COMPARISON OF FUNCTIONAL GAIN AND INSERTION GAIN IN CONDUCTIVE HEARING LOSS

(REGISTER NO. M 0109)

An Independent project submitted in part fulfillment of the First year M.Sc (Speech and Hearing), University of Mysore, Mysore

ALL INDIA INSTITUTE OF SPEECH AND HEARING
MANASAGANGOTHRI, MYSORE - 570006

MAY 2002


To Sir,
with love

Certificate

This is to certify that the Independent project entitled *"Comparison of Functional Gain and Insertion Gain in Conductive Hearing Loss"* is the bonafide work done in part fulfillment of the degree of Master of Science (Speech and Hearing) of the student (Register No. M 0109).

Mysore
May 2002

Director
All India Institute of
Speech & Hearing
Mysore-570006.

Certificate

This is to certify that the Independent project entitled *"Comparison of Functional Gain and Insertion Gain in Conductive Hearing Loss"* has been prepared under my supervision and guidance. It is also certified that this has not been submitted earlier in any other University for the award of any Diploma or Degree.

Guide

Dr. K. Rajalakshmi
Lecturer in Audiology
Department of Audiology
All India Institute of
Speech & Hearing
Mysore - 570006.

Mysore
May 2002

Declaration

I hereby declare that this Independent project entitled *"Comparison of Functional Gain and Insertion Gain in Conductive Hearing Loss'"* is the result of my own study under the guidance of Dr. K. Rajalakshmi, Lecturer in audiology, Department of audiology, All India Institute of Speech and Hearing, Mysore and has not been submitted earlier or in any other University for the award of any Diploma or Degree.

Mysore

May 2002 Register No. M 0109

ACKNOWLEDGEMENTS

I would like to extend my heartfelt gratitude to my teacher and guide **Dr. K Rajalakshmi,** Lecturer in Audiology, All India Institute of Speech and Hearing,for her guidance and support for this study.

I thank **Dr. M. Jayaram,** Director, All India Institute of Speech and Hearing Mysore, for allowing me to carry out the study.

A special thanks to **Ms. Vijayalakshmi** for her timely help without which this project would not have materialized.

I thank **Dr. Acharya and Dr. Lancy** for helping me with statistics.

Thanks is due, to all those patients who participated in this study.

Sir, Dr. B. Rajshekar, words are hardly enough to thank you. I would like to offer my sincere gratitude for shaping a professional out of me.

My sincere gratitude to **Rama mam, Aithal sir, Kanaka mam, Veena mam, Usha mam and Rekha mam.** I would not have reached here with out you.

Dearest **Anupriya,** words are not enough to thank you. You have always been there through my ups and downs, to listen to me to, hold me and say 'you can', I will miss you a lot.

Thanks a lot **Divya mam,** for every thing that you have done. Its nice to know a gem of a person like you.

Thank you **Animesh sir,** for extending your help out of your tight schedule.

Dear **Komal didi,** thanks a lot for the encouragement that you have been giving.

Thank you **Ajith** for your suggestion.

Thank you **Prasanna** for your support and help.

Dear **Srividya, Sreelakshmi, Indu, Gilu, Lini, Asha, Anitha,** we have been the greatest pals. I miss you always.

Praveen Garu, Rampi and Ramji. I miss you guys!

A special Thanks to **Sethu, Ponnu and Ramya,** for pepping me up in my low tides. I enjoy your company.

Dear **trouble,** thank you for making my troublesome times trouble free!

All my classmates. . . . .nice that we are friends! thanks a lot for your encouragement and support.

Thank you **Sapna** .that you kept an eye on me and i could finish my work on time.

Thank you God for showering on me the wonderful parents I have!

TABLE OF CONTENTS

INTRODUCTION

The history of hearing aid selection and evaluation in audiology is both interesting and frustrating. The wheel has been reinvented many a time and significant progress and insight has been slow in coming.

In the early 1940s, several insightful experimenters expressed their opinion on how input signal should be shaped by the hearing aid to maximize speech intelligibility. They suggested bisecting the residual dynamic range and creating amplified signals that were equally loud across frequencies. This idea is represented in several of today's frequency response schemes. The publications of Pascoe (1975) Berger, Hagberg and Ranes (1977), Bryne and Tonnison (1976) (cited in Hawkins, 1987) are evidence for this.

Pascoe (1975)(cited in Hawkins, 1987) popularized the term "functional gain" to define the difference between unaided and aided sound field- thresholds, a value which represents the real ear gain of the hearing aids.

Many of the audiologjsts today continue to use this procedure to specify how the hearing aid is performing. Perhaps the greatest contribution that the concept of functional gain has made to the field of hearing aid evaluation is that it initiated the present era of concern with real ear effects of individual hearing aid fitting. In the early 1940s, either a flat or mildly sloping response was recommended for every one. This might have been justified, since hearing aid

performance then was limited by technology. Since then hearing aid technology has made considerable progress, in terms of providing potential hearing aid fittings. Functional gain provides one of the earliest measurements to understand the real ear effects of such fittings (Haskell, 1987).

Despite the simplicity of measurement procedure functional gain provides a number of advantages. It provides a frequency specific measure of hearing aid gain. It accounts for all the individual variables that affect real ear hearing aid gain. It is simple to instrument, it is adaptable to a wide range of stimuli test protocols and it is largely independent from absolute calibration problems in sound field. Also, it being a behavioral threshold reflects what the individual actually hears. (Haskell, 1987).

Concurrent with the acknowledgement of some of the limitations of functional gain, like inability to obtain thresholds if hearing loss is severe, aided thresholds being masked by internal circuit noise in the presence of regions of normal or near normal hearing etc., (Hawkins, 1987), clinically feasible ear canal probe tube microphone measurements became available.

The original clinical measurements were made by inserting a small hearing aid microphone in the ear canal near the tympanic membrane. While these measurements have proved useful, it was not until the measurement microphone

was moved outside the ear and a soft probe tube connected to the microphone was placed in the canal that the procedure began gaining popularity (Hawkins, 1987).

While behavioral measurements of functional gain are still used extensively, ear canal probe tube microphone measurements of insertion gain, the electroacoustic analog of functional gain is rapidly gaining popularity.

Though these procedures estimate gain and are used interchangeably, the equality of these procedures both functional gain and insertion gain is open to conjecture. Theoretically, it is possible to argue that both are equal and this equality should not be affected by the state of the subject's middle ear (Dillon and Murray, 1987). This is explained in terms of transmission gains at the eardrum needed to reach the threshold. Transmission gain is defined as the SPL at the eardrum relative to SPL in the undisturbed field.

Thus, transmission gain when measuring insertion gain is obtained at some midcanal location.

The previous transmission gains can be thought of as these latter transmission gains plus transmission gain from mid canal location to the eardrum. The difference (aided-unaided) in the field to ear drum transmission gain is only equal to transmission gain from mid canal to ear drum, if the transmission gain from midcanal to eardrum is independent of whether the subject is aided or unaided.

Ringdahl and Leijon (1984) state that such a theorizing is true provided the sound field in the canal is propagating down the canal as a plane sound wave with no significant transverse component.

In contradiction to the above argument several authors have questioned whether insertion gain and functional gain are numerically equal. McCandless (1980XHawkins, Mueller, Northern, 1992) has reported differences up to 4 dB averaged across 17 subjects.

Duffy and Zelnic (1985); Hawkins and Schum (1984); Breves and Rumoshosky (1976), Preves and Orton (1978)(cited in Dillon and Murray, 1987) have reported varying differences between the two measures.

However, the recently published results (Mason and Popelka, 1986) show no significant average differences between insertion gain and functional gain.

Most of the above studies, which were done on subjects with sensory neural hearing loss, report overall equivalence of the two gains.

However, in some cases of conductive hearing loss, the agreement is found to be poor. Reports by Cleaver, (1998) suggest systematic discrepancy between probe microphone and functional gain measurements in ears with conductive hearing loss.

He suggested that whatever the mechanical process that is involved, this feature of air conduction thresholds in people with severe conductive hearing loss can clearly have a significant influence on the results of real ear measurements. It was believed to be the result of bone conduction stimulation of the ear exposed to high intensities of air borne sound during threshold measurement.

Studies using probe microphone measurements (Moryl, Danhaver and Di Barholomio, 1992; Ciyantos and Meyer, 1990; Talbotto, Masumato, 1990 cited in Hawkins, Mueller and Northern, 1992) suggest that the condition of middle ear can have significant effects on probe microphone measurements.

Though, hearing aids are occasionally selected for individuals with middle ear pathologies, it becomes imperative to understand such discrepancies to avoid misleading results. Since functional gain must relate to aided benefits, the probe microphone measurements in such cases should be interpreted with caution. Further, studies done in this direction are few and have considered a small group of subjects. The present study is thus taken up with a larger subject group with the following aims.

1. To compare functional gain and insertion gain in ears with conductive pathology.
2. To determine if such a Functional Gain - Insertion Gain (FG-IG) discrepancy varies as a function of frequency of stimulation.

REVIEW

The challenge of developing scientifically based methods of selecting, evaluating and fitting hearing aids moved a giant step forward with the advent of computerized probe microphone real-ear technology. Although measuring the amplified output of a hearing aid in the patients ear canal had been attempted since the early 1970's successful clinical applications were dependent on the culmination of a number of technological innovations achieved during the 1980's. These developments included the microprocessor based desktop computer, the miniaturization of an appropriate microphone and utilization of a special flexible silicon tubing that could be inserted under the earmold of the In The Ear hearing aid and in to the ear canal without interfering with sound transmission

J. Donal Harris (1971Xcited in Hawkins, Mueller& Northern, 1992) concluded that the purpose of clinical hearing aid work to "present to the ear as faithful, a representation of the acoustic world as if the aid were infact not present".

Historically the road to successful hearing aid fitting has been rough, with numerous divergent and digressive trends. It is difficult even to describe the development of a routine clinical hearing aid evaluation procedure due to our lack of standardized terminology and procedures. In fact the only agreed on concept in fitting personal amplification devices is our understanding that it is difficult to

validate the benefits of one fitting procedure over another, so that no one evaluation method seems superior to any other evaluation method. The search for a universally acceptable approach to hearing aid selection continues to this day and the solution to a certain extent continues to be elusive (Libby 1985 cited in Hawkins, Mueller & Northern, 1992). We find ourselves with a myriad of fitting methods mat have been utilized with varying degree of commitment.

Hearing instrument evaluation procedure ranges from formal mathematically based techniques to non-standardized, informal methods based on intuition of the audiologjst or the subjective impression of the patient. Accordingly to Libby (1985)(cited in Hawkins, Mueller & Northern, 1992) ear canal measurements performed with computerized probe microphone assembly have introduced a new dimension of auditory research and should lead to improvement in the quality of hearing aid fittings.

Beck (1991) (cited in Hawkins, Mueller & Northern, 1992) has pointed out that there has been a consistent evolution of measurement procedures progressing from the 2cm3 coupler to Zwislocki coupler to the Knowles Electronics Manikin for Acoustic Research (KEMAR) to the hearing aid user directly, resulting in a level of realism that cannot be duplicated by any laboratory coupler measure. She stated that the dilemma that exists between using insitu measures (i.e., measurements with the hearing aid on the ear or in the ear canal) and 2cm3 coupler data is analogous to talking in two different languages. While correction

factors can be applied to resolve differences between the two procedures, this mathematical solution is only an approximation of real ear human performance.

Preves (1984) suggested a technique to obtain a more realistic level of hearing aid performance assessment with the 2cm3 cavity by using the client's actual earmolds with the HA1 coupler. Although the precise effects of the earmold characteristic cannot be accurately assessed with this technique, variations in the electroacoustic response with various earmold styles were shown by Northern and Hattler (1970). The problem with attempting to evaluate earmold venting in the 2cm3 coupler is that the hard walled coupler has no relative component causing vent resonance's (increases in sound pressure level in low frequencies due to the vent itself resonating) to be far larger when measured in the coupler than in the real ear. A number of studies (Cox, 1979, Preves, 1977, Studebaker, Cox and Wark, 1978, Studebaker and Zachman, 1970 cited in Hawkins, Mueller & Northern, 1992) have shown that measurement of venting effects in a $2cm^3$ coupler will not be representative of what occurs in the real ear.

Madsen (1987) concluded that, from a clinical point of view, real ear gain measurement is more reliable than coupler gain measurement. Real ear gain describes the change in hearing conditions for the patient while wearing the hearing aid Madsen also summarized the main reasons for differences that are found between real ear and coupler gain are as follows.

1. In clinical use, the hearing aid is mounted on the head of the body of a patient, which changes the gain and response characteristics of the hearing aid due to diffraction effects.
2. The actual dimension of the sound channel in the earmold may differ from the dimensions of channels in the earmold simulator of the 2cm3 coupler.
3. During clinical use the earmold will not always be a tight fit in the ear canal thereby creating "slit leak" of acoustic energy and creating change in the amplified low frequency response.
4. The acoustic impedance of the volume between the earmold and eardrum, combined with the impedance of the middle ear, will not be equivalent to the impedance of a simple hard walled cavity.
5. The insertion of an earmold into the ear canal changes the resonance pattern of the ear canal.

It has always been clear that optimal measurement of the hearing aid performance should some how be taken near the tympanic membrane, while the amplification system is being worn and used by the subject. Unoccluded probe microphone measurements along the external ear canal were reported as early as 1946, by Weiner and Ross (cited in Hawkins, Mueller & Northern, 1992). A number of subsequent studies were reported by many authors using various fixed probe microphone measurement techniques and equipment systems to evaluate earmold acoustics and hearing aid amplification. The Europeans produced many of

the early studies including works reported by Ewertsen, Ipsen and Nieber (1956), Daalsgaard and Dyrlund Jensen (1976), Johansen (1975) and Ringdahl and Leijon (1984) (cited in Hawkins, Mueller & Northern, 1992).

The North America research efforts with probe microphone measurements and hearing aids were published by Mc Donalds Studebaker (1970), Studebaker and Zachman (1970), Schwartz (1982), Preves (1982) Mc Candless (1982)(cited in Hawkins, Mueller & Northern, 1992) probe microphone measurements of hearing aid amplification had been available. However in the early years, the available equipment limited application of the technique only to laboratory environments. The early insitu hearing aid measurements were made by inserting a small hollow metal pipe through the earmold into the canal, which led to an external microphone located outside this canal - a situation described as "cumbersome instrumentation and not very applicable to a clinical situation".

The Harford - Preves(cited in Hawkins, Mueller & Northern, 1992) technique utilized an exceedingly small (4x5x2 mm) Knowles electret microphone with a wide, flat frequency response. This microphone was so small that it could be actively placed within an adult's ear canal while a hearing aid was being worn. A sweep frequency oscillator and amplifier were placed in an acoustically treated sound chamber and a compression circuit was utilized to maintain a constant pre-selected sound pressure level at the location of miniaturized test microphone. This system was designed to record the sound pressure level of a sweep frequency test

signal, amplified through a hearing aid from within a subjects external ear canal. The initial protocol with this equipment utilized relative measurements and compared aided and unaided data. The measurements were obtained from a miniature microphone placed in the opposite (unaided test) ear canal. The technique required the establishment of an unaided baseline known as unaided equalization reference. Then, hearing aid was placed on the test ear and turned on with the miniature test microphone in the ear canal and a second recording was obtained known as aided frequency response. The difference between the two recordings was called the hearing aid insertion gain, a term originated by Ayers, 1953(cited in Hawkins, Mueller & Northern, 1992). Thus, actual hearing aid evaluation procedure was described by Romanov as early as 1942. (cited in Hawkins, Mueller & Northern, 1992)

Harford and his colleagues continued to develop and describe the clinical application of this real ear insitu measurement technique (Harford, 1980a, 1980b, 1984, Harford, Leijon, Liden, Ringdahl and Dahlberg, 1983, Wetzell and Harford, 1983, Dalsgaard and Dyrlund-Jensen 1976 cited in Hawkins, Mueller & Northern, 1992) compared real ear probe microphone measurements in occluded and unoccluded ear canal conditions with earmold and hearing aid in place. Then result demonstrated that the 2cm3 coupler response of a Behind The Ear hearing aid and earmold overestimates gain between 2000 to 4000 Hz by 12-18 dB, while in the

low frequency range the 2cm3 coupler response, underestimates the real ear gain by 5-7 dB.

These publications clearly established the value of insitu real ear verification of the ear canal amplification measurements obtained in routine clinical settings. The real ear probe microphone measurements are easy and quick to establish objective, noninvasive, relatively inexpensive and required only positive co-operation from patients.

Harford (1980a) (cited in Hawkins, Mueller & Northern, 1992) concluded in what can now be regarded as a considerable understatement, that in our judgment, in utilization of these tiny precision microphone has the potential for improving the current state of art for selecting and monitoring wearable amplification for the hearing impaired.

Ear canal measurements performed with probe tube microphone instrumentation introduced a new dimension to the knowledge, quality and expertise of hearing aid fitting. Acoustic measurements performed in the ear canal, with and without the earmold and hearing aid in place provide valuable information regarding the total combination of influences on the amplification device including the impedance characteristic of the ear anatomy as well as acoustic plumbing and the natural resonance of the ear canal (Libby and Westermann, 1988 cited in Hawkins, Mueller & Northern, 1992). Sound pressure

measurements are taken with and without the fitted hearing aid in place and insertion gain is determined as the difference between the low response curves. This technique is a considerable advance over previous efforts to make real ear microphone measurements requiring only modest co-operation from the patient and minimum testing timing with good data reliability, provided appropriate care is taken in obtaining the measures.

Hawkins (1987) noted that the use of these real ear probe microphone measurements alone does not results in better hearing aid fitting. The critical feature of this method is that professionals have a goal to achieve with the hearing aid fitting, then the real ear probe microphone measurements can be used to validate and verify the specific advantage provided by the amplification system under evaluation.

However, Preves (1984) commented that the highest level of "realism" attainable in hearing aid measurement techniques is that of sound field audiometry for obtaining functional gain - that is the amount by which hearing aid improves the patients hearing threshold level. This is a real ear technique of evaluating hearing aid performance based on behavioral measurements.

Functional gain measurements are commonly used by most audiologists, in one-way or the other, during the hearing aid selection if only to demonstrate

improved hearing provided by the new hearing instrument compared with unaided performance.

Functional gain is a disarmingly simple technique for measuring real ear gain of hearing aids. Hardly a new concept, it is basically the same as one of the earliest techniques for measuring real ear gain called as "orthotelephonic gain". It was described but discounted by Romanov in 1942 (cited in Masson & Popelka, 1986), in his paper introducing the 2cm3 coupler. More recently it was popularized by Pascoe in 1975. Presently computer driven probe tube measurement devices seem to replace functional gain as the most popular hearing aid evaluation technique. Nevertheless, functional gain continues to have a place in the audiology clinic and understanding the advantages, disadvantages and historical contribution is worthwhile. (Haskell, 1987).

On an informal basis, this procedure is often used to show the listening advantages gained while wearing the instrument. The technique is also used in clinical procedures whereby actual sound field unaided thresholds are obtained for speech and warble tones (or narrow band noise) and compared with the same measurements with the hearing aid turned on and in place.

Perhaps the greatest contribution the concept of functional gain has made to the field of hearing aid evaluations is that it initiated the present era of concern with the real ear effects of individual hearing aid fittings.

The procedure for making functional gain measurement is simple. The subject's thresholds are measured without the hearing aid and then under the same conditions with hearing aid earmold combination. Aided sound field thresholds used alone are compared to earphone - derived unaided thresholds are not functional gain despite this apparent simplicity, the functional gain has a number of advantages (Haskell, 1987).

1. It provides a frequency specific measure of hearing aid gain.
2. It accounts for all the individual variables that can affect real ear hearing aid gain
3. It is a simple instrument, it is adaptable to a wide range of stimuli and test protocol and is largely independent from absolute calibration problems in sound field
4. It is a behavioral threshold and reflects what the individual actually hears. The frequency specificity of functional gain is closely linked to the test protocol selected.

Functional gain measurements are generally easy to obtain and are therefore popular techniques to use with young children, elderly clients and uncooperative patients.

At the same time however, because this technique is used in the sound field, a constant concern for accurate calibration without standing waves must be given consideration. Should the patient move even slightly between the aided and

unaided conditions measurement, the result of hearing evaluation might be altered. Functional gain measurements usually differ from 2cm3 coupler data because of the influence of ear canal resonance, the body and head baffle influence and normal variations expected from behavioral threshold measurements.

Humes and Kirn (1990) showed test-retest reliability of unaided and aided sound field thresholds and functional gain values derived from these measurements. They found that test-retest standard deviations were significantly larger for derived functional gain values man for the unaided thresholds but only slightly larger than for aided threshold.

The functional gain hearing aid evaluation has certain limitations, since the technique is based on behavioral measurements, all the well known factors leading to variability noted in behavioral auditory test will influence functional gain test results as well. As functional gain fitting is conducted in sound field, considerable attention must be given to careful calibration of test stimuli and masking of non-test ear to eliminate contamination of results when attempting to evaluate hearing aid performance. Since functional gain measurements are often made with acoustic signals at octave intervals only the general characteristics of frequency response will be noted, while inter octave spikes and valleys in the frequency response will be overlooked small changes in the electroacoustic output of the hearing instrument on acoustic modifications created by manipulation of the acoustic

coupling system may create alterations in the frequency response and gain characteristic of hearing aid that will not be noted with functional gain.

While behavioral measurements of functional gain are used extensively, ear canal probe like microphone measurements of insertion gain, the electroacoustic analog of functional gain is rapidly gaining popularity.

Though the procedures estimate the gain and are used inter changeably, the equality of the procedure both functional gain and insertion gain is open to conjecture.

When probe microphone measurements first became popular, there were some suggestions that real ear insertion gain might not be equivalent of functional gain. The argument was that real ear insertion gain measurements took place in the ear canal, where as the functional gain measurements assessed the processed signal through the central auditory system. Three entities have addressed mis issue by comparing real ear insertion gain and functional gain on the same sets of subjects. The first study to report such data was by Masson Popelka (1986). Although there were some subjects for whom differences were present, the obvious conclusion from these data is that real ear insertion gain and functional gain yields similar values. Results similar to this have been reported by Dillon and Murray (1987). It is possible that the observed differences are a result of variability and not true differences between the measurements themselves.

Dillon and Murray (1987) state that, theoretically, it is possible to argue that both are equal and this equality should not be affected by the state of the subject's middle ear. They explain it by making the basic assumption that for a given and fixed, middle ear input impedance and transmission characteristic, threshold is reached when the SPL at the eardrum (or more exactly suitably average across the surface of it) reaches a particular value.

The differences between the unaided and aided field levels needed to keep the ear drum SPL at this threshold value is by definition the difference between the aided and unaided transmission gains of the ear where the transmission gain is defined as the SPL at the ear drum relative to the SPL in the undisturbed field.

When insertion gain is obtained field level is kept constant (rather than the ear drum level) and the difference in SPL (aided minus unaided) at some mid canal location is measured. This is also equal to the difference between aided and unaided transmission gains, which are defined from undisturbed field to midcanal measurement point.

The previous transmission gains can be thought of as these later transmission gains plus (in dB) the transmission gains from the midcanal location to the eardrum.

The difference (aided minus unaided) in the field eardrum transmission gain is thus only equal to transmission gain from mid canal location to ear drum and is independent of whether the subject is aided or unaided.

As pointed out by Ringdahl and Leijon (1984), this_is true provided the sound field in the canal is propagating down the canal (and being reflected back) as a plane sound wave with no significant transverse component.

In contradiction to the above argument several authors have questioned whether insertion gain and functional gain are numerically equal.

McCandless (1982) (cited in Dillon&Murray, 1987) has reported differences up to 4dB when averaged across 17 subjects and presumably had much larger differences within individual subjects.

Duffy and Zelnick (1978Xcited in Dillon&Murray, 1987) argued against the use of insertion gain on the grounds that it is not as valid as subjective sound field measurements.

Hawkins and Schum (1984) derived differences up to 9dB between insertion gain measured on KEMAR and median functional gain for a group of subjects. Preves and Rumoshosky (1982) (cited in Dillon &Murray, 1987) report average differences of up to 1 OdB and differences within individual subjects of up to 28dB. Preves and Orton (1978) (cited in Dillon&Murray, 1987), hypothesize

that such differences in ear drum impedance or external ear canal volume and report a correction of 0.58 between canal volumes and insertion gain minus functional gain differences.

Results recently published show no significant average differences between insertion gain and functional gain except at 1500Hz where a 60dB difference was found.

Results obtained by Dillon and Murray (1987) show that average insertion gain was within 2dB of average functional gain except that at 1 kHz, where the differences was 5dB was significant at 0.05 level.

At this frequency, the discrepancy was dominated by the two subjects with near normal hearing at 1kHz and this had almost certainly been caused by invalid functional gain estimates originating from masked aided thresholds. In addition, this study did not report within individual differences of insertion gain and functional gain measures.

Stelmachowicz and Lewis (1988)(cited in Dillon&Murray, 1987) report that the validity of either methods depends on the circumstances of the measurement. If there are regions of normal or near normal hearing sensitivity, then the functional gain estimates may underestimate the magnitude of gain. However, if the loss is profound and the responses may be vibratory, the functional gain estimates should supplement or even replace real ear measurements.

In the case of a nonlinear hearing aid or hearing aid in saturation, insertion gain measures are more valid than the functional gain measures, only because we are forced to obtain these measures at relatively high levels due to internal noise of measuring equipment.

Thus, most of the above studied done on subjects with sensory neural hearing loss report equivalence of the two gains. Though theoretically, the middle ear status should not affect the insertion gain and functional gain equally, clinical observations report otherwise.

The condition of the middle ear can have a substantial effect on both the unaided and aided response perhaps the most significant effect is observed for people with tympanic membrane perforations. The enlarged cavity and resultant change in ear canal and middle ear resonance can rather dramatically change the appearance of Real Ear Unaided Resonance (REUR). While considerable variability is present, REUR typically has two peaks when a perforation is present, especially if perforation is relatively large (Moryl, Danhaver and Bartolomio, 1992 cited in Hawkins, Mueller & Northern, 1992). The primary peak is often located between 750 and 1500 Hz and can have amplitude greater than 20dB. Thus same type of REUR pattern has been reported for patients with mastoidectomees (Ciyantos and Meyer, 1990 cited in Hawkins, Mueller & Northern, 1992). After tympanoplasty for patients with a large tympanic membrane perforation, normal REUR was obtained.

Findings such as these raise the issue of whether insertion gain measures are valid when a perforation is present.

Children and adults with ventilating tubes in place also have universal REUR (Talbolt and Masumoto, 1990 cited in Hawkin, Mueller & Northern, 1992). Simple changes in middle ear pressure of compliance can also have significant effects on probe microphone measurements. Such effects can be easily demonstrated by conducting pre- post Toyngbee test. When negative middle ear pressure and slightly reduced compliance were present, the peak of REUR shifted downward in frequency. Unless REUR changed in a similar manner, this minor alteration in middle ear pressure could cause real ear aided response values to appear better or worse when compared to desired target gain.

Larson, Egolf and Cooper (1991) (cited in Hawkin, Mueller & Northern, 1992) reported that abnormal eardrum impedance could cause pronounced changes in real ear performance of a hearing aid. It seems reasonable that, if a patient has transient middle ear pathology at the time of hearing aid fitting, such as negative middle ear pressures caused by allergies, it would be useful to repeat the probe microphone measurements when the condition has resolved to ensure that hearing aid fitting is satisfactory. In contrast to the reports by Mason and Popelka 1986, Dillon and Murray, 1987, which reported a good agreement between measured insertion gain and functional gain. Cleaver(1998) , reports a significant

discrepancy between insertion gain and functional gain measures in ears with conductive loses which mainly occurs in ears with substantial air bone gap.

According to the author, this result cannot be caused by non-linearity in the hearing aid used, which would have influenced the results in the reverse way to that observed here. The finding was originally thought due to artifacts in the probe tube measurement caused by middle ear pathology but the final conclusion must be that the functional/insertion gain discrepancy occurred because of the problems associated with measuring functional gain in ears with substantial air bone gap.

He suggested that whatever the mechanical process involved, this feature of air conduction thresholds in people with ensured conductive hearing loss can clearly have a significant influence on the results of real ear measurements. It was believed to be the result of bone conduction stimulation of the ear exposed to high intensities of air borne sound during sound field threshold measurement.

METHOD

The study is taken up to compare functional gain and insertion gain measurements in ears with conductive pathology.

Subjects

Twenty-five hearing impaired individuals in the age range of 18 to 55 years formed the subject group for the study.

Criteria **for subject** selection

1. All subjects had moderate to moderately sever conductive hearing loss in the better ear; as per pure tone audiometric findings the mean hearing thresholds in the test ear at frequencies 500Hz, 1000Hz, 2000Hz and 4000Hz was 54dB HL.
2. The presence of middle ear pathology in the test ear was confirmed with an ENT evaluation.
3. All subjects were hearing aid users (monaural hearing aid to the conductive ear) and wore their prescribed aids at the prescribed volume setting through out the study.

Instruments

The following instruments were used for the study

For **Functional Gain** Measurements:

Sound field audiometer : A calibrated two channel diagnostic audiometer MA-53 was used. The instrument was calibrated as per ANSI S3.26 (1989) standards.

Good calibration of the system was ensured throughout the data collection (sound field audiometer calibration Appendix I).

For Insertion Gain Measurements:

A FONIX 6500 C hearing aid test system with computer controlled real time analysis version 3.09 with probe tube microphone option was used to perform insertion gain measurements. The instrument was calibrated as per instructions given in the operation manual (Appendix II) and calibration was ensured through out the data collection.

Hearing aids : The subjects wore their own hearing aids which were prescribed using functional gain procedure at their prescribed volume setting. All the subjects had body level hearing aids.

Test Environment

Real ear measurements both functional gain and probe tube measurements were carried out in sound treated rooms where ambient noise levels were within permissible limits (ANSI, 1991).

Test Stimuli

For the functional gain measurements, warble tones (5%) were presented through the loudspeaker at frequencies viz 500Hz, 1000Hz, 2000Hz and 4000Hz. For the probe measurements, a composite signal was presented through the loudspeaker placed at an angle of 45° facing the subject at intensity of 60 **dB** SPL.

Procedure

Functional gain and insertion gain measurements were obtained from 25 ears with moderate to moderately severe conductive hearing loss. For all measurements subjects who were hearing aid users, wore their own hearing aids. The volume control was set to their prescribed volume setting. Functional gain and insertion gain measurements were obtained for all the subjects.

Procedure for Functional Gain Mesurements:

For the functional gain measurements subjects wore their own hearing aid in the test ear and were seated on a chair at a distance of 1meks from the free field speakers. The speakers were placed at an angle of 45 degrees facing the subject.

The following instructions were given before starting the measurements. "A tone will be presented. If you hear the tone please indicate by raising your finger. If you do not hear do not raise your finger. Listen carefully for the softest sound also and if you hear respond by raising your finger".

The thresholds for frequencies viz 500Hz, 1000Hz, 2000Hz and 4000Hz were established without any hearing aid.

The same procedure was repeated to establish the threshold using their hearing aid at the prescribed gain settings.

Procedure for Insertion Gain Measurement:

Before obtaining the measurements, the following pre-measurement procedures were carried out.

The instrument was leveled (Appendix III) . Leveling was done to ensure that the input to the hearing aid is properly controlled across the frequency spectrum. The subjects were seated 12 inches from the loudspeaker. The loudspeaker was placed at 45° azimuth. The headband was secured above the ears and the ear hanger was placed around the ear to be tested. The reference microphone was placed firmly over headband nearer to the ear to be tested. The probe length was marked at a distance of 25mm. The probe tube was placed in the ear canal with the marking resting at the inter tragal notch (Appendix HI).

The patient was instructed to look straight and not move or talk until the test was complete.

The following steps were carried out to obtain probe measurements. First real ear unaided response (REUR) was obtained using 60dB SPL as input. This response gave information regarding the ear canal resonance.

The hearing aid receiver with the ear mold was then placed along with probe tube into the ear canal.

The hearing aid at the prescribed volume control was switched on and real ear aided response (REAR) was obtained.

The test retest reliability for the insertion gain measurements was ensured.

RESULTS

The aim of the present study was to :

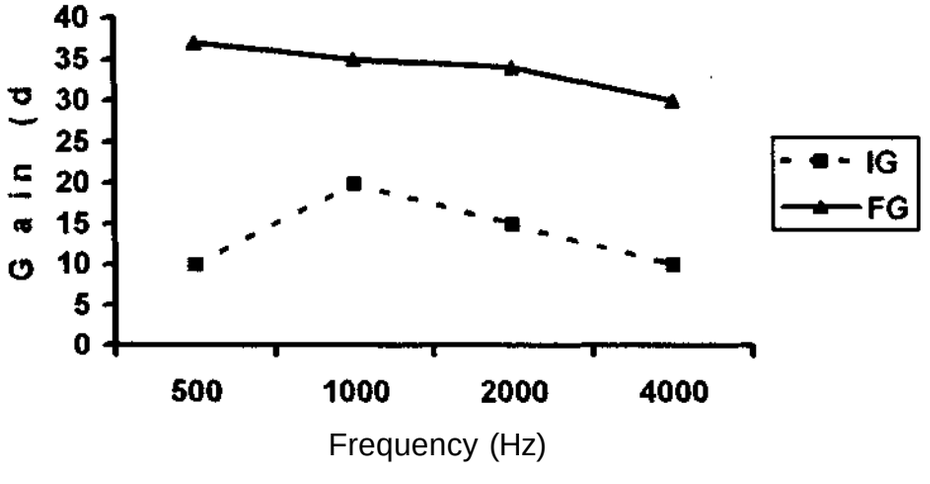
1) Compare functional gain and insertion gain measurements in conductive hearing loss subjects.
2) Determine if such a FG-IG discrepancy exists across frequencies.

Real ear measurements, both functional gain and insertion gain, were performed on 25 ears with conductive pathology at 500 Hz, 1000 Hz, 2000Hz and 4000Hz. The data obtained was subjected to statistical analysis using the statistical package, SPSS version 10.0.

The mean functional Gain and insertion gain were calculated at the test frequencies.

The mean functional gain and insertion gain obtained in the present study are as shown in the graph below.

Graph 1 : Mean, SD and 't' values of functional gain and insertion gain



As can be clearly seen from the Graph 1, the mean functional gam values are higher than the mean insertion gain values.

To determine whether mean functional gain values at each of the test frequencies were significantly different from insertion gain values, independent two-tailed 't' test was performed.

The mean FG and IG values, standard deviation and 't' value are shown in the table 1 below

Table 1 : Mean, S.D and 't' values of functional gain and insertion gain

Frequency gain		**Mean**	S.D	**t-value**
500 Hz	FG	37.3920	8.7930	* 10.062
	IG	10.3600	10.1545	
1000 Hz	FG	35.9000	7.3201	*6.720
	IG	20.7240	10.0532	
2000 Hz	**FG**	35.4000	8.4804	*7.640
	IG	15.3040	10.0532	
4000 Hz	FG	29.6000	7.9215	*8.329
	IG	8.1600	10.1440	
Total	FG	34.5730	8.5586	
	IG	13.6370	10.7722	

* Significant at 0.01 level.

There was a significant difference between functional gain and insertion gain at all test frequencies.

The standard deviations are found to be higher for insertion gain measurements at all test frequencies.

The functional gain/ insertion gain discrepancy across frequencies was also studied.

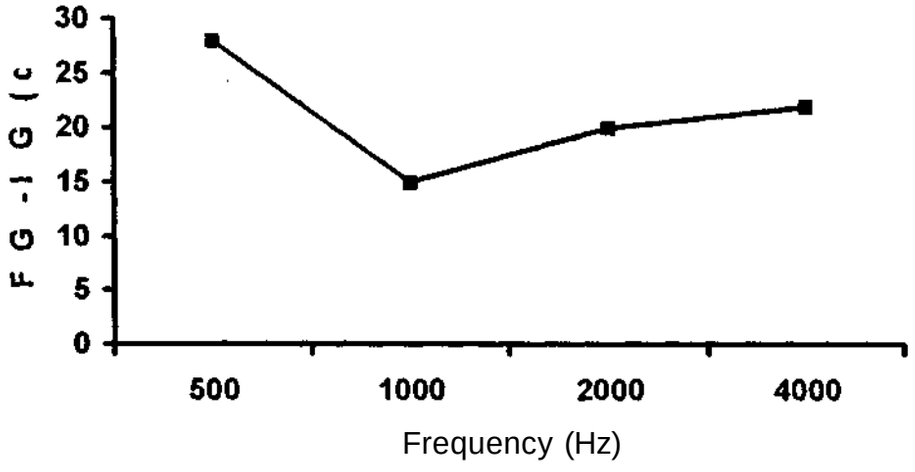
Statistical analysis was performed using independent't' test, to know if any significant difference existed for the FG-IG discrepancy across frequencies. The results are as shown in the table below.

Table 2 : FG - **IG** across frequencies

FG-IG	Mean (dBSPL)	S.D	t-value
500 Hz	27.032	12.8697	*3.668
1000 Hz	15.1760	9.7778	
500 Hz	27.032	12.8697	1.876
2000 Hz	20.0960	13.2647	
500 Hz	27.032	12.8697	1.469
4000 Hz	21.440	14.0155	
1000 Hz	15.1760	9.7178	-1.493
2000 Hz	20.0960	13.2647	
1000 Hz	15.1760	9.7778	-1.833
4000 Hz	21.440	14.015	
2000 Hz	20.0960	13.2647	0.348
4000 Hz	21.4400	14.0155	

(* significant at .01 level)

Graph 2 : FG-IG across frequencies



Comparisons were made across the frequencies for any such FG-IG discrepancy. The following frequency pairs were compared Viz. 500 Hz Vs 1000Hz, 500 Hz Vs 2000 Hz, 500 Hz Vs 4000 Hz, 1000 Hz Vs 2000 Hz, 1000 Hz Vs 4000 Hz, and 2000 Hz Vs 4000 Hz.

The above results show that no significant difference was seen across frequencies, except for frequencies 500 Hz Vs 1000 Hz, where a statistically significant difference was present at 0.01 level of confidence.

DISCUSSION

The advent of probe microphone measurements has provided a great deal of objectivity in real ear measurements for hearing aids selection and fitting.

However, subjective methods of functional gain measurements continue to play a role today. Theoretically, equality of both functional gain and insertion gain measurements has been established. However, this equivalence is proved in cases of sensorineural hearing loss only. Clinical experiences, however haven't observed such equivalence. The few studies done on conductive hearing loss subjects also suggest the same. However there is a dearth of literature supporting such findings. The present study was taken up to find any such discrepancies if existing and to investigate such discrepancies across frequencies.

The following Objectives were taken up for the study

1) To compare functional gain and insertion gain measurements in conductive hearing loss subjects
2) To determine if such an FG-IG discrepancy existed across frequencies.

Data was obtained from 25 ears with conductive hearing loss who met the subject criteria.

Parametric test statistics was performed. The data was subjected to 't' test for independent samples.

The differences were significant at 0.01 level of confidence for all test frequencies viz. 500Hz,1000Hz, 2000Hz and 4000Hz.

Such a difference shows that higher hearing aid gain was obtained using functional gain measurements whereas Insertion gain measurement would over estimate the gain for such subjects. Thus, functional gain measurements can be regarded as a better estimate of hearing aid gain in subjects with conductive pathology requiring a hearing aid.

The results obtained here are in harmony with reports in literature concerning the discrepancy between functional gain and insertion gain incases with conductive pathology. (Cleaver, 1998). This study was done on 8 subjects with conductive hearing loss (Cleaver, 1998) and reported functional gain to be a better estimate of real ear gain.

The better-aided thresholds obtained using functional gain could be attributed to the central processing of signal in such a procedure (Hawkins and Mueller, 1992)

Insertion gain on the other hand is a purely objective measure of real ear gain obtained in the external auditory canal.

The validity of insertion gain in middle ear pathology becomes questionable, as the condition of middle ear can have substantial effect on both aided and unaided responses.

As reported, the enlarged cavity and the resultant change in the ear canal and middle ear resonance can dramatically change the appearance of real ear unaided responses. (Danhauer, DiBartolomia and Moryl, 1992 cited in Hawkins, Mueller & Northern, 1992).

Researchers also report functional gain/Insertion gain discrepancy because of problems associated with measuring functional gain in ears with substantial ear bone gap. This happens when the individual concerned has sufficient conductive hearing loss, the stimuli will be perceived via bone conduction, even though the signal is initially air borne. This effect limits the size of the air bone gap that is possible to measure even in some with no functional middle ear at all. It also reports that at low frequencies the vibrations that reach the cochlea by bone conduction are 48-53 dB below the pressure of air borne sounds, and this is what corresponds with the threshold of gain difference found in his study. (Bekesy, 1960 cited in Cleaver, 1998).

However, the exact mechanism of transmission in some one with conductive hearing loss probably depends on the nature of middle ear pathology.

The higher standard deviation values for the insertion gain measurements obtained in the present study could be possibly attributed to inter subject variations in the ear canal geometry and probe microphone placement.

The FG-IG discrepancy across frequencies 500 Hz and 1000 Hz found in the present study however could not be explained at this stage because of dearth of literature in this direction. It can be hypothesized that a lesser FG-IG difference at 1000 Hz could be attributable to the middle ear resonance frequency, which is disturbed in middle ear pathologies.

Thus, it can be concluded that the validity of real ear measurements of insertion gain are questionable in conditions of conductive pathology. Such results should be interpreted with caution. Functional gain provides a better estimate of real ear gain in cases with middle ear pathologies.

SUMMARY AND CONCLUSION

The challenge of developing scientifically based methods of selecting, evaluating and fitting hearing aids has moved a giant step forward with the advent of computerized probe microphone real ear technology.

Even with the advance of technology, subjective methods continue to play a role in hearing aid fitting. As Preves (1984) commented that the highest level of realism attainable in hearing aid measurement technique is that of sound field audiometry in obtaining functional gain

Though, theoretically, both the gain measurements are explained to be equal, most of the studies, which support this equality, are done with subjects with sensorineural hearing loss. Such an equality in cases with conductive hearing loss has been questioned (Cleaver, 1998)

However, there is a dearth of literature supporting such an inequality.

Hence the present study was undertaken to

1) Compare Functional gain and Insertion gain in cases with conductive pathology
2) To determine if such an FG-IG discrepancy varies across frequencies.

Data from twenty-five ears of adults with moderate to moderately severe conductive hearing loss was obtained. Both functional gain and insertion gain measurements were obtained.

The results of the present study suggest that:

1) Real ear measures of functional gain provide a better estimate of gain in cases with conductive pathology.
2) No significant variation of FG-IG discrepancy exists across frequencies.

Thus, it can be concluded that the validity of real ear measurements of insertion gain is questionable in conditions of conductive pathology. Such results should be interpreted with caution. Functional gain provides a better estimate of real ear gain in cases with middle ear pathologies.

However, the above results were obtained from a small group of subjects and the results cannot be generalized. A similar study can therefore be taken up, with a larger subject group, considering different pathologies of the conductive system of the ear.

References

American National Standard Institute. American National Standards Specifications for Audiometer, ANSI S3.6-1989, New York.

Byrne, D., & Tonnison, W. (1976). Selecting the gain of hearing aids for persons with sensorineural loss hearing impairment, Scandinavian Audiology. 5, 51-9.

Cleaver., V. C. G. (1998). Real-ear measurements in conductive hearing loss : Discrepancies between probe-tube microphone measurements and sound field test results. British Journal of Audiology, 32, 205-209.

Dillon, H., & Murray, N. (1987). Hearing aids and aural rehabilitation : Accuracy of twelve methods for estimating the real ear gain of hearing aids, Ear and Hearing, 8, 2-11.

Gilman, S., & Dirks, D. (1986). Acoustics of ear canal measurement of eardrum SPL in simulators. Journal of Acoustical Society of America, 80, 783-793.

Hawkin, D., & Mueller, G. (1986). Some variables affecting the accuracy of probe tube microphone measurements hearing instruments, Ear and Hearing, 37, 8, 11-12,50.

Hawkins, D.B, & Schum, D.J. (1984). Relationship among various measures of hearing aid gain : Journal of Speech and Hearing Disorder, 49, 94-97.

Humes, L., & Kirn, E. (1990). The reliability of functional gain. Journal of Speech and Hearing Disorders, 55, 193-197.

Madsen, P. (1986). Insertion Gain Optimization. Hearing Instruments. 37(1), 28-32.

Mason, D., & Popelka, G.R. (1986). A comparison of hearing aid gain with functional coupler probe tube measurements. Journal of Speech and Hearing Research. 29, 218-226.

McDonald, F., & Shidekaker, G. (1970). Earmold alteration as measured in the human auditory meatus. Journal of Acoustical Society of America. 48, 1366-1372.

Morgan, D.E., Dricks, D.D. & Bower, DR. (1979). Sound pressure levels of frequency modulated tones in sound field. Journal of Speech and Hearing Disorders, 44, 37-54.

Mueller, H.G., Hawkins, D.B., & Northern, J.L. (1992). Probe microphone measurements : Hearing aid selection and assessment. San diego : singular Publishing Group Inc.

Northern, J., & Hattler, K. (1970). Earmold influence on aided speech identification tasks. Journal of Speech and Hearing Research. 13, 162-172.

Pascoe, D. (1975). Frequency responses of hearing aids and their effects on the speech perception of hearing impaired subjects. Annals of Otology. Rhinology and Laryngology. 84, (Suppliment 23).

Pedersen, B. (1982). Probe placement for sound pressure measurements in the aided ear. Scandinavian Audiology. 11, 281-283.

Rines, D., Stelmachowiz, P., & Gorga, M. (1984). An alternate method for determining functional gain of hearing aids, Journal of Speech and Hearing Research, 27, 627-633.

Ringdahl, A., & Leijpn, A. (1984). The reliability of insertion gain measurement using probe microphone in the ear canal. Scandinavian Audiology, 13, 173-178.

Stephens, M.M., & Rintelmann, W.F. (1978). A comparison of hearing aid gain with functional coupler probe tube measurements. Journal of Speech and Hearing Research. 29, 218-226.

Walker, G., Dillon, H., & Byrne, D. (1984) Sound field audiometry : Recommended stimuli and procedures. Ear and Hearing. 5, 13-21.

Watson, N., & Knudsen, V. (1940). Selective amplification in hearing aids, Journal of Acoustical Society of America, 11, 406-419.

Wetzell, C, & Harford, E.R. (1983). Predictability of real ear hearing aid performance from coupler measurements, Ear and Hearing, 4, 237-242.

APPENDIX I

SOUND FIELD CALIBRATION

Intensity Calibration

Intensity calibration for warble tones in the sound field was carried out with setting the audiometer output to 60 dB. A one-inch condenser microphone (B&K 4145) with a 90 degree grid azimuth was placed at the point in the room where the head of the subject would be positioned during testing. The distance from the microphone to the loudspeaker was one meter. The microphone was connected to a sound level meter (B&K 2209) and the octave filter set (B&K 1613). The output SPL was compared for the frequencies 250Hz to 6KHz, with the values given by Morgan et. al., (1979). A discrepancy of more than 2.5 dB between the observed SPL values and the expected values (Morgan et. al., 1979), was corrected by means of an internal calibration.

Microphone Calibration

Microphone input calibration for speech audiometry was done by presenting a recorded 1KHz signal at 60 dB. The VU meter gain was set so that the needle peaked at '0'. The placement of the sound level meter was similar to that done for sound field warble tone testing. The output SPL was noted on the sound level meter on the linear scale and compared with the standards (Morgan et.al., 1979). If the reading exceeded 2.5 dB, internal calibration was done.

Linearity Check

The linearity of the audiometer attenuator was checked. The procedure used was similar to that utilized to check the intensity calibration except that the intensity dial of the audiometer was set at the maximum level and the frequency dial was set to 1000 Hz. The attenuator on the sound level meter was set at a level corresponding to the maximum level on the audiometer. The attenuator setting on the audiometer was decreased in 5 dB step till 30 dB and the corresponding reading on the sound level meter was noted. For every decrease in the attenuator setting the sound the level meter indicated a corresponding reduction.

Frequency Response Characteristic of Loudspeaker

The frequency response characteristics of the free field loudspeaker were obtained using B&K signal generator (1023), free field microphone (B&K 4145), frequency analyzer (B&K 2107) and a graphic level recorder (B&K 2616). The electrical output of the signal generator (1023) was fed to the loud speaker. The output picked up by the microphone (B&K 4145) was fed to the frequency analyzer (B&K 2107). The output was recorded on the graphic level recorder (B&K 2616).

APPENDIX II

CALIBRATION OF THE QUICK PROBE II OF THE FONIX 6500-C HEARING AID SYSTEM

The calibration was carried out as per the procedure described below :

Instruments Required

FONIX Sound Level Calibration (Quest CA-12) ; 14 mm to 1 inch adapter, probe microphone calibrator adapter and calibration clip.

Procedure

The sound level calibrator's battery was initially checked for good condition. Following this, a 14 mm - 1 inch adapter is used to connect the calibrator and the reference microphone. To calibrate the reference microphone, the calibrator was switched on the measured microphone signal was compared to the intensity of the signal (1000Hz at 110dB) generated by the calibrator. If the intensity of the reference microphone was not within 1 dB of the calibration value, the gain of the reference microphone was adjusted with small screwdriver using control marked REFERENCE on the bottom of the quick probe module.

To calibrate the probe tube microphone, the reference microphone was removed from the calibrator and the probe tube microphone adaptor was inserted. The probe tube was fully inserted in to the calibrator adapter. It was checked to make certain that nothing was clogging the probe tube, and that it

was properly connected to the body of the probe microphone. The measured microphone signal was compared with the intensity of the calibrator level. If the value of the probe amplitude was significantly below the calibration level (1 lOdB for quest CA-12), it was checked to see that the probe tube has gone all the way in to the adaptor. This was done by taking the probe calibrator adaptor out to check. If necessary, the gain of the probe microphone was adjusted with a small screwdriver using the control marked PROBE on the bottom of the remote module. Using the above procedure, calibration was done for the reference and probe microphone of the FONIX 6500-C.

Calibrating the Sound Field Loudspeaker of FONIX 6500-C

The subject wearing the headband was seated at a distance of 1 meter and an angle of 45° from the loudspeaker.

The reference microphone and the probe microphone were combined with the calibration clip. The tip of the probe tube was kept at the center of the grid of the reference microphone. Both microphones were positioned on the headband just above the ear nearest to the loudspeaker. The test signal was turned 'on'.

The rms source SPL was compared to the rms OUT SPL. If the levels were within 3 dB of each other, the calibration was correct. When the difference was greater than 3 dB, the adjustment for the loudspeaker on the back panel of the main module was adjusted, until the rms source and rms OUT SPLs were within 3 dB of each other.

APPENDIX III

After calibrating the FONIX 6500-C system, leveling (Automatic Adjustment of the loudspeaker Response) was done as per instructions given in the instruction manual of the FONIX 6500-C.

With the speaker, the reference microphone and probe tube in position, the 'level' button on the remote control was operated.

A composite tone at 60 dB SPL was presented from the speaker. Depending on the instrument location and the ambient noise, one of the following three different level conditions resulted.

a) If leveling was achieved within 2 dB in the frequencies between 600 and 5000Hz, the word 'leveled' appeared on the screen. The measured response curve appeared in the lower graph. Probe testing was continued only if the displayed curve was within the acceptable limits.

b) If the rms amplitude of the reference microphone was not within 6 dB of the target, the screen showed the word 'unleveled'.

Following this, it was checked to see if :

(i) The speaker was too close or too far away from the reference microphone

(ii) The microphone were unplugged, and

(iii) The calibration of the sound field speaker and the microphones were checked.

If still unsuccessful, calibration was repeated

c) If leveling was attempted and neither 'leveled' nor 'unleveled' appeared in the message area, it meant that the present leveling compensation was some where between the conditions described in (a) and (b) above. The sound field conditions and the position of the reference microphone were checked once again before leveling.