TEST RE-TEST RELIABILITY AND CLINICAL FEASIBILITY OF MINIATURE PROBE MICROPHONES FOR USE IN HEARING AID EVALUATIONS

by

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Thank you, Terry, for being silent but strong.

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INTRODUCTION

A major concern for an audiologist fitting a hearing aid is how closely an aid's performance on a client's head and ear match the performance of the aid outlined in the hearing aid specification sheet. Although ANSI S3.22 (1976), "Specifications of Hearing Aid Characteristics" has set guidelines for electroacoustic characteristics of aids which are helpful in comparisons of various hearing aids, an aid's actual operating characteristics are affected by factors such as head and body diffraction, residual ear canal volume, middle ear impedance, earmold configurations, outer ear resonance characteristics and microphone location (Hawkins and Haskell, 1982).

Since present standards are set using a 2 cc hard walled coupler, these factors are not adequately taken into account when attempting to ascertain the actual functional gain (aided vs. unaided gain) an aid provides an individual. It is unlikely that the volume, diameter, and configuration of individual ears are going to be average, and therefore will not provide the same characteristics as the 2 cc coupler (Tonisson, 1975).

Several studies have shown that the performance

characteristics of a hearing aid measured in a 2 cc coupler change when the aid is placed on the head and ear of a human subject (Pascoe, 1975; Lybarger,1978; Killion and Monser, 1980; Hawkins and Haskell, 1982). These studies have taken into consideration changes caused by occluded versus non-occluded ears and tell us that not only are body baffle effect, head diffraction, middle ear impedance and ear canal response a concern, but that these factors vary with the individual (Tonisson, 1975).

Since so many variables must be considered in determining the electroacoustic characteristics of an aid, it seems unreasonable to rely on the 2 cc coupler as the only means of determining hearing aid performance characteristics. Logic would persuade us that if real ear measurements of hearing aid performance can be made with reliability, the practice of using the 2 cc coupler for determining performance characteristics of an aid on a human will lose some of its value. We should return, perhaps, to using it strictly for quality control between clinics, the purpose for which it was originally developed.

For ease of reviewing the current literature, the 2 cc coupler will be discussed first as it relates to electroacoustic performance characteristics of an aid, then the Zwislocki coupler, the Knowles Electronics Mannequin for Acoustic Research (KEMAR), and finally, real ear measures of gain.

REVIEW OF THE LITERATURE

The 2 cc Coupler

The original 2 cc coupler, first developed 35 years ago, was not, as some believe, designed to acoustically simulate the human ear or yield a response similar to that of a human ear on which a hearing aid has been placed (Pollack, 1981). The 2 cc coupler was designed with the intent of providing a means of comparing the output of one aid with that of another and provide a consistent electroacoustic measurement standard for exchange of data between clinics (Pollack, 1981). However, it appears that today many formulas for determining functional gain of aids, and current hearing aid selection procedures are based on 2 cc coupler gain measures rather than real ear gain measures (Pollack, 1981).

A 2 cc volume of air was used in the design of the current 2 cc hard walled coupler because it was thought to closely simulate the volume of the average human ear canal on which an aid has been placed (Pollack, 1981). As it turns out, this volume of air does not approximate the acoustic compliance of a human ear. This volume is actually closer to 1.2 cc. In view of this, the 2 cc coupler should not be used as a method of selecting a hearing aid, but rather as a means of quality control between clinics

(Pollack, 1981).

Recent research has begun to demonstrate the problems that result from relying on 2 cc coupler measurements for determining performance characteristics of an aid on a real ear. Van Eysbergen and Groen (1959) compared the frequency response obtained with the 2 cc hard walled coupler with that of the actual high frequency performance of an aid as experienced by a normal listener. They obtained pure tone threshold data in monaural free field for ten trained listeners. Thresholds were determined for seventeen fixed frequencies from 90 Hz - 8000 Hz. Next, they used a miniature condenser telephone receiver connected to a tone generator via a calibrated attenuator. Using both a wide and a narrow insert tip ear piece to couple the receiver to the ear, they obtained data for the same seventeen fixed frequencies. Threshold levels were then converted into sound pressure units by connecting the condenser telephone receiver to the standard 2 cc coupler. The audiometer threshold data were then compared to the converted 2 cc measures. Van Eysbergen and Groen's findings showed the 2 cc coupler overestimating real ear gain in the frequency range from 90 Hz - 1000 Hz. The frequency range of 1000 Hz - 3000 Hz showed numerous peaks and troughs of different magnitudes and they attributed this to the coupled vibrational properties of the ossicles. The most significant differences were noted between 3000 Hz - 4000 Hz. There was a 20 dB difference between these frequencies

with the 2 cc coupler underestimating real ear gain. This 20 dB difference is maintained up to 8000 Hz. These investigators suggest that this difference may be responsible for too much high frequency tone emphasis of aids which result in client complaints of poor tone quality in the high frequencies.

Given their results, van Eysbergen and Groen suggest the 2 cc coupler be used for informational exchange between clinics only, and that a 0.5 cc coupler be used for measuring frequency response of aids in addition to the 2 cc coupler. They state that the 0.5 cc coupler could be used to establish the useful frequency range of the hearing aid. The 2 cc coupler could then be used to provide information for international exchange between clinics.

Sachs and Burkhard (1972) investigated the sound pressure levels measured in real ears and compared this to 2 cc coupler measurements. Real ear measures were made using a probe tube microphone. Five different insert phones (hearing aid receivers) were used. Their data showed that below 500 Hz sound pressure in the 2 cc coupler is about 4 dB lower than that in real ears. Between 500 Hz and 5000 Hz, diferences increase with frequency about 2.5 dB per octave to about 12 dB at 5000 Hz.

The reason for these differences may be related to the fact that at frequencies above 800 Hz, "the acoustic impedance components of resistance and inertance dominate eardrum response and govern the level of sound pressure

build-up for a fixed incident pressure" (Kasten and Franks, 1981, p.60). Also, acoustic compliance of the aveage human ear is less than 2 cc when occluded by an earmold (Kasten and Franks, 1981).

Pascoe (1975) used a master hearing aid with on-the-head transducers and an adjustable frequency response to investigate the difference between hearing aid frequency response and speech discrimination abilities. Pascoe computed functional gain of the master hearing aid and compared it to the 2 cc coupler response before he attempted to determine speech discrimination ability differences with the aid. Five frequency responses were used, two of them defined by their response in a 2 cc coupler and the other three defined in terms of functional gain.

Functional gain was determined by using one-third octave bands of noise at center frequencies from 0.2 kHz to 6.3 kHz. The bands were used as external inputs to a Bekesy audiometer. Unaided sound field thresholds were obtained until six threshold crossings were completed for each one-third octave. The mean of the midpoint was used as estimate of threshold. Next, aided thresholds were obtained in the same manner.

Pascoe used these aided thresholds to obtain a functional gain value that could be simulated by the master aid. Frequency responses of the master aid were then used to establish aided thresholds for each subject's ear. These frequency responses were: 1) uniform (flat) in the coupler,

2) the spectrum rising at a 6 dB per octave slope in the coupler, 3) adjusted individually to provide uniform functional gain, 4) adjusted individually to produce uniform hearing level, and 5) functional gain responses similar to those obtained with the subject's own aid. Functional gain was measured by the reduction of the signal from the unaided to aided threshold. Pascoe then compared the mean functional gain of the five frequency responses with the associated coupler measurements and found that the coupler measurements were significantly different from functional gain. The data showed 2 cc coupler gain to underestimate functional gain from 1000 Hz - 2000 Hz and to overestimate it from 2000 Hz - 5000 Hz. Pascoe attributes these differences to head diffraction, outer ear resonance characteristics and the 2 cc coupler's inexact replication of middle-ear impedance. He states that the results of these misrepresentations are " a greatly reduced functional frequency range compared to that inferred from coupler calibration" (p. 31). It is likely then that aids which are supposed to amplify frequencies up to 4000 Hz are probably not providing significant amplification above 2.5 kHz (Pascoe, 1975).

More recently, Hawkins and Haskell (1982) compared functional gain in the occluded and unoccluded condition. Functional gain was determined by comparing unaided to aided sound field thresholds for narrow bands of noise. The noise was generated by a Bekesy audiometer. The subjects tracked their own threshold for the frequencies 200 Hz through 6000

Hz. In comparing the unoccluded and occluded aided thresholds with the 2 cc coupler gain, they found the occluded condition functional gain to be less than 2 cc coupler gain below 1000 Hz. Median functional gain values showed the two gains similar in the 1000 Hz - 1500 Hz region. In the high frequency region, functional gain was from 5 dB to 15 dB less than coupler gain.

For the unoccluding earmold condition, median functional gain values show the difference between functional gain and 2 cc coupler gain to be greatest below 2000 Hz. In the high frequencies, functional gain was approximately 10 dB less than coupler gain.

The Zwislocki Coupler

Problems inherent in the design and use of the 2 cc coupler led Zwislocki (1970) to review the problem and develop what he determined was a more realistic human ear canal simulator. In rationalizing the need for the development of such a simulator, Zwislocki (1970) stated "if a coupler for earphone calibration could be made so that its geometry is acoustically equivalent to the geometry of the concha and the ear canal, and its acoustic impedance is the same as the real ear, the sound pressure developed by any earphone at any essential point of the coupler would closely approximate the sound pressure developed in the ear. Such a coupler could be considered as an acoustically ideal

coupler" (p. 5).

Working with these factors in mind, Zwislocki developed a coupler consisting of essentially four main ports. A lower section contains an acoustic resonator and a tube with a carefully defined length and diameter. The resonator simulates the impedance at the eardrum, and the tube simulates the ear canal. An upper section contains two cavities connected via small openings which correspond to the concha and pinna (Zwislocki, 1971). The volume of these four ports is designed to more closely estimate the volume of the ear canal, from earmold tip to eardrum, when an earmold is placed in the ear.

Tests of acoustic reactance and resistance measurements of the Zwislocki coupler and real ears do not coincide completely, but Zwislocki (1971) attributes the differences to measurement artifacts. Tests of sound pressure level at various locations in real ear canals show variable results. Median sound pressure ratios between that at the eardrum and that at a point in the canal 1 cm away from the entrance show coupler and real ear measure differences are random and on an order of 1 dB SPL up to 6000 Hz. At 7000 Hz - 10,000 Hz, differences are approximately 3 dB SPL with the coupler overestimating gain at these frequencies (Zwislocki, 1980). Median sound pressure ratios between the eardrum and the canal entrance revealed no significant differences between the real ear and coupler measurements. No data exists on the use of the Zwislocki coupler above 10,000 Hz.

Sachs and Burkhard (1972) compared sound pressures developed in five real ears and pressure in a Zwislocki coupler. Below 500 Hz they found sound pressure in the coupler to be essentially identical to sound pressure measured with a probe microphone in real ears. They say this implies a real ear equivalent volume of approximately 1.2 cc. Sachs and Burkhard also compared measured differences observed with the Zwislocki coupler versus real ear measurements with differences noted between the 2 cc coupler and real ear measurements. The real ear versus Zwislocki coupler difference was no more than plus or minus 2 dB at 5000 Hz, while difference in the real ear versus 2 cc coupler was approximately plus or minus 12 dB at 5000 Hz. They noted that above 5000 Hz, pressure in real ears decreased with increasing frequency relative to both couplers.

Zwislocki's studies (1970, 1971) and Sachs and Burkhard (1972) have provided evidence that an ear simulator can be made that at best only approximates the acoustic characteristics of an average human ear.

Hearing aid measurements made in a test box with the 2 cc coupler and the Zwislocki coupler do not account for individual head and pinna diffraction, body baffle, or ear canal resonances. Zwislocki's (1970) attempt at matching the impedance of the human ear canal more closely was relatively successful, but it still has limitations for use in hearing aid selection procedures. The reason for this is obvious.

Zwislocki (1980) explained that "the ear simulator can at best simulate the median or average characteristics of real ears. They will never obviate the need for individual tests" (p. 146).

KEMAR

Knowles Electronics, Inc. developed an anthropometric mannequin to facilitate on-the-head measurement of hearing aid performance characteristics. Knowles Electronics Mannequin for Acoustic Research (KEMAR) was designed to equate the acoustic properties of the average human head and torso (Kasten and Franks, 1981).

It is common practice to place a Zwislocki coupler on KEMAR. This combination provides advantages that are not present when using the Zwislocki coupler or the 2 cc coupler individually. First, it is possible to observe head and body diffraction effects on a signal in a sound field since KEMAR is used in an anechoic chamber. Second, the use of KEMAR and the Zwislocki coupler in this fashion provides a uniform means of testing hearing aids from clinic to clinic. A tireless subject and continuity of placement of KEMAR in the sound field are other obvious advantages (Pollack, 1981).

The advantages of using KEMAR would seem to outweigh the disadvantages, but this is not actually the case. Pollack (1981) states that very little of the data obtained on KEMAR has clinical applicability. There are several reasons for

this. One of the difficulties in using KEMAR is the need for an anechoic chamber to eliminate reflections and standing wave problems. Unfortunately, most clinics have neither the money or the space for such a chamber (Pollack, 1981).

Little data exists on the use of KEMAR combined with the Zwislocki coupler compared to real ear measurements. Dirks and Gilman (1979) studied KEMAR fitted with a Zwislocki coupler in terms of field-to-drum acoustic function and compared these transfer functions to the averaged real ear functions of Shaw (1974b). Using eight different azimuth locations, their data showed close agreement between frequency responses obtained with KEMAR and averaged real ear measures. The shape of the field-to-drum transfer function was, however, determined by the angle of incidence of the signal. They concluded that KEMAR and averaged real ear data are in close enough agreement that KEMAR can be safely used for testing hearing aid performance characteristics. They cautioned that the use of KEMAR in conjunction with a Zwislocki coupler will not allow determination of the ouput of a hearing aid exactly as it would appear at the eardrum.

If a Zwislocki coupler is used in conjunction with KEMAR, it should be kept in mind that the measurements obtained are only simulated average ear measurements. Use demands that allowance be made for physical differences of the head, pinna, and ear canal sizes along with differences

in tympanic membrane impedances (Kasten and Franks, 1981).

Real Ear Measures

The concept of using real ear measures to predict hearing aid performance characteristics is not a new one. In fact, probe microphone measurements have been used for more than 30 years.

Weiner and Ross (1946) were pioneers in utilizing probe microphones to obtain real ear measures. Since then, probe microphone measures have been conducted and reported, but, unfortunately, these measurements have not been used much clinically. Harford (1980) suggests the main reason for this is the notion that an anechoic chamber is needed for these measurements, and no unobtrusive probe microphone system has been commercially available.

Real ear measurements have traditionally been accomplished by inserting a hollow tube into the ear canal of an individual. This tube then led to a transducer outside the ear canal (Harford, 1980). Knowles Electronics has developed a new wide-range, flat-response miniature electret microphone to be used in real ear measurements. The tiny microphones measure approximately 5 x 2 x 4 millimeters and can be easily and comfortably inserted into the ear canal. A matched pair of microphones, a test and a regulator, allow the easy measurement of the sound pressure level of the acoustic output of a hearing aid in a human ear

canal. This is done by measuring the sound pressure difference between the test microphone and the regulator microphone. The test microphone reads the sound pressure in the ear canal, and the regulator microphone measures the sound pressure around the subject and can therefore compensate for standing waves. Traditionally, hearing aid evaluations could not be performed in sound field with pure tones because of a lack of repeatability caused by standing wave problems (Starkey Laboratories, Inc.).

As mentioned earlier, real ear measurements are not new. It has been pointed out that many studies have been done in comparing real ear gain measures with those obtained in a 2 cc hard walled coupler, a Zwislocki coupler, and KEMAR fitted with a Zwislocki coupler. However, there is a paucity of data currently available on the clinical use and the test-retest reliability of these measures.

Harford (1980) used Starkey miniature probe microphones in the ear canal to verify hearing aid performance characteristics. To determine reliability of real ear measurements, Harford obtained five different measurements by the same tester on two different subjects, but on unoccluded ears. The test and regulator microphones were placed in opposite ear canals and a recording was obtained. The tester then removed the microphones and the subject left the test area briefly before the next measurement. The subjects then re-entered the test area, microphones were reinserted and another recording obtained. This procedure

was repeated five times. Harford found inconsistencies in the higher frequencies for one of the subjects while the other subject showed good agreement between measurements. Harford then had three clinicians obtain real ear measurements on the same subject with an unoccluded ear. He found inconsistencies once again in the higher frequencies.

Harford infers from this study that a clinician can be trained to develop a technique for inserting the probe microphones and be consistent in measurements. However, this study was done using unoccluded ears and no reliability data on occluded ears are available.

More recently Berger (personal communication) conducted a study of real ear measurements on six subjects and noted a mean aided probe tube discrepancy on the order of 1.1 dB to 6.5 dB. He raised the question of the reliability measures over time using the probe microphones.

Due to the lack of a viable and reliable method of determining actual hearing aid performance characteristics on a human ear using the 2 cc coupler, there appears to be a need for further study of a procedure of measuring real ear gain of an aid. Before this is done, however, it must be determined if real ear measurements are reliable. If occluded real ear measurements can be proven to be consistently reliable, audiologists may then use these measurements to select a hearing aid that will provide the most benefit to an individual based on the actual sound pressure level developed in the ear canal.

The purpose of this study was to investigate the test-retest reliability measures of actual sound pressure levels generated in a human ear canal in the occluded condition. It was anticipated that these data would provide considerable information concerning the clinical feasibility of the probe microphones.

METHOD

Subjects

The subjects for this research were ten hearing impaired individuals whose ages ranged from 14 years, 10 months to 78 years, 10 months. Subjects consisted of five males and five females whose losses ranged from moderate to profound. All subjects had been evaluated at the Kansas State University Speech and Hearing Center. All subjects completed the test procedure.

Instrumentation

The Starkey RE 4 probe microphone system was used in conjunction with a Phonic Ear HC 2000 hearing aid test box to obtain real ear measures of sound pressure generated in the external ear canal. The probe microphones were coupled to the Phonic Ear HC 2000 hearing aid test box and HC 2200 strip chart recorder with a Starkey RE 4 interface system.

The pure tone signal for use in the real ear measurement was generated by a Phonic Ear HC 2000 hearing aid test box and the level was recorded by a Phonic Ear HC 2200 strip chart recorder. Prior to the arrival of each subject at the test site, the Phonic Ear HC 2000 was

calibrated according to the manufacturer's specification. The microphones were calibrated in the following manner: a Bruel and Kjaer sound level generator, Type 4230, was placed on the Phonic Ear HC 2000 test microphone, and chamber calibration adjusted until the test box exhibited a 94 dB SPL readout. The test chamber was then calibrated by placing the test microphone and regulator microphone perpendicular to each other approximately one-quarter inch apart. The input from the Phonic Ear HC 2000 was set at 60 dB SPL for 1000 Hz. The chamber calibration was adjusted to read 60 dB SPL. The Phonic Ear HC 2000 test microphone was then replaced by the Starkey RE 4 system test probe microphone (Channel A), and the above procedure was repeated. Next, the regulator microphone (Channel B) from the Starkey RE 4 system replaced the regulator microphone of the Phonic Ear HC 2000 and the procedure was repeated again. The final step was to plot the output of the microphones in the closed field condition using a Phonic Ear HC 2200 strip chart recorder. This procedure was done prior to each set of three trials. See Figure 1 for an example of the linearity check of the probe microphones in closed field.

After the above procedure was completed, the Starkey RE 4 probe microphones were transferred into the sound chamber. The Industrial Acoustics Company chamber consisted of a double-walled, single-room sound treated test environment which satisfied ANSI 1969 ambient noise level standards. The output of the Phonic Ear HC 2000 was channeled to the

loudspeaker in the sound booth. A linearity check was then made in the sound field by placing the regulator and test probe microphone at a distance of approximately one meter from the loudspeaker. The 60 dB SPL output of the test microphone was plotted on the Phonic Ear HC 2200 strip chart recorder. See Figure 2 for an example of the linearity check of the probe microphone system in the sound field condition.

The Starkey RE 4 probe microphone system utilized two miniature microphones that measured approximately 5 x 2 x 4 millimeters. These microphones were covered with an acoustic damping screen and a disposable plastic cover which was changed after each set of three trials for a given subject. See Figure 3 for an example of the test environment.

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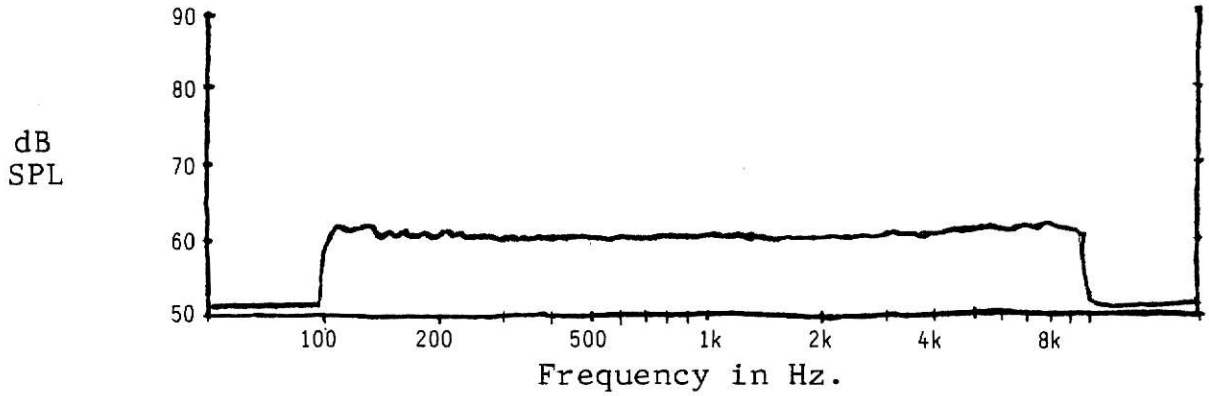

Fig. 1. Linearity check of the probe microphones in closed field condition.

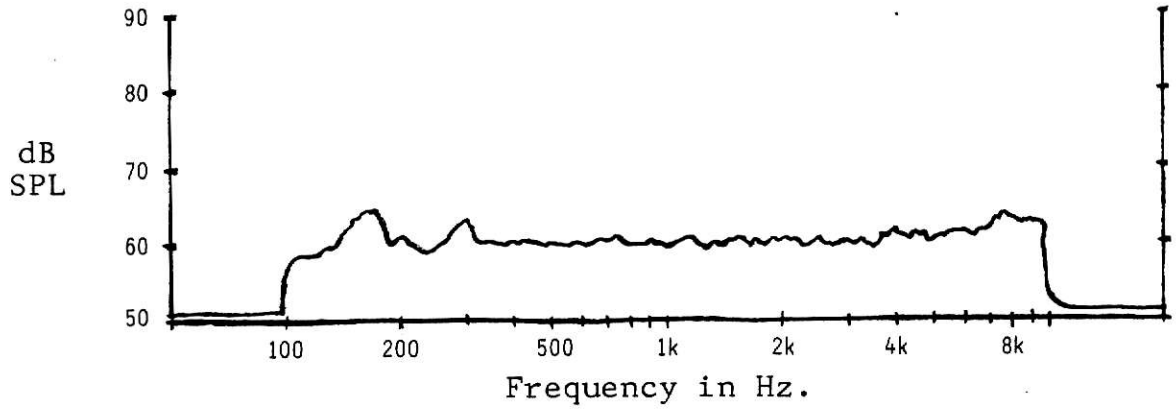

Fig. 2. Linearity check of the probe microphones in sound field condition.

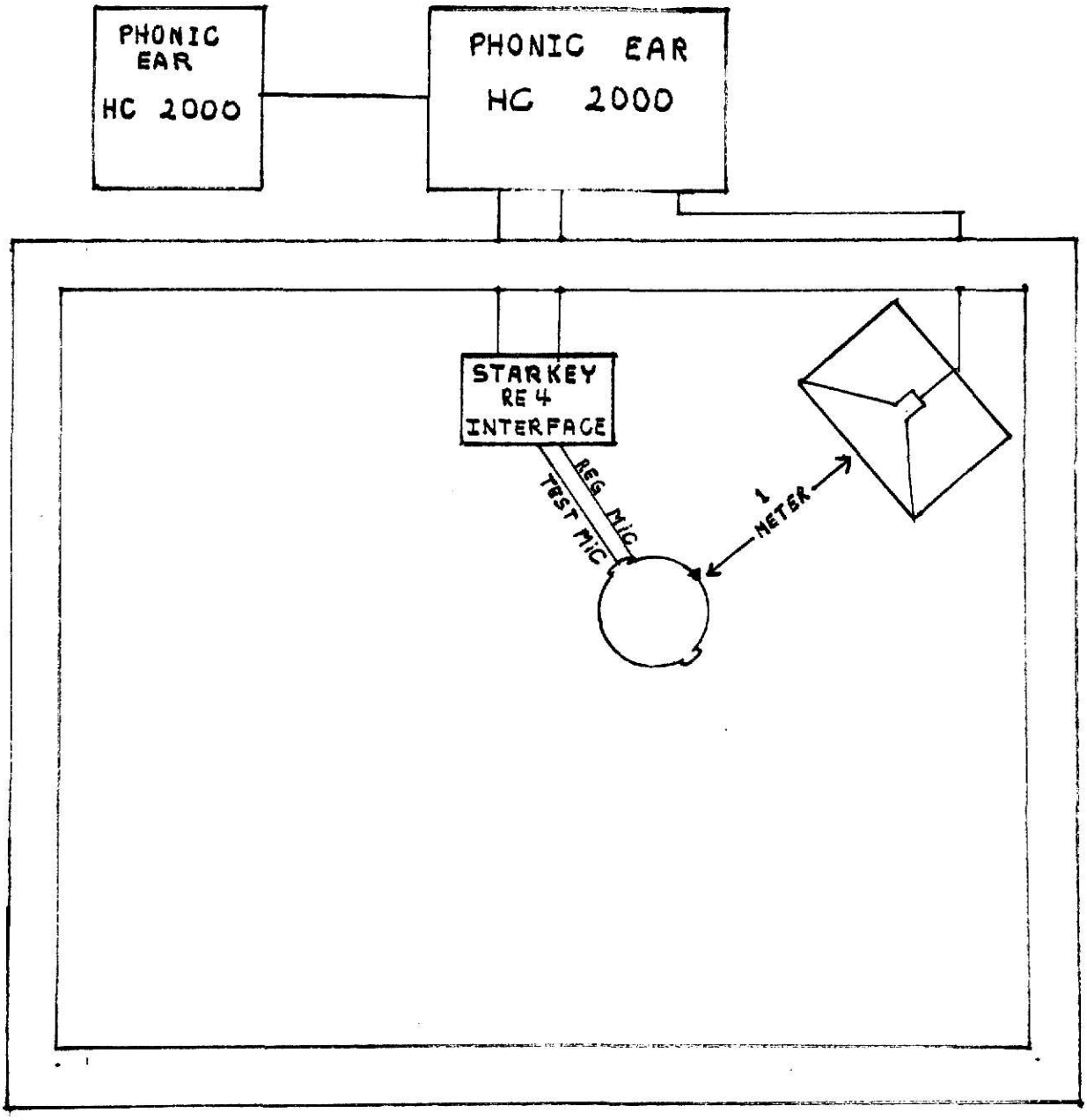

Fig. 3. Block diagram of subject and test environment.

Procedure

Prior to obtaining data, each subject was counseled regarding the procedure to be followed, any questions were answered, and the subject's written consent was obtained. An otoscopic examination was performed before each session to check for obstructions or infections in the external canal. Using an American Electromedics Tympanometer, Model 86AR, a tympanogram was obtained on the test ear to provide an approximate volume measurement of the external canal.

Before each session, a voltage check was made of the subject's hearing aid battery, and the hearing aid volume control position was recorded and the volume control taped in place in order to assure identical gain setting for each separate trial. A distance of approximately one meter in front of the loudspeaker was measured and tape marks were placed on the floor so that the subject's chair could be in approximately the same position for each trial.

The subject was seated in the sound chamber approximately one meter from the front of the loudspeaker. The test probe microphone was inserted approximately 1 cm into the subject's ear canal. The distance from the tip of the micrphone to the end of the strain relief on the microphone cord was approximately 1 cm, therefore the end of the strain relief was used as a reference for placement into the entrance of the ear canal. The regulator microphone was

placed over the pinna of the same ear approximately one inch from the hearing aid microphone and was taped in place to guard against slippage of the microphone. The real ear gain from 100 Hz to 10,000 Hz was then charted by the Phonic Ear HC 2200 strip chart recorder for an input of 60 dB SPL. Between each trial, the regulator microphone, earmold, and test microphone were removed from the subject. This time was utilized to inspect the test microphone for wax accumulation or slippage of the plastic covering on the test microphone. Prior to the next trial, the probe microphone was reinserted and the regulator microphone taped in place.

RESULTS

Figure 4 provides an example of real ear responses charted by the Phonic Ear HC 2200 strip chart recorder. The frequencies 500, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, and 5000 Hz were selected for comparisons of real ear responses between trials. These frequencies were selected for comparisons because, 1) they include the most useful range for speech, 2) they include those used in standard procedures for computing the gain of a hearing aid, and 3) they are amplified significantly by hearing aids (Kasten and Franks, 1981).

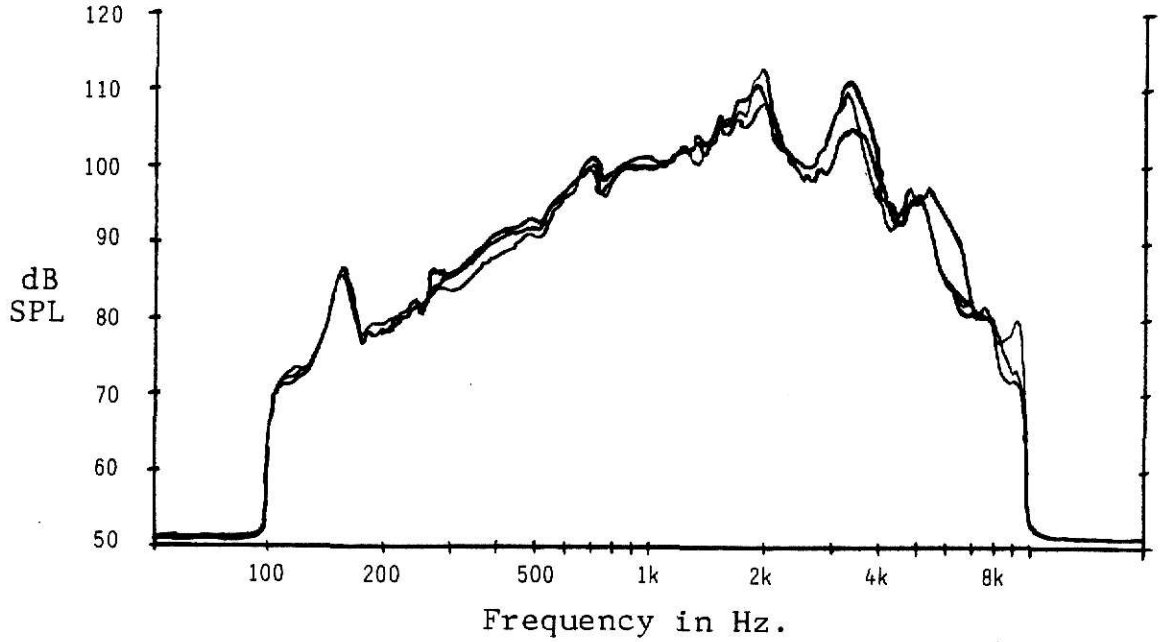

Fig. 4. Three real ear responses recorded with Phonic Ear HC 2200 strip chart recorder.

The sound pressure level generated in the ear canal was read directly from the Phonic Ear strip chart record. The gain at each frequency was determined by subtracting 60 dB from each of those levels.

The gain at each frequency was estimated by computing the mean of the three trials for day 1 and for day 2. It could be argued that the mean is the best estimate of gain for a subject's aid on a single day.

Next, the mean absolute deviation from the average gain estimate was computed for the three trials on the two separate days. This value was computed by taking the mean absolute value of each deviation from the mean gain and dividing by three, the number of observations. This final value was how far each real ear response deviated around the average gain on a single day.

Table 1 shows the estimate of mean gain and the mean deviation from the mean for each subject at each frequency. (The estimates of mean deviation from the mean gain are plotted in Figure 5.) The four entries in each cell give the mean gain and the mean deviation from the gain for three trials on day 1 and day 2 for each subject at each of the ten frequencies.

In looking at Figure 5, graphs (a) though (j), for day 1, it can be seen that the mean deviation over all subjects ranged from 0 dB to 10 dB. The 10 dB deviation was obtained on subject VL who was the third subject seen by the experimenter during this study. VL was an unusual case in

that her earmold had been built up twice by the dispenser. This made it difficult to obtain real ear response curves due to a feedback problem resulting from the inadequate seal in the ear canal.

In looking at Figure 5, graphs (a) though (j) for day 2, it can be seen that the mean deviation ranged from 0 dB to 5.3 dB. This is a decrease in the range of the mean deviation of 4.7 dB from day 1 to day 2. This change largely occurred because of subject VL, mentioned above. The results for VL on day 2 were less variable than on day 1. This could be attributed in part to a learning effect for placement of the probe microphones by the experimenter in addition to a better seal of the earmold in the ear being obtained.

TABLE I. Values are mean gain of the 3 real ear responses and average deviations around the mean gain for day 1 and day 2.

		500 Hz		1000 Hz		1500 Hz		2000 Hz		2500 Hz		3000 Hz		3500 Hz		4000 Hz		4500 Hz		5000 Hz	
		$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$	$\bar{X}$	$D\bar{X}$
LH	D1	37.7	0.9	47.0	0.0	47.3	1.8	43.0	0.0	41.3	0.4	45.7	0.4	37.7	0.4	40.3	0.4	35.3	1.8	32.3	0.4
	D2	38.0	1.3	47.0	0.0	52.3	0.4	44.3	1.1	44.0	1.3	45.0	1.3	41.3	2.4	43.0	5.3	39.3	3.8	32.0	4.0
LP	D1	2.0	0.0	7.3	0.4	15.3	0.4	21.7	0.4	20.7	2.9	25.3	0.9	31.0	2.0	22.3	1.1	16.3	1.6	17.3	0.4
	D2	1.0	0.0	6.0	0.0	14.7	0.4	23.0	0.0	19.3	0.4	28.6	0.4	35.0	0.7	21.3	1.8	14.0	1.3	14.3	2.4
SK	D1	16.7	0.9	36.3	0.4	32.3	1.1	41.7	0.9	32.7	1.6	28.0	0.7	25.3	0.4	26.0	0.7	17.7	2.2	6.3	1.8
	D2	14.3	1.1	32.7	0.4	32.7	0.4	41.0	2.0	31.3	0.4	26.3	0.4	24.3	1.6	27.0	2.0	19.3	2.2	7.7	1.8
CR	D1	15.3	2.2	28.3	3.6	28.0	0.7	33.7	1.6	37.7	3.6	30.3	3.1	28.7	4.4	18.7	4.4	14.3	2.2	9.0	2.0
	D2	19.0	2.7	32.7	1.1	35.7	0.9	34.7	0.4	41.7	1.1	35.0	0.7	29.7	1.8	22.0	1.3	19.0	2.0	16.0	2.7
RB	D1	23.0	2.0	37.0	0.7	36.0	1.3	45.3	0.4	31.0	0.0	31.3	0.4	39.0	2.7	33.0	0.7	23.0	2.7	20.7	1.8
	D2	19.3	2.2	30.3	1.3	28.3	1.6	40.0	1.3	31.3	3.8	28.7	1.1	31.0	1.3	29.3	2.4	23.3	2.2	19.7	1.8
KB	D1	2.0	0.0	10.3	0.4	13.0	1.3	19.0	0.0	24.7	0.4	18.0	0.0	12.0	0.7	4.7	2.4	1.0	0.0	3.0	0.0
	D2	0.3	0.4	4.0	0.7	5.0	2.0	14.3	2.4	20.3	3.1	14.0	1.3	7.3	2.4	1.3	1.8	0.7	0.4	2.0	0.7
DVH	D1	1.0	0.0	3.0	0.0	10.7	1.1	18.3	0.9	28.3	0.4	22.3	1.1	21.3	0.4	21.7	0.4	18.7	1.1	16.3	1.8
	D2	1.0	0.0	4.0	0.0	11.3	0.4	15.0	0.7	23.7	0.4	26.3	0.9	29.0	0.7	25.0	1.3	15.7	0.4	19.3	1.8
ML	D1	47.3	0.9	47.3	0.4	55.0	2.0	47.7	2.4	39.3	1.1	42.7	0.4	46.7	0.9	42.7	2.4	35.7	1.8	36.7	0.9
	D2	46.0	0.0	47.0	0.0	54.3	2.4	51.3	2.9	42.3	0.9	40.3	0.4	44.3	3.1	47.3	0.9	39.3	2.2	36.0	2.0
JT	D1	32.0	0.7	40.3	0.4	45.0	0.7	49.7	1.6	39.7	0.4	43.3	2.2	47.3	1.8	37.3	2.2	33.3	0.4	35.7	0.4
	D2	31.7	0.4	38.3	0.4	46.7	1.8	47.7	1.8	36.0	2.7	40.3	0.4	39.0	0.7	31.3	1.1	33.0	2.7	34.3	2.2
VL	D1	31.0	2.0	41.0	2.7	37.0	1.3	38.3	0.4	39.3	3.6	32.0	4.0	31.7	3.1	36.0	4.7	36.0	10.0	25.3	9.6
	D2	27.0	4.0	37.0	0.0	31.7	1.6	41.7	1.8	33.7	0.9	27.3	0.4	28.7	0.9	37.0	1.3	33.7	3.6	27.7	1.8

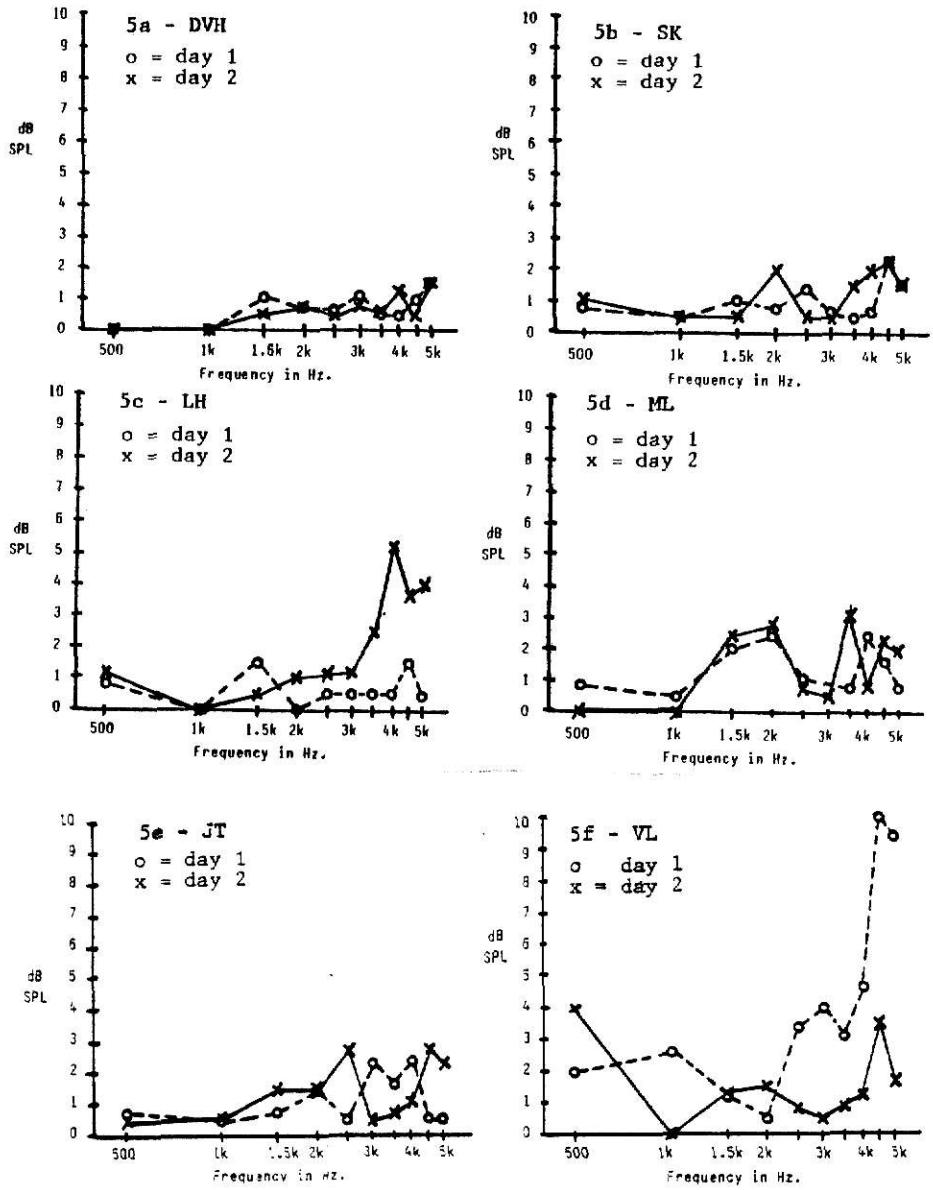

Fig. 5. Graphs (a) through (j). Mean deviations by frequency for each subject on day 1 and on day 2.

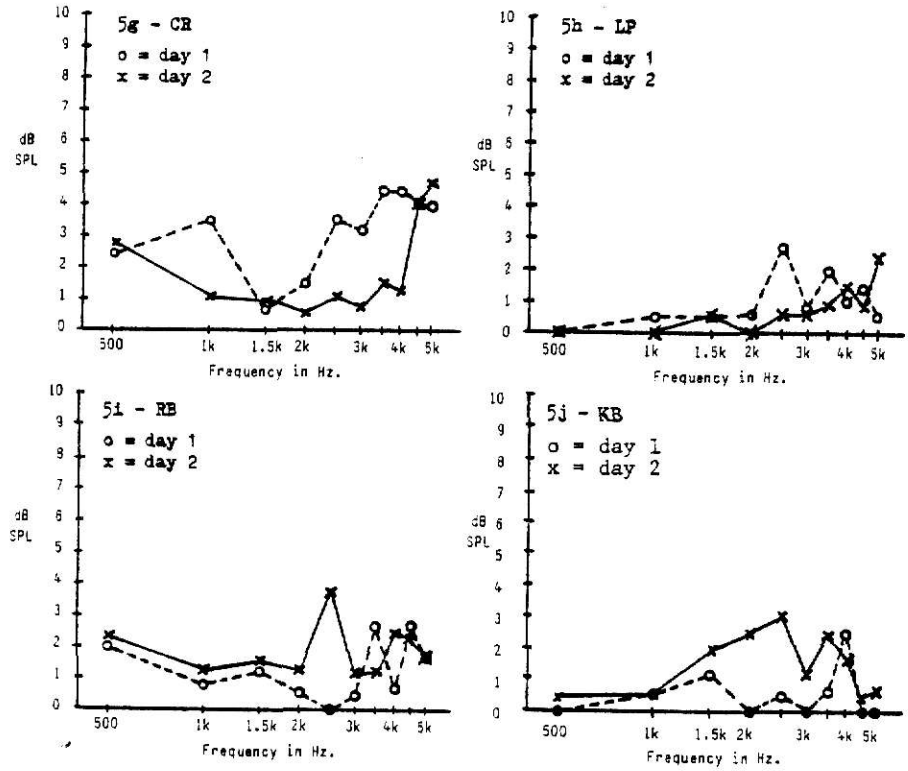

Fig. 5. Graphs (a) through (j) continued.

Subjects were grouped according to the amount of gain provided by their aid. Six subjects used high gain aids (60 dB or greater) and five subjects used mild gain aids (40 dB or less). Figure 6 is a graph of the averaged deviation from the means over both days grouped according to gain category. One subject used an aid in the moderate gain category. Those data are not shown in Figure 6. Although no statistical measure was obtained, it can be noted that the high gain means lie above the low gain means at eight of the ten frequencies. There did appear to be a tendency for greater deviation around the mean for the higher gain aids, especially at the frequencies of 3500 Hz through 5000 Hz.

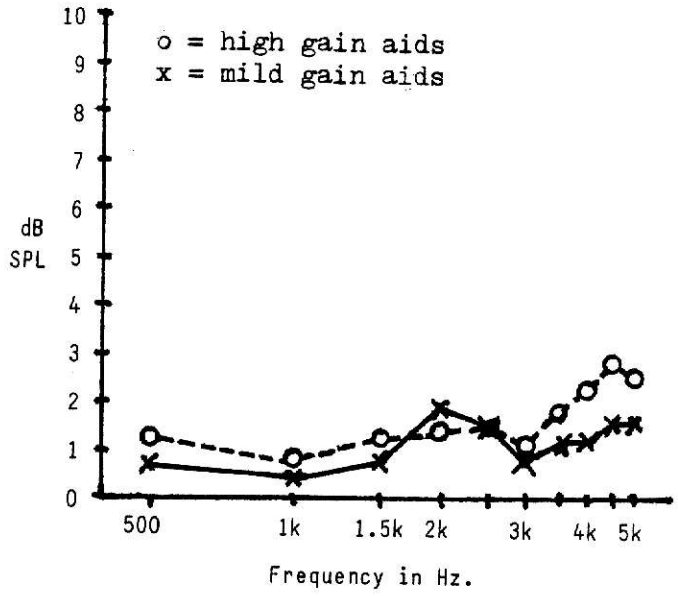

Fig. 6. Average deviation from the mean over both days grouped according to aid gain category.

Statistical analysis of the deviation from the mean gain was accomplished using the Statistical Analysis System (SAS) two-way analysis of variance (subject by frequency). Separate analyses were done for day 1 and day 2. Table 2 summarizes the results of the ANOVA for day 1. Both subject and frequency were found to be significant effects at the .01 level.

TABLE 2. Analysis of variance subject by frequency for day 1.

SOURCE	DF	ANOVA SS	F VALUE
SUB	9	365.57096667	18.11*
FREQ	9	65.77763333	3.26*

* Values are significant at the .01 level

Duncan's Multiple Range Test analysis was applied to the f values to determine at what frequencies and for which subjects significant differences occurred. Table 3 shows the individual subject means for day 1. Means identified by the same letter are not significantly different from each other. Subjects VL and CR were significantly different from all other subjects and from each other.

TABLE 3. Duncan's Multiple Range Test for Deviation.

Duncan Grouping	Mean	Subject
A	4.3333	VL (HG)*
B	3.0300	CR (HG)
C	1.3300	ML (HG)
C	1.2633	RB (MG)
C	1.1067	JT (HG)
C	1.0667	SK (HG)
C	0.9533	LP (MG)
C	0.7500	DVH (MG)
C	0.6733	LH (HG)+
C	0.5300	KB (MDG)

HG = high gain aids
MG = mild gain aids
MDG = moderate gain aid
* = earmold problems
+ = earmold complaints
(Means with the same letter are not significantly different.)

Table 4 shows the frequency effect for day 1. The most significant deviation occurred at 4500 Hz. As can be seen by the list of mean deviations, the greatest deviation occured from 3500 Hz through 5000 Hz. The least significant deviation occurred at 500, 1000 and 2000 Hz.

TABLE 4. Duncan's Multiple Range Test for Deviation.

Duncan Grouping			Mean	Frequency
	A		2.3767	4500 Hz
B	A		1.9067	5000 Hz
B	A		1.8967	4000 Hz
B	A	C	1.6833	3500 Hz
B		C	1.4667	2500 Hz
B		C	1.4637	1500 Hz
B		C	1.3300	3000 Hz
		C	0.9600	500 Hz
		C	0.9067	1000 Hz
		C	0.8733	2000 Hz

(Means with the same letter are not significantly different.)

Table 5 summarizes the SAS two-way analysis of variance (subject by frequency) for day 2. Both subject and frequency were found to be significant effects at the .01 level.

TABLE 5. Analysis of Variance subject by frequency.

SOURCE	DF	ANOVA SS	F VALUE
SUB	9	54.83750000	4.34*
FREQ	9	83.34883333	6.59*

* Values are significant at the .01 level.

Table 6 shows the values for subject effect on day 2 obtained from Duncan's Multiple Range Test. Subject LH showed the largest deviation on day 2. His mean deviation was not significantly different from six of the remaining nine subjects. He was, however, significantly different from SK, LP, and DVH.

TABLE 6. Duncan's Multiple Range Test for Deviation.

Duncan Grouping		Mean	Subject
	A	2.1067	LH
B	A	1.9100	RB
B	A	1.6233	VL
B	A	1.5267	KB
B	A	1.4900	ML
B	A	1.4767	JT
B	A	1.4633	CR
B		C 1.2400	SK
		C 0.7500	LP
		C 0.6633	DVH

(Means with the same letter are not significantly different.)

Table 7 shows the frequency effect for day 2. The data are quite similar to those observed on day 1. The greatest deviation occured at 3500 Hz and upward again. These were the same four where the most deviation occurred on day 1.

TABLE 7. Duncan's Multiple Range Test for Deviation.

Duncan Grouping			Mean	Frequency
	A		2.1067	5000 Hz
	A		2.0900	4500 Hz
	A		1.9300	4000 Hz
B	A		1.5533	3500 Hz
B	A		1.5067	2500 Hz
B	A		1.4867	2000 Hz
B		C	1.2200	500 Hz
B		C	1.1967	1500 Hz
	D	C	0.7633	3000 Hz
	D		0.3967	1000 Hz

(Means with the same letter are not significantly different.)

The average deviation over all subjects and all frequencies on day 1 was 1.48 dB. The average deviation on day 2 was 1.425 dB, slightly less than on day 1. Although no statistical analysis was done, this did not appear to be a clinically relevant difference.

DISCUSSION

The most important question considered in this study is whether or not the probe microphone measurements of real ear gain in standard hearing aid evaluation procedures are sufficiently reliable for routine clinical use. That is, is the deviation from the mean gain within reasonable limits from a clinical point of view? Is the ease of insertion, reliability of the clinician, lack of client discomfort and client satisfaction sufficient to allow their use on a daily basis?

Although the SAS two-way analysis of variance shows that there is a definite high frequency effect, the largest mean deviation of the most variable subject over all frequencies is 2.4 dB on day 1 and 2.1 dB on day 2. These values are relatively small given that current hearing aid selection procedures utilize a plus or minus 5 dB variability in spondee reception thresholds for performance with a given hearing aid. In addition, several studies have demonstrated differences between real ear and 2 cc coupler measures of hearing aid gain ranging from 4 dB to 20 dB (Hawkins and Haskell, 1982; Nelson, 1982). If real ear measures are considered the more valid of the two, then from a clinical point of view, a maximum deviation of 2.4 dB around the mean is certainly acceptable.

There were several subjects who varied significantly

from the other subjects over the two separate days. On day 1, VL varied significantly from subject CR, and even more significantly from the remaining eight subjects. There could be several reasons for the variability exhibited by VL. First, VL used a high gain hearing aid. Second, considerable difficulty was encountered in achieving a seal with her earmold. As a result of a large weight loss, VL's earmold had been modified twice.

In an attempt to alleviate the feedback problem, a slight change could have been made in the placement angle and depth of the probe microphone within the ear canal. According to Stinson, Shaw and Lawton (1982), sound pressure generated in the external canal may vary as much as 10 to 12 dB with a change of 2 to 18 millimeters in depth of placement of the probe tube pickup. It is likely that the large deviation noted for VL is related to the depth of placement of the test microphone. Variability was reduced on day 2 (4.1 dB versus 1.6 dB). The experience gained by the experimenter prior to the collection of data on day 2 was undoubtedly beneficial in achieving more reliable data.

Table 3 from day 1 shows that subject CR was also significantly different in response reliability from the other subjects. CR was the first subject in the study on which repeated measurements were obtained. As with VL, variability with CR would be suggestive of a learning effect, particularly because variability decreased from day 1 to day 2 (3.0 dB versus 1.5 dB).

Subject LH provided an interesting variation from day 1 to day 2 (refer to tables 3 and 6). On day 1, LH was one of the two least variable subjects on which real ear responses were obtained. On day 2, he was the most variable subject. LH wore a high gain aid, and at the time of this study was complaining about his earmold being uncomfortable, as well as experiencing feedback problems. As with VL, attempts to stop the feedback by readjusting the lead wire feeding out of the ear canal could have resulted in changing the placement depth and angle of the probe microphone.

The SAS analysis of variance for both days showed a definite frequency effect for the high frequencies. Tables 4 and 7 show that 4000 Hz, 4500 Hz and 5000 Hz are the three most variable across both days. Although these three frequencies were more variable than the other seven on both days. the real ear response could still be considered clinically acceptable because the largest deviation from the frequency mean was only 2.4 dB on day 1 and 2.1 dB on day 2.

In analyzing the data for causal differences in repeated real ear measures, there is a trend for high gain aids to show greater deviation. This trend is shown in Figure 6. Grouping of high gain aids and low gain aids show the maximum deviation between the two groups to be approximately 2.2 dB. This deviation occurs at 4500 Hz. This is consistent with the findings of this study which show a trend towards more deviation in the higher frequencies.

The data were examined to determine if earmold style was

related in some way to mean deviation. No apparent correlation was observed.

Although an ANOVA showed significant effects for both subjects and frequency, data suggest that the routine use of insert microphones in hearing aid fitting is clinically feasible. The greatest subject deviation occurred in individuals who had somewhat poorly fitting earmolds. It would be desirable for subjects to have custom fitting earmolds prior to the use of the probe microphones in a hearing aid evaluation.

The greatest frequency deviation occurred in the frequencies 3500 through 5000 Hz. However, if we exclude those subjects with the poorly fitting earmolds, and subject CR who was the first subject, none of the mean deviations range higher than 2.7 dB. This indicates a range on the order of 5+ dB. Even with a range of 5+ dB in the mean deviation, these are superior to those obtained with the 2 cc coupler.

The use of the miniature probe microphones for obtaining real ear responses would seem to have a place in standard hearing aid evaluation procedures. However, it is suggested that if real ear responses are to be used as a clinical tool at least two tracings should be made with each different aid with the microphone reinserted for the second tracing. The time required to do this would be approximately two minutes. Variables such as placement depth of the test microphone, regulator microphone

placement, and head placement in reference to sound source should be closely monitored. Controlling these variables as closely as possible would guard against the few instances where unacceptable variations might occur. In addition, the examiner should thoroughly practice inserting the probe microphones.

The Starkey RE 4 probe microphone system is not difficult to operate. However, one must be familiar with calibration procedures. The approximate cost of the microphones system ($1200.00) is not so expensive that it could not become a part of every audiology clinic.

The probe microphones appear to cause little discomfort to the subjects. Only one subject complained of mild discomfort from having the tiny microphone placed in her ear.

A few problems arose with the frequent use of the microphone system. The strain relief that was used to connect the wiring to the small microphone became loose after a number of insertions and had to be epoxied onto the microphone case in order to assure that the wires would not be pulled from the microphone. No further problems were encountered after this was done. Also, the protective conformal coating that covered the microphone separated from the case and started to peel off. Care had to be taken to prevent damage to the delicate wiring until the microphone could be recoated.

It is generally concluded that real ear measures of

sound pressure generated in the external canal by hearing aids, as measured by probe microphones, is a more valid measure than hearing aid output measured in a 2 cc coupler. Because mean deviation of sound pressure recorded in the external canal does not exceed approximately 2.4 dB when measured by the Starkey RE 4 probe microphone system, it is concluded that the use of the probe microphone system is clinically feasible. Because a slight variation in placement can affect sound pressure measured in the external canal, the clinician should be thoroughly practiced in insertion technique before using the system.

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TEST RE-TEST RELIABILITY AND CLINCIAL FEASIBILITY OF MINIATURE PROBE MICROPHONES FOR USE IN HEARING AID EVALUATIONS

by

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AN ABSTRACT OF A MASTER'S THESIS

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A major concern for an audiologist fitting a hearing aid is how closely an aid's performance on a client's head and ear match the performance of the aid outlined in the hearing aid specification sheet. Although ANSI S3.22 (1976), "Specifications of Hearing Aid Characteristics" has set guidelines for electroacoustic characteristics of aids which are helpful in comparisons of various hearing aids, an aid's actual operating characteristics are affected by factors such as head and body diffraction, residual ear canal volume, middle ear impedance, earmold configuration, outer ear resonance characteristics and microphone location. Since present standards are set using a 2 cc hard walled coupler, factors such as these are not adequately taken into account when choosing an aid that *would be most beneficial* to an individual.

The purpose of this study was to investigate the test-retest reliability measures of actual sound pressure levels developed in the human ear canal using the Starkey RE 4 Probe Microphone System. It was anticipated that these data would provide considerable information concerning the clinical feasibility of the probe microphones.

The results of this study have shown that the use of miniature probe microphones for obtaining real ear responses would seem to have a place in standard hearing aid evaluation procedures. Although there was the tendency for greater deviation between measures in the high frequencies,

the maximum deviation for both days was only 2.4 dB. This value is still very good given that current hearing aid selection procedures utilize a plus or minus 5 dB variability in spondee reception thresholds for performance with a given hearing aid. In addition, a plus or minus 5 dB variation in estimated pure tone threshold is acceptable.

Variations were noted in subjects who had earmold problems. A poorly fitting earmold caused a problem with feedback and attempts to alleviate it could have caused changes in the placement of the probe microphone. Earmolds undoubtedly play an important part in real ear measures, therefore it would be desirable for subjects to have custom fitting earmolds prior to the use of the probe microphones in a hearing aid evaluation.