Efficacy of directional-microphone hearing aids

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

Québec

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Technical note prepared for AETMIS
by François Bergeron

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Agence d'évaluation
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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 technical aids 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

EFFICACY OF DIRECTIONAL-MICROPHONE HEARING AIDS

As part of the review of the *Programme d'aides auditives*, the *Ministère de la Santé et des Services sociaux* formed an advisory group mandated to recommend appropriate amendments to ministry officials. The work of the subcommittee on new technologies led the group to ask the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) to rule on the clinical efficacy of directional-microphone hearings aids.

Difficulty understanding speech in the presence of noise is a common cause of users' dissatisfaction with hearing aids. Several technological approaches have been explored to offer hearing-impaired people better listening ability in noisy environments. Work on microphone directionality has pursued this goal.

According to AETMIS's evaluation, the few studies presenting an intermediate level of evidence allow us to classify as "experimental" technologies both single-microphone solutions and approaches based on a microphone array. These solutions appear promising but further controlled trials will be required to confirm their efficacy.

Dual-microphone approaches can be considered "accepted" technologies but only in optimal listening conditions, when the speaker and the noise are diametrically opposite each other in environments with low reverberation. The application of this technology in other conditions reduces (sometimes significantly) their effectiveness. Finally, eligibility requirements for devices with the directionality option must take into account the candidate's physical and cognitive abilities to use the directional properties effectively.

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

Renaldo N. Battista
President and chief executive officer

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SUMMARY

Origin of the request for evaluation

Since 1979 the *Ministère de la Santé et des Services sociaux* (MSSS) has offered a program giving free access to hearing devices to Québec residents with a hearing loss. Administered by the *Régie de l'assurance maladie du Québec*, this program has since undergone several changes in both its coverage and its eligibility requirements. Initially limited to hearing aids for people up to the age of thirty-five, the program now includes a wide range of hearing devices available to people of all ages.

To take into account technological advances and to better meet people's needs, the MSSS formed an advisory group mandated to review this program and to recommend appropriate amendments to ministry officials. The work of the subcommittee on new technologies led the advisory group to ask AETMIS to rule on the clinical efficacy of multi-microphone hearing aids.

Description of hearing aids

Deafness is essentially manifested by a reduced ability to perceive acoustic signals in the environment. Even when audibility has been restored by means of a hearing aid, people with hearing impairment need better listening conditions than people with normal hearing to perform well on speech-intelligibility tasks. Difficulty understanding speech in the presence of noise is a common cause of users' dissatisfaction with hearing aids, irregular use and disuse. Several technological solutions have been explored to offer hearing-impaired people better listening ability in a noisy environment. Work on microphone directionality has pursued this goal.

The application of the principles of directionality to hearing aids offers the possibility of improving the signal-to-noise ratio (SNR) even when speech and noise are similar. This solution is especially relevant when speech and noise come from sources that are spacially separate. In theory, omnidirectional microphones pick up sounds equally from all directions, as opposed to directional microphones that respond more to sounds emitted from a specific direction. Applied to deafness, directionality targets sounds coming from the front, that is, where a speaker would normally be.

The first directional microphones were incorporated into hearing aids at the beginning of the 1970s. By 1980 they represented nearly 20% of all manufacturers' sales. The popularity of in-the-ear hearing aids, along with distributors' scepticism, later led to a gradual decline in the demand for this approach. Newer technological prospects, particularly miniaturization, as well as advances in electronic and digital signal processing, have recently renewed researchers' interest in hearing-aid directionality.

Analysis of scientific data

The literature-search strategy for querying the databases located seventeen articles dealing with directional hearing aids in the last decade. Nineteen supplementary documents were obtained from the expert group or taken from the bibliographic references cited in the articles. This literature includes twenty-four studies reporting on clinical trials. None of the reports relies on a study design with the highest level of evidence, that is, a randomized crossover trial with high statistical power, but all of them present data comparing hearing aids with different directionality (e.g., omnidirectional vs directional) worn by the same subjects, following a crossover design, with or without randomization. The sample sizes are generally small.

Regardless of the technological approach used, all of the studies (i.e., those with an intermediate level of evidence as well as those with a low level of evidence) show that hearing aids with directional properties provide speech-intelligibility benefit in noisy environments. This advantage is optimal in listening conditions where the noise is behind and the speaker in front of the hearing-impaired person in an environment with low reverberation. In listening situations more representative of daily reality, where noise is diffuse and the room reverberant, this advantage decreases to

the point of becoming comparable to that provided by conventional hearing aids with omnidirectional microphones.

Conclusion

With respect to directional properties, the few studies available presenting an intermediate level of evidence allow us to classify as "experimental" technologies both single-microphone solutions and approaches based on a microphone array. These solutions seem promising, but additional controlled trials will be required to confirm their efficacy.

Dual-microphone approaches can be considered "accepted" technologies but only in optimal listening conditions, when the speaker and the noise are diametrically opposite each other in rooms with low reverberation. The application of this technology in other conditions reduces (sometimes significantly) their effectiveness. Finally, eligibility requirements for devices with the directionality option must take into account the candidate's physical and cognitive abilities to use the directional properties effectively.

GLOSSARY

Anechoic:
Having no reverberation.

Assistive listening device (ALD):
Any device that is part of a user's environment and designed to compensate for a hearing impairment, to prevent or alleviate a handicap situation.

Binaural:
Involving both ears. Binaural means that a hearing aid is fitted to each ear, as opposed to a monaural system in which only one ear is fitted with a hearing aid.

Hearing aid:
Any device worn by a user that is designed to correct a hearing impairment, to compensate for a hearing disability, to prevent or alleviate a handicap situation.

Hearing device:
Any device designed to correct a hearing impairment, to compensate for a hearing disability, to prevent or alleviate a handicap situation.

Linear:
Relating to a hearing aid that provides a fixed level of amplification regardless of the intensity of the incident acoustic signal. By definition, these devices do not have compression circuits allowing for more or less advanced methods of processing the dynamic range of the sound environment.

Signal-to-noise ratio (SNR):
Ratio of the sound intensity of a signal and that of competing noise, expressed in decibels (dB).

Speech reception threshold (SRT):
The sound intensity required for recognition of 50% of two-syllable words, expressed in decibels (dB).

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1. INTRODUCTION

1.1. Origin of the request for evaluation

Since 1979 the *Ministère de la Santé et des Services sociaux* (MSSS) has offered a program giving free access to hearing devices to Québec residents with a hearing loss. Administered by the *Régie de l'assurance maladie du Québec*, this program has since undergone several changes in both its coverage and its eligibility requirements. Initially limited to hearing aids for people up to the age of thirty-five, the program now includes a wide range of hearing devices available to people of all ages. Tables A1a and A1b in Appendix A summarize the coverage and eligibility requirements drawn from the latest revision of the program (1997).

To take into account technological advances and to better meet people's needs, the MSSS formed an advisory group mandated to review this program and to recommend appropriate amendments to ministry officials. The work of the subcommittee on new technologies led the advisory group to submit two requests for evaluation to AETMIS to allow it to rule on the clinical efficacy of multi-microphone hearing aids, on the one hand, and on that of programmable analog hearing aids, on the other. This technical report deals with the first request, that is, the analysis of multi-microphone hearing aids.

1.2. A technological solution to improving hearing: microphone directionality

Deafness is essentially manifested by a reduced ability to perceive acoustic signals in the surrounding environment. Depending on the degree and nature of the hearing loss, perceptual disorders will be more or less pronounced. For the majority of people with a hearing loss, neither medical nor surgical treatment is recommended because of the sensorineural origin of their auditory-system lesions. For such people, the therapeutic approach initially favoured consists in fitting them with one or two hearing aids. An attempt is thus made to compensate for the loss of audibility of the sound environment and, more particularly, of speech, by selectively amplifying the sounds rendered inaudible through the hearing loss.

Furthermore, restoring audibility compensates for only part of the disabilities caused by deafness. In fact, sensorineural lesions cause other psychoacoustic disturbances, notably distortions in frequency, dynamic and temporal perception. The disabilities resulting from these distortions arise particularly in adverse listening situations such as conversations in groups or classrooms, or in noisy workplaces. Difficulty understanding speech in noise is a frequent cause of users' dissatisfaction with hearing aids, irregular use and disuse [May et al., 2000]. As a result, even when audibility is restored, people with a hearing loss need better listening conditions to perform well on speech-intelligibility tasks [May et al., 2000]. Table 1 shows the increasing need to favour speech sounds over noise (signal-to-noise ratio) in relation to the degree of hearing loss.

According to Soli and Nilsson, each improvement by 1 dB in signal-to-noise ratio could lead to an improvement in speech-recognition performance of the order of 8.5% [Soli and Nilsson, 1994, cited in Valente et al., 1995]. These findings have led to the exploration of a wide range of technological approaches to offering improved listening ability in noisy environments. Work on microphone directionality has pursued this goal.

Table 1.
Relationship between degree of deafness and loss of signal-to-noise ratio (tested at high intensity)

Degree of deafness (average of pure tones at 0.5, 1 and 2 kHz)	Average loss of signal-to-noise ratio
30 dB HL	4 dB
40 dB HL	5 dB
50 dB HL	6 dB
60 dB HL	7 dB
70 dB HL	9 dB
80 dB HL	12 dB*
90 dB HL	18 dB*

Abbreviations: dB (decibel); dB HL (hearing level)
* Estimated
Source: Killion, 1997.

2. METHODS

The evaluation methods used here are based on the critical appraisal of scientific publications and on the contributions of members of a working group composed of experts who have studied this topic. This group included seven experts from the disciplines of audiology, audioprothesis, economics and engineering. The list of members, their respective disciplines and their institutional affiliations appear in the Acknowledgments section of this report.

The literature search was carried out through MEDLINE and Cochrane database queries covering the period from January 1990 to May 2002. It was limited to publications written in French or in English. The specific strategy used and the results are presented in Table 2. The database query was supplemented by publications provided by the experts consulted or taken from the bibliographical references cited in the articles.

Table 2.
Literature-search strategy

Filter	Keywords			Results	
				M	C
Directional hearing aid	hearing aid	AND	multimicrophone multiple microphone dual microphone microphone array directional	16	1

M=MEDLINE, C=Cochrane

The articles retrieved from the search, as well as the supplementary publications submitted by the group of experts, were appraised according to the critical-appraisal checklist shown in Appendix B. This checklist was developed by the French National Agency for Accreditation and Evaluation in Health (*Agence nationale d'accréditation et d'évaluation en santé,* ANAES, 2000) with a view to standardizing the literature-classification procedure according to the quality of the methodology and the level of scientific evidence. The level of scientific evidence is based on the classification proposed by ANAES (Appendix C). The presence of multiple methodological bias in a study lead to a downgrading of the quality level. Following the literature search and critical appraisal of the selected articles, a draft of this document was submitted to the expert group.

Hearing-aid evaluation protocols are often based on a study plan with a crossover design. This type of controlled trial is appropriate in the case of relatively stable chronic conditions and for the study of short-term effects. In this experimental design, all the trial subjects undergo the same treatment or wearing periods. The subjects become their own controls since they are exposed in turn to the different devices. Crossover trials are considered randomized when the order of the wearing period is selected at random for each subject. This procedure implies that half of the subjects receive hearing aid A followed by hearing aid B, and the other half receive hearing aid B followed by hearing aid A. Randomization is important for controlling delayed effects (the continuation of the effect produced by the first hearing aid while the second is being worn) and order effects (the extent of the effect of wearing hearing aid A may be modified if it precedes or follows the wearing of hearing aid B).

3. DESCRIPTION OF DIRECTIONAL MICROPHONES

3.1. Principles

The approach generally favoured for improving speech intelligibility in noise by optimizing the signal-to-noise ratio is based on attenuating noise in a frequency spectrum other than that for speech [Ricketts and Dhar, 1999]. This solution poses an obvious problem when competing noise is or resembles speech. Applying the principle of directionality offers the possibility of improving the signal-to-noise ratio even when speech and noise are similar. This alternative solution is especially relevant when speech and noise come from sources that are spatially separate.

In theory, omnidirectional microphones pick up sounds equally from all directions, as opposed to directional microphones that respond more to sounds emitted from a specific direction. Applied to deafness, directionality targets sounds coming from the front, that is, where a speaker would normally be. This configuration is in fact generally chosen in order to favour the visual cues derived from lipreading. Although it is often desirable to give priority to frontal sounds, situations exist in which this configuration is not optimal and even to be avoided. This is especially true in the case of a new speaker entering a room, intercom messages or alarm signals.

The design of a directional microphone is based on the acoustic or electronic subtraction of similar sounds received in two different places. The acoustic approach makes use of a single microphone with two ports (Figure 1). Sound coming from behind is initially picked up by the first (or rear) port. Delayed by a mechanical resistance, it reaches the surface of the microphone diaphragm at the same time as the same noise is picked up in turn by the second (or front) port. By exerting equal pressure on both sides of the diaphragm, the two practically identical signals cancel each other out. In contrast, speech coming from the front will not be attenuated because of the delay caused by the physical gap between the two ports and by the mechanical resistance. The electronic approach is similar: this process makes use of the electrical signal emitted by two or more microphones, and the delay is caused electronically or, more recently, digitally (Figure 2).

Figure 1. Directional microphone with two ports

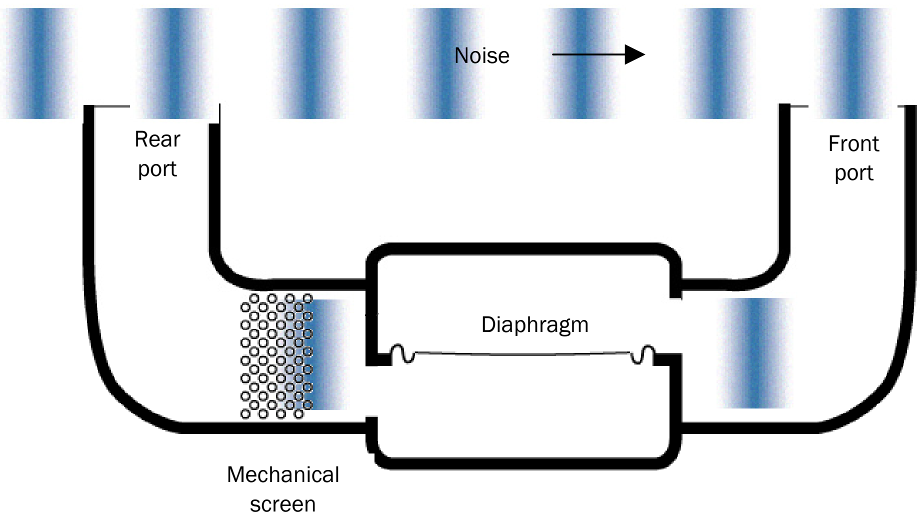
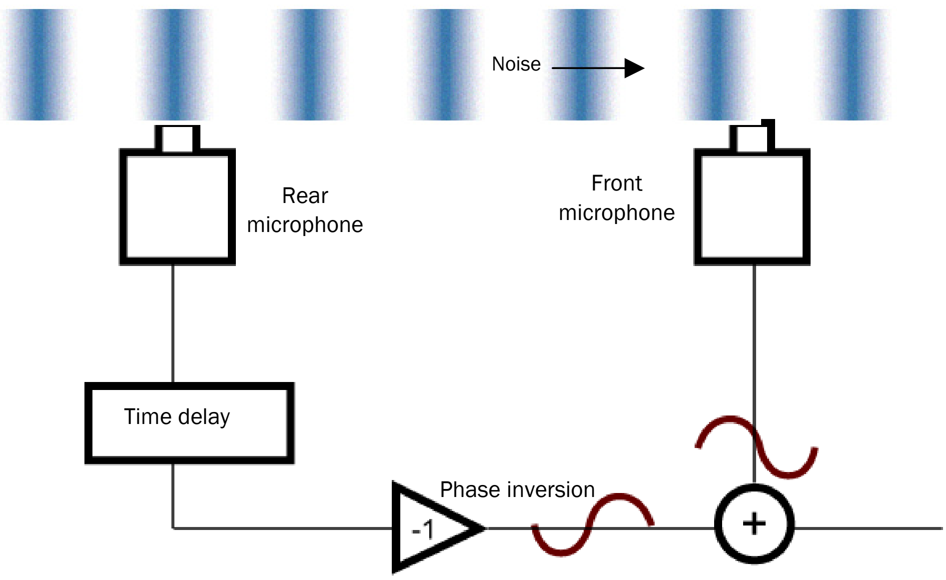


Figure 2. Multi-microphone directional system



3.2. Properties

The system's directional properties are determined by the ratio of the time delay caused by the port spacing in the microphone(s) (external delay) to the mechanical or electronic delay (internal delay). Because of the importance of the external delay in ensuring functional directivity, the microphone-array solution cannot be applied directly to behind-the-ear or in-the-ear hearing aids given that the microphones take up too much space. These systems are therefore incorporated into the temples of a pair of eyeglasses or into a neck-worn apparatus (Figure 3). The directional properties are generally displayed as a polar plot (Figures 4 and 5) indicating the microphone's sensitivity at 360 degrees azimuth. The polar patterns in Figure 4 are derived from test conditions in which the microphone is placed alone in an anechoic chamber. The following numerical indices are also used:

- FBR (front-to-back ratio): difference between a microphone's sensitivity to sounds at 180 degrees and its sensitivity to sounds at 0 degrees.
- UI (unidirectional index): ratio of a microphone's sensitivity to frontal sounds (between 270 and 90 degrees) to its sensitivity to sounds coming from the back (between 90 and 270 degrees).
- DI (directivity index): difference between a microphone's sensitivity to sounds directly in front of the microphone (0 degrees) and its sensitivity to sounds coming from any other direction.
- AI–DI (articulation index–weighted directivity index): weighted directivity index for speech comprehension (articulation index).

Figure 3. Microphone array on a neck-worn apparatus

Figure 4. Polar patterns of microphones with different directional properties [Gennum, 2000]

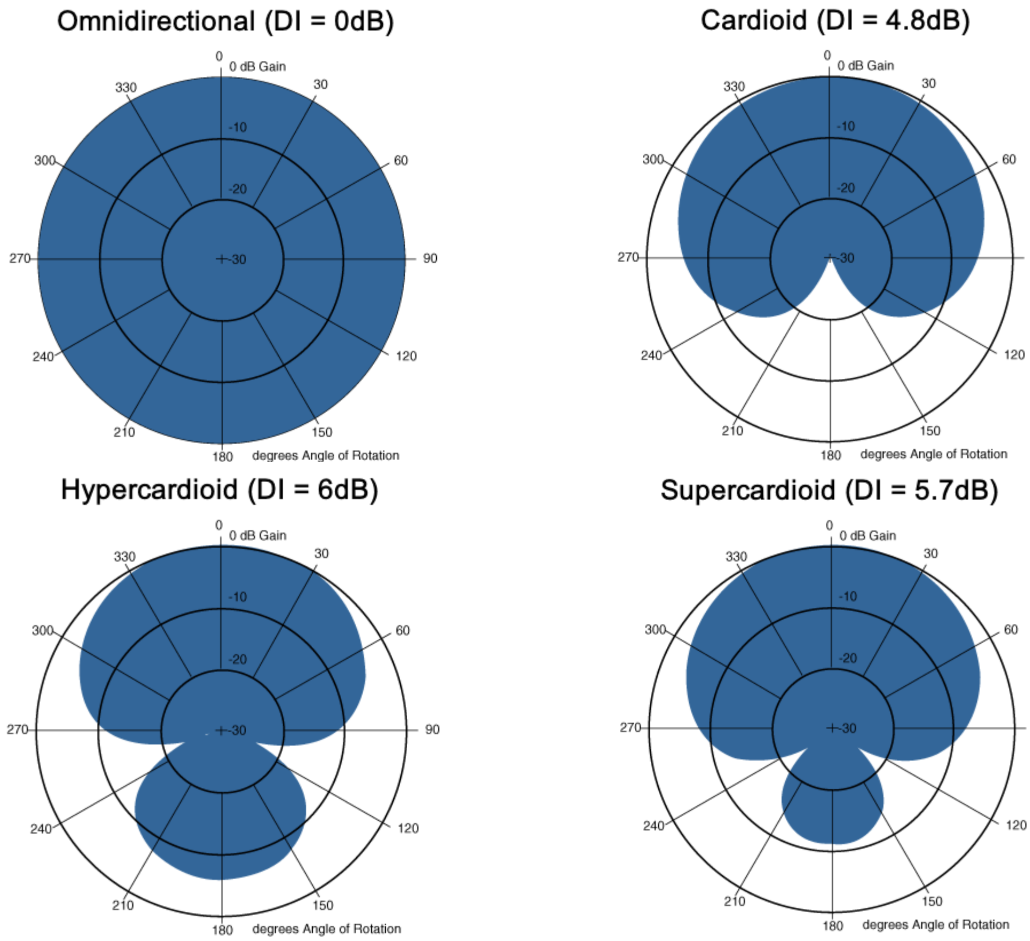
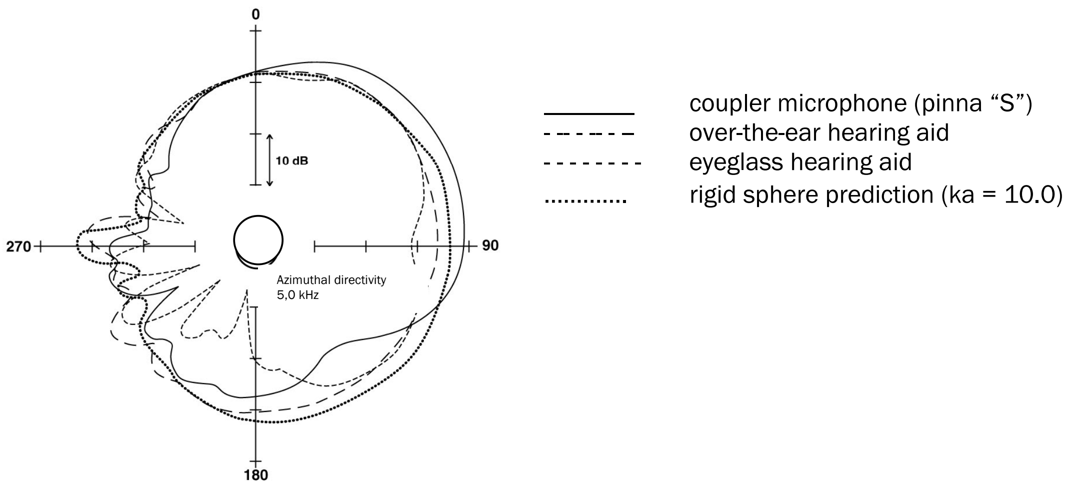


Figure 5. Polar plot at 5kHz of two models of omnidirectional hearing aids showing that the position in situ produces a directional effect [Kuhn, 1980]



3.3. Use

The first directional microphones were integrated into hearing aids in the early 1970s [Mueller et al., 1981, cited in Ricketts and Mueller, 1999]. By 1980 directional hearing aids represented nearly 20% of manufacturers' sales. The popularity of in-the-ear aids—which are too small to house a directional microphone—along with researchers' scepticism about the real benefits that users could derive from it, led to a gradual decline in demand for this approach. Killion et al. [1998] indicate that directional aids at that time had a directivity index (DI) of 1.6 dB, that is, a gain comparable to that obtained by placing the hand behind the external ear.

New technological prospects, especially miniaturization, as well as advances in electronic and digital signal processing, have recently rekindled researchers' interest in hearing-aid directionality. Supply and demand are nevertheless weak: a brief investigation reveals that Canadian manufacturers offer the directional option in only 2% of their products and barely 1% of the hearing aids sold have it. Consumer interest in this option seems to be on the rise, but consumers must spend from $100 to $300 more for each hearing aid. This option is included in several of the new fully digital models.

4. RESULTS

The literature-search strategy for querying the databases located seventeen articles. Nineteen supplementary publications were obtained from the expert group or taken from the bibliographic references cited in the articles. This literature includes twenty-four studies reporting on clinical trials of directional hearing aids. Table 3 (a, b, c) summarizes the studies according to the technological approach used to ensure directionality, that is, a) single microphone and acoustic-cancellation procedure; b) dual microphone with electronic or digital signal processing; and c) microphone array with electronic or digital signal processing. In each category, the studies are ranked in descending order of strength of evidence according to the classification scheme presented in Appendix C.

None of the studies involves a design with the highest level of evidence, that is, a randomized crossover trial with high statistical power (with a sufficiently large sample size and devoid of bias affecting the internal validity). All of the studies, however, include a crossover design, some of which are randomized, but with low statistical power, and others not. The classic study plan is based on a comparison of the sound intensity required (threshold) for recognition of 50% of speech material presented frontally (0° azimuth) in a noisy environment with and without making use of the hearing aid's directional capability. Results are expressed in speech reception threshold (SRT) reduction or in signal-to-noise ratio (SNR) improvement. The nature and source of the ambient noise are variable: certain study protocols are carried out in everyday listening situations (sentence recognition in a restaurant); others are carried out in typical laboratory conditions (recognition of words presented at 0 degrees in a controlled environment in the presence of a noiseband emitted by a loudspeaker located at 180 degrees). Sample sizes are generally small.

Table 3.

Summary of the selected studies according to the principle of directionality and level of scientific evidence

a) Directionality using one microphone

Source	Method			Results	Level of evidence
Author, year (country)	N	Study design	Variables		
Leeuw and Dreschler, 1991 (Netherlands)	12 n	Randomized crossover trial	Independent: hearing aid (omnidirectional vs directional), noise direction and level, reverberation, binaurality Dependent: frequency spectrum, SRT in noise (0°, 45°, 90°, 135°, 180°), location	SRT with directional aid < 1.5 to 7 dB Reverberation effect Effect from direction of background noise (non-reverberant environment)	2
Novick et al., 2001 (USA)	10 h	Non-randomized crossover trial	Independent: configuration (omni vs directional), amplitude-compression release times, binaurality, reverberation Dependent: sentence recognition in noise (2 tests)	SNR with directional configuration > 1.5 to 2.5 dB No release-times effect Binaural > monaural Reverberation effect No significant effect with the second test	2
Killion et al., 1998 (USA)	12 n 24 h	Non-randomized crossover trial	Independent: configuration (omni vs directional), simulated environment (restaurant, street, museum) Dependent: sentence recognition in noise	SNR with directional configuration > 3.5 to 11.5 dB Environmental effect	2
Kuk et al., 1999 (USA)	20 h	Non-randomized crossover trial	Independent: hearing aid (personal omnidirectional analog vs digital directional), degree of hearing loss (mild-to-moderately-severe vs moderate-to-severe) Dependent: word recognition in noise (180°), evaluation (questionnaires)	SNR with digital directional hearing aid > 5.5 to 8 dB Effect from degree of hearing loss Subjective preference for digital directional aid	3

n = subjects with normal hearing; h = subjects with a hearing loss.

Table 3.
Summary of the selected studies according to the principle of directionality and level of scientific evidence (cont'd)

b) Directionality with two microphones

Source	Method			Results	Level of evidence
Author, year (country)	N	Study design	Variables		
Larsen et al., 1998 (study described in May et al., 2000) (Denmark)	19 h	Randomized crossover trial	<u>Independent</u>: hearing aid (digital vs digitally programmable multi-microphone) <u>Dependent</u>: recognition of monosyllables in noise (45°, 135°, 225°, 315°), evaluation (scales, questionnaires)	SNR with multimicrophones > 3.6 dB Preference for multimicrophones (13/19)	2
Preves et al., 1999 (USA)	10 h	Non-randomized crossover trial	<u>Independent</u>: configuration (omni vs 2 microphones) <u>Dependent</u>: sentence recognition in noise (115° + 245°), preferences (questionnaires, interview, paired-comparison judgments)	SNR with 2 microphones > 2.5 dB Non-significant preference for 2 microphones Importance of having both omni and directional options	2
Ricketts, 2000b (USA)	25 h	Randomized crossover trial	<u>Independent</u>: hearing aid (3 brands), configuration (omni vs directional), reverberation (living room vs class-room), noise source (4 loudspeaker configurations) <u>Dependent</u>: sentence recognition in noise (different angles)	Thresholds in directional mode < 1.5 to 7.8 dB Significant interaction among the type of aid, reverberation and position of noise source	2

n = subjects with normal hearing; h = subjects with a hearing loss.

b) Directionality with two microphones (cont'd)

Source	Method			Results	Level of evidence
Author, year (country)	N	Study design	Variables		
Ricketts et al., 2001 (USA)	47 h	Randomized crossover trial	Independent: configuration (omni vs directional), compression vs linear, type of aid (behind-the-ear vs in-the-ear) Dependent: sentence recognition in noise (2 tests, diffuse noise, by 5 loudspeakers)	Thresholds in directional mode < 2.2 to 2.9 dB Speech recognition in directional mode > 13% to 23% No compression effect Behind-the-ear < in-the-ear Directivity Index (DI) predicts directional benefit.	2
Ricketts, 2000c (USA)	20 h	Randomized crossover trial	Independent: configuration (omni vs directional), binaurality (monaural vs binaural), listening angle (0°, 15°, 30°) Dependent: sentence recognition in noise (diffuse, by 5 loudspeakers)	Thresholds in directional mode < 3 to 4.3 dB Directional effect > binaural effect + listening angle	2
Walden et al., 2000 (USA)	40 h	Randomized crossover trial	Independent: configuration (omni vs directional), type of aid (linear vs 2-channel analog wide dynamic range compression vs digital) Dependent: sentence recognition in noise, questionnaires (90°, 180°, 270°)	Speech recognition in directional mode > 20% to 30% Analog wide dynamic range compression = digital dynamic compression > linear No subjective differences in everyday listening environment	2
Agnew and Block, 1997 (USA)	20 h	Randomized crossover trial	Independent: configuration (omni vs dual- microphone) Dependent: sentence recognition in noise (180°)	SNR with dual-microphone > 7.5 dB	2

n = subjects with normal hearing; h = subjects with a hearing loss.

b) Directionality with two microphones (cont'd)

Source	Method			Results	Level of evidence
Author, year (country)	N	Study design	Variables		
Gravel et al., 1999 (USA)	20 h	Randomized crossover trial	Independent: configuration (omni vs dual-microphone), speech material (words vs sentences), age (4- to 6-yr-olds vs 7- to 11-yr-olds) Dependent: recognition of speech material in noise (180°) (2 tests, diffuse noise, by 5 loudspeakers)	SNR with dual-microphone > 4.7 dB Significant effect from age Significant effect from type of speech material	2
Labonté, 2000 (Canada)	21 n	Randomized crossover trial	Independent: configuration (omni vs 2 microphones), noise source (2 angles) Dependent: SRT in noise (180°, 210°, SNR 0 dB),	SRT with 2 microphones < 13 dB No effect from noise-source angle	2
Lurquin and Rafhay, 1996 (Belgium)	20 n 33 h	(Non-randomized ?) crossover trial	Independent: configuration (normal hearing vs omni vs dual-microphone) Dependent: recognition of two-syllable words in noise (180°)	SNR with dual-microphone > 6.6 dB = normal	2
Pumford et al., 2000 (Canada)	24 h	Randomized crossover trial	Independent: configuration (omni vs directional + party response algorithm) Dependent: recognition of sentences in noise (by 4 loudspeakers)	Thresholds in directional mode + party response algorithm < 5.8 dB with a behind-the-ear aid < 3.3 dB with an in-the-ear aid	2

n = subjects with normal hearing; h = subjects with a hearing loss.

b) Directionality with two microphones (cont'd)

Source	Method			Results	Level of evidence
Author, year (country)	N	Study design	Variables		
Ricketts and Dhar, 1999 (USA)	12 h	Randomized crossover trial	Independent: configuration (omni vs directional), hearing aid (3 brands), reverberation (anechoic room vs living room) Dependent: sentence recognition in noise (delivered by 5 loudspeakers)	Thresholds in directional mode < 5 to 7 dB Reverberation effect No brand differences	2
Valente et al., 1995 (USA)	50 h (two sites)	Randomized crossover trial	Independent: configuration (omni vs dual-microphone) Dependent: sentence recognition in noise (180°), evaluation (questionnaire)	SNR with dual-microphone > 7.4 to 8.5 dB Significant preference for dual-microphone in noise	2
Wouters et al., 1999 (Belgium)	10 h	Non-randomized crossover trial	Independent: hearing aid (personal omni vs programmable omni vs 2 microphones), type of noise (speech, traffic, restaurant), speech material (words vs sentences) Dependent: recognition of speech material in noise (90°)	SNR with 2 microphones > 3.4 dB	2

n = subjects with normal hearing; h = subjects with a hearing loss.

b) Directionality with two microphones (cont'd)

Source	Method			Results	Level of evidence
Author, year (country)	N	Study design	Variables		
Kompis and Dillier, 1994 (Switzerland)	9 n 6 h	Non-randomized crossover trial	Independent: configuration (omni vs directional vs digital processing) Dependent: Identification of consonants and vowels in noise (45°)	Digitally controlled omni and directional modes > directional > omni	3
Kühnel et al., 2001 (Switzerland)	21 h	Non-randomized crossover trial	Independent: configuration (omni vs directional + party response algorithm) Dependent: sentence recognition in noise (180°), evaluation (questionnaires)	Thresholds in directional mode + party response algorithm < 13.7 dB Subjective preference for directional mode + party response algorithm	3
Warland, 1998 (study described in May et al., 2000) (Norway)	22 h	Non-randomized crossover trial	Independent: hearing aid (personal digital vs multimicrophones) Dependent: recognition of monosyllables in noise (0°), evaluation (scales, questionnaires)	Better performance with multimicrophones (16/20) Preference for multimicrophones (17/22)	4

n = subjects with normal hearing; h = subjects with a hearing loss.

Table 3.
Summary of the selected studies according to the principle of directionality and level of scientific evidence (cont'd)

c) Directionality with a microphone array

Source	Method			Results	Level of evidence
Author, year (country)	N	Study design	Variables		
Saunders and Kates, 1997 (USA)	16 h	Randomized crossover trial	Independent: microphone (omni vs cardioid vs 2 array-processing techniques), reverberation (office vs conference room) Dependent: SRT in noise (60°, 105°, 180°, 255°, 300°)	SRT with superdirective array processing < 4.7 to 6.2 dB Cardioid < 1.9 to 4.3 dB Digitally controlled array < 0.9 to 1.5 dB Significant reverberation effect	2
Hoffman et al., 1994 (USA)	10 n	Non-randomized crossover trial	Independent: number of micro-phones (1 vs 3 vs 7), reverberation (anechoic room vs living room vs conference room) Dependent: recognition of two-syllable words in noise (45°)	SNR with 7-microphone array > 3.1 to 22.7 dB SNR with 3-microphone array > 1.4 to 15.4 dB Reverberation effect	3
Bilsen et al., 1993 (Netherlands)	30 n 45 h	Randomized crossover trial	Independent: microphone (omni vs array), deafness (subjects with normal hearing vs subjects with hearing impairment) Dependent: SRT in noise (diffuse)	SNR with microphone array > 6.8 to 7 dB	4

n = subjects with normal hearing; h = subjects with a hearing loss.

Directionality with a single microphone

Very few studies published since 1990 have been found to make use of the acoustic approach for hearing-aid directionality. This finding reveals manufacturers' predilection for modern multi-microphone formulas and rejection of a strategy considered less effective as early as the 1980s. The conclusions drawn in a study from The Netherlands support this tendency: although in optimal listening conditions (anechoic chamber, competitive noise at 180 degrees), an advantage on the order of 7 dB is reported in favour of the directional technique, this advantage is less marked in a reverberant environment (approximately 1.5 dB) [Leeuw et Dreschler, 1991]. According to the authors, this gain does not seem large enough to provide significant benefit to hearing-impaired people in everyday listening situations. More effective directional microphones must be developed.

To that end, American researchers have proposed a new technical approach: a capsule housing both an omnidirectional and a directional microphone, each optimized for its purpose, is incorporated into an in-the-ear hearing aid [Killion et al., 1998]. Subject to the methodological limitations in the study, the advantages of the directional microphone seem substantial, especially since the measurements were taken in real-life listening situations. The same microphone was used in another study but with less positive results, however [Novick et al., 2001].

Directionality with two microphones

The application of dual-microphone directionality received special attention throughout the last decade. In fact, most of the studies identified make use of this technological solution. Regardless of the strength of scientific evidence, these studies unanimously conclude that directional-microphone hearing aids provide a gain of 1.5 to 8.5 dB, the best performances having generally been observed in favourable listening conditions. Thus, the large gain of 13 dB reported in the Québec study [Labonté, 2000] would have been favoured by the location of the noise sources and the recruitment of subjects with normal hearing.

Directionality with a microphone array

Systems with microphone arrays attempt to push even further the principle of improving directionality by cancelling omnidirectional noise. Considering the complexity involved in developing such systems that are both effective and ergonomic, this technological approach belongs even more to the experimental field than to commercial use. All the selected studies give an advantage of the order of 1.4 to 22.7 dB for the multi-microphone directional approach. As in the case of the other solutions, applying this approach in non-optimal listening situations reduces its effectiveness. This drop in performance nevertheless seems to be less for designs making use of a greater number of microphones.

5. DISCUSSION

Regardless of the technological approach used, all the studies identified (i.e., those with an intermediate level of evidence as well as those with a low level of evidence) show that directional hearing-aids offer speech-in-noise benefit. The benefit is greatest in listening situations where the noise and the speaker are respectively placed behind and in front of the person with a hearing loss in an environment with low reverberation. In situations more representative of daily life, where noise is diffuse and the room reverberant, this gain diminishes to the point of becoming comparable to that provided by conventional omnidirectional hearing aids.

These findings agree with the conclusions reached in a meta-analysis of eighteen studies, including those that we retained [Amlani, 2001]. The study selection criteria in the analysis included the use of commercial models of hearing aids, the application of directionality using one or two microphones, and performance ratings based on SNR improvements. The meta-analysis examined 72 experiments on omnidirectional hearing aids (totalling 1057 subjects) and 74 experiments on directional-microphone hearing aids (totalling 1086 subjects). Compiled performances reveal an overall gain of 4 dB for the directional approach in a low-reverberant room where the source and the noise are in different positions, that is, 0° vs 90° or 180°. This advantage disappears in a reverberant environment with diffuse noise.

The technological solution based on a microphone array seems *a priori* more robust in degraded sound environments. Ergonomic considerations nevertheless limit the applicability of this approach. Also, different algorithms can be used to process signals coming from several microphones and can theoretically produce different directional properties. Additional well-conducted controlled trials are therefore necessary to explore these alternative solutions and to confirm the advantages of this approach. Similarly, the benefits reported by Killion et al. [1998] regarding the new directional-microphone capsule must be confirmed by controlled trials.

According to the information available, we cannot with any certainty draw conclusions regarding the efficacy of the single-microphone solution: it must therefore be classified as "experimental," based on the classification scheme adopted in 1994 by AETMIS.[1] This conclusion relies as much on the weak clinical benefits in reverberant environments as on the low validity of the selected studies. This classification is, however, biased by the analysis window excluding studies conducted before 1990. It applies nevertheless to new applications such as microphone capsules.

The dual-microphone approach may, on the other hand, be designated "accepted," but for specific applications. In fact, its efficacy in specific listening situations has been demonstrated repeatedly in studies with a higher level of evidence. When the signal of interest arrives from the front and the competing noise from the back in a low-reverberant environment, the directional approach seems effective. This is the case, for example, for a student facing the teacher and sitting in the first row in a classroom whose acoustic properties are controlled by acoustic tiles, curtains or carpets. The SNR gain would theoretically allow for up to 60% better speech comprehension. However, the further the drift away from optimal conditions, the less effective this formula becomes. The gain may even be nil in places such as churches or conference rooms (reverberant environments), shopping centres or industrial buildings (diffuse noise).

The multi-microphone approach seems interesting because it attempts to cancel noise coming from all directions. Because of the limited number of clinical studies with a high level of evidence demonstrating its efficacy, and the need to solve the ergonomic problems, it must remain an "experimental" approach.

Besides the indications for use specified above, hearing specialists must use prudence when recommending, selecting and fitting directional-microphone hearing aids. In actual fact, the directionality option is designed to favour the audibility of frontal signals over those coming from other directions. In situations where the signal of interest comes from other directions, for example, classmates answering questions in the classroom, colleagues talking in a meeting, or an alarm sounding at work, the use of directional hearing aids is not recommended, and may even be harmful. Some aids offer the possibility of alternating between omnidirectional and directional modes by means of a switch on the hearing-aid case or by remote control. Nevertheless, this solution seems applicable only for people with the necessary physical and cognitive abilities to use this function at the right time and in the right places [Kuk, 2000].

Furthermore, manufacturers' specifications regarding the directional properties of a specific hearing aid may often be wrong, owing to the significant effect caused by venting and microphone orientation [Ricketts, 2000a]. In addition, given that electroacoustic transducers are liable to suffer from sensitivity drift

1. The classification adopted in 1994 by AETMIS (then known as the *Conseil d'évaluation des technologies de la santé du Québec*) for designating the status of a technology is the following:

An "accepted" technology is one that is well established and for which there is a long history of use and considerable knowledge or, failing that, universal acceptance of its efficacy in all its applications.

An "innovative" technology is one that has gone beyond the experimental stage and whose efficacy has been established. However, because of a lack of experimentation, its application procedures and even its indications for clinical use are not yet clearly defined. To improve our knowledge of this technology, it would be important to systematically gather all the data derived from its use and to communicate this information to the medical community, whether in the form of a clinical research report, a systematic review or an appropriate registry. To promote these objectives and to prevent its premature routine clinical use, this technology must be restricted to certain authorized centres with the necessary resources and knowledge.

An "experimental" technology is one whose efficacy has not yet been established. This technology must therefore not be used in health-care institutions, except in the case of research projects, nor must it be part of the government's insured services.

because of wear, particularly in excessive temperatures and humidity [Kuk, 2000], directional properties are not necessarily stable over time.

6. CONCLUSION

All the studies reporting on the clinical efficacy of directional hearing aids have only an intermediate level of evidence. The few studies available allow for single-microphone and microphone-array approaches to be classified as "experimental" technologies. Additional controlled trials will be necessary to confirm their efficacy.

Dual-microphone approaches may be considered "accepted" technologies but only in optimal listening conditions when the speaker and the noise are diametrically opposite each other in a room with low reverberation. Applying this technology in other conditions reduces (sometimes significantly) its efficacy. Although its use in less optimal conditions (less localized noise, controlled reverberation) may sometimes be justified despite the lower benefit, use of this technology in noisy or reverberant environments seems ineffective. Finally, eligibility requirements for the directionality option must take into account candidates' physical and cognitive abilities to use the directional properties effectively.

APPENDIX A – COVERAGE OF THE *PROGRAMME D'AIDES AUDITIVES* AND ELIGIBILITY REQUIREMENTS

Table A1a.
Coverage by age of insured participant

Age group	Types of devices insured	Insured services		
		Purchase and replacement	Repairs during warranty period	Repairs after warranty period
0–5	hearing aid	yes	yes	yes
	ALD* (FM** system only)	yes	yes	yes
6–11	hearing aid	yes	yes	yes
	ALD (except FM system)	yes	yes	yes
12–18	hearing aid	yes	yes	yes
	ALD (except FM system in the case of an elementary or secondary school student)	yes	yes	yes
19–74 non-student	hearing aid	yes	yes	yes
	ALD (except FM system)	yes	yes	yes
19–74 student	hearing aid	yes	yes	yes
	ALD	yes	yes	yes
75 and over	hearing aid	yes	yes	yes
	ALD	yes	yes	yes

* ALD = assistive listening device.
** FM system = frequency-modulation system.

Sources:
a) Régie de l'assurance maladie du Québec. Programs and Insured Services – Hearing Devices. Available at: *http://www.ramq.gouv.qc.ca/crc/eng/public/progservass/auditive.shtml* (Page consulted on February 26, 2003).
b) Regulation respecting hearing devices insured under the Health Insurance Act. R.S.Q. c-A29, r.0.02.

Table A1b. Eligibility requirements by age of insured participant

Age group	Types of devices insured	Documents required – authorized providers				
		Medical certificate	Audiogram	Proof of need for hearing aid	Recommend-ation for ALS	Proof of school attendance
0–5	hearing aid	ENT ***	—	audiologist	—	—
	ALD (FM system only)	ENT	—	—	audiologist	—
6–11	hearing aid	ENT	—	audiologist	—	—
	ALD (except FM system)	ENT	audiologist	---	audiologist	—
12–18	hearing aid	ENT	ENT or audiologist	ENT or audiologist	—	—
	ALD (except FM system in the case of an elementary or secondary school student)	ENT	audiologist	—	audiologist	—
19–74 non-student	hearing aid	ENT	ENT or audiologist	ENT or audiologist	—	—
	ALD (except FM system)	ENT	audiologist	—	audiologist	—
19–74 student	hearing aid	ENT	ENT or audiologist	ENT or audiologist	—	school, college, university
	ALD	ENT	audiologist	—	audiologist	
75 and over	hearing aid	ENT	audiologist	audiologist	—	—
	ALD	ENT	audiologist	—	audiologist	—

* ALD = assistive listening device.
** FM system = frequency-modulation system.
*** ENT = ear, nose and throat specialist.

Sources:
a) Régie de l'assurance maladie du Québec. Programs and Insured Services – Hearing Devices. Available at: *http://www.ramq.gouv.qc.ca/crc/eng/public/progservass/auditive.shtml* (Page consulted on February 26, 2003).
b) Regulation respecting hearing devices insured under the Health Insurance Act. R.S.Q. c-A29, r.0.02.

APPENDIX B – CRITICAL APPRAISAL CHECKLIST

Critical appraisal checklist for a therapy article [ANAES, 2000]

Title and author of article: ____

Journal/Year/Vol./Pages ____

Topic of article: ____

	YES	NO	?
1. The objectives are clearly defined	☐	☐	☐
2. Study methodology			
▪ This is a controlled trial	☐	☐	☐
- *the trial is prospective*	☐	☐	☐
- *the trial is randomized*	☐	☐	☐
▪ The number of patients was calculated a priori	☐	☐	☐
▪ The study population corresponds to the population usually treated	☐	☐	☐
▪ All clinically relevant variables are taken into account	☐	☐	☐
▪ The statistical analysis is appropriate	☐	☐	☐
▪ It is an intention-to-treat analysis	☐	☐	☐
3. The results are consistent with the study objective and take into account potential side effects	☐	☐	☐
4. Clinical applicability			
▪ The clinical relevance is given	☐	☐	☐
▪ Treatment procedures are applicable on a routine basis	☐	☐	☐

Comments:

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APPENDIX C – CLASSIFICATION OF LEVELS OF EVIDENCE

Levels of scientific evidence provided by the publication [ANAES, 2000]

Level 1 (high level of evidence or established scientific evidence)
- Randomized controlled trials with high statistical power
- Meta-analysis of randomized controlled trials
- Decision analysis based on well-conducted studies

Level 2 (intermediate level of evidence or scientific presumption)
- Randomized controlled trials with low statistical power
- Well-conducted non-randomized controlled trials
- Cohort studies

Level 3 (low level of scientific evidence)
- Case-control studies

Level 4 (low level of scientific evidence)
- Controlled trials with significant bias
- Retrospective studies
- Case series
- Descriptive epidemiological studies (cross-sectional, longitudinal)

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