

INVESTIGAÇÃO DAS FALHAS TÉCNICAS VERIFICADAS EM PRÓTESES AUDITIVAS DE USUÁRIOS DE UM PROGRAMA PÚBLICO DE SAÚDE AUDITIVA

Investigation of verified technical failures in hearing aids for users of a public hearing health program

Clari Dumke ⁽¹⁾, Ângela Ribas ⁽²⁾, Claudia Giglio de Oliveira Gonçalves ⁽³⁾,
Jackeline Martins ⁽⁴⁾, Diego Malucelli ⁽⁵⁾

ABSTRACT

Purpose: to analyze the technical problems in hearing aids for a user group Program Hearing Health at a university in Curitiba. **Methods:** we analyzed the technical report of 104 implants users who attended the service for follow-up visit. **Results:** the report pointed to defects: 21% receiver, 15% cash, 12% suspension; microphone 9%, 2% amplifier. With regard to the probable cause of the defect: 58% wear a function of time of use, 25% humidity, 23% misuse. As the value of repairs: minimum of R\$ 44.00 for review and cleaning (36%) and maximum of R\$ 900.00 for replacement parts (9.6%), 21% of the sample was held between the budget R\$ 100, 00 and R\$ 500.00, 37% of the devices were replaced. **Conclusion:** the defects were due to handling problems among recent users, and burnout among older users.

KEYWORDS: Hearing Aids; Perception; Unified Health System; Speech, Language and Hearing Sciences

■ INTRODUCTION

Hearing is considered one of the essential senses for cognitive, emotional and psychological human development. According to the World Health Organization¹ there are 42 million people in the world, over three years of age, with moderate to profound hearing loss. According to the American Academy of Audiologia², 0.1% of live births per year worldwide, have severe and profound hearing loss. The International Federation of Oto-Rhino-Laryngological Societies³ estimated a 10%

incidence in the world population of individuals with hearing loss.

In Brazil, 6.8% of patients with disabling hearing loss, which can be moderate, severe and profound hearing loss, have difficulties or impediments in the development of oral language without the intervention of a specialist or using amplification devices⁴.

The Ministry of Health in Brazil, in line with the global reality, instituted the National Policy on Hearing Health Care (PNASA)⁵ in 2004, considering, among other issues, the need to develop strategies to promote quality of life, education, protection and restoration of health, as well as the prevention of hearing damage in the Unified Health System (SUS).

One resource for those who have hearing loss is hearing aids. The PNASA defines the minimum technical criteria for the operation and evaluation of services that perform auditory rehabilitation, as well as its monitoring mechanisms in order to optimize the results of the implementation of hearing aids. The question regarding their use for deaf cases, however, began in Brazil when the Ministry of Health

⁽¹⁾ Tuiuti University of Paraná – UTP, Curitiba, Paraná, Brazil.

⁽²⁾ Tuiuti University of Paraná – UTP, Curitiba, Paraná, Brazil.

⁽³⁾ Masters and Doctorate Program in Communication Disorders at Tuiuti University of Paraná – UTP, Curitiba, Paraná, Brazil.

⁽⁴⁾ Tuiuti University of Paraná – UTP, Curitiba, Paraná, Brazil.

⁽⁵⁾ Tuiuti University of Paraná – UTP, Curitiba, Paraná, Brazil.

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established the policy for granting hearing aids to SUS patients⁶.

The PNASA ensures public access to technologies that minimize the effects of hearing loss, providing engagement at three different levels of health attention⁷: 1) Primary Care: includes actions to promote hearing health, prevention and early identification of hearing problems in the community, as well as informative actions, educational, family counseling and referrals when necessary for hearing health care service of medium complexity, 2) Medium Complexity: constitutes the first reference for primary care and counter reference for dealing with high complexity in hearing loss. Aims to provide specialized assistance to people with ear diseases and especially for people with hearing impairment, and 3) High Complexity: constitutes the reference for the diagnosis of hearing loss and its rehabilitation in children under three years of age and in patients with associated disorders (neurological, psychological, genetic syndromes, blindness, low vision), unilateral loss and those that are having difficulty in getting an audiological assessment for service of lower complexity. In this sense, equipment must be relied on to make the differential diagnosis of hearing loss.

The services enabled by the Ministry of Health as medium and high complexity, after the process of patient assessment, having found that hearing loss, may indicate and provide prostheses to rehabilitate hearing. Regulations currently in effect provide for the classification of devices as class A (R\$ 525.00), class B (R\$ 700.00) and class C (R\$ 1,100.00). According to the same regulations, after the granting of a hearing aid, maintenance is the responsibility of the users, who have expenses with batteries, ear molds, compartment changes, and possible repairs. When the prosthesis has technical failures, many users stop using them or ask for help in replacement due to the inability to pay for repairs. In recent years, a considerable increase in service replacement prostheses has been registered for several reasons: loss, theft, wear and tear, audiological changes, and technical failures in general.

Studies have shown that hearing aid users have difficulties with handling their hearing aids, which is one of the factors that can lead to malfunction of the prosthesis and its deterioration, thereby generating maintenance expenses^{8,9}.

The objective of this work was to verify the occurrence of technical failures in hearing aids for a user group in the Hearing Health Program in a University in Curitiba.

■ METHODS

This study had the approval of the Ethics Committee CEP-UTP-027/2008. All subjects signed an consent form in accordance with Resolution MS/CNS/CNEP 196/96.

This is a descriptive cross-sectional study and was done over six months, during annual follow-up visits conducted on 515 service users. We analyzed 895 hearing aids. Among the subjects analyzed, 239 (46.40%) were males and 276 (53.60%) were female. The majority of the population served was between the ages of 50 and 69 (57%).

The Hearing Health Program at the School Clinic of Speech Therapy at the researched University performed ENT and hearing evaluations, selection, appointment and fitting of hearing aids, as well as audiological monitoring of hearing aid users throughout their lives. Besides getting the initial hearing aid, the patient is also entitled to replacement devices. In 2010, SUS, through the program of the University Hearing Health study, granted a total of 1,136 devices at a cost of R\$ 978,175.00.

The criteria for inclusion in the study were: to be a University speech therapy clinic patient, to be a unilateral or bilateral hearing aid user, and to have attended the annual follow-up visit.

To characterize the sample, the medical records of 515 patients and their hearing conditions were analyzed. The following variables were considered: age, gender, hearing loss, hearing aids used (type and rating), and the time of use.

Upon returning for their annual follow-up visit, the subjects had their hearing aids evaluated and likely complaints from users about their operation were investigated.

The prostheses that had malfunctions were then referred for evaluation at a specialized laboratory. The technical report of the laboratory was analyzed in the following aspects: data on the general conditions of the device and its components (microphone, receiver, amplifier, ear hook, mold, compartment, and connective tubing), the presented defect, the probable cause of the defect, and the cost in Brazilian Reals for repair.

The data were put into a spreadsheet, categorized and treated statistically with parametric tests. We used Chi Squared and Difference of Proportions tests, and values below 0.05 were considered significant. For statistical analyses the following dependent variables were considered: the causes of defects of hearing aids, types of failures, and time of use, while the independent variables were: gender and age of the user.

■ **RESULTS**

During the period considered for this study (six months), 515 hearing aid users completed their annual follow-up, and a total of 895 hearing aids (760 prostheses adapted bilaterally and unilaterally 135) were observed.

Of the 515 users, 323 were using in-ear prostheses and 192 used BTE.

Most had been wearing hearing aids for over 37 months, according to Table 1.

Of the 515 patients enrolled, 86 (16%) complained of problems with the operation of their devices. Thus, of 895 prostheses adapted and evaluated in follow-up, 104 (11%) were defective.

The causes of defects, after the technical evaluation of the hearing aid, in relation to time of use are recorded in Table 2.

Table 1 – Sample Distribution based on time of use in months (N=515)

TIME OF USE	FEMALE	MALE	TOTAL
up to 12 months	25	13	38
13 – 24 months	34	22	56
25 – 36 months	18	28	46
37 – 48 months	116	87	203
49 – 60 months	36	34	70
61 months or more	47	55	102
TOTAL	276	239	515

Table 2 – Defect causes in relation to time of use

DEFECT CAUSE	TIME IN MONTHS			TOTAL	P*
	Up to 24	25 – 48	More than 49		
Incorrect Use	16 (61.4%)	5 (19.2%)	5 (19.2%)	26 (100%)	0.0000
Other causes	3 (8.2%)	14 (37.8%)	20 (54.1%)	37 (100%)	0.0000

Note: * Chi-Squared Test $p < 0.05$ (5%)

Most cases of misuse of hearing aids occurred within 24 months, while the causes for other problems, worn parts, for example, occurred after 49 months of use of the hearing aids.

We used the Chi Squared test and observed that there was significant dependence between the

causes of the defect and time of use of hearing aids ($p = 0.0000$).

The defects presented in the prosthesis were categorized through the technical report by the affected component in Table 3.

Table 3 – Partes with registered defects in technical reports (n=104)

Defect Location	Absolute Frequency	Relative Frequency %
Molds or Capsules	62	59
Case	45	43
Debris impeding function	41	39
Connecting tubes	33	31
Receiver	21	21
Hook	12	11

39% of the prostheses registered were just dirty and 85% of these prostheses were from recent users with 12 to 24 months of use.

We investigated the defect presented in relation to the time of use of the prosthesis, in Table 4; the defect presented in relation to the age of the user, in Table 5; and the defect presented in relation to gender, in Table 6.

Table 4 – Defect by time of use

DEFECT	TIME IN MONTHS			TOTAL
	Up to 24	25 – 48	More than 49	
Molds or Capsules	47 (75.8%)	8 (12.9%)	7 (11.3%)	62 (100%)
Case	19 (42.2%)	16 (35.6%)	10 (22.2%)	45 (100%)
Connection tubes	15 (45.5%)	11 (33.3%)	7 (21.2%)	33 (100%)
Internal Components	8 (17.8%)	11 (24.4%)	26 (57.8%)	45 (100%)

Table 5 – Defect by Age

DEFECT	AGE IN YEARS			TOTAL	P*
	Up to 30	31 – 50	More than 50		
Molds or Capsules	16 (25.8%)	17 (27.4%)	29 (46.8%)	62 (100%)	0.1567
Case	2 (4.4%)	13 (28.9%)	30 (66.7%)	45 (100%)	0.7656
Connection tubes	8 (24.2%)	10 (30.3%)	15 (45.4%)	33 (100%)	0.7334
Internal Components	8 (17.8%)	9 (20.0%)	28 (62.2%)	45 (100%)	0.2556

Note: * Difference of Proportions Test $p < 0.05$ (5%)

Table 6 – Defect by Sex

DEFECT	SEX		TOTAL	P*
	Male	Female		
Molds or Capsules	41 (37.6%)	21 (27.6%)	62 (33.5%)	0.1579
Case	27 (24.8%)	18 (23.7%)	45 (24.3%)	0.8640
Connection tubes	19 (17.4%)	14 (18.4%)	33 (17.8%)	0.8614
Internal Components	22 (20.2%)	23 (30.3%)	21 (24.3%)	0.1170
TOTAL	109 (100%)	76 (100%)	185 (100%)	

Note: * Difference of Proportions Test $p < 0.05$ (5%)

Defects in mold, case, and connective tubing for hearing aids were mainly observed within 24 months, while failures in internal components were found after a longer time of use.

Users over 50 years old were the group that complained most. The most important problems were found in the hearing aid case.

There was no significant dependence between defect and age or defect and gender, through the Difference of Proportions Test.

With respect to estimated repair costs, it was observed that the lowest amount was R\$ 44.00 for cleaning, in 39% of the prostheses analyzed; 38% had estimates between R\$ 51.00 and R\$ 300.00; 19% had estimates between R\$ 301.00 and R\$ 600.00; and 4% were more than R\$ 601.00.

23 prostheses (37%) were replaced because users could not afford the cost of repair. SUS replaced six class A, five class B, and 12 class C prostheses.

In case of repair, the total estimated value was R\$ 7,589.00. With the substitutions SUS spent R\$ 19,250.00.

■ **DISCUSSION**

The Hearing Health Policy provides that after the period for evaluation and adaptation of the prosthesis, program users receive continued attention. During the period of data collection, children up to three years old were entitled to have four follow-up visits per year, children up to 12 years old could have two annual follow-up visits, and adult patients, one follow-up per year.

It is at this follow-up that the audiologist reassesses users' hearing and checks the devices' operating condition. Hearing aids are designed to

improve auditory perception for communication skills, preventing social isolation and depression. However, when the device becomes uncomfortable for the patient, it is a sign that something is not working well. In these cases it is important to reassess the user's hearing, to verify significant changes in hearing thresholds, and also to evaluate the operating conditions of the prosthesis¹⁰.

In this study it was established that 16% of the study sample complained of problems with the prosthesis and the misuse of the hearing aid was the cause. Experienced users tend to have fewer problems with the handling of the hearing aids, probably because they are accustomed to using them (see Tables 1 and 2).

Thirty-nine percent of the prostheses evaluated were dirty and poorly maintained. Preservation and cleaning of the prosthesis are essential for its proper function¹¹. It is not uncommon that cerumen obstructs the sound outlet in BTE hearing aid molds, or even cause damage to the in-ear receiver.

In this study, with the majority of the sample (62%) using an in-ear hearing aid, one can infer that extra care must be taken to prevent damage to the receiver because of cerumen accumulation around the sound outlet, which is positioned inside the auditory canal of the patient. When fitting a hearing aid, the audiologist should explain the importance of cleaning the equipment to the user. However, as there is much information, forgetting the cleaning procedures is a common problem.

Studies^{12, 13} show that it is necessary to invest in counseling sessions after the adaptation process, because in these sessions, the speech therapist discusses the importance of communication for the elderly, the impact of hearing loss, its emotional effects, and the proper use the prosthesis. Currently the PNASA does not provide this kind of service by

a speech-language pathologist. The studied service performs work as a group, where guidance and advice are given to the user and family once the prosthesis is provided.

It was possible to verify that the devices for recent users have problems in the molds/ capsules, compartment, or connective tubing. The apparatus of older users have malfunctioning internal components, which allows us to infer that the use and experience of handling problems diminish. It is noteworthy that, despite the significant association, no studies were found that were able to establish correlations.

The exchange of molds or capsules should be performed annually in the case of adult users, for reasons of hygiene and adaptation to the ear which undergoes changes over time,¹¹ thus most of the problems presented here would be eliminated with more frequent access to technical services.

Devices with faulty internal components do not amplify sound, or may result in distorted amplified power (muffled sound, intermittent squeaking, and static, among other things). These defects can be caused by wear on parts, which affects electronic equipment in general, or improper use (falls, impacts, water, or exposure to high temperatures, among other accidents). According to the data collected, 14 (31%) devices presented component failure due to wear on parts due to time of use. However, in 21 (46%) devices, it was found that time of use was not relevant because the problems were detected in new users, which allows us to infer that the probable cause of the failure was lack of care. There was an association between defects and the time of use of the hearing aids. However, there was no statistically significant relationship between age and gender with the presented defects.

Another relevant fact is that 36% of the prostheses were replaced because the users were not able to afford the repair costs. The studied service caters, evidently, to the lower social classes.

This data allows us to recommend that the rules be revised so that the population can afford the maintenance and repair of prostheses, thus avoiding, replacements that burden the government indiscriminately.

Considering that the investments made by the government in the provision of hearing aids and prostheses currently provided by the Hearing Health program of the government vary from R\$ 525.00 to R\$ 1,100.00, and that in this study 34.9% of repairs were estimated at under R\$ 500.00, it can be said that there is a flaw in the policy of maintaining these prostheses, i.e., the government spends more resources replacing the damaged hearing aids than if there were a policy for repairs.

It was found that even though devices are replaced when they could still be repaired, people who still do not have hearing aids are waiting in line with hearing health services. When a user requires a new device, he does not go to the back of the line, the health service evaluates the defective device and provides the necessary referral.

The Ministry of Health invests considerable sums in providing hearing aids. Publish data¹ report that in 2002 the Ministry of Health invested R\$ 47,081,886.75 in the program providing 35,297 hearing aids through 84 Service Providing Units. But in 2004, when rule GM 2073/04 became effective, these costs climbed to R\$ 162,705,737.00. In 2010, expenditures exceeded R\$ 224,000,000.00, granting more than 170,000 devices¹⁴.

In a period of six months, SUS spent R\$ 19,250.00 on new devices for users at the clinic studied, yet only 30% of this expenditure would have been needed to carry out repairs on the defective prostheses.

The PNASA⁵ has enabled many citizens, mostly from less privileged socioeconomic classes, to have access to hearing aids and quality rehabilitation. However, this study showed that part of the budget that should benefit new users has been designed to replace damaged devices because users cannot afford device maintenance after the warranty period.

Finally, it is believed that with a larger number of consultations, the patient has the opportunity to answer questions about maintenance and care, thus increasing the life of the device, which is not always possible in only one annual follow up. Note that these patients require more attention since technical problems cause stoppage of use of the device, which reduces the benefits of better hearing from the social point of view. Campaigns that promote explanations and understanding of hearing aids may help to reduce future expenditures, such as replacement devices that were damaged because of a lack of information given to patients.

The data collected highlights the need for a cautious revision of rules regarding hearing health in Brazil, which lends to an emerging attitude that places an importance on the allocation of funds for prosthesis maintenance. Such a change would generate less of a burden on the government and would result in longer service life of the given prosthesis. With this reduction in spending, the government could provide a greater number of hearing aids, benefiting many more people who need to hear again. The longer the wait, the greater the loss for the patient with hearing problems, and the greater the difficulty of restoring his hearing.

Another important factor in hearing health services is investment in patient guidance, audio visual support materials such as brochures and explanatory videos, in order to improve knowledge about the handling and care of prostheses, improving the overall understanding of the population.

The results suggest the importance of monitoring patients with hearing aids aimed at prevention and technical problem guidelines arising from lack of opportunity to correct them.

■ CONCLUSION

The study concluded that the majority of technical failures were related to the molds or capsules of hearing aids, and hearing aid problems in the case. The occurrence of technical problems arose predominantly within 24 months of use, and was related to wear on parts. Recent users (under 24 months) had difficulties in handling and longer users (over 24 months) in trouble for wear on parts.

RESUMO

Objetivo: analisar as falhas técnicas em próteses auditivas de um grupo de usuários do Programa de Saúde Auditiva de uma Universidade em Curitiba. **Métodos:** analisou-se o relatório técnico de 104 próteses de usuários que compareceram ao serviço para a consulta de acompanhamento. **Resultados:** o relatório apontou para defeitos em: 21% receptor; 15% caixa; 12% suspensão; 9% microfone; 2% amplificador. Com relação à causa provável do defeito: 58% desgaste em função do tempo de uso; 25% umidade; 23% mau uso. Quanto ao valor dos consertos: mínimo de R\$44,00 para revisão e limpeza (36%) e máximo de R\$900,00 para substituição de peças (9,6%); 21% da amostra teve o orçamento realizado entre R\$100,00 e R\$500,00; 37% dos aparelhos foram substituídos. **Conclusão:** Os defeitos detectados deveram-se a problemas de manuseio entre os usuários recentes, e desgaste entre os usuários mais antigos.

DESCRIPTORIOS: Auxiliares de Audição; Percepção; Sistema Único de Saúde; Fonoaudiologia

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Mailing Address:

Ângela Ribas

Rua José Isidoro Biazetto, 845 – ap 501

Curitiba – PR

CEP: 81200-240

E-mail: angela.ribas@utp.br