Recalled Advanced Bionics HiRes Ultra Cochlear Implants Demonstrate a 73% Failure Rate

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Introduction

In 2020, Advanced Bionics announced a voluntary recall of its V1 series HiRes Ultra and HiRes Ultra 3D cochlear implant models due to hearing degradation (characterized by decreased audibility, distorted loudness perception, speech clarity, and general responsiveness to sound) and interruption of stimulation.[1] The cause was attributed to fluid impaction of the implant electrode.[2] Patients were not harmed by the device itself, but many required revision surgery to replace their cochlear implant, imparting expense, pain, and decreased quality of life while living with an impaired hearing device.

Classifying device failures proves challenging due to the high incidence of “soft failures,” whereby the cochlear implant functions according to manufacturer software, but the patient does not perform at the expected speech perception outcome threshold. This study evaluates the rate of Advanced Bionics HiRes cochlear implant failures at the University of Florida with special attention focused on the longitudinal information required to diagnose soft failures.

Methods

A retrospective chart review was performed for all patients implanted with a V1 series HiRes Ultra or HiRes Ultra 3D cochlear implant at UF Health in Gainesville, FL. Cases were evaluated with respect to both hard and soft failures. Hard failures were defined as devices that would not power on or no stimulation was achieved. Soft failures were defined as declining speech perception outcomes despite external equipment exchange and mapping / programming adjustments.

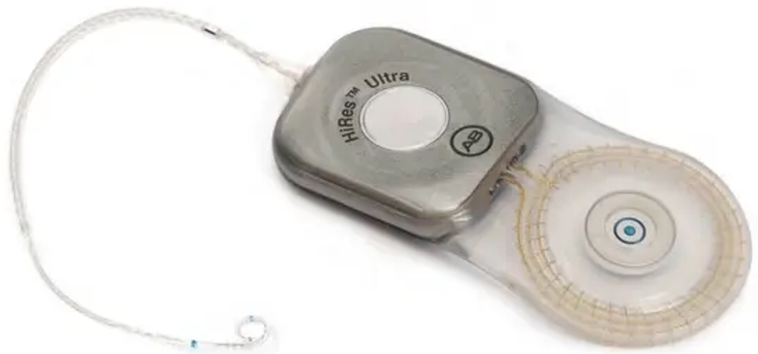

Fig 1. Advanced Bionics HiRes Ultra cochlear implant.[3]

Results

15 HiRes Ultra (V1) and 3 HiRes Ultra 3D (V1) devices were implanted from December 2016 to January 2020 at University of Florida Health’s Gainesville campus. Mean age at implantation was 68.5 years. 73.3% of HiRes Ultra devices exhibited soft failures (11/15). There were no HiRes Ultra 3D device failures, and there were no hard failures in patients using either device. Median time to failure was 31 months. 72.7% of patients with device failures had successful revision surgeries with V2 series HiRes Ultra devices (8/11). The remaining 27.3% declined revision or were lost to follow up (3/11).

Discussion

Advanced Bionics issued an updated statement in 2022 that found the original version (V1) of the HiRes Ultra and HiRes Ultra 3D cochlear implants demonstrated an 11.3% failure rate of implanted devices.[2] This is a significantly lower than the 73.3% failure rate discovered through our single-institution retrospective review. Our study found long-term follow-up of patients implanted with recalled Advanced Bionics devices demonstrated an alarming failure rate when taking soft failures into account. Similar findings have been reported by other institutions with 21% known failures at Vanderbilt and more than 50% at Hannover Medical School [5]. The challenge of identifying soft device failures makes it difficult to elucidate the true rate of device failures.

Patients who were implanted with recalled devices should be regularly monitored, allowing for early intervention in the case of device failure.

References

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