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A Multicenter Trial of an Assess-and-Fit Hearing Aid Service Using Open Canal Fittings and Comply Ear Tips

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Large potential benefits have been suggested for an assess-and-fit approach to hearing health care, particularly using open canal fittings. However, the clinical effectiveness has not previously been evaluated, nor has the efficiency of this approach in a National Health Service setting. These two outcomes were measured in a variety of clinical settings in the United Kingdom. Twelve services in England and Wales participated, and 540 people with hearing problems, not previously referred for assessment, were included. Of these, 68% (n = 369) were suitable and had hearing aids fitted to NAL NL1 during the assess-and-fit visit using either open ear tips, or Comply ear tips. The Glasgow Hearing Aid Benefit Profile was used to compare patients fitted with open ear tips with a group of patients from the English Modernization of Hearing Aid Services evaluation, who used custom earmolds. This showed a significant improvement in outcome for those with open ear tips after allowing for age and hearing loss in the analysis. In particular, the benefits of using bilateral open ear tips were significantly larger than bilateral custom earmolds. This assess-and-fit model showed a mean service efficiency gain of about 5% to 10%. The actual gain will depend on current practice, in particular on the separate appointments used, the numbers of patients failing to attend appointments, and the numbers not accepting a hearing aid solution for their problem. There are potentially further efficiency and quality gains to be made if patients are appropriately triaged before referral.

Keywords: hearing aids; open canal fitting; ear tips; assess and fit

The United Kingdom (U.K.) National Health Service (NHS) has consulted with patients across a wide range of conditions and has made policy decisions that relate to providing care closer and more accessible to home, and whenever possible, to minimize the need for multiple appointments (Department of Health, 2007a). Introducing new technology to achieve this vision for hearing services (Department of Health, 2007b) may be possible by using assess-and-fit technologies, particularly open canal fittings. Traditionally, patients entering the hearing aid service attend clinic three times, once for assessment and aural impression taking, once for fitting of hearing aids with custom-made earmolds, and once for follow-up. An assess-and-fit service allows the first two attendances to be replaced by a single attendance because aural impressions and subsequent manufacture of custom earmolds are not needed.

Open canal fittings involve a nonoccluding earmold, which may be custom made, but currently it is more likely to be a universal silicone tip, available

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in a variety of sizes, attached to the hearing aid via a thin tube. Although open canal fittings are not a new concept, recent advances in technology mean that they are now suitable for a wide range of patients with mild to moderate hearing impairment. The reason for the increase in the number of potential patients is primarily because of digital feedback cancellation. In the past, custom earmolds needed to fit tightly to avoid feedback, but now this is not the case. Other reasons for the increase in the number include faster hearing aid processing time, which avoids unpleasant time delays between natural and amplified sound (echoes), and low-frequency gain compensation, which allows for some gain at low frequencies despite leaks from the open ear tip.

There are several potential advantages to patients of open canal fittings for hearing aids. Less physical contact with the ear canal and a softer tip mean that the open ear tips are more comfortable than custom earmolds, and many patients are able to forget they are there almost immediately. The thin tubes on the open canal fittings are much less visible than regular tubing, and the tip is pushed out of sight in the ear canal. This provides a cosmetic advantage, which would also encourage greater use. Reduced occlusion occurs, as low-frequency sound is allowed to enter and exit the ear canal naturally through the open tip. This leads to a more natural and acceptable sound quality, in particular for the patient's own voice. There are data (Jespersen, Groth, Kiessling, Brenner, & Jensen, 2006) suggesting that occlusion is a significant reason for patients to prefer unilateral rather than bilateral fittings, so open canal fittings may lead to a further advantage if there is a greater uptake of bilateral fittings. If so, this would add to the general acceptance that in many cases of bilateral hearing impairment, a bilateral hearing aid fitting is more beneficial than a unilateral fitting, in terms of speech discrimination, localizations, and sound quality (for a review, see Mencher & Davis, 2006).

Directional microphones were available on the hearing aids used in the trial, and their use may lead to greater patient benefit through increased discrimination of speech in noise. One possible disadvantage to patients with open canal fittings is in loss of directionality, but data suggest that directional information is still available above 1 kHz (Kiessling, 2006). Mueller and Ricketts (2006) also found that directional information at frequencies greater than 1 kHz is still present with open canal fittings (although they noted that directionality is not present at low frequencies where there is no gain). Keidser, Carter, Chalupper, and Dillon (2007) reported that their patients generally preferred only natural low frequencies rather than amplified low frequencies that would allow both directionality and noise reduction algorithms to be enabled. Improved speech recognition in patients was also measured when directionality and noise reduction were activated in aids with no low-frequency gain.

Given that it is not necessary to manufacture a custom earmold, this means that it is possible to assess-and-fit suitable patients in one session. This reduces patients' time in visits to the clinic as well as possibly reducing staff time. This may result in a more efficient service to patients. If patients attending an assess-and-fit session are not suitable for open canal fittings, then it is possible to use other instant solutions, such as the Comply ear tip (CET; Hearing Components Inc, Oakdale, Minnesota) solution (Smith, Riley, Davis, Davies, & Jeffs, 2008), which is suitable for more severe hearing losses than many of the universal open canal fittings. The CET is a heat sensitive foam tip, available in a variety of sizes, that becomes very compliant at body temperature, leading to increased comfort, particularly during jaw movements. However, not all patients will be suitable for an assess-and-fit service depending on the type and extent of hearing loss, manual dexterity, cognitive ability, and vision. Some of these patients who are unsuitable for assess-and-fit may still be suitable for open canal fittings, or for CET fittings, but they would need additional time.

Because there is a limit on the gain achievable with open ear tips, one of the main determinants of successful open canal fitting would seem to be hearing threshold levels. One method to increase the efficiency of an assess-and-fit service would be by triaging patients using a pure-tone screening test. The most efficient service will preselect patients (for hearing, cognition, dexterity, and vision), so that everyone attending an assess-and-fit service is suitable. There could be two different patient pathways, one for those suitable for assess-and-fit and another for those requiring separate assessment and fitting appointments. At this stage, it is not known how many first-time users (or existing users) might meet the suitability criteria for an assess-and-fit service. Hearing aid manufacturers are keenly promoting the advantages of universal open canal fittings, in particular for first time users of hearing aids. However, Kiessling (2006) suggested that existing patients who have used aids long-term might still appreciate the naturalness of open canal fittings. Despite the apparent increased uptake of open canal fittings worldwide, there have been few studies to indicate numbers of patients who are suitable and to indicate patient outcomes in the short or longer term. Kiessling (2006) suggested that 70% of patients can successfully use hearing aids with open or almost-open canal fittings (by "almost open," he referred to the tulip-shaped dome tips that provide a tighter fit and some occlusion).

This study aimed to test this suggestion in the context of the U.K. NHS by considering the following:

- the proportion and type of new patients suitable for assess-and-fit in terms of audiometric thresholds, age, patient needs, and other factors;
- the distribution of patient outcomes for open canal fittings and CET fittings for those fitted both unilaterally and bilaterally; and
- the effects on the service of assess-and-fit clinics and whether a triage tool could aid efficiency.

Method

Sites

Twelve NHS hearing aid clinics were recruited by invitation and participated in this trial. Eleven were in England, and one was in Wales. The data were collected during a 3- to 4-month fixed time period, and the aim for each site was to see a minimum of 50 relevant patients. Audiologists fitted hearing aids with which they were familiar and that were on contract to the English and Welsh NHS. Six sites fitted Oticon hearing aids, and six sites fitted Siemens hearing aids. Both were digital signal processing (DSP) aids with multiple programs, wide dynamic range compression, noise management systems, and digital feedback by way of phase cancellation. One was a six-channel aid with automatic and adaptive directionality; the other was a four-channel aid with adaptive directionality.

The sites were asked to support the patients for a minimum of 3 years post trial, and these sites incurred no additional costs for taking part in the study. Each site received training and was required to follow the whole agreed protocol even if they were not typically doing so at the time (e.g., all patient outcomes had to be collected; real ear measurements had to be attempted). Sites were not under pressure to introduce the new service post completion of the trial.

Patient Pathways

Each site aimed to see 50 new patients for hearing aids who were invited without selection from the top of their local waiting list.

Typically, NHS hearing aid services involve patients in three visits to the audiology department, one for assessment and aural impression taking (at least 45 minutes), one for fitting (at least 45 minutes), and one for follow-up (at least 30 minutes). For this trial, three different types of patient pathway were introduced that were followed as appropriate:

Direct referral pathway. Most patients followed this pathway, whereby they had been referred directly to audiology from their primary care practitioner. They were given a 90-minute appointment in audiology, during which a full assessment was carried out, followed immediately, whenever possible, by fitting of hearing aid(s) with either open ear tips or CET's.

Ear, nose, and throat (ENT) referred pathway. A number of patients, who had been referred to audiology following a consultation with an ENT doctor, followed this pathway. They already had audiometry carried out in ENT and were given a 60-minute appointment in audiology, during which any remaining assessment procedures were completed, followed by fitting with hearing aid(s) with open ear tips or CET's.

Opportunistic fitting. A small number of patients attending ENT clinics who were referred to audiology were fitted opportunistically with assess-and-fit technology on the same day. These appointments were not prearranged, nor were they of a fixed duration, but staff members were able to take advantage of any capacity because of the unpredictable nature of ENT clinics, nonattendance, and cancelled meetings.

Procedures

Assessment

Every assessment comprised at least the following elements:

- *Measurement of pure tone audiometric thresholds*, by both air and bone conduction, according to the procedure recommended by the British Society of Audiology (2004).
- *Tympanometry*: Clinical experience so far had indicated that the hearing threshold levels alone could not always predict success with open canal

fittings. *Tympanometric* measures (middle-ear volume, pressure, and compliance) were taken to see whether they might be relevant in predicting success.

- *Completion of the Glasgow Hearing Aid Benefit Profile (GHABP; Gatehouse, 1999) Part 1*. This is a self-report measure whereby patients answer questions by interview on each of four predefined listening situations and up to a further four patient-nominated situations. For each listening situation, Part 1 comprises an initial question to check that the listening situation is relevant to the individual, and if so, there are two further questions, on hearing disability and hearing handicap. The patient responds by choosing one of five response options; for example, for hearing disability, the options are *no difficulty*, *only slight difficulty*, *moderate difficulty*, *great difficulty*, and *cannot manage at all*.

In some sites, a screening test was undertaken, whereby a series of six pure tones was presented to each ear in turn by means of a battery-operated handheld device, Siemens' Hear Check. The screener delivered tones at 55, 30, and 20 dB HL at 1 kHz and at 75, 55, and 35 dB HL at 3 kHz. The number of tones (out of a total of six per ear) that a patient heard provided a score. This type of screen had been identified as useful in a large study of 55- to 74-year-old people (Davis, Smith, Ferguson, Stephens, & Gianopoulos, 2006). The screening was not used in any clinical decision making in the present study; however, the scores were documented for analysis to estimate how many patients from these presenting in this study might be preselected for an assess-and-fit service model based on audiometric thresholds alone.

Fitting

Appropriate patients were first offered the universal open canal fit. As very rough guidance, sites were advised that patients with sensorineural losses and hearing thresholds better than 40 dB HL for frequencies up to 1 kHz, better than 60 dB HL for frequencies at 2 kHz, and greater would probably be suitable for open canal fitting; however, this was something that would be analyzed at the end. This fitting guidance was in agreement with the manufacturers and fell well within the range specified in their technical data sheets. Open ear systems were available in a range of sizes; the length of the tubes and the diameter of the tips varied.

When patients were not suitable for open ear tips, the reason was recorded, and when appropriate, they were offered the universal CET's (Smith et al., 2008). These too were available in a range of depths and diameters and available either with or without venting. They were recommended for patients with more severe hearing impairment for whom sufficient amplification was unachievable with open canal fittings. Finally, if these technologies were not suitable or not acceptable (to patient or audiologist), the reason for this was recorded. Aural impressions for custom earmolds were then taken, and the patient returned for a separate fitting appointment.

For reasons of equity, sites were ethically obliged to continue their usual practice of providing unilateral or bilateral fittings. Although most sites were offering all suitable patients bilateral hearing aids, this was not the case at all sites, and two departments (totaling 52 patients) offered only a single hearing aid for historical reasons of cost. It was not the aim of this study to change this practice. Whenever possible, fittings were verified to National Acoustic Laboratories nonlinear hearing aid fitting software (NAL-NL1; Dillon, 1999) using real ear insertion gain (REIG), as specified in national guidance (British Society of Audiology/British Academy of Audiology, 2007). For measurement of insertion gain with open canal fittings, a substitution type method (Lantz, Jensen, Haastrup, & Olsen, 2007) was used. This method involved the reference microphone being turned off during measurements to avoid error when the signal leaked out from the ear and reached the reference microphone, causing the system to reduce the output of the loudspeaker. Recommendations were given to fit hearing aids using REIG to within 5 dB of NAL-NL1 at 2 kHz and within 8 dB at 3 and 4 kHz. No specific recommendation was given for frequencies less than 2 kHz, although data were collected on insertion gain for a 65 dB SPL signal, at frequencies between 0.5 and 4 kHz. (British Society of Audiology/British Academy of Audiology, 2007). It was recognized that open canal fittings may require a slightly different approach from that accepted for hearing aids with custom earmolds, and so emphasis was placed on using patient report in conjunction with real ear measurements at the fitting appointment.

Follow-Up

All patients were given a 30-minute follow-up appointment at 6 to 8 weeks post fitting. This was either conducted face to face or by telephone, as per usual service locally. Data was entered into the

Table 1. Number of Patients Attending Each Patient Pathway and Their Mean Ages

Type of Appointment	Mean Age (range)	No. of Patients	%
90-min direct referral appointment (Pathway 1)	73 years (18-97)	403	74
60-min ENT referred fitting appointment (Pathway 2)	65 years (18-94)	117	22
Opportunistic appointment (Pathway 3)	63 years (34-88)	22	4
Other or not filled in	67 years (57-76)	2	<1
Total		540	100

database for all patients who were fitted with open ear tips or CET's. At this appointment, as well as addressing patient needs, outcome measures were taken as follows:

- GHABP Part 2. Using each of the situations that were identified in Part 1, patients answered further questions relating to hearing aid use, benefit, residual disability, and satisfaction. Each question offered a choice of five response options as examples for use, including *never/not at all*, *about one fourth of the time*, *about half of the time*, *about three fourths of the time*, and *all the time*.
- Comfort questionnaire (see Appendix A) includes questions on comfort, feedback, occlusion, insertion, and ease of use, adapted from Smith and Oliveira (2001). This questionnaire also included data on how many tips and tubes had been used during the period since fitting and whether the patient had needed any extra unscheduled appointments.
- A follow-up questionnaire (see Appendix B) includes standard (for the English NHS) questions on insertion, retention, and cleaning as well as checks on patient understanding of multiprograms and volume controls.

The patients answered all questions themselves during the follow-up interview.

Results

Overall Numbers of Patients Fitted

A total of 540 patients from all 12 sites together were entered into the database. The number of patients seen in each site varied from 9 to 78. Approximately half the patients who were fitted with hearing aids received Oticon models (49%), and the other half (51%) received Siemens models. Just fewer than half the patients (43%) who were fitted received bilateral aids; this varied significantly across sites. The majority of appointments were 90-minute direct referrals (DR), as is seen in Table 1. This table also shows the age (mean and range) of patients in each referral group. Table 2 shows the number of ears (rather than patients) fitted with each type of earpiece.

Table 2. Numbers of Patients With Each Type of Fitting

	Number[a]	% of Total Seen
Patients fitted with open ear tips in at least one ear	297	55
Patients fitted with Comply ear tips in at least one ear	72	13
Patients fitted with soft tips in at least one ear[b]	11[b]	2[b]
Patients to be fitted with earmold in at least one ear	90	16
Patients fitted with bone conduction aid	1	0.1
Other (i.e., not fitted in either ear, data not available, etc.)	87	16

[a]These numbers add up to more than 540 because some patients had different technology in each ear.
[b]Although soft tips were not part of the protocol, one site used these as instant fitting devices in 11 patients.

Of the entire sample of 540 patients who were appointed, 297 (55%) of them were fitted with open ear tips in at least one ear. Of the 453 patients who were eventually fitted with hearing aids, the group of 297 who received open ear tips represented 66%. To make inferences to the population of patients who might typically be seen in a DR or ENT-referred clinic, each group of the patients reported here were divided into two to reflect these referral routes. Typically (but not universally) in the U.K. NHS, patients older than 50 years of age are referred directly to audiology, and younger patients are referred via ENT. Therefore, an arbitrary age limit of 50 years was used to filter out those who would not be referred directly to audiology. In the DR group, there were 305 people fitted, of whom 75% (confidence interval [CI] = 73%–77%) could be assessed and fitted in one session. In the ENT group, there were 115 people fitted, of whom 90% (CI = 88%–92%) could be assessed

Table 3. Reasons Given by the Audiologists for Not Using Assess-and-Fit Technologies

Reason Given	For Not Using Open Ear Tips	For Not Using Comply Ear Tips[a]
Audiogram outside fitting range	51	49
Gain not obtained without feedback	28	25
Unable to fit comfortably	2	6
Unable to fit securely	1	5
Patient unable to manage	16	18
Other, including medical reasons	12	11|

Note: Numbers represent ears.
a. This group excludes patients who were fitted with open ear tips

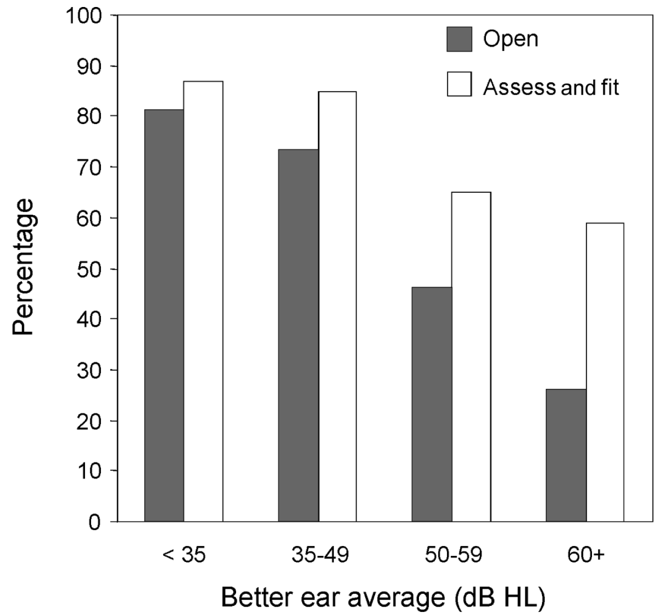

Figure 1. The percentage of patients with open canal fittings and with assess-and-fit as a function of air-conduction hearing threshold levels (averaged over 0.5, 1, 2, and 4 kHz) in the better hearing ear. Assess-and-fit includes open canal fittings and CET fittings.

and fitted in one session. In terms of open canal fitting, these were 61% (CI = 59%–63%) and 77% (CI = 75%–80%). The different referral routes did lead to significantly different numbers of patients being assessed and fit ($\chi^2 = 15.2$; $df = 4$; $p < .01$). This finding was the same when the arbitrary age limit was set to 60 years. Clearly, those who could be fitted following an ENT appointment were more likely to be suitable for an open canal fitting, as hearing threshold levels were already known.

The main reason given for not using assess-and-fit technologies (both open ear tips and CET's) was that the patients' hearing threshold levels were too poor, outside the fitting range. This was followed by reports that sufficient gain could not be obtained without feedback, which may also relate to thresholds being toward the poor end of the fitting range. Table 3 shows the numbers of ears in each of these categories for both open ear tips and CET's.

The total number of patients whose follow-up data were entered into the database was 304, out of the 369 who were assessed and fit, representing 82%. No attempt was made to follow up the remainder as part of this study. Follow-up data for patients in the study with custom earmolds were not available, so the following analyses focus on the groups of interest—that is, those with open ear and CET's. The average length of time between fitting and follow-up within this evaluation was 7 weeks.

At the follow-up appointment, the majority of patients who underwent assess-and-fit intended to continue with their original fittings. The number intending to continue with open canal fittings was encouragingly high, at 87%. The number intending to continue with CET fitting was smaller, at 54%, but still shows that the technology produces satisfactory solutions for some patients. These numbers would be expected to increase as audiologists became more familiar with the technology and, therefore, more efficient in selecting the appropriate earpiece for each patient.

Characteristics of Patients Fitted

It can be seen from Figure 1 that the more severe the patient's hearing impairment, the less likely ($\chi^2 = 21.4$; $df = 3$; $p < .01$) they are to be fitted in an assess-and-fit clinic. As hearing impairment increases, the proportions of those fitted with open ear tips decreases, and more are fitted with CET's. This finding was expected, and Figure 1 clearly illustrates how the use of CET's together with open ear tips may be used to increase the number of patients undergoing an assess-and-fit pathway.

Good manual dexterity was required for patients undergoing assess-and-fit because there was a fixed time available to ensure that they could manage the aid insertion and controls. Therefore, it was possible that older patients would not be suitable for assess-and-fit, regardless of hearing threshold levels. Figure 2 shows that the older the patient, the less

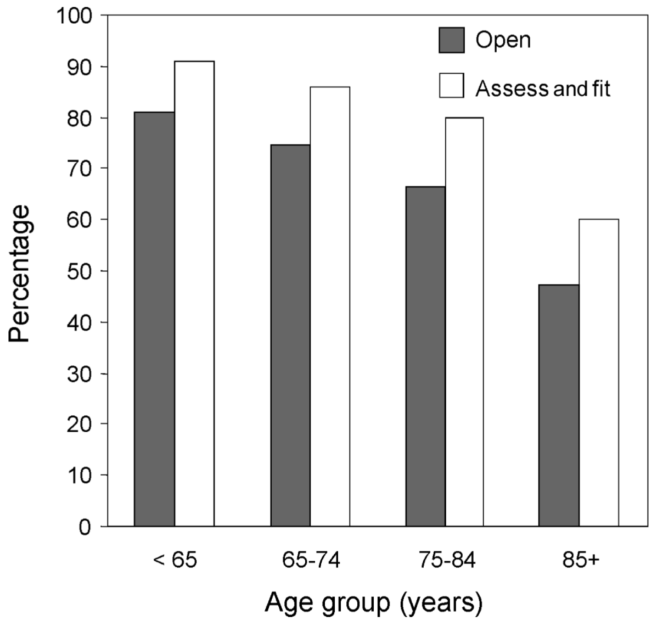

Figure 2. The percentage of patients with open canal fittings and with assess-and-fit as a function of age group. Assess-and-fit includes open canal fittings and CET fittings.

likely ($\chi^2 = 28.5$; $df = 3$; $p < .01$) they are to be suitable for assess-and-fit, although more than half the group in this study aged 85 years and older were fitted using assess-and-fit technology. This suggests that any preselection of patients would not be appropriate using age alone.

Table 4 presents data on age and hearing threshold level for patients who were fitted with each of the different earpieces. Analysis of variance (ANOVA) showed significant effects of better-ear average hearing threshold level ($F = 12.5$; $df = 4$; $p < .01$) and of age ($F = 3.3$; $df = 4$; $p = .01$) on type of earpiece received. Younger patients with milder hearing losses were more likely to receive open ear tips. It is not surprising to see that those fitted with open ear tips are, on average, at least 5 years younger than all the other groups. Younger patients will tend to have less hearing impairment, better manual dexterity, and perhaps better concentration, all of which make them more suitable for a 90-minute assess-and-fit appointment.

Table 5 shows the type of hearing loss for the patients with open ear and CET fittings. Patients did not always have the same type of hearing loss in both their ears, so these data are presented for each ear separately. As expected, most patients presented with sensorineural hearing losses and received open canal fittings. The small number of patients with a conductive element to their loss who were fitted with open ear tips was also expected; these patients would generally have required more gain, and audiologists had been advised to vary protocols to meet individual patients' needs.

Representativeness of Patients in Present Trial

To see how representative the patients in the present trial were, their age and hearing threshold levels were compared with those from a large group of patients ($n = 800$), who participated in an evaluation of the first wave of Modernisation of Hearing Aid Services (MHAS) in England from the year 2000 to 2001. These patients had been directly referred from primary care to audiology. They had been fitted with then-current DSP hearing aids with wide-range dynamic compression and using a clearly defined patient pathway, which included administration of the GHABP. The aids fitted were from four different manufacturers and included some in the ear models but no open canal fittings or CET fittings.

Figures 3 and 4 show a comparison of the hearing impairment group and age group as a function of study (present study versus the MHAS evaluation trial). The two populations are quite similar, although overall there was a difference between the two, with the present study having slightly younger people with less hearing impairment. The findings in terms of their projection onto the current hearing impaired referrals are, therefore, quite reasonable. If the current sample is weighted to bring it in line with the MHAS sample in terms of degree of hearing loss and age, then the percentage with open canal fittings or assess-and-fit does not change much. The percentage of open canal fittings was about 60% rather than 61%, as stated above for the DR group. The percentage of those who were able to benefit from an assess-and-fit clinical service increased slightly.

Middle Ear Status

Another possible factor in determining a successful open canal fitting is the middle ear status. It was originally thought that a large ear canal volume and/or tympanic membrane with low compliance might be a contraindication to open canal fittings, in that adequate gain would not be obtained without feedback. If that were so, there would have been

Table 4. Mean (and Standard Deviation) for Age and Hearing Threshold Level (Averaged Over 0.5, 1, 2, and 4 kHz) of Patients for Each Type of Earpiece

	Age, years	Better Ear, dB HL	Worse Ear, dB HL	Left Ear, dB HL	Right Ear, dB HL
Open	68 (13)	36 (10)	42 (13)	39 (13)	38 (11)
N	288	243	243	243	242
Comply	73 (13)	46 (14)	55 (17)	51 (19)	50 (13)
N	61	47	47	47	47
Earmold	76 (12)	46 (15)	58 (16)	52 (17)	52 (16)
N	87	72	72	72	72
Soft tip	74 (11)	50 (14)	56 (12)	51 (15)	54 (12)
N	11	5	5	5	5

Table 5. Type of Hearing Losses Measured in the Patients: A Conductive Element to a Hearing Loss Was Defined as an Air–Bone Gap of Greater Than 15 dB Averaged Over 0.5, 1, and 2 k Hz

Type of Loss	Total No. of Ears Studied	No. of Ears With Open Ear Tip Fitting	No. of Ears With Comply Ear Tip Fitting
Sensorineural	745	362	64
Conductive	15	1	1
Mixed	77	15	15

Note: Data were not available for all patients.

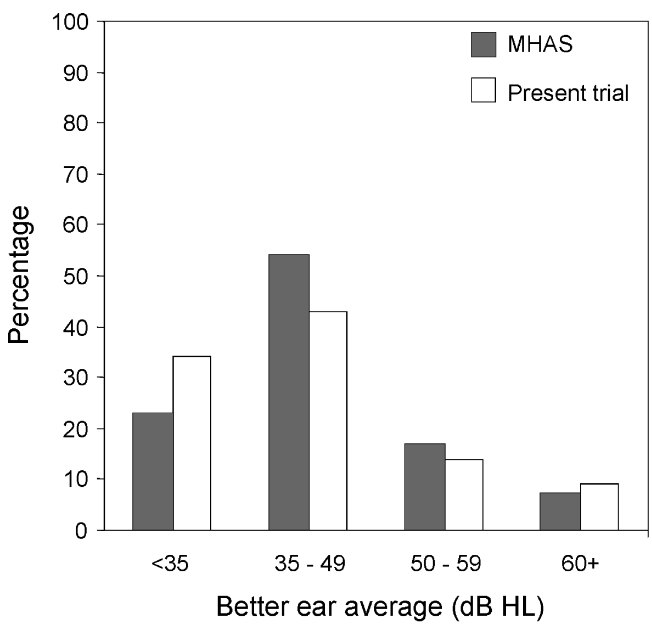

Figure 3. Comparison of air conduction hearing threshold levels (averaged over 0.5, 1, 2, and 4 kHz) in the better-hearing ear of patients in the present trial and those in the MHAS evaluation.

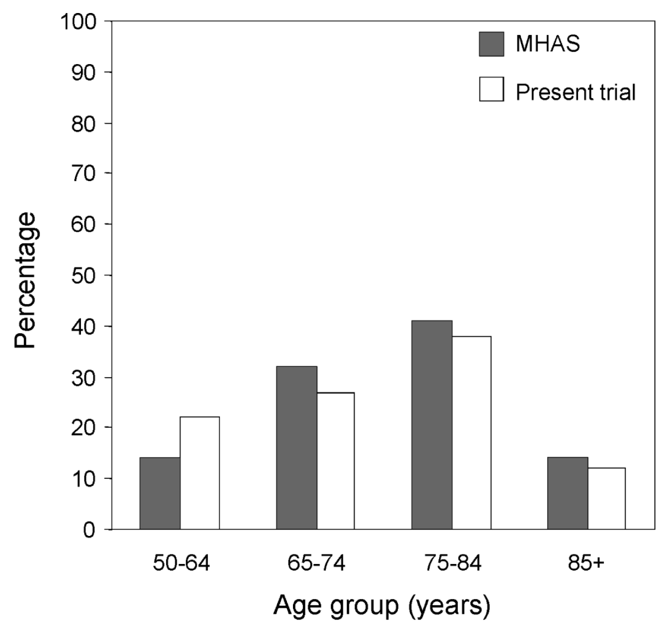

Figure 4. Comparison of age of patients in the present trial and those in the MHAS evaluation.

differences in middle ear variables between the groups, but this was not the case.

Table 6 shows that there were no differences in middle ear measures across the groups. Further analysis showed no correlations with any of the following rating scores: comfort, feedback, ear not feeling blocked, ease of use, quality of sound, quality of sound of own voice, satisfaction with hearing aid, and satisfaction with service.

Table 6. Mean, Standard Deviation (*SD*), and Numbers for Ear Canal Volume, MEP, and MEC for Each Type of Earpiece

		Mean	*SD*	*N*
Volume right ears cm^3	No aid	1.30	0.32	19
	Open	1.25	0.36	147
	Comply	1.30	0.38	34
	Earmold	1.08	0.24	31
	Total	1.24	0.35	231
MEP right ears daPa	No aid	–44	88	19
	Open	–32	57	147
	Comply	–25	55	34
	Earmold	–33	34	31
	Total	–32	57	231
MEC right ears cm^3	No aid	0.76	0.46	19
	Open	0.69	0.45	147
	Comply	0.56	0.49	34
	Earmold	0.63	0.66	31
	Total	0.67	0.49	231
Volume left ears cm^3	No aid	1.23	0.24	19
	Open	1.21	0.31	147
	Comply	1.21	0.39	34
	Earmold	1.07	0.24	31
	Total	1.20	0.31	231
MEP left ears daPa	No aid	–37	65	19
	Open	–30	58	147
	Comply	–28	55	34
	Earmold	–35	54	31
	Total	–31	57	231
MEC left ears cm^3	No aid	0.86	0.48	19
	Open	0.73	0.45	147
	Comply	0.57	0.57	34
	Earmold	0.53	0.34	31
	Total	0.69	0.47	231

Note: MEP = middle-ear pressure; MEC = middle-ear compliance.

Gain Obtained Using Hearing Aids

Real ear insertion gains had been recorded for assess-and-fit patients, along with the NAL-NL1 target at frequencies of 0.5, 1, 2, 3, and 4 kHz for an input signal of 65 dB SPL. The square of the difference between attained and target measurement was taken and weighted as follows: 0.05 for 0.5 kHz, 0.2 for 1 kHz, 0.3 for 2 kHz, 0.3 for 3 kHz, and 0.15 for 4 kHz. This weighting was an intuitive scheme based on the articulation index, such that the weights added up to 1. Data were then summed, and the square root of the sum was taken. When there were two ears fit, the lower value of the two ears was used. The end result was like a standard deviation (weighted) so the units used were dB difference.

It had already been shown that CET's could obtain prescription targets (Smith et al., 2008), but there remained particular concern that the open canal fittings would not be capable of obtaining adequate gain without feedback. Real ear insertion gain data from 231 ears with open canal fittings were available. This represents 57% of all ears fitted with open ear tips; data from the other ears were not available for a variety of reasons, such as practical difficulties inserting the probe tube. An ANOVA showed no significant difference between the group with REIG and the group without REIG in terms of hearing level, GHABP, or age. The results showed that for these open canal fittings in this study, which are representative of the whole group, 61% were within 5 dB across 0.5, 1, 2, 3, and 4 kHz, 94% were within 10 dB, and 99% were within 15 dB of the NAL-NL1 targets.

Despite missing data from some sites and large differences between sites, most audiologists were fitting the open canal hearing aids satisfactorily to target. Overall, the real ear data indicate that the majority of open canal fittings were within acceptable limits of the NAL-NL1 prescription. This verifies that the feedback management systems within the aids were adequate for the gain requirements of this group of patients.

Patient Use and Benefit of Assess-and-fit Technology

Use of Aids

Because occlusion has been identified as an important factor in patients' poor use of bilateral hearing aids, it was of interest to look at the data on use of open canal fittings (i.e., nonoccluding fittings) used both unilaterally and bilaterally. Table 7 shows patients' reported use for both the open tip and, also for comparison, the CET fittings.

In general, Table 7 shows that the patients were making reasonably good use of their aids, with about half of the patients with open canal fittings using their aids for more than 8 hours a day. It is good to note that of the open canal fittings, those with bilateral aids are just as likely to use them as much as those with unilateral aids. These data, showing little difference between unilateral and bilateral use on nonoccluding ear pieces, are consistent with the notion that occlusion is a relevant factor in patients' poor use of bilateral hearing aids. However, there were significant numbers of patients who were not using their aids as much, and the importance of this would have been addressed in the follow-up appointments.

Table 7. Patients' Reported Average Use of Aid(s) Each Day

Estimated Time	Unilateral Open-Tip Fitting (%)	Bilateral Open-Tip Fitting (%)	Unilateral Comply-Tip Fitting (%)	Bilateral Comply-Tip Fitting (%)
Less than 4 hours	28 (23)	17 (27)	5 (28)	3 (23)
4 to 8 hours	33 (27)	16 (25)	4 (22)	5 (38)
8 hours or more	62 (50)	31 (48)	9 (50)	5 (38)

Benefit From Aids

Following from the encouraging data on bilateral use of aids with open canal fittings, other outcome measures were then investigated. GHABP data were analyzed and compared with 12-week follow-up data from the evaluation phase of the MHAS project. These data have been corrected for hearing threshold level and age (they were covariates in the ANOVA), and account was taken of the site (which was a factor in the ANOVA) where hearing services were provided.

Figure 5 shows that there was more benefit for patients with open canal fittings (present trial) than with custom earmolds (MHAS). It is also clear to see that patients with bilateral open canal fittings report more benefit than those with unilateral fittings. Analysis of variance showed that the difference between studies was significant ($F = 60.2$; $df = 1$, $p < .01$), and there was a significant interaction between study and unilateral and bilateral fitting. There was a significant difference in benefit ($p = .03$) reported by the patients with unilateral open canal fittings compared with those with bilateral open canal fittings, after taking age, hearing level, and site into account. There are some large site differences, which might mean that the bilateral advantage is overstated, as some sites fitted mainly unilaterally, whereas other sites fitted mainly bilaterally. However, even when effect of sites was controlled, there still exists a bilateral advantage that has been difficult to show in other earlier studies, such as MHAS. (Davis, 2006).

This is most encouraging and provides much needed evidence in favor of bilateral fitting. Nevertheless, the two patient groups cannot be guaranteed to be equivalent as the two studies were conducted several years apart using different technology and with different aims. Although this analysis only used patients with mean better ear hearing thresholds < 49 dB HL, factors such as cognitive ability and manual dexterity were not controlled, and, unlike the MHAS group, the group with open canal fittings would not have included anyone who was unable to manage the tips. It is also noteworthy that in MHAS, patients were formally allocated randomly to unilateral or bilateral fitting, whereas in the present study, this was not the case.

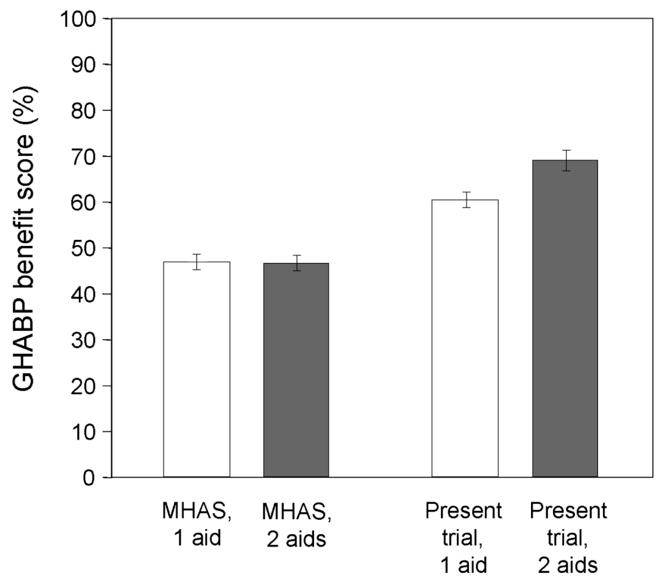

Figure 5. The benefit domain from the GHABP (mean and 95% CI) for four groups of patients: those fitted unilaterally with custom earmolds in MHAS ($n = 521$), bilaterally with custom earmolds in MHAS ($n = 194$), those from the present study with unilateral open canal fittings ($n = 101$) and the present study with bilateral open canal fittings ($n = 49$). This comparison relates to patients with air-conduction hearing threshold levels (averaged over 0.5, 1, 2, and 4 kHz) in the better hearing ear < 49 dB HL.

A similar pattern is seen for the other three domains of the GHABP—that is, use of aids, satisfaction with the aids, and residual disability. All domains of the GHABP relate very specifically to the situations that are relevant to the individual patient. The use and satisfaction data show the same bilateral advantage for open canal fittings, whereas it is the satisfaction and residual disability data that show the same advantage to patients with open canal fittings (present trial) than with custom earmolds (MHAS).

Table 8. Patients' Ratings for Various Aspects of the Aids and the Service Where 1 is the Worst Condition, and 10 is the Best

	Open Ear Tips				Comply Ear Tips			
	N	Mean	*SD*	Grouped Median	*N*	Mean	*SD*	Grouped Median
Comfort	256	8.2	1.9	8.5	54	8.2	1.9	8.7
Feedback	257	7.8	2.3	8.4	53	7.6	2.1	8.1
Ear not feeling blocked	253	8.6	2.1	9.3	52	8.2	2.1	8.7
Ease of use	251	8.5	2.1	9.1	53	8.0	2.3	8.6
Quality of sound	255	8.3	1.8	8.7	53	8.1	1.9	8.4
Quality of sound of own voice	254	8.4	1.7	8.8	52	8.2	1.7	8.4
Satisfaction with hearing aid	256	8.6	1.8	9.1	52	8.3	2.0	8.7
Satisfaction with service	211	9.6	0.8	9.8	37	9.5	1.0	9.7

Table 9. Some of the Data From the Follow-Up Questionnaire for Open Ear Tip Fittings and Comply Ear Tip Fittings (%, *n*)

	Open Ear Tip Fittings		Comply Ear Tip Fittings	
	Yes	No	Yes	No
Insert without too much trouble?	91 (124)	9% (13)	91 (20)	9% (2)
Feel secure in ear so it won't fall out?	85 (117)	15 (20)	77 (17)	23 (5)
Comfortable in ear?	96 (132)	4 (5)	91 (20)	9 (2)
Free from whistles except if altering the aid?	70 (95)	30 (41)	82 (18)	18 (4)

Patient Report on Comfort, Feedback, and Ease of Use

Eight aspects of the aids and the service were assessed using a simple questionnaire in which patients rated each aspect on a scale from 1 (*worst*) to 10 (*best*). This was to check for any possible problems with the assess-and-fit service. Table 8 shows the summary findings.

Overall, the patients' scores are very high; however, there were some poor scores on the feedback question and also on both the questions relating to quality of sound, both in general and of their own voice. Although quality of sound can probably be addressed by some fine tuning and by counseling, the feedback problems may indicate that a small number of the aids were not able to obtain the required gain satisfactorily. Satisfaction with the service achieved the highest score and suggests that the patients did appreciate the assess-and-fit type of service.

The follow-up questionnaire was completed by interview for all patients; Table 9 shows the results for questions relating to whether patients were able to insert their aids easily, whether they felt secure in their ear, whether they were comfortable, and whether they felt they were free from whistles. Again, the aim was to check for any possible problems with the assess-and-fit service.

There was no significant difference (χ^2) between the open and the CET fittings on any of these questions. Again, these data show that there is some room for improvement to the feedback technology, which for both hearing manufacturers' hearing aids, used a phase cancellation system, with only 70% open and 82% CET fittings being free from whistling.

Factors Affecting Costs and Savings

The first factor to consider was the cost of the universal tips and the numbers required, compared with custom earmolds. Manufacturers' recommendations were that the open systems would last approximately 3 months, and the CET's needed changing every 2 to 3 weeks. As part of the data collection, the number of tips used for each ear was recorded; however, the data have not been corrected for amount of use of the aids, and the time period of 6 to 8 weeks was rather short to make good cost estimates. The numbers of tubes and tips used were small; most of the patients (93% open ear tip users and 71% CET users) had used a single or one extra tip during that time. The cost of products at the time of the trial meant that assess-and-fit earpiece costs were higher than those associated with a custom earmold. However, time may be saved, and if assess-and-fit services were to be adopted widely throughout the NHS, costs of the universal tips and tubes would be expected to reduce significantly through economies of scale and the bulk purchasing contract arrangements

Another important factor in estimating any possible additional capacity released as a result of assess-and-fit appointments is the extra unscheduled appointments that may be necessary as patients require extra help or find feedback that was not apparent at the time of fitting. Of the 304 patients with open and CET who were followed up, 60 (20%) needed a further appointment (second follow-up), which was booked for 30 minutes for the majority of these patients. The 20% is not a particularly high percentage compared with traditional patient pathways (15% to 20% is the estimate from recent clinical databases of patients requiring a second follow-up in a traditional pathway) and would, therefore, not add a significant resource requirement. In fact, patients seen for the 90-minute appointments (assess-and-fit) did not require more follow-up appointments than patients seen for separate assessment and fitting appointments (60-minute fitting appointment after assessment in ENT). The number of patients (20%) requiring a second follow-up appointment might be expected to reduce as staff gain more experience with assess-and-fit and are able to more accurately identify those who will be suitable.

In addition to these appointments after the scheduled follow-up, there were a number of patients who had required an unscheduled appointment before their follow-up. By the time of the follow-up, 52 patients had already visited the department once since fitting, and 10 patients had visited the department twice since the fitting. The most common reasons for patients needing these extra unscheduled appointments related to feedback and blockage of the open ear systems, neither of which would be expected from a traditional service but would be expected to decrease as audiologists gained more experience with the systems.

To estimate the audiologists' time required for an assess-and-fit compared with the traditional service, only the DR appointments were considered. This is because the DR's were the major group of interest; the other groups already had pure-tone audiograms available from which predictions of open canal fittings were made.

Of the 405 DR appointments made, 253 (62%) patients were fitted at the 90-minute assess-and-fit appointment. Although these figures indicate that the percentage of patients suitable for assess-and-fit is high, there remain 38% of these appointments that were underused. However 135 (33%) did attend and undergo the assessment, so only the time allocated to fitting the aids was unproductive. The patients who failed to attend or who cancelled at short notice (4%) are assumed to be the same in number as though a separate assessment appointment had been booked; therefore, only part of the 90 minutes was unproductive for each of these.

Table 10 also shows the potential time saved for each patient group, first assuming that departments usually book DR assessments for 60 minutes and fitting appointments for 60 minutes. Overall, and based on these figures, it is possible that by giving all DR patients a 90-minute assess-and-fit appointment, with no preselection, there could be a net gain of 30 minutes for about 25% referrals. This translates to about 5% to 10% gain in capacity, with no preselection of patients. This can be expected to increase with prereferral screening. However, assuming that departments usually book DR assessments for 45 minutes and fitting appointments for 45 minutes, there is little potential for audiologists' time saving. However, there will always be potential for reduced travel time for patients and the reduction of their total waiting time for being fitted. On the administrative side, there will also be reduced mailings and telephone calls relating to booking of appointments.

These simple comparisons that indicate possible efficiencies have not considered the effects of any unscheduled appointments, which may (at least in the short term) reduce efficiency until audiologists gain experience, and some preselection and triage of patients takes place before referral.

Screening and Triage

Across all sites, 110 patients were tested with the screener (potential triage test), and the data were compared with their pure-tone thresholds. A score of six tones heard indicated that the patient heard tones of 20 dB HL at 1 kHz and 35 dB HL at 3 kHz.

It can be seen from Figure 6 that the screener does seem to separate the patients appropriately, in

Table 10. Outcomes for the 90-Minute Direct Referral Appointments and a Comparison of Time Needed for Assess-and-Fit Compared With Two Other Traditional Patient Pathways

	DNA or Cancelled at Short Notice	Open Ear Tip Fitting	Comply or Soft Tip Fitting	Impression Taken for Earmold	Seen But Not Fitted	Total
Number	17	191 (48% bilateral rate)	62 (51% bilateral rate)	77 (50% bilateral rate)	58	405[a]
% of total	4	47	15	19	14	100
Time saved per patient relative to 2 × 60-min sessions	–30 min	30 min	30 min	–30 min	–30 min	
Time saved per patient relative to 2 × 45-min sessions	–45 min	0	0	–45 min	–45 min	

a. Note that patients who cancelled at short notice were booked a further appointment, and so some patients are counted twice. DNA = data not available.

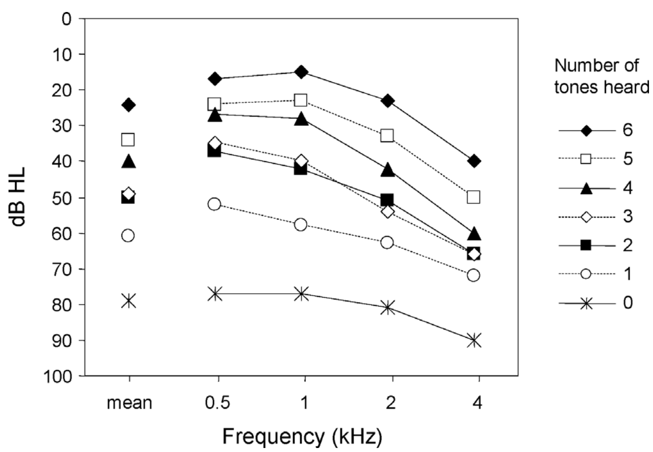

Figure 6. Pure-tone threshold levels for four individual frequencies and the mean of all four, from the better hearing ear for each of the screener outcomes (from no tones heard to all six tones heard).

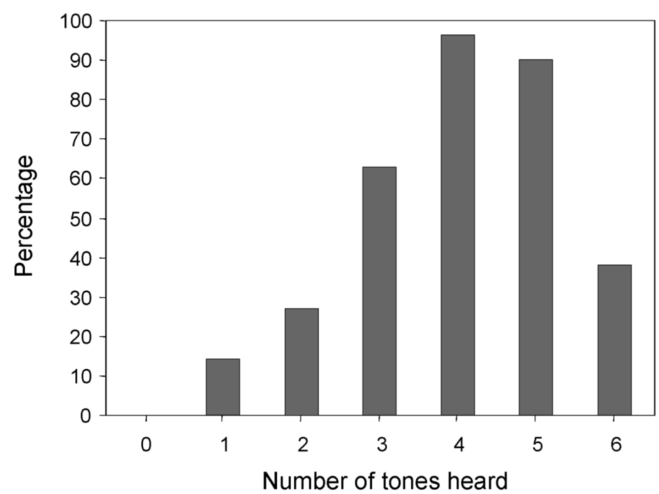

Figure 7. The percentage of patients with open canal fittings as a function of number of screening tones heard.

that patients hearing only zero or one of the six tones presented had audiograms in the better ear that were outside the fitting range for open canal fittings. (The fitting range guidance for the present study stated hearing thresholds better than 40 dB HL for frequencies up to 1 kHz and better than 60 dB HL for frequencies at 2 kHz and greater). These data indicate that it could be useful at a prereferral stage to determine which patients might be audiologically suitable for an assess-and-fit appointment.

Figure 7 shows that the majority of patients fitted with open ear tips had heard three, four, or five tones. About a quarter of those hearing two tones were also fitted with open ear tips. There are, of course, other factors besides hearing threshold levels that determine a patient's suitability for an assess-and-fit service. These factors include cognitive ability in which the patients need to be able to concentrate for a longer period of time; they also need good vision and manual dexterity to learn how to use the aids and tips in a fixed length of time. So in addition to the Hear Check type of triage, if patients were also screened prereferral in primary care for vision, dexterity, and cognitive ability, then an assess-and-fit service could become very efficient. This has yet to be tried.

Discussion

Universal open ear tips for hearing aids are now widely available and being recommended by manufacturers for patients with mild to moderate hearing impairment. This study set out to look at both the clinical effectiveness and efficiency of using open ear tip (as preferred option) and CET fittings within an assess-and-fit service. In terms of numbers of suitable patients, there was a total of 68% of the original sample of 540 who underwent assess-and-fit using NAL-NL1. Rather than taking the entire sample of 540 patients, considering only those who were fitted with hearing aids ($n = 453$), the total being assessed and fitted was 81%. Patients were more likely to receive open canal fittings if they had better hearing threshold levels and if they were younger; however, more than 40% patients aged 85 years and older were successfully fitted.

Patients who were found by the audiologists to be unsuitable for assess-and-fit had hearing threshold levels outside the manufacturers' fitting range, were unable to obtain sufficient gain without feedback, or were unable to manage the tips because of poor manual dexterity. There were a number of other reasons given for patients being unsuitable, but mainly it was to do with either insufficient gain or inability to manage. There were no indications that tympanometric measures could predict success of open canal fittings.

As far as possible, REIG measurement was used to verify the hearing aid fittings, and these data broadly indicated that sufficient gain was obtained in most cases. Good practice guidelines in the United Kingdom suggest real ear measurement at the time of fitting for all patients, and there was no reason to deviate from this guidance for open canal fittings.

The majority of patients who were assessed and fit in a single session were intending to continue with use of their devices at the follow-up appointment, which was 6 to 8 weeks post fitting. Reported use was good, both in terms of hours per day and for situations described in the GHABP.

Benefits to patients, as measured using the GHABP, suggest that open canal fittings can provide more benefit than custom earmolds; however, the comparison patients were fitted 5 years ago with DSP hearing aids of that time. The present sample has been shown to be representative of the whole population; both groups of patients underwent the same elements within their pathways, so it is reasonable to conclude that it is the technology that is mainly responsible for the improved outcomes measured. It is not possible to know how much improvement is because of the earpiece and/or how much to the signal processing, but the additional gains reported from bilateral users, together with the comfort questionnaire scores (particularly on sound quality of own voice) would suggest that the open canal fittings are leading to additional patient benefits.

There seems to be, therefore, sufficient evidence to recommend that bilateral open canal fittings be used widely when appropriate. The point under discussion is whether an assess-and-fit service is also to be recommended for widespread use, and this is where measures of service efficiency are relevant. This study did not aim to compare open canal fittings in a traditional two-appointment system with a single assess-and-fit appointment, but if a service is efficiently managing its workload with minimal waiting times, then there may be little advantage of using assess-and-fit from a service perspective. There will always be an advantage from a patient perspective in that patients are fitted with no delay, and they need to make only one journey, and that is particularly convenient in rural areas, for example, or where travel is time consuming and/or difficult. There is a group of patients, though, for whom a short wait between assessment and fitting may be advantageous: Those patients who need some time to accept their hearing loss and adjust to the idea of using hearing aids. In the U.K. NHS, many patients still present to audiology services after waiting approximately 10 years after noticing a hearing difficulty (Davis et al., 2007) so this may not be a frequent issue. However, if a service wishes to increase efficiency, an analysis of time spent on each part of the patient pathway, and of types of patients presenting to the service, may reveal opportunities for further service efficiencies. This study revealed 16% patients who failed to attend appointments, who declined hearing aids, or who did not need hearing aids. If this figure could be reduced, it could lead to large improvements in efficiency. Other ways to improve efficiency include further use of the opportunistic fittings, as described earlier, or use of skill mix whereby an audiologist will carry out the programming part and verification of the fitting and then an assistant will continue with instruction and care of the aids.

Data from use of the triage tool, and also data from Parving (unpublished data, 2008) on the same instrument, suggest that this may be a very efficient prereferral tool to identify the patients most suitable audiologically for open canal fittings, who could be sent a longer assess-and-fit appointment. In addition to this type of triage, if patients were also screened for vision, manual dexterity, and cognitive ability, then an assess-and-fit service could become very efficient. There is an urgent need to try this.

In summary, the gains to patients in terms of benefit in hearing, time and travel saved, as well as comfort, discretion, and natural quality of sound all suggest that the open canal fittings are to be recommended for widespread use. CET's enable patients with slightly more severe losses to be fitted in a single session, and with the introduction of appropriate triage, yet to be formally trialed, this type of assess-and-fit service model may in the future provide care for a majority of first time hearing aid users.

Conclusion

Of 540 patients attending for first fitting of hearing aids across 12 NHS audiology departments, 68% of them were assessed and fit within a single visit, 55% with open fit technology, and a further 13% with CET's.

Taking the unselected patients who were directly referred into audiology services (rather than through an ENT department), 62% of these were assessed and fit within a single visit. From the data collected, and assuming a traditional service of 60-minute assessment and 60-minute fitting appointments, it is estimated that a 5% to 10% gain in capacity can be obtained by use of assess-and-fit appointments for all unselected DR patients. Further efficiency gains may be possible using a mix of skills.

Real ear insertion gain data indicated that there was no systematic problem in meeting the gain prescribed by NAL-NL1, and a total of 21 patients returned for an extra appointment complaining about feedback.

GHABP data indicated significantly greater benefit for patients with open canal fittings when compared with a group from the evaluation phase of the MHAS program. Patients who had been fitted bilaterally with open canal hearing aids showed significantly more benefit than those fitted unilaterally. This led to a recommendation that open canal fitting be used for patients with mild to moderate hearing losses who may be concerned about the appearance of their aids and who have good manipulation skills. It is also recommended for tinnitus patients with mild hearing losses. Bilateral (rather than unilateral) fitting with open ear technology should be offered to all patients who meet these criteria. Use of CET's is recommended in patients with more severe losses as part of an assess-and-fit service.

Further work is required to pilot a triage in primary care to refer patients to the most appropriate care pathway either for an assess-and-fit appointment or for an assessment appointment. The triage should include hearing, vision, dexterity, and cognitive function. This has the potential to further increase efficiency for an assess-and-fit service.

Appendix A
Comfort Questionnaire

Comfort rating (1 = very uncomfortable, 10 = very comfortable)

Right	1	2	3	4	5	6	7	8	9	10
Left	1	2	3	4	5	6	7	8	9	10

Feedback/whistling rating (1 = constant feedback, 10 = no feedback)
(Exclude feedback occurring while aid is going in/out of ear)

Right	1	2	3	4	5	6	7	8	9	10
Left	1	2	3	4	5	6	7	8	9	10

How blocked does your ear feel when using the hearing aid (1 = very blocked, 10 = not blocked at all)

Right	1	2	3	4	5	6	7	8	9	10
Left	1	2	3	4	5	6	7	8	9	10

Ease of use rating (1 = not at all easy to use, 10 = very easy to use)

Right	1	2	3	4	5	6	7	8	9	10
Left	1	2	3	4	5	6	7	8	9	10

Quality of sound rating (1 = very poor sound quality, 10 = very good sound quality; do not include the sound of your own voice)

Right	1	2	3	4	5	6	7	8	9	10
Left	1	2	3	4	5	6	7	8	9	10

Quality of the sound of your own voice (1 = very poor sound quality, 10 = very good sound quality)

Right	1	2	3	4	5	6	7	8	9	10
Left	1	2	3	4	5	6	7	8	9	10

Satisfaction with your hearing aid (1 = very dissatisfied, 10 = very satisfied)

Right	1	2	3	4	5	6	7	8	9	10
Left	1	2	3	4	5	6	7	8	9	10

Satisfaction with the service you received (1 = very dissatisfied, 10 = very satisfied)

	1	2	3	4	5	6	7	8	9	10

Appendix B
Follow-up Questionnaire

Now some questions about ease of use and comfort over the past 2 weeks have you been able to put your hearing aids in without too much trouble?
Yes / No

When your hearing aids are in, is the earpiece securely in your ear, so it won't fall out?
Yes / No

When your hearing aids are in, are they comfortable?
Yes / No

After you have put your hearing aids in and turned them on, are they free from whistles except if altering the aid?
Yes / No

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