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Invited Review

Considerations and Rationale for Cochlear Implant Electrode Design – Past, Present and Future

Frank Risi

Group Product Manager, Surgical & Implants, Cochlear Limited, New South Wales, Australia

ORCID ID of the author: F.R. 0000-0002-8342-7696.

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The electrode array of a cochlear implant forms a permanent, often lifelong interface between the implanted electronics and neural structures of the cochlea. A cochlear implant is primarily prescribed to restore hearing via electrical stimulation of the auditory nerve. As with any neural stimulator intended to either deliver electrical stimulus or record a neural response, the aim is to place the electrodes in close proximity to the target neural structures. The broadening of indications and the concept of preservation of low-frequency residual hearing over the last two decades has resulted in an increased understanding of the mechanisms and implications of intracochlear trauma for both the hearing preservation surgery and electrical stimulation outcomes with cochlear implantation, as well as the influence of many biographic and audiological patient factors correlated with achieving better hearing outcomes. These two goals, the proximity to the cochlear nerve for electrical stimulation and the preservation of cochlear structures, have typically been viewed as mutually exclusive, with perimodiolar electrode arrays being preferred for the former, and lateral wall electrode arrays for the latter. The design evolution of both the lateral wall and perimodiolar electrodes is presented, considering the cochlea anatomy and continued understanding of the mechanics and dynamics of electrode insertion, along with the influence of the ongoing changes to the intracochlear environment to provide a rationale for the electrode design with the intent to provide the greatest patient benefit over their implanted lifetime.

KEYWORDS: Cochlear implant, electrode, perimodiolar, lateral, trauma, design, insertion depth

INTRODUCTION

The cochlear implant has successfully restored hearing, improving the quality of life in adults and providing children with normal developmental and educational opportunities. More recently, indications for cochlear implantation have expanded to not only include bilateral severe-to-profound hearing loss, but also to patients with single-sided deafness, moderate-to-severe hearing loss, and those with significant (even normal) levels of residual low-frequency hearing. A combination of technological advancements in device hardware and processing capabilities, along with the development of improved surgical techniques and evidence supporting earlier implantation, have all resulted in significant improvements in outcomes over the past 30 years. In a prospective study of 114 patients followed up to 24 months [1], a number of biographic, audiological and device factors were identified that correlated with either higher- or-poorer performing patient outcome groups. Electrode factors, such as correct scala placement and modiolar proximity were found to correlate positively with patient outcomes. This is an important consideration as the electrode forms a permanent and lifelong interface between the cochlear implant delivering stimulation and the neural structures of the cochlea.

Early Studies

The primary objective of any cochlear implant system is to effectively electrically stimulate the auditory nerve. Early multichannel cochlear implant electrodes were all straight in design ("lateral wall" electrodes), containing between 8 and 22 electrode contacts and up to 1.3 mm in diameter. The size and stiffness of these early lateral wall electrodes were a function of the technology at the time, and they supported the surgical aims to place a multichannel electrode within the cochlea to deliver electrical stimulus to the auditory nerve.

Early studies with pre-curved ("perimodiolar") electrode arrays, designed to be placed close to the medial margin of scala tympani, demonstrated reduced Electrical Auditory Brainstem Response (EABR) thresholds in a cat model relative to electrodes positioned

Corresponding Address: Frank Risi E-mail: FRisi@cochlear.com

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along the lateral wall, with the EABR threshold reducing as the electrode array was moved from a lateral to a medial position [2]. The scientific and clinical evidence and rationale for perimodiolar electrode placement at that time led all three commercial cochlear implant companies (Cochlear Ltd., Advanced Bionics and MED-EL) to actively develop perimodiolar electrode arrays, with each taking very different approaches to achieve modiolar proximity: Cochlear Ltd. with the Contour electrode (stylet based), Advanced Bionics with the Hi-Focus electrode (positioner based), and MED-EL with the Peri-Modiolar Electrode (push-wire based) designs. Although different in design, all three achieved a final position close to the modiolus. All were initially inserted straight, achieving full insertion as a lateral wall electrode, and only after the initial insertion did the electrodes achieve a final position closer to the modiolus [3, 4].

Studies with all three early perimodiolar electrode designs showed that they could be physically positioned more closely to the modiolus; however, trauma to cochlea structures was evident in all three, with the degree of trauma comparable for all three electrode designs. At that time, the resultant trauma was considered equal to or less than the trauma reported for straight multichannel arrays [4].

At the same time that these electrodes were being developed and commercialized, the concept of both soft surgery and combined electric and acoustic (hybrid) stimulation was being introduced [5, 6], the goal being to preserve the cochlea structure and potentially preserve residual low-frequency hearing in patients who had some levels of functional hearing but were not benefiting from auditory amplification via hearing aids alone. This resulted in the development of thinner, shorter, and more flexible lateral wall electrodes, such as the Hybrid-L24 and Slim Straight electrodes (Cochlear Ltd., Sydney Australia), the Flex series (MED-EL, Innsbruck Austria) and SlimJ (Advanced Bionics, Valencia USA). These lateral wall electrodes were developed with smaller diameters to facilitate round window insertion and shorter lengths to minimize trauma and total loss of residual low-frequency hearing [7, 8].

The recently developed perimodiolar electrodes on the other hand were larger in diameter, and so they typically required a separate cochleostomy. The Contour Advance (Cochlear Ltd.) was developed soon after as a variant of the original Contour electrode, but with a unique Advance off Stylet (AOS) surgical technique. This insertion technique was specifically developed to reduce contact with, and therefore trauma to, the structures of the lateral wall during initial insertion [9]. A multicenter study to assess conservation of residual hearing with the Contour Advance [10] found that hearing could be conserved with the Contour Advance when the recommended surgical technique was strictly adhered to and that non-use of the recommended AOS technique or enlarged cochleostomy was associated with greater levels of hearing loss. However, the requirement of a small cochleostomy along with the large variability of cochleostomy placement, in many cases directly into scala vestibule [11, 12], and poor or non-compliance with the AOS technique have contributed to mixed clinical outcomes with respect to hearing preservation.

Lateral Wall Electrode Arrays

The most commonly reported type of intracochlear trauma due to electrode insertion is trauma to the structures of the lateral wall [13]. By virtue of their design and the mechanics and dynamics of electrode insertion, all lateral wall electrodes will impact the lateral wall of scala tympani. As the electrode is inserted, it will initially impact the lateral wall at approximately 180°, after which the insertion force profile increases significantly as a function of the insertion depth, as does the frictional force, as the contact area between the spiral ligament and the silicone carrier of the electrode increases [14].

Lateral wall electrode diameter and cochlea anatomy

Histological studies assessing scala dimensions and morphology [15, 16] show that the height of the scala tympani, specifically the height at the lateral aspect of the scala tympani, begins to reduce significantly beyond 360° to 450°. As the height reduces, the slope of the lateral scala wall increases significantly, resulting in lateral wall electrodes experiencing an increasing outward and upward force toward the basilar membrane [9]. The height of the lateral aspect of scala tympani is an important metric in defining the maximum apical diameter of a lateral wall electrode, which is required to fit within this space without interference or placing upward pressure on the basilar membrane. This scala height, relative to electrode diameter becomes more critical apically as the basilar membrane is not a homogeneous structure with consistent properties along its length, but progressively increases in width while decreasing in thickness and stiffness from base of the cochlea to the apex [17, 18].

The maximum electrode diameter therefore that fits within the lateral aspect where the basilar membrane joins the spiral ligament at 450° is approximately 0.4 mm, reducing to approximately 0.3 mm at 540° [15, 16]. The smallest apical dimension (vertical height) of current commercially available lateral wall electrodes is 0.35 mm (Hybrid L24 and Slim Straight electrodes from Cochlear Ltd.). Figure 1 shows the apical heights of all current commercially available lateral wall electrodes.

Figure 1. Maximum apical (vertical) heights of current commercially available lateral wall electrodes. The shaded area highlights the height of the lateral aspect of scala tympani between 450° and 540°.

Insertion forces with lateral wall electrodes

Translocation of the electrode array from scala tympani to scala vestibuli will not only result in loss of any remaining residual hearing, but it will also result in poorer hearing outcomes with electrical stimulation [1]. A study to quantify the force required to puncture the intrascalar partition [19] used micro dissected fresh (post mortem<120 hours), human temporal bones to expose the osseous spiral lamina, basilar membrane, and Reissner's membrane complex. Using a 0.3-mm-diameter indenter (force sensor) a range of rupture forces between 42 to 122 mN with a mean of 88 mN were identified. As the indenter in this study was positioned directly above the

intrascalar partition in the area within the first 90° of the basal turn in all samples, measures will have been biased toward the narrower and stiffer basal end of the basilar membrane which likely require greater force to rupture than wider, more flexible apical positions. In another study comparing the insertion forces of flexible lateral wall electrodes (Flex 28 from MED-EL) and histological evaluation of trauma in temporal bones [14], traumatic insertion was identified in five of 12 (42%) specimens, with translocation always occurring in the 150° to 180° region with the insertion force correlated with the degree of intracochlear trauma. In cases showing intracochlear trauma and translocation, an irregular force profile was observed, with the presence of an early peak force of 30±18.2mN. These forces are lower than those reported by [20], however these translocations occurred more deeply , and the mechanisms of impacting the basilar membrane were also different between the two studies.

Insertion force studies with lateral wall electrodes have a typical force profile during electrode insertion, that is, initial impact and increase in force as the electrode contacts the lateral wall (between 150° and 180°), followed by an exponential increase as the electrode travels around the narrowing spiral of the cochlea and friction between the soft tissue and silicone of the electrode increases. As there is no recognized standard providing guidance on insertion force testing, there have been a wide range of reported lateral wall insertion forces, as highlighted by the grey-shaded area in Figure 2, which outlines insertion forces reported by a number of studies [20-24]. The large variation in force profiles is not always a function of the electrodes models tested, but it can also be related to 1) the model adopted (plastic model or temporal bone); 2) whether or what lubrication was used; 3) the cochlear size or diameter (especially in plastic models in which larger diameters can significantly reduce the force profile); and 4) the electrode trajectory or path (which in plastic models can be well controlled but in temporal bones is blind and more likely to take an errant course).

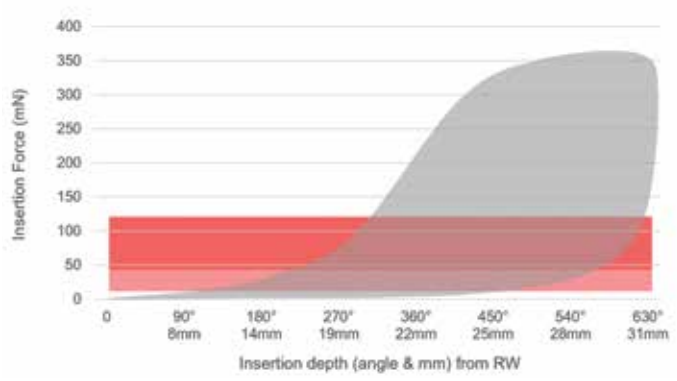

Figure 2. Lateral wall electrode insertion forces. Grey shaded area showing the range of insertion force profiles from literature [20-24]. Red-shaded bands showing the range in force measured in vitro to rupture [20] or result in translocation [14].

Lateral wall electrode lengths

Trending the development of lateral wall electrode lengths over time (Figure 3) shows a convergence to a lateral wall length of 20 mm (approximately 360°) to minimize trauma and preserve functional hearing and 25 mm (approximately 450°) to preserve structure and maximize coverage of the spiral ganglion population for electrical stimulation. Figure 3 also highlights two very different approaches taken that have ultimately arrived at the current approach of a 20-25 mm insertion depth, balancing both cochlear trauma with cochlear coverage [25].

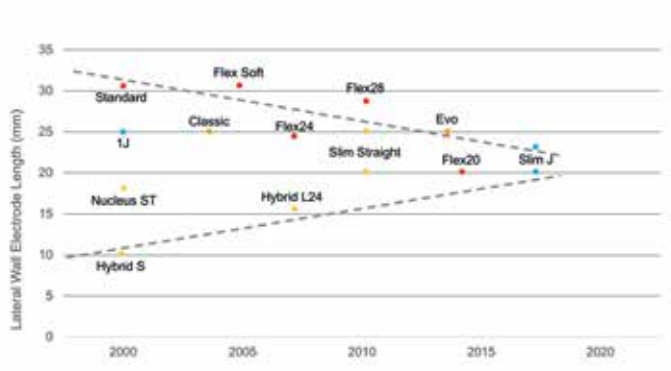

Figure 3. Trend in lateral wall electrode lengths over time (note: 2000 is used as a reference for electrodes available prior to this date).

Although trauma to structures of the lateral wall is one of the most commonly reported types of insertional damage, buckling or kinking of the electrode in the basal turn, resulting in basal fracture of the osseous spiral lamina, is another commonly reported mechanism of trauma with flexible lateral wall electrodes. This was first reported in 1997 [26], and in a latter temporal bone study [27] using four different electrode arrays from the one manufacturer (MED-EL, Innsbruck Austria). A 7 out of 33 (21%) rate of basal trauma due to basal electrode buckling was reported with more than half of these (4 of 7) being Grade 4 trauma (fracture of the osseous spiral lamina). The authors postulated that basal buckling occurs when the insertion beyond resistance is attempted, causing electrode buckling and trauma to the osseous spiral lamina or basilar membrane in the lower basal turn. The mean insertion depth in this study was 23mm (SD=4mm) with a mean radiological insertion depth of 375° (SD=125°). Another study that used microdissected temporal bones to expose the basilar membrane [13] also identified that insertion beyond resistance, typically the result of the lateral wall electrode tip becoming impinged against the spiral ligament, or friction against the underside of the basilar membrane, resulted in the basal electrode buckling and corresponding fracture to the osseous spiral lamina in the basal turn (Figure 4).

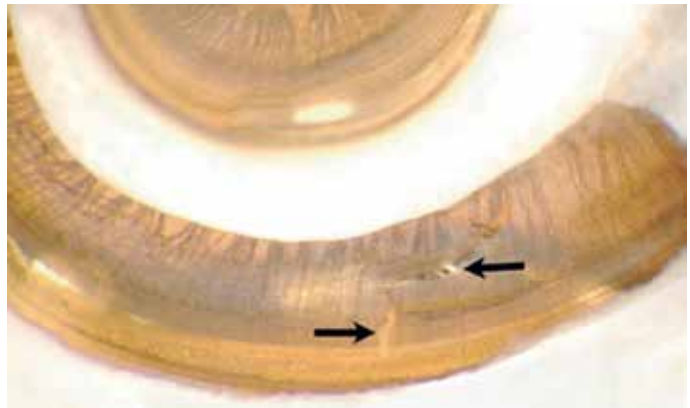

Figure 4. Image of microdissected temporal bone [13] showing lateral wall electrode tip meeting resistance in the second turn (top of image), resulting in the elevation of the basilar membrane. Continued effort to advance the electrode results in buckling in the lower basal turn and fracture of the osseous spiral lamina (arrows).

In a human temporal bone study [24] that measured 3-dimensional insertion, basal trauma to the basilar membrane and osseous spiral lamina was identified, resulting from basal buckling in six of seven

cochleae with corresponding changes in the force profiles but not necessarily the result of higher peak forces This suggests intracochlear trauma caused by basal buckling cannot be detected by the surgeon in clinical practice. The mean insertion depth in this study was only 18.8 mm (SD=0.6mm) or 327° (SD=22).

The underlying mechanisms and potential for trauma with lateral wall electrodes have been extensively studied. Although trauma has been successfully minimized with contemporary lateral wall electrode designs by reducing apical diameters and limiting insertion depths, the mechanisms will always be present, and it is not always possible to predict or influence these intra-operatively. This underlying mechanism has resulted in the development of physiological feedback tools such as real-time acoustic electrocochleography using the intracochlear electrodes to measure the growth of response magnitudes relative to the intrascalar electrode depth and proximity to the residual outer hair cells, with impedance of residual auditory function or trauma resulting in a reduction in the response magnitudes [28, 29]. An observational study [29] found that the Cochlear Microphonic (CM) increased normally to 20 mm insertion of a lateral wall electrode however dropped suddenly when inserting beyond 20 mm. The authors postulated that this pattern is a result of the lateral wall electrode physically contacting or elevating the basilar membrane due to the decreasing height of the lateral aspect of ST in the second turn and thereby impeding acoustic function.

Post-operative changes to the cochlear environment

In addition to electrode insertion trauma, with the potential for acute damage to intracochlear structures, post-operative changes to the intracochlear environment are also important to consider, especially if the aim is functional hearing preservation. If atraumatic electrode insertion with a lateral wall electrode is achieved, the electrode will always be positioned directly adjacent and in a very close proximity to the basilar membrane. Intracochlear fibrosis consisting of inflammation, fibrosis, and neoosteogenesis will form around the electrode array due to the opening of the cochlea, foreign body tissue response, or disruption of any soft tissue or venous structure of scala tympani during insertion [13]. Changes to the intracochlear environment have been reported in several histopathological studies of temporal bone specimens donated by deceased cochlear implant patients [30-32]. The build-up of fibrosis around the electrode over time will potentially impact or form a connection to the spiral ligament and basilar membrane, which will result in mechanical impedance with reduction or complete loss of hearing over time.

Explant trauma with lateral wall electrodes

These post-operative changes are also important when considering the explantation of electrode arrays, especially considering that in young children, explanation may be expected during their lifetime. The intracochlear environment after 10, 20, or 30 years of implantation may therefore be similar to that identified in post-mortem studies mentioned above. An *in vitro* study [33] utilized a plastic cochlea model backfilled with a gel formulation representing soft tissue surrounding the electrode array. It found that explant trauma, measured as disruption to the gel surrounding the electrode correlated with the depth of insertion, with deeper insertion of a lateral wall electrode, resulting in greater disruption. Figure 5 shows the difference in the *in vitro* modelling of a 20 mm and 28 mm lateral wall insertion depth. As the 28 mm electrode is explanted, the load forces the electrode medially so that the electrode contacts the modiolus from approximately 300° with significant disruption of the surrounding gel as the electrode moves from a lateral to a medial position. In contrast, a shallower 20 mm insertion remains lateral within the electrode lumen due to reduced load and friction, with only minor disruption of the surrounding gel.

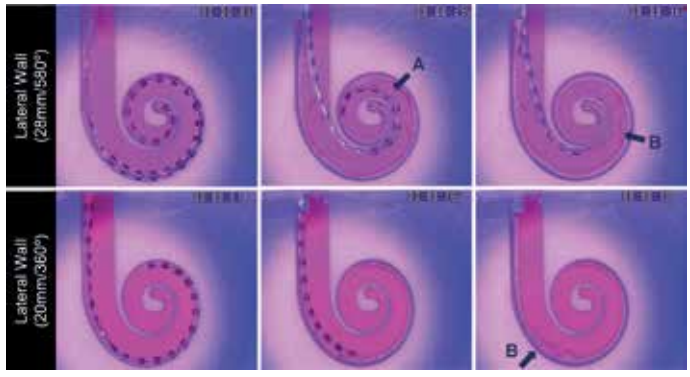

Figure 5. In vitro model of explant trauma [33] showing explant of a deeper (28mm) insertion (top panel, left to right) with associated trauma as the electrode path moves from the lateral to the medial position A and disrupts the surrounding gel B versus explant of a shallower (20mm) insertion (lower panel, left to right) where the electrode remains within the lumen with minimal disruption (B).

Stylet-Based Perimodiolar Arrays

Although the height of the lateral aspect of scala tympani reduces significantly beyond 360° to 450°, the height of the medial aspect of scala tympani remains relatively consistent and up to twice the height of the lateral aspect [15, 16]. The insertion depth and diameter of the tip of perimodiolar electrodes are therefore not constrained as much by the reducing height of scala tympani, as is the case with lateral wall electrodes. Figure 6 illustrates the relative position of equivalently sized lateral wall and perimodiolar electrodes positioned in scala tympani.

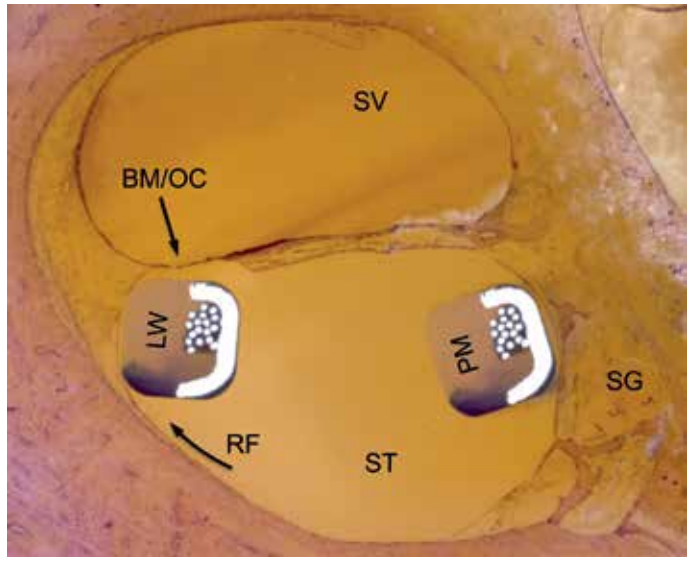

Figure 6. Position of both the lateral wall (LW) and perimodiolar (PM) electrode in scala tympani and relative proximity to the basilar membrane (BM), organ or Corti (OC), and spiral ganglion (SG).

Figure 6 highlights the difference in heights of the medial and lateral aspects of the scala tympani and the effect of the slope of the lateral wall on the rising force (RF) with the resulting proximity of a lateral wall electrode to the basilar membrane. In contrast, the perimodiolar

electrode has much greater clearance in terms of the medial scala tympani height and much greater proximity to the spiral ganglion, as well as being much further from the functional structures of the basilar membrane and the organ of Corti.

The apical electrode diameter of current stylet-based perimodiolar electrodes is 0.5 mm (Contour Advance from Cochlear Ltd.; Midscala from Advanced Bionics), which is a technical constraint created by the requirement of an internal stylet. Although a 0.5 mm apical electrode dimension is not dissimilar to the dimensions of contemporary lateral wall electrodes (see Figure 1), space within the narrowing scala tympani is not the concern, but rather the ability to insert via round window. So, a separate cochleostomy has typically been required, which then exposes the risk of incorrect cochleostomy placement [12] and in many cases an anterior cochleostomy directly into scala vestibule or contributing to early translocation from ST to SV [11].

Insertion forces with perimodiolar electrode arrays

As for the lateral wall electrodes, a number of studies measuring insertion forces have been conducted with stylet-based perimodiolar electrodes [9, 34-37]. All of these have investigated insertion forces using the two insertion techniques possible with stylet-based perimodiolar electrodes, these being the Standard Insertion Technique (SIT), where the electrode is inserted fully in the same way as a lateral wall electrode prior to the stylet being removed, and the AOS technique, where the electrode is partially inserted into the basal turn only, and the electrode then is advanced off the stylet.

Figure 7 highlights the difference in the insertion force profiles between these two techniques, with the SIT (shaded area) having a similar insertion force profile to lateral wall electrodes, that is, as the electrode contacts the lateral wall, the insertion forces increase significantly. As perimodiolar electrodes are shorter in the linear length (17-18 mm), the peak force with a SIT is typically less than with longer lateral wall electrodes typically inserted 20 mm to 31 mm (see Figure 2). When the stylet is withdrawn after the initial insertion, the force on the lateral wall reduces to zero, almost immediately as the electrode moves from a lateral to a medial position and the angular insertion depth also goes from approximately 270° to 420°.

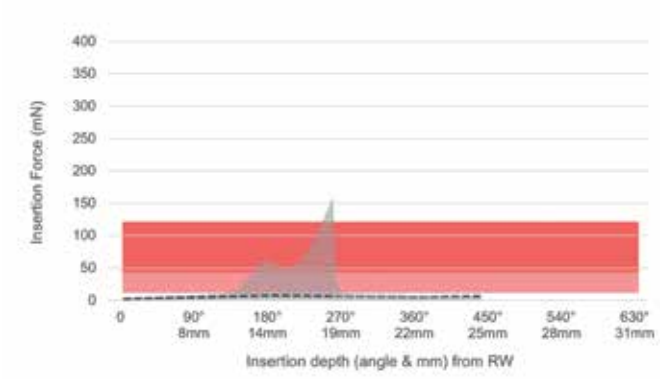

Figure 7. Stylet-based perimodiolar electrode insertion forces. Grey-shaded area showing the range of insertion force profiles from literature [9, 34-37] for the Standard Insertion Technique (SIT) and thick dotted line for the Advance off Stylet (AOS) insertion technique. (Refer to figure 2 for relative lateral wall electrode insertion forces).

With the AOS insertion technique, the electrode avoids contact with the lateral wall completely and therefore the insertion forces remain near zero throughout the insertion (dotted line in Figure 7). The mechanism of trauma to the spiral ligament and basilar membrane between 150° and 180° with a SIT is therefore similar to that of lateral wall electrodes; however, the risks are likely higher due to the relative stiffness of the electrode with the stylet in place. With the AOS insertion, however, the lateral wall forces are minimized or negated such that they remain below the threshold for trauma or rupture of the intrascalar partition.

Therefore, in addition to variability in cochleostomy placement [12], another challenge with stylet-based electrodes is the variability of, or compliance with, the AOS insertion technique, which is designed to avoid contact with the lateral wall structures.

Considering the significant number of temporal bone and histological studies conducted with stylet-based perimodiolar electrodes, there is little evidence to suggest the risk of trauma to the modiolus [9]. In a recent study using lateral wall electrodes, but inserted with a large round window angle so that the electrodes were directed towards the modiolus with the electrode sliding along the modiolar wall, during insertion. No trauma to the modiolus was identified using micro-CT analysis, suggesting that the forces exerted on the modiolar wall were too small to induce visible trauma [24].

When inserted into scala tympani using the correct technique, perimodiolar electrodes are atraumatic and provide the best opportunity to ensure long-term integrity of the functional structures of the cochlea, such as the basilar membrane and organ of Corti. Figure 8 shows two histological examples of post-mortem temporal bones from two cochlear implant patients [38]. On the left (A) is a perimodiolar electrode with no lateral wall contact and no trauma to the spiral ligament or basilar membrane (127 months post-implantation), and right (B) with lateral wall contact and trauma to both the spiral ligaments and basilar membrane (147 months post implantation).

Figure 8. a, b. Post-mortem temporal bone histology [38] of cochlear implant patients with (a) perimodiolar electrode with no lateral wall contact and no trauma to the spiral ligament or basilar membrane; and (b) with lateral wall contact and trauma to both the spiral ligaments and basilar membrane.

The authors suggested that the damage to both the lateral cochlea wall and osseous spiral lamina tend to cause new bone formation and fibrous tissue within scala tympani, with similar studies [31] also finding that the new bone and fibrous tissue formation is positively correlated with trauma to the lateral cochlear wall.

Sheath-based perimodiolar electrode

The majority of published studies, both *in vivo* and *in vitro*, of perimodiolar electrodes have been conducted with stylet-based designs (Contour

and Contour Advance from Cochlear Ltd. and Helix and Mid Scala from Advanced Bionics). More recently, the Slim Modiolar Electrode (CI532 implant) from Cochlear Ltd. introduced a new concept of a "sheath-based" perimodiolar electrode, as opposed to "stylet-based". This difference in approach to straighten and insert a pre-curved electrode is a significant advancement that addresses the two main challenges identified as contributing to the higher rates of trauma with stylet-based perimodiolar electrodes, being 1) variability or compliance with the AOS insertion technique, and 2) the ability to insert via the round window. The sheath-based design also allows for ease of reloading the electrode if required.

Variability or compliance with the AOS insertion technique: The sheath design ensures that the insertion technique (outlined in Figure 9) results in the electrode being inserted only 5.5 mm into the basal turn initially (Step B), with no possibility of inserting further as with the SIT. This ensures that when the pre-curved electrode is advanced through the sheath (Steps C1, C2, and C3), it avoids contact and trauma to lateral wall structures. When the sheath is removed, the electrode contacts remain in close proximity to the modiolus.

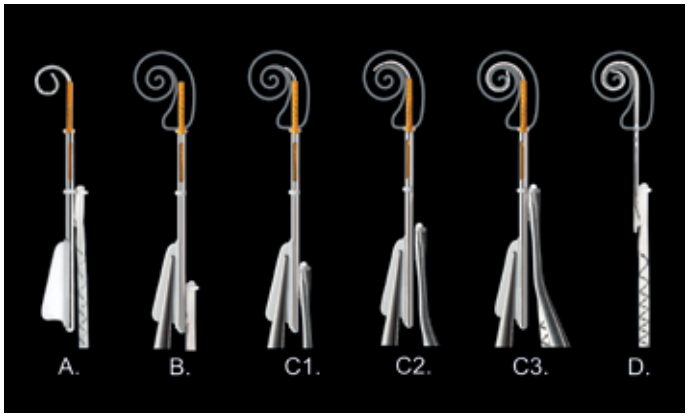

Figure 9. Slim Modiolar Electrode (CI532) insertion technique. A: Electrode in sheath prior to loading; B: electrode loaded in sheath and sheath inserted into cochlear; C1, C2, C3: electrode progressively advanced through sheath; and D: sheath removed from electrode.

Ability to insert via round window: The sheath design removes the need for an internal stylet allowing for a significantly thinner electrode array, with apical dimension of 0.35x0.4 mm and 0.5 mm basally, which is smaller than or equivalent to contemporary lateral wall electrodes (see Figure 1). The sheath, which is inserted 5.5 mm into the basal turn, is only 0.68 mm in diameter and thus smaller than or equivalent to the basal diameters of contemporary lateral wall electrodes (0.6 mm for Slim Straight from Cochlear Ltd. and 0.8 mm for Flex 20/24/28 from MED-EL). The soft and flexible sheath design therefore allows for round window insertion, ensuring placement in the scala tympani.

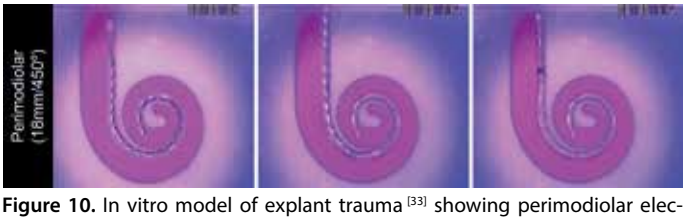

Figure 10. In vitro model of explant trauma [33] showing perimodiolar electrode where the electrode array remains within the lumen during explantation with no disruption of the surround gel and no disruption of gel at the lateral aspect of scala tympani.

Explantation trauma with perimodiolar electrodes

Explant trauma was also investigated for perimodiolar electrodes utilizing a plastic cochlea model backfilled with a gel formulation to represent soft tissue fibrosis [33]. Disruption to the gel, representing the tissue surrounding the electrode, was found to be minimal, with the electrode remaining within the electrode lumen (Figure 10). Unlike lateral wall electrodes (see Figure 5), there was no disruption of gel at the lateral aspect of scala tympani. As with the concept of minimizing contact and trauma to the functional structures of the cochlea during insertion, a perimodiolar electrode also minimizes trauma and maintains integrity of the functional structure of the lateral wall on explant.

Clinical Rationale for Lateral or Perimodiolar Electrodes

The primary objective of cochlear implantation is to restore hearing via electrical stimulation of the auditory nerve. As with any neural stimulator intended to deliver stimulus or record a response from either a central or peripheral nerve, the aim is to position the electrodes in close proximity to the target nerve. For cochlear implantation, placing the intracochlear electrodes in close proximity to the auditory nerve has been shown to provide greater neural specificity [39-41], reduced stimulation levels [42-44], and improved hearing performance [1, 45]. The broadening of indications and concept of preservation surgery over the last two decades have resulted in an increased understanding of the implications of intracochlear trauma to outcomes for patients that will rely on either electrical stimulation alone [1, 11] or for those who may benefit from additional acoustic input combined with electrical stimulation [46, 47]. Cochlear implant surgery can therefore be viewed with two distinct aims: 1) preservation of structure and integrity of the cochlea for optimal electrical stimulation,where hearing preservation is a marker for atraumatic insertion/structure preservation; and 2) preservation of functional hearing with the aim of acoustic amplification of the preserved low-frequency thresholds. For 1), the primary benefit being delivered by cochlear implantation is electrical stimulation of the auditory nerve, and for 2), the primary benefit is electrical stimulation supplemented by acoustic amplification of the low frequencies whilst still present.

Lateral wall electrodes have been shown to be reliably and consistently placed in scala tympani [48, 49]; although translocations can still occur [50], especially if deeper insertions are attempted. There is also a potential for basal trauma to the osseous spiral lamina or basilar membrane due to basal buckling, especially with flexible lateral wall electrode with larger basal diameters [13, 26, 27]. Hearing preservation has been extensively reported on; but clinically there is a relationship between increased depth of insertion and poorer hearing preservation rates with lateral wall electrodes [51-53], reflecting the results of anatomical studies [54]. Thus limiting the insertion depth of a lateral wall electrode to 360°-450° (20-25mm) therefore seems a pragmatic approach if aiming to preserve the structure or hearing. A lateral wall electrode should also have an apical dimension less than 0.4 mm to fit within the narrow aspect of the lateral scala tympani and reduce the potential contact and pressure on the basilar membrane. A smaller basal diameter and the presence of basal stabilization may also help limit the potential for trauma due to basal buckling. The underlying mechanics however remain in that lateral wall electrodes will, by design, be positioned in close proximity to the basilar membrane. With the subsequent foreign body reaction

and build-up of fibrosis around a lateral wall electrode, there is an increased potential for contact with, adherence to and impedance of basilar membrane function over time and associated decline of preserved low frequency hearing. In these cases, the patient will ultimately rely on electrical stimulation alone, and with the electrode contacts positioned much further away from the auditory nerve electrical stimulation efficiency will be reduced as will performance outcomes [1].

Preservation of cochlear structure and optimized electrical stimulation

There are other factors in addition to electrode insertion trauma and that contribute to either complete, partial, or minimal loss of residual hearing at surgery, or more importantly the impact on the stability of hearing preservation over time. Therefore, even if functional preservation is achieved at surgery, the subsequent changes to the intracochlear environment due to the surgery and presence of the electrode will likely result in a gradual decline over time or accelerate any progressive loss that was present prior to surgery. Therefore, depending on the patient's age and the rate of decline, they may end up relying entirely on electrical stimulation for most of their implanted life.

Preservation of cochlear structure and optimized electrical stimulation should therefore be the goal for all cochlear implant patients, and if functional hearing is preserved, the goal should be to maintain the functional benefit for as long as possible to extend the benefits of acoustic amplification. Considering the anatomy, physiology, and dynamics of electrode insertion described in the above sections, Cochlear's approach to achieve these have been:

Ensure a consistent and full scala tympani placement with a full-length electrode to achieve 1.5 cochlear turns and to avoid the risk of trauma to the narrow apical second and third cochlear turns.

Avoid the electrode contact or proximity to the functional structures of the basilar membrane and organ of Corti, both during and after the insertion for preservation and maintenance of soft tissue structures in the long term.

Place the electrodes in close proximity to the auditory nerve for efficient and optimized performance with electrical stimulation

Early Clinical Experience with the Slim Modiolar Electrode (CI532)

The Slim Modiolar electrode (CI532 device) was developed specifically to achieve these three goals, incorporating the clinical and non-clinical experiences with the Contour Advance electrode and the technology and manufacturing advancements with the Slim Straight and Hybrid L24 electrodes. Pre-clinical safety studies in cadaveric temporal bones [55] have demonstrated that the Slim Modiolar Electrode (SME) can be reliably and consistently implanted through the round window without major trauma irrespective of the cochlea size. As the SME is still relatively new in terms of clinical availability, there is a limited but growing body of clinical evidence. In the first reported multicenter clinical study all 44 subjects implanted with the SME had a complete scala tympani placement [56]. Cuda and Murri [57] reported complete scala tympani insertions in 67 subjects implanted with the SME with 61 via round window and 6 via cochleostomy (due to otosclerotic severe round window ossification). Shaul et al. [58] also reported complete scala tympani insertion in 18 subjects implanted with the SME, compared to 14/79 (14%) translocation rate and 7/70 (9%) wholly in scala vestibuli for the Contour Advance (CI512). McJunkin et al. [59] reported a complete scala tympani placement in 20/23 patients, with a 13% translocation rate. They reported the crossover angle for the three translocations as 80°, 120°, and 125°, indicating that all three translocated in the basal turn potentially soon after exiting the sheath. Orientation of the sheath of the SME prior to advancing the pre-curved electrode is important to ensure the electrode curves in plane with the first cochlear turn, as misorientation of the sheath would potentially result in the electrode exiting the sheath toward SV.

Cuda and Murri [57] also reported pre-post implantation audiometric shifts in 67 patients. Although the pre-operative thresholds were not consistent (<80dB at 125Hz only specified), post-operative hearing was still detectable across all frequencies and a mean post-operative threshold shift of just over 10dB was reported. In a randomized study [61] evaluating hearing preservation outcomes with a SME compared with the Slim Straight (CI522) and Contour Advance (CI512) arrays, no statistical difference was found in the preservation of low-frequency residual hearing between the SME and Slim Straight (CI522) groups at 12 months, whereas the Contour Advance (CI512) had a much lower complete and partial preservation rate.

In a study evaluating the effect of the electrode–modiolus distance on electrode discrimination [60], the Slim Modiolar electrode (CI532) was found to have significantly closer and more consistent modiolar proximity than both the Slim Straight electrode (CI522) and Contour Advance (CI512), which resulted in significantly improved electrode discrimination scores with the Slim Modiolar electrode (CI532). Shaul [58] also found speech performance (CVC words at 12 months post-op) of 18 Slim Modiolar electrode (CI532) subjects was significantly better (80% vs 69%) than a matched group of 31 Contour Advance electrode (CI512) subjects (p=0.017).

Reported complication rates with the SME have been low and in many cases attributed to surgical error and a learning effect with the new device and new surgical technique. With any new medical device and/or surgical technique, performance tends to improves and complication rates decrease with experience [62]. In the first multicenter clinical study with the SME [56], there were 2/45 (4.4%) cases of tip fold-over reported. Both were due to surgical error and both were re-implanted successfully. McJunkin et al. [59] reported 9/117 (7.7%) cases of tip fold-over with eight of these identified intraoperatively, with the same electrode reloaded and reinserted successfully. The cause of the initial fold-over is not clear as the same electrode was reinserted successfully in a second attempt, and the authors did not comment on any difference in surgical approach between the first and second insertions. In this study only one patient (0.85%) left the operating theatre with a tip fold-over, with this patient having preserved their low frequency residual hearing and benefiting from complimentary acoustic amplification. Gabrielpillai et al. [63] reported 6/57 (10.5%) rate of fold-over identified post-operatively in a retrospective study. These all seem to have been attributed to the one implanting surgeon. They also reported higher rates of tip fold-over with perimodiolar electrodes in general (1.67%) compared with lateral wall electrodes (0.23%) in their study cohort. Tip fold-overs

therefore can occur with both electrode types, but the rate is higher with perimodiolar electrodes due to the pre-curved nature of the electrode array. Other electrode complication types however, such as basal kinking or buckling [64] or electrode migration [65], tend to be more common with lateral wall electrodes. Although complication rates in general are very low, it is therefore important to consider all the potential types of complications that may be encountered and how best to identify and manage these.

These early clinical experiences with the SME suggest that the sheath design does overcome the challenges identified with stylet-based perimodiolar arrays and provides confidence that the SME can be consistently placed in scala tympani preserving the cochlear structure and with close proximity to the cochlear nerve for an optimal electrical stimulation. Further clinical experience and evidence, however, are required to further validate the design intent of the SME.

DISCUSSION

The scientific foundations of perimodiolar placement were established by Shepherd et al. [2], who demonstrated reduced EABR thresholds in a cat model. More recently, hearing outcomes with cochlear implants have been shown to be positively correlated with modiolar proximity for electrodes placed wholly in scala tympani [1]. Advances in the design of lateral wall electrodes over the last decade, however, with thinner more flexible arrays, along with the challenges in compliance with the AOS technique and cochleostomy placement for stylet-based perimodiolar electrodes have meant that in cases where hearing preservation or round window insertion is the goal, a lateral wall electrode is currently preferred and In cases where hearing preservation is not a goal, a perimodiolar electrode is preferred [66]. These preferences are based on the experience and evidence available, which is predominantly with stylet-based perimodiolar electrodes. Variable compliance with AOS surgical technique have provided mixed clinical experiences and outcomes, resulting in the perception that perimodiolar placement and hearing preservation are mutually exclusive. Similar to the innovations that resulted in thinner and less traumatic lateral wall electrodes and positive experiences and evidence supporting preservation, advances in the design of perimodiolar electrodes, specifically moving from a stylet-based design to a sheath-based design for the Slim Modiolar electrode (CI532), has resulted in a much thinner and more flexible pre-curved electrode array. This approach provides a perimodiolar electrode that is 1) suitable for round window insertion, 2) ensures 100% compliance with a surgical technique that avoids electrode contact with the lateral wall and basilar membrane, while 3) positioning the electrodes in close proximity to the auditory nerve for optimal electrical stimulation. The SME therefore provides significant advantages over stylet-based designs, with the potential to preserve structure as reported in early clinical studies [57, 59, 61].

A cochlear implant is prescribed to electrically stimulate the auditory nerve, and all patients receiving a cochlear implant rely on electrical stimulation. Even if some level of functional hearing is preserved initially, it will likely decline over time, especially if considering hearing preservation in children. When selecting an electrode for an individual cochlear implant candidate, it is therefore important to consider the patient's lifetime implanted-hearing needs. A cochlear electrode that has atraumatic properties and an atraumatic surgical technique, avoiding contact with and preserving cochlea structure and reducing the impact of ongoing biological changes, while placing the electrode contacts in close proximity to the neural elements being stimulated for improved stimulation efficiency and outcomes will best satisfy these lifetime implanted-hearing requirements.

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