A retrospective analysis of cochlear implant electrode deactivation in paediatric patients

A study submitted in partial fulfilment of the requirements for the degree of Master of Science of the University of Hertfordshire

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List of Abbreviations

AB	Advanced Bionics
BCS	Bawtry Computer Services
CBCT	Cone Beam Computed Tomography
CI	Cochlear implant
CIN	Client Identification Number
CT	Computed Tomography
ECDA	Ethics Committee with Delegated Authority
ED	Electrode deactivation
ENT	Ear, Nose and Throat
ERGO	Ethics and Research Governance Office
FBR	Foreign Body Response
FDA	United States Food and Drug Administration
IT	Initial tuning
MAP	Term used to denote a programme in a cochlear implant sound processor
NAS	Non-auditory Stimulation
NHS	National Health Service
RCCP	Registration Council for Clinical Physiologists
REC	Research Ethics Committees
REVS	Recording of Electrode Voltages on the Skin
SDA	Secondary Data Analysis
SSAH	Social Sciences, Arts and Humanities
UK	United Kingdom
UoS	University of Southampton
USAIS	University of Southampton Auditory Implant Service
WMA	World Medical Association

ABSTRACT

Cochlear implants are neuroprosthetic devices designed to produce a sensation of sound in people too deaf to benefit from acoustic hearing aids, middle ear implants or bone conduction devices. The internal part of the system consists of a receiver-stimulator package and an electrode array. Electrode arrays contain between 12 and 22 electrode contacts (depending on the manufacturer). Sometimes one or more of these electrodes needs to be deactivated for one of a range of reasons. For people with cochlear implants, the electrodes are where coded sound from the outside world is transmitted to the auditory nerve so it is important to understand when, where and why electrodes in the array are deactivated. Research into electrode deactivation is retrospective in nature meaning published research often relates to generations of implants that have since been superseded by newer models. It would be hoped that each new generation of implant/array is an improvement on the previous version, particularly with regards to reliability. However, there is currently a lack of published research into the performance of the newer arrays being implanted at auditory implant services in the UK. The present study aimed to address this gap. A retrospective secondary data analysis was carried out into the temporal (when), spatial (where) and causal (why) characteristics of electrode deactivation in 235 cochlear implant arrays, implanted in paediatric patients under the care of the University of Southampton Auditory Implant Service. Four models of array were investigated – 151 Cochlear Nucleus CI512 Contour Advance arrays, 6 Cochlear Nucleus CI522 Slim Straight arrays, 50 Advanced Bionics HiFocus Mid-Scala arrays and 28 MED-EL FLEX28 arrays. Electrode deactivation characteristics were determined and comparisons made between manufacturers and between pre-curved and straight array types.

Overall, incidence of electrode deactivation was lower in the present study than in previous studies, though the incidence of open and short circuits was similar to previous reports suggesting there is still room for improvement in this area. The majority of arrays in the present study had no electrode deactivations. Where there were deactivations it usually affected only one electrode, with each

additional electrode deactivation occurring more and more infrequently. When electrode deactivation occurred it typically happened within the first two years of implant use, and within the first year in many cases. On average, electrode deactivation appeared to occur earlier in pre-curved arrays than in straight arrays. The timing of electrode deactivations was influenced by the reason for the deactivation, with deactivations for reasons requiring subjective feedback from the patient generally occurring later than deactivations for reasons that could be identified objectively. For all manufacturers and array types, the majority of electrode deactivations occurred in the basal region of the array closest to the round window. Open circuits were the most common reason for electrode deactivation. Together with short circuits they accounted for over a third of deactivations. Absent or abnormal nerve response or absent auditory percept accounted for nearly another third; with NAS, sound quality complaint, extracochlear electrodes and tip fold-over together making up the remainder. Overall, there was a strong association between the reason for electrode deactivation and the location of the deactivation in the array.

The findings of this study have helped address a gap in knowledge regarding the incidence and characteristics of electrode deactivation in the newer generation of arrays, demonstrating the value of analysing routinely collected data.

1. INTRODUCTION

This chapter introduces some key concepts concerning cochlear implant design which will assist the reader in understanding the present study.

1.1 Cochlear implants

Cochlear implants are neuroprosthetic devices consisting of a surgically implanted receiver-stimulator package and electrode array, which when used with an external sound processor can produce a sensation of sound in the recipient. During surgery, the receiver-stimulator package is placed under the skin behind the ear and the array of electrode contacts is inserted into the scala tympani of the cochlea in the inner ear. (For readers unfamiliar with cochlear implants, detailed information on how the system produces the sensation of sound can be found in Appendix 1.) Implant manufacturers typically offer one primary receiver-stimulator package with a range of arrays.

1.2 Types of electrode array

There are three main types of electrode array in common use: lateral wall, perimodiolar and mid-scala.

- Lateral wall, or straight, arrays are linear in shape and are designed to lie next to the outer (lateral) wall of the cochlea. The design is intended to be atraumatic to the cochlea (Gibson & Boyd, 2016).
- The tips of perimodiolar arrays are pre-curved and designed to hug the modiolus of the cochlea, bringing the electrode contacts closer to the spiral ganglion cells they stimulate (Gibson & Boyd, 2016).
- Mid-scala arrays are also pre-curved but are designed to sit in the middle of the scala tympani to limit damage to the lateral and medial walls of the cochlea during insertion and from static pressure post-implantation (Boyle, 2016). Mid-scala arrays are generally considered a type of perimodiolar array (Dhanasingh & Jolly, 2017).

Due to their slightly different positions within the cochlea, straight (lateral) arrays are thought to stimulate auditory nerve fibres in the Organ of Corti while pre-

curved (perimodiolar and mid-scala) arrays are believed to stimulate spiral ganglion cells in the modiolus (Dhanasingh & Jolly, 2017).

1.3 Electrode contacts

Electrode arrays typically contain either planar (flat) or half-band (C-shaped) electrode contacts. The number of electrode contacts in each manufacturer's arrays differs. Advanced Bionics arrays contain 16 electrodes, Cochlear arrays contain 22 electrodes and MED-EL arrays contain 12. The proprietary programming software from each manufacturer is designed specifically for its range of arrays and enables equally good speech and listening outcomes to be achieved by all three manufacturers' devices.

Sometimes one or more electrode contacts in an array requires deactivating for some reason. It is usually possible to program around deactivated electrodes so that the patient continues to receive the full range of frequencies, though the remaining active electrodes will need to cover an increased bandwidth of frequencies to achieve this.

1.4 Active length of the array

The section of the array containing the stimulating electrodes is termed the active length and is shorter than the total array length (measured from the tip to a stopper marker at the round window). The distance between the most basal stimulating electrode and the stopper is known as the buffer length. The buffer length ensures that the stimulating electrodes are fully inside the cochlea, helping to avoid poor stimulation of neurons near the round window and assisting with high frequency neuro-tonotopicity. The buffer length varies between manufacturers so the match between the stimulus frequency and tonotopic place pitch also varies. In particular, the length of the array determines the neuro-tonotopic matching at low frequencies in the apical region of the cochlea (Dhanasingh & Jolly, 2017). It is important to remember that a cochlear implant does not generate sound, it produces electrical stimulation. While the stimulation sent to each electrode relates to a specific bandwidth of frequencies, it is the tonotopic organization of the cochlea (in association with

the brain) that determines the pitch perception elicited by the stimulation. For this reason, stimulation relating to low frequency sound input is sent to apical electrodes and stimulation relating to high frequency sound input is sent to basal electrodes.

1.5 Present study

The present study investigated electrode deactivation (ED) in the current generation of arrays from Advanced Bionics, Cochlear and MED-EL being implanted at USAIS. It considered:

- The temporal (time to ED), spatial (location of ED in the array) and causal (reason for ED) characteristics of electrode deactivations in the arrays;
- How arrays from the different manufacturers compared;
- How different types of array compared (i.e. straight versus pre-curved).

1.6 Outline of chapters

Chapter 2 examines the reasons why electrodes may be deactivated, reviews the existing published literature around electrode deactivation, and sets out the rationale for the present study.

Chapter 3 describes the methodology for the present study. It describes the chosen method, the specific arrays included in the study, the patient selection criteria and the approach taken to the collection, analysis and interpretation of data. It also reflects on ethical considerations and on study reliability and validity.

Chapter 4 details the results, starting with general findings before moving on to analyse the temporal, spatial and causal characteristics of electrode deactivation in depth.

Chapter 5 discusses the key findings of the data analysis, setting them within the context of previous and ongoing research. The chapter also reflects on the limitations of the study, and considers the implications of the study findings for further research and for clinical practice.

2. LITERATURE REVIEW

This chapter examines the reasons why electrodes may be deactivated, reviews the existing published literature around electrode deactivation, and sets out the rationale for the present study.

2.1 Electrode deactivation (ED)

Electrode deactivation (ED) in cochlear implants is relatively common (Carlson et al., 2010; Schow et al., 2012). One or more electrode contacts in an array may be deactivated for a variety of reasons including:

- Electrode short circuits
- Electrode open circuits
- Non-auditory stimulation
- Absent or abnormal neural responses or absent sound percept
- Sound quality complaint
- Extracochlear electrodes
- Array tip fold-over

(Schow et al., 2012; Dietz et al., 2016; Dhanasingh & Jolly, 2019)

2.1.1 Electrode short and open circuits

Short and open circuits are generally considered electrode failures and are identified through electrode impedance telemetry measurements. Electrode impedance is the resistance to charge transfer between an electrode and the cochlear fluid surrounding it. Normal electrode impedance values vary between manufacturers and implants. Table 1 shows the normal impedance values for each manufacturer for the arrays that were analysed in the present study. Impedance is normally low at the time of surgery, rises between surgery and initial tuning due to tissue growth and protein adsorption around the array, and reduces again once electrical stimulation of the implant commences (Newbold et al. 2015). Electrode impedance is measured by the manufacturer's tuning

software which automatically detects and alerts the audiologist when an impedance level falls outside of the manufacturer's acceptable range.

Table 1: Normal electrode impedance values for the arrays analysed in the present study (after Wolfe & Schafer, 2015)

	Normal range
Advanced Bionics	1 kΩ - 30 kΩ
Cochlear	565 Ω - 30 kΩ
MED-EL	5 kΩ - 15 kΩ

An electrode with a short circuit exhibits very low impedance below the normal range, while an electrode with an open circuit exhibits very high impedance above the normal range. A short circuit occurs when electrode leads or contacts become unintentionally coupled, resulting in low electrical resistance and an identical voltage in all affected electrodes when only one is stimulated. This is usually due to physical contact between leads/contacts, excessive array distortion or an electrical fault. Open circuits can be due to broken leads or faulty contacts but may also occur with cochlear ossification or from protein or air bubble build-up on the electrode contact (Wolfe & Schafer, 2015). Abnormal impedance levels can cause a range of issues including poor sound quality, poor speech perception, non-auditory stimulation or inadequate loudness growth (Zeitler et al., 2008; Wolfe & Schafer, 2015).

2.1.2 Absent or abnormal nerve response or auditory percept

Sometimes a group of spiral ganglion neurons or auditory nerve fibres may not be able to respond to the electrical stimulus received from an electrode and/or may respond in an abnormal manner. When this happens:

- nerve response telemetry measurements may elicit no response from the auditory nerve or only at a level that causes discomfort to the patient,
- impedance telemetry may record electrical impedance that is abnormally high compared to that of neighbouring electrodes, or
- a patient may have no sound perception when the electrode is stimulated.

2.1.3 Non-auditory stimulation (NAS) and Sound Quality Complaint

Non-auditory stimulation occurs when current passing from the electrode to the auditory neurons spreads to non-auditory neurons. The most common form of non-auditory stimulation affects the facial nerve and ranges from patient awareness of the unwanted stimulus to visible nerve twitching and/or pain (Berrettini et al., 2011). Sound quality complaint, meanwhile, occurs when a patient perceives the sound from an electrode to be uncomfortable or to be causing distortion of the overall sound.

2.1.4 Extracochlear electrodes

Extracochlear electrodes can result from cochlear malformations or surgical insertion difficulties meaning one or more electrodes in the array remains outside the cochlea. Extracochlear electrodes always need deactivating as the electrical stimulus will not reach the correct part of the auditory nerve and the current may cause non-auditory stimulation or other issues. Extracochlear electrodes are typically noted at the time of surgery or on post-operative X-ray. However, electrodes can also extrude from the cochlea at a later date if an array migrates (Dietz et al., 2016). Possible causes of electrode extrusion are spring forces from the electrode lead or increased pressure in the scala tympani (Radar et al., 2016), and trauma, infection, skull growth, lack of lead coiling in the mastoid, and mastoid adhesion (Vaid et al., 2011).

2.1.5 Array tip fold-over

Array tip fold-over can occur during implant surgery. Occasionally during insertion the tip of an array becomes caught on an intra-cochlear structure such as the modiolus wall and folds back on itself, usually without the surgeon’s knowledge (Dhanasingh & Jolly, 2019). This results in a shallower array insertion than planned, and potentially electrode interactions, vertigo, facial twitching, tinnitus or pitch confusion when the implant is activated (Gabrielpillai et al., 2018; Sabban et al., 2018).

2.1.6 Identifying problems that require the deactivation of electrodes

Problems that require the deactivation of electrodes may be identified objectively or subjectively as shown in table 2, but an electrode will only actually become deactivated if it is removed from the patient's MAP (tuning programme) by the audiologist.

Table 2: Objective and subjective identification of problems that usually require the deactivation of electrodes

Reason for ED	Identification
Open circuit	Objectively identified by the implant tuning software
Short circuit	Objectively identified by the implant tuning software
Absent or abnormal nerve response	Nerve response telemetry is an objective measurement carried out at individual electrode level, but the audiologist subjectively decides if and when to do the measurement and which electrodes to include
Absent auditory percept	Subjective reporting by the patient and/or the audiologist has been unable to detect a behavioural response to electrode stimulation over repeated tests
Non-auditory stimulation	Objectively identified if facial nerve twitching is visible to the audiologist. Subjectively identified if a patient reports non-auditory sensations that are not visible to other people
Sound quality complaint	Subjectively reported by the patient
Extracochlear electrodes	Objectively identified if noted at the time of surgery, otherwise subjectively identified by the surgeon from the post-surgery X-ray image
Tip fold-over	Subjectively identified by the surgeon from the post-surgery X-ray image

2.2 Previous studies relating to electrode deactivation

A comprehensive search of peer-reviewed publications relating to electrode deactivation was carried out using Google Scholar and DelphiS (University of Southampton library) search engines, focusing on papers published from 2008 onwards. Given the retrospective nature of ED studies, extending the search parameters further back in time would have increased the likelihood that studies

would be focusing on early array models and programming approaches which would be less pertinent to the present study. It was evident that over time the focus of research had moved from investigating electrode and implant failure to concentrating more on surgical and biomedical factors. Table 3 shows the results of previous studies into electrode deactivation.

2.2.1 Studies into overall ED

In a study by Schow et al. (2012), 54% of arrays had one or more ED. 7% of arrays and 7% of electrodes had deactivations due to electrode failure (evenly distributed along the array) with 3% of arrays having one or more failed electrodes at initial tuning. The other 93% of deactivations were for programming reasons and usually occurred in the basal region. The researchers reported no statistically significant difference in the rate of electrode failure between manufacturers. Meanwhile, in a study involving 250 MED-EL arrays, Sanderson et al. (2019) also reported electrodes were most often deactivated in the basal region of the array. Sanderson et al. noted an increasing number of ED in the first two years post-implantation, something Francis et al. (2008) had also reported in their own study. In 2008, Zeitler et al. reported incidences of ED for non-auditory stimulation (47%), poor sound quality (7%), open circuits (20%) and short circuits (27%). However, unlike other researchers they excluded electrode faults that occurred prior to initial tuning meaning the true incidence of open and short circuits in their sample and overall incidence of ED may have been higher than reported.

2.2.2 Studies of open and short circuits

Carlson et al. (2010) reported 12% of arrays in children had one or more electrode failures. Nearly two-thirds of failures were open circuits, nearly a third were short circuits and the remainder were alternating short circuits (where adjacent odd or adjacent even numbered electrodes are shorted). They reported no significant difference between the incidence of failure in pre-curved and straight arrays, or between manufacturers. They reported 72% of electrode failures occurred by initial tuning with 58% identified intraoperatively and postulated that array damage was occurring during insertion. As impedance is

usually high at initial tuning, Meanwhile, Goehring et al. (2013) reported 8% of arrays had an open or short circuit at initial tuning, 94% being open circuits and 6% being short circuits - though they acknowledged that the telemetry they used to measure impedance was poor at identifying short circuits. No array was found to have more than two open or short circuits. Comparing manufacturers, Lin et al. (2009) reported that the number of arrays with one or more faulty electrodes was higher for MED-EL than for Cochlear and Advanced Bionics, with the latter manufacturer faring best. They claimed that Cochlear and MED-EL arrays showed similar patterns of greater ED in the basal portion and apical half of the array (though the graphs are not convincing). Meanwhile, Newbold et al. (2015) recorded electrode status at initial tuning and after 8-12 years of implant use. They reported electrode failures had occurred across the array, with the majority of short and open circuits present at initial tuning with some further increase in number over time.

Given the number of studies reporting the presence of electrode failure at initial tuning, Zeitler et al.'s (2008) decision to exclude pre-initial tuning electrode failures from analysis seems flawed.

2.2.3 Studies into non-auditory stimulation (NAS), absent or abnormal nerve response and absent auditory percept

Few studies appear to have commented on non-auditory stimulation and ED. However, Verschuur et al. (2019) reported that ED due to non-auditory stimulation occurred along arrays with a greater incidence in the basal and apical regions, while Berrettini et al. (2011) noted that when NAS occurred it typically did so within the first year of implant use.

There do not appear to have been any detailed studies into absent or abnormal nerve response or absent auditory percept in relation to incidence of ED.

2.2.4 Studies into sound quality complaint

While ED due to sound quality complaint is mentioned in some research studies (e.g. Sanderson et al. (2019) where it was found to affect mainly basal electrodes) there do not appear to have been any studies focusing on this issue

in depth. Nadol (1997) noted that patients often find it hard to report on sound quality for basal electrodes, possibly because spiral ganglion neuron survival may be poorer in this area, while Vaerenberg et al. (2014) have suggested that patients with previous long-term severe-profound hearing loss may lack a clear reference point against which to make judgements on sound quality.

2.2.5 Studies involving extracochlear electrodes and array migration

Unlike problems with nerve response, auditory percept, NAS or sound quality complaint, extracochlear electrodes and array migration have been researched in depth over the last 12 years. Some researchers have reported that deeper inserted straight arrays are less likely to extrude (e.g. Vaid et al., 2011) while others (such as Radar et al., 2016) have reported extrusion occurring with only straight arrays. Dietz et al. (2016) have postulated that modern straight arrays are very thin and exert minimal insertion forces (to improve hearing preservation) with the disadvantage that the reduced intracochlear friction may make them more vulnerable to extrusion. Holder et al. (2018) suspect that inserted arrays may move slightly during the latter stages of surgery and/or during the early stages of healing. Array migration may also occur months and years after surgery, sometimes signalled by deteriorating speech perception and/or non-auditory stimulation. Rader et al. (2016) investigated patients reporting deterioration in sound quality and/or non-auditory stimulation. They reported that extrusion typically occurred 4-22 months post-implantation. (In their paper, they also state that Brown et al. (2009) reported a 9% incidence of electrode extrusion but this is misreporting. The Brown study actually reported the percentage of *revision surgeries* (explant/re-implant) resulting from electrode extrusion.)

In a 2012 study, Van der Marel et al. reported a 29% incidence of electrode migration but the study's methodology was questionable as migration was defined as any movement of ≥1mm of the most basal electrode, even when the electrode remained well inside the cochlea. Only 5% (2 patients) actually had extracochlear electrodes, and the small number of total patients in the study means results should be viewed with caution. Van der Marel et al.

acknowledged that migration is most likely to occur in the weeks following surgery, before the array becomes fixed by fibrous tissue and prior to initial tuning, so would not necessarily impact long-term listening. Holder et al. (2018) noted that the definition of ‘complete insertion’ of an array varies by manufacturer with Cochlear arrays having minimum and maximum insertion guides 8mm apart with any insertion between the two lines considered ‘full’. This makes Van der Marel et al.’s claim that ≥1mm array movement is significant somewhat debatable.

In 2013, Causon et al. reviewed the United States FDA-maintained Manufacturer and User Facility Device Experience database which records adverse events mandatorily reported by manufacturers and implant centres in the United States, Asia and Australia. They reported that the incidence of extracochlear events had nearly halved between 2000 and 2010 as a proportion of total events reported. However, Holder et al. (2018) reported that nearly a seventh of ears in their study had at least one extracochlear electrode and while surgeons had reported incomplete insertion in 26% of these cases the number of electrodes affected was only correctly noted in 6% of reports. The researchers found neither impedance measurements nor auditory percept could be relied upon to signal extracochlear electrodes as current could spread to neighbouring neural tissue creating false results. However, Holder et al. comment that extracochlear electrodes are not necessarily negative. They state that differences in cochlear duct length of up to 1cm means that extracochlear electrodes may sometimes prevent over-insertion, avoiding damage to the cochlea and/or the occurrence of scalar deviation (when the array enters the scala vestibuli instead of remaining in the scala tympani (Dhanasingh & Jolly, 2017)).

Holder et al. (2018) suggest that post-surgery X-rays may falsely suggest correct electrode placement due to limited detail and image capture angle. They recommend CT scanning, but accept that this comes with a significantly higher radiation dose. Both they and Radar et al. (2016) advise that CT scanning is performed in cases of tuning difficulties or poor patient performance, especially

when basal electrodes have required deactivation. Dietz et al. (2016) prefer CBCT to CT scanning as it carries a lower radiation dose but accept CBCT scans take longer to perform which increases the likelihood of head movement affecting image clarity.

2.2.6 Studies into tip fold-over

Serrano et al. (2019) reported that incidences of tip fold-over occurred only with early use of a new perimodiolar array while surgeons perfected the insertion technique. Aschendorff et al. (2017) also stated that tip fold-overs were the result of surgical error. Although arrays have coloured markers to assist surgeons in achieving the correct insertion depth, individual differences in cochlear shape and size mean the markers may mislead (especially for cochleae smaller in height and diameter) resulting in tip fold-over and/or scalar deviation (Ketterer et al., 2017; Shaul et al., 2018). Tip fold-over or kinks in the array have been associated with greater formation of bone or fibrous tissue around the site (Trakimas et al., 2018) which can lead to worse auditory performance. Zhou et al. (2015) postulated that the use of a round window surgical approach may lead to a greater number of tip fold-over events than a cochleostomy or extended round window approach, due to the more acute insertion angle involved. Both Grolman et al. (2009) and Cosetti et al. (2012) have suggested that spread of excitation measured intraoperatively could identify tip fold-over, allowing it to be corrected. Post-operatively, Dirr et al. (2013) have suggested that tip fold-overs may sometimes be detected by post-operative X-ray, while Gabrielpillai et al. (2018) suggest that CT scanning is better suited to this purpose.

2.3 Justification for the present study

By their very nature, electrode deactivation studies are retrospective and the research reported on in the published literature has focused on previous generations of implants/arrays that are now legacy devices. It would be hoped that each new generation of implant/array would be an improvement on previous models, particularly regarding reliability and performance. Improved array designs, soft surgical techniques and newer sound processing strategies

may all affect the incidence of ED. To date, no comprehensive study has focused on electrode deactivation in the newer generation of arrays currently implanted at auditory implant centres across the UK. For people with cochlear implants, the electrodes are where coded sound from the outside world is transmitted to the auditory nerve so it is important to monitor electrode performance. The present study aimed to address the current gap in research by using electrode deactivation as a clinical outcome measure. The study examined the temporal (timing of ED), spatial (location of ED along the array) and causal (reason for ED) characteristics of electrode deactivations in the newer generation of arrays currently implanted at USAIS, from Advanced Bionics, Cochlear and MED-EL. The study compared arrays from each of these manufacturers and the two basic types of array (straight and pre-curved). The study aimed to answer the questions:

- What are the temporal, spatial and causal characteristics of electrode deactivation in the arrays?
- Does electrode deactivation have the same characteristics for all three manufacturers?
- Does electrode deactivation have the same characteristics in straight and pre-curved arrays?

Table 3: Results of previous studies into electrode deactivation

Authors	Date	Sample size	Manufacturers included in study	Study findings	Involved same arrays as current study?
Francis et al.	2008	209 arrays (children ≤5 years old)	Cochlear	1 or more electrode deactivations: Initial tuning: 11% (23 arrays) 6 months: 18% 12 months: 23% 2 years: 24% (51 arrays)	No
Zeitler et al.	2008	1520 (children and adults)	AB, Cochlear, MED-EL	1 or more electrode deactivations: 0.99% (15 arrays)	No
Schow et al.	2012	322 arrays (adults) 5586 electrodes	AB, Cochlear, MED-EL	1 or more electrode deactivation: 54% (173 arrays) 8% of electrodes were deactivated	No
Lin et al.	2009	264 (children)	AB, Cochlear, MED-EL	1 or more open or short circuits: 19.7% of total arrays (52/264 arrays) 3.3% of AB arrays 15.2% of Cochlear arrays 25.0% of MED-EL arrays	No
Carlson et al.	2010	636 total 164 children <18 years 472 adults	AB, Cochlear	1 or more open or short circuits: 9.0% (57 arrays) 63.2% were open circuits 30.0% were short circuits 7.0% were alternating short circuits	No
Goehring et al.	2013	194 (children & adults)	AB, Cochlear, MED-EL	1 or more open or short circuits: 8.2% (16 arrays) at initial tuning	No
Newbold et al.	2015	232 (adults)	Cochlear	1 or more open or short circuits: At initial tuning: 0.3% electrodes 4.3% arrays At 8-12 years post-implant: 0.5% electrodes 5.6% arrays	No
Zawawi et al.	2018	298 (children)	Cochlear (lateral wall arrays)	Open circuits: 2% (4 arrays)	5 Cochlear CI522 equivalent to 1.74% of total arrays. (None had open circuits)

Authors	Date	Sample size	Manufacturers included in study	Study findings	Involved same arrays as current study?
Connell et al.	2008	580 ears (children & adults)	AB, Cochlear, MED-EL	Extracochlear electrodes: 0.3% (2 arrays) due to re-ossification around split arrays	No
Causon et al.	2013	MAUDE database 237 adverse incidents (2000) 2543 adverse events (2010)	AB, Cochlear, MED-EL, Neurelec	Extracochlear electrodes: 6.75% of adverse events (2000) 3.62% of adverse events (2010)	Unable to determine
Dietz et al.	2016	201 arrays (children & adults)	Cochlear MED-EL	Extra-cochlear electrodes: 0% perimodiolar arrays 6.0% (12 arrays) lateral wall	1 MED-EL FLEX28 had extracochlear electrodes equivalent to 0.5% of total arrays
Rader et al.	2016	826 arrays (children & adults) 468 pre-curved arrays 358 lateral wall arrays	AB, Cochlear, MED-EL	Extracochlear electrodes: 0% pre-curved arrays 2.8% (10 arrays) lateral wall	3 Concerto FLEX28 had extracochlear electrodes equivalent to 1.08% of total arrays
Holder et al.	2018	262 arrays 149 pre-curved arrays 113 lateral wall arrays	AB, Cochlear, MED-EL	Extracochlear electrodes: 13.4% (35 arrays) 2.6% of pre-curved arrays 27.4% of lateral wall arrays	8 MED-EL FLEX28 had extracochlear electrodes equivalent to 3.05% of total arrays
Grolman et al.	2009	72 perimodiolar arrays (children & adults)	Cochlear	Tip fold-over: 5.6% (4 arrays)	No
Aschendorff et al.	2017	44 perimodiolar arrays (adults)	Cochlear CI532	Tip fold-over: 4.5% (2 arrays)	No
Zuniga et al.	2017	303 arrays (children & adults) 52% right ears, 48% left ears 48% perimodiolar arrays 41% lateral wall arrays 10% mid scala arrays	Not reported	Tip fold-over: 1.98% (6 arrays) 83.3% right side and pre-curved arrays (5 ears) 16.7% (1 array) tip bent at 90 degrees but not fully folded over	Unable to determine

Authors	Date	Sample size	Manufacturers included in study	Study findings	Involved same arrays as current study?
Gabrielpillai et al.	2018	1722 arrays (children & adults) Including: 778 pre-curved arrays 883 lateral wall arrays	AB, Cochlear, MED-EL	Tip fold-over: 0.87% (15 arrays) 67% (10 arrays) right side 1.67% (13 arrays) perimodiolar 0.23% (2 arrays) lateral wall	3 Cochlear CI512 arrays and 1 Cochlear CI522 array had tip fold-over equivalent to 0.17% and 0.06% respectively of total arrays
Dhanasingh & Jolly	2019	Meta-analysis 3177 arrays	AB, Cochlear, MED-EL & Neurelec	Tip fold-over 1.57% (50 arrays) 86% were pre-curved arrays 14% were lateral wall arrays	Unable to determine
Mittmann et al.	2019	85 perimodiolar arrays	Cochlear CI532	Tip fold-over 4.7% (4 arrays) 75% (3 arrays) right side	No
Serrano et al.	2019	40 perimodiolar arrays (children & adults)	Cochlear CI532	Tip fold-over 7.5% arrays	No

3. METHODOLOGY

A research method covers the collection, analysis and interpretation of data (Creswell & Creswell, 2018). This chapter describes the methodology for the present study. It describes the chosen method, the specific arrays included in the study, the patient selection criteria and the approach taken to the collection, analysis and interpretation of data. It also reflects on ethical considerations and on study reliability and validity.

3.1 Research method and rationale

The intention of this study was to examine data on ED to establish when, how and why electrodes in arrays were being deactivated by USAIS audiologists. In order to study electrode deactivation characteristics, data needs to be collected over a lengthy period of time and then reviewed, so the most appropriate approach for the present study was a secondary data analysis (SDA) in the form of retrospective descriptive nonexperimental research (Johnson, 2001). As the data used in the study related only to USAIS patients and USAIS clinical practice the study can also be judged to be a service evaluation (CNWL, 2019; HRA, 2017).

The overall aim of SDA is the same as for other research methods except in its reliance on existing data (Johnston, 2014). In areas where technology is constantly changing, use of existing data can allow contributions to knowledge to be made while the technology is still in use (Johnston, 2014). However, as Boslaugh (2007) and Doolan & Froelicher (2009) have pointed out, a disadvantage of SDA is that the original data is not collected for the purpose of answering the research questions. The data required for the present study did not exist as a single dataset at the outset – information from a number of different databases and paper records had to be combined. The data entered into these databases and records was collected previously by clinicians for another primary purpose, namely patient care. By collating data from these multiple sources it was possible to create a suitable dataset for the present study.

3.2 Electrode arrays included in the present study

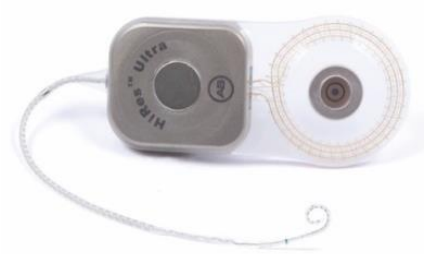
This study focused on the four electrode arrays most commonly implanted at USAIS for which no comprehensive study into electrode deactivation has yet been published, namely the:

- Cochlear Nucleus CI512 Contour Advance array and Cochlear Nucleus CI522 Slim Straight array (used with Nucleus Profile cochlear implants)
- Advanced Bionics HiFocus Mid-Scala array (used with Ultra and Hi Res 90k Advantage cochlear implants)
- MED-EL FLEX28 array (used with Mi1200 SYNCHRONY and Mi1000 CONCERTO cochlear implants)

As the focus of the study was on the current generation of arrays (rather than the receiver-stimulator attached to them) the Advanced Bionics HiRes 90k Advantage and MED-EL Mi1000 CONCERTO implants were included. Although these receiver-stimulators were superseded by the Advanced Bionics HiRes CI Ultra and MED-EL Mi1200 SYNCHRONY the modifications related to reduced receiver-stimulator size and/or MRI compatibility and the arrays themselves remained unchanged.

Figure 1 shows the arrays included in the present study with the stimulator-receivers to which they attach. This combination of arrays allowed both the different manufacturers to be compared and the different array types. For example, the Cochlear CI512 Contour Advance and Advanced Bionics HiFocus Mid-Scala are pre-curved arrays. Pre-curved arrays are considered to be at greater risk of tip fold-overs and may be more vulnerable to bending during implantation (Gabrielpillai et al., 2018; Dhanasingh & Jolly, 2019). In contrast, the Cochlear CI522 Slim Straight and MED-EL FLEX28 are straight arrays. The risk of tip fold-over is considered to be lower in straight arrays but they may be at greater risk of electrode extrusion (Dietz et al., 2016).

Figure 1: The four arrays included in the present study and the six stimulator-receivers to which they attach

Manufacturer	**Advanced Bionics**
Receiver-stimulator	**HiRes 90K Advantage**
Array	**HiFocus Mid-Scala electrode**
Array type	Mid-scala (pre-curved)
Release year	2012
Image *Advanced Bionics (2019a)*	
Manufacturer	**Advanced Bionics**
Receiver-stimulator	**HiRes Ultra CI**
Array	**HiFocus Mid-Scala electrode**
Array type	Mid-scala (pre-curved)
Release year	2016
Image *Advanced Bionics (2019b)*	
Manufacturer	**Cochlear**
Receiver-stimulator	**Nucleus Profile CI512**
Array	**Contour Advanced Electrode**
Array type	Perimodiolar (pre-curved)
Release year	2014
Image *Cochlear Ltd (2019a)*	

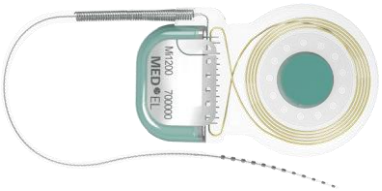
Manufacturer	**Cochlear**
Receiver-stimulator	**Nucleus Profile CI522**
Array	**Slim Straight Electrode**
Array type	Lateral wall (straight)
Release year	2015
Image *Cochlear Ltd (2019b)*	
Manufacturer	**MED-EL**
Receiver-stimulator	**CONCERTO (Mi1000)**
Array	**FLEX28 electrode**
Array type	Lateral wall (straight)
Release year	2011
Image *MED-EL (2019a)*	
Manufacturer	**MED-EL**
Receiver-stimulator	**SYNCHRONY (Mi1200)**
Array	**FLEX28 electrode**
Array type	Lateral wall (straight)
Release year	2014
Image *MED-EL (2019b)*	

Table 4 compares the physical characteristics of the four arrays. As can be seen, the arrays vary not only in the number of electrode contacts they contain but also in aspects such as type of contact, contact spacing, array length and array diameter. These different characteristics can influence electrode performance. For example, the longer the array, the deeper the most apical electrodes will sit inside the cochlea (making greater use of the cochlea's tonotopic organisation for lower frequency

sounds), while electrode contacts that are wider apart may experience less current spread to neighbouring contacts (which can improve sound quality).

Table 4: Physical characteristics of the four arrays

Array	HiFocus Mid-Scala	Contour Advance	Slim Straight	FLEX28
Shape	Pre-curved	Perimodiolar (pre-curved)	Straight	Straight
Number of contacts	16	22	22	12
Basal to Apical numbering	16 basal – 1 apical	1 basal – 22 apical	1 basal – 22 apical	12 basal – 1 apical
Contact type	Planar	Half-band	Half-band	5 single contacts at apex, 7 contact pairs at base (19 contacts in total)
Contact material	Platinum	Platinum	Platinum	Platinum
Contact spacing	0.975 mm	0.4 mm – 0.8 mm	0.85 mm – 0.95 mm	2.1 mm
Spacing	Even	Uneven	Uneven	Even
Active array length*	15.0 mm	14.25 mm	19.1 mm	23.1 mm
Array length**	23.7 mm	19.0 mm	19.1 mm	28.0 mm
Array diameter	0.7 mm basal - 0.5 mm apical	0.8 mm basal – 0.4 mm apical	0.6 mm x 0.5 mm basal – 0.35 mm x 0.25 mm apical	0.8 mm basal – 0.5 x 0.4 mm apical
Insertion depth markers	Yes	Yes	Yes	Yes
Area of each contact	0.12 mm^2 min	Not provided	0.19 mm^2 – 0.14 mm^2	Not provided
Reference	*Advanced Bionics (2017)*	*Cochlear Ltd (2016a)*	*Cochlear Ltd (2016b)*	*MED-EL (n.d.)*

* Active array length = the part of the array containing the stimulating electrodes
** Array length = the total length of the array from the tip to a stopper at the round window

3.3 Generating the study dataset

The dataset required for this study did not exist at the outset so had to be generated by collating data from a number of existing databases and paper records at USAIS. The original data had been collected during implant operations and routine clinic appointments. No additional data was required and patients were not approached for additional information.

Only personal data required to answer the study questions was collated and no personal sensitive data. The data was collected into a single, password protected Microsoft Excel spreadsheet and (together with a back-up copy) kept securely on an encrypted university server.

3.3.1 Data collected

To determine the study population, a series of reports were run on the USAIS BCS admin database to identify all the paediatric patients who were using (or had ever used) one or more of the arrays under investigation. The following data was then collected for this population of patients.

- From the USAIS BCS admin database:
  - Client Identification Number (CIN) – a unique patient identifier used at USAIS. This was used to ensure that data from the different databases and paper records could be associated with the correct patient.
  - Patient name – for collection of ED data only as the manufacturers' programming software uses patient names, not CINs. Once data from the relevant programming database was associated with a patient's CIN the patient's name was deleted from the spreadsheet.
  - Make and model of cochlear implant – required to allocate patients to the correct implant array group.
  - Patient sex, to compare ED incidence by sex at group level.
  - Patient age at implantation, for patient demographics.
  - Whether the array was a first implant or the result of revision surgery (explant/re-implant) as revision surgery may increase damage to the cochlea which in turn may affect electrode performance.
  - Date of initial tuning (when the implant was first programmed or 'switched on') to allow the calculation of time from initial tuning to ED event and the age of the array on 31 August 2019 (the final date for which data was included in the study).

- From the manufacturers' programming software (MED-EL MAESTRO 7.0.3, Cochlear Custom Sound 5.2 and Advanced Bionics Soundwave 3.2.12):
  - The number of deactivated electrodes in each array
  - The electrode number of any deactivated electrode
  - The date of deactivation for each deactivated electrode
  - The reason for deactivation for each deactivated electrode (where available)

- Where the reason for electrode deactivation was not recorded in the manufacturer's programming software, the reason for deactivation was obtained from the patient's paper audiology record using the date of deactivation as a reference.

3.3.2 Patient consent

Parents/carers consented to the collection of the original data used in this study. The University of Southampton (UoS) governance office has previously stated that further patient consent is not required to use such data in anonymised form for retrospective analysis. Parents/carers are free to withdraw consent for USAIS to collect, process and store their child's data at any time if they wish. Consent forms for the original data collection are saved electronically in patient files and in hard copy in the patient's paper audiology file.

3.3.3 Ethical considerations

No ethical risks were raised by this research. The study did not use human participants so a risk assessment was not required. Patient personal data was used so a Data Protection Act plan was completed as part of the UoS ethics approval process. Prior to analysis, the collated data was anonymised by removing the CIN references.

The accuracy of the original data was ensured because it was collected and recorded by clinical staff in accordance with University and USAIS policies and procedures. The researcher was also familiar with these policies and procedures, something Boslaugh (2007) and Smith et al. (2011) consider important if a researcher is to be able to judge the relevance of pre-collected data.

3.3.4 Patient inclusion criteria

Patients were considered eligible for inclusion in the study if:

1. They were aged between 0 and 19 on 31 August 2019. At USAIS, children and young people are classed as 'paediatric' up until their 19th birthday.

2. They had received one or more of the following arrays/implants included in the study and had had at least one tuning session for their device(s) by 31 August 2019 – the date chosen as the cut-off for data to be included in the study.
   - Cochlear Nucleus CI512 Contour Advance array or Cochlear Nucleus CI522 Slim Straight array (used with Cochlear Nucleus Profile cochlear implants)
   - Advanced Bionics HiFocus Mid-Scala array (used with Advanced Bionics Ultra and Advanced Bionics Hi Res 90k Advantage cochlear implants)
   - MED-EL FLEX28 array (used with MED-EL Mi1200 SYNCHRONY and MED-EL Mi1000 CONCERTO cochlear implants)

3. Patients with one or more of the above arrays who were implanted at another centre and transferred to USAIS after implant activation were included in the study provided their implant programming record from initial activation onwards was available. All transfer patients with one or more of the above arrays met this criterion and were included.

Table 5 shows the resulting group sizes for the study for each manufacturer and array type.

The group of patients whose arrays were under investigation in the present study are part of a larger population of paediatric patients at USAIS using a variety of implants by Cochlear, Advanced Bionics (AB) and MED-EL. USAIS supports approximately 360 children who between them have over 660 implants (USAIS, 2019). The USAIS paediatric population are in turn part of a UK paediatric cochlear implanted population of over 6000 children and young people (Hanvey, 2020).

Table 5: Group sizes for the study

Manufacturer	Implant (Array)	No. of arrays	No. of electrodes
Advanced Bionics (AB)	*Advantage (HiFocus Mid-Scala array)*	31	496
	Ultra (HiFocus Mid-Scala array)	19	304
AB Total		**50**	**800**
Cochlear	*CI512 (Contour Advance array)*	151	3322
	CI522 (Slim Straight array)	6	132
Cochlear Total		**157**	**3454**
MED-EL	*CONCERTO (FLEX28 array)*	9	108
	SYNCHRONY (FLEX28 array)	19	228
MED-EL Total		**28**	**336**
Straight arrays	*Cochlear CI522 (Slim Straight array) & MED-EL CONCERTO & SYNCHRONY (FLEX28 array)*	**34**	**468**
Pre-curved arrays	*AB Advantage & Ultra (HiFocus Mid-Scala array) & Cochlear CI512 (Contour Advance array)*	**201**	**4122**
All arrays		**235**	**4590**

3.4 Data analysis

3.4.1 Temporal characteristics

The timing of ED events was not treated as a continuous variable as it reflected the organisation of implant tuning appointments. Several tuning appointments occur in the first month after initial tuning (IT) with the frequency of appointments reducing thereafter. From 12 months onwards appointments are usually annual with additional interim appointments only if a patient or audiologist requests it. Appointments are scheduled according to the date of initial tuning, not the date of surgery which is typically 3-4 weeks prior to implant activation. ‘Time from initial tuning to ED event’ data was therefore grouped into time bins as shown in table 6. This division reflected

that more tuning is carried out during the first year (and particularly the first month) than in successive years. Electrodes may be deactivated from initial tuning onwards; they are never deactivated at the time of surgery.

Table 6: Time bins used in the analysis of time from initial tuning to ED event

Time bin (years)	Equivalency
0.00 – 0.09	0.00 years = first tuning appointment
0.10 – 0.49	0.09 years = ~1 month post-IT
0.50 – 0.99	0.50 years = 6 months post-IT
1.00 – 1.99	1.00 years = 12 months post-IT
2.00 – 2.99	2.00 years = 2 years post-IT
Up to …	etc.
7.00 – 7.99	

3.4.2 Spatial characteristics

As each manufacturer's array had a different number of electrodes and different contact spacing, the location of ED in different arrays could not be compared just by comparing the electrode numbers of the deactivated electrodes. Instead, each array was divided into six regions – lower and higher basal, lower and higher middle, and lower and higher apical. 'Lower basal' was closest to the round window of the cochlea and 'higher apical' was closest to the apex. Where the number of electrodes did not divide evenly the most basal and apical regions contained the same number of electrodes and the other regions had one extra. Table 7 shows the electrode numbers that fell into each region for each manufacturer. Schow et al. (2012) adopted a similar approach in their study of ED although they used only three divisions. Using six divisions allowed for a more detailed examination of the relative locations of ED along the array. It was not possible to establish the exact location of electrodes within the cochlea as each person's cochlea is different and while the array lengths were known the depth of insertion achieved in individual patients was not.

Table 7: Electrode numbers falling into each array region

AB and MED-EL number their electrodes from apical to basal while Cochlear numbers its electrodes from basal to apical

Manufacturer	Array region					
	Higher apical	**Lower apical**	**Higher middle**	**Lower middle**	**Higher basal**	**Lower basal**
AB	1-2	3-5	6-8	9-11	12-14	15-16
Cochlear	22-20	19-16	15-12	11-8	7-4	3-1
MED-EL	1-2	3-4	5-6	7-8	9-10	11-12

3.4.3 Statistics

All analysis was carried out on anonymous data (with names and CIN references removed). Descriptive statistics were used to describe and summarise the data. As group sizes for the manufacturers and the different array types were unequal, frequency data was converted into percentages to allow comparisons between manufacturers and between array types. 'Microsoft Excel 2010' was used to produce charts. Where possible, statistical tests were performed to determine the significance of results, i.e. whether a result was likely to have occurred simply by chance. The study involved nominal data, unequal group sizes and often very kurtotic data distribution so non-parametric tests were required (Glen, 2014). Correct selection of test is important as using an inappropriate test may increase the risk of a Type I error (where a null hypothesis is incorrected rejected) or Type II error (where a false null hypothesis is accepted) (McHugh, 2013). Two-tailed probability with an alpha level of .05 was chosen as the significance level for all tests. This alpha level is typical for health-related research (Pett, 1997) and means the probability of a Type I error occurring was 5% or 5/100 tests. Table 8 lists the non-parametric tests used in this study, their function and the test assumptions that had to be met if results were to be valid. Chi-square statistics are often calculated using an approximation to the true distribution to produce an asymptotic *p*-value. In contrast, exact tests are calculated using the true distribution and produce an exact *p*-value but this is computationally intensive, especially for larger contingency tables. The statistics software used in this study (IBM SPSS Statistics, Version 26) was powerful enough to produce exact significance values for most tests. When this was not possible, Monte Carlo *p*-values with confidence intervals were used in preference to asymptotic *p*-values as the

latter are not reliable when data is unequal or sparse (Mehta & Patel, 2012) as was often the case. As the relevance of statistical significance depends on the context in which the outcome occurs and a result can be statistically significant without being clinically significant (Sun et al., 2010; Salkind, 2017), Cramer's V coefficient was used to assess strength of association.

Table 8: Non-parametric tests used in this study (after Cohen, 1988; Pett, 1997; Salkind, 2017)

Test	Function	Test assumptions
Pearson's Chi-square goodness-of-fit	Examines whether observed frequencies are what would be expected to occur by chance	• Sample size >20 • Nominal data • Single variable with two or more levels • For a dichotomous variable: all cells should have an expected frequency ≥5 • For a variable with >2 levels: no more than 20% of cells should have an expected frequency <5 and no cells should have an expected frequency <1
Pearson's Chi-square test for independence	Examines whether two different nominal levels of measurement are independent	• Sample size >20 • Nominal data • Dependent variable with >2 levels • For a dichotomous variable: all cells should have an expected frequency ≥5 • For a variable with >2 levels: no more than 20% of cells should have an expected frequency <5 and no cells should have an expected frequency <1
Fisher's exact	Calculates all possible combinations of the data to evaluate the probability of obtaining those proportions by chance	• Independent and dependent variables are both dichotomous • Valid for all sample sizes • 2x2 contingency table only • Expected frequencies in cells can be <5
Freeman-Halton exact	Calculates all possible combinations of the data to evaluate the probability of obtaining those proportions by chance	• Extension of Fisher's exact test for contingency tables larger than 2x2 • Valid for all sample sizes • Expected frequencies in cells can be <5
Cramer's V coefficient	Tests the strength of association between two nominal variables	• Valid for all table sizes • Value ranges from 0 to 1 • 0 no association .1 weak association .3 moderate association ≥.5 strong association

3.5 Ethics approval

This study was sponsored by the University of Southampton. Ethics approval for the study was obtained from the University of Southampton Faculty of Engineering and Physical Sciences Ethics and Research Guidance Office (Ethics number 52435). An 'EC1C Declaration of Involvement in a Non-UH Approved Study' form was submitted to the University of Hertfordshire SSAH ECDA office along with the Southampton ethics paperwork and approval. SSAH ECDA stated that no additional ethics clearance was required from them. NHS REC approval was not required as the study did not involve randomised groups or a change in treatment and the findings were not intended to be generalizable or transferrable to other settings. The study abided by the 'WMA Declaration of Helsinki ethical principles for medical research involving human subjects' (WMA, 2013).

3.6 Study reliability and validity

The study is reliable as another researcher would be able to repeat and reproduce the findings using the same data and methodology. The study has good internal validity in that it is a comprehensive and systematic review of ED characteristics in this group of arrays and appropriate statistical tests were used when evaluating results for statistical significance and strength of association. All USAIS paediatric patients who had received one or more of the arrays listed in 3.2 met the selection criteria and were included in the study. This not only removed the risk of researcher bias in patient selection but also meant the groups in the study were directly equivalent to the paediatric population at USAIS using these arrays. This means the findings of the study are valid for this USAIS population even though group sizes for some manufacturers and array types were small.

The study was not intended to have external validity as it was a service evaluation (as defined by HRA, 2017). The USAIS paediatric population is a small part of the much larger UK paediatric population of cochlear implant users and electrode deactivation characteristics in arrays may vary between centres for a range of reasons.

3.7 Reflexivity

The researcher is a qualified Teacher of the Deaf and RCCP-registered Educational Audiologist. She is employed by the University of Southampton and works in the University's Auditory Implant Service. She had approved access to the databases and paper records required for the present study but was not involved in the production of the original data and does not carry out implant tuning as part of her role. Her principal day to day work involves supporting children and young people and their families through the assessment process for a cochlear implant and with (re)habilitation following cochlear implantation. She has a special interest in implant-related audiology and, in particular, factors that may influence implant-cochlea interactions and therefore patient listening and speech outcomes.

4. RESULTS

This chapter details the results of the study, starting with general findings before moving on to analyse the temporal, spatial and causal characteristics of electrode deactivation in depth.

All eligible arrays and all electrode deactivations present in any of those arrays on 31 August 2019 were included in the analysis. All the arrays had been implanted by experienced ENT surgeons who had undergone specialist training in each manufacturer's recommended implant procedure. There is no nationally agreed guidance regarding electrode deactivation but USAIS audiologists receive training in implant tuning from the implant manufacturers and from more experienced colleagues in the service.

For all statistical tests, two-tailed probability with an alpha level of .05 was used. Test assumptions were met for all the tests used.

4.1 General findings

4.1.1 Array failure

BCS admin database records showed that none of the arrays in the study had failed or otherwise required revision.

4.1.2 Patient demographics

There were 142 male and 93 female ears in the study. There was no significant difference between the sexes in the percentage of arrays with ≥1 ED [X^2 (1, N=235) = 2.5, P = .13]. Patient age at time of surgery ranged from 10 months old to nearly 17 years old. The median age at implantation was 2.59 years (interquartile range 1.46 years to 6.40 years).

4.1.3 Number of arrays from each manufacturer

The difference in the number of arrays from each manufacturer was statistically significant [X^2 (2, N=235) = 121.6, P <.001]. However, the difference in the number of ED in AB Advantage and AB Ultra implants was not significant [Fisher's exact (n=50) = 3.5, P = .51], nor in MED-EL CONCERTO and MED-EL SYNCHRONY implants [Fisher's exact (n=28) = 4.1, P = .44]. The pairs of implants were therefore

combined and treated as one array group for each manufacturer. As no Cochlear CI522 arrays had ED this array could only be included in statistical analysis for the presence or absence of ED. For other analyses only Cochlear CI512 arrays represented this manufacturer.

4.1.4 Number of each array type

The difference in the number of straight and pre-curved arrays in the study was statistically significant [X^2 (1, N=235) = 118.7, P <.001]. As no Cochlear CI522 arrays had ED this array could only be included in statistical analysis for the presence or absence of ED. For other analyses the straight arrays were represented only by MED-EL arrays.

4.1.5 ED at array and electrode level

18.7% of arrays (44/235) contained ≥1 ED and 1.8% of total electrodes (84/4590) were deactivated.

Figure 2 shows the percentage of each manufacturer's arrays with ≥1 ED. 32.1% of MED-EL arrays had ≥1 ED, more than double the percentage of Cochlear arrays. The difference between the three manufacturers was statistically significant with a weak strength of association between a manufacturer and the number of arrays with ≥1 ED [Freeman-Halton (N=235) = 5.9, P = .046, Cramer's V = .16].

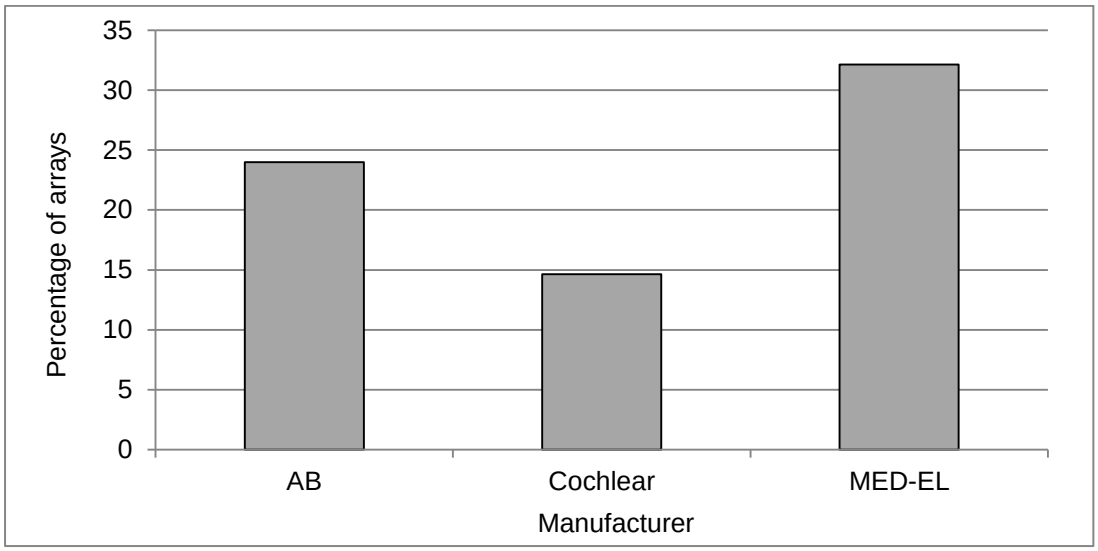


Figure 2: The percentage of each manufacturer's arrays that contained one or more deactivated electrodes

Overall, 4.8% of MED-EL electrodes were deactivated, over three times as many as in the Cochlear arrays and nearly twice as many as in the AB arrays (figure 3). However, while this was statistically significant the strength of association was negligible [X^2 (2, N=4590) = 21.8, P <.001, Cramer's V = .07]

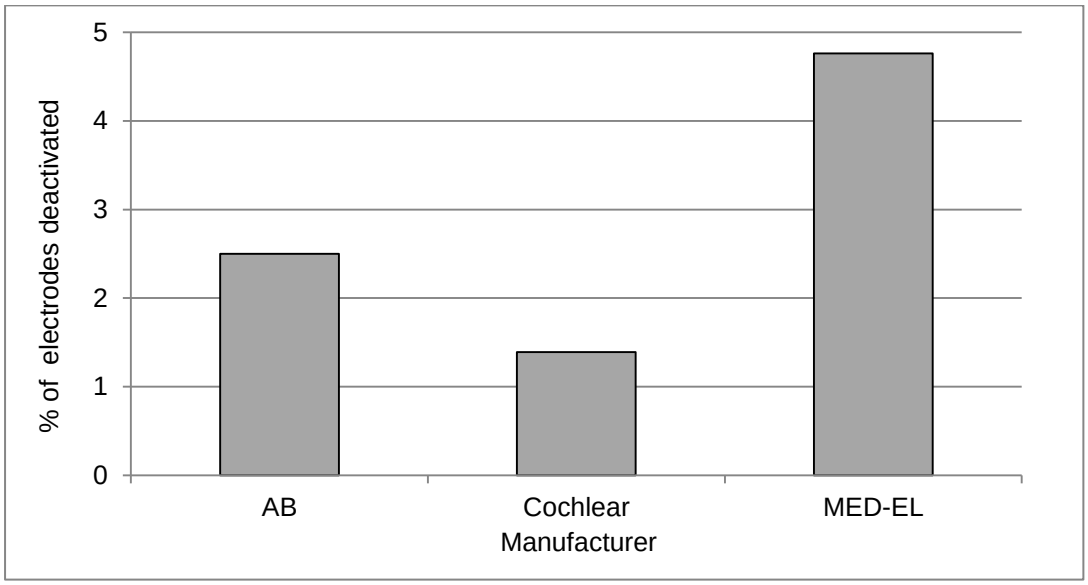


Figure 3: The percentage of each manufacturer's electrodes that were deactivated

Figure 4 shows the percentage of straight arrays and pre-curved arrays with ≥1 ED. The difference was not statistically significant [X^2 (1, N=235) = 1.6, P = .24].

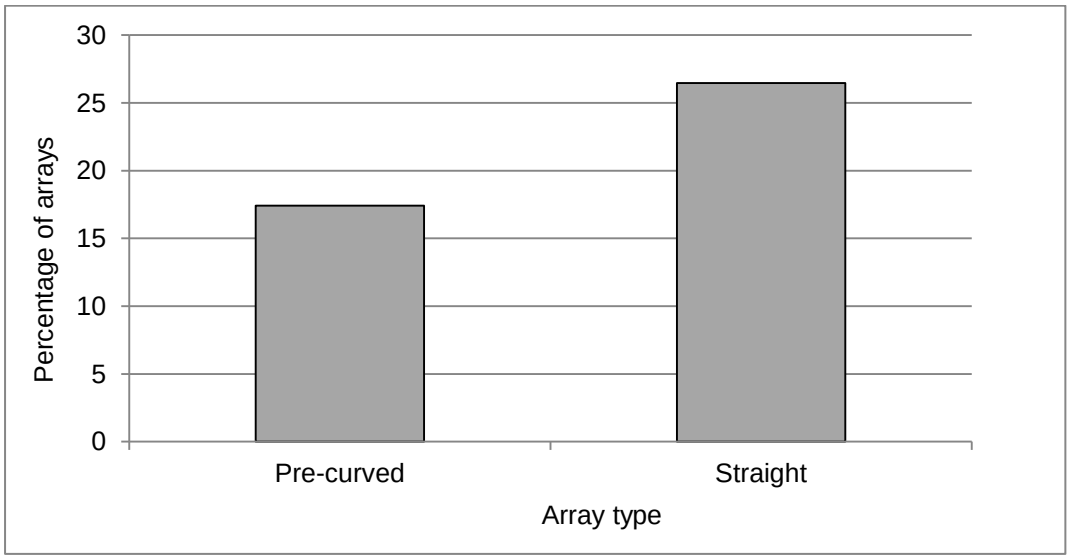


Figure 4: The percentage of pre-curved and straight arrays with one or more ED

Twice as many electrodes in straight arrays were deactivated as in pre-curved arrays (figure 5). This was statistically significant but lacked strength of association [X^2 (1, N=4590) = 17.3, P <.001, Cramer's V = .06].

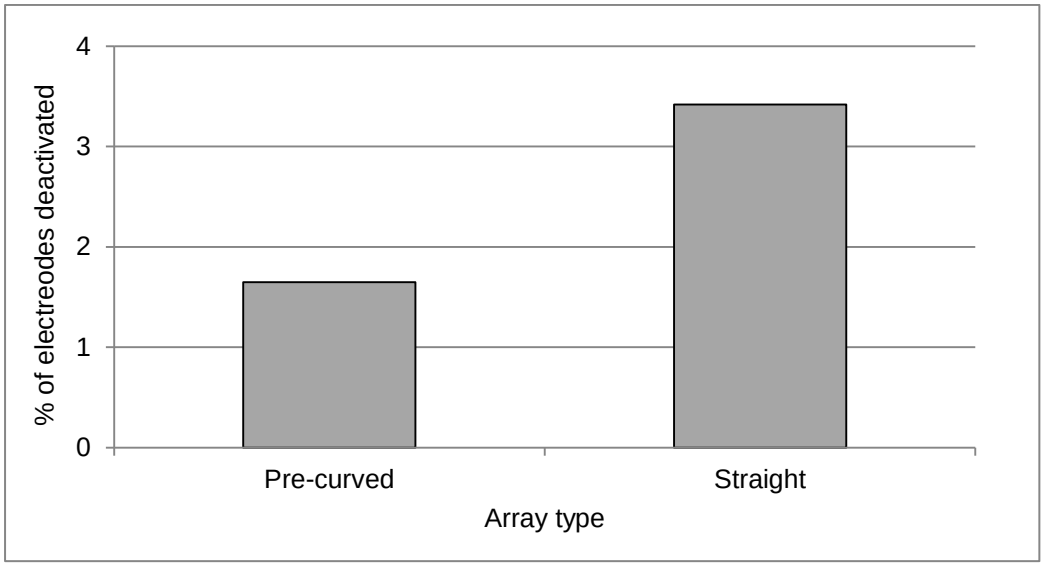


Figure 5: The percentage of deactivated electrodes in the pre-curved and straight arrays

4.1.6 Number of ED in an array

81.3% of arrays (191/235) had no deactivations. The percentage of arrays with 1, 2 and 3 deactivations was 8.9%, 5.5% and 3.0% respectively. The number of arrays with four or more ED was 1.3% (3/235 arrays) (figure 6).

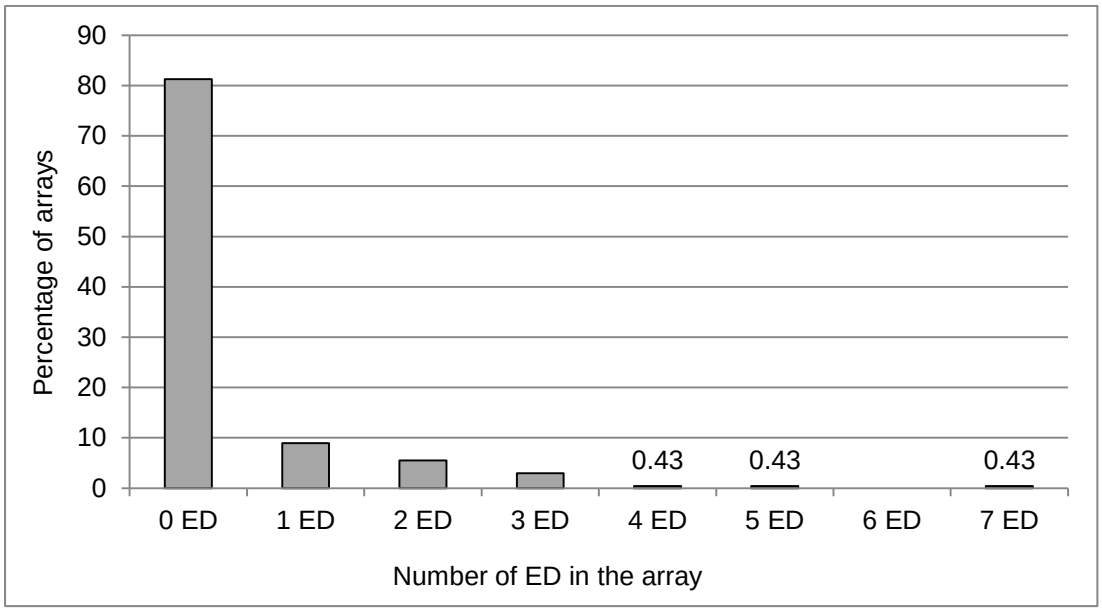


Figure 6: The percentage of arrays containing different numbers of deactivated electrodes

There were no deactivations in 67.9% of MED-EL arrays, 76.0% of AB arrays and 85.4% of Cochlear arrays. The differences were not statistically significant [Freeman-Halton (N=235) = 16.6, *P* = .11]. Figure 7 shows the percentage of each manufacturer's arrays with different numbers of ED. Two Cochlear arrays and one MED-EL array had 4 or more electrodes deactivated. The largest single number of deactivations was 7 in a Cochlear array. The highest percentage of deactivated electrodes in a single array was 18.8% (3 ED) for AB, 31.8% (7 ED) for Cochlear and 41.7% (5 ED) for MED-EL.

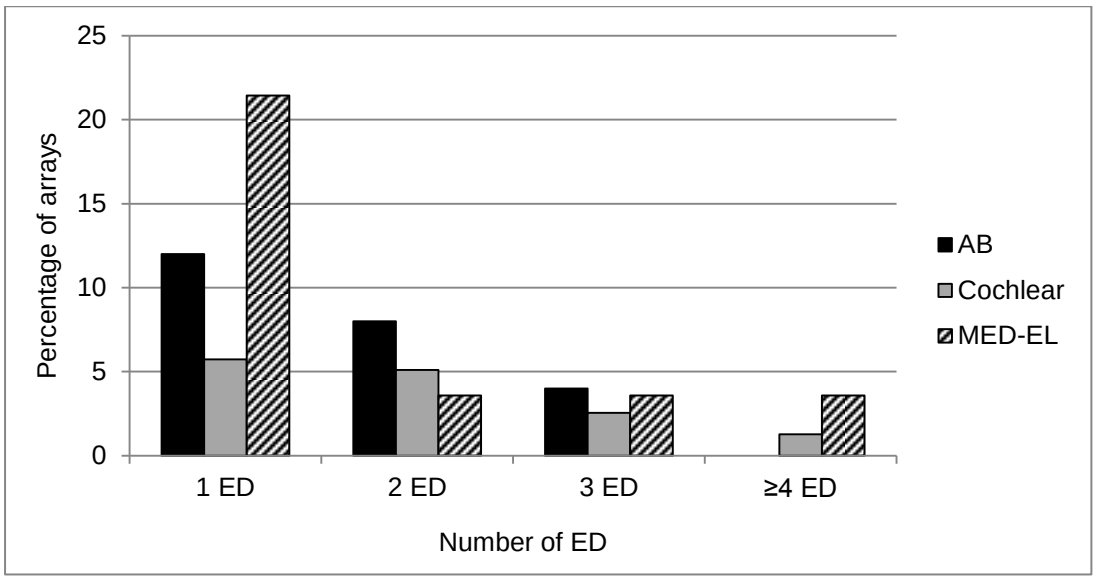


Figure 7: The percentage of each manufacturer's arrays containing different numbers of deactivated electrodes. One MED-EL array and two Cochlear arrays had ≥4 electrode deactivations but the different manufacturer group sizes affects the percentages.

Figure 8 shows the percentage of straight and pre-curved arrays with different numbers of ED. There were no deactivations in 73.5% of straight arrays and 82.6% of pre-curved arrays. The difference was not statistically significant [Freeman-Halton (N=235) = 9.1, *P* = .16].

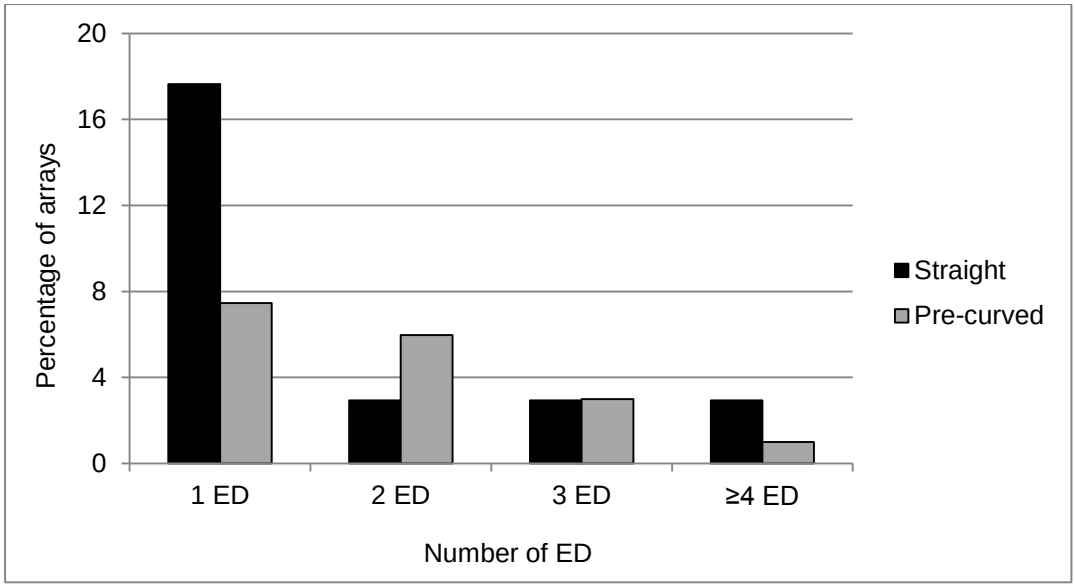


Figure 8: The percentage of straight and pre-curved arrays containing different numbers of deactivated electrodes

4.1.7 Initial implants and revision implants

3.0% of arrays (7/235) were revision implants. All had replaced previous models of implant that had failed or required revision for another reason. The difference in incidence of ED between initial and revision arrays was not statistically significant [Freeman-Halton (N=235) *P* = .12].

4.2 Temporal characteristics of ED

4.2.1 Time to ED

Figure 9 shows the cumulative percentage of arrays with ≥1 ED from initial tuning onwards. 8.9% of arrays had ≥1 ED at initial tuning (IT), while 15.7% of arrays contained ≥1 ED by the end of the first year of implant use. After 2 years the number of additional arrays developing ≥1 ED plateaued.

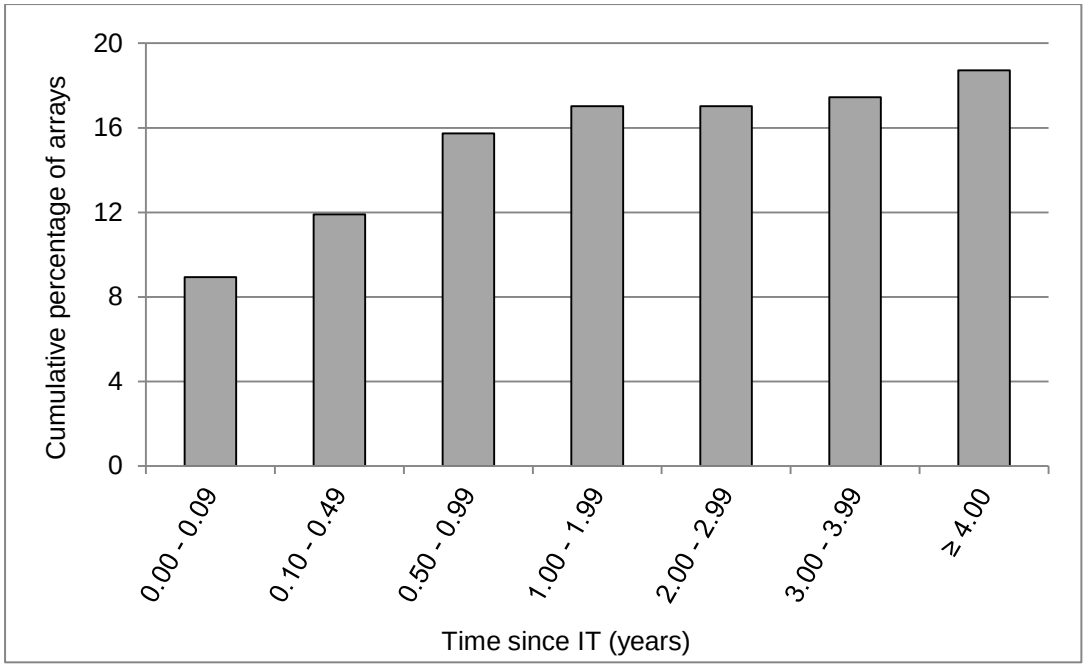


Figure 9: The cumulative percentage of arrays with one or more electrode deactivations at different time points from initial tuning onwards. The majority of first deactivations occurred within the first year of implant use.

Examining the timing of individual electrode deactivations, the median time from IT to deactivation was 0.28 years (interquartile range 0.00 to 1.05 years) while the modal time was 0.00-0.09 years. Over 40% of deactivations occurred at initial tuning or within the first month of implant use. 75% of deactivations had occurred by one year post-IT with 85% occurring by 2 years post-IT.

Figure 10 shows the cumulative percentage of arrays with ≥1 ED from initial tuning onwards for each manufacturer. The overall shape is similar to the combined-array distribution. There were fewer MED-EL arrays with ≥1 ED at initial tuning than AB and Cochlear arrays, but the percentage of additional MED-EL arrays developing ≥1 ED between IT and 2 years increased at a faster rate than with the other two manufacturers. The differences were not statistically significant [Freeman-Halton (n=44) = 14.8, *P* = .13].

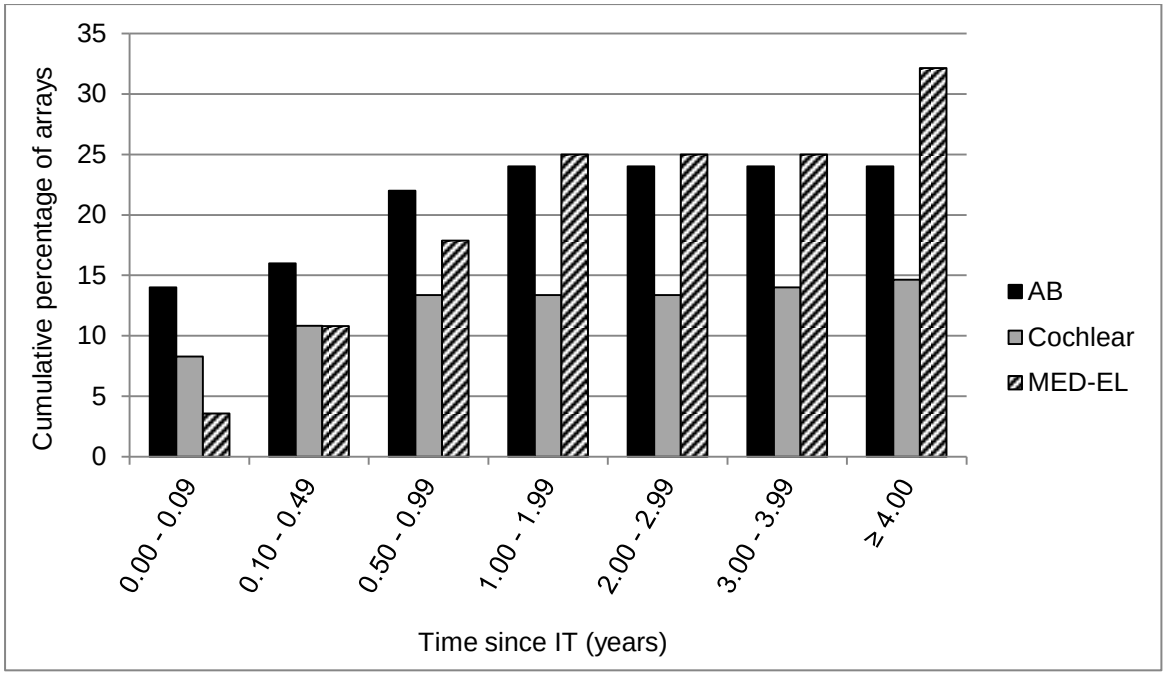


Figure 10: The cumulative percentage of arrays from each manufacturer with one or more electrode deactivations at different time points from initial tuning onwards

Examining the timing of individual electrode deactivations in each manufacturer's arrays, table 9 shows the median time, interquartile range and modal time from IT to first ED in an array by manufacturer. The difference in the timing of ED between AB/Cochlear and MED-EL can be seen more clearly.

Table 9: Median time, interquartile range and modal time from initial tuning to first electrode deactivation in an array for each manufacturer

Manufacturer	Median time to ED (years)	Interquartile range (years)	Modal time to ED (years)
AB	0.05	0.00 – 0.80	0.00 – 0.09
Cochlear	0.27	0.00 – 0.62	0.00 – 0.09
MED-EL	1.54	0.23 – 3.31	1.00 – 1.99

Figure 11 shows the cumulative percentage of arrays with ≥1 ED from initial tuning onwards for straight and pre-curved arrays. The pattern reflects the difference between AB/Cochlear (pre-curved arrays) and MED-EL (straight arrays) mentioned above. There was a strong association between array type and time to first deactivation event in an array [Freeman-Halton (n=44) = 12.5, P = .02, Cramer's V = .54].

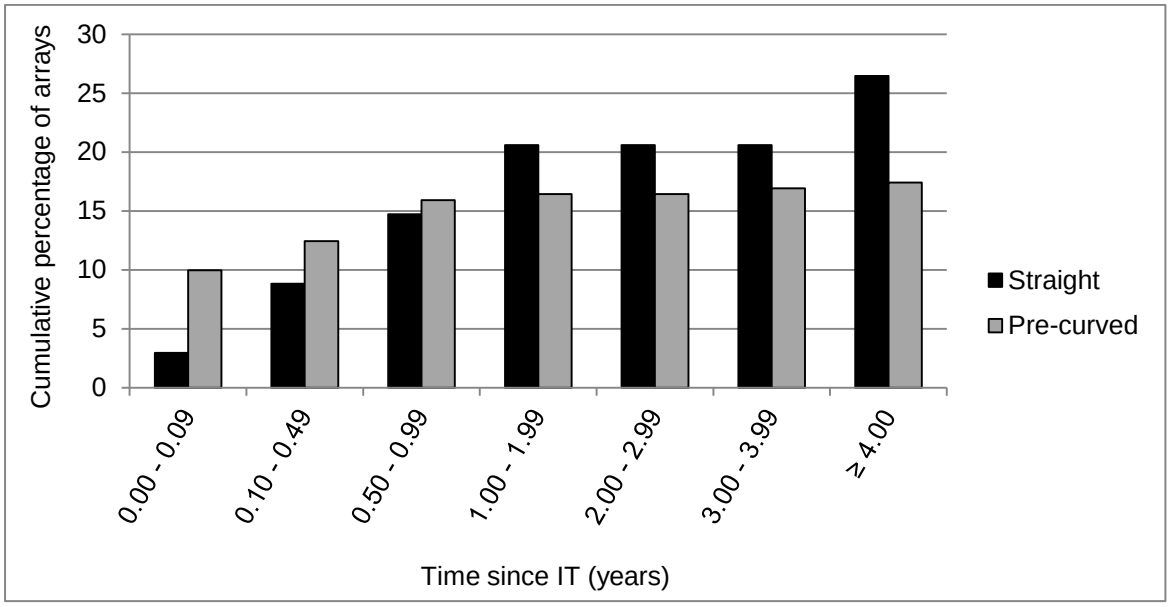


Figure 11: The cumulative percentage of straight and pre-curved arrays with one or more electrode deactivations at different time points from initial tuning onwards

Analysing the timing of individual electrode deactivations in straight and pre-curved arrays, table 10 shows the median time, interquartile range and modal time from IT to first ED in an array for each array type. The results reflect the timing of deactivations in the AB/Cochlear (pre-curved) and MED-EL (straight) arrays.

Table 10: Median time, interquartile range and modal time from initial tuning to first electrode deactivation in pre-curved and straight arrays

Array type	Median time to ED (years)	Interquartile range (years)	Modal time to ED (years
Pre-curved arrays	0.19	0.00 – 0.80	0.00 – 0.09
Straight arrays	1.54	0.23 – 3.31	1.00 – 1.99

4.2.2 Array data available at different time points from initial tuning onwards

Figure 12 shows the number of arrays from each manufacturer with data available at different time points from initial tuning onwards. Only a small number of arrays from all three manufacturers had been implanted for ≥4 years. The oldest Cochlear array had been in use for 5.1 years, while for AB it was 6.2 years and MED-EL, 7.6 years.

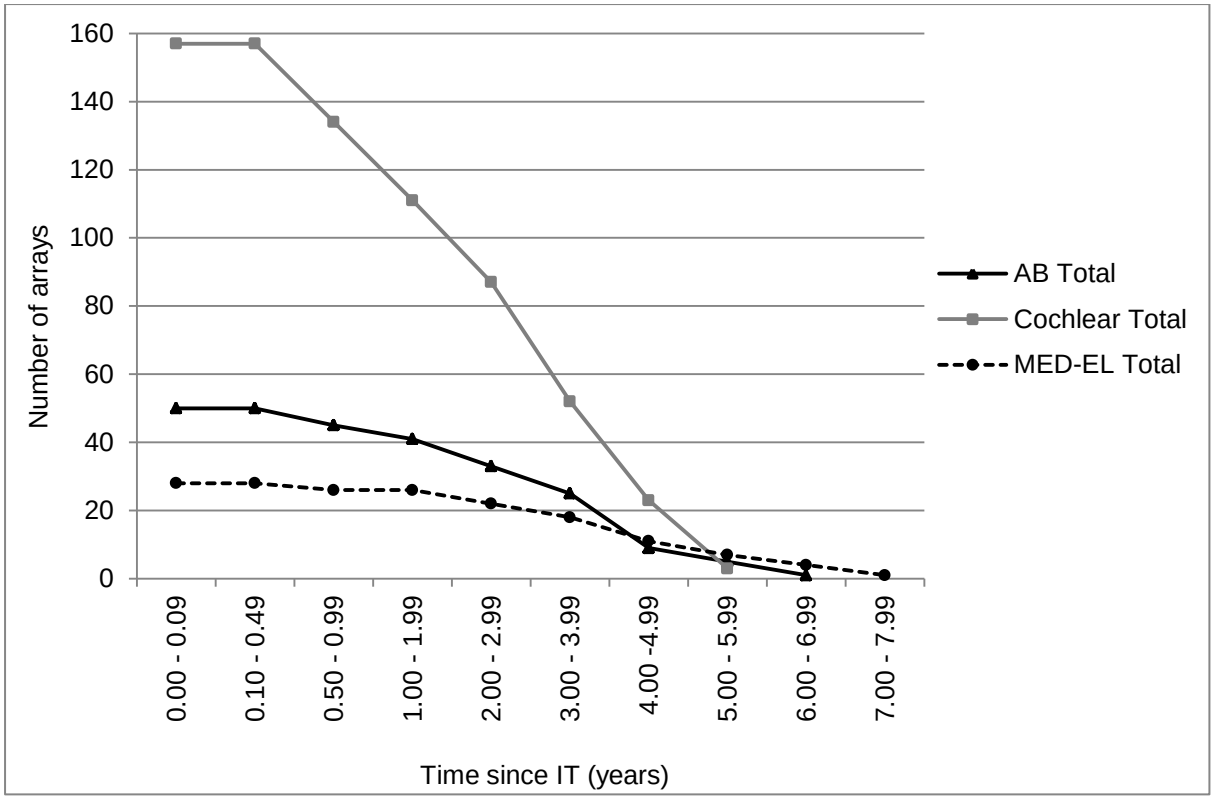


Figure 12: The number of arrays from each manufacturer with data available at different time points from initial tuning onwards

4.2.3 Array age and number of ED

To examine whether arrays accumulated ED over time (i.e. the number of ED in an array was simply a factor of array age), the number of ED in each array was plotted against the length of time the array had been in use (figure 13). There was no statistically significant association between array age and the number of electrode deactivations in an array [Freeman-Halton (N=235) Monte Carlo significance *P* = .08 [.07, .08]].

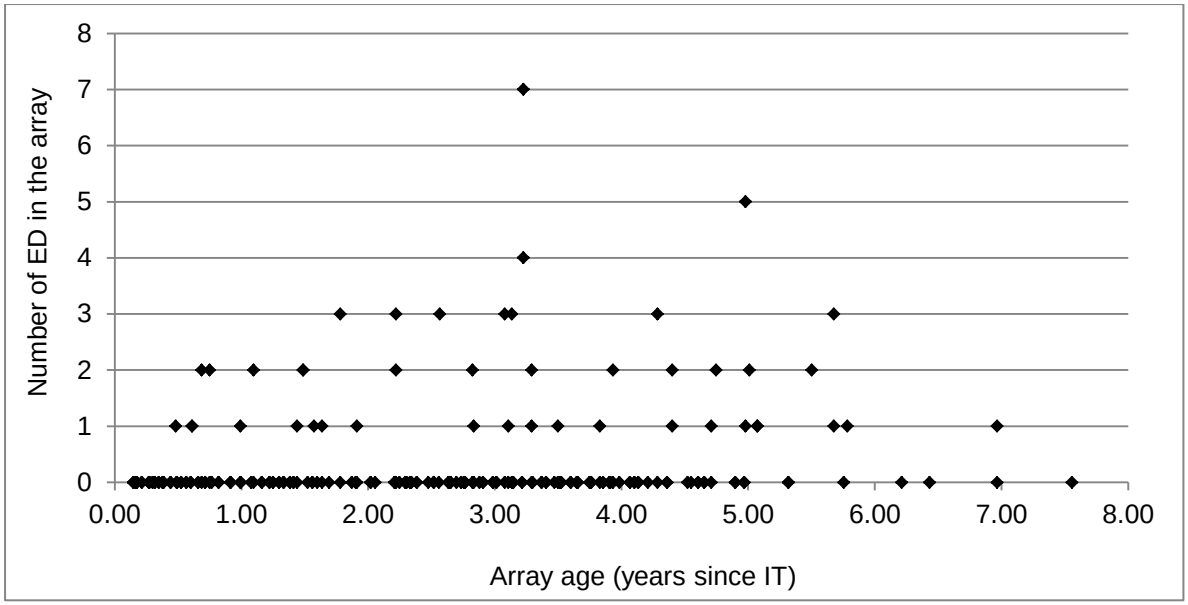


Figure 13: The number of electrode deactivations in an array against array age (in years since initial tuning). The number of electrode deactivations did not rise with increased length of implant use.

4.3 Spatial characteristics of ED

51.2% of ED occurred in the lower basal region with the remainder of deactivations spread relatively evenly along the rest of the array (figure 14). The middle regions saw slightly fewer deactivations overall than the apical areas. The distribution was statistically significant [X^2 (5, n=84) = 74.1, P <.001].

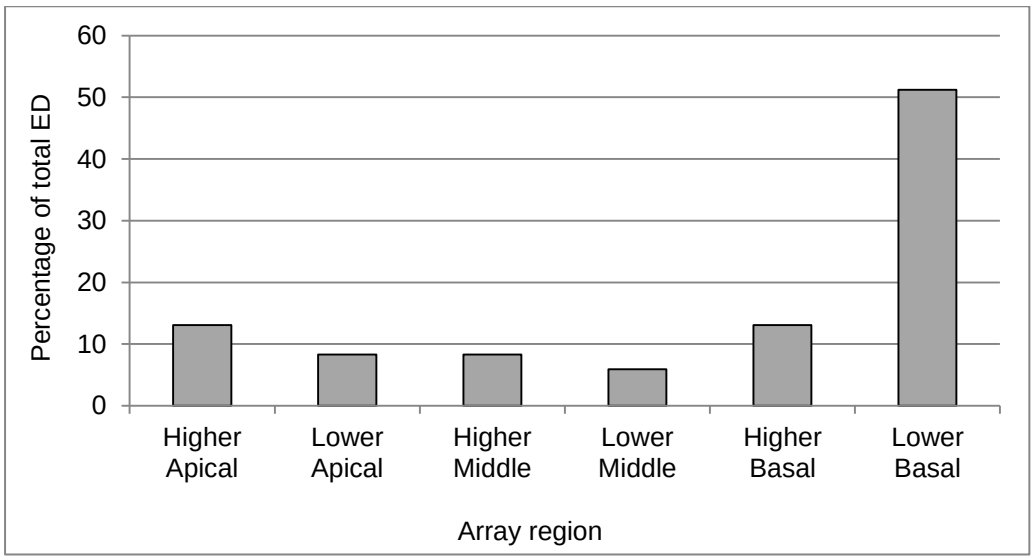


Figure 14: The percentage of electrode deactivations occurring in different regions along the array. The lower basal region is closest to the round window and the higher apical region is closest to the cochlear apex.

All three manufacturers had most deactivations in the lower basal region, with 70% of ED in AB arrays occurring in this region. Both Cochlear and MED-EL had least deactivations in the middle regions while for AB it was in the apical regions (figure 15). The difference in distribution was statistically significant with a moderate strength of association [Freeman-Halton (n=84) = 17.0, *P* = .03, Cramer's V = .34].

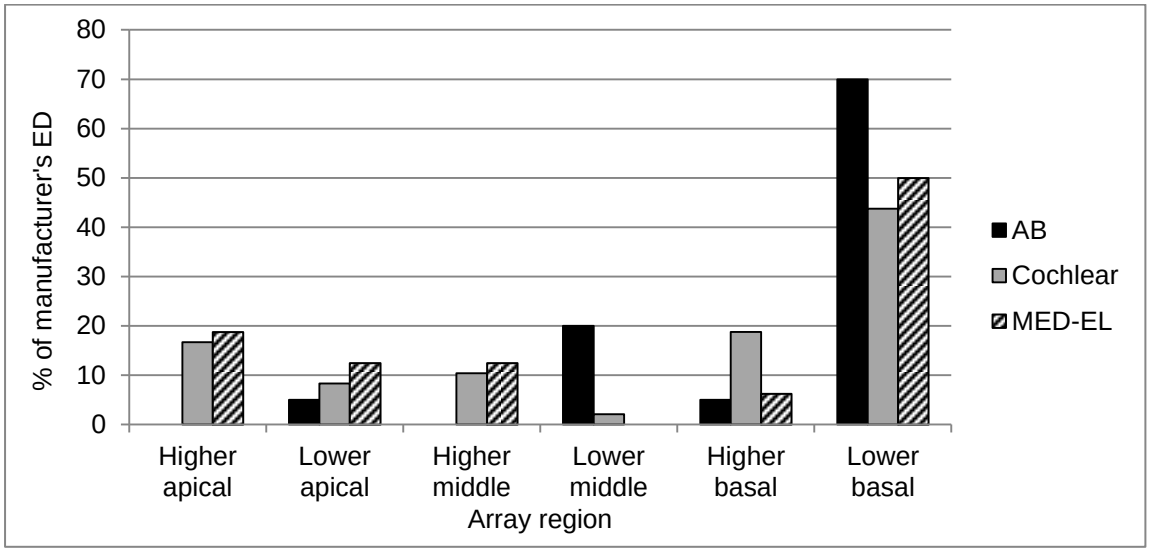


Figure 15: The percentage of electrode deactivations in different regions along the array, by manufacturer

Both straight and pre-curved arrays saw most ED in the lower basal region. Remaining deactivations were spread fairly evenly along the array in pre-curved arrays but were slightly skewed towards the upper half of the array in straight arrays (figure 16). The difference in distribution was not statistically significant [Freeman-Halton (n=84) = 3.2, *P* = .67].

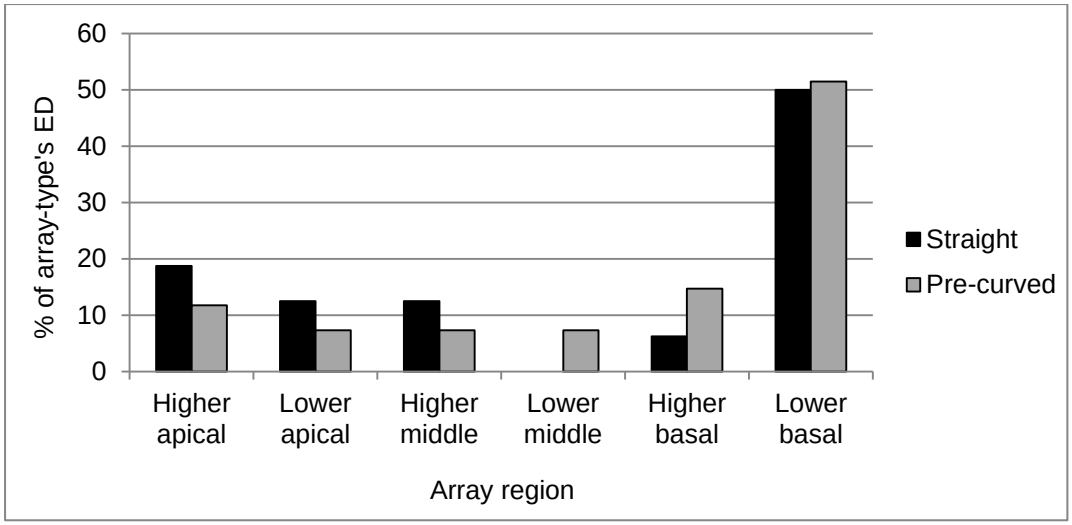


Figure 16: The percentage of electrode deactivations in different regions along the array, by array type

4.4 Causal characteristics of ED

Open circuits were the most common reason for ED followed by short circuits. Together, these electrode faults accounted for over 36% of deactivations. Absent or abnormal nerve responses or no auditory percept accounted for another 30%, with NAS, sound quality complaint, extracochlear electrodes and tip fold-over making up the remainder (figure 17).

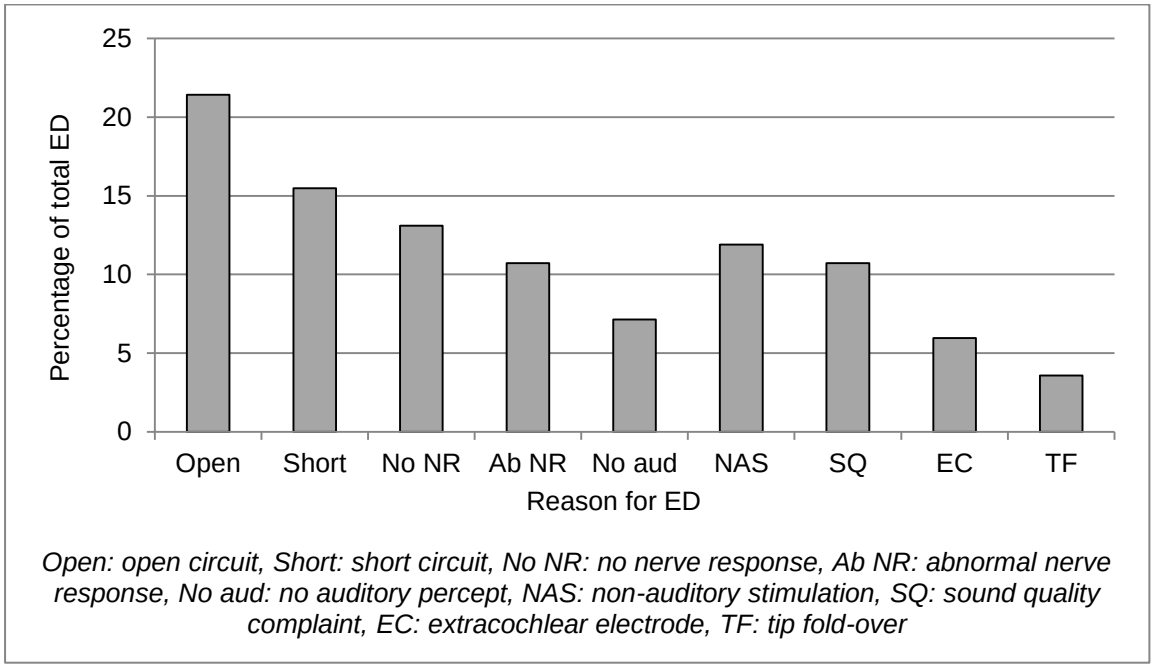
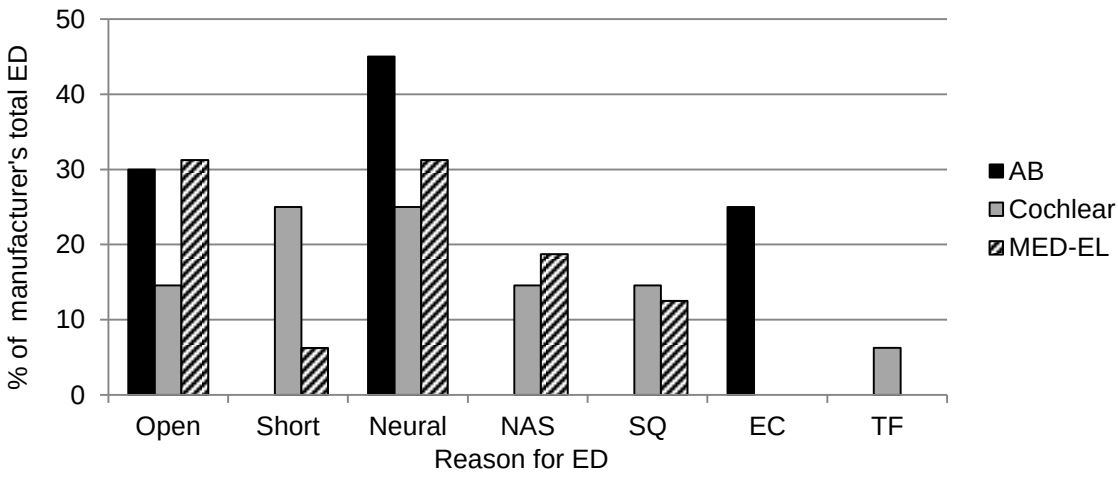


Figure 17: The percentage of electrode deactivations associated with each reason for deactivation

Figure 18 shows the percentage of ED for each reason for deactivation by manufacturer. The difference between manufacturers was statistically significant with a moderate strength of association [Freeman-Halton (n=84) = 31.9, *P* = .001, Cramer's V = .47]. To aid plotting, absent and abnormal nerve responses and no auditory percept were combined into one 'neural' category in figure 18.



Open: open circuit, Short: short circuit, Neural: no nerve response, abnormal nerve response or no auditory percept, NAS: non-auditory stimulation, SQ: sound quality complaint, EC: extracochlear electrode, TF: tip fold-over

Figure 18: The percentage of electrode deactivations for each reason, by manufacturer

Figure 19 shows the percentage of ED for each reason for deactivation in straight and pre-curved arrays. Only pre-curved arrays had deactivations for extracochlear electrode or tip fold-over reasons. The differences were not statistically significant [Freeman-Halton (n=84) = 4.3, *P* = .86].

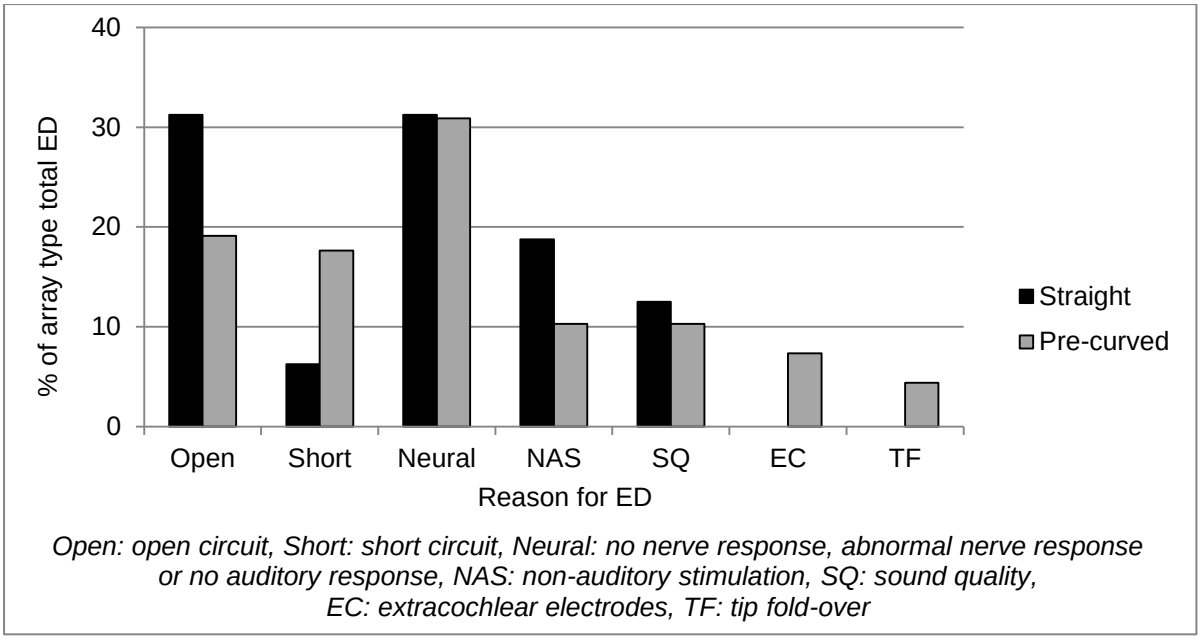


Figure 19: The percentage of electrode deactivations for each reason, by array type

4.5 Causal characteristics and array region

Overall, the reason for ED was strongly associated with the location of the deactivation in the arrays [Freeman-Halton (n=84) = 73.0, Monte Carlo *P* <.001 [<.001, <.001], Cramer's V = .50].

At manufacturer level, the reason for ED was strongly associated with the location of the deactivation in the array in AB and Cochlear arrays but not in MED-EL arrays [*AB:* Freeman-Halton (n=20) = 16.9, *P* = .02, Cramer's V = .55; *Cochlear:* Freeman-Halton (n=48) = 63.3, *P* <.001, Cramer's V = .58; *MED-EL:* Freeman-Halton (n=16) = 27.0, *P* = .22].

Comparing array types, the reason for ED and the location of deactivation in the array were strongly associated in pre-curved arrays but not in straight arrays [*Pre-curved*: Freeman-Halton (n=68) = 72.2, *P* <.001, Cramer's V = .57; *Straight*: Freeman-Halton (n=16) = 27.0, *P* = .22].

4.6 Breakdown of causal characteristics and array region

4.6.1 Open and short circuits in different array regions

Short circuits were seen in only the upper half of arrays while open circuits occurred along the array but with highest incidence in the lower half (figure 20).

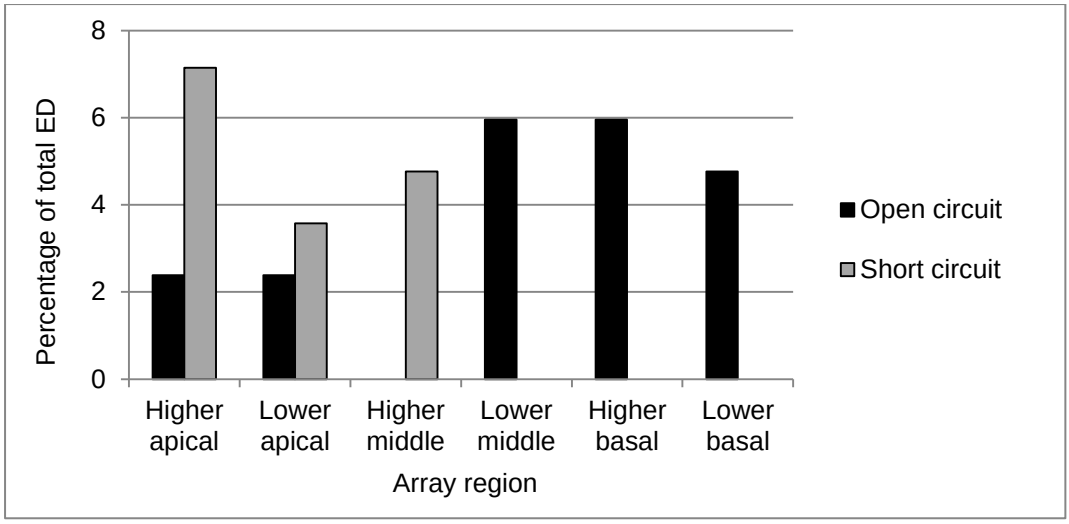


Figure 20: The percentage of electrode deactivation due to open and short circuits in different regions of the array

Open circuits occurred most often in the lower middle region in AB arrays, the higher basal region in Cochlear arrays and at either end of the array in MED-EL arrays (figure 21).

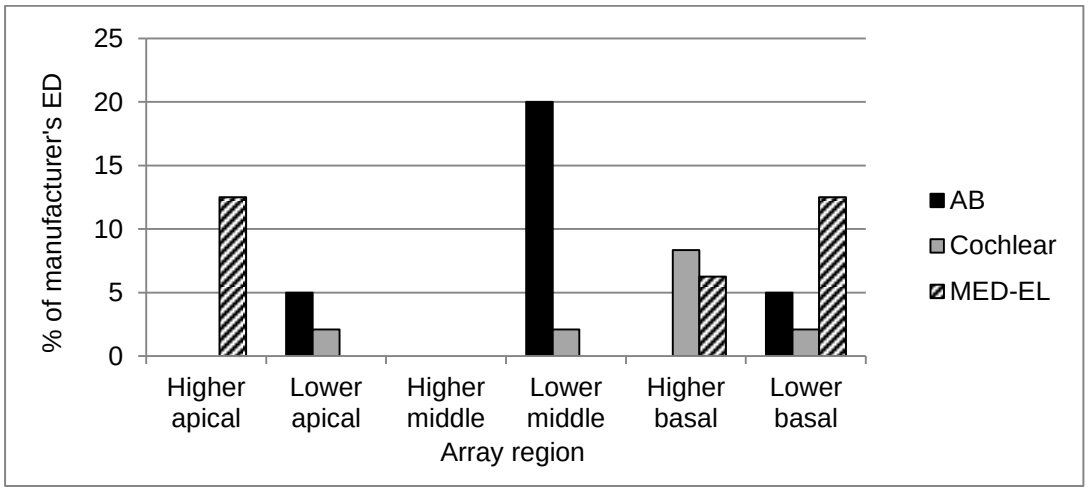


Figure 21: The distribution pattern along the array of open circuits, by manufacturer

No AB arrays and only one MED-EL array had an electrode deactivation for a short circuit. Cochlear arrays saw short circuits across the upper half of the array (figure 22) and accounted for 92% of short circuits in the study.

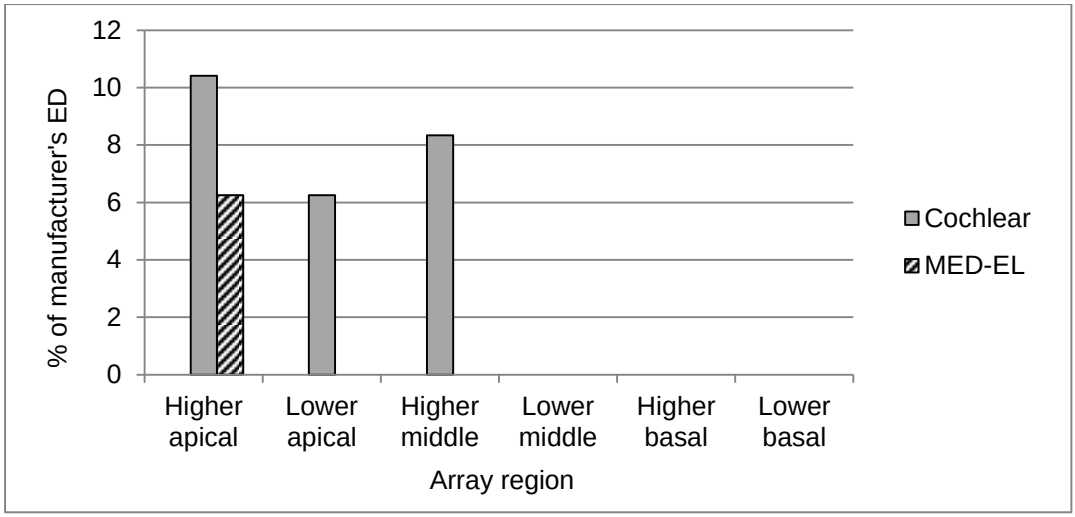


Figure 22: The distribution pattern along the array of short circuits, by manufacturer

Open circuits occurred in only the basal and higher apical regions in straight arrays. In pre-curved arrays they occurred predominantly in the lower half of the array with a small number of occurrences also in the lower apical region (figure 23).

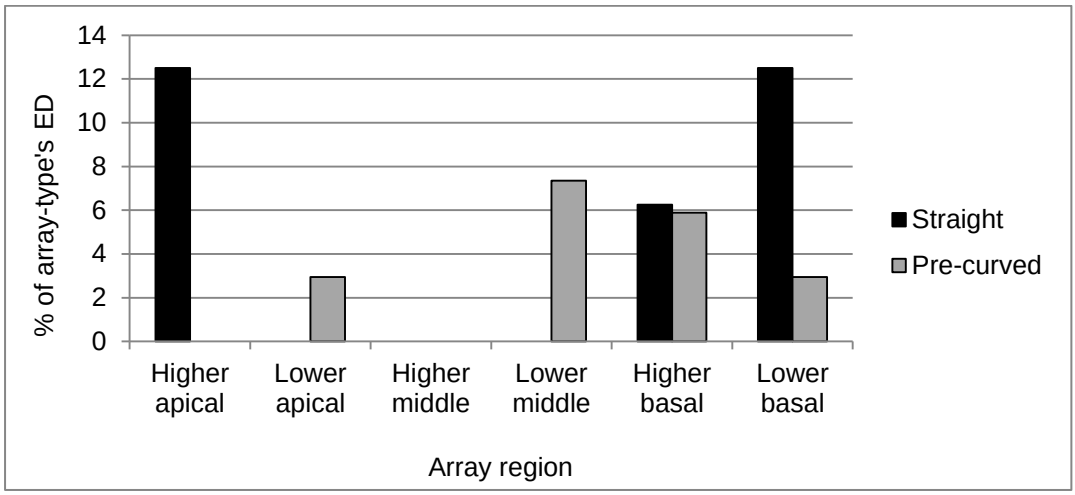


Figure 23: The distribution pattern along the array of open circuits, by array type

Electrode deactivations for short circuits occurred in only Cochlear CI512 (pre-curved) and MED-EL (straight) arrays so results for the array-type comparison were identical to the manufacturer comparison.

4.6.2 Absent or abnormal nerve response and absent auditory percept in different array regions

The distribution of ED due to absent or abnormal nerve response or absent auditory percept was strongly skewed towards the basal end of the array (figure 24).

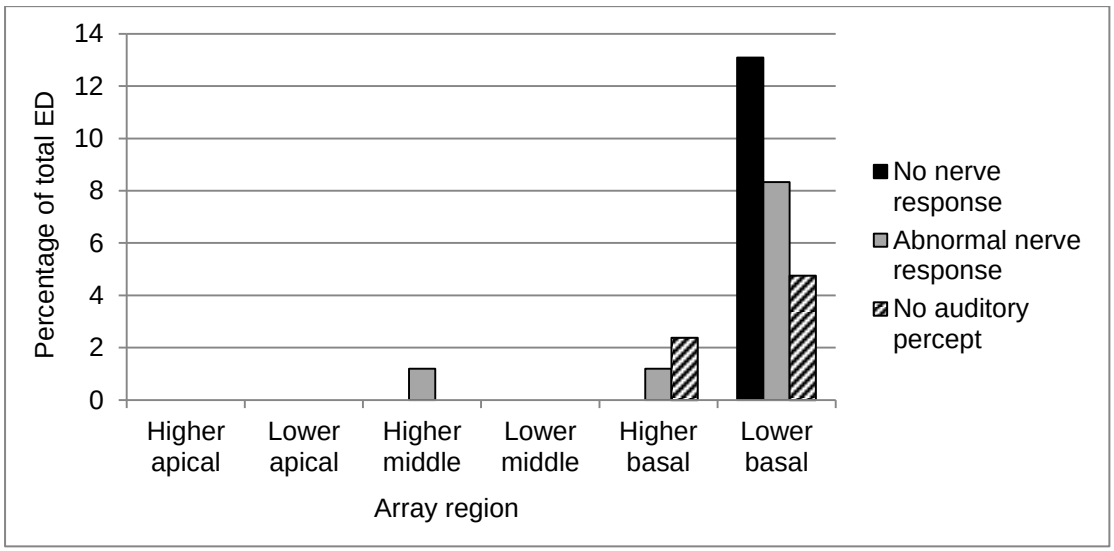


Figure 24: The percentage of electrode deactivations due to absent or abnormal auditory nerve response or absent auditory percept in different regions of the array

Comparing manufacturers, ED for absent nerve response occurred in only the lower basal region for all three manufacturers. ED for abnormal nerve response occurred in only the lower basal region in AB and MED-EL arrays, and the basal and higher middle regions in Cochlear arrays. ED for absent auditory percept was found in only the lower basal region in AB and MED-EL arrays and in only the higher basal region in Cochlear arrays. Figure 25 shows the distribution along the array of ED for these neural reasons, by manufacturer, with absent and abnormal nerve responses and no auditory percept combined into one category to allow plotting.

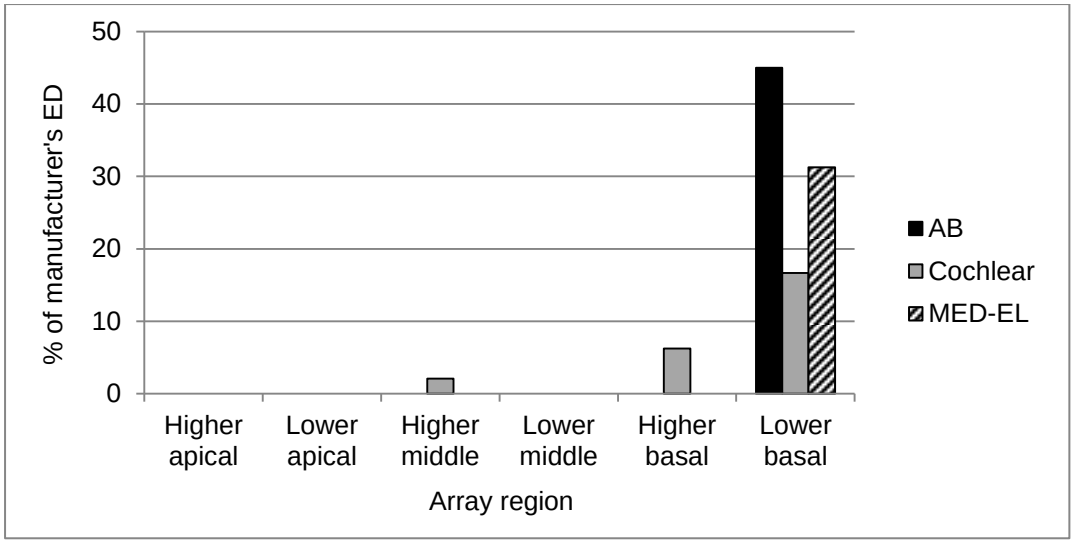


Figure 25: The distribution pattern along the array of electrode deactivations for neural reasons (no nerve response, abnormal nerve response or no auditory percept), by manufacturer

Figure 26 shows the distribution along the array of ED for neural reasons by array type. Deactivations occurred most often in the lower basal region in both pre-curved and straight arrays.

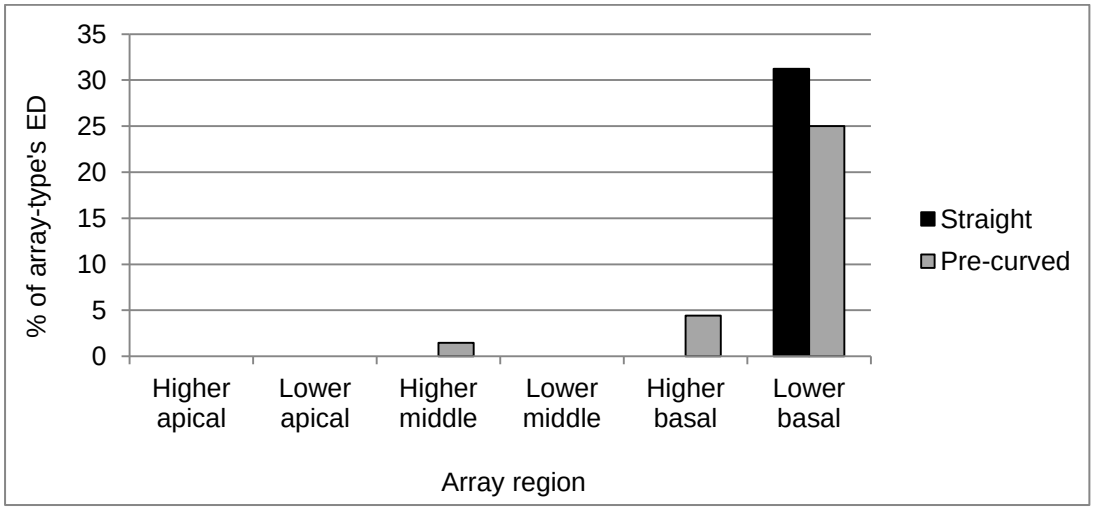


Figure 26: The distribution pattern along the array of electrode deactivations for neural reasons (no nerve response, abnormal nerve response and no auditory percept), by array type

4.6.3 Non-auditory stimulation and sound quality complaint in different array regions

Electrode deactivations for NAS and sound quality complaint occurred in multiple array regions but were seen most often in the lower basal region (figure 27).

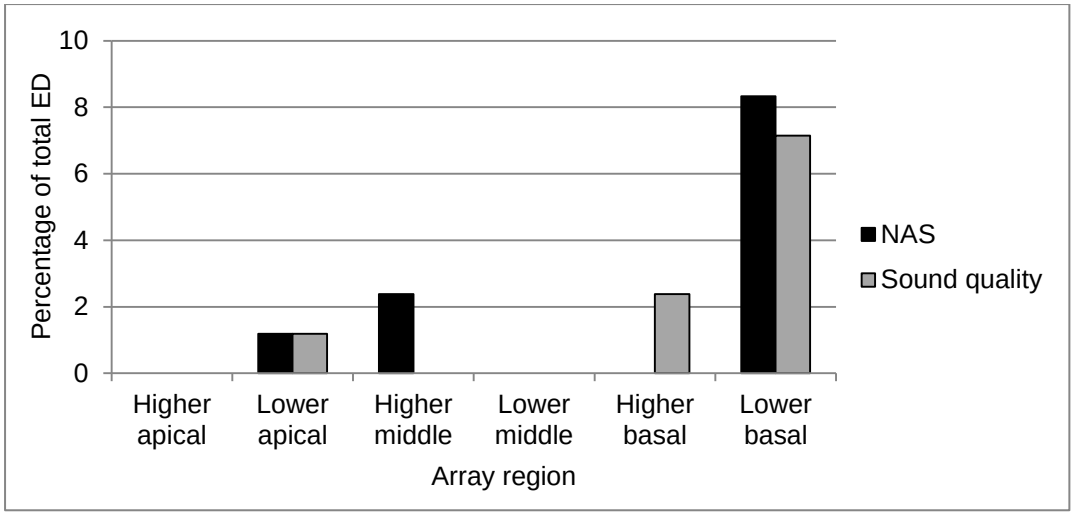


Figure 27: The percentage of electrode deactivations due to non-auditory stimulation and sound quality complaint in different array regions

Electrode deactivation for NAS was not found in AB arrays. All occurrences in Cochlear arrays were in the most basal electrodes while MED-EL arrays saw occurrences in the higher middle and lower apical regions (figure 28).

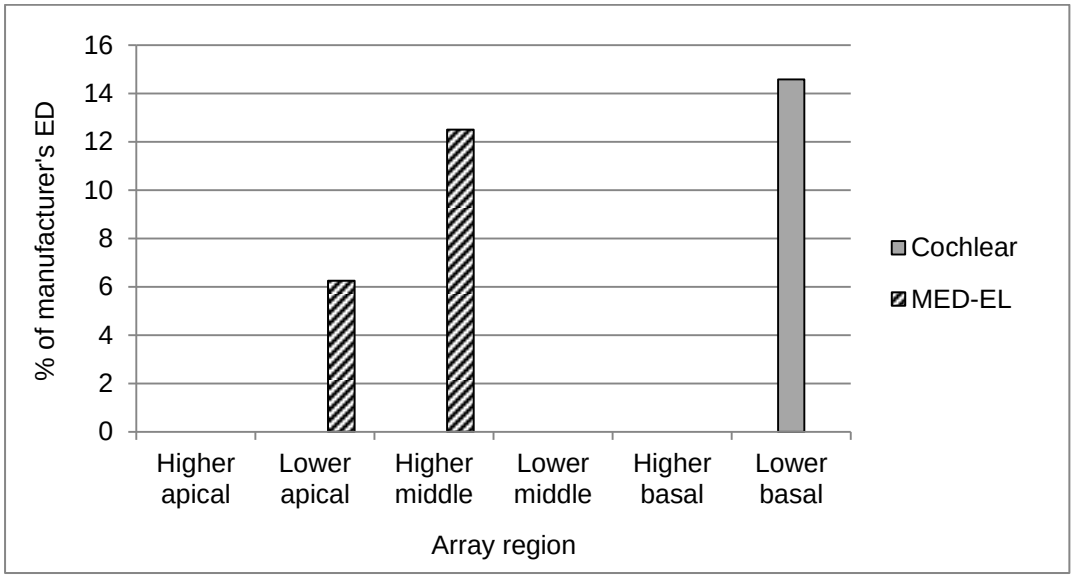


Figure 28: The distribution pattern along the array of non-auditory stimulation, by manufacturer

ED for sound quality complaint was not seen in AB arrays. In Cochlear arrays it occurred in only the basal regions, while in MED-EL arrays it occurred in both lower basal and lower apical regions (figure 29). The lower apical deactivation was found in one MED-EL array where neighbouring electrodes were deactivated due to open

circuits. It is possible that the cause of the open circuits also affected sound quality at this electrode.

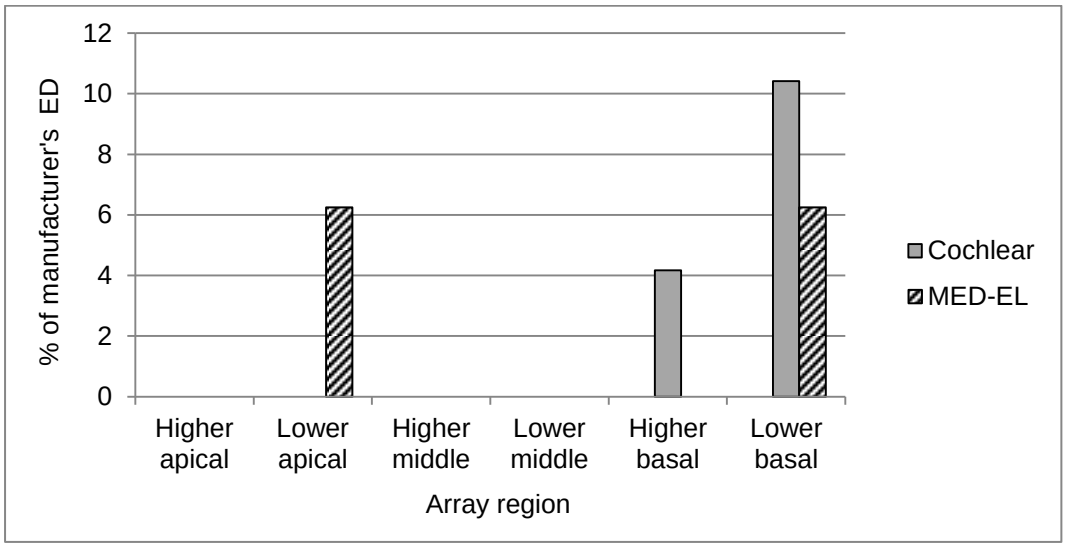


Figure 29: The distribution pattern along the array of sound quality complaint, by manufacturer

Deactivations for NAS and sound quality complaint occurred in only Cochlear CI512 (pre-curved) arrays and MED-EL (straight) arrays so the results for the array-type comparison were identical to the manufacturer comparison.

4.7 Temporal characteristics of different reasons for ED

Table 11 shows the median time, interquartile range and modal time from IT to ED event for different reasons for ED. Time to ED was likely influenced by the reason for the deactivation. Open circuits, short circuits and absent or abnormal nerve responses can be measured objectively using the manufacturers' software so do not require input from the patient, and NAS is visible to the audiologist if it causes facial nerve twitching. In contrast, sound quality complaint and absent auditory percept require feedback from the patient (or persistent absence of response to electrode stimulation in the case of a young child). Extracochlear electrodes and tip fold-over identified during surgery or on post-surgical X-ray were deactivated at initial tuning.

Table 11: Median time, interquartile range and modal time from initial tuning to electrode deactivation for different reasons for deactivation

Reason	Median time to ED (years)	Interquartile range (years)	Modal time (years)
Open circuit	0.00	0.00 – 0.17	0.00 – 0.09
Short circuit	0.55	0.28 – 0.97	0.50 – 0.99
No nerve response	0.28	0.02 – 2.36	0.00 – 0.09
No auditory percept	1.89	1.46 – 2.32	1.00 – 1.99
Abnormal nerve response	0.51	0.30 – 0.80	0.50 – 0.99
Non-auditory stimulation	0.06	0.00 – 0.06	0.00 – 0.09
Sound quality complaint	3.04	0.32 – 3.09	0.10 – 0.49
Extracochlear electrode	0.00	0.00 – 0.00	0.00 – 0.09
Tip fold-over	0.00	0.00 – 0.00	0.00 – 0.09

5. DISCUSSION

This chapter discusses the key findings of the data analysis, setting them within the context of previous and ongoing research. The chapter also reflects on the limitations of the study and considers the implications of the study findings for further research and for clinical practice.

5.1 Incidence of ED

In the present study, 19% of arrays had ≥1 ED and 2% of electrodes were deactivated, significantly lower than the 54% of arrays and 8% of electrodes reported by Schow et al. (2012). 9% of the arrays in the present study had deactivations at IT, similar to the 11% of arrays in the Francis et al. (2008) study, but at one year post-IT the percentage of ED in the newer arrays had only increased to 16% compared with 23% in the Francis study. This suggests that improvements in array design, surgical technique and/or tuning developments have resulted in a decreased incidence of electrode deactivation in the newer arrays.

During data collection for the present study it was observed that electrode deactivation is occasionally temporary, as in a small number of arrays one or more electrodes had been deactivated for a while and then reactivated again. (These historic deactivations were not included in the study as they were not present on 31 August 2019.) This change in electrode status may relate to the age or listening experience of the patient at the time of initial deactivation. Very young patients (and older children with limited experience of hearing) cannot provide detailed feedback on their hearing when the implant is first activated but this skill develops with age and listening experience. Once a certain level of maturity/experience is reached the child's involvement in tuning decisions increases and (depending on the original reason for deactivation) a disabled electrode may be re-trialled in a patient's MAPs. If the trial is successful the electrode is left re-activated.

5.2 Number and timing of ED

The vast majority of arrays in the present study (81%) had no ED. Where an array had a deactivation it involved only a single electrode in 9% of cases, two electrodes in 6% of cases and three electrodes in 3% of cases. It was rare for an array to have more than 3 electrodes deactivated. Of the electrode deactivations that occurred,

40% did so at IT, with 75% occurring by one year post-IT and 85% by two years post-IT. This suggests that ED is most likely to occur during the first year or two of implant use, confirming previous findings by Francis et al. (2008) and Sanderson et al. (2019). At manufacturer level, <4% of MED-EL arrays had deactivations at IT compared with 14% of AB arrays and 8% of Cochlear arrays. However, while the majority of ED in Cochlear and AB arrays had occurred by 1 year post-IT, deactivations in MED-EL arrays continued to increase over the first two years of implant use. This difference may relate to array-type rather than manufacturer. The AB and Cochlear arrays with ED were pre-curved while the MED-EL arrays were straight and there may be differences in how the two array types interact with, and respond to, changes in the cochlear environment post surgery. Shaul et al. (2019) studied impedance spikes (sudden unexpected increases in electrode impedance, defined as a median rise of ≥4kΩ across all array electrodes) in pre-curved and straight arrays from Cochlear. Patients with pre-curved arrays experienced more spikes in the first 12 months of implant use, while patients with straight arrays experienced more spikes between 12 and 24 months, with the study reporting a higher overall rate of impedance spikes in the straight arrays. This mirrors the overall pattern of ED timing and incidence of deactivations in pre-curved and straight arrays in the present study, suggesting that spikes and some causes of ED may result from similar cochlear processes. In Shaul et al.'s study, over half of patients experiencing spikes had a concurrent inner ear event such as onset of tinnitus, vestibular dysfunction or loss of post-implant residual hearing compared with fewer than 20% of non-spike patients. Many of the present study's paediatric patients were implanted at a young age making it unlikely they would report such events, and post-implant residual hearing is not routinely tested in paediatric patients (unless they are using electro-acoustic stimulation). Shaul et al. further reported that impedance levels often failed to return to pre-spike levels, leading the researchers to conclude that spike episodes are associated with cochlear inflammation that increases cochlear fibrosis and leads to permanently raised impedance levels. (The effect of fibrosis on ED is discussed in 5.4.1.2). Shaul et al. comment that the lateral wall of the cochlea (along which straight arrays sit) has a role in immune surveillance and immune system regulation meaning straight arrays may elicit a stronger foreign-body response, while pre-curved arrays are associated with greater ossification in the basal turn of the cochlea which may explain the higher incidence of early spikes in this array type.

5.3 Reason for ED

5.3.1 Incidence of open and short circuits

In the present study, 6% of arrays had an open circuit and 3% had a short circuit, similar to the incidence reported in Carlson et al.'s study (2010). The 2:1 occurrence ratio of open circuits to short circuits and the incidence of electrode failure in straight and pre-curved arrays are also very similar to those reported in the Carlson study. Newbold et al. (2015) reported most electrode failures were present at IT. In the present study, this held true only for open circuits in AB and Cochlear arrays. Short circuits in these arrays occurred during the first year of implant use, while short and open circuits in MED-EL arrays typically occurred at around 18 months post-IT. In pre-curved arrays, nearly all deactivations for open circuits occurred at initial tuning. As open circuits caused by tissue, air or protein build-up on the electrode contact may sometimes resolve over time, Wolfe and Schafer (2015) recommend re-evaluating any electrode deactivated due to an open circuit at IT once consistent implant use has been established.

92% of short circuits recorded in the present study occurred in Cochlear CI512 arrays, though it should be noted that this incidence equated to only 3% of CI512 arrays (5/151) and in each case a circuit shorted to 2-3 neighbouring electrodes. All deactivations occurred in the upper third of the array (electrodes 14-22). The spatial distribution suggests that electrodes and/or wiring in this portion of the array may be more prone to damage during surgical insertion, though no deactivations for short circuits occurred at initial tuning suggesting that surgical factors alone cannot explain why these short circuits occurred.

5.3.2 Incidence and timing of NAS and sound quality complaint

In the present study, all deactivations due to NAS occurred within the first month of implant use, a much smaller timeframe than that reported by Berretini et al. (2011). The present study also saw many fewer deactivations due to NAS than was reported by Zeitler et al. (2008) (12% in the newer arrays compared to 47% in the Zeitler study) suggesting that array design and/or advances in implant tuning have reduced the incidence of this problem. Incidence of sound quality complaint was only marginally higher in the present study than in Zeitler et al.'s paper, 11% compared to

7%. Nearly all sound quality complaints involved basal electrodes so may be linked to poor spiral ganglion survival (Nadol, 1997). Hearing experience may also play a role as Vaerenberg et al. (2014) have commented that audiologists rely on patient subjective feedback to decide on MAP changes for sound quality reasons and a patient's judgement may not align with optimal performance. Vaerenberg et al. suggest that a patient who has never had normal hearing or has been deprived of it for many years prior to implantation may lack a clear reference point against which to make judgements on sound quality.

5.3.3 Extracochlear electrodes

Although previous studies have suggested straight arrays are at greater risk of extracochlear electrodes, in the present study only AB arrays (all pre-curved) had ED for this reason. However, it is possible that other arrays may have experienced electrode extrusion in the months and years following implantation, resulting in electrode deactivations for other reasons without the audiologist realising array migration had occurred (see 5.4.1.1).

5.4 Location of ED

In the present study, 64% of ED was in the basal region of the arrays, with 51% occurring in the lower basal region closest to the round window. Overall, the distribution of ED along the array was similar to that reported in previous studies. There was a strong association between reason for ED and location of ED in Cochlear and AB arrays. The apparent lack of association in MED-EL arrays may have been due to the much smaller group size for this manufacturer so the result should be treated as inconclusive rather than evidence of no association (see 5.5.1).

5.4.1 Deactivation of basal electrodes

As with previous studies (e.g. Francis et al., 2008; Sanderson et al., 2019; Schow et al., 2012), in the present study ED occurred most frequently in the basal region of the array, particularly the area closest to the round window. This was particularly true for AB arrays which saw 70% of ED affecting only electrodes 15 and 16, the most basal electrodes. The basal region is where electrodes stimulate neurons usually associated with high frequency sounds. Many causes of deafness result in greatest losses in the high frequencies and it is possible that some causes of deafness affect

not only the inner hair cells but also the health of spiral ganglion neurons and/or auditory nerve fibres in this region of the cochlea. Other possible explanations for the high incidence of ED in the basal region include array migration and fibrosis.

5.4.1.1 Array migration

It is possible that unidentified post-surgery array migration may have occurred in some arrays in the present study. A post-surgery X-ray is carried out the day after surgery but Holder et al. (2018) have suggested that X-ray may not be a reliable means of identifying extracochlear electrodes. In addition, any migration occurring after the initial X-ray will be missed. Some deactivated electrodes at the most basal end of the array (disabled due to open circuits, abnormalities in nerve response, absent auditory percept, NAS or sound quality complaint) may be extracochlear with the reported reason for deactivation actually being the result of electrical stimulation at the round window or outside the cochlea. At USAIS, if there is a concern that one or more electrodes are extracochlear the REVS test ['Recording of Electrode Voltages on the Skin' developed by Grasmeder (2017, 2020)] can be performed. The test involves placing three electrodes on the patient's head and recording the surface potential produced by each electrode when stimulated by the manufacturers' tuning software. Extracochlear electrodes produce a reverse polarity trace. If the REVS test suggests array movement has occurred an X-ray or CT scan can be performed to ascertain the array position.

70% of ED in AB arrays involved the two most basal electrodes. AB's mid-scala array sits in the middle of the scala tympani rather than along the lateral wall (like straight arrays) or the medial wall (like perimodiolar arrays). It is possible that reduced friction within the cochlea may lead to array migration and electrodes 15 and 16 becoming extracochlear in some patients (before the array position stabilises again). It is also possible that mid-scala arrays trigger greater fibrosis at the round window for some reason than either straight or perimodiolar arrays.

5.4.1.2 Fibrosis

Cochlear implantation triggers an inflammatory response which results in the formation of a fibrous sheath around the array and sometimes formation of new bone within the cochlea. This fibrotic response is most prevalent in the basal turn of the

cochlea near the round window (Li et al., 2007; Seyyedi & Nadol, 2014) and is unrelated to length of implant use (Ishai et al., 2017). The fibrotic response occurs in two stages. An initial acute response occurs at the time of surgery, caused by damage to the cochlear structures and/or disruption to cochlear fluids. This is then followed by a delayed inflammatory host-mediated foreign body response (FBR) when the body reacts to the presence of the array and the biomaterials that form it (Anderson et al., 2008; Sheikh et al., 2015; O'Malley et al., 2017). The FBR causes the formation of fibrous tissue which along with protein adhesion, new bone and/or changes in the composition of the fluids surrounding the electrodes leads to an increase in electrode impedance which affects electrode function (Foggia et al., 2019). Soft surgery techniques involving slow array insertion via the round window with minimal pressure are commonly used in an attempt to reduce intracochlear trauma and therefore the fibrotic response (Friedland et al., 2009). Contemporary research is focussing on further reducing the FBR through the use of Dexamethasone eluding arrays (Needham et al., 2020) and hydrogel array coatings (Leigh et al., 2019). FBR may be involved in electrode deactivations occurring after initial tuning but the present study did not include electrode impedance data so a potential association between changes in impedance levels and ED characteristics could not be evaluated.

5.4.2 Distribution of NAS along the array

In the present study, NAS occurred in only the higher basal region in Cochlear CI512 arrays (specifically electrodes 1-3) and in only the higher middle and lower apical regions in MED-EL FLEX28 arrays (specifically electrodes 4-6). Although different array regions are implicated in each array, when array type is considered it is found that the same extracochlear area may be being stimulated in both cases by current flow through the lateral wall of the cochlea. The Cochlear CI512 array is perimodiolar meaning it hugs the modiolus, while the MED-EL FLEX28 array is straight and lies along the lateral wall of the cochlea. When the spiral structure of the cochlea is considered and the deactivated electrode positions are drawn onto a photo of a membranous labyrinth (using the manufacturer's predicted electrode positions for an implanted array) it is evident that the two array regions sit close to the same extracochlear area (figure 30). The same non-auditory nerves could therefore be being stimulated in both cases. This information may be useful to

audiologists in cases involving these arrays where a patient reports intermittent NAS that cannot be reproduced in clinic. This possible association between NAS and ED location would not have been detected if only three rather than six array divisions had been used in the present study.

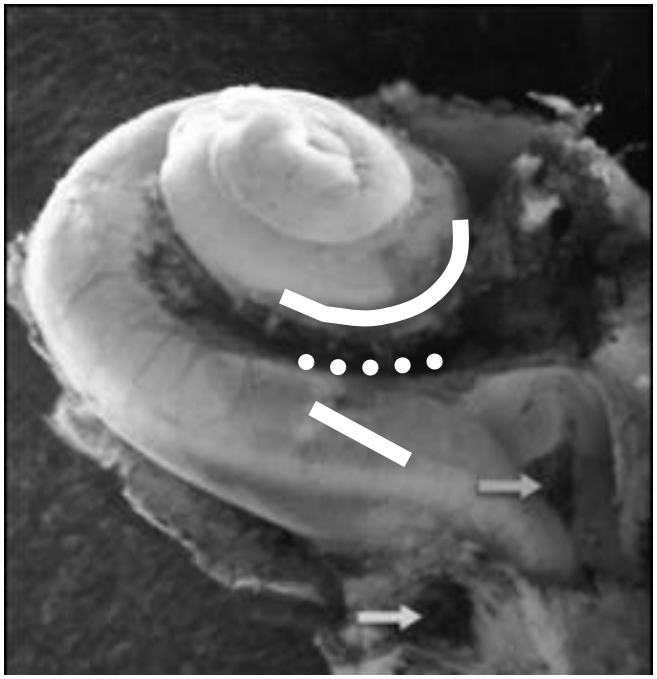


Image adapted from Lavigne-Rebillard (2016)

Key:

Upper white curve = predicted location of electrodes deactivated due to NAS in the MED-EL FLEX28 arrays (electrodes 4-6)

Lower white line = predicted location of electrodes deactivated due to NAS in the Cochlear CI512 arrays (electrodes 1-3)

Dotted white line = extracochlear region that both arrays may be stimulating

(The arrows are on the original photograph and point to the oval and round windows)

The post-implantation electrode positions are taken from diagrams in the manufacturers' surgeon guides (Cochlear, 2016a and MED-EL, n.d.)

Figure 30: The predicted location of the electrodes deactivated due to NAS in Cochlear CI512 and MED-EL FLEX28 arrays and the possible extracochlear region being unintentionally stimulated

5.5. Limitations of the study

5.5.1 Small group sizes for some manufacturers and array types

USAIS offers devices by three manufacturers and parents/patients are free to choose whichever manufacturer they prefer (unless a patient has a specific surgical or tuning need that can only be met with a particular manufacturer's device). It would be unethical for clinicians to attempt to influence parent/patient choice of manufacturer in order to implant an equal number of each manufacturer's devices for the purpose of making future research easier. As a result, group sizes in the present study varied significantly between manufacturers and for the different types of array.

In order to compare data from the different manufacturers and array types it was necessary to convert raw frequency data into percentages. As group sizes were

unequal the resulting percentages, though accurate for each manufacturer or array type, need to be compared with caution in order to avoid making inaccurate assumptions about what the data shows. Statistical tests of significance and strength of association were employed to safeguard internal validity and, as the data was not normally distributed, the use of the arithmetic mean to describe averages was avoided.

Small group sizes can sometimes affect the statistical power of tests performed on data. Lang and Secic (2006) have stated that for small sample sizes, large clinically relevant effects can sometimes be statistically insignificant due to insufficient data being available to identify a difference. In the present study, this problem may have affected the statistical results for MED-EL/straight arrays and possibly some results for AB arrays.

As there were only six Cochlear CI522 (straight) arrays in the study and none had ED it was not possible to determine whether the ED characteristics relating to MED-EL arrays were manufacturer specific or straight-array specific. This prevented any clear conclusions being drawn regarding differences in ED characteristics between pre-curved and straight arrays.

5.5.2 Length of time arrays had been in use

All arrays in the present study had been in use for at least a month by 31 August 2019 (the cut-off date for data to be included in the study) and at least 50% of the arrays from each manufacturer had been implanted for 3 years. However, only 18% of all arrays had been in use for over 4 years and only 6% for over 5 years. Although most ED appears to occur within the first two years of implant use, while there does not appear to be an association between age of array and number of ED in an array there was insufficient long-term data to emphatically confirm this.

5.6 Future steps

5.6.1 Expanding the group sizes

The present study has identified the temporal, spatial and causal characteristics of the newer arrays and has found differences between manufacturers and possibly array types. These findings now need to be confirmed and further developed through

a larger study. One option is to undertake a follow-on study incorporating data from the adult patients at USAIS and further data from the paediatric patients as their array use continues. By including both adult and paediatric patients, a total array group of at least 740 arrays could be achieved (consisting of approximately 120 AB arrays, 460 Cochlear arrays and 160 MED-EL arrays), significantly increasing the statistical power of the research.

In future, the study could be further extended to include other auditory implant services in the UK. This would not only increase the power of the study still further but would also reduce the effect of any centre-specific factors that might influence ED practice at local level. There is no nationally agreed guidance relating to electrode deactivation so it is possible that different audiologists and centres take slightly different approaches to the issue.

5.6.2 Electrode impedance levels and ED

FBR-induced fibrous tissue growth, protein adhesion, new bone growth and changes in the composition of fluids surrounding an electrode all affect electrode impedance and, as a result, electrode function. Electrode impedance levels are therefore a useful clinical outcome measure for assessing the functioning of an array within its cochlear environment. The present study could be broadened to investigate how changes in electrode impedance over time relate to the ED characteristics already identified. The need for such research is supported by the findings of Shaul et al. (2019) relating to impedance spikes (mentioned in 5.2 above) as the timing and incidence of spikes appeared to reflect the timing and incidence of ED found in the present study suggesting a possible connection between electrode impedance and ED characteristics.

5.6.3 ED and long-term speech perception performance

While the present study determined the key characteristics of ED, it did not investigate the effect of ED on patient speech perception. Previous research into the effects of electrode deactivation on speech perception has generated mixed results. Some studies have reported no long-term effects (Zeitler et al., 2008; Caiado et al., 2017), some studies that it has a negative effect (Schvartz-Leyzac et al., 2017) while others have suggested it may sometimes be beneficial (Sagi & Svirsky, 2018). Many

of the studies have involved adult subjects but as Francis et al. (2008) have pointed out, electrode deactivation may be more problematic for children than for adults as children's brains need the best auditory signal possible to support the development of good listening and language skills. It would therefore be interesting to evaluate the long-term speech perception performance of patients in the present study who have different numbers of deactivations and different patterns of deactivation (i.e. neighbouring electrodes versus non-neighbouring electrodes).

5.7 Comments for USAIS clinical practice

The study generated the following supplementary points for USAIS clinical practice.

- When an electrode has been deactivated at initial tuning due to exhibiting an open circuit, it may be appropriate to consider re-evaluating it after a period of implant use unless the impedance level at initial tuning was so high it could only have been due to a permanent fault in the electrode contact or lead.
- If a patient reports intermittent NAS with a Cochlear CI512 or MED-EL FLEX28 array and the problem cannot be replicated in clinic, it may be worth focusing on electrodes 1-3 in the Cochlear CI512 array or electrodes 4-6 in the MED-EL FLEX28 array as these electrodes appear most likely to be associated with NAS.
- When deactivating electrodes at the basal end of the array, consideration should be given as to whether the electrode(s) could be extracochlear. Of particular concern would be where multiple neighbouring basal electrodes are involved. If there are concerns that the array may have migrated or dislodged, the REVS test should be performed.

6. CONCLUSION

The present study analysed the temporal, spatial and causal characteristics of electrode deactivation in 235 arrays implanted in paediatric patients at USAIS - namely the Cochlear Nucleus CI512 Contour Advance array, Cochlear CI522 Slim Straight array, AB HiFocus Mid-Scala array and MED-EL FLEX28 array. The study was able to identify the incidence of electrode deactivation in these arrays and its temporal, spatial and causal characteristics. Potential associations between these characteristics were discovered. The study also determined that there are differences in the characteristics of electrode deactivation between different manufacturers, and possibly between different array types.

Overall, incidence of electrode deactivation was lower in the present study than in previous studies, though the incidence of open and short circuits was similar to previous reports suggesting there is still room for improvement in this area. The majority of arrays in the present study had no electrode deactivations. Where there were deactivations it usually affected only one electrode, with each additional electrode deactivation occurring more and more infrequently. The largest number of deactivations recorded in a single array was seven but very few arrays had four or more electrodes deactivated. When electrode deactivation occurred, it typically happened within the first two years of implant use, and within the first year in many cases. On average, electrode deactivation appeared to occur earlier in pre-curved arrays than in straight arrays. The timing of electrode deactivations was influenced by the reason for the deactivation. Deactivations for reasons requiring subjective feedback from the patient generally occurred later than deactivations for reasons that could be identified objectively through the manufacturer software or visible twitching of the facial nerve.

For all manufacturers and array types, the majority of electrode deactivations occurred in the basal region of the array and particularly the lower basal region closest to the round window. In AB arrays, 70% of deactivations involved one or both of the two most basal electrodes in the array.

Open circuits were the most common reason for electrode deactivation. Together with short circuits they accounted for over a third of deactivations. Neural issues (absent or abnormal nerve response or absent auditory percept) accounted for nearly another third; with NAS, sound quality complaint, extracochlear electrodes and tip fold-over together making up the remainder. Overall, there was a strong association between the reason for electrode deactivation and the location of the deactivation in the array.

The findings of this study have helped address a gap in knowledge regarding the incidence and characteristics of electrode deactivation in the newer generation of arrays. The study has evaluated current clinical practice at USAIS regarding electrode deactivation and has demonstrated the value of analysing routinely collected data. It has provided clinicians at USAIS with insights into their collective practice and highlighted areas worthy of further research.

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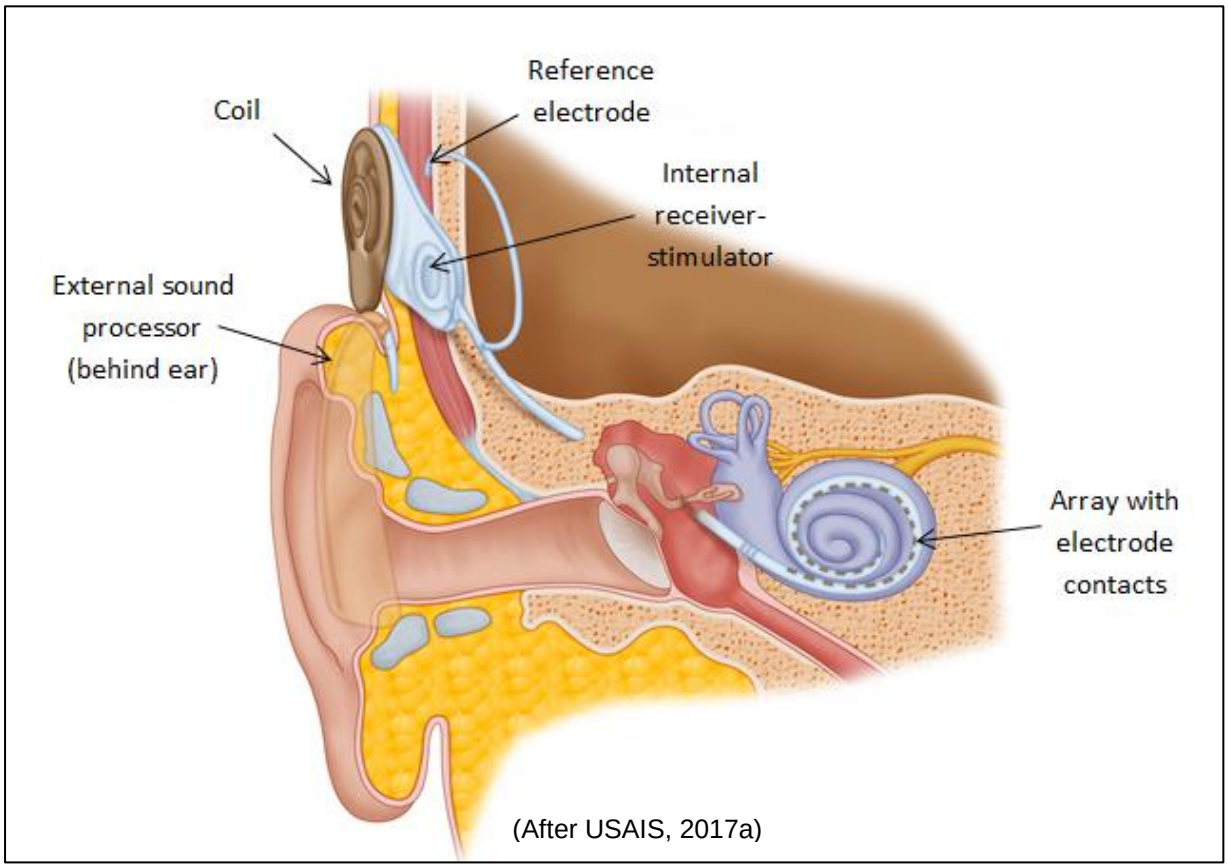
APPENDIX 1: How a cochlear implant works

A cochlear implant is a neuroprosthetic device consisting of a receiver-stimulator package, an electrode array and an external sound processor. During surgery, the receiver-stimulator package is placed under the skin behind the ear and an array of electrode contacts is inserted into the scalar tympani of the cochlea in the inner ear.

The external sound processor captures acoustic signals and processes the sound according to the parameters set in the user's MAPs (programmes). The resulting digital electrical code is converted to an electrical signal and sent to a headpiece coil where it is transmitted through the skin to a coil in the internal receiver-stimulator using electromagnetic induction. Magnets in the headpiece coil and receiver-stimulator coil ensure the two components stay aligned. The electromagnetic induction also provides power to the implant.

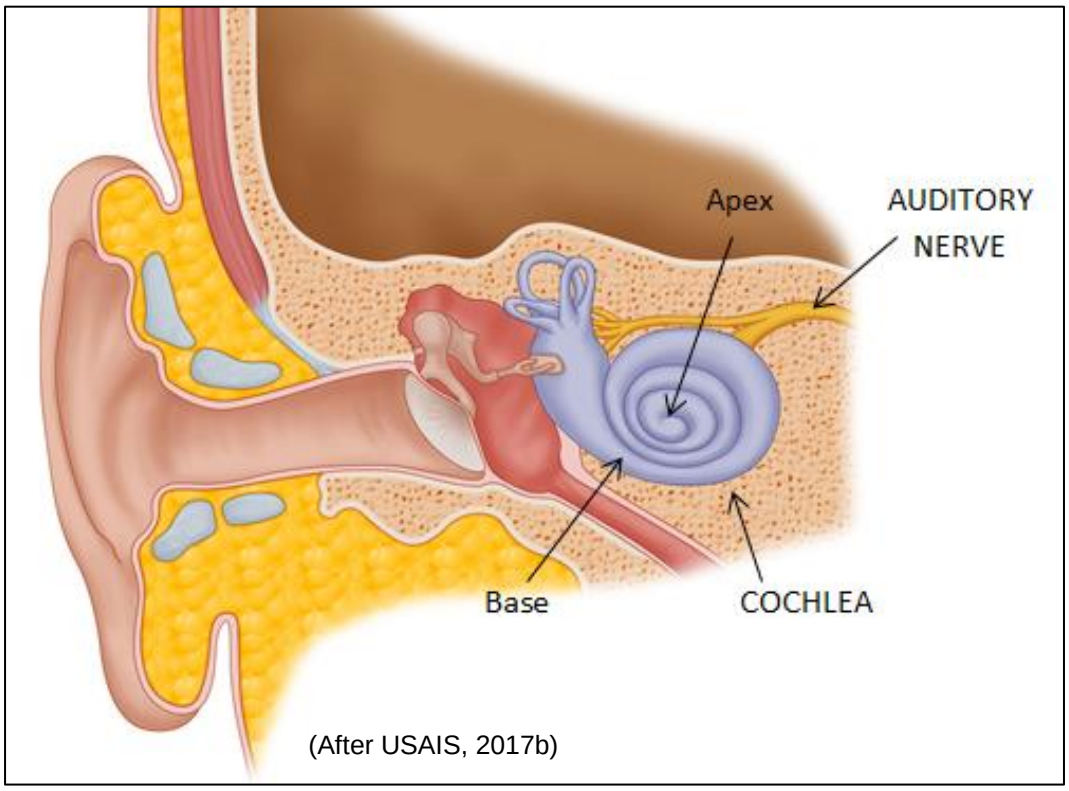


(After USAIS, 2017a)

The receiver-stimulator contains a digital signal processor which converts the received signals back into a digital code and then into pulses of electrical current.

The electrical pulses travel down the array leads to the intracochlear electrode contacts and through the perilymph of the scalar tympani to stimulate spiral ganglion cells in the modiolus and/or auditory nerve fibres in the Organ of Corti. The electrical circuit is completed by the current returning to an extracochlear electrode (known as the ground or reference electrode), located on the receiver-stimulator package or at a location away from the primary electrode lead (depending on the implant model).

The frequency information in the original acoustic signal is delivered to the intracochlear electrode contacts consistent with the cochlea's tonotopic layout. Stimulation relating to low frequency sound is sent to the apical electrodes and stimulation relating to high frequency sound is sent to the basal electrodes.



(After USAIS, 2017b)

APPENDIX 2: Ethics Approval for the present study

Parker E.A.

From: ERGOII
Sent: 20 September 2019 10:07
To: Parker E.A.
Subject: Approved by Faculty Ethics Committee - ERGO II 52435

Approved by Faculty Ethics Committee - ERGO II 52435

UNIVERSITY OF Southampton

ERGO II – Ethics and Research Governance Online https://www.ergo2.soton.ac.uk

Submission ID: 52435
Submission Title: A retrospective analysis (SDA) of cochlear implant electrode deactivation in paediatric patients.
Submitter Name: Elizabeth Parker

Your submission has now been approved by the Faculty Ethics Committee. You can begin your research unless you are still awaiting any other reviews or conditions of your approval.

Comments:

•

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E.A.Parker@soton.ac.uk coordinator

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