ENGN2226 Systems Engineering Analysis Portfolio

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Topic: Improving the effectiveness of cochlear implants

Abstract

Introduction

The cochlear implant is the most successful neural prosthesis device with over 300,000 implantations worldwide. The success of the cochlear implant is due to not only the interdisciplinary work of many engineers, but the collaboration of engineers with physiologists, psychologists and entrepreneurs. This portfolio aims to suggest improvements to the cochlear implant system.

Methods

This portfolio analyses the cochlear implant using systems methods.

Results

We found three promising ways to improve the performance of the cochlear implant. Firstly, using a liquid crystal polymer for the internal casing of the implant has many advantages over the traditional titanium casing, such as allowing for signal transmission and allowing the possibility of a more compact, reliable and energy efficient unibody case. Secondly, we determined that pre-curved electrode arrays have distinct advantages over their straight counterparts such as reducing power consumption, allowing for more accurate stimulation and increases in the number of electrodes. Finally, we analysed a closed-loop control system and determined that it has significant performance, cost and time benefits for patients and the health system.

Conclusions

We recommend further research into pre-curved electrode arrays, liquid crystal polymers closed-loop control. If any of these areas are realised they will transform the cochlear implant and have many performance, safety and financial benefits.

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1 Introduction

1.1 Motivation

The cochlear implant is the most successful device in neural prosthetic engineering but there are still many ways it can be improved. There are concerns about the reliability of the cochlear implant, particularly that of the internal packaging. Cochlear implant users still have difficultly recognising individual sounds and have poor perception of music. Post-operative rehabilitation is also very time consuming and expensive.

The societal cost of prelingual hearing loss is enormous. Reduced employment opportunities, increased educational costs and other costs adds up to around $1.7 million AUD over a lifetime of a child (Mohr et al. 2000). The cost of a cochlear implant is significantly less, around $40,000 AUD for an implant alone (An et al. 2007). The cochlear implant has been shown to have significant cost benefits for both adults and children (Bond et al. 2009; Cheng et al. 2000) Therefore it is very important that every effort is made to improve the cochlear implant, as this will not only encourage more people to use it, but it will be economically beneficial for society.

1.2 Hearing Loss

About 10% of the world's population suffers from hearing loss. Causes of this include exposure to intense noise, infection and overuse of medications (Oishi & Schacht 2011). Around 0.2% of the population suffers from severe to profound hearing loss. These people are the main candidates for cochlear implants (Mohr et al. 2000).

1.3 Anatomy

The figures below show the anatomy of the human ear, which is very important when understanding the cochlear.

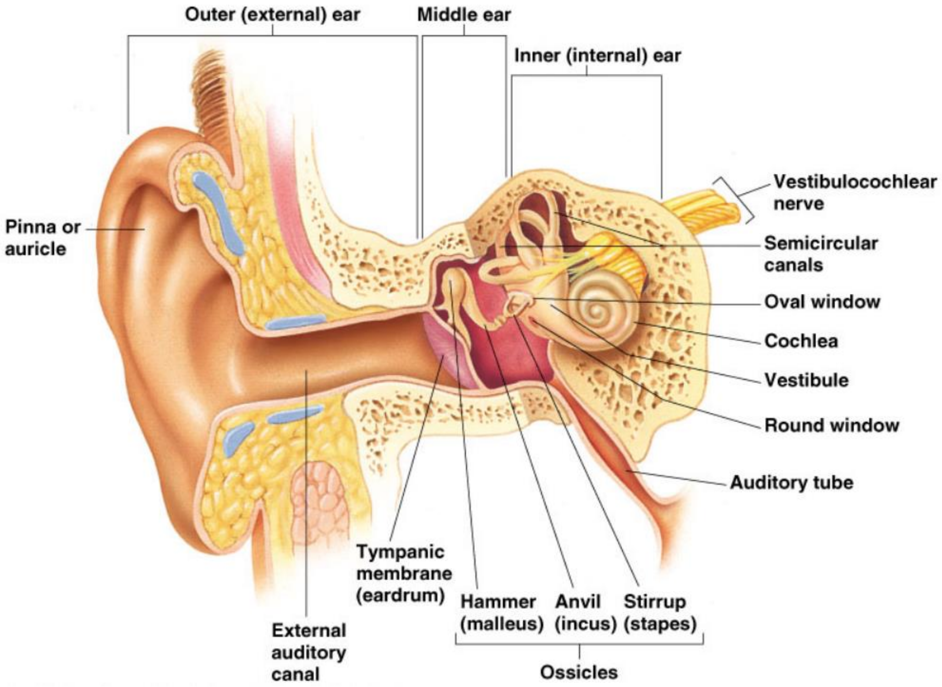


Figure 1: Anatomy of ear (Marieb 2008).

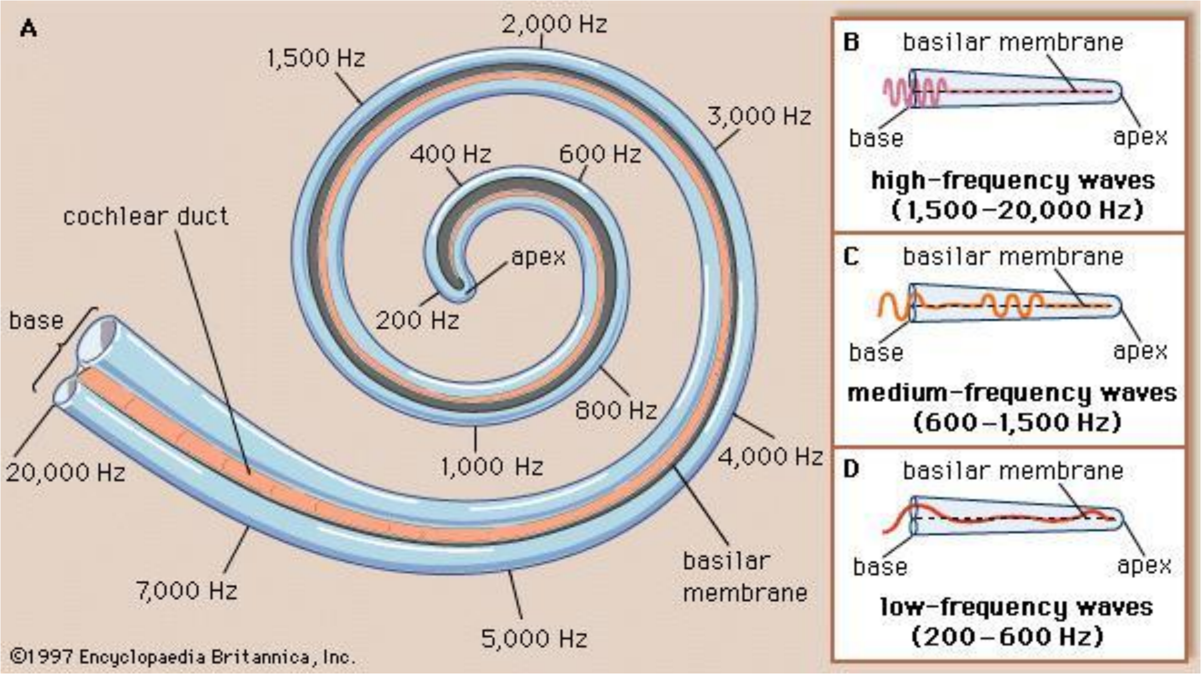


Figure 2: basilar membrane of cochlea (Encyclopaedia Britannica 1997).

Figure 2 shows where the different frequencies of sound are detected in the cochlea. The highest frequency sounds are detected at the base of the cochlear while the lowest frequencies are detected at the apex of the cochlea. Notice that the base is much wider than the apex (Sabi 2012).

1.4 Physiology

The auditory system converts acoustic energy into mechanical energy and then electrical energy. Sound waves hit the tympanic membrane and cause it to vibrate. This vibration is then transferred the Mallues, Incus and Stapes, three bones in the middle ear. The Stapes is attached to the oval window, a flexible membrane in the bony shell. Vibrations in Stapes cause the oval window to move inward and outward which cause changes in pressure in the cochlear fluid. High frequency sounds activate hair cells near the base and lower frequencies activate hair cells near the apex. These hair cells then generate electrical stimulation of the auditory nerve, which connects to the primary auditory cortex, which give a sensation of hearing (Sabi 2012).

1.5 Cochlear Implant

The cochlear implant is an implanted electronic medical device that replaces the function of the damaged inner ear. Both children and adults who are deaf or severely hard of hearing are eligible for cochlear implants. A cochlear implant is different to a hearing aid. Hearing aids amplify sounds so that damaged ears can perceive them. However, cochlear implants bypass the damaged portions of the ear and stimulate auditory nerve directly (Cochlear 2015a).

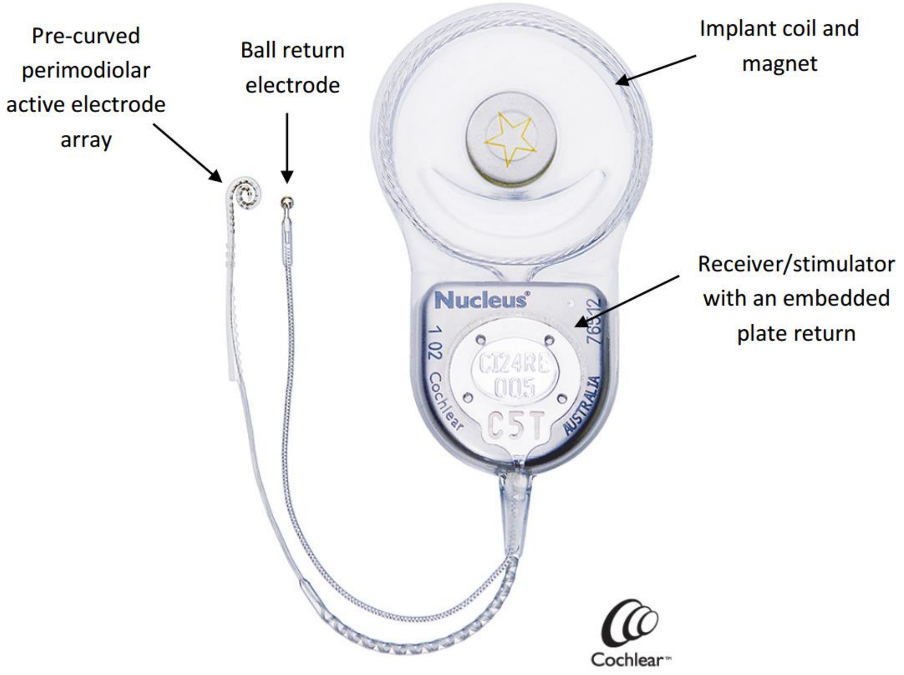
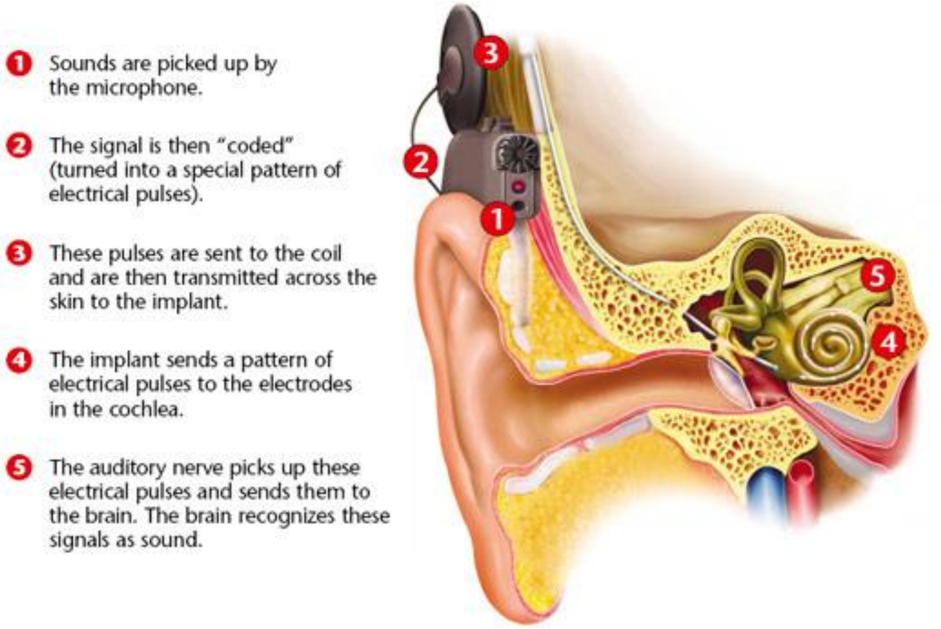


Figure 3: A cochlear implant: Cochlear Contour Advance (Sabi 2012).

In Figure 3, the electrode is the small wound part. This is implanted inside the cochlea. The titanium-covered box is the receiver and stimulator. The electronics are sealed inside this package. The coil and magnet is used to receive wireless power from the external unit (Sabi 2012).

There are three manufacturers of cochlear implants, namely Cochlear Corporation, Advanced Bionics Corporation and MeDel. The main elements of the design of cochlear implants across the manufacturers is very similar (Sabi 2012).



❶ Sounds are picked up by the microphone.

❷ The signal is then "coded" (turned into a special pattern of electrical pulses).

❸ These pulses are sent to the coil and are then transmitted across the skin to the implant.

❹ The implant sends a pattern of electrical pulses to the electrodes in the cochlea.

❺ The auditory nerve picks up these electrical pulses and sends them to the brain. The brain recognizes these signals as sound.

Figure 4: How the cochlear implant works (Eastern Virginia Medical School 2015). Here we see that sound signal bypasses the outer and middle ear as described in section 1.4: Physiology.

1.6 Cochlear Implants: A qualitative perspective

The aim of this section is to use qualitative analysis to frame the cochlear implant within its societal context.

Parents choosing cochlear implants for their children

One study investigated parental decisions processes when they decided to provide cochlear implants for their children. The results show that the parents who want their children to have cochlear implants can be categorised into two broad groups. The first type of parent is primarily motivated by a desire for “normal” communication. The second type of parent is motivated by their child’s lack of communication skill (Kluwin & Stewart 2000). Furthermore, 90% of parents with deaf children are not deaf themselves, so it is not surprising that upon discovering that their child is deaf, that parents see their child as different to themselves, and thus seek out any means possible to remove this difference (Crouch 1997).

However, there are some who see deafness not as a disability, and therefore not something that needs to be cured. Many in the Deaf community see the decision to forgo cochlear implantation not as hindrance or disability, but as a positive consequence to remaining and being part of the Deaf community, which has a rich tradition, language and community of its own. Often those who get cochlear implants will miss out on becoming part of this community, and as such some see cochlear implantation as a threat to the Deaf community (Crouch 1997).

Qualitative benefits of cochlear implantation

There are many advantages beyond having a better sense of hearing that the cochlear implant can offer. Cochlear implant receivers are less depressed, lonely and anxious after 18 months of implementation (Knutson et al. 1991). This shows that cochlear implants can have emotional impacts on a persons’ life.

Performance of cochlear implants

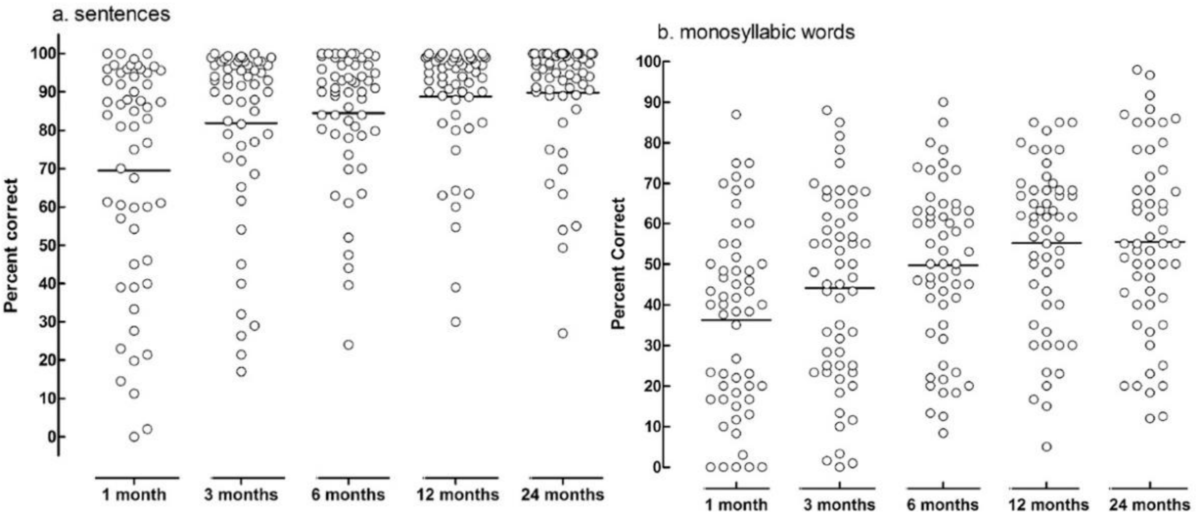


Figure 5: Performance scores for 55 cochlear implant users (Wilson & Dorman 2008)

Figure 5 shows how 55 cochlear implant users perform when recognising sentences and words after a specified period of implementation. There are remarkable scores for understanding sentences, but poor scores for individual syllables. This is because cochlear implant users often don't understand every word in a sentence but can work out what unknown words are based on context (Wilson & Dorman 2008). Notice that it can take many years for a cochlear implant user to become proficient at recognising sounds. It also takes much time and expense, as patients will typically have to get specialised audiology treatment for a number of years. Also observe that even though there are positive results for the majority of patients, there are still some left behind with sentence understanding scores less than 80%. Section 4.2 will introduce closed-loop control, which could allow the system to self-improve and increase the performance of the implant, hopefully assisting those with poor scores in Figure 5. Closed-loop control also has the potential to decrease the need for specialised audiology treatment. Section 3 will also introduce some ways the perception of sound can improved by changing the design of the electrode array.

2 Choosing the best material for internal packaging

2.1 Causes of failure in packaging

Hard and Soft Failures

In this section the causes of failure in cochlear implants will be examined by investigating the literature on this subject. Failure can be split into two broad categories, hard failure and soft failure. Hard failure is defined as complete failure of the cochlear implant. This is when there is no auditory input from the device and no connection can be made to the device externally. Soft failure is defined as a suspected device malfunction, or a clinical failure of the cochlear implant. The device itself may provide some auditory input, however, there may be other adverse symptoms, or the patient is not hearing as well as they should (Balkany et al. 2005; Cullen et al. 2008).

Revision surgery

Research conducted on 806 cochlear implants showed that 5.5% of cochlear implants were revised between 1992 and 2006. This also shows that 78% of the revision reasons were because of device failure and the most common source of failure was due to a cracked case or loss of hermetic seal (Brown et al. 2009). Zeitler et al. (2009) found that 3-8% of all cochlear implant procedures required revision surgery. The most common reason for this surgery was due to hard failure (40-80%), but other common reasons included soft failure, infection, improper electrode array placement and electrode extrusions.

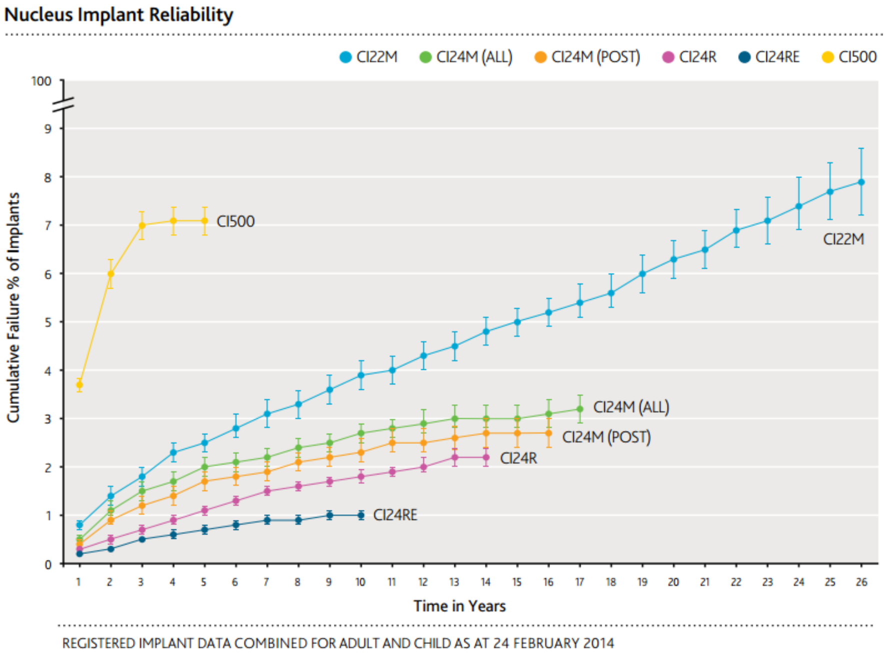
Package Breakage

Another study found that 50% of Clarion devices (a particular model of implant) had failures do to breakage of the hermetic seal. This study also found that the rate of device failure decreased with every new generation of cochlear implant. (Côté et al. 2007). This is encouraging because it shows the manufacturers are making an effort to improve the reliability of their products.

Therefore the above studies show that hard failures are the most important area of improvement for the cochlear implant, and as such this will be a main area to improve in this report. In particular, Côté et al (2007) found that the packaging of the implant is a common area for failure, so this area will be analysed further in properties of materials (section 2.4).

2.2 Reliability of various cochlear implants

A behaviour over time graph was utilised here to determine the reliability of the system over time.



REGISTERED IMPLANT DATA COMBINED FOR ADULT AND CHILD AS AT 24 FEBRUARY 2014

Figure 6: Reliability of Cochlear Branded Implants (Cochlear 2014).

Figure 6 shows the reliability of the various cochlear implants (manufactured by Cochlear). This shows the failure rate as a function of time of their various models (Cochlear 2014). Since this data was collected and published by Cochlear, it only shows their models and no other manufacturers. This data is biased in the sense that it does not include other manufacturers, but this is not particularly surprising since Cochlear is encouraging people to buy their product. The data shows that with the exception of one model, the newer models are more reliable.

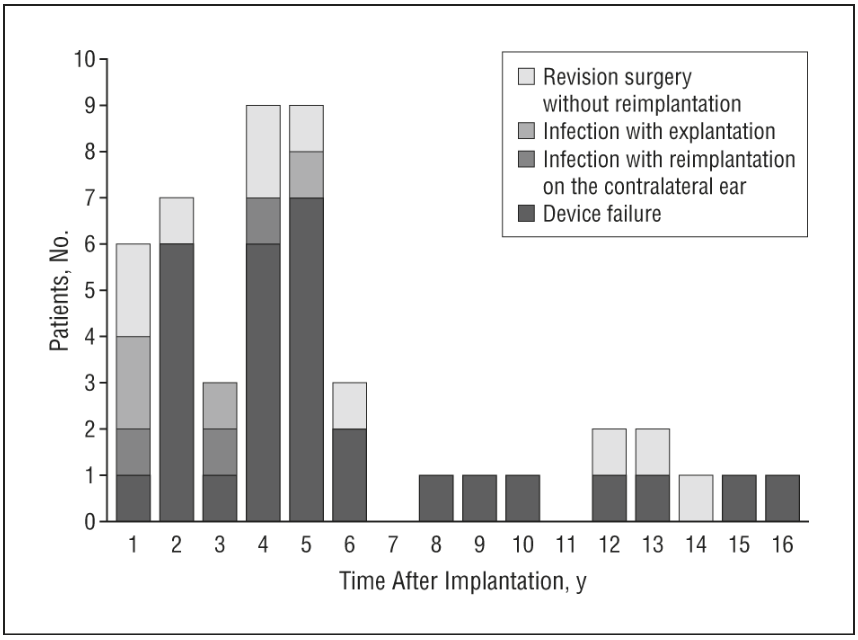


Figure 7: Failure of various cochlear implants from a retrospective study of 500 cochlear implantations (Venail et al. 2008).

The data in Figure 7 shows that most of the failures happen within the first 5 years. This is consistent with the ‘bathtub curve’, as the high failure rate in the first 5 years represents the wear-in period. In another study, Maurer et al. (2005) found that there also existed a higher failure rate in the first few years of implementation. Also, the data shows that most of the failures were due to device failure, which indicates that this is an area in need of improvement. Venail et al. (2008) found that electronic failure was the most common source of failure (43%) followed by failure of hermetic seal (13%), a defective electrode array (13%) and impact failure (10%). As will be explained later in section 2.4, we believe that the Liquid Crystal Polymer has the potential to improve the failure rates related to hermetic seals, and impact failures.

2.3 Human Requirements for Internally implanted devices

Energy exposure is also an important human factor in the CI system. The types of energy that are encountered in cochlear implant include heat, electrical, sound and light energy. There are limits on how hot the components can be for safe operation. External devices that have contact with the skin should not exceed 43°C and internal devices must have temperatures below 39°C according to IEC standards. This presents difficulties when designing cochlear implants for hot climates (Zeng et al. 2008). This limits the amount of energy that can be transferred to inside the body.

One issue with using large amounts of metallic materials in the body is that it inhibits the user from taking an MRI, due to the large magnetic field that is put through the body. This means cochlear implant users who need to have an MRI have to have surgery to remove their implant, which is very inconvenient (Kim 2012). Therefore it is advisable that research in the future should be focussing on ensuring that implants do not have large amounts of metal in them.

2.4 Properties of Materials

The materials used in cochlear implants are of huge importance because they interact directly to both the internal and external parts of the body. In terms of reliability, the external components are not as important as the internal components because these can be easily replaced with minimum complication and no surgery. On the other hand, the internal components are of much higher importance as if these components fail, surgery may be required. Since some of the internal components (such as silicon electronics) degrade inside the body, they have to be packaged in a suitable material. This is a very important issue, so the packaging of the implantable component of the cochlear implant is the focus of this section. The packaging is analysed using a modified materials audit (Table 1).

Materials audit

In this section, a modified materials audit will be conducted to determine the ideal material for the packaging (see Figure 3 for photo of implant). The material should have the following properties:

- Biocompatible: should not degrade within or be poisonous to body.
- Hermetic: water-tight so that the components inside the package are not damaged.
- Mechanical Properties: should be durable.
- Allows signal transmission: so that power can be transmitted from external coil to internal coil.

Table 1: Materials audit for internal packaging.

Material	**Biocompatible**	**Hermetic**	**Mechanical Properties**	**Allows signal transmission**
Titanium	Yes (Zeng 2008)	Yes (Stöver & Lenarz 2011; Zeng 2008)	Ductile (Stöver & Lenarz 2011)	No (Stöver & Lenarz 2011; Zeng 2008)
Ceramic	Yes (Zeng 2008)	Yes (Stöver & Lenarz 2011)	Brittle (Stöver & Lenarz 2011)	Yes (Stöver & Lenarz 2011)
Liquid Crystal Polymer (LCP)	Yes (Jeong 2015)	Yes (Hassler 2010 p.24; Jeong 2015)	Thermo-bonding and forming, high compressive and tensile strength (Jeong 2015)	Yes (Jeong 2015)
	Yes (Zeng 2008)	Yes (Zeng 2008)	Ductile (Zeng 2008)	Yes (Stöver & Lenarz 2011)
Silicone	Yes (Stöver & Lenarz 2011)	Yes (Stöver & Lenarz 2011)	Flexible (Stöver & Lenarz 2011)	Yes (Stöver & Lenarz 2011)

Titanium is current the material of choice for the cochlear implant package. However since it does not allow for signal transmission, the coil must be housed separately which results in a cumbersome design. Notice that Liquid Crystal Polymer (LCP) is the only material that satisfies all four chosen categories (Silicone is not suitable for housing the electronics because it is not rigid). In addition to the criteria described in the Table 1, LCP is safe to use for an MRI, whereas titanium is not (Kim 2012). The LCP is still in the research stage and as of yet has had limited clinical trials (Jeong 2015). Ceramic encasings have been used in the past, however these generally have a higher risk of cracking and for this reason, this material is not used very commonly in newer implantable medical devices. Silicone is used for the encasing of the coil on conventional cochlear implant models.

We therefore recommend further research into the LCP polymer because this has the potential to revolutionise cochlear implants by housing the coil and the electronics in the same encasing. This would make the implant smaller, which would increase the safety of surgery, and have cosmetic benefits. It could also allow for an increase in coil size, which would have improve the energy efficiency (see section 2.5 for more information). This could decrease the heat dissipation inside the body, which would have safety outcomes (see section 2.3 for more information). LCP also has promising mechanical properties, which could reduce some of the cracking problems explained in section 2.1 and 2.2.

2.5 Energy use in cochlear implants

Energy efficiency is a very important aspect of the cochlear implant. According to Advanced Bionics (2015), a single AAA battery delivers up to 60 hours battery life. Let us determine which components of the cochlear require power. There are several components in the cochlear implant that require power, which are shown in the Sankey diagram.

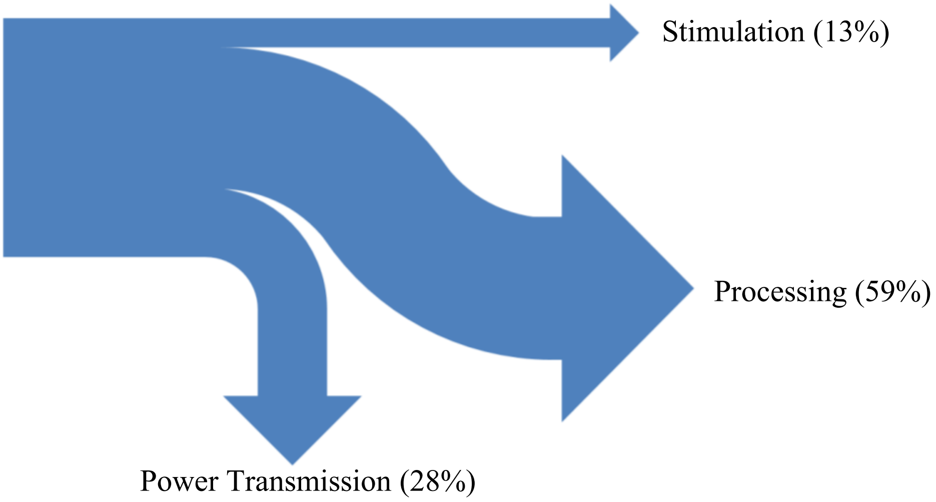


Figure 8: Sankey diagram of energy use in typical cochlear implant (total 40 mW) (Sabi 2012).

The Sankey diagram (Figure 8) shows processing uses the most power. Even though processing uses the most power, improvement is limited by integrated circuit design and computing algorithms which deemed are out of the scope of this topic. Therefore, the area with the most potential for improvement is the coil. There are several ways that this could be improved; however they have limitations. For example, placing the coils closer together would improve the efficiency, however, the layer of skin that is between the coils fundamentally limits this. Improving the design of the coils would also help; this is an ongoing research area. Increasing the size of the coil is a simple way to improve efficiency. As explained in section 2.4, changing the material to a LCP could allow for a more compact design and therefore allow a larger coil. Improving the energy efficiency of the coil has important benefits in terms of human factors. This would reduce the amount of heat dissipated in this body and ensure that the surface temperature of the internal components is less than 39°C, as explained in section 2.3.

2.6 Recommendations

Based on the above analysis, we recommend further research into the Liquid Crystal Polymer, and other alternative materials. The main advantage of the LCP is it allows transmission of power into the implant. This would allow for the entire internal portion of the cochlear implant to be housed in one casing. It also has the potential to increase the efficiency of the coil and therefore reduce the amount of heat loss inside the body. Non-metallic materials, such as the LCP will allow cochlear implant users to undergo an MRI.

3 Choosing an ideal electrode array shape

3.1 Anthropometrics of human cochlea

The cochlea is the auditory part of the inner ear. It converts sound energy into electrical impulses which are interpreted by the brain. See section 1.4 for information on this topic.

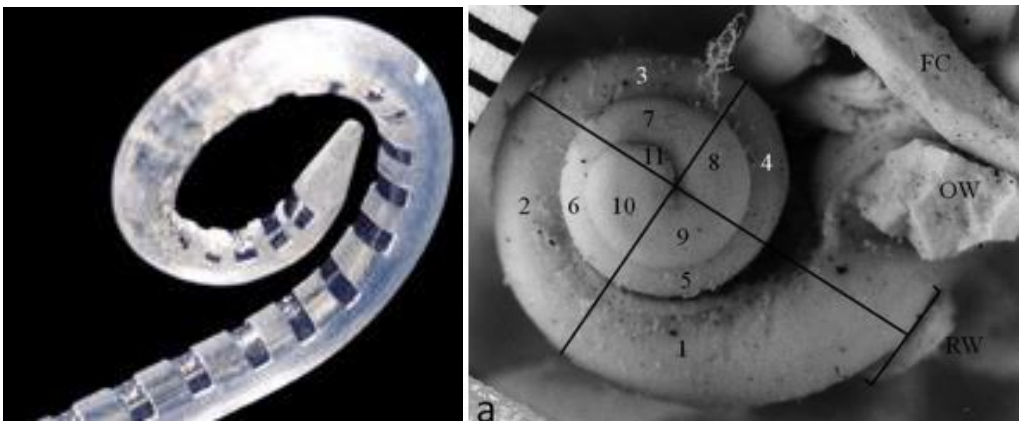


Figure 9: Left: Implantable electrode array (Warren Centre for Advanced Engineering 2010). Right: Cast of human cochlea (Rask-Andersen et. al. 2012).

Table 2: Lengths of different parts of the cochlea (Rask-Andersen et. al. 2012).

Outer wall length (mm)	Mean	Range	SD	n
Half diameter of the Round Window	1.1	0.3-1.6	0.21	65
First half first turn	13.5	12.1-15.0	0.73	67
First turn (quadrant 1-4)	22.6	20.3-24.3	0.83	65
Second turn (quadrant 5-8)	12.4	10.7-13.3	0.63	63
Third turn (quadrant 9-11 (12))	6.1	1.5-8.2	1.40	58
Total length	42.0	38.6-45.6	1.96	58

Table 2 (above) shows that the mean total length of the cochlea is very small (42mm) (Rask-Andersen et. al. 2012). The range of lengths is also reasonably consistent, considering that 95% of cochleae have lengths between 38mm and 46mm. The half-diameter of the round window was determined to be between 0.7 and 1.5mm for 95% of the population. This measurement is important because the round window is the hole in which the electrode array must fit to be surgically placed in the cochlear. Therefore we recommend that manufacturers take careful notice of the range of cochlear sizes when designing electrode arrays, so that they can fit all of the population, and that medical professionals determine the size of the cochlea of the patient before the surgery.

3.2 Limitations of electrode arrays

It would be sensible to think that increasing the number of sites on the electrode would increase hearing perception. This is because, theoretically, increasing the number of sites increases the resolution, so the user should be able to hear finer frequencies of sounds. However, this turns out not to be the case.

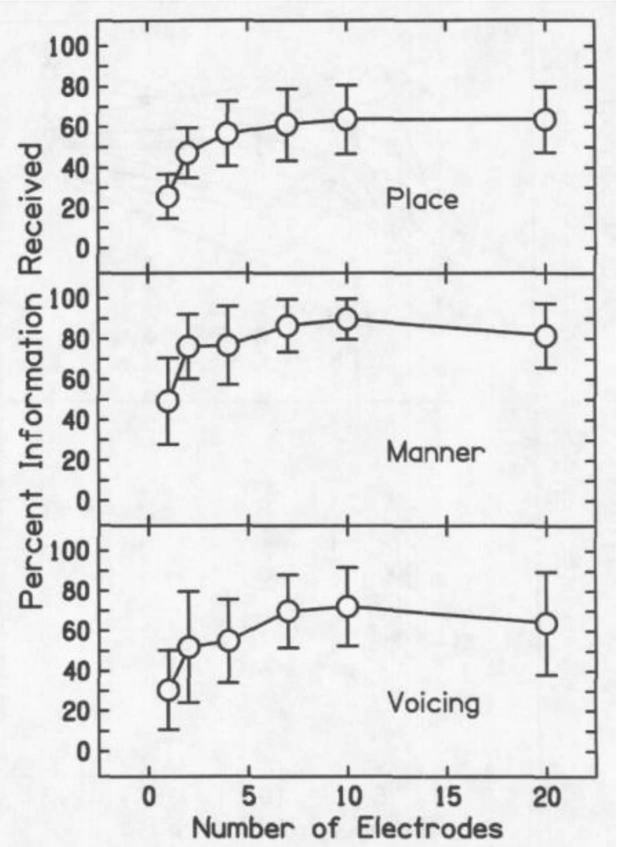


Figure 10: Performance of electrode array as a function of electrodes used (Fishman et al. 1997)

Figure 10 shows once 7 electrodes is reached, performance of the implant does not increase further (Fishman et al. 1997). Wilson & Dorman (2008) suggest that one reason for this phenomenon is that the spatial specificity of stimulation means that there are no more 4-8 independent sites available for stimulation. This could be partially due to the electrodes having quite a large stimulation area and so nearby electrodes actually stimulate the same area. So we see that increasing the number of electrodes without other measures is not the answer.

A human factor that limits how many electrodes can be used on an electrode array is the safe charge density. First of all, stimulation of the cochlea requires exposure to a sufficient amount of charge and the standard parameter used to measure the delivery of electrical energy is charge density. Electrical contacts (electrodes) vary in area from 0.12mm^2 to 1.5mm^2. The typical safe charge density is less than 15 to 65µC/cm^2 (Zeng et al. 2008). This presents many challenges because this limits how small electrodes can be made. This in turn limits how many electrodes can fit inside the cochlea, which limits the quality of sound that can be perceived.

So therefore, we have two limiting factors. Due to the limited spatial specificity of stimulation, increasing the number of electrodes does not increase the performance and the number of electrodes is limited also by the maximum allowable charge density.

3.3 Analysis of pre-curved and straight electrodes arrays

There are two main types of electrode arrays, being pre-curved and straight. Straight electrodes are curved inside the cochlear, while pre-curved electrodes are curved during manufacturing (Zeng 2008).

However, Poley et al. (2015) found that there was a statistically significant difference in the power consumption of straight electrodes and curved electrodes. This is because the distance between the electrode and the nerve is minimised. This implies that curved electrodes require less current to stimulate the nerve. A follow on from this is that the area of stimulation is smaller, so this means that that are more independent sites available for stimulation. This means the pre-curved electrode array has the potential to fix the problems described in Figure 10 as an increased number of electrodes may increase the perception of sound in the pre-curved electrode.

Another advantage is the reduced power consumption, which as explained in section 2.5 will reduce the amount of heat dissipated inside the body, which will have safety benefits and allow for expansions in the number of electrodes in the array.

Also, Tykocinski, M et al. (2001) found that there was an equivalent probability of trauma between curved and straight electrodes. Therefore, at least according to this study, there is no difference between the safety of curved and straight electrodes. One drawback of this study was the small sample size of 15 participants and the fact that only 2 different models of electrode were used. Similar results were also observed by Briggs, R et al. (2001) who found that implantation can be achieved without damage provided the electrode array is of appropriate size and shape. This highlights the importance of ensuring that the electrodes are of the right shape, in terms of the anthropometrics explained in section 3.1

3.4 Recommendations

It is suggested that the curved electrode array has more potential than straight electrodes because of it requires less power and current. This means that there is less charge and heat dissipation inside the body. The higher spatial specificity has the potential to allow for further increases in the number of electrodes in the array and thus provide a better perception of sound and allow for a better perception of music.

4 Possibilities of a closed loop control system

4.1 Introduction to a closed loop system

Cochlear Implant: An open loop system

An open loop system has an input and an output with no feedback. The cochlear implant is largely an open loop system since it requires much initial fitting, tuning and ongoing consultation to have a high level of performance. In this way a trained audiologist conducts the settings and calibrations of the cochlear implant, which is an expensive and time consuming procedure. Even with expert calibration, the performance of the cochlear implant is not optimum (Lu et al. 2012). The traditional way an audiologist conducts calibration is that they may conduct a series of behavioural tests to gain quantitative data about the performance of the implant. The audiologist may also ask the patient about their implant to gain qualitative data. They also may use various other brain recording instruments such EEG. Based on the above information, the audiologist changes the parameters associated with the cochlear implant (McLaughlin et al. 2012).

Closed loop system: Possibilities

In a closed loop system the output (or another relevant parameter) is measured and the input changes according to this information. Closed loop cochlear implants is a research area. A couple of recent medical and engineering advances are making a closed loop cochlear implant a possibility. Firstly, the recording of evoked potentials from the nervous system. This potentially allows for recording from the auditory cortex (the portion of the brain that processes audio), brainstem and authority nerve (nerve that connects brain to ear). An evoked potential is electrical potential (voltage) recorded from the nervous system, following a stimulus. Measuring these evoked potentials provide us information about the performance of the implant. Also, further development of hardware and signal processing strategies allows for more efficient and accurate interpretation of the information contained in the evoked potentials (McLaughlin et al. 2012).

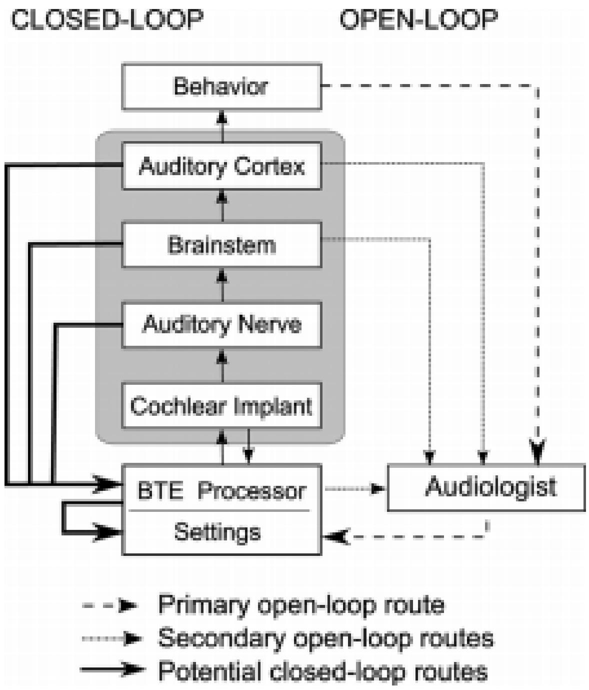


Figure 11: Potential areas for closed loop control (McLaughlin et al. 2012).

In Figure 11, several of the steps that are conducted to optimize the implant are shown. A computer inside the cochlear implant could replace the audiologist in some of the areas shown in the Figure 11. One possible implementation is described in the feedback loop below:

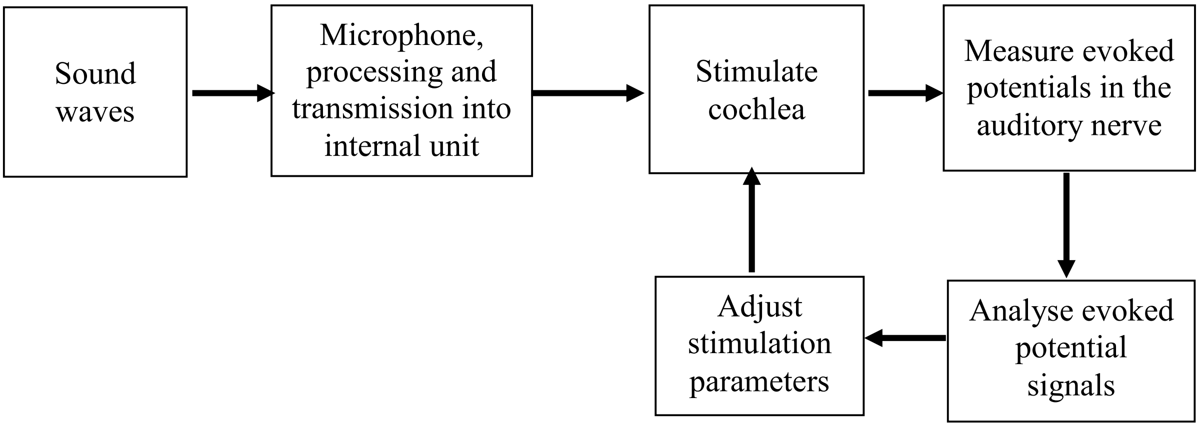


Figure 12: A possible control system for a closed-loop cochlear implant

Other possibilities where closed loop could be implemented are in the dynamic use of the implant throughout the day. For example, the settings of the cochlear implant could be automatically changed in a noisy environment. Implementing closed-loop control has financial benefits, which are explained in section 4.2.

However, the main disadvantage of the closed-loop system is that more power will be required to process the signals received from the auditory nerve.

4.2 Cost-benefit analysis of the closed loop system

In this section, the cost-benefits of implementing a closed loop system will be analysed. The main benefit of such a system is that there will be less need for specialised audiology post-operative treatment.

Firstly, the cost of audiology rehabilitation needs to be determined. This was done using quantitative methods. Table 3 shows that four studies were used to determine the cost of audiology rehabilitation in the first year of the implant. These figures were taken from cost-benefit journal articles from the United States and Great Britain. The data shows that there is variation in the cost of this treatment. This is mostly likely due to differences in medical costs in the two countries.

Table 3: Cost of audiology rehabilitation.

	Cost of audiology rehabilitation		
Study	**USD/GBP**	**2015 USD/GBP**	**2015 AUD**
Wyatt et al. 1996	7,157 USD 1996	10,870 USD	15,400
Cheng 2000	5148 USD 1999	7,364 USD	10,400
Summerfield et al. 2002	2793 GBP 1999	4,448 GBP	9,600
O’Neill 2009	4000 GBP 2009	4,767 GBP	10,300
		Average	11,400
		Standard Dev	2,700

In Table 3, The currency conversions calculated using XE (2015). The inflation conversions were calculated using data from The World Bank (2015). It is acknowledged that the inflation rate is not exactly indicative of increases in medical expenses, and exchange rates are subject to unpredictable change. For this reason we have included the standard deviation between the Australian prices as an error bound.

Cochlear Corporation sells around 25,000 implants a year (Cochlear 2015b) and it was estimated that closed loop control will greatly reduce the time it takes the audiologist to fit the implant (Lu et al. 2011) and as such reduce the audiology costs by between 25% to 75%. Using the above information and Table 3, figure 13 was obtained. The errors were propagated using standard techniques to give a 95% confidence interval shown as dotted lines.

Figure 13: Projected savings resulting from a commercial implementation of closed loop control

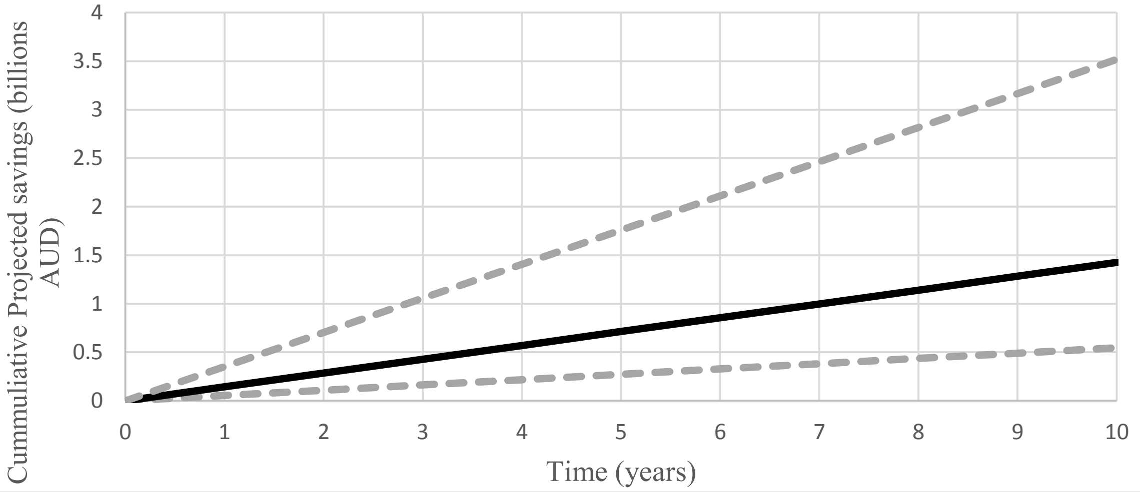


Figure 13 shows the projected savings resulting from a product wide implementation of closed-loop control by the largest manufacturer. The dashed lines represent a 95% confidence interval. The graph shows that even if a conservative estimate is made about the recommendation's success, then it has potential to save substantial funds from the health system. The dark line represents the average savings, of 142 million AUD per year. This is equivalent to 78% of Cochlear Corporation's annual research and development budget. After 10 years of implementation, this proposal is expected to pay for 8 years of research of development (Cochlear 2015b). Therefore it is clear that closed-loop control is an economic area to research, and we recommend it be pursued by manufacturers.

4.3 Recommendations

Based on analysis from control and cost factors, we recommend that manufacturers pursue this closed-loop control for further research, as this has been potential economic benefits for the health system in the future.

5 Conclusion

In conclusion, we believe that these three recommendations will allow for the next generation of cochlear implants. The current internal packaging design has remained unchanged in the past 20 years. The LCP will allow for a unibody, structurally integral package that allows for greater energy efficiency, safety and a more compact design. Pre-curved electrodes arrays have the potential to improve the energy efficiency, allow for expansions in the number of electrodes in electrode arrays and thus a truer perception of sound. Finally, we believe that closed-loop control has the potential to allow the cochlear implant to self-adjust to increase performance and significantly reduce medical expenses and stress on the health system. Therefore we recommend that these areas are given considerable attention by cochlear implant manufacturers and researchers so that we can ensure that cochlear implants continue to be the most successful device in neural prosthetics for many years to come.

Reference List

Advanced Bionics 2015, *Accessories - Power Advanced Bionics*. Available from: <http://www.advancedbionics.com/com/en/products/accessories/power.html>. [11 August 2015].

An, SK et al. 2007 'Design for a Simplified Cochlear Implant System', *IEEE Transactions on Biomedical Engineering,* vol. 54, no. 6, pp. 973-882.

Balkany, T et al. 2005, 'Cochlear implant soft failures Consensus Development Conference Statement', *Cochlear Implants International,* vol. 6, no. 3, pp. 105-122.

Bond, M et al. 2009, 'The effectiveness and costeffectiveness of cochlear implants for severe to profound deafness in children and adults: a systematic review and economic model', *Heath Technology Assessment,* vol. 13, no. 44, pp. 1-330.

Briggs, R et al. 2001, 'Surgical implications of perimodiolar cochlear implant electrode design: avoiding intracochlear damage and scala vestibuli insertion', *Cochlear Implants International,* vol. 2, no. 2, pp. 135-149.

Brown, K et al. 2009, 'Incidence and indications for revision cochlear implant surgery in children', *The Laryngoscope,* vol. 119, no. 1, pp. 152-157.

Cheng, AK et al. 2000, 'Cost-Utility Analysis of the Cochlear Implant in Children', *Journal of the American Medical Association,* vol. 284, no. 7, pp. 850-856.

Cochlear 2014, 'Cochlear Nucleus Reliability Report', Cochlear Limited.

Cochlear 2015a, *Cochlear Hearing Implants _ Cochlear International*. Available: <http://www.cochlear.com/wps/wcm/connect/intl/home>. [18 August 2015].

Cochlear 2015b, 'Cochlear Annual Report 2014', Cochlear Limited.

Côté, M et al. 2007, 'Cochlear reimplantation: causes of failure, outcomes, and audiologic performance', *The Laryngoscope,* vol. 117, no. 7, pp. 1225-1235.

Crouch, R 1997, 'Letting the deaf be deaf. Reconsidering the use of cochlear implants in prelingually deaf children', *The Hastings Centre Report,* vol. 27, no. 4, pp. 14-21.

Cullen, R et al. 'Revision Cochlear Implant Surgery in Children', *Otology & Neurotology,* vol. 29, pp. 214-220.

Eastern Virginia Medical School 2015, *Cochlear Implant - Eastern Virginia Medical School (EVMS), Norfolk, Hampton Roads*. Available: <http://www.evms.edu/patient_care/services/ent/patient_education/hearing_and_balance/cochlear_implant/>. [1 October 2015].

Encyclopaedia Britannica 1997, *Basilar membrane*. Available: <http://www.britannica.com/science/basilar-membrane>. [10 October 2015].

Gosepath, J et al. 2009, ‘Analysis of fifty-six cochlear implant device failures’, *ORL J Otorhinolaryngol Related Specialities,* vol. 71, no. 3 pp. 142-147.

Hassler, C 2010, ‘Polymers for Neural Implants’, *Journal of Polymer Science: Part B: Polymer Physics,* vol. 49, pp. 18-33.

Jeong, J 2014, ‘A Miniaturized, Eye-Conformable, and Long-Term Reliable Retinal Prosthesis Using Monolithic Fabrication of Liquid Crystal Polymer (LCP)’, *IEEE Transactions on Biomedical Engineering,* vol. 62, no. 3, pp. 982-989.

Kim, J 2012, ‘Magnetic Resonance Imaging Compatibility of the Polymer-based Cochlear Implant’, *Clinical & Experimental Otorhinolaryngology,* vol. 5. Suppl. 1.

Kluwin, T & Steward, D 2000, ‘Cochlear Implants for Younger Children: A Preliminary Description of the Parental Decision Process and Outcomes’, *American Annals of the Deaf,* vol. 145, no. 1, pp. 26-32.

Knutson, J et al. 1991 ‘Psychological change following 18 months of cochlear implant use’ *Annals of Otology, Rhinology & Laryngology*, vol. 100, no. 11 pp. 877-882.

Lu, T McLaughlin, M & Zeng, F 2012, *A Closed Loop Cochlear Implant System Which Monitors Auditory Evoked Potentials From The Peripheral And Central Auditory Pathway And Uses,* US Patent 20150018699.

Marieb, E 2008, *Essentials of Human Anatomy & Physiology Laboratory Manual,* Benjamin-Cummings Publishing Company, San Francisco.

Maurer, J & Marangos, N & Ziegler, E 2015, ‘Reliability of cochlear implants’, *Otorhinolaryngology-Head and Neck Surgery,* vol. 132, no. 5, pp. 746-750.

Mohr, P et al. 2000, ‘The societal costs of severe to profound hearing loss in the United States’. *International Journal of Technology Assessment in Health Care,* vol. 16, no. 4, pp. 1120-1135.
Oishi, N & Schacht, J 2011, ‘Emerging treatments for noise-induced hearing loss’, *Expert Opinion on Emerging Drugs,* vol. 16, no. 2, pp. 235-245.

National Institute on Deafness and other Communication Disorders (NIDCD) 2014, *Cochlear Implants*. Available from: <https://www.nidcd.nih.gov/health/hearing/pages/coch.aspx>. [11 August 2015].

O’Neill, C 2009, ‘A Cost-Utility Analysis of Pediatric Cochlear Implantation’, *The Laryngoscope,* vol. 110, no. 1, pp.156-160.

Poley, M et al. 2015, ‘Does pediatric cochlear implant insertion technique affect intraoperative neural response telemetry thresholds?’, *International Journal of Pediatric Otorhinolaryngology,* vol. 79, no. 9, pp. 1404-1407.

Rask-Andersen, H et al. 2012, ‘Human Cochlea: Anatomical Characteristics and their Relevance for Cochlear Implantation’, *The Anatomical Record,* vol. 295, no. 11, pp. 1791-1811.

Sabi, R 2012, *Cochlear Implant Modelling: Stimulation and Power Consumption*, Ph.D. thesis, University of Southampton.

Schow, B et al. 2012, ‘Electrode failure and device failure in adult cochlear implantation’, *Cochlear Implants International,* vol. 13, no. 1, pp. 35-40.

Stöver, T & Lenarz, T ‘Biomaterials in Cochlear Implants’, *GMS Current Topics in Otorhinolaryngology - Head and Neck Surgery,* vol. 8, doc. 10.

Summerfield et al. 2002, ‘A Cost-utility Scenario Analysis of Bilateral Cochlear Implantation’, *Archives of Otolaryngology - Head and Neck Surgery, vol. 128, no. 11, pp.1255-1262.*

Tykocinski, M et al. 2001, ‘The Contour Electrode Array: Safety Study and Initial Patient Trials of a New Perimodiolar Design’, *Otology & Neurotology,* vol. 22, no. 1, pp.33-41.

Venail, F et al. 2008, ‘Reliability and Complications of 500 Consecutive Cochlear Implantations’, *Archives of otolaryngology--head & neck surgery*, vol. 134, no. 12, pp. 1276-1281.

Warren Centre for Advanced Engineering 2010, *Engineering Icons*. Available: <http://www.engineeringicons.org.au/engineering-icons/australian/cochlear-implants/challenges.html>. [16 August 2015].

The World Bank 2015, *Inflation, consumer prices (annual %) _ Data _ Table*. Available: <http://data.worldbank.org/indicator/FP.CPI.TOTL.ZG>. [3 October 2015].

Wilson, B & Dorman, M 2008, ‘Cochlear Implants: A Remarkable Past and a Brilliant Future’, *Hearing research*, vol. 242, pp. 3-21.

Wyatt, J 1996, ‘Cost Utility of the Multichannel Cochlear Implant in 258 Profoundly Deaf Individuals’, *The Laryngoscope,* vol. 106, no. 7, pp. 816-821.

XE 2015, *XE - The World's Trusted Currency Authority*. Available: <http://www.xe.com/>. [3 October 2015].

Zeitler, D et al. 2009, ‘Revision cochlear implantation’, *Current Opinion in Otolaryngology & Head and Neck Surgery,* vol. 17, no. 5, pp.334-338.

Zeng, FG et al. 2008, ‘Cochlear Implants: System Design, Integration and Evaluation.’ *IEEE reviews in biomedical engineering,* vol. 1, pp. 115-142.