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Evaluating the Physical Fit of Receiver-in-the-Ear Hearing Aids in Infants

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Sueli Aparecida Caporali*
Erik Schmidt*
Åsa Eriksson†
Birgitta Sköld†
Barbara Popecki‡
Josefina Larsson§
Jane Auriemmo**††

Abstract

Background: In spite of early identification and intervention efforts achieved by Early Hearing Detection and Intervention (EHDI) programs, many infants with hearing loss experience delays in early vocabulary development in comparison to peers with normal hearing (Mayne, Yoshinaga-Itano, Sedey, 2000a; Mayne, Yoshinaga-Itano, Sedey, Carey, 2000b; Moeller et al, 2007a, 2007b). One of the several factors that may contribute to individual differences in outcomes is inconsistent hearing aid use in this age group. This may be associated with the physical fit when using traditional behind-the-ear (BTE) hearing aids, since they are relatively large in comparison with the small and soft ear of an infant. Receiver-in-the-ear (RITE) hearing aids may be advantageous for use in pediatric fittings, since they are very tiny and lightweight and therefore sit comfortably on a small soft ear.

Purpose: To evaluate the use of a RITE hearing aid with an instant ear-tip especially developed for infants in terms of physical fit, stability, safety, and security of the device, as well as the use of retention tools (remedies for keeping the hearing aid securely on the ear) with this age group.

Research Design: A longitudinal study with hearing impaired infants fitted with RITE hearing aids was performed.

Study Sample: Eighteen infants with mild to moderate/severe hearing loss participated in the study. The age range was 2–36 mo. Sixteen infants had worn hearing aids prior to their participation in the study.

Intervention: Each hearing impaired infant was fitted with the RITE hearing aid and an instant ear-tip, the size of which was chosen by the audiologist. The infants used the device for a period of 2–5 mo.

Data Collection and Analysis: Audiologists and parents completed questionnaires at every visit (5–7 visits in total). Responses were obtained using a category rating scale (Stevens, 1975) from 0 to 10. The data were analyzed using descriptive statistics and nonparametric statistics.

Results: Sixteen of the 18 children completed the study. At the end of the study, 11 of the 16 children were using the instant ear-tip, whereas five children were fitted with the receiver mounted in a custom earmold. The audiologists rated the RITE solution to provide a safe, stable, and secure fit. The general trend was that ratings improved over time. At the final follow-up session, all median ratings were between 8 and 10.

Conclusions: Based on the positive results obtained in the study, the use of an appropriately designed RITE hearing aid is recommended for infants.

*Applied Research Team, Widex A/S, Denmark; †Hörselhabilitering Barn Ungdom, Karolinska University Hospital, Sweden; ‡LIJ Hearing and Speech Center, Department of Otolaryngology and Communicative Disorders, North Shore, Long Island Jewish Health System; §Widex Office of Research in Clinical Amplification (ORCA) Europe; **Widex New York (At the time of the study); ††Center for Hearing and Communication, New York (Currently)

Sueli Aparecida Caporali, Widex A/S, Nymoellevej 6, Lynge, Denmark 3540; E-mail: sac@widex.com

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Abbreviations: BTE = behind the ear; CI = cochlear implant; RITE = receiver in the ear

The implementation of universal newborn hearing screening (UNHS) programs has increased globally. There are available guidelines for diagnosis and intervention such as Early Hearing Detection and Intervention (EHDI). The Joint Committee on Infant Hearing (JCIH, 2007) recommended that the hearing loss be identified by 1 mo and evaluated by 3 mo and the intervention initiated by 6 mo. As a result of these screening programs, infants with hearing loss are identified (Vohr et al, 1998; Harrison et al, 2003) and receive amplification devices at earlier developmental stages than in the past (Uus and Bamford, 2006). Pediatric audiologists fit amplification to babies as early as possible to optimize their auditory development and provide auditory foundations for language learning (Sininger et al, 1999).

In spite of early identification and intervention efforts, studies have found that many infants with hearing loss still experience delays in early vocabulary development in comparison to peers with normal hearing (Mayne, Yoshinaga-Itano, Sedey, 2000a; Mayne, Yoshinaga-Itano, Sedey, Carey, 2000b; Moeller et al, 2007a, 2007b). The wide variability in performance outcomes among early identified hearing impaired children demands studies to examine closely the factors that contribute to individual differences (Moeller et al, 2007).

Wake et al (2005) evaluated language and related skills in a group of 7- to 8-yr-old children with hearing loss. They found that degree of hearing loss was predictive of outcome, but overall, age at diagnosis was not. Nicholas and Geers (2006) measured spoken language skills in 3- to 5-yr-old children with cochlear implants (CIs) and found that hearing level and duration of implant use were predictive of outcome, but age at fitting of CI amplification was not. Fitzpatrick et al (2007) also failed to find a predictive relationship between age at identification or intervention, on the one hand, and language outcome in children with hearing loss, on the other. Sininger et al (2010) investigated the influence of selected predictive factors (primarily age of fitting of amplification and degree of hearing loss) on auditory-based outcomes in young children with bilateral sensorineural hearing loss. The results were contradictory with the findings of earlier studies. The age of fitting of amplification has the greatest influence and was an important factor in all outcome models. The degree of hearing loss was also an important factor in the modeling of speech production and spoken language outcomes. These findings are in agreement with Yoshinaga-Itano et al (1998) and Yoshinaga-Itano (2003).

Moeller et al (2009) examined the relationship between age of diagnosis, age of fitting, degree of hearing loss, and language outcomes and inferred that consistency of device use was one of the factors that may contribute to the wide variability in performance outcomes. Optimal benefit from amplification may only be achieved with consistent and appropriate hearing aid use.

Moeller et al (2009) found that consistency of hearing aid use was variable at early ages but improved with age. By 28.5 mo of age, toddlers used amplification in most settings. Considering that auditory system development, particularly the development of speech perception, is guided by access to relevant acoustic and linguistic information in life (Kuhl, 2000), full-time use of amplification is necessary as early as possible. In other words, it may delay language development if hearing aids are not used full-time in the first 2 yr of age.

One could argue that inconsistent hearing aid use by infants is primarily a parenting issue. Parents' persistence is certainly an ingredient in achieving full-time hearing aid use. However, it is very clear that this process is also affected by child-related issues, bidirectional (parent-child) issues, situational issues, and most importantly, parent adjustment issues that complicate the process (Moeller et al, 2009).

It is not uncommon for parents of hearing-impaired children to experience an array of emotions at the time of diagnosis. Parents experience a grief process and common emotions as they begin to accept their child's hearing loss. These emotions typically occur in stages, that is, shock, anxiety; anger, depression; guilt, resentment; vulnerability, overprotection; confusion, panic, and denial. These stages may vary in duration and severity from parent to parent (Luterman, 1996). Since the hearing aid fitting process most frequently occurs shortly after the hearing loss diagnosis, an array of emotions may be expected, as the hearing aids make the child's hearing loss visible to the parents.

Sjoblad et al (2001) suggested that parental affective responses to diagnosis and hearing aid fitting play a role in early device adjustment. Parents expressed three primary areas of concern about amplification: how to maintain the devices, device appearance, and potential benefit for the child/infant. In addition the parents show emotional responses regarding initial worry that the child may not be accepted socially after hearing aids were fitted, and concerns about the impact of hearing loss/aids on development.

Martin et al (2005) also reported consistent concerns when interviewing hearing impaired infants' parents regarding adjustment to hearing aid use and acceptance. Parents indicated that they would appreciate more information or support in the following areas: (a) emotional support, (b) accessories (for safety, retention,

checking devices), and (c) awareness of potential complications.

Moeller et al (2009) reported consistent parental safety concerns in her study, indicating that preventing loss of the hearing aids and ensuring child safety are issues that need to be addressed directly and comprehensively by audiologists in the early stages of hearing aid fitting. They need to support parents, providing a realistic expectation of the potential benefits of hearing aids.

One factor that may be related to the consistency of hearing aid use is the physical fit of hearing aids for infants. One of the greatest challenges when fitting hearing devices to babies is to obtain a good physical fit in relation to the baby's tiny pinnas. Traditional behind-the-ear (BTE) hearing aids are relatively large in comparison to the small, soft ears of infants under 2–3 yr of age. This can be a potential problem that may prevent the infants from using the hearing aids full time, as the hearing aid can fall off the ears and might get lost. Moreover, the fact that babies' ear canals are small and growing presents ongoing fitting and refitting challenges (Scollie and Bagatto, 2010), since earmolds need to be replaced very often, either because of problems with the physical fit or whistling problems.

According to Scollie and Bagatto (2010), filtered pediatric-sized tone hooks that improve the physical fit to the baby's tiny pinnas, well-made soft earmolds, and a care kit that allows families to inspect and care for the devices are important features when selecting hearing aids for babies. Additionally, the selection of hearing aids for babies may generally include programmability, nonlinear signal processing to allow audibility of soft sounds, and lockable features such as tamper-proof battery doors and lockable volume controls.

Parents' concerns relating to the size, safety, and retention of hearing aids (Martin et al, 2005; Moeller et al, 2009) indicate that there is a need for hearing aids that are specifically dedicated to infants, to address these problematic and relevant issues.

Receiver-in-the-ear (RITE) hearing aids may potentially be a good solution for hearing impaired infants in their first years of life due to the small size and light weight,[1] combined with instant change of ear-tip as the infant's ear canal grows. The small size provides better chances for good hearing aid retention.

A RITE hearing aid is often used in combination with an instant ear-tip that fits into the users' ear canals, thereby minimizing the need for custom earmolds (Hallenbeck and Groth, 2008). It is not unusual for babies to receive new earmolds every 2–3 mo (Australian Hearing, 2008) because ears and ear canals grow quickly in infants. Instant ear-tips might also be a good solution for infants, as they can be changed easily whenever necessary, without the need to take frequent earmold impressions. In cases where the hearing aids have feedback problems, changing to new ear-tips can be done in the same session with the audiologists. This would ensure uninterrupted use of the hearing aids and preserve the consistent auditory input to the developing brain. Thus, the use of ear-tips can potentially reduce the number of visits to the clinic. Furthermore, the time saved with earmold impressions can be used for counseling and for the fine-tuning and verification of hearing aids.

Even though today's RITE hearing aids can be very tiny, they are very sophisticated in terms of technology and sound processing. RITE hearing aids can offer a range of advanced features, including adaptive directionality, noise reduction, feedback cancellation, and Bluetooth among other features (Martin, 2008).

Another advantage of placing the receiver in the ear (i.e., the use of RITE hearing aids) is the potential for extended bandwidth. A broad bandwidth is problematic in BTE hearing instruments because of the high-frequency roll-off generated by the hook and long tubing (Kuk and Baekgaard, 2008). The upper frequency limit of many BTE instruments is below the frequency spectrum of /s/ spoken by children and women (Stelmachowicz et al, 2001). As a result, providing adequate gain in the 6–8 kHz range is difficult, particularly for infants and young children. This is aggravated by the common occurrence of acoustic feedback due to the rapid growth of the children's ear canals from the slight sound leakage from the earmolds.

The importance of broad-bandwidth hearing aids for speech and language development in children has been extensively discussed (Pittman and Stelmachowicz, 2000; Stelmachowicz et al, 2000, 2001, 2002, 2004; Pittman et al, 2003, 2005; Moeller et al, 2007a, 2007b). Children with moderate or moderate-severe hearing losses may be challenged in their speech and language development. Misarticulation of fricatives and affricates is common, particularly for children with pure-tone averages (at 500, 1000, and 2000 Hz) greater than 45 dB HL. In addition, significant delays in vocabulary development, verbal abilities, and reasoning, and increased errors in noun and verb morphology have been reported (Stelmachowicz et al, 2004).

Although RITE devices have the potential to offer a number of advantages for hearing impaired infants, their ease of use and safety must first be verified. The stability and durability of the RITE wire is an important issue, because infants are more inclined to remove the aids than adults. The wire connection must be durable from potential abuse. Secondly, exposure of the receiver to moisture and cerumen is greater with a RITE instrument. Thirdly, placing the receiver in the ear could pose an ingestion risk unless special design features (or instructions to parents) are in place to minimize such risks.

Additionally, RITE hearing aids may demand more training and support for both audiologists and parents. The small components, that is, the instant ear-tip, soft anchor, and earwire, must be chosen correctly to guarantee

a good physical fit from the beginning. Some training/practice is needed for both audiologists and parents to insert the ear-tip in the ear canal since the material is very soft and the earpiece is very small.

The study was conducted to investigate if the current RITE hearing aids designed with a special instant ear-tip solution provide an adequate physical fit on infants. Audiologists and parents were asked to evaluate the physical fit of the RITE hearing aids as they were worn by the infants. Stability, safety, and security of the RITE hearing aids,[2] along with the parents and audiologists' impressions on these issues over time, were also investigated.

METHOD

Study Sites

The study was conducted at two audiology clinics: Hearing and Speech Center at Karolinska University Hospital (Sweden) and Hearing and Speech Center, Department of Otolaryngology and Communicative Disorders, North Shore, Long Island Jewish Health System. The two clinics have considerable experience with fitting hearing aids to infants and have treated a large number of infants with hearing loss for hearing aid intervention and follow-up services. The children who participated in the study were routine patients from the two hearing clinics. The parents of the children were given oral and written information and signed full subject consent before each child was included in the study. The parents were also informed that they could withdraw from the study without any penalties and that they could return to their "own" hearing aids at any time if they so wished. The parents were not offered any inducements to take part in the study. The study was approved by the individual sites' institutional review boards (IRBs). At the conclusion of the study, the parents were offered the study hearing aids used in the study free of charge.

A local Widex representative functioned as monitor and provided support for the audiologists carrying out the investigation.

Participants

Inclusion criteria for participants in the study were hearing impaired infants with mild to moderate-severe hearing loss between the ages of 2 and 36 mo.[3] The degree of hearing loss and the age range were chosen on the basis of the fitting range of the hearing aid (30–80 dB HL at all frequencies) and the age group for which the hearing aid was designed. A variety of hearing losses were accepted, congenital or acquired, sensorineural or conductive/mixed. Infants with or without a history of hearing aid use were included. The parents of the infants had to agree to engage in the particular aural habilitation program at each clinic and cooperate with the study requirements. Exclusion criteria were children with chronic middle ear infections and infants with physical abnormalities in the outer or middle ear.

The study took place over a period of 6 mo. Initially, 18 families consented to participate in the study. Two families withdrew early in the study. One of the children had very small ears, and the minimum size of the instant ear-tip was still too large. The parents did not wish to attempt the custom earmold solution. The parents of the other child withdrew from the study after 1 wk because they were afraid that the RITE hearing aid may be fragile, since the receiver was placed in a very soft ear-tip and the earwire was very thin compared to the tubing used in conventional BTE.

Sixteen infants completed the study. Eight were from Sweden, and eight were from the United States. There were eight females and eight males. The age range of the infants was evenly distributed from 2 to 36 mo, with a mean age of 17 mo (SD = 9.6). All the children had sensorineural hearing losses ranging in degree from mild to moderate/severe (see Fig. 1). Fifteen infants were fitted with the study RITE hearing aids binaurally, and one infant was fitted monaurally due to a unilateral hearing loss. Fourteen children had worn traditional digital BTE hearing aids prior to the trial. (See Table 1 for subject information.) All audiogram configurations were within the fitting range of the hearing aid. The number of follow-up sessions varied from 5 to 7. The duration of the trial varied from 2.5 to 5.5 mo depending on the needs of the infants and their parents.

Description of the Test Device

The device used in the study was a miniature BTE, which had the receiver placed in the concha bowl of the ear (RITE). The small, lightweight BTE housing was placed behind the ear. A picture of the RITE hearing aid (with earpiece) is shown in Figure 2.

All the components for processing the sound and the battery were contained in the BTE housing. There was no volume control or program buttons on the BTE. The battery compartment was tamper-proof to prevent the child from accidentally removing the battery from the device. There was a built-in LED (light emitting diode) on the BTE housing that would flash briefly at regular intervals to indicate that the device was turned on and the battery was active.

The receiver used in the study was a two-way receiver that had been chosen specifically for its extended bandwidth. Because baby ears are very small, the receiver had to be placed in the concha bowl of the outer ear and connected by a thin wire to the BTE. The wires were available in different lengths to provide for different

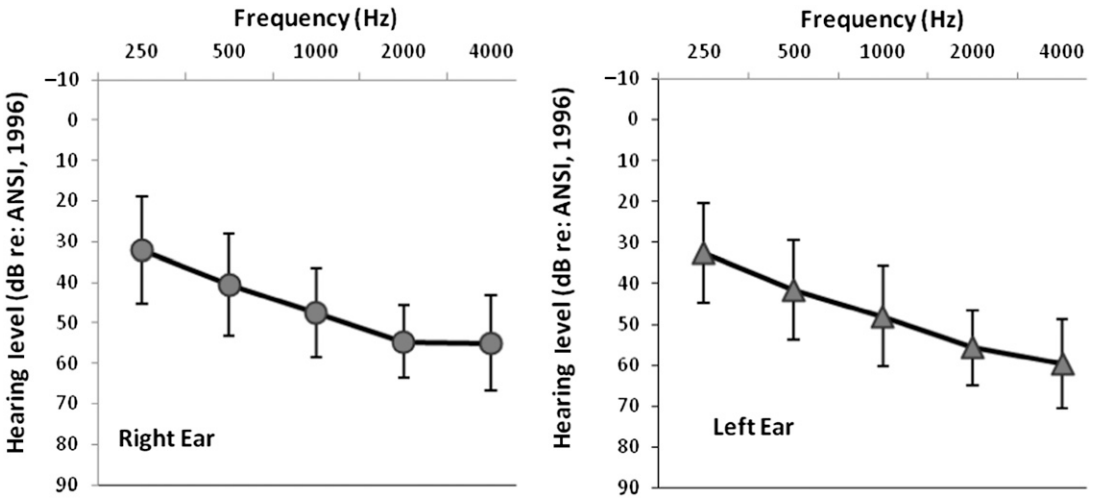

Figure 1. Mean pure-tone thresholds (dB HL) for right and left ears of the 16 hearing-impaired infants in the study. Error bars indicate ±1 SD (dB).

sizes of children's ears. The wire connection between the BTE hearing aid and the receiver in the ear had been reinforced with a Kevlar thread to strengthen the pull force on the wire.[4] Additionally the connection at the plug of the wire had been reinforced to prevent detachment of the wire from the receiver or the hearing aid. This special design aimed to improve durability of the earwire and safety of the device.

There are two ways that the receiver can be mounted in the ear. It can be mounted in an instant ear-tip or to a custom-made silicone earmold.[5] The instant ear-tip was mounted with a soft anchor that supported the tip in the concha and kept the receiver module in place. The instant ear-tip came in six different sizes and could easily be changed by the audiologists. The soft anchor was available in four sizes.

Retention tools, such as the soft anchor, an adhesive tape,[6] and a retention strap were also provided during the fitting to add extra safety and security. The retention strap was fully integrated into the hearing aid at

Table 1. Subject Information

No.	Gender	Age (mo)	Degree of hearing loss	First time user?	Previous HA	HA use prior to the study (months)	Problems with previous HA?
1	Female	2	Moderate	Yes			
2	Male	7	Moderate	Yes			
3	Female	8	Moderate/ severe	No	BTE	4	No
4	Female	8	Moderate/ severe	No	BTE	2	No
5	Male	9	Moderate/ severe	No	BTE	6	Yes, feedback problems caused by earmolds.
6	Male	13	Moderate	No	BTE	8	No
7	Male	13	Mild	No	BTE	6	Yes, infant likes to pull HA out by dragging the tubing. Mother reports this is for attention-seeking purpose.
8	Female	14	Moderate	No	BTE	9	No
9	Female	15	Moderate/ severe	No	BTE	11	No
10	Female	17	Moderate	No	BTE	13	No
11	Male	23	Moderate	No	BTE	6	No
12	Male	26	Mild	No	BTE	13	Yes, hearing aids flop off the ears and he pulls hearing aid out.
13	Female	27	Moderate/ severe	No	BTE	21	Yes, child essentially is a nonuser. Cries whenever anyone attempts to put HAs on.
14	Male	27	Moderate	No	BTE	23	Yes, hearing aid flops off ear and/or he pulls HA away by dragging the tubing.
15	Male	28	Moderate	No	BTE	25	No
16	Female	36	Moderate	No	BTE	30	No

Figure 2. Picture of the RITE hearing aid and instant ear-tip used in the study.

one end and to a clip at the other end. The strap was clipped to the child's clothes behind the head. When two hearing aids were worn, one retention strap was connected to both hearing aids and attached to a single clip on the collar of the infant's clothes. The purpose of the strap was to prevent the child from losing the hearing aids if they fell off the ears and to prevent the child from putting the hearing aid in his/her mouth. The adhesive tape was used to tape the BTE to the baby's skin behind the ear during daily use.

The hearing aid had wide dynamic range compression sound processing in 15 channels, a noise reduction algorithm based on the Speech Intelligibility Index (SII) optimization, adaptive directionality, and digital feedback cancellation as default features. The fitting range of the device was a maximum of 80 dB both in the low frequencies and in the high frequencies (see Fig. 3).

The amplification provided by the hearing aid was prescribed on the basis of the audiogram thresholds of the individual child. It was possible to choose between two different fitting algorithms: the manufacturer's proprietary fitting rationale or the Desired Sensation Level (DSL) 5.0 rationale. Half the infants were fitted using the manufacturer's proprietary fitting rationale, and half were fitted using the Desired Sensation Level (DSL) 5.0.

Data Collection

All of the families followed the same procedure for data collection. Each child/family made between 5 and 7 visits to the respective clinics. The visits included (1) an initial interview with the parents, (2) the first hearing aid fitting session, (3) follow-up sessions, and (4) the final session. The first follow-up occurred within a week of the first fitting session. The number of follow-up sessions was dependent on the age and needs of the individual infant. There was no limit for the maximum number of follow-up sessions, but a minimum of three follow-up visits were required prior to completing the study. It was recommended that two follow-up sessions per month were needed while the child was participating in the study. At each visit, the audiologists filled out questionnaires and case report forms on each child.

Questionnaires

Questionnaires for the Audiologists

Specific questionnaires had been developed for the first fitting session and follow-up sessions. The

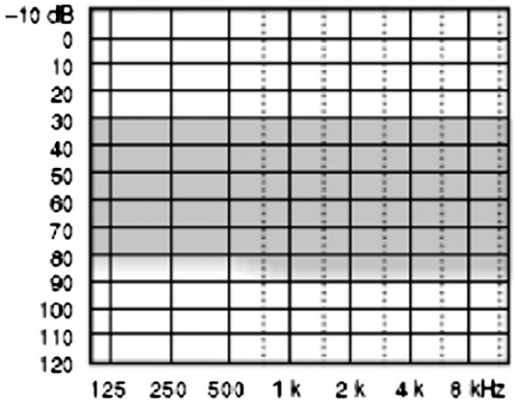

Figure 3. Fitting range for the study hearing aid.

questionnaires were tested internally, and the wording of some questions was adjusted wherever it was clear that the formulation was ambiguous or confusing. Additionally, audiologists and parents were informed that they could see the final follow-up results, to give them a baseline when making a new evaluation. The first fitting questionnaire contained 8 questions, and the follow-up questionnaire 17 questions. The follow-up questionnaire was divided into two sections: audiologists' impressions and parents' impressions. The parents' impression part was made in a survey form. The questionnaires covered the physical fit, stability, safety, and security of the RITE hearing aid. Responses were obtained using a category rating scale varying in steps from 0 to 10. In addition, five descriptors were positioned at 0, 2.5, 5, 7.5, and 10 to guide subject judgment. Comments were also encouraged when completing the questionnaires (see the questionnaire in Appendix A).

Case Report Form

All information obtained at every session regarding the hearing aids, technical problems, changing of components, size, and so on were stored in a case report on each child.

RESULTS

The study was conducted at two clinical sites. A Mann-Whitney *U*-test for independent samples was performed to examine if the distribution of ratings between the two sites and visits were the same across categories. A significantly statistical difference between sites ($p < 0.01$) and between visits (first and final follow-up) ($p < 0.001$) was observed. The results from each site are therefore presented separately. The general differences seen between the Swedish and the U.S. data were that most ratings from the Swedish data were already high at the first follow-up visit and ceiling effects were seen at the last follow-up, while in the U.S. data the ratings were evenly distributed between high categories (7–10) at both first and final follow-up visits. The ratings concerning the physical fit, safety, and security improved over time, and high ratings were seen at the last follow-up visit at both sites.

There were 25 questions in the questionnaire; however, only the nine questions relevant to the aim of this article will be presented and discussed.

Evaluation of the Physical Fit

The audiologists evaluated the physical fit of the ear-tips and hearing aids separately for the right and the left ears. As the individual ratings for the right and left ears were similar at both the first and last follow-up visits, the mean of the ratings for the right and left ears was reported instead. The median ratings for ear-tip at the first follow-up session were 8.5 (well) for the Swedish infants and 8 (well) for the American infants. The median ratings rose to 10 and 9 (very well) respectively at the final follow-up session. The clinicians' ratings of the physical fit of the ear-tips for each subject at the first and final follow-up sessions for the Swedish and the American infants are reported in Figure 4. The ratings were high at the first visit, and they increased at the final follow-up visit.

Although the ear-tip ratings were high, the ear-tips needed to be changed to custom earmolds in five of the infants (out of 16 infants). The reasons for changing to custom earmolds varied among the five subjects. The earmold of one infant (14 mo old) was changed to custom earmolds at the second follow-up session because the

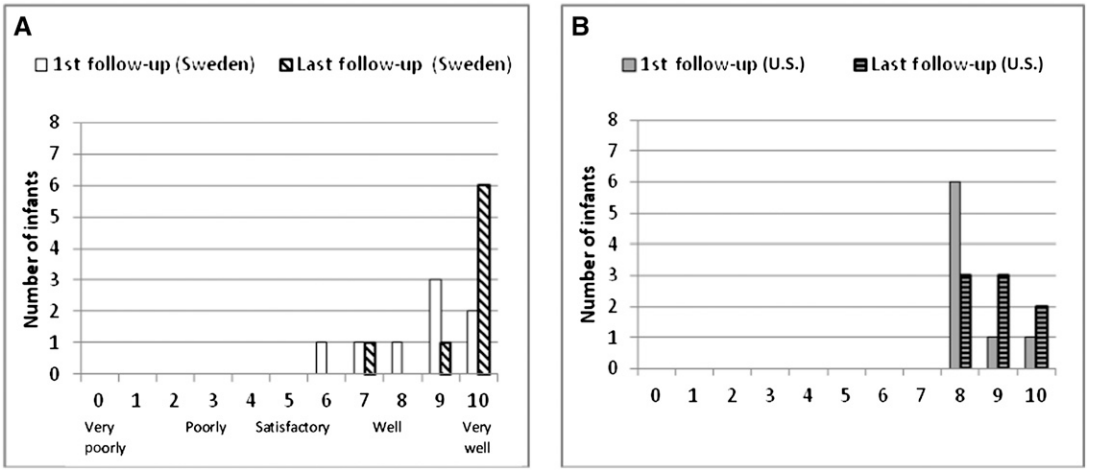

Figure 4. Frequency distribution of ratings for audiologists' evaluation of "How well do the ear-tips fit the infant's ears?" for the Swedish *(A)* and the American *(B)* infants. The graphics show the ratings for the first and final follow-up sessions. The category scale varied in steps from 0 to 10.

physical fit of the ear-tip was not optimal. (It was rated at 5.5 at the first follow-up, and the custom earmold was rated at 10 at the final follow-up.) The ear-tip was changed in another infant (23 mo old) at the second follow-up because the ear-tip slipped out of the ears, even though it was rated to provide a good physical fit (7). The final rating of the custom earmold was 10. The ear-tips of two infants (27 and 28 mo old) were changed due to the parents' or caregivers' difficulties in inserting the ear-tips. The ear-tips were also initially rated to provide a good physical fit (8 and 9, respectively, at first follow-up) for these children. When the ear-tips were subsequently changed for these children (at the third follow-up and at the final sessions, respectively), the final ratings of the custom earmolds were 9.5 and 7 for the instant ear-tip. Finally, the earmold of one infant (8 mo old) was changed to custom earmolds at the fourth follow-up session because of feedback problems. (The initial rating of the ear-tip was 8, and the final rating was 9 with custom earmolds.)

The audiologists' ratings on the physical fit of the hearing aid were also high, indicating that the physical fit was adequate for the majority of infants (see Fig. 5). The median score for hearing aids at the first follow-up was10 (very well) for the Swedish infants and 8 (well) for the American infants. At the final follow-up, the median ratings were 10 (very well) and 9 (very well) for the Swedish and American infants, respectively.

Retention Tools

The audiologists were asked to evaluate "the usefulness of the retention tools (adhesive tape and retention strap) in terms of making the parents feel more secure when they placed the hearing aids on their child's ears." The median ratings for the first and final follow-up sessions were 10 (very well) for the Swedish infants and 8 (well) for the American infants. Figure 6 shows the frequency distribution of the ratings. Note that there were two low ratings at the first follow-up sessions. These were attributed to the retention strap being too short to result in a pulling of the hearing aid from the ears. These two infants did not use the retention strap at all.

Stability, Safety, and Security of the Hearing Aids

Parents were also asked, "How often do the hearing aids move out of place when the infant walks or moves freely" in everyday situations? The median ratings for the first follow-up visit were 8.5 (rarely) for the Swedish infants and 7.5 (rarely) for the American infants at the first follow-up, and 10 (never) and 8.8 (almost never), respectively, at the final follow-up session. Figure 7 shows the frequency distribution of the ratings. The high ratings (8–10) obtained across sites indicate that the hearing aids were physically stable for all infants.

The parents also answered "How often does the infant try to remove the hearing aids at home?" The median ratings were 7.3 (rarely) for the Swedish infants and 6.8 (sometimes) for the American infants at the first follow-up session and 9.8 (never) and 6.7 (sometimes) for the American infants at the final visit. Figure 8 shows the histograms of the ratings for the Swedish and the American infants, respectively. The ratings improved over time with the Swedish infants. At the final follow-up the ratings varied between 9 and 10, indicating that the infants never removed the hearing aids. However, the same trend was not seen with the American infants. The initial and final ratings varied between 5 and 8 (sometimes and rarely). An improvement of the ratings was not seen at the final visit at the U.S. site.

Safety and security issues were rated by the parents. Figure 9 shows the frequency distribution of the ratings for the question "How often are there indications of irritations (redness, chafing) or pain after hearing aid use?"

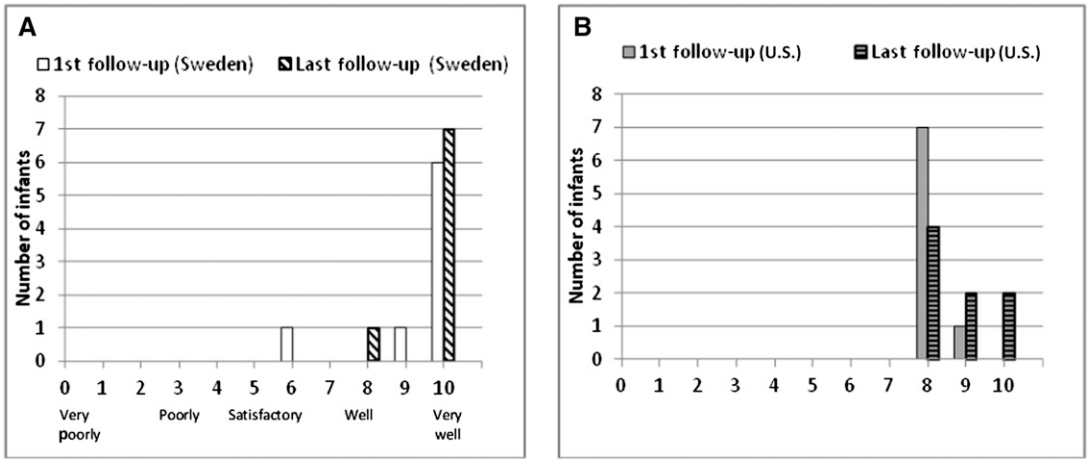

Figure 5. Frequency distribution of ratings for audiologists' evaluation of "How well do the hearing aids fit the infant's ears?" for the Swedish *(A)* and the American *(B)* infants at the first and final follow-up session.

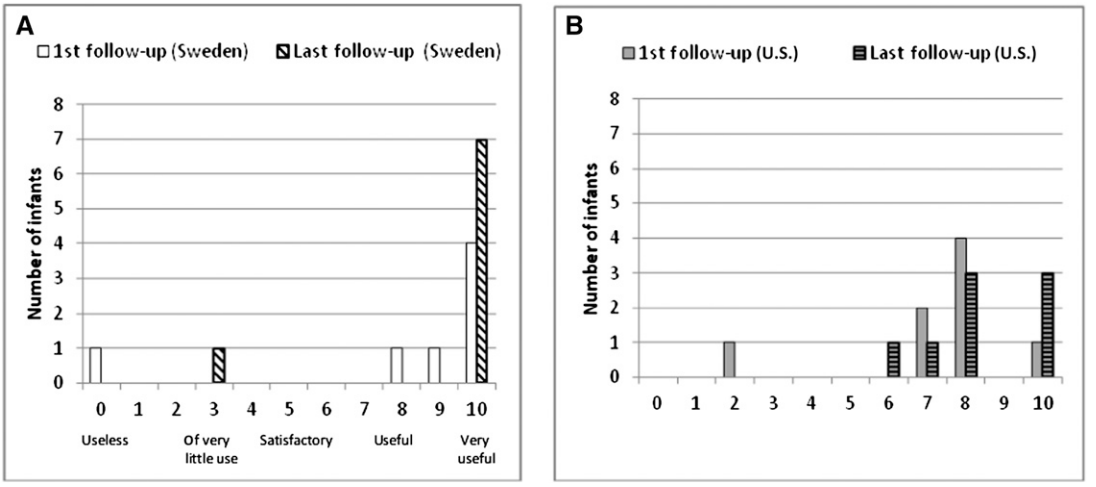

Figure 6. Frequency distribution of ratings for audiologists' evaluation of "How useful are the retention tools (adhesive tape, anchor and retention strap) in terms of making the parents feel more secure when they place the hearing aids on their child?" for the Swedish *(A)* and the American *(B)* infants at the first and final follow-up session.

The median ratings were 10 for both the Swedish and the American infants at the first and final sessions. This means that irritation or pain never occurred to any of the infants.

The ease of ear-tip separation from either the receiver or the hearing aid was also rated by parents during the study. The median ratings were 10 for both the first and final follow-up sessions for the Swedish infants. The median ratings for the American infants were 10 at first follow-up and 9 for the final follow-up, suggesting that this would be a very rare occurrence. The frequency distribution of these ratings is reported in Figure 10.

Audiologists' Impressions of Parents' Experiences

The audiologists rated the ease at which parents handled insertion of the hearing aids in the infants' ears. The median scores at the first follow-up were 9 (very easy) for the Swedish infants and 6.5 (satisfactory) for the American infants, and these increased to 10 and 8.5, respectively, at the final follow-up session. The frequency distribution is shown in Figure 11. It seems that Swedish parents did not have any difficulties handling the hearing aids, while some American parents had problems handling the hearing aids at the beginning of the study. However, the situation improved over time.[7] The handling of hearing aids was not considered a problem at the final session.

Parents' overall impressions of the hearing aids were also evaluated. The median rating was 8.8 (good) at the first follow-up, and this increased to 10 (very good) at the final follow-up session for the Swedish infants. The median rating for the American infants was 7.8 at first follow-up and 8.5 at final follow-up. The parents' overall impressions at final follow-up varied between "good" and "very good." Figure 12 shows the frequency distribution.

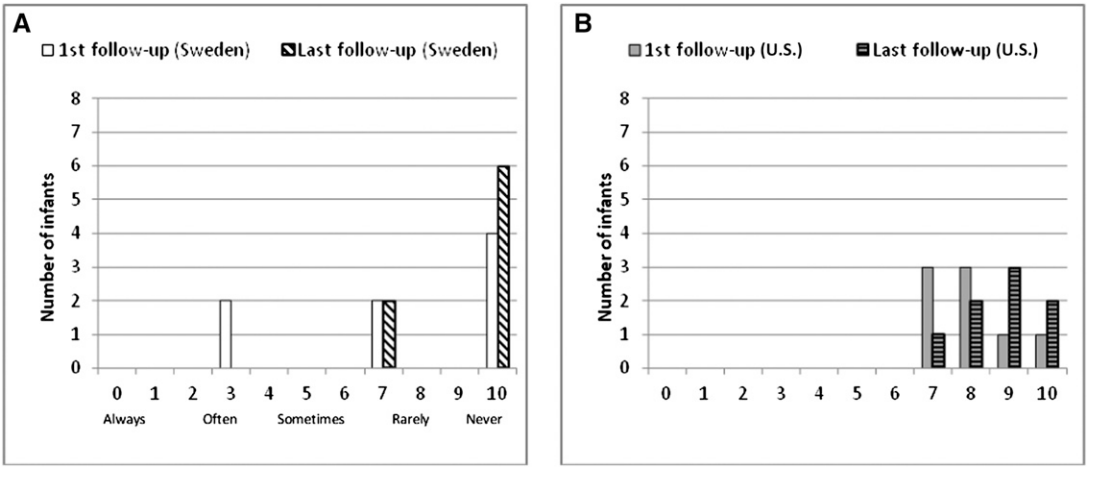

Figure 7. Frequency distribution of parents' evaluation of "How often do the hearing aids move out of place when the infant walks or moves freely?" for the Swedish *(A)* and the American *(B)* infants at the first and final follow-up session.

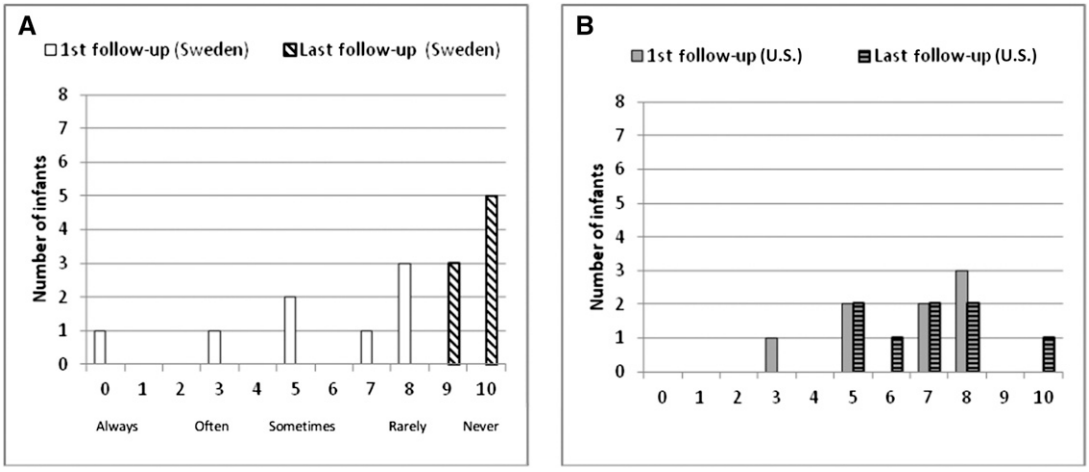

Figure 8. Frequency distribution of parents' evaluation of "How often does the infant try to remove the hearing aids at home?" for the Swedish *(A)* and the American *(B)* infants at the first and final follow-up session.

DISCUSSION

The results of this study showed that the physical fit, stability, safety, and security of the study RITE hearing aid (and earpiece) were evaluated positively by audiologists and parents at both sites. The high positive ratings were evident at the beginning of the fitting process, but they also improved over time to reflect increased ease of handling of the devices at both sites from the audiologists and the parents. The difference in the rating distribution between Swedish and American data was not expected, since the audiologists had the same support and training from the manufacturer during the study. The Swedish ratings were close to the ceiling (10) while the American data were more spread between categories 8 and 10.

RITE hearing aids have been commercially available for several years, and a large number of adults have been fitted successfully with this type of hearing aid (Hoen and Fabry, 2007; Lindley, 2008). However, up until now, RITE hearing aids that are exclusively dedicated to infants have neither been available nor advocated. The results obtained in the present study indicate that RITE hearing aids with the design features implemented can provide a good physical fit for infants.

Two observations can be made regarding the evaluation of the instant ear-tip. The ratings for the physical fit of the ear-tip were positive at the first visit and continued to improve during the study. At the same time, the number of ears with ear-tip problems decreased from the first to the final follow-up session. The increased experience of the audiologists in choosing the right size of ear-tips (and soft anchors) and in inserting them in the small ears contributed to the improved ratings obtained at the final session.

Although the ear-tip ratings were positive, the ear-tip did not fit well in five of the infants. The most typical problem was that the ear-tips slipped out of the baby's

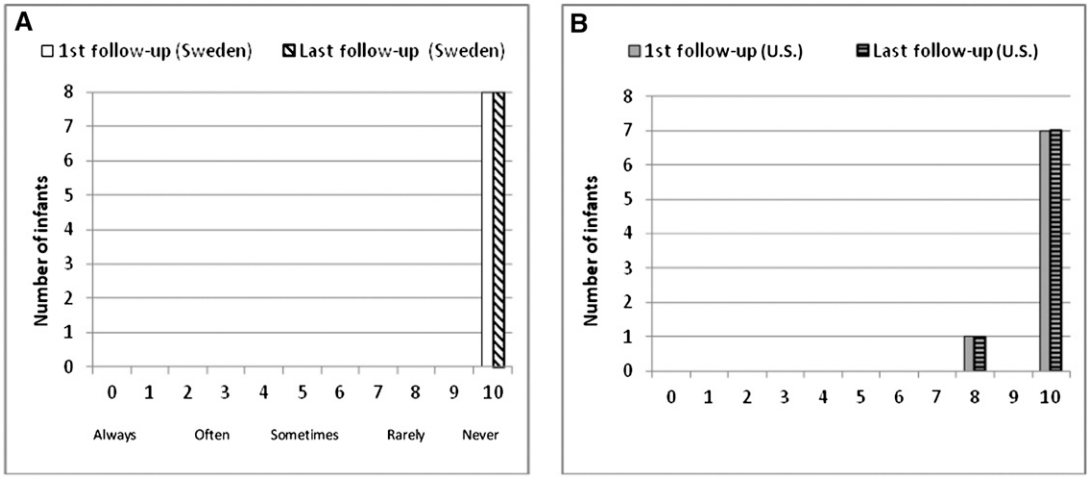

Figure 9. Frequency distribution of parents' evaluation of "How often are there indications of irritation (redness, chafing) or pain after hearing aid use?" for the Swedish *(A)* and the American *(B)* infants at the first and final follow-up session.

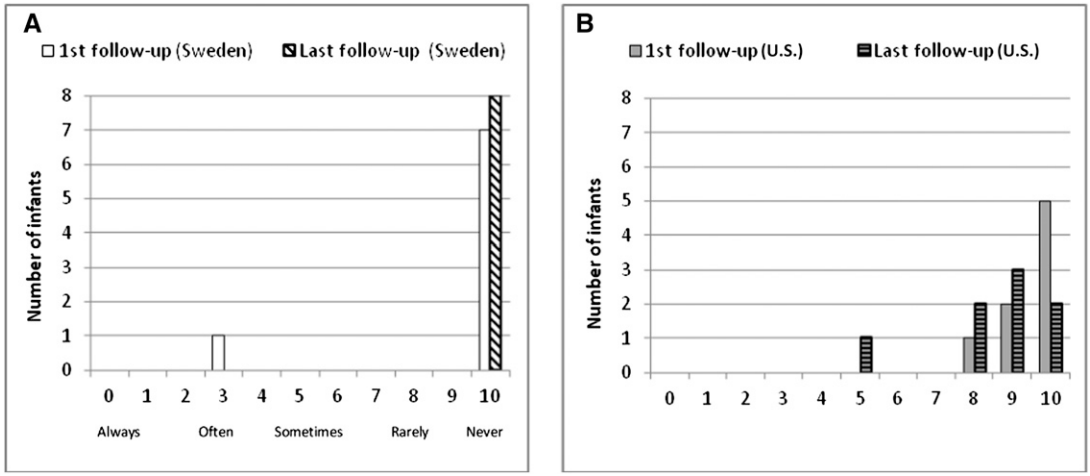

Figure 10. Frequency distribution of parents' evaluation of "How often does the ear-tip separate from either the wire or the hearing aid case?" for the Swedish *(A)* and the American *(B)* infants at the first and final follow-up session.

ears. Five of the 16 children had changed to custom earmolds by the final follow-up session. Four of them had done so to avoid the risk of the ear-tip slipping out of the ear. Only one child had changed to custom earmolds because of feedback problems.

Considering that no previous study has tested either instant ear-tip or RITE hearing aids in infants, the results obtained are very encouraging concerning the physical fit. Seventy percent of infants ended the study using instant ear-tips; however, it may also be necessary to use custom earmolds in order to provide an adequate physical fit of the hearing aids in a minority of cases.

Retention tools are often used when hearing aids are fitted to hearing-impaired infants. Parents are generally afraid to lose the hearing aids (Sjoblad et al, 2001; Martin et al, 2005; Moeller et al, 2009). Several tools are available to help parents keep their baby's hearing aids in place (Australian Hearing, 2008), but they are not integrated into the hearing aids. The integrated retention strap used in this study helped stop parents from worrying about losing the hearing aids, especially during the first months of the hearing aid use.

An interesting finding of the study is that even though the retention tools were evaluated as being useful for the majority of parents (15 of 16) at the final follow-up session, the parents of only nine infants reported that they continued to use the strap at the end of the study. The remaining six parents did not feel the need to use the retention tools any longer. One possible reason for this is that the hearing aids were stable in the ears; the infants were no longer trying to remove them, and so the parents were not afraid of losing the hearing aids.

These findings on the stability and safety of the hearing aids seem to agree with the favorable evaluations by the audiologists to the physical fit of the hearing aids.

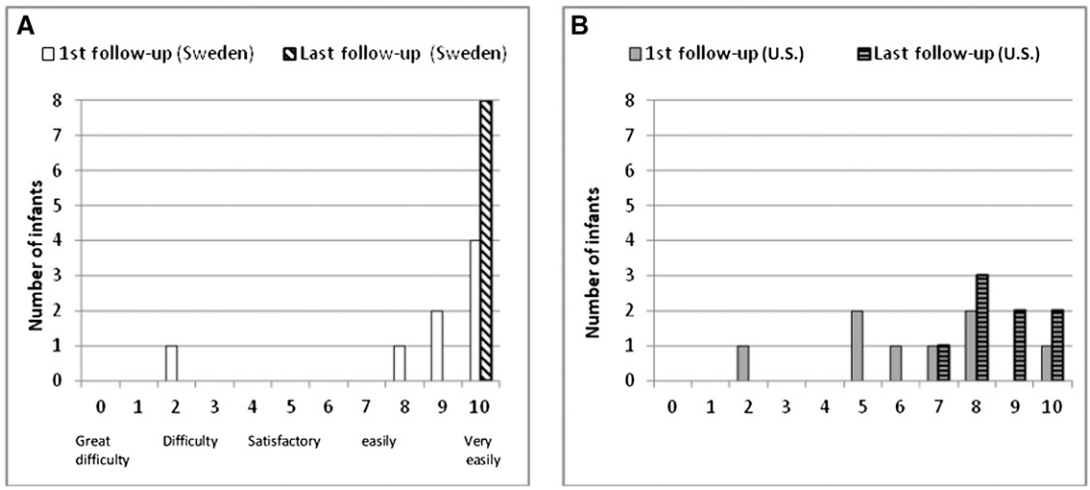

Figure 11. Frequency distribution of audiologists' evaluation of "How easily are the parents able to handle the hearing aids and insert them into the child's ears?" for the Swedish *(A)* and the American *(B)* infants at the first and final follow-up session.

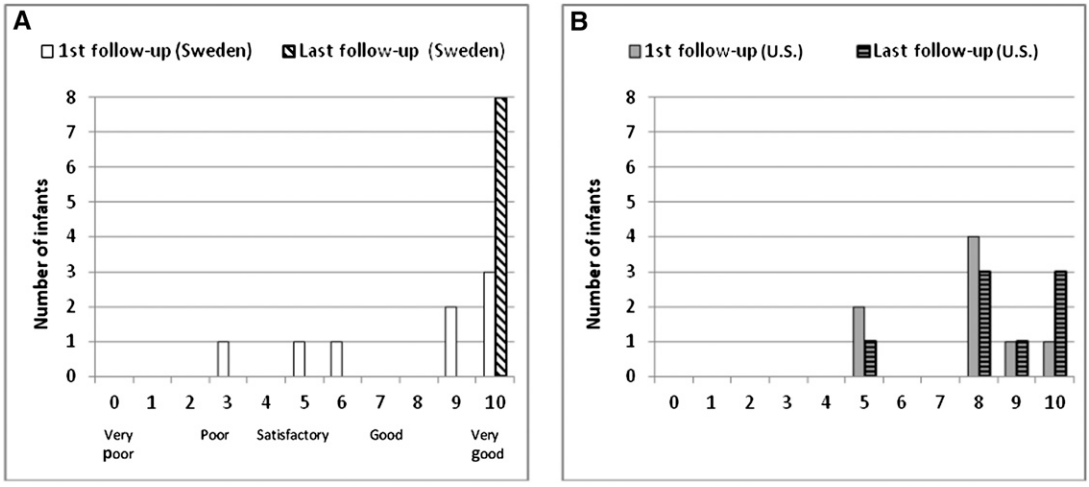

Figure 12. Frequency distribution of parents' evaluation of "Parents' overall impression of the hearing aid experience since the previous visit?" for the Swedish *(A)* and the American *(B)* infants at the first and final follow-up session.

The small size and light weight of the hearing aid might have contributed to its good physical fit because the hearing aids did not move out of the ears even when the infants were playing at home or outside. The same positive evaluation was seen toward the frequency of removal of the hearing aids. Even though the evaluation was positive at the first visit, the ratings concerning physical stability and removal of hearing aids improved over time. The fact that the majority of infants did not try to remove their hearing aids indicates that the aids sat in the infants' ears comfortably. One may speculate that the low frequency of removal of hearing aids was because most of the infants had previously been fitted with other hearing aids prior to this study. It may be impossible to verify this hypothesis, as the study did not investigate the removal of hearing aids before the fitting of RITE hearing aids. However, the ratings concerning the removal of hearing aids for the Swedish infants changed over time. By the end of the study, parents reported that the infants almost never removed their hearing aids. Another factor that may have contributed to the changes observed in the physical stability and removal of the hearing aids is that, with time, the audiologists became more experienced in choosing the right components (ear-tip, anchor, and earwire size), and the parents learned how to place the hearing aids more correctly in the ears. This could potentially contribute to a consistent use of hearing aids in this age group. In fact, most parents reported at the follow-up visits that the infants were using the hearing aids during all waking hours and rarely removed them. However, no hearing aid data logging was accessed to confirm the parents' reports.

Moreover, one of the major concerns regarding RITE hearing aids for infants is the safety issue relating to the detachment of an ear-tip from either the receiver or the hearing aid in everyday situations. If a child tries to remove the hearing aid, the earwire could potentially be pulled off the ear-tip or hearing aid. However, the findings of this study indicated that this was not a concern. There was no indication that the ear-tip separated from the receiver housing during hearing aid removal. It should be noted that the strength of the earwire was especially reinforced in this hearing aid compared to the strength of earwires used in conventional RITE hearing aids.

The parents' handling of the hearing aids and their overall impression of the hearing aids also revealed a positive impression of the RITE hearing aids for infants. It should be noted that some parents reported difficulties handling the hearing aids at the first session, due to the small size of the hearing aids and the softness of the ear-tip. These difficulties disappeared over time. By the end of the study, all the parents reported that it was easy to handle the hearing aids and decided to keep the study hearing aids. The same trend was observed in the parents' overall impressions of the hearing aids. The median rating increased from the first to the final follow-up session, when it was close to the scale's maximum value. The difference in ratings between the first and the final follow-up sessions reflects the learning process that parents underwent during the study. This result underlines the need to provide parents with training and support. Other studies such as Martin et al (2005) have reported that the parents' greatest concerns are their children's acceptance of the hearing aids and their fear of losing or breaking the hearing aids. Furthermore, Sjoblad et al (2001) reported that in the early stages of hearing aid use, parents are concerned about the device's appearance and how to maintain it. It seems that the training and support provided to the parents during the study helped them to feel more confident in dealing with the hearing aids, and this is also reflected in the high ratings given at the final follow-up session.

Only two infants had not used hearing aids prior to the study, but the impressions reported by the study audiologists and the children's parents followed the same patterns as the other infants'. The initial ratings of the physical fit, safety, and security of the hearing aids were high (7–9), and they also increased at the final session.

Experience Needed

The results obtained in this study indicate that obtaining a successful fitting of RITE hearing aids in infants demands both training and support for the audiologists in two areas: (1) the physical fit, for example, choosing the correct sizes of the earpiece part and earwire; and (2) learning earpiece insertion in small infant ears, because the earpiece (i.e., ear-tip and soft anchor) is very soft. The increased ratings observed in the physical fit of ear-tips and hearing aids in the last sessions must reflect the experience achieved by the clinicians in choosing the correct sizes. The same can be concluded about the parents' experience. The use of RITE hearing aids also requires training of the parents, during fitting in the first visits, on how to insert the ear-tips in the small ears. The support and training provided to the parents by the audiologists seems to have contributed to the positive results concerning the evaluation of the RITE hearing aids for the infants in terms of physical fit.

CONCLUSION

The results of the present study indicate that appropriately designed RITE hearing aids provide an adequate physical fit for infants. The main goal is to ensure acceptance of the hearing aids and to avoid the devices being pulled off the ears by the infants.

The general trend in the data is that both audiologists' and parents' ratings of the device improved from the first to the final follow-up session. These findings indicate that RITE solutions and instant ear-tips can provide an adequate physical fit and a safe, stable, and secure fit suitable for infants and children.

The use of RITE hearing aids makes certain demands on the part of the audiologists with respect to knowledge on how to select the right sizes of the components, mount the device, and fit the hearing aid to the child. Careful instruction of audiologists and parents with regard to handling the hearing aid components is essential for a successful outcome.

Acknowledgments. The authors of this paper wish to thank the parents and their children in Sweden and the United States for their valuable time and feedback during this study. Also we would like to thank the two audiological clinics in Stockholm and New York for their participation in and commitment to the study.

NOTES

1. The term *infant* as used in this article refers to a child between 0 and 3 yr of age (*Merriam-Webster* (www.m-w.com), s.v. "infant.") The age between birth and 3 yr of age comprises a diverse range of developmental milestones, both physical and cognitive. It was, however, decided to use the term *infants* in this article because it can accommodate the target group (2–36 mo) for which the study RITE hearing aids were developed.
2. When this article refers to *stability,* it means the hearing aid is physically stable or fits snugly on the child's ear. *Safety* means the hearing aid is not harmful to the child, and *security* means the hearing aid does not fall apart.
3. The degree of hearing loss was defined by the pure-tone average at 500, 1000, and 2000 Hz for each ear separately.
4. The standard earwire of an ordinary RITE hearing aid can withstand a pull force of 10 N. The reinforced earwire in the "designed" RITE hearing aid can withstand a pull force of 50 N. The standard plug connection of an ordinary RITE hearing aid can withstand a pull force of 7 N. The reinforced plug connection of the "designed" hearing aid can withstand a pull force of 15 N.
5. The ear-tip and earmold materials were hypoallergenic and were approved according to ISO 10993-5:1999, Biological evaluation of medical services Part 5: Tests for in vitro cytotoxicity.
6. ISO 10993-1:2003, Biological evaluation of medical devices Part 1: Evaluation and testing. The following biological risks were evaluated: cytotoxicity, irritation, and sensitization.
7. Note that the follow-up period (i.e., the time from the first to the final follow-up session) varied from child to child but typically was between 2 and 5 mo.

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Appendix A. Audiologist's Questionnaire

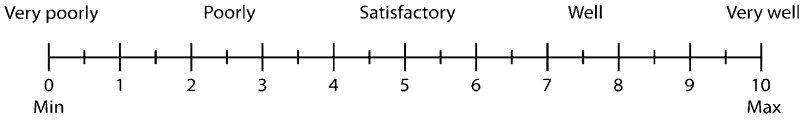
Instructions

The questions in this questionnaire are presented in categories. You have to assign numbers between 0 and 10 to reflect your judgment. Zero (0) corresponds to the worst judgment, while 10 corresponds to the best judgment. You should mark the number that best represents your judgment for the specific question. Use O for the right ear and X for the left ear in questions 1.1, 1.2, 1.3, 1.4, 2.10, and 2.11.

1. FIRST FITTING SESSION

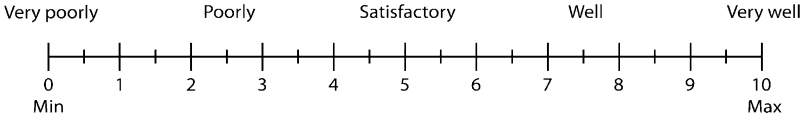
Physical Fit

1.1 How well do the ear-tips fit in the infant's ears? (**please mark O for right ear and X for left ear**)



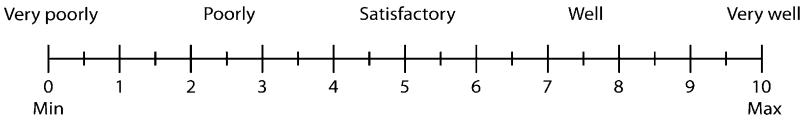
Comments:

1.2 How well do the wires fit on the infant's ears? (**please mark O for right ear and X for left ear**)



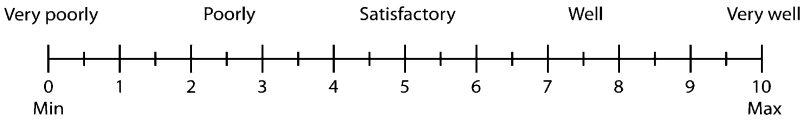
Comments:

1.3 How well does the anchor fit on the infant's ears? (**please mark O for right ear and X for left ear**)



Comments:

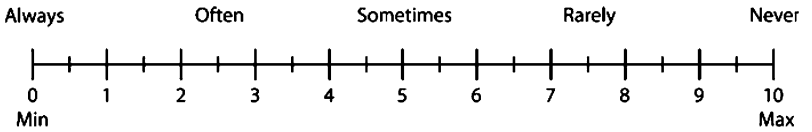
1.4 How well does the retention strap fit on the infant? (**please mark O for right ear and X for left ear**)



Comments:

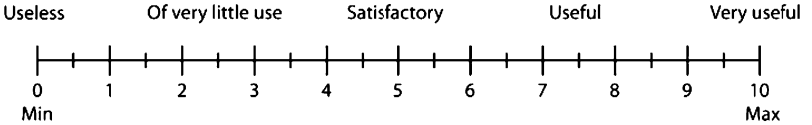
Safety and Security

1.5 How often does the infant try to remove the hearing aids during the fitting session?



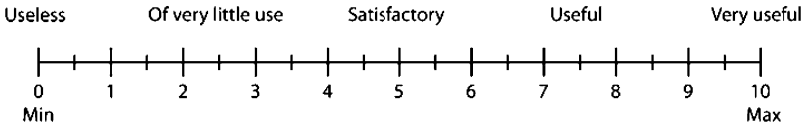
Comments:

1.6 How useful is the adhesive tape and anchor in terms of stability to the hearing aids when placed on the infant's ears?



Comments:

1.7 How useful is the retention strap in preventing the infant from putting the hearing aids in his/her mouth?



Comments:

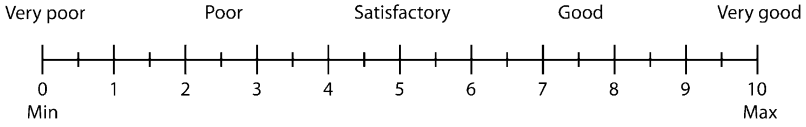
1.8 Additional comments:

2. FOLLOW-UP SESSIONS

PARENTS' IMPRESSION

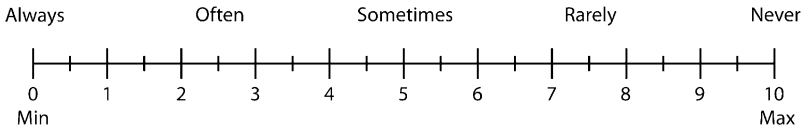
General

2.1 Which describes the parents' overall impression of the hearing aid experience since the previous visit?

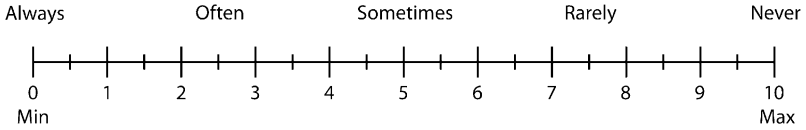


Physical Fit

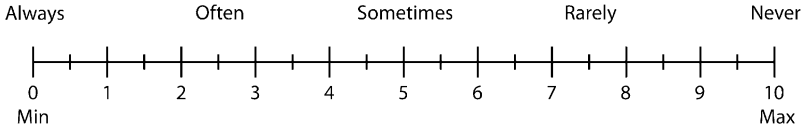
2.2 How often does the infant try to remove the hearing aids at home?



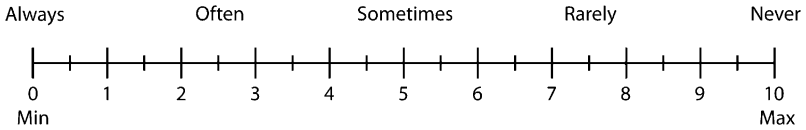
2.3 How often do the hearing aids move out of place when the infant walks or moves freely?



2.4 How often are there indications of irritations (redness, chafing) or pain after hearing aid use?

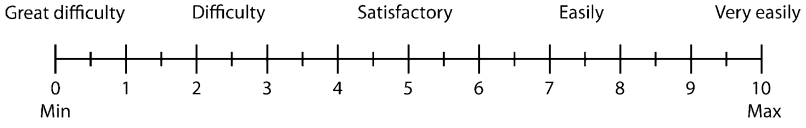


2.5 How often does the ear-tip separate from either the wire or the hearing aid case?

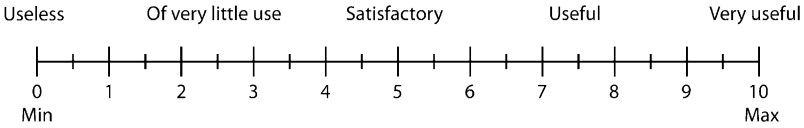


Safety and Security

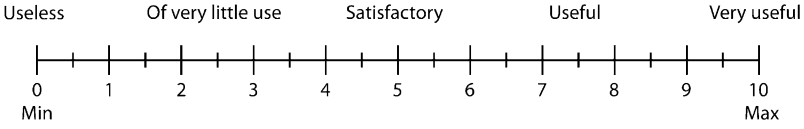
2.6 How easily are the parents able to handle the hearing aids and insert them into the child's ears?



2.7 Overall, how useful are the retention tools (adhesive tape, anchor, and retention strap) in terms of making the parents feel more secure when they place the hearing aids on their child?



2.8 How useful is the LED (light emitting diode) in terms of helping parents to be sure that the hearing aid is turned on?

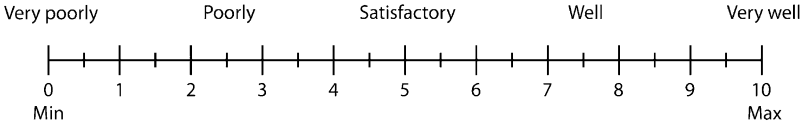


2.9 Additional comments:

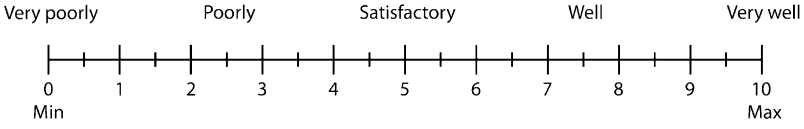
AUDIOLOGIST'S IMPRESSION

Physical Fit

2.10 How well do the hearing aids fit in the infant's ears? (**please mark O for right ear and X for left ear**)



2.11 How well do the ear-tips fit in the infant's ears? (**please mark O for right ear and X for left ear**)



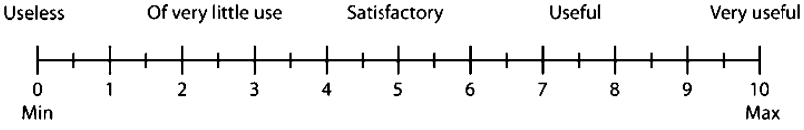
Audiologist's Summary—Physical Fit

2.12 Are any problems observed concerning the physical fit of the devices?
☐ Yes
☐ No
2.12.1 If Yes, please explain:

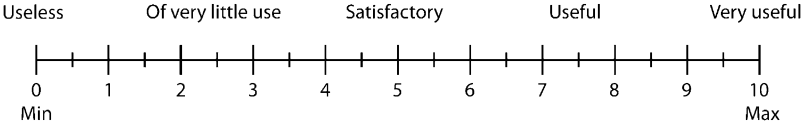
2.13 Additional comments:

Safety and Security

2.14 How useful are the adhesive tape and anchor in terms of stability to the hearing aids when placed on the infant's ears?



2.15 How useful is the retention strap in preventing the infant from putting the hearing aids in his/her mouth?



Audiologist's Summary—Safety and Security

2.16 Are any problems observed concerning retention, safety, or the security system for the devices?
☐ Yes
☐ No
2.16.1 If Yes, please explain:

2.17. Additional comments