Efficacy of programmable analog hearing aids

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

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Technical note prepared for AETMIS
by François Bergeron

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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 PROGRAMMABLE ANALOG 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 programmable analog hearing aids.

The technological options offered by conventional hearing aids do not always achieve auditory-assistance objectives. Several technological approaches have been explored to offer well-fitted hearing aids to people with a hearing loss, regardless of the sound environment. Work on programmable analog hearing aids has pursued this goal.

According to AETMIS's evaluation, there is a consensus that these hearing aids are at least as effective as conventional hearing aids in improving hearing. Additional benefits are nevertheless limited, the indications for clinical use compared with those of less advanced technologies are not clear, and costs are higher. Further controlled trials will be required to gather more information on the effectiveness of these approaches.

Although this innovative technology may be offered to certain candidates in need of well-fitted hearing aids, there are no grounds for its routine clinical use. This prudence is even more necessary since manufacturers are increasingly losing interest in programmable analog hearing aids in favour of fully digital technologies: therefore the need for cost-benefit analyses of this approach appears even more vital.

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 programmable analog hearing aids.

Description of hearing aids

Deafness is essentially manifested by a reduced ability to perceive sound signals in the surrounding environment. By selectively amplifying sounds rendered inaudible through hearing loss, an attempt is made to compensate for the loss of audibility of the sound environment and, more particularly, of speech. However, while the proposed adjustments ensuing from theoretical models for hearing-aid tuning are becoming increasingly precise, the technological options available on conventional hearing aids do not always achieve target values. Even after audibility has been restored, people with impaired hearing need better listening conditions than people with normal hearing in order to perform well on speech-intelligibility tasks. Moreover, given the wide variety of listening conditions, hearing-aid wearers must be able to adjust the amplification configurations to match these conditions. Several technological solutions have been explored to offer well-fitted hearing aids to people with a hearing loss, regardless of the sound environment. Work on programmable analog hearing aids has pursued this goal.

Programmable analog hearing aids process sound signals in a way comparable to conventional hearing aids. The control potentiometers, however, are replaced by one or more microprocessors that handle all the functions of the hearing aid. Moreover, the gain in space allows for the integration of a greater variety of adjustment parameters. These parameters are programmed (and reprogrammed) by computer or by a specialized programming unit. Memory storage also makes it possible to quickly compare different configurations and to find the most effective and comfortable adjustments for different listening situations.

Analysis of scientific data

The literature-search strategy for querying the databases located eighteen articles. Nineteen supplementary documents were obtained from the expert group or taken from the bibliographic references cited in the articles. This literature includes ten studies reporting on clinical trials on programmable analog hearing aids. Almost all of them involve non-randomized crossover trials, sometimes containing a retrospective analysis. The sample sizes are generally limited.

Irrespective of the level of evidence, almost all of the studies identified show that programmable hearing aids are superior to personal amplifiers, which are usually linear single-channel hearing aids without an advanced signal-processing system. This superiority is seen in terms of both speech-intelligibility performance and users' subjective impressions in different listening situations.

Conclusion

If only studies with the highest levels of evidence are taken into account, programmable analog hearing aids must be designated "innovative." In fact, despite the limited number of well-conducted studies, there is a consensus that this formula is at least as effective as conventional hearing aids in compensating for hearing impairment. Additional benefits nevertheless seem limited, and the indications for clinical use compared with those of

less advanced technologies are not clear. Further controlled trials must be undertaken to gather more information on the efficacy of these solutions. Considering the extra costs and the limited gains found thus far compared with those of conventional hearing aids, cost-benefit analyses must be undertaken before the routine clinical use of programmable analog hearing aids can be recommended.

GLOSSARY

Analog hearing aid (conventional):
Hearing device using electronic circuits to amplify and control incident sound signals.

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.

dB HL (hearing level):
Unit of measurement of the ratio of sound intensities where the reference sound pressure is based on thresholds established for a normal-hearing population. A sound intensity of 0 dB HL corresponds to an intensity of 7.5 dB SPL at 1000 Hz (ANSI S3.6-1996).

dB SPL (sound pressure level):
Unit of measurement of the ratio of sound intensities where the reference sound pressure is 0.000020 Pa or 20 µPa. A sound pressure of 20 µPa corresponds to a sound intensity of 0 dB SPL.

Dynamic range:
The difference, expressed in decibels (dB), between a person's auditory threshold and pain threshold.

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 hearing aid:
Hearing device that provides a fixed level of amplification regardless of the intensity of the incident sound 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.

Programmable analog hearing aid:
Hearing device that uses electronic circuits to amplify incident sound signals as well as algorithms programmed into one or more microprocessors to control the sound signals.

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 note deals with the second request, that is, the analysis of the efficacy of programmable (or digitally controlled) analog hearing aids.

1.2. A technological solution to improving hearing

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. However, while the proposed adjustments ensuing from theoretical models for hearing-aid tuning are becoming increasingly precise, the technological options available on conventional hearing aids do not always achieve target values.

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].

Finally, the adjustments proposed in hearing-aid fitting protocols refer to a theoretical environment. Yet, the sound environment of hearing-aid wearers is highly variable, which requires the availability of amplification configurations adapted to different listening conditions.

These observations have led to the exploration of a wide range of technological approaches to offering well-fitted hearing aids to people with a hearing loss, regardless of the environmental sound conditions. Work on programmable analog hearing aids has pursued this goal.

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 1. The database query was supplemented by publications provided by the experts consulted or taken from the bibliographical references cited in the articles.

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).

Table 1. **Literature-search strategy**

Filter	Keywords			Results	
				M	C
Digitally controlled analog hearing aids	hearing aid	AND	programmable OR signal processing	18	0

M=MEDLINE, C=Cochrane.

3. DESCRIPTION OF HEARING AIDS

3.1 Conventional hearing aids

Figure 1 shows the overall operation of a conventional hearing aid: the acoustic signal is received and transformed into an electrical signal by the microphone, increased in amplitude by the amplifier and reconverted into an acoustic signal by the earphone. One or more potentiometers (or variable resistances), according to the space available, control a few signal parameters: the degree of amplification is mainly governed by the volume control; high-pass and/or low-pass filters help vary the enhancement of the amplification at high or low frequencies; and clipping and/or compression circuits limit the maximum amplification to ensure listening safety and comfort.

3.2 Programmable hearing aids

The principle of a programmable hearing aid is illustrated in Figure 2. These aids process acoustic signals in a way comparable to conventional hearing aids. The potentiometers, however, are replaced by one or more microprocessors that control all the functions of the hearing aid. Moreover, the gain in space allows for the incorporation of a wider variety of adjustment parameters. These parameters are programmed (and reprogrammed) by computer or by a specialized programming unit. Memory storage makes it possible to quickly compare different configurations and to find the most effective and most comfortable adjustments [Sammeth, 1990] for different listening situations.

Figure 1. **Components of a conventional hearing aid**

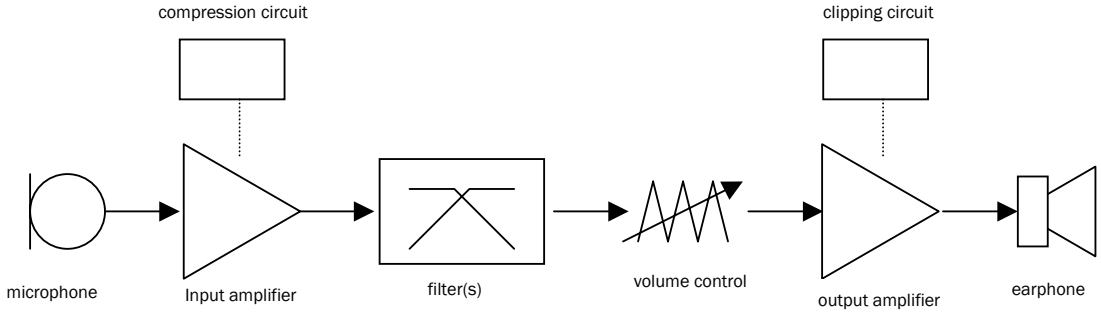
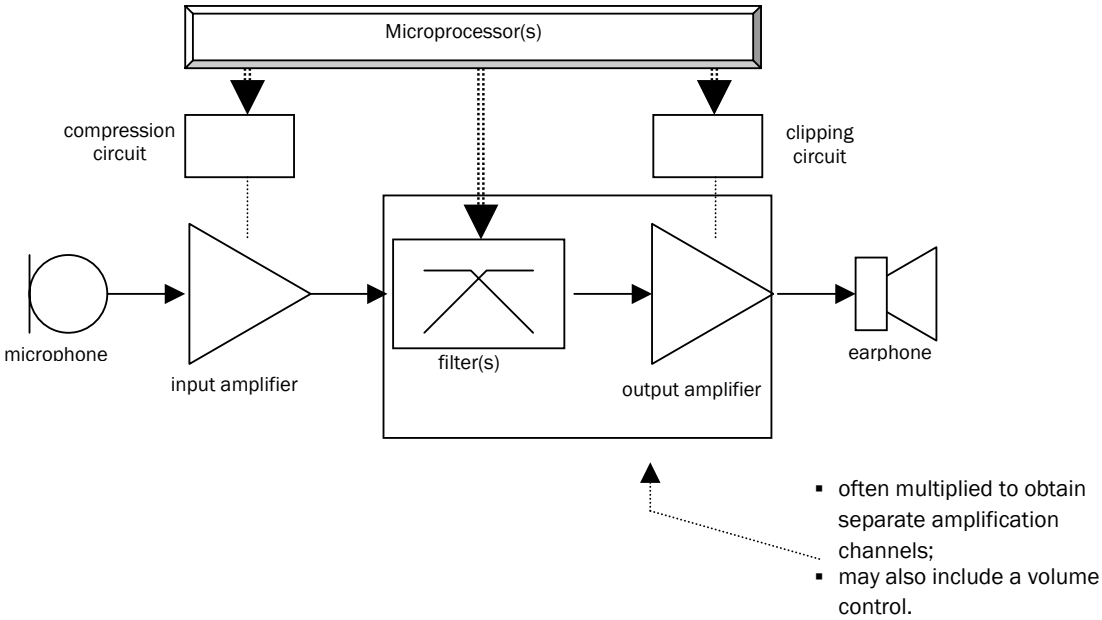


Figure 2. **Components of a programmable analog hearing aid**



According to the manufacturer's objectives, programmable hearing aids may have the following options:

- Advanced signal processing

The degree of amplification can be adjusted automatically according to the sound intensity of the environment. Softer sounds are amplified more than louder sounds, as opposed to conventional linear circuits that provide a set amount of gain regardless of the environment. This translates into the underamplification of soft sounds and the overamplification of loud sounds. Different signal-compression techniques are used to achieve this objective.

- Multi-channel capability

Signals are managed by two or more amplification channels, each responsible for a set frequency band. Low-frequency signals are processed independently of high-frequency signals. Different compression parameters can be applied to permit the audibility of high-frequency speech sounds, while reducing the gain of low-frequency sounds characteristic of noisy environments. Multiplying the number of channels also permits a better adjustment of the amplification curve defined by theoretical calculations of the degree of amplification required to compensate for the loss of audibility at each audiometric frequency.

- Multi-memory capability

The availability of a memory block allows for the storage of different hearing-correction configurations that can quickly be retrieved by means of a remote control or a switch on the hearing aid. It is then theoretically possible to adapt the amplification parameters to the different listening situations encountered by a hearing-aid user.

- Remote control

Moving the control buttons to a remote control makes it possible to design instruments that are more inconspicuous and easier to use by people with poor manual dexterity or by parents with young children fitted with hearing aids.

Advanced signal processing and multiple channels are not, however, exclusive to programmable hearing aids. In fact, electronic circuits governing these functions can also be incorporated into certain conventional analog hearing aids.

Programmable analog hearing aids cost much more than conventional hearing aids. According to the 2001 statistics shown on the Web site of the *Régie de l'assurance maladie du Québec*, 74 people acquired this type of hearing aid (behind-the-ear), for an average purchase price of $954. By comparison, 9 570 people acquired conventional hearing aids (in-the-ear or behind-the-ear), for an average cost of $577 [*Régie de l'assurance maladie du Québec*, 2003].

A brief investigation reveals that programmable analog hearing aids represent up to 25% of the product range offered by Canadian manufacturers and constitute nearly one-third of all sales. Consumer demand for this product is therefore quite high.

4. RESULTS

The literature-search strategy for querying the databases located eighteen articles. Nineteen supplementary publications were obtained from the expert group or taken from the bibliographic references cited in the articles. This literature includes ten studies reporting on clinical trials on programmable analog hearing aids. Table 2 summarizes the studies ranked in descending order of strength of evidence according to the classification scheme presented in Appendix C.

Most of the studies presented in Table 2 were carried out during the first half of the last decade, a time when manufacturers were promoting their programmable analog products, then considered state-of-the-art technology. Manufacturers' shifting interest towards fully digital technologies appears to be proportional to researchers' lack of interest in hybrid approaches. In fact, several of the studies seen in Table 2 are clearly linked to a manufacturer. The more recent studies usually examine fully digital technologies in comparison with hybrid and analog approaches.

Only one of the selected studies involves a genuine randomized controlled trial [Yueh *et al.*, 2001]. Actually, the subject allocation in this study is only partly random because the cause of deafness on one side of the randomization procedure is potentially different from that on the other side. All the other studies involve a prospective crossover trial, sometimes containing a retrospective analysis. The classic study design compares the performance of programmable hearing aids in terms of speech intelligibility in silence and/or in noise, in relation to that of commonly used hearing aids. Subjective impressions are also gathered. The sample sizes are generally small.

Regardless of the level of evidence, the selected studies show that programmable hearing aids are superior to personal amplifiers, which are usually linear single-channel aids without an advanced signal-processing system. This superiority is seen in terms of both speech-intelligibility performance and users' subjective impressions in different listening situations. The only exception to this tendency is found in the study conducted by Bentler and Duve, who report no significant gain in using programmable aids over other contemporary hearing aids [Bentler and Duve, 2000]. In fact, the authors even comment that in the presence of significant competing noise, the most recent technologies do not perform better than old-fashioned ear trumpets.

Table 2. **Summary of selected studies**

Source	**Method**			**Results**	**Level of evidence**
	N	Study design	Variables		
Yueh et al., 2001 (USA)	60 n	Randomized controlled trial	Independent: hearing aid (**U**naided vs **A**ssistive listening device vs **C**onventional vs **P**rogrammable with directional microphone) Dependent: quality of life (QOL), subjective evaluation (questionnaire), hours of use, willingness to pay	QOL: U < A < C < P Subjective evaluation: U < A < C < P Hours of use: A < C < P Willingness to pay: A < C < P	2
Bentler and Duve, 2000 (USA)	20 e	Non-randomized crossover trial	Independent: hearing aid (**E**ar trumpet vs **B**ody-aid vs **L**inear vs **C**ompression vs 2-channel **P**rogrammable compression vs **D**igital) Dependent: electroacoustic features, sentence recognition in noise, subjective evaluations (sound quality, listening effort)	Bandwidth and gain: E = B < L = C = P = D Sentences: low noise: B < E < L = C = P = D high noise: E = B = L = C = P = D Subjective evaluation: L = C = P = D	2
Moore et al., 1992 (USA)	20 e	Non-randomized crossover trial	Independent: hearing aid (**O**wn vs **L**inear vs 2-band programmable **C**ompression vs **U**naided), presentation level (50, 65, 80 dB SPL), sound orientation, binaurality Dependent: sentence recognition, subjective evaluation (questionnaire)	In quiet: C > L > O > U at 50 dB SPL only SRTs in babble: C 0.6 dB < L 3.8 dB < U Binaural > monaural Subjective evaluation: C > L > O No gain with C in subjects with dynamic range > 27 dB	2

n = new, i.e., subjects wearing hearing aids for the first time.
e = experienced, i.e., subjects who have already worn hearing aids.
AGC = automatic gain control.
dB HL (hearing level): *see* glossary for definition.
dB SPL (sound pressure level): *see* glossary for definition.

Table 2. **Summary of selected studies (cont'd)**

Source	Method			Results	Level of evidence
	N	Study design	Variables		
Walden et al., 1998 (USA)	40 e	Non-randomized crossover trial	Independent: hearing aid (Personal **L**inear vs 2-channel programmable **C**ompression vs **U**naided vs **N**ormal hearing), presentation level (50, 65, 80 dB SPL), sound orientation, binaurality Dependent: sentence recognition, subjective evaluation (questionnaire)	All environments: N > C > U Subjective evaluation: N > C > U; C > L, except for sound quality	2
Benson et al., 1992 (USA)	18 e	Non-randomized crossover trial + retrospective analysis	Independent: hearing aid (**P**ersonal vs 2-channel programmable **C**ompression vs **U**naided), presentation level (50, 65, 80 dB SPL) Dependent: functional gain, dynamic range, sentence recognition, insertion gain, subjective evaluation (questionnaire)	Functional gain: C > P Dynamic range: C > P Sentences: C > P > U at 50 and 65 dB SPL Insertion gain: C > P at 500 Hz, 4 and 5 kHz Subjective evaluation: C > P	3
Kiessling and Steffens, 1991 (Germany)	26 e	Non-randomized crossover trial	Independent: hearing aid (1-channel AGC vs 3-channel AGC), type of noise, signal-to-noise ratio Dependent: monosyllables in noise, subjective quality evaluation	Speech recognition in noise: 3 channels = 1 channel Wideband noise: 3 channels > 7% to 21% Signal-to-noise ratio effect Quality: 3 channels > 1 channel	3

n = new, i.e., subjects wearing hearing aids for the first time.
e = experienced, i.e., subjects who have already worn hearing aids.
AGC = automatic gain control.
dB HL (hearing level): *see* glossary for definition.
dB SPL (sound pressure level): *see* glossary for definition.

Table 2. **Summary of selected studies (cont'd)**

Source	Method			Results	Level of evidence
	N	Study design	Variables		
Ringdahl et al., 1990 (Sweden)	22 e	Non-randomized crossover trial	Independent: hearing aid (personal vs 2 channels, 8 programs), listening situations Dependent: insertion gain, sentence recognition in noise, preferences	Sentences > with programmable aid Preference for programmable aid in 81/120 listening situations Preference for programmable aid: 20/22 subjects	3
Hall and Jacobs, 1991 (USA)	18 e	Non-randomized crossover trial + retrospective analysis	Independent: hearing aid (personal vs 2-channel programmable) Dependent: hearing-aid benefit and sound quality (questionnaire)	Programmable aid > personal: 18/18 subjects	4
Mangold et al., 1990 (Sweden)	14 e	Non-randomized crossover trial	Independent: hearing aid (personal vs 2 channels, 8 programs), listening situations Dependent: sentence recognition in noise, preferences	Sentences with programmable aid > 11/13 subjects Preference for programmable aid in 65/82 listening situations	4
Zorowka and Lippert, 1995 (Germany)	13 n 52 e	Non-randomized crossover trial + retrospective analysis	Independent: hearing aid (linear vs programmable, different models) Dependent: functional gain, discomfort level, word recognition (50, 65, 80 dB HL) with and without competing noise, subjective evaluation (questionnaire)	Programmable: better functional gain Words: programmable aid > 14% (50 dB), 18% (65 dB), 4% (80 dB) Subjective evaluation: programmable > linear	4

n = new, i.e., subjects wearing hearing aids for the first time.
e = experienced, i.e., subjects who have already worn hearing aids.
AGC = automatic gain control.
dB HL (hearing level): see glossary for definition.
dB SPL (sound pressure level): see glossary for definition.

5. DISCUSSION

The overall finding of the superiority of programmable analog hearing aids over personal amplifiers drawn from Table 2 must be qualified. Actually, the experimental designs of the trials identified do not really test the concept of digital control but instead compare hearing-aid advanced signal-processing circuits in relation to hearing aids with basic linear amplification. It is therefore the concept of signal processing that is being studied. Yet, such circuits can be incorporated into analog hearing aids without the need for digital control. The digital-control approach, however, does make this easier by reducing the physical space required, while increasing the variety of options. Recent fully digital technologies push this concept even further. As for the efficacy of each of the signal-processing options presented above, all the studies identified report benefits related to the single or combined use of dynamic compression and multi-channel or multi-memory capability.

In agreement with the overall finding, the study led by Moore et al. [1992] reveals the superior efficacy of a programmable aid with two-channel independent compression, the data show that the efficacy gain for speech recognition compared with linear amplification (15% in silence at 50 dB SPL, 1% at 65 dB SPL; 0.6 dB in noise) is distinctly inferior to that obtained by the first fit of a linear aid in people with a hearing loss (60% in silence at 50 dB SPL, 38% at 65 dB SPL; 3.8 dB in noise).

This finding is supported by a double-blind multicentre randomized trial comparing the performance of 360 subjects in word and sentence recognition according to three compression configurations (linear, output compression, variable compression) programmed within the same digitally controlled analog hearing aid [Larson et al., 2000]. Results show that, although the benefits offered by signal-compression configurations are superior to those of a linear approach, they are less significant than those obtained through the simple fitting of a hearing aid, regardless of its configuration.

Another double-blind multicentre study carried out among 110 subjects shows that applying a strategy for reducing low-frequency gain to optimize speech recognition in noise provides fewer additional benefits than those already provided by linear amplification [Humes et al., 1997]. Parving and Sibelle analyzed the answers to a questionnaire completed by 32 694 hearing-aid wearers, that is, 71% of the cohort fitted with hearing aids throughout the 1990s at the Department of Audiology, Bispebjerg Hospital (Copenhagen, Denmark), a public hospital offering services covered by the National Hearing Health Services [Parving and Sibelle, 2001]. The answers show no significant difference in perceived benefits and user satisfaction, regardless of the technology offered, that is, analog, programmable or digital signal-processing hearing aids. To a degree, the dissatisfaction rate seems a little higher among users of digital signal-processing hearing aids.

If only studies with the highest level of evidence (intermediate level) are taken into account, programmable analog hearing aids must be designated "innovative," according to the classification scheme adopted in 1994 by AETMIS.[1] In fact, despite the limited number of well-conducted studies, there is a consensus that this formula is at least as effective as conventional hearing aids in compensating

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.

for hearing impairment. Additional benefits nevertheless seem limited, and the indications for clinical use compared with those of less advanced technologies are not clear.

6. CONCLUSION

There is only a limited number of studies with a high level of scientific evidence demonstrating the clinical efficacy of programmable analog hearing aids. The few available studies allow it to be classified as an "innovative" technology. Controlled trials must be undertaken to gather more information on the efficacy of these approaches. With respect to the additional costs and modest gains in relation to conventional hearing aids, cost-benefit analyses must be conducted before their routine clinical use can be recommended. Nevertheless, manufacturers are currently becoming more interested in fully digital technologies, and the submission of such studies may end up coinciding with the obsolescence of this technological approach. The trend in favour of digital technology was recently confirmed when leading manufacturers announced the withdrawal of all their analog hearing aids, including programmable ones, from their catalogue in the United States. Since these instruments still cost much more, the need for cost-benefit analyses of the programmable approach seems even more vital.

Although based on the same premises, namely that the scientific evidence for their additional benefits is low, these conclusions differ from those recently formulated by the National Institute for Clinical Excellence in England [NICE, 2000]. This organization is in fact proposing to revise the list of hearing aids offered as part of the government program in order to immediately include the full range of existing analog hearing aids—including programmable aids. This recommendation is based on the principle that hearing aids must be optimally adjusted to suit users' needs and that more precise fittings can presumably be made on advanced programmable analog hearing aids than on basic linear hearing aids. This theoretical argument can also be applied to the safety of hearing aids. In fact, access to advanced signal processing, especially variable compression, could more easily prevent the overamplification of sounds and thus avoid a worsening of hearing loss.

According to the data in three studies [Moore et al., 1992; Humes et al., 1997; Larson et al., 2000], the first fit of a linear hearing aid would provide benefits superior to the additional gain provided by advanced signal-processing hearing aids. Consequently, clinical practice and its supporting social programs must be able to offer at least a basic hearing aid to everyone for whom such a need is identified, and for as long as necessary. Since programmable analog hearing aids have been classified as an "innovative" technology, they must be offered in institutions equipped with the necessary specialized resources, and for specific indications. A priori the selected studies suggest that programmable analog hearing aids could be provided to candidates faced with noisy environments or a wide variety of listening situations, and to those who have a reduced dynamic range or an audiometric configuration that is difficult to correct.

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

Table A1a. **Coverage by age of insured participant**

		Insured services		
Age group	**Types of devices insured**	**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**

		Documents required – authorized providers				
Age group	**Types of devices insured**	**Medical certificate**	**Audiogram**	**Proof of need for hearing aid**	**Recommend-ation for ALD**	**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 trial 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:

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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