BONE-ANCHORED HEARING AIDS

SUMMARY

AGENCE D'ÉVALUATION DES TECHNOLOGIES
ET DES MODES D'INTERVENTION EN SANTÉ

Québec

BONE-ANCHORED HEARING AIDS

SUMMARY

Report prepared for AETMIS by
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May 2006

Agence d'évaluation des technologies et des modes d'intervention en santé
Québec

The content of this summary was translated from an official French publication of the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Both the original report, titled *Les aides de corrections auditives à ancrage osseux*, and the summary are available in PDF format on the Agency's Web site.

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How to cite this document:

Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Bone-Anchored Hearing Aids. Report prepared by François Bergeron (AETMIS 06-05). Montréal: AETMIS, 2006, vii pp.

Legal deposit
Bibliothèque et Archives nationales du Québec, 2006
Library and Archives Canada, 2006
ISBN 2-550-47186-5 (PDF)

MISSION

The mission of the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) is to contribute to improving the Québec health-care system and to participate in the implementation of the Québec government's scientific policy. To accomplish this, the Agency advises and supports the Minister of Health and Social Services as well as the decision-makers in the health-care system, in matters concerning the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including assistive devices for disabled persons, as well as the modes of providing and organizing services. The assessments take into account many factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic implications.

FOREWORD

BONE-ANCHORED HEARING AIDS

As part of the work of amending the regulation respecting hearing devices in order to update the list of hearing aids insured under the Health Insurance Act, the Ministère de la Santé et des Services sociaux du Québec requested that AETMIS (Agence d'évaluation des technologies et des modes d'intervention en santé) assess bone-anchored hearing aids.

Bone-anchored hearing aids (BAHA) operate on the principle of bone-conducted auditory stimulation. The product of Swedish research in the early 1990s on the osseointegration of titanium fixtures used in implanting dental, auricular and, more generally, craniofacial prostheses, the BAHA technology involves surgically implanting a titanium fixture into the mastoid portion of the temporal bone. An external vibration transducer is attached to the fixture through a percutaneous titanium abutment. This vibration transducer is designed to directly stimulate the cochlea embedded in the temporal bone.

According to the AETMIS assessment, which is, however, based on limited evidence, bone-anchored hearing aids yield audiometric benefits, chiefly including a subjective post-implantation quality-of-life improvement. These benefits emerge especially for users of bone-conduction hearing aids but also for those who wear conventional hearing aids and who suffer from chronic middle-ear infections. Eligible patients include children aged five and over, although attention must be paid to the greater risk of complications, such as skin infections. The other applications for the bone-anchored hearing aid (bilateral implantation, unilateral sensorineural hearing loss, tinnitus) are not based on evidence of clinical utility and must continue to be considered experimental.

In submitting this report, AETMIS hopes to provide policy makers in the Québec health-care system with the necessary information to offer appropriate services to people with hearing loss.

Dr. Luc Deschênes
President and Chief Executive Officer

ACKNOWLEDGEMENTS

This report was prepared at the request of the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) by **François Bergeron**, PhD, Assistant Professor, Department of Rehabilitation, Faculty of Medicine, Université Laval, and Associate Researcher, Centre interdisciplinaire de recherche en réadaptation et intégration sociale (CIRRIS). We would like to express all our gratitude for the work he accomplished.

AETMIS would also like to thank the external reviewers for their many comments, which helped improve both the quality and the content of this report.

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DISCLOSURE OF CONFLICTS OF INTEREST

None declared.

SUMMARY

RATIONALE FOR THE ASSESSMENT REQUEST

Since 1979, the MSSS (Ministère de la Santé et des Services sociaux) has offered hearing-impaired Québec citizens free access to the assistive devices they require to compensate for their hearing loss. The program administered by the RAMQ (Régie de l'assurance maladie du Québec) has since undergone many changes in terms of both its coverage and its eligibility requirements. Initially limited to hearing devices for people up to the age of 35, the current program includes a wide range of hearing aids for beneficiaries of all ages.

In 2003, the MSSS undertook to amend the regulation respecting hearing devices in order to update the list of hearing aids covered by the RAMQ. In relation to this process, the MSSS received a request to add bone-anchored hearing aids to the list of covered devices. In that request, it was mentioned that candidates for this type of hearing aid cannot be helped by any of the options offered in the current program and must appeal to charity organizations to obtain the necessary funds to purchase their hearing aids.

To support its reflection in considering whether it would be advisable to add bone-anchored hearing aids to the list of covered devices, the MSSS asked AETMIS to assess this technology.

DESCRIPTION OF BONE-ANCHORED HEARING AIDS

Bone-anchored hearing aids (BAHA) operate on the principle of bone-conducted auditory stimulation. The product of Swedish research in the early 1990s on the osseointegration of titanium fixtures used in implanting dental, auricular and, more generally, craniofacial prostheses, the BAHA technology involves surgically implanting a titanium fixture into the mastoid portion of the temporal bone. An external vibration transducer is attached to the fixture through a percutaneous titanium abutment. This vibration transducer is designed to directly stimulate the cochlea embedded in the temporal bone.

In the United States, the BAHA technology was approved by the Food and Drug Administration (FDA) in 1996. Approval for pediatric applications and the Cordelle version was granted in 1999. The BAHA system is indicated for people with conductive or mixed hearing loss who are unable to wear conventional hearing aids or to undergo ossicular-replacement surgery because of chronic suppurative otitis media, congenital malformation of the middle or external ear, or any other acquired malformation preventing the use of a conventional hearing aid. The device is contraindicated for children under the age of five. In Canada, the BAHA was approved by Health Canada in August 2004 for these same indications and was registered as a class III medical device (Licence 11960).

ANALYSIS OF THE SCIENTIFIC EVIDENCE

In September 2002, the Medical Advisory Secretariat (MAS), Ontario Ministry of Health and Long-Term Care, published a scientific literature review on bone-anchored hearing aids to document the clinical effectiveness and cost-effectiveness of this technology. All the examined studies provided a low level of scientific evidence because they were either case series or non-randomized comparative studies in which subjects acted as their own controls.

Analysis of the studies selected by the MAS shows that the objective audiometric measures confirm that the BAHA significantly improves users' hearing thresholds and speech

recognition in quiet and in noise. Although the audiometric benefits were ambiguous for users of conventional air-conduction hearing aids, the BAHA helped reduce the frequency of ear infections, especially in people with chronic middle-ear conditions. In addition, patient satisfaction surveys showed subjective quality-of-life improvements: users reported better speech intelligibility, better sound comfort, less pressure on the head, less skin irritation, enhanced esthetics and greater self-confidence. Reported shortcomings included wind noise, acoustic feedback (Larsen effect) and difficulty in talking on the telephone. The overall benefits appear to be the same for pediatric patients. In all cases, the BAHA is judged to be safe. The literature search yielded no cost-effectiveness studies.

Other literature reviews carried out in 2001 and 2004 produced similar conclusions. On the one hand, users of bone-conduction hearing aids gain audiometric benefits. Consequently, the BAHA should be offered to all candidates eligible for a bone-conduction hearing aid, whether or not they experience difficulty with this type of device. On the other hand, the benefits achieved by users of conventional hearing aids do not seem as significant and appear to be linked to the size of the gap between the air-conduction and bone-conduction thresholds (air–bone gap). The BAHA apparently offers greater benefits beyond an air–bone gap of 25 dB to 30 dB. The authors suggest that conventional hearing aids not be proposed as a first option to people with chronic ear discharge. Others point out that hearing aids can cause chronic discharge and that, in that case, implanting a BAHA would be preferable to retaining the conventional hearing aid.

To confirm the conclusions of these comprehensive reviews and to provide specific answers to the MSSS, we located and analyzed the clinical trials published after the Ontario report. In fact, owing to the high quality of the Ontario assessment, it was used as the starting point for our own analysis.

The literature search strategy, covering the period from June 2002 to December 2005, retrieved 32 articles from the MEDLINE database. One of them describes the consensus statements that emerged from June 2004 expert roundtable meetings. Ten or so complementary documents were selected from the reference lists in these articles and from the manufacturer's documentation. Among this literature, twenty studies reported on clinical trials of bone-anchored hearing aids and five dealt only with complications. None of the studies were randomized controlled trials, which provide the highest level of evidence. In fact, most were non-randomized studies comparing the BAHA with the hearing aids worn before the implant. These less well-designed studies were also weakened by their often limited sample sizes and were therefore usually assigned the lowest level of evidence. Given the limited number of patients who can use this technology, the chances that rigorous studies with greater statistical power will be conducted are rather poor.

Although the demonstration of the utility of BAHA remains weak, as was already indicated in the Ontario assessment, research findings do converge: the BAHA system provides benefits, even if they mostly concern subjective post-implantation quality-of-life improvements (as measured by a specific questionnaire). These benefits are achieved first by users of bone-conduction hearing aids and then by users of conventional hearing aids who suffer from chronic middle-ear infections. The other applications for the bone-anchored hearing aid (bilateral implantation, unilateral sensorineural hearing loss, tinnitus) are not based on sufficient evidence of clinical utility. This technology is nevertheless safe; most of the complications are skin reactions, which are treatable with appropriate therapeutic solutions that are readily available. Skin reactions are somewhat more frequent in pediatric patients.

CONCLUSION

Available information shows, in a limited way, the effectiveness of bone-anchored hearing aids. For the usual applications for users of bone-conduction hearing aids and for wearers of conventional hearing aids who present with chronic middle-ear infections, they have gone beyond the experimental stage and may be classified as *innovative*. This development status nevertheless restricts the implantation of these hearing aids to centres with a specialized technical platform, that is, those with the appropriate resources, knowledge and expertise, especially given the small number of patients who would benefit from this type of device. An expert group recommends that the BAHA implantations be performed by a team that would include at least one otorhinolaryngologist and one audiologist, and, for children, one pediatric anesthesiologist and one speech-language pathologist. The same group recommends that these referral centres treat at least fifteen new cases per year. Eligible patients include children aged five and over. The innovative status also means that data must be collected to better identify methods of use and indications. In the same vein, it would also be advisable to conduct cost-utility studies to better assess the quality-of-life effects.

The other applications for the bone-anchored hearing aid (bilateral implantation, unilateral sensorineural hearing loss, tinnitus) are still considered to belong to the *experimental* field, which implies that they are to be restricted to research studies. In fact, additional controlled trials are needed to confirm the efficacy of these solutions.

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