

### Critical Review:

What are the objective and subjective benefits provided by the BAHA hearing system in children with unilateral hearing loss.

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A historical perspective among physicians, educators, and many audiologists has been that children with unilateral hearing loss (UHL) generally experience few, if any, communicative or psycho educational difficulties. However, recent research yields a contemporary review of UHL which suggests that children with UHL are at risk for a variety of communicative, educational and psychosocial problems (Porter & Bess, 2011). Despite these findings, the management strategy for these children remains relatively incomprehensive. Outcomes associated with various types of amplification for children with UHL are undefined and merit future study (Mackay 2008). Specifically, efficacy research on BAHA(s) has suggested benefit for adults with UHL, but has not been done on children. As a starting point for future research and current practice, my research question looks at the existing literature and asks: What are the objective and subjective outcomes of fitting a bone anchored hearing aid to children with unilateral hearing impairment?

### *Introduction*

In the past, unilateral hearing loss (UHL) was not thought to have any significant consequences on the development of a child. This is because it was presumed speech and language developed appropriately with one normal hearing ear. However, recent research indicates that children with UHL are at higher risk for academic, speech-language, and social-emotional difficulties than their normal hearing peers (Porter & Bess, 2011). This suggests that intervention is advisable for children with UHL; however the management strategy for these children remains relatively incomprehensive.

FM systems and preferential seating are often recommended for children with UHL to improve listening conditions in classroom situations, but do not address listening difficulties in all environments. While efficacy research on BAHA(s) has suggested benefit for adults with UHL, a lot of uncertainty exists around this option for children.

This critical review examines the objective and subjective benefit that a BAHA may provide to children with unilateral hearing loss.

### *Objectives*

The primary objective of this paper is to critically review the existing literature regarding the objective and subjective benefit provided by the BAHA hearing system in children with unilateral hearing loss.

### *Methods*

#### Search Strategy

Computerized databases including CINAHL, Scopus, PubMed and Google Scholar were searched using the following search strategy:

- (BAHA) OR (bone anchored hearing aid) AND (children) OR (pediatric)
- (BAHA) OR (bone anchored hearing aid) AND (children) OR (pediatric) AND (unilateral hearing loss)

No limitations were applied to this search strategy.

#### Selection Criteria

Studies selected for inclusion in this critical review paper were required to investigate the effect that fitting a BAHA had on the auditory abilities and quality of life among children with unilateral hearing loss. Children were defined as individuals under 18 years of age.

#### Data Collection

This literature search resulted in the following types of articles in line with the above mentioned selection criteria: two within-group repeated measure designs and two retrospective questionnaire studies.

### *Results*

#### Objective Outcomes

Kunst et al. (2007) used a within group repeated measure design to study the audiological outcome of BAHA application in patients with congenital unilateral conductive hearing impairment. The experimental group comprised 20 patients, including adults and children, with a mean air-bone gap of 50 dB. For the purposes of

this paper, strictly the results from the 10 pediatric patients, varying from age 6-14 years, will be reviewed and discussed.

Sound localization was tested in the horizontal plane using 5 loudspeakers placed at 60 degree intervals. Stimuli consisted of 1-second short bursts of one-third octave filtered white noise with either a 500 or a 3000 Hz centre frequency. Per presentation, the difference in azimuth was measured between the position of the loudspeaker that provided the sound and the position of the loudspeaker indicated by the patient. The outcome measure was the mean absolute difference in azimuth (MAE) per measurement condition (500 and 3000 Hz, unaided and aided). A change in MAE was considered significant if it was greater than 27 and 34 degrees in the 500 and 3000 Hz conditions, respectively. Results showed wide variability in performance across listeners. In the 500 Hz measurement, 3 children showed a significant improvement in MAE, while 2 children showed significant deterioration. In the 3000 Hz measurement, two children showed significant improvement, and significant deterioration was not observed.

A second outcome, speech perception in noise, was measured by presenting standard Dutch word list of 11 words from the front speaker at an average level of 60 dB SPL, and speech shaped noise simultaneously on the side of the normal ear at 65 dB SPL creating a fixed - 5 dB Signal-to-noise ratio. Difference between unaided and aided phoneme scores were measured. A significant improvement was noted for five of eight children for whom complete data sets were available. Overall, results indicated the BAHA led to 23% more of the phonemes being repeated correctly. However, it is not known if the results were significant for the entire group because unaided speech recognition scores were not available for two of the 10 children.

The relation between test outcomes and BAHA use was studied. The Spearman rank correlation coefficient was 0.55 ( $p = 0.02$ ), indicating a positive correlation between BAHA use and outcomes. The authors note that compliance with BAHA use in this patient group was remarkably high, which is suggestive of patient benefit.

Taken together, the results suggest BAHA application to patients with congenital unilateral hearing loss provides limited benefit in sound localization, but does provide benefit in speech recognition in noisy environments. It was found that when noise was presented on the same side of the BAHA, the performance of most subjects was not negatively affected. This may help diminish the

concern that patients experience interference caused by amplification of the noise when presented on the same side of the BAHA. The authors suggest that patient satisfaction with BAHA use for unilateral hearing impairment may relate to perceptual factors such as loudness growth effects, which were not tested and warrant further study.

Extensive details of patient inclusion and exclusion criteria was lacking in this study. However, the study adequately described the participant population regarding characteristics such as gender, age, pure-tone and bone conduction thresholds, time elapsed since implantation, and hours of BAHA use per day and week. The patients included in the study all have congenital unilateral aural atresia, which may limit the applicability of the results to individuals with other types of conductive hearing loss. The procedures used for surgery and fitting of the Bahas were not reported, as well as the specific device that was fit. The lack of detail regarding the methods make it difficult to reasonably replicate them if required.

The chosen outcome measures are known to be reliable and are commonly used in audiological practice when quantifying sound localization and speech discrimination performance. Since standard Dutch word lists were used instead of sentences results were reflective of hearing and not language competence, thereby eliminating this as a confounding variable. Considering the small sample size, the data were appropriately reported using group mean values, and significant differences were quantified using test-retest data to determine 95% confidence intervals, necessary for significance at the  $p < 0.05$  level. However, due to the small number of participants it is difficult to determine any definitive trends in performance. Overall, the level of evidence provided by this study is suggestive due to the use of valid outcome assessments to measure benefit, data analyses, and carefully controlled experimental manipulations.

Saliba et al. (2010) performed a prospective longitudinal study to assess audiometric and clinical results of children fitted with BAHA with specific emphasis on speech discrimination in different sound environments after one year of use. Of the 17 patients included, ranging in age from 5 to 18 years old, 14 had unilateral conductive hearing loss and 3 had bilateral conductive hearing loss. Tonal and vocal evaluations were performed pre-operatively, the day of processor insertion, six months and 12 months after processor insertion. Tonal evaluation consisted of measuring sound reception thresholds at 500, 1000, 2000 and 4000 Hz. Results indicated BAHA gain is clinically significant at all frequencies and time intervals. A

significant increase in gain was found between the day of insertion and the pre-operative condition. No significant gain was found between post-insertion BAHA gains at 1 day, 6 months and 12 months. These results suggest a significant improvement of hearing thresholds once the BAHA is inserted, and that this improvement is maintained at least one year post-device insertion. Hearing thresholds were measured with the better ear plugged, and may not accurately reflect benefits of the BAHA when worn in “real-life” situations.

Vocal evaluation was performed using 4 modalities: voice from the impaired hearing side in a silent room (VS), voice facing the patient in a silent room (VF), voice from the impaired hearing side with noise facing the patient (VS/NF), and voice facing the patient with noise from the impaired hearing side (VF/NS). A fixed SNR of 5 dB was created by presenting noise at 57 dB SPL and speech at 63 dB SPL.

All results were significantly better with the BAHA device, with the most significant improvement in situations where the voice was directed toward the BAHA with confounding noise facing the patient. The poorest thresholds occurred when speech and noise sources were in the same location, and lowest (best) thresholds were noted when the speech and noise were separated 90 degrees. Moreover, an improvement in speech discrimination was observed over time. While the average BAHA gain in pre-operative and day 1 are relatively low, this value doubles at 6 months and remains approximately stable at 12 months. This clinically significant finding falls short of statistical significance due to a small sample size.

The outcome of this study suggests that pure-tone average improves after BAHA insertion, and remains steady for at least one year post-insertion. As well, speech discrimination gain improves significantly within the first year of BAHA installation.

The terms tonal evaluation and vocal evaluation are not commonly reported nomenclature in audiology practice. Rather, they are more consistently referred to as tests of audibility and speech recognition, respectively. Moreover, key details regarding these evaluations were not provided. Specifically, the authors did not indicate the type of speech sample used in the vocal evaluations i.e sentences, words or phoneme list. Sentences can influence results to be more dependent on language competence than hearing, whereas words that are considered too easy can potentially overestimate speech recognition ability. Consequently, the results may be potentially confounded by type of speech sample that was chosen.

The small sample size used in this study makes it difficult to make broad generalizations. In addition, extensive details of patient inclusion and exclusion criteria was lacking in this study. The authors failed to provide adequate participant description such as cognitive ability and speech and language abilities. It is uncertain whether subjects were similar at baseline regarding these important indicators, thereby confounding interpretation of the results. Also, the authors did not segregate the data for children with UHL and BHL which may have also confounded the results.

Due to the insufficient description of the methods and criteria for participant inclusion and exclusion, replication of this study would be difficult. The lack of validated measures, small sample size, and confounding variables makes the validity and reliability of this study difficult to accept. Given the limitations of this study, the overall evidence is equivocal.

### Subjective Outcomes

Kunst et al. (2008) conducted a prospective evaluation to assess the subjective hearing benefit of a unilateral BAHA in patients with congenital unilateral conductive hearing impairment. For the purposes of this paper, strictly the results of the patients under 18 years old (10 of the 20 patients included) will be reviewed. Patients and their parents/care providers were asked to complete the Glasgow Children’s Benefit Inventory (GCBI). The instrument covers 4 domains: emotional benefit, physical health, improvements in learning ability, and vitality. A summary score on the GCBI was calculated to produce a score on a scale from – 100 (maximum deterioration) to + 100 (maximum improvement). The GCBI demonstrated a subjective overall benefit of +34. Studied per domain, learning revealed most positive change, with a mean score of +60. The emotional, physical, and vitality domains scored +31, +29, +12, respectively.

A second questionnaire, the Speech, Spatial, and Qualities of hearing scale (SSQ) was used to assess benefit in spatial hearing and speech perception. Children completed the recently developed children’s version of the SSQ under the supervision of an adult. Patients were asked to rate themselves on each item with a score out of 10, higher scores reflect greater ability. The questionnaire contained 3 aspects of hearing: speech perception, spatial hearing, and quality of hearing. Mean scores on the domains were 6.1, 5.6, and 7.1, respectively, with a total mean score of 6.6.

Unlike the GCBI, the SSQ is not a retrospective questionnaire. As such, the scores reflect the subject's view of their present abilities. Since a pre-BAHA SSQ score was not measured, it is hard to determine whether the participant's ability score is reflective of experience with the BAHA. Due to the lack of any baseline measurement, it is uncertain whether any treatment effect represents a significant change from pre-treatment abilities. Furthermore, the SSQ is not a validated questionnaire and no reference data exists on the literature on the new children's version of the SSQ questionnaire. This makes the validity and reliability of the results on the SSQ difficult to accept.

To avoid enthusiasm bias, it was required that patients be fitted with the BAHA for at least 6 months before filling out questionnaires. However, the actual time elapsed since implantation beyond 6 months was not indicated for each patient. Thus the time since BAHA fitting may have been a variable that distorted the findings. Similarly, although duration of BAHA use was reported for each participant, a statistical analysis of the correlation between use and reported satisfaction was not conducted. Consequently, duration of device use may also be a nuisance variable that distorted the results.

The study's participant eligibility and inclusion criteria were not included in the article. However, participant information age at implantation and duration of BAHA use were reported for each subject. Although 11 children were included in the study, results from only 10 participants were reported. An explanation for the exclusion of this participant was not provided. Given the inherent limitations of this study including use of a non-validated outcome measure, nuisance variables, lack of participant inclusion and exclusion criteria, the overall evidence of this study is equivocal. The results of this study should be cautiously interpreted and inferences about causality should be limited.

Wolf et al. (2011) conducted a retrospective questionnaire study to simultaneously assess the disability, handicap, benefit, and QOL of BAHA users. Three validated questionnaires were used: 1) the GCBI (2) the Abbreviated Profile of Hearing Aid Benefit (APHAB) (3) the Health Utilities Index Mark 3 (HUI-3). The inclusion criteria were a minimum age of 4 years at BAHA fitting and 1 to 4 years of BAHA use. The patient population was divided into 2 groups, those with BHL and those with UHL. For the purposes of this paper, only the results of the UHL group will be reviewed. The UHL group consisted of 15 children, all of whom had normal cognition and a congenital origin of their unilateral hearing loss.

A daily device use questionnaire was designed for this study to evaluate BAHA use in daily situations. Results indicated 7 children (47%) were using their BAHA devices for more than 8 hours a day, and 6 children (40%) were using them for 4 to 8 hours a day. The BAHA was considered to be either worth the effort or very worth the effort by 10 children (67%).

Scores on the GCBI were highest on the learning subdomain. The authors suggest this indicates that in children with a unilateral air-bone gap, the BAHA is particularly beneficial in educational settings. This finding is similar to that found by Kunst et al. (2008). Three of the 15 children in the UHL group had a negative score on one of the subdomains. The authors state these results emphasize the importance of performing a trial with a headband to predict which children will benefit most from a BAHA in different listening conditions. The APHAB was completed twice by study participants, one based on the current situation with the BAHA and the second based on the previous situation without the BAHA. According to the APHAB assessment made with the criteria defined by Cox, only 4 children in the UHL group (42.7%) derived significant overall benefit from the BAHA. Scores were lower in the ease of communication (EC) subdomain, than compared to reverberation (RV) and background noise (BN) subdomains. Based on the results of the APHAB, the authors reiterate the importance of children with UHL to undergo a training period with the BAHA to determine whether it will provide optimal treatment.

The HUI-3 is a preference-based instrument used to measure general health-related quality of life. The disability scale on the HUI-3 categorized patients as having no disability (13%), mild disability (20%), moderate disability (53.3%), or severe disability (13%).

The outcomes of this study suggest the subjective benefit for children with BAHA varies from child to child and varies for domains and settings assessed. Consequently, it is recommended in children with UHL, the decision to use a BAHA should be made on a trial by trial basis.

The study's participant eligibility and inclusion criteria were not included in the article. However, participant information age at implantation and duration of BAHA use were reported for each subject. The response rate to questionnaires was 82% (31 of 38 children). This value represents the dropout rate for the entire study, but does not specify the number of dropouts for each specific subgroup i.e. BHL and UHL. Consequently, the dropout rate for the UHL group may be significantly higher than 82%.

To complete the retrospective questionnaires, parents and children had to recall their situation previous to having the BAHA fitted, which was as long as 4 years ago. This may have compromised the reliability of the results as it may have been difficult for parents to sufficiently recall this information. Responses from HUI-3 indicate a patient's view of their present disability status. Since pre-treatment disability was not measured, it is hard to determine whether the participant's ability score is reflective of experience with the BAHA. Due to the lack of any baseline measurement, it is uncertain whether any treatment effect represents a significant change from pre-treatment abilities. Overall, the evidence of this study is equivocal.

### *Conclusion*

From this limited body of evidence concerning the objective and subjective outcomes of fitting a BAHA to children with unilateral hearing loss, it appears that the results are inconsistent. Unfortunately, the small number of studies, small sample sizes, and lack of validated measures makes it difficult to draw definite conclusions about whether or not BAHA will benefit all children with unilateral hearing loss. Measured objective benefit in terms of localization and speech recognition ability was highly variable between subjects. Similarly, perceived subjective benefit was also highly variable between subjects and across different domains. Nevertheless, many BAHA users preferred to use the device regularly. This suggests that the outcome measures used in experimentally controlled situations in these studies may not be sensitive enough to reveal improvements with the BAHA that patients may realize in real-world settings. There may be several reasons for this, and further research is required to determine which factors best predict benefit with BAHA for children with UHL. Moreover, it should be noted that evidence does not yet exist to classify which children with UHL will experience difficulties, and consequently which children will benefit from amplification. In the interim, it is recommended decisions be made on a child-by-child basis. The use of Baha Softband during a trial period may provide some indication of expected benefit. In this way, patients and their families could determine the potential benefits before making a decision to undergo surgery.

### *Clinical Implications*

The articles examined in this review have given some insight into the possible benefits a BAHA device may provide children with unilateral hearing loss, but provide an inadequate degree of evidence to make

conclusive recommendations that each child with this hearing profile should be prescribed a BAHA. Therefore, audiologists should consider a paradigm shift in considering treatment options for children with unilateral hearing loss. Instead of determining success of the BAHA with this population as a whole, an individual-centered approach focusing on personal history and communication needs may be more effective for concluding the appropriateness of the BAHA for individual patients.

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