

When Hearing Aids Go Bad: An FM Success Story

Rachel McArdle*†
Harvey B. Abrams*†
Theresa Hnath Chisolm†*

Abstract

Both clinical and research findings support the effectiveness of frequency-modulated (FM) technology among individuals who continue to encounter significant communication problems despite the use of conventional hearing instruments. The use rate of FM devices throughout the nation, however, remains disappointingly low. The authors present a case of a longtime hearing aid user whose hearing aids provided decreasing benefit as his hearing impairment increased to the extent that cochlear implantation was considered. Through the establishment of patient-specific treatment goals, the provision of appropriate FM technology as verified through real-ear measurements, and careful and deliberate counseling and follow-up, this patient was able to realize significant communication benefits as reported through several self-assessment measures. The cost-benefit implications of FM technology versus cochlear implantation are discussed.

Key Words: Bilateral, hearing aids, hearing loss, rehabilitation of hearing impaired

Abbreviations: BTE = behind the ear; CI = cochlear implant; COSI = Client-Oriented Scale of Improvement; CPHI = Communication Profile for the Hearing Impaired; FM = frequency modulated; NAL-R = National Acoustic Laboratories—Revised; REIG = real-ear insertion gain; RMS = root mean square; SG = some guy; VA = Veterans Affairs; VAMC = Veterans Affairs Medical Center; WTP = willingness to pay

Sumario

Tanto los hallazgos clínicos como de investigación apoyan la eficiencia de la tecnología de frecuencia modulada (FM) entre aquellos individuos que continúan presentando problemas significativos de comunicación a pesar del uso de instrumentos auditivos convencionales. La tasa de uso de los dispositivos de FM en el país, sin embargo, continúa siendo frustrantemente baja. Los autores presentan el caso de un usuario de audífonos de larga evolución, para quien su auxiliar auditivo aportaba un beneficio en disminución conforme su hipoacusia aumentaba, al punto que se consideró colocarle un implante coclear. Luego de establecer metas de tratamiento específicas para el paciente, con el uso de una tecnología FM apropiada, verificada a través de mediciones de oído real, y con una consejería y un seguimiento cuidadosos, este paciente pudo obtener beneficios significativos en la comunicación, pudiéndose demostrar usando varias medidas de auto-evaluación. Se discuten las implicaciones de costo/beneficio de la tecnología FM versus la implantación coclear.

Palabras Clave: Bilateral, auxiliares auditivos, hipoacusia, rehabilitación del hipoacúsico

*Bay Pines VA Healthcare System, Bay Pines, Florida; †University of South Florida

Rachel McArdle, Ph.D., Bay Pines VA Healthcare System, Audiology (126), P.O. Box 5005, Bay Pines, FL 33744; Phone: 727-398-9395; Fax: 727-319-1209; E-mail: Rachel.mcardle@med.va.gov

Portions of this work were supported by Phonak, Inc. and by Rehabilitation Research and Development Service, Department of Veterans Affairs through a Merit Review.

Abreviaturas: BTE = retroauricular; CI = implante coclear; COSI = Escala de Mejoría Orientada al Cliente; CPHI = Perfil de Comunicación del Hipoacúsico; FM = frecuencia modulada; NAL-R = Laboratorio Nacional de Acústica – Revisado; REIG = ganancia de inserción en oído real; RMS = raíz media cuadrada; SG = alguna persona; VA = Asuntos de Veteranos; VAMC = Centro Médico de Asuntos de Veteranos; WTP = deseo de pagar

The Veterans Affairs (VA) National Hearing Aid Program has a significant impact on the hearing aid industry. In fiscal year 2004, over 312,000 hearing aids were dispensed to eligible veterans (an average rate of 1,240 instruments each business day) at a cost of over \$118,000,000. The hearing aids issued by the VA in calendar year 2003 represented 54.4% of the entire hearing aid industry's market growth (Strom, 2004). The VA now accounts for more than one in seven (14.4%) of all hearing aids dispensed in the United States (Strom, 2004).

Of the close to 200,000 veterans who received hearing aids this year, an estimated 25% have a severe-to-profound hearing impairment (Dennis, pers. comm., 2004). Individuals with severe-to-profound hearing impairment present a significant challenge for audiologists since the severity of their hearing impairment imposes a greater impact on their communication abilities than typically can be resolved by conventional amplification alone. Consequently, to maximize their limited communication abilities, many of these patients require multiple visits, placing a further strain on a system attempting to manage ever-increasing workload demands.

Among treatment options available to veterans with severe-to-profound hearing impairment is cochlear implantation. Presently there are ten VA Cochlear Implant (CI) Centers that have historically been established through a review and approval mechanism that takes into account facilities, staffing, training, and experience. Selected VA Medical Centers have been performing cochlear implantations for over ten years. Patients seen at non-CI VA Medical Centers who are candidates for implantation are referred to a VA CI Center in their general geographical region for evaluation and implantation if they meet the audiological and surgical criteria set forth by the Food and Drug Administration. Once implanted, patients are required to return to the VA CI Center for subsequent programming and follow-up. This process usually requires six

return visits in the first year following implantation. In the event that the device requires service, the CI patient returns to the VA CI Center as VA audiology clinics in non-CI VA Medical Centers generally do not have clinicians with the knowledge, skills, or equipment to repair or modify the processor.

While clinical experience indicates the outcomes associated with cochlear implant procedures performed in the VA are very good, the need to travel to a CI Center, often far from home, for multiple visits may be limiting the number of potential CI recipients in the veteran population who elect to undergo the preliminary evaluation. In addition, there are patients who are ineligible for implantation due to comorbid conditions, and/or otologic and audiological contraindications, as well as those who decline due to spousal responsibilities, and/or objections to or fear of the surgery. Indeed, it is estimated that only 50 veterans were implanted at VA CI Centers in the past year (Dennis, pers. comm., 2004).¹ If 25% of the 200,000 veterans receiving hearing aids this year have severe-to-profound hearing loss, and are thus cochlear implant candidates, then one can only conclude that the percentage of eligible veterans receiving cochlear implants is relatively small.

The relatively low implantation rate suggests a need to evaluate other treatment options for veterans with severe-to-profound hearing impairment, who continue to report significant communication problems despite regular use of amplification. One promising treatment option is the use of FM (frequency-modulated) technology. Despite research findings that have demonstrated the clinical efficacy of FM technology (Jerger et al, 1996; Sanford and Kierkhaefer, 2002; Boothroyd, 2004), our clinical experience and manufacturer report (Ermann, pers. comm., 2003) indicate a low use rate of FM systems in the adult population. Researchers have suggested several reasons for this low use rate including a lack of convenience (e.g., a need to recharge batteries daily), cosmetics (e.g., increased attention to hearing loss due to

the need to “point” a transmitter at the speaker), a need for considerable instruction in device use, and/or device cost (e.g., Jerger et al, 1996; Boothroyd, 2004; Valente, pers. comm., 2005). While high cost may be a deterrent to FM use in the private sector, within the VA healthcare system, FM devices (receivers and transmitters) are provided to eligible veterans at no cost to the patient through the VA national hearing aid contract. During fiscal year 2004, approximately 1100 FM systems were issued to veterans nationwide (Noe, pers. comm., 2004), a seemingly low figure considering the incidence of significant hearing loss in the veteran population.

Recently, the authors undertook a study at two VA audiology clinics (Bay Pines VAMC [Veterans Affairs Medical Center] and Mountain Home VAMC) to examine outcomes of FM use in veterans with significant hearing loss who are provided with considerable counseling, coaching, and instructions during a trial period of device use (Chisolm et al, 2004; Noe et al, 2004). During counseling sessions, issues related to convenience and cosmetics as well as repeated instructions on device use were addressed. Several of the participants in this study met the audiological criteria to be considered candidates for a cochlear implant. The authors present a case of one of these participants to highlight the potential use of an FM system as an alternative treatment option for those who might not wish to undergo surgical implantation or for whom surgical implantation is contraindicated.

BACKGROUND INFORMATION

In February 2000, SG (some guy), a 79-year-old male, was seen at the Bay Pines VAMC. SG was a seasonal resident of Florida, as are many of the patients seen at Bay Pines VAMC. SG had a history of military noise exposure, with records indicating he was last fit binaurally with Oticon Multifocus® behind-the-ear (BTE) hearing aids in 1997 at a Northern VAMC. SG was referred to the Bay Pines VAMC audiology clinic by his primary care provider because of a “failure of his hearing aids to work properly.” Audiometric data indicated a severe-to-profound sensorineural hearing loss (see Figure 1) with poor word-recognition scores in quiet, that is, 25% for the right ear and 0% for the left ear. Air-conduction thresholds and word-recognition scores in quiet were consistent with the audiometric testing completed in 1997. SG reported his primary communication goal for hearing aid use, as determined through the Client-Oriented Scale of Improvement (COSI; Dillon et al, 1997), was to hear better one-on-one in quiet. Although when first seen in our clinic, SG met audiometric criteria for consideration as a candidate for a cochlear implant, records do not indicate that this option was discussed at the time.

In March 2000, SG was fit binaurally with Phonak PowerZoom® BTE hearing aids with a DHC-2® remote control. Clinical protocol involved fitting hearing aids to NAL-R (National Acoustic Laboratories—Revised) prescription (Byrne and Dillon, 1986) with verification of fit using real-ear measurements. Both hearing aids were programmed for use in quiet on Program 1,

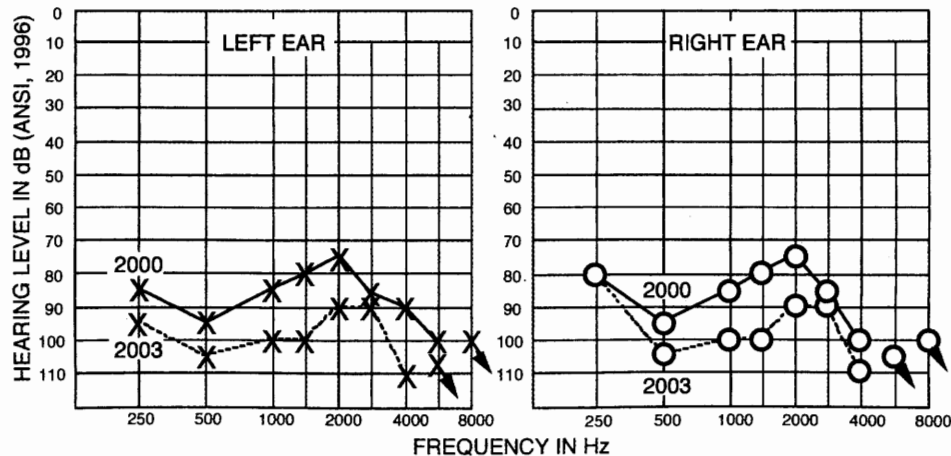


Figure 1. Pure-tone air-conduction thresholds for the right and left ear obtained in February 2000 and March 2003.

use in mild noise on Program 2, and moderate noise on Program 3. For Programs 2 and 3, the AudioZoom® feature of his hearing aids was turned on, which activated the fixed hypercardioid directional microphones and reduced the low-frequency gain. Based on his highly elevated auditory thresholds and poor word-recognition skills in quiet, SG was counseled regarding realistic expectations for communication, such as the limitations of conventional amplification when listening in less than optimal conditions (e.g., background noise, large distance from speaker, lack of visual cues). Attendance of a Hearing Loss Education (HLE) class offered at Bay Pines VAMC was also recommended for SG and his spouse. The curriculum for the HLE class included instruction on the functional effects of hearing loss, instruction and role-playing on communication strategies for both the person with hearing loss and his or her significant other with normal hearing, and counseling on the importance of both the listener with hearing loss and his or her primary communication partner changing maladaptive communication behaviors that do not facilitate effective communication. Finally, SG was counseled that he might be a candidate for a cochlear implant, but no referrals for a CI evaluation were made at that time.

In May 2000, SG was seen for a routine post-hearing-aid-fitting follow-up appointment in which it was determined that his goal had been satisfactorily achieved. Specifically, SG indicated that he could communicate effectively with his wife at home as long as visual cues were available.

SG returned to the North and was not seen again in our clinic until October 2000. During this visit, SG reported that when listening in Program 1 (quiet program), the volume was too loud. In addition, he reported that noise was bothersome. Overall gain was reduced in Program 1, and it was determined that both microphones on each hearing aid were clear of debris. If debris is blocking, even partially, one of the microphones in a dual microphone system as used in the PowerZoom, the directionality can be negatively impacted as a result of microphone mismatch. SG was reminded of the limitations with conventional amplification for an individual with his degree of hearing loss. Cochlear implantation, as an option, was presented again, and SG was encouraged to explore information about the benefits and limitations of cochlear implantation.

Two weeks later (November 2000), SG returned to the clinic, this time reporting difficulty understanding speech in noisy backgrounds. After determining that both microphones were clear of debris, adjustments to the frequency responses in Programs 2 and 3 were made by reducing gain in the low frequencies and increasing gain in the midfrequency regions. Between December 2000 and February 2001, SG was seen an additional three times, each time with a similar report that Program 2 and Program 3 were not beneficial in noisy situations. Minor adjustments were made to the frequency response, and additional counseling was provided in each session. SG returned to his summer home up North and was not seen again until November 2001.

Between November 2001 and April 2002, SG was seen four times in the Hearing Aid Repair Clinic by an experienced audiology technician to address reports that hearing aids were not working appropriately. The technicians made minor programming adjustments and physical modifications on the basis of subjective report (real ear measures are not used by the audiology technicians in our clinic to verify the results of programming changes). After spending the summer months up North, SG returned to the Hearing Aid Repair clinic in November 2002, not only complaining about the functioning of his hearing aids but reporting a noticeable decrease in his overall hearing ability. SG was referred for a comprehensive audiological reevaluation.

PRE-FM FITTING AUDIOLOGICAL ASSESSMENT

SG was seen for the audiological evaluation in early March 2003. During the evaluation, SG reported that his ability to understand speech had declined and that he was experiencing extreme difficulty communicating in all situations, especially in group situations with background noise. SG expressed frustration with his current communication ability and was interested in any hearing device that might improve his ability to communicate even if improvement was minimal.

Results from audiometric testing showed a 10–15 dB decrease in air-conduction thresholds since his previous examination in 2000 (see Figure 1). After reviewing test

results, the possibility of cochlear implantation was again discussed. SG said he had explored cochlear implants and was not interested in undergoing surgery. As the authors were currently recruiting participants for the FM research study, the protocol was described to SG, and he agreed to participate. In addition to enrolling SG into the study, the audiologist decided to replace the three-year-old Phonak PowerZoom BTE hearing aids with a new set of the same make and model instruments. While the audiologist could have chosen to use new technology (i.e., digital hearing aids), there was no clinical advantage to be achieved with digital signal processing for this patient. SG was proficient in the operation of his current hearing aids; the electroacoustic properties of the PowerZoom instruments were appropriate for the degree of impairment; the PowerZoom instruments were compatible with Phonak Microlink® FM system use, and most importantly, SG expressed a great desire to try the FM system as soon as possible. If the hearing aid technology was changed, the study protocol would have required at least a one-month trial period with new hearing aids prior to FM use.

INITIAL STUDY VISIT

SG enrolled in the study at the end of March 2003. The purpose of the initial study visit was twofold. The first objective was to verify that the participant's current hearing aids were functioning and programmed appropriately. Since SG's hearing aids had just been checked, and new instruments ordered, this was not done. The second purpose of this visit was to establish specific goals for FM use utilizing COSI and to obtain baseline measures for selected items from the Communication Profile for the Hearing Impaired (CPHI; Demorest and Erdman, 1987) and MarkeTrak survey (Kochkin, 1990) with reference to use of hearing aids alone.

Goals for FM Use

The COSI was designed as a goal attainment scaling tool to be used by the clinician to identify important individual listening situations that are pertinent to a specific patient. Once identified, the individual listening situations become communication goals to be achieved through

treatment with amplification and/or an assistive listening device such as an FM system. During the initial visit, SG was asked to identify three main listening situations in which he wanted to improve his ability to communicate through the use of an FM system. The main communication goal for SG was to be able to understand his wife in a one-on-one situation (i.e., in the kitchen, riding in the car, taking walks together). His second communication goal was to improve his ability to hear his friends in a one-on-one situation at a restaurant during Friday night happy hour. His third goal was to improve his ability to understand on the telephone.

SG was asked to rate his "final ability" with his hearing aids (i.e., how much of the time he could communicate effectively in the situations he nominated as treatment goals), by choosing from five options: "hardly ever" (10%), "occasionally" (25%), "half of the time" (50%), "most of the time" (75%), and "almost always" (95%). SG reported that with his current Phonak PowerZoom BTE hearing aids, he was able to understand his wife only 50% of the time, communicate effectively at happy hour only 25% of the time, and understand on the phone 10% of the time. Typically, patients are asked to note their "degree of change" from no hearing aids to use of hearing aids as either "worse," "no change," "slightly better," "better," or "much better." This was not measured in the study due to the long-term use of hearing aids prior to his initial study visit.

Baseline Outcomes Data

CPHI

The CPHI is a 145-item questionnaire assessing self-perception of communication performance, communication importance, communication environment, communication strategies, and personal adjustment. An advantage of the CPHI is that it provides comprehensive information about the effects of hearing loss on an individual's functioning. A disadvantage, particularly from a clinical perspective, is the length of administration time. For the purposes of this clinical investigation, the authors decided to use only the 18 items related to self-perception of communication performance. These items provide five scale scores. Three of the scales assess communication effectiveness in

different types of situations—social, work,² and home. The other two scales assess communication effectiveness as a function of type of listening condition—Average and Adverse. For each item, SG indicated whether or not he could communicate effectively by using a 5-point response scale ranging from 1 for “Rarely or Almost Never” to 5 for “Usually or Almost Always.” The scores SG reported for each of the Communication Performance scales using hearing aids alone are shown by the black bars in Figure 5. All scale scores were close to 2, which indicated that with hearing aid use alone, SG, on average, perceived his communication to be effective only “Occasionally or Sometimes” across the various situations and environments.

MarkeTrak Survey

Items that appeared relevant to FM as well as hearing aid use were selected from the MarkeTrak Hearing Aid Owner survey. Several of the selected items related to overall satisfaction, hours of device use, overall quality of life, and negative feelings of

embarrassment, ridicule, or rejection. The responses obtained for hearing aid use alone are shown in the second column of Table 1. SG reported he was “neutral,” neither satisfied or dissatisfied with his current hearing aids, wore them about 16 hours a day, that the hearing aids “sometimes” improved his quality of life, and that he “never” had negative feelings regarding hearing aid use.

Another set of questions from MarkeTrak assessed satisfaction with device features and functioning in different listening situations (see Table 2). SG indicated his level of satisfaction using a 5-point scale, ranging from 1 for “Very Dissatisfied” to 5 for “Very Satisfied.” As can be seen in the second column of Table 2, SG appeared relatively satisfied with the hearing aid features but relatively dissatisfied with how the hearing aids functioned, particularly in noise and with soft sounds.

Responses by SG to questions about satisfaction with hearing aid use in a variety of listening situations and how important it was for him to hear well in each of these situations is shown in Table 3. The second column shows the baseline data obtained for

Table 1. Responses to Questions from MarkeTrak Survey for Items Related to Overall Satisfaction, Use, Overall Quality of Life, and Negative Feelings

Item	HA Alone	FM Six Weeks	FM One Year
Overall Satisfaction	Neutral	Very Satisfied	Very Satisfied
Hours of Use	16	12-16	12+
Quality of Life improvement due to device use	Sometimes	Most of time	Most of time
Feeling embarrassed, Ridiculed, or rejected due to device use.	Never	Never	Never

Table 2. Satisfaction with Device Features and Functioning

Feature	HA Alone	FM Six Weeks	FM One Year
Visibility to others	4	5	5
Clearness of tone and sound	3	4	4
Reliability	4	5	5
Improves your hearing	4	5	4
Use in noisy situations	2	4	3
Ability to hear soft sounds	2	3	4
Comfort with loud sounds	3	3	4

Note: Responses were on a 5-point scale: 1 = Very Dissatisfied, 2 = Dissatisfied, 3 = Neutral, 4 = Satisfied, and 5 = Very Satisfied.

Table 3. Satisfaction with Devices in Specific Listening Situations

Situation	HA Alone	FM Six Weeks	FM One Year
Conversation with one person	2 (4)	5 (4)	4 (3)
In small groups	1 (3)	4 (3)	4 (3)
Outdoors	2 (3)	3 (2)	4 (3)
In large groups	1 (3)	3 (0)	2 (1)
At a concert/movie	1 (3)	NR (0)	NR (0)
Riding in a car	3 (3)	4 (2)	3 (2)
On the telephone	1 (3)	3 (3)	NR (0)
Listening to music	1 (3)	NR (0)	NR (0)
In a place of worship	1 (2)	NR (0)	NR (0)
In a restaurant	2 (2)	4 (2)	4 (1)
Leisure activities	3 (2)	4 (2)	4 (3)

Note: Responses were on a 5-point scale: 1 = Very Dissatisfied, 2 = Dissatisfied, 3 = Neutral, 4 = Satisfied, and 5 = Very Satisfied. NR = no response. Numbers in parenthesis indicate how important SG reported it was to "hear well" in each situation. Responses were on a 4-point scale: 1 = Not Important, 2 = Somewhat Important, 3 = Important, and 4 = Very Important. A "0" indicates that an importance rating was not given.

listening with hearing aids alone. The satisfaction ratings, obtained using a 5-point scale, with 1 for "Very Dissatisfied" and 5 for "Very Satisfied," are shown first, followed by a number in parentheses, which indicates the importance rating. The importance rating was obtained using a 4-point scale with 1 for "Not Important" and 4 for "Very Important." SG was not satisfied with his hearing aids in any of the listening situations, and he indicated that being able to hear in all of the situations was at least "somewhat important." Note that SG indicated there was only one situation in which it was "Very Important" for him to hear well. This was "Conversation with one person," for which he indicated he was "Dissatisfied" with the use of hearing aids.

The last MarkeTrak question asked SG to indicate the degree of change he had experienced, since he had started using the device (i.e., hearing aids), in a variety of different areas related to quality of life. These areas are shown in the first column in Table 4, and his responses for hearing aids alone in the second column. The data show no areas for which hearing aids resulted in an improvement in perception. For example, SG reported that mental ability, feelings about himself, and sense of safety were "the same" with hearing aids as without hearing aids. His mental and emotional health and confidence in himself and his ability to participate in group activities were all perceived to be "somewhat worse" with hearing aids than without.

Table 4. Changes SG Believed Occurred as a Result of Device Use

Area	HA Alone	FM Six Weeks	FM One Year
Mental/emotional health	2	4	4
Mental ability	3	3	3
Physical health	3	3	3
Relationships at home	2	5	5
Social life	2	3	4
Feelings about yourself	3	3	3
Ability to participate in group activities	1	4	4
Sense of independence	2	5	4
Sense of safety	3	3	3
Confidence in yourself	2	3	3

Note: Responses were on a 5-point scale: 1 = A lot worse, 3 = The same, 5 = A lot better. No terms were provided for 2 or 4.

STUDY VISIT 2

The purpose of the second study visit was to fit the FM device and provide general training in the use of the FM system and specific training related to the first goal for FM use as determined through COSI. In addition, SG was fitted with the new set of Phonak PowerZoom hearing aids with a DHC-2 remote. For the FM system, SG was fit with Phonak MLx[®] receivers (Figure 2) bilaterally and a Phonak HandyMic[®] transmitter (Figure 3), which is a handheld transmitter that can also be worn on a lanyard. To fit the FM devices, the hearing aid response was first compared to the NAL-R insertion gain target (Byrne and Dillon, 1986). RMS (root mean square) difference between the NAL-R target and real ear insertion gain (REIG) with a 65 dB SPL composite noise input was less than 5 dB from 500–2000 Hz bilaterally. Next, the FM transmitter was placed 15 cm from the real-ear system speaker, and the hearing aid and FM receiver were set to the “FM only” mode. A 65 dB SPL composite signal was presented, and the REIG as processed through the FM system was compared to the REIG of the hearing aid. The purpose of the verification was to assure the FM system was providing a smooth and appropriate frequency response when coupled to the hearing aid. This procedure also allowed for verification that equal gain was

present for the FM-only and hearing aid-only modes by observing a higher SPL for the FM-only REIG (due to the microphone 15 cm from the speaker) than the hearing aid REIG (microphone at 1 m from the speaker).

Once the fitting was verified, SG was provided instructions on the general use of the FM system. This included how to couple the FM system to the hearing aids, the various programs available through the hearing aid remote and through the FM receivers, the transmitter settings, and how to charge the FM transmitter battery. After this general instruction, SG was provided with specific instructions and practice using the FM system to improve communication with his wife in one-on-one listening situations. SG was accompanied by his wife to this session so that she could learn appropriate use of the transmitter. The audiologist demonstrated how to select the appropriate settings on the transmitter, receivers, and the hearing aid remote control. SG and his wife engaged in several role-playing activities to practice switching from hearing aid use alone to FM use alone to hearing aid and FM use combined. In addition, SG was provided a handout with step-by-step instructions for setting up the FM system for one-on-one situations. He was also given quick-reference instruction cards to carry in his pocket.



Figure 2. MLx[®] wireless FM receiver coupled to a PowerZoom BTE hearing aid.



Figure 3. HandyMic[®] FM transmitter.

STUDY VISIT 3

The next visit for SG occurred two weeks following the FM fitting. The purpose of the third study visit was to introduce a new goal for FM use and to monitor progress and reinforce the first goal. SG indicated that he was benefiting from FM use when communicating with his wife and daughter in one-on-one situations. He reported some confusion regarding how to set the system into FM-only mode, so re-instruction was provided. SG was then instructed on how to use the FM system most effectively to reach his second communication goal, that is, improved communication with friends at happy hour on Friday nights. Once again, SG received verbal instructions, handouts with step-by-step instructions for activating the FM system for small group in noise situations, instruction cards to carry in his pocket for quick reference, hands-on demonstrations, and role-playing in a situation similar to a happy hour setting.

STUDY VISIT 4

After an additional two weeks of practice, SG returned for his fourth study visit. By this time, SG had mastered the use of the HandyMic transmitter and was reporting benefit and success with his first two communication goals. For his third communication goal, that is, improved telephone communication, an additional transmitter, TelCom® (Figure 4), was needed to connect to the telephone. The TelCom is an FM transmitter that connects to both the telephone and an audio signal such as the

television that allows for convenient switching between the telephone and audio device, so that when the FM system is broadcasting an audio signal, the TelCom sends the telephone ring through the FM system to the hearing aid. When an FM user answers the telephone, the TelCom automatically mutes the audio signal and transmits the telephone signal through the FM receivers. The volume of the television or radio is not altered for others in the room. When the telephone handset is replaced, the audio signal transmitted to the hearing instruments is turned back up to the previous volume setting. If the FM user answers the phone and the call is intended for someone else, the user can override the TelCom and reengage the audio signal, allowing the other person to talk on the phone in private. SG practiced answering a telephone connected to a TelCom and was provided with written instructions to follow at home over a final two-week period of time.

FINAL STUDY VISIT

During the final study visit, SG was asked to indicate his "final ability" and "degree of change" for each COSI goal, complete selected items from the CPHI and Marketrak questionnaires with a focus on FM use, indicate how much he would be willing to pay for an FM system if one were to be purchased, and finally, to decide whether or not he wished to continue using the FM system beyond the study protocol. The report by SG of his goal attainment and data collected from selected outcome measures are described.



Figure 4. TelCom® FM transmitter.

Goals of FM Use

In terms of the first COSI goal identified by SG, improved communication with his wife, SG reported he could communicate effectively “95% of the time,” and he also reported the degree of change from hearing aid use to hearing aids plus an FM system to be “much better.” During communication situations involving happy hour (i.e., the second goal), SG reported that he could communicate effectively “50% of the time” and also that communication during happy hour was “much better” with the FM system than with hearing aids alone. For his final communication goal, improved telephone communications, SG reported that he was only able to communicate on the telephone “occasionally” but that it was “better” with the addition of the FM system. Given SG’s auditory word-recognition ability, the ability to “occasionally” to communicate via hearing alone on the telephone was a very encouraging finding. In face-to-face communication, SG was able to use both auditory and visual cues to understand messages. On the telephone, without visual cues, it would be expected that communication would be much more difficult for SG.

Outcomes Data

CPHI

Responses for the Communication Performance scales are shown by the diagonal bars in Figure 5. The responses given by SG indicated improvement in self-perception of communication effectiveness on all subscales. In fact, except for the work subscale, all of the increases exceeded the 90th percentile confidence intervals reported by Erdman and Demorest (1990) for a clinically significant change. The greatest improvement was for communication at home. This result is consistent with the treatment emphasis given to the first COSI goal reported by SG, communicating in one-on-one situations with his wife.

MarkeTrak

Responses to MarkeTrak survey items are shown in column 3 of Tables 1–4. As indicated in Table 1, overall satisfaction with the FM system was high, and SG reported he was using the FM system at least 12 hours

a day. He reported his quality of life was improved “most of the time” due to FM system use and that he had no negative feelings associated with FM use. As with hearing aids, satisfaction with device features was high (Table 2), and in contrast to hearing aid functioning, with which SG was not satisfied, he was now “satisfied” with “use in noisy situations” and now “neutral” with regard to “ability to hear soft sounds” and “comfort with loud sounds.”

When SG was asked to indicate satisfaction with FM use in specific listening situations (Table 3), further validation regarding his communication goal of improved communication in one-on-one conversations was obtained. He indicated that he was “very satisfied” with FM use in this situation. High levels of satisfaction were found for several other situations—small groups, riding in a car, in a restaurant, and leisure activities. As might be expected from the COSI data, SG indicated that he was “neutral” with regard to satisfaction with FM use on the telephone. This finding was not surprising, however, because SG had very poor auditory speech recognition ability. Neutral responses were also obtained for listening outdoors and in large groups. Although SG initially indicated that listening at concerts/movies, listening to music, and listening in places of worship were at least somewhat important to him prior to the FM trial period, he did not provide a satisfaction rating for these situations. It is not known why ratings were not provided by SG. Several possibilities exist. First, it may be that he had

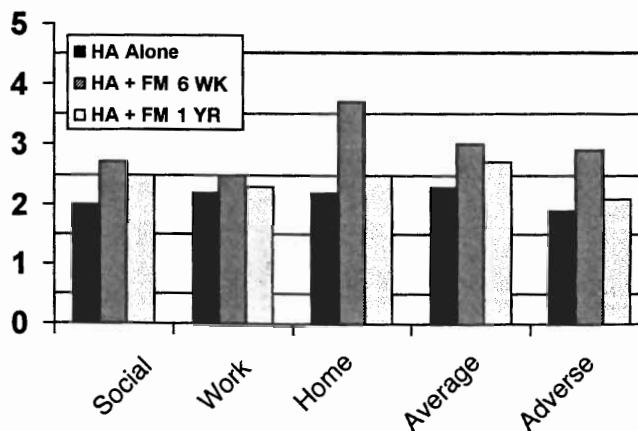


Figure 5. Scores for Communication Performance subscale of the CPHI.

no experience in any of the situations or that they were no longer perceived to be important. Indeed, when asked to rate his self-perceived importance, he left these items blank. Second, another possible explanation is that SG did try the FM system in these situations and found them to be frustrating. In this case, SG may have in essence "given up" the idea of hearing well in such situations. A third possible reason for the lack of responses to these items may have been due to a greater need for counseling on FM use in the specific listening situations. For example, when an FM system is used in a place of worship, it is important that the microphone be placed on or near the talker or that the microphone be connected through the direct audio input cable to the sound system. The latter would also be important in concerts or movies, if available. While this information was given to SG, it is not known if he remembered to follow the instructions. Similarly, when listening outdoors, different recommendations are made based on whether the specific activity involves listening at a near versus far distance or in a fixed versus a mobile situation. SG did not provide any specific outdoor listening goals; thus, this area was not fully explored during follow-up, and specific directions were not given. Finally, as seen in Table 4, SG indicated his mental/emotional health, relationships at home, ability to participate in group activities, and sense of independence were all better as a result of FM use.

Willingness to Pay

While clinical outcome measures reveal critical information concerning benefit, additional information concerning how much an individual values a service or device can be obtained through a willingness-to-pay (WTP) question (Palmer et al, 1995; Chisolm and Abrams, 2001). As with the other participants in the FM study, the authors asked SG how much more (using a retail value of \$4,000 for the hearing instruments alone as an anchor) he would be willing to pay for the FM transmitter and receivers given the benefits achieved with his FM system. Although eligible veterans are not required to pay out of pocket for hearing aids or FM systems, SG provided a WTP value of \$3000. Although this does not mean that SG would have paid this amount, it does suggest that SG perceived the value of an FM system to

be relatively high compared to the value of hearing aids. That is, the FM system was worth 75% of the cost of hearing aids.

Decision to Keep FM

SG elected to keep his FM system. His final study visit was in May of 2003. SG did not contact the audiology clinic again until May of 2004, at which time he reported that his hearing aids and FM system were not performing as well as when first received. During this visit, the audiologist replaced the tubing on both earmolds, which had become hard and brittle, and reviewed the importance of using the transmitter close to the mouth of the speaker to improve the signal. SG reported the hearing aid sound quality was much improved with the new tubing, and he was satisfied with the performance of the FM system again as well.

Soon after the May 2004 visit, SG, as well as all other participants, was sent follow-up CPHI and MarkeTrak study questions. The purpose was to determine which, if any, of the positive outcomes observed at the end of the FM study trial period were maintained. The gray column in Figure 5 shows the one-year responses for the CPHI subscales. While there were decreases from six weeks post for all scales, none of these decreases exceeded the 90% confidence intervals for a clinically significant change. It is somewhat disappointing that self-perceived communication performance for all scales measured in this study on the CPHI from pre-FM to one-year post-FM fitting were minimal. Since no objective testing was completed at one-year post-FM fitting, it is not clear if the relatively small changes in communication performance are due to an initial overinflation of benefit due to the Hawthorne effect or to a change in hearing status and/or device function.

With regard to MarkeTrak, the resulting data for the one-year follow-up are shown in the last column in Tables 1–4. SG reported no changes in overall satisfaction and use after one year of FM use as compared to six weeks of FM use (Table 1). Similarly, as seen in Table 2, SG reported no changes in satisfaction of device features and functioning after one year of use as compared to six weeks of FM use, except for use in noise, which after six weeks, SG reported being "satisfied" with, but after one year, SG reported being "neutral" (neither satisfied nor dissatisfied). With

regard to satisfaction in specific listening situations (Table 3), SG reported a slight decrease at one year as compared to six weeks post-FM use for three of the 11 situations: (1) conversation with one person (very satisfied to satisfied), (2) in large groups (neutral to dissatisfied), and (3) riding in a car (satisfied to neutral). Improvements noted after six weeks in terms of mental health, relationships, participation, and sense of independence were maintained after one year. In addition, SG reported improvement in his social life as a result of FM use at one year (Table 4).

SUMMARY AND CONCLUSIONS

The case of SG is representative of many patients who seek audiologic care at the VA. Patients with significant hearing loss may have experienced reasonable success with hearing aids in the past, but as they age and their hearing loss progresses, the benefits of conventional amplification become increasingly limited. As a result, patients with significant hearing loss often make multiple visits to the clinic for replacement hearing instruments or to make repeated adjustments to their current instruments to resolve growing problems with speech intelligibility, particularly in adverse listening environments. Similar to SG, many of the patients with significant hearing loss assume their hearing aids "aren't working right." At some point, the clinician becomes aware that conventional amplification will no longer meet the communication needs of the patient regardless of technology and that a decision needs to be made to pursue alternatives to amplification; for many patients, the option of choice is cochlear implantation. As is illustrated in this case, however, not all patients are agreeable to the implant option and, given results for SG on the COSI, CPHI, MarkeTrak, and WTP, a convincing case can be made that FM technology is a viable and effective alternative to cochlear implantation. It is particularly important to note that the self-perception of benefit by SG as measured by the MarkeTrak questionnaire remained fairly stable for most situations over the course of 12 months.

Given the potential for good clinical outcomes with FM, a cost-effectiveness comparison between CI and FM cannot be ignored. The cost to the VA for two digital BTE instruments, two receivers, one transmitter,

and a remote control is approximately \$2,900 as compared to an implant cost of about \$23,000. The cost difference in the private sector is likely to be even greater (even with the higher FM device costs) given the surgeon and hospital fees associated with the CI procedure. Several of the participants in our study who initially requested evaluation for an implant were so pleased with the FM results that they no longer wished to be considered for an implant. Of course, the authors do not know if SG's outcome would have been better with a cochlear implant, but that he is satisfied enough with the results of his FM system to continue to refuse referral for a CI suggests that any additional benefit would not have been "worth the cost." In fact, FM receivers are manufactured specifically for cochlear implants, suggesting that the problem of understanding speech in adverse listening environments continues to remain a problem for many CI users.

The authors believe similar success with FM technology can be achieved with other patients exhibiting severe-to-profound hearing impairment providing two important rules are followed. First, the clinician and patient must identify specific situations not being met with conventional hearing aids, and the clinician must determine if the identified situations can be reasonably achieved with FM technology. The authors found the COSI to be a particularly effective tool for this purpose. Second, the patient must be carefully followed through regular and frequent follow-up visits, particularly among older patients who may feel overwhelmed with the technology (transmitters, receivers, adaptors, shoes, telephone devices, etc.). The authors also found it important to address one communication problem at a time (starting with the highest priority problem) and to ensure the patient was comfortable with the technology in this situation before moving on to the next.

In summary, the results of this case study may be interpreted to suggest that FM technology can be a reasonable alternative to cochlear implantation for some subset of veterans with significant hearing loss, in terms of both clinical outcomes and cost-effectiveness. Given the success achieved by SG, clinicians may want to reconsider their protocols when treating patients with severe-to-profound hearing impairment to include a trial with FM technology prior to referral for CI evaluation.

NOTES

1. Additional implantations were likely performed at universities with sharing agreements with the nearby VA Medical Centers, but as these affiliations are not recognized as VA CI Centers, the number of these cases is unknown to national program officials and therefore not captured for statistical purposes.
2. As detailed in the CPHI manual, subjects who did not work were asked to consider a comparable situation for the items describing work environments.

Acknowledgment. This work was supported by Phonak, Inc. We would like to thank Amanda Hemard and Richard Wilson for their assistance in this project.

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