# **Outcomes from Clarion Implantation in India**

# Sandra G. Desa Souza,<sup>1-3</sup> Dillon D'Souza,<sup>2,3</sup> Jaya Kochure,<sup>2,3</sup> and Natasha D'Souza<sup>2,3</sup>

<sup>1</sup>AJB Municipal Hospital, <sup>2</sup>Desa's Hospital, and <sup>3</sup>Jaslok Hospital and Research Centre, Bombay, India

> Abstract: We evaluated the results of the use of Clarion (Advanced Bionics, USA) implants in 30 Indian patients. Cases included in the study were prelingual and postlingual patients in whom the cochlea was normal and prelingual patients in whom the cochlea had a Mondini defect or was ossified. We found that multiple speech strategies available with the Clarion implant were a distinct advantage. The postlingual patients fared better with speech discrimination in noise using the high-resolution strategy, and young prelingual patients developed hearing and speech faster using simultaneous analog stimulation and multiple pulsatile stimulation strategies. Moreover, in Mondini cases, all electrodes could be inserted using the enhanced bipolar device.

Key Words: cochlear implants; postlingual; prelingual; speech strategies

O ur cochlear implant program started in 1987 in Bombay and, since its inception, we have placed implants in 123 patients. Several types of implants were used in our series (Table 1).

# MATERIALS AND METHODS

### Materials

The 30 patients who underwent surgery with Clarion implants from 2000 to 2003 were from India, Bangladesh, and Sri Lanka. They were followed up for a period from 2 to 30 months. The implants consisted of both internal and external components. The internal component that was surgically implanted was an enhanced bipolar device in which the electrode cable was precurved, with 8 electrodes on the medial side and 8 on the lateral side, or the CII Bionic Ear or the HiFocus I (Advanced Bionics, USA), wherein the 16 electrodes were medially oriented and mounted perpendicular to the medial wall of the cochlea (Fig. 1) [1]. The external component was a sound processor worn either on the body or behind the ear (Fig. 2).

The speech strategy options [2] available with the different devices were fully simultaneous analog stimulation of electrodes (SAS) [3,4], multiple pulsatile stimulation of electrodes (MPS), non-simultaneous continuous interleaved sampling of electrodes (CIS) [3,4] (Fig. 3), and high-resolution (HiRes) with twice the number of stimulation channels as SAS, CIS, or MPS. The rate of stimulation with CIS was 6,800 pulses per second; with MPS, it was 13,600 pulses per second, with SAS, 104,000 samples per second and, with HiRes, 91,000 pulses per second. A Software CLINician (SCLIN; Advanced Bionics) 2000 module (Fig. 4) and a HiRes neural response telemetry (NRT) module were used for mapping the patients.

In those in the group having a normal cochlea, the CII Bionic Ear was used in two postlingual patients and eight prelingual patients; the HiFocus I was used in three postlingual patients and five prelingual patients; and the enhanced bipolar device with a positioner was used in two prelingual patients and without a positioner in three prelingual patients and one postlingual patient. In patients in the abnormal group, four prelingual patients with a Mondini defect [5] received an enhanced bipolar electrode without a positioner, and one received a HiFocus I. The prelingual adult with a partially ossified cochlea received a HiFocus I (Fig. 5) [6].

Reprint requests: Sandra Desa Souza, M.D., Desa's Hospital, 15, Dadyseth Road, Chowpatty, Bombay, 40000, India. Phone: +91 22 23633050; Fax: +91 22 23631893; E-mail: dr\_sandradesasouza@hotmail.com

Table 1. Types of Cochlear Implants Used in Bombay, India, Program from 1987 Through 2003 (N = 123)

Type of Implant	No. of Patients
Hortman Implex (1987–1991)	~
Single-electrode and multielectrode multichannel device	51
Medel (1993–2002)	
2 Single-channel and ball electrode comfort	15
Combi 40	6
Combi 40+	8
Combi 40 Compressed	1
Combi 40 Split	1
Nucleus (1993-2002)	
Nucleus 22	6
Nucleus 24	4
Nucleus 24 Contour	1
Clarion (2000-2003)	
Enhanced bipolar	11
HiFocus	9
CII HiFocus I	7
CII HiFocus II	3

# Subjects

The ages of 15 prelingual patients ranged between 1 year 8 months [7] and 8 years, and those of 9 older prelingual patients were between 9 and 41 years. The ages of the six postlingual patients ranged from 34 to 75 years. A male predominance was seen in all groups. The commonest cause of deafness in prelingual patients was congenital disorder, and in the postlingual patients was progressive hearing loss and chronic serous otitis media with bilateral mastoidectomy (Table 2).

# **Operative Techniques**

All patients were subjected to an inverted J incision and to a simple mastoidectomy, a posterior tympanotomy, and a cochleostomy according to the Clarion gauge [8]. A bed was made for the receiver, and it was fixed with nonabsorbable Proline sutures. In the five Mondini patients, the cochleostomy was sealed with vein-graft and tissue glue. Two patients developed an endolymph leak on the second and fourth postoperative day and had a lumboperitoneal shunt implanted. In the one case of ossification, the basilar turn of the cochlea was drilled



MPS

Simultaneous Digital

Pulses

CIS

Non-Simultaneous

Digital Pulses

SAS Digitally Reconstructed Analog Waveforms

Figure 3. Simultaneous analog stimulation (SAS), multiple pulsatile stimulation (MPS), and continuous interleaved sampling (CIS).

Figure 2. Platinum body-worn speech processor and Auria behind-the-ear speech processor.



Figure 4. Patient mapping with Software CLINician 2000.

out. Another two patients had a radical mastoid cavity, which was obliterated with a muscle graft. In all patients, including those with Mondini and ossified cochleas, all electrodes were inserted. A modified Stenver's view of the cochlea was taken in all cases on a digital subtraction angiography machine to visualize the electrodes (Figs. 6–8).



Figure 5. Types of implants used. (pos = positioner.)

Table 2. Etiology of Deafness

Patient Type	No. of Patients
Prelingual	
Congenital (including Mondini deformity)	21
Meningitis	2
Other infections	1
Postlingual	
Streptomycin toxicity	1
Progressive sensorineural loss	1
Idiopathic	2
Chronic serous otitis media with bilateral radical	
mastoidectomy	2

#### **Programming and Rehabilitation**

All patients were mapped 5–6 weeks after surgery [2]. Two patients were fitted with CII behind-the-ear speech processors (BTEs), 4 were fitted with platinum BTEs, 13 with an S series speech processor, and 11 with a platinum series body-worn processor. The speech-processing strategies used were CIS, SAS, MPS, and HiRes (Fig. 9) [9].

Rehabilitation was carried out in seven languages: English, Hindi, Marathi, Gujarati, Bengali, Tamil, and Singhalese. The results after rehabilitation [10] were tabulated at 1 week, 4 weeks, and 3 months after speechprocessor fitting in the postlingual group and at 1 week, 4 weeks, and 6 months after fitting in the younger prelingual and the older prelingual patients.



Figure 6. Postoperative electrodes of a CII Bionic Ear in a 2-year-old prelingual patient with normal cochlea.



Figure 7. (A) Preoperative computed tomography and (B) postoperative electrodes of an enhanced bipolar device in the first Modini deformity case.



Figure 8. (A) Preoperative computed tomography and (B) postoperative electrodes of an enhanced bipolar device in the second Modini deformity case. On computed tomography (A), cochlea is seen to be communicating with internal auditory meatus.



Figure 9. Speech-processing strategies in Clarion implant patients. (CIS = continuous interleaved sampling; SAS = simultaneous analog stimulation; MPS = multiple pulsatile stimulation; HiRes = high-resolution; Pre = preoperatively; Post = postoperatively.)



Figure 10. Implantation results in postlingual patients. (Discr. = discrimination; VCV = vowel-consonant-vowel recognition.)

# RESULTS

The results [11] in the first three postlingual patients [12], with vowel-consonant-vowel, sentence recognition, paragraph tracking, and open-set discrimination after the first, fourth, and twelfth weeks (Fig. 10), showed the average test score to be 100% at the end of 12 weeks. In the fourth patient (aged 75 years), the speech perception score fluctuated, with an average of

69%. The patient's speech strategy then was changed from CIS to the HiRes strategy, and the score increased to 80%. The two remaining postlingual patients with HiRes scored 100% at the end of 12 weeks. The results in the first 11 young prelingual patients [2], including 2 Mondini cases, using detection of speech sound, discrimination and recognition of vowels, discrimination and recognition of consonants, and recognition of words (Figs. 11, 12) showed the average test score at 6 months



Figure 11. Implantation results in postlingual patients aged 1.75–7 years. (Discr. = discrimination.)



Figure 12. Implantation results in prelingual patients aged 1.75-8 years. (Discr. = discrimination.)

to be 90%. The result at 6 months in the six older prelingual patients [13,14], including the two Mondini cases, using vowel-consonant-vowel recognition, word recognition, and closed-set speech recognition was 89% (Fig. 13). The average test score of the four Mondini cases separately was 77%, and the score of the patient with an ossified cochlea was 78%.

We observed that the average test score results in postlingual patients with CIS strategy in all types of cochlear implants were similar [15] but were achieved faster in postlingual patients using the HiRes strategy (Fig. 14). However, with the prelingual patients, we observed that the speech perception scores at 6 months were higher with the SAS and MPS strategies (Figs.15, 16). In addition, speech production in the prelingual patients with MPS and SAS was achieved much earlier. Using the enhanced bipolar device, it was possible to insert all the electrodes into the cochlea in the Mondini cases, thereby achieving better results. Moreover, the electrodes were on both sides of the cable, thereby



Figure 13. Implantation results in older prelingual patients aged 9-41 years. (VCV = vowel-consonant-vowel recognition.)



Figure 14. Comparative results in postlingual patients. (CIS = continuous interleaved sampling; HiRes = high-resolution.)



**Figure 15.** Comparative results in prelingual patients aged 1.75-7 years. (*CIS* = continuous interleaved sampling; *SAS* = simultaneous analog stimulation; *MPS* = multiple pulsatile stimulation.)



Figure 16. Comparative results in older prelingual patients aged 9–41 years. (VCV = vowel-consonant-vowel recognition; CIS = continuous interleaved sampling; SAS = simultaneous analog stimulation; MPS = multiple pulsatile stimulation.)

ensuring that the spiral ganglia in these cases were stimulated.

#### CONCLUSION

The overall results of cochlear implantation in India with the Clarion implant in postlingual and prelingual patients were very encouraging. Speech perception and speech production [16,17] developed faster in young and older prelingual patients with the enhanced bipolar, HiFocus I, and HiFocus II devices with SAS and MPS. HiRes strategies produced better results in postlingual patients. Patients with Mondini cochleas could undergo cochlear implant surgery with full insertion of all electrodes of the enhanced bipolar device and achieved better hearing and improved good speech production.

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