

# Audiological outcomes utilizing a transcutaneous osseointegrated implant system in pediatric patients

## Abstract

**Background:** Percutaneous bone conduction hearing aids have proven to be audiometrically successful, but too often result in soft tissue issues at the abutment site. To counter this possibility, a magnetized, transcutaneous bone conduction hearing aid has been developed, the Baha Attract®. However, only limited research exists to demonstrate efficacy and verification measures of the Baha Attract® System.

**Purpose:** The purpose of this study was to evaluate audiologic outcomes when using the Baha Attract® magnetic osseointegrated system in pediatric patients by measuring functional gain and post-implant user satisfaction with the Children's Home Inventory for Listening Difficulties (CHILD) scale.

**Research design:** The authors used a retrospective chart review of pediatric patients implanted with the Attract® System from 2014 to 2017 at Cook Children's Medical Center located in Fort Worth, Texas.

**Study sample:** One ear of fourteen pediatric patients aged 5 to 18 years with bilateral or unilateral conductive hearing loss implanted unilaterally (13 children) or bilaterally (1 child, 1 ear randomly chosen for inclusion) with the Cochlear Baha Attract® System.

**Data collection and analysis:** Aided and unaided thresholds were collected for 14 patients. Effective gain testing occurred approximately three months after the initial fitting appointment.

Additionally, results of the CHILD survey were collected from seven of these children. A 2-factor analysis of variance test was used to examine the audiometric data, descriptive statistics were employed for the CHILD scores and correlations were run between CHILD scores and 1) overall functional gain, 2) frequency-specific functional gain and 3) age.

**Results:** Participants in this study showed a statistically significant improvement in bone conduction thresholds at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz when using the Baha Attract® System compared to the unaided condition. CHILD survey results showed a mean score of 6.5 and median score of 7 on a scale of 8. Correlation R values ranged from 0.14 to 0.79.

**Conclusion:** For these children with conductive losses, a transcutaneous, magnetic osseointegrated hearing implant is a viable treatment option that provides significant audiometric functional gain. The CHILD results suggest that the children positively benefit from the implant, and that the perceived benefit may increase with age.

**Keywords:** baha attract®, transcutaneous, osseointegrated implant, baha connect

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**Abbreviations:** FDA, food and drug administration; CHILD, children's home inventory for listening difficulties

## Introduction

### Background

Osseointegrated implants began as a treatment for children and adults with inoperable microtia/atresia commonly seen in syndromes such as Treacher-Collins syndrome. Since the initial Food and Drug Administration approval in 1996,<sup>1</sup> these implants have emerged with many more indications, including mixed hearing loss, unilateral conductive hearing loss, and unilateral, profound sensorineural losses. Traditional osseointegrated implants are composed of three parts: a titanium implant, an external abutment, and a detachable sound processor. What makes the traditional Baha System work well is the

direct bone conduction achieved by a percutaneous abutment. Sound is conducted directly from the microphone through the temporal bone, bypassing the outer and middle ears to directly stimulate the cochlea. However, this skin penetrating percutaneous abutment opens the door to infection. The most commonly reported complication of the percutaneous implant is soft tissue reaction around the abutment. This has been associated with significant healthcare expenditures,<sup>2</sup> and for children this often means time in which the processor cannot be worn, leading to potential further delays in listening, speech, and language skills. Lee et al.,<sup>3</sup> reported higher infection rates in children than adults, which makes the pediatric population more vulnerable to critical times of development.

There are various treatment options for soft tissue reactions. These may include topical or oral antibiotics, topical steroids, tissue cauterization, and occasionally surgical revision. Holgers' classification

scheme (1=slight, 4=severe) is often used to assign severity to soft tissue reactions. Various studies have shown percutaneous implants with Grade 2 and higher skin reactions occur in 25-78% of patients,<sup>4-7</sup> suggesting such an outcome is possible. Further, a Holgers grade 4 classification may require abutment removal.<sup>6,8</sup>

In 2014 Cochlear Corporation released an additional osseointegrated implant system known as the Baha Attract® System. The Attract® System uses a magnetic attachment between the internal implant and sound processor (Figure 1) instead of a percutaneous abutment. The sound processor picks up the sound vibrations and then passes the vibrations through the external magnet and tissue to the internal magnet. The internal magnet is attached to the titanium implant in the skull, starting the bone conduction process. An important question the field must answer about these osseointegrated devices is does the transcutaneous system provide enough audiological and medical benefit to replace the percutaneous abutment? As a beginning to answering that question, the focus in the current study is whether the Attract® device provides improved thresholds compared to the unaided condition. We did not make direct comparisons between transcutaneous and percutaneous devices.

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**Figure 1** Schematic of the transcutaneous Attract® System.

As with legacy bone conduction hearing aids and osseointegrated implants, aided threshold testing remains the most widely used and accepted method for verification in conductive and mixed hearing losses. The speculation surrounding the Attract® System is that its functional gain is comparable to a Softband fitting because the transcutaneous abutment prevents direct bone conduction, as occurs with the percutaneous abutment. If this is true, then is there a need to implant? Nicholson et al.,<sup>9</sup> reported average functional gains for Softband usage in children at 500 Hz and 1000 Hz of 42 dB each, 39 dB functional gain at 2000 Hz and 35 dB at 4000 Hz. These data indicate significant improvement with Softband use, suggesting use of the Attract® device, if comparable to the Softband, would be efficacious for wearers. However, Softbands were developed for use with infants and young children while awaiting surgical intervention. It seems unlikely that older children or adults, given the option between an elastic band and surgery, would choose the former.

Cedars et al.,<sup>10</sup> reported on the conversion of traditional percutaneous implants to the Baha Attract® transcutaneous implant in four pediatric patients. Their results revealed not only somewhat reduced hearing threshold improvements, but also less severe post-surgical complication with Attract® compared to the Connect®

percutaneous device. The authors also stated patients were satisfied with the sound available using the Attract® and noted that in a more recent comparison they found that there were no statistically significant group differences between the percutaneous and transcutaneous systems. Iseri et al (2015) also reported similar audiometric thresholds at 500, 1000, 2000 and 4000 Hz in adults between the percutaneous and transcutaneous systems.

The purposes of the present study were to document: (1) audiometric functional gain in children aged 5-18 years who were implanted with a Cochlear Attract® bone conduction hearing aid and to (2) listening difficulties with the Children's Home Inventory for Listening Difficulties (CHILD) questionnaire.

## Methods

Following approval by the Cook Children's Medical Center institutional review board (IRB Protocol # 2016-068), a retrospective chart review was conducted of 25 children implanted with the Baha Attract® System through the Audiology Department at Cook Children's Medical Center between 2014 and 2017.

## Participants

Fourteen children of the 25 reviewed met the following criteria and were included in the analysis: (1) 5 to 18 years of age, (2) bilateral or unilateral conductive hearing loss, (3) implanted with the Baha Attract® System, (4) unaided and aided soundfield thresholds were available for at least 500, 1000, 2000, and 4000 Hz, and (5) were followed at Cook Children's Audiology Program for at least 6 months.

## Procedure

Data available in the medical record were collected in one of the nine sound booths at Cook Children's Medical Center. All sound booths were equipped with a diagnostic audiometer calibrated to meet the American National Standards Institute (ANSI) specifications (ANSI, 1996). Because all the participants exhibited conductive hearing loss due to atresia/microtia, otoscopy and tympanometry were most often not performed and therefore not reported in this study. All participants were able to perform traditional behavioral testing by pressing a button, raising a hand, or saying 'yes' when they heard the stimulus for both aided and unaided conditions.

Aided and unaided bone conduction thresholds for 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz were recorded from audiograms available in the medical records. For aided conditions, soundfield thresholds were obtained with the speaker positioned at 90-degrees azimuth to, i.e., pointed directly toward, the target ear. In the cases of unilateral hearing loss, the soundfield aided information was obtained using masking via an insert earphone or supra-aural headphone on the non-test ear. Aided testing was performed with narrow band noise while unaided testing was completed with warble tones or narrow band noise.<sup>11</sup> If a participant exhibited a bilateral loss, thresholds for only the implanted ear were obtained for this study. The data used in this study are from the three month follow up appointment.

Nine of the participants used the Baha 5 and five of the participants the Baha 4 for testing. The Children's Home Inventory for Listening Difficulties (CHILD) questionnaire<sup>12</sup> is a 15-item instrument used to assess a child's auditory functioning in home and family situations. The CHILD is designed to be completed by children aged 7 years or older, or a caregiver of any aged child. Scores on the CHILD range from a low of 1, "Huh? Don't know that someone is talking, miss

all of message” to a high of 8, “Great Hear every word, understand everything.” The CHILd was used post-implantation to assess the efficacy of the Attract® device for the children. In this study six children completed the CHILd on their own, and a clinician obtained responses of a 5-year old by reading the questions to him. The remaining seven participants did not complete the CHILd due to time constraints during appointments or lack of parent/patient participation.

Anderson & Smaldino<sup>12</sup> did not publish validation data for the CHILd. However, they suggested its use in a variety of applications, including as an initial assessment for a family to understand their child’s abilities, parent counseling, and pre-/post-hearing device fitting. Bagatto et al.,<sup>8</sup> rated the CHILd a ‘B’ (on their A, B, C scale, A = highest grade) on test-retest reliability, ecological validity, and respondent burden and responsiveness, i.e., the tool scores change in the expected direction with changes in hearing status or intervention.

**Data analysis**

An analysis of variance was used to examine differences between the unaided and aided conditions at each frequency. Bonferroni-corrected post-hoc t-tests were run to look at the hearing aid condition by frequency interaction, and an a priori family-wise p-value of 0.05 was chosen for significance on the statistical tests. For the CHILd scores, descriptive statistics were reported for the overall scores, and correlations between the CHILd scores and age, overall gain and frequency-specific gain were run.

**Results**

Participant demographic information is provided in Table 1. Forty-three percent of the participants are Hispanic, with 57% Caucasian; 35% female and 65% male. Eighty-six percent of participants’ right ears and 14% of left ears are included in the sample. Participant 1 had both ears implanted and her right ear was chosen randomly for

inclusion in the data set. All participants presented with the same etiology.

**Table 1** Demographic information of participants

Participant	Age (yrs)	Ethnicity	Sex	Ear	Etiology
1	10	Hispanic	F	R	atresia/microtia
2	16	Caucasian	M	R	atresia/microtia
3	13	Hispanic	M	R	atresia/microtia
4	5	Caucasian	M	R	atresia/microtia
5	8	Hispanic	M	R	atresia/microtia
6	17	Caucasian	M	R	atresia/microtia
7	15	Caucasian	F	R	atresia/microtia
8	15	Hispanic	F	R	atresia/microtia
9	5	Caucasian	M	L	atresia/microtia
10	8	Hispanic	M	R	atresia/microtia
11	9	Caucasian	F	R	atresia/microtia
12	11	Hispanic	M	R	atresia/microtia
13	9	Caucasian	F	R	atresia/microtia
14	18	Caucasian	M	L	atresia/microtia
Mean (sd)	11.4 (4.3)				

Individual audiometric thresholds are shown in Table 2. The amount of conductive hearing loss ranges from mild (e.g., P5, P9, P10, P12) to moderate/moderately severe (e.g., P2, P6, P7, P13). Participant 9 demonstrated mild loss in the low frequencies and thresholds within the normal limits at 2000 Hz and 4000 Hz. It is disappointing but not surprising that this child’s thresholds are slightly poorer through the implanted device.

**Table 2** Unaided and aided (Attract®) bone conduction thresholds for each participant

Participant	Unaided thresholds (dB HL)				Attract thresholds (dB HL)			
	500 Hz	1000 Hz	2000 Hz	4000 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
1*	45	45	50	50	15	20	15	35
2*	60	40	45	45	20	20	30	40
3*	55	55	55	50	40	20	35	40
4*	45	55	50	50	25	10	15	25
5*	30	30	35	55	0	5	30	40
6	50	40	60	55	5	5	20	50
7*	65	65	50	60	20	20	20	15
8	50	45	40	40	15	15	15	20
9	35	30	15^	20^	20	20	20^	30^
10	35	40	25	35	20	20	20	25
11	45	45	55	55	10	5	15	45
12	35	25	35	40	15	10	30	35
13	65	45	60	65	20	20	25	25
14*	70	65	40	50	20	20	20	20

\*Completed the Children’s Home Inventory for Listening Difficulties (CHILd) survey.  
 ^The two instances that aided thresholds were poorer than unaided ones.

Table 3 displays the average overall gain; individual frequency-specific gain and CHILD score, if available. The Attract® provides 30 dB average gain at 500 and 1000 Hz, about 22 dB at 2000 Hz and 16 dB at 4000 Hz, with a range between -10 (poorer aided threshold) and

45 dB. Setting the criterion for “within the normal limits” at 20 dB HL, the Attract® raises group thresholds to within the normal limits at 500 and 1000 Hz, to a slight loss at 2000 Hz, and to the mild loss region at 4000 Hz.

**Table 3** Average overall gain, individual frequency-specific gain and average frequency-specific gain

Participant	Average individual gain	Gain				Child score
		500 Hz	1000 Hz	2000 Hz	4000 Hz	
1	26.3	30	25	35	15	7.3
2	20.0	40	20	15	5	7.1
3	20.0	15	35	20	10	5.2
4	31.3	20	45	35	25	5.9
5	18.8	30	25	5	15	5.0
6	31.3	45	35	40	5	
7	41.3	45	45	30	45	7.0
8	27.5	35	30	25	20	
9	2.5	15	10	-5	-10	
10	12.5	15	20	5	10	
11	31.3	35	40	40	10	
12	11.3	20	15	5	5	
13	36.3	45	25	35	40	
14	36.3	50	45	20	30	8.0
<b>Average Gain (sd)</b>		31.4 (12.6)	29.6 (11.5)	21.8 (14.9)	16.1 (14.8)	6.5 (1.1)

Table 4 contains the mean thresholds and standard deviations for the unaided condition, the Baha Attract® condition and the mean functional gain. Also included in Table 4 are the 95% confidence intervals for all measures. A 2-factor analysis of variance, 2 X 4, hearing aid condition X frequency, with repetition on hearing aid condition, was run to examine the data. Results revealed statistical differences for hearing aid condition (F1,52=186.8, p<0.001), frequency (F3,52=3.71, p=0.017), and the hearing aid condition X frequency interaction (F3,52=3.88, p= 0.014). We examined the interaction of hearing aid condition and frequency using the gain measure with a series of one-sided post hoc t-tests with a Bonferroni correction. These multiple comparisons indicated that there were statistical differences in gain between 500 Hz and 4000 Hz, as well as between 1000 Hz and 4000 Hz. No other comparisons were significant.

Seven of the Attract® recipients in the group reported here completed the CHILD questionnaire with the results shown in Table 3 & Table 5. Table 5 also contains the relevant demographic and audiometric data for these participants. With only seven data points we want to observe great caution on interpretation of these data. However, there are some interesting trends that warrant presentation. First, this sub-group of participants closely mirrors the whole group in terms of sex, ethnicity, and age. However, the three children with lower CHILD scores is younger than the group as a whole, while the four with higher CHILD scores is older than the group as a whole.

A t-test revealed a non-significant difference in age between these groups, but on a practical level there are likely developmental

differences. To understand these data better, we ran correlations between the CHILD scores and age, overall gain, and frequency-specific gain. The single highest correlation coefficient is gain at 500 Hz, with an R-value of 0.79. It is the case that the older group experienced a much larger gain at 500 Hz, about 20 dB higher than the younger group, which seems likely to be driving that correlation. Age is the factor with the second highest R-value, 0.63, suggesting age may underlie at least part of the CHILD scores obtained, with older children stating greater benefit was received than younger children.

**Table 4** Average frequency-specific thresholds for unaided and aided thresholds and gain

Condition	500 Hz	1000 Hz	2000 Hz	4000 Hz
<b>Unaided</b>				
M (sd)	48.9 (12.7)	44.6 (12.2)	43.9 (13.2)	47.9 (11.4)
95% CI	41.9, 56.0	37.9, 51.4	36.6, 51.2	41.6, 54.2
<b>Attract</b>				
M (sd)	17.5 (9.4)	15.0 (6.5)	22.1 (6.7)	31.8 (10.5)
95% CI	12.3, 22.7	11.4, 18.6	18.4, 25.9	26.0, 37.6
<b>Gain</b>				
M (sd)	31.4 (12.6)	29.6 (11.5)	21.8 (14.9)	16.1 (14.8)
95% CI	7.5, 17.8	6.2, 16.8	11.9, 17.9	12.6, 17.1

**Table 5** Patient-generated CHILD scores, individual gain and R values

Participant/ Measure	Child score (Max=8)	Ethnicity	Sex	Age	Average gain	500 Hz gain	1000 Hz gain	2000 Hz gain	4000 Hz gain
P2	5.2	Hispanic	M	13	20	15	35	20	10
P3	5.9	Caucasian	M	5	31.3	20	45	35	25
P4	5	Hispanic	M	8	18.8	30	25	5	15
Mean	5.4			8.7	23.4	21.7	35	20	16.7
Std Dev	0.5			4	6.9	7.6	10	15	7.6
P1	7.3	Hispanic	F	10	26.3	30	25	35	15
P2	7.1	Caucasian	M	16	20	40	20	15	5
P7	7	Caucasian	F	15	41.3	45	45	30	45
P14	8	Caucasian	M	18	36.3	50	45	20	30
Mean	7.4			14.8	31	41.3	33.8	25	23.8
Std Dev	0.4			2.9	8.3	7.4	11.4	7.9	15.2
R value		Not run	Not run	0.63	0.57	0.79	0.14	0.36	0.33

## Discussion

The data presented in this paper indicate that 13 of 14 children in the current study experienced substantial threshold gains with the Baha Attract® device compared to the unaided condition. The 14<sup>th</sup> participant displayed high frequency thresholds within the normal range, and testing indicated a 5- and 10-dB decrease in gain at 2000 Hz and 4000 Hz, respectively, with the device in place. Overall, however, these audiological data are promising and with care can be made to give pediatric patients access to the speech spectrum just as the legacy osseointegrated anchored implants have done.

Comparing these data to the Softband data of Nicholson et al.,<sup>9</sup> we note that the functional gains reported here are poorer than those of Nicholson et al. by about 12 dB at 500 Hz and 1000 Hz, and about 17 and 19 dB at 2000 Hz and 4000 Hz, respectively. These two studies have notable differences in the participants. The average age in the current study is 11.4 years and it is 5.6 years in Nicholson et al. Due to this age difference the testing method was necessarily different across participants in Nicholson et al.,<sup>9</sup> but all participants in the current study were able to provide thresholds with traditional test procedures (i.e., say yes or raise their hand). Another point stemming from the age difference might be seen in skull transmission characteristics. Mackey et al.,<sup>13</sup> demonstrated systematic mechanical impedance changes in the skin-covered skull of infants through 7 years of age, and children versus adults. These authors theorize that infant-adult differences may be partly due to properties of the skull itself, with some differences coming from the overlying skin and tissue. The Mackey et al. data do not completely explain the differences in our study and Nicholson et al.<sup>9</sup> However, their data on age-based mechanical impedance differences combined with the age differences of the participants between the studies makes such an explanation plausible. There is need for additional research to determine at what age skull transmission characteristics become adult-like.

A noteworthy point is that all of these results were obtained at the three month follow up appointment, where many times magnet strengths are still being determined. Getting the appropriate magnet strength and then deciding if magnet pads need to be added for comfort often requires multiple appointments for patients. It is also important to acknowledge when working with the Attract® System that magnet

strengths become critical just as the precision of the Softband fitting is, and they can have some negative impact on aided thresholds. The best protocol for an accurate fitting is aided testing over a period of time to ensure comfort of the device and good responses to aided threshold testing.

Another note in these preliminary data is the seeming need to simply give more gain at 4000 Hz. Some pediatric audiologists might be uncomfortable with this solution because there are no agreed-to objective measures available at this time to verify the changes, such as there are for traditional hearing aid fittings with real ear measures. Based on the current data, as well as the earlier cited studies on percutaneous implant sequelae of infection,<sup>4-7</sup> we would argue that, given the adequate gain levels at 500, 1000 and 2000 Hz, combined with the elimination of infection with the use of the Attract®, audiologists should attempt to provide more gain at 4000 Hz, using the patient's uncomfortable loudness thresholds as a guide. Only by providing adequate gain at 4000 Hz within the programming software can audiologists ensure that pediatric patients are hearing all sounds well across the speech spectrum, in order to promote listening and speech development.

## Conclusion

For these children with conductive losses, a magnetic bone conduction hearing implant is a good option for treatment as it reduces the risk of trauma and eliminates the need for daily cleaning associated with a traditional percutaneous or skin-penetrating device. Magnetic bone conduction hearing implants may be considered the first choice of treatment in pediatric patients with a conductive hearing loss as it also provides a statistically significant amount of gain. As results continue to emerge regarding the Baha Attract® System, it is helpful to remember that the traditional osseointegrated implant is still an option for patients especially those with mixed losses that would require more gain.

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## Conflicts of interest

The author declares there is no conflicts of interest.

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