

H S A C



HEALTH SERVICES  
ASSESSMENT COLLABORATION

# A systematic review of the literature

August 2008

The effectiveness of digital hearing aids and assistive  
listening devices for adults with hearing loss

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This review was undertaken by the Health Services Assessment Collaboration (HSAC). HSAC is a collaboration of the Health Sciences Centre of the University of Canterbury, New Zealand and Health Technology Analysts, Sydney, Australia. This report was authored by Dr Wasan Ali, Researcher, who developed and undertook the literature search, extracted the data, conducted the critical appraisals, and prepared the report. Consideration of the economic implications of the technology (Level 1) was undertaken by Arsupol Suebwongpat, Health Economist and Dr Adele Weston, Director, HSAC.

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Staff at the University of Canterbury Libraries assisted with the retrieval of articles.

The current review was conducted under the auspices of a contract funded by the New Zealand Ministry of Health (Disability Services). This report was requested to assist them in addressing a range of policy issues related to funding equipment for people with hearing loss.

A working group provided advisory input to the review (see **Appendix A** for membership). The systematic review of the evidence will ultimately be used by the working party to inform policy decision making in conjunction with other information to address a range of policy issues related to funding equipment for people with hearing loss. The content of this review alone does not constitute clinical advice or policy recommendations.

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## Plain Language Summary

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This review summarised the evidence from eight studies that evaluated the effectiveness of digital hearing aids for adults with hearing loss. Adults with hearing loss showed better satisfaction and some benefit from using various styles of digital hearing aids.

In five of the eight included studies 1429 adults with various degrees of hearing loss were more satisfied and less dissatisfied when using various styles of digital hearing aids at various aspects (including overall satisfaction). Participants were more satisfied with less negative features of the hearing aids (such as background interferences, acoustic feedback, and problems with the telephone). Satisfaction was also reported with service and cost, which considered the provider competence, aid reliability, and cost evaluation. Open canal digital hearing aids showed better features in sound of own voice, sound of chewing/swallowing, wind noise, visibility to others and location. Therefore, participants were more satisfied with these features than the non-open canal fittings. On another finding, multiple microphone digital hearing aids, showed better overall satisfaction and quality of life with less time worn per day than single-microphone digital hearing aids.

Evidence from two studies that included 67 adults with various degrees of hearing loss showed that there was some benefit from using hearing aids. In particular benefit from hearing aids was noticed three months following fitting of a hearing aid (irrespective of the protocol used) in one study, and also was noticed for both open canal and non-open canal hearing aids in another study. Benefit was observed more with ease of communication, reverberation and background noise.

One study on 150 adult patients with tinnitus and hearing loss showed that the use of digital hearing aids decreased the severity of loudness of tinnitus as compared to no use of hearing aids.

The conclusion of this review derives from assessing eight studies that looked at the effectiveness of digital hearing aids in adult patients with hearing loss. The majority of the studies were fair or better in their quality but they were of low level of evidence with some weaknesses in their design. Some of the studies included very small number of patients, and many of the studies relied mainly on subjective measures (from the subjects' personal perspective) rather than on objective measures. The studies were heterogenous particularly in the types and styles of hearing aids. They also varied in the population included, type and degree of hearing loss, assessment tools and outcomes measured. Therefore, results from these studies should be interpreted with care and in accordance with weighing the quality and level of evidence as well as their generalisability to the New Zealand setting.

## Executive Summary

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### Introduction

#### Background

Hearing loss is a prevalent major public health problem and is one of the most common sensory disorders that causes disability. The condition is associated with poor quality of life, including negative affects on interpersonal relationships, communication, socialisation and independence. In New Zealand, hearing loss is a major cause of disability with a prevalence of 10.3%, which is comparable to figures from other countries. Incidence of hearing loss increases with age.

People aged 15 years or more with mild hearing loss cannot detect tones at an average level below 25 to less than 45 dB HL (decibel hearing level) in their better-hearing ear; those with moderate loss cannot detect tones at an average of 45 to less than 65 dB HL; and those with severe hearing loss cannot detect tones at 65 or more dB HL in their better-hearing ear.

Properly fitted hearing aids can improve communication in at least 90% of people with hearing loss as well as improving adult's health-related quality of life. A hearing aid is a battery-operated device that makes the sound louder and that can be worn in or around the ear. Hearing aid devices are available in different shapes, sizes and types, but all share the same components. Components of any hearing aid are a microphone, amplifier, speaker, earpiece, and a battery. Hearing aids now incorporate digital components which have enhanced the ability to process and customise sound precisely to suit different hearing loss. Hearing aids shifted from analogue to digital technology about ten years ago. Currently this technology, is replacing the analogue hearing aid and eventually they will become the 'basic' type. Therefore, this systematic review will focus only on digital hearing aids.

Sometimes hearing aids cannot address the problem of hearing loss alone, and thus assistive listening devices are used either on their own or in conjunction with hearing aids. Assistive listening devices (ALDs) are any type of device that can help people to function better in day-to-day communication. An ALD can be used with or without hearing aids to overcome the negative effects of distance, background noise or poor room acoustics.

#### Objectives

The main purpose of this systematic review was to summarise and critically appraise the evidence pertaining to the effectiveness of various types of digital hearing aids and assistive listening devices in managing adults with hearing loss.

The New Zealand Ministry of Health's Health & Disability National Services Directorate (DSD) requested the systematic review, to assist in addressing a range of policy issues related to funding equipment for people with hearing loss.

## Methods

The aim of this review was to evaluate the clinical- and cost-effectiveness of digital hearing aids, when compared to no use of hearing aids or various styles of digital hearing aids.

The study research questions were:

- What is the effectiveness of digital hearing aids for adults with hearing loss?
- What is the effectiveness of assistive listening devices for adults with hearing loss?

A systematic method of literature searching, study selection, data extraction and appraisal was employed in the preparation of this report. The literature was searched using the Medline and Embase bibliographic databases. In addition, Web of Science and Embase electronic databases were also searched to identify relevant papers citing pivotal references and/or related articles of selected studies, the bibliographies of included papers were examined for relevant studies. Other sources as well as hand searches, list of references from identified searches were also searched to help identifying any peer-reviewed evidence that may have been missed in the literature search. The Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effects (DARE), and Health Technology Assessment databases were searched to help identify existing systematic reviews. Searches were limited to English-language material published from January 2000 to November 2007 (inclusive).

Initially studies were included only if they were randomised trials of crossover or parallel-group design, which compared the use of digital hearing aid (of any style, fitting, and microphone) by an adult patient aged 18 years of age or older with any level of hearing loss for at least 10 weeks, to other digital hearing aids or no use of a hearing aid. When such studies were not found, the criteria were expanded to include other study designs (including observational studies), although the number of participants was stipulated to be at least 20. The key outcomes examined were: patient satisfaction, benefit, overall hearing aid outcomes, speech perception in various background conditions, word recognition, and other clinically relevant outcomes. The criteria were applied to assistive listening device studies.

NHMRC dimensions of evidence, levels of evidence and quality assessment criteria were used to evaluate each of the included studies. Data was extracted onto standardised data extraction forms by one reviewer.

A systematic search of the published literature was also conducted to identify any relevant economic evaluations of digital hearing aids. The literature was searched using Medline and Embase bibliographic databases. Searches were limited to English-language material published through to February 2008. This review was primarily concerned with digital hearing aids, as they represent the current standard of care. However the economic literature search was also inclusive of evaluations of analogue hearing aids, in the event that such studies were informative for assessing the economic implications of digital hearing aids.

## Key results

### Number and quality of effectiveness studies of hearing aids

The search strategy identified a total of 1563 citations for the clinical effectiveness section. After consideration of titles and abstracts using the study selection criteria, 333 full papers were retrieved and scrutinised in detail for possible inclusion in the review. For excluded studies, the reasons for exclusion were documented. As a result of this process eight publications were ultimately included in the review, with one pseudo-randomised controlled trial, and the remainder being various retrospective and prospective designs. The studies showed considerable heterogeneity at all levels (participant, intervention, comparisons, and outcomes measured), in particular the interventions and comparisons conducted varied across all the studies.

One publication compared two fitting protocols of digital hearing aids, two publications compared open-canal digital hearing aids to non-open canal fittings, one publication compared use of digital hearing aids to no use of digital hearing aids at various background conditions, one publication compared a unilateral digital hearing aid to a bilateral digital hearing aid at various background conditions, one publication compared the use of a digital contralateral routing signal (CROS) hearing aid to a bilateral contralateral routing signal (BiCROS) digital hearing aid in patients with high frequency hearing loss, another publication assessed the effectiveness of a digital hearing aid to no use of hearing aids or use of a sound generator in patients with tinnitus, and one publication surveyed the use of digital hearing aids (single and multiple microphones) and compared it to the MarkeTrak Norm.

Overall, the methodological quality of the included studies varied between good (two studies) and poor (one study), with five studies rated fair on the quality assessment tool. Many of the studies involved small number of participants, various patient groups and conducted at various settings. The two good studies had their own setback, one study involved small number of participants, and the other study looked at the effect of hearing aids on tinnitus (as the participants were with tinnitus rather than with hearing loss alone). All included studies were conducted outside New Zealand. In general, the studies lacked randomisation, did not clearly show concealment of treatment and did not show evidence of accounting for withdrawals and drop-outs (if at all mentioned) in their analyses. Therefore, generalisability of the results of the studies may be restricted to patients included in these studies.

### Number and quality of effectiveness studies of assistive listening devices

Although few studies were potentially eligible and were retrieved fully, the same search strategy did not identify any eligible publication that met the inclusion criteria for assessing the effectiveness of assistive listening devices. Therefore, this systematic review does not report on clinical- or cost-effectiveness of this intervention.

### Effectiveness of hearing aids

Although the studies varied in their design, level of hearing loss, interventions and comparisons, and outcomes, there were very few similarities in the tools used to assess the effectiveness of hearing aids. Five studies measured patient satisfaction (and dissatisfaction), two measured the hearing benefits of hearing aids using the abbreviated profile of hearing aid benefit (APHAB), two studies measured the

international outcome inventory for hearing aids (IOI-HA), two studies measured speech perception/speech recognition in noise/or silence, and one measured loudness of tinnitus among patients with tinnitus (but also have hearing loss). Other outcome measures were also used by the studies. Therefore, results from the studies are presented herein (within the text) according to the outcome measures used, whereas they are tabulated according to the level of evidence.

The results are presented below firstly on the basis of the most frequent outcome measure used across the studies, down to the least frequent measure used.

### Satisfaction with hearing aids

Five studies (total number of participants = 1429) measured satisfaction (and dissatisfaction) with hearing aids using the satisfaction with amplification in daily life (SADL) or customer satisfaction questionnaires. The studies varied in design, and used four different questionnaires (two studies used the SADL, whereas the remainder used one of each of Amplifiron Satisfaction Survey, MarkeTrak survey, Survey questionnaire for the (CROS and BiCROS hearing aids)). The heterogeneity in these results precludes any combination of the results; hence a meta-analysis was not undertaken.

#### Satisfaction with amplification in daily life (SADL) results

- Results from the SADL questionnaires in one good study, which involved 32 patients with hearing loss, indicated that satisfaction increased 3-months after fitting of digital hearing aids with one protocol. This was shown by the significant decrease in the scores for services and costs subscales (SC) and for negative features (NF), whereas no significant changes were seen in the other fitting protocol.
- Similar satisfaction with open canal digital hearing aids was also seen in one fair study that included 338 patients as compared to non-open canal digital hearing aids on the Negative Features subscale of the SADL questionnaire.

#### Amplifiron satisfaction survey results

- Results from a study that compared between open-canal digital hearing aids and non-open canal digital hearing aids among 54 experienced hearing aids users showed that overall satisfaction was higher with open canal hearing aids than non-open canal hearing aids.
- The open canal type showed significantly better features in sound of own voice, sound of chewing/swallowing, wind noise, visibility to others and localisation.

#### Knowles' MarkeTrak survey

- Results reported from the survey (N=914) showed better overall satisfaction, quality of life, and hours worn per day (less time worn) with multiple microphone digital hearing aids compared to single microphone digital hearing aids.

Survey questionnaire for the contra-lateral routing of signal (CROS) and bilateral contra-lateral routing of signal (BiCROS) hearing aids (N=91)

- Satisfaction in patients with severe-to-profound asymmetric hearing loss was better with the new generation of digital CROS and BiCROS hearing aids compared to the satisfaction in previously reported studies.

### Hearing benefit with hearing aids

Two studies (total number of participants = 67) have used the abbreviated profile of hearing aid benefit (APHAB) to measure any improvement in hearing aid benefit.

- In one good study that compared two fitting protocols for digital hearing aids, results of the APHAB questionnaire showed no significant differences between the two protocols as well as no changes at 45 days and three months post-fitting.
- In another study, both open canal and non-open canal hearing aids showed benefits 3-months after fitting. The APHAB survey in new hearing aid users that compared between open-canal digital hearing aids to non-open canal digital hearing aids showed benefits with EC (Ease of communication), RV (Reverberation), and BN (Background noise).

Two studies (total participants = 373) measured the international outcome inventory for hearing aids (IOI-HA). Both studies used the IOI-HA to measure the effect of open-canal and non-open canal hearing aids overall as well as individually in terms of benefit, daily use, handicap, satisfaction, and changes in quality of life following hearing aid use.

- One study among new hearing aid users examined the scores for hearing aid usage, and showed markedly higher scores of hearing aid usage, residual activity limitation, and residual participation restriction for those who wore the open-canal hearing aids.
- The other study indicated that open canal hearing aids rated better in all items of the questionnaire (benefit, satisfaction, and improvement in quality of life). In particular this superiority was in terms of daily use time, and the amount of difficulty experienced with hearing aids.

### Speech recognition in noise and silence

Two studies (total number of participants = 52) measured speech perception/speech recognition in noise/or silence. Measurement tools used in the first study were the Hagerman speech test, Speech and Visual Information Processing System (SVIPS). The second study used speech-in-noise test and threshold-of-interference test.

- The first study (N=24) compared use of digital hearing aids to no use of digital hearing aids at silence and with background noise conditions. The most benefit derived from amplification with the digital hearing aids was in the background without noise. Significantly less effort was perceived when hearing aids were used as compared to no use of hearing aids.

- The second study (N=28) compared the use of one digital hearing aid to two digital hearing aids. Speech recognition in background noise was better while using unilateral amplification to the better ear than using bilateral amplification.

Other outcome measures were:

### OC (occlusion effect) questionnaire

An additional and supplemented questionnaire to the SADL and the IOI-HA was used in one study (N=338) to evaluate occlusion effect, feedback, phone use, and overall sound quality. Subjects in the open canal group scored better than those in the non open canal group especially with their own voice and occlusion questions. Only thirty-nine percent of the subjects returned their questionnaires

### Return-for-credit (RFC)

The above study analysed data for open canal and non-open canal digital hearing aids. Analyses showed open-canal hearing aids were associated with fewer return for credit rates than non-open canal.

### Loudness of tinnitus

One study (total number of participants = 150) measured the loudness of tinnitus. The study compared digital hearing aids to no use of hearing aids and to the use of sound generators. Long term reductions in tinnitus severity were shown to be significant in hearing aid patients compared to patients who did not use a device.

In a specific population (patients with asymmetric severe-to-profound hearing loss), satisfaction with contra-lateral routing of signal digital hearing aids was better than the older models. This was shown by better acceptance rates when using the new models as compared to the patients' old models.

## Economic implications

The literature search identified 15 economic papers, five of which were relevant for the economic review. These five papers were economic evaluations that compared at least one type of hearing aid intervention with no hearing aid, and examined both the costs and benefits of these interventions.

All five included papers attempted a cost-utility analysis. A comparison between digital hearing aids versus no hearing aids was evaluated in only one instance (Grutters *et al.*, 2007), and therefore that publication is the most relevant to the current review. The other four papers related to analogue hearing aids, or did not specify the type of hearing aid(s) evaluated.

The findings of Grutters *et al.*, 2007 clearly indicate that the cost-effectiveness of hearing aid use is highly dependent upon the magnitude of the quality of life gain. The authors report a base case cost per quality-adjusted life year (QALY) ranging from €15,811 to €647,209, indicating considerable uncertainty. Firstly, the lack of good quality, relevant evidence means that there is uncertainty surrounding the size of the

clinical benefit that underpins the quality of life gain *per se*. This is further complicated by the fact that the two most accepted preference-based multi-attribute utility instruments (i.e. HUI3 and EQ-5D) place very different weighting upon the quality of life domains that are affected by hearing loss. This results in a large difference in the utility gain when utility weights derived using these two instruments are applied within an economic evaluation. Such variation ultimately results in highly variable cost-effectiveness results. Finally, much of the benefit of hearing aids relates to improvements in work force productivity, and these benefits are only incorporated in a cost-effectiveness analysis that is inclusive of indirect societal costs. In summary, at present the cost-effectiveness of digital hearing aids relative to no hearing aids is unclear.

## Conclusions

The review conclusions are based on the current evidence available from this report's critical appraisal of literature published on the effectiveness of digital hearing aids and assistive listening devices for people with hearing loss.

Although hearing aids do not restore hearing to normal, the studies in this review indicated that adult patients with hearing loss may benefit from using various styles of digital hearing aids. In particular this systematic review has found that satisfaction was gained from the use of various styles and fittings of digital hearing aids. It is noteworthy that the majority of these studies relied on subjective measures to assess the satisfaction with the use of hearing aids, rather than objective measures of hearing ability. Furthermore, the evidence underpinning this finding comes from low level studies, that is, non randomised and with various strengths and weaknesses according to the quality of the methods used. The methodological quality of the included studies ranged from good to poor. The two good quality studies were limited by the small number of the patients included in one study and by the inclusion of patients with tinnitus but also have hearing loss in the other. All studies included were conducted overseas and no individual study was conducted in New Zealand or Australia, therefore it is not known if the results can be generalised to the New Zealand setting.

For patients with high-frequency hearing loss, open canal fittings were much more preferable than non-open canal devices.

For patients with asymmetric severe-to-profound hearing loss, contra-lateral routing of signal digital hearing aids may improve satisfaction (as shown by better acceptance rates for the new hearing aids than the older models).

At present this systematic review could not identify relevant evidence to support the routine use of the one-to-one communicator (assistive listening devices).

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## List of Abbreviations and Acronyms

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<b>aBDI</b>	Abbreviated version of Beck Depression Inventory
<b>AC</b>	Audiological Centre
<b>ACC</b>	Accident Corporation Compensation
<b>ALD/s</b>	Assistive Listening Device/s
<b>ANOVA</b>	Analysis of Variance
<b>APHAB</b>	Abbreviated Profile of Hearing Aid Benefit
<b>ASHA</b>	American Speech-Language-Hearing Association
<b>AV</b>	Aversiveness of sound
<b>BDI</b>	Beck Depression Inventory
<b>BERA</b>	Brain-Stem-Evoked-Response-Audiometry
<b>BiCROS</b>	Bilateral Contralateral Routing Of Signal
<b>BN</b>	Background Noise
<b>BTE</b>	Behind-the-ear
<b>CDSR</b>	Cochrane Database of Systematic Review
<b>CI</b>	confidence interval
<b>CIC</b>	Completely-in-the-canal
<b>COSI</b>	Client Oriented Scale of Improvement
<b>CROS</b>	Contralateral Routing Of Signal
<b>DARE</b>	Database of Abstracts of Reviews of Effects Variance
<b>dB</b>	decibel
<b>dB HL</b>	decibel Hearing Level
<b>dB SPL</b>	decibel Sound Pressure Level
<b>DFR</b>	Digital Feedback Reduction
<b>DHBs</b>	District Health Boards
<b>DNR</b>	Digital Noise Reduction
<b>DSD</b>	Disability National Services Directorate
<b>DSE</b>	Digital Speech Enhancement
<b>DSP</b>	Digital Signal Processing
<b>EC</b>	Ease of Communication
<b>ENT</b>	Ear Nose and Throat
<b>ESS</b>	Environmental Support Services
<b>EQ-5D</b>	EuroQoL 5 Dimension
<b>GDS</b>	Geriatric Depression Scale
<b>GP</b>	General Practitioner
<b>GS</b>	Global Score
<b>HA</b>	Hearing aid/s
<b>HI</b>	Hearing Instrument
<b>HHIE</b>	Hearing Handicap Inventory for Elderly
<b>HINT</b>	Hearing-in-Noise Test
<b>HRQoL</b>	Health Related Quality-of-Life
<b>HUI</b>	Health Utility Index
<b>HUI2</b>	Health Utility Index Mark II
<b>HUI3</b>	Health Utility Index Mark III
<b>Hz</b>	Hertz (unit of frequency)
<b>ICER</b>	Incremental cost-effectiveness ratio
<b>IOH-HA</b>	International Outcome Inventory for Hearing Aids
<b>ITC</b>	In-the-canal

<b>ITE</b>	in-the-ear
<b>LDL</b>	Loudness Discomfort Level
<b>Ioth</b>	Impact on other
<b>MCL/UCL</b>	Most Comfortable Level/Un-Comfortable Level
<b>MSD</b>	Ministry of Social Development
<b>NAL-R</b>	National Acoustic Laboratory-Revised
<b>NAL-P</b>	National Acoustic Laboratory-Profound
<b>NHMRC</b>	National Health and Medical Research Council
<b>NHS</b>	National Health Services
<b>NIDCD</b>	National Institute on Deafness and Other Communication Disorders
<b>NF</b>	Negative Feature
<b>NTE</b>	Non-test ear
<b>OC</b>	Open canal
<b>OC questionnaire</b>	occlusion effect questionnaire
<b>PE</b>	Positive Effect
<b>PI</b>	Personal Image
<b>QALY</b>	quality adjusted-life years
<b>QDS</b>	Quantified Denver Scale of Communication Function
<b>QoL</b>	quality-of-life
<b>QuickSIN</b>	Quick Speech-in-Noise Test
<b>RAL</b>	Residual activity limitation
<b>RPP</b>	Residual participation restriction
<b>RCT</b>	Randomised Controlled Trial
<b>REAR</b>	Real-Ear Aided Response
<b>REUR</b>	Real-Ear Unaided Response
<b>RFC</b>	Return-For-Credit
<b>RV</b>	Reverberation
<b>SADL</b>	Satisfaction with Amplification in Daily Life
<b>SC</b>	Service and Cost
<b>SD</b>	Standard Deviation
<b>SELF</b>	Self-Evaluation of Life Function
<b>SF-36V</b>	36-Item Short-Form Health Survey modified for Veteran population
<b>SMPSQ</b>	Short Mental Portable Status Questionnaire
<b>SNHL</b>	Sensori-Neural Hearing Loss
<b>SNR</b>	Signal-to-Noise Ratio
<b>SPL</b>	Sound pressure level
<b>SRT</b>	Speech Recognition Threshold
<b>SVIPS</b>	Speech and visual information processing system
<b>TE</b>	Test ear
<b>TTO</b>	Time Trade-Off
<b>US</b>	United States
<b>VANZ</b>	Veterans' Affairs New Zealand
<b>VAS</b>	Visual analogue scale
<b>WHO</b>	World Health Organisation
<b>WTP</b>	Willingness-To-Pay

## Introduction

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### Objective

The purpose of this systematic review is to provide a summary of the evidence pertaining to the relative effectiveness of digital hearing aids in managing adults with hearing loss, when compared to no use of hearing aids or to the use of various styles of digital hearing aids. The intention of the review was also to assess the effectiveness of assistive listening devices, in particular the one-to-one communication devices.

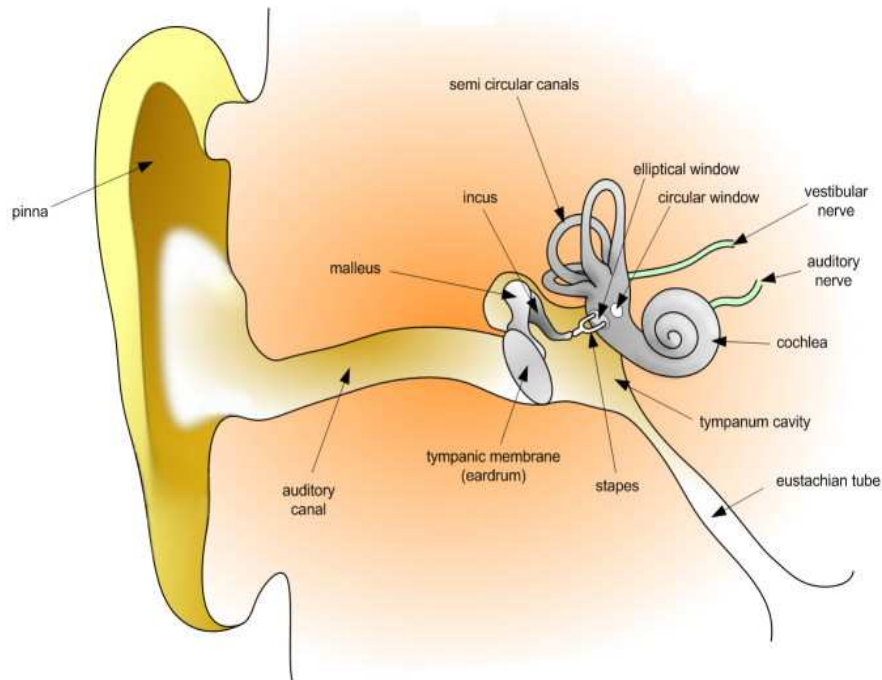
The review included all studies in adults aged 18 years or more with various types of hearing loss, irrespective of setting. All styles of hearing aids (in-the-ear, behind-the-ear, in-the-canal or completely-in-the-canal), fitting (one ear or both ears) and microphones (mono- or omnidirectional) of digital hearing aids as well as open canal and non-open canal were considered. The review aimed to look at various patient-based outcome measures including those that assess whether the intervention meets the communication needs of the patient.

### Background, indication, and current treatment practice: anatomy of the ear

The ear is composed of the external ear, the middle ear, and the inner ear. The external ear consists of the pinna (auricle) and the external auditory canal (**Figure 1**); it has a protective function, but with its physical configuration may provide moderate (5-15 dB) passive augmentation of sounds at the upper range (Yueh *et al.*, 2003).

The middle ear is an air-filled cleft consisting of 3 ossicles (malleus (Hammer), incus (Anvil), and stapes (Stirrup)) that transducer vibrations from the tympanic membrane (Eardrum) to the oval (elliptical) window of the fluid-filled cochlea. The substantially larger area of the tympanic membrane, compared with that of the oval window, and the relatively minor mechanical gain from the ossicular configuration combine to amplify sound pressures by 20 to 30 dB (approximately the difference between a whispered voice and normal conversational speech).

The inner ear includes the cochlea, the vestibular apparatus, and the vestibule-cochlear (acoustic) nerve (cranial nerve VIII). The fluid channels within the cochlea are stimulated by the vibrating stapes footplate through the membranous oval window at the base of the cochlea. The base of the cochlea responds to high-frequency sounds, and the apex responds to low-frequency sounds.



**Figure 1 Diagram of the human ear**

Note: The length of the auditory canal is exaggerated in this image (*courtesy to Wikipedia*) <http://en.wikipedia.org/wiki/Image:HumanEar.jpg>

The eardrum and the three tiny bones conduct sound from the eardrum to the cochlea. Sound waves funnel into the ear via the external ear canal and hit the eardrum (tympanic membrane). Consequently the compression of the wave set this thin membrane in motion, causing the inner ear bones (the ossicles; malleus, incus and stapes) to move. Hearing occurs when sound waves move to the nerves of the inner ear and then the brain. Sound waves can travel to the inner ear by air conduction (through the ear canal, eardrum, and bones of the middle ear) or bone conduction (through the bones around and behind the ear) (Medline Plus, 2008). <http://www.nlm.nih.gov/medlineplus/ency/imagepages/1092.htm>

## Hearing loss

Alternative terms are decreased hearing, deafness or hearing impairment.

### Levels of hearing loss

Frequency or tone of sound is measured in hertz (Hz); with one hertz representing one vibration, for example low bass tones range around 50 to 60 Hz, whereas shrill, high-pitched tones range around 10,000 Hz or higher

The intensity or strength of sound is measured by a scale of *decibels* (dB) that ranges between 0 (silence) 20 (a whisper) and 140 decibels e.g. shotgun blast (where physical damage immediately occurs).

In a healthy ear, sound frequencies from about 20 Hz up to 20 KHz (20,000 Hz) can be processed, and the ear can detect sounds as soft as  $0.0002 \text{ dynes/cm}^2$  (0 dB) and it

can tolerate stimuli of up to a million times more intense ( $200 \text{ dynes/cm}^2$  (120 dB) e.g. a Jet engine) for limited periods of exposure. The ear is particularly sensitive to signals between 500 and 4000 Hz, which includes the frequencies most important for speech processing (Yeuh *et al.*, 2003, and Access Economics, 2006).

Hearing loss is the total or partial inability to hear sound in one or both ears.

According to The World Health Organisation (WHO) hearing impairment is a broad term used to describe the loss of hearing in one or both ears. A person does not have hearing impairment when he/she has no or very slight hearing problems and is able to hear whispers (at 25 dB or better in the better ear).

[http://www.who.int/pbd/deafness/hearing\\_impairment\\_grades/en/index.html](http://www.who.int/pbd/deafness/hearing_impairment_grades/en/index.html) (date accessed 5 April 2008).

Hearing impairment ranges between slight to profound according to the audiometric value as follows:

- Slight impairment: the person is able to hear and repeat words spoken in normal voice at 1 metre (audiometric value in the better ear is 26-40 dB).
- Moderate impairment: the person is able to hear and repeat words spoken in raised voice at one meter (41-60 dB in the better ear).
- Severe impairment: the person is able to hear some words when shouted into better ear (61-89 dB).
- Profound impairment: the person is unable to hear and understand even a shouted voice (81 dB or better in the better ear).

According to the Access Economics (Australia), the severity of hearing loss for people aged 15 years or more is divided into Mild ( $\geq 25 \text{ dB}$  and  $< 45 \text{ dB}$ ); Moderate ( $\geq 45 \text{ dB}$  and  $< 65 \text{ dB}$ ); and Severe ( $\geq 65 \text{ dB}$ ) hearing loss (Access Economics, 2006).

### Types of hearing loss

The three basic types of hearing loss are conductive, sensorineural and mixed. Conductive hearing loss involves the outer and middle ear, a mechanical or physical obstruction to air conduction prevents the proper transmission of sound waves through the external auditory canal and/or the middle ear. Causes for conductive hearing loss can be congenital, or caused by blockage of wax, a punctured eardrum, birth defects, trauma, severe otitis media, otosclerosis, neoplasms, or atresia of the ear canal. It is characterised by an almost equal loss of all frequencies. Usually, this type of hearing loss can be corrected medically or surgically. Sensorineural or (nerve) hearing loss is more common and involves damage to the inner ear (cochlea) or the eighth cranial nerve. It occurs when the sensory receptors of the inner are dysfunctional. It is characterised by the lack of sound perception and is mostly caused by a defect in the cochlea and/or the auditory division of the vestibulocochlear nerve. Sensorineural hearing loss is an insidious, potentially devastating chronic health condition if left unmanaged (Chisolm *et al.*, 2007). This type of hearing loss is irreversible and it tends to be unevenly distributed, with greater loss at higher frequencies. Sensorineural hearing loss could be caused by aging, congenital or hereditary, prenatal or birth-related problems or may result from intense noise, trauma, viral or bacterial infections, ototoxic drugs (e.g., Cisplatin, salicylates, loop diuretics), fractures of the temporal bone, meningitis, Ménière's disease, cochlear otosclerosis, aging (or called presbycusis), or congenital malformation of the inner ear. Mixed hearing loss is conductive hearing loss coupled with sensorineural hearing loss.

Other causes that can lead to hearing loss or contribute to a decrease in threshold sensitivity could be due to aging or environmental factors. The exposure to intense sounds, such as loud music, occupational noise, or recreational noise (such as hunting, shooting, or motorcycles) may cause hearing loss (Cook and Hawkins, 2006).

### Epidemiology

Hearing loss is a prevalent major public health problem and is one of the most common sensory disorders that causes disability (Taylor *et al.*, 2001). It is associated with poor quality of life, including negative affects on interpersonal relationships, communication, socialisation and independence. It can lead to poor general health and mood disorders such as depression and anxiety (Donaldson *et al.*, 2004) as well as to reliance on community support services contributing to early aged care replacement (Smith *et al.*, 2005). According to the National Institute on Deafness and Other Communication Disorders (NIDCD), hearing loss affects 17 in 1000 children under the age of 18. Beyond the age of 50, the prevalence estimates are well over 10%, approaching 50% by 70-74 years (Taylor *et al.*, 2001). The incidence increases with age: 314 out of 1000 people over the age of 65 have hearing loss, as do 40-50% of people over the age of 75. Hearing loss is a silent problem that affects millions of people around the world. It affects more than 31.5 million people in the United States and is considered the third most common chronic health condition in the USA, exceeded only by arthritis and hypertension in persons 65 years and older (Cook and Hawkins, 2006; Healthy People 2010, 2004). Figures from the National Health Services (NHS) in the UK estimated that the prevalence of hearing loss among adults is 20%, and age is the major predictor of hearing impairment (Department of Health, 2007). The figures show that only 20-25% of people who report hearing difficulties in the British population possess a hearing aid (Gianopoulos *et al.*, 2002). In Sweden, about 560,000 adults have severe hearing impairment and required a hearing aid; approximately 270,000 adults have hearing aids, with more than 50% using their aid regularly (Swedish Council on Technology Assessment in Health). Estimates from Australia show that about 3.55 million Australians suffer from some form of hearing impairment (one in six) and the incidence is predicted to increase to reach one in four by 2050 (Access Economics, 2006; Wilson *et al.*, 1998). Despite these figures and similar to other overseas countries, data from Australia showed poor use of hearing aids (Smith *et al.*, 2005). The Australian Blue Mountains Hearing Study found that overall, only half of those with measured moderate or worse hearing loss had a hearing aid. The study evaluated the hearing of 2965 people aged 49 and over in the Blue Mountains region west of Sydney between 1997 and 2003 (Sindhusake *et al.*, 2001; Smith *et al.*, 2005).

### Burden of hearing loss and the extent of the problem in New Zealand

The condition is a common and significant cause of disability in New Zealand society and figures are comparable to those in other countries. In New Zealand, the study of hearing impaired and deaf people showed a prevalence of hearing loss of 10.3% [or just under 400,000 people (for people reporting hearing loss)] and also 0.05% [one in 2,100 people over 15 years who cannot hear one person talking] (Greville, 2005). Men were more likely to suffer from hearing loss than women. This difference is similar to that found in other developed countries and is partially related to hearing loss associated with noise exposure. The Accident Compensation Corporation (ACC) stated that hearing loss is a common claim and that in the financial year 2001, ACC

compensated 13,353 claims for hearing loss. These figures included 3,921 new claims and 9,432 ongoing claims, with a total cost of more than \$NZ25.7 million (Evidence Based Healthcare Group, 2003). In more recent ACC figures, there were 4081 new claims for noise-induced hearing loss in 2004/05 (around 11 New Zealanders successfully claiming compensation for a new case of noise-induced hearing loss each day) (Thorne, 2006). The overall rehabilitation costs directly related to noise-induced hearing loss in the 2004/05 year totalled about \$43 million. Figures from the Environmental Support Services show that hearing loss of some degree has been reported in about 8% to 10% of the total population, including people in residential care (Disability Resources Centre, 2005).

Results from the 2001/02 New Zealand Disability Survey showed that 29% of people with hearing disability (66,600 people) used hearing aids. Other figures from the survey showed the prevalence of use of other devices:

- 21,000 adults in households used amplified telephones
- 6,700 used teletext
- 3,500 used fax machines
- 3,000 used flashing alarms
- 2,500 used loop, FM or infra-red systems
- 2,000 used computers to communicate.

It was estimated that 34,500 people indicated that they needed hearing aids, but did not have them, and another estimate of 5,000 people had unmet needs for an amplified phone. For unmet needs, affordability was the major issue for 23,000 people (67%) (Greville, 2005).

In New Zealand, there are more than 300 types and models of hearing aids available and their cost vary significantly. Service providers in general have access to many ranges and styles of hearing aid, and the audiologist provide advice as to what style of hearing aid best suits the hearing needs of the patient (e.g., Hearing Advantage) <http://www.hearingadvantage.co.nz/Funding.aspx>. (date accessed 5 April 2008). The cost of purchasing hearing aids depends on a variety of factors including:

- the degree and type of hearing loss
- the complexities of the listening environment in which hearing aids will be used
- the wearers personal cosmetic preferences
- the need for one or two hearing aids.

Hearing aid costs have also been affected by developments in technology over the last decade. In general hearing aids can be classified according to cost as follows:

**Basic Digital or Analogue:** \$1200-\$2000 per pair of hearing aids. Aids in this category generally perform well in quiet situations. These aids do not offer maximum assistance in group conversations, crowds, or meetings. These aids generally offer options such as manual volume, different listening programs for different sound environments, telecoil compatibility (in some models) and use of a remote control to change volume and other features (in some models).

**Middle Range Digital:** \$2400-\$5000 per pair of hearing aids. These instruments offer a great range of features compared to the basic models. Additional features include

reduction of non-speech noise and directional microphones to reduce the interference of background noise.

Advanced Digital: \$5000-\$7000+ per pair of hearing aids. In addition to the above features advanced hearing aids use the latest technology and are better able to cope with changes in the listening environment. This results in better speech understanding in a greater range of situations including the presence of background noise. Many user options are available that make them easy to use, and some aids within this category are adjustable via a remote control. They also provide the Audiologist with the greatest flexibility to optimise the devices for the individual person's hearing.

Funding options in New Zealand could be through an ACC scheme, Environmental Support Services (ESS), War Pensions Scheme, or Universal Hearing Aid Subsidy outlined below.

#### ACC Scheme

Individuals may be eligible for funding of hearing aids through the ACC scheme if their hearing loss is the result of prolonged occupational noise exposure or a sudden trauma that has damaged hearing. Funding is available if occupational noise exposure occurred before the introduction of the ACC scheme in 1972. However, funding is not typically available if a sudden trauma occurred prior to 1972 that caused hearing loss.

Assessment for ACC eligibility begins with a hearing test. Noise exposure produces a pattern of hearing loss that a qualified Audiologist is trained to identify. If a noise induced hearing loss is found, which is consistent with the history of occupational noise exposure, the Audiologist will recommend that an ACC claim be initiated. An ACC claim must be lodged through a General Practitioner or other Registered Medical Specialist. After lodging a claim, a patient must be examined by an Otolaryngologist (Ear, Nose, and Throat (ENT) surgeon). If an ACC claim is approved, the cost of appropriate hearing aids is met by the ACC scheme. Lump sum compensation payments are not available.

If an individual believes they may have a hearing loss associated with noise exposure they are encouraged to act now, even if they do not feel they need hearing aids. If left too late (after retirement, for example) then it may be difficult to prove that the hearing loss was caused by noise exposure alone, rather than a natural deterioration over time with age.

#### Environmental Support Services, Ministry of Health

Accessible NZ (Meremere North) and Enable NZ (South Island) provide wholesale cost of hearing aids for people who are in full-time study, employment, or who are unemployed but registered as seeking work or who are primary caregivers of young dependent people.

#### War Pensions Scheme

Individuals who were exposed to noise through high-powered rifle or artillery fire while serving in the armed services (during war or peace time) may be eligible for

funding for hearing aids. Eligibility depends on a number of factors, including whether the person receives a War Pension, and the degree of any assessed disability. Individuals who believe they may be eligible for a hearing aid through the War Pension system should have their hearing assessed at Hearing Advantage.

#### Hearing Aid Subsidy, Ministry of Health

All adult patients who purchase a hearing aid and do not receive funding through the ACC, or War Pensions are eligible for a Hearing Aid Subsidy. The subsidy is currently set at \$198 GST inclusive per hearing aid and is available to individuals every 5 years. The subsidy is applied to each hearing aid.

A Stocktake of Access and Eligibility criteria (Disability Resources Centre, 2005) noted that the area of sensory disability has historically had the most limited access to ESS funding. The Stocktake considered hearing aids a priority within a project designed to assess the ability of the current ESS system to meet the needs of people with sensory impairment. Additional consultation with Deaf and Hearing impaired stakeholders was also carried out to elucidate issues related to access to equipment. There was remarkable consistency with the issues presented by Deaf and Hearing impaired people, accredited assessors and providers. They raised the following concerns about access and eligibility:

- Hearing loss not being regarded as a significant disability by Government and society (as it is invisible). Deaf and Hearing impaired people appeared to have inequitable access to equipment and other support services compared with other disability groups.
- The current funding available for equipment for Deaf and Hearing impaired people was reported as inadequate, fragmented and too complex.
- The current eligibility criteria and prioritisation process was reported as inappropriate for Deaf and Hearing impaired people, and needs to be extended to provide equitable access.
- Deaf and Hearing impaired people desired access to equipment to meet all of their support needs, not just for education and work. This would include having access to funding for assistive listening devices and alerting devices for the home.
- The issue of the funding of hearing aids was consistently reported as a key concern. Many people who were not eligible for funding of hearing aids reported not being able to pay for the aids themselves.
- Older and disabled people not currently in employment saw themselves as excluded from ESS funding under the current criteria.

Issues around service delivery are listed as follows:

- There were significant workforce issues in relation to Audiologists identified. Public Audiological services in many areas were reported as being inaccessible.
- Deaf and Hearing impaired people perceived access to ESS funding as fragmented and identified a need for a holistic and co-ordinated service based on providing a continuum of support of cover for the whole of life.
- The quality and range of equipment provided within the ESS system was reported to be of concern to Deaf and Hearing impaired people.

## Treatment options for hearing loss

It is well documented that untreated hearing impairment may affect non-auditory aspects of life such as a reduction in effective social functions, diminished psychological well-being, lower self-esteem and reduction in general quality of life. These in turn may have impact on the patient's communication deficits (Valente *et al.*, 2007). The inability to communicate because of hearing loss can be severely disabling, but with the remarkable improvement in the ability to amplify sounds there comes the ability to provide various treatment options tailored to the needs of the hearing-impaired individuals (Kim and Barrs, 2006). Research has well documented the benefits of amplification in general in improving auditory and non-auditory outcomes for adults with hearing loss. According to the WHO, properly fitted hearing aids can improve communication in at least 90% of people with hearing impairment. In a recent systematic review and meta-analysis concerning the benefits of amplification in adults with sensorineural hearing loss (SNHL), the American Academy of Audiology Task Force concluded that hearing aid use improves adults' health-related quality of life (HRQoL) by reducing psychological, social, and emotional effects of sensorineural hearing loss (Chisolm *et al.*, 2007). Hearing aids improve a person's ability to comprehend speech, even in a noisy environment and are of greatest benefit for those with moderate hearing loss (Swedish Council on Technology Assessment in Health). Satisfaction with hearing aid use was related to experience, expectation, personality and attitude, usage, type of hearing aids, sound quality, listening situations, and problems in hearing aid use (Wong *et al.*, 2003). Other research looked at whether one or two hearing aids would be better (Noble, 2006; Noble & Gatehouse, 2006; Swedish Council on Technology Assessment in Health), or whether directional microphones offer additional advantage over amplification alone (Agence d'Evaluation des Technologies et des Modes d'Intervention en, 2003; Bentler, 2005).

Most patients undergo audiological evaluation by an Audiologist who assesses the patient's communication needs and measures the degree and type of hearing loss. If the underlying cause of hearing difficulties is medical, the patient should be referred to an Otolaryngologist. Surgical treatment may be effective in some conductive types. If medical or surgical interventions are unnecessary, hearing aids or other assistive listening devices may be used to improve hearing sensitivity. The audiologist will assist in making the decision whether an individual would need one (monaural) or two (binaural) hearing aids, what size and style of hearing aids are to be fitted, and the internal circuitry details (see next section). Binaural amplification is recommended for most patients. However, monaural fittings may be warranted based on specific patient needs and in particular cases of asymmetry, binaural interference, and financial and/or cosmetic concerns (Valente *et al.*, 2007).

There is no single 'best device' for all patients with hearing loss. The auditory and non-auditory needs of the patient as well as the amplification systems and hearing aid technologies all tailor the best device for each individual. The style of hearing aid most appropriate for a patient depends on hearing test results, ear canal size and shape, required features, and patient preference (Cook and Hawkins, 2006). Successful use of hearing aids depends on several factors, including hearing demands, environments where problems are experienced, and motivation of the patient to adjust to using hearing aids (Cook and Hawkins, 2006). The hearing ability, listening demands and patient control over the device determine which hearing aid is

appropriate for each person. Hearing aid is only one part of a rehabilitation process that aims to minimise disability and avoid handicap. Counselling and consistent follow-up care with the audiologist are also crucial to the success of the appropriate hearing aid for the individual patient (Cook and Hawkins, 2006; Kim and Barrs, 2006).

### Hearing aids

A hearing aid is a battery-operated device that makes the sound louder and that can be worn in or around the ear. Hearing aid devices are available in different shapes, sizes and types. However, they all work in a similar way and involve four essential parts:

- a built-in microphone to pick up the sound
- an amplifier to make the sound louder (either by analogue or digital circuits)
- a speaker to bring sound to the ear (the resulting signals are passed to a receiver, or earphone, in the hearing aid, where they are converted back into sounds to hear)
- a battery.

Types of hearing aids include: conventional analogue hearing aids, analogue programmable hearing aids, and digital processing hearing aids.

According to the American Speech-Language-Hearing Association (ASHA), hearing aids can have various characteristics according to their style, the technology involved and special features of the various types (**Tables 1, 2 and 3**). For the purposes of this review, the following sections will provide brief background and describe the styles, technology involved and special features of hearing aids.

There are many different types of hearing aids. The most commonly used types are:

- The behind-the-ear-hearing-aid, a skin-coloured plastic case containing a microphone, an amplifier and a loudspeaker, which sits just behind the ear and increases the volume of sounds as they enter the ear. This model usually fits over the ear and directs sound into the ear canal through a tube and ear mould. The ear mould is a custom-fitted piece, but the behind-the-ear portion is a standard size. This style has the greatest number of circuit and feature options, and it is easy for most people to handle.
- The in-the-ear-hearing-aid, a smaller, less powerful hearing aid that sits inside the ear. It is custom-fitted to the patient, and fills the entire concha of the external ear and projects slightly into the ear canal. Although this style is easy to handle and can support a large number of features it may not be useful for people with severe hearing impairment as it is too small to contain a powerful amplifier.
- The in-the-canal hearing aid which is relatively small and protrudes slightly into the concha. It generally uses a smaller battery, and many have fewer features. Some patients find this style difficult to handle, or their ears may be too small for the hearing aid to fit well.
- The completely-in-the-canal-hearing-aid is a very small device for people with mild hearing impairment, which fits completely inside the ear canal and is

almost unseen outside the ear. Because of the small size, handling of this model requires good vision and dexterity (Valente *et al.*, 2007). This model is contained within the ear canal and does not noticeably extend into the concha. This style uses the smallest batteries and has the fewest available features. It is usually recommended for patients who express concerns about the outward appearance of hearing aids and have mild to moderate hearing loss and a moderate-sized ear canal.

Difficulty understanding speech in a background of noise is one of the most frequent complaints of the hearing aid user. Therefore, many hearing aids at present are implemented with various clinical strategies and circuitry schemes to improve speech understanding both in quiet and noisy environments. Such schemes include binaural (in both ears) amplification, reduction of low-frequency amplification, compression amplification, directional microphones, and digital noise reduction (Bentler, 2005).

In fact, hearing aid technology has progressed dramatically over the past decade and many models of hearing aids now incorporate digital components. Digital hearing aids incorporate the conversion of sound into data that can be processed by a chip inside the aid. Digital hearing aids are able to process and customise sound precisely to suit different hearing loss. Hearing aids shifted from analogue to digital technology about ten years ago, and currently this technology, is replacing the analogue hearing aid and eventually they will become the 'basic' type (Kim and Barrs, 2006). In the USA alone, 93% of the hearing aids sold in 2005 contained Digital Signal Processing (DSP) technology (Edwards, 2007). The capability of digital hearing aids supports a greater number of features and programming options rather than improving the quality of the hearing aid.

Compression, noise reduction and feedback reduction are only some features of DSP technology. Compression refers to technology where softer sounds are amplified more than louder sounds, the drawback is that too much auditory information is lost and thus the sound is distorted. The noise reduction feature refers to a programme, which attenuates low frequencies and enhances high frequencies, thus controlling background noise. Current digital hearing aids attempt to differentiate between noise (constant input) from speech (modulates), and therefore with the noise reduction feature it can take the noise signal and selectively decrease low-frequency gain, while maintaining all the frequencies in the speech signal. The drawback is that it is more effective only if there are a high number of frequency channels, or bands to evaluate, since control can be more frequency specific. Feedback suppression implements the production of a counter-phase signal that nullifies the feedback as opposed to decreased gain (Kim and Barrs, 2006).

In more detail, the potential digital advantages include those related to the following:

- Gain processing (potential for increased audibility of sound of interest without discomfort resulting from high intensity sounds).
- Digital Feedback Reduction (DFR; the most advanced feedback reduction schemes monitor for feedback while the listener is wearing the hearing aid).

- Digital Noise Reduction (DNR), this processing is intended to reduce gain, either in the low frequencies or in specific bands, when steady-state signals (noise) are detected.
- Digital Speech Enhancement (DSE), these systems act to increase the relative intensity of some segments of speech.
- Directional Microphones and DSP, the ability of directional hearing aids to improve the effective signal-to-noise ratio provided to the listener is now well established.
- Digital Hearing Aids as Signal Generators, since digital hearing aids have a DSP at their heart, they are able to perform loudness growth and threshold testing in order to obtain fitting information specific to an individual patient's ears in combination with a specific hearing aid.

Another major progress in addressing poor signal to noise is the introduction of a directional microphone. The interest in directional microphones is based on the available increased directivity today, ability to implement directional microphones in-the-ear and in-the-canal style hearing aids, and the ability of the wearer to switch between omni and directional microphones (Dhar *et al.*, 2004; Voll, 2000). The standard hearing aid contains a microphone that collects all auditory input without regard for the direction of that input (omnidirectional), thus amplifying all noise (Kim and Barrs, 2006). Some directional microphones exist in a dual-microphone configuration with two omnidirectional microphones that can switch to a directional mode. Aids with directional microphones work by creating a polar pattern where a point relative to the microphones has the greatest sensitivity. Directional microphones input and amplify sounds that originate for example from in front of the microphone and not from another location (e.g. from behind). The mechanism is through improvement of the signal-to-noise ratio, which results in improved speech recognition in noise. The benefit from the directional microphone was assessed by Bentler *et al.*, (2004) in a comparative study, and hearing in noise was found to approach that of normal-hearing individuals when they used directional microphone-equipped digital hearing aids.

Lastly, fitting patients with high-frequency hearing losses with appropriate amplification has long been problematic. Those patients experience difficulty with speech understanding in background noise and for soft or high-pitched voices (Gnewikow and Moss 2006). The completely-in-the-canal (CIC) and other in-the-ear (ITE) instruments can offer cosmetic advantages; however, occlusion effects often are present and can be challenging. Occlusion effect is the hollowness of voice when chewing or talking. Many fittings can lessen the effects but are not free of problems of feedback concerns of the open feedback loop (e.g., behind-the-ear, or the traditional tube). The open-canal style has addressed many of the concerns that patients and dispensers have expressed about fitting high-frequency hearing losses. In spite of the limited research on these devices, some suggest that they may have some advantage for problems related to occlusion, voice quality (improved sound quality of the wearer's own voice), comfort, and better localisation ability (Taylor, 2006). The OC product uses a small, non-occluding, non-custom eartip placed in the ear canal, essentially eliminating the occlusion effect due to significant leak venting. OC fittings

devices are small enough to be minimally visible and physically unobtrusive for most patients, while reportedly providing sufficient gain to improve audibility and understanding for high-frequency losses.

The following pictures show styles of hearing aids (from Applied Hearing in NZ <http://www.appliedhearing.co.nz/hearingaids.html> (date accessed April 2008)), followed by tables that summarise the features and characteristics of various styles, characters and special features of hearing aids adopted from the American Speech-Language-Hearing Association (ASHA).



**Figure 2** Example of hearing aid styles in NZ

Compliment to Applied Hearing

<http://www.appliedhearing.co.nz/hearingaids.html>

**Table 1 Hearing aids styles (from ASHA)**

Style	Character	Feature
In the canal and completely in the canal	Tiny case fits partly or completely into the ear	Smallest available  Offer cosmetic and some listening advantages
In-the-ear	Shell fills in the outer part of the ear	Larger  May be easier to handle
Behind-the-ear	Small plastic case rests behind ear, case connected to ear mould by piece of clear tubing	Chosen for young children for safety and growth reasons

**Table 2 Hearing aids technology**

Type	Character	Features
Conventional/analogue	Particular frequency response based on audiogram  Manufacturer install required settings  Amplifies all sound (speech noise) in the same way	Least expensive  May be appropriate for various types of hearing loss
Analogue programmable	Have a microchip  Audiologist uses computer to programme for different listening situations	Can store many programmes  Change setting (button) with change in listening environment  More expensive  Longer life span  Better hearing in different situations
Digital programmable	All features of analogue programmable but uses digitalised sound processing to convert sound waves into digital signals  Self-adjusting	Self-adjusting  More flexibility in programming  Most expensive  Greater precision in fitting, management of loudness discomfort, control of acoustic feed back (whistling), noise reduction

**Table 3 Special features in hearing aids**

Hearing Aid built-in feature	Characteristics	Features
Directional microphone	Responds to sound coming from specific direction (face-to-face) conversation  Switch from Omni directional* to directional microphone	Reduced background sound
Telephone Switch capability	Induction coil inside "T" switch, to hear better on the telephone	Environment sound eliminated  Can be used in theatres, auditorium, etc
Direct audio input capability	Allows to plug in a remote microphone or an FM assistive listening system, connect directly to a TV, or connect with other devices "computer", CD player, tape player, radio, etc.	Self-adjusting More flexibility in programming Most expensive Greater precision in fitting, management of loudness discomfort, control of acoustic feed back (whistling), noise reduction

Omni directional\* non-directional, picks up sound from any direction

T Switch- Telecoil may be useful with some of the special assistive listening sound systems available in many auditoriums, theatres and other public places.

When hearing aids alone cannot address hearing impairment, assisted listening devices can be used either on their own or in conjunction with hearing aids (Lesner, 2003). The following section will elucidate use and types of assistive listening devices.

### Assistive listening devices (ALDs)

Assistive listening devices and systems (ALDs) used either solely or in conjunction with personal hearing aids, can facilitate listening in various acoustic environments, especially those in which excessive noise, reverberation and distance exist between the listener and sound source. Listening situations that are especially problematic, even with hearing aids, such as listening in large groups, on the telephone, in restaurants and at concerts and movies are ideally suited for ALD use (Lesner, 2003). Therefore, ALDs can offer greater ease of hearing in many day-to-day communication situations and thus reduce stress and fatigue. There are over 30 different alternative listening devices currently approved for fitting under the Australian Government Hearing Services Program (Australian Government Department of Health and Ageing , 2005). These can be grouped together into a few types. They commonly consist of headphones and a microphone, which can be pointed at the sound source. Other types of alternative listening devices consist of headphones connected by a wire or electronically to a television or another electronic device. Alternative devices can amplify a sound, but their primary purpose is not to make a sound louder. Rather, they generally place a microphone close to the sound source, so that it becomes louder compared to the other sounds in the environment. Examples of ALDs include the following:

- Personal frequency modulation (FM) systems- are useful e.g. in listening to a travel guide or book review, in a classroom lecture, in a restaurant, in nursing homes or a senior centre.

- Infrared systems, are often used with TV sets, but also can be used in large settings like theatres.
- Induction loop systems are most commonly used in large group areas.
- One-to-one communicators are useful in amplifying and delivering the sound directly into the hearing aid (or headset) e.g. when the hearing-impaired needs to talk to one person in a group of people (restaurant, lecture, etc).
- Other ALDs such as telephone amplifying devices for cordless, cell, digital and wired phones; amplified answering machines; amplified telephones with different frequency responses; paging systems; computers; and wake-up alarms (ASHA).

For the purposes of the proposed systematic review only ALDs that are used for one-to-one communication will be considered.

## Purposes and structure of the report

1. The objective of this systematic review is to determine the clinical- and cost-effectiveness of hearing aids and also of assistive listening devices (without hearing aids) for adults with various types of hearing loss and in meeting their communication needs. The review considers and focuses on digital hearing aids and personal (one-to-one) communicators. The review will look at and identify options of hearing aid use that may prove to be of benefit and if so under what circumstances and to which group of people the benefit applies. The results from the review will provide an evidence-based background that helps in identifying what range of hearing aids the Ministry of Health (Health & Disability National Services Directorate) should consider funding for.
2. This report is divided into sections, followed by Glossary and detailed appendices, including the search strategy, all excluded papers annotated by reason for exclusion, and the completed data extraction tables for included papers. The report sections are:

**1. Methods section:** Describes the review's methods and includes the research questions, search strategy, inclusion and exclusion criteria, the data extraction, appraisal and synthesis methods, and the methodological limitations of the evidence review.

**2. Results section:** Considers the included appraised studies, reporting first on the systematic reviews and meta-analyses, and then on the original primary research for each research question. Study characteristics and findings are reported in separate tables and synthesised in the text, and the body of evidence for each research question is reported. Primary studies are presented in the characteristics section in the order of the level of evidence (highest level first then lower level, most recent first). The primary study results section is presented differently according to the outcomes measured from the studies (more frequent measured first then less frequent measure used).

**3. Economic considerations section:** Describes the methods and results of the economics evaluations.

**4. Summary and conclusions section:** Summarises results, briefly discusses the limitations of the evidence base, identifies gaps in knowledge, and presents key conclusions.



## 1. Methods

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The scope of this review was defined by staff from the Ministry of Health's Health & Disability National Services Directorate, and Population Health Directorate, and an informal working party (**Appendix A**) in conjunction with the reviewers. In general, the aim of this review was to evaluate the effectiveness of digital hearing aids in treating hearing loss in adults. The aim of the review also included the evaluation of effectiveness of assistive listening devices (ALDs). However, the search strategy identified a very limited number of papers that assessed assistive listening devices (**Appendix C**). Potentially eligible papers were fully retrieved and accessed, then weighted against the inclusion/exclusion criteria, but no paper was eligible for inclusion. Therefore, this systematic review will pertain only to the assessment of the effectiveness of digital hearing aids.

### 1.1 Research questions

The clinical question to be answered by this review was defined by staff from the Ministry of Health's Health & Disability National Services Directorate and Population Health Directorate, and an informal working party in conjunction with the reviewers. In general, the aim of this review was to evaluate the relative effectiveness and cost-effectiveness of digital hearing aids in adults with hearing loss as compared to no use of hearing aids or to the use of other styles of digital hearing aids.

The primary research question to be addressed by this review was:

What is the effectiveness of digital hearing aids in treating adults with hearing loss?

The review questions are defined according to the PICO (or PICOT) criteria:

- patient population
- intervention
- comparator (where appropriate)
- outcomes
- time consideration (should be considered with regard to all of the above domains).

Accordingly the question was structured as follows:

Will an adult with hearing loss (**P= patient**) have better (e.g.) speech recognition in noise (**O= outcome**) with the use of a digital hearing aid (**I= intervention**) as compared to no use of digital hearing aid (**C= comparison**)?

The second question pertains to assistive listening devices:

What is the effectiveness of assistive listening devices (one-to-one communicators) for adults with hearing loss?

For inclusion in the current review, the evidence had to fulfil the criteria outlined in **Table 4** and **Table 5**. These criteria were developed *a priori* and described in the scoping protocol prepared prior to commencement of the review.

**Table 4 Criteria for determining study eligibility**

<b>Patient population</b>	<p>Inclusion: Adults aged <math>\geq</math> 18y diagnosed with various severity of hearing loss at all settings</p> <p>Exclusion: Presence of a developmental disorder or mental retardation Presence of psychiatric illness Normal hearing individuals</p>
<b>Intervention</b>	<p>Inclusion: Where at least &gt;75% of the intervention group have had digital hearing aid (irrespective of style, fitting, or microphone) this may include any of the following variables: Styles (in-the-ear, behind-the-ear, or in-the-canal/completely-in-the-canal, or open canal) Fitting (monoaural/in one ear or binaural/in both ears) Microphones (directional e.g. mono- or omni-directional) Assistive listening devices restricted to personal devices that do not require the use of hearing aids such as one-to-one communicators (e.g. sennhieser audioport)</p> <p>Exclusion: Analogue hearing aids (if both analogue and digital hearing aids are included in a study and 75% or more of the patients have had analogue hearing aids) Bone Anchored Hearing Aids Cochlear implants Other surgical implants Amplified telephones, loop systems, FM systems, visual or vibrating alert systems</p>
<b>Comparator</b>	<p>Inclusion: No hearing aids Within other options (fitting, style, microphone/ programme), this may include the following: Different styles of digital hearing aids Monaural or binaural hearing aids Mono-directional or omni-directional hearing aids</p> <p>Exclusion: Analogue hearing aids Cochlear implants Bone Anchored Hearing Aids Other surgical implants</p>
<b>Outcomes</b>	<p>Inclusion: Any of (but not restricted to) the following measures and patient-relevant measures – Outcome measures for communication needs and function such as Client Oriented Scale of Improvement (COSI), Expected Consequences of Hearing Aid Ownership (ECHO)(Cox &amp; Alexander, 2000b; Dillon, James, &amp; Ginis, 1997 ) Self-report measures (such as Abbreviated Profile of Hearing Aid Benefit (APHAB), Hearing Handicap Inventory, Knowles hearing aid satisfaction survey, Hearing aid daily use log, and Preference ratings) Treatment effectiveness outcome measures (including Improvement in social and emotional function, Improvement in communication function, Improvement in depression, Improvement in quality-of-life measures) Other outcome measures (including Patient preferences, Patient adherence to treatment, Self-assessed level of improvement in hearing, Feed-back from family or carer, and Impact on the ability of patient to live as others do)</p> <p>Exclusion: Where outcome measures are purely technical (instrumental) and not patient-relevantbrain-stem-evoked response audiometry (BERA)</p>

It is important to note that studies which were unable to answer the research question, because of their design, were excluded.

**Table 5 Nature of the evidence**

<b>Publication type</b>	<p>Inclusion criteria: Studies published in the English language, including primary (original) research published as full original reports and secondary research (systematic reviews and meta-analyses) appearing in the published literature.</p> <p>Exclusion criteria: Papers for which an abstract is not available for review via the bibliographic database Primary papers identified and appraised by an included systematic review Non-systematic reviews, letters, editorials, expert opinion articles, book chapters, conference proceedings, comments and articles published in abstract forms. Publication superseded by a later publication with longer follow up data and overlap in the patient population</p>
<b>Study design</b>	<p>Inclusion criteria: Those that provide at least Level II evidence according to the National Health and Medical Research Council (NHMRC) interim levels of evidence for intervention research questions (2005) Appendix 5. This includes: Randomised clinical trials (Level II evidence) of crossover or parallel-group design, or systematic reviews and meta-analyses of Level II evidence examining the effect of hearing aids in adults with hearing loss. If insufficient Level II papers meet the inclusion criteria then Level III papers will be considered for inclusion (systematic reviews of comparative studies will be given priority. If these are not available then comparative primary studies of other design will be considered for inclusion)</p> <p>Exclusion criteria: Evidence below Level II if relevant sufficient Level I and II studies found.</p>
<b>Study duration</b>	At least 10 weeks on each treatment/intervention
<b>Sample size</b>	At least 20 evaluable patients per study arm (or exposed to both treatments). If insufficient studies are available then this number will be reduced to 10 patients per study arm.

## 1.2 Literature search

A systematic method of literature searching and selection was employed in the preparation of this review. Searches were limited to English language material published from January 2000 onwards. The searches were completed on 22 November 2007. Studies published after this date were not eligible for inclusion in the systematic review.

The following databases were searched:

### Bibliographic databases

- Embase
- Medline

## Review databases

The following were searched through the Cochrane Library:  
<http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME>:

- Cochrane Database of Systematic Reviews
- Cochrane Central Register of Controlled Trials
- Database of Abstracts of Reviews of Effectiveness
- Health Technology Assessment database
- NHS Economic Evaluation database

## HTA groups

- INAHTA website database: <http://www.inahta.org/Search2/?pub=1>
- MSAC: <http://www.msac.gov.au/>
- ANZHSN: <http://www.horizonscanning.gov.au/>
- NZHTA: <http://nzhta.chmeds.ac.nz/>
- NICE: <http://www.nice.org.uk/>
- AHRQ/USPSTF: <http://www.ahrq.gov/>
- CADTH: <http://www.cadth.ca/>
- SBU: <http://www.sbu.se>
- KCE: <http://kce.fgov.be>

## Clinical practice guidelines

- National Guideline Clearing House database: <http://www.guideline.gov/>

## Other sources of information (snowballing)

- Using the Web of Science and Embase electronic databases were also searched to identify relevant papers citing pivotal references /and related articles of selected studies. Individual journal websites were also electronically searched to find additional studies.
- Hand searches: Bibliographic/reference lists of selected papers and relevant reviews were also scanned to identify any peer-reviewed evidence that may have been missed in the literature search.
- The reference lists as well as included studies in selected systematic reviews that were deemed to be relevant to the review initially but later were excluded for various reasons (next section) were also checked.

As a final process, the entire list of references identified by the search was sent to the Working Group to consult a professional audiologist to identify any peer-reviewed evidence that may have been missed from the literature search. When required, attempts were made to contact authors for unpublished data.

Whilst grey literature and unpublished material such as conference abstracts were not included in the evidence review, they may be referred to in background sections.

Terms were searched as keywords, exploded where possible, and as free text within the title and/or abstract, in the Embase and Medline databases. Variations on these terms were used for Cochrane library and other databases modified to suit their keywords and descriptors. The search terms, search strategy and number of citations identified are presented in **Table 6**.

**Table 6 Search strategy**

Database	Date searched	Search no.	Search terms	Citations
EMBASE + MEDLINE (combined)	2000 - 22 November, 2007, English language, human studies, Explode, keywords, free text	#1	('hearing aid'/exp OR 'hearing aid') OR ('hearing aids'/exp OR 'hearing aids')	11,039
		#2	(assist* AND listening AND device*) OR amplifi* OR (digit* AND ('processing'/exp OR 'processing')) AND signal)	119,765
		#3	(('hearing'/exp OR 'hearing') AND loss) OR ('hearing loss'/exp OR 'hearing loss') OR ('deafness'/exp OR 'deafness') OR ('deaf'/exp OR 'deaf')	70,117
		#4	#2 AND #3	1,691
		#5	#1 OR #4	11,676
		#6	#1 OR #4 AND [english]/lim AND [humans]/lim AND [1997-2008]/py	5,053
		#7	('clinical effectiveness'/exp OR 'clinical effectiveness') OR effect*	4,073,369
		#8	#6 AND #7	1,279
		#9	#8 AND [2000-2008]/py	1112
		#10	Duplicate removed	1051
Cochrane Library	Search completed 22 November, 2007, considered free text and keywords	#1	('hearing aid'/exp OR 'hearing aid') OR ('hearing aids'/exp OR 'hearing aids')	220
		#2	(assist* AND listening AND device*) OR amplifi* OR (digit* AND ('processing'/exp OR 'processing')) AND signal)	99
		#3	(('hearing'/exp OR 'hearing') AND loss) OR ('hearing loss'/exp OR 'hearing loss') OR ('deafness'/exp OR 'deafness') OR ('deaf'/exp OR 'deaf')	1,432
		#4	('clinical effectiveness'/exp OR 'clinical effectiveness') OR effect*	322,815
		#5	#1 AND #2 AND #3 AND #4	62
Sub-total after exclusion of duplicate citations				1113
Bibliographies of included studies and other sources/ snowballing				450
Non duplicate citations		1563		
Additional economic string search		99 + individual studies from the systematic reviews (1)		

### 1.3 Assessment of study eligibility

Eligibility was assessed using criteria based on those identified in the clinical question. Studies were selected for appraisal using a two-stage process. First, titles and abstracts (where available) identified from the search strategy were scanned and excluded as appropriate. Second, the full text articles were retrieved for the remaining studies and selected for inclusion and appraisal in the review if they fulfilled the study selection criteria outlined below. Double-checking of the eligibility of studies by a second reviewer was not undertaken. A further step in the process was undertaken, where all individual studies identified by excluded systematic reviews were retrieved fully and were weighted against the inclusion/exclusion criteria to decide their eligibility for inclusion.

Citations were excluded for the following reasons:

1. Not a clinical study: including non-systematic reviews, case reports, animal studies, short notes, letters, editorials, conference abstracts, in-vitro studies, study types not deemed appropriate to the research question or nature of review.
2. Wrong patient group: does not include the correct patient group for example children or people aged less than 18 years, or patients with comorbid mental health problem.
3. Wrong intervention: does not include the correct intervention/s, such as studies where one group is wearing cochlear implants, or bone-anchored hearing aids. Or studies where hearing aids are not specified.
4. Wrong comparator: does not include the correct comparator/s, such as studies where one group is using cochlear implants or bone-anchored hearing aids.
5. Wrong outcomes: does not include the results relating to at least one of the identified outcomes of interest, measured pre- and post- treatment [e.g. Pure laboratory outcomes].
6. Not in English: due to time constraints non-English publications were not included.
7. Wrong sample size: Fewer than 20 number of patients per study arm at baseline
8. Wrong level of evidence: Evidence below Level II, if sufficient evidence Level I and II studies are identified.
9. Wrong study duration: on each arm of the study if the treatment duration is less than 10 weeks (e.g. hearing aids worn only at testing conditions in lab).
10. Paper superseded by longer follow-up paper later publication with longer follow-up data in the patient population.
11. Papers appraised by an identified and included systematic review.
12. Papers for background information.
13. Papers published before 2000.

There were 1563 non-duplicate studies identified by the search strategy (as detailed in **Table 6** above). As detailed in **Table 7**, 333 full text articles were eligible for retrieval after excluding studies from the search titles and abstracts. Of the full papers retrieved, 325 did not fulfil the inclusion criteria. Therefore, eight articles were fully

appraised and are included in this report (listed in **Appendix B**). All excluded articles are presented in **Appendix C**, annotated by reason for exclusion based on the exclusion criteria detailed above. Reasons are presented hierarchically such that the first reason in the list that applied is reported. Other cited publications (including those providing background material and methodology) are presented in the **References** to this review.

**Table 7 Application of selection criteria to citations**

Exclusion criteria	Number
Total citations identified	1563
Excluded from review of title/abstract:	1230
Not a clinical study	141
Wrong patient group/indication	280
Wrong intervention	666
Wrong comparator	12
Wrong outcomes	80
Not in English	3
Wrong sample size	20
Wrong study duration	1
Other reasons*	27
Full papers (retrieved as full text) reviewed	333
Excluded from review of full paper:	325
Not a clinical study	65
Wrong patient group/indication	6
Wrong intervention	144
Wrong comparator	30
Wrong outcomes	31
Not in English	2
Wrong sample size	20
Wrong study duration	9
Other reasons*	18
Total included citations	8

Note: definitions of these exclusions are provided in the text above, \* other reasons include paper superseded, paper published before 2000, or paper not available.

## 1.4 Appraisal of included studies

### 1.4a Dimensions of evidence

The aim of this review was to find the highest quality evidence to answer the clinical question. In accordance with NHMRC guidance, the following dimensions of evidence were reviewed for each of the included studies (**Table 8**). It is important to recognise that the value of a piece of evidence is determined by all of these dimensions, not just the level of evidence.

**Table 8 NHMRC Dimensions of evidence**

Dimension	Reviewers definition
Strength of the evidence Level (see Table 9 below)  Quality  Statistical precision	The study design used, as an indication of the degree to which bias has been eliminated by the design alone. The levels reflect the effectiveness of the study design to answer the research question.  The methods used to minimise bias within an individual study (i.e., other than design per se)  An indication of the precision of the estimate of effect reflecting the degree of certainty about the existence of a true effect, as opposed to a effect due to chance
Size of effect	Determines the magnitude of effect and whether this is of clinical importance
Relevance of evidence	The considers the relevance of the study to the specific research question and the context in which the information is likely to be applied, with regard to a) the nature of the intervention, b) the nature of the population and c) the definition of the outcomes.

The evidence was assessed according to the dimensions outlined in **Table 8** above. Each study was also assigned a level of evidence in accordance with the NHMRC (2005) interim levels of evidence (**Table 9**).

The highest level of evidence available is a systematic review of randomised controlled trials, which are considered the study type least subject to bias. Individual randomised controlled trials (RCTs) also represent good evidence. However, comparative observational studies such as cohort and case-control studies or non-comparative case series may often be more readily available. Such studies are often conducted early in the development of a technology, or to detect rare outcomes or outcomes, which develop long after an exposure (e.g., cancer, cardiovascular disease). Nevertheless, these lower levels of evidence remain subject to considerable bias.

**Table 9 NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies**

Level	Intervention
I *	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> <li>• Non-randomised, experimental trial †</li> <li>• Cohort study</li> <li>• Case-control study</li> <li>• Interrupted time series with a control group</li> </ul>
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> <li>• Historical control study</li> <li>• Two or more single arm study ‡</li> <li>• Interrupted time series without a parallel control group</li> </ul>
IV	Case series with either post-test or pre-test/post-test outcomes

Table notes

\* A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of Level II evidence.

† This also includes controlled before-and-after (pre-test/post-test) studies, as well as indirect comparisons (i.e. utilise A vs B and B vs C, to determine A vs C).

‡ Comparing single arm studies i.e. case series from two studies.

Note: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question e.g. level II intervention evidence; Level IV diagnostic evidence; Level III-2 prognostic evidence.

Source: National Health and Medical Research Council (2005)

Even within the levels of evidence stated above there is considerable variability in the quality of evidence. In accordance with NHMRC guidelines, it was necessary to consider the quality of each of the included studies. NHMRC quality checklists (1999) will be employed to appraise included articles (**Appendix D**). For observational studies/surveys the checklist was adopted from applying combined questions from the checklists below (in particular for cohort and case-control studies). The assessment of the quality of the evidence addresses the methods that the studies used to minimise bias and to control for potentially confounding variables. The characteristics and quality of each included study were assessed using a number of quality criteria, as shown in **Table 10**, and in details in data extraction tables for each individual study (**Appendix E**). Studies were rated as good, fair or poor on the quality assessment tool. This rating reflects the internal validity of the studies (a quality criteria checklist is used). A study with a fatal flaw in one or more category of the internal validity is ‘poor’. An example of this would be self-selection to study arms (e.g. decision to purchase one hearing aid rather than another). Ideally, a study that meets all of the quality criteria checklist is ‘good’, whereas a ‘fair’ quality may include studies with different strengths and weaknesses. The answers for each question on the quality criteria checklist would include one of three options:

- adequate/reported
- inadequate
- unknown/not reported.

For each individual answer, the following scores were assigned:

- adequate/reported = 2
- inadequate = 1
- unknown/not reported = 0

Ideally, the best quality option would have all answers as “Adequate/reported” (e.g. for 7 questions on the quality criteria the study will score an overall of  $7 \times 2 = 14$ ).

The following thresholds for study quality have been applied:

- an overall study score of 1-4 is rated poor
- an overall study score of 5-10 is rated fair
- an overall study score of 11-14 is rated good.

**Table 10 Quality criteria for different levels of evidence (NHMRC, 2000b)**

Study type	Quality criteria
Systematic review	<p>Was a clinical question clearly defined?</p> <p>Was an adequate search strategy used?</p> <p>Were the inclusion criteria appropriate and applied in an unbiased way?</p> <p>Was a quality assessment of included studies undertaken?</p> <p>Were the characteristics and results of the individual studies appropriately summarised?</p> <p>Were the methods for pooling the data appropriate?</p> <p>Were sources of heterogeneity explored?</p>
Randomised control trial	<p>Was allocation to treatment groups concealed from those responsible for recruiting subjects?</p> <p>Was the study double-blinded?</p> <p>Were patient characteristics and demographics similar between treatment arms at baseline?</p> <p>Were all randomised participants included in the analysis?</p> <p>Were the statistical methods appropriate?</p> <p>Were any subgroup analyses carried out?</p>
Cohort	<p>How were subjects selected for the 'new' intervention?</p> <p>How were subjects selected for the comparison or control group?</p> <p>Does the study adequately control for demographic characteristics, clinical features and other potential confounding variables in the study design or analysis?</p> <p>Was the measurement of outcomes unbiased (i.e., blinded to treatment group and comparable across groups)?</p> <p>Was follow-up long enough for outcomes to occur?</p> <p>Was follow-up complete and were there exclusions from analysis?</p>
Case-control	<p>How were the cases defined and selected?</p> <p>How were the controls defined and selected?</p> <p>Does the study adequately control for demographic characteristics and important potential confounders in the study design or analysis?</p> <p>Was measurement of exposure to the factor of interest (e.g. the new intervention) adequate and kept blinded to case/control status?</p> <p>Were all selected subjects included in the analysis?</p>

Adapted from NHMRC (2000)

### 1.4b Data extraction

Data was extracted into specifically designed data extraction forms, including information regarding study design, patient characteristics, details of intervention, relevant outcomes, study quality and relevant results. Data was extracted by one reviewer.

Unless otherwise specified, the data that was most adjusted for confounders and/or multiple comparisons is reported. Furthermore, where subgroup analyses were available, these were reported if they were deemed relevant to this review.

Completed data extraction forms containing detailed information regarding study characteristics and quality, together with a brief summary of study results, can be found in **Appendix E**.

### 1.4c Data synthesis

In addition to the level and quality of evidence of individual studies, the review considers the body of evidence in total. This involves consideration of the volume of evidence and its consistency.

Ideally, for systematic reviews with analyses involving evidence from RCTs, a meta-analysis should be performed when appropriate using the methodology of the Cochrane Collaboration (Mulrow & Oxman, 1997). However, this review identified only one pseudo-randomised clinical trial, with the remainder being of various non-randomised designs (including observational), various styles of hearing aids, as well as various outcomes. This heterogeneity in the studies precludes any meta-analysis or quantitative pooling of the results. Data from observational studies is subject to considerable heterogeneity and to biases that vary between studies.

The review therefore, will not be able to present the statistical precision of the estimated effect size, nor a discussion of its proposed clinical significance. The review will look at the data from each study. If possible, data will be presented according to the outcome category (if more than one study has similarity in the outcome and population group). If this is not possible then the review will present the data from each study separately.

Finally, the review considers the relevance of the evidence, both with regard to the applicability of the patient population and the intervention, as well as the relevance to the New Zealand health care setting.

## 1.5 Limitations of the review methodology

This review used a structured approach to review the literature. However, there were some inherent limitations with this approach. All types of study are subject to bias, with systematic reviews being subject to the same biases seen in the original studies they include, as well as biases specifically related to the systematic review process. Reporting biases are a particular problem related to systematic reviews and include publication bias, time-lag bias, multiple publication bias, language bias and outcome reporting bias (Egger *et al.*, 2001). A brief summary of the different types of reporting bias is shown in **Table 11**. Other biases can result if the methodology to be used in a review is not defined *a priori* (i.e., before the review commences). Detailed knowledge of studies performed in the area of interest may influence the eligibility criteria for inclusion of studies in the review and may therefore result in biased results. For example, studies with more positive results may be preferentially included in a review, thus biasing the results and overestimating treatment effect.

**Table 11 Reporting biases in systematic reviews\***

Type of bias	Definition and effect on results of review
Publication bias	The publication or non-publication of research findings. Small, negative trials tend not to be published and this may lead to an overestimate of results of a review if only published studies are included.
Time-lag bias	The rapid or delayed publication of research findings. Studies with positive results tend to be published sooner than studies with negative findings and hence results may be overestimated until the negative trials 'catch up'.
Multiple publication bias	The multiple or singular publication of research findings. Studies with significant results tend to be published multiple times which increases the chance of duplication of the same data and may bias the results of a review.
Citation bias	The citation or non-citation of research. Citing of trials in publications is not objective so retrieving studies using this method alone may result in biased results. Unsupported studies tend to be cited often which may also bias results.
Language bias	The publication of research findings in a particular language. Significant results are more likely to be published in English so a search limited to English-language journals may result in an overestimation of effect.
Outcome reporting bias	The selective reporting of some outcomes but not others. Outcomes with favourable findings may be reported more. For example, adverse events have been found to be reported more often in unpublished studies. This may result in more favourable results for published studies.

\* Adapted from Egger *et al.*, (2001).

Some of these biases are potentially present in this review. Only data published in peer-reviewed journals are included. No attempt was made to include unpublished material, as such material typically has insufficient information upon which to base quality assessment, and it has not been subject to the scrutiny of the peer-review process. In addition, the search was limited to English-language publications only so language bias is a potential problem also. Outcome reporting bias and inclusion criteria bias are unlikely as the reviewers had no detailed knowledge of the topic literature, and the methodology used in the review and the scope of the review was defined *a priori*.

The review scope was developed with the assistance of Ministry of Health staff to support policy and purchasing relevant to New Zealand. All the studies included in this review were conducted outside New Zealand, and therefore, their generalisability to the New Zealand population and context may be limited and needs to be considered. This review was confined to an examination of the efficacy of the interventions and did not consider ethical or legal considerations associated with these interventions. Papers published pre-2000 were not considered as these tended to concern outdated hearing aids as the intervention of interest and comparator.

The studies were initially selected by examining the abstracts of these articles. Therefore, it is possible that some studies were inappropriately excluded prior to examination of the full text article. However, where detail was lacking ambiguous papers were retrieved as full text to minimise this possibility. Reasons for exclusion for every article included in the review are presented in **Appendix C** for transparency.

Data extraction, critical appraisal and report preparation was performed by a single reviewer.

This review has greatly benefited from the advice provided by the Working Party and has been reviewed by HSAC directors. However, it has not been exposed to wider peer review.

The review was conducted over a limited timeframe (November, 2007 – April, 2008). For a detailed description of interventions and evaluation methods, and results used in the appraised studies, the reader is referred to the original papers cited.

## **1.6 Evaluation of economic implications**

In addition to the review of the clinical effectiveness, the current review included a systematic search of the published literature to identify any relevant economic evaluations. Following identification and quality assessment of relevant existing economic evaluations, this review considered the generalisability of their findings to the NZ setting, before finally considering the cost of hearing loss more generally. As the search strategy for this review did not include study type limits, an additional economic search strategy was not required. Instead, the search strategy was re-run on 20 February 2008 for Embase and Medline databases combined with an additional search string to identify a sub-set of economic papers. This string was:

('cost effectiveness analysis'/exp OR 'cost effectiveness analysis') OR ('economic evaluation'/exp OR 'economic evaluation') OR ('health economics'/exp OR 'health economics') OR ('cost minimization analysis'/exp OR 'cost minimization analysis') OR ('cost minimisation analysis') OR ('cost utility analysis'/exp OR 'cost utility analysis') OR ('quality adjusted life year'/exp OR 'quality adjusted life year') OR ('qaly'/exp OR 'qaly') OR ('life year saved')

This additional search identified 99 citations (many of which were already identified by the clinical effectiveness search). Of these citations, there were 15 potentially eligible for inclusion, which were retrieved in full. Additionally individual studies cited by eligible systematic reviews were also retrieved fully. Ultimately, only five studies provided economic information relevant to this report and are discussed in the economic considerations section of this report.

Other literature was reviewed non-systematically in order to consider the cost of hearing loss to New Zealand society more broadly.



## 2. Results

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### 2.1 Overview

Methodological information and results extracted from included studies on digital hearing aids are presented below, first for systematic reviews and meta-analyses, then for original included studies. In this report, eleven systematic reviews were located that were fully retrieved and deemed relevant to the review question, but not one of these systematic reviews, when further assessed, primarily addressed the aims of this review. Reasons for exclusions of these systematic reviews are: Did not specify the type of hearing aids included (Chisolm *et al.*, 2007; Agence 2003<sup>a</sup>; Noble 2006; Mueller 2005; Mueller and Bentler 2005; Bentler 2005), included analogue hearing aid as the intervention or as a comparator (Taylor 2001; Danish Centre 2001; Agence 2003<sup>b</sup>; Taylor and Paisley 2000), or included the wrong population group (Palmer and Grimes, 2005). More detailed information is available in the original papers. For these reasons, a critical appraisal of the systematic reviews (that assessed the cost-effectiveness of hearing aids) was not carried out on these reviews. Alternatively results from ten reviews will be only summarised and narrated in a separate section (results section 2.2). One review assessed hearing aids in a paediatric population (Palmer and Grimes, 2005) so will not be included in the narrative review. Only data relevant to the current review is presented. Although some of these excluded systematic reviews included economic evaluations, the latter were similarly not relevant to the current review.

The search was completed in November 2007, and identified 1563 citations. Of the 333 papers identified as eligible for inclusion in the review and fully retrieved, ten were systematic reviews/ meta-analyses, and eight were original research studies.

### 2.2 Systematic reviews and meta-analyses

#### 2.2a Characteristics

The search strategy identified eleven relevant reviews. As discussed above, study characteristics will not be described, but the following section summarises the results and conclusions from each of the ten systematic reviews. Reviews will be presented by the date of publication (the most recent will be presented first). For more detailed information on the data and/or methods used within these reviews or the individual studies included, the reader should refer to the original papers.

#### 2.2b Results

The systematic review and meta-analysis by **Chisolm *et al.*, (2007)** presented the final report of the American Academy of Audiology Task Force on the Health-Related Quality of Life (HRQoL) Benefits of Amplification in Adults. The authors used both qualitative and quantitative systematic review of the available research literature and assessed the evidence pertaining to the nonacoustic benefits in using hearing aids in adults. In particular the review assessed the use of hearing aids for improving HRQoL for adults with sensorineural hearing loss (SNHL).

Using various search strategies and various databases, the review considered assessing randomised controlled trials, quasi-experimental, and non-experimental pre-post test designed studies that included new or previous hearing aid users of at least 18 years of age with normal cognitive function, independent or assisted living conditions, and sensorineural hearing loss with unaided severity ranging from mild to profound. All studies meeting the inclusion criteria were considered regardless of the type of hearing aid style (e.g. behind-the-ear, in-the-ear, completely-in-the-ear, or others), signal processing circuitry (e.g. analogue or digital), microphone technology (e.g., omnidirectional or directional), or fitting strategy (e.g. monaural versus binaural) they employed. Sixteen studies were included; they used nine different outcome measures. The majority were not controlled studies. A random-effects meta-analysis showed differential results for generic versus disease-specific HRQoL measures for within- and between- subject designs. Thirteen of the sixteen studies included were Level III evidence (non-analytic studies such as case reports, or case series). Results for disease-specific outcomes in Level III studies support a conclusion that hearing aids provide a small to medium effect on HRQoL.

This systematic review with meta-analysis concluded that hearing aid use improves adults' health-related-quality-of-life (HRQoL). This was shown by the reduction in psychological, social and emotional effects of sensorineural hearing loss (SNHL), an insidious, potentially devastating chronic health condition if left unmanaged. However, the strength of the evidence was limited by the quality of the studies included in the review; therefore, authors suggested that future research should attempt to use RCT designs and generic HRQoL measures that are sensitive to the effects of and treatments for hearing loss.

The systematic review by **Noble (2006)** looked at assessing the literature on self-assessed outcomes from bilateral and unilateral hearing aid fitting. The review included the studies cited in a Swedish report about comparing two hearing aids to one. It also included other studies from data-base searches. Fourteen studies were identified in the review; however, three of them were retrospective surveys of clinic clients several months or years after fitting with one versus two hearing aids; and another one involved small number of people with a second bone-anchored hearing aid. Eight were follow-up studies, and two used a cross-over design.

Self-report literature on one versus two hearing aid effects showed considerable mix of samples, purposes, procedures, and settings. However, authors predicted that where there is no contraindications (such as binaural interference), in moderate-to-severe bilateral hearing loss listening with two hearing aids will be preferred. It may further be predicted that for people whose lives include critical listening tasks in dynamic settings, bilateral hearing aid fitting will also be preferred profile. Among people with milder loss, and/or typically facing less complex listening tasks, it is less likely that two hearing aids will be used.

**Bentler (2005)** reviewed systematically the effectiveness of directional microphones and noise reduction schemes in hearing aids. In an attempt to answer the question of whether experienced or trained users of hearing aids with directional microphones report better amplification outcomes in daily life than users of hearing aids without a directional microphone Bentler (2005) searched Medline, ComDiDome, and the Cochrane Database of Systematic Reviews. Studies that involved children, multiple

disabilities, cochlear implants and middle ear implants were excluded. Nine studies were included in the review; they were published between 1999 and 2005 and involved between 11-105 subjects. Satisfaction with directional microphones was assessed using an overall scale or by using the Satisfaction with Amplification in Daily Life (SADL) inventory. The review looked at evidence drawn from randomised controlled trials, non-randomised interventions, and descriptive studies. The authors concluded that modest evidence supports the effectiveness of using directional microphones. For the noise reduction feature, the evidence is unclear, as only two studies were identified (both of cross over design) that involved 16 and 40 subjects. Only three individual items of one (Abbreviated Profile of Hearing Aid Benefits) APHAB subtest (Aversiveness AV) supported the effectiveness of that feature. In the same study, the authors concluded that there was no extra benefit from the combined use of directional microphones and noise reduction over directional microphones alone.

A review by **Mueller and Bentler (2005)** attempted to answer the following question: Are the clinical measurements of loudness discomfort level (LDL) for adult patients predictive of aided satisfaction of loudness for high inputs in the real world? Only three articles met the inclusion criteria, the level of evidence was weak (Level IV). Authors concluded that the evidence tends to support the use of clinically measured frequency-specific LDLs for selecting the real ear maximum output of hearing aids. However, the level of evidence prevents making a strong recommendation supporting this clinical procedure.

In another review, **Mueller (2005)** examined the evidence available that supports the use of specific gain requirements for hearing aid fitting. Specifically the review looked at whether real-world outcome measures from adult patients show a preference of the gain prescribed by a specific prescriptive fitting procedure. The search strategy aimed initially to assess all articles that have studied the prescriptive fitting of hearing aids or hearing aid use gain. The review identified eleven studies, with eight of them supported gain similar to that prescribed by the National Acoustic Laboratories (revised/or profound) [NAL-R] or NAL-RP methods. Three studies supported prescribed gain less than the NAL-R or NAL-RP. There was no evidence that gain greater than that prescribed by the NAL methods should be used. The level of evidence was moderate, and several of the studied used technology that is not commonly used today. Even in the studies using “modern technology”, features such as digital noise reduction and low-level expansion were not implemented.

A technical report produced by the Agence d'évaluation (**Agence 2003<sup>a</sup>**) assessed the clinical efficacy of directional-microphone hearing aids. The review identified 24 studies published between 1991 and 2001 that present data comparing hearing aids with different directionality (e.g., omnidirectional vs directional) worn by the same subjects, following a crossover design, with or without randomisation. Results from the studies showed that hearing aids with directional properties provide speech-intelligibility benefit in noisy environments. The authors stated that this advantage is optimal in listening conditions where the noise is behind and the speaker in front of the hearing-impaired person in an environment with low reverberation. In listening situations more representative of daily reality, where noise is diffuse and the room reverberant, this advantage decreases to the point of becoming comparable to that provided by conventional hearing aids with omnidirectional microphones.

Authors concluded that efficacy of single-microphone solutions and approaches based on a microphone require additional controlled trials. Dual-microphone approaches can be considered “accepted” technologies but only in optimal listening conditions, when the speaker and the noise are diametrically opposite each other in rooms with low reverberation. The application of this technology in other conditions reduces (sometimes significantly) their effectiveness. Finally, eligibility requirements for devices with the directionality option must take into account the candidate’s physical and cognitive abilities to use the directional properties effectively.

The other technical report by the Agence d’évaluation (**Agence 2003<sup>b</sup>**), assessed the efficacy of programmable analogue hearing aids. This type of hearing aids does not fulfil the inclusion criteria of our HSAC systematic review. Therefore, conclusions are not relevant and will not be summarised from this report.

In two publications of the same systematic review by **Taylor *et al.*, (2001)** and **Taylor & Paisley (2000)** the clinical and cost-effectiveness of digital hearing aids were assessed in comparison to other forms of hearing aid technology and in particular the analogue-based hearing aids. The review identified sixteen studies published between 1987 and 1999, eight of the studies assessed the clinical effectiveness and the other eight studies assessed the cost-effectiveness of the digital hearing aids. Of the clinical effectiveness studies that compared digital to non-digital hearing aids only one was a randomised controlled trial, the other seven were randomised crossover trials. The majority of the studies were of small sample size (sample ranges between 24 and 200 participants), and trial quality assessment indicated poor methodological quality. In nine out of 13 outcomes assessed, there was no evidence of a significant difference in either laboratory scores (nine out of 13 outcomes assessed) or user function/quality of life scores (six out of nine outcomes assessed) between digital and non-digital hearing aids. When pooled across studies the review found no significant difference in patient preference for digital hearing aids compared to control aids (relative risk 1.93; 95% CI 0.7-5.35).

In terms of cost-effectiveness, only three economic evaluations were identified and the review found no studies directly comparing digital to non-digital devices. Two of these studies did not fulfil the inclusion criteria for the HSAC systematic review (Joore 1999, and Newman & Sandridge 1998). The third study is relevant to our review and is included in the economic section of this HSAC review (Mulrow *et al.*, 1990).

The authors concluded that the review provides no significant evidence of the clinical benefit of digital devices compared to analogue-based aids. However, the studies were of small sample sizes and may have reflected a lack of power rather than a true evidence of a lack of effect. There are currently no direct ‘head to head’ cost utility studies comparing digital versus analogue hearing aids. The incremental cost effectiveness of digital devices (compared to analogue devices) is highly sensitive to their incremental cost and could range from less than £10,000 to more than £20,000 per QALY. It was elucidated that these results are difficult to generalise to current UK practice as the analogue aids and types of fitting in the trials are not those typically used in the NHS.

The literature review by the **Danish Centre for Evaluation and Health Technology Assessment (2001)** and the survey performed in this project aimed specifically at answering questions on definition, assessment, and prevalence of hearing impairment in adults and at exploring the current organisation of hearing services in the Nordic countries and in the United Kingdom. One of the aims that the review looked at was hearing aid outcome. Five scientifically valid studies fulfilling the applied criteria were included. Three out of these were double-blind, and the remaining two were single-blind. All studies included adult subjects with sensorineural hearing impairment. These studies did not provide uniform data in favour of non-linear amplification, but showed some subject preference for the newer technology. Authors concluded that although many of the studies excluded in the literature search may have clinical relevance at specific sites, they cannot be generalised into larger populations. Even fewer studies correlate rehabilitation outcome with the degree of hearing impairment, disability or handicap. Therefore, conclusions could not be drawn regarding the degree of hearing impairment and the effects of amplification.

## 2.3 Original primary studies

### 2.3a Characteristics

The search identified eight eligible primary research studies. Characteristics of the primary studies included in this review and comparisons are described in **Table 12**.

Studies used various designs and comparisons, some were uncontrolled, or used historical controls, or within-group controls and presented data for a case series of patients receiving digital hearing aids. The majority have pre/post designs, three obtained data in a prospective fashion (including the pseudo-randomised study) (Hill *et al.*, 2006; Folmer and Carroll 2006; Shi *et al.*, 2007), and five used retrospective review of data and design (Taylor 2006; Gnewikow and Moss 2006; Kochkin, 2000; Hällgren *et al.*, 2005; Henkin *et al.*, 2007). In many of the studies, participants were their own controls. All the studies were conducted outside New Zealand. Six studies were based in the United States (Shi *et al.*, 2007; Folmer *et al.*, 2006; Taylor, 2006; Gnewikow and Moss, 2006; Kochkin, 2000; Hill *et al.*, 2006); the other two were based in Sweden (Hällgren *et al.*, 2005) and Israel (Henkin *et al.*, 2007). There were 1,720 participants in total, with sample sizes ranging from 24 to 914, follow up ranging from one month to 48 months, and participants age ranging from 21 to 89 years. The quality of the included studies was good in two studies (Shi *et al.*, 2007; Folmer and Carroll, 2006), fair in five studies (Taylor, 2006; Gnewikow and Moss 2006; Hällgren *et al.*, 2005; Henkin *et al.*, 2007; Hill *et al.*, 2006) and poor in the remaining one study (Kochkin, 2000). Five studies had a separate control group (Shi *et al.*, 2007; Folmer and Carroll, 2006; Gnewikow and Moss, 2006; Kochkin, 2000).

All included studies containing relevant efficacy data are presented below. The studies were variable in their aims, designs and outcomes measured. The only study that used randomisation in its design was in fact a study that assessed and compared two fitting protocols for hearing aids rather than the effectiveness of two different hearing aids. This study also did not use an adequate randomisation procedure and used a pseudo-randomised design, therefore was assigned a lower level of evidence (III-1).

The study by **Shi *et al.* (2007)** is a pseudo-randomised controlled single-blind design which compared the benefits and user satisfaction of two fitting protocols for hearing aids. The design included a pre and post fit comparison for each protocol, that is a within group comparison. Method of randomisation was alternating in which the first participant who consented to participate in the study was assigned one method (A) then the following participants were alternately assigned to Group B and A when they consented to be in the study. The methodological quality of the study was considered good; however, the study sample was small.

The study by Folmer (**Folmer and Carroll, 2006**) aimed to assess the long-term changes in tinnitus severity exhibited by patients who used hearing aids or ear-level sound generators as part of a tinnitus management programme. The study analysed data from mailed questionnaires to 150 patients six to forty-eight months following their initial appointment. Fifty-patients purchased and used hearing aids, 50 patients purchased and used in-the-ear sound generators for an average of 18 months after their initial appointment, and 50 patients did not use ear-level devices. All hearing aids were digital and programmable from variety of major manufacturers. Methodological quality of the study was considered good.

The study by **Taylor (2006)** reported on two patient survey studies. The study used the MarkeTrake survey to answer the question of whether experienced and new hearing aid users would benefit more from the use of an open canal hearing aid than from the older non-open canal hearing aid use. Both studies used self-report outcome measures to assess real-world benefit and satisfaction of OC users with people wearing non-OC products. Survey questionnaires were administered 1-3 months post-fitting. The methodological quality of the study was considered fair, with a retrospective design, and selected patients.

In a retrospective study, **Gnewikow and Moss (2006)** used questionnaires to assess the satisfaction experienced by participants fitted with open canal hearing aids as compared to participants using non-open canal hearing aids. The methodological quality of the study is fair; the study used selected patients, and did not provide data on demographic or baseline characteristics of study participants.

In another retrospective study that used the MarkeTrak questionnaire, Kochkin reported the results from the MarkeTrak survey. The survey is based on 45 ratings of customer satisfaction with hearing instruments and hearing health services (**Kochkin, 2000**). Specific manufacturers of digital hearing instruments were asked to recruit dispensing professionals to send out Knowles MarkeTrak surveys to consumers of digital hearing instruments within the past year. Four items are behavioural in nature (hours worn, extent to which the consumer would recommend hearing aids, recommend the dispenser and repurchase the current brand of hearing aid). One item is a quality-of-life rating and 40 items are rated on a five-point Likert scale taking the values “very dissatisfied,” “dissatisfied,” “neutral,” “satisfied” and “very satisfied.” This study is poor in methodological quality as it has the potential for bias (selection).

The study by **Hällgren *et al.*, (2005)** reports on the effect of hearing aid use on word recognition and cognitive functions important for speech understanding, in silence as well as in two different noises with different cognitive involvement. This study involved two groups of patients (young group aged 25-45 years, and an older group

aged 65-80 years). All patients were with moderate to severe sensorineural hearing loss who were experienced hearing aid users of at least nine months and used bilaterally fitted hearing aids. Although the study is of fair methodological quality the study involved very small sample size.

The study by **Henkin *et al.*, (2007)** also used similar methodological design to the previous studies. They used the same patient group in comparing the speech recognition in noise in two aided situations. Patients were 28 individuals with sensorineural hearing loss who were experienced bilateral hearing aids users (between 1 and 32 months). Speech in noise tests were compared for both bilateral situation, and aided right ear and aided left ear among each individual. Although this study is fair in its methodological quality the use of hearing aid was based on the participants' preferences and dexterity, and study sample was very small.

**Hill *et al.*, (2006)** reports on the findings from a 30-day trial of using hearing aids. The study used a survey questionnaire consisting of 8-questions enquiring about the satisfaction with the new digital hearing aids. Ninety-one patients with severe to profound asymmetric hearing loss due to various reasons used either digital contra-lateral routing of signal (CROS) or bilateral contra-lateral routing of signal (BiCROS) hearing aids. Follow-up was conducted two weeks after the trial, then four weeks by the mailed questionnaire, and two weeks after by phone for those not responding to the questionnaire. The study was rated of fair quality; although the study used within-group comparison (used the same patient group).

**Table 12 Study characteristics: effectiveness of digital hearing aids**

Citation	Study type Study quality	Population	Intervention	Comparator	Outcomes
Intervention Level III-1 evidence (A pseudorandomised controlled trial, i.e. alternate allocation or some other method)					
Shi <i>et al.</i> , (2007)  (USA)	Pseudo-RCT Single-blinded (participants)  Follow-up 45 days and 12 weeks for both groups  Good	Participants who came to Gebbie Hearing Clinic at Syracuse University  Patients who were recommended midlevel digital BTE or ITE hearing aid during the recruitment period for this study invited to participate  N=32	Hearing aids protocol A (electroacoustic analysis, real-ear measures, and hearing aid adjustments based on users' comments)  (n=16)	Hearing aids protocol B (all of protocol A and a speech-in-noise test, loudness discomfort levels, and aided loudness)  (n=16)	Abbreviated Profile of Hearing Aid Benefit (APHAB)  Satisfaction with SADL
Intervention Level III-2 evidence (A comparative study with concurrent controls)					
Folmer and Carroll (2006)  (USA)	Prospective  Questionnaire  Median follow-up 6-48 m  Good	Consecutive patients with tinnitus  N=150	Hearing aids (one or two)  (n=50)	One or two in-the-ear (ITC) sound generators (n=50)  No ear-level device (n=50) but used other forms of acoustic therapy (e.g. add sound [music, relaxation CDs] to quiet environments to obtain relief from tinnitus)	Loudness of tinnitus (1-10 self-rating scale)  Tinnitus Severity Index TSI (12 questions)  Abbreviated version of Beck Depression Inventory (ABDI)  Further question (did the device help your tinnitus?)

**Table 12 Study characteristics: effectiveness of digital hearing aids (*continued*)**

Citation	Study type Study quality	Population	Intervention	Comparator	Outcomes
Taylor (2006) USA	Comparative retrospective		Digital hearing aids (open canal)	Digital hearing aids (non open canal)	
	(Study A) Experienced hearing aids users 1-3m post-fit  Fair	(Study A) Two groups of experienced hearing aid users (bilateral)  <b>n= 54</b>	(Study A) Group 1 experienced hearing aid users wearing Open Canal (OC) devices for the first time  N=27	(Study A) Group 2 experienced hearing aid users of non-open Canal recently fitted with another pair of non-OC devices  N=27	(Study A) Self reports of satisfaction through Question 36 from the MarkeTrak survey
	(Study B) New hearing aids users 1-3m post-fit  Fair	(Study B) Two groups of participants recently fitted with hearing aids for the first time  n= 35  N=89	(Study B) Group 1 participants wearing OC devices for the first time  N=22	(Study B) Group 2 participants wearing non-OC products for the first time  N = 13	(Study B) Abbreviated Profile of Hearing Aid Benefit (APHAB)  International Outcome Inventory for Hearing Aids (IOI-HA)
Intervention Level III-3 evidence (A comparative study without concurrent controls)					
Gnewikow and Moss (2006)  (USA)	Retrospective 1-year period  Fair	Patients with high frequency sensorineural hearing loss who purchased hearing aids from July 2004 to July 2005  Vanderbilt Bill Wilkerson Centre  N= 338	Open canal hearing aids (GN ReSound Air) n=97	Traditional closed canal (non-OC) hearing aids n= 241 (106 wore BTE, 54 wore ITE, 41 wore ITC & 40 wore CIC)	Mailed 3 measures: SADL  IOI-HA  Questionnaires (133/338) completed the questionnaires

**Table 12 Study characteristics: effectiveness of digital hearing aids *continued***

Citation	Study type Study quality	Population	Intervention	Comparator	Outcomes
Kochkin, (2000)  (USA)	Survey questionnaire  Retrospective Past year  Poor	Consumers of digital hearing aids within the past year  N= 914	Digital hearing aids  Single-Mic n=200: BTE (0%), ITE 44%, and ITC (56%),  Multiple Mic n=296: BTE (69%), ITE (31%), ITC (0%)  N=496	MarkeTrak norm group  N=418 hearing instruments between 3-12 months of age, excluding CIC hearing aids  Derived from the Knowles MarkeTrak V database (historical controls)  N=418	Customer satisfaction and customer dissatisfaction
Intervention Level IV evidence (Case series with either post-test or pre-test/post-test outcomes)					
Hällgren <i>et al.</i> , (2005)  (Sweden)	Pre and post study (with and without hearing aids)  Retrospective  Fair	Patients with sensorineural hearing loss. Used hearing aids for at least 9m  N=24	Hearing aids (Oticon Digifocus II) used bilaterally  N=24 (20 relevant to review as used digital hearing aids)	No hearing aids In both silent or noisy backgrounds  N=same patients with no digital hearing aids	Speech recognition in noise and in silence  Perceived effort scores
Henkin <i>et al.</i> , (2007)  (Israel)	Pre and post study (same patients with bilateral hearing aids then with unilateral hearing aids)  Retrospective  Fair	Patients with sensorineural hearing loss. Used bilateral hearing aids between 1 and 12 m (n=21) and 14-32 m (n=7)  N=28 patients	Bilateral hearing aids  N=28	Unilateral hearing aids (based on the participant preferences and dexterity)  N=same patients with: Aided right ear and Aided left ear (N=28)	Speech recognition in noise

**Table 12 Study characteristics: effectiveness of digital hearing aids (*continued*)**

Citation	Study type Study quality	Population	Intervention	Comparator	Outcomes
Hill <i>et al.</i> , (2006) (USA)	Pre and post study  Prospective  Using Survey questionnaire (30-day trial of hearing aids) then followed by questionnaire at 2, 4 wks. and further 2 wks with telephone)  Fair	Patients with severe to profound asymmetric hearing loss and poor speech discrimination scores  N= 91	Digital contra-lateral routing of signal (CROS) or bilateral contra-lateral routing of signal (BiCROS) hearing aids  N=91	Previous aided experience/device  Same patients comparing satisfaction with their new device  N=91	Satisfaction By 8-questions questionnaire

Abbreviations :APHAB, abbreviated profile of hearing aid benefit; BTE, Behind the ear; CIC, completely in the canal; IOI-HA, international outcome inventory for hearing aids; ITC, in the canal; ITE, in the ear; Mic, microphone; m, month; OC, open canal; SADL, Satisfaction with Amplification in Daily Life.

### 2.3b Results

Results from eight primary studies are presented below (section 2.3b (i to v)) and (**Tables 13-20**), with more detailed data extraction tables shown in (**Tables 24-31**). The studies presented various outcome measures, five studies measured satisfaction (and dissatisfaction) (Shi *et al.*, 2007; Taylor, 2006; Gnewikow and Moss, 2006; Kochkin, 2000; Hill *et al.*, 2006), two measured benefit of hearing aids using the abbreviated profile of hearing aid benefit (APHAB) (Shi *et al.*, 2007; Taylor, 2006), two studies measured the international outcome inventory for hearing aids (IOI-HA) (Taylor, 2006; Gnewikow and Moss, 2006), two measured speech perception/speech recognition in noise/or silence (Hällgren *et al.*, 2005; Henkin *et al.*, 2007), and one measured loudness of tinnitus (Folmer and Carroll, 2006).

#### 2.3b (i) Satisfaction (and dissatisfaction)

Five studies (total number of participants N = 1429) measured satisfaction (and dissatisfaction) with hearing aids using the satisfaction with amplification in daily life (SADL) or customer satisfaction questionnaires. The results of the five studies (Shi *et al.*, 2007 (n=32); Taylor, 2006 study A (n=54); Gnewikow and Moss, 2006 (n=338); Kochkin, 2000 (n=914); Hill *et al.*, 2006 (n=91)) are summarised in **Tables 13, 15, 16, 17 and 20** respectively. The tools used to assess satisfaction and dissatisfaction are:

SADL, which is the Satisfaction with Amplification in Daily Life. It is a self-report inventory designed to quantify patient satisfaction. The questionnaire yields a global satisfaction score as well as a profile of subscale scores, which address Positive Effects (PE), Service and Cost (SC), Negative Features (NF), and Personal Image

(PI). The profile of subscale scores depicting different domains of satisfaction is a unique feature of the SADL inventory. It consists of 15 items written at a seventh grade reading level and typically requires less than 10 minutes to complete. The subscale Positive Effect consists of six questions, covering improved communication, sound quality, and psychological aspects of hearing aid use. The Negative Features subscale consisted of three questions on background interferences, acoustic feedback, and problems with the telephone. Three questions on the appearance of the aid and the user's perception of the reaction of other people comprised the Personal Image subscale. The Service and Cost subscale also consisted of questions on provider competence, aid reliability, and cost evaluation.

The Amplifiron Satisfaction Survey is a non-standardised, 13-question survey that attempts to quantify satisfaction with various product features and performances. This survey differs from the MarkeTrak questions in that one question quantifies overall satisfaction with the current hearing aids.

MarkeTrak survey consists of 45 ratings of customer satisfaction with hearing instruments and hearing health services. Four items are behavioural in nature (hours worn, extent to which the consumer would recommend hearing aids, recommend the dispenser and repurchase the current brand of hearing aid), one item is a quality-of-life rating and 40 items are rated on a five-point Likert scale taking the values "very dissatisfied," "dissatisfied," "neutral," "satisfied" and "very satisfied". In addition to an overall hearing aid satisfaction rating the survey measures satisfaction with eight product features, 12 performance/value factors, six dispenser attributes and in 13 listening situations. Question 36 from the MarkeTrak questionnaire consists of 23 sub-questions that measure self-reports of satisfaction for a number of product features. These questions used a 5-point Likert scale. A rating of 5 means the patient strongly prefers the new hearing aid, whereas a rating of 1 means the patient strongly prefers the feature of the old hearing aid.

Survey questionnaire for the CROS and BiCROS hearing aids, is made up of 8 questions, responses were quantified on a scale from 1 (very dissatisfied) to 5 (very satisfied). The questions were:

- Your experience with your new CROS/BiCROS hearing aid has been enjoyable?
- You are able to locate where sound is coming from?
- You are able to understand speech in background noise, groups, and restaurant better?
- You are able to hear better in the car?
- You are able to hear better using the noise-reduction button in noise?
- Are you satisfied overall with your new CROS/BiCROS?
- Would you recommend a CROS/BiCROS to other hearing-impaired people?

The five studies are presented below:

**Shi *et al.*, (2007)** (N=32) measured the satisfaction with amplification in daily life (before and after fitting hearing aids) to compare two hearing aid fitting protocols.

Participants were alternately assigned to fitting the hearing aid using either Protocol A (n=16) or Protocol B (n=16). There were no significant differences between the two

groups in terms of age ( $U = 271.500$ ), or degrees of hearing loss ( $p > 0.05$ ). However, group B showed poorer thresholds than group A and this difference approached statistical significance at 2000 Hz ( $t = -1.962$ ,  $p = 0.055$ ). In terms of hearing aids, 11 of the 16 participants in group A and 10 of the 16 participants in group B were fitted with hearing aids for the first time. Hearing aid experience was comparable among the other participants in the two groups (range 5-20 years). In terms of hearing aids make, model and style these were not controlled for but were comparable between the two groups (they all have three programs and similar standard features such as directional microphone, feedback cancellation, digital noise reduction, and telecoil). The majority of hearing aids used in the study were GN ReSound make (11 in group A, 10 in group B), behind-the-ear style (12 participant in each group), and were worn on both ears (12 in group A, 13 in group B).

Data were collected over six visits to the clinic including pre-fitting consultation, hearing aid fitting, three post-fitting follow-ups within the 45-day trial period, and one last visit scheduled at three months post-fitting.

In addition to a review of pure-tone and speech audiometric test results during the two-hour pre-fitting consultation, each participant completed the unaided section of the APHAB questionnaire. Different types of hearing aid styles, models, and features available for the participant's degree of loss were also discussed with the participant; and warranty and trial period information were provided. For group B two more tests were conducted during the pre-fitting consultation, the QuickSIN and the LDL.

For post-fitting follow-ups, participants were scheduled to return to the clinic every two weeks after the initial hearing aid fitting. Therefore, they were scheduled for three visits within their 45-day trial period. Hearing aid adjustments were made on the basis of the participants' comments. Group B were given two additional tests: the QuickSIN and aided loudness tests. At the last of the three post-fitting visits, both groups were asked to complete the aided section of the APHAB and SADL. The clinicians were not present while these questionnaires were being filled out.

Participants were asked to come back to the clinic at three months following the fitting, to complete these questionnaires again, to test the estimate of longer term benefit and satisfaction. For participants who could not return to the clinic, the questionnaires were mailed to them.

Only 11 in group A, and 14 in group B completed the questionnaires three months after hearing aid fitting.

Group A participants' scores on the services and costs (SC) and negative features (NF) subscales of the SADL were significantly lower at three months compared to 45 days (SC:  $t = 2.701$ ,  $p = 0.022$ ; NF:  $t = 2.250$ ,  $p = 0.048$ ). The Wilcoxin rank test was used to analyse the personal image (PI) subscale scores because the distribution of the data failed the normality test. The PI score was significantly lower for Group A participants at the end of three months compared to 45 days ( $W = -34.00$ ,  $p = 0.016$ ).

In summary: SADL scores decreased between 45 days and three months for protocol A which included an electroacoustic analysis, real-ear measure, and hearing aid adjustments based on users' comments.

**Gnewikow and Moss (2006)** (N=338) used a retrospective analysis to determine whether significant differences were present in hearing aid outcomes for patients with high-frequency sensorineural hearing losses fitted with traditional and open canal (OC) hearing aids. Three hundred and thirty eight (338) adult hearing users at the Vanderbilt Bill Wilkerson Centre with normal/mild sloping hearing loss who purchased hearing aids from July 2004 to July 2005 were recruited. Of the participants 97 had GN ReSound Air OC hearing aids, and the remainder were fitted with various closed canal devices (of various styles and technologies).

The study used three measures of hearing aid outcome, the SADL, the IOI-HA and an empirically designed questionnaire (refer to other hearing aid outcomes below). The three measures were mailed to the potential participants for completion and return in a postage-paid envelop. Also included was a cover letter providing details of the study to recipients and informing them that completion and return of the questionnaires would serve as informed consent to include their results in this study.

Of the 133 who completed the questionnaires, 41 were OC users, 92 non-OC users, of which 49 used BTE, 17 ITE, 13 ITC and 13 CIC users.

Results from the study showed that participants fitted with OC hearing aids were less dissatisfied on the Negative Features of the SADL subscale than did users fitted with traditional amplification (mean score for OC group 4.36 compared to non-OC group 3.86,  $F=2.985$ ,  $P>0.05$ ).

**Taylor (2006)**, reported on the use of The Amplifon Satisfaction Survey from two separate patient-survey studies which were conducted through Amplifon USA affiliate clinics. Both studies aimed to assess real-world benefit and satisfaction of open canal users as compared to non-open canal users using self-report measures. One study (A) involved 54 adults experienced hearing aid users divided in two groups (one group were recently fitted with OC devices whereas the other group had been recently fitted with binaurally new non-OC hearing aids). The other study (B) similarly compared both OC and non-OC fittings but among 35 adults who were first-time hearing aid users (new users). Persons with greater than 45-dB loss at 500 Hz and/or greater than 85 dB at 4000 Hz were excluded from both groups.

The study of the experienced users used the MarkeTrak survey along with another satisfaction survey (the Amplifon Satisfaction Survey), whereas the study among the new hearing aid users (Study B), administered the APHAB and IOI-HA 1-3 months post-fitting.

Experienced hearing aid users **study A** (n=54): Using Question 36 of the MarkeTrak Satisfaction Survey to compare satisfaction rates between the two groups of both OC and non-OC groups, the mean satisfaction scores across all 23 product features surveyed showed a preference for the new hearing aids over their old ones. Five features were rated significantly higher by the OC group than the non-OC group, these are: sound of own voice, sound of chewing/swallowing, wind noise, visibility to others, and localization.

Results from this survey indicate that both groups of subjects preferred their new hearing aids to their old ones (ranked by the degree of difference between the two

groups for each of the sub-questions). Also overall satisfaction was higher with OC group (mean 3.95) as compared to the non-OC group (mean 4.41).

Results from the studies showed that there is little real-world evidence indicating that experienced hearing aids users receive greater benefit and satisfaction from OC devices than users of non-OC devices. While both groups of experienced hearing aid users, on average, preferred their new hearing aids to their old ones there were some product and performance features that the OC group favoured more strongly than the non-OC users did.

**Kochkin (2000)** (N=914), is a cross-sectional (retrospective) study of customer satisfaction and dissatisfaction that used the MarkeTrak questionnaire. The study documented results from a survey of manufacturers of digital hearing instruments. Specific manufacturers were asked to recruit dispensing professionals to send out Knowles' MarkeTrak surveys to consumers of digital hearing instruments within the past year. Dispensers were given detailed instructions for selecting unbiased samples of customers to participate in the study as well as a package containing a letter from the manufacturer, a MarkeTrak survey and a self-addressed envelope for returning the survey.

All surveys were conducted in the USA from a single European based manufacturer. From 500 customer satisfaction surveys returned, 200 were single omnidirectional microphone digital hearing aids, and 296 were multiple digital hearing aids. Single microphone hearing aids were either in-the-ear style (44%) or in-the-canal style (56%). Whereas the majority of multiple microphone hearing aids (69%) were behind-the-ear style and 31% were in-the-ear style.

Data from the returned surveys were compared to the MarkeTrak Norm group of 418 (hearing aids between 3-12 months of age, excluding CIC hearing aids) which were derived from the Knowles MarkeTrak V database.

Results were presented as customer satisfaction/dissatisfaction for the MarkeTrak, single microphone and multiple microphone digital samples and also as customer satisfaction difference scores between each of the samples.

Results reported from the survey showed that multiple microphone digital hearing aids were rated significantly higher than single microphone digital aids on overall satisfaction (78% versus 64%), quality of life (82% versus 72%) and hours worn per day (11.9 versus 10.8). The author concluded that the hearing aid style is unlikely to account for the significant differences in the overall satisfaction between the single and multiple microphone digital samples.

**Hill et al., (2006)** (N=91) The prospective study by **Hill et al., (2006)** aimed to determine whether technological advancements in digital signal processing have improved the efficacy of digital contra-lateral routing of signal (CROS) and bilateral contra-lateral routing of signal (BiCROS) hearing aids. The CROS\BiCROS hearing aid device picks up sound from the deaf ear and transfers it to the better hearing ear so the brain thinks that hearing is from the deaf ear. They have been used for patients with unilateral hearing loss in an attempt to restore the head shadow effect and improve sound localisation. However, their acceptance was limited by performance factors such as ineffectiveness in high ambient noise and distortion.

The study conducted a case review and administered a survey questionnaire to compare the satisfaction with the new device of 104 patients with severe to profound asymmetric hearing loss (unilateral) and poor speech discrimination scores (<40% in the worse ear). Thirteen patients were excluded as they did not meet eligibility criteria, and the remaining 91 adult patients (mean age 70.6) were made up of 43 men and 48 women. Various causes of hearing loss were reported (including Ménière's disease, acoustic neuroma, autoimmune inner ear disease, temporal bone fracture, and noise exposure).

Patients were fitted with either a corded contra-lateral routing of signal device (n=9) or with bilateral contra-lateral routing of signal device (n=82); respectively, 73 of the devices and 9 of the devices were cordless. The selection of the specific type of hearing aid was based on audiometric data, configuration of hearing loss, availability, and patient preference.

Two follow-ups were conducted, first was after one week post-fitting, and the second was two weeks after the end of the free 30-day trial. Mailed survey questionnaires consisting of 8-questions were mailed to all patients, and four weeks later follow-up questionnaires were mailed to patients who had did not respond to the first questionnaire. This later was followed up (two weeks after) by a telephone call if still participants did not respond. Responses to questions were rated as scale 1 (very dissatisfied) to scale 5 (very satisfied).

Satisfaction with the new generation of digital CROS and BiCROS hearing aids was high, as was shown by the percentage of patients who accepted and kept their hearing aids after the trial (66.7% for CROS and 73.2% for BiCROS). However, only 51.5% of patients who accepted their hearing aids actually completed the questionnaire, and 36% of those who returned their hearing aids completed the questionnaire. Of the 48 remaining, 29 were lost to follow-up and 19 declined to participate. Therefore, the true acceptance rate for all patients falls from 72.5% to 67% (61/91).

The authors mentioned that this satisfaction, which ranged for both types from 33.3% to 78.1%, was higher than acceptance rates reported in studies of analogue devices (10-20%). The study was limited by the low response rate 47.2% (43/91), and the validity and reliability were not accounted for.

### 2.3b (ii) Benefit of hearing aids

Two studies (total number of participants = 67) have used the abbreviated profile of hearing aid benefit (APHAB) to measure any improvement in hearing aid benefit (Shi *et al.*, 2007; Taylor, 2006).

The abbreviated profile of hearing aid benefit (APHAB) is a subset version of the 66-item profile of hearing aid benefit (PHAB) and consists of 24 items of 4 subscales designed to quantify the disability associated with hearing loss and the reduction of disability achieved with using a hearing aid (Cox, 1995).

These items are scored in four 6-item subscales, three of which (Ease of Communication EC (EC), Reverberation (RV), and Background Noise (BN)) address speech understanding in various everyday environments. The fourth subscale,

Aversiveness of Sounds (AV) quantifies negative reactions to environmental sounds. A benefit score is computed by comparing unaided and aided APHAB scores.

The results of the two studies (Shi et al 2007 n=32, and Taylor 2006 study B, n=35) are summarised in (Tables 13 and 15). The two studies are presented below:

**Shi et al., (2007)** (N=32) measured the abbreviated profile of hearing aid benefit (before and after fitting hearing aids) to compare two hearing aid fitting protocols.

Data were collected over six visits to the clinic including pre-fitting consultation, hearing aid fitting, three post-fitting follow-ups within the 45-day trial period, and one last visit scheduled at three months post-fitting.

In addition to a review of pure-tone and speech audiometric test results during the two-hour pre-fitting consultation, each participant completed the unaided section of the APHAB questionnaire. Different types of hearing aid styles, models, and features available for the participant's degree of loss were also discussed with the participant; and warranty and trial period information were provided. For group B two more tests were conducted during the prefitting consultation, the QuickSIN and the LDL.

For post-fitting follow-ups, participants were scheduled to return to the clinic every two weeks after the initial hearing aid fitting. Therefore they were scheduled for three visits within their 45-day trial period. Hearing aid adjustments were made on the basis of the participants' comments. Group B were given two additional tests: the QuickSIN and aided loudness tests. At the last of the three post-fitting visits, both groups were asked to complete the aided section of the APHAB and SADL. The clinicians were not present while these questionnaires are filled out.

Participants were asked to come back to the clinic at three months following the fitting, to complete these questionnaires again, to test estimate longer term benefit and satisfaction. For participants who could not return to the clinic, the questionnaires were mailed to them.

Only 11 in group A, and 14 in group B completed the questionnaires three months after hearing aid fitting. A paired t-test revealed that there were no significant differences between Group A participant's scores on the APHAB at 45 days and three months post-fitting ( $p>0.05$ ). No significant within-group differences on the APHAB and SADL were observed for Group B participants at 45 days and three months. Thus, satisfaction remained constant for participants in Group B but decreased over time on some subscales for participants in Group A.

**Taylor (2006), (study B)** (n=35): Two separate patient-survey studies were conducted through Amplifon USA affiliate clinics. Both studies aimed to assess real-world benefit and satisfaction of open canal users as compared to non-open canal users using self-report measures. One study (A) involved 54 adults experienced hearing aid users divided in two groups (one group were recently fitted with OC devices whereas the other group had been recently fitted with binaurally new non-OC hearing aids). The other study (B) similarly compared both OC and non-OC fittings but among 35 adults who were first-time hearing aid users (new users). Persons with greater than 45-dB loss at 500 Hz and/or greater than 85 dB at 4000 Hz were excluded from both groups.

The study among the new hearing aid users (study B), administered the APHAB and IOI-HA, whereas the study of the experienced users used the MarkeTrak survey along with another satisfaction survey (the Amplifon Satisfaction Survey) 1-3 months post-fitting.

Results from the APHAB survey in the new hearing aid users showed that EC (Ease of Communication), RV (Reverberation), and BN (Background Noise) benefit subscales were greater than 20-point difference for both the OC and non-OC groups, indicating no difference in benefit between the OC and non-OC groups.

### 2.3b (iii) International outcome inventory for hearing aids (IOI-HA)

Two studies (total participants is 373) measured the international outcome inventory for hearing aids (IOI-HA) (Taylor, 2006; Gnewikow and Moss, 2006). Both studies used the IOI-HA to measure the effect of open-canal and non-open canal hearing aids.

IOI-HA is a questionnaire designed to assess overall hearing aid outcome, including benefit, daily use, handicap, satisfaction, and changes in quality of life following hearing aid use. It is a standardised measure that consists of seven items written precisely, at a low reading level, and with low cognitive requirements. These items are: Use (in hours of hearing aid use per day), Benefit, Residual Activity Limitation (RAL), Residual Participation Restrictions (RPR), Impact on other (Ioth), Quality of Life (QoL). It is believed to complement the information gathered by other self-report measures of outcome, such as the abbreviated profile of hearing aid benefits (APHAB).

The results of the two studies (Taylor, 2006 study B (n=35); Genwikow and Moss, 2006 (n=338)) are summarised in (**Tables 15 and 16**). The two studies are presented below:

Taylor (2006) (**study B**) (N=35) among new hearing aid users: The IOI-HA was used to measure benefit, satisfaction, and quality of life changes resulting from the use of open-canal or non-open canal hearing aids among new hearing aid users. Mean scores for all the seven questions of the measure show that both groups derive significant benefit, satisfaction, and improvement in quality of life from amplification compared with published IOI-HA norms for patients with mild to moderate hearing loss. In particular the results showed that scores for hearing aid usage, residual activity limitation, and residual participation restriction were markedly higher for the open-canal group.

**Gnewikow and Moss (2006)** (N=338): All items were designed with five possible responses. To maximise the clarity of the inventory, each item has a separate response scale, and the responses are presented in order so that the most favourable item appears on the right.

For the IOI-HA there were no statistical significance on the overall IOI-HA, however, the OC and non-OC groups differ- significantly on daily use time (with non-OC reported more daily use than OC group) and the amount of difficulty still experienced with hearing aids (better rating for OC group than non-OC group).

### 2.3b (iv) Speech perception/speech recognition in noise/or silence

Two studies (total number of participants is 52) measured speech perception/speech recognition in noise/or silence (Hällgren *et al.*, 2005 (n=24) from Sweden, and Henkin *et al.*, 2007 (n=28) from Israel). Measurement tools used in the first study (Hällgren *et al.*, 2005 ) were the Hagerman speech test, Speech and Visual Information Processing System (SVIPS), Rating perceived effort during listening, and word recognition test (description of these tests is summarised below). The second study used speech-in-noise test and threshold-of-interference test, details of which are given within the study text below (Henkin *et al.*, 2007).

Hagerman speech test: is a measure of speech recognition, which consists of eleven lists with ten sentences in each. Each sentence contains five low-redundancy words. All sentences have the same structure (name-verb-number-adjective-noun). The same 50 words appear in all the lists but in different combinations. Between each sentence there is a pause, long enough for the subject to repeat the words that he recognised. The session started with a training list and the signal to noise ratio (S/N) was initially large. Then the speech signal adjusted adaptively in order to reach 40% correct responses. Two more lists were presented and the mean value of the S/N in these sentences was used as the outcome measure.

SVIPS: is a cognitive test battery used for assessment of speech and visual information processing skills. The tests where both number of correct answers and reaction were measured include: Semantic decision making, Lexical decision making, and Name matching.

Rating perceived effort: subjects are asked to rate the degree of perceived effort during performance of the tasks in all background conditions in the different modalities of presentation of the signal (Background conditions include quiet, and in the presence of two background noises: Hagerman noise which is a computer generated noise using samples of 5 word sentences from the Hagerman test, and Speech background noise which is the voice of a female speaker reading a continuous story from a novel.).

Word recognition test: a test list of 25 real words put together from the SVIPS tests was presented to the subject at the stimulus and noise level used in the SVIPS test in each background condition. This is to see if the different words in the SVIPS test battery were actually heard by the subject.

The results of the two studies (Hällgren *et al.*, 2005 (n=24) and Henkin *et al.*, 2007 (n=28)) are summarised in (**Tables 18 and 19**). The two studies are presented below:

The study by **Hällgren *et al.*, (2005)** (N=24) aimed to assess the perceived effort, speech perception and cognitively demanding speech understanding tasks of hearing aids in silence as well as in noisy environment. In particular, the study looked at word recognition and cognitive functions important for speech understanding, in silence as well as in two different noises with different cognitive involvements. The study involved 24 adults with mild-to-moderate degree of sensorineural hearing loss. All persons were experienced hearing aid users (at least nine months) and all used bilaterally fitted hearing aids (majority used Oticon Digifocus II hearing aids).

Using objective measures and scores of perceived effort, tests were performed to assess effect (with and without hearing aids) in silence and with background conditions of speech spectrum random noise and ordinary speech.

The study showed that the most benefit derived from amplification with hearing aids was achieved in the background condition without noise. The hearing threshold for Speech was 7 dB SPL lower in the Hagerman speech test and performance was increased in cognitive tasks with low redundancy items. In noise, the only effect of hearing aid use was a lower hearing threshold for Speech in the Hagerman speech test (2.5 dB S/N).

Despite minor benefits of hearing aid amplification in the objective measures, especially in the cognitive tests, significantly less effort was perceived when hearing aids were used. This underlines the importance of considering perceived effort as a dimension when evaluating hearing aid benefit, in further research as well as in clinical practice.

The study by **Henkin *et al.*, (2007)** (N=28) aimed at assessing speech recognition in noise when using unilateral as opposed to bilateral amplification conditions. Other aims were: to investigate the association between performance with one as opposed to two hearing aids and central auditory as measured by a dichotic test; and to determine the effect of increasing age on speech recognition in background noise in the different test conditions, and on performance in a dichotic test.

Participants were 28 elderly patients with bilateral symmetrical mild-to-severe sensorineural hearing loss who were initially fitted with bilateral digital hearing aids. The duration of hearing aid use ranged between 1 to 34 months. Fifteen patients were fitted with in-the-canal style, 5 were fitted with in-the-ear style and 8 were fitted with behind-the-ear hearing aid style. All hearing aids were digital and of the same manufacturer.

Speech-in-noise was tested using the Hebrew version of the AB open-set monosyllabic word test. The test consists of 10 lists of 10 consonant-vowel-consonant phonemically balanced words. Speech stimuli were presented at 70 dB SPL and a signal-to-noise ratio (SNR) of +10 dB was measured by a sound level meter at the patient's position. Mean word and phoneme recognition scores were presented under three conditions (aided right ear, aided left ear, and aided bilaterally) in a randomised order. Other scores used were the 'bilateral-unilateral difference' score which is the difference between speech recognition in noise-in percent correct words with bilateral versus unilateral amplification to the 'better ear'.

Threshold-of-interference ranged from -55 dB HL to +25 dB HL. Negative values indicate that presentation levels to the non-test ear (NTE) were higher than those presented to the test ear (TE) without interference. Thus, higher values reflect greater susceptibility to interference.

Results show:

There is no significant difference between mean word and phoneme recognition scores among these test conditions.

A higher performance of unilateral amplification was reported among 19 patients as compared to 6 patients with higher performance with bilateral amplification and equal performance scores for both unilateral and bilateral amplification among three patients.

The poorer performance of bilateral amplification was found when compared to the 'better' ear and when compared to the 'poorer' ear performance (11 of 28 patients).

Significantly better (negative) thresholds-of-interference were obtained in the right ear compared to the left ear ( $T=2.1$ ,  $p=0.04$ ).

No significant correlation was found between the bilateral-unilateral difference scores, aided right, and aided left conditions and the thresholds-of-interference in the right and left ears.

The major finding of the study is that for the vast majority of the sample (71%), speech recognition in background noise was better while using unilateral amplification to the 'better' ear compared to bilateral amplification.

### 2.3b (v) Other outcome measures of hearing aids

**OC Questionnaire:** The study by **Gnewikow and Moss (2006)** used also an empirically designed questionnaire which was mailed to the potential participants (with other questionnaires) for completion and return in a postage-paid envelop. Also included was a cover letter providing details of the study to recipients and informing them that completion and return of the questionnaires would serve as informed consent to include their results in this study (**Table 16**).

The OC questionnaire was an additional and supplemented questionnaire to the SADL and the IOI-HA to specifically evaluate occlusion effect, feedback, phone use, and overall sound quality using a Likert scale. Analyses showed significant differences between hearing aid groups in own voice and occlusion questions, with subjects in the OC group scored significantly higher/better than those in the non OC group. No significant between-group differences on the other three questions were found.

**Return-for-credit (RFC):** A further analysis was also conducted by **Gnewikow and Moss (2006)** (**Table 16**). This was the return-for-credit (RFC) data for all 338 hearing aid users who met the inclusion criteria (average RFC percentages for the clinic). Percentages were obtained for both closed fittings and open fittings and compared with clinic averages, as well as with national averages. Analyses showed that OC fittings resulted in RFC rate of 1.8% compared to 11.3% of the non-OC fittings. The authors commented that this indicates 88.7% of the closed-fitting subjects experienced a degree of satisfaction sufficient to warrant the cost of the aids, compared with 98.2% of those with OC fitting who did.

**Loudness of tinnitus** One study (total number of participants = 150) measured the loudness of tinnitus (Folmer and Carroll, 2006) (**Table 14**).

The total number of participants is 150 (with tinnitus) having their loudness of tinnitus measured using the Tinnitus Severity Index questions and 1-to-10 tinnitus loudness self-rating scale. **Folmer and Carroll, 2006** aimed to assess long-term changes in tinnitus severity exhibited by patients who used hearing aids or ear-level generators as part of a tinnitus management programme. They compared three groups of patients with tinnitus using the tinnitus severity index. Fifty patients used hearing aids, fifty patients used sound generators, and fifty patients who did not use hearing aids or sound generators were encouraged to use other forms of acoustic therapy. Of those with hearing aids, thirty-two patients purchased and used two hearing aids, whereas the rest (had disabled hearing loss on one side) used only one hearing aid. Fifteen patients used behind-the-ear style hearing aids; 35 used in-the-ear or in-the-canal style aids. All hearing aids were digital and programmable from a variety of major manufacturers.

Baseline characteristics, showed hearing aid patients had significantly higher averaged pure tone air conduction thresholds (two-tailed  $p < 0.0001$ ) than sound generator patients for all frequencies tested between 250-8,000 Hz for both ears. Threshold from no device patients fell between the averaged values for sound generator and hearing aid patients.

Hearing aid patients returned to the tinnitus clinic 1-3 times after the initial fitting for additional device adjustments. Patients of all groups were contacted by telephone one month after the initial appointment; follow-up questionnaires were mailed to patients 6-48 months after the initial appointment (patients used their devices daily during the follow-up period). Follow-up questionnaires also contained an abbreviated version of the Beck Depression Inventory (BDI) and the following question: "Did the [hearing aid *or* sound generator] help your tinnitus?" Possible choices included: (1) not at all; a little; (3) a moderate amount; (4) quite a bit; or (5) very much.

The study reported long-term reductions in tinnitus severity; the greatest amount of improvement was experienced by patients who used ear-level devices (hearing aids or sound generators). In particular, the results of the study showed that in hearing aid patients and compared to responses on initial questionnaires, there was a significant reduction in self-rated loudness of tinnitus (16%;  $p \leq 0.0005$ ) as compared to patients who did not use a device (8% reduction;  $p \leq 0.001$ ). Hearing aid patients also exhibited a 23% reduction in Tinnitus Severity scores as compared to 17% reduction for patients using sound generators.

The study discussed the beneficial effect of hearing aids for tinnitus patients who also have significant hearing loss. The study stressed the following points with the patients in this study:

- Tinnitus does not cause hearing loss, but hearing loss makes it more likely for a person to hear tinnitus.
- Even if their tinnitus stopped completely, patients with significant hearing loss would still have communication difficulties.
- Hearing aids do not amplify tinnitus. In fact, hearing aids usually reduce the loudness of tinnitus by amplifying external sounds.

- Hearing aids improve speech perception for patients with significant hearing loss. This should relieve some of the frustration, isolation, and depression experienced by these patients.
- If hearing could be restored to pre-tinnitus threshold, many cases of tinnitus would be cured. At the moment the most practical way to restore hearing is by using hearing aids. This does not mean that hearing aids “cure” tinnitus. However, amplification can contribute to reductions in loudness and severity of the symptom.
- Using hearing aids to stimulate the auditory system could contribute to permanent reductions in neural activity responsible for tinnitus generation and perception.

**Table 13 Primary studies results: effectiveness of digital hearing aids (*Shi et al., 2007*)**

Shi <i>et al.</i> , (2007) – Short-term and long-term hearing aid benefit and user satisfaction: a comparison of two fitting protocols				
Real-ear measure results				
Outcome (REARs)	Speech input (dB SPL)	Protocol A	Protocol B	Test of significance
	55 dB SPL (soft)	REARs > all participants' pure-tone threshold up to 2000Hz, <thresholds for more severe hearing loss at higher frequencies		NS
	70 dB SPL (average)	All REARs met targets up to 3000 Hz, at >3000Hz the REARs were lower than target		
	75 dB SPL (loud)	REARs were below the LDL values, so gain was not too high to cause loudness discomfort		
Gain adjustments				
Outcome		Protocol A	Protocol B	Test of significance, <i>p</i>
Number of hearing aid adjustments made within the 45-day trial period	Average overall adjustments	3.5	2.5	$t = 1.229, p > 0.05$ (not significant)
	Average overall adjustments based on user comments	2.6	1.5	$t = 2.149, p = 0.040$ (significant)
	Complaints made by several of the group A participants were related to noises and loudness, whereas few such complaints were made by group B. ~ percentages are approximates only as figures were extracted from histogram			
Benefit of hearing aids by APHAB questionnaire		Protocol A	Protocol B	Paired t-test, <i>p</i>
		At the end of the 45-day trial		
Mean benefit score % ~	Ease of communication (EC)	~ 19	~ 24	$p > 0.05$ (not significant)
	Reverberation (RV)	~ 21	~ 20	
	Background noise (BN)	~ 18	~ 12	
	Aversiveness of sound (AV)	~ -20	~ -18	
Complaints made by several of the group A participants were related to noises and loudness. ~percentages are approximates only as figures were extracted from histogram				
Benefit of hearing aids by APHAB questionnaire		Protocol A (11/16)*	Protocol B (14/16)**	Paired t-test, <i>p</i>
		At the end of the 3-months post-fitting		
Mean benefit score %~	Ease of communication (EC)	~ 20	~ 24	$p > 0.05$ (not significant)
	Reverberation (RV)	~ 28	~ 18	
	Background noise (BN)	~ 18	~ 12	
	Aversiveness of sound (AV)	~ -26	~ -10	
* one switched to another model at the end of the trial period, 2 did not complete follow-up for health reasons, 2 displeased with performance of hearing aid. **one did not respond to mail or phone, other upgraded hearing aids. ~ percentages are (approximates only) as extracted from histogram				

**Table 13 Primary studies results: effectiveness of digital hearing aids (Shi *et al.*, 2007) (continued)**

Shi et al (2007) – Short-term and long-term hearing aid benefit and user satisfaction: a comparison of two fitting protocols (continued)				
Satisfaction with hearing aids by SADL questionnaire		Protocol A	Protocol B	Paired t-test, <i>p</i>
		At the end of the 45-day trial		
<b>Outcome</b>  <b>Mean satisfaction score % ~</b>	Global Score (GS)	~ 5	~ 4.6	Data on statistical significance not shown individually
	Positive Effect (PE)	~ 4.8	~ 4.2	
	Service and Cost (SC)	~ 5	~ 4.8	
	Negative Feature (NF)	~ 5	~ 4.9	
	Personal Image (PI)	~ 5.8	~ 5.3	
~ percentages are approximates only as figures were extracted from histogram				
Satisfaction with hearing aids by SADL questionnaire		Protocol A (11/16)*	Protocol B (14/16)**	Paired t-test, <i>p</i>
		At the end of the 3-mths post-fitting		
<b>Outcome</b>  <b>Mean satisfaction score %~</b>	Global Score (GS)	~ 5	~ 4.8	Data on statistical significance not shown individually
	Positive Effect (PE)	~4.8	~4.2	
	Service and Cost (SC)	~ 4.8	~ 5	
	Negative Feature (NF)	~ 4.4	~ 4.9	
	Personal Image (PI)	~ 5.8	~5.6	
<p>* one switched to another model at the end of the trial period, 2 did not complete follow-up for health reasons, 2 displeased with performance of hearing aid. **one did not respond to mail or phone, other upgraded hearing aids.</p> <p>Group A participants scored significantly less on the SC and NF subscales of the SADL at 3 months compared to 45 days see below.</p> <p>Differences in Group B participants were not significant (no data on the test of significance were shown), and satisfaction remained constant across all the SADL subscales.</p> <p>~ percentages are approximates only as figures were extracted from histogram</p>				
Satisfaction with hearing aids by SADL questionnaire Protocol A (11/16)*		45-day trial	3-mths post-fit	Paired t-test, <i>p</i>
<b>Outcome</b>  <b>Mean satisfaction score %~</b>	Global Score (GS)	More	Less	Not significant, data not shown
	Positive Effect (PE)	Less	More	
	Service and Cost (SC)	More	Less	t=2.701, <i>p</i> = 0.022
	Negative Feature (NF)	More	Less	t=2.250, <i>p</i> =0.048
	Personal Image (PI)	More	Less	Wilcoxon signed rank test, ( <i>W</i> = -34.00, <i>p</i> = 0.016)
Abbreviations: <i>t</i> student test				

The results of the pseudorandomised study are summarised in Table 10. Although the study involved concurrent controls, and was rated good but was limited by the small number of participants. The study participants in the two groups differed significantly in thresholds at 2000 Hz ( $t = -1.962$ ,  $p = 0.055$ ), with group B having poorer thresholds than participants in group A.

**Table 14 Non-RCT primary studies results: effectiveness of digital hearing aids (Folmer and Carroll, 2006)**

<b>Folmer and Carroll (2006) – Long-term effectiveness of ear-level devices for tinnitus</b>				
<b>Mean responses by 50 patients who used hearing aids</b>		<b>Initial</b>	<b>Follow-up</b>	<b>P≤</b>
<b>Outcome</b>	Self-rated loudness of tinnitus (1-10 scale)	7.5 ± 1.7	6.3 ± 1.9	0.0005
	Tinnitus Severity Index score	38.2 ± 8.3	29.6 ± 8.4	0.0001
	Beck Depression Inventory score	5.2 ± 6.1	5.2 ± 5.6	NS
<b>Mean responses by 50 patients who used in-the-ear sound generator</b>		<b>Initial</b>	<b>Follow-up</b>	<b>P≤</b>
<b>Outcome</b>	Self-rated loudness of tinnitus (1-10 scale)	7.6 ± 1.6	6.2 ± 1.9	0.0001
	Tinnitus Severity Index score	38.6 ± 8.9	32.8 ± 8.9	0.0001
	Beck Depression Inventory score	5.0 ± 3.8	4.4 ± 4.6	NS
<b>Mean responses by 50 patients who did not use ear level devices</b>		<b>Initial</b>	<b>Follow-up</b>	<b>P≤</b>
<b>Outcome</b>	Self-rated loudness of tinnitus (1-10 scale)	7.1 ± 1.9	6.5 ± 1.8	0.001
	Tinnitus Severity Index score	38.1 ± 9.0	33.8 ± 8.9	0.001
	Beck Depression Inventory score	5.1 ± 5.3	5.2 ± 6.0	NS

**Table 15 Non-RCT primary studies results: effectiveness of digital hearing aids (Taylor, 2006)**

Taylor (2006) – Real-world satisfaction and benefit with open-canal fittings. Study A (Experienced hearing aids users)				
Mean satisfaction rating*		Non-open canal (non-OC)	Open canal (OC)	P≤
<b>Outcome (Differences)</b>	Sound of own voice	3+	4+	NS
	Phone comfort	3++	4+	NS
	Sound localisation	3+	4+	NS
	Appearance	3+++	4+	NS
	Overall satisfaction	3.95	4.41	NS (for each of the dimensions, the mean difference between the OC and non-OC group exceeded 0.80)
<b>Outcome (Similarities)</b>	Feedback on Phone	3+++	3+++	NS
	Battery Life	3++~	3+++	NS
	Understand on Phone	3++++	~4	NS
	Wax Accumulation	3++	3+++	NS
Mean difference for MarkeTrak Satisfaction Survey (question 36)		Non-open canal (non-OC)	Open canal (OC)	P≤
<b>Outcome (five dimensions of satisfaction with the greatest difference between the two groups)</b>	Sound of own voice	3	4+	NS
	Sound of chewing	3	4+	NS
	Wind noise	3	4+	NS
	Visibility	3+++	4++	NS
	Localisation	3+	4+	NS
Mean difference for MarkeTrak Satisfaction Survey (question 36)		Non-open canal (non-OC)	Open canal (OC)	P≤
<b>Outcome (four product dimensions of least difference between the two groups)</b>	Battery Life	3+++	3++~	NS
	Use in Noise	3++++	3++++	NS
	Maintenance	3+++~	3++++	NS
	Value	3+++~	4	NS

\* rating 1-5 (1 is “strongly prefer old hearing aids” and 5 is “strongly prefer new hearing aids.”)  
Abbreviations: + and ~ are approximates as data extracted from graphs

**Table 15 Non-RCT primary studies results: effectiveness of digital hearing aids (Taylor, 2006) (continued)**

Taylor (2006) <i>continued</i> – Real-world satisfaction and benefit with open-canal fittings. Study B (New hearing aids users)				
<b>APHAB</b>		<b>Non-open canal (non-OC)</b>	<b>Open canal (OC)</b>	<b>P≤</b>
<b>Outcome Mean benefit score on three sub-scale of the</b>	Ease of communication (EC)	22	27	NS
	Reverberant environment (RE)	41	37	NS
	Background noise (BN)	38	29	NS
<b>IOI-HA</b>		<b>Non-open canal (non-OC)</b>	<b>Open canal (OC)</b>	<b>P≤</b>
<b>Outcome Mean score</b>	Use	4.1	4.8	NS
	Benefit	3.8	3.9	NS
	RAL	3.4	4.2	NS
	Satisfaction	3.4	3.6	NS
	RPR	3.3	4.2	NS
	loth	3.6	3.9	NS
	QoL	3.6	3.8	NS
<b>Customer satisfaction with Hearing Instrument Performance Factors</b>		<b>Non-open canal (non-OC)</b>	<b>Open canal (OC)</b>	<b>MarkeTrak VI</b>
<b>Outcome % Dissatisfied vs % Satisfied (P value not stated)</b>	Whistling/feedback	15% vs 43%	15% vs 45%	26 vs 41%
	Value	0% vs 51%	0% vs 49%	17% vs 54%
	Use in noisy situations	15% vs 54%	15% vs 51%	38% vs 30%
	Visibility	11% vs 4%	4% vs 60%	5% vs 65%
	Comfort with loud sounds	11% vs 43%	4% vs 62%	27 vs 42%
	Fit/comfort	11% vs 70%	4% vs 65%	7% vs 79%
	Ability to hear soft sounds	11% vs 70%	8% vs 65%	23% vs 48%
	Improves hearing benefit	8% vs 57%	4% vs 70%	8% vs 76%
	Natural sounding	15% vs 63%	8% vs 78%	15% vs 54%
	Sound of voice	30% vs 41%	8% vs 81%	10% vs 55%

Abbreviations: APHAB abbreviated profile of hearing aid benefit, EC Ease of communication, RE reverberant environment, BN background noise, IOI-HA International Outcome Inventory for Hearing Aids, RAL residual activity limitation, RPR residual participation restrictions, loth Impact on others, QoL quality of life, NS not stated, vs versus.

**Table 16 Non-RCT primary studies results: effectiveness of digital hearing aids (Gnewikow and Moss, 2006)**

Gnewikow & Moss (2006) – Hearing aid outcomes with open- and closed-canal fittings						
1. SADL Results		Open Canal (OC)		Closed Canal Non-OC		(ANOVA) F, p
Outcome SADL means	Global	~ 5		< ~ 5		F=2.98, p>0.05 (not significant)
	Negative Features (NF)	4.36		3.86		F= 4.055, p<0.05 (S)
	Positive Effects (PE)	~ 5		< ~ 5		All other subscales were not significant
	Service and Cost (SC)	~ 5		< 5		
	Personal Image (PI)	6		~ 6		
2. IOI-HA Questions		Open Canal (OC)		Closed Canal Non-OC		(ANOVA) F, p
Outcome Mean score	Overall IOI-HA	Not shown		Not shown		F=0.893, p>0.05 (not significant)
	Daily Use	Less daily use (~4)		More daily use (>4)		(significant but test of significance data not shown)
	Helpful	~ 4		~ 4		NS
	Difficulty	amount of difficulty still experienced with hearing aids is more (~4)		amount of difficulty still experienced with hearing aids is less (~ 3.5)		(significant but test of significance data not shown)
	Worth	> ~ 4		4		All differences in the groups means are not significant (test of significance data not shown)
	QoL	> 4		> 4		
	Others	> 4		4		
	Enjoyment	< 4		4		
3. OC Questionnaire		Open Canal (OC)		Closed Canal Non-OC		(ANOVA) F, p, no data shown
Outcome Mean score by question	Feedback	~ 5		< 5		Not significant
	Benefit	> 5		~ 5		Not significant
	Own voice	~ 5		> 4		Significant
	Other voices	> 5		< 5		Not significant
	Occlusion	> 5		< 5		Significant
4. Return-for-credit percentages RFC		US avg	VBWC avg	open	Closed	P≤
Outcome % of hearing aids returned for credit		19%	8%	2%	10%	NS

~ and all figures (not the percentages) are approximates only as data extracted from graphs, Abbreviations: SADL satisfaction with amplification in daily life (questionnaire yields a global satisfaction score and a profile of subscale scores), ANOVA analysis of variance, S significant, NS not stated, NF negative features, PE positive effects, SC service and cost, PI personal image, IOI-HA International Outcome Inventory for Hearing Aids, QoL quality of life, RFC return-for-credit, avg average, VBWC Vanderbilt Bill Wilkerson Centre.

**Table 17 Non-RCT primary studies results: effectiveness of digital hearing aids (Kochkin, 2006)**

Kochkin (2006) – Customer satisfaction with single and multiple microphone digital hearing aid										
Customer satisfaction		MarkeTrak Norm (N=418)		Single Microphon(n=200)		Multiple Microphone (n=296)		% Satisfied Differences		
		Dissatisfied %	Satisfied %	Dissatisfied %	Satisfied %	Dissatisfied %	Satisfied %	Single Mic vs MarkeTrak	Multiple Mic vs MarkeTrak	Multiple Mic vs Single Mic
<b>Outcome</b>	<b>Overall satisfaction</b>	11	61	15	64	7	78	3.0	17.0	14.0
	<b>Consumer behaviour</b>									
	Quality of life (note 1)	3	70	3	72	0	82	2.0	12.0	10.0
	Recommended hearing aids to friend (note 2)	4	84	5	87	1	92	3.0	8.0	5.0
	Recommended person who fit hearing aid (note 2)	10	80	4	90	1	92	10.0	12.0	2.0
	Repurchase current brand of hearing aid (note 2)	10	51	4	61	3	66	10.0	15.0	5.0
	Wear hearing instrument (note 3)	17	83	7	93	3	97	10.0	14.0	4.0
	<b>Product Features</b>									
	Fit/comfort	5	81	6	82	3	81	1.0	0.0	-1.0
	Ease/volume adjustment	8	75	22	33	23	38	-42.0	-37.0	5.0
	Visibility	7	67	4	75	5	68	8.0	1.0	-7.0
	Packaging	1	71	1	74	0	73	3.0	2.0	-1.0
	Frequency of cleaning	7	64	3	70	4	72	6.0	8.0	2.0
	Warranty	7	67	4	66	6	64	-1.0	-3.0	-2.0
	Ease/Battery change	5	85	3	89	1	92	4.0	7.0	3.0
	Ongoing expense	11	47	13	47	5	57	0.0	10.0	10.0

**Table 17 Non-RCT primary studies results: effectiveness of digital hearing aids (Kochkin, 2006) (continued)**

Kochkin (2006) – Customer satisfaction with single and multiple microphone digital hearing aid (continued)										
Customer satisfaction		MarkeTrak Norm (N=418)		Single Microphone (n=200)		Multiple Microphone (n=296)		% Satisfied Differences		
		Dissatisfied%	Satisfied%	Dissatisfied%	Satisfied%	Dissatisfied%	Satisfied%	Single Mic vs MarkeTrak	Multiple Mic vs MarkeTrak	Multiple Mic vs Single Mic
<b>Outcome</b>	<b>Overall satisfaction</b>	11	61	15	64	7	78	3.0	17.0	14.0
	<b>Performance/value factors</b>									
	Battery life	19	55	21	52	11	69	-3.0	14.0	17.0
	Improves my hearing (perceived benefit)	5	82	9	78	2	86	-4.0	4.0	8.0
	Reliability	7	71	7	74	4	77	3.0	6.0	3.0
	Clearness tone/sound	12	62	9	66	4	78	4.0	16.0	12.0
	Natural sounding	15	54	6	60	6	70	6.0	16.0	10.0
	Sound of voice	9	64	18	52	9	65	-12.0	1.0	13.0
	Able to hear soft sounds	24	52	20	52	14	52	0.0	0.0	0.0
	Value (Price vs Performance)	13	54	21	47	17	54	-7.0	0.0	7.0
	Directionality	15	57	13	57	12	57	0.0	0.0	0.0
	Comfort with loud sounds	28	43	17	54	14	60	11.0	17.0	6.0
	Whistling/Feedback/Buzzing	26	42	18	53	17	55	11.0	13.0	2.0
	Use in noisy situations	36	32	33	39	19	48	7.0	16.0	0.0

**Table 17 Non-RCT primary studies results: effectiveness of digital hearing aids (Kochkin, 2006) (continued)**

Kochkin (2006) – Customer satisfaction with single and multiple microphone digital hearing aid (continued)										
Customer satisfaction		MarkeTrak Norm (N=418)		Single Microphone (n=200)		Multiple Microphone (n=296)		% Satisfied Differences		
		Dissatisfied%	Satisfied%	Dissatisfied%	Satisfied%	Dissatisfied%	Satisfied%	Single Mic vs MarkeTrak	Multiple Mic vs MarkeTrak	Multiple Mic vs Single Mic
<b>Outcome</b>	<b>Overall satisfaction</b>	11	61	15	64	7	78	3.0	17.0	14.0
	<b>Listening Environments</b>									
	One-On-One	3	92	3	90	2	94	-2.0	2.0	4.0
	T.V.	8	78	9	76	9	77	-2.0	-1.0	1.0
	Small groups	12	68	17	66	8	74	-2.0	6.0	8.0
	Listening to music	9	68	7	77	8	74	9.0	6.0	-3.0
	Place of worship	10	64	10	63	9	63	-1.0	-1.0	0.0
	Outdoors	10	62	7	67	4	76	5.0	14.0	9.0
	Leisure activities	6	61	8	68	3	70	7.0	9.0	2.0
	Car	14	59	15	61	12	57	2.0	-2.0	-4.0
	Restaurant	19	54	30	44	20	52	-10.0	-2.0	8.0
	Concert/Movie	21	50	18	48	13	55	-2.0	5.0	7.0
	Workplace	11	46	13	52	8	58	6.0	12.0	6.0
	Telephone	29	45	26	46	31	38	1.0	-7.0	-8.0
	Large group	40	29	38	27	29	33	-2.0	4.0	6.0

**Table 17 Non-RCT primary studies results: effectiveness of digital hearing aids (Kochkin, 2006) (continued)**

Kochkin (2006) – Customer satisfaction with single and multiple microphone digital hearing aid (continued)										
Customer satisfaction		MarkeTrak Norm (N=418)		Single Microphone (n=200)		Multiple Microphone (n=296)		% Satisfied Differences		
		Dissatisfied%	Satisfied%	Dissatisfied%	Satisfied%	Dissatisfied%	Satisfied%	Single Mic vs MarkeTrak	Multiple Mic vs MarkeTrak	Multiple Mic vs Single Mic
<b>Outcome</b>	<b>Overall satisfaction</b>	11	61	15	64	7	78	3.0	17.0	14.0
	<b>Dispenser Service</b>									
	Professionalism/Dispenser	3	91	1	97	0	97	6.0	6.0	0.0
	Knowledge/Dispenser	2	91	2	97	0	95	6.0	4.0	-2.0
	Quality of service (during fitting)	3	91	1	96	1	95	5.0	4.0	-1.0
	Explained how to care for H.I.	3	92	1	95	0	96	3.0	4.0	1.0
	Explained what to expect from H.I.	5	86	3	89	1	93	3.0	7.0	4.0
	Post-Purchase service	6	85	3	89	2	90	4.0	5.0	1.0

Abbreviations: HI hearing instrument, Mic microphone, vs versus

**Table 17 Non-RCT primary studies results: effectiveness of digital hearing aids (Kochkin, 2006) (continued)**

Kochkin (2006) – Customer satisfaction with single and multiple microphone digital hearing aid (continued)						
Customer satisfaction	Mean Scores			Statistical significance		
	MarkeTrak Norm (N=418)	Single Mic Digital (N=200)	Multiple Mic Digital (N=296)	Single Mic Vs MarkeTrak	Multiple Mic Vs MarkeTrak	Multiple Mic Vs Single Mic
<b>Overall satisfaction</b>	3.68	3.71	3.96	No significant difference	Multiple better (p<.0001)	Multiple better (p<.01)
<b>Consumer behaviour</b>						
Quality of life*	70	72	82		Multiple better (p<.0001)	Multiple better (p<.01)
Recommend hearing aids to friend*	84	87	92		Multiple better (p<.001)	
Recommend person who fit hearing aid*	80	90	92	Single better (p<.001)	Multiple better (p<.0001)	
Repurchase current brand of hearing aid*	51	61	66	Single better (p<.05)		
Wear hearing instruments–hours per day	9.53	10.76	11.86	Single better (p<.01)		Multiple better (p<.01)
<b>Product Features</b>						
Fit/comfort	4.07	4.05	4.07			
Ease/volume adjustment	3.92	3.09	3.13	Single worse (p<.0001)	Multiple worse (p<.0001)	
Visibility	3.78	3.98	3.80	Single better (p<.01)		Multiple worse (p<.05)
Packaging	3.90	3.89	3.94			
Frequency of cleaning	3.72	3.75	3.80			
Warranty	3.82	3.71	3.70			
Ease/Battery change	4.17	4.21	4.31		Multiple better (p<.01)	
Ongoing expense	3.48	3.39	3.64		Multiple better (p<.05)	Multiple better (p<.01)

**Table 17 Non-RCT primary studies results: effectiveness of digital hearing aids (Kochkin, 2006)**  
(continued)

Kochkin (2006) – Customer satisfaction with single and multiple microphone digital hearing aid (continued)						
Customer satisfaction	Mean Scores			Statistical significance		
	MarkeTrak Norm (N=418)	Single Mic Digital (N=200)	Multiple Mic Digital (N=296)	Single Mic Vs MarkeTrak	Multiple Mic Vs MarkeTrak	Multiple Mic Vs Single Mic
<b>Overall satisfaction</b>	3.68	3.71	3.96	No significant difference	Multiple better (p<.0001)	Multiple better (p<.01)
<b>Performance/Value Factors</b>						
Battery life	3.48	3.32	3.70	No significant difference	Multiple better (p<.01)	Multiple better (p<.001)
Improves my hearing (perceived benefit)	4.07	3.99	4.19		Multiple better (p<.05)	Multiple better (p<.05)
Reliability	3.86	3.92	3.94			
Clearness Tone/Sound	3.66	3.73	3.91		Multiple better (p<.001)	Multiple better (p<.05)
Natural Sounding	3.53	3.64	3.77			
Sound of Voice	3.69	3.34	3.67	Single worst (p<.0001)	No significant difference	Multiple better (p<.001)
Able to hear soft sounds	3.38	3.31	3.41	No significant difference		
Value (Price vs performance)	3.56	3.32	3.40	Single worst (p<.01)	Multiple worse (p<.05)	
Directionality	3.54	3.45	3.52	No significant difference		
Comfort with loud sounds	3.20	3.37	3.49		Multiple better (p<.001)	
Whistling/Feedback/Buzzing	3.21	3.36	3.43		Multiple better (p<.01)	
Use in noisy situations	2.94	3.02	3.32		Multiple better (p<.0001)	Multiple better (p<.01)
<b>Listening Environments</b>						
One-on-One	4.32	4.26	4.41	No significant difference	No significant difference	Multiple better (p<.05)
TV	3.88	3.82	3.91			
Small groups	3.71	3.61	3.80			Multiple better (p<.05)
Listening to music	3.74	3.83	3.82			

**Table 17 Non-RCT primary studies results: effectiveness of digital hearing aids (Kochkin, 2006)**  
(continued)

Kochkin (2006) – Customer satisfaction with single and multiple microphone digital hearing aid (continued)						
Customer satisfaction	Mean Scores			Statistical significance		
	MarkeTrak Norm (N=418)	Single Mic Digital (N=200)	Multiple Mic Digital (N=296)	Single Mic Vs MarkeTrak	Multiple Mic Vs MarkeTrak	Multiple Mic Vs Single Mic
<b>Overall satisfaction</b>						
<b>Listening Environments (continued)</b>						
Place of worship	3.67	3.64	3.69			
Outdoors	3.74	3.70	3.87		Multiple better (p<.001)	Multiple better (p<.05)
Leisure activities	3.67	3.70	3.78			
Car	3.55	3.52	3.55			
Restaurant	3.43	3.13	3.39	Sing mic worse (p<.001)		Multiple better (p<.01)
Concert/ Movie	3.35	3.36	3.51		Multiple better (p<.05)	
Workplace	3.40	3.48	3.60		Multiple better (p<.01)	
Telephone	3.20	3.20	3.04			
Large group	2.86	2.80	3.02		Multiple better (p<.05)	Multiple better (p<.05)
<b>Dispenser Service</b>						
Professionalism/Dispenser	4.38	4.62	4.67	Single better (P<.0001)	Multiple better (p<.0001)	
Knowledge/Dispenser	4.42	4.61	4.63	Single better (P<.001)		
Quality of service (during fitting)	4.39	4.61	4.62			
Explained how to care for HI	4.38	4.56	4.55	Single better (P<.01)	Multiple better (p<.001)	
Explained what to expect from HI	4.25	4.41	4.47	Single better (P<.05)		
Post-purchase service	4.26	4.45	4.50	Single better (P<.01)	Multiple better (p<.0001)	

\*Significance tests based on difference in proportions from the previous table, all others based on mean differences, sing mic single microphone

**Table 18 Non-RCT primary studies results: effectiveness of digital hearing aids Hällgren *et al.*, (2006)**

Hällgren <i>et al.</i> , (2006) – Speech understanding in quiet and noise, with and without hearing aids			
Hagerman speech test			
Outcome Objective measurements	With and without hearing aids		2-way (ANOVA) P value
No-noise conditions	Sound pressure level for 40% correct word recognition	7dB less with hearing aid than without hearing aids	<0.001
Outcome Objective measurements	With and without hearing aids		3-way (ANOVA) P value
two-noises conditions	Signal-to-noise ratio (S/N)	1.6 dB improvement in S/N with hearing aids	=0.008
	There was also a main effect of noise condition (p=0.02); the S/N -3.8dB in Hagerman noise and -5.8dB in Speech (averaged over hearing aid use). A significant interaction was found between hearing aid use and noise condition (p=0.006). The hearing aid benefit was less in Hagerman noise than in Speech.		
Outcome Objective measurements	With and without hearing aids		3-way (ANOVA) P value
Perceived Effort (PE)	PE values at the 40% correct word recognition background conditions	No main effects of hearing aid use but main effect of background conditions: No noise= 6.1 Hagerman noise= 6.6 Speech= 7.3	=0.042

Abbreviations: ANOVA analysis of variance, PE perceived effort Hagerman speech test: is a test of speech recognition, the speech material consists of eleven lists with ten sentences in each. Each sentence contains five low-redundancy words. All sentences have the same structure: name-verb-number-adjective-noun. The same 50 words appear in all the lists but in different combinations. Between each sentence there is a pause, long enough for the subject to repeat the words that he/she recognised. The session started with a training list and the S/N was initially large. Then the speech signal was adjusted adaptively in order to reach 40% correct responses. Two more lists were presented and the mean value of the S/N in these sentences was used as the outcome measure.

**Table 18 Non-RCT primary studies results: effectiveness of digital hearing aids Hällgren *et al.*, (2006) (continued)**

Hällgren <i>et al.</i> , (2006) – Speech understanding in quiet and noise, with and without hearing aids (continued)			
SVIPS (Speech and Visual Information Processing System) - cognitive tests			
<b>Outcome Accuracy</b>	<b>With and without hearing aids</b>		<b>4-way (ANOVA) P value</b>
	Lexical decision Semantic decision Name matching	No main effects of hearing aid use was found	NS
<b>Outcome Reaction time</b>	<b>With and without hearing aids</b>		<b>4-way (ANOVA) P value</b>
	Lexical decision Semantic decision Name matching	Significant effect of background condition in the lexical and semantic test, but no main effects of hearing aid use were found	=0.048
<b>Outcome Perceived Effort (PE)</b>	<b>With and without hearing aids</b>		<b>4-way (ANOVA) P value</b>
	Values	0.7 units lower than without hearing aids (less effort with hearing aids than without)	<0.001
There was also a significant interaction between background condition and hearing aid use (p=0.019) this showed the subjective benefit of hearing aids was high in silence and decreased in background noise.			
Word recognition test			
<b>Outcome</b>	<b>With and without hearing aids</b>		<b>3-way (ANOVA) P value</b>
	Number of correctly heard items	94.6% of the words were correctly repeated with hearing aid compared to 92.3% without hearing aids.	=0.022
There was also a significant interaction between hearing aid use and background condition (p=0.018), this showed that the benefit of hearing aids was different in the various background conditions (in silence (96.7% vs 96.5%), Hagerman noise (94% vs 90%), and in Speech (90.5% vs 93%) (with hearing aid vs without hearing aids).			
There was a significant main effect of noise (p<0.001), in silence 96.5% of the test words were identified, in Hagerman noise 92%, and in Speech 91.8%.			

Abbreviations: ANOVA analysis of variance, S significant, NS not stated,

**Table 19 Non-RCT primary studies results: effectiveness of digital hearing aids Henkin *et al.*, (2007)**

Henkin <i>et al.</i> , (2007) – The benefits of bilateral versus unilateral amplification for the elderly: are two always better than one?						
Speech-in-noise test (The Hebrew version of the AB open-set test)						
Outcome		Aided right ear	Aided left ear	Aided bilaterally	Aided better ear**	Pearson correlation coefficients
Speech recognition in noise score performance	Word Score mean (SD)	45.9 (25.8)	46.1 (25.5)	43.4 (27.3)	51.6 (25.5)	NS
	Phoneme* Score mean (SD)	66.2 (20.6)	66.8 (22.5)	65.7 (22.6)	70.8 (20.5)	
	No significant differences were found among test conditions					
Outcome		Bilateral hearing aids		Unilateral hearing aids		Pearson correlation coefficients
Speech recognition in noise score performance	Bilateral-unilateral difference scores*** (in %) n=28	(score >0, range 5-25%), n=6 patients		(score <0, range -5 to -35%), n=19 patients		NS
	The effect of ear (right versus left) was not significant and the better performing ear was right in 15 patients and left in 13 patients					
Threshold-of-interference test (modified version of the Willeford competing sentences test)						
Outcome		Right ear	Left ear		Statistical analysis	
	Mean threshold-of-interference	-14.23 dB HL (range -55 to +35, SD 23.3)	-6.15 dB HL (range -45 to +25, SD 21.2)		T= 2.1, $p=0.04$	
Pearson correlation coefficient analysis used to assess relationship between speech recognition in background noise in the different conditions and the thresholds-of-interference results. Non-significant correlations were found between the 'bilateral-unilateral difference scores', aided right, and aided left conditions and the thresholds-of-interference in the right and left ears.						

Abbreviations: \* phonemes (in % correct), \*\*better ear=ear that exhibited higher scores, \*\*\* Bilateral-unilateral difference scores= the difference score represents the bilateral minus unilateral performance of the "better" ear. Negative thresholds-of-interference are better (meaning less susceptible to interference); SD standard deviation; dBHL decibel hearing level.

Hebrew version of the AB open-set test consists of 10 lists of 10 consonant-vowel-consonant phonemically balanced GSI words. Pre-recorded normalised AB words were presented from a computer to a loudspeaker via a GSI-61 audiometer. Wilkerson Centre.

**Table 20 Non-RCT primary studies results: effectiveness of digital hearing aids Hill *et al.*, (2006)**

Hill <i>et al.</i> , (2006) – Assessment of patient satisfaction with various configurations of digital CROS and BiCROS hearing aids										
The CROS and BiCROS questionnaire										
Outcome		Corded			Cordless			All		
		Total	Kept	Returned	Total	Kept	Returned	Total	Kept	Returned
Number (%) After 30-day trial	CROS	9	6(66.7)	3(33.3)	0	0	0	9	6(66.7)	3 (33.3)
	BiCROS	73	57(78.1)	16 (21.9)	9	3(33.3)	6 (66.7)	82	60(73.2)	22 (26.8)
	All	82	63(76.8)	19 (23.2)	9	3(33.3)	6 (66.7)	91	66*(72.5)	25 (27.5)
The CROS and BiCROS questionnaire										
Outcome Response*					Satisfaction Overall average by 34 out of 66 patients who kept their hearing aids			Satisfaction Overall average by 9 out of 25 patients who returned their hearing aids		
Satisfaction (mean value) 1= very dissatisfied 5= very satisfied	CROS				3.2			1.1		
	BiCROS corded				3.6			2.2		
	BiCROS cordless				2.5			1.1		
	BiCROS total				3.5			2.0		
	Overall average				3.4			1.9		

\* responses items are: (experience enjoyable, locate sound, background noise, hearing in care, noise reduction, spouse/family, general satisfaction, recommended to others) Abbreviations: CROS contra-lateral routing of signal, BiCROS bilateral contra-lateral routing of signal

## 2.4 Efficacy summary and body of evidence

In an attempt to illustrate the entire body of evidence directly relevant to the current review, **Table 21** summarises the evidence presented in accordance with the NHMRC dimensions of evidence. Only data for the primary efficacy outcomes of statistical significance and overall satisfaction are summarised. The current evidence provided in this systematic review on the effectiveness of digital hearing aids comes from studies of low level of evidence. In all cases, the level of evidence was NHMRC III or lower.

There has been considerable research undertaken to investigate the efficacy of hearing aids for people with hearing loss. The one recent relevant systematic review used the term “amplification”, which includes all types of hearing aids with all technologies (not exclusive to digital hearing aids) (Chisolm, 2007). The large body of evidence that could have come from other systematic reviews was excluded because the majority of these reviews either did not specify the hearing aid technology or assessed traditional “analogue” or mixed “analogue and digital” or compared to analogue hearing aids.

Of the eight primary studies identified, five studies were graded Level III, and three studies were graded Level IV. Two studies were of good quality (Shi *et al.*, 2007; Folmer and Carroll, 2006). Neither the excluded systematic reviews nor the literature search identified any randomised clinical trial eligible for inclusion in this review.

As shown in the sections above, in the primary included studies, the effect of digital hearing aid upon hearing loss outcomes was investigated by various comparing variables. However, all the studies compared any style of digital hearing aids, to either no use of hearing aid or other style. This represents some reasonability in addressing the research question (although the level of evidence was low). However, there were reports from pre- and post-test assessment of series of patients using digital hearing aids and being their own comparison groups which make meaningful interpretation of the results more difficult.

Despite the inclusion of these studies, no single or double-blind randomised controlled trials have been undertaken, outcomes were rarely assessed in a blinded fashion, and patient follow-up has generally been inadequate. All the body of evidence comes from Level III and IV, the majority of which comes from fair quality studies. The studies suffered from some weaknesses in their design, and the good quality studies were either of small sample size or used the severity of loudness in tinnitus as the main outcome measure. As indicated in **Table 21** below the relevance to the practice in New Zealand is partial and sometimes unclear.

Notwithstanding the low level of the evidence, synthesising the body of evidence as a whole is problematic for several other factors; (i) the research covers a broad range of digital hearing aids, and typically there are a limited number of studies in each type; (ii) the outcomes reported in each study are different and sometimes poorly defined and (iii) follow-up of patients is highly variable. As a result it is not appropriate to statistically meta-analyse the results.

At present time, there are no peer-reviewed publications available to support the use of assistive listening device (the one-to-one communicator).

In summary, the results presented in **Tables 13-20** above indicate that there is some evidence to support the routine use of digital hearing aids for adults with hearing loss. There was some consistency in the studies particularly with customer satisfaction. However, these results come from lower level of evidence so careful interpretation in applying the results to the New Zealand setting.

**Table 21 Body of evidence: Efficacy of digital hearing aids - Various outcomes**

Citation	Hearing loss	Strength of evidence				Clinically relevant effect?	Relevant to current New Zealand practice? <sup>b</sup>
		Comparison	Level of evidence	Quality of evidence	Statistical precision <sup>a</sup>		
<b>Level I</b>							
none available							
<b>Level II</b>							
none available							
<b>Level III</b>							
Level III-I (A pseudorandomised trial, i.e. alternate allocation or some other method)							
Shi <i>et al.</i> , (2007) (USA)	A: Moderate to severe hearing loss (30 dB to >70 dB) B: slight to severe hearing loss (>20 dB to <90 dB)	Protocol A vs Protocol B (pre and post fit for each protocol, that is a within group comparison)	III-1	Good	Not significant	Yes, but not significant	Not clear

**Table 21 Body of evidence: Efficacy of digital hearing aids - Various outcomes (continued)**

Citation	Hearing loss	Strength of evidence				Clinically relevant effect?	Relevant to current New Zealand practice? <sup>b</sup>
		Comparison	Level of evidence	Quality of evidence	Statistical precision <sup>a</sup>		
Level III-2 (a comparative study with concurrent controls)							
Concurrent controls							
Folmer and Carroll (2006)  (USA)	patients with tinnitus, 18 had aided hearing loss on one side  averaged pure tone air conduction thresholds: Rear: ranged between 26.6 (±18.0) at 250Hz frequency to 63.6 (±24.5) at 8,000 Hz frequency L ear: ranged between 26.2 (±16.5) at 250 Hz frequency to 68.9 (±20.1) at 8,000 Hz frequency	HA (1 or 2) vs (1 or 2) in-the-ear sound generators  HA (1 or 2) vs no ear-level device	III-2	Good	Yes, $p \leq 0.0001$  Yes, $p \leq 0.0005$	Yes, for people with tinnitus and hearing loss	Probably If similar population and setting
Taylor (2006) (USA)	dB HL $\leq 45$ at 500 Hz and or $\leq 85$ at 4000 Hz	Open canal hearing aids vs non-open canal hearing aids	III-2	Fair	Not stated	N/A	Probably no

**Table 21 Body of evidence: Efficacy of digital hearing aids - Various outcomes (continued)**

Citation	Hearing loss	Strength of evidence				Clinically relevant effect?	Relevant to current New Zealand practice? <sup>b</sup>
		Comparison	Level of evidence	Quality of evidence	Statistical precision <sup>a</sup>		
Level III-3 (A comparative study without concurrent controls)							
Gnewikow and Moss (2006)  (USA)	high frequency sensorineural	OC hearing aid vs non-OC hearing aids	III-3	Fair	SADL (PE) yes, $p < 0.05$ other outcomes significant (IOI-HA daily use, difficulty, and OC questionnaire own voice significant but data not shown on significance) or not significant	N/A	Probably no
Kochkin (2000)  (USA)	mild to profound hearing loss	Digital HA vs MarkeTrak norm group Digital HA vs HA (3-12 months of age) Multiple Mic vs MarkeTrak  Multiple Mic vs Single Mic	III-3	Poor	Yes, $p < 0.01$  Yes, $p < .0001$  Yes, $p < .05$ to $p < .001$	Overall satisfaction	Not clear
Level IV (Case series with either post-test or pre-test/post-test outcomes)							
Hällgren <i>et al.</i> , (2005)  (Sweden)	sensorineural hearing loss	HA vs No HA (silence) HA vs No HA (noise)	IV	Fair	Yes, $p < .001$ , $p = 0.022$ , $0.008$ , $0.042$	Yes (including word recognition)	Not clear

**Table 21 Body of evidence: Efficacy of digital hearing aids - Various outcomes (continued)**

Citation	Hearing loss	Strength of evidence				Clinically relevant effect?	Relevant to current New Zealand practice? <sup>b</sup>
		Comparison	Level of evidence	Quality of evidence	Statistical precision <sup>a</sup>		
Henkin <i>et al.</i> , (2007)  (Israel)	sensorineural hearing loss	Bilateral HA vs Unilateral HA (same patients)	IV	Fair	Not stated	Yes, (including speech recognition)	Probably yes
Hill <i>et al.</i> , (2006)  (USA)	asymmetric hearing loss	Digital contra-lateral routing of signal (CROS) vs previous aided experience  Bilateral contra-lateral routing of signal (BiCROS) hearing aids vs previous aided experience	IV	Fair	Not stated	N/A	Probably no

Abbreviations: N/A, not applicable

<sup>a</sup> True effect rather than a chance finding?

<sup>b</sup> To be applicable to the digital hearing aid practice that is currently available in New Zealand, the study must have used similar fitting protocol, style, hearing aid and for similar type of population

### 3. Economic Considerations

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This section presents the results of the economic literature search, considers the generalisability of existing economic evaluations to the NZ setting, before finally considering the cost of hearing loss more generally.

#### 3.1 Economic evaluation literature review

The objective of the economic literature search was to identify existing published economic evaluations that compared using hearing aids with not using hearing aids. This review was primarily concerned with digital hearing aids, as they represent the current standard of care. However, the economic literature search was also inclusive of evaluations of analogue hearing aids, as the methodology and results of these evaluations may also be informative.

The literature search identified 15 economic papers, five of which were relevant for the economic review. These five papers were economic evaluations that compared at least one type of hearing aid intervention with no hearing aid, and examined both the costs and benefits of these interventions. A summary of the key features is presented in **Table (22)** with their summarised results presented separately in **Table (23)**.

All five included papers have attempted a cost-utility analysis. A comparison between digital hearing aids versus no hearing aids was evaluated in only one instance (Grutters *et al.*, 2007), and therefore that publication is the most relevant to the current review. The other four papers related to analogue hearing aids, or did not specify.

The population of interest in the majority of the papers was adult patients who were 18 years and older with some form of hearing loss, however Mulrow *et al.*, (1990) and Abrams *et al.*, (2002) specifically focussed upon an elderly veteran population. Several of the included analyses disaggregated their study population by either age group or gender (Joore *et al.*, 2003; Grutters *et al.*, 2007; Boas *et al.*, 2001).

With regard to the source of clinical evidence, only one evaluation (Mulrow *et al.*, 1990) drew their clinical evidence of benefit from a randomised control trial (RCT) of hearing aids versus no hearing aids. Abrams *et al.* (2002) used data from a RCT, however this was designed to compare hearing aids with and without rehabilitation, rather than to compare to no hearing aids. The three remaining papers obtained their clinical outcomes from before and after data from case series.

There is considerable variation in the choice of quality of life (QoL) measures across the economic evaluations. Two of the evaluations did not use preference-based utility weights (Mulrow *et al.*, 1990; Abrams *et al.*, 2002). These two evaluations were overly simplistic and used flawed methodology. Therefore the cost-utility results are unreliable. In fact the analyses by Abrams appears to have applied quality of life results showing a change in 3.0 and 1.5 units as utility weights (that by convention requires a 0–1 scale), multiplying them by the remaining life years. This has resulted in a profound overestimation of the utility gain, and therefore an incorrect cost-utility

result. The remaining three papers used preference-valued multi-attribute utility instruments including the EQ-5D and the Health Utility Index (HUI).

The perspectives of the analyses ranged widely from the societal perspective to inclusion of the purchase price of hearing aids alone. Time horizon of the included models was between four months to lifetime.

**Table 22 Existing economic evaluations: method**

Author	Mulrow <i>et al.</i> ,	Joore <i>et al.</i> ,	Grutters <i>et al.</i> ,	Boas <i>et al.</i> ,	Abrams <i>et al.</i> ,
Year	1990	2003	2007	2001	2002
Country	United States	Netherlands	Netherlands	Netherlands	United States
Focus of publication	Impact of hearing aids on quality of life of elderly (economic evaluation not a major focus)	To determine cost-effectiveness of hearing aid fitting	Compare results using different multi-attribute utility instruments	Focuses on use of dynamic modeling, using hearing aids as an example	To compare hearing aid fitting with and without short-term post-fitting audiologic rehabilitation
Intervention	HA (analogue)	HA (unspecified)	Digital HA	Fitting HA program alone,  Post-purchase counseling HA program	HA alone  HA with post-fitting audiologic rehabilitation
Comparator	Unaided	Unaided	Unaided	Unaided	Unaided
Population	Elderly veterans who were over 64 years old	Adults	Adults	Adults	Veterans (no age criteria specified, but mean age 73)
Economic results by sub-group	No	Yes, by age group	No	Yes, by age group	No
Source of clinical benefit	The paper itself reports the findings of an RCT, but designed to compare hearing aids with and without rehabilitation, but not no hearing aids.	Prospective study of patients receiving hearing aids at University Hospital (28%) and an audiological centre (72%). No prospective control data.	Before-after study of hearing aid provision in three different Dutch regions (AZOS working group, 2006)	SIHI study (SIHI, 1999) A Dutch population receiving hearing aids, No control data.	Outpatients recruited to an RCT comparing hearing aid fitting with and without short-term post-fitting audiologic rehabilitation. No control data
Quality of life assessment	Disease-specific measure: HHIE, QDS. Generic measures: SPMSQ, GDS, and SELF No preference-based utility	EQ-5D index VAS Hearing-specific VAS.	EQ-5D UK tariff EQ-5D Dutch tariff HUI2 HUI3	EQ-5D	SF-36V: Mental Component Scale No preference-based utility
Perspective	Direct medical costs	Societal perspective	Direct medical costs	Societal perspective	Direct medical costs
Time horizon	Unclear, assumed to be 4 months	Lifetime	One year	Lifetime	NR

**Table 22 Existing economic evaluations: method (continued)**

<b>Discounting</b>	-	Costs and benefits are discounted at a rate of 5%.	-	Costs and benefits are discounted at a rate of 5%.	-
<b>Note</b>	Paper primarily relates to the RCT. Economic evaluation presented in the Discussion section only, with HQALY crudely based on the percent improvement in HHIE	-	-	-	- Paper used an overly simplistic and flawed QoL measure. It appears to have applied QoL results showing a change in 3 and 1.5 units as utility weights

Abbreviation: HA, hearing aid; NR, not reported; HHIE, Hearing Handicap Inventory for Elderly; QDS, Quantified Denver Scale of Communication Function; SMPSQ, Short Mental Portable Status Questionnaire; GDS, Geriatric Depression Scale; SELF, Self-Evaluation of Life Function; DSP, Digital Signal Processing; QoL, Quality of life; EQ-5D, EuroQoL 5 Dimension; VAS, Visual Analogue Scale; HUI2, Health Utilities Index Mark II; HUI3, Health Utilities Index Mark III; SF-36V, 36-Item Short-Form Health Survey modified for veteran population; RCT, randomised control trial

**Table (23)** summarises the results of the included economic evaluations. As mentioned earlier, the evaluations by Mulrow *et al.*, (1990) and Abrams *et al.*, (2002) were overly simplistic on flawed methodology, making their cost-utility results unreliable. Therefore their results are not considered further.

Based on the three remaining studies, the cost-effectiveness of using hearing aids is inconclusive. The cost per quality-adjusted life year (QALY) reported in the base-case ranged from €15,807 to €647,209. The cost-effectiveness results were heavily dependent upon the utility gains, which were in turn dependent upon the utility instrument. The utility gains from using hearing aids appeared to be quite low, which were between 0.003 and 0.119 per person per year. From the publications included here, there was no clear evidence that the utility gained from using digital hearing aids were different from that obtained by using other types of hearing aids.

Based on the lifetime model of a cohort study, Boas *et al.*, (2001) concluded that the cost per QALY of €21,154 was very sensitive to both changes in the price of hearing aids and the utility gain. Univariate sensitivity analyses showed that the cost per QALY increased to €25,570 when increasing the average price of a hearing aid by 25%, and decreased to €10,577 per QALY when increasing utility gain from 0.02 to 0.04. The costs of hearing aid fittings included general practitioner (GP) visits, Ear Nose and Throat (ENT) or Audiological Centre (AC) visits, and hearing aids. The study attempted to include the indirect healthcare costs and productivity loss, but there was little information available. Therefore these costs were not included in the analyses.

Joore *et al.*, (2003) reported the base-case lifetime cost-effectiveness ratio to be €15,807 when utility was measured with the EQ-5D. The positive gain (0.03) in the quality of life measured by the EQ-5D (that the authors included in the economic evaluation) was however ambiguous because the 95% confidence interval of the change included zero [-0.03 and 0.08]. This corresponded to -€15,807 to €5,936 per QALY. The authors also reported the findings of hearing-VAS that showed a significant quality of life of 0.27 (95% CI: 0.22-0.30). However the hearing- visual analogue scale (VAS) is not a preference-valued measure. Furthermore, disease-specific instruments such as hearing-VAS distort the overall quality of life and, for this reason, should not be used directly as utility weight in cost-utility analyses. The average cost of fitting hearing aids amounted to €781, which comprised GP visits, ENT or AC visits, battery, and repair. Similar to Boas *et al.*, (2001), Joore *et al.*, (2003) considered the inclusion of productivity loss but did not include it in the analyses because there was lack of information.

The study by Grutters and colleagues is considered to be the most relevant study to the topic of interest as it specially investigated the cost-effectiveness of digital hearing aids. It is therefore used to guide the current analysis and is discussed in detail below. Grutters *et al.*, (2007) conducted a head to head comparison of four types of multi-attribute utility measures (EQ-5D UK tariff, EQ-5D Dutch tariff, HUI2, HUI3). They were particularly interested in the impact of each measure on the incremental cost-effectiveness ratio (ICER).

The EQ-5D system consists of five questions presenting five dimensions of health-related quality of life, which are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The scoring function is derived with the time trade-off (TTO) method based on the sample of the United Kingdom (UK) population of 2,997 respondents (EQ-5D UK tariff). The range of possible utility scores is from -0.59 to 1.00. Similarly EQ-5D Dutch tariff is based on the EQ-5D system but its scoring function is constructed from the sample of 298 Dutch respondents. EQ-5D Dutch tariff's possible scores ranges from -0.33 to 1.00. HUI2 and HUI3 are versions of the HUI system, which consists of 15 questions. The HUI system is primarily designed to capture the impairment of disability. HUI2 consists of seven attributes, which are sensation, mobility, emotion, cognition, self-care, pain, and fertility. HUI3 consists of eight attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain). Note that only HUI3 has a specific attribute to capture hearing impairment. Both HUI2 and HUI3 are derived from both standard gamble (SG) and VAS. In the Grutters' study, the utility data was collected from a before-after study, which was carried out in 2004-2005 in three regions in the Netherlands. Persons were recruited from the participating ENT departments, AC, and hearing aid dispensers.

The mean utility score at baseline in the population with hearing complaints was the highest for the EQ-5D Dutch tariff (mean 0.86; SD 0.18). The mean utility scores for EQ-5D UK tariff, HUI2, and HUI3 were 0.83 (SD 0.21), 0.77 (SD 0.14), and 0.61 (SD 0.24) respectively. HUI2 and HUI3 showed more responsiveness to changes after fitting hearing aids. The mean change of 0.12 (SD 0.18) in utility was the highest in HUI3 and it was statistically significant. As expected, the change in the HUI3 score occurred in the hearing attribute. Almost no change was detected in the other attributes of HUI3. Some mean change in utility was also detected in HUI2 (mean 0.07). Minimal changes in EQ-5D UK (mean 0.003) and Dutch tariffs (mean 0.01) were observed.

The average cost of hearing aid fitting in the Grutters' economic evaluations was €1,877 in year one, which consisted of GP visit, ENT visits, and a hearing aid. The mean cost of no hearing aid, which was doing nothing, was assumed to be zero. The incremental mean cost in year one was therefore €1,877. The incremental cost-effectiveness ratio (ICER) was €15,811/QALY in the first year when measured the utility with HUI3, and €25,337/QALY when measured with HUI2. However when applying the results from EQ-5D UK and Dutch tariffs, the cost per QALY rapidly increased to €286,866 and €647,209 respectively. A cost-effectiveness threshold used in the Netherlands is approximately €20,000/QALY, so fitting hearing aids was deemed by the authors to be cost-effective only when measured the benefits with HUI3. It is also important to note that Grutters' model had time horizon of one year. In reality benefit from using hearing aids would continue over many years, with minimal additional costs (e.g. repairs, and batteries). Therefore these results are conservative.

In summary, the results of Grutters *et al.*, (2007) indicate that the cost-effectiveness is highly dependent upon the extent of utility gain, which is in turn dependent on the instrument used to determine the utility weights.

**Table 23 Existing economic evaluations: results**

<b>Author</b>	Joore <i>et al.</i> ,	Grutters <i>et al.</i> ,	Boas <i>et al.</i> ,
<b>Year</b>	2003	2007	2001
<b>Country</b>	Netherlands	Netherlands	Netherlands
<b>Cost of hearing aid</b>	€671 for monoaural HA	€1545 on average	€864 for monoaural HA
<b>Other cost</b>	GP, €24; ENT, €243; AC, €122; battery cost, €34; repair cost, €19	GP, €37; ENT, €295	GP, €27; ENT specialist, €107; AC, €212
<b>Utility weight improvement</b>	0.03 (EQ-5D), 0.27 (hearing-VAS)	0.01 (EQ-5D UK tariff) 0.00 (EQ-5D Dutch tariff) 0.07 (HUI2) 0.12 (HUI3)	0.02
<b>Incremental cost</b>	€781 (discounted)	€1,877	NR
<b>Incremental utility gain</b>	0.05 after weighting by age distribution and life expectancy <sup>a</sup>	0.0065 (EQ-5D UK tariff) 0.0029 (EQ-5D Dutch tariff) 0.0741 (HUI2) 0.1187 (HUI3) <sup>a</sup>	NR
<b>Cost-effectiveness result</b>	€15,807/QALY (population)	EQ-5D UK tariff: €286,866/QALY EQ-5D Dutch tariff: €647,209/QALY HUI2: €25,337/QALY HUI3: €15,811/QALY	Fitting HA alone: €21,154/QALY  Post-purchase counselling + HA: €18,046/QALY
<b>Sensitivity analysis</b>	Range of gains : [-0.03:0.08] = [-€15,807, €5,9336]/QALY  Range of costs of HA: [350:1000]= [11,209:20,575]/QALY	95% CI: EQ-5D UK tariff: [Inferior:€47,082]/QALY EQ-5D Dutch tariff: [Inferior:€61,934]/QALY  HUI2: [€38,012: €19,356]/QALY HUI3: [€24,654: €11,664]/QALY	For Fitting HA program:25% rise in price of monaural HA: €21,154/QALY  100% rise in proportion of binaural fitting: €24,687/QALY  100% rise in utility gain: €10,577/QALY

**Table 23 Existing economic evaluations: results (continued)**

<b>Author's conclusion</b>	The cost-effectiveness ambiguous. QoL gains included zero.	Utility scores and hence ICER heavily depends on utility measure.	Cost/QALY is sensitive to both changes in price of HA and utility gain.
<b>Reviewer's note</b>	85% of hearing aids fitted at an ENT clinic.  75% of fittings are monoaural fittings.  Productivity loss not included.  No control data to interfere extent of incremental gain (assume to be zero in no hearing aid arm).	One year model.  In reality benefit would continue over many years, with minimal additional cost (e.g. repair and batteries). Therefore these results are conservative.	85% of hearing aids fitted at an ENT clinic.  75% of fittings are monoaural fittings.  Productivity loss not included.  No control data to interfere extent of incremental gain (assume to be zero in no hearing aid arm).

Abbreviation: QALY, Quality-Adjusted Life Year; NR, not reported; QoL, Quality of life; EQ-5D, EuroQoL 5 Dimension; VAS, Visual Analogue Scale; HUI2, Health Utilities Index Mark II; HUI3, Health Utilities Index Mark III; HA, hearing aid; ICER, incremental cost-effectiveness ratio; ENT, Ear Nose and Throat; AC, audiological centre

<sup>a</sup> calculated by reviewer using reported ICER and incremental cost.

## 3.2 Generalisation of cost-effectiveness findings to NZ setting

### 3.2 (a) Cost of intervention in New Zealand

There are many types of digital hearing aids in NZ ranging from basic to advanced with costs ranging from NZ\$1,200 to over NZ\$7,000 per pair<sup>1</sup>. Middle range digital hearing aids cost between NZ\$2,400 and NZ\$5,000 per pair, and offer practical features such as reduction of non-speech noise, and directional microphones. In addition, there are other costs associated with fitting a hearing aid. A typical procedure of obtaining a hearing aid starts with an initial GP consultation and is followed by two to three consultations with an audiologist or an ENT specialist. During the visits to the audiologist or the ENT specialist, the person would undergo a formal examination, fitting of a hearing aid, and receive an orientation on its use. In some cases, especially for first-time users, there might be further costs in relation to post-purchase rehabilitation or a counselling programme, which is designed to assist the new user. Such programmes have been shown to increase the users' satisfaction and encourage compliance over time (Boas *et al.*, 2001). Other than the fixed costs in year one mentioned earlier, over a period of time there is likely to be some variable costs such as battery replacement and repairs. Currently there is no information to quantify these costs for NZ. The total costs are likely to be shared between District Health Boards (DHBs), Accident Compensation Corporation (ACC), Veterans' Affairs New Zealand (VANZ), the Ministry of Social Development (MSD), and the individuals. The split of the costs between these organisations depends on the individuals' status and caused of hearing loss.

In summary, the costs used in the economic evaluation of Grutters are broadly transferable to the NZ setting.

### 3.2 (b) Qualitative discussion of incremental cost

To ultimately assess the cost-effectiveness of a digital hearing aid in comparison to no hearing aid (doing nothing), it is necessary to consider the incremental costs relative to the incremental outcomes. The incremental costs in the Grutters analysis is simply equal to the cost of hearing aid fitting as the cost of the comparator (no aids) is assumed to be zero – cost of doing nothing. With regard to cost-offsets, some savings especially in productivity loss can be expected in spite of the lack of evidence in the published literature. Working people with hearing loss are more likely to be unemployed, and if employed they are likely to earn less than hearing peers (Shield, 2006), and possibly face early retirement (Access Economics, 2006). The impact of these losses in productivity/earnings to NZ society has the potential to be considerable, particularly in times of high employment. The use of hearing aids is also postulated to avoid adverse effects of untreated hearing loss, which would otherwise incur costs to the health-care and education system. Some untreated hearing complaints are found to suffer from adverse effects such as depression (Mulrow *et al.*, 1990; Joore *et al.*, 2003).

Mohr *et al.*, (2000) found that the average total cost per person is closely related to the age when the individual experience hearing loss. A person who experiences hearing

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<sup>1</sup> Source: [www.hearingadvantage.co.nz/funding.aspx](http://www.hearingadvantage.co.nz/funding.aspx)

loss at a young age costs more to the society than those that experience the loss in later years. This implies considerable cost-offsets in the younger population with hearing loss. Undoubtedly there would be potential cost-savings associated with the use of hearing aids, however there is little quantitative information, so it is difficult to estimate the magnitude of cost-offsets due to the used of hearing aids.

### 3.2 (c) Qualitative discussion of incremental benefit

Hearing aids are unarguably beneficial to hearing-impaired persons. In reviewed studies, there appears to be issues around (1) the clinical evidence of benefits, and (2) accurate translation of these benefits into utility. Gains in quality of life in terms of QALY from hearing aids appear to be present but not of a consistent magnitude. Estimates in literature found the utility weights from the use of digital hearing aids to range from 0.003 to 0.12 depending upon the QoL instruments (Grutters *et al.*, 2007). The authors concluded that HUI3 is the appropriate QoL measure in the population of hearing loss complaints because of its high sensitivity and responsiveness. However, others would argue that the HUI2 and HUI3 may over-represent the impact of hearing upon persons' entire health-related quality of life.

In summary, it is not possible to draw a conclusion on the cost-effectiveness of digital hearing aids because of the uncertainty around the magnitude of the benefits. In transforming the improvement in hearing to a utility gain, the choice of utility instrument is clearly a key determinant of the size of the ICER. It is also important to consider appropriate time horizon when investigating the cost-effectiveness of hearing aids.

### 3.3 Cost of hearing loss

Hearing loss has increasingly become a priority for governments around the world as it is anticipated that the prevalence of hearing loss will rise in the future. If hearing loss is left untreated, it could create financial and resource implications to the health system, education system, social welfare system, and society in general. Hearing loss does not only impair the communication ability of the sufferers, but also adversely affects other aspects of their daily lives. Hearing loss impacts upon physical, cognitive, emotional, behavioural and social function, as well as employment status (Taylor and Paisley, 2000).

Cost of hearing loss studies were found for the United States (US), Europe and Australia. However, no published cost of hearing loss study for NZ was identified. All the costs reported below are crudely converted to NZ dollars but not inter-temporally adjusted<sup>2</sup>. Mohr *et al.*, (2000) examined the societal costs of severe to profound hearing loss in the US and estimated the cost to society to be US\$4.6 (NZ\$6.2) billion over the lifetime of persons with severe to profound hearing loss. This equates to \$0.297 (NZ\$0.403) million per the lifetime of an individual. A large proportion of these costs (67%) were accounted for by losses in work productivity. A further 21% were due to the costs in special education, especially for children, and informal carers. Unlike other diseases and illnesses, the direct medical cost accounted for only 11%.

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<sup>2</sup> An average exchange is calculated based the actual monthly exchange rates obtained from Reserve Bank New Zealand

The report further explained that an average cost per person is inversely related to the age when persons experience hearing loss. Prelingual onset of severe to profound hearing loss was the most expensive to the society with a cost of over US\$1 (NZ\$1.4) million over the lifetime of the person. This per person lifetime cost dropped to US\$0.920 (NZ\$1.3) million and US\$0.043 (NZ\$0.059) million if the hearing loss incurred in young children and during retirement age respectively.

Shield (2006) estimated the cost of hearing loss at all levels in Europe, based on the 'quality of life' approach, to aggregate to €284 (NZ\$772) billion in 2004. Persons with moderate hearing impairment contributed the most to this total cost explaining 48% of €284 (NZ\$772) billion, while those with severe hearing loss contributed 14% to the total. The author considered a 'quality of life' approach to be superior to a purely monetary approach, which ignored the impact of psychological costs in the hearing loss population.

In Australia, Access Economics conducted an analysis of the economic impact and cost of hearing loss and reported similar findings for Australia. The productivity loss, in terms of reduced earnings, accounted for over half (56%) of the total financial cost of A\$11.75 (NZ\$13.3) billion or 1.4% of GDP in 2005. The losses in productivity were mainly due to early retirement from hearing loss. The authors reported that there is no evidence of additional absenteeism from hearing-impaired employees. In Australia the costs of informal carers were the second largest component (27%) accounting for A\$3.2 (NZ\$3.6) billion. The informal carers provided general communication assistance in daily life. In comparison, the direct medical costs such as diagnosis, treatment and management, contributed only slightly to the total, accounting for 6%. In addition to these costs, there were also financial implications to the government. The reduced earnings from early retirement consequently decreased tax revenue (both direct and indirect taxes) and increased dependence on the welfare payment. These two components together were estimated to further cost the society A\$2.6 (NZ\$2.9) billion.

Given that no published 'cost of hearing loss' studies for NZ were identified, the Australian costs estimates are considered an appropriate proxy for NZ. The financial cost of hearing loss to NZ society is estimated to total to about  $(1.4\% * \text{NZ GDP}^3) = \text{NZ\$1.8 billion in 2007}$ . About NZ\$1 billion ( $\text{NZ\$1.8} * 56\%$ ) of these is attributed to productivity loss and NZ\$0.5 billion ( $\text{NZ\$1.8} * 27\%$ ) is accounted for by costs incurred by informal carers of those with hearing loss.

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<sup>3</sup> Source: Annual chain-volume GDP in 2007 (NZ\$131 billion) obtained National Accounts unit, Statistics New Zealand



## 4. Summary and Conclusions

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### 4.1 Summary of evidence for evidence review

This report systematically reviewed the international evidence for the effectiveness of digital hearing aids of any style of fitting for adult people with hearing loss. The main results are presented below.

The available studies have been very mixed in their designs, level of hearing loss, interventions and comparisons, and outcomes. There were very little similarities in the use of tools used to assess the effectiveness of hearing aids. Five studies measured satisfaction (and dissatisfaction), two measured benefit of hearing aids using the abbreviated profile of hearing aid benefit (APHAB), two studies measured the international outcome inventory for hearing aids (IOI-HA), two studies measured speech perception/speech recognition in noise/or silence, and one measured loudness of tinnitus (but also have hearing loss). Other various measures were also used by the studies. Therefore, results from the studies were presented (within the text) according to the outcome measures used, whereas they were tabulated according to the level of evidence. Below results are presented firstly on the basis of the most frequent measure used, then the least frequent measure used.

#### 4.1 (a) Satisfaction with hearing aids

Five studies (total number of participants = 1429) measured satisfaction (and dissatisfaction) with hearing aids using the satisfaction with amplification in daily life (SADL) or customer satisfaction questionnaires. The studies varied in the design, and used four different questionnaires (two studies used the SADL, whereas the rest each used one of each of the Amplifiron Satisfaction Survey, MarkeTrak survey, Survey questionnaire for the CROS (contra-lateral routing of signal) and BiCROS (bicontra-lateral routing of signal) hearing aids. The heterogeneity in these results precluded any combining of the results.

##### SADL Results

- Results from the SADL questionnaires in one study indicated that satisfaction increased after 3-months post-fitting with one protocol of digital hearing aid. This was shown by the significant decrease in the scores of the subscales SC (services and costs) and NF (negative features), whereas no significant changes were seen in the other fitting protocol.
- Similar satisfaction was seen for open canal digital hearing aids as compared to non-open canal digital hearing aids on the Negative Features subscale of the SADL questionnaire in another study.

##### Amplifiron Satisfaction Survey Results

- Results from a study that compared between open canal digital hearing aids and non-open canal digital hearing aids among 54 experienced hearing aid wears showed that overall satisfaction was higher with open canal hearing aids than non-open canal hearing aids.

- The open canal type showed significantly better features in the sound of own voice, sound of chewing/swallowing, wind noise, visibility to others and localisation.

#### Knowles' MarkeTrak survey

- Results reported from the survey showed better overall satisfaction, quality of life, and hours worn per day (less time worn) with multiple microphone digital hearing aids than with single microphone digital hearing aids.

#### Survey questionnaire for the CROS and BiCROS hearing aids

- Satisfaction in patients with severe-to-profound asymmetric hearing loss was better with the new generation of digital CROS and BiCROS hearing aids than the satisfaction in previously reported studies.

### 4.1 (b) Benefit with hearing aids

Two studies (total number of participants = 67) have used the abbreviated profile of hearing aid benefit (APHAB) to measure any improvement in hearing aid benefit.

- In one study that compared two fitting protocols for digital hearing aids, results of the APHAB questionnaire showed no significant differences between the two protocols as well as no changes at 45 days and three months post-fitting.
- In another study, both open canal and non-open canal hearing aids showed benefits 3-months after fitting. The APHAB survey in new hearing aid users that compared between open-canal digital hearing aids to non-open canal digital hearing aids showed benefits with EC (Ease of communication), RV (Reverberation), and BN (Background noise).

#### International outcome inventory for hearing aids (IOI-HA)

Two studies (total participants = 373) measured the international outcome inventory for hearing aids (IOI-HA).

Both studies used the IOI-HA to measure the effect of open-canal and non-open canal hearing aids in overall as well as individually in terms of benefit, daily use, handicap, satisfaction, and changes in quality of life following hearing aid use.

- One study among new hearing aid users the scores for hearing aid usage, residual activity limitation, and residual participation restriction were markedly higher for the open canal group.
- The other study indicated that open canal hearing aids rated better in all items of the questionnaire (benefit, satisfaction, and improvement in quality of life). In particular in terms of daily use time, and the amount of difficulty experienced with hearing aids.

### 4.1 (c) Speech recognition in noise and silence

Two studies (total number of participants is 52) measured speech perception/speech recognition in noise/or silence. Measurement tools used in the first study were the Hagerman speech test, Speech and Visual Information Processing System (SVIPS). The second study used speech-in-noise test and threshold-of-interference test.

- The first study compared use of digital hearing aids to no use of digital hearing aids at silence and with background conditions. The most benefit derived from amplification with the digital hearing aids was in the background without noise. Significantly less effort was perceived when hearing aids were used as compared to no use of hearing aids.
- The second study compared the use of one digital hearing aid to two digital hearing aids. Speech recognition in background noise was better while using unilateral amplification to the better ear than using bilateral amplification.

#### 4.1 (d) Other outcome measures

##### OC questionnaire

An additional and supplemented questionnaire to the SADL and the IOI-HA was used in one study to evaluate occlusion effect, feedback, phone use, and overall sound quality. Subjects in the open canal group scored better than those in the non open canal group especially with own voice and occlusion questions.

##### Return-for-credit (RFC)

The same above study analysed data for open canal and non-open canal digital hearing aids. Analyses showed open-canal hearing aids were associated in less return for credit rates than non-open canal.

##### Loudness of tinnitus

One study (total number of participants =150) measured the loudness of tinnitus. The study compared digital hearing aids to no use of hearing aids and to sound generators. Long term reductions in tinnitus severity were significantly shown in hearing aid patients as compared to patients who did not use a device.

In a specific population (patients with asymmetric severe-to-profound hearing loss), satisfaction with contra-lateral routing of signal digital hearing aids was better than the older models. This was shown by better acceptance rates when using the new models as compared to the patients' old models.

## 4.2 Summary of evidence for economic evaluation

It is not possible to draw a conclusion on the cost-effectiveness of digital hearing aids because of the uncertainty around the magnitude of the benefits. In transforming the improvement in hearing to a utility gain, the choice of utility instrument is clearly a key determinant of the size of the ICER. It is also important to consider appropriate time horizon when investigating the cost-effectiveness of hearing aids.

## 4.3 Limitations of evidence base

The evidence considered in this review exhibited methodological limitations which are summarised below. Systematic reviews are only as good as the quality of the information contained within the included studies. There are many biases that may impact on the internal validity of individual clinical trials such as selection bias,

performance bias, detection bias and attrition bias (Egger *et al.*, 2001). This report did not critically appraise the systematic reviews narrated in the earlier sections, as they did not fulfil the criteria for inclusion.

Of all the experimental designs, randomised-controlled trials (RCTs) have the least likelihood of introducing any biases that may affect results, particularly when double blinding is used. This report showed that hearing aid studies included were not randomised (except one was pseudo randomised). The principal difference between randomised and non-randomised studies lies in the latter's considerable susceptibility to selection bias. Concealed randomisation specifically removes the possibility of selection bias or confounding in RCTs, i.e. any differences between the groups are attributable to chance or to the intervention, all else being equal. For nonrandomised studies, confounding between groups is likely.

The quality of data is crucially affected by the methods used to collect the data, and in this report many studies collected data retrospectively raising the significant potential for bias. The majority of the studies used non-experimental designs and lacked appropriate control groups; this increased the possibility for bias limiting the applicability of their findings. Many studies suffer from small patient numbers and therefore are susceptible to type II error (i.e. failure to detect a true difference).

The studies failed to provide appropriate sample size calculation (power analyses), as well as lacked information on withdrawals or drop-outs, and did not account for these drop-outs in their analyses (intention-to-treat analyses). Studies sometimes have consecutive patients, treatment allocation was not always concealed, and inclusion/exclusion criteria sometimes were not specified. However, it is not always possible to conceal treatment and studies may use blind assessment or objective measure to account for this lack in the design.

A number of studies used a before and after design but it may be more appropriate in some situations to use this design because of the wide variation and heterogeneity in the degree and type of hearing loss.

Several studies used survey questionnaires to collect data and compare with historical or previous responses. One of the main weaknesses of survey designs is the lack of time dimension, which limits assessing the effect over time, thus makes interpretation of the results of concern. Furthermore, observational studies are particularly subject to selection bias as well as information bias and may be profoundly affected by confounding. Biases commonly present in observational studies in digital hearing aids research include:

- selection of patients suitable for (hearing aids)
- differences in the intervention that is purportedly common to both arms
- acutely for concurrent controls
- historically for controls gathered from an earlier time period
- failure to blind patient and clinician to the nature of the treatment
- failure to adequately define outcome measures
- failure to assess outcomes in a manner that is blind to treatment assignment
- inadequate follow-up of patients, and failure to account for missing patients in analyses.

The current systematic review of the clinical evidence was limited to studies published between 2000 to November 2007 (inclusive). Therefore, studies conducted after that time if any may have been missed. The studies included in this systematic review were conducted overseas; therefore the applicability of the results to the New Zealand setting may be limited.

#### Recommendations for future research

To strengthen the recommendations regarding the benefits of Health-related quality of life from the use of hearing aids Chisolm *et al.*, 2007 recommended that future research in this area should strive to include appropriate control groups and the RCTs as the optimal strategy.

## 4.4 Conclusions

This report systematically reviewed the evidence for effectiveness of digital hearing aids in the management of hearing loss in the adult population.

At present with the absence of good quality randomised controlled trials that assessed the effectiveness of digital hearing aids, it is difficult to draw conclusion for the effectiveness of digital hearing aids for adult people with hearing loss. The review however, found some limited evidence that may support the use of digital hearing aids under conditions similar to those reported in the studies such as the fittings used or populations who used these hearing aids for adult patients with hearing loss. This limited evidence based on results from low level of evidence studies but with fair or good methodological quality. Whilst a considerable volume of clinical reports and related information exists, the study design, conduct and reporting comes from studies of non-experimental nature, thus making it inadequate for assessment of treatment efficacy. Furthermore the efficacy results are inconsistent, with the possible exception of the effect on satisfaction where, on balance, there is suggestion of an overall satisfaction with the use of various types of digital hearing aids assessed in the studies included in the review.



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## Glossary

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**Analogue:** Traditional way of processing signals, where the signals are processed continuously and in real time.

**Analogue hearing aid (conventional):** Hearing device using electronic circuits to amplify and control incident sound signals.

**Analysis of variance (ANOVA):** A statistical analysis involving the comparison of variance reflecting different sources of variability.

**Acceptable Noise Level (ANL):** The difference between the patient's most comfortable level (mcl) for speech and the highest level of background noise that the patient reports as acceptable, referred to as the background noise level (bnl). (speech mcl minus the bnl equals the anl).

**Applicability:** The degree to which the results of an observation, study or review hold true in other settings. (See also **External validity** and **Generalizability**).

**A priori:** A term that denotes propositional knowledge based on existing information. In the context of systematic reviews, 'a priori' indicates that the inclusion and exclusion criteria are derived from pre-existent information about populations, interventions, and outcomes, and are defined before comprehensively searching the literature.

**Assistive listening device (ALD):** Any device that is part of a user's environment and designed to compensate for a hearing impairment, to prevent or alleviate a handicap situation.

**Before-and-after study (pretest/ post-test study):** A study design where a group is studied before and after an intervention. Interpretation of the result is problematic, as it is difficult to separate the effect of the intervention from the effect of other factors.

**Bias:** Deviation of results or inferences from the truth, or processes leading to such deviation. Any trend in the collection, analysis, interpretation, publication, or review of data that can lead to conclusions that are systematically different from the truth.

**Binaural:** Involving both ears. Binaural means that a hearing aid is fitted to each ear, as opposed to a monaural system in which only one ear is fitted with a hearing aid.

**Blinded study:** A study in which observers and/or subjects are kept ignorant of the group to which they are assigned. When both observers and subjects are kept ignorant, the study is referred to as double blind.

**Case control study:** An epidemiological study involving the observation of cases (persons with the disease, such as cervical cancer) and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined by comparing retrospectively the past history of the people in the two groups with regard to how frequently the attribute is present.

**Case series:** A descriptive study of a subset of a defined population (i.e. a single patient or group of patients) which aims to describe the association between factors or attributes which the sample are exposed to, and the probability of occurrence of a given disease or other outcome. Case series are collections of individual case reports, which may occur within a fairly short period of time.

**Citation:** The record of an article, book, or other report in a bibliographic database that includes summary descriptive information, e.g. authors, title, abstract, source, and indexing terms.

**Clinical effectiveness (effectiveness):** The extent to which a specific intervention, procedure, regimen, or service does what it is intended to do under ordinary circumstances, rather than controlled conditions. Or more specifically, the evaluation of benefit to risk of an intervention, in a standard clinical setting, using outcomes measuring issues of importance to patients (e.g. ability to do daily activities, longer life, etc.).

**Clinical (practice) guideline:** A systematically developed statement to assist practitioner and patient decisions about appropriate health care for one or more specific clinical circumstances. The development of clinical practice guidelines can be considered to be a particular type of HTA; or, it can be considered to be one of the types of policymaking that is informed or supported by HTA

**Cochrane Central Register of Controlled Trials (CENTRAL):** A database of references to controlled trials in health care compiled from the specialised registers of the Cochrane groups and other organisations, searches of MEDLINE, EMBASE and other databases.

**Cochrane Database of Systematic Reviews (CDSR):** This database includes the full text of all available Cochrane Collaboration systematic reviews, and the protocols for reviews that are currently underway.

**Cohort study:** The analytic method of epidemiologic study in which subsets of a defined population can be identified who are, have been, or in the future may be exposed or not exposed in different degrees, to a factor or factors hypothesised to influence the probability of occurrence of a given disease or other outcome. Studies usually involve the observation of a large population, for a prolonged period (years), or both.

**Concealment of allocation:** The process used to assign patients to alternative groups in an RCT in a manner that prevents foreknowledge (by the person managing the allocation as well as the patients) of this assignment. Medical record numbers, personal identification numbers, or birthdays are not adequate for concealment of allocation. Certain centralised randomisation schemes and sequentially numbered sealed, opaque envelopes are among adequate methods of allocation concealment.

**Concurrent control:** A control group that is observed by investigators at the same time as the treatment group, but that was not established using random assignment of patients to control and treatment groups. Differences in the composition of the treatment and control groups may result.

**Confidence interval:** The computed interval with a given probability, e.g. 95%, that the true value of a variable such as a mean, proportion, or rate is contained within the interval. The 95% CI is the range of values in which it is 95% certain that the true value lies for the whole population.

**Conflict of interest:** A situation in which the private interests of someone involved in the assessment or evaluation process (e.g. interviewer, rater, scorer, evaluator) have an impact (either positive or negative) on the quality of the evaluation activities, the accuracy of the data, or the results of the evaluation.

**Confounder:** A third variable that indirectly distorts the relationship between two other variables, because it is independently associated with each of the variables.

**Confounding:** A situation in which the measure of the effect of an exposure on risk is distorted because of the association of exposure with other factor(s) that influence the outcome under study.

**Contra-lateral:** On the other side

**Cost-benefit analysis:** A comparison of alternative interventions in which costs and outcomes are quantified in common monetary units

**Cost-effectiveness analysis (CEA):** A comparison of alternative interventions in which costs are measured in monetary units and outcomes are measured in nonmonetary units, e.g. reduced mortality or morbidity.

**Cost per QALY:** A measure used in CUA to assist in comparisons among programmes; expressed as monetary cost per unit of outcome.

**Cost-utility analysis (CUA):** A form of cost-effectiveness analysis of alternative interventions in which costs are measured in monetary units and outcomes are measured in terms of their utility, usually to the patient, e.g. using QALYs.

**Critical appraisal:** The process of assessing and interpreting evidence by systematically considering its validity, results and relevance.

**Crossover design:** A clinical trial design in which patients receive, in sequence, the treatment (or the control), and then, after a specified time, switch to the control (or treatment). In this design, patients serve as their own controls, and randomisation may be used to determine the order in which a patient receives the treatment and control.

**Cross-sectional study:** A study that examines the relationship between diseases (or other health related characteristics), and other variables of interest as they exist in a defined population at one particular time.

**Database of Abstracts of Reviews of Effects (DARE):** DARE is a database of quality assessed systematic reviews of the effects of health care interventions.

**dB HL (hearing level):** Unit of measurement of the ratio of sound intensities where the reference sound pressure is based on thresholds established for a normal-hearing population. A sound intensity of 0 dB HL corresponds to an intensity of 7.5 dB SPL at 1000 Hz (ANSI S3.6-1996).

**dB SPL (sound pressure level):** Unit of measurement of the ratio of sound intensities where the reference sound pressure is 0.000020 Pa or 20  $\mu$ Pa. A sound pressure of 20  $\mu$ Pa corresponds to a sound intensity of 0 dB SPL.

**Decibel:** dB (deciBel) and the dB scale is used all over the world for measurements of sound level. The deciBel scale is a logarithmic scale where a doubling of sound pressure corresponds to a 6 dB increase in level. It is very important to realize that 'dB' can have different meanings and is not a fixed value like volt, meter etc. The value of dB depends on the context in which it is used. Very often the sound pressure is expressed either in dB SPL, with reference to the weakest sound at 1000 Hz which a normal hearing person can detect or in dB HL where the reference corresponds to the normal hearing threshold of the specific sound. (e.g. from 125 Hz to 8000 Hz) 0 dB SPL and 0 dB HL is therefore not the same. dB HL is used in audiograms, which shows what a person can hear in relation to a young person with normal hearing. When the audiogram curve exceeds 25 dB, we have an abnormal condition - a hearing loss.

**Digital:** Digital sound processing means that the sound is registered mathematically. Digital sound is encoded as a series of numbers (0 and 1), which reflect its pitch and volume at a given instant. The processing is very precise and can be manipulated electronically.

**Direct costs:** The fixed and variable costs of all resources (goods, services, etc.) consumed in the provision of an intervention as well as any consequences of the intervention such as adverse effects or goods or services induced by the intervention. Includes direct medical costs and direct nonmedical costs such as transportation or child care.

**Directional microphones:** Directional microphones pick up signals for sounds coming from directly in front of the user and attenuating sounds originating from other directions.

**Dynamic range:** The difference, expressed in decibels (dB), between a person's auditory threshold and pain threshold. For normal hearing persons, this range is around 100 dB.

**Economic evaluation:** The comparative analysis of alternative courses of action, in terms of their costs and consequences.

**Effectiveness** See also **Clinical effectiveness:** The benefit (e.g. to health outcomes) of using a technology for a particular problem under general or routine conditions, for example, by a physician in a community hospital or by a patient at home.

**Efficacy:** The benefit of using a technology for a particular problem under ideal conditions, for example, in a laboratory setting, within the protocol of a carefully managed randomised controlled trial, or at a "center of excellence."

**Efficiency:** The extent to which the maximum possible benefit is achieved out of available resources.

**EMBASE :** A biomedical and pharmacological database (Excerpta Medica database). The database has particularly strong coverage of European publications. Years of coverage - 1970 to present.

**Evidence table:** A summary display of selected characteristics (e.g. of methodological design, patients, outcomes) of studies of a particular intervention or health problem.

**Explode:** Expansion of the word at the search level to include all relevant indexing terms to avoid limiting the search. When 'explode' a term, the software will search for all the papers that have been indexed with the narrower concepts which are included under the broader term.

**External validity:** The extent to which the findings obtained from an investigation conducted under particular circumstances can be generalized to other circumstances. To the extent that the circumstances of a particular investigation (e.g. patient characteristics or the manner of delivering a treatment) differ from the circumstances of interest, the external validity of the findings of that investigation may be questioned. (See also **Applicability** and **Generalisability**)

**Follow-up:** The ascertainment of endpoints, events, or other outcomes in patients during or following an intervention, or during the natural course of disease or condition, at one or more stated time intervals after initiating the intervention or other baseline of observation. Also: the ability of investigators to collect data on all patients who were enrolled in or otherwise identified for a study for its full duration. To the extent that data on relevant patient outcomes are lost, e.g., among patients who move away or otherwise withdraw from the study, the results may be affected, especially if there are systematic reasons why certain types of patients are lost to follow-up. Investigators should report on the number and type of patients who could not be evaluated, so that the possibility of bias may be considered. (See also **Intention-to-treat analysis**)

**Generalisability:** Generalisability is the degree to which the results of a study or systematic review can be extrapolated to other circumstances, in particular to routine health care situations. (See also **Applicability** and **External validity**)

**Gray/grey literature:** Research reports and other literature in print and electronic formats that is not found in traditional peer-reviewed publications or otherwise controlled by commercial publishers. Examples are government agency monographs, symposium proceedings, and industry reports.

**Health Technology Assessment (HTA):** the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods.

**Health Utilities Index (HUI®):** A generic, preference-scored, comprehensive system for measuring health status, health-related quality of life, and producing utility scores ([www.fhs.mcmaster.ca/hug/](http://www.fhs.mcmaster.ca/hug/))

**Hearing aid:** Any device worn by a user that is designed to correct a hearing impairment, to compensate for a hearing disability, to prevent or alleviate a handicap situation.

**Hearing device:** Any device designed to correct a hearing impairment, to compensate for a hearing disability, to prevent or alleviate a handicap situation.

**Heterogeneity:** In meta-analysis heterogeneity refers to variability or differences in the estimates of effects among studies. A distinction is sometimes made between "statistical heterogeneity" (differences in the reported effects), "methodological heterogeneity" (differences in study design) and "clinical heterogeneity" (differences between studies in key characteristics of the participants, interventions or outcome measures). Statistical tests of heterogeneity are used to assess whether the observed variability in study results (effect sizes) is greater than that expected to occur by chance. However, these tests have low statistical power.

**Historical control:** A control group that is chosen from a group of patients who were observed at some previous time. The use of historical controls raises concerns about valid comparisons because they are likely to differ from the current treatment group in their composition, diagnosis, disease severity, determination of outcomes, and/or other important ways that would confound the treatment effect. It may be feasible to use historical controls in special instances where the outcomes of a standard treatment (or no treatment) are well known and vary little for a given patient population.

**Incidence:** The rate of occurrence of new cases of a disease or condition in a population at risk during a given period of time, usually one year.

**Incremental cost:** The additional costs that one intervention imposes over another.

**Incremental cost effectiveness ratio (ICER):** The additional cost of the more expensive intervention as compared with the less expensive intervention divided by the difference in effect or patient outcome between the interventions, e.g. additional cost per QALY.

**Intention-to-treat (ITT) analysis:** An analysis in which all the participants in a trial are analysed according to the intervention to which they were randomised, whether they: received it or not, completed the study, complied with the study protocol, or crossed over to another group. Intention-to-treat analyses are favoured in assessments of effectiveness as they help to account for the non-compliance and treatment changes

that are likely to occur when the intervention is used in practice and because of the risk of attrition bias when participants are excluded from the analysis. However, for equivalence trials, per protocol analyses are preferred as ITT analyses may dilute treatment effects and thus bias towards equivalence.

**Linear hearing aid:** Hearing device that provides a fixed level of amplification regardless of the intensity of the incident sound signal. By definition, these devices do not have compression circuits allowing for more or less advanced methods of processing the dynamic range of the sound environment.

**Mean (arithmetic mean):** The average value, calculated by summing all the observations and dividing by the number of observations.

**Median:** The middle value in a ranked group of observations. This can be a better estimate of the average value if there are extreme outlying values that may skew the arithmetic mean.

**MEDLINE (MEDlars onLINE):** An electronic database produced by the United States National Library of Medicine. It currently indexes over 12 million references from more than 4,600 biomedical journals. Years of coverage – 1966 to present.

**MeSH:** *Medical Subject Headings*, the controlled vocabulary of about 19,000 terms used for **MEDLINE** and certain other US National Library of Medicine *MEDLARS* databases.

**Meta-analysis:** Systematic methods that use statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study. (Also known as data synthesis or quantitative overview.)

**Methodological quality:** The extent to which the design and conduct of a study are likely to have prevented systematic errors (bias). Variation in quality can explain variation in the results of studies included in a systematic review. More rigorously designed (better 'quality') trials are more likely to yield results that are closer to the 'truth'. (See also **External validity** and **Validity**)

**Nonrandomised controlled trial:** A controlled clinical trial that assigns patients to intervention and control groups using a method that does not involve randomization, e.g. at the convenience of the investigators or some other technique such as alternate assignment.

**Observational study:** A study in which the investigators do not manipulate the use of, or deliver, an intervention (e.g. do not assign patients to treatment and control groups), but only observe patients who are (and sometimes patients who are not as a basis of comparison) exposed to the intervention, and interpret the outcomes. These studies are more subject to selection bias than experimental studies such as randomised controlled trials.

**P-value:** In hypothesis testing, the probability that an observed difference between the intervention and control groups is due to chance alone if the null hypothesis is true. If  $p$  is less than the  $\alpha$ -level (typically 0.01 or 0.05) chosen prior to the study, then the null hypothesis is rejected.

**Parallel group trial:** A trial that compares two contemporaneous groups of patients, one of which receives the treatment of interest and one of which is a control group (e.g. a randomised controlled trial). (Some parallel trials have more than one treatment group; others compare two treatment groups, each acting as a control for the other.)

**Power:** The ability of a study to demonstrate an association if one exists.

**Prevalence:** The number of people in a population with a specific disease or condition at a given time, usually expressed as a proportion of the number of affected people to the total population.

**Primary (research) study:** (1) "Original research" in which data are first collected. The term primary research is sometimes used to distinguish it from "secondary research" (reanalysis of previously collected data), meta-analysis, and other ways of combining studies (such as economic analysis and decision analysis). However, because systematic reviews can provide answers not possible from individual studies they can also be considered to be primary research. (2) An investigation that collects original (primary) data from patients, e.g. randomised controlled trials, observational studies, series of cases, etc.

**Programmable analog hearing aid:** Hearing device that uses electronic circuits to amplify incident sound signals as well as algorithms programmed into one or more microprocessors to control the sound signals.

**Prospective study:** (1) In evaluations of the effects of healthcare interventions, a study in which people are divided into groups that are exposed or not exposed to the intervention(s) of interest before the outcomes have occurred. Randomised controlled trials are always prospective studies and case control studies never are. Concurrent cohort studies are prospective studies, whereas historical cohort studies are not (see cohort study), although in epidemiology a prospective study is sometimes used as a synonym for cohort study. (2) A study in which the investigators plan and manage the intervention of interest in selected groups of patients. As such, investigators do not know what the outcomes will be when they undertake the study.

**Pseudo- or quasi- random allocation:** A method of allocating participants to different forms of care that is not truly random; for example, allocation by date of birth, day of the week, medical record number, month of the year, or the order in which participants are included in the study (alternation). A quasi-randomised trial uses quasi-random method of allocating participants to different interventions. There is a greater risk of selection bias in quasi-random trials where allocation is not adequately concealed compared with randomised controlled trials with adequate allocation concealment.

**Randomisation:** The process of allocating patients to intervention and control groups in clinical trials using a truly random mechanism such as a random number table or a computer generated random number list under blinded conditions. Proper randomisation of patients reduces potential bias in patient assignment because it tends to neutralize known and unknown patient prognostic factors by spreading them evenly among intervention and control groups. Randomisation is necessary for valid use of many statistical tests. Pseudorandomisation methods (or systematic allocation) based on events such as day of the week, name, date of birth, etc are not equivalent to randomisation and can lead to serious biases.

**Randomised controlled trial (RCT):** An experiment of two or more interventions in which eligible people are allocated to an intervention by randomisation. The use of randomization then permits the valid use of a variety of statistical methods to compare outcomes of the interventions.

**Recall bias:** Systematic bias due to differences in accuracy or completeness of recall or memory of past events or experiences.

**Reliability:** The extent to which an observation that is repeated in the same, stable population yields the same result (i.e. test-retest reliability). Also, the ability of a single observation to distinguish consistently among individuals in a population.

**Retrospective study:** study in which investigators select groups of patients that have already been treated and analyse data from the events experienced by these patients. Retrospective studies are subject to selection bias because investigators can select groups of patients with known outcomes or exposures or that are otherwise not truly representative of the broader population of interest. Case control studies are always retrospective, cohort studies sometimes are, randomised controlled trials never are.

**Sample size:** the number of patients studied in a trial, including the treatment and control groups, where applicable. In general, a larger sample size decreases the probability of making a type I (false-positive) error ( $\alpha$ ) and increases the power of a trial, i.e. decreases the probability of making a type II (false-negative) error ( $\beta$ ). Large sample sizes decrease the effect of random variation on the estimate of a treatment effect. In designing a study, the desired sample size can be calculated using statistical formulae based on the acceptable levels of  $\alpha$  and  $\beta$ , the difference between intervention groups considered to clinically relevant, and the associated variance.

**Search strategy:** The combination of sources, terms and limits used in the literature search to identify information for the systematic review or health technology assessment.

**Secondary research:** Research that does not generate primary data but that involves the qualitative or quantitative synthesis of information from multiple primary studies. Examples are literature reviews, meta-analyses, decision analyses and consensus statements.

**Selection bias:** Error due to systematic differences in characteristics between those who are selected for inclusion in a study and those who are not (or between those compared within a study and those who are not).

**Single blind (single masked):** The investigator is aware of the treatment/intervention the participant is getting, but the participant is unaware.

**Speech reception threshold (SRT):** The sound intensity required for recognition of 50% of two-syllable words, expressed in decibels (dB).

**Statistical significance (See P-value) Statistical significance:** A conclusion that an intervention has a true effect, based upon observed differences in outcomes between the treatment and control groups that are sufficiently large so that these differences are unlikely to have occurred due to chance, as determined by a statistical test. Statistical significance indicates the probability that the observed difference was due to chance if the null hypothesis is true; it does not provide information about the magnitude of a treatment effect. For example, a p-value of 0.05 for a risk difference of 10% means that there is less than a one in 20 (0.05) chance of a risk difference as large or larger having occurred if there was really no difference in risks. It is then stated that the risk difference is "statistically significant" at  $p = 0.05$ . A typical cut-off for statistical significance is  $p = 0.05$ , or 0.01 for meta-analyses or 0.10 for assessment of interactions. However, these cut-offs are arbitrary and have no specific importance.

**Systematic review:** Literature review reporting a systematic method to search for, identify and appraise a number of independent studies.

**Time trade-off (TTO):** A method of measuring value by finding the point at which the respondent is indifferent between two health states for different lengths of time. For chronic states, the choices are the index health state for time  $t$  followed by death, or perfect health for a shorter time followed by death. For temporary states, the choices are the index health state for time  $t$  followed by an explicitly specified outcome (usually healthy), or a worse health state for a shorter time followed by the same specified outcome.

**Validity:** The degree to which a result (of a measurement or study) is likely to be true and free of bias (systematic errors). Also, the degree to which a measure or parameter accurately reflects or assesses a concept of interest. Multiple types of dimensions of validity are recognised in research. Internal validity refers to the extent to which the observed cause-and-effect relationship in a study is true for the people and conditions of a study; whereas external validity or generalisability refers to the extent to which the effects observed in a study truly reflect what can be expected in a population and set of conditions those of the study. Among other types of validity are: construct, content, and face validity.

**Willingness to pay (WTP):** The maximum amount that a person is willing to pay: (i) to achieve a particular good health state or outcome, or to increase its probability of occurrence; or (ii) to avoid particular bad health state or outcome, or to decrease its probability.

## Appendix A: Working Party Membership

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<b>Name and area of expertise</b>	<b>Affiliation</b>
John Wilkinson	Population Health Directorate, Ministry of Health,
Sarah Hamlin	Contract Relationship Manager, Health and Disability National Services Directorate, Ministry of Health
Sue Primrose	ESS Development Manager, Health and Disability National Services Directorate, Ministry of Health



## Appendix B: Included Studies

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## Appendix C: Excluded Studies Annotated by Reason for Exclusion

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### Digital hearing aids

Fully retrieved papers excluded for the reason of **not a clinical study**

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## Appendix D: Quality Checklists for Appraising Interventions

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### Method of treatment assignment

- correct, blinded randomisation method described OR randomised, double-blind method stated AND group similarity documented
- blinding and randomisation stated but method not described OR suspect technique (e.g. allocation by drawing from an envelope)
- randomisation claimed but not described and investigator not blinded
- randomisation not mentioned.

### Control of selection bias after treatment assignment

- intention to treat analysis AND full follow-up
- intention to treat analysis AND <15% loss to follow-up
- analysis by treatment received only OR no mention of withdrawals
- analysis by treatment received AND not mention of withdrawals OR more than 15% withdrawals/loss to follow-up/post-randomisation exclusions.

### Blinding

- blinding of outcome assessor AND patient and care giver
- blinding of outcome assessor OR patient and care giver
- blinding not done.

### Outcome assessment (if blinding was not possible)

- all patients had standardised assessment
- no standardised assessment OR not mentioned.

Source: NHMRC (1999) How to review the evidence: systematic identification and review of the scientific literature. Canberra: NHMRC. Modified from I Chalmers, Cochrane Handbook, available on the Cochrane Library CD-ROM



## Appendix E: Data Extraction Tables

**Table 24 RCT Data extraction table: Shi *et al.*, (2007)**

<b>Citation</b>	Shi LF, Doherty KA, Kordas TM and Pellegrine JT. (2007) Short-term and long-term hearing aid benefit and user satisfaction: a comparison of two fitting protocols. <i>J Am Acad Audiol</i> 18:482-495.
<b>Level of evidence *</b>	III-I
<b>Country</b>	US
<b>Research question/aims</b>	The objective was to compare two hearing aid fitting protocols in their effects on benefit and satisfaction. The two protocols were compared to determine whether the inclusion of loudness and speech-in-noise measures would result in improved hearing aid benefit and user satisfaction, as assessed by the APHAB and SADL.
<b>Study type/design</b>	Single-site, pseudo-Randomized controlled trial, single-blinded.
<b>Patient group</b>	<p><u>Participants</u>: patients who came at Gebbie Hearing Clinic at Syracuse University</p> <p><u>Inclusion criteria</u>: Patients who were recommended midlevel digital BTE or ITE hearing aid during the recruitment period for this study</p> <p>Exclusion criteria: not specified</p> <p><u>Subject disposition</u>: Of 32 participants, the first participant to accept the offer to participate in the study was randomly assigned to one of the two groups (which happened to be Group A). The following participants were alternately assigned to Group B and Group A when they consented to be in the study.</p> <p><u>Group A arm</u>: N=16 (who were fitted with digital hearing aids according to protocol A), 62.5% male, median age 78.0, mean (74.5) (<math>\pm</math> SD) 11.3 years. 11 were fitted for the first time</p> <p><u>Group B arm</u>: N=16 (who were fitted with digital hearing aids according to protocol B), 50% male, median age 76.5, mean (74.4) (<math>\pm</math> SD) 9.9 years. 10 were fitted for the first time</p> <p>A Mann-Whitney <i>U</i>-test indicated that there was no significant differences between the two groups of patients' ages (<math>U = 271.500</math>, <math>p = 0.792</math>) and degrees of hearing loss (<math>p &gt; 0.05</math>), differences in thresholds between the two groups reached statistical significance at 2000 Hz (<math>t = -1.962</math>, <math>p = 0.055</math>), with participants in Group B with poorer thresholds than participants in Group A.</p>
<b>Intervention</b>	<p>Digital hearing aids are: GN ReSound Canta2 and 4 series (n=11) Oticon Gaia (n=1), Phonak Aero (n=1), and Unitron Unison6 (n=3). All have 3 programmes and similar standard features (directional microphone, feedback cancellation, digital noise reduction and telecoil), 2 BTE, 4 ITE, 12 binaural and 4 monaural</p> <p>Protocol A: Electroacoustic analysis, real-ear measures, and hearing aid adjustments based on users' comments.</p>
<b>Comparator</b>	Protocol B (all of protocol A and a speech-in-noise test (QuickSIN test), loudness discomfort levels, and aided loudness). Both protocols included 2-cc coupler responses and real-ear measures.

**Table 24 RCT Data extraction table: Shi *et al.*, (2007)  
(continued)**

<p><b>Outcome definitions</b></p>	<p>Real-ear measure in various speech inputs (soft, average and loud) at baseline for both groups.</p> <p>Gain adjustments (number of hearing aid adjustments made within the 45-day trial period) for both groups. Calculating average overall adjustments and average overall adjustments based on user comments.</p> <p>Benefit of hearing aids by APHAB questionnaires (mean benefit score %) at the end of 45-day trial period and at the end of the 3-month after fitting the hearing aid (for both groups).</p> <p>Patients satisfaction with hearing aids as measured through the SADL questionnaire (mean satisfaction score %) for both groups at the end of 45-day trial period and at the end of the 3-month after fitting the hearing aid.</p>
<p><b>Data analyses &amp; statistics</b></p>	<p><u>Analyses</u>: effectiveness analyses of both fitting protocols were based on subjects who returned their questionnaires (all at the end of 45-day trial, and 11/16 for protocol A, and 14/16 for protocol B after 3-months of the fitting). Analyses were made using paired <i>t</i>-test. Results were reported as either number of adjustments or mean scores percentages.</p> <p><u>Sample size calculation</u>: Power analysis based on APHAB and SADL normative data, indicated that the sample size was sufficient to achieve <math>\beta = 0.80</math> at <math>\alpha = 0.05</math>. That is a total of 16 subjects per arm were required to ensure 80% of power to claim APHAB and SADL normative data difference of 0.5%.</p>
<p><b>Study quality</b> † See below for “A-G” quality criteria questions</p>	<p>A. <u>Adequate for a pseudo-randomised study</u>. First patient was randomly assigned to one group, then used alternation for the following patients. (2)</p> <p>B. <u>Inadequate</u>. Those assigned to Group A fitted with Protocol A and those assigned to B were fitted with Protocol B. (1)</p> <p>C. <u>Reported</u>. No significant differences between two groups in terms of age and degree of hearing loss. Stated that the two groups showed similarity in their gender as well as experience with hearing aids. The difference in thresholds between the two groups approached statistical significance at 2000 Hz (<math>t = -1.962</math>, <math>p = 0.055</math>), with participants in Group B having poorer thresholds than participants in Group A. (2)</p> <p>D. <u>Inadequate</u>. Inclusion criteria only. (1)</p> <p>E. <u>Adequate</u>. Mean benefit score % and mean satisfaction score % were reported at trial period and post-fit. (2)</p> <p>F. <u>Inadequate</u>. Effectiveness analyses were based on the number of subjects who responded to the follow up rather than on an ITT basis. After 45 days, all participants completed the APHAB and SADL questionnaires so analyses were same for pre and post fit. Whereas 3-months following the hearing aid fitting, there were drop-outs (7) and they were not included in the analysis. (1)</p> <p>G. <u>Adequate</u>. The numbers of subjects who did not complete follow-up or withdrew from the study with reasons were stated. 7 subjects (5 in Protocol A arm and 2 in Protocol B arm) did not complete the study. 1 switched to another model, 2 withdrew for health reasons, 2 displeased with performance of hearing aid, 1 did not respond to mail or phone, and 1 upgraded hearing aids. (2)</p> <p>Overall study quality: <b>Good (rated 11)</b></p>

**Table 24 RCT Data extraction table: Shi *et al.*, (2007)  
(continued)**

<p><b>Results (within scope of systematic review update)</b></p>	<p>Mean benefit score % at end of study: Protocol A vs Protocol B no significant differences, <math>p &gt; 0.05</math></p> <p>Mean satisfaction score % at end of study: Protocol A vs Protocol B no significant differences, <math>p &gt; 0.05</math></p> <p>Protocol A Mean satisfaction scores % change from 45-day to study end (3-months): Service and Cost subscale Lower at 3-month (<math>t = 2.701, p = 0.022</math>)</p> <p>Negative Feature subscale Lower at 3-month (<math>t = 2.250, p = 0.048</math>)</p>
<p><b>Authors' conclusions</b></p>	<p>Fewer hearing aid adjustments were made to the hearing aids for participants fitted with Protocol B than participants fitted with Protocol A, but final gains were similar for both groups. The inclusion of LDL, aided loudness, and speech-in-noise measures in a hearing aid fitting protocol tended to reduce the total number of hearing aid adjustments and significantly reduced the number of adjustments based on patient comments. Although these measures did not improve initial hearing aid benefit and satisfaction, patients who did not receive them showed a significant decrease in their hearing aid satisfaction over time.</p>
<p><b>Reviewer's notes</b></p>	<p>The main objective was to compare the effectiveness of fitting protocols rather than actually assessing the effectiveness of a particular style of digital hearing aid.</p> <p>Small sample size in each arm of the study.</p>
<p><b>Relevance to study question</b></p>	<p>At study entry, participants were those who came to the Hearing Clinic were recommended digital hearing aid (BTE or ITE).</p> <p>Participants were adults (mean age <math>&gt; 74</math> years).</p> <p>Intervention and comparator appropriate (both digital hearing aids)</p>

Abbreviations: BTE, behind-the-ear, ITE, in-the-ear, LDL, loudness discomfort level, \* As per NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies, † The quality of RCTs was assessed using the following questions: (A) Was the assignment to the treatment groups really random?; (B) Was the treatment allocation concealed?; (C) Were the groups similar at baseline in terms of prognostic factors?; (D) Were the eligibility criteria specified?; (E) Were the point estimates and measure of variability presented for the primary outcome measure?; (F) Did the analysis include an intention-to-treat analysis?; (G) Were withdrawals and dropouts completely described?

**Table 25 Non-RCT Data extraction table: Folmer and Carroll (2006) (concurrent controls)**

<b>Citation</b>	Folmer RL and Carroll JR (2006). Long-term effectiveness of Ear-level devices for Tinnitus. <i>Otolaryngology-Head and Neck Surgery</i> 134, 132-137.
<b>Level of evidence *</b>	III-2
<b>Country</b>	USA
<b>Research question/aims</b>	To assess long-term changes in tinnitus severity exhibited by patients who used hearing aids or ear-level sound generators as part of a tinnitus management program. To contribute to the development and refinement of effective assessment and management procedures for tinnitus.
<b>Study type/design</b>	Prospective
<b>Patient group</b>	<p><u>Participants</u>: Patients who purchased and used ear-level devices (hearing aids or sound generators).</p> <p><u>Inclusion criteria</u>: Patients who purchased and used one or two hearing aids or in-the-ear generator daily for 6 months.</p> <p>Exclusion criteria: Not specified</p> <p><u>Subject disposition</u>: allocation to treatment was based on the patient's audiological evaluations, specific devices were described and demonstrated. Patients with mild hearing loss: sound generators or behind-the-ear digital hearing aids were recommended, for significant, aidable hearing loss: digital hearing aids were recommended. Consecutive patients who purchased and used one or two hearing aids, 1 or 2 in-the-ear sound generator for at least 6 months, and patient who did not use ear-level devices.</p> <p><u>Hearing aid arm</u>: N=50 (consecutive patient who purchase and used one or two hearing aids), 60% male, age 55.8 (<math>\pm</math> 17.0y). Higher thresholds for all frequencies tested between 250-8,000 Hz (<math>p</math> &lt;0.0001) at baseline. 7.5 (<math>\pm</math> 8.4y) years from tinnitus onset to initial clinical appointment.</p> <p><u>Sound generator arm</u>: N=50 (consecutive patient who purchase and used one or two in-the-ear sound generator), 76% male, age 49.8 (<math>\pm</math> 12.2y). Lesser thresholds for all frequencies tested between 250-8,000 Hz than hearing aid arm (<math>p</math> &lt;0.0001) at baseline. 4.0 (<math>\pm</math> 5.9y) years from tinnitus onset to initial clinical appointment.</p> <p><u>No device patients</u>: N=50 (consecutive patient who did not use ear level devices, 70% male, age 52.8 (<math>\pm</math> 13.0y). Averaged pure tone thresholds fell between the averaged values for sound generator and hearing aid patients. 6.9 (<math>\pm</math> 7.5y) years from tinnitus onset to initial clinical appointment.</p>
<b>Intervention</b>	Hearing aid (digital behind-the-ear)
<b>Comparator</b>	Concurrent control groups: Sound generator (in-the-ear), No device

**Table 25 Non-RCT Data extraction table: Folmer and Carroll (2006) (continued)**

<p><b>Outcome definitions</b></p>	<p>As part of the initial appointment evaluation, audiological evaluations included pure tone air and bone conduction thresholds; word recognition in quiet and noise; MCL (most comfortable sound level) / UCL (uncomfortable sound level) testing; tympanometry.</p> <p>Mean responses to questionnaires by the groups, at initial time and follow-up (6-48 months, mean 18m) for all groups.</p> <p>Self-rated loudness: Patients rated the loudness of their usual tinnitus on a 1-to-10 scale, 1 being very quiet, and 10 very loud (details provided in the actual paper).</p> <p>Tinnitus Severity Index: An indicator of the negative impacts of tinnitus upon patients that includes 12-questions (details provided in the actual paper)</p> <p>Back Depression Inventory score: From a questionnaires contained an abbreviated version of the BDI with additional one question (5 answer choices). Details provided in the paper.</p>
<p><b>Data analyses &amp; statistics</b></p>	<p>Results were accompanied by <i>p</i> values, no details were stated on how statistical analyses were performed</p> <p>HA users: Self –rated loudness and Tinnitus Severity Index scores reduced at follow-up (<math>p \leq 0.0005</math>, and <math>p \leq 0.0001</math>), no change in Depression Inventory scores.</p> <p>Non HA users also showed similar significant reductions at follow up. Reductions in HA users were more than reductions in non-HA users.</p>
<p><b>Study quality</b>  <b>† See below for “A-G” quality criteria questions</b></p>	<p>A. <u>Inadequate</u>. Consecutive patients. (1)</p> <p>B. <u>Inadequate</u>. Treatment allocation not concealed, but based on results from evaluations of acoustic therapies. (1)</p> <p>C. <u>Reported</u>. Differences between the three groups in duration of tinnitus before appointment (HA experienced tinnitus for a longer time), higher thresholds for HA group for all frequencies. (2)</p> <p>D. <u>Inadequate</u>. Inclusion criteria only (1)</p> <p>E. <u>Adequate</u>. Mean responses and outcome scores were reported at initial appointment and at follow-up. (2)</p> <p>F. <u>Adequate</u>. Although the authors did not mention they used an ITT analysis, analyses at initial and end of study included all subjects from all groups. (2)</p> <p>F. <u>Adequate</u>. Although the authors did not mention there were withdrawal or drop outs or loss to follow-up. All responses were obtained and tabulated from all included subjects. (2)</p> <p>Overall study quality <b>Good (score 11)</b></p>

**Table 25 Non-RCT Data extraction table: Folmer and Carroll (2006) concurrent controls (continued)**

<b>Results (within scope of systematic review update)</b>	<p>Responses to follow-up mailed questionnaires (6 to 48 months following initial appointment)</p> <p>Significant reductions in self-rated loudness of tinnitus, and Tinnitus Severity Index scores. (<math>p \leq 0.0005</math>, and <math>p \leq 0.0001</math>)</p> <p>Self-rated loudness of tinnitus scores Hearing aids 16% reduction vs 18% reduction with sound generators</p> <p>Tinnitus Severity Index scores Hearing aids 23% reduction vs 17% reductions with sound generators</p>
<b>Authors' conclusions</b>	<p>Hearing aids improve speech perception for patients with significant hearing loss. Ear level devices such as hearing aids or sound generators can help a significant number of patients who experience chronic tinnitus. Both types of devices reduce patients' perception of tinnitus and can facilitate habituation to the symptom. Amplification provides additional benefits of improved hearing and communication.</p>
<b>Reviewer's notes</b>	<p>Patients were evaluated and treated within a tinnitus management programme.</p>
<b>Relevance to study question</b>	<p>32 Patients suffer hearing loss, age <math>\geq 18</math> years</p> <p>Intervention (one arm is digital hearing aids), allocation of the devices was based on audiological/acoustic evaluations.</p> <p>Comparator (one arm is no use of any device)</p>

Abbreviations:\* As per NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies

† The quality of RCTs was assessed using the following questions: (A) Was the assignment to the treatment groups really random?; (B) Was the treatment allocation concealed?; (C) Were the groups similar at baseline in terms of prognostic factors?; (D) Were the eligibility criteria specified?; (E) Were the point estimates and measure of variability presented for the primary outcome measure?; (F) Did the analysis include an intention-to-treat analysis?; (G) Were withdrawals and dropouts completely described?

**Table 26 Non-RCT Data extraction table: Taylor (2006)**

<b>Citation</b>	Taylor B (2006). Real-world satisfaction and benefit with open-canal fittings. <i>The Hearing Journal</i> 59(11):74-82
<b>Level of evidence *</b>	III-2
<b>Country</b>	USA
<b>Research question/aims</b>	To determine the real-world benefit and satisfaction of open-canal (OC) style hearing aids as compared to non-open-canal (non-OC) style of hearing aids.
<b>Study type/design</b>	Two separate patient-survey studies. (Of pre-post comparative nature)
<b>Patient group</b>	<p>Study A</p> <p><b>Study question:</b> “Are experienced hearing aid users who are now wearing an OC product more satisfied than experienced users of non-open products who also received new hearing aids?”</p> <p><u>Participants:</u> Experienced hearing aid users</p> <p><u>Inclusion criteria:</u> Not specifically stated.</p> <p><u>Exclusion criteria:</u> If hearing loss was greater than 45-dB at 500 Hz and / or greater than 85 dB at 4000 Hz.</p> <p><u>Subject disposition:</u> Participants were randomly chosen by clinicians to take part in the study. Participants’ age ranged from 41 to 80 years of age.</p> <p><u>Open canal arm:</u> (Experienced hearing aid users wearing open canal devices for the first time), N=27 (18 male, and 9 female). Opted to obtain these devices because they had struggled with occlusion problems in the past or they wanted more cosmetically appealing instruments.</p> <p><u>Non-open canal arm:</u> (Experienced users of non-open products recently fitted with another pair of non-OC devices), N =27 (16 male, and 11 female), had hearing aids that were more than 5 years old, and they opted for new devices. They were generally satisfied with their current devices and interested in getting hearing aids very similar to their devices.</p> <p>Study B</p> <p><b>Study question:</b> “Do new users of OC hearing aid perceive more benefit and satisfaction than new users of non-OC hearing aids?”</p> <p><u>Participants:</u> New hearing aid users</p> <p><u>Inclusion criteria:</u> Not specifically stated.</p> <p><u>Exclusion criteria:</u> If hearing loss was greater than 45-dB at 500 Hz and / or greater than 85 dB at 4000 Hz.</p> <p><u>Subject disposition:</u> Participants who were recently fitted with hearing aids for the first time. Subjects ranged from 47 to 75 years of age.</p> <p><u>Open canal arm:</u> (New hearing aid users wearing open canal devices for the first time), N=22 (16 male and 6 female).</p> <p><u>Non-open canal arm:</u> (New hearing aid users wearing non-open canal devices for the first time), N=13 (9 male, and 4 female).</p> <p>All participants were fitted bilaterally.</p> <p>Hearing aids were fitted and adjusted to match prescribed targets using the National Acoustic Laboratory (NAL-R) prescriptive formula for average intensity inputs.</p>
<b>Intervention</b>	Hearing aid (open canal)
<b>Comparator</b>	Hearing aid (non-open canal)

**Table 26 Non-RCT Data extraction table: Taylor (2006)**  
(continued)

<p><b>Outcome definitions</b></p>	<p>Both studies used self-report outcome measures to assess real-world benefit and satisfaction of OC users with people wearing non-OC products. Survey questionnaires were administered 1-3 months post-fitting.</p> <p>Study A Used Question 36 from MarkeTrak survey and Amplifon Satisfaction survey. Question 36 consists of 23 sub-questions that measure self-reports of satisfaction (using 5-point Likert scale) for a number of product features. Amplifon Satisfaction Survey is a non-standardized, 13-question survey (uses 5-point Likert scale), it also attempts to quantify satisfaction with various product features and performance. It differs from the MarkeTrak questions in that one question quantifies overall satisfaction with the current hearing aids. Product feature categories are: comfort and fit, sound quality, telephone use, overall sound quality, and overall satisfaction.</p> <p>Study B Used APHAB and IOI-HA APHAB is 24-question, self report scale, measures benefit (calculated by comparing responses in unaided condition to aided condition). Four subscales (Ease of Communication, Background Noise, Reverberation, and Aversiveness). IOI-HA is a 7-question survey, addresses benefit, satisfaction, and changes in quality of life following hearing aid use.</p>
<p><b>Data analyses &amp; statistics</b></p>	<p>No details on the Statistical analyses carried out for the survey questionnaires were provided and no test of significance was stated.</p> <p>Results were presented in tables and figures, with data on mean scores were presented in histograms.</p> <p>Study A Mean satisfaction ratings for OC and non-OC groups: Amplifon Survey: Results showed OC users are more satisfied than their non-OC users on four of the 12 sub-questions (sound quality of own voice, phone comfort, sound localisation, and appearance/cosmetics). No test of significance was shown in the results.</p> <p>For MarkeTrak Satisfaction Survey: Higher satisfaction by OC group than non-OC group on sound of own voice, sound of chewing/swallowing, wind noise, visibility to others, and localisation (no test of significance was shown in the results).</p> <p>Study B Mean satisfaction ratings for OC and non-OC groups (test of significance was not stated): APHAB: Average degree of benefit on three of the four subscales of the APHAB for the two groups. Results for each of the EC, RV and BN benefit subscales shows a greater than 20-point difference for both OC and non-OC groups, (no difference in benefit between the two groups). IOI-HA: Mean scores for all seven questions indicate that both groups derive significant benefit, satisfaction, and improvement in quality of life from amplification compared with published IOI-HA norms for patients with mild to moderate hearing loss.</p>
<p><b>Study quality</b> † See below for “A-G” quality criteria questions</p>	<p>A. <u>Unknown</u>. For study A it was only mentioned that participants randomly chosen by clinicians to take part in the study, and study B did not specify. (0)</p> <p>B. <u>Inadequate</u>. Both studies did not conceal the treatment allocation. (1)</p> <p>C. Not reported. (0)</p> <p>D. <u>Inadequate</u>. Exclusion criteria only. (1)</p> <p>E. <u>Adequate</u>. Mean benefit score, and mean satisfaction, similarities and differences, score were reported 1-3 months post-fit. (2)</p> <p>F. <u>Inadequate</u>. Effectiveness analyses were based on the number of subjects who responded to the follow up rather than on an ITT basis. (1)</p> <p>G. <u>Unknown</u>. No information was provided on whether there were withdrawal or dropouts. (zero)</p> <p>Overall study quality: <b>Fair (rated 5)</b></p>

**Table 26 Non-RCT Data extraction table: Taylor (2006)**  
**(continued)**

<b>Results (within scope of systematic review update)</b>	<p>Study A Relatively high rating of overall satisfaction: Mean 3.95 (non-OC) and 4.41 (OC group)</p> <p>Study B (1-3m post-fit)</p>
<b>Author's conclusions</b>	<p>For experienced hearing aid users, who now wear OC products, in terms of overall satisfaction they are not more satisfied than users of non-OC devices. However, there are some important expectations. Users of OC devices appear to enjoy a real-world advantage over users of non-OC devices in the areas of sound localisation, quality of their own voice, and appearance.</p> <p>For new hearing aid users, in the areas of communication assessed by the APHAB, the data did not reveal real-world evidence that OC devices offer greater benefit than non-OC. The results of IOH-HA also showed that OC users have fewer residual activity limitations and participation restrictions than do non-OC users. This may suggest that OC hearing aids are a better choice for patients wishing to lead an active lifestyle.</p> <p>In conclusion based on the outcome of both studies, it appears that when hearing aids are properly fitted and the patient is motivated, there is no substantial difference in real-world outcomes between OC and non-OC groups. However, there are a few key product features unique to OC devices that would make them a superior choice for some patients.</p>
<b>Reviewer's notes</b>	<p>Both studies collected data from multiple hearing aid dispensing sites around USA. All participants completed a routine audiological test battery and pre-fitting needs assessment using the Client Oriented Scale of Improvement (COSI) prior to the fitting.</p> <p><u>Conflict of interest:</u> The author of this paper is the Director of Professional Development of Amplifon USA</p>
<b>Relevance to study question</b>	<p>Participants were with hearing loss Aged <math>\geq</math> 18y Intervention and comparators are appropriate Outcomes appropriate (satisfaction)</p>

Abbreviations:

\* As per NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies

† The quality of RCTs was assessed using the following questions: (A) Was the assignment to the treatment groups really random?; (B) Was the treatment allocation concealed?; (C) Were the groups similar at baseline in terms of prognostic factors?; (D) Were the eligibility criteria specified?; (E) Were the point estimates and measure of variability presented for the primary outcome measure?; (F) Did the analysis include an intention-to-treat analysis?; (G) Were withdrawals and dropouts completely described?

**Table 27 Non-RCT Data extraction table: Gnewikow and Moss (2006)**

<b>Citation</b>	Gnewikow and Moss (2006) Hearing aid outcomes with open- and closed-canal fittings. <i>The Hearing Journal</i> 59(11):66-72
<b>Level of evidence *</b>	Level III-3
<b>Country</b>	US
<b>Research question/aims</b>	The objective was to determine if significant differences were present in hearing aid outcomes (satisfaction, benefit, and return-for-credit percentage) for patients with high-frequency sensorineural hearing losses fitted with traditional and open canal hearing aids.
<b>Study type/design</b>	Retrospective
<b>Patient group</b>	<p><b>Participants:</b> Patients with high frequency sensorineural hearing loss who purchased hearing aids from July 2004 to July 2005 at Vanderbilt Bill Wilkerson Centre</p> <p><b>Inclusion criteria:</b> Any patients whose sensorineural hearing loss thresholds fell within normal/mild sloping to moderately-severe range were included as potential participants, regardless of the hearing aids with which they were fitted.</p> <p><b>Exclusion criteria:</b> Patients who returned their hearing aids for credit were excluded as potential participants.</p> <p><b>Subject disposition:</b> (Adults, age not specified), Of 338 recruited, 97 had GN ReSound Air OC hearing aids, remainder were fitted with various closed canal devices. 106 of non-OC were BTE, 54 ITE, 41 ITC and 40 CIC. Questionnaires were completed by 133/338 subjects from both groups (39.3%); (41/97; 42% from OC users), (92/241; 38% from non-OC users).</p> <p><b>OC Group arm:</b> N= 97 adults fitted with GN ReSound Air OC hearing aids, no other information was provided.</p> <p><b>Non-OC Group arm:</b> N= 241 adults fitted with variety of non-OC hearing aid styles (and technologies), no other information was provided.</p>
<b>Intervention</b>	OC digital hearing aid GN ReSound Air.
<b>Comparator</b>	Non-OC hearing aids

**Table 27 Non-RCT Data extraction table: Gnewikow and Moss (2006) (continued)**

<p><b>Outcome definitions</b></p>	<p>Three measures of hearing aid outcome (SADL, IOI-HA, and an empirically designed questionnaire) mailed to the potential participants for completion and return in a postage-paid envelop. A return-for-credit data were also analysed.</p> <p>SADL (questionnaire): Self-report inventory to quantify patient satisfaction, provides global satisfaction score and a profile of subscale scores (Positive Effects, Service and Cost, Negative Features, and Personal Image). It has 15-items at seventh-grade reading level. Requires less than 10 minutes to complete (reliability stated as good, and internal and external validity supported by references).</p> <p>IOI-HA (questionnaire): Designed to assess overall hearing aid outcome, including benefit, use, handicap, and satisfaction. Consists of 7-items at a low reading level, with low cognitive requirements</p> <p>OC (questionnaire) a supplement to SADL and IOI-HA: An additional questionnaire to specifically evaluate occlusion effect, feedback, phone use, and overall sound quality using a Likert scale.</p>
<p><b>Data analyses &amp; statistics</b></p>	<p>Upon receipt of the completed questionnaires, data were blinded (removed all identifying information) and data were analysed using analysis of variance (ANOVA).</p> <p>SADL overall ANOVA of the HA global means did not reach significance (<math>F=2.98</math>, <math>p&gt;0.05</math>). A follow-up showed significant effect of hearing aid for the Negative Features (<math>F=4.055</math>, <math>p&lt;0.05</math>), with a mean for the OC group of 4.36 vs 3.86 (non-OC group).</p> <p>IOI-HA overall ANOVA of the HA means did not reach statistical significance (<math>F=0.893</math>, <math>p&gt;0.05</math>). Significant differences on daily use (non-OC group reported more use), and pertaining to the amount of difficulty still experienced with hearing aids (OC rated better than non-OC groups).</p> <p>OC questionnaire analyses revealed significant differences between hearing aid groups with subjects in the OC group scored significantly higher than those in the non-OC group. No other significant between-group differences on the other questions.</p> <p>Return-for-credit percentages for the two hearing aid groups showed lesser rates for OC than non-OC hearing aids (1.8% vs 11.3%). (no ANOVA results were shown)</p>
<p><b>Study quality</b> † See below for “A-G” quality criteria questions</p>	<p>A. <u>Inadequate</u>. Selective patients (1). B. <u>Inadequate</u>. Treatment allocation not concealed, no other information provided (1). C. <u>Not reported</u> No information on demographic or other baseline characteristics. (0) D. <u>Adequate</u>. Inclusion criteria, and specified who to exclude (2) E. <u>Inadequate</u>. Mean responses and outcome scores were reported only once at time of collecting data. (1) F. <u>Inadequate</u>. ITT analysis was not carried out as analyses involved only responses on questionnaires from participants who returned their responses. (1) F. <u>Unknown</u>. Although data showed very poor response rate, there were no information on reasons for this or no information on follow-up for those who did not respond. (0) Overall study quality <b>Fair (rated 6)</b></p>

**Table 27 Data extraction table: Gnewikow and Moss (2006)**  
(continued)

<b>Results (within scope of systematic review update)</b>	<p>Of the 133 who completed the questionnaires, 41 OC users, 92 non-OC users, of which 49 used BTE, 17ITE, 13 ITC and 13 CIC users.</p> <p>Results from the study showed that participants fitted with OC hearing aids were less dissatisfied on the Negative Features of the SADL subscale than did users fitted with traditional amplification (mean score for OC group 4.36 compared to non-OC group 3.86, <math>F=2.985</math>, <math>P&gt;0.05</math>).</p> <p>No statistical significance on the overall IOI-HA, however, the OC and non-OC groups different significantly on daily use time (with non-OC reported more daily use than OC group) and the amount of difficulty still experienced with hearing aids (better rating for OC group than non-OC group).</p> <p>Significant differences between hearing aid groups in own voice and occlusion questions, with subjects in the OC group scored significantly higher/better than those in the non OC group.</p> <p>As for the Return-for-Credit (RFC) rates: Percentages were obtained for both closed fittings and open fittings and compared with clinic averages, as well as with national averages. Analyses showed that OC fittings resulted in an RFC rate of 1.8% compared to 11.3% of the non-OC fittings.</p>
<b>Authors' conclusions</b>	<p>There were significant differences in open and closed canal hearing aid fittings, it is likely that the overall SADL and IOI-HA scores do not specifically take into account the variables that contribute to the significantly lower return rates.</p> <p>The cosmetic, localisation, and comfort advantages reported by Taylor (2006), data from dispensers of open canal and no-open canal products, as well as the improved ratings of satisfaction with respect to occlusion and comfort, decreased reported difficulty in key listening environments, and the decreased return-for-credit rates give dispensers strong support for fitting OC devices on appropriate audiometric candidates.</p>
<b>Reviewer's notes</b>	<p>Response rate was poor</p> <p>Age was not specified</p>
<b>Relevance to study question</b>	<p>Participants were with hearing loss</p> <p>Aged <math>\geq 18y</math></p> <p>Intervention and comparators are appropriate</p> <p>Outcomes appropriate (satisfaction)</p>

Abbreviations:

\* As per NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies

† The quality of RCTs was assessed using the following questions: (A) Was the assignment to the treatment groups really random?; (B) Was the treatment allocation concealed?; (C) Were the groups similar at baseline in terms of prognostic factors?; (D) Were the eligibility criteria specified?; (E) Were the point estimates and measure of variability presented for the primary outcome measure?; (F) Did the analysis include an intention-to-treat analysis?; (G) Were withdrawals and dropouts completely described?

**Table 28 Data extraction table: Kochkin (2000)**

<b>Citation</b>	Kochkin S (2000). Customer satisfaction with single and multiple microphone digital hearing aids. <i>The Hearing Review</i> November 2000.
<b>Level of evidence *</b>	III-3
<b>Country</b>	USA- a single European-based manufacturer
<b>Research question/aims</b>	To survey the consumers' reaction and satisfaction to new digital technology (new digital hearing aids).
<b>Study type/design</b>	(Cross-sectional) Retrospective Survey questionnaire (MarkeTrak)  Specific manufacturers of digital hearing instruments were asked to recruit dispensing professionals to send out Knowles' MarkeTrak surveys to consumers of digital hearing instruments within the past year.
<b>Patient group</b>	<u>Participants:</u> Consumers of digital hearing instruments  Inclusion criteria: Not stated  Exclusion criteria: Not stated  <u>Subject disposition:</u> MarkeTrak surveys sent to consumers of digital hearing aids. Of nearly 496 customer satisfaction surveys returned, 200 were single omnidirectional microphone, 296 were multiple microphone digital hearing instruments.  <u>Single microphone arm:</u> N=200 adults, mean age 70y, 58% male, 84% bilateral loss, 75% binaural fitting, 57% moderate hearing loss, 34% severe hearing loss, 56% ITC hearing aid, 44% ITE, age of hearing aid 6.8 months  <u>Multiple microphone arm:</u> N=296 adults, mean age 71y, 60% male, 90% bilateral loss, 76% binaural fitting, 41% moderate hearing loss, 53% severe hearing loss, 69% BTE hearing aid, 31% ITE, age of hearing aid 6.6 months  <u>MarkeTrak arm:</u> N=418 adults, mean age 68y, 63% male, 82% bilateral loss, 50% moderate hearing loss, 38% severe hearing loss, 43% ITC hearing aid, 40% ITE, 17% BTE, age of hearing aid 7.8 months
<b>Intervention</b>	Digital hearing aids (single)
<b>Comparator</b>	Digital hearing aids (multiple microphone) MarkeTrak Norm

**Table 28 Data extraction table: Kochkin (2000) (continued)**

<b>Outcome definitions</b>	<p>Comparison of responses returned from the MarkeTrak survey questionnaire (Customer satisfaction)</p> <p>Customer satisfaction and dissatisfaction for single microphone digital and multiple microphone digital samples assessed and documented.</p> <p>Customer satisfaction difference scores between each of the samples.</p> <p>Overall satisfaction factors were ranked in order as: benefit (improved hearing), clarity of sound, value (price relative to performance), reliability, use of hearing instrument in leisure activities, natural sounding, use in noisy situations, use in large group situations, use in restaurants, and use outdoors.</p>
<b>Data analyses &amp; statistics</b>	<p><u>Analyses:</u> Were based only on responses returned from the questionnaires (total returned were 496). These were compared to the MarkeTrak Norms (total 400) derived from the Knowles MarkeTrak V database. Customer satisfaction was assessed by percentage difference in customer ratings. All variables with at least a 10% improvement in ratings due to digital or matched multiple microphone technology were graphed.</p> <p>Sample calculation: Not stated</p>
<b>Study quality</b> † See below for “A-G” quality criteria questions	<p>A. <u>Inadequate</u>. Selective patients. (1)</p> <p>B. <u>Unknown</u>. (0)</p> <p>C. <u>Reported</u>. The digital users in the study tended to be slightly older, significantly more affluent, with higher degrees of hearing loss (multiple microphone sample only), and higher incidence of binaural fittings, average age for the digital hearing instruments was slightly more than six months. (2)</p> <p>D. <u>Unknown</u>. Not stated (0)</p> <p>E. <u>Not applicable</u>. As responses were for a one time period, however, customer satisfaction scores between the samples were presented, mean scores and statistical significance test results between the three samples. (1)</p> <p>F. <u>Not applicable</u>. Analysis was only for responses on questionnaires from participants who returned their responses. (0)</p> <p>F. Not applicable. (0)</p> <p>Overall study quality <b>Poor (rated 4)</b></p>

**Table 28 Data extraction table: Kochkin (2000) (continued)**

<b>Results (within scope of systematic review update)</b>	<p>Overall satisfaction: multiple microphone digital hearing aids vs single microphone digital aids better overall satisfaction (78% versus 64%), quality of life (82% versus 72%) and hours worn per day (11.9 versus 10.8).</p> <p>Single microphone (omnidirectional): rated higher than MarkeTrak on 4/39 variables (not including dispenser ratings) (none of which make the top-10 list of factors most correlated with overall satisfaction).</p> <p>Multiple microphone (directional): rated 17% higher on consumer satisfaction, and 18/39 factors (not including dispenser ratings); rated higher (by 14% point) than single microphone on overall satisfaction, on 14/39 factors (not including dispenser ratings); showed double digit customer satisfaction improvements on 14 customer satisfaction variables compared to 4 for single microphone digital instruments Dispensers of digital technology: rated superior to the dispenser of typical hearing aids</p>
<b>Author's conclusions</b>	<p>Considering this present study and a review of the literature, it appears that multiple microphone products distinguish themselves by having the ability to impact appreciably user satisfaction in noisy or difficult listening situations. Since performance in noise is one of the main barriers to growth of the hearing aid market, the number one hearing aid feature desired by current end-users and the second most frequent reason why close to a million hearing aids are in the drawer in the US, it would appear to be in the best interests of the worldwide hearing care industry to fit the majority of end-users with multiple microphone technology, therefore increasing the likelihood that consumers will derive more value and utility from their hearing instruments.</p>
<b>Reviewer's notes</b>	<p>Conflict of interest: Authors' address of correspondence is at Knowles Electronics Both the consumer and dispenser were given incentives to participate in this survey.</p>
<b>Relevance to study question</b>	<p>Study participants received digital hearing aids (single or multiple microphone)</p> <p>Patients were with hearing loss, and aged <math>\geq 18</math>y</p> <p>Intervention and comparator appropriate</p>

## Abbreviations:

\* As per NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies

† The quality of RCTs was assessed using the following questions: (A) Was the assignment to the treatment groups really random?; (B) Was the treatment allocation concealed?; (C) Were the groups similar at baseline in terms of prognostic factors?; (D) Were the eligibility criteria specified?; (E) Were the point estimates and measure of variability presented for the primary outcome measure?; (F) Did the analysis include an intention-to-treat analysis?; (G) Were withdrawals and dropouts completely described?

**Table 29 Data extraction table: Hällgren *et al.*, (2005)**

<b>Citation</b>	Hällgren B, Larsy B, Lysell B and Arlinger S (2005). Speech understanding in quiet and noise, with and without hearing aids. <i>International Journal of Audiology</i> , 44:10, 574-583.
<b>Level of evidence *</b>	IV
<b>Country</b>	Sweden
<b>Research question/aims</b>	To study the effect of hearing aids on perceived effort, speech perception, and cognitively demanding speech understanding tasks, in silence as well as in noisy environments. Questions are specifically on how the benefit from hearing aid amplification is related to: the background condition of silence or noise the meaningfulness of the interfering noise the age of the hearing-impaired subject the signal presentation modality (auditory/audiovisual)
<b>Study type/design</b>	Pre and post study (with and without hearing aids)
<b>Patient group</b>	<u>Participants:</u> Hearing impaired with sensorineural hearing losses of mild-to-moderate degree, experienced hearing aid users (at least 9 months)  Inclusion criteria: Not stated  Exclusion criteria: Not stated  <u>Subject disposition:</u> Patients (n=24) were of two age groups; a young group (n=12, aged 25-45y mean 36.8± SD7.1), an elderly group (n=12, aged 65-80y mean 71.8± SD3.8),
<b>Intervention</b>	Digital hearing aids (majority Oticon Digifocus II (n=20))
<b>Comparator</b>	Same subjects (same digital hearing aids)

**Table 29 Data extraction table: Hällgren *et al.*, (2005)  
(continued)**

<b>Outcome definitions</b>	<p>Assessed Speech perception/speech recognition with and without hearing aids in both silent or noisy backgrounds</p> <p>Used the following tests and outcomes: Hagerman speech test: is a measure of speech recognition</p> <p>SVIPS: is a cognitive test battery used for assessment of speech and visual information processing skills</p> <p>Rating perceived effort: subjects are asked to rate the degree of perceived effort during performance of the tasks in all background conditions in the different modalities of presentation of the signal. Perceived effort values at 40% correct response level in Hagerman speech test were analysed.</p> <p>Word recognition test: a test list of 25 real words put together from the SVIPS tests was presented to the subject at the stimulus and noise level used in the SVIPS test in each background condition</p>
<b>Data analyses &amp; statistics</b>	<p><u>Analyses</u>: pure-tone hearing threshold levels were measured for the frequency range 0.125-8.000KHz and entered into an ANOVA to evaluate differences between subject groups. Further ANOVAs for results in the Hagerman speech test (dB SPL or signal-to-noise ratio) and SVIPS tests (accuracy or reaction item) as dependent variables.</p> <p>Sample calculation: Not stated</p>
<b>Study quality</b> † See below for “A-G” quality criteria questions	<p>A. <u>Unknown</u>. Not indicated whether treatment assignment was random or not. (0)</p> <p>B. <u>Unknown</u>. Not indicated whether treatment was concealed or not. (0)</p> <p>C. <u>Reported but inadequate</u>. Same patients before and after fitting with hearing aids. (1)</p> <p>D. <u>Unknown</u>. Inclusion / exclusion criteria not stated. (0)</p> <p>E. <u>Reported</u>. Mean scores of perceived efforts with and without hearing aids were reported as well as correct answer percentages (2)</p> <p>F. <u>Unknown</u>. (0)</p> <p>G. Not reported but no reports of drop-outs or withdrawals from the study indicating all selected subjects included in the analysis. (2)</p> <p>Overall study quality <b>Fair (rated 5)</b></p>

**Table 29 Data extraction table: Hällgren *et al.*, (2005)  
(continued)**

<b>Results (within scope of systematic review update)</b>	<p>PE values at the 40% correct word recognition background conditions: (no main effects of hearing aid use) but main effect of background conditions: No noise= 6.1, Hagerman noise= 6.6, Speech= 7.3 (p=0.042)</p> <p>There was also a significant interaction between background condition and hearing aid use (p=0.019) this showed the subjective benefit of hearing aids was high in silence and decreased in background noise.</p> <p>Word recognition test: 94.6% of the words were correctly repeated with hearing aid compared to 92.3% without hearing aids. P=0.022</p>
<b>Authors' conclusions</b>	<p>Hearing aid use improved speech recognition in silence (7dB) and in the condition with speech as background (2.5 S/N), but did not change the perceived effort scores. In the cognitive tests no hearing aid benefit were seen in objective measures, while there was an effect of hearing aid use in scores of perceived effort, subjects reported less effort. There were no age effects on hearing aid benefit.</p> <p>Hearing aid use may result in reduced effort in listening tasks that is not associated with improvement in objective scores.</p>
<b>Reviewer's notes</b>	<p>Very small sample size Same patient group (as comparators) Subjects were paid (approximately €10) for their participation.</p>
<b>Relevance to study question</b>	<p>Participants were hearing-impaired Participants were aged ≥ 18y Intervention and comparator appropriate (with and without hearing aids) Outcome speech recognition</p>

Abbreviations:

\* As per NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies

† The quality of RCTs was assessed using the following questions: (A) Was the assignment to the treatment groups really random?; (B) Was the treatment allocation concealed?; (C) Were the groups similar at baseline in terms of prognostic factors?; (D) Were the eligibility criteria specified?; (E) Were the point estimates and measure of variability presented for the primary outcome measure?; (F) Did the analysis include an intention-to-treat analysis?; (G) Were withdrawals and dropouts completely described?

**Table 30 Data extraction table: Henkin *et al.*, (2007)**

<b>Citation</b>	Henkin y, Waldman A and Kishon-Rabin L (2007). The benefits of bilateral versus unilateral amplification for the elderly: are two always better than one? <i>Journal of Basic &amp; Clinical Physiology &amp; Pharmacology</i> , 18(3): 201-213
<b>Level of evidence *</b>	IV
<b>Country</b>	Israel
<b>Research question/aims</b>	To assess speech recognition in noise in elderly hearing-impaired patients who were initially fitted with bilateral amplification, when tested with unilateral as opposed to bilateral amplification conditions. Secondary goals were: 1. to investigate the association between performance with one as opposed to two hearing aids and central auditory function as measured by a dichotic test. 2. to investigate the effect of increasing age on speech recognition in background noise in the different test conditions, and on performance in a dichotic test.
<b>Study type/design</b>	Pre and post study (same patients with bilateral hearing aids then with unilateral hearing aids)
<b>Patient group</b>	<u>Participants:</u> Patients with sensorineural hearing loss. Used bilateral digital hearing aids between 1 and 32 months  Inclusion criteria: Not specified  Exclusion criteria: Not specified  <u>Subject disposition:</u> Patients' age between 62-87y (mean age 72.8y) mean monosyllabic word recognition scores in quiet at a comfortable listening level were 89.2% (range 60-100%, SD 9.3), and 87% (range 60-100%, SD 9.3) for the right and left ears, respectively.  All digital hearing aids from same manufacturer, 15 in-the-canal, 5 in-the-ear, 8 behind-the-ear.
<b>Intervention</b>	Bilateral hearing aids
<b>Comparator</b>	Unilateral hearing aids (aided right ear and aided left ear)

**Table 30 Data extraction table: Henkin *et al.*, (2007)  
(continued)**

<b>Outcome definitions</b>	<p>Speech recognition in noise (Hebrew version of the AB open-set monosyllabic word test).</p> <p>Threshold-of-interference ranged from -55 dB HL to +25 dB HL, higher values reflect greater susceptibility to interference.</p>
<b>Data analyses &amp; statistics</b>	<p>ANOVA for repeated measures was utilised to evaluate the effect of listening condition (aided right, aided left, aided bilaterally) on the performance in the Hebrew version of the speech-in-noise (AB) test scored for percent correct phonemes and words.</p> <p>Pearson correlation coefficients were used to assess the correlation between: Performance in the AB test in the different listening conditions and the threshold-of-interference in the right and left ears; and performance in the AB test in the different listening conditions and age; and threshold-of-interference in the right/left ears and age.</p>
<b>Study quality</b> † See below for “A-G” quality criteria questions	<p>A. <u>Unknown</u>. Not indicated whether treatment assignment was random or not. (0)</p> <p>B. Use of hearing aids was on patients preference and dexterity (0)</p> <p>C. Reported but <u>inadequate</u>. Same patients before and after fitting with hearing aids (1)</p> <p>D. <u>Unknown</u>. Inclusion / exclusion criteria not stated. (0)</p> <p>E. <u>Reported</u>. Mean scores of speech recognition performance scored for correct phonemes in the three test conditions (aided right, aided left, and aided bilaterally) (2)</p> <p>F. <u>Unknown</u>. (0)</p> <p>G. <u>Adequate</u>. No reports of drop-outs or withdrawals indicating no exclusions from analysis. (2)</p> <p>Overall study quality <b>Fair (rated 5)</b></p>

**Table 30 Data extraction table: Henkin *et al.*, (2007)  
(continued)**

<b>Results (within scope of systematic review update)</b>	<p>Speech recognition in noise</p> <p>No significant differences were found among the test conditions when scored for words and phonemes.</p> <p>Bilateral performance was poorer not only when compared to the 'better ear', but also when compared to the 'poorer' ear performance in 11/28 patients.</p> <p>Thresholds-of-interference</p> <p>Significantly better (negative) thresholds-of-interference were obtained in the right ear compared to the left ear (T=2.1, p=0.04).</p> <p>No significant correlations were found between the 'bilateral-unilateral difference scores', aided right, and aided left conditions and the thresholds-of-interference in the right and left ears.</p>
<b>Authors' conclusions</b>	<p>When testing speech understanding in noise in elderly bilateral hearing aid users, most patients exhibited higher performance while using unilateral amplification to the 'better' ear. Nonetheless, most of this study's patients continue to use bilateral amplification, suggesting that there are various listening situations in everyday life in which bilateral amplification provides benefits.</p> <p>Other performance measures for quantifying the bilateral advantage should be investigated in future studies in an attempt to identify the most appropriate measure.</p> <p>The decreased performance with age, however in both test measures used in the present study, provides further evidence for the deterioration of the aged auditory system and underscores the need to 'tailor' auditory habilitation to individual needs.</p>
<b>Reviewer's notes</b>	<p>Very small sample size</p> <p>Same group of patients</p> <p>Non-English language assessment (used the Hebrew version)</p>
<b>Relevance to study question</b>	<p>Participants were with hearing loss</p> <p>Aged ≥ 18y</p> <p>Intervention and comparators are appropriate</p> <p>Outcomes appropriate (speech recognition in noise)</p>

Abbreviations:

\* As per NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies

† The quality of RCTs was assessed using the following questions: (A) Was the assignment to the treatment groups really random?; (B) Was the treatment allocation concealed?; (C) Were the groups similar at baseline in terms of prognostic factors?; (D) Were the eligibility criteria specified?; (E) Were the point estimates and measure of variability presented for the primary outcome measure?; (F) Did the analysis include an intention-to-treat analysis?; (G) Were withdrawals and dropouts completely described?

**Table 31 Data extraction table: Hill *et al.*, (2006)**

<b>Citation</b>	Hill AL, Marcus A, Digges NB, Gillman N and Silverstein H (2006). Assessment of patient satisfaction with various configurations of digital CROS and BiCROS hearing aids
<b>Level of evidence *</b>	IV
<b>Country</b>	USA
<b>Research question/aims</b>	To describe patient satisfaction with the new digital contra-lateral routing of signal (CROS) and Bilateral contra-lateral routing of signal (BiCROS) hearing aid systems. To determine whether technologic advancement in digital signal processing have truly enhanced the efficacy of (CROS) and (BiCROS) devices and to identify any shortcomings that may remain.
<b>Study type/design</b>	Pre and post study (case-review) , Using Survey questionnaire
<b>Patient group</b>	<u>Participants:</u> Patients with severe to profound asymmetric hearing loss and poor speech discrimination scores  <u>Inclusion criteria:</u> severe-to-profound asymmetric hearing loss, and poor speech discrimination scores (<40% in the worse ear)  <u>Exclusion criteria:</u> Thirteen patients were excluded because they did not meet the above eligibility criteria.  <u>Subject disposition:</u> Patients (n=91), 43 men, aged 41-89 y(mean 70.6), causes of hearing loss included Meniere's disease, acoustic neuroma, autoimmune inner ear disease, temporal bone fracture, and noise exposure.  <u>CROS group:</u> (n=9) fitted with corded  <u>BiCROS group:</u> (n=82) 73 with corded fitting, and 9 with cordless fitting
<b>Intervention</b>	Digital contra-lateral routing of signal (CROS) or bilateral contra-lateral routing of signal (BiCROS) hearing aids
<b>Comparator</b>	Previous aided experience/device, Same patients comparing satisfaction with their new device

**Table 31 Data extraction table: Hill *et al.*, (2006)  
(continued)**

<b>Outcome definitions</b>	<p>(30-day trial of hearing aids) then followed by questionnaire at 2, 4 wks, and further 2 wks with telephone)</p> <p>Satisfaction was assessed by 8-questions questionnaire, responses quantified on a scale from 1 (very dissatisfied) to 5 (very satisfied).</p>
<b>Data analyses &amp; statistics</b>	<p>Analyses were performed on responses and results presented as:</p> <p>Number and % of patients who accepted, returned hearing aid at 30-day trial, and</p> <p>Mean value (and overall mean value) for the questionnaire responses by patients who kept their aids, and by patients who returned their hearing aids</p> <p>No statistical analyses and tests of significance were shown apart from the responses from the questionnaires.</p>
<b>Study quality</b> † See below for “A-G” quality criteria questions	<p>A. <u>Unknown</u>. Not indicated whether treatment assignment was random or not. (0)</p> <p>B. <u>Unknown</u>. Not indicated whether treatment was concealed or not. (0)</p> <p>C. <u>Inadequate</u>. Only summarised information on the baseline characteristics, with various reasons of hearing loss, ages vary (but details of each individual were not given). (1)</p> <p>D. <u>Inadequate</u>. Inclusion criteria only. (1)</p> <p>E. <u>Reported but inadequate</u>. Number and percentages of acceptance, mean value (overall mean) for the questionnaire responses (1)</p> <p>F. <u>Inadequate</u>. 13 patients were excluded because they did not meet eligibility criteria were not accounted for in the final analyses. (1)</p> <p>G. <u>Adequate</u>. About 50% of those accepted their hearing aids completed the questionnaires, of the 48 remaining, 29 were lost to follow-up and 19 declined to participate. (2)</p> <p>Overall study quality <b>Fair (rated 6)</b></p>

**Table 31 Data extraction table: Hill *et al.*, (2006)  
(continued)**

<b>Results (within scope of systematic review update)</b>	<p>Acceptance rate: 51.5% of patients who accepted their hearing aids actually completed the questionnaire, and 36 %of those who returned their hearing aids completed the questionnaire. Of the 48 remaining, 29 were lost to follow-up and 19 declined to participate. Therefore, the true acceptance rate for all patients falls from 72.5% to 67% (61/91).</p> <p>Reasons cited by 25 patients returning their devices: the new hearing aid was no better than their previous device, the device was too complicated, the device was too expensive, the use of the device was hindered by clinical circumstances such as otorrhoea or otalgia (meaning the patient was not a good candidate for the device), and the cord was bothersome.</p>
<b>Authors' conclusions</b>	<p>Our study demonstrated that patient satisfaction with the new generation of digital CROS and BiCROS hearing aids was higher than that seen in previously reported studies.</p> <p>The acceptance rates in our study ranged from 33.3% to 78.1%, compared with only 10 to 20% for analogue devices.</p> <p>Our study demonstrated that the corded devices are more popular than cordless models which is consistent with other reports in the literature.</p> <p>In addition to the benefits of digital technology, the high level of acceptance of these hearing aids in our study can be attributed to appropriate candidate selection, proper fitting, and close follow-up. Therefore, we believe that CROS and BiCROS corded hearing aids should again be offered as a viable alternative for patients with asymmetric sensorineural hearing loss.</p>
<b>Reviewer's notes</b>	<p>The BiCROS group has very small number of patients (9 only)</p> <p>Results confined to people with severe to profound unilateral (asymmetric) hearing loss.</p> <p>Response rate is very low (47%), acceptance rate was affected by the people who did not complete the questionnaire.</p>
<b>Relevance to study question</b>	<p>Participants were with hearing loss Aged <math>\geq</math> 18y Intervention and comparators are appropriate Outcomes appropriate (satisfaction)</p>

Abbreviations:

\* As per NHMRC Interim Levels of Evidence (NHMRC 2005) for Evaluating Intervention Studies

† The quality of RCTs was assessed using the following questions: (A) Was the assignment to the treatment groups really random?; (B) Was the treatment allocation concealed?; (C) Were the groups similar at baseline in terms of prognostic factors?; (D) Were the eligibility criteria specified?; (E) Were the point estimates and measure of variability presented for the primary outcome measure?; (F) Did the analysis include an intention-to-treat analysis?; (G) Were withdrawals and dropouts completely described?