Short- and Long-term Results With Implantable Transcutaneous and Percutaneous Bone-Conduction Devices

Ad F. M. Snik, PhD; Wouter A. Dreschler, PhD; Rinze A. Tange, MD, PhD; Cor W. R. J. Cremers, MD, PhD

**Objectives:** To compare the percutaneous bone-anchored hearing aid (BAHA; type NBC-HC-200, Nobel Biocare, Gothenburg, Sweden) and the transcutaneous temporal bone stimulator (TBS; Xomed-Treace, Jacksonville, Fla) with conventional hearing aids and to evaluate long-term results.

**Design:** In a prospective clinical study, the new implantable bone-conduction devices were compared with the patients' previous conventional hearing aids. Speech perception in quiet and in noise were studied, and a questionnaire concerning the actual use of the device and speech recognition was administered. During follow-up that exceeded 4 1/2 years, relevant technical and medical problems were documented.

**Patients:** Forty-one successive subjects who were fitted with a BAHA and 17 subjects who were fitted with a TBS.

**Results:** In most subjects who had previously used a bone-conduction device, the new BAHA and TBS devices led to improved or comparable results on speech recognition tests and the questionnaire. However, among the subjects who had previously used air-conduction hearing aids, the results were ambiguous. In the long-term, the percentage of nonusers in the BAHA group was 5% (2/39); in the TBS group, 65% (13/20). The main reasons for not using the TBS were insufficient gain and medical and technical problems. The vulnerability of the percutaneous coupling of the BAHA to trauma or inflammation was not a major issue; only 4 implants were lost during the total follow-up of more than 250 years.

**Conclusion:** Results indicate that the BAHA is the better choice.


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Some subjects who are hard of hearing and need a hearing aid can only be fitted with a bone-conduction hearing aid, because chronic draining of the ears or aural atresia make it impossible to fit hearing aids with ear molds. For many years, only 1 type of bone-conduction hearing aid was available, which transmitted the sound vibrations to the skull by means of a vibrator pressed on the skin in the mastoid region. In the early 1980s, Hakansson et al developed a bone-conduction hearing aid whose vibrator was anchored directly to the skull using a percutaneous titanium implant (BAHA; Nobel Biocare, Gothenburg, Sweden). Compared with the conventional bone-conduction device, the main advantages of the BAHA are that the transducer does not press against the skin, and that there are no sound-attenuating tissue layers between the vibrator and the skull. Hakansson et al reported that going through the skin and subcutaneous layers resulted in much more effective sound transmission, especially in the high-frequency range.

Hough et al developed a transcutaneous bone-conduction device, the temporal bone stimulator (TBS) or audient bone-conductor (Xomed-Treace, Jacksonville, Fla). In their mechanism, a permanent magnet is implanted in the temporal bone and covered by a thin layer of skin. This magnet is driven by an external coil positioned on the skin and kept in place by a small coupling magnet. The main advantage of this method compared with the BAHA seems to be less vulnerability to trauma and infections (no skin-penetrating implant). The main disadvantage is the relatively wide distance between the implanted magnet and the driving coil, which results in loss of power.

Although several studies have compared the TBS or the BAHA with conventional devices, very few studies have included both new types of bone-conduction hearing aid. Wade et al presented the results in 24 subjects with a TBS and 11 subjects with a BAHA. They reported that on average, the free-field thresholds with the BAHA were better than those with the TBS. Several subjects with a TBS did not use the device regularly because of insufficient gain. Only 1 subject with a BAHA did not use it, according to the authors, because of “a phobia against wearing it.” The authors suggested applying a TBS only in subjects with normal bone-conduction hearing aids.
SUBJECTS, MATERIALS, AND METHODS

SUBJECTS

The results of all the patients who fulfilled the inclusion criteria and were fitted with the new bone-conduction device from January 1, 1989, to August 31, 1992, were included in the study. The study group consisted of 41 subjects who were fitted with a standard BAHA and 20 subjects who were fitted with a TBS. The TBS users were initially fitted with the more powerful, body-worn processor. If there was sufficient reserve gain, an ear-level processor was applied.

Three of the 20 TBS users did not undergo evaluation. Before application of the new bone-conduction device, all subjects had used hearing aids. In the BAHA group, 33 subjects had used conventional bone-conduction hearing aids, and 8 had used air-conduction hearing aids. In the TBS group, these figures were 9 and 8, respectively. Some subject characteristics are presented in Table 1; the subjects in the BAHA and TBS groups were not matched. However, the mean values were comparable, and there was large overlap in the ranges.

MATERIALS AND METHODS

Before and shortly after fitting the new bone-conduction device, speech perception tests were performed to compare the subjects’ performance with their individually fitted BAHA or TBS and with the previous hearing aid. The new device was evaluated after a trial of at least 6 weeks.

Table 1. Subject Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>BAHA Users</th>
<th>TBS Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of subjects</td>
<td>41</td>
<td>17</td>
</tr>
<tr>
<td>Age, y</td>
<td>43 (10-70)</td>
<td>48 (28-72)</td>
</tr>
<tr>
<td>PTAAC, dB HL</td>
<td>55 (30-90)</td>
<td>53 (33-80)</td>
</tr>
<tr>
<td>PTABC, dB HL</td>
<td>16 (0-28)</td>
<td>12 (3-25)</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated, data are presented as mean (range). PTA indicates average hearing loss at 0.5, 1, and 2 kHz; AC, air conduction; BC, bone conduction; and HL, hearing level. Other abbreviations are given in the legend to the Figure.

†Three subjects did not undergo evaluation due to insufficient gain in the trial period.

We herein summarize our short- and long-term results with these direct bone-conduction devices. The BAHA was applied by our group at Nijmegen University Hospital, Nijmegen, the Netherlands, whereas the TBS was applied by our group at the Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands. Prospectively, strict protocols were developed under the supervision of the Dutch Council for Investigative Medicine of the Ziekenfondsraad, so that patient selection and the evaluation procedures were similar at both clinics. The selection criteria included binaural hearing loss of the conduction and technical problems were documented.

The test used was the Sentence Recognition in Noise Test, as described by Plomp and Mimpen. This test uses lists of 13 sentences and a steady-state, speech-shaped noise. The noise is presented at a fixed level, and the speech reception threshold of the sentences is established with an adaptive procedure. The difference between the speech reception threshold and the noise level (in decibels) is the critical speech-to-noise (S-N) ratio. Furthermore, the speech reception threshold was determined without noise, ie, speech reception threshold in quiet (SRT). In contrast to the SRT, the S-N ratio is independent of the volume setting of the hearing aid, as long as the speech level is above the subject’s threshold.

The change in the S-N ratio following the change in devices can be expressed as a change in the percentage of correctly repeated sentences knowing that change of 1 dB in the S-N ratio equals 17% change in sentence recognition.

We used a questionnaire to obtain subjective opinions about the previous and new hearing aids. It was administered twice, before surgery for the previous hearing aid and 3 to 5 months after fitting for the new bone-conduction device. The questionnaire has been described in detail elsewhere. We considered the questions on the recognition of speech in relatively quiet surroundings (5 subquestions) and in noisy situations (9 subquestions). The subjects answered the questions on a scale from 1 (impossible) to 10 (excellent). For each subject, the average score on the subquestions was calculated for both sets of items. During follow-up, the subjects were regularly asked about the actual use of the new device, and any relevant medical and technical problems were documented.

RESULTS

AFTER THE TRIAL PERIOD Table 2 presents the change in SRT, namely the SRT with the previous device minus that with the new device, aver-

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In the TBS group, minor improvements were found. No one previously used air-conduction hearing aids was zero. The median improvement in the BAHA users who had previously used bone-conduction devices, the median change was 1.6, presented. Among the BAHA users who had previously used bone-conduction hearing aids. In the other 3 subgroups, the median change was near zero.

The improvement in S-N ratio with the new device is also presented in Table 2. Whether the change in the S-N ratio was significantly different from zero is indicated. In the 2 BAHA subgroups, significant improvement was found, which was not the case in the TBS subgroups. The median change in the score for the question on speech recognition in noisy surroundings showed improvement in the BAHA subjects who had previously used bone-conduction hearing aids. In the other 3 subgroups, the median change was near zero.

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The percentage of users of the percutaneous titanium implant (BAHA; Nobel Biocare, Gothenburg, Sweden) and temporal bone stimulator (TBS; Xomed-Treace, Jacksonville, Fla) who, according to the short-term questionnaire, preferred the new bone-conduction device or their previous device or did not have any preference with regard to speech recognition in quiet (S-Q) or in noisy surroundings (S-N). The results of the 4 subgroups are presented separately. CBCHA indicates previous users of conventional bone-conduction hearing aid; ACHA, previous users of air-conducted hearing aid.

LONG-TERM RESULTS IN BAHA USERS

Two of the subjects in the BAHA group died of causes not related to their hearing problems. The long-term evaluation includes the remaining 39 subjects.

One subject had been using the BAHA successfully for more than 2 years, but then lost the implant because of inflammation. It was decided not to replace the implant because of psychological problems. Another subject had been using the BAHA for almost 3 years but experienced pain when using the device. No explanation could be found for the complaints, and at the subject’s request, the implant was removed. One subject lost the implant because of inflammation and 2 subjects, because of trauma. In these 3 subjects, the implant was replaced and has been used without any further problems for 4 1/2, 5 1/2, and 7 years. In 2 other patients, it was decided to reduce further the thickness of the subcutaneous layer around the implant to minimize the risk for inflammation. Altogether, 6 reoperations were performed.

Rejection of the BAHA because of insufficient amplification was not encountered. However, 1 subject suffered severe deterioration in the sensorineural hearing function.
loss component from 25 to more than 65 dB HL after surgery for cholesteatoma in the cerebellopontine angle. She was refitted with the more powerful BAHA type NBC-HC-220, but because of the severe deterioration of cochlear function, the result was poor.

At the last evaluation after at least 4 1/2 years of follow-up, 2 (5%) of the 39 BAHA recipients were nonusers. All the other subjects were using their BAHA on a daily basis.

LONG-TERM RESULTS IN TBS USERS

Medical problems with the TBS implant were encountered in 3 of the 17 subjects. The implanted magnet was removed from 1 patient because of inflammation and from 2 patients because of complaints about headaches and/or pressure on the skull. Beyond the trial period, 10 patients stopped using their device. Besides the medical problems mentioned above, lack of motivation and the vulnerability of the device that led to many repairs were reasons to discontinue use. In some of the older subjects, gradually amplification became insufficient because cochlear function deteriorated. Including the 3 patients who stopped using their TBS during the trial period, the total number of nonusers was 13 (65%) of 20 patients.

After the trial period, the results showed that in audiological terms, with some restrictions, application of both new types of bone-conduction device was successful. The results with the BAHA were somewhat better than those with the TBS. On average, it was found that in the subjects who had previously used a bone-conduction device, the new bone-conduction devices led to improved or comparable results on the tests as well as the questionnaire. However, among the subjects who had previously used air-conduction hearing aids, the results were ambiguous. This does not mean that an air-conduction hearing aid is still the first choice, because these subjects had been advised not to use their air-conduction hearing aid any longer owing to chronic draining of the ears. However, in such cases, before it is decided to change to a bone-conduction device, good counseling and a thorough audiological evaluation, including the use of a power CROS (contralateral routing of signals) air-conduction device with a vented ear-mold, are needed.

The long-term success rate with the BAHA was considerably higher than that with the TBS. Nonuse because of insufficient amplification was only encountered in the TBS group. In several other studies of TBS users who had sensorineural hearing loss within the manufacturer's criteria, similar results were found. The limited gain and output of the TBS, as shown by Gatehouse and Browning, may have played a role. The number of nonusers among the BAHA users was low, as in other studies. Rejection of the BAHA because of insufficient amplification was not encountered. In addition, in the case of deterioration of hearing loss, the more powerful BAHA type NBC-HC-220 can be fitted. This BAHA has been applied with success to subjects with a sensorineural hearing loss component of up to 65 dB HL. The percutaneous coupling of the BAHA might be a disadvantage, because it is vulnerable to trauma and inflammation. However, long-term clinical studies have shown that the titanium implant is reliable and stable in time. Nevertheless, implant loss may occur. In our study, with a total follow-up of more than 250 years, 4 implants were lost because of inflammation or trauma, which can be considered acceptable.

Encouraging long-term results were found with the BAHA, but not with the TBS. The good BAHA results are of great importance for subjects in whom the fitting of conventional hearing aids is troublesome because of aural atresia or chronic draining of the ears. The TBS should be applied only if the application of a percutaneous implant is contraindicated, eg, if regular adequate cleaning of the skin around the implant can not be guaranteed. Furthermore, to prevent rejection of the TBS because of insufficient gain, cochlear function should be normal or subnormal.

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REFERENCES