Objective: To study the long-term results (use, care, satisfaction, ear infections, and audiometry) of the application of a bone-anchored hearing aid (BAHA) to patients with conventional indications who had previously used air-conduction hearing aids.

Design: Follow-up study (mean duration, 9 years).

Setting: Tertiary referral center.

Patients: The study population comprised 27 patients with conductive or mixed hearing loss and who had participated in a previous study (N=34). Seven could not be included anymore as a result of death, Alzheimer disease, or problems related to the implant. Everyone filled out the questionnaire, and 23 patients underwent audiometric evaluation.

Main Outcome Measures: The patients filled out the adapted Nijmegen questionnaire. Aided free-field thresholds were measured as well as scores for speech in noise and in quiet. Results were compared with those obtained in the initial study.

Results: All 27 patients were still using their BAHA and appreciated it with regard to speech recognition in quiet, sound comfort, and improvements in ear infections. The audiometric results showed that most patients tested had stable bone-conduction thresholds over the years (after correction for age). Despite the treatment with BAHA, a significant deterioration in the cochlear hearing was observed in the other patients in the ear under study (their best hearing ear).

Conclusions: Positive patient outcome measures emphasized the importance of BAHA application to patients with conventional indications. The audiometric data showed fairly stable cochlear function but not for all patients. This underlines that conservative treatment should be chosen (fitting of bone-conduction devices).

cluded that the BAHA is an acceptable alternative for air-conduction hearing aids in patients with chronic ear problems; nevertheless, some patients had better speech scores with the conventional device.7,8 In the current era of extending the indications for a BAHA, it remains important to emphasize this conventional indication to consider a BAHA.

In light of this, the long-term follow-up of BAHA users previously using air-conduction hearing aids is interesting not only with regard to daily usage but also and perhaps even more with regard to satisfaction (patient outcome measures), ear infections, and audiological performance. The first question asked is “Are all these patients still using their BAHA?” Another important question is “Has patient satisfaction changed over time?” Furthermore, it is assumed that occluding ear moulds sustain chronic otorrhoea that might have lead in the long-term to cochlear damage. It might be questioned whether the use of a BAHA reduces otorrhoea to such an extent that it might lead to stable cochlear function. To find answers to these questions, the patients from the previous evaluation (Mylanus et al7) were invited for further follow-up. Audiometric measurements as well as patient outcome measures were collected and compared with those obtained during the initial study by our group.

METHODS

PATIENTS

The 34 consecutive patients in the Nijmegen BAHA series who participated in the study by Mylanus et al7 were invited to undergo further follow-up. These patients had bilateral symmetric or asymmetric conductive or mixed hearing loss and chronic ear problems. Eight patients had a second deaf ear. Before the BAHA was fitted, all these patients had been using air-conduction hearing aids. All 34 patients received the BAHA at first monaurally. In the initial study by Mylanus et al7, 2 patients had already stopped using the BAHA owing to problems with the implant and/or the abutment after 3 months and 2 and a half years of use, respectively. Thus, 32 patients were eligible for extended follow-up. We found that 3 of them had died, another patient had had the abutment removed owing to pain around the implant and had not had a reimplantation, and 1 patient had Alzheimer disease and could not participate. The remaining 27 patients who could be included in our study had an average age of 46 years and 7 months. All 27 patients were invited to participate in the present study. Without exception, they all filled out the questionnaire, and 23 of them took part in the audiometric evaluation. The 4 patients who did not participate in this part of the study were unable to visit our hospital for various reasons (poor physical condition, problems with traveling, or no reason). The duration of follow-up in the total group of participants varied from 6 years and 11 months to 14 years and 2 months, with an average of 9 years and 1 month.

In the group of 23 patients who also participated in the audiological evaluation, the pure-tone average air-conduction thresholds of 0.5, 1, 2 and 4 kHz were found to vary from 33 to 94 dB hearing level (HL) (mean, 61 dB HL). The pure-tone average bone-conduction thresholds at the same frequencies varied from 15 to 54 dB HL, with a mean value of 34 dB HL. The corresponding mean bone-conduction thresholds obtained at the time of implantation was 12 dB better. None of the patients had undergone reconstructive ear surgery. In the meantime, 3 of the 23 patients had received the BAHA binaurally. All the patients had initially been fitted with a BAHA HC 200, which was changed to an updated (but technically the same) version (HC 300 or BAHA Classic) after 5 years of use (Entific Medical Systems, Göteborg, Sweden). One patient who had previously been fitted with an HC 300 changed to a BAHA Cordelle (Entific Medical Systems).

QUESTIONNAIRE

The Nijmegen questionnaire was used, that is, the same one as used previously.7,9 It included 5 questions to compare the BAHA with the previous air-conduction hearing aid. Owing to the extended duration of follow-up, this particular comparison was considered as irrelevant due to recall bias. Thus, the Nijmegen questionnaire was slightly adapted and supplemented by another previously used questionnaire.9,10 The first part of the adapted questionnaire comprised 7 questions on daily use and care, patient satisfaction, and ear infections. In addition, there were 30 questions on speech recognition. These questions were derived from a previous study on hearing aids.9 Answers could be given on a scale from 1 to 10: score 1 represents the most negative answer (extremely poor) and score 10 the most positive answer (excellent). The 30 questions were divided into 4 different domains to represent speech recognition in quiet (quiet [SQ], 5 questions), speech recognition in noise (noise, 9 questions), quality of sound (quality, 11 questions), and whether the BAHA was comfortable to wear (comfort, 5 questions). The adapted questionnaire gives a static representation of a patient’s current opinion of the BAHA. Answers to corresponding items in this questionnaire and the initial questionnaire were compared (Mylanus et al7).

AUDIOLOGY

Air- and bone-conduction pure-tone thresholds were obtained using standard procedures and equipment and compared with the preimplantation thresholds. To assess whether cochlear hearing had deteriorated over time, not related to aging, age-appropriate P50 values12 were subtracted from the measured bone-conduction thresholds (at 0.5, 1, 2, and 4 kHz) and results were averaged per patient. Both the bone-conduction thresholds obtained at time of implantation and those obtained in the present study were corrected in this way for further analysis. Assuming that a change of 5 dB or less can be ascribed to the measurement error, a change greater than 5 dB was considered significant (P = .05).

Aided free-field thresholds (with warble tones) were measured; the set-up was calibrated according to Morgan et al.13 Furthermore, phonem scores at 65 dB (SQ) were derived from the measured free-field speech recognition-intensity function (speech audiogram).14 To quantify speech recognition in noise, the speech in noise (S/N) ratio was determined (Plomp and Milmun test).15 The noise was presented at a fixed level of 65 dB, whereas the speech level was adapted such that the speech reception threshold (SRT) was obtained. The S/N ratio is the difference between the noise level and the SRT. A difference of more than 1.7 dB between the 2 S/N ratios can be regarded as significant (P = .05).10 All the measurements were carried out in a double-walled sound-treated room. A loudspeaker that was placed 1 meter in front of the patient presented the tone and speech stimuli. A 2-tailed t test was applied to analyze differences in the results between the initial and the present measurements with the BAHA. P < .05 was chosen as the level of significance. The results were computed using the SPSS software package (version 11.0; SPSS Inc, Chicago, Ill).
RESULTS

QUESTIONNAIRE

All 27 patients filled out the questionnaire. They were still using their BAHA and wearing it for 7 days a week; 24 patients were using their BAHA for more than 8 hours a day, 2 patients for 4 to 8 hours a day, and 2 patients for 2 to 4 hours a day. In the study by Mylanus et al,7 no questions were asked about daily use of the BAHA.

In the initial study, 9 (27%) of the 33 patients who filled out the Nijmegen questionnaire reported that it was a burden to take care of the skin around the implant. In the present study, 4 (15%) of the 27 patients described this as a burden.

In the initial study, 32 of the 33 patients stated that the BAHA was better with regard to the occurrence of ear infections. In the present study, 15 (56%) of the 27 patients stated that they had not had ear infections in the past year, whereas the other 12 patients (44%) had ear infections. Two of these patients reported that they always had ear infections, while the other 10 patients reported an average of 4.3 ear infections in the past year, ranging from 1 to 14 ear infections.

Owing to ear infections, 12 (44%) of the 27 patients had visited the otolaryngologist in the past year. One patient (patient 8) had visited the otolaryngologist for 20 times for this reason and another patient (patient 24), 10 times; the median number of visits was 2 in the past year.

In the initial study, 27 (81%) of the 33 patients had preferred the BAHA, 5 patients had preferred the previous air-conduction hearing aid, and 1 patient had regarded the 2 hearing aids as equal. In the present study, 24 (89%) of the 27 patients preferred the BAHA, 2 patients did not have an opinion, and 1 patient stated that he would like to use the previous air-conduction hearing aid again if possible. The latter patient explained that he preferred the air-conduction hearing aid because of its better sound quality and the capacity for fine tuning.

Mean scores for speech recognition in the domains quiet, quality, and comfort were 7.7, 6.5, and 7.6, respectively. These scores were all classified as acceptable. The mean score for the domain noise was classified as poor, with a score of 5.0. An overview of these scores is given in Figure 1.

AUDILOGY

In the initial study, all 34 patients participated in the audiological evaluation. In the present study, 23 of the 27 patients participated in the audiological part. More specific comparisons could be made between the subgroup of 23 patients from the initial study corresponding to 23 patients in the present study.

Mean free-field thresholds obtained with the BAHA in the initial study and the present study are shown in Figure 2. In the initial study, the mean free-field thresholds at the frequencies 0.5, 1, 2, and 4 kHz were 37, 22, 24, and 34 dB, respectively (N = 34). The subgroup of patients who participated in both audiological studies (n = 23) initially had about the same mean free-field aided thresholds as the total initial group (shown in Figure 2). At the second audiometric evaluation after a mean duration of follow-up of 9 years and 1 month, at the same frequencies, these mean free-field thresholds were 7 dB poorer.

The SQ score of 97% (N = 34) in the initial study had decreased significantly to 86% (n = 23) in the present study (P < .05). In the initial study, 16 (47%) of the 34 patients obtained an SQ of 100% vs only 2 (9%) of 23 patients in the present study. The SQ varied from 80% to 100% in the initial study (N = 34) and from 26% to 100% in the present study (n = 23). Using the paired sample test, the SQ in the present study (n = 23) was compared with the SQ in the same patients in the initial study. In this subgroup, the mean SQ had decreased from 97% to 86%, which was statistically significant (P < .05).

Only 25 of the 34 patients in the initial study underwent signal-to-noise testing. Of these patients, 21 participated in the present study. This subgroup (n = 21) is referred to as the second subgroup. The mean S/N ratio in the second subgroup had deteriorated from –2.0 dB in the initial study to –0.1 dB in the present study, which was statistically significant (P = .001). A difference of more than 1.7 dB between the 2 S/N ratios in each individual patient was considered significant (see the “Methods” section). Eight patients (38%) showed significant deterioration in S/N ratio, and 1 patient showed significant im-

Figure 1. Mean scores on the domains: speech in quiet (SQ), speech in noise (SN), quality of sound (QS), and comfort (COM).

Figure 2. Mean aided thresholds with the bone-anchored hearing aid in the initial (N = 34) and present (N = 23) studies. Twenty-three of the patients participated in both the initial and present study.
provement. Unfortunately, data of 2 patients had to be excluded because of problems with the equipment. The S/N ratio in the other 11 patients (52%) remained stable. Correlation analysis between the changes in the speech scores in quiet and in noise and the changes in mean aided thresholds over time showed poor correlations.

To assess whether cochlear function deteriorated over time, we compared the preimplantation and recent bone-conduction thresholds at the frequencies 0.5, 1, 2, and 4 kHz after correction with P50 values according to International Organization of Standardization norms. Per patient, the average change was calculated; averaged over patients, a mean ± SD deterioration of 5.9 ± 8.6 dB was found. Assuming that a change of 5 dB or less can be ascribed to measurement error, 11 of the 23 patients showed a significant deterioration, with a mean ± SD of 13.3 ± 4.8 dB (range, 8-23 dB). The remaining 12 patients showed a mean ± SD change of −0.9 ± 4.7 dB. A comparison of these mean values and their standard deviations suggests that there are 2 well-separated subgroups: those with a stable cochlear hearing loss and those with a significant deterioration in cochlear hearing over time.

**COMMENT**

Over the past decades, BAHA has proven to be of great value, and the indications for its application have extended widely, which is reflected in BAHA application in patients with unilateral conductive impairment and in BAHA CROS application in patients with unilateral inner ear deafness. The pitfall in these new developments is that all the attention has focused on the new challenges encountered and we could lose sight of the long-term evaluation of the more conventional indications. In 1998, Mylanus et al reported that the BAHA proved to be an effective hearing aid for patients with chronic otorrhea who have problems with the fitting of a conventional air-conduction hearing aid. To emphasize the clinical relevance of this conventional indication for the application of the BAHA, we studied the long-term effects of a BAHA in bilaterally hearing-impaired patients who had previously been using air-conduction hearing aids.

All the patients who had participated in the study by Mylanus et al were invited for further follow-up, thus extending the mean duration of follow-up from 2½ years to 9 years and 1 month. One outstanding observation was that all the eligible patients were still using their BAHA for 7 days a week. The 9 patients (27%) in the initial study who had trouble taking care of the percutaneous implant diminished to 4 (15%) in the present study, which means that some patients took longer to become acquainted with taking care of the BAHA. Various factors associated with the yearly checkups may have played a role in this slight progress because at these visits the skin around the implant is cleaned, the screw connecting the abutment to the fixture is, if needed, tightened, and additional information is given.

Another striking observation was the satisfaction of the patients with the BAHA, which was reflected in the fact that 24 patients (89%) gave preference to the BAHA. Two patients did not have an opinion on this subject, and only 1 patient stated that he would rather use the previous air-conduction hearing aid because of its sound quality and fine tuning. Nevertheless, this patient still uses his BAHA every day. Allowing a selective usage of the conventional air-conduction hearing aid in listening situations requiring more fine tuning, alternated with BAHA usage in other listening situations, may be a good solution for such a patient.

With regard to the second part of the questionnaire concerning speech recognition, the BAHA was classified as acceptable in the domains quiet, quality, and comfort. The domain noise, however, was classified as poor. This can be explained by the unilateral hearing aid rehabilitation having a bilateral hearing impairment.

The conventional indication for a BAHA implies the existence of chronic middle ear problems and the negative effect of the occlusion of the ear canal by an ear mold on the inflammation process. The number and severity of middle ear and ear canal problems were found to decrease substantially after the conventional air-conduction hearing aid (with its occluding ear mold) had been replaced by a BAHA. In the present study, we only asked about the frequency of ear infections and otorrhea over the past year. Owing to the risk of recall bias, we did not ask whether the frequency of ear infections and otorrhea was subjectively different from the frequency in the period of air-conduction hearing aid use.

In the previous year, 12 patients (44%) had experienced 1 or more episodes of otorrhea (average, 4.3 episodes). In view of this high prevalence of ear infections, it is concluded that several patients still had (intermittently) chronic middle ear problems. The BAHA might have a positive effect, but it does not prevent middle ear infections in all the patients. Unfortunately, but obviously, there are no objective and prospective data on which to draw conclusions about the frequency of ear infections if these patients had continued to use their conventional air-conduction hearing aid.

Realizing that all the patients had ear infections at the time of BAHA implantation (one of the indications for BAHA application), the present prevalence of 44% means a substantial decrease. Research has shown that chronic otitis media might lead to cochlear damage. It has also been shown that the change from a conventional air-conduction hearing aid to a BAHA leads to a decrease in ear infections. Thus, it might be hypothesized that the use of a BAHA (ie, diminishing ear infections by means of no longer occluding the ear canal) might contribute to preventing further cochlear damage.

In this study, preimplantation and recent age-corrected bone-conduction thresholds were compared to assess changes in cochlear function not related to aging in the ear, ipsilateral to the BAHA. Of the 23 patients, 11 showed a significant deterioration over time in cochlear function. The other patients showed no change; they had stable bone-conduction thresholds over the years, which might (again) be the indirect result of the change from a conventional air-conduction hearing aid to a BAHA. However, at present it cannot yet be stated that the change from a conventional air-conduction hearing aid to a BAHA leads to more stable cochlear function, that is, no further increase in the sensorineural hearing loss component.
The free-field evaluations showed that, on average, the aided thresholds deteriorated by 7 dB. This might be ascribed to the deterioration in bone-conduction thresholds (a mean deterioration of 5.9 dB was found with P50 corrections and 12 dB without these corrections). It is expected that increasing the volume setting of the hearing aid can at least partially compensate for any deterioration in cochlear function. However, apparently, this is not what the patients did. It should be noted that the limited functional gain (the difference between sound field thresholds and bone-conduction thresholds) that can be provided by a standard BAHA might have played a role. Presumably, changing the standard BAHA for a body-worn BAHA (BAHA Cordelle) would have been beneficial for several of the present patients with deterioration in cochlear function.

On average, the SQ and S/N showed deterioration over time, which may have been the result of the deterioration in aided thresholds. However, correlations between the change in speech scores and the change in aided thresholds were poor, indicating that there must be at least 1 other factor. It is assumed that this is a device-related factor (variation in sound quality owing to aging of the device or owing to replaced, updated audio processors).

It can be concluded that the BAHA should be considered more often as a good option in the treatment of patients with chronic otitis media who need amplification or who experience problems with their conventional air-conduction hearing aids. Patient outcome measures were very positive after a mean follow-up of 9 years and 1 month. Remarkably, most patients in this study did not show any significant deterioration in cochlear function over time (after corrections for age). Although larger and prospective series are needed to come to firm conclusions, it is plausible that this is a positive indirect effect of BAHA use. The ongoing deterioration of cochlear function in the other patients once more stresses that these patients are still at risk. There may be a strong preference not to use an air-conduction hearing aid with an occluding ear mold because it may invoke ear infections in an ear with an open access to the middle ear; thus, fitting a bone-conduction device such as the BAHA instead of air-conduction hearing aids may be of greater benefit for these patients who experience problems with their conventional air-conduction hearing aids. Van der Pouw CT, Snik AF, Cremers CW. Intrindividu comparison of the bone-anchored hearing aid and air-conduction hearing aids. Arch Otolaryngol Head Neck Surg. 1998;124:271-276.

REFERENCES