dr. Gaurav Gupta (Bikaner)

Dr. Rajeev Pachauri (Agra)

Dr. Saumitra Shah (Surat).

CIGI

COCHLEAR IMPLANT GROUP OF INDIA