Effect of Real Ear Insertion Gain and Preferred Gain on Satisfaction Measures Among Adult Hearing Aid Users

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SEPTEMBER-2023

CERTIFICATE

This is to certify that this dissertation entitled "**Effect of Real Ear Insertion Gain on and Satisfaction Measures Among Adult Hearing Aid Users"** is a bonafide work submitted in part fulfillment for the degree of Master of Science (Audiology) of the student Registration Number: **P01II21S0062**. This has been carried out under the guidance of a faculty of this institute and has not been submitted earlier to any other university for an award of any other diploma or degree.

Mysuru
September 2023

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This is to certify that this dissertation entitled **"Effect of Real Ear Insertion Gain and Preferred gain on Satisfaction Measures Among Adult Hearing Aid Users"** is the result of my own study under the guidance Mr. Prajeesh Thomas, Assistant Professor of Audiology, Department of Audiology, All India Institute of Speech and Hearing, Mysore and has not been submitted earlier to any other University for award of any other diploma or degree.

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ಕೃಷ್ಣಂ ವಂದೇ ಜಗದ್ಗುರುಂ

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ABSTRACT

Fine-tuning of hearing aids for individuals with hearing impairment has an important role, particularly in speech perception and satisfaction. The use of real ear measurements (REMs) by means of probe microphone recordings for fitting hearing aids to an individual is considered to be a gold standard method for achieving appropriate gain settings. The present study aimed to evaluate the gain difference in insertion gain and preferred gain and the difference in satisfaction between two different gain conditions. Preferred condition is in which the person prefers listening to hearing aid amplified speech and routine hearing aid evaluation and REIG condition is where fine tuning was made to match the REM system REIG curve to the target gain as prescribed by prescriptive equations. Data were collected among thirty adult experienced hearing aid users. The participants were in the age range of 18 to 50 years with postlingual moderate to severe sensorineural hearing impairment. Insertion gains across two different gain settings mentioned above at three different input levels (50, 65, and 80 dB SPL) were measured. International Outcome Inventory for Hearing aid users (IOI HA) questionnaire was administered and satisfaction scores were obtained in the preferred gain condition, and after two months REIG matched condition. The results revealed that the REIG condition in an individual was found to give more insertion gain in both satisfied and unsatisfied users compared to the preferred condition. In satisfaction measures, scores were improved after two months in REIG condition. It can be inferred from the results of the present study that lack of appropriate gain delivery by hearing aids might be one factor contributing to the dissatisfaction among many hearing aid users. Hence, it is advisable to evaluate the satisfaction among hearing aid users using a quick questionnaire like IOI –HA. Those who are dissatisfied can be referred for REIG procedure for hearing aid fitting verification.

Chapter 1

Introduction

The National Sample Survey (NSSO, 2017) revealed that 0.3% of the population in India was identified as having hearing disability. Among the individuals with hearing impairment 49.8% of the population were reported to hear only loud sounds. While the medical line of treatment is restricted to pathologies related to outer, middle, and some of the inner ear, the majority of individuals with sensorineural hearing loss would opt for rehabilitation. For rehabilitation hearing aid fitting is the primary option for individuals with sensory neural hearing loss. Fitting of the hearing aids is done based on the prescriptive formulae.

Various prescriptive formulae have been developed over the years, most of which predict insertion gain in the ear canal of real ear (Dillon, 2001). Among these procedures NAL-NL1 and NAL-NL2 prescribe gain based on speech intelligibility and overall loudness (Rajkumar et al.,2013). Hearing aid gain prescription can be verified using different measures like functional gain and real ear measurements. Real-ear measurements (REM) are the main way in which a clinician can measure the hearing aids effects objectively and independently to gain a better idea of the hearing aids performance and suitability (Aazh & Moore, 2007). Insertion gain is a method of verifying the hearing aids output in decibel (dB) gain. While still using the measured sound at the probe microphone, the dB gain view only shows the amplification applied by the hearing aid (Pumford and Sinclair, 2001).

Even though probe microphone measurements of real ear response have consistently been advised for both adults and children, only 15% to 39% of the audiologists surveyed always perform verification and 20% never do (Tharpe et al., 2001). Insertion gains are rarely achieved for the open-fit hearing aids in the first fitting but can usually be achieved through adjustments based on Real ear insertion gain (REIG) measurements (Aazh et al., 2012).

The gold standard rule for the clinician in prescribing hearing aids is to ensure the adequate amount of prescribed gain reaches the ear canal, which is achieved using REIG measurements. Hence one of the primary factors to cross check when the client is not satisfied with hearing aid is to reassure the delivering of target gain into the ear canal through hearing aids.

The satisfaction with hearing aid among individuals with hearing loss have been studied using questionnaires. Cox and Alexander (2002) reported that participants used the hearing aid for 4.1 hours on an average and showed a significant improvement in satisfaction, and quality of life using IOI-HA questionnaire. However, based on administration of different questionnaires like IOI-HA, APHBA, HAUQ, various authors have reported that 61% of hearing aid users are not satisfied with the benefit obtained from their own hearing aid. (Dillon et al., 1999; Cox & Rivera, 1992; Forster & Tomlin, 1988). The major reasons associated with such dissatisfaction with hearing aid are cited as inadequate gain reaching ear canal, less effective in noisy situations, poor sound quality etc. In a study by (Prasad et al., 2021) revealed that only 9% of individuals denied facing any difficulty with the hearing device. The majority, 72% sometimes and 17% always, did complain about some problems with the device; the background noise and mould discomfort being the most common ones. Hence it is well understood that a significant number of hearing aid users are not satisfied with their device in terms of achieving their needs.

1.1 Need for the Study

To enhance speech intelligibility and thereby the quality of speech perception using the hearing aid, optimal fitting of the hearing aids becomes imperative. Conventional fitting of hearing aid is usually made using the prescriptive formula and verification of gain through functional gain measures. However, for optimal delivery of the gain through a hearing aid and to decide on the best effect of hearing aid output, verification using REIG measures are preferred.

Selmachowicz and Lelwis (1988) evaluated real ear versus functional gain measures for various hypothetical individuals. Even though they found that the functional gain is sometimes adequate, real-ear verification is typically a more accurate in-situ way to gauge hearing aid effectiveness. Even though ample literature discusses the importance of real ear measurements on the verification and validation of hearing aids (Campos, 2011 & Yanz, 2007), the literature on the REIG and the amount of fine-tuning required for optimum speech intelligibility are scanty. Hence it is important to ensure the use of real ear measures in hearing aid fitting verification owing to various reasons like the accuracy of providing prescribed gain, a better estimate of hearing aid gain delivered in the pediatric population, non-verbal and difficult to test population etc. The disagreement between the preferred gains over the insertion gain may have its effect on speech perception (Tharpe et al., 2001).

Kochkin et al., (2010) survey focused on the impact of the hearing healthcare profession on hearing aid user success, and it was reported that a few factors like physical fit, number of required visits, hearing healthcare professional attributes, use of real-ear measurements, and subjective benefit can improve the comfortability of patients. Also, using real ear measurements can reduce the required number of visits.

However, this survey reported that a high percentage of people are highly dissatisfied with hearing aids. It is possible and likely that these people are under-fit or under-counseled on appropriate expectations (Kochkin et al., 2010; Nachtegaal et al., 2009). Mueller (2005) suggested that by completing these measurements, there was a reduction in patient complaints, thus decreasing repeat appointments and return-for-credit aids.

Though the significance of real ear measures has been reported in the literature, there is a dearth of scientific studies in the Indian context to utilize these measures in hearing aid fitting either in institutional or private clinical setups. The lack of satisfaction with hearing aids has not been explored widely in the Indian context, and the primary factor to look for in this regard is the verification of adequate amplification reaching the ear canal to overcome the loss of audibility (Turan et al., 2019; Zhao & Bardsley, 2014). Hence, the current study can throw light on these grey areas in the decision-making process on hearing aid verification and satisfaction. Using these verification and validation measurements, the hearing aid provider confirms the value of the hearing aid which can be seen as an opportunity to improve patient care and provider satisfaction.

Although hearing aid technology is advancing exponentially, the need for these devices ultimately hinges on the perception of their satisfaction and benefits. Although there is a universally recognized criterion of hearing aid success, it could be claimed that a situation where a person with hearing loss (HI) frequently wears hearing aids and reports benefiting from them qualifies as a successful outcome. In a study, authors found that hearing aids were ineffective and/or produce poor sound quality in noisy environments (McCormack & Fortnum, 2013).

Earlier, stationary signals such as wave frequency sweeps and unmodulated noise signals were used to measure the performance of the hearing aids. ANSI 3.22 and IEC 60118 stated that these signals permit reproducible measurement. However, speech signals are the key stimuli that a hearing aid user encounters daily for his/her communication needs, and these stimuli are processed differently from the stationary signals, such as composite signals or Digi- speech in non-linear hearing aids.

European Hearing Instrument Manufacturers Association (EHIMA) developed a standardized test measurement procedure called international speech test signal (ISTS). ISTS enables the programming of hearing devices to settings found in real- life. Arehart et al. (2011) found a high correlation between American English listener's rating and ISTS sound quality ratings, thus reinforcing the validity of using ISTS. Hence, in the present study, ISTS was used for insertion gain measurements.

1.2 Aim of the Study

To study the effect of real ear insertion gain and preferred gain on satisfaction measures among adult hearing aid users with sensorineural hearing loss.

1.3 Objectives of the Study

1. To compare the REIG and preferred gain values while fitting with NAL NL2 prescriptive formulae at three different input levels (45 dB, 65 dB & 80 dB SPL), among unsatisfied and satisfied hearing users.
2. To compare the satisfaction scores among unsatisfied hearing users at the time of real ear measures-based fitting and after 2 months.
3. To correlate the hearing aid satisfaction scores between REIG and preferred gain among unsatisfied and satisfied hearing users.

Chapter 2

Review Of Literature

The primary objective of hearing aid fitting is to provide an adequate and comfortable listening level to individuals with hearing impairment. Real ear measurements using probe microphones following the prescriptive target is recognized as a standard method for verifying hearing aid fitting by many audiologists and organizations (BAA, BSA ASHA). Kochkin et al., (2010) found 18% additional improvement in patient satisfaction scores for those fitted using REM versus those not fitted with REM. It is an objective and precise method to match the gain of the hearing aid in an individual's ear to the target provided by prescriptive equations. There are many scientific reports on the use of real ear measurements in the fitting and verification of hearing aids.

2.1 Real ear measurements and manufacturer's initial fit

As a common practice, when real ear measurements are not implemented, audiologists would program the hearing aid to the initial fit as guided by the manufacturer's software. However, some audiologists would change the prescription formulae from the default one to their preferred one like NAL NL1, NAL NL2, DSL v5, etc. The gain, given by the hearing aid as shown in the manufacturer's software might match with the selected prescriptive formulae. Nevertheless, this gain match may not be achieved while measuring the gain in the ear canal through REM. The below-listed studies focus on these issues and emphasize the significance of REM in this context.

Hawkins and Cook (2003) investigated the performance of a hearing aid as estimated through the hearing aid fitting software and they found overestimation of actual real ear gain at high frequencies. In lower frequencies the difference between the insertion gain measurements varied between +/- 5dB whereas in high frequencies especially at 4 kHz the gain difference was around 10 dB than the stimulated insertion gain. Thus, they concluded that simulated gain values through the hearing aid fitting software can be used only during initial times and use of individual validation is necessary later.

Aarts and Caffee (2005) evaluated manufacturer's software and its accuracy in predicting the real ear aided response values. Authors suggested that audiologists cannot rely entirely on manufacturer technology for optimum fitting techniques because the results showed considerable disparities between predicted and measured real-ear values. Additionally, they observe the same pattern of overestimating expected gain in the very low and high frequencies as Hawkins & Cook (2003) had mentioned. The authors also put forth the theory that inadequate hearing aid satisfaction may be caused by faulty fits carried out on anticipated real-ear values. This might affect the individual's daily communication.

Mueller (2005) suggested that in terms of gains and outputs, manufacturers' fitting methods differ significantly from the validated approaches. The gain of the simulated real ear is very different from the gain of the real ear. There is therefore no substitute for probe-microphone measures if a dispenser is concerned about assisted audibility, speech intelligibility, and listening comfort.

Christen and Groth (2008) quoted that failure to use the REM was the major mistake to accurately measure the acoustic output or gain of the hearing aid in the individual's ear canal. Swan & Gatehouse, (1995) measured real-ear insertion gain after first fittings using software from the hearing aid manufacturer.

They observed that the majority of their subject population did not achieve prescribed goals at the first fitting. More participants were able to closely meet targets after the changes, although some still couldn't, and the authors concluded that the audiologist would not have an accurate estimate of whether the hearing aid provides an adequate amount of gain without the use of real-ear insertion gain data.

Aazh and Moore, (2007) evaluated actual discrepancies between software and in-situ measurements in real ear unaided response levels. Their findings showed that using pre-measured numbers versus monitoring unaided gain made a substantial impact. They also found that when comparing audiograms amongst patients, those with steeply sloping high frequency hearing impairments had a lower likelihood of matching desired values. Additionally, they found that hearing aids with more channels were better able to match target when alterations were made after initial fittings than those with fewer channels.

In connection with their earlier studies, Aazh et al., (2012) by using the manufacturer's first-fit programme and subsequent adjustment based on real ear measurements, it was determined to what extent the target real ear insertion gains were attained. It was found that for one or more frequencies between 0.25 and 4 kHz, 71% of the initial fits were not within 10 dB of the NAL-NL1 target real ear insertion gain. Real ear insertion gains between the first-fit and the target real ear insertion gains varied by as much as 22dB. The fittings of hearing aids based exclusively on the programming software of the manufacturer may not be sufficient, according to authors.

As supported in the above studies and their findings, it is clear that the gain setting provided by the prescriptive formula or manufactures initial fit isn't sufficient to provide the best outcomes and often provides less gain during the initial hearing aid fitting. After the hearing aid fitting of an individual, an assessment of how well the prescriptive formula supports hearing of an individual will reflect clinical usefulness in the rehabilitation of these individuals. There are plenty of studies which provide evidence in the support of REM.

Irrespective of these findings; there is still a dispute over whether obtaining REIG measurements are necessary. Therefore, from the above studies we can clearly infer that most of the time, there is discrepancy between the prescribed gain and the preferred gain setting. This discrepancy is seen mostly due to the programmable software and since gain prescribed is not favorable to the patient's needs. The most appropriate way to check for these discrepancies is to use gain at different input levels and REIG measures as it has been noted that there could be discrepancies in the output when compared with the target.

2.2 Real ear measurements and prescriptive formulae

Prescriptive procedures for non-linear hearing aids are broadly classified into suprathreshold based formulas and hearing threshold-based formulas. Prescriptive formulae derive target gains from the audiometric information of an individual. There are many such equations. Prescriptive equations have now evolved to be a common practice in hearing aid fitting. For non-linear hearing aids, threshold-based procedures such as National Acoustic Laboratory – Non-Linear version 1 (NAL –NL1), Version 2 (NAL-NL2) and Desired Sensation Level version 5.0 (DSL v5) and FIG6, are considered.

The supra threshold procedures aim to normalize loudness and it includes Loudness growth in half octave bands (LGOB), Independent hearing aid fitting forum (IHAFF) and ScalAdapt. Here, the client must rate the loudness of narrow-band noises on a rating scale. The average level corresponding to each loudness category in a hearing impaired person is compared to levels needed in a normal hearing person. Now, for each input level, the gain needed to normalize loudness is found out and applied. The amount of prescribed gain usually varies among the manufacturer for the same degree and configuration of hearing loss. It is also affected by the various factors such as hearing aid experience, type of hearing aid, gender and selected prescriptive method.

Nonlinear prescription can be viewed as specifying the gain frequency response for various input levels. Average gain and frequency responsiveness both change as input level changes. However, it is impractical to recommend a hearing aid based entirely on prescriptive approaches because evaluation of the final outcomes, such as customizing the device to each person's needs, is always necessary (Dermody & Byrne, 1975).

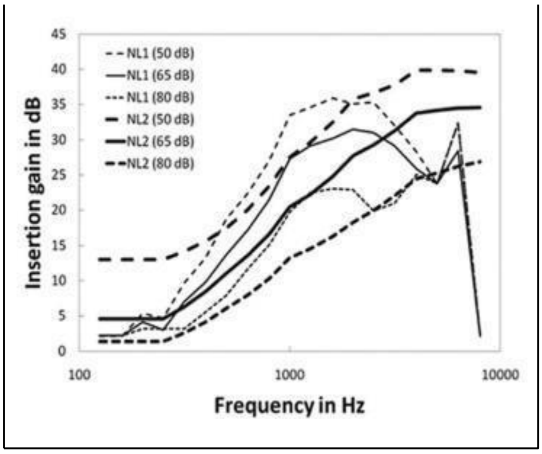
NAL NL1 objective was to determine the gain for several input levels that would result in maximal effective audibility. This is neither based on loudness normalization nor equalization. It is based on two models: Loudness model and speech intelligibility index. The only information required is the hearing thresholds and speech spectrum levels input to the ear after amplification. One of the main criterions is that the loudness of an amplified speech should not be louder than that perceived by someone with normal hearing.

The DSL v5 approach is frequently used to fit hearing aids for newborns, toddlers, and adults whose devices feature multichannel comprehension, expansion, and multi memory technologies. The DSL version 5.0 iteration extends the DSL version to take into account differences between adult and child listening preferences and requirements, avoiding loudness discomfort, and choosing a frequency response and comprehension characteristics that appropriately match technology to the user's needs. Among the available nonlinear prescriptive formulae, Non-Linear version 1 (NAL – NL1), Version2 (NAL-NL2) and Desired Sensation Level version 5.0 (DSL v5) are being used widely by audiologists (Ching et al., 2010).

NAL –NL2 uses intelligibility and loudness to calculate the perceived loudness of the hearing-impaired person (Keidser et al., 2011). On the two points, the theoretical derivation of NAL NL2 differs from that of NAL NL1. Firstly, the intelligibility model (ANSI, 1997) was modified, which is a revised version of the speech intelligibility index (SII) formula. The audibility factor differs between the original SII formula, and the speech intelligibility model used to produce NAL-NL1 and NAL NL2. The audibility factor in the original SII formula assumes that speech is fully understood when all speech components are audible, regardless of the degree of the hearing loss (Keidser et al., 2011). An overview of changes made to NAL-NL2 relative to the NAL NL1 across different input levels.

Figure 2.1

Comparison of NAL NL1 and NAL NL2 Prescriptive Formulas Insertion Gain



From the Figure 2.1, Keidser et al. (2011) compared the NAL NL1 and NAL NL2 formulae and suggested that for a 65 dB SPL input, adults with mild to moderate hearing loss chose a lower overall gain (3 dB on average) than what the NAL NL1 recommended. The same data set revealed that at least one study's participants with mild or moderate hearing loss favored a smaller gain reduction for lower input levels (50 dB SPL) but a larger gain reduction for higher input levels (80 dB SPL). Smeds et al., (2006) indicating that the adults chose a slightly greater compression ratio compared to the NAL NL1 recommended. Overall, NAL NL2 prescribes relatively more gain across low and high frequencies and less gain across mid frequencies than NAL-NL1 (Keidser et al., 2011).

Braida et al (1979) in his review mentioned that frequency gain characteristics according to the prescriptive methods were formulated and assessed with the main goal of users' ability to understand speech. Various prescriptive procedures have been developed and advocated over the past years, which predict the real ear insertion gain (REIG) based either on loudness equalization or speech intelligibility (Dillion, 2001).

Byrne et al., (2001) found that when averaged across the five sensorineural hearing loss, NAL-NL2 and DSL m [I/o] methods provided an estimated 96% predicted speech intelligibility at +10dB SNR, 77% at 0dB SNR, and 7% at a –10dB SNR for sentence level material of the connected speech test (Cox et al., 1987) with a transfer function from Humes (2002).

Bertozzo and Blasca, (2019) Evaluated REAR measurements in relation to the prescribed target values by NAL-NL2 and DSL v5.0a prescriptive procedures. Results showed that for 50 dB intensity, REAR measurements revealed better performance of DSL v5.0a in low and medium frequencies, while NAL-NL2 indicated a better result in high frequencies and for 65 dB of intensity, NAL-NL2 provided better performance in low and high frequencies, and at 80 dB intensity DSL v5.0a was more satisfactory only at the frequency of 2000 Hz, while in low and high frequency bands there was a better performance of NAL-NL2.

Sanders et al. in 2015 studied Speech intelligibility index and they obtained higher percentage with NAL-NL2 for lower input signal, which is 50dB, while for higher intensities of 65 and 80dB SPL, DSLv5.0a showed higher values. These results indicate that NAL-NL2 provides a greater number of audible and useful speech information when the individual is exposed to low intensity speech signals, and DSLv5.0a performs better with high input signals.

It is well-known that the binaural loudness summation concept may influence an individual's hearing threshold. Due to binaural summation, the difference in decibels in monaural hearing aid users is 3-5 dB for this reason, in NAL-NL2 and DSL v5 fitting formula, the monaural and binaural prescription targets are different. Therefore, the difference between the preferred gain and the NAL-NL2 and DSL v5 gain is not due to the monaural hearing aid.

From the above-mentioned studies we can infer that the NAL NL 2 prescriptive formula prescribes slightly higher compression ratios, it takes into consideration gender, experience and age of the individual. The NAL NL2 provides relatively more gain in low and high frequencies than NAL NL1. In addition, NAL NL2 accounts for binaural summation. When NAL NL2 and DSL v5 prescriptive formulas are compared, NAL NL2 provides greater audibility, speech information, and better performance in low and high frequency than the DSL v5 prescriptive formula.

2.3 Real ear measurements and hearing aid satisfaction

Kochkin et al., (2010) examined a total of 40 patients in one year after their hearing aid fittings. Of those sixteen patients who showed up for a second follow-up session, six of them were fitted using real ear measurements, whereas the other ten were fitted without real measurements. According to the study's findings, there is a considerable difference in the insertion gain between people with real ear measurements and without real ear measurements. Particularly, real ear measurements users exhibited greater gain at 3 kHz and 4 kHz. Additionally, patients who were fitted without taking real ear measurements were in fact "under-fit" in terms of target gain at the same frequencies. The author reported that One year later, satisfaction ratings drastically declined by 18% for those who were not fitted using real ear measurements in the Glasgow Hearing Aid Benefit Profile (Gatehouse, 1999).

Another study by Kochkin et al. (2010, 2011) evaluated the application of validation and verification for 788 hearing users. According to the authors, hearing aid users who undergo a thorough fitting technique that involves real ear verification experience higher levels of real-world success than those who undergo a protocol that excludes probing microphone verification. The hearing aid usage, benefit and satisfaction of the recipient's hearing aids served as the benchmark for success. Additionally, they stated that using verification and validation throughout the fitting procedure for hearing aids had been demonstrated to considerably cut down on patient visits.

Narayanan and Manjula (2022) compared the performance with hearing aid programmed to NAL-NL1 first-fit and optimized-fit. The authors measured REAR, REIG, aided thresholds, articulation index and word recognition score in quiet under two conditions. Results showed significantly better scores with the optimized fit compared to the manufacturer's NAL-NL1 first-fit. The authors concluded that optimized fit yields better audibility and improved word recognition in quiet.

Abrams et al., (2012) administered the Abbreviated Profile of Hearing Aid Benefit (APHAB; Cox and Alexander, 1995), to assess any differences resulting from the process of fitting hearing aids. The manufacturer's initial-fit procedure was compared to a validated prescription procedure. At the beginning and the end of each intervention, the APHAB was administered. The verified prescription procedure had mean scores that were greater than initial-fit method for the APHAB subscales of Ease of Communication, Reverberation, and Background Noise. The mean score for the aversiveness subscale in APHAB was also better (i.e., lower) for the verified prescription but was not statistically significant. Seven out of the twenty-two participants preferred initial fit prescription-based settings, whereas fifteen preferred verified prescription-based settings for their hearing aid.

Above studies support best practice guidelines of many professional organizations regarding the use of probe-microphone measurement as the “Gold standard” for verification of hearing aid fitting, thereby providing better satisfaction and quality of life to hearing aid users.

2.4 Real ear measurements and IOI-HA questionnaire

Since the perspectives, attitudes, communication needs, environments, and hearing losses differ, it is important to monitor outcomes for specific patients in order to individualize care for improvement in Health-related quality of life (HRQoL) (Chisolm et al., 2007). Hence it is important to document the treatment outcomes from various viewpoints like, patients who are using hearing aids, the research investigations, supervisors, clinicians, and financiers(Bentler & Kramer, 2000; Cox & Alexander, 2002) .

To assess the benefit of hearing aid in multiple domains such as satisfaction, benefit, participation restriction and activity limitations, many self- report measures have been developed. Below is a list of self-assessment questionnaires to assess the benefit of hearing aids in different domains.

1. Hearing handicap scale
2. Hearing measurement scale
3. Hearing performance inventory
4. Hearing aid performance inventory
5. Profile of hearing aid performance
6. Profile of hearing aid benefit
7. Shortened hearing aid performance inventory
8. Abbreviated profile of hearing aid benefit
9. Client oriented scale of improvement
10. Profile of aided loudness
11. Glasgow hearing aid
12. International outcome inventory-Hearing Aid (IOI-HA)

However, none of these self-report measures assess all of the domains. Hence clinicians use a battery of self- report measures to evaluate hearing outcomes, which is difficult to carry out. To overcome the above drawback, Cox et. al. (2000) proposed an alternative approach. They developed a self- rating questionnaire to assess the hearing aid fitting outcomes, termed as the international outcome inventory for hearing aids (IOI-HA). The IOIHA is proposed to be used as a supplement outcome measure along with the objective measures.

The IOI-HA is an 8- item questionnaire aimed to assess the effectiveness of hearing aid treatment. The eight items of the questionnaire cover a wide range of subjective factors that complement well with the audiological objective measures that are used to evaluate the fitting success of the hearing aid. Each item signifies a different outcome domain and has 5 response alternatives, where every single response ranges from the worst to the best outcome, and where higher scores indicate a better outcome. The original questionnaire is provided in Table 2.1.

Table 2.1

The IOIHA Questionnaire

<table>
<tr><th>Sl. No</th><th>Questionnaire</th></tr>
<tr><td>1</td><td>Think about how much you used your present hearing aid(s) over the past two weeks. On an average day, how many hours did you use the hearing aid(s)?
<table><tr><td>None</td><td>Less than 1 hours a day</td><td>1 to 4 hours a day</td><td>4 to 8 hours a day</td><td>More than 8 hours a day</td></tr></table></td></tr>
<tr><td>2</td><td>Think about the situation where you most wanted to hear better, before you got your present hearing aid(s). Over the past two weeks, how much has the hearing aid helped in that situation?
<table><tr><td>helped not at all</td><td>helped slightly</td><td>helped moderately</td><td>helped quite a lot</td><td>helped very much</td></tr></table></td></tr>
</table>

<table>
<tr><td>3</td><td>Think again about the situation where you most wanted to hear better. When you use your present hearing aid(s), how much difficulty do you STILL have in that situation?
<table><tr><td>very much difficulty</td><td>quite a lot of difficulty</td><td>moderate difficulty</td><td>slight difficulty</td><td>no difficulty</td></tr></table></td></tr>
<tr><td>4</td><td>Considering everything, do you think your present hearing aid(s) is worth the trouble?
<table><tr><td>not at all worth it</td><td>slightly worth it</td><td>moderately worth it</td><td>quite a lot worth it</td><td>very much worth it</td></tr></table></td></tr>
<tr><td>5</td><td>Over the past two weeks, with your present hearing aid(s), how much have your hearing difficulties affected the things you can do?
<table><tr><td>affected very much</td><td>affected quite a lot</td><td>affected moderately</td><td>affected slightly</td><td>affected not at all</td></tr></table></td></tr>
<tr><td>6</td><td>Over the past two weeks, with your present hearing aid(s), how much do you think other people were bothered by your hearing difficulties?
<table><tr><td>bothered very much</td><td>bothered quite a lot</td><td>bothered moderately</td><td>bothered slightly</td><td>bothered not at all</td></tr></table></td></tr>
</table>

7	Considering everything, how much has your present hearing aid(s) changed your enjoyment of life?

Worse	no change	slightly better	quite a lot better	very much better

(Cox et al., 2002), studied the psychometric functions of the original (English) version of IOI-HA. Through mail the authors administered the questionnaire on 260 adults using hearing aids with mean age of 72 years (range 26 to 98). Results indicated that less than 15% of the people indicated less outcome scores. Here the authors have discussed if the IOI-HA should be treated as mini profile i.e., reporting each question separately and comparing it with normative data. In addition, they decided to report the overall score or each factor-based score for comparison purposes.

REIG measurement remains an accurate and precise technique that predicts how well a hearing aid matches with prescription target of an individual, and for fine tuning of correctly match despite (Seewald et al., 1999), the importance of REIG measurements, probe microphones are used considerably lesser for the confirmation of the fitting accuracy.

Magni et al., (2005) measured hearing aid satisfaction between the digital hearing aid satisfaction between the digital hearing aid and the analog hearing aid users using the IOIHA questionnaire. The results found that the digital hearing aid users found less difficulty in listening in difficult conditions. Both digital hearing aid users and analog hearing aid users found satisfaction with their hearing aid, but the digital hearing aid users were more benefited.

Kozlowski, Almeida and Ribas (2014) studied the level of hearing impaired individuals' satisfaction with hearing aids using the IOI-HA questionnaire. In the results they found a high degree of satisfaction with their hearing aids which was reflected in the improvement in the quality of life of 52.78% of the patients after using hearing aid. Thus, the authors conclude IOI-HA is a simple and easy tool to use.

Lee et al., (2022) evaluated the Difference between the Preferred Gain and the NAL-NL2 Gain in Korean Hearing Aid Users, and they measured the satisfaction using APHAB questionnaire. And they found preferred gain in Korean hearing aid users was significantly higher than the NAL-NL2 gain and improvement in APHAB satisfaction scores.

Kumar (2018) studied the effect of attitude towards hearing loss through questionnaire ALHQ and hearing aid outcomes using IOI-HA questionnaire and speech identification scores. Results indicate there was significant correlation between ALHQ and SIS, and there was significant positive correlation between IOI HA and SIS.

Chinnaraj et al., (2022) studied the relationship between hearing aid benefit and auditory processing difficulties in hearing impairment individuals using SNR 50 and IOI HA. The authors found no correlation between IOI HA questionnaire and auditory processing abilities.

From the above studies it is clear that there are discrepancies between preferred gain and prescribed gain setting which do not meet the individual need. This discrepancy has shed its effect on speech perception in an individual. The present study aimed to evaluate the difference in insertion gain and difference in satisfaction scores between prescribed gain and real ear insertion gain setting using the NAL NL2 prescriptive formula in individuals with hearing impairment.

Chapter 3

Methods

The method involved selection of participants, administering the questionnaire and performing real ear measurements for obtaining REIG.

3.1 Study design

This study was conducted using a mixed quasi-experiment research design. The following sections give the procedures for each of these in detail.

3.2 Participants

Thirty participants diagnosed as having moderate to severe sensorineural hearing loss (45-75 dB HL) in the age range of 18 to 50 years were considered for the present study. The individuals who fulfill the following criteria were included in the present study. The fulfillment of inclusion and exclusion criteria were assessed using routine hearing evaluation and through detailed case history.

3.2.1 Participant inclusion criteria

1. Participants with unilateral/bilateral post-lingual moderate to severe sensorineural hearing loss [Difference of not more than 15 dB HL (Jerger, 1959) from 250 Hz to 8000 Hz] were included in the present study.
2. Speech identification scores (SIS) in quiet should not be less than 60%.
3. Immittance results with ‘A’ or ‘As’ type of tympanogram with reflex thresholds appropriate to the degree of hearing loss.
4. All the participants were native Kannada speakers.

5. Participants using Danavox Klar 398 or any other equivalent hearing aid with 8-12 channels, WDRC signal processing noise reduction (3-6 dB reduction), and adaptive directionality.
6. The participants in the present study included experienced hearing aid users using who have been hearing aids for at least six months. All of them should be using hearing aids for at least 4 hours per day.
7. On the IOI-HA questionnaire, the participants should fall under either completely satisfied category or not satisfied category.

3.3 Test Environment

A sound treated air-conditioned double room set-up was used to administer the test. The noise level was maintained within the permissible limits.

3.4 Instrumentation

- Auricle free Hearing aid analyzer was used to assess the insertion gain measurements
- The personal computer with windows 10 configuration was used to program the hearing aids connected to Noah Link Wireless (an interface) with the help of NOAH software. Specific software given by that particular hearing aid company was used to program the hearing aid.
- Their own digital WDRC hearing aid was used for the experiments.

3.5 Materials

- Digital behind the ear (BTE) hearing aids owned by the participants connected to custom ear molds were used. The hearing aids having features mentioned in the inclusion criteria with a fitting range from mild to severe degrees of hearing loss were selected.

- Stimuli used for the real ear measurements are the stimuli developed by the EHIMA known as ISTS that closely resemble properties of natural speech.

3.6 Procedure

The study was conducted in three phases:

Phase 1: Administering the questionnaire

The IOI-HA was administered to the hearing aid users. The IOI-HA consists of seven questions on a 5-point rating scale and it has a total score of 35. Cox and Alexander, (1999) reported higher the number (5 or 4), more satisfied the patient is, and lower the number (1 or 2), more unsatisfied the patient is. Based on their response, the participants were divided into either of the below two categories.

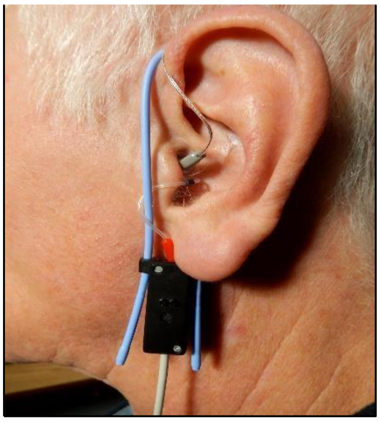
1. Satisfied hearing aid users (score of ≥ 4 in 4 or more questions)
2. Unsatisfied hearing aid users (score of ≤ 2 in 4 or more questions)

Phase 2: Real ear measures

An otoscopy examination always preceded the REM to ensure all participants are free from cerumen or wax. The inclusion criteria for these measurements are that the participants had to have normal middle ear functioning, which was assessed using Immittance testing. The audiogram was loaded into the Aurical system. A real ear SPL measurement option was chosen to find the SPL in the ear canal. An individual was made to sit at 45-degree azimuths concerning the loudspeaker and at a distance of 12 inches from the loudspeaker. The probe microphone of the Aurical system was inserted into the ear canal of the participant using the ‘composite’ method (Hawkins & Muller, 1992). The participants were instructed to maintain the same position during the recording. They were asked to inform in case of any discomfort during the procedure. Leveling was done once the probe was inserted into the ear canal. REM measurements were recorded with the default settings available within the instrument.

Figure 3.1

Picture depicting the Probe microphone placement



Real ear unaided response of all the participants was measured without his/her hearing aid on ears using an auricle hearing aid analyzer with ISTS stimuli. Following this, the hearing aid was switched on and real ear measurements for ISTS were recorded for the respective prescriptive formulas with the help of the auricle hearing aid analyzer. In the unsatisfied users, gain in the hearing aid was adjusted via hearing aid programming wherein the hearing aids were simultaneously connected to NOAH software through an interface until REIG (REAR - REUR) matches the target gain curve.

Phase 3: Hearing aid validation

The IOI-HA Questionnaire was re-administered after two months of hearing aid usage either through direct interview or through telephonic/video conferencing method to validate the real ear-based hearing aid fitting. Since hearing aid acclimatization in terms of speech perception is achieved by two months on an average of hearing aid use as per literature (Megha, 2019).

3.7. Statistical Analyses

Insertion gain measurements of satisfied and unsatisfied hearing aid users obtained at two different gain settings (REIG and preferred gain), at three input levels (50, 65 and 80dBSPL) across 250 Hz and 4000 Hz at octaves and mid octaves were tabulated in SPSS version 26. Statistical analysis was performed to see if the differences were statistically significant. A Shapiro- Wilk's test was performed to examine if the data collected followed normal distribution.

Chapter 4

Results

The current study aimed to evaluate the differences in the real ear gain and preferred gain and its relationship with satisfaction scores among satisfied and unsatisfied hearing aid users. In preferred gain the person preferred listening to amplified speech during routine hearing aid evaluation with reference to NAL NL2 prescriptive formula. Real ear gain was calculated by matching the hearing aid's gain settings with the REIG's target gain setting based on the NAL NL2 prescriptive formula.

For the present study, thirty ears' data were collected among thirty hearing aid users. The subjects included both unilateral (N= 19) and bilateral (N= 11) hearing aid users. The better ear was evaluated for this study in bilateral hearing aid users. The participants were in the age range of 18 and 50 years. All the participants used hearing aids with 8-12 channels, wide dynamic range compression (WDRC) signal processing noise reduction (3-6 dB reduction) and adaptive directionality.

4.1 Comparison of REIG and preferred gain among satisfied and unsatisfied users

Insertion gain measurements of satisfied and unsatisfied hearing aid users obtained at two different gain settings (REIG and preferred gain), at three input levels (50, 65 and 80 dB SPL) across 250 Hz and 4000 Hz at octaves and mid-octaves were tabulated in SPSS version 26. Statistical analysis was performed to see if the differences were statistically significant. Shapiro- Wilk's test was performed to examine if the data collected followed normal distribution. The REIG in dB SPL and preferred condition were subjected to Shapiro- Wilk's normality test. The results showed slight variations from normal distribution in both satisfied and unsatisfied groups; however, studying the interaction through a non-parametric test may not be possible. Hence, a parametric test was carried out for both groups. In addition, the data had relatively better standard deviation, no skewness and no floor or ceiling effect. These factors also supported going ahead with the parametric test.

Comparison of REIG and preferred gain in satisfied users

The mean, median and standard deviation (SD) of two different condition (preferred gain and REIG), at three input levels (50, 65 and 80 dB SPL) across frequencies (250 Hz and 4000 Hz at octaves and mid octaves) are given in Table 4.1. From Table 4.1 it can be observed that the insertion gain differed across two different gain settings at different input levels. The mean of the insertion gain was the highest for matched to target gain in the REM condition than the preferred gain condition at all the three intensity levels.

Table 4.1.

Comparison of mean gain in different condition (REIG and Preferred Gain) in Satisfied Users

Frequency		250Hz		500Hz		750Hz		1000Hz		2000Hz		3000Hz		4000Hz	
Input level (dBS PL)	Condition	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED
50	PG	18.27 (4.30)	18	17.47 (4.19)	18	16.80 (2.93)	18	18.0 (3.40)	19	20.27 (5.39)	22	20.73 (6.50)	22	22.13 (6.99)	20
	REIG	22.67 (3.81)	22	21.93 (3.03)	22	20.53 (3.90)	21	22.73 (2.60)	24	26.13 (5.68)	26	25.87 (5.81)	27	26.80 (6.36)	25
65	PG	10.07 (2.86)	9	8.13 (1.59)	8	8.07 (3.90)	8	9.00 (2.56)	9	11.80 (3.34)	12	12.87 (4.92)	12	13.60 (6.27)	11
	REIG	14.33 (3.22)	13	12.13 (1.40)	12	11.40 (1.59)	11	13.53 (2.10)	14	16.27 (3.65)	18	17.00 (4.97)	18	17.87 (6.30)	15
80	PG	3.27 (2.76)	2	2.20 (1.20	2	2.07 (1.96)	2	2.73 (1.43)	3	3.73 (1.94)	4	4.20 (2.56)	4	5.07 (4.20)	4
	REIG	6.33 (3.26)	5	5.20 (2.39)	5	5.27 (1.79)	5	6.47 (1.55)	7	7.27 (2.01)	8	8.07 (3.24)	8	8.33 (4.92)	8

Note: MED- Median, PG – Preferred gain and REIG- Real ear insertion gain

Repeated measures three-way ANOVA were done to check for the interaction effect of conditions (mean of preferred gain and REIG), for three different input levels (50, 65 and 80dBSPL) across frequencies (250 Hz and 4000 Hz for octaves and mid octaves). The results showed no significant interaction effect among preferred gain setting and REIG conditions for three different levels across 250 Hz and 4000 Hz at octaves and mid octaves ($F(12,168) = 0.932$, $P<0.05$).

However, further analysis showed a significant interaction effect between conditions (preferred gain and REIG) and frequencies (250 Hz and 4000 Hz at octaves and mid octaves) ($F(6,84) = 2.950$, $P<0.05$). Since there was an interaction effect in this condition, the Bonferroni correction of frequencies for the mean difference across conditions was done to see the group-wise difference. The results of the Bonferroni correction are presented in Table 4.2. It can be noted from Table 4.2 that there is a significant difference in the mean difference for all the frequencies except 250 Hz.

Further analysis also showed a significant interaction effect between conditions (preferred gain and REIG) and input levels (50, 65, and 80 dB SPL) ($F(2,28) = 8.864$, $P<0.05$). Since there was an interaction effect in this condition, the Bonferroni correction of input levels for mean difference across conditions was carried out to see the group wise difference. The results of the Bonferroni correction are presented in Table 4.3, which reveals there is a significant difference in the mean gain across all the input levels.

Table 4.2

Pairwise Comparison of Frequencies for the mean difference across condition in satisfied users

Frequency Comparison	250Hz Mean diff f-value	500Hz	750Hz	1000Hz	2000 Hz	3000 Hz	4000Hz
250 Hz	-	1.31 0.70	1.8 0.56	0.41 1	-1.75 1	-2.30 1	-3.14 1
500 Hz	-1.31 0.78	-	0.48 1	-0.9 1	-3.06* 0.006	-3.61 0.84	-4.45 0.17
750 Hz	-1.8 0.56	-0.48 1	-	-1.38 0.0	-3.55* 0.0	-4.1* 0.005	-4.94* 0.026
1000 Hz	-0.41 1	0.9 1	1.38* 0.0	-	-2.16* 0.004	-2.71* 0.047	-3.55 0.14
2000 Hz	1.75 1	3.06* 0.006	3.55 0.0	2.16* 0.004	-	-0.54 1	-1.38 1
3000 Hz	2.30 1	3.61 0.08	4.1 0.005	2.71* 0.047	0.54 1	-	-0.84 1
4000 Hz	3.14 1	4.45 0.17	4.94* 0.026	3.55 0.14	1.38 1	0.84 1	-

Note: * represents significant difference (*f* >0.05)

Table 4.3.

Pairwise Comparison of Input levels for mean difference across conditions in satisfied users

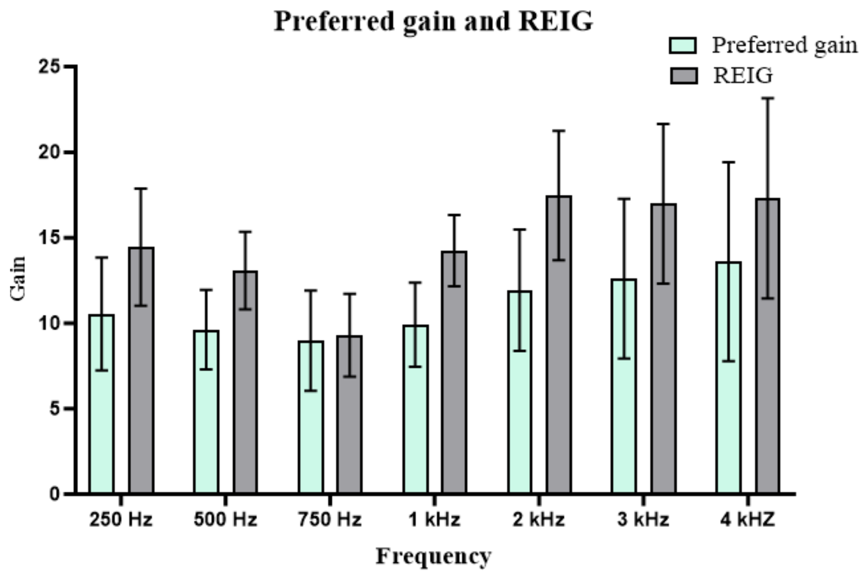
Input level	50dB	65dB	80dB
	Mean diff *f* value		
50dB	-	8.87* 0.0	16.43* 0.0
65dB	-8.87* 0.0	-	7.56* 0.0
80dB	-16.43* 0.0	-7.56* 0.0	-

Note: * represents significant difference (*f* >0.05)

Figure 4.1. depicts REIG vs. preferred gain among satisfied users. Figure 4.1 shows that the REIG condition has a higher mean gain than the preferred gain in all the frequencies. It can also be seen that the difference was largest at 2000 Hz, followed by 3000 Hz.

Figure 4.1.

Comparison of mean gain (averaged across three input levels) in different conditions (REIG and Preferred Gain) in Satisfied Users across frequencies



Comparison of REIG and preferred gain in unsatisfied users

The mean, median and SD of two different conditions (preferred gain and REIG), at three input levels (50, 65 and 80dBSPL) across frequencies (250 Hz and 4000 Hz at octaves and mid octaves. in unsatisfied users are given in Table 4.4. From Table 4.4 it can be observed that the insertion gain differed across two different gain settings at different input levels. The mean of the insertion gain was found to be the highest for matched to target gain in REM condition than preferred gain condition at all the three intensity level.

Table 4.4.

Comparison of mean gain in different condition (REIG and Preferred Gain) in Unsatisfied Users

Frequency		**250Hz**		**500Hz**		**750Hz**		**1000Hz**		**2000Hz**		**3000Hz**		**4000Hz**	
Input level (dBSPL)	Condition	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED	Mean dB (SD)	MED
50	PG	17.93 (6.19)	20	16.87 (4.67)	19	17.47 (4.30)	18	17.60 (4.05)	17	18.67 (5.18)	20	17.00 (6.53)	18	19.67 (8.14)	21
	REIG	30.67 (5.65)	30	29.27 (3.63)	30	27.4 (4.42)	28	27.13 (4.59)	26	28.87 (7.32)	30	27.07 (9.30)	30	28.40 (8.45)	30
65	PG	11.67 (6.42)	11	11.00 (6.89)	10	9.67 (4.13)	10	9.93 (4.00)	9	11.20 (3.38)	10	10.00 (5.66)	10	11.53 (7.71)	11
	REIG	21.53 (6.17)	22	21.40 (5.42)	22	19.60 (5.12)	20	18.73 (4.69)	19	18.93 (4.46)	18	18.53 (8.25)	16	18.67 (7.97)	18
80	PG	3.93 (3.28)	3	2.60 (2.29)	2	2.27 (.88)	2	3.07 (1.16)	3	3.00 (1.30)	3	4.60 (3.66)	4	5.27 (4.89)	4
	REIG	11.33 (5.16)	12	10.13 (4.67)	11	8.40 (3.37)	8	8.67 (3.33)	8	10.07 (3.49)	9	10.93 (4.23)	10	10.73 (5.31)	10

Note: MED- Median, PG – Preferred gain and REIG- Real ear insertion gain

Repeated measures three-way ANOVA were done to check for the interaction effect of conditions (mean of preferred gain and REIG), for three different input levels (50, 65 and 80dBSPL) across frequencies (250 Hz and 4000 Hz for octaves and mid octaves). The results showed there is no significant interaction effect among Preferred gain setting and REIG conditions for three different levels across 250 Hz and 4000 Hz at octaves and mid octaves ($F (12,168) = 1.107$, $P<0.05$).

However, further analysis showed a significant interaction effect between conditions (preferred gain and REIG) and frequencies (250 Hz and 4000 Hz at octaves and mid-octaves) ($F (6,84) = 4.480$, $P<0.05$). Since there was an interaction effect in this condition, the Bonferroni correction of frequencies for the mean difference across conditions was carried out to see the group wise difference. The results of the Bonferroni correction are presented in Table 4.5. It can be noted from Table 4.5 that there is no significant mean gain difference seen in all the frequencies.

Further analysis also showed a significant interaction effect between conditions (preferred gain and REIG) and input levels (50, 65, and 80dBSPL) ($F (2,28) = 404.098$, $P<0.05$). Since there was an interaction effect in this condition, the Bonferroni correction of input levels for mean difference across conditions was carried out to see the group wise difference. The results of the Bonferroni correction are presented in Table 4.6 which reveals there is a significant difference in the mean gain across all the input levels.

Table 4.5.

Pairwise Comparison of Frequencies for the mean gain difference across conditions in unsatisfied users

Frequency Comparison	250Hz	500Hz	750Hz	1000Hz	2000Hz	3000Hz	4000Hz
	Mean difference p-value						
250Hz		0.96 1	2.04 1	1.98 1	1.05 1	1.48 1	0.46 1
500Hz	0.96 1		1.07 1	1.02 1	0.08 1	0.52 1	-0.5 1
750Hz	-2.04 1	-1.07 0.55		0.05 1	0.98 1	-0.55 1	-1.57 1
1000Hz	-1.98 1	-1.02 1	0.05 1		-0.93 1	- 0.50 1	-1.52 1
2000Hz	-1.05 1	-0.89 1	0.98 1	0.93 1		0.43 1	-0.58 1
3000Hz	-1.48 1	-0.52 1	0.56 1	0.5 1	-0.42 1		-1.02 1
4000Hz	-0.46 1	0.5 1	1.57 1	1.52 1	0.58 1	1.02 1	

Note: * represents significant difference (*f* >0.05)

Table 4.6

Pairwise Comparison of Input levels for mean gain difference across condition in unsatisfied users

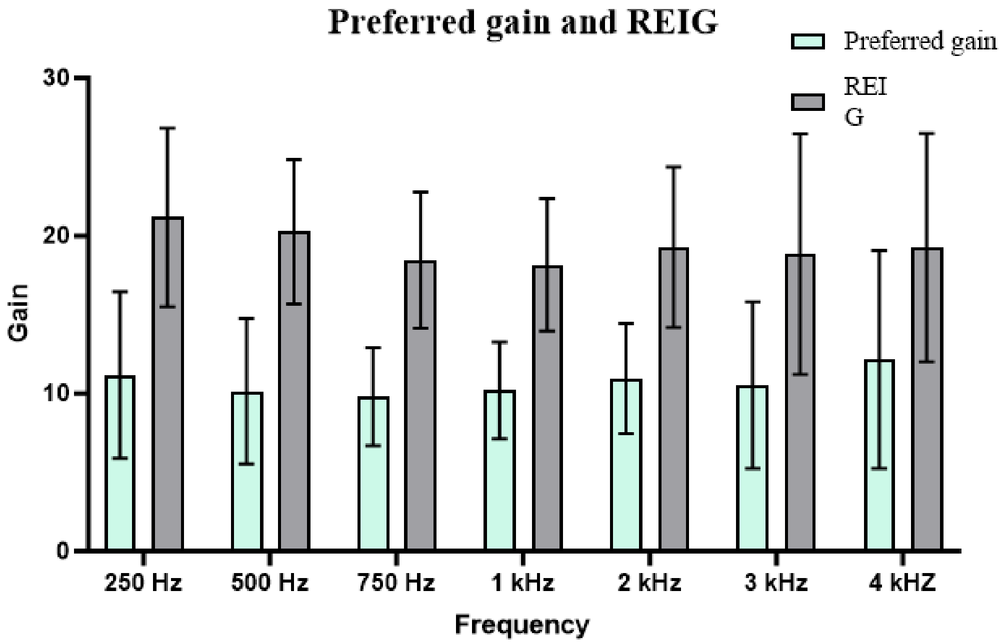
Input level	50dB	65dB	80dB
	Mean difference *f* value		
50Db	-	-7.97* 0.0	-16.35* 0.0
65dB	-7.97* 0.0	-	8.36* 0.0
80dB	-16.35* 0.0	8.38* 0.0	-

Note: * represents significant difference (*f* >0.05)

Figure 4.2. depicts REIG vs. preferred gain among unsatisfied users. From Figure 4.2, it can be noted that REIG condition has higher gain than the preferred gain in all the frequencies. The difference was largest at 250 Hz followed by 500 Hz.

Figure 4.2

Comparison of mean gain (averaged across three input levels) in different condition (REIG and Preferred Gain) in Unsatisfied Users across frequencies



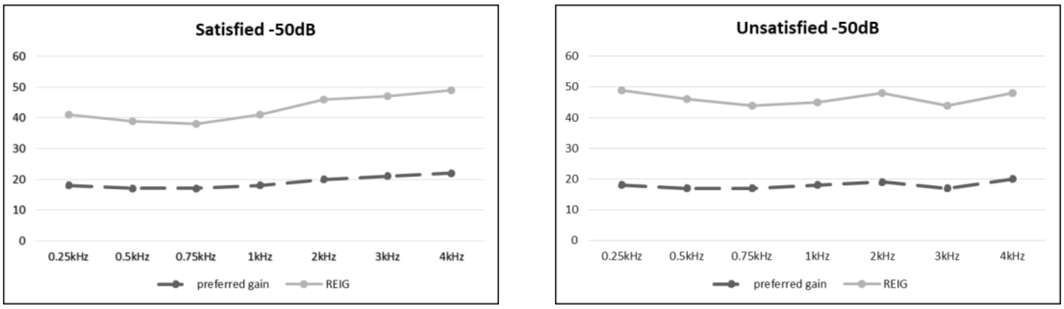
Comparison between satisfied and unsatisfied users

Comparisons of mean gain at different conditions (preferred gain and REIG), at three different input levels (50, 65 and 80dBSPL) between satisfied and unsatisfied users were not made since the thresholds of satisfied users and unsatisfied users were not the same and the gain provided by hearing aids is totally dependent on the thresholds of different frequencies. But with the graphical representation below we can observe that there was a difference in gain between preferred gain setting and REIG gain for satisfied users and unsatisfied users. The unsatisfied users have larger gain differences than the satisfied users and the difference was highest for 50 dB input level followed by 65 dB and 80 dB input level. Figure 4.3. (Fig 4.3.a, Fig 4.3.b and 4.3.c) depicts average REIG vs. preferred gain at three different input levels (50, 65 and 80 dB SPL) across frequencies among satisfied and unsatisfied users. The gain difference between satisfied and unsatisfied was found to be greater at lower input level (50 dB).

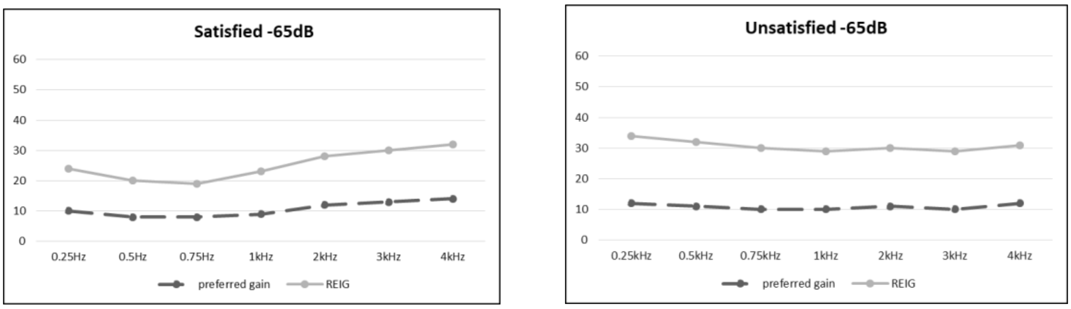
Figure 4.3.

Comparison of Preferred Gain and REIG across different input levels: 50 dB SPL, b- 65dB SPL, c- 65 80dB SPL) among satisfied and unsatisfied users

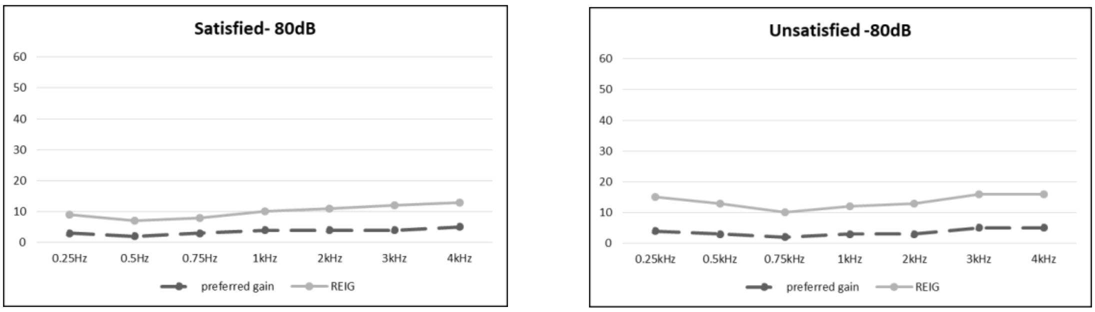
a.



b.



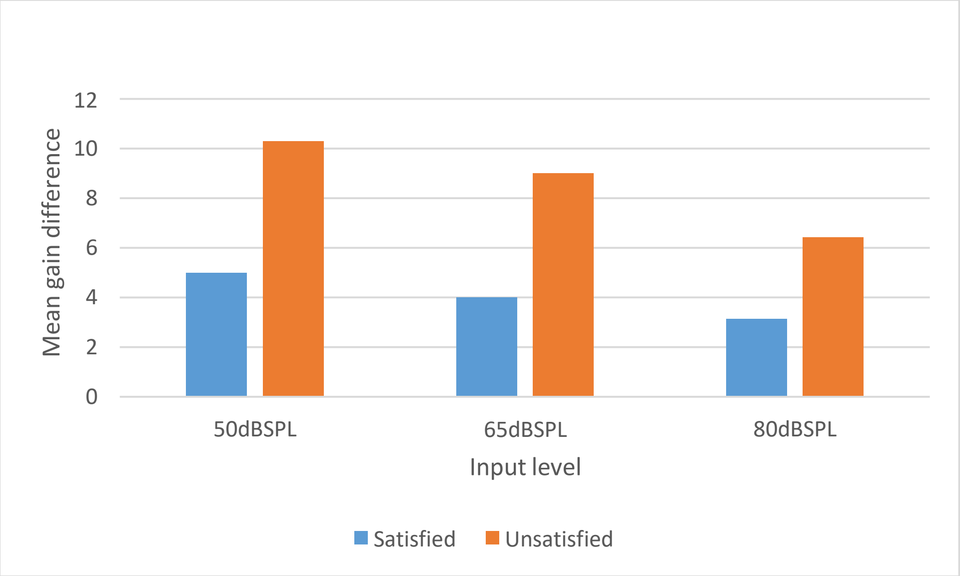
c.



The Figure 4.4. depict the average gain difference across different input levels (50, 65 and 80 dB) in both satisfied and unsatisfied users. The gain difference between satisfied and unsatisfied was found to be greater at lower input level (50 dB) compared to higher input level (80dB).

Figure 4.4.

Comparison of gain difference (averaged across frequencies) in different condition (REIG and Preferred Gain) in Satisfied and Unsatisfied Users across three input levels (50,65 and 80dBSPL)



4.2 Comparison of satisfaction scores between satisfied users and unsatisfied users prior to REM

The satisfaction questionnaire was administered twice among all the subjects, first before the performance of Real ear measurements (REM) and second after 2 months of performance of Real ear measurements (REM). This section of results describes the comparison of satisfaction scores between satisfied users and unsatisfied users prior to REM. The IOI-HA questionnaire scores were obtained in satisfied and unsatisfied hearing aid users. The mean and SD of IOIHA satisfaction scores between satisfied and unsatisfied users prior to REM are given in Table 4.7.

Table 4.7

Mean and SD of IOIHA Satisfaction Scores Between Satisfied Users and Unsatisfied Users Prior to REM

Type of user	Mean	SD
Satisfied users	28.33	1.04
Unsatisfied users	19.27	1.62

It can be observed from the table 4.7 that the mean IOIHA satisfaction scores of satisfied users are higher than that of unsatisfied users. Statistical analysis was performed to see if the differences were statistically significant. Shapiro- Wilk's test was performed in order to examine if data collected followed normal distribution. The results showed that data follows normal distribution and hence, parametric statistical analyses were performed. Independent t test was done to compare satisfaction scores of satisfied and unsatisfied users. The results showed that there was a significant difference in IOAIHA scores between satisfied hearing aid user and unsatisfied hearing aid user ($t(28) = 16.881$ $p < 0.05$).

Comparison of IOIHA satisfaction scores of unsatisfied users in pre and post REM

This section of results describes the comparison of IOIHA satisfaction scores of unsatisfied users between pre and 2 months post REM. Table 4.8 depicts the mean and SD of IOIHA satisfaction scores of unsatisfied users during pre and and post REM. From the Table 4.8 it can be noted that the IAIHA satisfaction improved post 2 months REM. Further, to compare if the difference is significant or not, Paired t test was done. The results showed that there was significant difference in mean satisfaction scores (t

(14) =11.75 P <0.05) between pre and post REM among unsatisfied users post REM. In post REM condition mean IOIHA scores were improved.

Table 4.8

Mean and SD of IOIHA Satisfaction Scores of Unsatisfied Users during pre and post REM

	Mean	SD
Pre REM	19.27	1.62
Post REM	25.47	1.59

4.3 Correlation between satisfaction scores and matched REIG among satisfied and unsatisfied users .

Karl Pearson correlation analyses were carried out to check the correlation between satisfaction scores and matched REIG. The results showed overall no significant correlation (>0.005) between satisfaction scores and matched REIG. However, the correlation was seen in 750 Hz with post REM at 50 dB and 80 dB respectively with $p<0.05$.

Chapter 5

Discussion

The objective of the study was to compare insertion gain and satisfaction scores across preferred gain and REIG settings at three different input levels among satisfied and unsatisfied hearing aid users. The results of the insertion gain and satisfaction scores are discussed below.

5.1 Comparison of preferred gain and REIG among satisfied and unsatisfied hearing aid users

Comparison of preferred gain and REIG matched setting across frequency follows same trend in satisfied and unsatisfied users and hence these results are discussed in general initially. However, some of the peculiar findings in satisfied users are addressed and discussed separately in subsequent sections.

The results of this study showed significantly higher gain difference for REIG matched across all the frequencies. However, maximum difference was observed in 1kHz, 2kHz and 3kHz frequency region. Similar results were consistent with other studies. Highest difference was seen above 1kHz specifically highest at 3kHz (Aazh, 2007; Hawkins and Cook, 2003). The discrepancies observed across frequency region might be owing to the frequency response of the unaided ear is subtracted from the response of the aided ear which is essential to consider while estimating the insertion gain. The client's ear canal resonance may not match the intended REIG and may exhibit unexpected peaks and dips in the REIG if it does not match average values in terms of centre frequency and magnitude.

In comparison of preferred gain and REIG matched setting across input level it is found that difference is higher for lower input level (50dB) and smallest for higher input level (80dB). As the principle of modern era digital compression hearing aids the lower input level receives higher gain with lower compression ratio which reflect in larger gain difference. Whereas in high input level generally greater compression ratio is applied to provide maximal comfort as per NAL NL2 principles resulting in smaller gain difference. These results are consistent with other studies (smeds et al., 2006).

The real ear insertion gain was found to be significantly higher for REIG matched target condition compared to preferred condition in both satisfied and unsatisfied users. This difference in the gain was larger in the unsatisfied hearing aid users. This indicates under fitting of hearing aid gain while considering clients preferred gain. Manjula et al (2021) compared the optimized fit and NAL NL1 performance and found that significantly better scores with the optimized fit compared to the manufacturer's NAL-NL1 first-fit. The authors concluded that optimized fit yields better audibility and improved word recognition in quiet.

The results of the present study can be compared to the one reported by Aarts and Caffee (2005) wherein they have compared real ear predicted values from one manufacturer's software to in situ measures on 41 subjects. Two styles of the manufacturer's hearing aids were programmed to two common hearing loss configurations seen in adult hearing aid users: a flat mild sensorineural loss and a mild sloping to moderately severe hearing loss. The authors reported that significant discrepancies were present between predicted and measured real-ear values, suggesting that audiologists cannot rely solely on manufacturer technology for best fitting procedures. The authors supported Hawkins and Cook's hypothesis that simulated or predicted values failed to consider individual differences, which can be measured on real ear measurement as real-ear unaided responses (REUR).

By completing real ear measurements there was a reduction in patient complaints, thus decreasing repeat appointments and return-for-credit aids (Mueller, 2005; Beck, 2010). Hence the current study also emphasizes the importance of using REIG based hearing aid verification to achieve adequate gain and thereby better satisfaction and quality of life among the hearing aid users.

5.2 Comparison of satisfaction scores among satisfied and unsatisfied users

In the present study satisfaction scores were measured pre-REIG (while using preferred gain setting) and post-REIG (2 months post REIG based gain settings) in unsatisfied users' group. However, satisfaction scores were measured only during pre-REIG (while using preferred gain setting) in satisfied users group owing to the lack of gain manipulation and high satisfaction scores. In satisfied users' group, the satisfaction scores have already reached near maximum value (28/35) during pre-REIG itself. As discussed earlier this could be due to the preferred gain almost matching with the REIG gain targets among satisfied users. However, in the unsatisfied users group the satisfaction scores have improved significantly between pre-REIG and post-REIG. The scores have reached to that of satisfied user's level, 2 months post-REIG.

The hearing aid users might have preferred to go with lower gain settings initially during the first fit looking for comfort fit and might have got adjusted to it later on. This must have compromised the speech perception skills among them sparing comfort in noisy and outdoor situations. The proper counselling, ensuring them about the benefit of having adequate gain, willingness to try existing options to improve might have brought better compliance among these hearing aid users to go for REIG gain settings.

The results of this research can be related to study by Kochkin et al. (2010) wherein they have found that real ear verification had greater levels of real-world success in terms of hearing aid usage, benefit and satisfaction.

5.3 Comparison of preferred gain and REIG gain setting in satisfied users

The results of satisfied users are discussed separately due to two reasons, one being lack of manipulation of gain settings in their hearing aids to match the REIG. Second being lack of measurement of satisfaction scores post REIG measurement since their hearing aids have not undergone manipulation and satisfaction scores almost reached maximum in preferred gain condition itself. Among satisfied users, the difference in preferred gain and real ear insertion gain was smaller. The preferred gain of satisfied users was almost reaching to the real ear insertion gain setting. Additional gain was not required as adequate gain was provided already while programming and the purpose of the study was to check for the improvement in satisfaction among unsatisfied users after REIG. Since satisfied users have got used to current gain settings and further changes might invite undesirable outcome, the gain settings of the satisfied users were left as it is. Nevertheless, minimal changes between the two gain settings and higher satisfaction scores makes us to infer that real ear measurement is one of the major factors contributing to the satisfaction with hearing aid in satisfied users' group as well.

Similar studies have been reported in the literature including Kochkin (2010) who evaluated the application of validation and verification of hearing aid users who undergo a thorough fitting technique that involves real ear verification experience higher levels of real-world success than those who undergo a protocol that excludes probing microphone verification. The hearing aid usage, benefit and satisfaction of the recipient's hearing aids served as the benchmark for success. Additionally, they stated that using verification and validation throughout the fitting procedure for hearing aids had been demonstrated to considerably cut down on patient visits.

5.3 Correlation of REIG and satisfaction scores among satisfied and unsatisfied hearing aid user

Real ear insertion gain was found to be significantly higher for REIG matched target condition compared to preferred condition in both satisfied and unsatisfied users. This difference in the gain was larger in the unsatisfied hearing aid users. However, when this difference was corrected with increasing gain through programming software, there was an improvement in satisfaction scores. Thus, in this study we can observe a trend of improvement in satisfaction scores with decrease in gain difference between REIG and preferred gain setting. When the difference was higher satisfaction scores were poorer. Even though there was improvement in satisfaction with decrease in gain difference, statistical analysis could not establish a correlation between REIG and satisfaction scores among both satisfied as well as unsatisfied users' group.

As the increase in gain with respect to REIG measurement has brought better satisfaction among less satisfied users, it may be concluded that REIG is one of the contributing factors to the satisfaction from hearing aid. Similar results were found by Beck (2010), in his study patients who were fitted without taking accurate ear measurements were in fact "under-fit" in terms of target gain. Particularly, real ear measurements users exhibited greater gain at 3 kHz and 4 kHz. According to the author, persons who were not fitted using real ear measurements saw a substantially larger fall in their satisfaction ratings one year later, up to 18%, according to the Glasgow Hearing Aid Benefit Profile (Gatehouse, 1999).

Though earlier studies have shown that the significant contributor to satisfaction from hearing aid is the gain provided in the ear canal, many studies have pointed out to other factors contributing to the overall satisfaction with hearing aids as well.

Kochkin et. al. (2010) studied the correlations between dispensing protocols and successful patient outcomes, and they have found some of the factors which contribute to satisfaction from hearing aid. Those are:

1) Fit and comfort and achieved sound quality (a proxy measure for optimal amplification of the residual auditory area and hearing aid functionality)

2) Number of visits to fit the hearing aid

3) HHP (Hearing healthcare providers) attributes

4) REM verification

5) Subjective benefit measurement

6) Loudness discomfort measurement

As discussed in the earlier section, since many factors are contributing to satisfaction with hearing aid, establishing correlation with one factor with limited number of participants may be difficult as seen in the current study. Satisfaction is composite of several factors which include maintenance of the hearing device, fit, comfort, attitude, factors related to the device, issues related to - feedback, psycho-social and duration of hearing aid usage. In this study only real ear measurements are taken into consideration. Many of these factors might play a role in satisfaction from hearing aid. However, in the current study we have not considered other factors affecting satisfaction due to study restrictions. This could be the reason for not correlating with REIG and satisfaction scores even with improvement in scores.

Many studies have focused on long term benefit with hearing aid and change in perception of satisfaction over period. Though there are equivocal reports, under the scope of this research section we have investigated the studies like our current study in terms of less satisfaction with hearing aids. Gianopoulos, Stephens, and Davis (2002) studied 116 adults fitted with hearing aids. On follow-up, they found that 66 of them were not using hearing aids. Similarly, in another study by Lupsakko, Kautiainen, and Sulkava (2005), 24 out of 100 were non-users of hearing aids. Bertoli, Staehelin, Zemp, Schindler, Bodmer, and Probst (2009) conducted a study on 8,707 individuals with hearing loss and found that 1,086 of them occasionally or never used hearing aids. Hartley, Rochtchina, Newall, Golding, and Mitchell (2010) on a follow-up session revealed that 78 out of 322 people were non-users of hearing aid. Most of these studies have listed out the possible reasons for lack of expected usage or satisfaction with hearing aid.

In addition, the patient preference in terms of loudness might also play a role in some aspects of satisfaction. Accounting to these factors the slight difference in preferred gain and REIG gain settings among satisfied users can be justified. Future research can focus on inclusion of all factors related to satisfaction and evaluate the significance of each. The possible reasons for lack of expected usage or satisfaction with hearing aid have been identified, including hearing aid cost, maintenance of the hearing device, fit, comfort, attitude, factors related to the device, issues related to -feedback, psycho-social or situational, attitudes of professionals, ear problems, and appearance (McCormack & Fortnum, 2013).

Another factor which might have contributed to the outcome of this study is the usage of IOI HA questionnaire which was mainly focusing on the hearing aid usage as an indicator of satisfaction. However, since the number of questions is limited in IOI-

HA, it may not be covering all aspects of satisfaction from hearing aid in detail. This might be reflecting in the gain difference between preferred and REIG gain settings among satisfied users. Moreover, IOI HA score alone was considered in this study for hearing aid satisfaction. Inclusion of other questionnaires and speech perception tests might throw light into better association between these factors.

In this study hearing aid outcome was measured based on the questionnaire which is a subjective method. The detailed method of verification of speech perception with hearing aid like Speech identification scores (SIS) in quiet and noise could not be included in the current study due to difficulty following up the hearing users for re-visits. Inclusion of these verification methods along with REIG might bring out the detailed benefit picture of the hearing aid. Probably that would overcome the sealing effect seen on IOI-HA and better relation between REIG and hearing aid benefit.

Even though many authors report acclimatization occurs within 2 months (on an average) there are individuals who require more time for acclimatization. In those cases, if satisfaction is measured after 2 months, they might not appreciate hearing aid benefit there may be scope for improvement in satisfaction scores even after 2 months of hearing aid usage in some of the users.

The current study has showcased the significance of the REIG measures especially in unsatisfied users. Also, improvement in satisfaction scores with REIG procedure for hearing aid fitting. However, these leaves an opportunity to further research on the individual and combined effect of the other factors affecting outcome, use of more questionnaire and sophisticated measures, unilateral v/s bilateral hearing aid users, hearing aids with varying number of channels etc.

Chapter 6

Summary and Conclusions

Fine- tuning of the hearing aids of the individual with hearing impairment has an important role particularly in speech perception and satisfaction. In many hearing aid protocols, especially pediatric protocols include insertion gain as the main hearing aid fitting procedure. While the difference between the target gain and prescribed gain is well documented, the difference between the insertion gain that is matched to the target curve of the prescriptive equation and preferred gain is not well understood in Indian context and this disagreement between the preferred gains over the insertion gain may have its effect on satisfaction as well. Literature support for this can be seen in Abrams et al. (2012) study where they have found real ear verified prescription procedure mean scores for the APHAB subscales of Ease of Communication, Reverberation, and Background Noise were greater than those produced by the initial-fit method.

Hence, the aim of the present study was to evaluate the difference in insertion gain and satisfaction scores between preferred gain and matched to the target gain by REM system. Thirty ears with post lingual moderate to severe sensorineural hearing impairment in the age range of 18-50 years participated in the study. The REIG was calculated at three input levels (50 dB, 65 dB and 80 dB SPL) and at two different gain setting as mentioned above. IOI HA questionnaire was administered, and satisfaction scores were obtained with preferred gain setting and two months after REIG matched setting.

Results showed that insertion gain was found to be significantly higher for REIG matched target condition ($p<0.05$) than preferred gain setting at all three input levels. Satisfaction scores were found to be improved in unsatisfied users with matched REIG setting. The difference in REIG and preferred gain condition was significantly larger in unsatisfied groups indicating under-fit of hearing aid gain. However, such difference was minimal in satisfied users.

Even though the current study could not establish a correlation between REIG and satisfaction scores, a general trend of improvement in satisfaction scores with gain approaching to that of REIG was seen in both satisfied and unsatisfied users. The results of the current study can be compared to that of previous studies reporting improvements in speech perception with hearing aid verification using REIG (Narayanan & Manjula, 2022; Sporck, 2011) as well as higher satisfaction with REIG fitting procedure (Abrams et al., 2012; Kochkin et al., 2010).

Despite having the trend of better satisfaction scores with REIG matched target, a lack of correlation between REIG and satisfaction scores can be attributed to many factors affecting outcome and limitations of the study. Satisfaction is composite of several factors which include maintenance of the hearing device, fit, comfort, attitude, factors related to the device, issues related to - feedback, psycho-social and duration of hearing aid usage. In this study only real ear measurements are taken into consideration. The detailed method of verification of speech perception with hearing aid like Speech identification scores (SIS) in quiet and noise could not be included in the current study due to difficulty following up the hearing users for re-visits. This measure might overcome the sealing effect of IOI-HA seen in this study.

It can be inferred from the results of the present study that lack of appropriate gain delivery by hearing aid might be one of the factor contributing to the dissatisfaction among many users. Hence it is advisable to evaluate the satisfaction among hearing aid users using a quick questionnaire like IOI –HA and those who are dissatisfied can be referred for REIG procedure for hearing aid fitting verification. Eventually performing REIG measurement as the final step of hearing aid verification for all hearing aid users may be the most desirable transition to evoke better satisfaction, acceptance, and client referral.

5.1. Implications of the Study

1. This study supports the importance of performing REIG measures as routine method of hearing aid fitting verification at least in users with lesser satisfaction.
2. It also guides in applying relevant questionnaires like IOI HA to understand the satisfaction level of hearing aid users and take appropriate measures to address it.
3. This study also recommends to do a regular follow up of hearing aid users to understand the usage and counsel for concerns.

5.2. Future directions

1. Further studies can be taken up by considering all the factors affecting satisfaction as mentioned in this study and to establish a correlation with REIG.
2. Future studies can focus on studying the association between satisfaction and REIG measures in unilateral and bilateral hearing aid users separately.
3. Researchers can expand the current study with large population, different questionnaires assessing various aspects of satisfaction and different levels of hearing aid technologies.

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APPENDIX I

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