



Clinical Results

The HiResolution™ Bionic Ear System from Advanced Bionics (AB) is designed to provide cochlear implant recipients with natural and effortless hearing. Through a combination of high-fidelity, front-end signal processing (T-Mic™, AutoSound™) and innovations in stimulus delivery (current steering, high stimulation rates), HiRes Fidelity 120™* sound processing (HiRes 120) provides high-resolution temporal and spectral information to AB implant recipients. Clinical studies show that the ability to hear speech in noise and to enjoy music with HiRes 120 surpasses previous-generation sound processing strategies (e.g., Brendel et al. 2008, Firszt et al. 2009, Oleson et al. 2008).

ClearVoice™* is the next innovation in HiResolution sound processing from Advanced Bionics proven to improve hearing in difficult listening situations for enhanced speech understanding. In challenging acoustic environments, ClearVoice identifies frequency bands in which non-speech energy is present and reduces the gain of those bands. The effect is to enhance the overall signal-to-noise ratio (SNR), which in turn provides the opportunity to hear the desired speech signal better. At the same time, ClearVoice does not affect performance in quiet settings. Thus, ClearVoice is intended for all-day use without requiring the user to switch programs when the listening environment changes.

Historically, cochlear implant manufacturers have gained regulatory approval for new sound processing strategies by demonstrating that a new strategy is not inferior to previously approved strategies. Some published studies have shown equivalence in performance and preference for new strategies (e.g., Cochlear 2009, Balkany et al. 2007, Magnusson 2011), while others show improvement in hearing and preference for the newer strategy (e.g., Advanced Bionics 2011, Koch et al. 2004).

In contrast, the ClearVoice clinical trial proposed evaluating the superiority of ClearVoice for hearing in noise. Thus, in order to receive regulatory approval for ClearVoice, demonstration of unambiguous improvement in listening was required. The data summarized below show unequivocally that ClearVoice provides superior listening in noise and that AB recipients overwhelmingly prefer to use ClearVoice for everyday hearing.

Study Design

The clinical study investigated the benefits of ClearVoice in adults who were experienced users of HiRes 120. ClearVoice has three gain setting options that allow individuals to select the one that provides the best hearing—Low, Medium, and High. A two-week randomized, crossover design was used to evaluate ClearVoice-Medium and ClearVoice-High. (ClearVoice-Low was evaluated acutely by all subjects during an initial test session.) These two settings were evaluated chronically to allow subjects the opportunity to use ClearVoice in a variety of everyday situations. Subjects used each gain setting alone for two weeks, then were fit with three programs [HiRes 120 without ClearVoice (Control), ClearVoice-Medium, and ClearVoice-High] for one week, after which they completed a questionnaire. Scores on the AzBio sentence test were compared between ClearVoice and the Control in quiet, in speech-spectrum noise, and in multi-talker babble at each test session. For testing with each type of noise, the SNR was adjusted individually for each subject while using the Control to yield a score approximately half of the score in quiet in order to provide headroom to evaluate any ClearVoice advantage.

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Subjects

Subjects were 46 adults (25 men, 21 women) with postlingual onset of severe-to-profound hearing loss who had used HiRes 120 for at least six months and who had moderate speech perception abilities (defined as a word recognition score of at least 50% in quiet). All subjects had been implanted with a CII/HiRes 90K™ implant and used a Harmony behind-the-ear processor throughout the study. Demographics are summarized in Table 1.

Table 1 Demographics of Study Population

Variable	Mean	Range
Age at implant	54 years	19 to 83 years
Age at time of study	59 years	26 to 87 years
Duration of severe-to-profound hearing loss at time of implant	11 years	< 1 to 48 years
Duration of implant use at time of study	4 years	< 1 to 13 years

ClearVoice Improves Speech Understanding in Steady-State Noise

ClearVoice significantly improved speech perception in steady-state noise (Figure 1), which is representative of the type of noise made by a fan or when riding in a car. The mean improvements in sentence scores were 7.6% for ClearVoice-Low, 8.7% for ClearVoice-Medium, and 10.6% for ClearVoice-High. After ClearVoice was turned on, subjects experienced immediate benefit.

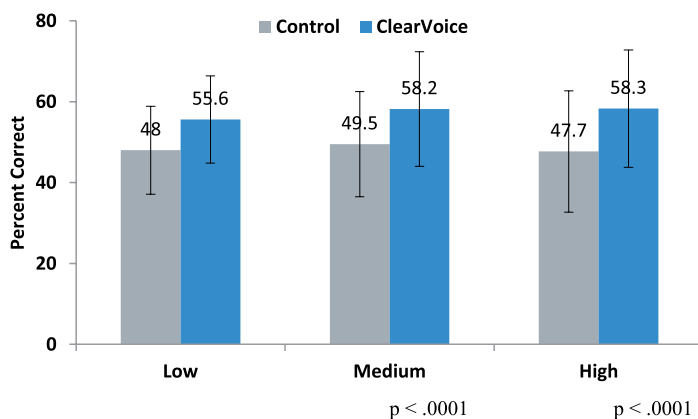


Figure 1. Mean AzBio sentence scores in steady-state noise for the Control, ClearVoice-Low, ClearVoice-Medium, and ClearVoice-High. (Note that the sentence scores in noise with the Control approximate 40-50% because the SNRs used were adjusted individually at the onset of the study to reduce subjects' scores to about half of their scores in quiet.)

ClearVoice Improves Speech Understanding in Multi-Talker Babble

ClearVoice also improved speech perception in multi-talker babble, which is representative of listening to a speaker in environments like a cafeteria or restaurant (Figure 2). The mean improvements in sentence scores were 4.3% for ClearVoice-Low, 3.2% for ClearVoice-Medium, and 1.2% for ClearVoice-High.

Although ClearVoice is designed to function best in steady-state noise, the results below demonstrate that ClearVoice can also be effective for helping individuals hear in noise that is more modulated. Modulated noise like multi-talker babble becomes more like steady-state noise in realistic environments where the modulations are smeared through reverberation, thereby allowing ClearVoice to have the most significant impact on improving the desired speech signal. Thus, ClearVoice would be effective in enhancing speech understanding in places like a classroom, restaurant, or shopping mall.

Individual results in both steady-state and multi-talker babble indicated that all but one subject (98%) showed improvement in noise with at least one ClearVoice gain setting.

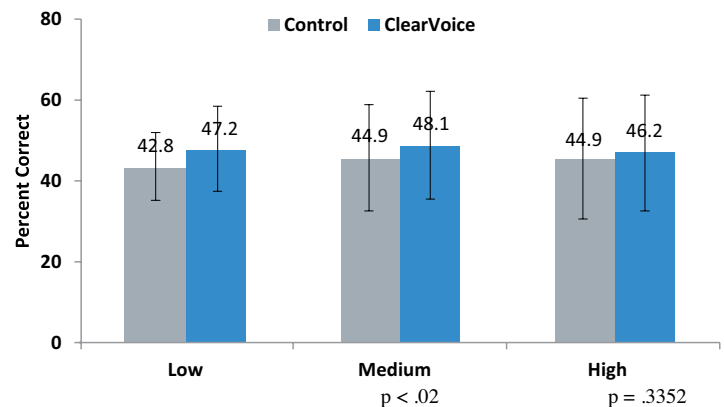


Figure 2. Mean AzBio sentence scores in multi-talker babble for the Control, ClearVoice-Low, ClearVoice-Medium, and ClearVoice-High. Although ClearVoice-High provided benefit, the results were not statistically significant. (Note that the sentence scores in noise with the Control approximate 40-50% because the SNRs used were adjusted individually at the onset of the study to reduce subjects' scores to about half of their scores in quiet.)

ClearVoice Does Not Compromise Listening in Quiet

For all three settings (Low, Medium, High), ClearVoice had no effect on speech perception in quiet (Figure 3). Thus, ClearVoice can be used all the time, allowing listeners to hear better in noise without compromising their ability to hear well in a quiet environment.

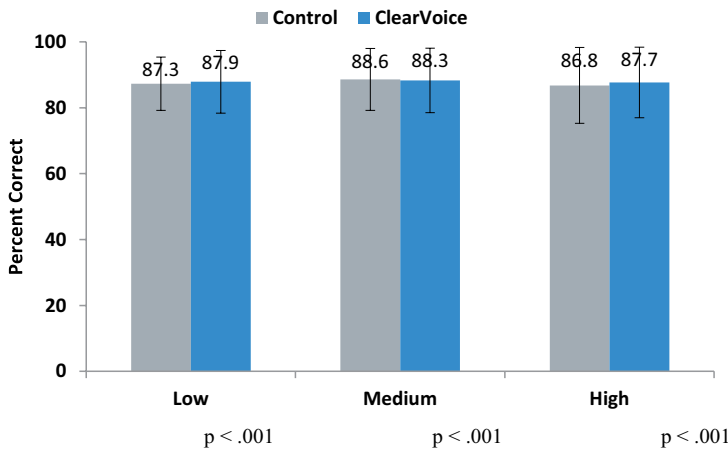


Figure 3. Mean AzBio sentence scores in quiet for the Control, ClearVoice-Low, ClearVoice-Medium, and ClearVoice-High.

These data, taken together with the results in noise, demonstrate that ClearVoice can be used as an everyday program that requires no switching by the user. Accordingly, ClearVoice is ideal for adults who want to hear effortlessly and for active children who need to hear in multiple acoustic environments throughout the day.

ClearVoice is Preferred for Everyday Listening

Preference ratings from the questionnaire indicated that 42 out of 45 subjects (93%) preferred ClearVoice to the Control for everyday listening (one subject did not complete the questionnaire). The mean strength of preference for the 42 subjects who preferred ClearVoice was 7.9 (1 = weak preference, 10 = strong preference). Of the 42 subjects preferring ClearVoice, 22 indicated they would use it all of the time, 17 indicated they would use it most of the time, and three indicated they would use it some of the time. Of the three subjects preferring the Control, all indicated they would use ClearVoice some of the time. In summary, remarkably 100% of study participants would use ClearVoice for some of the time every day.

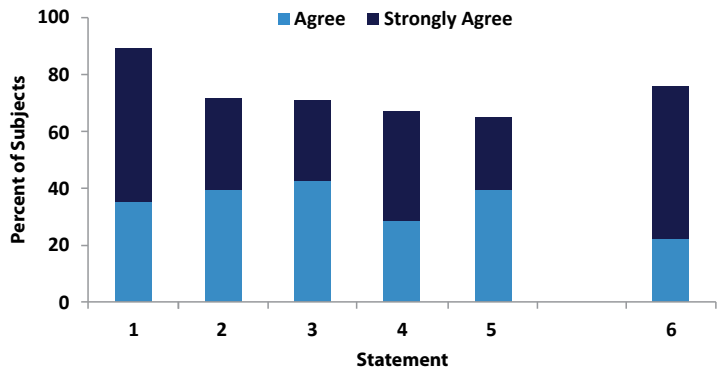
ClearVoice Offers Improved Hearing in Real-Life Situations

All 46 subjects reported that ClearVoice was helpful for listening in a car. Additionally, approximately three-quarters of subjects reported that ClearVoice was helpful while conversing at a party or restaurant (35/46), conversing in a group of people (33/46), or while watching TV or listening to talk radio (33/46) (Table 2). Over 90% of the subjects indicated to some degree that ClearVoice makes listening in challenging real-world situations decidedly easier, less tiring, and less stressful.

Table 2 Percentage of subjects (out of 46) indicating ClearVoice was helpful for nine everyday listening situations.

Situation	Percentage
Conversing in a car.	100%
Conversing at a party or restaurant.	76.1%
Conversing in a group of people.	71.7%
Watching TV or listening to talk radio.	71.7%
Listening to a public speaker in a church or auditorium.	63.0%
Understanding words in music (songs).	58.7%
Listening in a meeting.	54.3%
Using a telephone (including cell phone).	50.0%
Listening in a movie or theater.	34.8%

Subjects also rated statements about the benefits of ClearVoice on a scale from 1 to 7 (1 = strongly disagree, 7 = strongly agree). As seen in Figure 4, at least two thirds of the subjects rated all the statements as a 6 or 7. Notably, over half of the subjects responded with a 7 (strongly agree) to the statements that background noise was less bothersome with ClearVoice and that ClearVoice was the best improvement in listening that they had experienced since getting a cochlear implant.



- 1 = Background noise is less bothersome with ClearVoice.
- 2 = ClearVoice makes listening in challenging situations less tiring.
- 3 = ClearVoice makes listening in challenging situations less stressful.
- 4 = ClearVoice makes listening in challenging situations easier.
- 5 = ClearVoice makes listening in challenging situations more enjoyable.
- 6 = ClearVoice offers the best improvement in listening that I have experienced since getting a cochlear implant.

Figure 4. Percentage of subjects rating six statements regarding the benefits of ClearVoice as 6 and 7 (agree or strongly agree).

Summary

This study shows that ClearVoice is the first and only sound processing innovation to provide clinically superior performance in noise. The results demonstrate that:

- ClearVoice significantly improves speech understanding in steady-state noise
- ClearVoice significantly improves speech understanding in multi-talker babble
- ClearVoice does not compromise speech understanding in quiet, making it an ideal solution for everyday listening
- ClearVoice is preferred by most subjects (93%) for everyday listening
- Almost all subjects (98%) benefit from ClearVoice
- All subjects (100%) like and would use ClearVoice

ClearVoice represents just one of the many pioneering HiResolution sound processing options that have been developed to provide substantial hearing performance improvements for AB recipients in the last ten years. ClearVoice is available as an optional programming feature for users of HiRes 120 sound processing, and can be programmed for any AB recipient with CII or HiRes 90K implants.

These data served to support regulatory approval of ClearVoice in the United States. See 2012 Instructions for Use for complete study results.

Participating U.S. Sites

- House Ear Clinic, Los Angeles, CA
- Johns Hopkins University, Baltimore, MD
- Mayo Clinic, Rochester, MN
- Medical University of South Carolina, Charleston, SC
- Medical College of Wisconsin, Milwaukee, WI
- Midwest Ear Institute, Kansas City, MO
- University of Kentucky, Lexington, KY
- Washington University, St. Louis, MO

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*Not approved for pediatric use in the United States.