

TECHNICAL FAILURE OF HEARING AIDS PROVIDED BY THE NATIONAL HEALTH SYSTEM

Falhas técnicas dos aparelhos de amplificação sonora individual dispensados pelo sistema único de saúde

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ABSTRACT

Purpose: to investigate about repair issues of hearing aids at National Health System. **Methods:** it was analyzed hearing aids technical failures whose patients had showed complaints concerning the device on five different services considering the period from January to May 2009, analyzed by descriptive statistic. **Results:** the main technical failures found were: 37.44% of failures on amplifier, 25.59% of failures on microphone. Related to the device's technological sort and category it's verified that the behind the ear hearing aids and of category A presented higher technical failure incidence. It's also observable that the devices presented utility life of 22 months on average before presenting any technical failure. In the majority of the population studied, the cost for the repair of these devices was between R \$ 500,00 and \$ 1000.00. From the perception of hearing aids failure by the patient, 51.82% contacted the service seeking for care and 61% of analyzed hearing aids were still on guarantee term and they were fixed by technical assistance without additional cost to patient. **Conclusion:** the main technical failure found was failures on amplifier. The behind the ear hearing aids and of category A presented higher technical failure incidence.

KEYWORDS: Hearing Loss; Hearing Aids; Rehabilitation of Hearing Impaired; Unified Health System

■ INTRODUCTION

Since the end of last decade, concern about the auditory issues is growing around the world,

because the increased prevalence of hearing loss in recent years. In this sense, the (re)habilitation of sensorineural hearing loss through the use of a hearing aid (HA) is highly successful, helping to reduce the negative consequences of auditory disabilities ¹. These high cost devices are provided free of charge to Brazilian people through audiology services accredited by the Ministry of Health.

In Brazil, since 2004, the entire treatment is covered by the public healthcare system (SUS), from prevention through treatment. But a lot of patients does not use device after HA fitting, which leads the waste of financial resources allocated to the area. According a study conducted in order to verify the results after HA fitting dispensed in audiology service, 18.52% of patients did not use the device in daily life, which 7.41% did not use them because technical failure ².

One of the difficulties encountered in HA use can be generated by technical failures of HA ³⁻⁵. Professionals and the patients should be aware

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to this kind of problem, because any failure which interferes in HA can cause adverse effects for yours users.

According to the normative established by the Ministry of Health for HA selection and fitting, the devices offered by audiology services accredited by SUS must be registered at Brazilian Sanitary Vigilance Agency (ANVISA), which ensures, in part, the quality of devices are acquired by the hearing care services.

Regarding the indication for HA replacement, it should occur in the following situations: verified progressive hearing loss, when there is no possibility of changing the amplification characteristics of the HA previously fitted; instances of confirmed loss or robbery and technical failure of the internal and/or external components of the HA when the period of guaranty is already expired⁶.

When a technical issue is detected by an audiologist, the device should be send to original manufacturer to repair it. The device has 1-year or 2-years manufacturer's warranty, according each service. For devices that become damaged or encounter problems after the expiration of the manufacturer's warranty, costs are paid by the patient.

The repair cost may vary depending on the extent damage, but patients often cannot afford these costs. Faced with this fact, replacement of HA by audiology service (after the end of the warranty) usually is done, which increases spending on the provision of HAs by SUS. According to the information provided by the Ministry of Health, through the SUS Ambulatory Information System (SIA/SUS), since 2004, when it was deployed the National Policy on Hearing Health Care, until March 2010, R\$ 40.989.125,00 was spent for replacement of 45.944 HAs⁷.

Exploratory studies are necessary in order to investigate and discuss about the replacement of HAs due to technical failure, since few Brazilian studies deal with the subject. Based on the above consideration, the objective of this study was:

- 1) To identify what are the most frequent technical failures of HA;
- 2) To identify what type and technology category of HA have a higher number of technical failures;
- 3) To identify how long takes for a HA to present a technical failure,
- 4) To analyze the HA repair costs;
- 5) To identify what are the actions taken by the patient and service after device failure confirmation.

■ METHODS

This is a retrospective cross-sectional study, based on primary data collected by HA users files, from patients older than 18 years, with different degrees of hearing loss, who complain about HA technical failure between January to May 2009, totaling 317 cases. It should be pointed out that from manufacturer report was possible to define the cause of 211 HA technical failure and the data presented in this study refers to these 211 cases.

The investigation was done by five audiology services from states of São Paulo, Bahia and Mato Grosso do Sul, which are clinics listed in the medium or high complexity roster SUS.

Data were collected in these five audiology services by trained audiologists. A specific research protocol was used for data collection, as shown in Figure 1.

This research is part of the multicenter project "Indicators and proposal of quality evaluation of the audiology services from the Unified Health System" (CNPq, case number 409613/2006-1 and FAPESP case number 2006/51881-3) and was approved by Ethics and Research Dentistry School of Bauru – University of São Paulo (case No. 092/2008 and 89/2008 respectively).

After the data compilation, it was stored Excel database. Descriptive statistics was performed by the STATA statistical program, version 9.0.

Type of HA	0 – Behind-the-ear (BTE) 1 – In-the-ear (ITE) 2 – In-the-canal (ITC) 3 – Completely-in-the- canal (CIC) 4 – Open-Fit
Technological category	0 – A 1 – B 2 – C
Use time	Months
Patient complain	1 – Battery higher power consumption 2 – Bad contact 3 – Low sound 4 – Whistle 5 – Telephone does not work 6 – Noise 7 – Mute device
Technical failure (According manufacturer report)	0 – Distortion 1 – Microphone failure 2 – Receiver failure 3 – Amplifier failure 4 – Volume control lock failure 5 – T-coil failure 6 – Broken battery-chamber door 7 – Case problem 8 – Broken earhook
Budget	In Brazilian reais
Patient action	0 – Contacted audiology service to schedule an appointment and check the problem 1 – Contacted manufacturer technical assistance to solve the problem 2 – Waited for next appointment to inform about the problem 3 – Due to technical failure has stopped HA use 4 – Routine has not changed due to the problem
Audiology service action	0 – Warranty (repair) 1 – Replacement 2 – HA fixed (costs paid by user)

Figure 1 – Research protocol used in this study

■ RESULTS

Between January to May 2009 was identified 317 cases of HA technical failure complain, but was possible classify the cause of problem only in 211 cases (66.5%), based on manufacturer report. Data presented in this study refers to these 211 cases.

Regarding the HA type and technological category, behind-the-ear (BTE) HA and technological category A had higher rate of technical failure, as displayed in tables 1 and 2, respectively.

The results related to HA time of use that had technical failure can be seen in Table 3. In Table 4 are listed patients' complaints regarding HA.

According to manufacturer report responsible for HA repair (budget), the most frequent technical failures observed by audiology services can be visualized in Table 5.

Figure 2 provides information regarding budget of HA repair. Figures 3 and 4 show patient and service actions, respectively, from the technical failure presented by the devices.

Table 1 – Descriptive analysis, in percentage, HA types that presented technical failures

HA type	N	%
Behind-the-ear	176	83.41
In-the-ear	15	7.11
In-the-canal	15	7.11
Completely in-the-canal	5	2.37
Bone conduction	0	0.00
Total	211	100.00

Table 2 – Descriptive analysis, in percentage, HA technological category that presented technical failures

Technological category	n	%
A	100	47.39
B	52	24.64
C	59	27.96
Total	211	100.00

Table 3 – Use time, in months, of HA which presented technical failure

HA use	Months
Mean	22
Standard deviation	16
Median	16
Mode	24
Minimum	1
Maximum	84

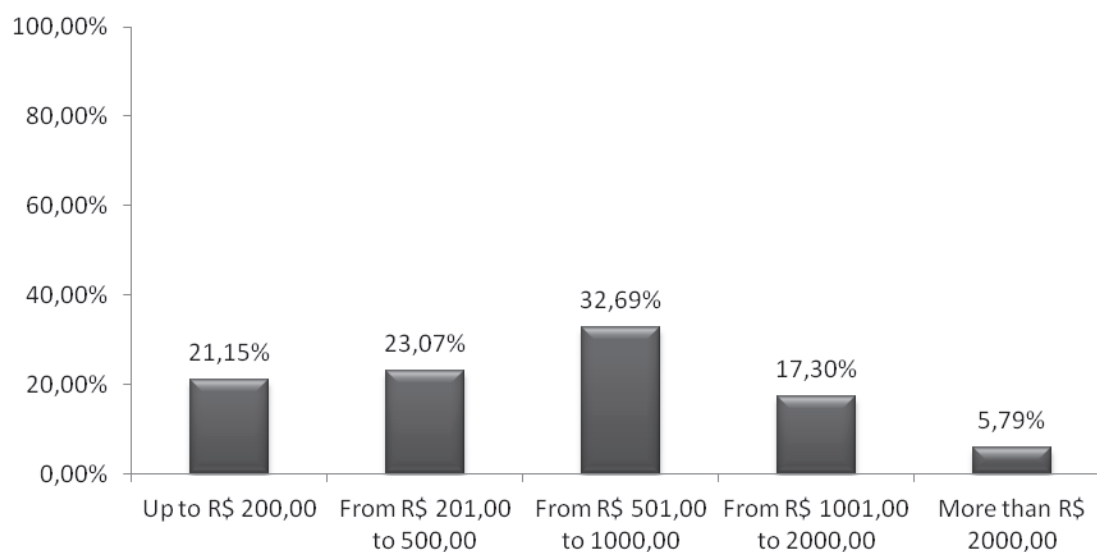
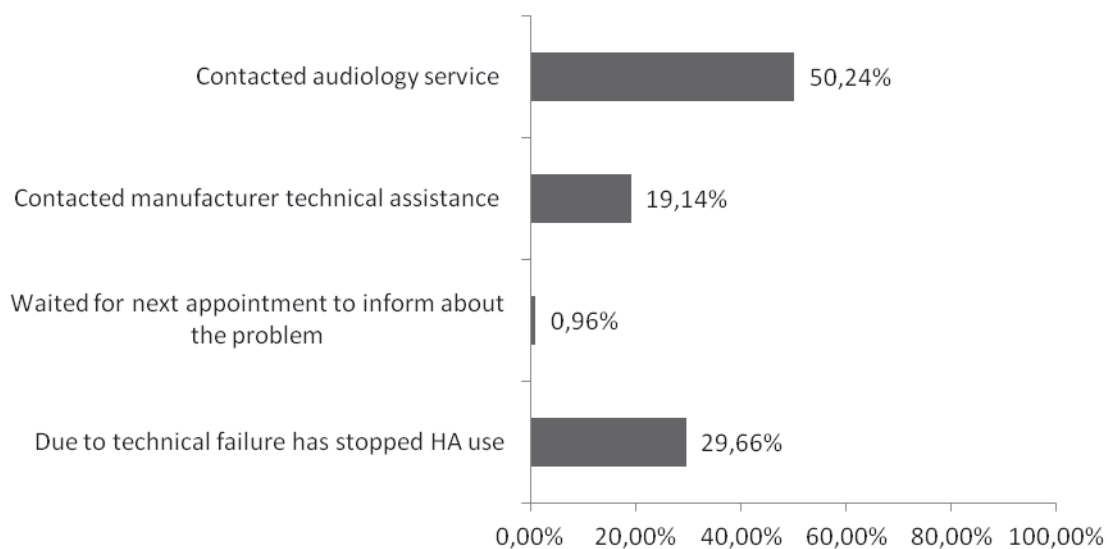
Table 4 – Relation between patient complaints and HA technical failure

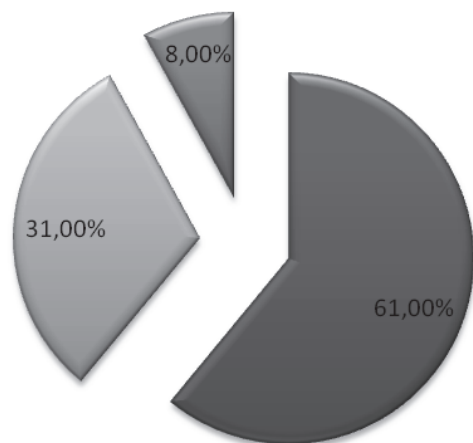
Patient's complain	n	%
Battery higher power consumption	5	2.44
Bad contact	50	24.39
Low sound	20	9.76
Whistle	9	4.39
Telephone does not work	5	2.44
Noise	17	8.29
Mute device	99	48.29
Total	205*	100.00

*Could not register the complaints of six patients

Table 5 – Most frequent technical failures observed by audiology services in this study

Technical failure	n	%
Distortion	19	9.00
Receiver failure	18	8.53
Microphone failure	54	25.59
Amplifier failure	79	37.44
Volume control lock failure	14	6.64
T-coil failure	8	3.79
Broken battery-chamber door	14	6.64
Case problem	3	1.42
Broken earhook	2	0.95
Total	211	100.00

**Figure 2 – Budget repair of HA with technical failure****Figure 3 – Patient action as from the HA technical failure, presented in percentage (N= 211)**



■ Warranty ■ Repair (by HA user) ■ Replacement

Figure 4 – Audiology service action as from the HA technical failure, presented in percentage (N=211)

■ DISCUSSION

Occurrence of technical failures of HA provided by audiology services which are listed in the Medium or High complexity roster SUS is an issue that deserves attention, although rarely discussed nationally. Trends obtained from this study may assist government to start the debate on the need for regulation of the HA maintenance services, from scientific foundations, since is required redefine such rules and reaching a consensus with electronic devices manufacturers.

In our study, among the devices that presented technical failure, BTE (82.94%) and technological category A (47.39%) had higher rate of technical failure (Tables 1 and 2, respectively). However, this finding may be related to rate of HA fitting by SUS, in the other words, the largest percentage of HA fitting by SUS are BTE and category A. Cannot affirm that these HA have more problems compared to others types dispensed by SUS due to lack of information regarding the number of HA fitting conducted at audiology services which participated in this research during the period of study. This makes it impossible to check the percentage of HA with technical failure from the total HA dispensed.

Another study⁸ shows the relation between the frequency of repair and type of HA: in general, the smaller the shell the greater the repair frequency. In the other words, completely in-the-canal (CIC) HA had the highest repair frequency.

A major factor in HA fitting, regardless of HA type, is the orientation to handling and use, which must be carried out properly, consistently and constantly by audiologists to patients who receive HA, in order to prevent breakages or technical failures caused by bad use. In this sense, it reinforces the importance of periodical follow up with audiological monitoring of the HA, allowing patients to get benefit provided by amplification⁹.

In a study on HA use for elderly, it was found that out of 36 HA evaluated, 61% were malfunctioning, 59% of HA were in-the-ear (ITE), 32% BTE and 9% in-the-canal (ITC). The main problems were related to low battery, sound quality and volume control broken. For the authors, audiologists should perform inspection to check HA functioning, allowing the detection of problems¹⁰.

The correct handling and maintenance of HA is an important factor for the successful of device use. In most cases, new HA receive a lot of information in a short period of time. This can be especially difficult for the elderly, because of memory deficits, all information necessary for the proper use¹¹ and maintenance cannot be memorized. This kind of information is critical for the correct manipulation of HA, which can make these users dissatisfied with their devices. In Brazil, the demand of audiology services consists largely of elderly people. The multicenter study coordinated by the Department of Speech, Language Pathology and Audiology from University of São Paulo Bauru (FOB / USP), performed in seven Brazilian audiology services, showed that these services, the elderly population refers to 55% of the total population served by these services⁹.

The present study demonstrated that the major technical failures found in HA (37.44% amplifier failure, followed by 25.59% microphone failure) can be caused mainly due to moisture, oxidation of components by use of poor quality batteries and small traumas and falls^{12,13}, besides problems with HA case (1.42%) and earhook (0.95%), indicating difficulties in handling the device. Another study shows the main reasons for repair is receptor replacement or due to accumulation of earwax and microphone replacement or cleaning due to skin oil or some other impurity¹¹.

Problems battery-chamber door and earhook were technical failures found in this study that may be related to the difficulty of HA handling. Patients who use their HA without fully understanding how to use them correctly cannot receive maximum benefit from their devices and thus reject them¹¹. Such technical failures can be minimized with orientation at different times of audiological treatment¹⁴. In

Brazil, one of the strategies that could strengthen the connection with HA user and allow constant evaluations about HA use is the presence of audiologists in health primary care services^{15,16}. Such professionals can be trained in order to act on the population that received their HA, minimizing or even preventing technical failures caused by difficulty of HA handling.

In this study, 29.67% patients have stopped HA use due to technical failure and 0.96% patients waited for next appointment to inform about the problem. This demonstrates a difficulty of SUS patients in expressing their right as a citizen¹⁷, who cannot contact audiology service to solve your problem. In this sense, it highlights the importance of audiological follow up, because at this time the patient has the opportunity to report their opinions and complaints about the HA. With this information the professional can assist the patient in auditory rehabilitation^{9,18}.

Regarding the HA quality granted by SUS, in Brazil, on July 6, 2005 was published Governmental Decree number 387, which established that HA companies shall provide a request for HA validation rating to general coordination of Middle and High Complexity, for further review and approval by the Technical Chamber of Hearing Health, with record already effected at ANVISA. In the same document it was established that HA companies should provide warranty for at least one year, in case of technical failures.

Considering the HA time of use before present any technical failure, the most common interval in the present study (mode) was 24 months post-fitting, varying a minimum of one month to 84 months (seven years). The durability of the devices was greater than HA warranty, but a short time to present problems. This raises questions to be reflected, such as the high cost of maintenance in some cases, hindering repair by users and generating HA non-use after short time post-fitting, as well as HA replacement, which increases government's costs for hearing loss treatment.

In case of technical issue to be inherent to device itself, in a year, for most audiology services, the manufacturer warranty covers the repair. After the expiration of the manufacturer's warranty, the costs are, or should be covered by own user. In most of the studied population, the cost to repair these devices was between R\$ 500.00 and R\$ 1,000.00. Because HA contain delicate digital electronics, repair costs are potentially high¹⁹, varying according to technical failure presented by the device.

The minimum value found in the analyzed budgets was \$ 100.00, which leads us to think there

may be cases of HA non-use due to lack of condition to cover these expenses. This fact occurs because the majority of patients attending in public audiology services cannot afford the costs of HA repair, even with a reasonable cost, depending on their socio-economic condition – most elderly – (who depends on retirement to support themselves) and reduced level of education²⁰.

In regard to audiology service action, in 61% of cases the HA were still under warranty and was repaired by the technical assistance, with no additional cost to the patient, while only 8% of cases were repaired by the user. Thus, 31% of cases received indicating the HA replacement by audiology service, and this finding also found in a previous study⁴, which 37% of HA were replaced by audiology service due to a technical failure.

The public spending used in replacement of HA, even in cases that HA repair not exceed \$100.00 Brazilian reais, may avoid new users being benefited from treatment⁶. Discussions between governments' representatives and HA companies should be resumed, in order to review and establish specific standards for HA replacement by NHS and find solutions for cases which repair is economically feasible.

We point out that the trends presented cannot be generalized to all audiology services accredited by SUS, because the technical failures have been analyzed in a short period of time (January-May 2009) and in a limited number of services. Thus, this analysis should be carried out by all audiology services, in order to generate information about most frequent HA technical failures and what audiology service action about it. Furthermore, the information from this study were limited to adult patients, but information regarding the HA use by children should be investigated, since the importance of HA in the development of this population.

■ CONCLUSION

From the analyzed data it can be concluded:

1. The HA technical failures most frequently are amplifier (37.44%) and microphone (25.59%) problems;
2. Behind-the-ear and technological category A are those with a higher incidence of technical failure, however, both have higher dispensing quantitative;
3. In 50% of the analyzed cases, the technical failure occur until 16 months after HA fitting;
4. In most cases the cost to repair these devices was between R\$ 500,00 and R\$ 1,000.00.

5. 50.24% of the cases analyzed contacted the hearing health service for verify the HA problem and in 61% of cases were still under warranty and HA was repaired by manufacturer with no additional cost to the patient.

Considering our data and limitations of this study, there is a need for further researches in this field.

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RESUMO

Objetivo: investigar quais as principais falhas técnicas dos aparelhos de amplificação sonora individual fornecidos nos serviços do Sistema Único de Saúde. **Métodos:** foram analisadas as falhas técnicas dos aparelhos de amplificação sonora individual em cinco serviços credenciados pelo Ministério da Saúde, entre janeiro e maio de 2009, utilizando-se estatística descritiva. **Resultados:** as principais falhas técnicas encontradas nos dispositivos foram 37.44% de falha no amplificador, seguidas de 25.59% de falha no microfone. Os aparelhos de amplificação sonora individual retroauriculares e de categoria tecnológica A são os que apresentam maior ocorrência de falha técnica. O tempo de vida útil dos aparelhos de amplificação sonora individual sem apresentar defeito foi de 22 meses, em média. Na maior parte da população estudada, o custo para o conserto destes dispositivos foi entre R\$500,00 e R\$ 1000,00. Dos casos analisados, 51.82% entraram em contato com o serviço de saúde auditiva para buscar atendimento e verificar o problema e em 61% dos casos os aparelhos de amplificação sonora individual ainda estavam no prazo de garantia e foram consertados pela assistência técnica sem custo adicional para o paciente. **Conclusão:** a principal falha encontrada refere-se à falha do amplificador. Os AASI retroauricular e de categoria tecnológica A são os que apresentam maior ocorrência de falha técnica.

DESCRITORES: Perda Auditiva; Auxiliares de Audição; Reabilitação de Deficientes Auditivos; Sistema Único de Saúde

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