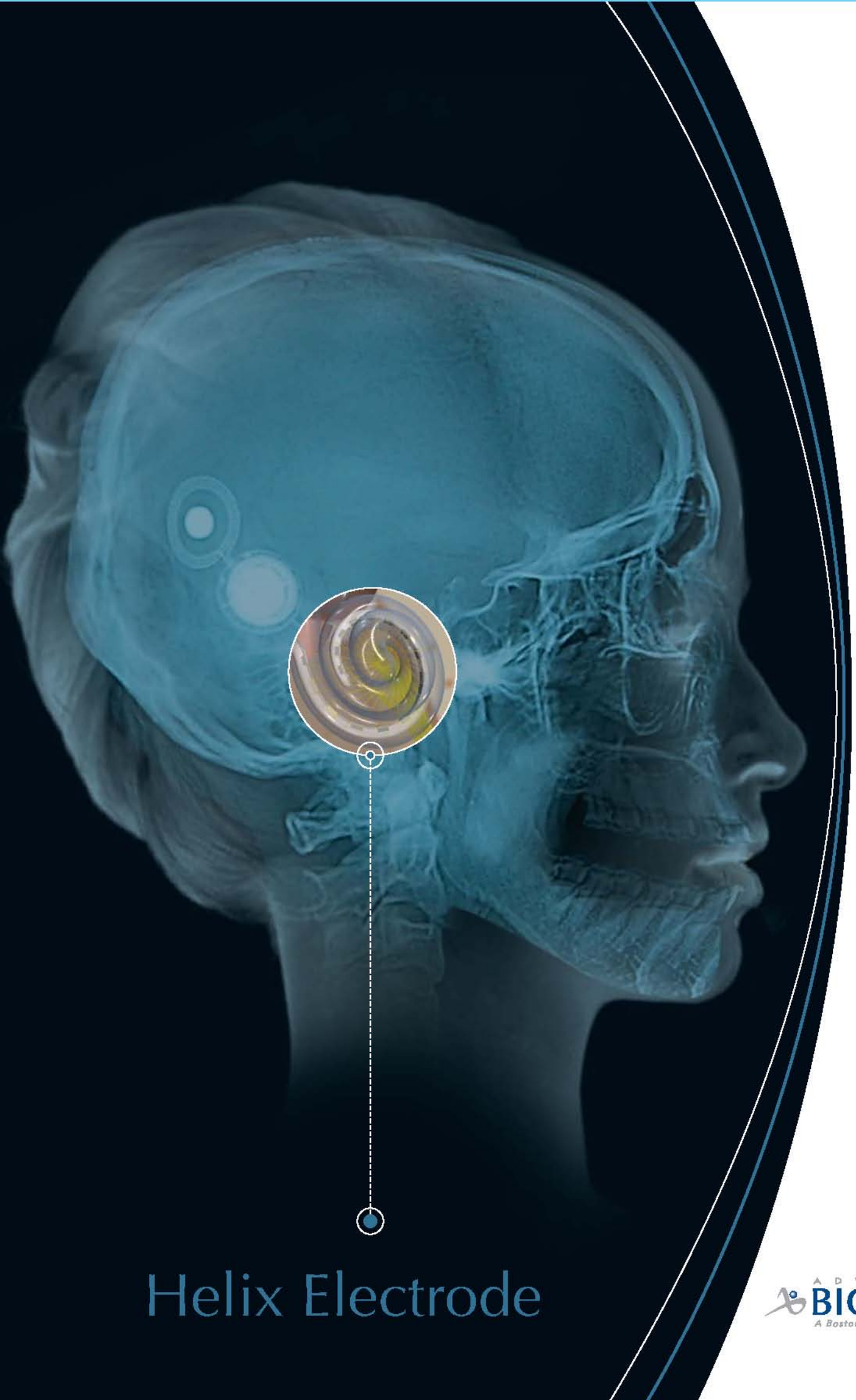


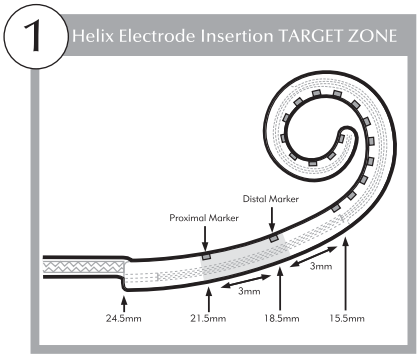
HiFocus® Electrode Series

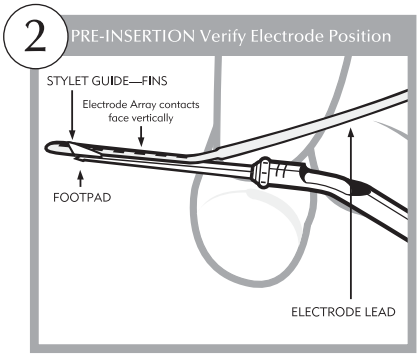
Helix Electrode

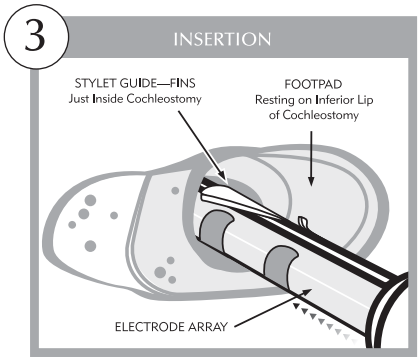
ADVANCED BIONICS®
A Boston Scientific Company

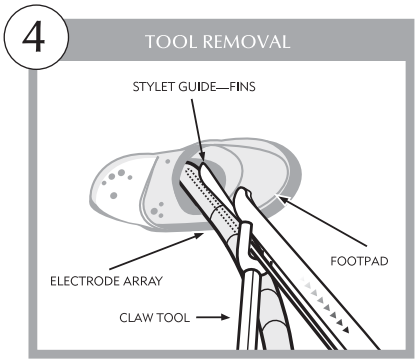
ADVANCED BIONICS
A Boston Scientific Company

HiFocus® Helix Electrode **Insertion Sequence**

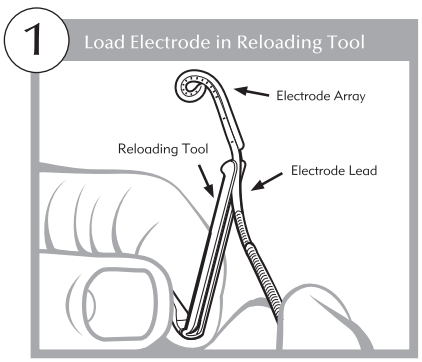


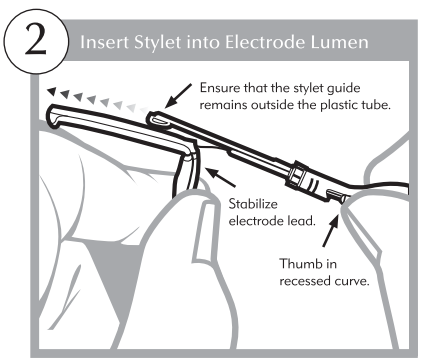


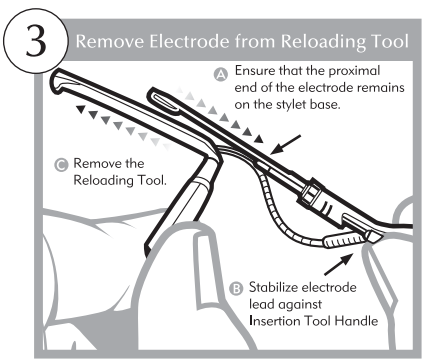




HiFocus® Helix Electrode **Reloading Sequence**







ADVANCED BIONICS®
A Boston Scientific Company

Quantity	Description	Part No.
1	HiRes 90K Surgeon's Manual	9055112-001
1	HiRes 90K Helix, 1j Surgeon's Video DVD	CI-8167
4	Helix Training Electrode	7005616-001
1	Helix Electrode Insertion Tool: Stylet Assembly With Handle	CI-4253 6045622-002
1	Claw Tool	CI-4252
1	Helix Plastic Cochlea Model and Base	CI-4600
1	Helix Electrode Loading Tool	7005593-001
1	HiRes 90K Mock-up	CI-4425

Contents

ADVANCED BIONICS
A Boston Scientific Company

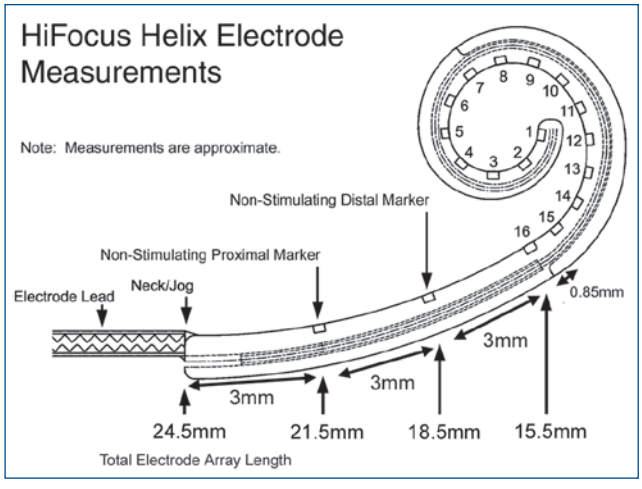


Figure 1. HiFocus Helix Electrode numbering (1–16, apex to base).

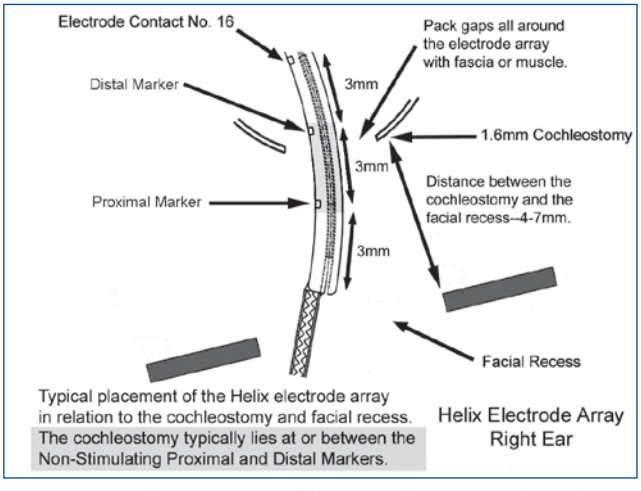


Figure 1. Relative position of the inserted HiFocus Ij Electrode following a typical insertion

HiFocus® Helix Electrode **Specifications**

(Approximate Measurements)

Electrode array tip diameter (distal)	≈ 0.6 mm
Electrode array base diameter (proximal)	≈ 1.1 mm
Spacing between active contacts (distance from midpoint of one contact to another)	≈ 0.85 mm
Total length of active contacts (distance that the electrode contacts are spread over)?	13 mm
Distance between non-stimulating marker pad and contact pad No. 16	≈ 3 mm
Neck/Jog to proximal non-stimulating marker pad.	≈ 3 mm
Total length of electrode array (distance from distal electrode tip to proximal electrode jog)	≈ 24.5 mm
Required facial recess minimum width	≈ 2 mm
Preferred cochleostomy dimensions (minimum) Optional cochleostomy size (a circle)	1.2 x 1.6 mm 1.6 mm diameter
Electrode lead length from device fantail to proximal electrode jog	≈ 6.5 cm
Distance that electrode array tip extends into cochlea following setup and prior to electrode insertion	4.5 mm
Approximate angular insertion	360°–420°

ADVANCED BIONICS®
A Boston Scientific Company

Surgeons may consider the following points with regard to a first HiFocus Helix electrode surgery:

- Obtain a Helix Training Kit CI-4503 prior to the surgery. The kit includes a new Surgeon's Manual and DVD. Due to the new insertion tools, technique, and reloading capability, it is vital to practice prior to your first HiFocus Helix case.

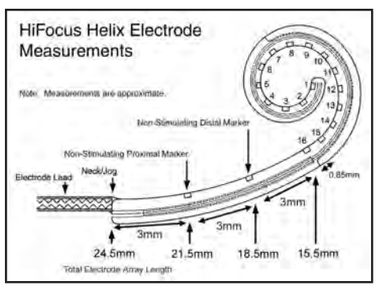
- When ordering your first HiRes 90K implant with Helix electrode CI-1400-02H, be sure to order the HiFocus Helix Electrode Instrument Kit CI-4501. This kit includes the following permanent tools for your set: Two (2) Helix Cochleostomy Sizing Gauges CI-4345 and two (2) Electrode Claw Tools CI-4252.

Important points to consider:
• Typical trans-mastoid approach.
• Typical HiRes 90K device placement.
• HiFocus Helix electrode insertion tools are included in the sterile tray and are single-use—disposable.
• The Helix electrode is reloadable with the reloading tool that is provided in the sterile tray.
• The facial recess may need to be slightly extended inferiorly to accommodate the footpad of the insertion tool.
• Preferred cochleostomy size is 1.2 mm x 1.6 mm to accommodate the fins of the insertion tool.
• The Helix electrode array is preloaded onto the stylet assembly. Mount the stylet assembly into the handle to assemble the insertion tool.
• Rest the footpad of the stylet assembly on the inferior aspect of the cochleostomy with the fins inserted into the cochleostomy 1 mm.
• To insert the Helix electrode off the insertion tool, press or push the handle forward.
• Following a full insertion of the Helix electrode the cochleostomy should appear at or between the distal or proximal marker pads.
• In a typical (complete) Helix electrode insertion the neck or jog of the electrode array is near the area of the facial recess—not at the cochleostomy.

Surgical Technique for the Implantation of the Advanced Bionics HiRes 90K Device with HiFocus Perimodiolar (Helix) Electrode

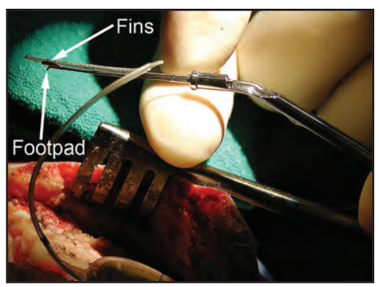
University of Ottawa Cochlear Implant Centres • Ottawa, Ontario Canada
David Schramm, MD, FRCSC, FACS • Assistant Professor, Department of Otolaryngology

Potential advantages of a perimodiolar electrode array include improved speech perception and reduced current requirements. Adult patients with postlingual severe to profound hearing loss were eligible for the HiFocus perimodiolar electrode clinical trial. The precurved electrode array is inserted into the cochlea using an electrode insertion tool with stylet assembly. Since October 2003, this device has been inserted in 17 patients at the Ottawa Hospital Cochlear Implant Centre. No surgical difficulties were encountered in the implantation and placement of the HiRes 90K device with the HiFocus perimodiolar electrode. A series of intraoperative tests consistently confirmed satisfactory device function after electrode insertion. Perimodiolar placement of the electrode array was demonstrated on postsurgical x-rays.



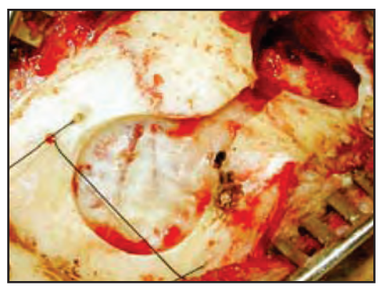
1. Helix Measurements

Typical insertion depth is between the proximal and distal non-stimulating markers (18–21 mm).



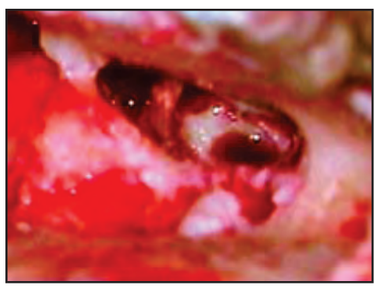
2. Helix electrode loaded on insertion tool

Stylet guide fins fit 1 mm in cochleostomy. The footpad rests on inferior lip of cochleostomy.



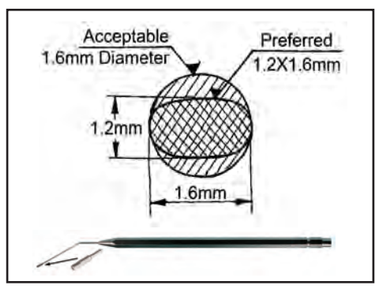
3. Mastoidectomy

After completion of a mastoidectomy-facial recess approach, the implant-receiver well/recess bed and electrode lead channel are drilled. Suture tiedown holes to stabilize the implant are placed.



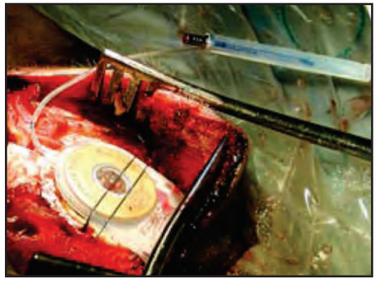
4. Facial Recess (2 mm)

Ensure facial recess is adequately developed inferiorly to accommodate the stylet assembly footpad.



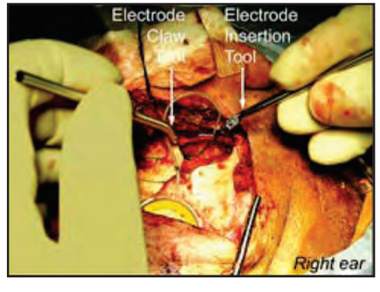
5. Cochleostomy—1.2 x 1.6 mm

The cochleostomy sizing gauge should easily fit 1 mm inside the cochleostomy.



6. Suture the receiver package in place.

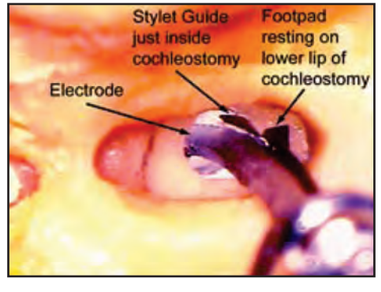
Slide the implant under the suture and scalp flap. Suture the implant in place.



7. Electrode insertion

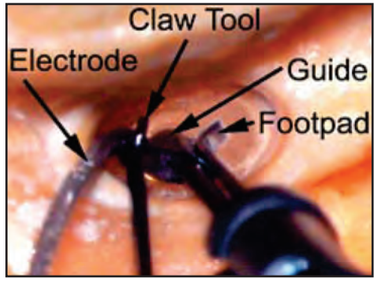
When inserting the Helix electrode, it is recommended to hold the electrode insertion tool in the same hand as the ear being implanted.

For example, when implanting a right ear, hold the insertion tool in the right hand.



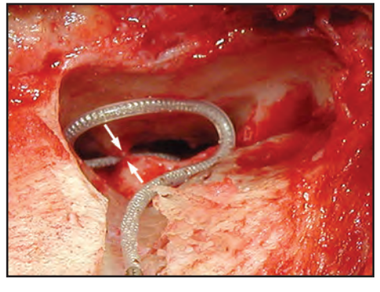
8. Insert the Helix electrode array into the cochleostomy.

As the insertion tool is pressed against the cochleostomy the electrode array advances off the stylet.



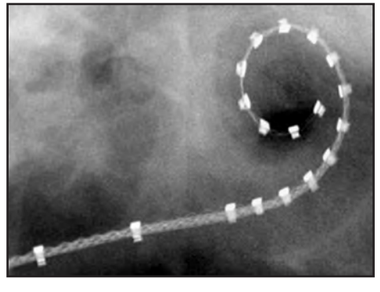
9. Stabilize the Helix electrode array.

Use the claw tool to slightly advance the neck of the Helix electrode into the cochlea. Stabilize the neck/jog of the electrode superiorly on the promontory.



10. Electrode lead placement

Coil the electrode lead in the mastoid cavity. Enlarging the mastoid tip during the mastoidectomy facilitates the coiling of the electrode lead. A split incus bridge technique may be used to further stabilize the electrode array. Pack fascia or muscle all around the cochleostomy.



11. Intraoperative x-ray

The skin incision is closed in layers. Intraoperative testing including Neural Response Imaging (NRI) may be performed. At the conclusion of the procedure, an intraoperative x-ray is strongly recommended to verify electrode placement. Note the perimodiolar location of the electrode array.

Patient Performance With the Advanced Bionics HiRes 90K Device With HiFocus Perimodiolar (Helix) Electrode

C. Séguin, D. Schramm, E. Fitzpatrick, S. Armstrong, J. Chénier
The Ottawa Hospital, Ottawa, Ontario, Canada

INTRODUCTION

Considerable attention has been placed on electrode design in attempting to improve the technological benefits of cochlear implantation. The Helix electrode has been designed to achieve perimodiolar placement. The HiRes 90K cochlear implant was initially commercially approved for use in adults and children with the HiFocus electrode. The Helix electrode, like its predecessor, the HiFocus electrode, consists of 16 stimulating contacts that face the modiolar wall with the goal of providing highly focused stimulation of the auditory nerve. The surgical insertion technique is intended to minimize the risk of damage to the basilar membrane or the lateral wall of the cochlea. A multi-center clinical trial of the HiRes 90K implant with Helix electrode was completed with adult recipients in September 2004. The results from our center where 32 adult patients have been implanted with the Helix electrode are reported here. The information obtained from clinical trials of new devices with adult populations have important implications for their eventual use in pediatric populations. The objectives of the study are to: 1) assess the safety of the device and 2) compare preoperative performance using conventional amplification with postoperative performance using the HiRes 90K device in conjunction with the Helix electrode.

METHODS

Participants were selected based on the clinical trial inclusion criteria:

- 18 years of age or older
- Post-lingual onset (> 6 years of age) of severe or profound hearing loss sensorineural hearing loss in both ears with a pure tone average of 70 dB HL or greater
- <50% open-set sentence score (HINT sentences) in the best-aided condition

At the completion of the clinical trial in September 2004, 22 patients at our institution had received the Helix electrode. An additional 10 have received the device since commercial approval by FDA and Health Canada was obtained. Demographic information on 32 patients is provided in Table 1. Speech recognition results are presented for clinical trial patients who have completed evaluations at various intervals after surgery. In keeping with previous clinical trial designs, the study employed a within-subjects repeated measures design. Participants were administered a battery of open-set speech perception measures at pre-implant and 1-month, 3-month and 6-month post-operative intervals. The results for open-set words and sentences were analyzed for this study. The open-set word measures consisted of: the CNC word test and the Hearing in Noise Test (HINT) administered in quiet (70 dB SPL) and in noise (+10 dB SN). All tests were scored as percent correct; a score of 0 was assigned when patients could not complete open-set testing (determined after 0% was obtained on the first twelve items).

Table 1.
Demographics for 32 patients implanted with the Helix electrode.

Age at Implantation (Mean & Range)	58.3 years	19.6–85.2 years
Duration of severe/profound deafness (Mean & Range)	10.2 years	0.5–39.0 years
Gender		
Female		53.1%
Male		46.9%
Primary Language		
English		71.8%
French		9.4%
Bilingual (French & English)		9.4%
Other		9.4%
Pure tone average right ear 109 dB		
Pure tone average left ear 100 dB		
Etiology of deafness		
Unknown		56.2%
Otosclerosis		12.5%
Familial		6.3%
Viral		6.3%
Noise exposure		6.3%
Head trauma		6.3%
Meniere's disease		3.1%
Meningitis		3.1%

RESULTS

Surgical and Audiologic Data:
Full insertion of the Helix electrode was achieved in all 32 patients. No post-operative complications occurred. All post-operative X-rays showed perimodiolar positioning of the electrode array. All 32 patients have been successfully fitted with their speech processors (29 Aurias and 3 PSPs) and are programmed using their preference of either a sequential or paired HiResolution speech- coding strategy.

Speech Recognition:
Six-month follow-up data are available for 19 of the 22 patients in the clinical trial. One patient has not yet reached the 6-month interval, one patient is not followed at our center and one French speaking patient was unable to complete the tests in English. The individual results for CNC words at the pre- and 6-months post-operative intervals are shown in Figure 1. One patient continues to show no speech recognition due to limited linguistic skills in English. The mean pre-operative CNC word score was 3.5%. At 6 months post-surgery, the mean CNC word score was 46.2%. Ten of the 19 patients showed greater than 50% open-set word recognition after 6 months. All but 4 patients achieved greater than 80% on the HINT Sentence test in quiet after 6 months of use (Figure 2) and 6 of 19 achieved over 80% sentence understanding in noise (Figure 3). The mean HINT scores are shown for those patients who have completed testing at the various follow-up intervals. (Figure 4).

CONCLUSIONS

The post-operative results from this study show that perimodiolar positioning of the Helix electrode was achieved without complications in all patients. No adverse events were encountered at our center. Nearly all patients demonstrated significantly improved openset speech recognition both in quiet and in noise 6 months after surgery.

ACKNOWLEDGEMENTS: We would like to thank Joanne Whittingham for assistance with the data.

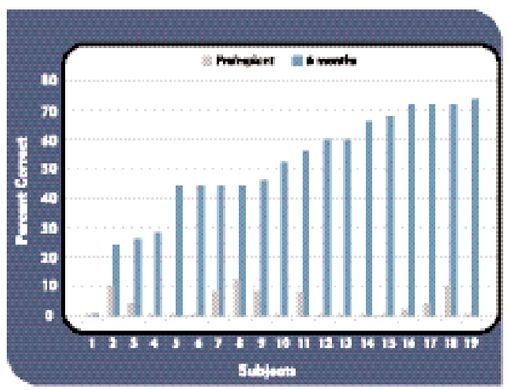


Figure 1. CNC Words (N=19)

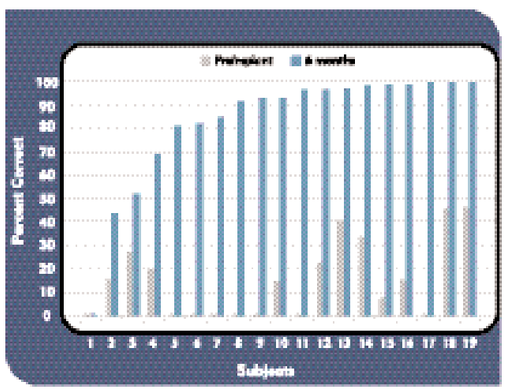


Figure 2. HINT Sentences in Quiet (N=19)

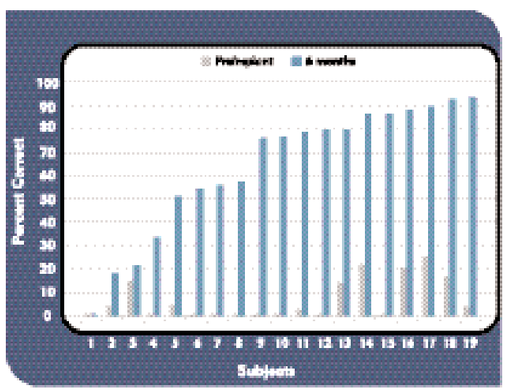


Figure 3. HINT Sentences in Noise (N=19)

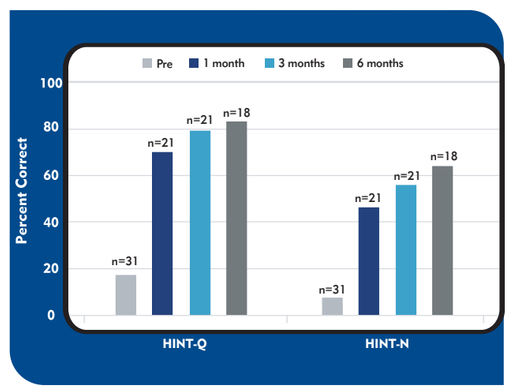


Figure 4. HINT-Quiet and HINT-Noise