

*Hearing Rehabilitation with the Closed-Skin Bone-Anchored implant Sophono Alpha1:
Results of a Prospective Study in 15 Children with Ear Atresia
Presented at the Politzer Society Meeting, November 16, 2013 in Antalya, Turkey*

*Summary of a Clinical Study
Françoise Denoyelle,
principal investigator*

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<p>Patients</p>	<ul style="list-style-type: none"> ■ 15 patients underwent Sophono implantation – 12 before and 3 during auricle reconstruction ■ Patient ages ranged from 5 years, 1 month to 12 years, 11 months; median age was 8 years ■ Follow-up period was between 12 and 30 months 						
<p>Evaluations</p>	<table border="1"> <tr> <td data-bbox="354 919 802 1167"> <p>At 6 and 12 months after implantation (M12):</p> </td> <td data-bbox="807 919 1461 1167"> <p>Tonal and vocal air-conduction audiometry in free field with masking of the contralateral ear, with and without Alpha 1</p> <p>Speech-in-noise tests with and without Alpha1, noise at 65 dB, in real-life conditions</p> </td> </tr> <tr> <td data-bbox="354 1173 802 1272"> <p>At 12 months and until 33 months after implantation (M12):</p> </td> <td data-bbox="807 1173 1461 1272"> <p>Skin evaluation at the end of follow-up</p> </td> </tr> </table>	<p>At 6 and 12 months after implantation (M12):</p>	<p>Tonal and vocal air-conduction audiometry in free field with masking of the contralateral ear, with and without Alpha 1</p> <p>Speech-in-noise tests with and without Alpha1, noise at 65 dB, in real-life conditions</p>	<p>At 12 months and until 33 months after implantation (M12):</p>	<p>Skin evaluation at the end of follow-up</p>		
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Timeline

- All 15 patients were enrolled and followed between October 2010 and November 2013

Clinical Results

(Note: Average air-bone gap was 57.4 dB)

	Pre-Op	Post-Op	Improvement
Pure-Tone Average	69.1 dB	28.4 dB	43.0 dB
Speech-In-Noise Ratio	71.7 dB	38.2 dB	33.5 dB

Alpha 1 vs. BAHA® testing with the BAHA used on a softband (Note: Performance for the Alpha 1 was the same on the softband and on the Sophono implant.)

PTA improvement: The Alpha 1 performed 5 dB (on average) better than the BAHA on softband.

The gain with Sophono processor falls between the gain on BAHA on softband and BAHA percutaneous.

Sophono is a "good indication in children" because it is easy for the child to put the processor in place. (Note: BAHA suffers from problems of granuloma/trauma and difficulties in thin cortical bones.)

Conclusion

- The Alpha 1 implant in children with congenital aural atresia showed satisfying auditory results (aided PTA / improvement of speech-in-noise), and good cutaneous tolerance with a mean follow-up of 20 months.

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