

Sophono Bone Anchored Hearing System Experience in Pediatric Patients

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Summary of a Clinical Study

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principal investigator

<p>Authors</p>	<ul style="list-style-type: none"> ■ Drew M. Horlbeck, MD ■ Christine Cook, MS, CCC-A Nemours Children's Hospital, Jacksonville, FL, USA 												
<p>Patients</p>	<ul style="list-style-type: none"> ■ 12 patients (ages 4 –17) were enrolled in this study¹ ■ 6 patients had bilateral conductive hearing loss ■ 5 patients had unilateral conductive hearing loss ■ 1 patient had single-sided deafness 												
<p>Other Parameters</p>	<table border="1"> <tr> <td>Average time between implantation and testing</td> <td>3.3 months</td> </tr> <tr> <td>Sophono processor type</td> <td>Alpha 1</td> </tr> <tr> <td>Most common cause of hearing loss</td> <td>Microtia</td> </tr> </table>	Average time between implantation and testing	3.3 months	Sophono processor type	Alpha 1	Most common cause of hearing loss	Microtia						
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Most common cause of hearing loss	Microtia												
<p>Timeline</p>	<ul style="list-style-type: none"> ■ All 12 patients were enrolled between November 2011 and January 2013 (enrollment continued) 												
<p>Clinical Results²</p>	<ul style="list-style-type: none"> ■ No operative complications. One patient had skin irritation and redness that resolved quickly. <div data-bbox="358 1171 773 1535"> <table border="1"> <caption>Functional Gain in Bilateral CHL Children²</caption> <thead> <tr> <th>Patient</th> <th>Pure-tone average (PTA) [dB]</th> </tr> </thead> <tbody> <tr> <td>Patient 1</td> <td>~28</td> </tr> <tr> <td>Patient 2</td> <td>~45</td> </tr> <tr> <td>Patient 3</td> <td>~40</td> </tr> <tr> <td>Patient 4</td> <td>~38</td> </tr> <tr> <td>Patient 5</td> <td>~38</td> </tr> </tbody> </table> </div> <ul style="list-style-type: none"> ■ Pure-tone averages (PTA) improved by 37.8 dB on average (indicated by red line on chart). ■ Bamford-Kowal-Bench Speech-In-Noise (BKB-SIN) improved by 1.9 dB on average. ■ All patients reached post-op PTAs of 25 dB and better. Post-operative speech discrimination scores average 89%. 	Patient	Pure-tone average (PTA) [dB]	Patient 1	~28	Patient 2	~45	Patient 3	~40	Patient 4	~38	Patient 5	~38
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<p>Conclusion</p>	<ul style="list-style-type: none"> ■ The Sophono bone anchored hearing system is a safe and effective surgically implanted device for conductive hearing loss. 												

¹Sophono devices are indicated for patients 5 years old and greater.

²These results represent the 5 Bilateral CHL Children that met the inclusion criteria of 5 years old or greater.

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