

constrictor, and placebo during transnasal flexible endoscopy. *J. Speech Lang. Hear. Res.* **40**, 1352–1357

- 8 Georgalas C., Sandhu G., Trosh A. *et al.* (2005) Cophenylcaine spray vs. placebo in flexible nasendoscopy: a prospective double-blind randomised controlled trial. *Int. J. Clin. Pract.* **59**, 130–133

9 Cain A.J., Murray D.P. & Mc Clymont L.G. (2002) The use of topical nasal anaesthesia before flexible nasendoscopy: a double-blind, randomized controlled trial comparing cophenylcaine with placebo. *Clin. Otolaryngol. Allied Sci.* **27**, 485–488

- 10 Machin D., Campbell M.J., Fayers P.M. *et al.* (1997) Sample Size Tables for Clinical Studies, 2nd Edn. Blackwell Sci., Oxford, p. 7

## Clinical evaluation of a fully implantable hearing device in six patients with mixed and sensorineural hearing loss: Our experience

Kam, A.C.S.,\*† Sung, J.K.K.,\*† Yu, J.K.Y.,\*† & Tong, M.C.F.\*†

\*Department of Otorhinolaryngology, Head & Neck Surgery, Chinese University of Hong Kong, and †Institute of Human Communicative Research, Chinese University of Hong Kong, Hong Kong, China

Accepted for publication 27 April 2012

Dear Editor,

The implantation of middle ear devices for the rehabilitation of sensorineural hearing loss has become routine clinical practice in Europe and the United States over the past few years.<sup>1</sup> Successful applications of middle ear implants in adults with mixed hearing loss have also been reported in recent studies,<sup>2,3</sup> although studies of users' degree of satisfaction with fully implantable middle ear devices remain sparse. The aim of the study reported herein was to evaluate the objective and subjective benefits of and level of satisfaction with a fully implantable hearing device among Chinese adult patients with sensorineural or mixed hearing loss.

### Material and methods

#### Subjects

Six adult subjects were implanted with a fully implantable hearing device Carina™ (Otologics, Boulder, CO, USA), at the Prince of Wales Hospital in Hong Kong between February 2008 and June 2009. All subjects had bilateral moderately severe to severe sensorineural or mixed hearing loss. The average hearing threshold across the

implanted side at 500, 1000 and 2000 Hz was 66.7 dB HL (SD = 7.0). Five of the subjects were experienced hearing aid users with an average hearing aid experience of 12.3 years (SD = 4.1). One subject (S3) was not a current hearing aid user, but had been using a pair of completely-in-the-canal hearing aids for several weeks prior to the study. Further middle ear surgeries instead of implantations were not considered for S1 and S2 as previous surgeries were unsuccessful, and complete closure of air-bone gap was impossible. Table 1 summarises the subjects' hearing manifestation and history. Figure 1 presents their pre- and postoperative audiograms. Informed consent was obtained from the subjects, and the principles outlined in the Declaration of Helsinki were followed. All subjects paid for the device (around USD 19 000), and all charges related to the surgery (around USD 10 000) on their own.

#### Equipment

**Fully implantable hearing device** The fully implantable hearing device evaluated in this study was the Otologics MET Carina™ (Otologics), which was originally designed for adults with moderate to severe sensorineural hearing loss. The device comprises four components: (i) an implant, (ii) a programming system, (iii) a charger and (iv) a remote control. The implant itself incorporates the electronics, including the microphone, battery, magnet, digital signal processor and connector. The system uses an

Correspondence: M.C.F. Tong, Department of Otorhinolaryngology, Head & Neck Surgery, The Chinese University of Hong Kong, 6/F, Clinical Sciences Building, Prince of Wales Hospital, Shatin, N.T., Hong Kong, China. Tel.: (852) 2632 2633; Fax: (852) 2632 4678; e-mail: mtong@ent.cuhk.edu.hk

**Table 1.** Characteristics and hearing manifestation of the subjects

Subject	Age	Gender	Cause of hearing loss	Type of hearing loss	Hearing aid experience	Operated ear	Placement of transducer	Complaint/problem with conventional hearing aids
1	52.3	F	Otosclerosis	Mixed	Bilateral BTE	Right	Round Window	Poor sound quality
2	56.0	F	Cholesteatoma	Mixed	Bilateral BTE	Right	Cortical bone on top of stapes head	Chronic suppurative otitis media
3	34.8	M	Congenital	Sensorineural		Left	Incus	Poor sound quality, cosmetic concern
4	61.1	M	Presbycusis	Sensorineural	Bilateral ITC	Right	Incus	Cosmetic concern, feedback problem
5	54.1	M	Unknown	Sensorineural	Bilateral CIC	Left	Incus	Occlusion
6	34.8	F	Unknown	Sensorineural	Bilateral BTE	Right	Incus	Phone listening, cosmetic concern, stigma

F, female; M, male; BTE, behind-the-ear; ITC, in-the-canal; CIC, completely-in-the-canal.

omni-directional microphone located under the skin that picks up sounds, which are then amplified and converted into an electrical signal. This signal is sent down the lead and into the transducer, and the MET ossicular stimulator is coupled directly with the ossicular chain.

### Procedure

*Preoperative assessment* Preoperatively, all subjects underwent otomicroscopic examination, pure tone and speech audiometry, and tympanometry. The subjects who were current hearing aid users were asked to fill in the Chinese version of the Abbreviated Profile of Hearing Aid Benefit (APHAB-CH)<sup>4</sup> and the Satisfaction with Amplification in Daily Life (SADL-CH).<sup>5</sup> All of the audiological testing was carried out in a sound booth.

*Operation* All of the surgeries were performed by the last author with a post-auricular incision and the mastoid placement of the microphone underneath the skin at the subcutaneous layer of the scalp. The transducer was placed on the round window for S1 and on a small piece of cortical bone graft on top of the mobile stapes supra-structure for S2, whereas S3, S4, S5 and S6 underwent incus placement. No surgically related complication was encountered in any of the subjects. The device was switched on 6–8 weeks after the surgery and was repeatedly adjusted until an optimal hearing level was obtained, as determined by the subject.

*Postoperative assessment* The subjects attended a 2-h session 12 months after the implant had been switched on. They underwent pure tone audiometry, aided sound field testing with the device turned on and the non-implanted ear

occluded with an earplug, and free field speech audiometry in both quiet and noisy conditions with the device switched on and off. The same test equipment, materials and self-administered questionnaires as those employed in the preoperative assessment were used during these tests.

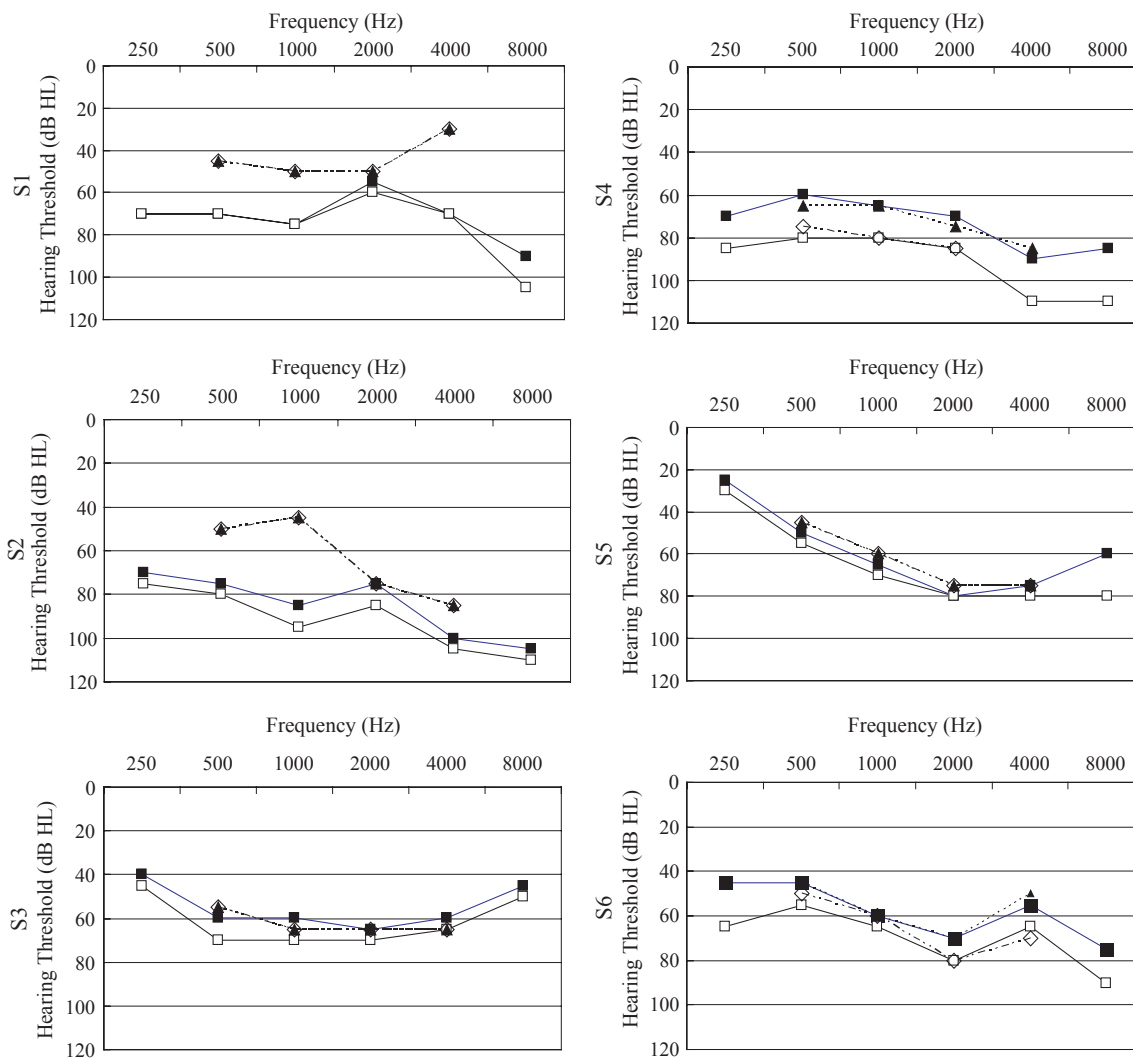
### Results

#### *Pre- and postoperative hearing thresholds*

As shown in Fig. 1, there was a general drop in the air-conduction threshold at certain frequencies in all subjects. The average drop in this threshold across 250–8000 Hz was 9.0 dB (range = 3.3–18.3 dB; *SD* = 5.3 dB). A Wilcoxon signed ranks test revealed a significant change in the pure tone air-conduction threshold pre- and post-operation ( $P < 0.05$ ). The bone thresholds remained unchanged after the operation in most cases except for that of S4, whose bone threshold dropped by 10–15 dB across 500–4000 Hz. The bone thresholds of S6 also dropped by 10 and 20 dB at 2000 and 4000 Hz, respectively.

#### *Functional gain and aided threshold*

The functional gain was calculated by subtracting the aided (device on) threshold from the unaided (device off) threshold obtained in free field with the test tones presented at zero degree azimuth. The average aided threshold at 500, 1000 and 2000 Hz was found to be 42.6 dB (range = 38.3–45.0 dB; *SD* = 2.53 dB) and 42.0 dB (range = 38.3–46.7 dB; *SD* = 3.2) with Carina and the conventional hearing aid, respectively. The average functional gain at 500, 1000 and 2000 Hz was found to be 35.6 dB (range = 28.3–48.3 dB; *SD* = 7.0 dB) and 35.0 dB



**Fig. 1.** Pre- and postoperative pure tone audiograms of the six subjects. Closed square = preoperative air-conduction threshold; open square = postoperative air-conduction threshold; closed triangle = preoperative bone-conduction threshold; open diamond = postoperative bone-conduction threshold. S1 = subject 1; S2 = subject 2; S3 = subject 3; S4 = subject 4; S5 = subject 5; S6 = subject 6.

(range = 21.7–48.3 dB;  $s_D = 9.7$ ) with Carina and the conventional hearing aid, respectively. The Wilcoxon signed ranks test revealed an insignificant difference between the conventional hearing aid and the Carina in terms of the average functional gain and aided threshold.

#### Speech test results

Speech recognition performance was assessed with the Cantonese Hearing In Noise Test (CHINT)<sup>6</sup> except for that of S3, a Mandarin speaker, who underwent the Mandarin Hearing In Noise Test (MHINT)<sup>7</sup> instead. The aided performance with conventional hearing aid was obtained unilaterally on the side to be implanted before

the operation. In the quiet condition, the sentences were presented at 65 dB HL. In the noisy condition, they were presented at 70 dB HL, and speech spectral noise was presented at 65 dB HL. Speech test results are summarised in Table 2. The Wilcoxon signed ranks test revealed an insignificant difference between the conventional hearing aid and the Carina in terms of speech recognition scores both in quiet and in noise.

#### Abbreviated profile of hearing aid benefits

The mean global score for the APHAB with the Carina and the conventional hearing aid was 84.9 ( $s_D = 7.9$ ) and 37.2 ( $s_D = 3.8$ ), respectively. The former provided signifi-

**Table 2.** Speech test results measured with CHINT

Subject	Unaided				Aided with Carina (post-operation)				Aided with conventional hearing aid (pre-operation)			
	Adaptive		Fixed		Adaptive		Fixed		Adaptive		Fixed	
	(SNR)		(% correct)		(SNR)		(% correct)		(SNR)		(% correct)	
	Quiet	Noise	Quiet	Noise	Quiet	Noise	Quiet	Noise	Quiet	Noise	Quiet	Noise
1	CNT	CNT	0	0	51.8	1.7	98	84.5	50.3	2	98	82.6
2	CNT	CNT	0	0	44.8	1.3	99	93.5	45.4	1.1	98.5	90.0
3*	70.4	CNT	33	0	50.8	CNT	100	61.0	DNT	DNT	DNT	DNT
4	CNT	CNT	0	0	58.6	CNT	78.5	39.0	60.2	CNT	75.5	41.5
5	72.2	7.5	35	0	45.2	-0.2	98.5	85.0	46.3	0.8	99	83.5
6	CNT	CNT	0	0	53.3	6.2	95	73.5	52.1	5.7	95	70.3

CNT, could not test; DNT, did not test as this subject did not have a conventional hearing aid; SNR, signal-to-noise ratio. \*MHINT was administered to this subject.

cantly more aided benefit than the latter, as revealed by the Wilcoxon signed ranks test ( $Z = 2.2$ ,  $P < 0.05$ ). The distribution of the APHAB scores is depicted in Fig. 2.

#### Satisfaction with amplification in daily life

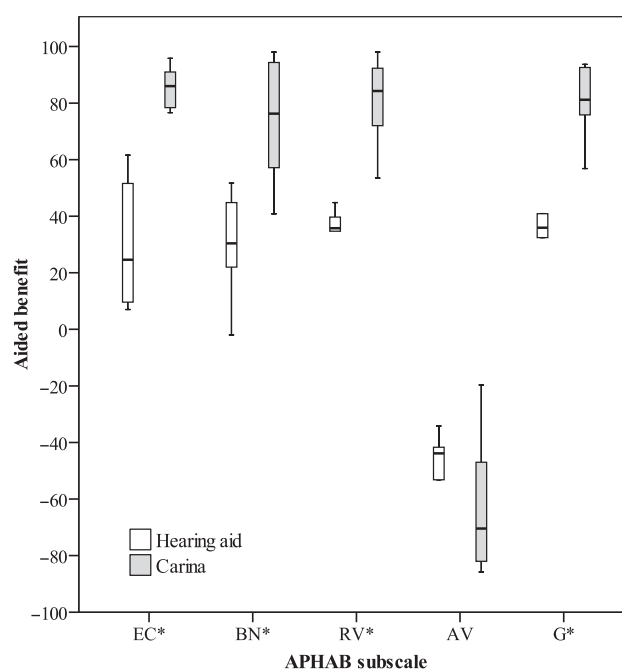
The average overall satisfaction score with the Carina and conventional hearing aid was 5.8 ( $SD = 0.8$ ) and 3.9 ( $SD = 0.4$ ), respectively. The Wilcoxon signed ranks test ( $Z = 2.2$ ,  $P < 0.05$ ) revealed significantly greater satisfaction with the Carina than with the conventional hearing aid.

#### Implant use and dysfunction

Subjects used their implants for an average of 13.7 h/day. The average daily battery charging time was 48.3 min. All subjects had mastoid tip placement of the microphone. Occasional feedback problems were noted in several subjects, but these were resolved through the fine-tuning of the fitting. One subject (S6) required the repositioning of the microphone to a more anterior mastoid tip position (anterior to the hairline) to reduce unwanted noise. Resolution was possibly due to the better directional orientation of the microphone relative to its original position.

#### Discussion

Although there was no significant difference in the objective aided performance provided by the two devices, all of the subjects reported more aided benefit and satisfaction with the Carina than with the conventional hearing aid. These findings do not necessarily imply that the added benefit of the Carina is solely psychological. Some



**Fig. 2.** Distribution of the APHAB scores for the conventional hearing aid and Carina across different subscales. The thick line within the box = median; upper end of the box = the third quartile; lower end of the box = the first quartile; upper end of the whiskers = largest non-outlier; lower end of the whiskers = smallest non-outlier. EC = ease of communication; BN = background noise; RV = reverberation; AV = aversiveness; G = global; \* $P < 0.05$ .

subjects did report that they like the Carina more because it is more cosmetically appealing, easier to use and provides better sound quality. Some other factors, such as personality, individuals' beliefs about their hearing and

expectations of hearing aids, which have not been controlled in the present study, may also influence the outcome.

Despite the high degree of satisfaction reported for the Carina, however, some subjects reported listening difficulties in noisy situations. All of the subjects who were hearing aid users at the beginning of the study continued to use their aid on the contralateral side either occasionally or all of the time for sound localisation and better speech discrimination, particularly in the presence of noise. It is possible that bilateral implantation of the Carina might provide similar benefit in sound localisation and speech discrimination in noise, further validation study on this aspect is warranted.

No statistically significant change in the hearing threshold after surgery has been reported in previous studies,<sup>2,8</sup> whereas a significant drop in the air-conduction threshold was noted in our subject group. In three of the six subjects (S2, S3 and S6), there was a noticeable decline in this threshold postoperatively. One subject (S4) experienced a significant reduction in the bone-conduction threshold, although no specific factors could be identified retrospectively. Transducer placement and ossicular loading exertion are possible explanations for this threshold shift, however.<sup>9</sup> The transducer was placed on the stapes head for S2, whereas S3, S4 and S6 had incus placement. The limited sample size did not permit evaluation of the effect of transducer placement on the hearing threshold shift.

### Keypoints

- The objective performance of the fully implantable Carina hearing device was similar to that of a conventional hearing aid in the study reported herein.
- Subjective satisfaction and reported hearing aid benefit was greater for the implant, but expectation bias could be the reason for this having undergone an operation and had an 'implant'.
- This fully implantable hearing device is thus deemed suitable for patients with hearing loss no worse than a severe grade.
- In view of the possible decline in air- and bone-conduction postoperative hearing thresholds, however, patients should be well informed of the risks of such implantation.

### Funding

No financial disclosures.

### Conflict of interest

None to declare.

### References

- 1 Sterkers O., Boucarra D., Labassi S. *et al.* (2003) A middle ear implant, the symphonix Vibrant Soundbridge: retrospective study of the first 125 patients implanted in France. *Otol. Neurotol.* **24**, 427–436
- 2 Lefebvre P.P., Martin C., Dubreuil C. *et al.* (2009) A pilot study of the safety and performance of the otologics fully implantable hearing device: transducing sounds via the round window membrane to the inner ear. *Audiol. Neurotol.* **14**, 172–180
- 3 Tringali S., Pergola N., Berger P. *et al.* (2009) Fully implantable hearing device with transducer on the round window as a treatment of mixed hearing loss. *Auris Nasus Larynx.* **36**, 353–358
- 4 Kam A.C.S., Tong M.C.F. & Van Hasselt A. (2011) Cross-cultural adaptation and validation of the Chinese Abbreviated Profile of Hearing Aid Benefit. *Int. J. Audiol.* **50**, 334–339
- 5 Kam A.C.S. (2012) Hearing-aid outcomes in Chinese adults: clinical application and psychometric properties of the Chinese version of the Satisfaction with Amplification in Daily Life questionnaire. *Int. J. Audiol.* **51**, 450–455.
- 6 Wong L.L.N. & Soli S.D. (2005) Development of the Cantonese Hearing In Noise Test (CHINT). *Ear Hear.* **26**, 276–289
- 7 Wong L.L.N., Soli S.D., Liu S. *et al.* (2007) Development of the Mandarin Hearing in Noise Test (MHINT). *Ear Hear.* **28**(2 Suppl) 70S–74S
- 8 Bruschini L., Forli F., Pasetti S. *et al.* (2010) Fully implantable Otologics MET Carina™ device for the treatment of sensorineural and mixed hearing loss: audio-otological results. *Acta Otolaryngol.* **130**, 1147–1153
- 9 Tringali S., Koka K., Deveze A. *et al.* (2011) Intraoperative adjustments to optimize active middle ear implant performance. *Acta Otolaryngol.* **131**, 27–35

Copyright of Clinical Otolaryngology is the property of Wiley-Blackwell and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.