Introduction

As indicated in Chapter 2, estimates indicate that over 29 million individuals in the U.S. exhibit some degree of sensorineural hearing loss (SNHL) (NIDCD, 2001). It is well accepted that the major sequela of SNHL is communicative difficulty, particularly in noisy or reverberant listening environments (Crandell, 1991, Crandell and Smallino, 2000, 2001; Dubno, Dirks, and Morgan, 1984; Killion, 1997; Moore, 1997; Nabalek and Mason, 1981; Plomp, 1986; Suter, 1985). Due to the deleterious effects of SNHL on communication, research has also indicated that individuals with hearing impairment can exhibit reduced psychosocial function, such as increased feelings of isolation, depression, loneliness, anger, fear, frustration, and disappointment (Bess, Lichtenstein, Logan and Burger, 1989; Bess, Lichtenstein and Logan, 1991; Christian, Dhuhy and O'Neill, 1989; Crandell, 1998; Hetu, Lalonde and Getty, 1987).

In addition to, and perhaps the direct result of, reduced psychosocial functioning, hearing impairment has also been shown to be related to an individual's degree of physical, or functional, health status (Bess et al., 1989; Crandell, 1998; Mulrow, Christine, Endicott, Tuley, Velez, Charlip, Rhodes, Hill, and Deniro, 1990). Specifically, a review of the literature suggests that persons with SNHL tend to exhibit a higher incidence of health-related difficulties, including hypertension, ischemic heart disease, arrhythmias, and osteoarthritis. In addition, hearing loss has been shown to be related to reductions in activity level, physical mobility, and overall quality of life (Bess et al., 1989; Crandell, 1998; Mulrow et al., 1990). For example, Mulrow et al. (1990) examined the relationship between quality of life measures and hearing impairment. Results indicated that hearing loss was significantly related to reduced quality of life in listeners with SNHL, particularly in emotional and social areas. Bess et al. (1989) reported that elderly listeners with reduced hearing sensitivity exhibited a significantly higher degree of health-related difficulties, such as hypertension and arthritic conditions. Moreover, the greater degree of hearing impairment, the more pronounced the health-related difficulty.

Despite the relationship between SNHL and reductions in psychosocial and functional health, few investigations have attempted to examine the effects of hearing aid utilization on improving these areas (Dye and Peak, 1983; Mulrow et al., 1990). This paucity of literature is surprising as it is well recognized that correctly fitted hearing aids can significantly improve the communicative deficits of individuals with SNHL. Thus, it is reasonable to assume that if communication function is improved, the adverse psychosocial and functional health effects of reduced communication could be minimized. To support this assumption, Dye and Peak (1983) reported that after only six weeks of utilizing amplification, persons with SNHL showed improvements in various areas of psychological function, such as depression and isolation. Mulrow et al. (1990) indicated a significant improvement in social, cognitive, emotional, and depression measures in individuals four months after utilizing amplification.

Crandell (1998) reported that the utilization of hearing aids could also improve functional health status. In this study, 20 elderly individuals with mild to severe SNHL were evaluated via the Sickness Impact Profile (SIP) (Gibson, Gibson, Bergner, 1975)
and the Medical Outcomes Short Form-36 (SF-36) (Ware and Sherbourne, 1992). Questionnaires were administered at pre-fitting, 3-months post-fitting, and 6-months post-fitting. After three months of hearing aid utilization, statistically significant improvements in functional health status were noted via the SIP. These functional health improvements remained stable 6 months after the initial fitting. Although not statistically significant, slight improvements in the SF-36 were also noted with the use of hearing aids. Moreover, in a survey of 2069 individuals with hearing loss (and 1710 family members), Kochkin and Rogin (2000) reported that hearing aid users were more likely to report higher emotional, mental, social, and physical health status than non-hearing aid users.

At present, however, it remains unclear whether such benefits in functional health status would be seen with other forms of amplification technology, such as Frequency Modulation (FM) systems. Such research seems reasonable as numerous investigators have demonstrated that FM technologies can significantly augment the listening environment for listeners with SNHL (Crandell and Smaldino, 2000, 2001, Crandell, Smaldino, and Flexer, 1995; Hawkins, 1984; Fabry, 1994; Pittman Lewis, Hoover, and Stelmachowicz, 1999). Certainly, such information is important to obtain as audiologists and/or hearing aid companies attempt to have healthcare agencies incorporate advanced levels of hearing aid technology into patient provision plans. At present, it is logical to assume that if healthcare agencies decide to provide amplification as part of a comprehensive medical plan, they would select the amplification system which offers the lowest cost (and presumably the lowest technological advances) with little regard to communicative, psychosocial, and/or functional health improvements.

With these considerations in mind, the purpose of this investigation was to examine the effects of utilizing hearing aids in conjunction with FM technology on functional health function. Functional health-related disorders were evaluated via the SF – 36 Health Survey. Subjects consisted of 46 individuals with mild-to-moderate SNHL. All subjects were fit with digital Phonak Claro 311 dAZ behind-the-ear (BTE) hearing aids and Phonak Microlink ML8 FM receivers bilaterally. All subjects were randomly fit with the Phonak amplification systems in one of the following conditions: (1) Phonak 311 dAZ BTE hearing aids only or (2) Phonak 311 dAZ BTE hearing aids used in conjunction with the Phonak Microlink FM system. Twenty-three of the subjects began the study in the hearing aids alone condition, while the remaining twenty-three subjects utilized the hearing aids in conjunction with the FM system. This investigation had a crossover design, in which at the end of three months the subjects switched experimental conditions. To control for hearing aid size effects, the FM modules remained attached to the BTE hearing aids in both conditions. The SF-36 was administered at seven different occasions: (1) pre-fitting; (2) 1 month post-fitting in the first experimental condition; (3) 2 months post-fitting in the first experimental condition; (4) 3 months post-fitting in the first experimental condition; (5) 1 month post-fitting in the second experimental condition; (6) 2 months post-fitting in the second experimental condition and (7) 3 months post-fitting in the second experimental condition.

Methods

Subjects

Subjects were recruited from the audiology clinics at two sites. Site I was the University of Florida in Gainesville, Florida and Site II was Washington University School of Medicine in St. Louis, Missouri. At Site I, twenty-three subjects were evaluated, of which 16 (70%) were male and seven (30%) were female. These subjects ranged in age from 24 to 84 years, with a median age of 73 years. At Site II, twenty-three subjects were evaluated, of which 13 (57%) were male and 10 (43%) were female. These subjects ranged in age from 34 to 81 years, with a median age of 73 years. A one-way ANOVA revealed that there was no statistically significant difference between the two sites in terms of age (p = 0.945).

Pure-tone air-conduction and bone-conduction thresholds were obtained bilaterally. Test results revealed mean pure-tone thresholds consistent with a mild sloping to severe SNHL bilaterally and a moderate sloping to severe SNHL bilaterally at Sites I and II respectively (see figures 1 and 2). Word recognition scores (WRS) were also obtained at the Most Intelligible Level (MIL) on each ear, using recorded NU-6 word lists, for all study participants. Test results revealed mean word recognition scores of 78% and 77% for the right and left ears respectively at Site I and 73.4% and 77.0% at Site II. There were no significant differences between the two ears in terms of...
pure-tone average (PTA) at Site I (p = 0.481) and at Site II (p = 0.119) and WRS at Site I (p = 0.931) and Site II (p = 0.188). However, a one-way ANOVA revealed that there were statistically significant differences between the two sites in terms of PTA for both right (p = 0.043) and left (p < 0.001) ears. There were no statistically significant differences between the two sites in terms of WRS for the right (p = 0.208) and the left (p = 0.953) ears. All subjects met the following inclusion/exclusion criteria:

1. Ear inspection via otoscopy within normal limits.
2. Normal middle ear function (±100 decaPascals [daPa]) and amplitude (+0.3 to +1.6 cubic centimeters [cc]) bilaterally as indicated by tympanometry.
3. No evidence of conductive or retrocochlear pathology as indicated by pure-tone testing and immittance measurements.
4. Mild (20 to 40 dB HL) – to-severe (65 to 85 dB HL) high frequency or flat SNHL as indicated by pure-tone test results (250 Hz to 8000 Hz, including 3000 and 6000 Hz).
5. Symmetrical hearing loss that does not differ by more than 15 dB at more than one audiometric test frequency as indicated by pure-tone test results.
6. Motivated to try amplification as reported by the participant.
7. Native speaker of English as reported by the participant.
8. No history of chronic or terminal illness, psychiatric disturbance, or senile dementia.
9. No history of being bedfast/chairfast as reported by the participant.
10. Not home or nursing home bound.
11. No history of stroke or cerebral vascular disorder with a paresis or aphasia as reported by the participant.

Amplification Systems

All subjects were fit with digital Phonak Claro 311 dAZ BTE hearing aids bilaterally. All earmolds had select-a-vent (SAV) venting and #13 or 3 mm horn tubing. In addition to the hearing aids, subjects were fit with Phonak MicroLink ML8 FM receivers bilaterally. These FM receivers attach to the bottom of a BTE hearing aid and may be utilized in either the “FM only” mode, which attenuates the hearing aid microphone by 20 dB, or in the FM plus hearing aid mode, which allows for FM input and input of environmental sounds via the hearing aid microphones without any attenuation of the hearing aid microphone. The Phonak TX3 HandyMic FM transmitter served as the FM transmitter. The hearing aids were fit as recommended via the Desired Sensation Level (DSL) prescriptive fitting.
formula on the Phonak Fitting Guideline (PFG) Version 7.3 software. All fittings were compared to prescriptive targets using probe-microphone measures.

Medical Outcomes Short Form-36 (SF-36)

Functional health status was evaluated via the Medical Outcomes Short Form-36 (Ware and Sherbourne, 1992). The SF-36 is a 36-item inventory that assesses eight health domains: (1) limitations in physical activities due to health problems; (2) limitations in social activities due to physical/emotional problems; (3) limitations in role activities due to physical health problems; (4) bodily pain; (5) mental health; (6) limitations in role activities due to emotional problems; (7) vitality and (8) general health perceptions. This inventory has been shown to have high test-retest reliability and construct validity.

Procedures

All subjects were fit with binaural Phonak Claro 311 dAZ BTE hearing aids and Phonak Microlink FM system using a double-blind procedure. Specifically, one investigator fit the hearing aids, while a different investigator obtained all questionnaire data. All subjects were randomly fit with the Phonak amplification systems in one of the following conditions: (1) Phonak 311 dAZ BTE hearing aids only or (2) Phonak 311 dAZ BTE hearing aids used in conjunction with the Phonak Microlink FM system. Twenty-three of the subjects began the study in the hearing aids alone condition, while the remaining twenty-three subjects utilized the hearing aids in conjunction with the FM system. This investigation had a crossover design, in which at the end of three months the subjects switched experimental conditions. To control for hearing aid size effects, the FM modules remained attached to the BTE hearing aids in both conditions. The SF-36 was administered at seven different occasions: (1) pre-fitting; (2) 1 month post-fitting in the first experimental condition; (3) 2 months post-fitting in the first experimental condition; (4) 3 months post-fitting in the first experimental condition; (5) 1 month post-fitting in the second experimental condition; (6) 2 months post-fitting in the second experimental condition and (7) 3 months post-fitting in the second experimental condition. In other words, each subject was evaluated with the SF-36 one time prior to receiving amplification and three times in each experimental condition. All subjects reported using both amplification systems 8–10 hours per day.

Results

The mean SF-36 scores for the hearing aid only and hearing aid plus FM conditions, as a function of time interval, are presented in figure 3. A repeated-measures analysis of variance (ANOVA) was conducted to determine if there was an overall statistical difference in SF-36 scores between the hearing aid only and hearing aid plus FM conditions. The ANOVA revealed no statistical difference ($F_{1,45} = 1.63, p = 0.465$) in SF-36 scores across the 6 month period of this investigation. Moreover, ANOVA results indicated no statistical difference ($F_{1,45} = 0.948, p = 0.335$) was seen in SF-36 scores for either the hearing aid only and hearing aid plus FM conditions. Finally, no statistical differences were seen across the individual eight subscales of the SF-36 for time interval or amplification system (Hearing aid only/Hearing +FM).

![Figure 3. Mean SF-36 scores for the hearing aid only and hearing aid plus FM conditions, as a function of time interval.](image)
Discussion

The purpose of this investigation was to examine the effects of utilizing hearing aids in conjunction with FM technology to benefit functional health status. Functional health-related disorders were evaluated via the SF-36 Health Survey. Subjects consisted of 46 individuals with mild-to-moderate SNHL. Results indicated no statistically significant difference in SF-36 scores across the 6-month period of this investigation. Moreover, no statistically significant difference was noted in SF-36 scores for the hearing aid only and hearing aid plus FM conditions. There are several possible explanations for these above-mentioned findings of which two of the most prominent are discussed below.

One hypothesis to explain these results could be that hearing aids and/or FM systems did not positively affect functional health status. This hypothesis seems unlikely, however, for several reasons. Previous studies have already demonstrated that the utilization of hearing aids alone could improve functional health status (Crandell, 1998; Kochkin and Rokin, 2000). Recall that Crandell (1998) studied functional health status in 20 elderly individuals with mild to severe SNHL. Functional health status was evaluated via the SIP and the Medical Outcomes SF-36 questionnaires. Oticon Multifocus hearing aids were used as the amplification system. Results indicated that after three months of hearing aid utilization, statistically significant functional health improvements were noted via the SIP. However, a major difference between the Crandell (1998) study and the present investigation was the available technology of the hearing aids used. In specific, the present investigation used hearing aids with digital signal processing strategies that were not widely available for the earlier study.

Furthermore, recall from the manuscript by Valente et al. in this collection, that speech perception in noise was significantly improved with the utilization of Claro hearing aids in the directional microphone mode and Microlink settings (see figure 4). Specifically, the directional microphone mode on the hearing aid yielded significantly better performance than the condition with the hearing aids in the omni directional microphone mode and the unaided listening condition. Stated otherwise, the utilization of hearing aids in the directional microphone mode improved speech perception in noise (Reception Threshold for Sentences – RTS) by 1.2 dB at Site I and by 3.4 dB at Site II over the omni directional microphone condition. The condition with the binaural hearing aids used with one FM receiver in the FM only mode resulted in significantly better speech-perception performance than either of the hearing aid conditions. On average, subjects improved by 14.2 dB at Site I by 16.7 dB at Site II with the use of one FM receiver over the use of two hearing aids alone in the directional microphone mode. However, it should be noted that performance in this condition was significantly poorer than the condition with two FM receivers. The best speech-perception scores were obtained when the subjects used binaural hearing aids with two FM receivers in the FM-only mode. The mean RTS for this condition was −18.0 dB for Site I and −19.8 dB for Site II. This performance was on average 2.7 dB and 2.5 dB better at Site I and II respectively than performance in the condition with one FM receiver. Once again, it is unreasonable to assume that such improvements in speech perception would not benefit psychosocial and/or functional health status. Given these propositions, it is unreasonable to assume that improvements in hearing aid technologies and speech-perception abilities would not benefit psychosocial and/or functional health status.

Therefore, a more reasonable hypothesis for these finding is that the SF-36 was not sensitive enough to detect changes in functional health status. As previously stated, the SF-36 is a 36-item inventory that assesses eight health domains, including limitations in physical activities due to health problems;

![Figure 4. Mean RTS for each listening condition at Site I and Site II.](image)
limitations in social activities due to physical/emotional problems; limitations in role activities due to physical health problems; bodily pain; mental health; limitations in role activities due to emotional problems; vitality and general health perceptions.

The SF-36 also is clinically feasible as it takes only 10–15 minutes to administer, which was a major reason this scale was utilized in the present investigation. In contrast, the SIP contains 136 questions and often takes 30–40 minutes for clients to complete. While statistically significant improvements in functional health were not noted in either study via the SF-36, Crandell (1998) reported that the utilization of hearing aids alone could improve functional health status via the SIP. We are currently examining differences between the scales in an effort to develop a quality of life scale that is as sensitive as the SIP for hearing loss and rehabilitation, but can be administered in a shorter time period.

It is hoped that data obtained from future investigations will provide important clinical, theoretical, and cost-management information concerning the amplification needs of individuals with hearing impairment in several ways. First, it is expected that the results of this form of research will be instrumental in designing more effective and relevant amplification programs for listeners with hearing impairment. If it can be demonstrated that hearing instrument utilization can reduce the handicapping effects of hearing loss, and consequently improve psychosocial function, quality of life and functional health for individuals with hearing impairment, hearing instrument selection paradigms will need to take into consideration such factors as the assessment of functional health and psychosocial function during the evaluation/selection of amplification devices.

Second, if it can be demonstrated that hearing instrument utilization can lead to reductions in health-related difficulties, such findings could have important implications for health-care funding for persons with hearing impairment. Specifically, if the utilization of amplification can result in a significant and meaningful improvement in the quality of life and health for listeners with hearing impairment, it would seem logical that managed healthcare facilities would be willing to include the provision of amplification in their basic patient care. This assumption seems logical as hearing instruments could provide an extremely cost-effective procedure in reducing the incidence and/or degree of functional health disorders.

Clearly, information from research in this area could significantly augment the number of hearing instrument users in this country. Present estimates suggest that less than 25% of all individuals with hearing impairment currently utilize amplification devices. With increasing attention on quality assurance in the process of dispensing amplification, research is needed to document the efficacy of hearing instrument utilization in numerous areas. As noted previously, there remains limited empirical data concerning the relationship between the influence of amplification on quality of life, psychosocial function and functional health.

References


