

Implantable Auditory Devices

Presented at the Ultimate Colorado Midwinter Meeting | February 3, 2015, Vail, Colorado

Summary of a Clinical Study
Darius Kohan MD, principal investigator

Title of Study	Implantable Auditory Devices																																																		
Physician / Clinic	<ul style="list-style-type: none"> ▪ Darius Kohan, MD ▪ Otology/Neurotology, Lenox Hill Hospital, Manhattan Eye, Ear, and Throat Hospital, New York City, NY, USA 																																																		
Objective	<ul style="list-style-type: none"> ▪ Retrospective analysis of 3 bone conduction systems in 15 patients; comparison of patient satisfaction and clinical function. 																																																		
Subjects and Methods	<ul style="list-style-type: none"> ▪ Three implantable bone conduction systems from two manufacturers: <ul style="list-style-type: none"> ▪ Alpha 2 with TET, [Sophono, Inc., Boulder, Colorado] ▪ Baha 4 Connect and Baha Attract [Cochlear Limited, Centennial, Colorado] <p>15 patients were selected from clinic's existing patient population; randomized by selecting in reverse chronological order. Average age 60.4, average use 21 months.</p>																																																		
Evaluations	<p>Same surgeon, multiple institutions for surgery, but all audiological evaluations performed in the same clinic.</p>	<table border="1"> <caption>Mean Pure Tone Frequency Gain by Device</caption> <thead> <tr> <th>Frequency (Hz)</th> <th>Sophono (n=5)</th> <th>Baha Attract (n=5)</th> <th>Baha Connect (n=5)</th> </tr> </thead> <tbody> <tr> <td>500</td> <td>26.0</td> <td>23.0</td> <td>38.0</td> </tr> <tr> <td>1000</td> <td>35.0</td> <td>26.0</td> <td>35.0</td> </tr> <tr> <td>2000</td> <td>25.0</td> <td>22.0</td> <td>30.0</td> </tr> <tr> <td>4000</td> <td>23.0</td> <td>16.0</td> <td>18.0</td> </tr> </tbody> </table>		Frequency (Hz)	Sophono (n=5)	Baha Attract (n=5)	Baha Connect (n=5)	500	26.0	23.0	38.0	1000	35.0	26.0	35.0	2000	25.0	22.0	30.0	4000	23.0	16.0	18.0																												
Frequency (Hz)	Sophono (n=5)	Baha Attract (n=5)	Baha Connect (n=5)																																																
500	26.0	23.0	38.0																																																
1000	35.0	26.0	35.0																																																
2000	25.0	22.0	30.0																																																
4000	23.0	16.0	18.0																																																
Clinical Results	<p>Reporting on AC, BC threshold; Aided and Unaided sound field results.</p>	<table border="1"> <thead> <tr> <th></th> <th>Sophono</th> <th>Baha Attract</th> <th>Baha Connect</th> </tr> </thead> <tbody> <tr> <td>PTA Unaided</td> <td>68.8 dB</td> <td>74.8 dB</td> <td>70.4 dB</td> </tr> <tr> <td>BC Threshold</td> <td>30.5 dB</td> <td>22.3 dB</td> <td>26 dB</td> </tr> <tr> <td>Air Bone Gap</td> <td>38.3 dB</td> <td>52.6 dB</td> <td>44.4 dB</td> </tr> <tr> <td>Gain (STDV)</td> <td>27.25 dB (5.9)</td> <td>21.8 dB (5.4)</td> <td>30.5 dB (5.3)</td> </tr> <tr> <td>Res. Air Bone Gap</td> <td>11.1 dB (4.2)</td> <td>30.8 dB (13.5)</td> <td>13.9 dB (15.1)</td> </tr> </tbody> </table>		Sophono	Baha Attract	Baha Connect	PTA Unaided	68.8 dB	74.8 dB	70.4 dB	BC Threshold	30.5 dB	22.3 dB	26 dB	Air Bone Gap	38.3 dB	52.6 dB	44.4 dB	Gain (STDV)	27.25 dB (5.9)	21.8 dB (5.4)	30.5 dB (5.3)	Res. Air Bone Gap	11.1 dB (4.2)	30.8 dB (13.5)	13.9 dB (15.1)	<table border="1"> <thead> <tr> <th></th> <th>Sophono</th> <th>Baha Attract</th> <th>Baha Connect</th> </tr> </thead> <tbody> <tr> <td>PTA Unaided</td> <td>68.8 dB</td> <td>74.8 dB</td> <td>70.4 dB</td> </tr> <tr> <td>BC Threshold</td> <td>30.5 dB</td> <td>22.3 dB</td> <td>26 dB</td> </tr> <tr> <td>Air Bone Gap</td> <td>38.3 dB</td> <td>52.6 dB</td> <td>44.4 dB</td> </tr> <tr> <td>Gain (STDV)</td> <td>27.25 dB (5.9)</td> <td>21.8 dB (5.4)</td> <td>30.5 dB (5.3)</td> </tr> <tr> <td>Res. Air Bone Gap</td> <td>11.1 dB (4.2)</td> <td>30.8 dB (13.5)</td> <td>13.9 dB (15.1)</td> </tr> </tbody> </table>		Sophono	Baha Attract	Baha Connect	PTA Unaided	68.8 dB	74.8 dB	70.4 dB	BC Threshold	30.5 dB	22.3 dB	26 dB	Air Bone Gap	38.3 dB	52.6 dB	44.4 dB	Gain (STDV)	27.25 dB (5.9)	21.8 dB (5.4)	30.5 dB (5.3)	Res. Air Bone Gap	11.1 dB (4.2)	30.8 dB (13.5)	13.9 dB (15.1)
	Sophono	Baha Attract	Baha Connect																																																
PTA Unaided	68.8 dB	74.8 dB	70.4 dB																																																
BC Threshold	30.5 dB	22.3 dB	26 dB																																																
Air Bone Gap	38.3 dB	52.6 dB	44.4 dB																																																
Gain (STDV)	27.25 dB (5.9)	21.8 dB (5.4)	30.5 dB (5.3)																																																
Res. Air Bone Gap	11.1 dB (4.2)	30.8 dB (13.5)	13.9 dB (15.1)																																																
	Sophono	Baha Attract	Baha Connect																																																
PTA Unaided	68.8 dB	74.8 dB	70.4 dB																																																
BC Threshold	30.5 dB	22.3 dB	26 dB																																																
Air Bone Gap	38.3 dB	52.6 dB	44.4 dB																																																
Gain (STDV)	27.25 dB (5.9)	21.8 dB (5.4)	30.5 dB (5.3)																																																
Res. Air Bone Gap	11.1 dB (4.2)	30.8 dB (13.5)	13.9 dB (15.1)																																																
Conclusion	<ul style="list-style-type: none"> ▪ All device options provide patient benefit. All devices were easy to insert in less than 30 minutes. No operative complications. Late local complications with the Baha Connect are common. Percutaneous Baha Connect provides the best PTA gain of 31 dB. Transcutaneous Sophono provides an average 6 dB better PTA gain vs. Baha Attract. Gain at high frequencies drops off for all devices, the least decline for Sophono. Ongoing study will enroll more patients and include Speech in Noise/QuickSIN, APHAB and Hearing in Noise. 																																																		

Rx only. Refer to product instruction manual/package insert for instructions, warnings, precautions and contraindications.

For further information, please call Medtronic ENT at 800.874.5797 or consult Medtronic's website at www.medtronicent.com.



Now owned by

Medtronic

Sophono Inc.

5744 Central Avenue
Suite 100
Boulder, CO 80301

International Telephone Numbers

Adriatic Region 385-1-488-1120	Israel 972-9-972-4400
Argentina 54-11-4898-5700	Italy 39-02-24137-324
Australia 1-800-668-670	Japan 81-3-6430-2017
Baltic Region 37-1-67560226	Korea 82-2-3404-3600
Belgium 32-2456-09-09	Lebanon 961-1-370-670
Brazil 55-11-2182-9200	Luxembourg 32-2456-09-09
Canada 1-800-217-1617	Malaysia 60-37-953-4800
Chile 56-2-2655-5110	Mexico 52-55-11-02-90-30
China 86-21-20325888	Netherlands 31-45-566-8800
Colombia 57-1-742-7300	Poland 48-22-4656900
Czech Republic 420-2-9657-9580	Russian Fed. 7-495-580-73-77
France 33-470-679-800	Singapore 65-6776-6255
Germany 49-2159-8149-209	South Africa 27-11-466-1820
Greece 30-210-67-79-099	Spain 34-91-625-05-40
Hong Kong 852-2919-1312	Taiwan 886-2-2183-6000
Hungary 36-188-90600	Thailand 662-232-7400
India 91-22-26836733	UK 44-1923-205-166

Sophono® and *The Leader in Magnetic Bone Conduction Hearing* are registered trademarks of Medtronic, Inc.

© 2016, Medtronic, Inc. S0584-09 Rev B UC201603541bEN 04.2016