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SSD MED/31

THE EFFECTS OF ELECTRODE-MODIOLAR INTERFACE CHARACTERISTICS ON ELECTROPHYSIOLOGICAL AND FUNCTIONAL OUTCOMES IN ADULT PATIENTS UNDERGOING COCHLEAR IMPLANTATION.

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XXXVII CYCLE
YEAR OF DOCTORAL DEGREE ATTAINMENT
2025

AKNOWLEDGEMENTS

To Brick and Ramone

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ABSTRACT

Sensorineural hearing loss represents a major indication for cochlear implantation (CI), which restores auditory function by electrically stimulating the auditory nerve. However, outcomes depend on multiple factors, including the anatomical relationship between the electrode array and the modiolus, defined as the electrode-modiolar interface. In this context, electrode-modiolar distance (EMD) and angular insertion depth (AID) are key parameters influencing neural stimulation efficiency and hearing performance.

This study aimed to assess the impact of EMI characteristics on electrophysiological and functional outcomes in adult CI recipients, comparing perimodiolar (PM) and lateral wall (LW) electrodes, and analyzing differences among the leading manufacturers. Additionally, the study evaluated longitudinal changes in clinical parameters up to 12 months post-activation, and the role of different fitting strategie (behavioral versus anatomy-based fitting).

The results showed significant differences between PM and LW arrays in terms of impedance, ECAPs, and M/C levels, with slightly better hearing outcomes in patients with LW electrodes, likely due to their greater insertion depth rather than a reduced EMD. Among the different manufacturers, all devices demonstrated favorable outcomes, though devices with longer and more flexible arrays, often used in conjunction with anatomy-based fitting, tended to yield particularly consistent results in some patient groups. Anatomy-based fitting proved especially beneficial in post-lingual patients, promoting more selective neural recruitment and reduced current spread, with a positive impact on speech perception. In pre-lingual patients, this benefit appeared less pronounced, suggesting a stronger dependence on neural plasticity and long-term rehabilitation.

These findings support the importance of a personalized approach to cochlear implantation, tailored to the individual cochlear anatomy and supported by advanced imaging and fitting technologies. Future studies should include longer follow-up, a broader patient population (including pediatric recipients), and integration of emerging technologies such as artificial intelligence, to further refine electrode selection and programming strategies—ultimately aiming to optimize clinical outcomes and quality of life in patients with severe-to-profound hearing loss.

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LIST OF ABBREVIATIONS

CI: Cochlear implant.

IHC: Inner hair cell.

OHC: Outer hair cell.

SGC: Spiral ganglion cell.

SNHL: Sensorineural hearing loss.

CNS: Central nervous system.

FDA: Food and drug administration.

PM: Perimodiolar.

LW: Lateral wall.

LTD: Limited.

CORP: Corporation.

GMBH: Gesellschaft mit beschränkter haftung.

RW: Round window.

AID: Angular insertion depth.

MRI: Magnetic resonance imaging.

MDCT: Multidetector computed tomography.

HRCT: High-resolution computed tomography.

CBCT: Cone-beam computed tomography.

DICOM: Digital imaging and communications in medicine.

ECAP: Electrically evoked action potentials.

ESRTs: Electrically evoked stapedial reflex thresholds.

T-LEVELS: Threshold levels.

M/C-LEVELS: Maximum/Comfort levels.

TIM: Trans impedance matrix.

NRT: Neural response telemetry.

NRI: Neural response imaging

ART: Auditory response telemetry.

EMD: Electrode-modiolar distance.

SDT: Speech detection threshold.

SRT: Speech reception threshold.

SIT: Speech intellection threshold.

MST: Matrix sentence test.

OLSA: Oldenburg sentence test.

SNR: Signal to noise ratio.

AC: Air conduction.

BC: Bone conduction.

NIM: Nerve intraoperative monitoring.

ANOVA: Analysis of variance.

1. INTRODUCTION

1.1 The inner ear: anatomy and physiology overview

The inner ear is an organ located at the level of the petrous portion of the temporal bone. It consists of a portion dedicated to auditory perception, the cochlea, and a portion constituting the peripheral vestibular system responsible for balance control, including the three semicircular canals and the vestibule. The inner ear is composed of a series of communicating hollow bony structures, collectively referred to as the "bony labyrinth" due to the complexity of their shape (Figure 1).

The labyrinth can be distinguished into three main portions:

- The three semicircular canals (lateral, superior, and posterior)
- The vestibule
- The cochlea

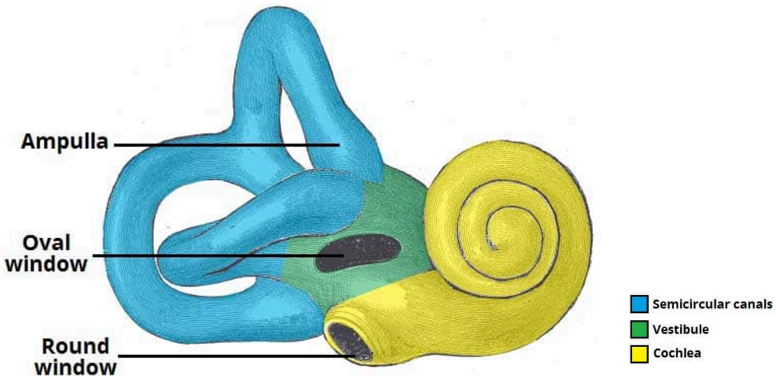


Figure 1: Bony labyrinth

Removing the bony labyrinth reveals the so-called membranous labyrinth, which has a similar shape to the bony labyrinth but is smaller in size. The space between the two labyrinths is filled with a fluid called perilymph, while the membranous labyrinth contains another fluid known as endolymph. The concentrations of ions within these fluids are crucial for the mechano-electrical transduction of the ear (Standring et al. 2008).

The cochlea is a tubular form twisted for about 2 and 3/4 turns. The cochlear duct divides into three *scalae*: vestibular, middle, and tympanic (Figure 2). The middle *scala* is part of the membranous cochlear labyrinth, while the other two are both traversed by perilymph and communicate through a small opening at the apex known as the helicotrema. It is through the vestibular *scala* that perilymph communicates directly with the vestibule and the cochlea (Sinnatamby, 2011).

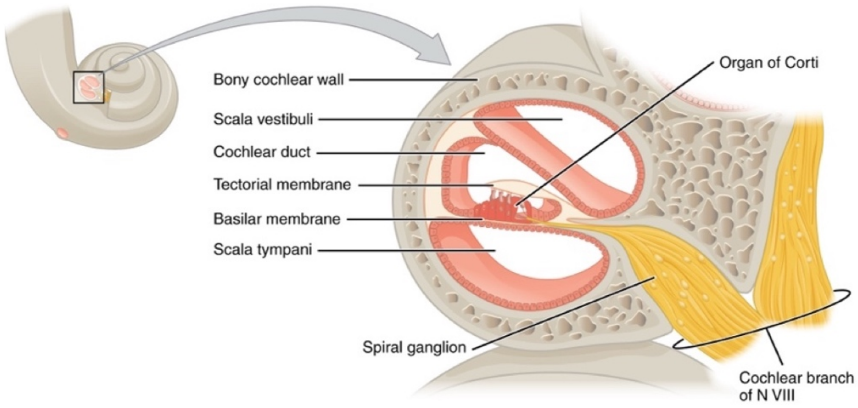


Figure 2: Cochlear section.

The vestibular *scala* opens directly into the vestibule, so the oval window specifically functions as an opening in the vestibular *scala*. In other words, the vestibular *scala* is the first to receive vibrations from the stapes footplate located in the oval window. The liquid "column" between the oval window and the vestibular *scala* constitutes the first link between the ossicular chain and the sensory part located in the middle *scala*.

The Reissner's membrane separates the middle *scala* from the vestibular *scala*; it attaches to the osseous spiral lamina and projects obliquely, adhering to the outer wall of the cochlea.

The cochlear duct is attached to the outer wall of the cochlea by the spiral ligament, a band of connective tissue. Covering the spiral ligament and in contact with the endolymph is a highly vascularized tissue, the *stria vascularis*, which marks the boundary between the middle *scala* and the tympanic *scala* of the spiral ligament.

On the basilar membrane lies the sensory part of the ear, the organ of Corti
(Kiernan et al., 2014).

The organ of Corti

The organ of Corti is composed of both supporting cells and sensory cells (Figure 3). The sensory cells of the organ of Corti are called hair cells, while the supporting ones are called pillar cells. As the name suggests, they emit extensions from their apex.

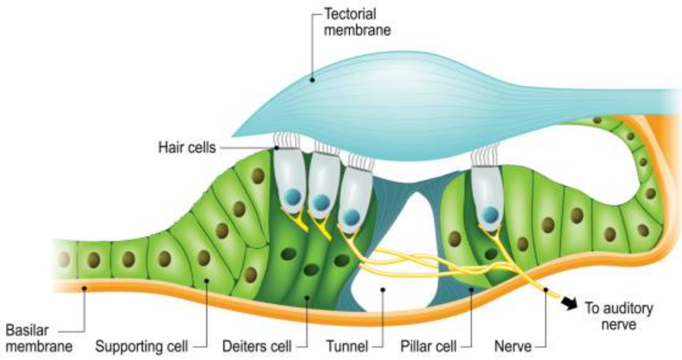


Figure 3: Organ of Corti.

The organ of Corti is composed of both supporting cells and sensory cells. The sensory cells of the organ of Corti are called hair cells, while the supporting ones are called pillar cells. As the name suggests, they emit extensions from their apex.

There are two types of hair cells in the organ of Corti of mammals: inner hair cells (IHCs) and outer hair cells (OHCs). A single row of IHCs cells runs longitudinally along the basilar membrane (Figure 4). These cells are flask-shaped and are called inner because they run on the side of the organ closest to the modiolus (in humans, there are 3,400 IHCs). As for the OHCs, there are three rows, which are cylindrical in shape and are located away from the modiolus (in humans, there are approximately 13,400). These two types of hair cells not only differ in the shape of their bodies but also in the configuration of the cilia or stereocilia located at the apex of the cell. The stereocilia of the IHCs are aligned to form a nearly continuous line along the organ of Corti (Lim, 1986).

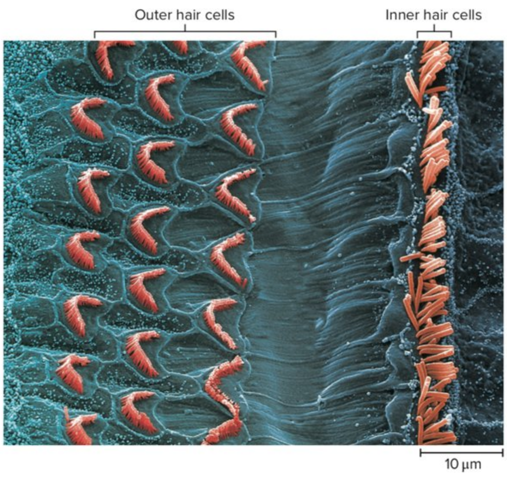


Figure 4: Inner and outer hair cells.

The spiral ganglion

In the inner ear, there is a channel formed by a bony mesh that winds parallel to the spiral labyrinth, called the Rosenthal canal. Within this structure reside the neuron bodies of the spiral ganglion cells (SGCs). Each cell body emits an efferent process that extends toward the organ of Corti and an afferent process that projects towards the auditory nerve (Figure 5). When the hair cells are stimulated by sound waves, they transform the signal from mechano-acoustic to electrochemical, which is subsequently transmitted to the cochlear nerve via synapses through the SGCs.

Two populations of neurons have been described in the spiral ganglion. Type I ganglion cells are large, bipolar, and represent 90-95% of the population. Type II ganglion cells are small, bipolar, or pseudomonopolar and represent 5-10% of the population (Nayagam et al., 2011).

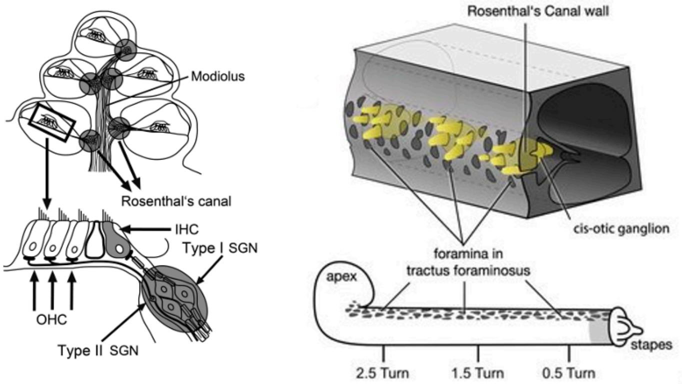


Figure 5: Spiral ganglion cells.

1.1.3 Physiology

The essential element that enables the complex and delicate mechanism of sound perception is represented by the so-called "mechanoelectrical transducer", the organ of Corti. This organ is located on the basilar membrane and extends throughout the length of the cochlea itself. It analyzes sounds, separating and highlighting significant components while dampening intense components and accentuating weaker ones, facilitating the revelation of acoustic details that allow for the identification of sound sources' characteristics. The organ of Corti is composed of numerous cellular populations, of which, from a functional perspective, the most important are the sensory cells (hair cells). The activation of hair cells, like all biological processes, relies on a series of highly complex ion and neurosecretory mechanisms.

The movement of the stapes against the oval window produces corresponding waves of compression and rarefaction in the fluid contained within the vestibular scala (the cochlear fluid completely fills the cochlea). Such oscillations, as the Reissner's membrane is extremely thin and flexible, are readily transmitted to the scala media and, from there, to the basilar membrane upon which the organ of Corti rests. During the compression wave, therefore, the basilar membrane will tend to flex towards the tympanic scala, whereas during the rarefaction wave, it will tend to flex towards the vestibular scala (Figure 6).

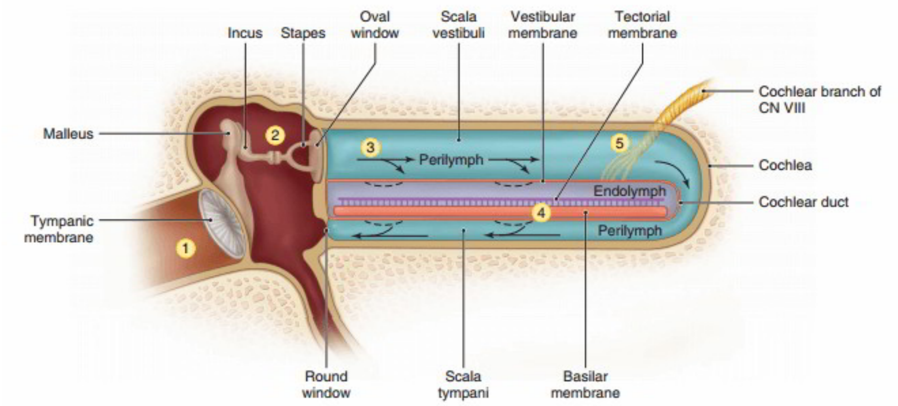


Figure 6: Cochlear stimulation model.

The amplitude of wave continuously grows until it reaches a maximum at a specific point, determined by the mechanical properties of the membrane, and then rapidly fades towards the apex.

The viscoelastic properties of the basilar membrane lead to high-frequency sounds (high-pitched sounds) causing oscillation in the portions of the basilar membrane closest to the oval window, whereas lower frequencies (low-pitched sounds) primarily induce oscillation in the terminal portions of the membrane, specifically those located towards the apical regions of the cochlea (Peterson et al., 2023) (Figure 7).

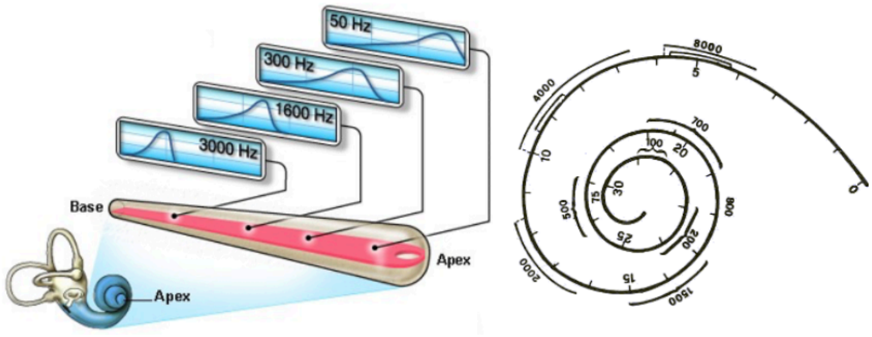


Figure 7: Cochlear tonotopy.

The point where the membrane deformation reaches its peak amplitude, dependent on frequency, corresponds to a region of the overlying organ of Corti that is most excited, thus, only a small group of healthy hair cells are stimulated by that sound frequency. Its amplitude then rapidly declines as it continues towards the apex of the cochlea. Due to the continuous variations in its mechanical properties, the membrane is tuned at each point for a different characteristic frequency, known as the tuning point. Characteristic frequencies vary monotonically and continuously along the cochlea, from a minimum of 20 Hz at the apex to a maximum of 20 kHz at the base. This relationship is not linear but logarithmic, and this specific localization of sound frequencies along the membrane constitutes the tonotopic map (White et al., 2023).

Regarding the role played by the OHCs, they perceive the vibrations of the basilar membrane through their bundles of stereocilia. The stereocilia are immersed in the endolymph, a fluid that possesses an electrical potential of +80 mV compared to that of the perilymph surrounding the lower part of the cell. In contrast, the interior of the cells has a negative potential of -70 mV, maintained by the sodium-potassium gradient of the cell membranes. Therefore, through the stereocilia, a potential difference of about 150 mV is formed, capable of generating electric currents of up to 8 nA. When the tallest stereocilia tilt slightly due to the oscillations of the tectorial membrane, the bundle of stereocilia fans out, putting tension on protein filaments that open the stereociliary channels. The opening of these channels results in the entry of electric currents sufficient to depolarize the cell by a few millivolts, causing the cell to contract (Patuzzi and Robertson, 1988).

The IHCs are located within the organ of Corti towards the interior relative to the axis of the cochlea. These non-contractile cells serve as the sensors transmitting signals to the auditory nerve. Like the OHCs, the opening of stereociliary channels results in the entry of an electric current causing intracellular potential to drop. Unlike the OHCs, the taller stereocilia of the inner hair cells are not anchored to the tectorial membrane; therefore, their deflection is not proportional to the relative movement of the membrane. Instead, they experience the viscous action of the fluid set in motion by the oscillations of the tectorial membrane. This results in the force acting on the stereocilia being proportional to the membrane velocity. This serves to equalize the electrical response to high-frequency signals by compensating for the drop in electrical potential caused by the parasitic capacitance of the cell membrane (Hone and Smith, 2002). From this, it is deduced that the inner hair cells are the true mechanical-electrical transducer, and the electrical impulses they generate activate the synapses of the auditory nerve. It should be noted that, also in this case, the organization of the hair cells exemplifies a tonotopic arrangement, which indicates a specific spatial organization: IHCs located in or near the apex of the cochlea exhibit heightened sensitivity to low-frequency sounds and they transmit this acoustic information to type I SGCs, which are also positioned near the apical region of the modiolus. Conversely, IHCs situated at the cochlear base are most responsive to high-frequency sounds, and they connect to SGCs located in the basal portion of the modiolus. This meticulously arranged configuration of neural processes, responsible for conveying auditory information, persists throughout all segments of the auditory pathway. It holds significant importance in discerning the frequency of the sound stimuli (Rusznák and Szucs, 2009).

1.2: Cochlear implant

Cochlear implant (CI) is the first sensory organ created with electronic technology by humans. It effectively compensates for the loss of functionality of the auditory system by restoring the auditory interface between the external environment and the central nervous system (CNS). The CI is an electronic device surgically inserted into the inner ear: the first individuals to experiment with this device were André Djourno and Charles Eyriès, who in 1957 inserted an electric stimulator into the inner ear of a deaf patient, evoking an auditory sensation for the first time in history (Seitz, 2002). Subsequently, in 1961, William House inserted five electrodes into the cochlea of a man using a round window approach (Eisenberg, 2015). While these initial attempts were unsuccessful, they paved the way for cochlear implantation.

The US Food and Drug Administration (FDA) approved the use of CIs in adults in 1984 and in children in 1990. Over the decades, there have been remarkable technological advances that have expanded clinical indications. Initially, the FDA approved use in children over two years old. However, the age limit was later lowered to one year old (Warner-Czyz, 2022). In addition to age-related indications, the use of cochlear implants has also been extended to patients with multiple disabilities.

Today, there is a wide variety of commercially available devices; however, the basic concept behind them is similar among manufacturers. While the concept behind the implant is simple, its production and function are extremely complex. With the evolution of computer technology and hearing aids, the necessary components for producing the hardware for a cochlear implant have developed into what we know today. The main challenge faced by CI developers was not only to create technology capable of sound perception but also to develop a biocompatible device capable of being placed in a space communicating with cerebrospinal fluid and potentially causing CNS side effects. These considerations were challenging and took a significant amount of time to perfect; however, the effort in perfecting the design was worthwhile because the CI became the prototype upon which many of the current electrical cranial nerve stimulators are designed (Eisele et al., 2003).

A CI consists of external and internal components (Figure 8). The external component includes a microphone and a speech processor, while the internal component includes a receiver/stimulator and an array of electrodes. A magnet-held external transmitter detects sounds from the external environment via microphones, the processor converts them into electrically encoded signals, and sends it via electromagnetic induction through the skin to an internal receiver-stimulator. The receiver-stimulator converts the signal into electrical impulses distributed to multiple electrodes on an electrode array implanted within the *scala* tympani of the cochlea. These electrical stimuli are then transmitted to the SGCs along the cochlear turns, and the electric stimulation travels along the auditory nerve axons to the brain for sound perception (Naples and Ruckenstein, 2022).

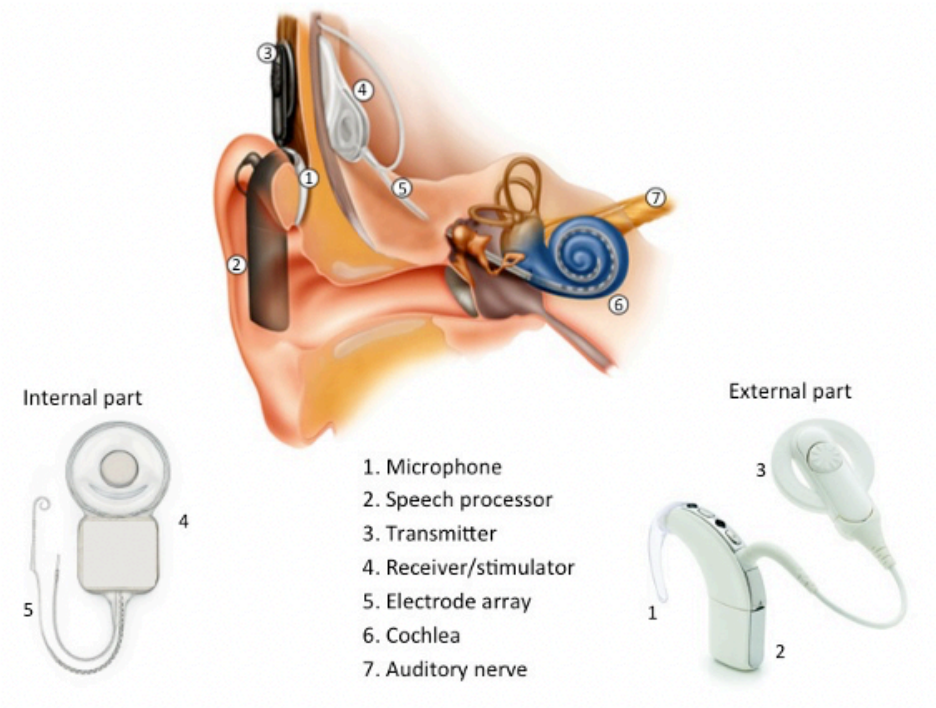


Figure 8: Cochlear implant components.

1.2.1 Electrode arrays

Electrode array is probably the component of the CI that has undergone the most evolution over the years. Indeed, several studies have demonstrated that the integrity and resolution of the signal introduced to the cochlear nerve depend on various specifications of the electrode array (Clark, 2009).

For the CI to provide full benefit, a series of factors must be considered: choosing an electrode array that matches the recipient's individual cochlear anatomy, atraumatic insertion, angular insertion depth (AID) with maximum cochlear coverage and neuro-tonotopic matching (O'Connell et al., 2017; Mady et al., 2017). For these reasons, over the decades, the materials, shapes, number of electrodes, inter-electrode distance, stiffness, and flexibility of the electrode have been modified (Ertas et al., 2022).

Perimodiolar vs Lateral wall electrode array

There are two models of electrode array: perimodiolar (PM) and lateral wall (LW) electrode arrays (Figure 9).

The PM arrays, as their name suggests, are pre-curved electrodes that, thanks to their design, can be positioned closer to the cochlear axis, inside which, at the level of the Rosenthal's canal, the SGCs reside (Dhanasingh and Jolly, 2017).

The LW arrays, on the other hand, are straight arrays that achieve their final curled position by following the lateral wall of the cochlear duct. Thus far, both LW and PM electrode arrays are commonly used in today's clinical practice as they each have their specific advantages.

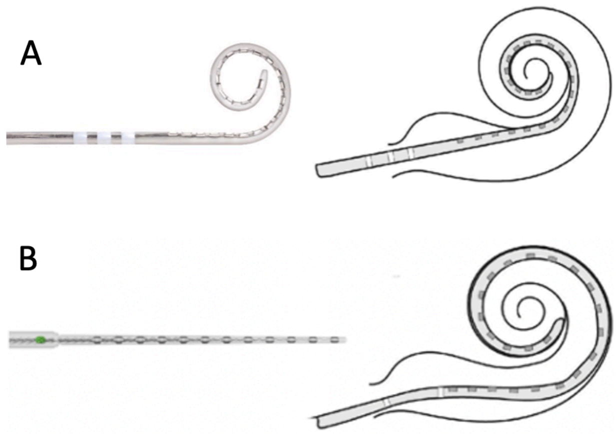


Figure 9: Perimodiolar (A) vs Lateral wall (B) electrode array

According to the PM electrode array manufacturers, the reduction in physical distance between the electrode array and the modiolus allows for stimulation of SGCs at lower current levels and will consequently reduce the overlap stimulation of different groups of SGCs, resulting in a more refined electrical stimulation and better hearing performances (Gstoettner et al., 2001) (Figure 10).

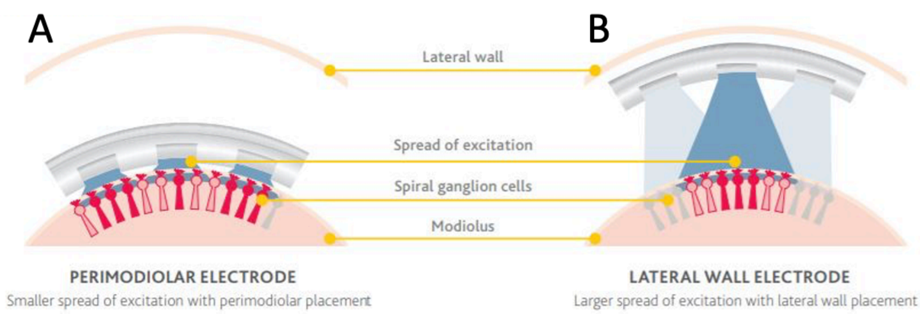


Figure 10: Stimulation models: Perimodiolar (A) vs Lateral wall (B) electrode array.

Some studies have described the patterns of cochlear electrical stimulation through various electrode configurations. The results of these experiments have shown that the gradient of the electric field increases as the distance between the electrodes and the SGCs (Briaire and Frijns, 2000; Finley et al., 1990; Frijns et al., 1995; Kral et al., 1998; Ranck, 1975; Rattay et al., 2001). At closer distances between the electrode and the SGCs, the electric field capable of stimulating neural elements increases more rapidly, whereas the opposite behavior is observed with increasing distance. Therefore, an electrode closer to the neural elements needs to deliver less current to stimulate the SGCs and evoke a response. The electric fields generated by PM electrodes also result in less current spread to adjacent neural populations, thereby decreasing the likelihood of interaction with different groups of SGCs (Frijns et al., 1996). Reduced overlap of stimulation could therefore lead to better frequency discrimination (McKay et al., 1999; Pfingst et al., 1999).

To date, two companies have commercialized the use of PM electrode arrays: Cochlear Ltd. (Sidney, Australia) and Advanced Bionics Corp. (Valencia, California). Cochlear Ltd. offers two different types of PM electrodes in its portfolio: the Contour Advance (CI612) and the new Slim Modiolar (CI632) (Figure 11). The first, the longest-standing PM electrode on the market, has been designed to maximize the proximity between the electrode and the modiolus and to provide maximum stability during insertion at the level of the tympanic scala; It is indicated for extended round window (RW) and cochleostomy surgical approaches. The second has been designed with a slimmer profile, making it suitable for insertion into smaller or anatomically more complex cochleae, and also features a higher degree of flexibility, making it particularly adaptable to interindividual anatomical variations. It is indicated for RW, extended RW, and cochleostomy surgical approaches. In addition to the already known ability to improve electrode pitch discrimination ability (Hughes and Abbas, 2006), studies conducted on the use of the new Slim Modiolar series have shown a reduced tendency for scalar translocation with a lower rate of tip fold over (Shaul et al., 2018), and a better speech perception score (Shaul et al., 2020) than the Contour advance electrode array.

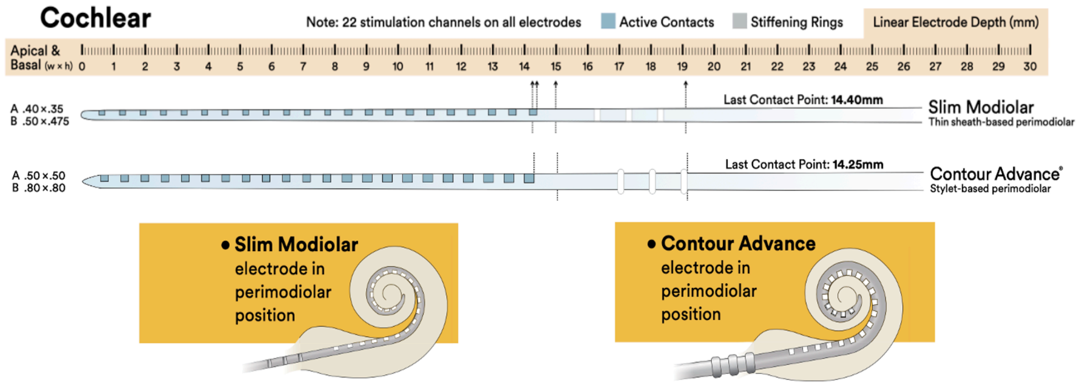


Figure 11: Cochlear Slim modiolar vs. Contour advance.

Advanced Bionics Corp. offers the HiFocus Mid-Scala PM electrode (Figure 12). The electrode dimensions easily fit within the scala tympani which has been shown to protect the delicate structures of the cochlea whilst avoiding damage to the modiolus, osseous spiral lamina and the basilar membrane (Gazibegovic and Bero, 2016; Svrakic et al., 2016). According to the manufacturer, HiFocus Mid-Scala, being located central to perimodiolar, has an ideal basal placement for high frequencies. The HiFocus Mid-Scala electrode can be inserted and reinserted up to three times. Moreover, the length and curvature of the HiFocus Mid-Scala allows for proven consistency of full spectral coverage with ≃420° AID signifying coverage of main SGCs population. It is indicated for round window, extended round window, or small cochleostomy approach.

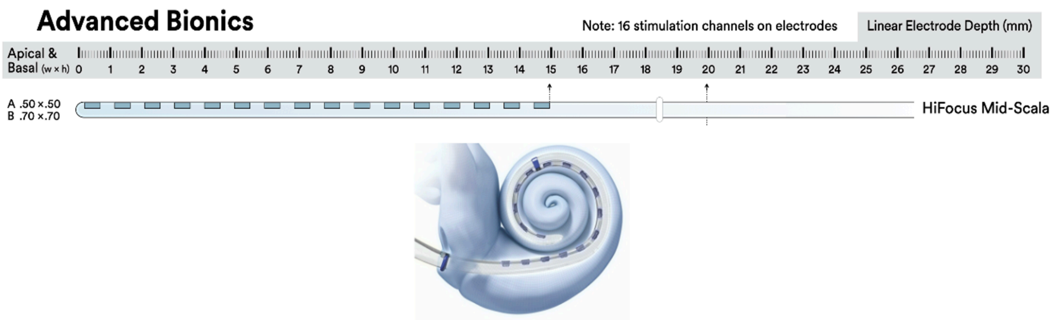


Figure 12: Advanced Bionics HiFocus Mid-Scala.

Despite the promising results obtained with the PM arrays, research conducted by several groups worldwide has demonstrated that while the reduced distance between the electrode and the modiolus offers an advantage for neural stimulation, it also poses an increased risk of damaging neural structures. Even though both LW and PM electrode arrays being able to cause intra-cochlear trauma, PM electrodes are more likely to deviate towards the vestibular scala compared to LW electrodes, leading to damage to the osseous spiral lamina/spiral ligament, which may induce new bone formation and further affect hearing quality (Dhanasingh and Jolly, 2017).

There are several theories that have attempted to explain this phenomenon. According to some authors, the mechanism can be attributed to the larger diameter of PM electrodes compared to LW ones, which, during insertion, especially when using an RW approach, would result in greater friction forces on the basilar membrane (Souter et al., 2011; Jeyakumar et al., 2014). According to other authors, the cause can be found in the devices used for inserting these types of electrodes: the use of a stylet, in addition to increasing the electrode's thickness, also increases its rigidity, potentially leading to penetration at the level of the spiral ligament (Wardrop et al., 2005; Eshraghi et al., 2003). Other authors have hypothesized that PM electrodes have a pre-determined shape which may not match the coiling pattern of individual cochlear geometries (Martinez-Monedero et al., 2011; Meng et al., 2016). The aspect concerning the AID and neuro-tonotopic matching represents a further debate when discussing about PM vs LW electrode arrays. Healthy normal-functioning human cochlea can hear sound signals in the frequency range of 20 kHz, in the basal region, to 20 Hz in the apical region (Greenwood, 1990). Straight LW electrodes are believed to stimulate the nerve fiber endings of the auditory neurons at the organ of Corti which is where the LW electrode array lies, whereas PM electrode arrays, which lie close to the modiolar wall, are believed to stimulate the SGCs. In either case how far the electrode should be inserted intra-cochlear to cover the neural elements is an important question. The organ of Corti extends to the full length of the cochlea whereas the SG cells inside the Rosenthal's canal extend 1.75 to 1.85 turns of the cochlea, which in terms of insertion angle is equivalent to 660 (Kawano et al., 1996; Locher et al., 2014; Rask-Andersen et al., 2012). However currently, there are no PM electrodes that can reach this depth, because, due to both design and manufacturing limitations, cannot be longer than 15-20mm and cannot be inserted deeper than 390-450º. For an average sized cochlea, 450° of AID would cover a frequency range of up to 500Hz in the low frequency end (Frisch et al., 2015; Briggs et al., 2011). To date, there is a mixed opinion regarding the relationship between insertion depth and user performance, although a correlation is observed between deep insertion and better hearing performance (Rivas et al., 2017; O'Connell et al., 2016; O'Connell et al., 2017; Buchman et al., 2014; Hochmair et al., 2015).

The LW electrode arrays were the first to be produced, and to date, all manufacturers have at least one in their portfolio.

Cochlear Ltd. offers two different types of LW electrode arrays: the Slim Straight (CI622) and the Slim 20 (CI624) (Figure 13). The former is designed to provide variable insertion depth up to 25mm, while the latter for an insertion depth of 20mm. Both are indicated for RW, extended RW, and cochleostomy surgical approaches.

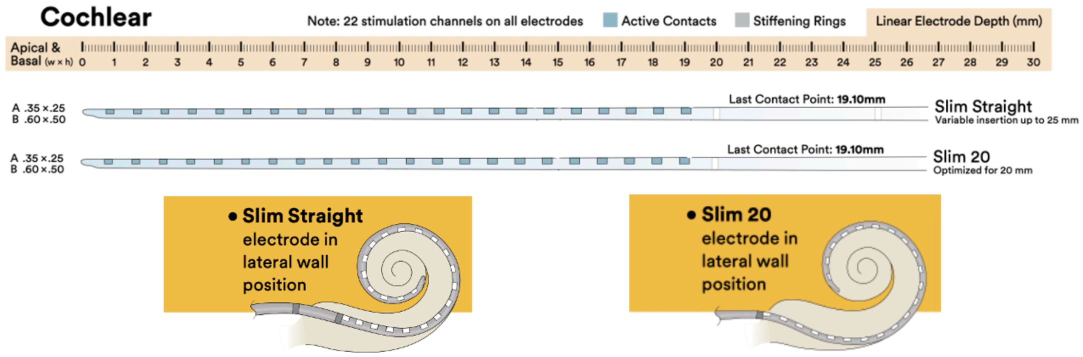


Figure 13: Cochlear Slim straight vs. Slim 20.

Advanced Bionics Corp. offers the Hi Focus SlimJ LW electrode (Figure 14). This type of straight electrode is characterized by the presence of a slight curvature at the tip, which makes it easier to insert as it allows the electrode to follow the natural curvature of the lateral wall of the cochlea up to the apex. It is indicated for round window, extended round window, or small cochleostomy approach.

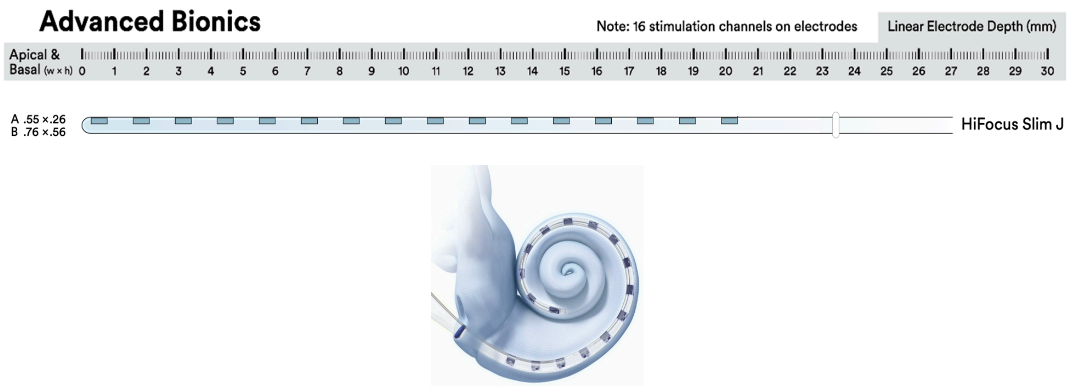


Figure 14: Advanced Bionics HiFocus SlimJ.

Due to the variability in the anatomical characteristics of the cochlear duct, Med-el GmbH (Innsbruck, Austria) offers a wide range of LW electrode array lengths (FlexSoft, FlexStandard, Flex28, Flex26, Flex24, Flex20 etc.), enabling the surgeon to select the optimal electrode for each case (Figure 15). Indeed, when some recipients of cochlear implants are profoundly deaf, electrical stimulation by the implanted electrode should cover the entirety of the cochlea. Conversely, patients with partial deafness and residual hearing, especially in the low frequencies, in cases where this remains stable over time, a shorter electrode will provide coverage of the frequency ranges where natural hearing is compromised.

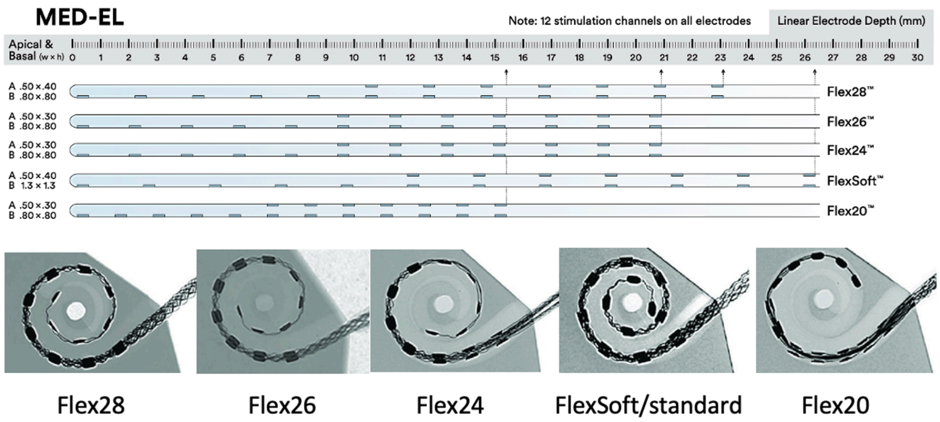


Figure 15: Med-el Flex Series.

Table 1 summarizes the length and AID specifications of all described electrodes (Dhanasingh and Jolly, 2017).

Table 1: Electrode arrays length and angular insertion depth.

	Manufacturer	Electrode array	Length (mm ≃)	AID (°≃)
	Med-el	FlexSoft/Standard	31.5	720
	Med-el	Flex28	28	580
	Med-el	Flex26	26	520
LW	Cochlear	Slim Straight	25	450
	Med-el	Flex24	24	450
	Advanced Bionics	HiFocus SlimJ	22	420
	Med-el	Flex20	20	360
	Cochlear	Slim Modiolar	18.4	360/420
PM	Cochlear	Contour Advance	20	360/420
	Advanced Bionics	HiFocus Mid-Scala	18.5	360/420

Technical specifications

CIs are based on the use of electrodes commonly made of platinum-iridium (Pt-Ir) and silicon carriers which hold electrodes and electrode wires (Cassar et al., 2019; Rebscher et al., 2008). However, current CIs have limitations regarding the stiffness of the electrode arrays, having an insufficient number of electrodes, and providing a sub-optimal hearing experience (Cowley, 2011; Migirov et al, 2009). Recent work on improving these concerns enabled CI designs that can provide a personalized sound experience (Profita et al., 2009; Cullington et al., 2016; Dhanasingh, 2021). Although electrode arrays and electrode materials vary between different designs, electrode shapes remain the same, mainly being square, rectangular, and spherical (Rebscher et al., 2008). On the other hand, active research is being pursued to discover new electrode array materials as alternatives to the commonly used silicon. Although polymer-based alloys and polymers were reported to be good candidates, an electrode array that can fully provide high biocompatibility, flexibility, a dielectric constant, biodegradability, and processability has not yet been demonstrated (Chen et al., 2006; Richardson et al. 2009; Johnson and Wise, 2013).

Another important factor for an efficient cochlear stimulation is represented by the inter-electrode distance. Even though current CIs have 12 to 22 electrodes and channels, due to channel interactions, the number of independent channels is smaller than the actual number of activated electrodes causing insufficient spectral resolution and decreased speech recognition (Padilla and Landsberger, 2016; Joly et al., 2021). For better hearing, larger interelectrode spacing can be used to reduce channel interactions between adjacent electrodes Büchner et al., 2017). Longer electrode arrays with fixed number of channels provide larger interelectrode spacing and reduce channel interaction. Although deeper insertion with a long electrode array enhances the range of place pitch coding, perceptual distances between adjacent electrodes are likely to decrease in the apex. To compensate for this, an electrode array could be designed such that spacing between the electrodes in the apex is greater than the spacing between the electrodes in the rest of the array (Zhao et al., 2019). As previously mentioned, during the insertion of CI electrode arrays, different ranges of trauma may occur at the delicate anatomical regions of the cochlea such as the basilar membrane, osseous spiral lamina, scala tympani, and scala vestibuli.

Intracochlear trauma may cause severe damage to the dendrites, spiral ganglion cells, and the specific distribution of these cells, and it can also result in the efficiency of the stimulation of sites located along the implant electrodes and a loss of high-fidelity sound (Rebscher et al., 2008; Kha et al., 2004). Properties such as tickness, stiffness, and flexibility are important factors for the insertion and final positioning of electrode arrays within the scala tympani and for the effective function of CI devices. The table two summarizes the electrode arrays number of electrodes, inter-electrode distance and width.

Table 2: Electrode arrays number of electrodes, inter-electrode distance and width.

Manufacturer	Electrode	Number of electrodes	Inter-electrode distance (mm)	Apex width (mm)	Base width (mm)
Cochlear	Slim Straight	22	1.15	0.3	0.6
Cochlear	Slim Modiolar	22	0.65	0.35	0.475
Cochlear	Contour Advance	22	0.65	0.5	0.8
Advanced Bionics	HiFocus Mid-Scala	16	0.95/3	0.5	0.7
Advanced Bionics	HiFocus SlimJ	16	1.1/2.5	0.5x0.26	0.76x0.56
Med-el	FlexSoft	12	2.4	0.5x0.4	1.3
Med-el	Flex28	12	2.1	0.5x0.4	0.8
Med-el	Flex20/24/26	12	1.28/1.74/1.74	0.5x/0.3	0.8

1.3 Electrode-modiolar interface evaluation

Differences in post-surgical speech perception may be influenced by various physiological characteristics specific to the patient, including the severity of deafness, age at the time of CI surgery, the cause of hearing loss, residual hearing levels, and several other cognitive factors present before implantation (O’Connel et al., 2017; Chakravorti et al., 2019). While these variables are non-modifiable, there are other controlling factors able to impact hearing outcomes dependent on the allocation of the CI electrodes inside the cochlea. The scalar position, the angular insertion depth (ADI) and the electrode-modiolar distance (EMD), are some aspects that, by potentially affecting both electrophysiological and psychoacoustic outcomes, represent parameters of great interest to researchers in this field. For these reasons, imaging has become crucial not only for the preoperative assessment of cochlear biometrics (length, width, presence of malformations, etc.) and for postoperative evaluation of potential electrode malpositioning (scalar translocation, tip fold-over, etc.), but also for precisely evaluating electrode positioning. This evaluation is essential for devising a tailored speech processor fitting strategy that effectively maps cochlear tonotopy, thereby maximizing post-cochlear implantation hearing outcomes. In many cases, the utilization of Magnetic risonance imaging (MRI) after a cochlear implant is restricted due to contraindications related to the presence of the implanted metal device, significant metallic artifacts, and the time and cost involved in execution.

The electrode position is usually assessed using conventional x-ray or Multidetector computed tomography (MDCT). However, the assessments after CI surgery require optimal imaging techniques: conventional x-ray can localize the implant position but does not provide much detail and is, therefore inadequate (Vogl et al., 2015). High-resolution computed tomography (HRCT) provides more anatomic details; however, it has remarkable metallic artifacts. Cone-beam CT (CBCT) is becoming increasingly popular for postoperative evaluation because of its high spatial resolution, more accurate details, fewer metallic artifacts, and relatively low radiation dose (Razafindranaly et al., 2016).

1.3.1 Cone-beam CT vs Multidetector CT

The use of CBCT in otology has increased during the last years providing a better resolution then MDCT for the bone structure with strong density contrast (Dahmani-Causse et al., 2011). Unlike traditional MDCT, which utilizes a narrow fan-shaped beam and requires multiple rotations around the patient to generate a volume of data, CBCT operates with a single rotation of a cone-shaped beam encompassing the entire field of view. Both the X-ray source and the flat-panel detector rotate around a fixed point situated at the center of the region of interest. The flat-panel detector indirectly detects X-rays by employing a scintillator to convert them into visible light. The X-ray beam can be continuous or pulsed to reduce dose exposure. CBCT resolution is determined by the pixel size of the detector, unlike conventional CT where it depends on slice thickness. Typically, the resolution of the area detector ranges between 75 and 300 µm. This resolution dictates the size of the voxels and thus the three-dimensional dataset of isotropic voxels, which are utilized to generate reconstructed images in the three orthogonal planes.

Several studies have investigated the reliability of CBCT in assessing the scalar position and the ADI of electrode arrays in isolated temporal bones (Kurzweg et al., 2010; Cusching et al., 2012; Güldner et al. 2012) or whole cadaveric heads (Diogo et al., 2014). Different types of electrode arrays may yield varying results in electrode position identification. Marx et al. reported a sensitivity of 100% and specificity of 90% in scalar position assessment for PM electrode arrays (Marx et al., 2014), while Kurzweg et al. reported that CBCT accurately identifying the exact position in 85% of cases (Kurzweg et al., 2010). PM electrode array position was also reliably assessed in the oblique sagittal plane or using midmodiolar reconstruction even in MDCT scans (Lane et al., 2007; Lercef et al., 2011). Identifying PM electrode arrays may be easier due to their consistent perimodiolar position, firmly held by the osseous spiral lamina. In contrast, LW electrode arrays may assume intermediate positions along the lateral wall of the cochlear lumen, making identification challenging. In a study conducted with Med-el flex series electrodes a low translocation rate (3%) and high agreement between raters for the correct intracochlear localization were found (Boyer et al., 2015). Razafindranaly et al. investigated the effectiveness of CBCT compared to MDCT in nine patients regarding scalar localization, ADI, and radiation doses. The researchers concluded that while both modalities showed good agreement in assessing insertion depth, CBCT might offer an advantage over MDCT in determining the scalar location of electrodes with lower radiation doses (Razafindranaly et al., 2016). In a similar study, optimal visualization of the electrode's scalar position was achieved in 78% of cases in the CBCT group, compared to 47% in the MDCT group. There was no statistically significant difference between the two groups regarding the ability to measure the ADI (Helal et al. 2021). The position of the most apical and/or basal electrode is also a significant consideration because deep insertion could potentially lead to trauma (Adunka and Kiefer, 2006), and insertion depth might be inversely correlated with speech perception (Finley et al., 2008). To accurately assess the ADI, it is important that scans are not significantly affected by artifacts, and that the position of the round window can be evaluated directly or estimated based on the anatomy of the semicircular canal and vestibule (Trieger et al., 2010; Cohen et al., 1996). The distance between electrode contacts and the inner wall is another crucial factor in speech perception outcomes. However, the evidence supporting this notion is limited, with several authors reporting no clear correlations (Theunisse et al., 2014). To directly measure the distance between the electrodes and cochlear walls, both the individual electrode contacts and the inner cochlear wall need to be visualized. Verbist et al. found that the evaluation of the lateral cochlear wall could be more accurate than that of the inner wall. This outcome was attributed to the thick lateral wall being a part of the otic capsule, characterized by dense bone, which provides better contrast with the cochlear lumen compared to the inner wall, which contains neural elements with lower density (Verbist et al., 2008). A similar study revealed a statistically significant difference between the two groups regarding the visualization of the cochlear outer wall ($p<0.001$), with 94% of patients in the CBCT group having perfect visualization compared to 53% in the MDCT group. However, there was no significant difference in the visualization of the cochlear inner wall ($p>0.99$) and the modiolus ($p>0.37$). Perfectly visualized cochlear inner walls and modiolus were reported in 69% and 78% of patients in the CBCT group, respectively, compared to 73.7% and 95% in the MDCT group.

One potential limitation of CBCT for analyzing submillimeter structures is the longer exam duration (18-36 sec) compared to MDCT (4-6 sec), which may lead to artifacts due to head movement. Additionally, higher spatial resolution increases sensitivity to patient movement, potentially displacing structures from their "correct" positions (Schulze et al., 2011).

1.3.2 Innovations in CI surgery imaging: Otoplan

Despite significant advancements in imaging technology, it became necessary to implement a system capable of enabling personalized examination of the patient's anatomy prior to scheduled surgery, rather than relying on a standardized approach to guide preparations for cochlear implant surgery. This was also necessary for post-operative evaluation to provide customized frequency maps based on the characteristics of the electrode-modiolar interface.

One emerging tool that may assist surgeons throughout various stages of surgery is Otoplan®, an otological planning software developed through collaboration between Cascination AG (Bern, Switzerland) and Med-el (Innsbruck, Austria). This system offers three-dimensional capabilities that enable otologists to preoperatively analyze cochlear anatomy, visualize electrode insertion depth, and select the most suitable electrode array for each patient. Postoperatively, it can be utilized to verify frequency allocation and ensure proper positioning of the cochlear implant (Paouris et al., 2023). By harnessing automated tools and advanced 3D visualization techniques, the system facilitates expedited and more accurate measurements in contrast to traditional manual approaches employing the standard Digital imaging and communications in medicine (DICOM) viewer. This advancement in quantifying cochlear parameters has the potential to optimize clinical processes and empower otosurgeons with increased control. The reliability of software-driven cochlear reconstructions, including cases involving inner ear anomalies, has been validated, with no instances of device-related issues documented in current literature (Dhanasingh et al., 2022).

When examining cochlear metrics using, various parameters are evaluated, each offering distinct perspectives on cochlear dimensions: the A-value denotes the diameter, which is defined as the maximum distance from the round window to the lateral wall of the basal turn, passing through the modiolus; the B-value depicts the cochlear width, measured perpendicular to the A-value line at the modiolus; the H-value signifies the cochlear height, measuring the distance between the center of the basal turn and the apex point. Otoplan effectively identifies the modiolus, round window, and cochlear walls to compute the cochlear duct lenght employing the elliptic-circular approximation technique (Schurzig et al., 2018). The capability of Otoplan in determining both the AID and the cochlear duct length has been validated and deemed comparable to that of other methods (Spiegel et al., 2022).

Currently, the standard speech processor fitting involves employing default settings for frequency allocation, which aim to simulate tonotopicity, thus emulating the natural cochlear response. However, when pre-set frequency programming is utilized, variations in the type of implant, cochlear duct length, and AID can result in mismatches between the cochlear tonotopy and the frequency presented by the electrode to that specific region of the cochlea, potentially leading to allocation discrepancies (Aljazeeri et al., 2022).

Otoplan is capable of overcoming this limitation by additionally producing a personalized frequency map using the Greenwood mathematical function, accurately pinpointing the specific intracochlear locations where neural fibers process different sound signal frequencies. This map, utilizing patient-specific data, aims to provide a fitting that closely aligns with natural tonotopic perception, considering critical parameters like the calculated tonotopic frequency of each electrode contact, determined by its angular location (Di Maro et al., 2022). The most recent version of Otoplan also incorporates the ability to combine CT and MRI images, improving preoperative assessment. Moreover, linking Otoplan with intraoperative electrophysiological testing has the potential to reduce misplacement and establish correlations with postoperative acoustic hearing, offering an added advantage.
In conclusion, the Otoplan software functions as a preoperative aid for surgeons, aiding in the selection of a tailored electrode array to enhance speech perception and streamline postoperative anatomy-based fitting (Gatto et al., 2023).

1.4 : Electrophysiological and functional parameters

The auditory rehabilitation of patients undergoing cochlear implant surgery involves assessing the functionality of the implant and determining the extent of benefit provided to the patient. To comprehensively evaluate the patient, both objective and subjective parameters are typically assessed.

Electrophysiological parameters are considered as objective measurements and encompass electrode impedances, trans-impedance matrix (TIM), electrically evoked compound action potentials (ECAP), electrically evoked stapedial reflex thresholds (ESRTs), threshold levels (T-Levels), and maximum/comfort levels (M/C-Levels). Impedances, ECAP, and ESRTs can be evaluated during intraoperative telemetry to indirectly determine the correct positioning of the electrode. Impedances and ECAP can also be assessed during postoperative phases to evaluate electrode functionality and neural responses. In the posto-operative phase, however, the parameters that the clinician primarily focuses on are represented by the T-levels and M/C-levels, whose values are set with the goal of achieving the best auditory performance. Intraoperative telemetry and post-operative fittings for cochlear implants are performed using advanced software solutions provided by leading manufacturers.

Cochlear Ltd. employs Custom Sound Version 7.0 (Sydney, Australia), Advanced Bionics Corp. uses SoundWave 2.3 (Valencia, California), Med-el GmbH utilizes Maestro 10 (Innsbruck, Austria).

The auditory performances of the patient are considered as subjective parameters. These are generally evaluated using pure tone audiometry (PTA), speech audiometry in quiet, and speech-in-noise audiometry. These assessments are typically performed during the speech processor fitting phase, which involves customizing and optimizing the cochlear implant settings to meet the specific auditory needs of each individual.

1.4.1 Electrophysiological parameters

Impedances

Electrode impedance is defined as the resistance encountered by current flow between an index electrode and the ground. Various factors, including intracochlear contents (bone, soft tissue, etc.) and type of electrode array contribute to overall impedance levels. The management of electrode impedances is critical for optimizing the electrical stimulation parameters used in stimulating the auditory nerve.

The lowest electrode impedances are typically measured intra-operatively immediately after the placement of the CI electrode (Neuburger et al., 2009). Studies have shown that electrode impedances tend to increase during the post-operative recovery period due to tissue and protein accumulation around the electrode array (Busby et al., 2002).

Elevated impedances can also occur when electrodes are disabled or the device is inactive (Dorman et al., 1992). Electrical stimulation through the CI electrodes leads to a significant decrease in electrode impedances during the initial hours to days of implant use (Newbold et al., 2010). Following this initial phase, electrode impedances generally stabilize for most CI patients. Multiple measurements of electrode impedance during clinical visits demonstrate good test-retest reliability, with variability typically less than 1 kΩ. Hey et al. reported high test-retest reliability with a median difference of 123 Ω during a single programming visit (Hey et al., 2015). A change of ≥4 kΩ in electrode impedances across clinical visits is considered significant and may indicate alterations in the protein composition and cell contents of inner ear fluids (Choi et al., 2017).

Over time, some basal electrodes may exhibit a gradual increase in impedance, attributed to the accumulation of fibrous tissue in the basal end of the cochlea (Hey et al., 2015). Electrode impedances are typically measured during each clinical visit, and adjustments to electrical stimulation parameters are made to ensure they remain within the maximum compliance voltage of the medical device. Exceeding this limit can result in issues such as diminished speech perception, poor sound quality, and potential damage to the platinum components of the device (Clark et al., 1995).

Different impedance values can also be due to the specific technical specifications of the various electrodes marketed. The main differences can be attributed to the different characteristics of the contact surface and the varying incidence of intracochlear trauma among different electrode array models (Zarowski et al., 2020; Degen et al., 2020; Velandia et al., 2020). Regarding differences in the contact surfaces, Zarowski et al. observed that electrodes with smaller contact surfaces, such as LW electrodes, may be responsible for higher impedances. However, the same author also suggests considering that within the same electrode array because contact surface values may vary depending on the electrode under consideration: for example, in the case of Cochlear Ltd. slim straight LW electrode array, higher impedance values can be recorded for electrodes in the middle turn (with smaller contact surfaces) and higher impedance values for electrodes in the basal and apical turns (with larger contact surfaces) (Zarowski et al., 2020). Other authors, on the other hand, have observed higher impedance values for Cochlear Ltd. PM contour advance electrode, which has a larger contact surface, compared to those of the slim straight series from the same company (Degen et al., 2020). Therefore, other factors must be evaluated to better understand the correlation between contact surface and impedance values.

Several studies have hypothesized that differences in electrode impedances may also be caused by the varying extent of surgical trauma caused by the electrode type. LW electrodes are generally less traumatic than PM electrodes; a lower degree of surgical trauma should result in less postoperative fibrotic reaction with lower electrical impedances (Zarowski et al., 2020). One study found that PM arrays have higher impedances at the basal turn (Velandia et al., 2020). This evidence is consistent with the findings of other studies suggesting that this condition could represent the result of post-traumatic fibrosis more commonly occurring at the basal turn following a cochleostomy approach (Leone et al., 2017; Molisz et al., 2015).

Another factor to consider, therefore, is the difference in surgical approach (Liu et al., 2019). The same author also noted that patients with LW arrays tended to have higher impedances toward the apical turn (Velandia et al., 2020). Other studies have reported similar results (Busby et al., 2002; Hughes et al., 2001; Sanderson et al., 2019); therefore, although LW arrays were designed to be more flexible, thinner, and less traumatic, it is possible that the greater insertion depth characteristic of LW electrodes could more easily cause damage to the spiral ligament, resulting in fibrosis and increased impedances, as demonstrated by some studies (Durisin et al., 2011). However, further research is needed to understand the reasons for impedance differences between LW and PM electrode arrays.

Trans Impedance Matrix (TIM)

The Transimpedance Matrix (TIM) is an objective measurement tool available in CustomSound EP (Version 7.0, Cochlear Ltd., Sydney, Australia) that utilizes the cochlear implant's capability for intraoperative telemetry. It is assessed during intraoperative telemetry.

The TIM consists of a table listing the transimpedance values recorded for each possible pair of stimulation and recording electrodes and is useful for evaluating the electrophysiological characteristics of the cochlear implant. It can provide valuable information for optimizing device programming and assessing potential issues such as tip fold over or improper electrode placement.

During a TIM measurement, the intracochlear potential profile is measured along each of the 22 electrode contacts while stimulating a single contact in monopolar mode. When recording and stimulation electrode coincide, the ratio is called the impedance. When they differ, the term trans-impedance is used. In electrode arrays that are correctly positioned in the cochlea, the intracochlear voltage is expected to decrease as the distance between stimulating and recording electrode contacts increases. The result of the TIM-measurement is a matrix of 22 × 22 (trans-)impedances. In the software the TIM matrix is color-coded from high (black and red) to low (green and blue) creating a heatmap. Highest values (black) are recorded at stimulating electrode contacts which can be seen as a diagonal line from the bottom left corner of the matrix (apical) to the top right (basal). Figure 16 shows an example of normal TIM values (Klabbers et al., 2021).

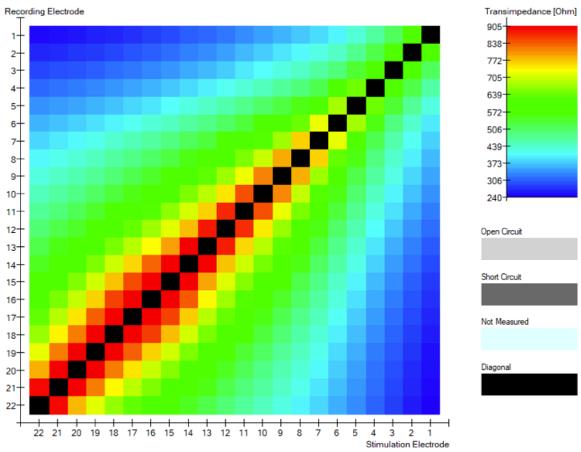


Figure 16: TIM normal values.

In the event of a tip fold over, the hypothesis is that the spatial distribution of electrode contacts in the cochlea is altered such that apical contacts are located abnormally close to more basal contacts. In the heatmap view, a column contains the voltage (transimpedance) profile along all recording electrodes. When moving away from the stimulation site (diagonal), the values first decrease up to the inflection point of the tip fold over. Beyond this, the values increase again as these apical contacts are physically closer to the stimulation site. This non-monotonic behavior manifests itself as a cross-pattern in the heatmap. The fold over can subsequently be estimated to be at the level of the middle of the “cross” formed by higher (trans-)impedance values (warmer colors) in the heatmap. Figure 17 depicts a case of TIM in a patient with tip foldover (Klabbers et al., 2021).

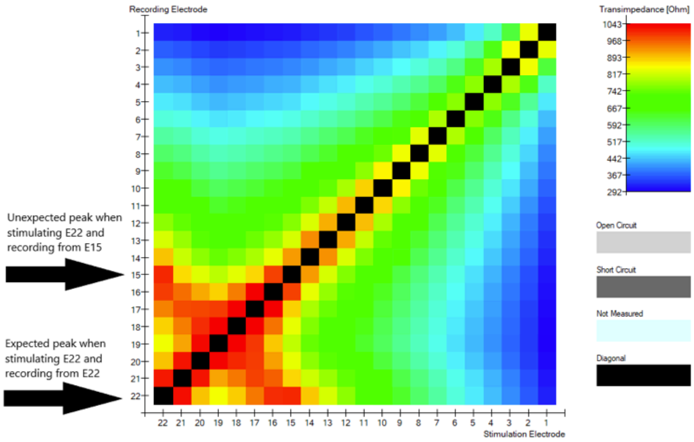


Figure 17: TIM in a tip fold over case.

Electrically evoked compound action potential (ECAP)

Since the advent of modern CIs with telemetry function, clinical research has focused on the use of the ECAP for fitting as an additive or alternative to behavioral fitting especially for those who have difficulty in showing the reliable behavioral response (Brown et al., 2000). The feasibility of this approach has been studied extensively in the last decades, however, with contradictory results (de Vos et al., 2018).

The ECAP represents a synchronized response generated by a group of electrically activated auditory nerve fibers, which makes it feasible to evaluate the physiological status of the auditory nerve. The importance of assessing the functionality of the auditory nerve has also been emphasized by the findings of several studies, which have suggested that the physiological status of the auditory nerve (i.e., number and responsiveness of neurons) represents an important factor influencing the auditory outcomes (Kim et al., 2010; Kirby and Middlebrooks, 2010, Kirby and Middlebrooks, 2012; Garadat et al., 2012, Garadat et al., 2013; Long et al., 2014; Pfingst et al., 2015).

Compared with other electrophysiological measures, the ECAP offers several advantages that make it of great value to hearing scientists and audiologists. First, measuring the ECAP in CI patients does not require extra equipment, special software, or an external recording electrode other than the standard equipment for clinical programming. It can be done through the telemetry function implemented in the CI and the commercial software provided by the manufacture. Second, it requires minimal patient cooperation and is not affected by patient's arousal status, which is an important advantage for working with pediatric CI users. Additionally, it is known to be a stable measure overtime in typical CI recipients and therefore can be a reliable indicator of change (de Vos et al., 2018).

Although all CIs measure the same electrophysiological response, each CI manufacturer has its own measurement method and terminology to depict the measurement of these neural responses: Neural Response Telemetry (NRT) by Cochlear, Neural Response Imaging (NRI) by Advanced Bionics, and Auditory Response Telemetry (ART) by Med-el. To enable the use of ECAP in clinical practice, CI manufacturers embedded ECAP measurement features in the fitting software. Especially the latest generation fitting software, for example, Custom Sound (Cochlear), Soundwave (Advanced Bionics), and Maestro (Med-el), have made the use of objective data to obtain direct baseline fitting maps easily accessible (de Vos et al., 2018).

The ECAP recorded using an intra-cochlear electrode in human CI users typically shows a biphasic morphology (Figure 18A). The biphasic ECAP consists of one negative peak (N1) within a time window of 0.2–0.4 ms after stimulus onset followed by a positive peak (P2) occurring around 0.6–0.8 ms (Brown and Abbas, 1990; Brown et al., 1990, 1998; Abbas et al., 1999). This single-peak ECAP accounts for more than 80% of all measurable eCAPs (Lai and Dillier, 2000; Cafarelli Dees et al., 2005; Miller et al., 2008). In addition to the single-peak response, eCAPs with two positive peaks (P1 and P2) have been observed (Stypulkowski and van den Honert, 1984; Lai and Dillier, 2000; van de Heyning et al., 2016). This type of response has been referred to as a double-peak or a Type II nerve response (Lai and Dillier, 2000) (Figure 18b).

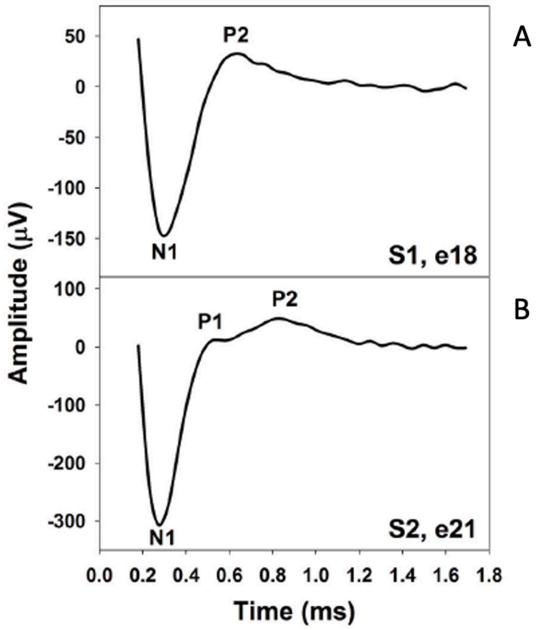


Figure 18: ECAP biphasic morphology, one positive peak (A), two positive peaks (B)

The ECAP amplitude can be as large as 1–2 mV. Due to its large amplitude, the ECAP is relatively resistant to contamination of myogenic activity. In addition, due to its peripheral neural origin, the ECAP is not affected by maturation of the central auditory system. As a result, morphological characteristics of ECAPs recorded in adult and pediatric CI users are similar (e.g., Brown et al., 1990; Eisen and Franck, 2004; Gordon et al., 2004) and show little or no change as the duration of CI use increases (Brown et al., 2010).

Nevertheless, amplitude and peak latency of the ECAP recorded in human CI users are affected by other factors, including intra-cochlear electrode location.
Some studies have reported that the ECAP thresholds were lower for the PM than for the LW and were lower in the apical region than in the basal and medial regions (Frijns et al., 1995; Parkinson et al., 2002; Cohen et al., 2001). Another study also reported that the ECAP amplitude was greater and the ECAP slope was steeper in the apical region than in the basal region, and the ECAP threshold was lower in the medial region than in the basal region of the cochlea (van de Heyning et al., 2016).

Although it is not known exactly why such differences in the ECAP response was obtained along the cochlea, these findings may be attributed to two things. One is the proximity of electrode to the modiolus, and the other is the density and integrity of surviving spiral ganglion cells at different electrode sites (Telmesani and Said, 2015;

Huang et al., 2006; Guedes et al., 2007).

The PM electrode, thanks to its proximity, would therefore allow evoking auditory potentials at lower current levels compared to the LW electrode array and it also seems to consume power more efficiently and stimulate spiral ganglia more specifically. Placing the electrode array as close to the modiolus as possible would minimize current dissemination, resulting in reduced channel interaction and potentially better frequency selectivity and speech perception (Shepherd et al., 1993; Frijns et al., 1995; Saunders et al. 2002). However, while lower ECAP values at lower current levels have been reported for PM electrodes in several studies, functional results in terms of speech perception have not yet been widely confirmed (Degen et al., 2020).

Electrically evoked stapedial reflex thresholds (ESRT)

ESRT is an objective measure similar to acoustic reflex thresholds, where the contraction of the stapedius muscle is monitored in response to varying amounts of sound input delivered through the CI. ESRT has been shown to be a helpful tool in CI fitting, specifically in predicting a patient's upper stimulation (C/M) levels and has been shown to remain stable/consistent over time postoperatively (Kosaner et al., 2009; Lira de Andrade et al., 2014). Previous studies have suggested that ESRT measurements fall within a similar range, or slightly above, a patient's psychophysical loudness judgments of upper stimulation (C/M) levels (Han et al., 2005; Walkowiak et al., 2011). However, ESRT cannot be measured in all CI users; it is currently estimated that ESRT is not measurable in approximately 20%–30% of patients (Van Den Abbeele et al., 2012). Now, there is no clear understanding as to why patients may or may not have a measurable ESRT. Despite the research available citing ESRT as a potential predictor of upper stimulation level, a survey of currently practicing audiologists has revealed that ESRT is rarely used in the clinical setting (Hemmingson & Messersmith, 2017).

As with ECAP and impedances, the correlation between ESRT activation levels and the characteristics of the electrode-modiolar interface has also been studied. If there were a strong correlation between stapedius reflexes and the EMD in this case as well, we would particularly anticipate observing a significantly higher ESRT for the LW electrode arrays compared to those in PM electrode arrays. However, the results of the study conducted by Degen et al. demonstrate that there is no higher ESRT for LW electrode arrays. Therefore, these data suggest that ESRT is independent from the EMD (Degen et al., 2020). It is important to note that ESRT is not an entirely objective measure but is recorded according to the surgeon's observation of the stapedius muscle. After reaching the threshold, the strength of the muscle contraction further increases with rising current levels. The reflex is weakened in a dose-dependent manner by anesthetic gas, which is ideally switched off before the electrode insertion to ensure correct measurements (Crawford et al., 2009). An individual tendency to determine higher or lower ESRTs may exist between surgeons. Whether there is a consistent tendency of some surgeons to over- or underestimate ESRT is not clear. Objective ESRT measurements may be useful in the future for more accurate measurements.

Threshold levels (T-levels) and Maximum/Comfort levels (M/C-levels)

In cochlear implants, threshold levels (T-levels) and maximum comfort/comfort levels (M/C-levels) are two important parameters used to adjust the electrical stimulation provided to the user.

T-levels represent the minimum level of stimulation needed for the user to perceive a sound. In other words, they are the lowest level of electrical intensity that generates an audible sensation. These levels can be individually adjusted for each electrode of the cochlear implant based on the user's hearing sensitivity.

M/C levels represent the maximum level of stimulation that the user can tolerate without experiencing discomfort or pain. They are adjusted to ensure that the stimulation provided by the cochlear implant is comfortable and enjoyable for the user without causing unpleasant sensations.

Properly adjusting both T and M/C levels is essential to ensure that the user obtains an optimal hearing experience with the cochlear implant, with sounds being audible without being too faint or too intense. These parameters are typically adjusted during cochlear implant programming sessions, which are conducted by audiologists or professionals specialized in hearing device fitting.

Just like impedances, ECAP, and ESRT, T and M/C level values can also be influenced by the characteristics of the electrode-modiolar interface, however, the conclusions of some studies on this matter show inconsistent results. Some studies have reported that the T and M/C-levels observed in LW and PM electrodes exhibit comparable trends; nonetheless, LW electrodes demonstrate greater variability in impedance across the electrode array. In general, PM electrodes have been noted to display lower T and M/C levels compared to straight electrodes (Jeong et al., 2015; Gordin et al., 2009). The same findings regarding the M/C-levels were obtained in a recent study (Degen et al., 2020). However, in another study, opposite trends were observed: the overall T and the M/C-levels measured for the basal contacts were significantly higher for the PM electrodes, while no significant differences were observed for the mid-portion and the apical electrode contacts (Zarowski et al., 2020). According to the authors, there are several factors that can account for this observation. The fact that the LW electrodes are positioned at a greater distance from the spiral ganglion cells and exhibit significantly higher ECAP thresholds may explain the higher T and M/C-levels (Park et al., 2017; Jeong et al., 2015; Telmesani and Said, 2015). On the other hand, the differences in the contact surface area and higher impedances of the LW electrodes may result in lower T and M/C-levels. According to the authors, since both factors work in opposite directions, this may result in the cancellation of both effects.

1.4.2 Functional parameters

Pure-tone audiometry (PTA)

Pure-tone audiometry (PTA) is an audiological evaluation procedure that measures a person's hearing ability in relation to pure tones of different frequency and intensity. During this test, the patient is presented with pure tones at various frequencies, typically ranging from 250 Hz to 8000 Hz, and is asked to indicate when they perceive the sound. The hearing threshold for each frequency is then recorded and represented on a graph called an "audiogram".

In evaluating the auditory performance of patients with CI, the test is conducted in a free field. Using pure tones at various frequencies and intensities, the patient's auditory threshold is examined, i.e., the lowest volume level at which they can perceive sound. This measurement provides an indication of the patient's levels of auditory sensitivity with CI. The results of the audiometry are interpreted considering the patient's subjective feedback and comparing the data with those obtained in previous tests. This provides a comprehensive evaluation of the patient's auditory performance with CI, guiding further adjustments and optimizations of the device to enhance their auditory experience.

Speech audiometry in quiet

Speech audiometry in quiet is an audiological evaluation procedure conducted in a quiet environment, without background noise. During this test, the patient is presented with verbal auditory stimuli, such as words or sentences, at various sound intensity levels. The main objective is to assess the patient's ability to understand and repeat the presented auditory material correctly at different intensities. This type of test is useful for evaluating auditory discrimination and the threshold of spoken language comprehension.

Speech recognition with CI is administered using an open-set, phonemically balanced word test. Ten meaningful disyllabic words are presented via free-field loudspeaker at different intensities; the loudspeaker is placed approximately 1 m in front of the participant’s head. In Italy, the percentage of correct answers are calculated to determine three different levels of their speech recognition score: (1) the minimum hearing level (dB HL) for speech at which an individual can just detect the presence of speech material 0% of the time (Speech Detection Threshold, SDT); (2) the minimum hearing level (dB HL) for speech at which an individual can recognize 50% of the speech material (Speech Reception Threshold, SRT); (3) the lowest intensity (dB HL) at which the patient can recognize the 100% of words (Speech Intellection Threshold, SIT).

Speech audiometry in noise

Speech audiometry in noise is an audiologic evaluation procedure that assesses a person's ability to understand spoken language in the presence of background noise. During this test, the patient is presented with verbal auditory stimuli, such as words or sentences, while background noise is added at varying intensities. The objective is to determine the threshold at which the patient can accurately comprehend spoken language compared to the level of background noise. This type of test is important for evaluating language comprehension ability in realistic situations similar to those encountered in daily life, where background noise may be present.

Speech recognition in a noisy environment can be administered using the Matrix Sentence Test (MST). This test also has an Italian version, known as the Italian MST. This Italian version is a versatile examination composed of 20 randomized lists of five-word, semantically unpredictable sentences (Houben et al., 2014). The test is preceded by a training session to minimize the learning curve. In CI patients the matrix sentences, structured as “name-verb-numeral-adjective-object” (e.g., “Marco-prende-quattro-palline-rosse”), are presented against a noisy background via free-field loudspeaker at 65 dB SPL, placed approximately 1.2 m in front of the participant’s head. The signal to noise ratio (SNR) is adaptively adjusted in to determine a predefined percentage of correct word recognition. The duration of a typical track of 20 sentences is about 4 minutes. The patient’s task is to repeat the sentence he/she hears, or at least the separate words if the patient found it difficult to repeat the sentence completely. The test yields three main measurements: (1) the SNR, in dB, at which the subject recognizes 50% of the presented words (SRT), even if it occurs in different sentences (SNR-SRT); (2) the slope of the discrimination function at SRT (Slope) in percentage (%/dB); and (3) the intelligibility percentage score, in terms of estimated accuracy in understanding whole sentences.

1.5: Speech processor fitting

The speech processor fitting, accompanied by speech therapy exercises, plays a crucial role in achieving good auditory quality through CI. The speech processor fitting not only determines the achievement of auditory comfort but also the understanding of speech in both quiet and noisy environments (Hoth and Müller-Deile, 2009; Müller-Deile, 2000). During this phase, the technical parameters that define the conversion of sound waves captured by the CI microphone into electrical stimulations are established. The set of parameters that defines the stimulation is called a "map" and is stored in the processor (Shapiro and Bradham, 2019). In addition to these parameters, the incoming acoustic signals can be pre-processed to adapt to a specific acoustic situation. This can occur, for example, through adaptive digital directional microphones or adjustments to the input dynamic range. The activation and adjustment of these pre-processing algorithms are therefore always part of CI fitting.

All CI manufacturers allow for the variation of numerous stimulation parameters for CI fitting, and these often influence each other. However, it is common to all systems that the T and M/C-levels must be defined to establish how high the minimum stimulation should be for each electrode and how high the maximum stimulation can be. Therefore, from a technical standpoint, CI fitting consists of defining the optimal stimulation parameters.

In traditional clinical practice, CI fittings are mostly based on a triad of results from psychophysical, electrophysiological, and audiometric measurements. Nonetheless, these methodologies lack formalized guidelines, leading many experts to establish their own procedures (Vaerenberg et al., 2014).

In recent years, a novel method known as 'anatomy-based fitting', which considers the unique anatomical characteristics of each patient, has emerged.

1.5.1 Psychophysical fitting

The psychophysical fitting method, also known as the 'behavioral' or 'subjective' fitting method, for adjusting the speech processor assumes that T-Levels and M/C-Levels are determined individually for each electrode by querying the patients about their auditory impressions. To do this, short pulse trains, starting with very low stimulation values, are repetitively offered at intervals of 1–2 s and slowly increased until an auditory impression occurs (T-Levels), and then further increased until the stimulus is just not classified as "too loud" (M/C-Levels). Care must be taken here to avoid overstimulation. The duration of each pulse train should not be less than 300 ms, as it is only above this threshold that loudness perception no longer increases with increasing stimulation duration (Hoppe et al., 2017).

T and M/C-Levels can be measured electrode by electrode, but several approaches have been developed to reduce the amount of effort required. One approach involves measuring T and M/C-levels at 5 electrodes spread across the electrode array and interpolating the levels for all other electrodes. Other approaches include measuring only C levels and setting T levels to 0 (Med-El) or to 10% of the C levels (Advanced Bionics); however, this method is not applicable for Cochlear Ltd. At the end of the fitting, the setting is in live mode, where audibility may be controlled by presenting certain sound stimuli (speech, music, noises). This also captures to what extent interactions between electrode stimulations lead to unexpected sensations such as extraordinary loudness summation. If necessary, the setting of the T and/or M/C-Levels is modified. The advantage of this psychophysical adjustment is that there is enough time for the wearer to acclimatize to the electrical stimulation, and individual electrodes with noticeable auditory impressions can be identified during the adjustment. Additionally, overstimulation by the CI system is most likely avoided through the checking of individual electrodes. However, the method is disadvantageous in that it consumes a lot of time. Additionally, this procedure is problematic for people whose statements about audibility and loudness are uncertain and who are generally limited in cooperation. The procedure is error-prone and may not be applicable in young children (Hoppe et al., 2017).

1.5.2 Electrophysiological fitting

The electrophysiological fitting method, also known as "objective" fitting, is based on objective electrophysiological measurements. Therefore, the initial setting of the stimulation parameters takes place independently of the subjective auditory impressions of the patient.

This objective approach derives T and M/C-levels from objective auditory responses (Wathour et al., 2021). Specifically, T-levels can be set based on the value of the ECAP, which is the electric threshold capable of stimulating a neural response, while M/C-levels can be set based on the value of the ESRT, which is an objective parameter for evaluating high loudness perception (Botros and Psarros, 2010; Carvalho et al., 2015; Stephan and Welzl-Müller, 2000). The advantage of this approach is that no active cooperation of the patient is required, and therefore it can also be applied to young children or uncooperative individuals. However, the method is disadvantageous in that not all patients are candidates for electrophysiological fitting, as, for example, ECAP measurements cannot always be performed. The obtained values are generally somewhat higher compared to psychophysical measurements, which, however, is often advantageous for children. The procedure can take place quickly and objectively but has the disadvantage that no acclimatization to the electrical stimulation occurs during the setting, which may lead to overstimulation when activating the CI system.

1.5.3 Outcome-based fitting

In outcome-based fitting, the settings of the CI system aren't determined by objective threshold measurements but rather by the outcomes of speech audiometry or PTA. These outcomes might include word recognition scores, speech reception thresholds in noise, or subjective loudness ratings. The assumption is that the individual's optimal loudness range for understanding and discriminating speech is also optimal.

The T and M/C-Levels are then derived from this. Alternatively, T-Levels can be determined first, followed by the determination of C-Levels, allocating a certain percentage of the individual's dynamic range to them. However, there's a risk of overstimulation, leading to a decline in speech understanding in noisy environments. An initial estimate of loudness impression can be obtained by measuring the ESRT, but these values typically exceed the T-Levels (Craddock et al., 2003). Outcome-based fitting is primarily used for older children, adults, and patients with postlingual hearing loss. The procedure also necessitates active cooperation from the patient but has the advantage of incorporating subjective listening impressions into the fitting process, thus reducing the risk of overstimulation.

1.5.4 Anatomy-based fitting

Anatomy-based fitting is an advanced approach that utilizes detailed anatomical data to optimize the placement and tuning of electrodes within the cochlea. This method aims to improve auditory outcomes by aligning the electrical stimulation more closely with the natural tonotopic organization of the cochlea.

The technique involves creating maps based on high-resolution imaging, which provide precise locations of electrode contacts within the cochlea. By correlating these positions with specific frequencies, clinicians can reduce the frequency-to-place mismatch that often occurs with traditional fitting methods (Kurz et al., 2023).

2. AIM OF THE PROJECT

The primary goal of this project is to investigate the effects of electrode-modiolar interface characteristics on electrophysiological and functional outcomes in adult patients undergoing cochlear implantation.

This research aims to explore how the electrode-modiolar interface correlates with electrophysiological parameters and hearing performances, specifically by comparing the results obtained with PM and LW electrodes, and among the LW electrodes, comparing the results obtained from different manufacturers. By analyzing the differences, the study will try to assess whether specific types of electrodes provide better results in terms of auditory perception and overall functionality.

Another objective of our study is to evaluate how electrophysiological and functional parameters change over time.

Additionally, the project seeks to examine the differences in hearing performance between behavioral speech processor fitting and anatomy-based speech processor fitting. This comparison aims to determine if a more personalized fitting approach, tailored to the unique anatomical features of each patient, can enhance the effectiveness of CI. To achieve this, the two fitting strategies will be evaluated to identify the most efficient methods for optimizing auditory outcomes.

A critical aspect of the research involves evaluating these results within two distinct patient groups: individuals with post-lingual deafness and those with pre-lingual deafness. By considering the differing auditory histories and rehabilitation needs of these groups, the study aims to provide a comprehensive understanding of how electrode-modiolar interface characteristics and different fitting strategies impact each population.

To evaluate the main goals of the study, we decided to follow a cohort of patients with severe/profound SNHL or mixed hearing loss undergoing CI surgery using both PM electrodes (from Cochlear Ltd.) and LW electrodes (from Med-el GmbH and Advanced Bionics Corp.).

Patients underwent intraoperative evaluation of electrophysiological parameters, followed by reassessment of these parameters along with auditory outcomes during processor activation, one month after surgery. The same electrophysiological parameters and auditory outcomes were reassessed at 1, 3, 6 and 12 months after speech processor activation.

Patients implanted with Cochlear Ltd. and Advanced Bionics Corp. electrodes underwent traditional speech processor fitting, while those implanted with Med-el GmbH electrodes underwent anatomy-based fitting.

Given the heterogeneity of the study group, which included both post-lingual and pre-lingual deaf patients, subjects were divided into two distinct groups and analyzed separately.

Overall, this project aspires to generate insights that could lead to improved cochlear implant outcomes, offering more tailored and effective solutions for adult patients with varying types of deafness.

3. MATERIALS AND METHODS

3.1 Study population

A prospective longitudinal clinical study was conducted by enrolling patients suffering from bilateral severe to profound SNHL or mixed hearing loss developed in the pre-lingual or post-lingual period.

After obtaining ethical committee approval, all participants were recruited from the Otorhinolaryngology Section of the University Hospital Policlinico “Paolo Giaccone” in Palermo between June 2021 and January 2024.

Inclusion criteria were patients aged over 16 years, patients with bilateral severe to profound SNHL or mixed hearing loss (PTA greater than 70dB in the ear to be implanted), patients with poor speech recognition ability even with optimal hearing aids (less than 50% sentence recognition in the ear to be implanted, and less than 60% in the best-aided condition), patients with either pre-lingual or post-lingual deafness. Exclusion criteria were patients with medical contraindication for surgery, patients with inner ear and/or cochlear nerve malformations determined by preoperative MRI and HRCT, patients with cognitive functional impairment.

All patients underwent otorhinolaryngology, audiological, and speech therapy evaluations. First, a detailed medical history was collected, including demographic data, the type, manner, and time of onset of symptoms, the possible presence of comorbidities, and any previous medical and/or surgical treatments performed. This was followed by a complete otorhinolaryngology examination with otomicroscopic evaluation to rule out middle ear pathologies and/or active infections.

Audiological evaluation began with PTA conducted in a soundproof booth using the Cello audiometer by Inventis Srl (Padua, Italy), assessing the air conduction (AC) hearing threshold at 250-8000Hz using headphones, and bone conduction (BC) at 250-4000Hz using a calibrated bone transducer, without the use of hearing aids. Subsequently, AC was also evaluated in a free field with hearing aids. Speech audiometry in quiet was performed using disyllabic words measured in a free field with hearing aids with the aim of evaluating the SRT. Speech audiometry in noise was performed using the MST, implemented with the OLSA test software by

HörTech GmbH (Oldenburg, Germany) in a free field with hearing aids, and conducted using the Cello audiometer by Inventis Srl (Padua, Italy), with the aim of evaluating the SNR. To assess the stability of middle ear function, tympanometry was performed using the GSI-39 tympanometer by Grason-Stadler (Eden Prairie, MN, USA). The procedure utilized a probe frequency of 226 Hz and an air pressure range from +200 to -400 mm H_2O, with automatic recording.

A speech therapy evaluation was then carried out to quantify linguistic communication skills in both understanding and speaking, also evaluating the patients' expectations and motivation.

The patients subsequently underwent HRCT of the petrous bone and MRI with and without contrast medium of the brain, internal auditory canals, and cerebellopontine angle. The radiological study was conducted to evaluate the anatomy of the middle and inner ear, to identify any anomalies and malformations, and to ensure proper surgical planning.

All patients also underwent blood sampling for routine blood tests, chest X-ray, and specialist pneumological, cardiological, and anesthetic evaluations.

Patients who met all inclusion and exclusion criteria were enrolled in this prospective longitudinal clinical study.

The selected patients were divided into 2 groups based on the onset of deafness: Group 1 (G1) comprised patients with post-lingual deafness, and Group 2 (G2) comprised patients with pre-lingual deafness.

Participants in each group were then randomized using Sealed Envelope Ltd. software (London, UK) based on the type of electrode array to be implanted: perimodiolar (PM) electrode array or lateral wall (LW) electrode array. Participants in the PM groups were selected to receive the Cochlear Nucleus Profile Plus (CI 632) Slim Modiolar electrode array by Cochlear Ltd. Participants in the LW groups were further randomized into two subgroups based on the manufacturer of the electrode array: one group selected to receive the HiRes Ultra 3D HiFocus SlimJ electrode array by Advanced Bionics Corp. and the other group selected to receive the electrodes by Med-el GmbH. In the latter case, the choice of the electrode array model to be implanted was made based on the specific anatomical characteristics of the inner ear, assessed through a preoperative HRCT study using the Otoplan® software by

Cascination AG.

Subsequently, the patients underwent cochlear implant surgery, which was performed by the same expert otosurgeon.

3.2 Surgical procedure

The surgery begins with the administration of general anesthesia to keep the patient unconscious and pain-free. The patient is positioned supine on the operating table. The head is turned to the opposite side of the ear to be implanted, fully exposing the surgical site. The area around the ear is thoroughly cleaned with an antiseptic solution, and sterile drapes are placed to maintain a sterile field. The surgeon starts by making a post-auricular incision, which is typically about 3-4 centimeters long. This incision goes through the skin and subcutaneous tissue, exposing the mastoid bone. Using a high-speed drill, the surgeon then performs a mastoidectomy, which involves removing part of the mastoid bone. During this process, the facial nerve is carefully preserved and monitored to avoid injury. The surgery is performed under Nerve Intraoperative Monitoring (NIM), a technique used to continuously monitor the facial nerve's function throughout the procedure, thereby minimizing the risk of nerve damage. Following the mastoidectomy, the surgeon proceeds with a posterior tympanotomy. This involves creating an access route through the facial recess to the tympanic cavity, providing direct access to the round window and the cochlea. The surgeon uses microsurgical instruments to carefully open this route, ensuring a clear path for the next steps.Next, a small opening is made in the cochlea, a process known as cochleostomy. There are two common approaches for this: drilling a direct hole into the basal turn of the cochlea or using the round window, a natural opening into the cochlea, for the insertion. The electrode array of the cochlear implant is then gently inserted through this opening into the cochlea. The surgeon ensures the electrodes are correctly positioned to optimize contact with the auditory nerve fibers. Special care is taken to minimize trauma to the delicate cochlear structures to preserve any residual hearing the patient might have. After the electrode array is in place, the internal receiver-stimulator of the implant is positioned in a small well or depression drilled into the skull bone behind the ear. The electrode lead is routed from the cochlea to the internal device, ensuring there is no tension on the electrodes.

Intraoperative telemetry ($T_{intraoperative}$) is then carried out, evaluating impedances and ECAPs for all three types of electrodes using specific software provided by various manufacturers (Custom Sound® Version 7.0 by Cochlear Ltd.; SoundWave 2.3 by Advanced Bionics Corp.; Maestro 10 by Med-el GmbH). For Cochlear Ltd. electrodes, TIM is also calculated. Once the device has been tested, the incision is closed in layers, and a compressive bandage is then applied. The patients were then discharged from the operating room with indication to follow prophylactic antibiotic therapy.

3.3 Post-operative follow-up

The day after the surgery, all patients underwent CBCT of the petrous bones using the same radiological equipment. The postoperative radiological examination was performed to assess the correct positioning of the electrode array within the cochlea and to identify any complications, such as electrode translocations or tip fold over.

The postoperative radiological images were also utilized for research purposes to calculate EMD. To calculate EMD, CT scans were processed using Otoplan® software to identify the positions of individual electrodes relative to the modiolar wall. The CT scan analysis involved three steps: 1) localizing the electrodes in the post-implantation CT scan, 2) localizing the modiolus in the pre-operative CT scan, where implant-related artifacts do not distort the cochlea, and 3) aligning the two CT scans to quantify the electrodes' locations relative to the modiolus. After localizing both the electrodes and the modiolus, the distance from each electrode to the nearest point on the modiolar wall was computed.

In the absence of complications, patients were discharged on the third postoperative day with instructions to complete the prophylactic antibiotic therapy. They were also advised to attend weekly check-ups during the first postoperative month for suture removal and to monitor the proper healing of the surgical site.

3.4 Speech processor activation and fitting

The activation of the speech processor was performed in all patients upon the completion of the surgical wound healing process, approximately one month after surgery. At the time of activation ($T_{activation}$), measurements were taken of both electrophysiological parameters (impedances, ECAP, T-levels, and M/C-levels) and functional parameters (PTA, speech audiometry in quiet, and speech audiometry in noise).

Upon completion of the activation, all patients began a speech therapy rehabilitation program with their speech therapist.

The patients were then invited to return to our hospital 1 (T_1), 3 (T_3), 6 (T_6), and 12 months (T_{12}) after activation for the continuation of the auditory rehabilitation program. At T_1, T_3, T_6, and T_{12}, measurements were taken of both electrophysiological parameters (impedances, T-levels, and M/C-levels) and functional parameters (PTA, speech audiometry in quiet, and speech audiometry in noise). After the first year, all patients were advised to have annual check-ups. The speech processor fitting strategy was chosen based on the characteristics of implanted electrode array.

Patients who received an electrode array by Cochlear Ltd. or Advanced Bionics Corp. underwent a behavioral speech processor fitting. Patients who received an electrode array by Med-el GmbH underwent an anatomy-based speech processor fitting.

All data collected during the preoperative, intraoperative, and postoperative phases were gathered and entered into a database for subsequent statistical analysis.

Since the values of ECAPs, T-levels, and M/C levels in the programming software vary between different manufacturers, the current levels (CL) provided by Cochlear Ltd. and the current units (CU) provided by Advanced Bionics Corp. were converted into charge units, the International System of Units expressed in Coulombs (C), defined as the amount of electric charge transported in one second by a current of one ampere (A). After providing the data to the respective manufacturers, these were converted into nanoCoulombs (nC) according to specific conversion protocols. Figure 19 summarizes the timeline of the study protocol.

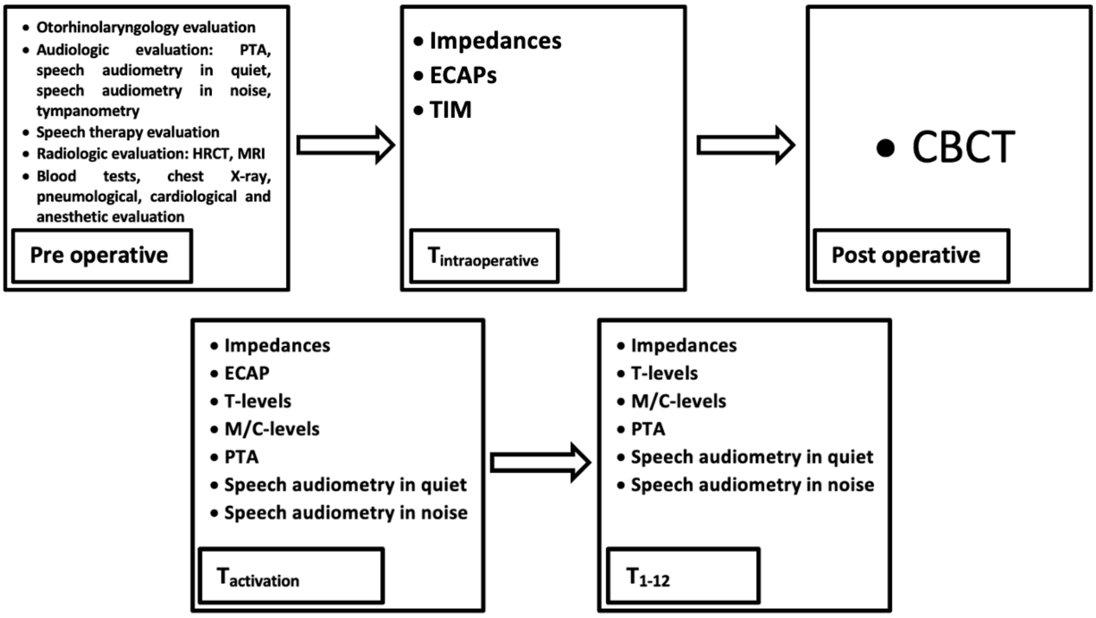


Figure 19: Timeline of the study protocol

3.5 Statistical analysis

All statistical analyses were conducted using JASP version 0.18.1 (Amsterdam University, Amsterdam, The Netherlands). Quantitative variables were summarized using means with 95% confidence intervals and medians, while categorical variables were presented as percentages. "Δ" was used to report percentage change. In the "pre vs post" comparisons within the same patients (paired data), the Wilcoxon signed-rank test was used, as it is a nonparametric test that takes into account the same population evaluated at two different time points.

The analyses were performed at three specific time points: $T_{intraoperative}$, $T_{activation}$ and T_{12}. For the comparison of variables between two groups, the Mann-Whitney test was utilized due to its suitability for non-parametric data, which does not assume normal distribution and is ideal for small sample sizes.

For the comparison of variables among multiple groups, the Kruskal-Wallis test was employed. This test was chosen because it is a non-parametric method that extends the Mann-Whitney test to multiple groups, allowing for the detection of differences in medians among the groups without assuming a normal distribution. Following the Kruskal-Wallis test, Tukey's post-hoc tests were conducted to identify specific differences between the groups.

To explore the relationship between variables, we calculated Spearman's correlation

(ρ). The Spearman correlation coefficient measures the strength and direction of a monotonic relationship between two variables:

-Positive ρ: When one variable increases, the other also tends to increase.

-Negative ρ: When one variable increases, the other tends to decrease.

-ρ close to 0: No monotonic correlation.

A p-value lower than 0.05 was considered statistically significant.

The correlation analysis between parameters was conducted using Spearman's correlation coefficient, for the following reasons:

-Non-normality of variables: The experimental data collected in this study may not follow a normal distribution. Spearman's correlation is a non-parametric test, making it suitable for this type of analysis.

-Monotonic relationships: Spearman's test is ideal for identifying monotonic relationships, meaning that an increase in one variable corresponds to either an increase or decrease in another, even if the relationship is not linear.

-Robustness to outliers: Spearman's correlation is less sensitive to outliers compared to Pearson's correlation, making it more reliable in heterogeneous experimental datasets.

4. RESULTS

4.1 Study population

A prospective longitudinal clinical study was conducted by enrolling a total of 48 patients suffering from bilateral severe to profound SNHL or mixed hearing loss. Out of the 48 patients, 24 had post-lingual deafness, and the remaining 24 had pre-lingual deafness. The patients were then divided into groups G1 and G2 based on the onset time of deafness.

Group G1 comprised 13 (54,16%) females and 11 (45,84%) males, whereas Group G2 included 5 (20,83%) females and 19 (79,17%) males. The mean age of Group G1 was 49.41 years (±14.26) (median: 49 years; range: 17-75), and for Group G2, it was 38.95 years (±12.93) (median: 35 years; range: 17-65). The average age of deafness onset in Group G1 was 28.79 years (±21.28) (median: 26 years; range: 4-63). In Group G2, 10 patients presented with congenital pre-lingual deafness, while the remaining 14 patients had an average onset age of 2.93 years (±3.18) (median: 2.5 years; range: 1-3). The mean BC-PTA in the ear to be implanted was 85 dB HL (±7 dB) (median: 88 dB HL; range: 75-100 dB HL) in the G1 group and 95 dB HL (±5 dB) (median 97 dB HL; range: 90-110 dB HL) in the G2 group. The mean free-field threshold with hearing aids was 55 dB HL (±8 dB) (median: 54 dB HL; range: 45-70 dB HL) in the G1 group and 65 dB HL (±6 dB) (median: 66 dB HL; range: 55-75 dB HL) in the G2 group. The mean SRT, determined through speech audiometry in quiet with hearing aids, was 60 dB HL (±6 dB) (median: 62 dB HL; range: 52-64 dB HL) in the G1 group and 78 dB HL (±5 dB) (median: 77 dB HL; range: 73-83 dB HL) in the G2 group. The mean SNR, determined through speech audiometry in noise with hearing aids, was 8 dB HL (±2 dB) (median 8 dB HL; range: 6-10 dB HL) in the G1 group. In the G2 group, it was not possible to conduct the test due to the severity of the hearing loss. Table 3 summarizes the main baseline characteristics of G1 and G2 groups. All patients in both groups showed a type “A” tympanogram.

Table 3: main baseline characteristics of G1 and G2 groups

	G1 group (n=24)	G2 group (n=24)
F/M	13/11	5/19
Mean age (SD)	49.41 (±14.26)	38.95 (±12.93)
Mean BC-PTA (SD)	85 dB HL (±7 dB)	95 dB HL (±5 dB)
Mean free-field threshold with HA (SD)	55 dB HL (±8 dB)	65 dB HL (±6 dB)
Mean SRT with HA (SD)	60 dB HL (±6 dB)	78 dB HL (±5 dB)
Mean SNR with HA (SD)	8 ± 2 dB HL	NA

F/M= female/male; SD= standard deviation; HA= hearing aids; NA= not available

The randomization process led to the selection of 24 (50%) patients to receive the PM electrode array Cochlear Nucleus Profile Plus (CI 632) Slim Modiolar by Cochlear Ltd. (12 from G1 group and 12 from G2 group), 12 (25%) patients to receive the LW electrode array HiRes Ultra 3D HiFocus SlimJ by Advanced Bionics Corp. [6 (12,5%) from G1 group and 6 (12,5%) from G2 group], and 12 (25%) patients to receive the LW electrode array by Med-el GmbH [6 (12,5%) from G1 group and 6 (12,5%) from G2 group]. Specifically, for this last type of electrode, following the study of anatomical characteristics using Otoplan® software by Cascination AG, in the G1 group, 4 (16,7%) patients received the Med-El Synchrony 2 (MI 1200) Flex 28 electrode and 2 (8,33%) patients received the Med-El Synchrony 2 (MI 1200) Classic standard electrode; in the G2 group, 2 (8,33%) patients received the Med-El Synchrony 2 (MI 1200) Flex 28 electrode and 4 (16,7%) patients received the Med-El Synchrony 2 (MI 1200) Flex 26 electrode. Table 4 summarizes the distribution of the different electrode models in G1 and G2 groups.

Table 4: distribution of the different electrode models in G1 and G2 groups

	Manufacturer	Electrode array model	G1 group (n=24)	G2 group (n=24)
PM	Cochlear Ltd.	Nucleus Profile Plus (CI 632) Slim Modiolar	12	12
LW	Advanced Bionics Corp.	HiRes Ultra 3D HiFocus SlimJ	6	6
	Med-el GmbH	Synchrony 2 (MI 1200) Flex 28/Flex 26/Standard	6	6

After assigning each patient to a specific type of electrode, we analyzed the baseline characteristics of the individual study groups (G1 and G2) based on the type of electrode to be implanted.

G1 group

In G1 group, the patients undergoing implantation with PM electrodes by Cochlear Ltd. included 7 (58,33%) females and 5 (41,67%) males, the average age was 46.84 (±13.81) years, the mean BC-PTA in the ear to be implanted was 84 dB HL (±7 dB), the mean free-field threshold with hearing aids was 57 dB HL (±7 dB), the mean SRT was 58 dB HL (±6 dB) and the mean SNR was 7 dB HL (±2 dB); the patients undergoing implantation with LW electrodes included 6 (50%) females and 6 (50%) males, the average age was 52,0 (±15.21) years, the mean BC-PTA in the ear to be implanted was 86 dB HL (±7 dB), the mean free-field threshold with hearing aids was 56 dB HL (±9 dB), the mean SRT was 63 dB HL (±6 dB) and the mean SNR was 7 dB HL (±2 dB). When evaluating the electrodes based on the manufacturers, the patients undergoing implantation with electrodes by Advanced Bionics Corp. included 5 females and 1 male, the average age was 54.34 years (±14.44), the mean BC-PTA in the ear to be implanted was 89 dB HL (±6 dB), the mean free-field threshold with hearing aids was 60 dB HL (±8 dB), the mean SRT was 64 dB HL (±4 dB) and the mean SNR was 8 dB HL (±1 dB); the patients undergoing implantation with electrodes by Med-el GmbH included 1 female and 5 males, the average age was 49.67 years (±16.21), the mean BC-PTA in the ear to be implanted was 82 dB HL (±8 dB), the mean free-field threshold with hearing aids was 52 dB HL (±9 dB), the mean SRT was 62 dB HL (±8 dB) and the mean SNR was 6 dB HL (±2 dB).

G2 group

In G2 group, the patients undergoing implantation with PM electrodes by Cochlear Ltd. included 2 (16,67%) females and 10 (83,33%) males, the average age was 33.25 years (±14.55), the mean BC-PTA in the ear to be implanted was 95 dB HL (±2 dB), the mean free-field threshold with hearing aids was 64 dB HL (±6 dB), the mean SRT was 76 dB HL (±3 dB); the patients undergoing implantation with LW electrodes included 3 (25%) females and 9 (75%) males, the average age was 44,7 (±8,1) years, the mean BC-PTA in the ear to be implanted was 94,5 dB HL (±6 dB), the mean free-field threshold with hearing aids was 66 dB HL (±6 dB), the mean SRT was 77,5 (±5 dB) dB HL. When evaluating the electrodes based on the manufacturers, the patients undergoing implantation with electrodes with electrodes by Advanced Bionics Corp. included 1 female and 5 males, the average age was 49.34 years (±7.81), the mean BC-PTA in the ear to be implanted was 98 dB HL (±5 dB), the mean free-field threshold with hearing aids was 69 dB HL (±5 dB), the mean SRT was 81 dB HL (±4 dB); the patients undergoing implantation with electrodes by Med-el GmbH. included 2 females and 4 males, the average age was 40 years (±5.85), the mean BC-PTA in the ear to be implanted was 91 dB HL (±8 dB), the mean free-field threshold with hearing aids was 63 dB HL (±7 dB), the mean SRT was 74 dB HL (±8 dB).

Table 5: baseline characteristics of G1 group based on the type of electrode

G1 group (n=24)	**PM**	**LW**	
Manufacturer	**Cochlear Ltd. (n=12)**	**Advanced Bionics Corp. (n=6)**	**Med-el GmbH (n=6)**
F/M	7/5	5/1	1/5
Mean age (SD)	46.84 (±13.81)	54.34 (±14.44)	49.67 (±16.21)
Mean BC-PTA (SD)	84 dB HL (±7 dB)	89 dB HL (±6 dB)	82 dB HL (±8 dB)
Mean free-field threshold with HA (SD)	57 dB HL (±7 dB)	60 dB HL (±8 dB)	52 dB HL (±9 dB)
Mean SRT with HA (SD)	58 dB HL (±6 dB)	64 dB HL (±4 dB)	62 dB HL (±8 dB)
Mean SNR with HA (SD)	7 dB HL (±2 dB)	8 dB HL (±1 dB)	6 dB HL (±2 dB)

F/M= female/male; SD= standard deviation; HA= hearing aids

Table 6: baseline characteristics of G2 group based on the type of electrode

G2 group (n=24)	PM	LW	
Manufacturer	**Cochlear Ltd. (n=12)**	**Advanced Bionics Corp. (n=6)**	**Med-el GmbH (n=6)**
F/M	2/10	1/5	2/4
Mean age (SD)	33.25 (±14.55)	49.34 (±7.81)	40 (±5.85)
Mean BC-PTA (SD)	95 dB HL (±2 dB)	98 dB HL (±5 dB)	91 dB HL (±8 dB)
Mean free-field threshold with HA (SD)	64 dB HL (±6 dB)	69 dB HL (±5 dB)	63 dB HL (±7 dB)
Mean SRT with HA (SD)	76 dB HL (±3 dB)	81 dB HL (±4 dB)	74 dB HL (±8 dB)
Mean SNR with HA (SD)	NA	NA	NA

F/M= female/male; SD= standard deviation; HA= hearing aids; NA= not available

4.2 Intraoperative electrophysiological measurements ($T_{intraoperative}$)

G1 group

- *Impedances*

Separating the data into LW and PM electrode arrays resulted in groups of 168 and 264 electrodes, respectively. Despite the sample having the same number of LW and PM electrode arrays, the analysis included significantly more electrodes from the PM arrays. This is due to the higher number of PM electrode arrays from Cochlear, which feature 22 intracochlear electrodes, compared to 16 and 12 for Advanced Bionics and Med-el, respectively. In the G1 group, the intraoperative mean impedance of the PM electrode arrays was 9,307 (±3,073) kΩ, with a median of 9.28 kΩ compared to 5,285 (±1,230) kΩ with a median of 5,2 kΩ for the LW electrode arrays. The Mann-Whitney U test indicated a significant difference in impedances between the PM and LW electrode arrays, with the PM arrays having a significantly higher mean impedance (Figure 20).

Mann-Whitney U test

	W	df	p
Intraoperative impedances	4631.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Intraoperative impedances	LW	168	5.285	1.230	0.095	0.233
	PM	264	9.307	3.073	0.189	0.330

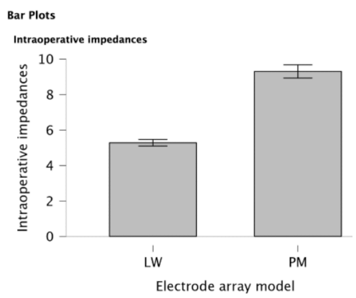


Figure 20: Comparison of intraoperative impedances between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the intraoperative mean impedance was 5,222 (±0,764) kΩ with a median of 5,75 kΩ for Advanced Bionics electrodes, 4,897 (±1,283) kΩ with a median of 4,53 kΩ for Med-el electrodes, and 9,307 (±3,073) kΩ with a median of 9,28 kΩ for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significantly higher mean impedance, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 21).

ANOVA

ANOVA – Intraoperative impedances

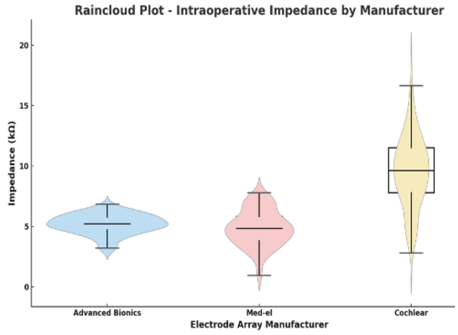
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	1836.289	2	918.145	148.313	< .001
Residuals	2655.756	429	6.191		

Note. Type III Sum of Squares

Descriptives

Descriptives – Intraoperative impedances

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	5.222	0.764	0.078	0.146
Cochlear	264	9.307	3.073	0.189	0.330
Med-el	72	4.897	1.283	0.151	0.262



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	−4.085	−4.783	−3.388	0.297	−13.776	< .001
	(Med-el)	0.324	−0.588	1.237	0.388	0.836	0.681
Cochlear	(Med-el)	4.410	3.632	5.188	0.331	13.330	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	232.159	2	< .001

Figure 21: Comparison of intraoperative impedances between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

- *ECAPs*

Regarding the intraoperative mean ECAP values, this was not calculated for every single electrode in the LW and PM electrode arrays, but only for those where the software was able to record a response. This was calculated for 84 electrodes in the LW arrays and 176 in the PM arrays. The mean ECAP values were 19,058 (±2,295) nC with a median of 18.25 nC for the LW electrode arrays and 13,948 (±6,140) nC with a median of 12,81 nC for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in ECAP values between the two types of electrodes, with the LW having a significantly higher mean ECAPs (Figure 21).

Mann-Whitney U test

Independent Samples T-Test

	W	df	p
Intraoperative ECAPs	11013.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Intraoperative ECAPs	LW	84	19.058	2.295	0.250	0.120
	PM	176	13.948	6.140	0.463	0.440

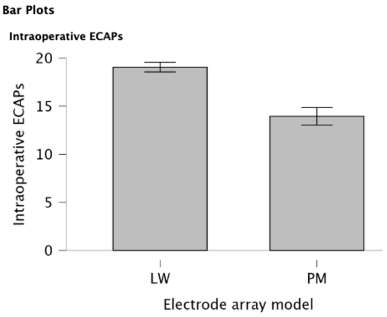


Figure 22: Comparison of intraoperative ECAPs between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the intraoperative mean ECAPs was 19,169 (±2.694) nC with a median of 18,4 nC for Advanced Bionics electrodes, 18,878 (±1.448) nC with a median of 17,25 nC for Med-el electrodes, and 13,948 (±6,140) nC with a median of 12,81 nC for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in ECAPs across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significantly lower mean ECAPs, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 23).

ANOVA

ANOVA – Intraoperative ECAPs

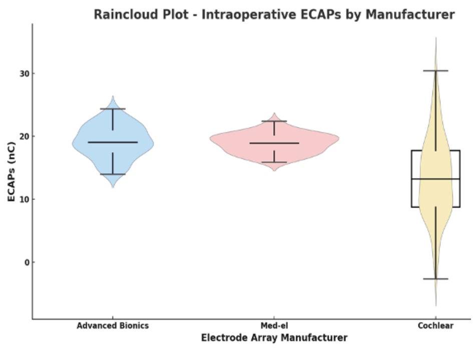
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	1486.673	2	743.337	27.166	< .001
Residuals	7032.125	257	27.362		

Note. Type III Sum of Squares

Descriptives

Descriptives – Intraoperative ECAPs

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advances Bionics	52	19.169	2.694	0.374	0.141
Cochlear	176	13.948	6.140	0.463	0.440
Med–el	32	18.878	1.448	0.256	0.077



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

		Mean Difference	95% CI for Mean Difference Lower	95% CI for Mean Difference Upper	SE	t	p_{tukey}
Advances Bionics	Cochlear	5.221	3.275	7.168	0.826	6.324	< .001
	(Med–el)	0.291	−2.479	3.062	1.175	0.248	0.967
Cochlear	(Med–el)	−4.930	−7.300	−2.560	1.005	−4.904	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal–Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	40.798	2	< .001

Figure 23: Comparison of intraoperative ECAPs between Advanced Bionics and Med-el electrode arrays in G1 group.

As for TIM, measured exclusively for patients implanted with PM-type electrode arrays by Cochlear Ltd, it was within the normal range in all 12 cases of the G1 group.

G2 group

- *Impedances*

In the G2 group, the intraoperative mean impedance was calculated for 168 LW electrodes and 264 PM electrodes. The mean impedance for the PM electrode arrays was 11,015 (±3,080) kΩ with a median of 11,28 kΩ, compared to 5,262 (±1,584) kΩ with a median of 5,29 kΩ for the LW electrode arrays. The Mann-Whitney U test indicated a significant difference in impedances between the PM and LW electrode arrays, with the PM having a significantly higher mean impedance (Figure 24).

Mann-Whitney U test

	W	df	p
Intraoperative impedances	3529.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Intraoperative impedances	LW	168	5.262	1.584	0.122	0.301
	PM	264	11.015	3.080	0.190	0.280

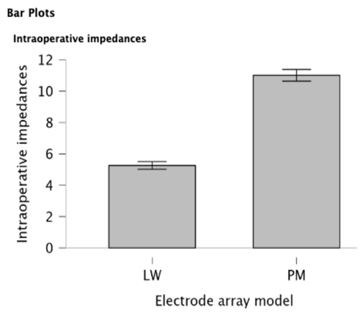


Figure 24: Comparison of intraoperative impedances between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the intraoperative mean impedance was 5,366 (±1.408) kΩ with a median of 5,5 kΩ for Advanced Bionics electrodes, 5,124 (±1,793) kΩ with a median of 6,67 kΩ for Med-el electrodes, and 11,015 (±3,080) kΩ with a median of 11,28 kΩ for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedances across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significantly higher mean impedance, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 25).

ANOVA

ANOVA – Intraoperative impedances

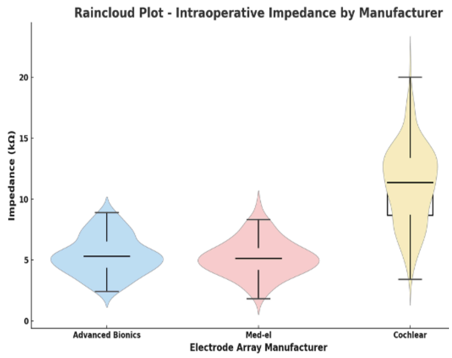
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	3399.742	2	1699.871	250.529	< .001
Residuals	2910.820	429	6.785		

Note. Type III Sum of Squares

Descriptives

Descriptives – Intraoperative impedances

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	5.366	1.408	0.144	0.262
Cochlear	264	11.015	3.080	0.190	0.280
Med-el	72	5.124	1.793	0.211	0.350



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	−5.649	−6.379	−4.919	0.310	−18.196	< .001
	(Med-el)	0.241	−0.714	1.197	0.406	0.595	0.823
Cochlear	(Med-el)	5.890	5.076	6.705	0.346	17.009	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	217.987	2	< .001

Figure 25: Comparison of intraoperative impedances between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

- *ECAPs*

Regarding the intraoperative mean ECAP values, they were calculated for 117 LW electrodes and 246 PM electrodes. The mean ECAP values were 19,520 (±2.655) nC with a median of 18,85 nC for the LW electrode arrays and 13,621 (±4,462) nC with a median of 13,28 nC for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in ECAP values between the two types of electrodes, with the LW having a significantly higher mean ECAPs (Figure 26).

Mann-Whitney U test

	W	df	p
Intraoperative impedances	24958.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Intraoperative impedances	LW	110	19.520	2.655	0.253	0.136
	PM	246	13.621	4.462	0.284	0.328

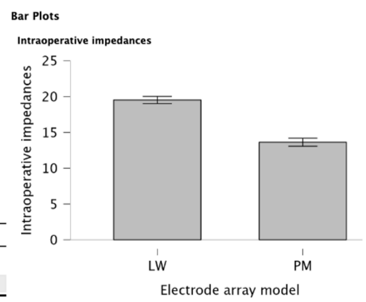


Figure 26: Comparison of intraoperative ECAPs between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the intraoperative mean ECAPs was 19,747 (±2,885) nC with a median of 19,4 nC for Advanced Bionics electrodes, 19,400 (±2.538) nC with a median of 18,8 nC for Med-el electrodes, and 13,621 (±4,462) nC with a median of 13,28 nC for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedances across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significantly lower mean ECAPs, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 27).

ANOVA

ANOVA – Intraoperative ECAPs

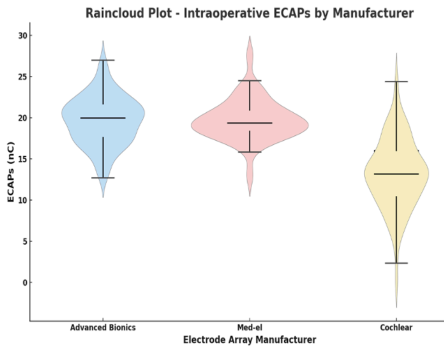
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	2647.640	2	1323.820	82.819	< .001
Residuals	5642.514	353	15.984		

Note. Type III Sum of Squares

Descriptives

Descriptives – Intraoperative ECAPs

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	38	19.747	2.885	0.468	0.146
Cochlear	246	13.621	4.462	0.284	0.328
Med−el	72	19.400	2.538	0.299	0.131



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

		Mean Difference	95% CI for Mean Difference Lower	95% CI for Mean Difference Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	6.126	4.486	7.766	0.697	8.791	< .001
	(Med−el)	0.347	−1.539	2.234	0.802	0.433	0.902
Cochlear	(Med−el)	−5.779	−7.039	−4.518	0.536	−10.787	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	162.282	2	< .001

Figure 27: Comparison of intraoperative ECAPs between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

As for TIM, measured exclusively for patients implanted with PM-type electrode arrays by Cochlear Ltd, it was within the normal range in all 12 cases of the G2 group.

4.3 Post-operative radiological measurements ($T_{post\text{-}operative}$)

G1 group

- *EMD*

None of the 24 patients in the G1 group experienced severe postoperative complications. In only 3 cases did transient postoperative vertiginous symptoms appear, which resolved spontaneously during the hospital stay. Postoperative radiological evaluation did not detect any scalar translocations, tip fold-overs, or other complications in any case. The analysis of postoperative CT images of the G1 group revealed an average EMD of 1,161 (±0,069) mm with a median of 1,162 mm for the LW electrode arrays and 0,517 (±0,041) mm with a median of 0,511 mm for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in EMD between the LW and PM electrode arrays, with the LW arrays having a significantly higher EMD (Figure 28).

Mann-Whitney U test

	W	df	p
EMD	144.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
EMD	LW	12	1.161	0.069	0.020	0.059
	PM	12	0.517	0.041	0.012	0.078

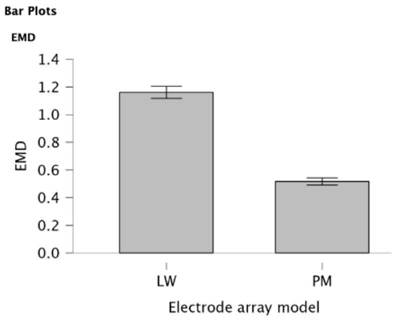


Figure 28: Comparison of EMD between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean EMD was 1,119 (±0,063) mm with a median of 1,117 mm for Advanced Bionics electrodes, 1,202 (±0,047) mm with a median of 1,192 mm for Med-el electrodes, and 0,517 (±0,041) mm with a median of 0,511 mm for Cochlear electrodes. The ANOVA indicated a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in EMD across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant lower EMD, differ significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el electrode arrays is not significant (Figure 29).

ANOVA

ANOVA – EMD

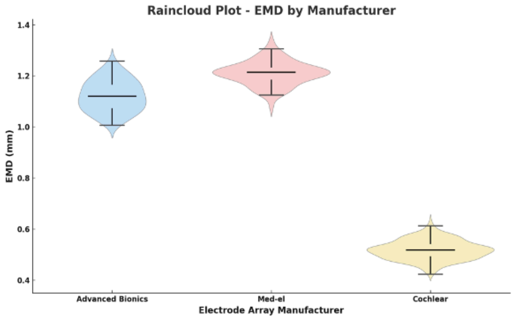
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	2.507	2	1.253	535.953	< .001
Residuals	0.049	21	0.002		

Note. Type III Sum of Squares

Descriptives

Descriptives – EMD

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	6	1.119	0.063	0.026	0.057
Cochlear	12	0.517	0.041	0.012	0.078
Med-el	6	1.202	0.047	0.019	0.039



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	0.602	0.541	0.663	0.024	24.905	< .001
	(Med-el)	−0.083	−0.153	−0.013	0.028	−2.973	0.019
Cochlear	(Med-el)	−0.685	−0.746	−0.624	0.024	−28.338	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	18.407	2	< .001

Figure 29: Comparison of EMD between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

- *AID*

Regarding the mean AID, it was found to be 513,750 (±97,308) degrees with a median of 500 degrees for the LW electrode arrays and 381,667 (±20,263) degrees with a median of 385 degrees for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in AID between the LW and PM electrode arrays, with the LW arrays having a significantly higher AID (Figure 30).

Mann-Whitney U test

	W	df	p
AID	140.500		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
AID	LW	12	513.750	97.308	28.090	0.189
	PM	12	381.667	20.263	5.850	0.053

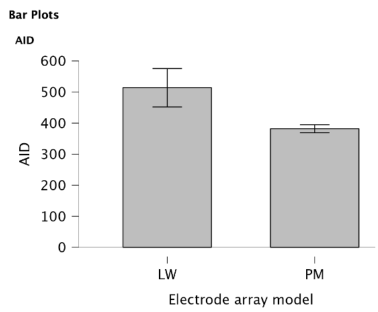


Figure 30: Comparison of AID between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean AID was 426,667 (±20,897) degrees with a median of 430 degree for Advanced Bionics electrodes, 600,833 (±46,842) degrees with a median of 587,5 degrees for Med-el electrodes, and 381,667 (±20,263) degrees with a median of 385 degrees for Cochlear electrodes. The ANOVA indicated a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in AID across the three manufacturers. The Tukey post-hoc test indicated that Med-el, having a significant higher AID, differ significantly from both Advanced Bionics and Cochlear, while the difference between Advanced Bionics and Cochlear electrode arrays is not significant (Figure 31).

ANOVA

ANOVA – AID

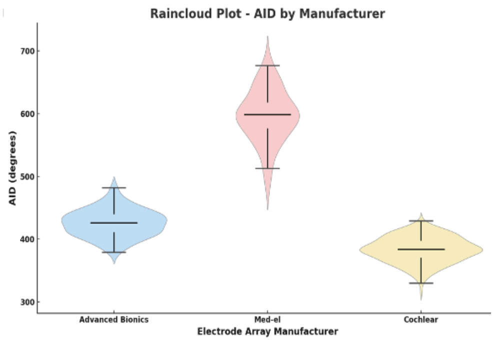
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	195678.125	2	97839.063	116.272	< .001
Residuals	17670.833	21	841.468		

Note. Type III Sum of Squares

Descriptives

Descriptives – AID

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	6	426.667	20.897	8.531	0.049
Cochlear	12	381.667	20.263	5.850	0.053
Med–el	6	600.833	46.842	19.123	0.078



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	45.000	8.442	81.558	14.504	3.103	0.014
	(Med–el)	−174.167	−216.381	−131.953	16.748	−10.399	< .001
Cochlear	(Med–el)	−219.167	−255.725	−182.608	14.504	−15.111	< .001

Note. P–value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal–Wallis Test

Kruskal–Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	18.337	2	< .001

Figure 31: Comparison of AID between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

G2 group

- *EMD*

None of the 24 patients in the G2 group experienced severe postoperative complications. In only 1 case did persistent postoperative vertiginous symptoms appear, caused by transient unilateral vestibular hypofunction. In this case, postoperative radiological evaluation detected the presence of pneumolabyrinth; however, no scalar translocations, tip fold-overs, or other complications were detected. The analysis of postoperative CT images of the G2 group revealed an average EMD of 1,131 (±0,105) mm with a median of 1,127 mm for the LW electrode arrays and 0,521 (±0,061) mm with a median of 0,511 mm for the PM electrode arrays. The Mann-Whitney U test revealed a significant difference in EMD between the LW and PM electrode arrays, with the LW arrays having a significantly higher EMD (Figure 32).

Mann-Whitney U test

	W	df	p
EMD	144.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
EMD	LW	12	1.131	0.105	0.030	0.093
	PM	12	0.521	0.061	0.018	0.117

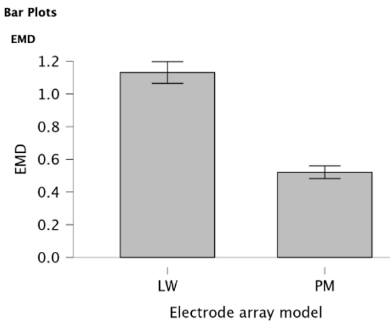


Figure 32: Comparison of EMD between LW and PM electrode arrays

When evaluating the electrodes based on the manufacturers, it was found that the mean EMD was 1,103 (±0.090) mm with a median of 1,075 mm for Advanced Bionics electrodes, 1,157 (±0,118) mm with a median of 1,157 mm for Med-el electrodes, and 0,522 (±0,060) mm with a median of 0,511 mm for Cochlear electrodes. The ANOVA test indicated a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in EMD across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant lower EMD, differ significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el electrode arrays is not significant (Figure 31).

ANOVA

ANOVA – EMD

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	2.229	2	1.114	155.992	< .001
Residuals	0.150	21	0.007		

Note. Type III Sum of Squares

Descriptives

Descriptives – EMD

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	6	1.103	0.090	0.037	0.082
Cochlear	12	0.522	0.060	0.017	0.116
Med-el	6	1.157	0.118	0.048	0.102

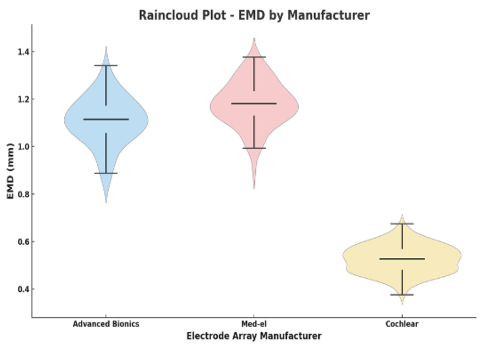
Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	0.582	0.475	0.688	0.042	13.763	< .001
	(Med-el)	−0.053	−0.176	0.070	0.049	−1.093	0.529
Cochlear	(Med-el)	−0.635	−0.742	−0.528	0.042	−15.025	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).



Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	17.402	2	< .001

Figure 33: Comparison of EMD between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

- *AID*

Regarding the mean AID, it was found to be 462,500 (±58,407) degrees with a median of 497,6 degrees for the LW electrode arrays and 378,333 (±22.088) with a median of 380 degrees for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in AID between the LW and PM electrode arrays, with the LW arrays having a significantly higher AID (Figure 30).

Mann-Whitney U test

	W	df	p
AID	139.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
AID	LW	12	462.500	58.407	16.861	0.126
	PM	12	378.333	22.088	6.376	0.058

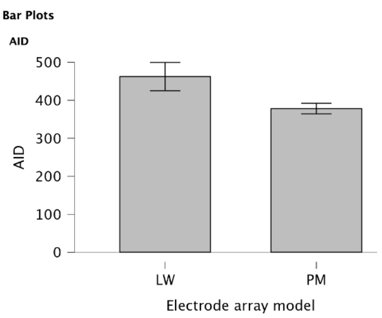


Figure 34: Comparison of AID between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean AID was 406,429 (±28,094) degrees with a median of 417,5 degree for Advanced Bionics electrodes, 509,167 (±45,543) degrees with a median of 497,5 degrees for Med-el electrodes, and 378,333 (±22,088) degrees with a median of 380 degrees for Cochlear electrodes. The ANOVA test indicated a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in AID across the three manufacturers. The Tukey post-hoc test indicated that Med-el, having a significant higher AID, differ significantly from both Advanced Bionics and Cochlear, while the difference between Advanced Bionics and Cochlear electrode arrays is not significant (Figure 35).

ANOVA

ANOVA – AID

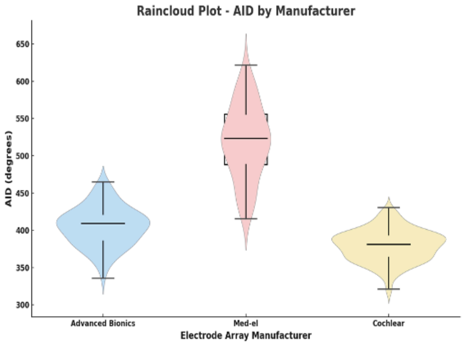
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	69682.786	2	34841.393	37.440	< .001
Residuals	20473.214	22	930.601		

Note. Type III Sum of Squares

Descriptives

Descriptives – AID

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionincs	7	406.429	28.094	10.619	0.069
Cochlear	12	378.333	22.088	6.376	0.058
Med–el	6	509.167	45.543	18.593	0.089



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionincs	Cochlear	28.095	−8.351	64.541	14.508	1.936	0.152
	(Med–el)	−102.738	−145.372	−60.104	16.972	−6.053	< .001
Cochlear	(Med–el)	−130.833	−169.150	−92.517	15.253	−8.578	< .001

Note. P–value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal–Wallis Test

Kruskal–Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	16.124	2	< .001

Figure 35: Comparison of AID between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

4.4 Speech processor activation electrophysiological measurements ($T_{activation}$)

G1 group

- *Impedances*

In the G1 group, the activation mean impedance of the PM electrode arrays was 12,130 (±3,959) kΩ, with a median of 13,31 kΩ compared to 7,655 (±1,006) kΩ with a median of 7,6 kΩ for the LW electrode arrays. The Mann-Whitney U test indicated a significant difference in impedances between the PM and LW electrode arrays, with the PM arrays having a significantly higher mean impedance (Figure 36). It was also found that there was a $\Delta_{\text{Tintraoperative-Tactivation}}$ of +30,33% of the mean impedance value for PM electrodes and +30,95% for LW electrodes. The Wilcoxon signed-rank test revealed a significant increase in mean impedance values for both PM and LW electrode arrays (p<0,001).

Mann-Whitney U test

	W	df	p
Activation impedances	8085.000		< .001

Note. Mann–Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Activation impedances	LW	168	7.655	1.007	0.078	0.132
	PM	264	12.130	3.959	0.244	0.326

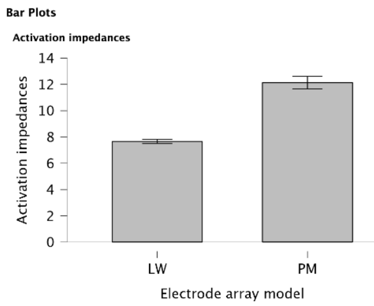


Figure 36: Comparison of activation impedances between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean impedance at the activation was 7,946 (±0,873) kΩ with a median of 7,9 kΩ for Advanced Bionics electrodes, 7,266 (±1,046) kΩ with a median of 7,16 kΩ for Med-el electrodes, and 12,129 (±3,958) kΩ with a median of 13,31 kΩ for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant higher mean impedance, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 37). It was also found that there was a $\Delta_{\text{Tintraoperative-Tactivation}}$ of +34,27% of the mean impedance value for Advanced Bionics, +32,60% for Med-el and +30,33% for Cochlear electrodes. The Wilcoxon signed-rank test revealed a significant increase in mean impedances values for the electrodes of all three manufacturers (p<0.001).

ANOVA

ANOVA – Activation impedances

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	2075.132	2	1037.566	104.202	< .001
Residuals	4271.676	429	9.957		

Note. Type III Sum of Squares

Descriptives

Descriptives – Activation impedances

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	7.946	0.873	0.089	0.110
Cochlear	264	12.130	3.959	0.244	0.326
Med–el	72	7.266	1.047	0.123	0.144

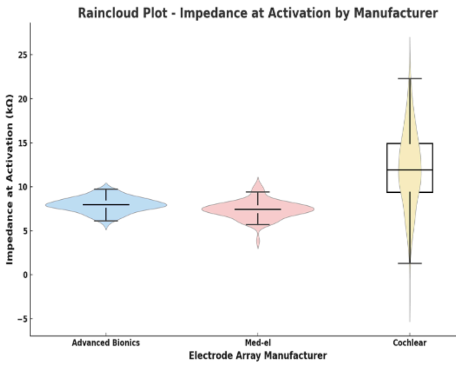
Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	−4.184	−5.068	−3.299	0.376	−11.125	< .001
	(Med–el)	0.680	−0.477	1.837	0.492	1.382	0.351
Cochlear	(Med–el)	4.864	3.877	5.850	0.420	11.593	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).



Kruskal–Wallis Test

Kruskal–Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	130.979	2	< .001

Figure 37: Comparison of intraoperative impedances between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

- *ECAPs*

Regarding the activation mean ECAP values, this was calculated for 96 electrodes in the LW arrays and 102 in the PM arrays. The mean ECAP values were 16,046 (±3,833) nC with a median of 16,4 nC for the LW electrode arrays and 12,491 (±5,694) nC with a median of 13,315 nC for the PM electrode arrays. The Mann-

Whitney U test indicated a significant difference in ECAP values between the two types of electrodes, with the LW having a significantly higher mean ECAPs (Figure 38). It was also found that there was a $\Delta_{\text{Tintraoperative-Tactivation}}$ of -11,66% of the mean impedance value for PM electrodes and -18,77% for LW electrodes. The Wilcoxon signed-rank test revealed a non-significant decrease in mean ECAPs values for both LW and PM electrode arrays (p=0,005; p=0,027).

Mann-Whitney U test

	W	df	p
Activation ECAPs	6740.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Activation ECAPs	LW	96	16.046	3.833	0.391	0.239
	PM	102	12.491	5.694	0.564	0.456

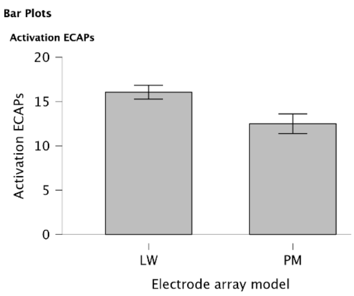


Figure 38: Comparison of activation ECAPs between LW and PM electrode arrays in G1 group.

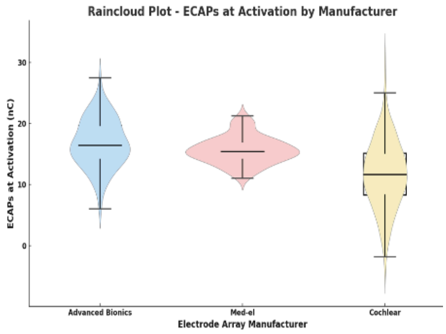
When evaluating the electrodes based on the manufacturers, it was found that the mean ECAPs at the activation was 16,273 (±4,255) nC with a median of 16,7 nC for Advanced Bionics electrodes, 15,777 (±2,294) nC with a median of 15,2 nC for Med-el electrodes, and 12,491 (±5,694) nC with a median of 12,58 nC for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant lower mean ECAPs, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 39). It was also found that there was a $\Delta_{\text{Tintraoperative-Tactivation}}$ of -17,79% of the mean ECAP values for Advanced Bionics, -19,65% for Med-el and -11,66% for Cochlear electrodes. The Wilcoxon signed-rank test revealed a non-significant decrease in mean ECAPs values for the electrodes of all three manufacturers (p=0,023; p=0,029; p=0,006).

ANOVA

ANOVA – Activation ECAPs

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	630.884	2	315.442	13.187	< .001
Residuals	4664.541	195	23.921		

Note. Type III Sum of Squares



Descriptives

Descriptives – Activation ECAPs

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	52	16.273	4.255	0.590	0.261
Cochlear	102	12.491	5.694	0.564	0.456
Med-el	44	15.777	3.294	0.497	0.209

Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	3.782	1.814	5.751	0.833	4.538	< .001
	(Med-el)	0.496	−1.870	2.862	1.002	0.495	0.874
Cochlear	(Med-el)	−3.286	−5.370	−1.203	0.882	−3.726	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	21.324	2	< .001

Figure 39: Comparison of intraoperative ECAPs between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

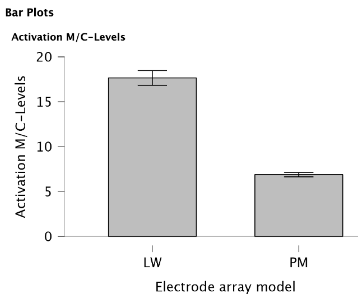
- *M/C-Levels*

Regarding the activation mean M/C-Levels, these were 17,654 (±5,417) nC with a median of 17,37 nC for the LW electrode arrays and 6,882 (±1,986) nC with a median of 7,19 nC for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in M/C levels between the two types of electrodes, with the LW having a significantly higher mean M/C Levels (Figure 40).

Mann-Whitney U test

	W	df	p
Activation M/C-Levels	44022.000		< .001

Note. Mann-Whitney U test.



Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Activation M/C-Levels	LW	168	17.654	5.417	0.418	0.307
	PM	264	6.882	1.986	0.122	0.289

Figure 40: Comparison of activation M/C-Levels between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean M/C-Levels at the activation was 17,342 (±3,514) nC with a median of 17,5 nC for Advanced Bionics electrodes, 18,069 (±7,224) nC with a median of 15,5 nC for Med-el electrodes, and 6,882 (±1,986) nC with a median of 7,19 nC for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant lower mean M/C-Levels, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 41).

ANOVA

ANOVA – Activation M/C-Levels

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	11935.403	2	5967.702	432.719	< .001
Residuals	5916.413	429	13.791		

Note. Type III Sum of Squares

Descriptives

Descriptives – Activation M/C-Levels

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	17.342	3.514	0.359	0.203
Cochlear	264	6.882	1.986	0.122	0.289
Med–el	72	18.069	7.224	0.851	0.400

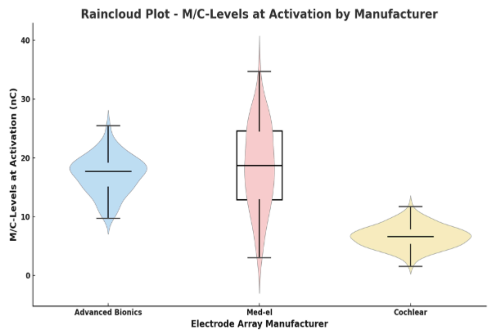
Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	10.461	9.420	11.502	0.443	23.634	< .001
	(Med–el)	−0.727	−2.089	0.634	0.579	−1.256	0.421
Cochlear	(Med–el)	−11.188	−12.349	−10.027	0.494	−22.659	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).



Kruskal–Wallis Test

Kruskal–Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	298.420	2	< .001

Figure 41: Comparison of intraoperative M/C-Levels between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

G2 group

- *Impedances*

In the G2 group, the activation mean impedance of the PM electrode arrays was 12,487 (±9,739) kΩ, with a median of 12,71 kΩ compared to 7,622 (±1,870) kΩ with a median of 7,3 kΩ for the LW electrode arrays. The Mann-Whitney U test indicated a significant difference in impedances between the PM and LW electrode arrays, with the PM arrays having a significantly higher mean impedance (Figure 42). It was also found that there was a $\Delta T_{intraoperative\text{-}Tactivation}$ of +4,43% of the mean impedance value for PM electrodes and +30,66% for LW electrodes. The Wilcoxon signed-rank test revealed a significant increase in mean impedance values for LW electrode arrays (p<0,001) and a non-significant increase in mean impedance values for PM electrode arrays (p=0,020).

Mann-Whitney U test

	W	df	p
Activation impedances	7655.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Activation impedances	LW	168	7.622	1.870	0.144	0.245
	PM	264	12.487	9.739	0.599	0.780

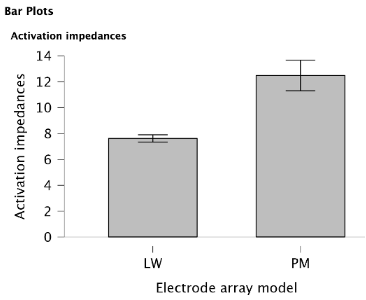


Figure 42: Comparison of activation impedances between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean impedance at the activation was 7,883 (±1,949) kΩ with a median of 7,31 kΩ for Advanced Bionics electrodes, 7,275 (±1,710) kΩ with a median of 7,16 kΩ for Med-el electrodes, and 11,730 (±3,944) kΩ with a median of 12,71 kΩ for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant higher mean impedance, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 43). It was also found that there was a $\Delta_{\text{Tintraoperative-Tactivation}}$ of +31,92% of the mean impedance value for Advanced Bionics, +29,56% for Med-el and +6,09% for Cochlear electrodes. The Wilcoxon signed-rank test revealed a significant increase in mean impedance values for Advanced Bionics and Med-el electrode arrays (p<0,001) and a non-significant increase in mean impedance values for Cochlear electrode arrays (p=0,020).

ANOVA

ANOVA – Activation impedances

Cases	Sum of Squares	df	Mean Square	F	p
Electrode manufacturer	1747.319	2	873.659	80.449	< .001
Residuals	4658.874	429	10.860		

Note. Type III Sum of Squares

Descriptives

Descriptives – Activation impedances

Electrode manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	7.883	1.949	0.199	0.247
Cochlear	264	11.730	3.944	0.243	0.336
Med-el	72	7.275	1.710	0.202	0.235

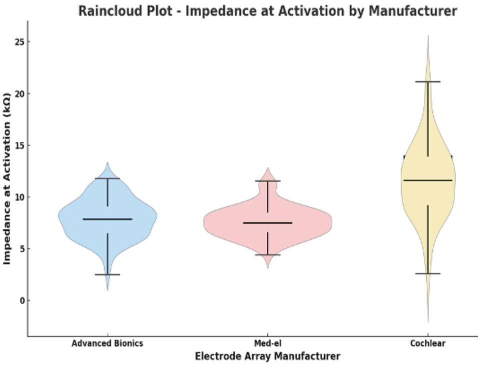
Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	−3.847	−4.771	−2.923	0.393	−9.795	< .001
	(Med-el)	0.608	−0.601	1.816	0.514	1.183	0.464
Cochlear	(Med-el)	4.455	3.424	5.485	0.438	10.167	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).



Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode manufacturer	133.314	2	< .001

Figure 43: Comparison of intraoperative impedances between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

- *ECAPs*

Regarding the activation mean ECAP values, this was calculated for 120 electrodes in the LW arrays and 108 in the PM arrays. The mean ECAP values were 15,608 (±2,883) nC with a median of 14,87 nC for the LW electrode arrays and 11,610 (±5,633) nC with a median of 10,5 nC for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in ECAP values between the two types of electrodes, with the LW having a significantly higher mean ECAPs (Figure 44). It was also found that there was a $\Delta_{\text{Tintraoperative-Tactivation}}$ of -17,32% of the mean impedance value for PM electrodes and -25,06% for LW electrodes. The Wilcoxon signed-rank test revealed a non-significant decrease in mean ECAPs values for both LW and PM electrode arrays (p=0,008; p=0,014).

Mann-Whitney U test

	W	df	p
Activation ECAPs	10556.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Activation ECAPs	LW	120	15.608	2.883	0.263	0.185
	PM	108	11.610	5.633	0.542	0.485

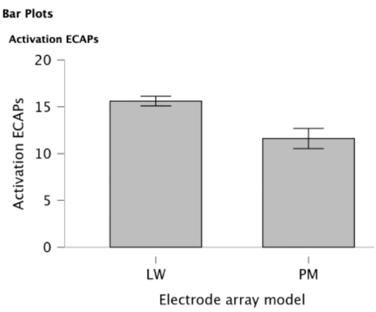


Figure 44: Comparison of activation ECAPs between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the

mean ECAPs at the activation was 15,966 (±2,855) nC with a median of 15,49 nC for Advanced Bionics electrodes, 15,250 (±2,889) nC with a median of 14,57 nC for Med-el electrodes, and 11,610 (±5,633) nC with a median of 10,5 nC for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant lower mean ECAPs, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 45). It was also found that there was a $\Delta_{\text{Tintraoperative-Tactivation}}$ of -21,50% of the mean ECAP values for Advanced Bionics, -27,21% for Med-el and -17,32% for Cochlear electrodes. The Wilcoxon signed-rank test revealed a non-significant decrease in mean ECAPs values for the electrodes of all three manufacturers (p=0,012; p=0,003; p=0,025).

ANOVA

ANOVA – Activation ECAPs

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	923.663	2	461.832	23.788	< .001
Residuals	4368.279	225	19.415		

Note. Type III Sum of Squares

Descriptives

Descriptives – Activation ECAPs

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	60	15.966	2.855	0.369	0.179
Cochlear	108	11.610	5.633	0.542	0.485
Med-el	60	15.250	2.889	0.373	0.189

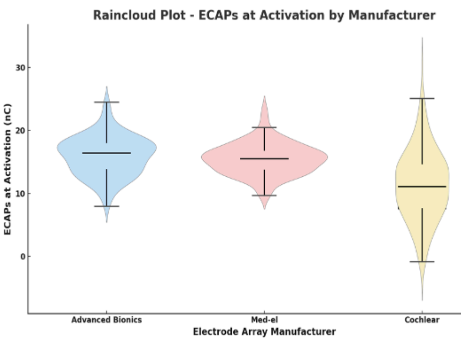
Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	4.355	2.681	6.029	0.709	6.139	< .001
	(Med-el)	0.716	−1.182	2.614	0.804	0.890	0.647
Cochlear	(Med-el)	−3.639	−5.313	−1.966	0.709	−5.130	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).



Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	68.074	2	< .001

Figure 45: Comparison of activation ECAPs between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

- *M/C-Levels*

Regarding the activation mean M/C-Levels, these were 14,801 (±4,017) nC with a median of 14 nC for the LW electrode arrays and 6,242 (±1,421) nC with a median of 6,33 nC for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in M/C-Levels between the two types of electrodes, with the LW having a significantly higher mean M/C-Levels (Figure 46).

Mann-Whitney U test

	W	df	p
Activation M/C-Levels	44175.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
Activation M/C-Levels	LW	168	14.801	4.017	0.310	0.271
	PM	264	6.242	1.421	0.087	0.228

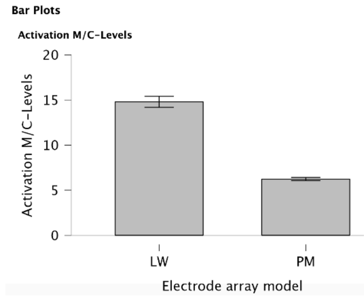


Figure 46: Comparison of activation M/C-Levels between LW and PM electrode arrays in G2 group

When evaluating the electrodes based on the manufacturers, it was found that the mean M/C-Levels at the activation was 14,938 (±2,734) nC with a median of 14,7 nC for Advanced Bionics electrodes, 14,618 (±5,282) nC with a median of 12,54 nC for Med-el electrodes, and 6,242 (±1,421) nC with a median of 6,33 nC for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant lower mean M/C-Levels, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 47).

ANOVA

ANOVA – Activation M/C-Levels

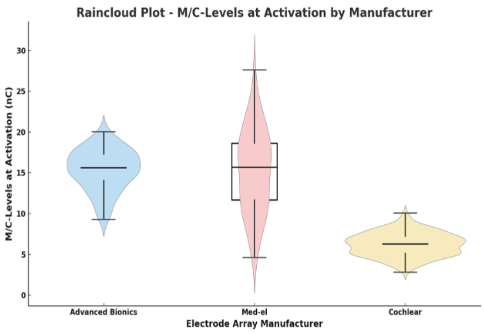
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	7525.127	2	3762.564	500.928	< .001
Residuals	3222.299	429	7.511		

Note. Type III Sum of Squares

Descriptives

Descriptives – Activation M/C-Levels

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	14.938	2.734	0.279	0.183
Cochlear	264	6.242	1.421	0.087	0.228
Med-el	72	14.618	5.282	0.622	0.361



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	8.696	7.928	9.464	0.327	26.623	< .001
	(Med-el)	0.320	−0.685	1.325	0.427	0.748	0.735
Cochlear	(Med-el)	−8.376	−9.233	−7.519	0.364	−22.988	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	303.460	2	< .001

Figure 47: Comparison of intraoperative M/C-Levels between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

4.5 Twelve-months measurements (T_{12})

4.5.1 Electrophysiological parameters

G1 group

- *Impedances*

In the G1 group, the T_{12} mean impedance of the PM electrode arrays was 8,501 (±3,191) kΩ, with a median of 7,84 kΩ compared to 6,317 (±1,192) kΩ with a median of 6,2 kΩ for the LW electrode arrays. The Mann-Whitney U test indicated a significant difference in impedances between the PM and LW electrode arrays, with the PM arrays having a significantly higher mean impedance (Figure 48). It was also found that there was a $\Delta_{Tactivation\text{-}T12}$ of -32,14% of the mean impedance value for PM electrodes and -17,47% for LW electrodes. The Wilcoxon signed-rank test revealed a significant decrease in mean impedance values for PM electrode arrays (p<0,001) and a non-significant decrease for LW electrode arrays (p=0,003).

Mann-Whitney U test

	W	df	p
T12 impedances	11946.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
T12 impedances	LW	168	6.317	1.192	0.092	0.189
	PM	264	8.502	3.192	0.196	0.375

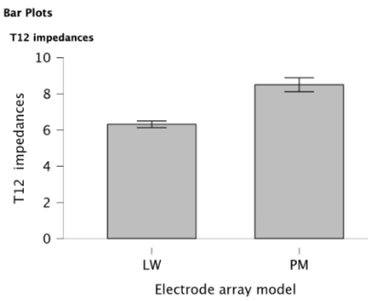


Figure 48: Comparison of T_{12} impedances between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean impedance at $T_{12}$was 6,371 (±1,31) kΩ with a median of 6,2 kΩ for Advanced Bionics electrodes, 6,244 (1,01±) kΩ with a median of 6,06 kΩ for Med-el electrodes, and 8,501 (±3,191) kΩ with a median of 7,84 kΩ for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant higher mean impedance, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 49). It was also found that there was a $\Delta_{Tactivation\text{-}T12}$ of -19,82% of the mean impedance value for Advanced

Bionics, -14,06% for Med-el and -32,14% for Cochlear electrodes. The Wilcoxon signed-rank test revealed a significant decrease in mean impedance values for Cochlear electrode arrays (p<0,001) and a non-significant decrease for both Advanced Bionics and Med-el electrode arrays (p=0,017; p=0,024).

ANOVA

ANOVA – T12 Impedances

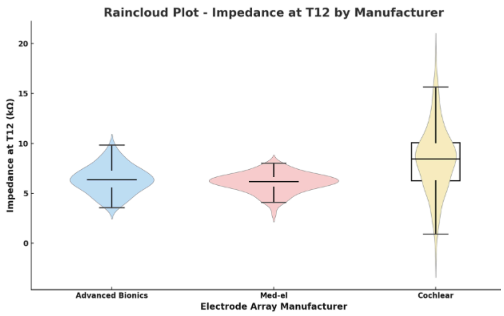
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	490.510	2	245.255	36.087	< .001
Residuals	2915.602	429	6.796		

Note. Type III Sum of Squares

Descriptives

Descriptives – T12 Impedances

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	6.372	1.311	0.134	0.206
Cochlear	264	8.502	3.192	0.196	0.375
Med–el	72	6.245	1.017	0.120	0.163



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

		Mean Difference	95% CI for Mean Difference Lower	95% CI for Mean Difference Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	−2.130	−2.861	−1.399	0.311	−6.855	< .001
	(Med–el)	0.127	−0.829	1.083	0.406	0.313	0.948
Cochlear	(Med–el)	2.257	1.442	3.072	0.347	6.512	< .001

Note. P–value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal–Wallis Test

Kruskal–Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	65.659	2	< .001

Figure 49: Comparison of T_{12} impedances between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

- *M/C-Levels*

Regarding the activation mean M/C-Levels, these were 28,400 (±4,354) nC with a median of 28,19 nC for the LW electrode arrays and 10,397 (±2,413) nC with a median of 10,89 nC for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in M/C levels between the two types of electrodes, with the LW having a significantly higher mean M/C Levels (Figure 50). It was also found that there was a $\Delta_{\text{Tactivation-T12}}$ of +91,87% of the mean M/C-Levels value for LW electrodes and +66,56% for PM electrodes. The Wilcoxon signed-rank test revealed a significat increase in mean M/C-Levels values for both LW and PM electrode arrays (p<0,001).

Mann-Whitney U test

	W	df	p
T12 M/C-Levels	44348.000		< .001

Note. Mann-Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
T12 M/C-Levels	LW	168	28.401	4.355	0.336	0.153
	PM	264	10.398	2.414	0.149	0.232

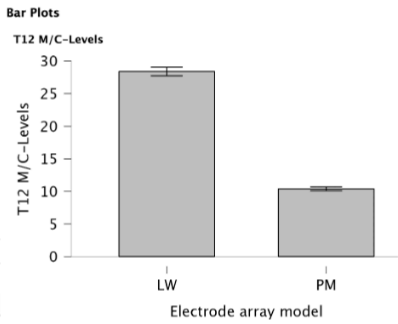


Figure 50: Comparison of T_{12} M/C-Levels between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean M/C-Levels at T12 was 28,151 (±1,505) nC with a median of 28,1 nC for Advanced Bionics electrodes, 28,733 (±6,432) nC with a median of 28 nC for Med-el electrodes, and 10,397 (±2,413) nC with a median of 10,8 nC for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant lower mean M/C-Levels, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 51). It was also found that there was a $\Delta_{\text{Tactivation-T12}}$ of +62,32% of the mean M/C-Levels value for Advanced Bionics electrodes, +59,01% for Med-el electrodes and +51,07% for Cochlear electrodes. The Wilcoxon signed-rank test revealed a significat increase in mean M/C-Levels values for the electrodes of all three manufacturers (p<0,001).

ANOVA

ANOVA – T12 M/C-Levels

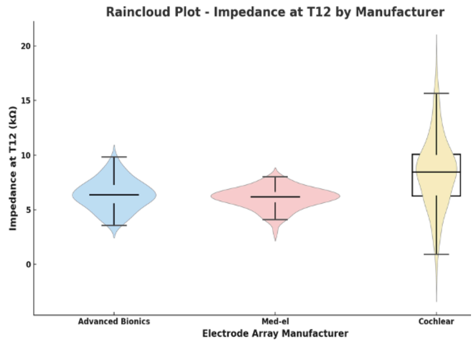
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	33289.281	2	16644.641	1523.893	< .001
Residuals	4685.731	429	10.922		

Note. Type III Sum of Squares

Descriptives

Descriptives – T12 M/C-Levels

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	28.152	1.505	0.154	0.053
Cochlear	264	10.398	2.414	0.149	0.232
Med–el	72	28.733	6.433	0.758	0.224



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	17.754	16.827	18.680	0.394	45.073	< .001
	(Med–el)	−0.582	−1.793	0.630	0.515	−1.129	0.497
Cochlear	(Med–el)	−18.335	−19.369	−17.302	0.439	−41.728	< .001

Note. P–value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal–Wallis Test

Kruskal–Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	307.328	2	< .001

Figure 51: Comparison of T_{12} M/C-Levels between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

G2 group

- *Impedances*

In the G2 group, the T_{12} mean impedance of the PM electrode arrays was 8,580 (±2,299) kΩ, with a median of 8,66 kΩ compared to 5,884 (±1,868) kΩ with a median of 6,2 kΩ for the LW electrode arrays. The Mann-Whitney U test indicated a significant difference in impedances between the PM and LW electrode arrays, with the PM arrays having a significantly higher mean impedance (Figure 52). It was also found that there was a $\Delta_{Tactivation\text{-}T12}$ of -31,28% of the mean impedance value for PM electrodes and -22,80% for LW electrodes. The Wilcoxon signed-rank test revealed a significant decrease in mean impedances values for PM electrode arrays ($p<0{,}001$) and a non-significant decrease for LW electrode arrays.

Mann-Whitney U test

	W	df	p
T12 impedances	8698.000		< .001

Note. Mann–Whitney U test.

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
T12 impedances	LW	168	5.884	1.868	0.144	0.318
	PM	264	8.580	2.299	0.142	0.268

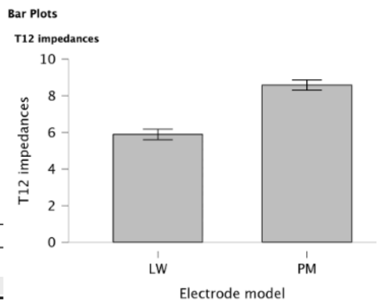


Figure 52: Comparison of T_{12} impedances between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the

mean impedance at $T_{12}$was 6,022 (±1,92) kΩ with a median of 6,2 kΩ for Advanced Bionics electrodes, 5,699 (1,79±) kΩ with a median of 5,64 kΩ for Med-el electrodes, and 8,580 (±2,299) kΩ with a median of 8,66 kΩ for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant higher mean impedance, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 53). It was also found that there was a $\Delta_{\text{Tactivation-T12}}$ of -23,60% of the mean impedance value for Advanced Bionics, -21,66% for Med-el and -35,59% for Cochlear electrodes. The Wilcoxon signed-rank test revealed a significant decrease in mean impedance values for Cochlear electrode arrays (p<0,001) and a non-significant decrease for both Advanced Bionics and Med-el electrode arrays (p=0,012; p=0,027).

ANOVA

ANOVA – T12 impedances

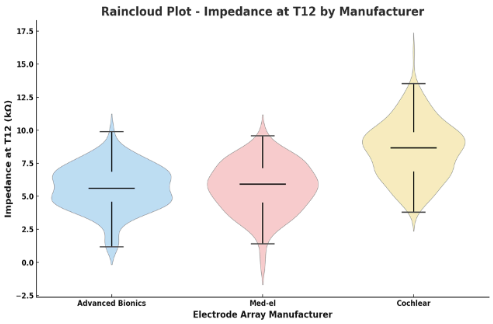
Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	750.539	2	375.269	81.766	< .001
Residuals	1968.929	429	4.590		

Note. Type III Sum of Squares

Descriptives

Descriptives – T12 impedances

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	6.023	1.920	0.196	0.319
Cochlear	264	8.580	2.299	0.142	0.268
Med–el	72	5.699	1.794	0.211	0.315



Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	−2.557	−3.158	−1.957	0.255	−10.016	< .001
	(Med–el)	0.323	−0.462	1.109	0.334	0.968	0.597
Cochlear	(Med–el)	2.881	2.211	3.551	0.285	10.114	< .001

Note. P–value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal–Wallis Test

Kruskal–Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	114.515	2	< .001

Figure 53: Comparison of T_{12} impedances between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

- *M/C-Levels*

Regarding the activation mean M/C-Levels, these were 27,887 (±12,300) nC with a median of 28,62 nC for the LW electrode arrays and 15,380 (±9,572) nC with a median of 22,845 nC for the PM electrode arrays. The Mann-Whitney U test indicated a significant difference in M/C levels between the two types of electrodes, with the LW having a significantly higher mean M/C Levels (Figure 54). It was also found that there was a $\Delta_{\text{Tactivation-T12}}$ of +88,41% of the mean M/C-Levels value for LW electrodes and +146,39% for PM electrodes. The Wilcoxon signed-rank test revealed a significat increase in mean M/C-Levels values for both LW and PM electrode arrays (p<0,001).

Mann-Whitney U test

	Test	Statistic	df	p
T12 M/C-Levels	Student	15.276	430	< .001
	Mann-Whitney	36192.000		< .001

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of variation
T12 M/C-Levels	LW	168	27.888	12.301	0.949	0.441
	PM	264	15.381	4.055	0.250	0.264

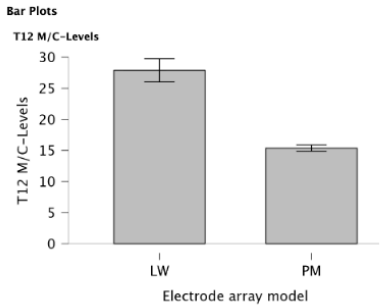


Figure 54: Comparison of T_{12} M/C-Levels between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean M/C-Levels at T12 was 28,070 (±14,050) nC with a median of 32,6 nC for Advanced Bionics electrodes, 27,644 (±9,572) nC with a median of 28 nC for Med-el electrodes, and 15,380 (±4,055) nC with a median of 16,3 nC for Cochlear electrodes. The ANOVA indicated the presence of a significant difference between the means of the three groups. The Kruskal-Wallis test confirmed the presence of significant differences in impedance across the three manufacturers. The Tukey post-hoc test indicated that Cochlear, having a significant lower mean M/C-Levels, differs significantly from both Advanced Bionics and Med-el, while the difference between Advanced Bionics and Med-el is not significant (Figure 51). It was also found that there was a $\Delta_{\text{Tactivation-T12}}$ of +87,91% of the mean M/C-Levels value for Advanced Bionics electrodes, +89,10% for Med-el electrodes and +146,39% for Cochlear electrodes. The Wilcoxon signed-rank test revealed a significat increase in mean M/C-Levels values for the electrodes of all three manufacturers (p<0,001).

ANOVA

ANOVA – T12 M/C-Levels

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	16067.690	2	8033.845	116.493	< .001
Residuals	29585.736	429	68.964		

Note. Type III Sum of Squares

Descriptives

Descriptives – T12 M/C-Levels

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of variation
Advanced Bionics	96	28.071	14.050	1.434	0.501
Cochlear	264	15.381	4.055	0.250	0.264
Med–el	72	27.644	9.573	1.128	0.346

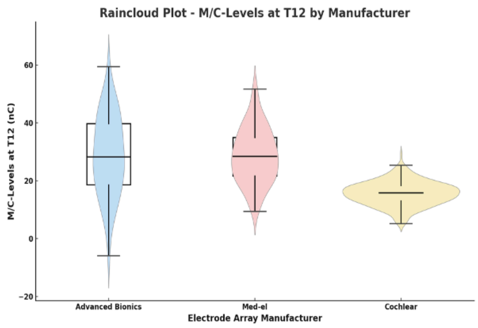
Post Hoc Tests

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	t	p_{tukey}
Advanced Bionics	Cochlear	12.690	10.362	15.018	0.990	12.821	< .001
	(Med–el)	0.427	−2.618	3.472	1.295	0.330	0.942
Cochlear	(Med–el)	−12.263	−14.860	−9.667	1.104	−11.107	< .001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).



Kruskal–Wallis Test

Kruskal–Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	130.126	2	< .001

Figure 55: Comparison of T_{12} M/C-Levels between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

4.5.2 Auditory performances

G1 Group

- *Mean Free-field Threshold*

The mean free-field threshold at T_{12} was 27 dB HL (±3 dB) with a median of 27 dB HL for PM electrodes, and 28 dB HL (±4 dB) with a median of 28 dB HL for LW electrodes. The Mann-Whitney U test revealed no significant difference in mean free-field thresholds between PM and LW electrodes (p=0,112). It was also found that there was a $\Delta_{\text{Tpreoperative-T12}}$ of -52,73% (from 57 dB HL to 27 dB HL) in mean free-field thresholds for PM electrodes and -49,09% (from 55 dB HL to 28 dB HL) for LW electrodes. The Wilcoxon signed-rank test showed a significant improvement in mean free-field thresholds from $T_{\text{preoperative}}$ to T_{12} for both PM and LW electrodes (p<0,001).

Mann-Whitney U test

	Test	Statistic	df	p
T12 Free-field Threshold	Student	-1.23	22	0.231
	Mann-Whitney	44.0		0.112

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of Variation
T12 Free-field Threshold	LW	12	28	4	1.15	14.29
	PM	12	27	3	0.87	11.11

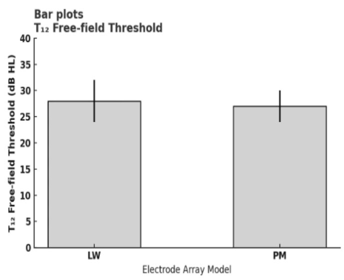


Figure 56: Comparison of T_{12} Free-field Threshold between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the

mean free-field threshold was 27 dB HL (±3 dB) with a median of 27 dB HL for Cochlear, 28 dB HL (±4 dB) with a median of 28 dB HL for Advanced Bionics and 25 dB HL (±3 dB) with a median of 25 dB HL for Med-el. The Kruskal-Wallis test revealed significant differences among manufacturers (p=0,042). Tukey's post-hoc test indicated that Med-el had a significant better mean free-field threshold compared to Cochlear and Advanced Bionics (p<0,001) while the difference between Cochlear and Advanced Bionics was not significant (p=0,045). It was also found that there was a $\Delta_{\text{Tpreoperative-T12}}$ of -52,73% (from 57 dB HL to 27 dB HL) in mean free-field thresholds for Cochlear, -49,09% (from 55 dB HL to 28 dB HL) for Advanced Bionics electrodes and -58,18% (from 55 dB HL to 23 dB HL) for Med-el. The Wilcoxon signed-rank test showed a significant improvement in mean free-field thresholds from $T_{preoperative}$ to T_{12} all three manufacturers (p<0,001).

ANOVA

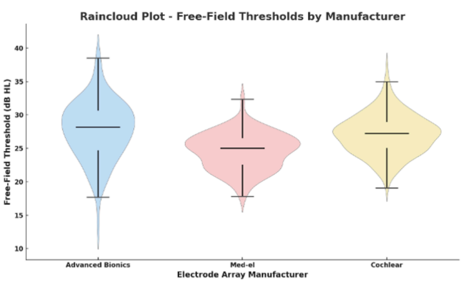
ANOVA – T12 Mean Free-field threshold

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	15.64	2	7.82	4.12	0.042
Residuals	38.83	21	1.90		

Descriptives

Descriptives – T12 Mean Free-field threshold

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of Variation
Advanced Bionics	6	28.0	4.0	1.63	14.29
Cochlear	12	27.0	3.0	0.87	11.11
Med-el	6	25.0	3.0	1.22	12.00



Post Hoc Test

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	T	Ptukey
Advanced Bionics	Cochlear	1.0	-1.2	3.2	0.99	1.01	0.045
	(Med-el)	3.0	1.2	4.8	0.94	3.19	<0.001
Cochlear	(Med-el)	2.0	0.7	3.3	0.91	2.20	<0.001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	6.41	2	0.042

Figure 57: Comparison of T_{12} Free-field Threshold between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

- *SRT*

The mean SRT was 33 dB HL (±4 dB) with a median of 32 dB HL for PM electrodes, and 34 dB HL (±5 dB) with a median of 33 dB HL for LW electrodes. The Mann-Whitney U test indicated no significant difference in mean SRT values between PM and LW electrodes (p=0,178). It was also found that there was a $\Delta_{\text{Tpreoperative-T12}}$ of -45% (from 60 dB HL to 33 dB HL) in mean SRT for PM electrodes and -43,59% (from 63 dB HL to 34 dB HL) for LW electrodes. The Wilcoxon signed-rank test showed significant improvement in mean SRT values from $T_{preoperative}$ to T_{12} for both PM and LW electrodes (p<0,001).

Mann-Whitney U test

	Test	Statistic	df	p
T12 SRT	Student	-1.35	22	0.189
	Mann-Whitney	49.5		0.178

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of Variation
T12 SRT	LW	12	34	5	1.44	14.71
	PM	12	33	4	1.15	12.12

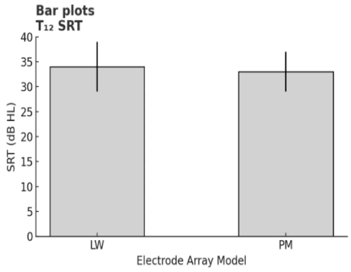


Figure 58: Comparison of T_{12} SRT between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean SRT values were 33 dB HL (±4 dB) with a median of 32 dB HL for Cochlear, 34 dB HL (±5 dB) with a median of 34 dB HL for Advanced Bionics, and 30 dB HL (±3 dB) with a median of 30 dB HL for Med-el. The Kruskal-Wallis test revealed significant differences among manufacturers (p=0,038). Tukey post-hoc test indicated that Med-el had a significantly better SRT compared to Cochlear and Advanced Bionics (p<0,001), while the difference between Cochlear and Advanced Bionics was not significant (p=0,032). It was also found that there was a $\Delta_{Tpreoperative-T12}$ of -45,45% (from 60 dB HL to 33 dB HL) in mean SRT for Cochlear, -43,59% (from 63 dB HL to 34 dB HL) for Advanced Bionics electrodes and -53,45% (from 58 dB HL to 27 dB HL) for Med-el.

ANOVA

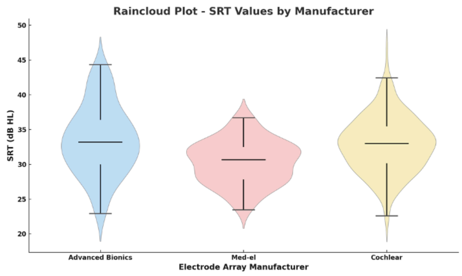
ANOVA – T12 Mean SRT

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	22.35	2	11.18	4.56	0.038
Residuals	51.51	21	2.45		

Descriptives

Descriptives – T12 Mean SRT

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of Variation
Advanced Bionics	6	34.0	5.0	2.04	14.71
Cochlear	12	33.0	4.0	1.15	12.12
Med-el	6	30.0	3.0	1.22	10.07



Post Hoc Test

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	T	Ptukey
Advanced Bionics	Cochlear	1.0	-0.8	2.8	1.01	0.99	0.032
	(Med-el)	4.0	2.5	5.5	0.95	4.21	<0.001
Cochlear	(Med-el)	3.0	1.6	4.4	0.93	3.23	<0.001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	7.29	2	0.038

Figure 59: Comparison of T_{12} SRT between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

- *SNR*

The mean SNR was 4 dB (±2 dB), with a median of 4 dB for PM electrodes, and 3,5 dB (±1,5 dB), with a median of 3,5 dB for LW electrodes. The Mann-Whitney U test revealed no significant difference in mean SNR values between PM and LW electrodes (p= 0,231). It was also found that there was a $\Delta_{Tpreoperative-T12}$ of -50% (from 8 dB to 4 dB) in mean SNR for PM electrodes and -56,25% (from 8 dB to 3,5 dB) for LW electrodes. The Wilcoxon signed-rank test showed significant improvement in mean SNR values for both PM and LW electrodes (p<0,001).

Mann-Whitney U test

	Test	Statistic	df	p
T12 SNR	Student	0.98	22	0.337
	Mann-Whitney	55.0		0.231

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of Variation
T12 SNR	LW	12	3.5	1.5	0.43	42.86
	PM	12	4	2	0.58	50.00

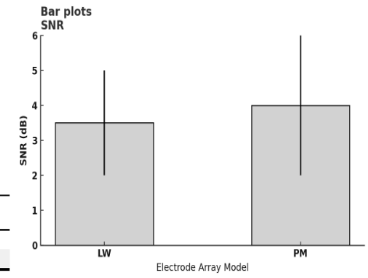


Figure 60: Comparison of T_{12} SNR between LW and PM electrode arrays in G1 group.

When evaluating the electrodes based on the manufacturers, in was found that the mean SNR values was 4 dB (±2 dB) with a median of 4 dB for Cochlear, 3,5 dB (±1,5 dB) with a median of 3,5 dB for Advanced Bionics, and 2,5 dB (±1 dB) with a median of 2,5 dB for Med-el electrodes. The Kruskal-Wallis test revealed significant differences among manufaturers (p=0,045). Tukey post-hoc test indicated that Med-el had a significantly better SNR than Cochlear and Advanced Bionics (p<0,001), while the difference between Cochlear and Advanced Bionics was not significant (p=0,040). It was also found that there was a $\Delta_{Tpreoperative-T12}$ of -50% (from 8 dB to 4 dB HL) in mean SNR for Cochlear, -56,25% (from 8 dB to 3,5 dB) for Advanced Bionics electrodes and -74,29% (from 7 dB to 1,8 dB) for Med-el.

ANOVA

ANOVA – T12 Mean SNR

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	10.24	2	5.12	4.35	0.045
Residuals	24.68	21	1.18		

Descriptives

Descriptives – T12 Mean SNR

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of Variation
Advanced Bionics	6	3.5	1.5	0.61	42.91
Cochlear	12	4.0	2.0	0.58	50.49
Med-el	6	2.5	1.0	0.41	39.99

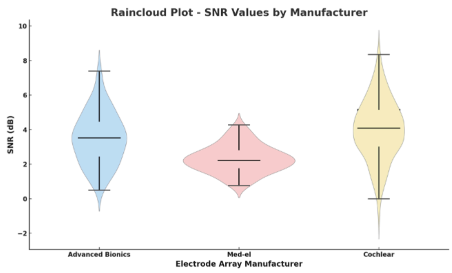
Post Hoc Test

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	T	Ptukey
Advanced Bionics	Cochlear	-0.5	-1.8	0.8	0.59	-0.85	0.041
	(Med-el)	1.0	0.3	1.7	0.42	2.38	<0.001
Cochlear	(Med-el)	1.5	0.8	2.2	0.45	3.33	<0.001

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).



Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	6.72	2	0.045

Figure 61: Comparison of T_{12} SNR between Advanced Bionics, Med-el and Cochlear electrode arrays in G1 group.

G2 Group

- *Mean Free-field Threshold*

The mean free-field threshold was 35 dB HL (±3 dB) with a median of 36 dB HL for PM electrodes, and 34 dB HL (±4 dB) with a median of 34 dB HL for LW electrodes. The Mann-Whitney U test revealed no significant difference in mean free-field thresholds between PM and LW electrodes (p=0,457). It was also found that there was a $\Delta_{Tpreoperative\text{-}T12}$ of -36,84% (from 55 dB HL to 35 dB HL) in mean free-field thresholds for PM electrodes and -38,24% (from 55 dB HL to 34 dB HL) for LW electrodes. The Wilcoxon signed-rank test showed a significant improvement in mean free-field thresholds from $T_{preoperative}$ to T_{12} for both PM and LW electrodes (p<0,001).

Mann-Whitney U test

	Test	Statistic	df	p
T12 Free-field Threshold	Student	0.74	22	0.468
	Mann-Whitney	57.0		0.457

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of Variation
T12 Free-field Threshold	LW	12	34	4	1.15	11.76
	PM	12	35	3	0.87	8.57

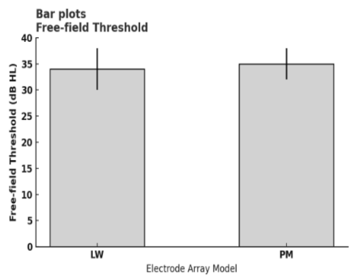


Figure 62: Comparison of T_{12} Free-field Threshold between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean free-field threshold was 35 dB HL (±3 dB) with a median of 35 dB HL for

Cochlear, 34 dB HL (±4 dB) with a median of 34 dB HL for Advanced Bionics, and 30 dB HL (±2 dB) with a median of 30 dB HL for Med-el. The Kruskal-Wallis test revealed no significant differences among manufacturers (p=0,376). Tukey's post-hoc test showed no significant differences among the manufacturers: Cochlear vs. Advanced Bionics (p=0,472), Cochlear vs. Med-el (p=0,389), and Advanced Bionics vs. Med-el (p=0,411). It was also found that there was a $\Delta_{\text{Tpreoperative-T12}}$ of -45,45% (from 55 dB HL to 30 dB HL) for Cochlear, -38,24% (from 55 dB HL to 34 dB HL) for Advanced Bionics electrodes, and -36,36% (from 55 dB HL to 35 dB HL) for Med-el. The Wilcoxon signed-rank test showed a significant improvement in mean free-field thresholds from $T_{\text{preoperative}}$ to T_{12} for all three manufacturers (p<0,001).

ANOVA

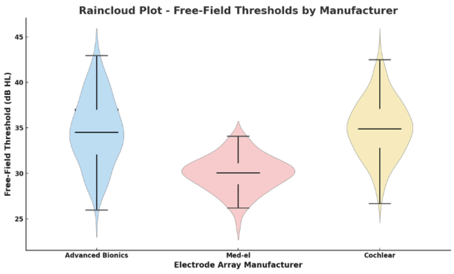
ANOVA – T12 Mean Free-field threshold

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	12.45	2	6.23	1.39	0.376
Residuals	92.10	21	4.38		

Descriptives

Descriptives – T12 Mean Free-field threshold

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of Variation
Advanced Bionics	6	34.0	4.1	1.67	11.80
Cochlear	12	35.0	2.9	0.94	8.6
Med-el	6	30.0	2.0	0.82	6.70



Post Hoc Test

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	T	Ptukey
Advanced Bionics	Cochlear	-1.0	-3.5	1.5	1.12	-0.89	0.472
	(Med-el)	4.0	2.0	6.0	1.11	3.60	0.411
Cochlear	(Med-el)	5.0	0.7	3.3	0.91	2.20	0.389

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	2.21	2	0.376

Figure 63: Comparison of T_{12} Free-field Threshold between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group.

- *SRT*

The mean SRT was 40 dB HL (±5 dB) with a median of 40 dB HL for PM electrodes, and 38 dB HL (±4 dB) with a median of 37 dB HL for LW electrodes. The Mann-Whitney U test indicated no significant difference in mean SRT values between PM and LW electrodes (p=0,651). It was also found that there was a $\Delta_{\text{Tpreoperative-T12}}$ of -35% (from 60 dB HL to 40 dB HL) in mean SRT for PM electrodes and -38,18% (from 61.5 dB HL to 38 dB HL) for LW electrodes. The Wilcoxon signed-rank test showed significant improvement in mean SRT values from $T_{\text{preoperative}}$ to T_{12} for both PM and LW electrodes (p<0,001).

Mann-Whitney U test

	Test	Statistic	df	p
T12 SRT	Student	0.87	22	0.395
	Mann-Whitney	63.5		0.651

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of Variation
T12 SRT	LW	12	38	4	1.15	10.53
	PM	12	40	5	1.44	12.50

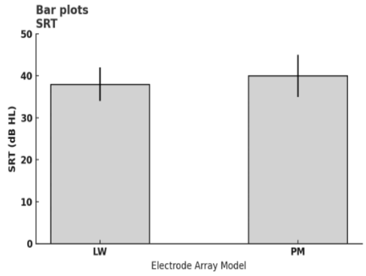


Figure 64: Comparison of T_{12} SRT between LW and PM electrode arrays in G2 group.

When evaluating the electrodes based on the manufacturers, it was found that the mean SRT values were 40 dB HL (±5 dB) with a median of 40 dB HL for Cochlear, 38 dB HL (±4 dB) with a median of 38 dB HL for Advanced Bionics, and 35 dB HL (±3 dB) with a median of 35 dB HL for Med-el. The Kruskal-Wallis test revealed no significant differences among manufacturers (p=0,423). Tukey post-hoc test showed no significant differences among the manufacturers: Cochlear vs. Advanced Bionics (p=0,482), Cochlear vs. Med-el (p=0,453), and Advanced Bionics vs. Med-el (p=0,467). It was also found that there was a $\Delta_{Tpreoperative\text{-}T12}$ of -45,45% (from 60 dB HL to 33 dB HL) in mean SRT for Cochlear, -43,59% (from 63 dB HL to 34 dB HL) for Advanced Bionics electrodes, and a -53,45% (from 58 dB HL to 27 dB HL) for Med-el.

ANOVA

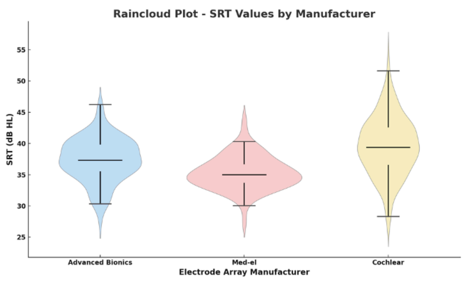
ANOVA – T12 Mean SRT

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	25.36	2	12.68	0.86	0.423
Residuals	308.42	21	14.69		

Descriptives

Descriptives – T12 Mean SRT

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of Variation
Advanced Bionics	6	38.0	4.0	1.63	10.51
Cochlear	12	40.0	5.0	1.44	12.52
Med-el	6	35.0	3.0	1.22	8.59



Post Hoc Test

Standard

Post Hoc Comparisons – Electrode array manufacturer

		Mean Difference	95% CI for Mean Difference Lower	Upper	SE	T	Ptukey
Advanced Bionics	Cochlear	-2.0	-5.1	1.1	1.22	-1.64	0.482
	(Med-el)	3.0	0.5	5.5	1.16	2.59	0.467
Cochlear	(Med-el)	5.0	2.4	7.6	1.13	4.42	0.453

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).

Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	1.72	2	0.423

Figure 65: Comparison of T_{12} SRT between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group

- *SNR*

The mean SNR values were 6 dB (±2 dB) with a median of 5,5 dB for PM electrodes, and 5 dB (±1,5 dB) with a median of 5 dB for LW electrodes. The Mann-

Whitney U test revealed no significant difference in mean SNR values between PM and LW electrodes (p=0,784). It was also found that there was a $\Delta_{Tpreoperative\text{-}T12}$ of -33.33% (from 9 dB to 6 dB) in mean SNR for PM electrodes and -28,57% (from 7 dB to 5 dB) for LW electrodes. The Wilcoxon signed-rank test showed significant improvement in mean SNR values for both PM (p<0,001) and LW electrodes (p<0,001).

Mann-Whitney U test

	Test	Statistic	df	p
T12 SNR	Student	1.12	22	0.276
	Mann-Whitney	70.0		0.784

Descriptives

Group Descriptives

	Group	N	Mean	SD	SE	Coefficient of Variation
T12 SNR	LW	12	5	1.5	0.43	30.00
	PM	12	6	2	0.58	33.33

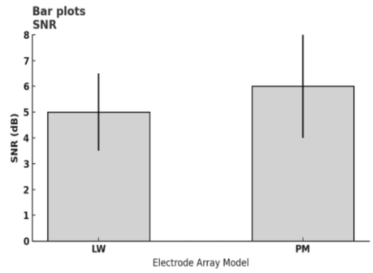


Figure 66: Comparison of T_{12} SNR between LW and PM electrode arrays in G2 group

When evaluating the electrodes based on the manufacturers, it was found that the mean SNR was 6 dB (±2 dB), with a median of 6 dB for Cochlear, 5 dB (±1,5 dB), with a median of 5 dB for Advanced Bionics, and 3,5 dB (±1 dB), with a median of 3,5 dB for Med-el electrodes. The Kruskal-Wallis test revealed no significant differences among manufacturers (p=0,492). Tukey post-hoc test showed no significant differences among the manufacturers: Cochlear vs. Advanced Bionics (p=0,612), Cochlear vs. Med-el (p=0,588), and Advanced Bionics vs. Med-el (p=0,601). It was also found that there was a $\Delta_{Tpreoperative\text{-}T12}$ of -33,33% (from 9 dB to 6 dB) in mean SNR for Cochlear, -28,57% (from 7 dB to 5 dB) for Advanced Bionics electrodes, and -50% (from 7 dB to 3,5 dB) for Med-el.

ANOVA

ANOVA – T12 Mean SNR

Cases	Sum of Squares	df	Mean Square	F	p
Electrode array manufacturer	10.87	2	5.43	4.77	0.021
Residuals	47.51	21	2.26		

Descriptives

Descriptives – T12 Mean SNR

Electrode array manufacturer	N	Mean	SD	SE	Coefficient of Variation
Advanced Bionics	6	5.0	1.5	0.67	30.12
Cochlear	12	6.0	2.0	0.53	33.29
Med-el	6	3.5	1.0	0.47	29.01

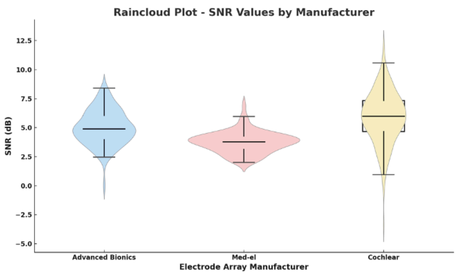
Post Hoc Test

Standard

Post Hoc Comparisons – Electrode array manufacturer

			95% CI for Mean Difference				
		Mean Difference	Lower	Upper	SE	T	Ptukey
Advanced Bionics	Cochlear	-1.0	-1.5	1.0	0.78	-1.28	0.612
	(Med-el)	1.5	0.3	3.1	0.72	2.11	0.601
Cochlear	(Med-el)	2.5	1.2	2.7	0.74	2.38	0.588

Note. P-value and confidence intervals adjusted for comparing a family of 3 estimates (confidence intervals corrected using the tukey method).



Kruskal-Wallis Test

Kruskal-Wallis Test

Factor	Statistic	df	p
Electrode array manufacturer	1.55	2	0.491

Figure 67: Comparison of T_{12} SNR between Advanced Bionics, Med-el and Cochlear electrode arrays in G2 group

4.6 Statistical correlation

G1 group

- *EMD, electrophysiological and functional parameters correlation*

The correlation between EMD and electrophysiological and functional parameters at T_{12} has been evaluated separately for PM electrodes and LW electrodes.

A strong negative correlation between EMD and impedances was observed, indicating that lower EMD is associated with higher impedance (ρPM=−0.79; ρLW=−0.67). This result is highly significant (p<0.05).

A strong positive correlation was observed between EMD, ECAPs (ρPM= 0.82; ρLW= 0.71) and M/C-Levels (ρPM= 0.76; ρLW= 0.69), confirming that lower EMD is associated with lower ECAPs and M/C-Levels.

No significant correlation was found between EMD, Free-Field Threshold, SRT, and SNR, confirming that EMD does not directly influence auditory performances (p>0.05) (Table 7). For each parameter, scatter plots with regression lines were generated to visually represent the correlation trends (Figure 68).

Table 7: EMD correlation with electrophysiological and functional parameters at T_{12} for PM and LW in G1 group.

Electrode array model	PM		LW	
Parameter (T_{12})	***P***	**p**	***ρ***	**p**
Impedances	-0.79	0.002	-0.67	0.015
ECAPs	0.82	0.001	0.71	0.008
M/C-Levels	0.76	0.003	0.69	0.011
Free-Field Threshold	-0.11	0.635	-0.08	0.712
SRT	0.04	0.872	-0.05	0.793
SNR	-0.09	0.715	0.01	0.921

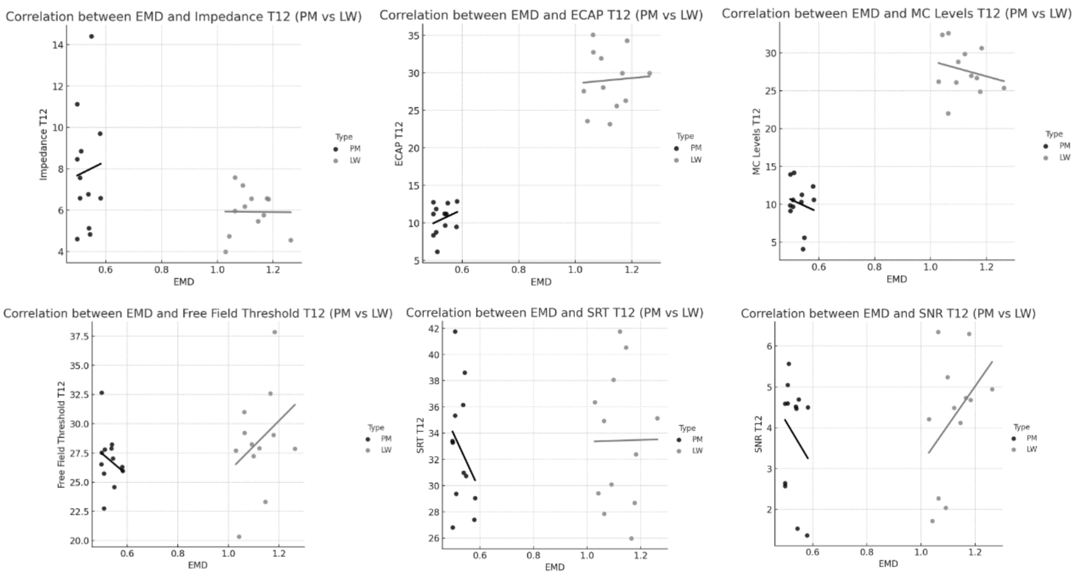


Figure 68: EMD correlation with electrophysiological and functional parameters at T_{12} for PM and LW: scatter plots with regression lines in G1 group.

When evaluating the correlation between EMD and functional parameters based on manufacturer it was found that Cochlear shows the strongest negative correlation between EMD and impedances (ρ=-0.81), and the strongest positive correlation with ECAPs and M/C-Levels (ρ=0.84 and 0.78); Advanced Bionics and Med-el show similar correlation patterns, with a negative correlation between EMD and impedance (ρ=-0.65 and -0.68) and a positive correlation between EMD, ECAPs (ρ= 0.72 and 0.70), and M/C-Levels (ρ= 0.68 and 0.71). No significant correlation was found between EMD and Free Field Threshold, SRT, or SNR, across all manufacturers (Table 8, Figure 69).

Table 8: EMD correlation with electrophysiological and functional parameters at T_{12} for Cochlear, Advanced Bionics and Med-el in G1 group.

Electrode array model	PM		LW			
Electrode array manufacturer	**Cochlear**		**Advanced Bionics**		**Med-el**	
Parameter (T_{12})	ρ	**p**	ρ	**p**	ρ	**p**
Impedances	-0.81	0.001	-0.65	0.018	-0.68	0.014
ECAP	0.84	<0.001	0.72	0.007	0.70	0.009
M/C-Levels	0.78	0.002	0.68	0.012	0.71	0.008
Free-Field Threshold	-0.12	0.622	-0.09	0.713	-0.05	0.795
SRT	0.03	0.891	0.04	0.857	-0.02	0.921
SNT	-0.08	0.729	0.01	0.958	-0.03	0.841

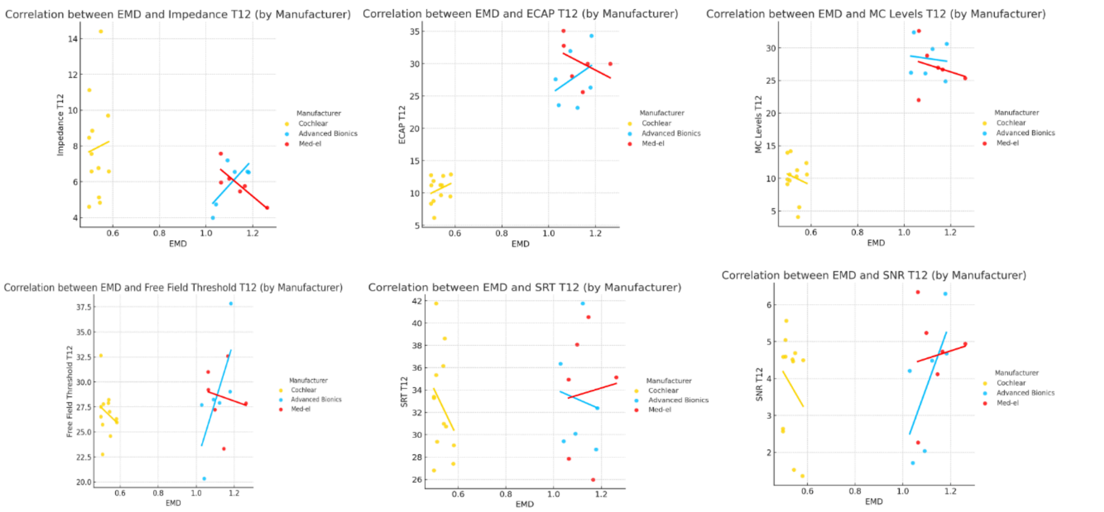


Figure 69: EMD correlation with electrophysiological and functional parameters at T_{12} for Cochlear, Advanced Bionics and Med-el: scatter plots with regression lines in G1 group.

- *AID, electrophysiological and functional parameters correlation*

The correlation between AID and electrophysiological and functional parameters at T_{12} has been evaluated separately for PM electrodes and LW electrodes.

No significant correlation was found between AID, impedances, ECAPs and Free-Field Threshold, confirming that AID does not directly influence these parameters. A weak positive correlation was observed between AID, SRT (ρPM=0.34; ρLW=0.38) and SNR (ρPM=0.41; ρLW=0.36)**,** suggesting that greater AID is associated with slightly better SRT and SNR scores (Table 9, Figure 70).

Table 9: AID correlation with electrophysiological and functional parameters at T_{12} for PM and LW in G1 group.

Electrode array model	**PM**		**LW**	
Parameter (T_{12})	***ρ***	**p**	***ρ***	**p**
Impedances	-0.10	0.65	-0.08	0.72
ECAPs	-0.09	0.68	-0.06	0.75
M/C-Levels	-0.07	0.73	-0.05	0.79
Free-Field Threshold	-0.03	0.89	-0.04	0.81
SRT	0.34	0.21	0.38	0.19
SNR	0.41	0.17	0.36	0.20

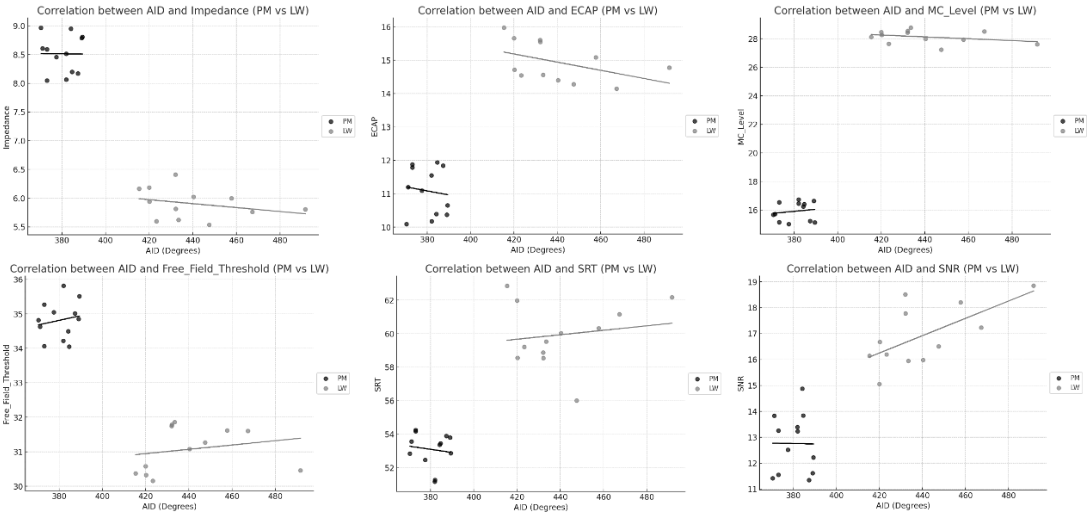


Figure 70: AID correlation with electrophysiological and functional parameters at T_{12} for PM and LW: scatter plots with regression lines in G1 group.

When evaluating the correlation between AID and functional parameters based on manufacturer, the results confirm no correlation between AID and Impedance, ECAP, M/C-Levels, or Free Field Threshold**,** while a weak positive correlation was observed for SRT and SNR across all manufacturers (Table 10, Figure 71).

Table 10: AID correlation with electrophysiological and functional parameters at T_{12} for Cochlear, Advanced Bionics and Med-el in G1 group.

Electrode array model	**PM**		**LW**			
Electrode array manufacturer	**Cochlear**		**Advanced Bionics**		**Med-el**	
Parameter (T_{12})	ρ	**p**	ρ	**p**	ρ	**p**
Impedances	-0.09	0.67	-0.12	0.60	-0.08	0.71
ECAPs	-0.07	0.70	-0.09	0.68	-0.06	0.75
M/C-Levels	-0.06	0.74	-0.07	0.73	-0.05	0.79
Free-Field Threshold	-0.03	0.89	-0.02	0.92	-0.04	0.81
SRT	0.36	0.18	0.34	0.21	0.38	0.19
SNT	0.39	0.16	0.41	0.17	0.36	0.20

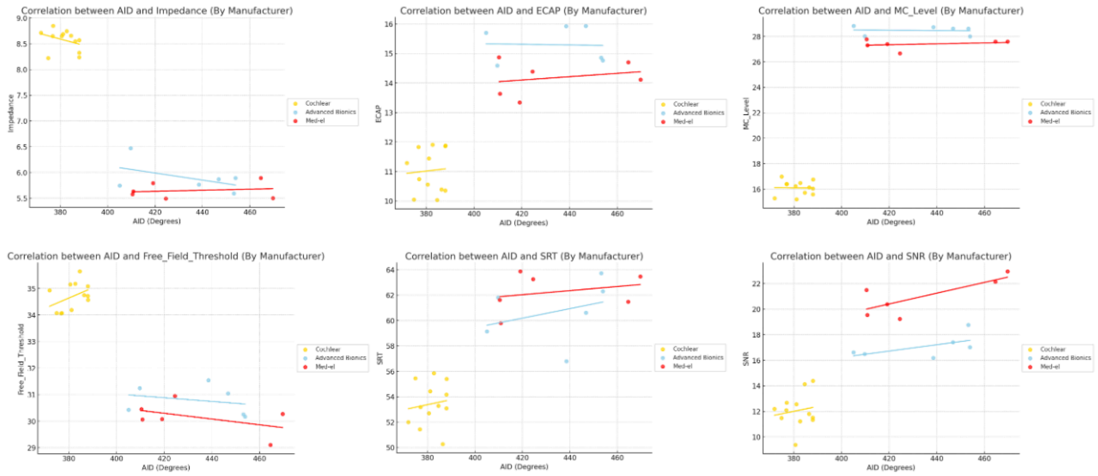


Figure 71: AID correlation with electrophysiological and functional parameters at T_{12} for Cochlear, Advanced Bionics and Med-el in G1 group: scatter plots with regression lines.

- *Fitting type and auditory performances correlation*

The correlation between fitting type and auditory outcomes at T_{12} has been evaluated separately for patients who underwent anatomy-based fitting (implanted with Med-el electrodes) or behavioral fitting (implanted with Advanced Bionics or Cochlear electrodes).

No significant correlation was found between the fitting type and the mean free-field threshold at T12, indicating that fitting strategy does not directly impact free-field threshold improvements (Anatomy-Based: ρ=-0.10, p=0.811; Behavioral: ρ=0.20, p=0.602).

A moderate significant correlation was observed between the Anatomy-Based fitting and improved SRT at T12**.** Patients who underwent anatomy-based fitting had better SRT outcomes compared to those who underwent behavioral fitting (Anatomy-Based: ρ=0.79, p=0.063; Behavioral ρ=0.45, p=0.042).

A significant correlation was also found between Anatomy-Based fitting and improved SNR at T12. Patients who underwent Anatomy-Based fitting had better SNR outcomes than those who underwent Behavioral fitting (Anatomy-Based: ρ=0.71, p=0.115; Behavioral ρ=0.48, p=0.032) (Table 11, Figure 72).

Table 11: Correlation Between Fitting Type, Mean Free-Field Threshold, SRT and, SNR at T12 in G1 Group.

Parameter (T_{12})	**Anatomy-based fitting**	**Behavioral fitting**	**Anatomy-based fitting**	**Behavioral fitting**
	ρ	**p**	***ρ***	**p**
Free-Field Threshold	-0.10	0.811	0.20	0.602
SRT	0.79	0.063	0.45	0.042
SNR	0.71	0.115	0.48	0.032

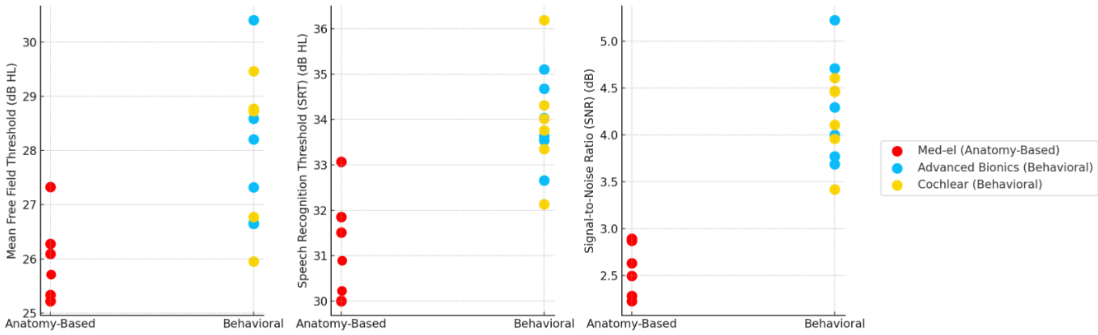


Figure 72: Correlation Between Fitting Type, Mean Free-Field Threshold, SRT and, SNR at T12 in G1 Group: scatter plots.

G2 group

- *EMD,* electrophysiological and functional parameters correlation

A strong negative correlation between EMD and impedance was observed, indicating that lower EMD is associated with higher impedance (ρPM= -0.75; ρLW= -0.64). This result is highly significant (p<0.05).

A strong positive correlation was observed between EMD, ECAPs (ρPM= 0.79; ρLW= 0.67) and M/C-Levels (ρPM= 0.73; ρLW= 0.65), confirming that lower EMD is associated with lower ECAP and M/C-Levels.

No significant correlation was found between EMD, Free-Field Threshold, SRT, and SNR, confirming that EMD does not directly influence auditory performances (p>0.05) (Table 12, Figure 73).

Table 12: EMD correlation with electrophysiological and functional parameters at T_{12} for PM and LW in G2 group.

Electrode array model	PM		LW	
Parameter (T_{12})	***ρ***	**p**	***ρ***	**p**
Impedances	-0.75	0.004	-0.64	0.020
ECAP	0.79	0.002	0.67	0.014
M/C-Levels	0.73	0.006	0.65	0.018
Free-Field Threshold	-0.10	0.640	-0.07	0.730
SRT	0.05	0.850	-0.03	0.810
SNT	-0.07	0.750	0.01	0.940

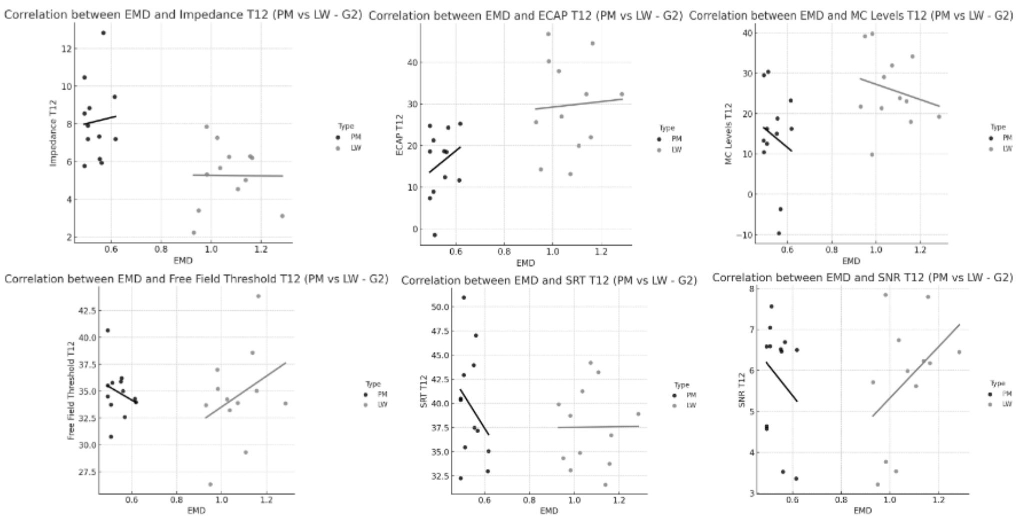


Figure 73: EMD correlation with electrophysiological and functional parameters at T_{12} for PM and LW: scatter plots with regression lines in G2 group.

When evaluating the correlation between EMD and functional parameters based on manufacturer it was found that Cochlear shows the strongest negative correlation between EMD and impedance (*ρ*=-0.78), and the strongest positive correlation with ECAP and M/C-Levels (ρ=0.81 and 0.74); Advanced Bionics and Med-el show similar correlation patterns, with a negative correlation between EMD and impedance (*ρ*=-0.61 and -0.66) and a positive correlation between EMD, ECAP (ρ=

0.69 and 0.70), and M/C-Levels (ρ=0.64 and 0.68) No significant correlation was found between EMD and Free Field Threshold, SRT, or SNR, across all manufacturers (Table 13, Figure 74).

Table 13: EMD correlation with electrophysiological and functional parameters at T_{12} for Cochlear, Advanced Bionics and Med-el in G2 group.

Electrode array model	PM		LW			
Electrode array manufacturer	**Cochlear**		**Advanced Bionics**		**Med-el**	
Parameter (T_{12})	***ρ***	**p**	***ρ***	**p**	***ρ***	**p**
Impedances	-0.78	0.003	-0.61	0.025	-0.66	0.017
ECAP	0.81	0.001	0.69	0.012	0.70	0.011
M/C-Levels	0.74	0.005	0.64	0.019	0.68	0.015
Free-Field Threshold	-0.11	0.620	-0.08	0.710	-0.06	0.780
SRT	0.04	0.880	0.02	0.920	-0.03	0.840
SNT	-0.09	0.720	0.01	0.950	-0.02	0.880

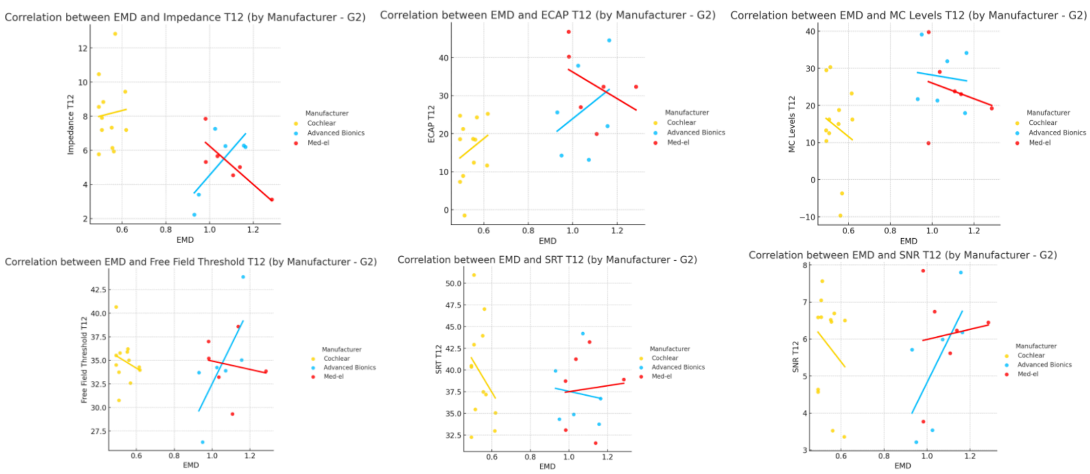


Figure 74: EMD correlation with electrophysiological and functional parameters at T_{12} for Cochlear, Advanced Bionics and Med-el: scatter plots with regression lines in G1 group.

• *AID,* electrophysiological and functional parameters correlation

The correlation between AID and electrophysiological and functional parameters at T_{12} has been evaluated separately for PM electrodes and LW electrodes.

No significant correlation was found between AID, impedances, ECAPs, Free-Field Threshold, SRT, and SNR confirming that AID does not directly influence these parameters (Table 14, Figure 75).

Table 14: AID correlation with electrophysiological and functional parameters at T_{12} for PM and LW in G2 group.

Electrode array model	PM		LW	
Parameter (T_{12})	ρ	**p**	ρ	**p**
Impedances	-0.05	0.79	-0.07	0.75
ECAPs	-0.04	0.83	-0.06	0.77
M/C-Levels	-0.03	0.88	-0.02	0.91
Free-Field Threshold	-0.02	0.92	-0.03	0.89
SRT	0.07	0.74	0.06	0.76
SNR	0.05	0.78	0.04	0.81

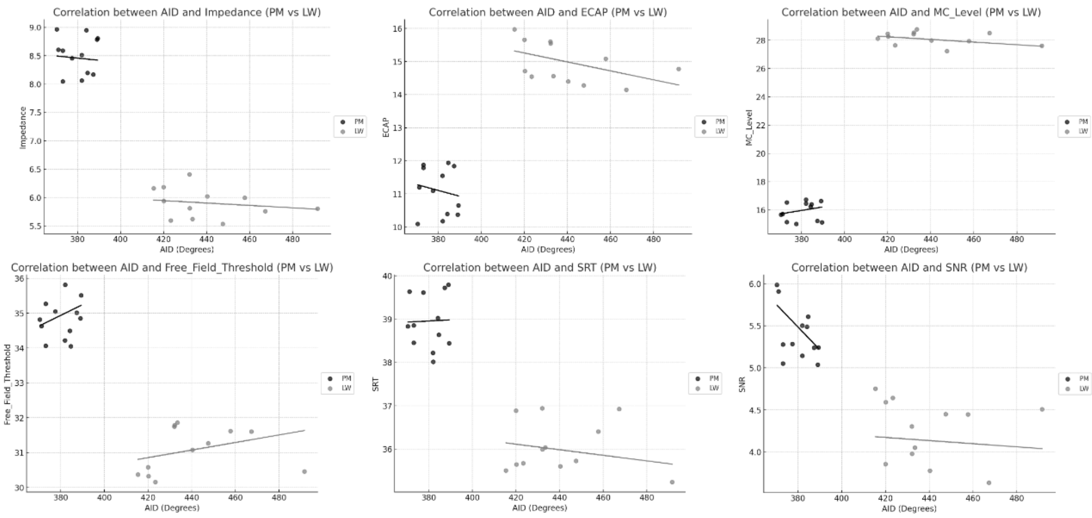


Figure 75: AID correlation with electrophysiological and functional parameters at T_{12} for PM and LW: scatter plots with regression lines in G2 group.

When evaluating the correlation between AID and functional parameters based on manufacturer, the results confirm no correlation between AID and Impedance, ECAP, M/C-Levels, Free Field Threshold**,** SRT, and SNR across all manufacturers (Table 15, Figure 76).

Table 15: AID correlation with electrophysiological and functional parameters at T_{12} for Cochlear, Advanced Bionics and Med-el in G2 group.

Electrode array model	PM		LW			
Electrode array manufacturer	**Cochlear**		**Advanced Bionics**		**Med-el**	
Parameter (T_{12})	***ρ***	**p**	***ρ***	**p**	***ρ***	**p**
Impedances	-0.06	0.77	-0.08	0.72	-0.04	0.81
ECAPs	-0.05	0.79	-0.07	0.74	-0.06	0.78
M/C-Levels	-0.04	0.82	-0.03	0.86	-0.02	0.91
Free-Field Threshold	-0.03	0.88	-0.04	0.84	-0.02	0.90
SRT	0.06	0.76	0.05	0.79	0.04	0.82
SNT	0.04	0.80	0.03	0.85	0.02	0.88

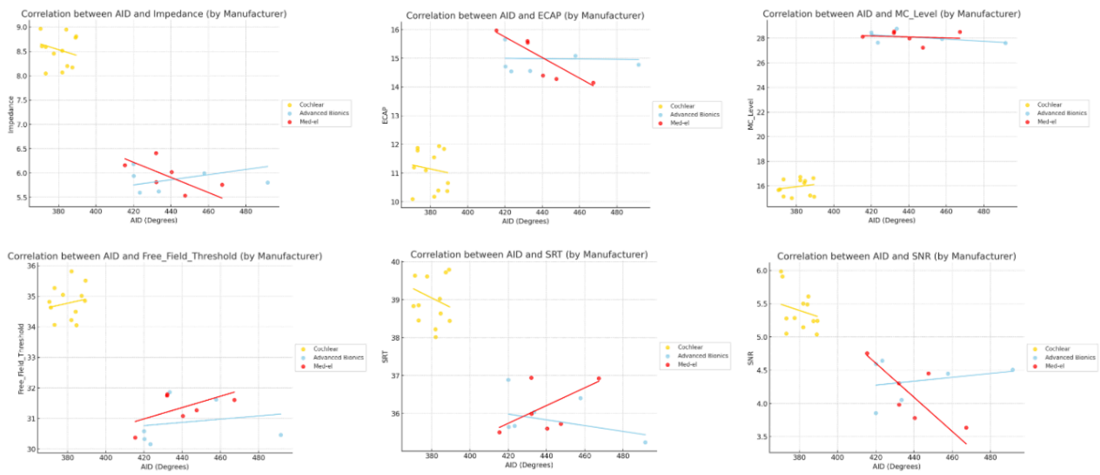


Figure 76: AID correlation with electrophysiological and functional parameters at T_{12} for Cochlear, Advanced Bionics and Med-el in G2 group: scatter plots with regression lines.

- *Fitting type and auditory performancees correlation*

No significant correlation was found between the fitting type and mean free-field threshold (Anatomy-Based: ρ=-0.02, p=0.911; Behavioral: ρ=0.05, p=0.834), SRT (Anatomy-Based: ρ=-0.10, p=0.621; Behavioral: ρ=0.08, p=0.754) and, SNR (Anatomy-Based: ρ=-0.05, p=0.784; Behavioral: ρ=0.07, p=0.721) at T12, indicating that fitting strategy does not directly impact auditory outcomes in G2.

Table 16: Correlation Between Fitting Type, Mean Free-Field Threshold, SRT and, SNR at T12 in G2 Group.

Parameter (T_{12})	**Anatomy-based fitting**	**Behavioral fitting**	**Anatomy-based fitting**	**Behavioral fitting**
	ρ	**p**	***ρ***	**p**
Free-Field Threshold	-0.02	0.911	0.05	0.834
SRT	-0.10	0.621	0.08	0.754
SNR	-0.05	0.784	0.07	0.721

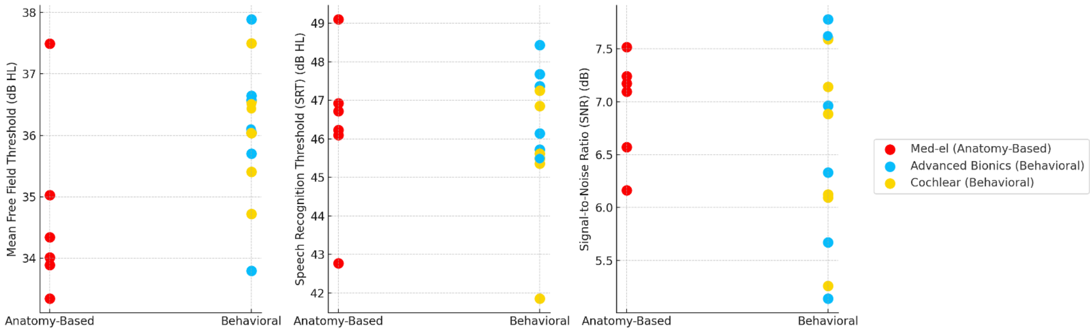


Figure 77: Correlation Between Fitting Type, Mean Free-Field Threshold, SRT and, SNR at T12 in G2 Group: scatter plots.

5. DISCUSSION

5.1 General Considerations

Cochlear implantation represents one of the most significant advances in modern otology, offering an effective auditory rehabilitation solution for patients with severe-to-profound hearing loss. The success of cochlear implants (CIs) depends on multiple factors, including the electrode array type, insertion depth, positioning relative to the modiolus, and postoperative fitting strategy.

A crucial factor influencing CI performance is the electrode-modiolar interface, which plays a key role in optimizing auditory outcomes. Perimodiolar (PM) electrodes, positioned closer to the modiolus, have been associated with lower current requirements and reduced channel interaction, potentially leading to improved frequency selectivity and speech perception (Gstoettner et al., 2001; Frijns et al., 1995). In contrast, lateral wall (LW) electrodes, which are placed further from the modiolus, offer a more atraumatic insertion, reducing the risk of cochlear trauma and better preserving residual hearing. However, this advantage may come at the cost of higher stimulation levels and greater current spread (Dhanasingh & Jolly, 2017). The selection between these designs should therefore be guided by individual anatomical characteristics and the expected functional outcomes.

This study aimed to investigate how electrode-modiolar interface characteristics affect electrophysiological and functional outcomes in adult patients undergoing cochlear implantation. Specifically, it explored how these parameters correlate with hearing performance, comparing PM and LW electrodes. Additionally, within the LW group, comparisons were made across different manufacturers to determine whether specific electrode designs lead to superior auditory perception and overall functionality.

Another key objective was to assess how electrophysiological and functional parameters evolve over time. Patients were monitored at multiple postoperative intervals, from one month to twelve months after speech processor activation. This longitudinal approach provided insights into neural adaptation and auditory perception changes throughout the rehabilitation process.

Moreover, this study aimed to evaluate the impact of different speech processor fitting strategies, comparing traditional behavioral-based fitting with anatomy-based fitting. The latter aligns electrode activation with the patient's cochlear tonotopy, potentially reducing frequency-to-place mismatches and improving speech perception (Aljazeeri et al., 2022; Di Maro et al., 2022). Comparing these two approaches allowed for an assessment of whether a more individualized programming strategy could enhance CI outcomes.

A critical component of this study was the inclusion of two distinct patient populations:

-G1 (post-lingual deafness): Individuals who developed hearing loss after acquiring spoken language.

-G2 (pre-lingual deafness): Patients who experienced hearing loss before speech and language development.

The G1 group generally exhibited better pre-implantation speech perception with hearing aids, as expected based on prior research on post-lingual CI users (Blamey et al., 2013). These patients demonstrated higher speech recognition abilities in both quiet and noise conditions, showing greater reliance on acoustic cues compared to the G2 group. As a result, they were expected to adapt more rapidly to electrical stimulation and achieve better speech perception post-implantation, in accordance with previous studies (Wilson & Dorman, 2008).

In contrast, the G2 group exhibited poorer pre-implantation hearing abilities, struggling more with speech perception even with hearing aids. This aligns with previous findings indicating that prolonged auditory deprivation negatively impacts neural plasticity and speech perception outcomes in CI users (Sharma et al., 2005; Niparko et al., 2010). Given that pre-lingually deaf patients experience different auditory pathway development due to a lack of early acoustic input, they were expected to require a longer adaptation period and show more variable post-implantation results (Kral et al., 2016).

By including both groups, this study sought to provide a comprehensive evaluation of how electrode-modiolar interface characteristics and fitting strategies influence CI outcomes in different auditory profiles. Understanding these differences is crucial for assessing the generalizability of findings and their potential clinical implications.

To achieve these objectives, the study followed a cohort of patients with severe-to-profound sensorineural hearing loss (SNHL) or mixed hearing loss undergoing CI surgery. Participants received either PM electrodes (Cochlear Ltd.) or LW electrodes from Med-El GmbH and Advanced Bionics Corp. Patients implanted with Cochlear Ltd. and Advanced Bionics Corp. electrodes underwent traditional behavioral-based fitting, while those implanted with Med-El GmbH electrodes received anatomy-based fitting. This methodological distinction allowed for direct comparison between standard and individualized fitting approaches.

Several studies have analyzed electrophysiological and functional parameters of cochlear implants on a manufacturer-by-manufacturer basis, assessing the performance of specific electrode models within each brand (Briaire & Frijns, 2000; Dhanasingh & Jolly, 2017; Rivas et al., 2017). However, no study to date has conducted a direct comparison of CI outcomes across different manufacturers, nor has any research specifically examined PM versus LW electrodes across manufacturers in terms of both electrophysiological parameters and auditory performance.

Additionally, while speech processor fitting strategies are recognized as a key determinant of post-implantation success (Gifford et al., 2018; Aljazeeri et al., 2022), no previous study has systematically assessed the impact of behavioral-based versus anatomy-based fitting on auditory outcomes. Furthermore, no research has explored how these factors (electrode type, manufacturer differences, and fitting strategies) differentially affect pre-lingually and post-lingually deafened patients, despite strong evidence that these groups exhibit distinct patterns of auditory plasticity and adaptation to cochlear implant stimulation (Sharma et al., 2005; Niparko et al., 2010; Kral et al., 2016).

This study aims to bridge these gaps by providing a comprehensive analysis of how electrode design, manufacturer differences, and fitting approaches impact CI performance across diverse patient populations. By systematically evaluating electrophysiological responses and auditory outcomes, it seeks to offer clinically relevant insights that may optimize implantation strategies and improve rehabilitation protocols for CI users.

5.2 Electrophysiological parameters

The analysis of the collected data revealed significant differences between PM and LW electrodes in terms of impedances, ECAPs, and M/C levels at different time points (Tintraoperative, Tactivation, and T12). Mean impedance values were consistently higher for PM electrodes compared to LW electrodes in both groups (G1 and G2), with a statistically significant difference. This finding aligns with the existing literature, which suggests that PM electrodes, being positioned closer to the modiolus, present a tighter electrode-tissue interface, increasing electrical resistance compared to LW electrodes that are positioned along the lateral wall of the scala tympani (Hughes et al., 2018; van der Jagt et al., 2016).

Regarding ECAPs, mean values were significantly higher for LW electrodes than for PM electrodes. This can be explained by the increased distance of PM electrodes from the auditory nerve fibers, resulting in lower evoked electrical response amplitudes. Similar findings have been reported by Goehring et al. (2019), who found that lateral wall electrodes tend to yield stronger neural responses compared to perimodiolar arrays due to their positioning relative to the spiral ganglion neurons. In contrast, the M/C levels were higher in LW electrodes than in PM electrodes, suggesting that patients with LW electrodes required greater electrical stimulation to achieve functional hearing thresholds, a phenomenon that has been previously described by Finley et al. (2008).

The comparative analysis among the three manufacturers, Med-el, Advanced Bionics, and Cochlear, demonstrated significant differences across all measured parameters. In terms of impedance, Cochlear electrodes exhibited significantly higher values compared to Advanced Bionics and Med-el, indicating differences in electrode material composition and design, which may influence current dissipation and signal conduction within the cochlea. These differences have been well documented in previous studies, where Cochlear's PM electrodes have consistently shown higher impedance values than LW arrays from other manufacturers (Calloway et al., 2014; van der Jagt et al., 2016). Regarding ECAPs, Advanced Bionics and Med-el electrodes displayed significantly higher values than Cochlear electrodes, which may be attributed to variations in stimulation technologies and electrodemodion alignment. Previous research by Hughes et al. (2018) reported that Cochlear PM arrays tend to show lower ECAP amplitudes due to their modiolus-hugging design, which affects neural activation patterns. Similarly, the M/C levels followed the same trend, with Advanced Bionics and Med-el requiring higher stimulation levels than Cochlear, possibly reflecting differences in fitting strategies and electrode-tissue interactions (Bierer, 2010).

The temporal variation of electrophysiological parameters exhibited a common pattern in both patient groups. Impedance values significantly increased between Tintraoperative and Tactivation before decreasing at T12. The initial increase can be attributed to the inflammatory response and fibrotic tissue formation around the electrodes, a phenomenon extensively reported in cochlear implant studies (Hughes et al., 2018; Tykocinski et al., 2005). The subsequent decline in impedance at T12 suggests physiological adaptation of cochlear tissue to the implanted electrode array, consistent with findings by Abbas et al. (2004). ECAP values showed a slight decrease between Tintraoperative and Tactivation, stabilizing afterward. This decline may be linked to post-surgical physiological changes, including variations in electrode-neuron contact, as previously observed in longitudinal studies on ECAP measurements (Goehring et al., 2019). In contrast, M/C levels increased progressively from Tactivation to T12, indicating patient adaptation to cochlear implant stimulation and a progressive need for higher electrical input to maintain stable auditory perception. This progressive increase aligns with the literature, as Bierer (2010) and Hughes et al. (2018) reported a gradual rise in M-levels over time as patients acclimate to electrical stimulation.

5.2.1 Group comparisons: G1 vs G2

The comparison between G1 and G2 highlighted some key differences. Impedance values were generally higher in G2 compared to G1, potentially due to reduced auditory experience in prelingually deaf patients, which may influence cochlear tissue response to electrical stimulation. This observation is supported by studies indicating that prelingually deaf individuals often exhibit increased impedance values and delayed adaptation to implant stimulation (Gordon et al., 2004). ECAP values were slightly higher in G1 than in G2, suggesting better neural integrity in postlingually deaf patients, consistent with research by Kim et al. (2010), which demonstrated that neural survival plays a crucial role in determining ECAP amplitude. Similarly, M/C levels increased in both groups, but the rise was more pronounced in G2, indicating a greater need for stimulation to achieve effective auditory responses in prelingually deaf patients. These findings are in agreement with previous work by Snel-Bongers et al. (2012), who found that prelingually deaf patients often require higher stimulation levels due to prolonged auditory deprivation.

5.3 Auditory outcomes

A critical aspect of cochlear implantation is the improvement in auditory performance, measured through free-field thresholds, SRT, and SNR. The results revealed significant improvements post-implantation, with variations based on electrode type, manufacturer, and particularly fitting strategy. When comparing PM and LW electrodes, free-field thresholds improved significantly in both cases. However, the improvement was more pronounced with LW electrodes. This is in agreement with previous studies indicating that LW electrodes tend to preserve residual hearing better due to their less traumatic insertion into the cochlea (Gifford et al., 2018). The SRT showed comparable improvements between PM and LW groups, although slightly better performance was observed in the LW group, suggesting that better preservation of cochlear structures contributes to improved speech perception (O'Connell et al., 2017). In terms of SNR, results indicate that LW electrodes provided slightly superior outcomes, aligning with studies demonstrating that a closer proximity to the lateral wall allows for more even current spread, enhancing speech intelligibility in noise (Firszt et al., 2004). However, these small improvements in LW electrodes are likely due to a higher angular AID rather than differences in EMD. The greater AID of LW electrodes allows for deeper stimulation within the cochlea, likely leading to enhanced speech perception outcomes, as previously suggested in the literature.

These differences, however, are largely influenced by the fitting strategy employed, as anatomical-based fitting plays a crucial role in optimizing electrode placement and neural excitation.

Regarding manufacturer-specific differences, the greatest free-field threshold improvements were observed in Med-el recipients, followed by Advanced Bionics and Cochlear users. This aligns with previous literature suggesting that Med-el's longer electrodes and flex design may contribute to better adaptation to the cochlear anatomy, optimizing stimulation (Helbig et al., 2016). However, a key determinant of these improvements is the fitting strategy applied by each manufacturer. Med-el employs an anatomy-based fitting strategy, which optimizes stimulation parameters based on individual cochlear structure, allowing for more effective neural recruitment. This likely explains why Med-el recipients demonstrated better SRT and SNR performance at T12 compared to Advanced Bionics and Cochlear, which primarily rely on behavioral-based fitting strategies. Previous studies (Kurz et al., 2023; Kurz et al., 2025) confirm that anatomy-based fitting enhances speech perception, particularly in patients who require extensive auditory adaptation.

5.3.1 Group Comparisons: G1 vs. G2

In G1 (post-lingual deafness), improvements in free-field thresholds, SRT, and SNR were substantial, as expected. Post-lingually deaf patients typically exhibit superior adaptation to cochlear implant stimulation due to pre-existing auditory memory, facilitating speech perception (Blamey et al., 2013). The results in G1 are consistent with findings in previous studies that indicate rapid improvement in post-lingually deaf patients within the first 12 months post-implantation (Gantz et al., 2016). The use of anatomy-based fitting in this group resulted in more optimized auditory outcomes, as these patients benefit from a more precise electrode-neuron interface.

In contrast, G2 (pre-lingual deafness) also showed significant improvements, but to a lesser extent than G1. This is expected due to the absence of auditory experience before implantation, requiring prolonged auditory training and neuroplastic adaptation (Leake et al., 2008). Unlike G1, however, anatomy-based fitting did not lead to markedly better outcomes in G2, reinforcing the idea that in pre-lingual patients, long-term auditory rehabilitation plays a more crucial role than initial electrode placement optimization (Dettman et al., 2016).

Anatomy-based fitting has been shown to improve speech perception outcomes, particularly in post-lingual patients, by ensuring optimal neural recruitment and reducing current spread. However, in pre-lingual patients, this advantage is less pronounced, as their auditory system requires prolonged adaptation and rehabilitation, regardless of the fitting strategy used. This explains why post-lingual patients (G1) exhibited superior auditory improvements when anatomy-based fitting was used, whereas in pre-lingual patients (G2), the impact of the fitting method was less significant. Studies in cochlear implant programming (Kurz et al., 2023; Kurz et al., 2025) support this finding, indicating that while anatomy-based fitting benefits post-lingual patients by optimizing electrode placement, it does not drastically alter outcomes in pre-lingual patients who rely more on long-term neuroplasticity.

5.4 Limitations

Despite these significant findings, certain limitations should be acknowledged. The study cohort consisted of a limited number of patients, which, while providing meaningful insights, restricts the generalizability of the findings. A larger sample size would allow for greater statistical power and a broader understanding of the impact of different variables on outcomes. Additionally, the follow-up period was limited to twelve months post-implantation, a time frame that captures early adaptation trends but does not fully assess long-term stability and progressive improvements that might occur beyond this period. The selection of patients, which focused solely on adults with severe-to-profound sensorineural hearing loss, may have introduced selection bias, limiting the applicability of results to other populations, such as children or patients with auditory neuropathy spectrum disorder. Another consideration is the variability in electrode placement due to individual cochlear anatomy, which, despite efforts to optimize fitting, may have influenced the observed results. Moreover, while the study compared anatomy-based and behavioral-based fitting strategies, variations in clinical fitting approaches within these categories may have introduced additional variability in outcomes. The absence of pediatric patients further limits the study’s applicability to younger populations, where neuroplasticity plays a crucial role in auditory development. Finally, speech perception in noise was assessed, but the testing conditions did not fully replicate real-world auditory environments, highlighting the need for future studies incorporating more ecologically valid assessments of cochlear implant performance.

6. CONCLUSIONS AND FUTURE DIRECTIONS

This study provides insights into the impact of electrode type, manufacturer, and fitting strategy on electrophysiological parameters and auditory performance in cochlear implant recipients. The findings indicate that perimodiolar and lateral wall electrodes exhibit significant differences in impedance, ECAPs, and M/C levels over time, with lateral wall electrodes demonstrating slightly better auditory performance, likely due to their greater angular insertion depth rather than differences in electrode-modiolus distance. Among the manufacturers, Med-el recipients achieved the best overall auditory outcomes, which can be attributed to the longer and more flexible electrode arrays as well as the use of an anatomy-based fitting strategy. Advanced Bionics performed comparably to Med-el in some parameters, particularly in ECAPs and M/C levels, while Cochlear devices demonstrated higher impedance values, likely due to the perimodiolar placement of the electrodes, which results in increased electrode-tissue interface resistance. Despite these differences, all three manufacturers showed significant post-implantation improvements, underscoring the efficacy of cochlear implantation regardless of specific device selection.

The fitting strategy played a crucial role in shaping these outcomes. Anatomy-based fitting was particularly beneficial for post-lingual patients, as it allowed for more precise neural recruitment and reduced current spread, leading to improved speech perception. However, this advantage was less pronounced in pre-lingual patients, where auditory system development relies more heavily on long-term neural plasticity and auditory training rather than immediate optimization of electrode placement. The results suggest that while anatomy-based fitting provides a clear benefit in optimizing speech perception in experienced auditory users, it does not have the same immediate impact in individuals who lack pre-existing auditory memory. This reinforces the idea that post-lingual patients benefit more rapidly from precise electrode placement, while pre-lingual patients require prolonged auditory rehabilitation regardless of the fitting strategy.

Future research should aim to address these limitations by conducting longitudinal studies with extended follow-up periods to evaluate long-term performance stability. Expanding the patient cohort to include a more diverse range of cases, including pediatric patients, would enhance the applicability of findings across different age groups. Additionally, incorporating advanced imaging techniques, such as high-resolution MRI and ultra-fine CT scans, could provide more precise assessments of electrode positioning and its relationship to auditory outcomes. Investigating the development of personalized electrode selection strategies, combining preoperative anatomical analysis with post-implantation electrophysiological data, may further optimize fitting approaches. Speech perception testing in more complex auditory environments, integrating background noise, reverberation, and multispeaker conditions, would provide a more comprehensive evaluation of real-world cochlear implant performance. Furthermore, exploring the role of cognitive factors, such as auditory working memory and neuroplastic adaptation, could help explain individual variability in outcomes. The integration of artificial intelligence-assisted fitting strategies and real-time adaptation algorithms also represents a promising avenue for future research, potentially enhancing cochlear implant customization and patient outcomes.

The findings of this study reinforce the importance of individualized cochlear implant programming based on electrode type, manufacturer, and patient-specific factors. The results highlight that the choice between perimodiolar and lateral wall electrodes, as well as the selection of fitting strategy, must be tailored to the patient's auditory history and neural plasticity potential. Long-term follow-up and personalized rehabilitation strategies remain essential in maximizing the benefits of cochlear implantation. Addressing the identified limitations and pursuing future research directions will contribute to the continued evolution of cochlear implantation, ultimately leading to improved auditory outcomes and quality of life for individuals with severe-to-profound hearing loss.

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