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Development of a simple index to predict benefit and satisfaction from amplification

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DEVELOPMENT OF A SIMPLE INDEX TO PREDICT BENEFIT AND SATISFACTION FROM AMPLIFICATION

By

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Abstract: The purpose of this study was to evaluate the use of non-audiological patient-based variables; amount of bother, importance of improved hearing, and expectations, as reliable predictors of benefit and satisfaction from amplification. Study findings were then used to develop two initial prognostic indices.

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TABLE OF CONTENTS

LIST OF TABLES

Introduction

According to Cox (2003) healthcare has become increasingly consumer-driven and focus now needs to be placed on the patient subjective impressions and self-perceived benefit. Consumer information is readily available and patients want to know how a specific treatment will benefit them in the real-world. Third-party payers are putting more emphasis on the value of care, rather than cost alone (Beck, 2000). Today audiologists are expected to demonstrate the efficiency of services in relation to the overall well being of the patient (Beck, 2000). Until recently, Audiology has not placed a high degree of significance on self-report measures to evaluate and direct patient management. Instead, the focus has been predominantly grounded in research and evaluation-oriented methods (Gatehouse, 2001). In the context of a paradigm shift to patient-oriented healthcare however, this is likely to change.

Many of those seeking amplification are of an elderly age. The proportion of older adults is expected to increase dramatically in the coming years (National Center for Health Statistics, 2005). The quickest growing age group will be comprised of individuals 85 years and older and will unquestionably influence the practice of audiology (Kricos, 2006). The challenge to Audiology is to improve it's credibility and visibility within society and ensure audiological services are well utilized. Specifically, justification of positive patient-perceived outcomes through rehabilitative services and use of amplification devices will be paramount.

Documentation of patient-based outcomes using a systematic and reliable approach is currently the standard in healthcare systems. According to Beck (2000), outcome measures are highly valuable for growth in evidence-based practices, development of clinical practice guidelines, and quantification of patient-based outcomes. Beck (2000) proposes there are three important measures to consider if Audiology is to advance: improvement in patient satisfaction, improvement in functional status, and improvement in quality of life. The information gained through such measures is thought to improve planning and treatment of the individual along with overall quality of life (Cox, 2000).

A substantial number of self-report measures, particularly patient satisfaction, have been developed and validated in Aural Rehabilitation. Satisfaction is defined by Wong, L., Hickson, L., and McPherson, B. (2003) as "a pleasurable emotional experience as an outcome of an evaluation of performance" (p.117). Satisfaction is complex with several underlying concepts and influences (Gatehouse, 2001). In regards to amplification, satisfaction is a perception, an emotional experience as a result of performance with a device in relation to expectations. Proponents of self-report measures insist patient satisfaction has a direct effect on patient retention, hence consistent use of such measures in the fitting process is not only recommended, but vital (Cox and Alexander, 1999; Dillion et al., 1999; Kochkin, 2000).

As gathered by the author, the most commonly used measurement in assessing satisfaction for clinical and investigational use with new hearing aid users is the Satisfaction with Amplification in Daily Life (SADL) (Cox and Alexander, 1999). This fifteen item self-administered questionnaire was developed by identifying influential elements of hearing aid satisfaction, analyzing these content areas, and conducting several focus group evaluations (Cox and Alexander, 1999). It was designed as a clinical measure to assess satisfaction from the

patient's point of view. The SADL is brief, typically taking less than ten minutes to complete, and is considered clinically acceptable in the estimation of an "inherently multidimensional variable" (Cox and Alexander, 1999, p.306).

The items on the SADL are written at a seventh-grade reading level and scores are provided in four subscales of hearing aid satisfaction in addition to global satisfaction (Cox and Alexander, 1999). The four subscales are: Positive Effect, Service and Cost, Negative Features, and Personal Image. Positive Effect— positive changes in communication as a result of amplification—is heavily weighted in the calculation of global satisfaction and together with Service and Cost represent nine of the fifteen items (Hosford-Dunn and Halpern, 2001). Negative Features, or problems experienced due to use of the hearing aids, along with Personal Image, which address aesthetic issues, are weighted less (Hostford-Dunn and Halpern, 2001). Patients' responses to each item are obtained using a seven-point Likert Scale ranging from "Not at all" to "Tremendously". An example of an item/statement would be: "How natural is the sound from your hearing aids?" Global Satisfaction is calculated from the mean of all response items. Subscale values are the product of averaged responses of items included in that subscale, which vary as previously noted. All subscales however, contain at least one item that is significantly linked to satisfaction (Hosford-Dunn and Halpern, 2001). To view the complete SADL questionnaire, please refer to Appendix A.

Satisfactory construct and internal validity of the SADL was reported in 2001 by Cox and Alexander through means of cross validation, item refinement, factor structure, and norm comparisons. At that time, interim norms previously suggested by Cox and Alexander (2001) were successfully validated for private-pay individuals in all subscales, except Negative Features. Also, comparisons of SADL scores and other single-item measures of satisfaction

concluded a statistically significant correlation, indicating strong construct validity (Cox and Alexander, 2001).

Benefit is another patient-based outcome that has been widely studied in new hearing aid users. Patient-perceived benefit is an outcome measurement strongly routed in the disability domain (Gatehouse, 2001). Unlike satisfaction, the assessment of patient *benefit* does not account for any emotional or psychological factors the patient has experienced. Rather, benefit focuses solely on improvement of functional communication by the individual (Gatehouse, 2001). From a clinical perspective, there are several advantages to measuring benefit with new hearing aid users. First, it can help the clinician determine whether the patient is obtaining significant benefit, i.e. he/she reports notable improvement with amplification compared to their unaided condition, or, reports more benefit with one aid over another. Second, questionnaires provide an objective approach to quantify benefit and can be systematically used to guide rehabilitation management. As with satisfaction, benefit is a subjective patient-based outcome gaining attention in Audiology (Cox, 1997).

Several outcome measures have been developed to quantify patient benefit from amplification. The Hearing Handicap Inventory for the Elderly (HHIE) (Ventry and Weinstein, 1982), Client-Oriented Scale of Improvement (COSI) (Dillion, James, and Ginis, 1997) and Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox and Alexander, 1995) all focus on the patient's problems, disabilities, and handicaps to some extent.

The APHAB, in particular, has become a staple in patient-based outcomes, with wide levels of application in the clinic and research. The APHAB is a 24-item self-assessment patient inventory designed to quantify the disability of hearing aid users. The complete APHAB can be viewed in Appendix B. Developed from a lengthier 66-item inventory called The Profile of

Hearing Aid Benefit (PHAB) (Cox and Gilmore, 1990), the APHAB takes approximately ten minutes to complete and produces four subscales in addition to an overall score. The four subscales are: Ease of Communication—the difficulty of communicating in favorable conditions (EC), Reverberation—communication in reverberant rooms like banquet halls (RV), Background Noise—communication in settings with levels of background noise (BN), and Aversiveness—the unpleasantness of environmental sounds (AV). Patient responses' follow a seven-point Likert Scale ranging from "Always" to "Never" with different point values assigned to each. The patient completes the 24-item inventory prior to hearing aid fitting to obtain an unaided score and again several weeks later to obtain an aided score. The difference, or benefit, is then calculated for each item subscale. Scoring software allows for individual scores to be viewed graphically along side norm groups for comparison (Cox, 1997).

Evaluation of reliability and critical differences of the APHAB were determined using data from twenty-seven subjects who had previously completed the PHAB (Cox and Alexander, 1995). Test-retest correlation coefficients were found to be consistent with other measures of comparable size and content. Critical differences for APHAB subscales with those correlated to PHAB subscales were relatively large, as expected. When APHAB subscales that quantify positive experiences (EC, RV, and BN) were considered together, the critical differences were smaller. Developers Cox and Alexander (1995) advocate use of the APHAB as a valid and reliable outcome measure in the assessment of hearing aid fittings.

Patient satisfaction with hearing aids as reported in the literature, is moderate. As reported by Kochkin (2005), the 2004 Marke Trak Survey of the US found overall customer satisfaction with new hearing instruments to be 77%. Two earlier studies by Kochkin, (1999; 2000), also using the Marke Trak Survey revealed overall patient satisfaction with hearing aids

was 53-54% (Wong, Hickson, and McPherson, 2003). Similar findings were observed in a number of comparable studies; Kochkin (1996) and Billie et al., (1999) showed more than 66% of both new and experienced hearing aid users were either satisfied or very satisfied with their devices. In 1990, Kochkin surveyed 1128 hearing aid users to find 58%, 23% were neutral, and 20% were dissatisfied.

The literature on patient satisfaction points to a puzzling trend. Despite a significant increase in new hearing aid fittings and notable technology improvements in the last twenty years, patient satisfaction has failed to increase (Killion, 2004). This finding refutes a common belief that technological advances lead to improved patient satisfaction. One reasonable suggestion for this lack of increased hearing aid satisfaction is a continued expansion of hearing aid fitting criteria. Improvements in advanced signal processing, adaptive feedback algorithms, and the development of noise reduction algorithms allow a wider range of hearing loss magnitudes and configurations to benefit from amplification. Comparable advancements however, in the area of objective fitting protocols, verification methods, and outcome would counter this argument.

In 2003, Wong, Hickson, and McPherson reported on 32 studies that investigated general satisfaction among hearing aid users and 19 studies that looked at specific components of satisfaction. The studies identified a number of patient variables related to satisfaction. These variables included; personality, expectations, usage, listening situations, and attitude.

Among these the non-audiological variables, researchers investigated the relationship between self-reported handicap and satisfaction. Stock, Fichtl, and Heller (1997) found no significant correlation between self-perceived unaided disability and satisfaction. Authors also found that an individual's degree of "bother" as a result of a hearing loss had very little

correlation to his or her satisfaction ($r = -0.14$, $p<0.05$). A similar study by Bentler, Niebuhour, Getta, and Anderson (1993) found less then 8% of variance in patient satisfaction scores was accounted for by the scores on the Hearing Performance Inventory (HPI-38) (Lamb, Owens, and Schubert, 1983), a hearing disability handicap measure. Conversely, a study by Hosford-Dunn and Halpern (2001) found that higher ratings of self-perceived hearing handicap did in fact correlate with the Positive Effect and Global SADL scores ($r = 0.25$, $p < 0.005$). The finding was not clinically significant however. As a result, Hosford-Dunn and Halpern (2001) recommended further research using additional variables could lead to the development a clinical prediction index of user satisfaction. In other words, if clinicians were able to reliably predict patient satisfaction and benefit prior to the fitting process it could influence individual recommendations, considerations, and counseling methods (Northern, 2000).

In contrast to studies by Stock et al. (1997) and Bentler et al. (1993), Kochkin (1997) found that self-perceived handicap is inversely related to satisfaction. In this study, individuals who reported less disability were more likely to be satisfied with amplification. Kochkin (1997) attributed these findings to better localization of sounds and improved hearing in difficult listening conditions, such as background noise. Additional evidence to support a relationship between self-perceived handicap and satisfaction is presented by Dillon, Koritschoner, Lovegrove, (1991) who found a correlation between scores on the Hearing Handicap Inventory for the Elderly (HHIE) and overall satisfaction ($r > 0.50$, $p <0.05$). Typically, studies investigating the relationship between self-perceived handicap on satisfaction, whether results reported significant relationships or not, are largely inconsistent across methods and results.

The influence of new hearing aid user's expectations on satisfaction has also been investigated. Research findings from these studies are variable, but in general it has been shown

that high expectations do not guarantee greater ratings of satisfaction (Wong, 2003). In a 1994 study by Gatehouse, patient's expectations were found to account for less than 2% of variance in satisfaction, while Ziecheck (1993) found a significant correlation; 93% of patients with high pre-fitting expectations were "satisfied" compared to 75% of patients with low expectations (Wong, 2003). Norman, George, and McCarthy (1994) examined the effects of subject disability, age, gender, and expectations on satisfaction, and found no relationship between any of these factors. This finding is similar to those of Cox and Alexander (2000), who, in using the SADL as a primary outcome measurement and found the domains of Service and Cost and Personal Image to be unrelated to satisfaction. An unspecified relationship between the psychological and psychoacoustic domains however, was observed. Again, the referenced studies suggest no clear relationship between patient expectation and satisfaction. It was noted, by Wong (2003) that a complex interaction involving additional subject variables in combination with expectation cannot be ruled-out (Wong, 2003).

In 1999, an international group of experts attended The Eriksholm Workshop on "Measuring Outcomes in Audiological Rehabilitation Using Hearing Aids" to examine current issues in outcome measures and determine specific goals for future research and development of such tools (Cox et al., 2000). In addressing research needs, the panel made a recommendation that the relationship between expectations and outcomes, especially satisfaction, be further explored. This was suggested because much is still unknown about the influence of pre-fitting expectations on post-treatment outcomes. The expert panel urged for better delineation of the effects of non-audiological factors like personality, age, and gender in outcome assessments. The studies which had been reported thus far provided some insight into the contribution of non-audiological factors in treatment effectiveness, but lacked any definitive findings relevant for

clinical use. As acknowledged by Humes (2003), the only way to optimize patient outcomes is through large-scale multicenter collaboration examining the influence of patient-based variables on various outcome models. The experts also addressed the value of assessing patient satisfaction using a global question. Experts agreed that a global question, such as "Overall, how satisfied are you with your new hearing aids?" effectively taps into the individuals perception of both quality and value (Cox et al., 2000). Further questioning based on the response to a global question can uncover more detail about the underlying basis for the patient's response (Cox et al., 2000).

Quantification of non-audiological variables, specifically patient-perceived impairment and likelihood that hearing aids will decrease life's problems as a result of hearing loss, were shown to predict patient satisfaction in a 1997 pilot study by the Washington University School of Medicine Clinical Research Outcomes Office (Piccirillo, 1997 unpublished). Using a multivariate analytic technique and a sample size of 150 subjects, Piccirillo (1997) was able to successfully develop a Benefit Prediction Index based on two non-audiological factors; overall "bother" due to hearing loss and likelihood that hearing aids will decrease life's problems as a result of hearing loss. Until this study, no research had been conducted on the simultaneous interaction and relative association between the patient's degree of bother and belief that treatment will improve life's problems on user satisfaction with amplification. To date, there is still no multi-factorial instrument clinically available to reliably predict patient-outcomes prior to fitting of amplification. It should be concluded that further investigation of these non-audiological variables, including use of well established standardized measures, current digital hearing aid technology, and a larger sample size, will provide the statistical data necessary to develop a reliable composite prognostic index to predict hearing aid satisfaction.

Purpose

The current study investigated the use of non-audiological variables as reliable predictors of patient benefit and satisfaction from amplification. Variables of interest were expanded from the Piccirillo (1997) study to include: degree of patient-perceived impairment, importance of improved hearing, and expectations of improved performance with the hearing aids. This prognostic research may help lead to improved methods of identifying individuals who are likely to obtain benefit and satisfaction from amplification.

The specific aim of the current study is:

1. To determine if non-audiological variables: patient-perceived impairment, importance of improved hearing, and belief that amplification will improve hearing, can reliably predict patient benefit and satisfaction from amplification.

   Hypothesis: Non-audiological variables can be combined to form a composite prognostic index to predict patient satisfaction and benefit from amplification.

This study aims to give clinicians and researchers a better understanding of how these variables interact with one another to generate a specific outcome. Overtime, this could improve patient benefit and satisfaction.

Methodology and Design

The current study employed a prospective, observational design. Subject variables and treatment outcomes were observed without intervention in effort to gain a better understanding

of how they occur naturally. The population consisted of 11 community-based subjects with presbycusis who had not previously worn hearing aids. Study participants were recruited from the Division of Adult Audiology at Washington University in St. Louis School at three locations within St. Louis, MO. IRB approval for this study was obtained in November 2008 through the Human Research Protection Office (HRPO) at Washington University School of Medicine, St. Louis, MO. Individuals who met the outlined inclusion criteria were identified by an audiologist at their scheduled hearing aid evaluation (HAE) and were asked permission to be contacted by the primary investigator (PI) regarding participation in a student research study.

Inclusion Criteria

Eligible subjects for the current study were male and female, between ages 50 and 85 years. Each participant needed a current audiogram (within the last six months) consistent with symmetrical presbycusis. For purposes of this study, presbycusis was defined as sensorineural hearing loss with pure tone average (PTA)—average hearing threshold at 500, 1000, and 2000 Hz— between 25 dB HL and 70 dB HL. Subjects had no prior experience with amplification and were seeking bilateral amplification.

Exclusion Criteria

Subjects whose hearing loss was not consistent with presbycusis were not eligible for the study. Subjects with an asymmetrical hearing loss—defined as a 15 dB or greater difference in thresholds between ears at more than one frequency between 500-4000 Hz were not eligible. Additionally, subjects who exhibited a mean air-bone gap exceeding 10 dB at 500 to 3000 Hz in either ear did not qualify. Those displaying asymmetries in speech discrimination scores of

greater than 20% were also excluded. Subjects with a history of middle ear surgery or middle ear pathology within the last five years were not included in the study. Ineligibility occurred if there was a documented or confirmed diagnosis of dynamic cochlear pathology such as Meniere's disease, sudden hearing loss, perilymphatic fistula, or superior semicircular canal dehiscence (SSCD). The focus of the current study was aimed toward bilateral users of amplification and persons seeking monaural amplification were not eligible to participate.

When contacted by the PI, the subject was briefed on the study protocol and asked if he/she would like to participate (See Appendix C for phone script). If the subject consented to participate, the initial questionnaire packet was mailed within one to two business days. The initial packet included a letter summarizing the study (See Appendix D), and unaided APHAB questionnaire. Additional questions to determine patient-perceived impairment, importance of improved hearing, and expectations of improved hearing as a result of pursuing hearing aids were added to the end of the APHAB (See Appendix B). The returned completion of the initial packet represented implied consent by the subject to participate in the study.

The second outcome packet was mailed out four weeks following the participant's initial hearing aid fitting to allow acclimatization. The second packet included the SADL, aided-APHAB, and a global question related to overall satisfaction at the end of the SADL (See Appendix A). With each packet, the participant was provided a postage paid envelope with instructions on how and when to return completed materials. The return mailing of the second questionnaire packet represented the final contribution by the subject.

The primary outcome measure to assess patient satisfaction were individual SADL scores ranging from 1-7 with 1 being least satisfied and 7 being most satisfied. The primary measure

used to quantify benefit were individual benefit scores on the APHAB ranging from -100% to 100% benefit. The three non-audiological patient-based predicative variables; patient-perceived impairment (amount of bother), importance of improved hearing, and expectations for improved hearing with amplification were determined using the following ascending 5-point Likert Scale: 1—not bothered, not important, and no expectations of improvement; 2—bothered a little but not much, slightly important, and very slight expectations of improvement; 3—bothered more than a little, moderately important, and slight expectations of improvement; 4—bothered a lot, very important, and moderate expectations of improvement; and 5—extremely bothered, extremely important, and great expectations for improvement.

Initial inspection and descriptive statistics of study data provided a quantitative summary of participant responses. Cross tabulation matrices were used to identify those baseline patient-based non-audiologic variables that were predictive of satisfaction and benefit. Observed data trends and correlations were used to develop two initial prognostic indices to predict patient satisfaction and benefit from amplification.

Results

A moderate range of responses were observed in subject answers to questions evaluating the three non-audiological patient-based variables. Prior to being fit with amplification, subject ratings of bother due to hearing loss ranged from *bothered a little, but not much* to *extremely bothered.* Subject responses to the question addressing expectations of improved hearing from amplification ranged from expecting *slight improvement* to expecting *great improvement.* Responses to the importance of improved hearing ranged from *moderate* to *extreme*. Outcome questionnaires, i.e. the SADL and APHAB produced a wide range of scores across the 11

subjects. This Satisfaction (SADL) scores ranged between 4.0 and 6.5 with a mean of 5.4, while Benefit (APHAB) scores were between 0.10-68.9% with a mean of 27%. A summary of response variation in predictive variable and outcome measures is provided in Table 1. Note that one subject did not answer the "importance" question; therefore an *n* of 10 was used for that variable. In reviewing SADL and APHAB questionnaires for credible and accurate completion, participant number four's APHAB score of 0.10% was suspicious. In addition to being the lowest APHAB score in the sample, subjectively, it was inconsistent with his above average SADL score of 5.8. In addition, the subject's audiologist documented the patient as reporting good benefit and being overall satisfied with the hearing aids at subsequent follow-up appointments. Due to this ambiguity, subject four's APHAB score was excluded from further multivariable analysis in the current study.

Table 1. Response variation in predictive variables and measures of satisfaction (SADL) and benefit (APHAB) for the 11 subjects.

Measure	Mean	Std. Deviation	N	Range
Amount of Bother due to hearing loss	3.91	1.04	11	2-5
Importance of Improved Hearing	4.2	0.6	*10	3-5
Expectations of Improved Hearing	4.36	0.64	11	3-5
Satisfaction (SADL)	5.38	0.69	11	4.0-6.5
Benefit (APHAB)	27%	20.4%	11	0.10-68.9%

*Only 10 subjects responded to the question assessing *importance* of improved hearing.

Visual inspection of cross tabulation tables of predictive factors and benefit scores produced the following data trends. Subjects who reported it was *extremely important* to improve their hearing had higher benefit scores (mean=40.8%, N=3) than those reporting a degree of *very important* (mean=20.6%, N=6). The only subject to report a *moderate* degree of importance produced the lowest benefit score, 11%. The same trend was observed in the amount of bother patients reported in relation to benefit. *Extremely* bothered subjects produced a mean score of 45% (N=4), subjects *bothered a lot* had a mean score of 27% (N=3), and *bothered more a little, but not a lot* subjects produced a mean of 25% (N=3). In examining the predictive value of expectations, subjects reporting *slight* or *moderate* expectations had an average score of 18.4% (N=6), while those reporting *great* expectations had a higher mean score of 41% (N=5).

Patterns in data were also noted through cross tabulation of SADL scores and predictive variables. Subjects reporting *extreme* and *very* ratings of importance had a mean SADL of 5.4 (N=9) which was greater than the one subject who rating the importance of improved hearing as *moderate*, scoring 4.0. As reported amount of bother from hearing loss increased from *little* to *extremely* subject's scores also increased. The *extremely* bothered subjects produced a mean SADL score of 5.8 (N=4), subjects bothered *a lot* had a mean of 5.2 (N=3), the bothered *more than a little, but not a lot* group averaged 5.3 (N=3), and the single subject reporting *little* bother scored 4.0. Finally, a positive relationship was noted between level of expectations and SADL

scores. Subjects with *great* expectations produced a mean SADL of 5.9 (N=5), subjects with *moderate* expectations had a mean of 5.0 (N=5), and the single subject indicating *slight* expectations scored 5.4.

Due to small sample size of the current study, bivariate analytic techniques to identify significant associations between predictive variables and outcomes of satisfaction and benefit could not be performed with high validity. Through observation of data trends however, an undefined relationship between the predictive variables, i.e. perceived impairment, importance of improved hearing and expectations, and outcome measures of benefit and satisfaction as measured by the APHAB and SADL is clear.

Table 2. Mean APHAB and SADL Scores as a Function of Rating of Bother and Expectation of Improved Hearing. (SADL scores indicated in parenthesis)

	Expectation of improved hearing						
Amount of bother due to hearing loss	No Improvement	Very slight improvement	Slight improvement	Moderate improvement	Great improvement	Total	N
Not bothered							
Bothered a little				11% (4)		11% (4)	1
Bothered more than a little, but not a lot			23% (4.5)	26.5% (5.35)		25% (5)	3
Bothered a lot				5% (5.2)	26% (5.5)	16% (5.35)	3 *2
Extremely bothered					45% (5.8)	45% (5.8)	4
Total			23% (4.5)	14% (4.85)	35.5% (5.65)		
N			1	5 *4	5		

A process known as Conjunctive Consolidation (Feinstein, 1996) allows for substantive, non-automated judgments, of the simultaneous effect of two or more variables. This multivariable analytic technique is useful when predictive variables demonstrate a non-linear or interactive effect, as the current study hopes to unveil (Piccirillo, 1997). Average benefit (APHAB) and satisfaction (SADL) scores in each conjoined amount of bother and expectations of improved hearing cell are illustrated in Table 2. As demonstrated, subjects who reported high expectations of improvement from amplification and who were most bothered by their hearing loss had higher APHAB and SADL scores than subjects with fewer expectations and who were bothered less by their hearing loss.

Table 3 is a similar division of the data except APHAB and SADL scores are shown as a function of the predictive variables bother and importance of improved hearing. Data indicates those who reported a higher level of importance for improved hearing and more bother due to a hearing loss averaged higher APHAB and SADL scores than those who reported less importance in improved hearing and bother from a hearing loss. A single deviation, a reversal, in this trend is noted between the mean APHAB and SADL scores of subjects who reported *little bother* and subjects reporting *more than a little bother, but not a lot*. This is likely the result of limited sample size.

***Indicates sample size used to calculate mean APHAB score.**

Table 3. Mean APHAB and SADL Scores as a Function of Rating of Bother and Importance of Improved Hearing. (SADL scores indicated in parenthesis)

	Importance of improved hearing						
Amount of bother due to hearing loss	Not important	Slightly important	Moderately important	Very important	Extremely important	Total	N
Not bothered							
Bothered a little			11% (4)			11% (4)	1
Bothered more than a little, but not a lot			23% (5.4)	26.5% (5.35)		24.8% (5.4)	3
Bothered a lot				26% (5.65)	5% (4.5)	16% (5.0)	3 *2
Extremely bothered				23% (5)	59% (5.9)	41% (5.45)	3
Total			17% (4.7)	25% (5.35)	32% (5.2)		
N			2	5 *4	3		

***Indicates sample size used to calculate mean APHAB**

Based on the observed data trends and in an effort to decrease the number of conjoined cells, consolidation was performed and an Initial Three-category Benefit Predication Index was created (Table 4). As shown, subjects are assigned to one of three different benefit groups based on their response to the two predictive questions. For example, a subject reporting extreme bother and great expectations for improved hearing falls into Group III and is predicted to receive more benefit than those in Group I and Group II. The mean benefit scores for each group are indicated along with sample size on the right key (Table 4).

Table 4. Creation of Initial Three-Category Benefit Prediction Index Based on Rating of Bother and Expectation of Improved Hearing.

	Expectations of improved hearing		
Amount of bother due to hearing loss	Slight improvement	Moderate improvement	Great improvement
Bothered a little		11%	
Bothered more than a little, but not a lot	23%	26%	
Bothered a lot		5%	26%
Extremely bothered			45%

Benefit Group	**Shading**	**Mean APHAB Score**
I		11% N=1
II		18% N=4
III		36% N=5

To determine if the third predictive variable of interest, importance of improved hearing, provided an additional predictive element, the variation in APHAB and SADL scores within categories of expectations based on ratings of importance were reviewed (Table 5). As predicted, no observable or reliable variation of APHAB and SADL scores within categories of expectation based on *importance* were noted. Thus, the variable of *importance* was left out of the index, as it did not provide an additional predictive element. With a sufficient sample size of 175 subjects this finding would suggest similar underlying constructs exists between the two variables. The limited sample size in the current study however, prohibits this conclusion and only yields speculation.

Table 5. APHAB and SADL score variation within categories of expectation based on rating of importance.

	Importance of improved hearing		
Expectations	Moderate	Very	Extremely
Slight	23% (5.4)		
Moderate	11% (4)	26% (5.5)	5% (4.5)
Great		24.5% (5.3)	59% (5.9)

Table 5. Variations are speculative due to limited sample size.

Table 6. Creation of Initial Two-Category Satisfaction Prediction Index Based on Rating of Bother and Expectation of Improved Hearing.

	Expectation of improved hearing		
Amount of bother due to hearing loss	Slight improvement	Moderate improvement	Great improvement
Bothered a little		4	
Bothered more than a little, but not a lot	4.5	5.4	
Bothered a lot		5.2	5.5
Extremely bothered			5.8

Satisfaction Group	**Shading**	**Mean SADL Score**
I		4.8 N=6
II		5.7 N=5

Cell consolidation was also performed in the development an Initial Two-Category Satisfaction Prediction Index, as viewed in Table 6. Group I has a lower mean SADL score of 4.8 compared to Group II's mean score of 5.7. It is hypothesized that with a larger sample (N=175) and through the process of multivariable Conjunctive Consolidation, that benefit and satisfaction, as measured by the APHAB and SADL, would be statistically significantly associated with the resultant prediction index.

Discussion

The current study reports markedly distinct data trends through the investigation of non-audiological variables as reliable predictive factors of benefit and satisfaction using a very small number of subjects (N=11). Initial Benefit and Satisfaction Prediction Indices were configured based on data observation and descriptive statistics. Due to small sample size, data for each cell combination could not be obtained, thus complete and reliable interpretation was not possible. It is important to note that while the indices predict different amounts of benefit and satisfaction based on predictive factors, these differences can not be assumed clinically meaningful. For this, additional research must demonstrate that values associated with each benefit and satisfaction group are clinically distinct.

Although not statistically significant, data trends in the current study are similar to those observed by Piccirillo (1997) which examined the use of amount of bother and belief that hearing aids will decrease life's problems as a result of hearing loss variables as reliable predictors of benefit. In addition to Piccirillo (1997), the current study expanded the scope of investigation to include the outcome measure of satisfaction. Findings suggest satisfaction is

subject to similar interactional consequences of predictive variables *amount of bother, expectations, and importance in improved hearing*.

Results of the multivariable analysis were not of sufficient statistical power to effectively confirm or reject findings from previous studies that have examined the association of perceived handicap (bother) and expectations on outcome measures. Data trends do, however, support previous work that concludes some degree of interactional relationship between non-audiological patient-based variables and outcomes of satisfaction and benefit (Hosford-Dunn and Halpern, 2001; Kochkin 1997; Dillon, Koritschoner, Lovegrove, 1991; and Ziecheck, 1993).

The most notable limitation of the current study was a small sample pool. A sample of 175 subjects would have provided the statistical power necessary to perform multivariate analysis on the predictive variables and evaluate statistical significance of benefit and satisfaction with the resulting prediction indices.

Other limitations of the current study were seen in the aspects of the study design and recruitment methods. A patient's candidacy in terms of meeting audiological criteria was determined by her/his audiologist during his/her HAE. Medical records to confirm the subject met inclusion criteria were not available. This protocol left room for error in candidacy determination and may have resulted in inclusion of subjects not meeting criteria and exclusion of subjects meeting criteria.

Limitations in recruited subjects suggest candidacy criteria for inclusion may have been too narrow. Audiologists who participated in the recruitment process reported many instances where patients did not qualify due to an asymmetrical hearing loss, a significant conductive component, or previous use with amplification. Careful expansion of the study inclusion criteria

may have facilitated more patient inclusion without sacrificing good generalizability for the intended population.

Future research investigating predictive reliability of non-audiological variables on outcome measures of benefit and satisfaction should consider using a multi-site design. A moderate-sized sample of 175 subjects from various graphical and demographical backgrounds would better represent the diverse population experiencing presbycusis. A multi-site study would need to be carefully designed; most specifically, the various diagnostic tests and fitting procedures used by different audiologists/centers would need to be controlled. Finally, a simplified candidacy checklist completed by both the audiologist and patient would be helpful. This checklist could be kept with the patients study file and confirmed with him or her on the phone by a study member.

Conclusions

It is generally understood that hearing aid outcome measures, satisfaction and benefit, provide valuable information that assists audiologists in giving excellent patient care. Unfortunately, the literature indicates satisfaction with hearing aids is moderate. That fact, paired with an inevitable move towards a patient-focused health care system, underscores the emergent need for researchers and clinicians to better understand and predict patient outcomes. In the current study, non-audiological patient-based variables: patient-perceived bother, importance of improved hearing, and belief that amplification will improve hearing appear to provide a predictive value to outcomes of satisfaction and benefit as measured by the SADL and APHAB, however no predictive factors were deemed statistically significant. Further definition of these associations, discovery of the others, and exploration into how they interact with one

another to generate a specific outcome will help clinicians predict patient satisfaction and benefit prior to being fit.

The current study developed two initial prognostic indices to predict patient satisfaction and benefit from amplification. A very small sample size, however, limited the statistical basis on which it was developed and therefore does not warrant its use clinically. In conclusion, use of a simple, clinically applicable, prognostic index in predicting satisfaction and benefit would be an ideal tool for audiologists and over time could increase patient satisfaction and benefit from amplification.

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SATISFACTION WITH AMPLIFICATION IN DAILY LIFE

Instructions:
Listed below are questions on your opinions about your hearing aids. For each question, please circle the letter that is the best answer for you. The list of words on the right gives you the meaning for each letter.

A	**Not At All**
B	**A Little**
C	**Somewhat**
D	**Medium**
E	**Considerably**
F	**Greatly**
G	**Tremendously**

1. Compared to using no hearing aid at all, do your hearing aids help you understand the people you speak with most frequently?	A B C D E F G
2. Are you frustrated when your hearing aids pick up sounds that keep you from hearing what you want to hear?	A B C D E F G
3. Are you convinced that obtaining your hearing aids was in your best interest?	A B C D E F G
4. Do you think people notice your hearing loss more when you wear your hearing aids?	A B C D E F G
5. Do your hearing aids reduce the number of times you have to ask people to repeat?	A B C D E F G
6. Do you think your hearing aids are worth the trouble?	A B C D E F G
7. Are you bothered by the inability to get enough loudness from your hearing aids without feedback (whistling)?	A B C D E F G
8. How content are you with the appearance of your hearing aids?	A B C D E F G
9. Does wearing your hearing aids improve your self-confidence?	A B C D E F G
10. How natural is the sound from your hearing aids?	A B C D E F G
11. How helpful are your hearing aids on MOST telephones with NO amplifier or loudspeaker? **If you hear well on the telephone without hearing aids, please check here [ ]	A B C D E F G

A	Not At All
B	A Little
C	Somewhat
D	Medium
E	Considerably
F	Greatly
G	Tremendously

12. How competent was the person who provided you with your hearing aids?	A B C D E F G
13. Do you think wearing your hearing aids makes you seem less capable?	A B C D E F G
14. Does the cost of your hearing aids seem reasonable to you?	A B C D E F G
15. How pleased are you with the dependability (how often they need repairs) of your hearing aids?	A B C D E F G

Please Answer the Following Questions:

1. How often do you wear your hearing aids? (circle one)

   a. None
   b. Less than 1 hour per day
   c. 1-4 hours per day
   d. 4-8 hours per day
   e. 8-16 hours per day

2. Overall, how satisfied are you with your hearing aids? (circle one)

   a. Extremely Satisfied
   b. Very Satisfied
   c. Moderately Satisfied
   d. Slightly Satisfied
   e. Not Satisfied at All

X_____ **DATE** _____

Participants Signature

ABBREVIATED PROFILE OF HEARING AID BENEFIT

Instructions:
Please circle the answers that come closest to your everyday experience. Notice that each choice includes a percentage. You can use this to help you decide on your answer. For example, if the statement is true about 75% of the time, circle C for that item.

If you have not experienced the situation we described, try to think of a similar situation that you have been in and respond for that situation. If you have no idea, leave the item blank.

Notice that for some items, an answer of Always (99%) means you have few problems. Other items are written so that an answer of Always (99%) means you have a lot of problems. Here is an example. In item (a), an answer of Always (99%) means that you usually have problems. In item (b), the same answer means that you only have problems once in a while.
****NOTE** Only select answers in the *"Without Hearing Aids"* column if you have not been fitted with hearing aids.**

A	**Always (99%)**
B	**Almost Always (87%)**
C	**Generally (75%)**
D	**Half-the-time (50%)**
E	**Occasionally (25%)**
F	**Seldom (12%)**
G	**Never (1%)**

EXAMPLE

	Without Hearing Aids	With Hearing Aids
a. When I'm talking with a friend outdoors on a windy day, *I miss a lot of the conversation.*	A B C D E F G	A B C D E F G
b. When I am in a meeting with several other people, *I can comprehend speech.*	A B C D E F G	A B C D E F G

QUESTIONS BEGIN ON NEXT PAGE

A	Always (99%)
B	Almost Always (87%)
C	Generally (75%)
D	Half-the-time (50%)
E	Occasionally (25%)
F	Seldom (12%)
G	Never (1%)

	Without Hearing Aids	With Hearing Aids
1. When I am in a crowded grocery store with the cashier, I can follow the conversation.	A B C D E F G	A B C D E F G
2. I miss a lot of information when I am listening to a lecture.	A B C D E F G	A B C D E F G
3. Unexpected sounds, like a smoke detector or alarm bell are uncomfortable.	A B C D E F G	A B C D E F G
4. I have difficulty hearing a conversation when I am with one of my family members at home.	A B C D E F G	A B C D E F G
5. I have trouble understanding dialogue in a movie or at the theatre.	A B C D E F G	A B C D E F G
6. When I am listening to the news on the car radio, and family members are talking, I have trouble hearing the news.	A B C D E F G	A B C D E F G
7. When I am at the dinner table with several people, and I am trying to have a conversation with one person, understanding speech is difficult.	A B C D E F G	A B C D E F G
8. Traffic noises are too loud.	A B C D E F G	A B C D E F G
9. When I am talking with someone across a large empty room, I understand the words.	A B C D E F G	A B C D E F G

A	Always (99%)
B	Almost Always (87%)
C	Generally (75%)
D	Half-the-time (50%)
E	Occasionally (25%)
F	Seldom (12%)
G	Never (1%)

	Without Hearing Aids	With Hearing Aids
10. When I am in a small office, interviewing or answering questions, I have difficulty following the conversation.	A B C D E F G	A B C D E F G
11. When I am in a theater watching a movie or play, and the people around me are whispering and rustling paper wrappers, I can still make out the dialogue.	A B C D E F G	A B C D E F G
12. When I am having a quiet conversation with a friend, I have difficulty understanding.	A B C D E F G	A B C D E F G
13. The sounds of running water, such as a toilet or shower, are uncomfortably loud.	A B C D E F G	A B C D E F G
14. When a speaker is addressing a small group, and everyone is listening quietly, I have to strain to understand.	A B C D E F G	A B C D E F G
15. When I am in a quiet conversation with my doctor in an examination room, it is hard to follow the conversation.	A B C D E F G	A B C D E F G
16. I can understand conversations even when several people are talking.	A B C D E F G	A B C D E F G
17. The sounds of construction work are uncomfortably loud.	A B C D E F G	A B C D E F G

A	Always (99%)
B	Almost Always (87%)
C	Generally (75%)
D	Half-the-time (50%)
E	Occasionally (25%)
F	Seldom (12%)
G	Never (1%)

	Without Hearing Aids	With Hearing Aids
18. It's hard for me to understand what is being said at lectures or church services.	A B C D E F G	A B C D E F G
19. I can communicate with others when we are in a crowd.	A B C D E F G	A B C D E F G
20. The sound of a fire engine siren close by is so loud that I need to cover my ears.	A B C D E F G	A B C D E F G
21. I can follow the words of a sermon when I am listening to a religious service.	A B C D E F G	A B C D E F G
22. The sound of screeching tires is uncomfortably loud.	A B C D E F G	A B C D E F G
23. I have to ask people to repeat themselves in one-on-one conversation in a quiet room.	A B C D E F G	A B C D E F G
24. I have trouble understanding others when an air conditioner or fan is on.	A B C D E F G	A B C D E F G

Please Answer the Following Questions:

1. How important is it for you to hear better? (circle one answer)
   a. Extremely Important
   b. Very Important
   c. Moderately Important
   d. Slightly Important
   e. Not Important at All

2. How bothered are you by your hearing loss? (circle one answer)
   a. Extremely bothered
   b. Bothered a lot but not extremely
   c. Bothered more than a little but not a lot
   d. Bothered a little but not much
   e. Not bothered at all

3. How motivated are you to wear and use hearing aids? (circle one answer)
   a. Extremely Motivated
   b. Very Motivated
   c. Moderately Motivated
   d. Slightly motivated
   e. Not very Motivated

4. How well do you think hearing aids will improve your hearing? (circle one answer)

I expect them to:
   a. Greatly improve my hearing
   b. Moderately improve my hearing
   c. Slightly improve my hearing
   d. Very slightly improve my hearing
   e. Not Improve my hearing

5. What is your most important consideration regarding hearing aids? Rank order the following factors with **1** as the most important and **4** as the least important. Place an **0** on the line if the item has no importance to you at all. You must select one consideration as the most important.
If you wish, indicate another consideration (one not mentioned) and rank order them 1 thru 5.

____ Hearing aid size and ability of others not to see the hearing aids

____ Improved ability to hear and understand speech

____ Improved ability to understand speech in noisy situations (e.g., restaurants, parties)

____ Cost of hearing aids

____ (Other) Please Indicate: _____

X_____ **DATE** _____
Participants Signature

Appendix C

Phone script:

Hello, this is Katie Niehl. I am an audiology graduate student at Washington University School of Medicine. I believe you were recently seen (date of hearing aid evaluation) for a hearing aid evaluation at (location). Your audiologist asked if I could contact you to talk about a hearing aid study that I'm conducting. Do you have a minute for me to explain what the study is and what it would it will require of you, if you choose to participate? It should be brief.

This study is looking at the benefit and satisfaction new hearing aid users achieve after several weeks of wearing their new hearing aids. To do this, I need to get some information regarding how you feel about your hearing loss and how much help you think the hearing aid will provide. Then, after you've worn the hearing aids for several weeks I need to measure your benefit and satisfaction. The good thing about this is that I can get all this information by having you, and other study participants, complete a few short questionnaires. One would be sent out today for you to complete and another one in 3-4 weeks after you've been fit with hearing aids. If you would like to participate I would send you the first questionnaire as well as a letter explaining more about the study and your rights as a participant. There will be clear instructions on how to complete the questionnaire as well as a pre-paid postage envelope for you to mail it back in. Mr/Mrs. _____, do you think you would like to participate in this study?

Let me give you my personal number in case you have any questions about completing your questionnaires (my number #). I will be sending the study materials to you directly, so let me confirm the address you provided (confirm address).

I will be sending out the study materials today, and you should receive them within a few days. Because the first questionnaire needs to be completed before your hearing aid fit please open, fill out, and mail the questionnaire as soon as possible.

Mr./Mrs. _____, thank you for taking time to participate in this study. Again, please feel free to call me with any questions, but hopefully I've designed everything to be straight forward.

Have a wonderful day.

Appendix D

Washington University in St.Louis

Date _____

Mr./Mrs. _____,

You are being invited to participate in a research study focused on the experiences of new hearing aid users. This study is being conducted by Katie Niehl a 3rd year clinical doctorate student at Washington University in St. Louis School of Medicine. Her mentor for this study is Jay Piccirillo M.D. an Ear Nose and Throat Doctor and Director of the Clinical Research Outcomes Office at Washington University School of Medicine.

What is this study about?

This study aims to identify characteristics, in addition to the individual's degree of hearing loss, that reliably predict the amount of benefit and satisfaction he/she will experience with their hearing aids. In the future, this information will help audiologists tailor counseling to the individuals needs.

What I'm being asked to do?

To participate in this study you are being asked to complete two short questionnaires. The first questionnaire, which you should have received in today's packet, needs to be completed ***before*** your hearing aid fitting and promptly mailed back using the pre-paid postage envelope. This first questionnaire is expected to take less than 20 minutes to complete. Four weeks after your hearing aid fitting you will be mailed a second questionnaire, which you will be asked to complete and mail back. We expect this second questionnaire to take 20-30 minutes to complete. Once we have received the second questionnaire your participation is complete.

What about confidentiality?

In effort to maximize your confidentially the research team will only use and share your information as talked about in this letter. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this letter.

What if I have questions?

If you have any questions about how to complete the questionnaires please contact Katie Niehl (314) 362-7511. If you have concerns, or complaints about the study, or feel that you are injured because of the study please call Katie Niehl at (314) 362-7511 or Dr. Piccirillo at (314) 362-8641. If you wish to talk to someone else, or have questions or concerns about you rights as a research subject, all Dr. Philip Ludbrook, Chairman of the University's Human Research Protection Office, at (314) 633-7400 or (800) 438-0445.

Taking part in this research study is voluntary. You may choose not to take part in this research study or you may withdraw your consent at any time. Your choice will not at any time affect the commitment of your care providers to administer care. There will be no penalty or loss of benefits to which you are otherwise entitled.

Thank you for participating in hearing aid research at the Washington University School of Medicine.

Katie Niehl, B.S.
Principle Investigator

Jay Piccirillo, M.D.
Faculty Sponsor