Growth in device use after Bonebridge placement under expanded indications: Implications for early auditory experience

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Background

- Early access to hearing technology is an important step in the hearing loss identification and intervention sequence (Tomblin et al., 2015). To achieve the maximum benefits of intervention, families must work to establish full-time device use and maximize early auditory experience.
- For children with permanent conductive hearing loss in one or both ears, a bone conduction device may be the best option to deliver auditory information to the inner ear consistently.
    - Microtia/atresia
    - Post-surgical ears with persistent conductive hearing loss
    - Poor tolerance of occluding earmolds (e.g., chronic drainage or stenotic canals)
- Soft-band bone conduction devices have several drawbacks that create challenges to establishing full-time device use (Gordey et al., 2021). This can be especially true as children get older.
- Novel, active transcutaneous bone conduction implants are now an option for the treatment of conductive and mixed hearing loss. Active bone conduction implants allow for improved transmission of sound energy with decreased skin-related complications compared to traditional passive bone conductive devices (Hundertpfund et al., 2020; Magele et al., 2019).
- Delayed access to surgical solutions may create a time window where children reject soft-band solutions but are not yet candidates for fully implantable options. This may coincide with school ages years when listening for learning is paramount.
- Abutment-based surgical solutions are approved in younger children; however, parents may find them less acceptable than fully-implantable solutions and elect to wait.

Materials & Methods

This study will assess the initial outcomes of an active transcutaneous bone conduction implant in children under 12 years of age to evaluate if indications should be expanded to include a younger patient population. Our data represent a cohort of site-specific participants as part of a larger multi-center FDA trial.

This study uses an anatomy-based indication, rather than an age-based indication.

In addition to changes in audiological and auditory access characteristics of participants, we will also specifically examine device use trends in our patients. When available, we will examine growth in device use following transcutaneous bone conduction implantation compared to pre-surgical baseline in the soft-band condition.

Table 1. Participant Characteristics and baseline data.

Participant	Age Yr.; Mo	Contralateral ear	Pre-Operative				
			SRT dB HL	Unaided Audibility (SII)	PTA in implanted ear (4-frequency)	Etiology	Datalogging Hours/day
F3	8;3	WNL	70	.00	70	Microtia/Atresia	-
M1	8;7		65	.00	75	VACTERL	-
F2	5;2	HL, equivalent	45	.14	51.25	Canal Stenosis	7.5
F1	6;10	HL, equivalent	50	.21	47.5	Canal Stenosis	8.1

Results

To date, four participants have been enrolled at the University of North Carolina Chapel Hill and completed baseline testing. Three have undergone surgery, and one is currently ready for surgery.

Figure 1. Growth in device use after surgical placement (timepoint 0), compared to growth during the baseline condition. Red line references our 10 hour/day goal.

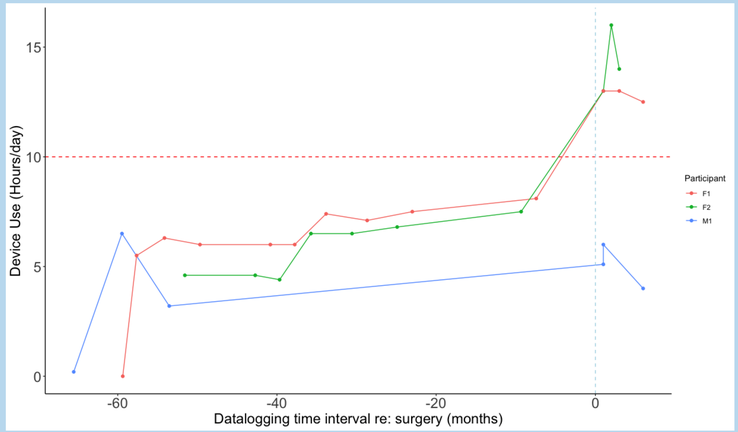
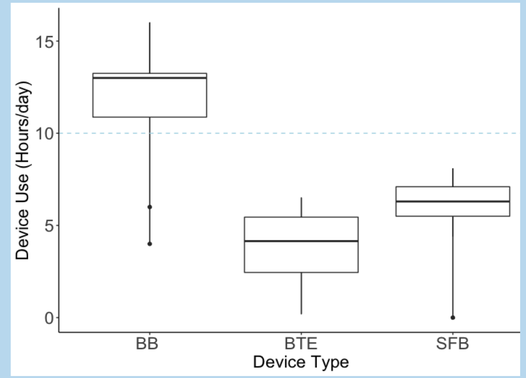


Figure 2. Device use rates across device type in observations, compared to 10 hour/day goal.



BB=Bonebridge, BTE=Behind the ear HA, SFB=Soft Band Bone conduction device

Table 2. Post surgical placement aided SRT and Speech perception (SP) at 1-, 3-, and 6-month intervals.

Participant	Baseline SRT dB HL	SRT (1) dB HL	SP (1) %	SRT (3) dB HL	SP (3) %	SRT (6) dB HL	SP (6) %	Final Datalogging hours/day
F3	*70*	N/A	N/A	N/A	N/A	N/A	N/A	N/A
M1	*65*	30	60%	30	48%	N/A	N/A	4.0
F2	*45*	30	80%	25	25%	20	95%	14.0
F1	*50*	25	72%	30	30%	25	82%	12.5

Table 3. Adverse events in enrolled subjects.

	Surgery Date Mo.; Yr.	Adverse Event	Response
F3	TBD	None	-
M1	01/2024	Perceived neck stiffness	OTC NSAIDS
F2	01/2024	Post-Op Covid	ED Visit
F1	11/2023	None	-

Conclusions

- Active transcutaneous bone conduction implants in the pediatric (3–12-year-old) patient population are safe, efficacious, and produce a subjective improvement in quality of life.
- Of the research participants currently enrolled in the clinical trial, all have experienced growth in device use. This has important implications for supporting increased auditory experience during the school-age years and facilitating language and academic outcomes.
    - Average daily use rates with Bonebridge (11.4 hours/day [SD:4.1]) exceeded use rates of pre-surgical amplification device (5.5 hours/day [SD: 2.16]).
    - Age at observation likely explains some of the increase over time.
- Preliminary findings support the expansion of indications to include younger children with conductive and mixed hearing loss.
- This project will continue in conjunction with other participating sites.
- Changes to FDA approval for other active transcutaneous systems during the interval of this FDA-approval trial validate the use of such devices in a younger population of children with educationally and developmentally significant hearing loss.

References

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