

The search for the Panacea hearing aid

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[*panacea* n. A remedy for all diseases, evils, or difficulties; a cure-all]

Abstract

Much of the research carried out to develop improved hearing-aid systems carries an implied assumption that what is good, is good for everybody. Likewise the popular prescription rules implicitly support the convenient idea that the optimum audiological goal of a hearing aid is the same for all clients. Thus research becomes a search for a 'Panacea', development and marketing tread the path of least effort, and clinical practice risks following the same path. These claims will be supported by evidence from the research literature, and by consideration of natural mechanisms operating in the hearing-aid community.

Surveying a large number of published studies comparing alternative hearing-aid systems, it is notable that research study designs typically have rather small sample sizes, and tend to focus on group mean effects.

However, closer inspection reveals that when study designs have sufficient statistical power to uncover patterns of individual differences, they almost always find such differences.

Apart from leading to an excess of null or conflicting results, weak study designs perpetuate the myth that fitting hearing aids optimally to individual clients will be easy, once we find the right 'formula'.

Well-designed generic prescription rules achieve good results for a large proportion of clients with little clinical effort. This does not mean that each client is receiving the best possible fitting, even within the technological constraints of the hearing aid in question.

New features are constantly being added to hearing aids. Few of them are likely to be good for everyone, all the time. The secret of success with each new advance lies in identifying candidate clients and providing tools for the targeting process which clinicians will use, a task which is at least as great as the technical development of features.

Introduction

This work was motivated by a desire to clarify several unreconciled impressions in the author's mind. Firstly, the apparently over-riding need for simple stories in the Marketing departments of the hearing-aid industry. Secondly, the growing evidence that achieving optimal benefit for an individual hearing-aid client is not a simple matter of 'correcting for the audiogram' in the same way for everyone. Thirdly, the apparent inability of the hearing-aid research community to agree on anything much other than that directional microphones provide improved speech recognition in noise – under the right circumstances. And finally, the impression that the research community nevertheless largely continues to believe that simple answers 'are out there somewhere'.

The connecting concept turns out to that of a 'Panacea': a wonder treatment which can cure anyone, whatever their ailment. This concept seems to be behind much of what is mentioned above. The

purpose of this paper is to elucidate how this may be so, to argue that this is not an advisable approach, and to suggest an alternative way forward.

There is an ongoing debate in the hearing-aid research community regarding issues of experimental design such as blinding and placebo effect, and whether or not randomised controlled trials (RCTs) are the only valid form of evidence. These issues, important as they are for the quality of research being carried out, are not considered in this paper.

In the following sections we consider why it might be attractive to search for Panaceas, and what happens when a non-Panacea is marketed as a Panacea. Thereafter, the research literature is used as a source of evidence of a search for Panaceas, as well as providing evidence for and against the actual existence of Panaceas. The generic prescription concept is briefly considered in relation to the Panacea debate, before conclusions are drawn and tentative suggestions are made regarding how to move forward in a more appropriate manner than hitherto.

A few concepts used throughout this paper deserve to be explained beforehand:

Universal benefits are benefits available to all hearing-aid clients.

Individual differences and *Candidature* express the fact that given the task of comparing two treatments A and B, some patients may gain most from treatment A, while others may gain most from treatment B. This of course extends to any number of treatments being compared.

Indication/Contraindication is the term used in diagnostics when evaluating (before treatment) which treatment among possible alternatives is likely to give best results for the individual patient.

Any given treatment may be *indicated* or *contraindicated* by the presence or absence of some characteristic in the patient's condition, there being a known statistical correspondence between such characteristics and the efficacy of one or more treatments.

Why look for Panaceas?

There are a number of mechanisms operating in the field of hearing-aid practice which may make the Panacea idea attractive. Firstly of course, if one finds a Panacea, then there is much money to be made. Secondly, Panaceas are much easier to market than products which require an explanation involving candidature. Thirdly, the service delivery chain in any given marketplace (be it publicly or privately based) in general is unlikely to embrace demands for new differential diagnostic procedures without very strong evidence of their value, both because of natural inertia and because resource pressures often encourage procedures to be as similar as possible for every patient.

In the field of hearing-aid research, one good reason for searching for Panaceas is provided by the fact that the field is relatively immature. Thus there may still be some aspects of hearing aids which are open to universal improvement.

Previous 'Panaceas': the risks

Two examples from recent history provide illustrations of at least some of the potential risks that arise when the 'Panacea' label is incorrectly applied to a new hearing-aid feature.

The advent of non-linear amplification in the late 1980's and early 1990's was accompanied by a marketing message that this was something that everyone would benefit from, relative to the 'old-fashioned' linear amplification. However there is now a body of evidence which refutes this idea. General, universal benefits of non-linear amplification relative to linear amplification are rather elusive (Humes et.al. 1997, Larson et.al. 2000, Walden et.al. 2000), and several studies have found evidence that linear amplification may actually provide better performance for identifiable sub-

groups of hearing-aid users (e.g. Verschuure et.al. (1998), Lunner et.al. (1997a, 1997b), Haskell et.al. (2002), Gatehouse et.al. (in press). Despite these results, generated by some of the most statistically powerful studies in the literature, the natural superiority of non-linear is essentially unquestioned in practice, and 'low-tech' linear has acquired Cinderella status. As a consequence, those clients who would benefit from linear amplification are unlikely to be identified and offered linear as the superior option for them.

Over a period during the 1990's, loudness scaling and subsequent loudness compensation via individually-tailored compression was promoted as something which one should do as part of the standard fitting protocol, for all clients. Over time, clinical experience indicated that it made little difference for most clients, compared to a compression prescription based on the hearing threshold alone. Later theoretical considerations confirmed that loudness scaling would be unlikely to make a material difference in more than about 25% of fittings (Elberling, 1999). The mismatch between marketing message and clinical experience caused the method to fall into disrepute and disuse. If it had been recognised from the start that this technique was only likely to help a minority of clients (and ways to identify those clients had been developed), then that sub-group of clients (who often have severe problems with their fittings) might be better served today.

Evidence of a search for Panaceas

In this section we consider whether the research literature bears characteristics indicative of a tendency to search for Panaceas.

The literature survey

A review was carried out to summarise features of published studies in which comparisons had been made between alternative signal-processing features for hearing aids. Journals inspected were:

1. Journal of the Acoustical Society of America
2. Journal of the American Academy of Audiology
3. Ear & Hearing
4. International Journal of Audiology and predecessors (British Journal of Audiology, Audiology, and Scandinavian Audiology),

these being the journals judged as carrying the greatest density of such studies. Publication dates within the period 1995 – 2004 were inspected. Further criteria for inclusion were:

1. The study concerned acoustic air-conduction hearing aids
2. Hearing-impaired listeners were involved
3. Comparisons were not solely against the listeners' 'own hearing aids'
4. There was more than one processing scheme involved
5. The study concerned new data, not only data from other publications
6. Full article in English.

The comparison might be non-technological in nature (e.g. unilateral vs. bilateral fittings), but must have affected the signals reaching the listeners' ears. Thus for example studies on the effects of counselling were excluded.

Studies satisfying all the above criteria might still be excluded if the subject under consideration made the subsequent classification of experimental factors unreasonable in relation to the aim of this work. Thus for example studies were excluded if they were mainly concerned with:

1. the structure of outcomes, e.g. factor analyses of outcomes,
2. finding which particular listening situation(s) a given processing feature provided benefit in,
3. interactions between features (e.g. directional microphones and venting).

Occasionally, several articles were published concerning the same study. In such cases, the study only counts once in the statistics quoted here.

The result of this process was a collection of 98 studies. These are listed separately from the reference list at the end of this article.

Possible evidence of a Panacea approach

The following characteristics, if they appear in a sizeable proportion of studies, might be considered to be evidence of a Panacea approach in research into hearing-aid signal-processing:

- Poor statistical power, such that only strong universal trends are reliably detectable,
- Candidature not considered at the stage of study design,
- Only group mean effects in the results scrutinised,
- Individual differences which are noted in the results are not examined in pursuit of patterns or explanations.

The first of these is considered in the following section, and thereafter the other three are considered together.

Statistical power

Statistical power was mentioned explicitly in the design phase of only four of the 98 studies. In two cases this was in the context of estimating required sample sizes, and in the other two cases it was in a more general context concerning experimental variables. Thus in 94 of the 98 studies, there was no discussion of whether the experimental design possessed sufficient statistical power to answer the questions being posed.

Sample size is not in itself a definitive indicator of the statistical power of a study, but is a primary determining factor. Experimental design factors and the properties of the outcome measures being used will also affect statistical power. Such factors varied enormously amongst the 98 studies, and a formal evaluation of the power of each study is beyond the scope of the present work. Furthermore, statistical power is itself open to diverse interpretations, for example concerning appropriate limits for the risks of making Type I (rejecting the null hypothesis when it is true) and Type II (accepting it when it is false) errors. As a very rough indication of the likely statistical power of studies carried out nowadays, we may for convenience look at the properties of the designs typically used at the Oticon Research Centre. The reader will hopefully agree that these are reasonably representative. Given:

- The Danish-language Dantale-II test (Wagener et.al. 2003) (very similar to the Swedish Hagerman Sentences (Hagerman, 1984) and German Oldenburger SatzTest (Kollmeier and Wesselkamp, 1997; Wagener et.al. 1999)), which yields a SRT for 50% correct in steady-state noise with a test-retest standard deviation of 0.8 dB in our protocol,
- A desire to be able to detect a group mean effect size of 0.5 dB between two alternative hearing aids (with the Dantale-II test this corresponds to approx. 6% correct),
- A two-sided test (we don't know which hearing aid is best),
- We will accept a risk of 5% ($\alpha = 0.05$) of wrongly rejecting the null hypothesis and 20% ($\beta = 0.2$, 'Power' = 0.8) of wrongly accepting it,

then we need at least $N = 23$ test subjects, according to estimation methods available in standard statistical textbooks.

The smallest adequate N can be reduced by:

- reducing the test-retest variance (more word lists per subject and/or more sensitive test material),
- increasing the threshold of 'a worthwhile difference' between the hearing aids under test,
- hypothesizing about which aid is best,
- increasing the acceptable risk of erroneous conclusions.

The smallest adequate N will be increased if the above factors are adjusted in the opposite direction, and (importantly) if:

- the background noise is non-steady (test-retest variance increases dramatically),
- we wish to look beyond group mean effects to sub-groups of listeners (e.g. according to severity of hearing loss).

Figure 1 shows the distribution of sample sizes in the 98 studies. About two-thirds of the studies have sample sizes not exceeding $N = 20$ subjects, and one-quarter have $N = 10$ or less. Unless many of these are utilising exceptionally sensitive and reliable outcome measures, it is difficult not to conclude that too many studies are being published with insufficient statistical power to support the conclusions being drawn. This is in agreement with a survey carried out by the National Institute for Clinical Excellence in the United Kingdom National Health Service, which concluded that the audiological literature is not very robust in comparison with other medical and clinical fields (National Institute for Clinical Excellence, 2000).

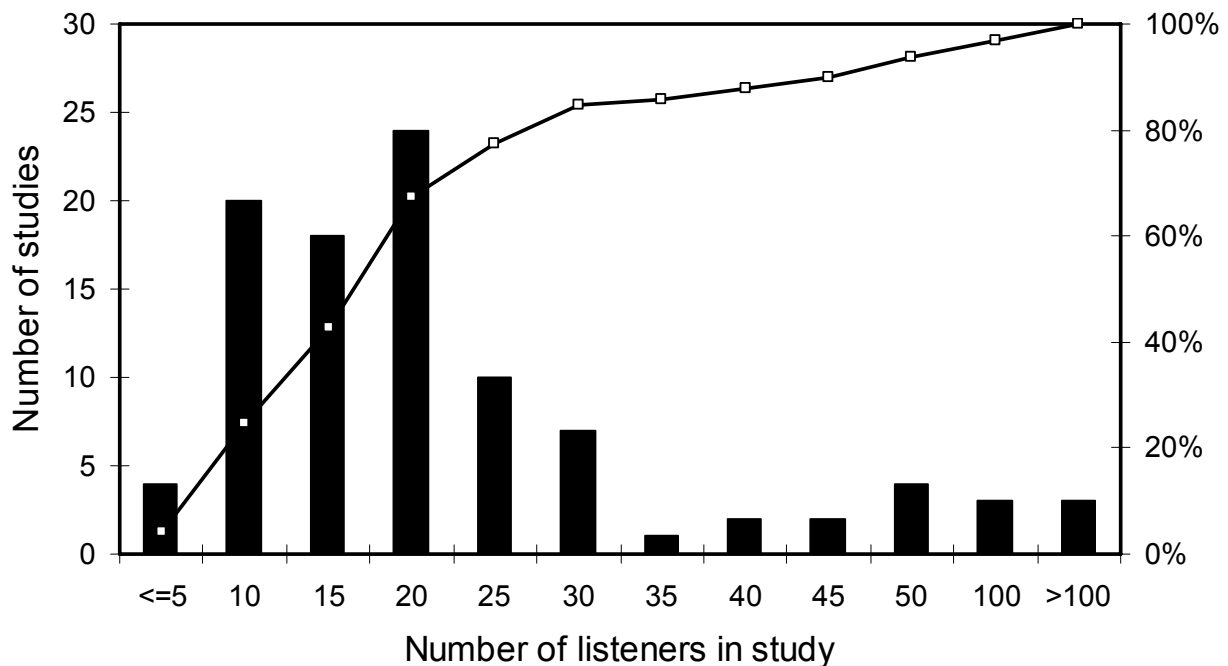


Figure 1: Histogram (left-hand axis) and cumulative histogram (right-hand axis) showing distribution of sample sizes in 98 studies.

In defence of studies with small sample sizes, it is only fair to mention that a very few of the studies, with the very smallest sample sizes (exact numbers not registered), legitimately by-passed the issue of statistical power by taking an explicit case-study approach, in which the behaviour of individual subjects is of interest but group statistics are not.

Inclusion of candidature aspects in treatment of design and results

Figure 2 shows a breakdown of the 98 studies according to how candidature was or was not considered at various stages of each study.

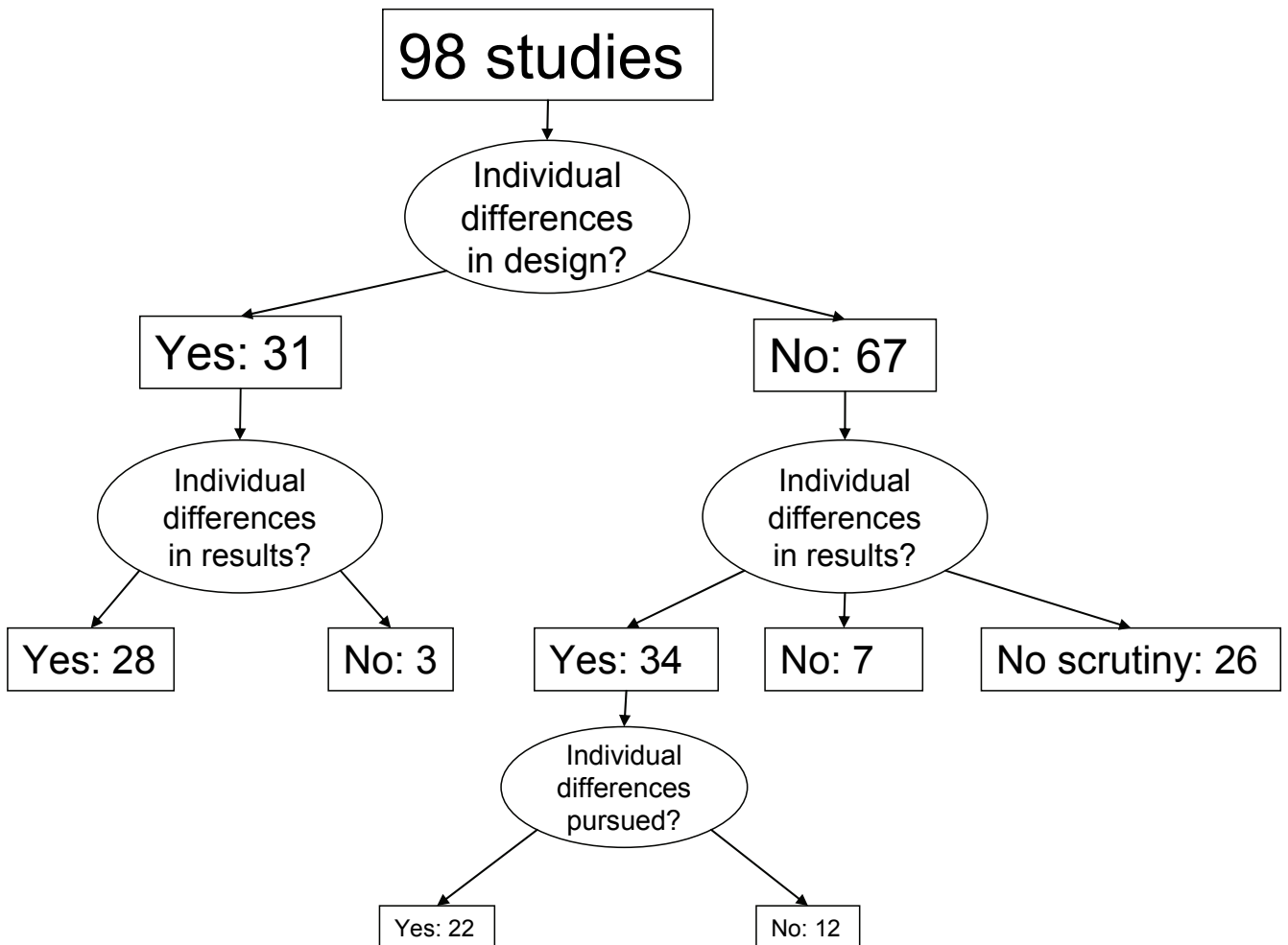


Figure 2: Breakdown of the 98 studies according to the treatment and appearance of individual differences.

In 31 cases, the issue of candidature was considered at the design stage to such an extent that a candidature variable was included in the design, either as a simple co-variate (usually in the audiogram domain, by ensuring a diversity of audiograms) or as a grouping or stratification (e.g. subjects with vs. without suspected cochlear dead-zones). In many (precise number was not

registered) of the remaining 67 cases, the introductory phase contained mention of the possibility that the effect under study might be dependent on individual characteristics (usually hearing loss), but this factor was given no further mention or treatment.

In 26 cases, scrutiny of the results beyond group mean effects was never mentioned. In these cases it is thus impossible to conclude whether or not notable individual differences occurred.

In 34 studies, candidature was not part of the design, but individual differences sufficiently distinct to warrant the authors' attention occurred in the results. In 22 of these 34 cases, the individual differences were discussed or pursued in search of an explanation.

Overall, the picture here is mixed, but candidature appears to be consistently present in the approach in only a minority of studies.

Evidence of universal benefits: Support for the Panacea idea

The previous section provided evidence that much of the research into hearing-aid signal processing may be characterised as searching for Panaceas. In this section we consider whether there in fact is support for the Panacea idea in the literature. Before considering the 98 studies included in the present review, we may note that the balance of professional opinion is strongly in favour of the idea that modern hearing aids are superior to those of the past; as time goes by, hearing aids become better and better. This supports the Panacea idea, insofar as there historically have always been aspects of hearing aids which were open to improvement for everyone. The study of historical hearing aids by Bentler and Duve (2000) provides a general confirmation of this impression, as well as evidence that in some respects the journey towards modern devices has not been unequivocally in a forwards direction at all times. (The historical intention of the Bentler and Duve study rendered it unsuitable for inclusion in the collection of studies for review.)

Given the general impression of contradictory results which one gains from the hearing-aid research literature, it may be surprising to note that no less than 82 of the 98 studies reviewed concluded that one of the systems being evaluated was superior to at least one of the others, in the outcome domain of interest. Of course, many of these 82 studies are themselves part of the contradictory picture; they do not agree with each others' conclusions. Some of this contradiction is well-founded in experimental conditions and details of the systems being compared, but we should be aware that a certain proportion of erroneous conclusions will always occur, and that lack of statistical power will cause that proportion to increase. Finally, publication bias may also be partly responsible for the large proportion of studies with non-null results.

Evidence of non-universal benefits: Refutation of the Panacea idea

Essentially, only one thing is required to refute the Panacea idea; evidence that individual differences are to be found. Referring to Figure 2, it may be seen that $28 + 34 = 62$ of the 98 studies produced results with individual differences sufficiently conspicuous that the authors considered them to be real (whether or not statistical methods were used to confirm this). Going one step further, we may compare the proportions of studies showing individual differences as a function of sample size (as a rough surrogate for statistical power). Table 1 shows the resulting proportions. It seems as though individual differences are always there, it is just a question of looking closely enough. One may debate whether all individual differences are worth studying, and undoubtedly some may be statistically significant without being scientifically or clinically significant.

Nevertheless, individual deviations from group mean behaviour are often as large as the group mean effects themselves, and thus equally important for the individual listener. And this is true

regardless of whether we are able to explain the individual effect on the basis of audiometric or other characteristics.

	Sample size (N)			
	<= 10	11-20	21-50	> 50
Occurrences of individual differences in results	13/24 = 54%	23/42 = 55%	20/26 = 77%	6/6 = 100%

Table 1: Occurrences of individual differences in results as a function of sample size, across the 98 studies.

Are generic prescriptions attempts at Panaceas?

It is natural to pose the question as to whether the more or less widespread ‘generic prescriptions’ (NAL-RP, POGO-2, NAL-NL1, DSL-i/o, IHAF, FIG6, etc.) are manifestations of Panacea thinking. Examining the literature describing the development of such prescriptions, one does not meet statements to the effect that the prescription in question is expected to be the best one for all hearing-aid clients, but rather to the effect that it is designed to compensate for one of the major perceptual consequences of peripheral hearing loss. Thus it would be unfair to accuse the generic prescriptions of deliberately promoting Panacea thinking. However, issues of candidature are generally not considered in any explicit way.

The implicit aim (again, rarely stated), of providing a procedure which can be applied to almost all clients in a consistent manner, and with a documented general level of efficacy, is naturally highly attractive to clinical service providers. Thus the generic prescriptions have become popular in many different types of service delivery contexts. There is a risk involved in this, which is that it may be tempting to regard the fulfilment of a well-defined prescription target as synonymous with providing the individual client with an optimal fitting. This risk is increased if clinicians experience that the generic prescriptions do in fact give good results for the majority of their clients. The general clinical success of a generic prescription rests on the fact that it is reasonably successful in compensating for an impairment suffered by almost all clients. Again, this is not the same as saying that it compensates optimally for all impairments the client suffers, nor that all clients suffer the impairment it is designed to alleviate.

The generic prescriptions promote a good basic standard of quality in hearing-aid fittings, which clients in diverse types of delivery context should benefit from. However, they may at the same time unintentionally promote Panacea thinking in the research, manufacturing and clinical communities.

Conclusions and suggestions

There are strong mechanisms motivating Panacea thinking in the hearing-aid industry and the practice of hearing-aid dispensing. Furthermore there seem to be indications of widespread Panacea thinking in the research community as well. All of these instances continue, despite clear evidence that candidature is a pervasive factor when hearing-aid systems are compared against each other with regard to their beneficial effects for end-users.

When a hearing-aid feature is marketed as a Panacea, but turns out not to fulfil this promise, it is liable to fall into disrepute and disuse, despite being beneficial for some portion of the client population.

Too many studies are published which possess inadequate statistical power. This may lead to erroneous conclusions being drawn in an excessive (and unidentifiable) proportion of studies, and thereby to unnecessary confusion in the research field.

There are aspects of hearing aids which are open to universal improvement, and these should be identified and pursued. However, most ideas for improving hearing-aid systems are probably not of the type which provides improvement for all users, and a Panacea approach to their study may not be the most appropriate.

The generic prescription rules are not the result of explicit Panacea thinking. Well-designed generic prescription rules achieve good results for a large proportion of clients with little clinical effort, and thus promote a good basic standard of hearing-aid fitting. This does not mean that each client is receiving the best possible fitting, even within the technological constraints of the hearing aid in question. Furthermore, the widespread application of generic prescriptions, by 'levelling hearing-aid fittings upward', may unintentionally promote Panacea thinking in the research, manufacturing and clinical communities.

A number of efforts are required:

- Studies with greater statistical power should be encouraged, so that false conclusions are acceptably rare and so that the effects of candidature may be convincingly demonstrated
- When candidature effects are seen, predictive variables for the candidature need to be identified
- Predictive variables need to be transformed into feasible clinical indicators and contraindicators
- Manufacturers need to provide alternative fitting features corresponding to the proven effects and capable of being coupled intelligently to the clinical indicators.

Such efforts are at least as challenging as the technical development of new signal-processing features, but they are necessary if the potential benefits of hearing aids are to be fully realised.

The 98 studies

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