Clinical Experience and Outcomes with the New Slim Modiolar CI532 Electrode

The CI532 Profile Series Cochlear Implant, featuring the new Slim Modiolar electrode, is the newest addition to Cochlear's electrode portfolio and is now available for clinical use. The Slim Modiolar electrode combines the advantages of perimodiolar stimulation, as demonstrated by the Contour Advance electrode, with the thin, flexible physical properties of the Slim Straight electrode. Perimodiolar positioning has been previously associated with improved psychophysical and hearing performance outcomes. Rocky Mountain Ear Center (RMEC) in Denver, Colorado (USA) incorporated the CI532 Slim Modiolar electrode (CI532) implant into our clinical practice April of 2016. Since introduction, 72 patients have received the device. The information contained herein details clinical experience to date.

Introduction

A study done by Blamey et al and Lazard et al, retrospectively looked at 2,251 patients at 15 centers. With over 2,000 subjects, they were able to look at differences in a larger population to identify predictors of good performance with a cochlear implant. One of the unique factors about this study is that it not only looked at patient-related factors that affect the performance of cochlear implant recipients, but it also looked at key design features of an electrode that contribute to good outcomes. The study identified four patient factors: duration of hearing loss, age at implantation, age onset of severe to profound hearing loss and etiology. They also identified four design factors that are predictors of good cochlear implant performance: greater number of electrodes within the scala tympani, an absence of translocation from the scala tympani to the scala vestibuli, a not excessively deep insertion, and a reduced distance to the modiolus.[1,2]

Number of Electrodes and Scala Tympani Placement

The ability to insert the electrode array within scala tympani is important, because dislocation of the electrode to the scala vestibuli causes trauma to the basilar member and is associated with reduced speech recognition.[3-5] Recipients with an electrode situated entirely within the scala tympani show a 13% improvement in word recognition compared to those with partial or complete insertion in the scala vestibuli.[5] In addition, there is a positive correlation between the number or proportion of electrodes in the scala tympani and speech recognition scores.[3,4] In a recent study[6] the authors looked at the performance of cochlear implant recipients in relation to the number of electrodes in the cochlea and found that the greater the number of electrodes in scala tympani, the better the performance. When testing in words in quiet (CNC),[7] and sentences in quiet and +5dB noise (AzBio),[8] they found that 22 electrode contacts were significantly better than 4, 6, 8, 10, and 12 electrodes.[1]

Perimodiolar Advantage

Perimodiolar positioning places the electrode close to the target of stimulation (i.e., the spiral ganglia of the auditory nerve, see Figure 1) which has been associated with reduced channel interaction,[9,10] lower electrophysiological response thresholds,[10-12] reduced spread of excitation,[13] and lower electrical stimulation thresholds.[14-16] Perimodiolar placement is also associated with hearing performance benefits such as improved pitch discrimination[7] and greater speech recognition.[4,5,17] Regardless of the electrode type and length, closer proximity of the electrode to the modiolus is correlated with better speech recognition.[4,17,18] Perimodiolar positioning may yield further benefits when paired with future stimulation strategies, such as phased array stimulation which is still under investigation.[19-21]

A Not Excessively Deep Insertion

Spiral ganglion cells located within the modiolus, adjacent to the scala tympani, and extending approximately 450° from the base of the cochlea represent the target of electrical stimulation[22] in cochlear implantation. As a result, electrodes inserted to 400 - 450° provide optimal coverage of spiral ganglia. Many studies have shown deep insertion can cause pitch confusion and trauma of delicate structures of the cochlea.[3,23-25]

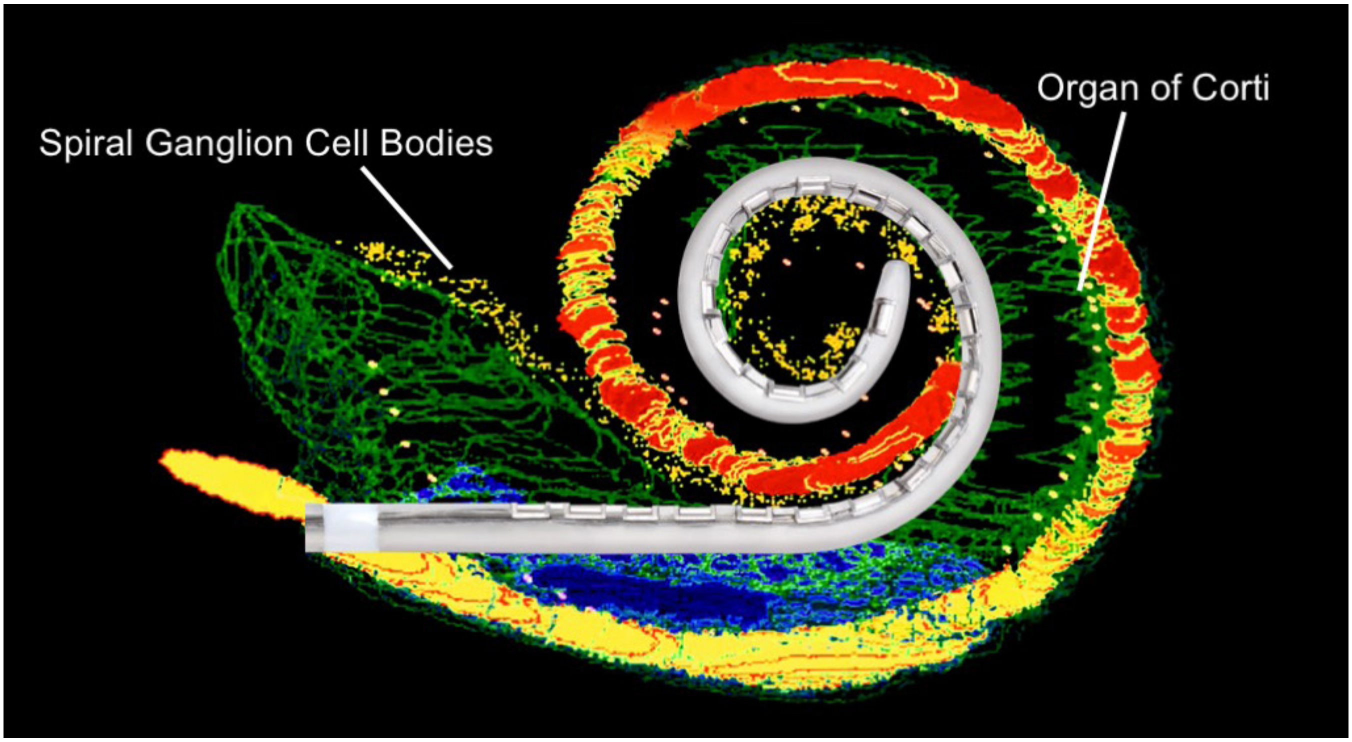

Figure 1—Slim Modiolar electrode overlaid on reconstructed image of human cochlea. Note how the perimodiolar design approximates the spiral ganglion cells and is positioned opposite the organ of Corti. Image courtesy of The HEARing CRC, Melbourne (Australia).

Slim Modiolar Electrode Design Objective

The purpose in creating the CI532 was to combine the advantages of perimodiolar stimulation, as demonstrated by the Contour Advance electrode,[4] with the thin, flexible physical properties of the Slim Straight electrode.[26] The Contour Advance has a pre-curved shape designed to wrap around the modiolus, approximating the medial wall of the cochlea. In contrast, the Slim Straight electrode has a thin, flexible linear form designed to adopt a curved position on the lateral wall after insertion into the cochlea. The Contour Advance was designed for insertion through a cochleostomy, whereas the Slim Straight was designed for round window, extended round window or cochleostomy insertion. Both electrode types have demonstrated excellent outcomes.[27] The CI532 was designed to: maintain a consistent perimodiolar position; provide 22 electrode contacts for optimal electrical stimulation; to preserve intracochlear structures during and after insertion; and to facilitate insertion through round window, extended round window or cochleostomy approaches.

The Slim Modiolar electrode is the thinnest perimodiolar electrode and occupies 60% less volume than the Contour Advance.[34] Insertion studies with CI532 have demonstrated excellent perimodiolar placement, no evidence of trauma, and negligible force on cochlear structures, with insertion angles ranging from 390 to 450°[28]. A multi-center clinical study with CI532 also demonstrated 100% scala tympani placement in all 44 subjects.[29] The CI532 electrode's unique sheath-based insertion system is tailored for round window, extended round window, or cochleostomy approaches, in any size cochlea.[28] This allows surgeons to choose their preferred insertion approach or to adapt the insertion intraoperatively based on anatomical considerations. Thin, flexible electrodes are designed to prevent trauma to the basilar membrane, and dislocation into the scala vestibuli.[23] These electrodes have also demonstrated the ability to preserve residual acoustic hearing.[30-32] Figure 2 below demonstrates perimodiolar positioning of the CI532 electrode using images rendered from computed tomography scans of the electrode in situ in a human cochlea.

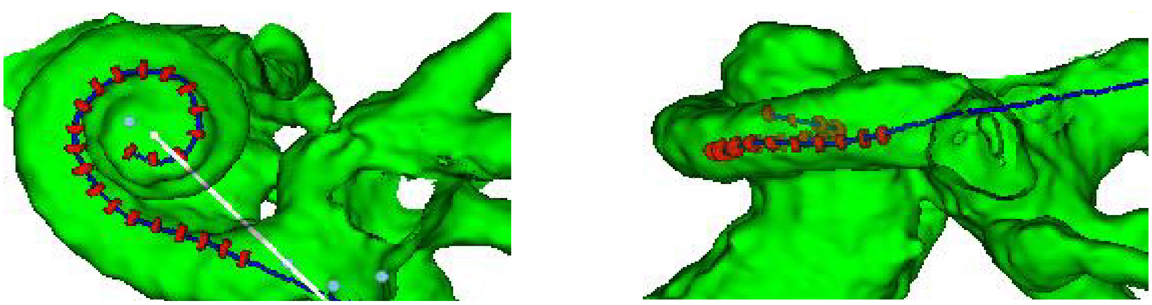

Figure 2—Perimodiolar positioning of Slim Modiolar electrode. Images rendered from computed tomography scans of the electrode in situ in a human cochlea. Courtesy of Washington University School of Medicine, BJC Barnes Hospital and BJC Barnes St. Louis.

Retrospective Chart Review

Patient Demographics

During the period between April 2016 and July 2017 our team placed 83 CI532 implants in 72 patients *(59 ears in 56 adults and 24 ears in 16 children)*, including 11 *(3 adults and 8 children)* who underwent simultaneous bilateral implantation *(Table 1)*. Of the 11 patients implanted bilaterally, 10 received CI532 implants in both ears and one adult received a CI532 *(Slim Modiolar electrode)* in one ear and a CI522 *(Slim Straight electrode)* in the other. Eleven patients *(8 adults and 3 children)* received a CI532 contralateral to a previously placed prior-generation device. A twelfth adult patient received CI532 devices sequentially in each ear but the second-side revised from a CI532 to a CI512 *(Contour Advance)* following a postoperative infection that did not respond to antibiotic treatment.

	Adults	Children
Variable	**Mean ± SD (range)**	
Age at implantation (years)	65.4 ± 18.0 (26.0-96.3)	5.2 ± 15.1 (0.9-15.2)
Duration of hearing loss (years)*	32.6 ± 18.6 (3.0-74.8)	4.5 ± 4.7 (0.9-15.2)
	Number of Ears	
Preoperative low-frequency PTA (250 & 500 Hz)^		
Mild (26-40 dB HL)	1	1
Moderate (41-55 dB HL)	11	0
Moderate-Severe (56-70 dB HL)	12	0
Severe (71-90 dB HL)	20	5
Profound (>90 dB HL)	15	3
Treatment ear†		
Unilateral Right	31	11
Unilateral Left	28	13
	Number of Patients	
Gender		
Female	33	10
Male	23	6
Etiology		
Unknown	27	7
Familial/Genetic	7	4
Noise Exposure	5	-
Familial/Noise Exposure	2	-
Otosclerosis	3	-
Syndromic	2	1
Connexin 26	-	2
Prematurity/Maternal Age	-	1
Large Vestibular Aqueduct	-	1
Other	10	-

Table 1—Demographics and baseline characteristics of participants with post-operative hearing performance data (n = 59 ears in 56 Adults, n = 24 ears in 16 children).

"Other" adult etiologies: Chronic Middle Ear Issues (2), Meniere's Disease (2), rubella (2), head trauma (2), hydrocephalus (1), autoimmune inner ear disease and noise exposure (1).

*n = 54 adults, age at onset could not be determined for 2 adult patients.

^n = 59 CI532 ears in 56 adults; n = 9 ears in 7 children, 9 children were 3 years and under (6 bilateral, 1 second side CI532 and 2 unilateral) did not complete behavioral testing.

† Two adults and 8 children received bilateral CI532 implants simultaneously, one adult received a CI522 contralateral to a CI532 simultaneously. One adult received bilateral CI532 implants sequentially, 8 adults and 3 children received second-side CI532 implants contralateral to a prior generation device.

PTA (Pure-Tone Average); SNHL (Sensorineural Hearing Loss)

Surgical Methods

After making a post auricular incision, the surgeon created two pericranial pockets and opened the mastoid and facial recess *(posterior tympanotomy)* widely to provide good visibility of the round window niche and to facilitate the correct orientation of the electrode during insertion. In cases where the round window membrane was large enough and had a favorable *(lateral)* orientation as shown in Figure 3A, the electrode was inserted through the membrane via an opening made with a micro knife. If the round window niche was too small for this approach, or if the membrane presented an unfavorable *(medial)* orientation, we used an extended round window approach was used instead. In these cases, a linear incision was made with a micro knife at the inferior edge of the round window membrane, and the membrane was reflected superiorly. Bone was removed with a 0.5 mm diamond burr from the inferior edge of the round window niche *(the crista fenestrae)* to enlarge the opening and improve the electrode's insertion trajectory. Suctioning of intracochlear fluid was avoided. The electrode was inserted into the cochlea as described below, and then repositioned if necessary, to allow visualization of the three white markers. Small pieces of soft tissue *(fascia or muscle)* were packed around the electrode at the level of the round window niche. Intraoperative impedance measurement, NRT and X-ray imaging were performed to confirm device function and appropriate electrode placement.

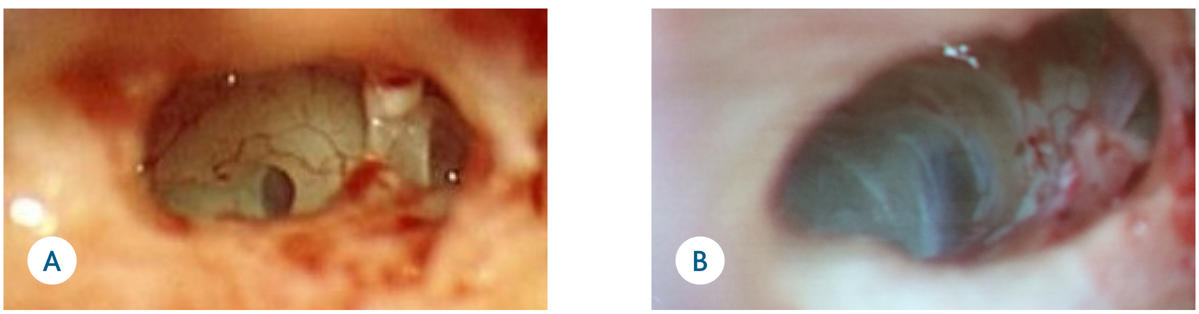

Figure 3—Round window orientation with a favorable, laterally-facing membrane (A) and unfavorable, medially-facing membrane (B).

The Slim Modiolar electrode may be inserted through the round window, extended round window or a cochleostomy, using the following steps:

Step 1: Load the electrode

- Grip the electrode lead with the Cochlear offered AOS insertion forceps, just behind the white marker
- Grip the sheath handle with straight forceps in the opposite hand
- Gently draw the electrode back into the sheath using the AOS forceps

Step 2: Insert the sheath

- Align the sheath handle toward the modiolus (superiorly)
- Guide the sheath into the cochlea until the stopper is flush with the round window or cochleostomy

Step 3: Insert the electrode array

- Stabilize the sheath handle while slowly advancing the electrode with the AOS forceps
- When the two white markers align, the electrode is fully inserted

Step 4: Remove the sheath

- Slowly withdraw the sheath along the axis of the electrode while holding the electrode in place
- When the sheath has been completely removed, release the AOS forceps from the electrode

Surgical Results

Table 2 summarizes the outcomes of the 83 surgical procedures. Electrodes in this series were inserted through the round window *(13%)* or using an extended round window approach *(87%)*. In our experience, the CI532 electrode and sheath system are well suited to the round window and extended round window approaches. In most of our patients *(87%)*, extending the round window approach provided the access necessary for electrode insertion. We consider an opening of 0.8-1.0 mm the ideal size, and suggest using Cochlear's sizing tool to assess this. A major advantage of the Slim Modiolar electrode, compared to the Contour Advance, is its adaptability for different insertion approaches. This allows the surgeon to choose the preferred approach intraoperatively.

Intra-operative X-rays were available for 60 of the 83 ears. Complications included two tip fold-overs during the first insertion attempt, one sheath fracture and one case of ossification. Reinsertion of the electrode using the re-loadable sheath resolved one of the tip fold-overs. In the second case, the electrode was replaced with an alternate CI532 implant. The sheath fracture likely resulted from the distal end of the sheath catching on the bone edge during insertion and was also resolved by replacing with a back-up CI532. In the ossification case, partial drill-out of the basilar turn revealed a patent lumen, allowing full insertion of a Slim Modiolar electrode.

As with any electrode, there is a learning curve to handling and inserting the Slim Modiolar electrode. We have found that the electrode trajectory as it exits the sheath sometimes aligns imperfectly with sheath's handle. Surgeons can check and correct for this prior to insertion by advancing the electrode far enough to observe its trajectory, then rotating the sheath to offset the handle accordingly and orient the electrode in the same plane as the cochlea. We also recommend training and ample practice inserting the CI532 electrode in temporal bones prior to clinical use as this can mitigate the risk of complications.[26]

Outcome measure	Adult ears	Pediatric ears	Total ears
Insertion approach			
Round window	4 *(7%)*	7 *(29%)*	11 *(13%)*
Extended round window	55 *(93%)*	17 *(71%)*	72 *(87%)*
Total	59	24	83
Complications			
Tip fold-over*	2 *(3%)*	0 *(0%)*	2 *(2%)*
Sheath fracture	0 *(0%)*	1 *(4%)*	1 *(1%)*
Ossification	1 *(2%)*	0 *(0%)*	1 *(1%)*
Total	3 *(5%)*	1 *(4%)*	4 *(5%)*

***During the first insertion attempt.**

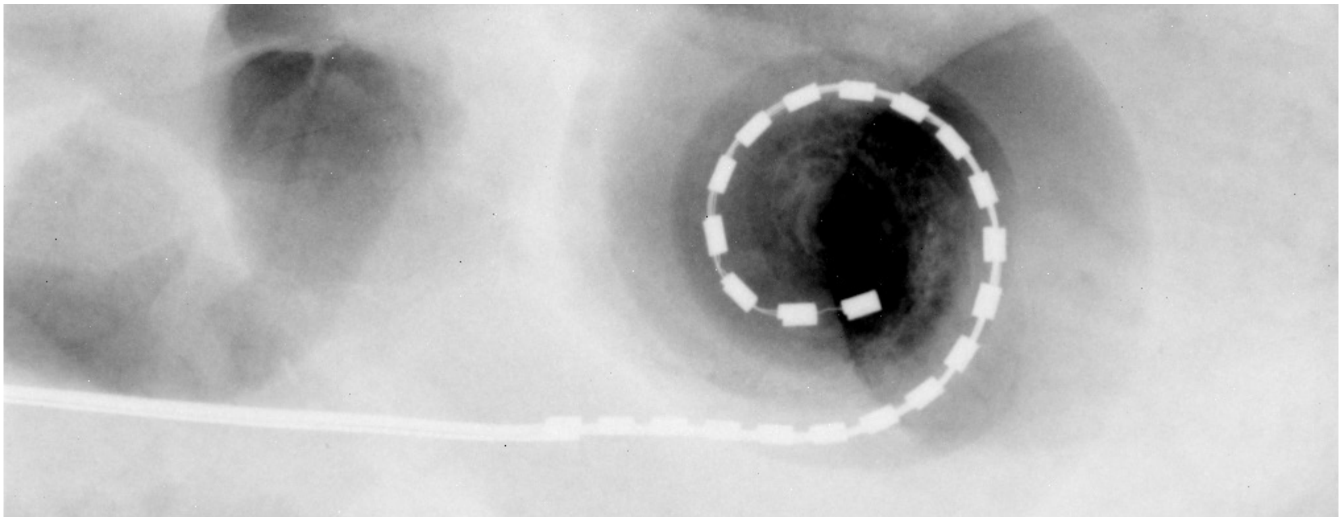

Figure 4—Plain film X-ray showing typical perimodiolar positioning of a Slim Modiolar electrode.

Hearing Performance Outcomes

To date, 32 adult recipients had speech recognition scores at three and/or six months after cochlear implant activation. Streamlined programming methodology and defaults were used with the exception of map parameter changes associated with the specific sound processor used. Patients who were activated using a standard Behind the Ear (BTE) sound processor (e.g., Nucleus® 6 or Nucleus 7) were programmed using Custom Sound® software defaults whereas for patients who were activated using the Off the Ear (OTE) sound processor (e.g. the Nucleus Kanso®), alternative rate and maxima were utilized to optimize battery life and telecoil use.

A previous report by our clinic[33] revealed differences between the perimodiolar Slim Modiolar and lateral wall Slim Straight electrodes, but not between the both perimodiolar Slim Modiolar and Contour Advance electrodes. Perimodiolar electrodes demonstrated significantly lower electrode impedance, lower neural response telemetry thresholds, and lower behavioral thresholds and comfort levels when compared to Slim Straight electrodes.

Patients were evaluated in a sound booth using recorded CNC[7] words and AzBio[8] sentences in quiet at 55, 60, or 65 dB HL or dBA. Performance scores were grouped within subjects for analysis. Each subject served as his or her own control and therefore subject numbers vary for each test and assessment interval. For two of these patients, who underwent simultaneous bilateral implantation with CI532, the poorer performing ear preoperatively was selected for grouped analysis. For patients sequentially implanted only scores for the CI532 ear were considered. The group speech recognition data are summarized in Figure 5. CNC word scores improved by 55 and 54 percentage points, on average, after three and six months post-activation, respectively. AzBio sentence scores in quiet improved by 63 and 66 percentage points after three and six months, respectively. AzBio sentences in noise performance were not routinely assessed in our clinic. Binomial analysis of individual patient outcomes revealed significantly improved word recognition in 22/24 (92%) recipients with three-month post-activation scores and no change in 2/24 (8%) after three months. All recipients with six-month post-activation scores (n = 17) showed significant improvement by six months. Regarding sentences in quiet, the analysis found significant improvement for 100% of the recipients with scores available after three (n = 25) and six months (n = 14), respectively.

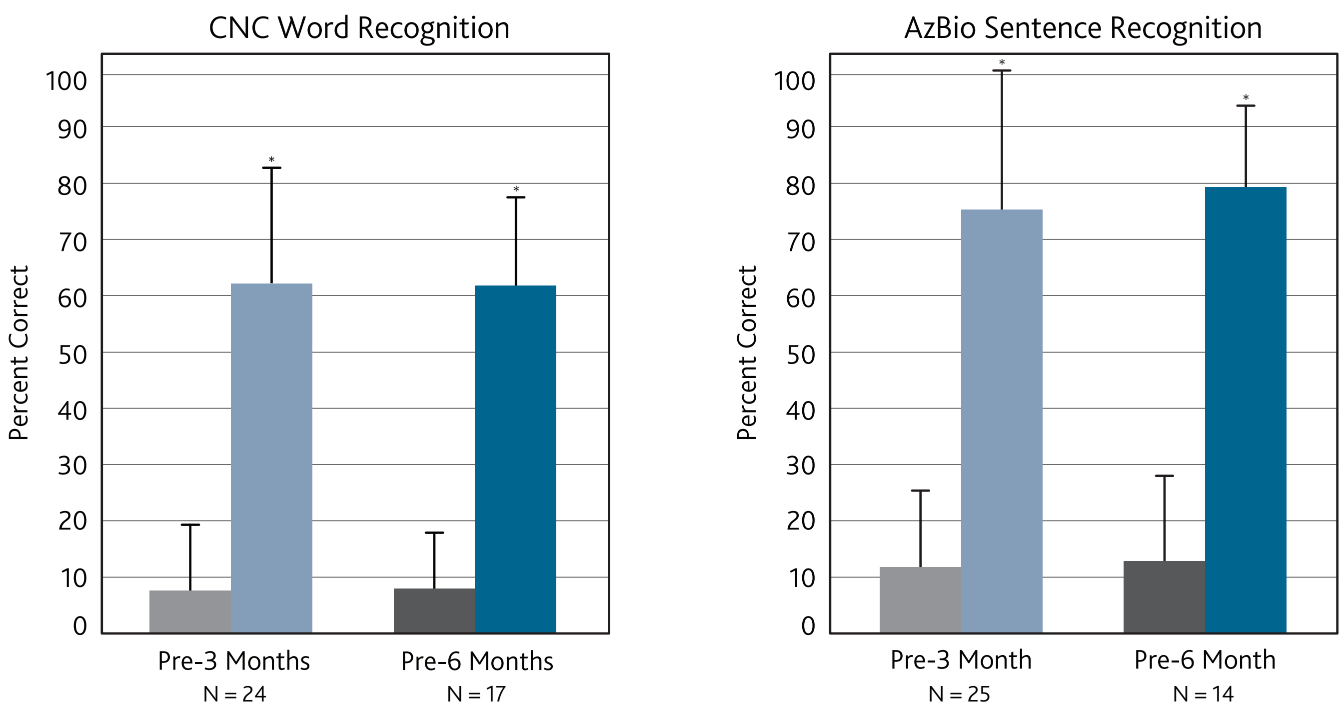

Figure 5—Mean speech recognition in quiet scores in the unilateral aided pre-operative and unilateral cochlear implant post-operative conditions. Presentation level = 60 dB(A) recorded speech. Scores are matched within subjects for each test and assessment interval. Error bars represent standard deviations. * p < 0.001 based on paired t-tests.

Discussion

Although the CI532 and CI522 devices share the same indications, candidates were selected differentially based on their residual hearing at RMEC. The Slim Straight electrode was selected for patients with moderate low-frequency hearing loss (41-55 dB HL audiometric thresholds for 250-500 Hz) and reserved the CI532 electrode for patients with greater levels of low frequency hearing loss. Our criteria changed as we gained experience with the Slim Modiolar electrode, because the benefits we observed led to expanded use to include those with moderate low frequency thresholds pre-operatively.

According to Lazard et al and Blamey et al, predictors of good cochlear implant performance are: a greater number of electrodes within the scala tympani, an absence of translocation from the scala tympani to the scala vestibuli, a not excessively deep insertion, and a reduced distance to the modiolus.[1,2] The new CI532 electrode delivers on all the key factors. The thin shape and soft, flexible characteristics of the electrode enables insertion with minimal trauma, and has demonstrated to provide consistent scala tympani placement. The CI532 electrode provides 22 electrode contacts that may be successfully inserted using a round window or extended round window approach to an ideal depth of insertion, and also provides consistent perimodiolar positioning closer to spiral ganglion cells. Recipients of the CI532 implant included in this retrospective review demonstrated excellent hearing performance outcomes, showing improvements of 54 percentage points in word recognition and 66 percentage points for sentences in quiet by six months post-activation. Use of the perimodiolar electrodes is associated with improved (lower) impedance, neural response thresholds, and psychophysical measurements compared to lateral wall electrodes.

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FUN2973 ISS1 JAN18