

# Outcomes Using Bilateral Cochlear Implants in Adults

Cochlear™ recently collaborated with a number of centers world-wide to measure the benefits of bilateral Nucleus® cochlear implants in adults. These research studies were conducted in the US,<sup>1,2</sup> UK<sup>3,4</sup> and German-speaking centers in Germany and Switzerland.<sup>5</sup> This report summarizes the main findings, gives some guidelines about bilateral implants, and raises new questions about bilateral implants for further research.

For normally hearing listeners the most significant benefits of binaural hearing are improved speech understanding in noisy situations and sound localization. The “cocktail party effect” is an example of binaural hearing benefit, with listeners being able to focus on the person speaking and reduce the impact of background noise. Listening with two ears is essential to locate and identify the person speaking or the location of a sound in the environment.

The benefits of simultaneous bilateral implantation, where the recipient received two implants in the one surgical procedure, were studied in the US multi-center study<sup>1,2</sup>. The benefits of sequential bilateral implantation, where there was a considerable time period between the first and second implants, were investigated in the UK multi-center study.<sup>3,4</sup> Also studied was the cost-effectiveness of bilateral implants. The multi-center study in Germany and Switzerland<sup>5</sup> measured the benefits of sequential and simultaneous bilateral implants in German-speaking recipients.

## **Bilateral advantage**

Overall benefit of using bilateral implants over a single implant.

## **Bilateral headshadow benefit**

Using the ear with the better SNR in spatially separated speech and noise.

## **Binaural squelch**

Additional advantage above the headshadow effect in spatially separated speech and noise; the contribution of the ear with the poorer SNR.

## **Binaural redundancy**

Difference between bilateral and better ear performance in spatially coincident speech and noise.

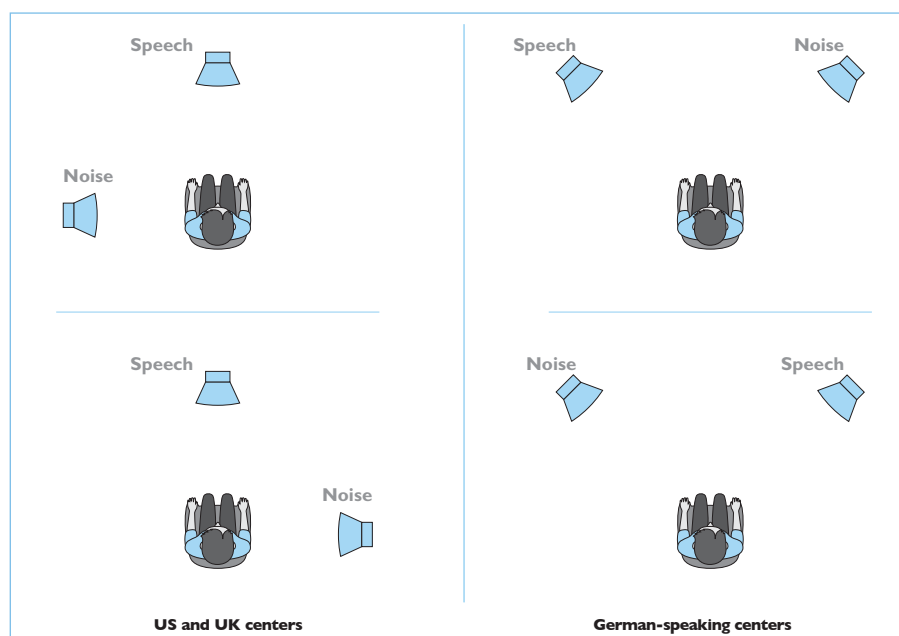


FIGURE 1. Setup for testing in spatially separated speech and noise. In the US and UK centers speech was from the front and noise was either 90° from the left or right. In the German-speaking centers speech was from the left and noise from the right, or speech was from the right and noise from the left. The angular separation of the speakers was 90°.

### ASSESSING BILATERAL SPEECH PERCEPTION

Speech perception in noise was measured using two test setups:

- Spatially separated speech and noise: Speech and noise presented from separate loudspeakers (Figure 1).
- Spatially coincident speech and noise: Speech and noise presented from a single loudspeaker in front of the subject (Figure 2).

Speech perception in quiet, to compare binaural and monaural performance, was assessed using a single loudspeaker in front of the subject.

The bilateral advantage is the overall benefit of using bilateral implants compared to a single implant. In spatially separated speech and noise, the bilateral advantage combines the contributions from the bilateral headshadow effect and binaural squelch. In spatially coincident speech and noise, the bilateral advantage is the difference between the bilateral and better ear scores and is equivalent to the binaural redundancy from diotic hearing.

### WHAT ARE THE ADVANTAGES FROM BILATERAL IMPLANTS?

The same general trends were found across studies even though there were differences in test materials, methods and data analysis.

#### Spatially separated speech and noise

All studies clearly showed that almost all bilaterally implanted adults were able to take advantage of the signal-to-noise ratio (SNR) difference between the ears, resulting from the headshadow effect, and use the ear with the better SNR. Those recipients who could not take advantage of this benefit had very poor performance in one of the ears. This bilateral headshadow benefit is not available to unilaterally implanted recipients. With one ear implanted, there will be occasions when this ear is positioned more favorably but, on average, there will be an equal number of occasions when it is positioned less favorably. With two implants, in many situations one of the ears will likely be positioned more favorably and the recipient can use the ear with the better SNR.

For example, the bilateral headshadow benefit can be clearly seen in the outcomes from

the German-speaking centers (n=23). Bilateral headshadow benefit was measured by comparing the monaural scores (see Figure 3). Scores for the Hochmair-Schulz-Moser (HSM) sentences in noise were analyzed with respect to better and poorer ears monaurally. Figure 3 shows that recipients could take advantage of the difference in SNR between the two ears and use the ear with the better SNR, irrespective of the monaural difference between the two ears.

In addition, a significant bilateral advantage was found using bilateral implants over a single implant in the ear with the poorer SNR. That is, bilateral performance was significantly better than monaural ear performance for the ear closest to the noise source. Results from the US study (n=30) in Figure 4 show the improvement in SNR using bilateral implants compared to a single implant in the ear closest to the noise source for the Bamford-Kowal-Bench Speech in Noise (BKB-SIN) sentence test. These average improvements were greater than 5 dB SNR.

In some cases a significant binaural squelch effect was found. In the German-speaking center study, the average bilateral score for HSM sentences (n=23) was 8% higher than the score for the ear with the better SNR, indicating a contribution from the ear with the poorer SNR.

#### Spatially coincident speech and noise

In normally hearing subjects, the bilateral advantage in spatially coincident speech and noise is typically much smaller than the bilateral advantages for spatially separated speech and noise. Depending on the speech material used, it can be difficult to obtain a significant group effect. A bilateral advantage was found in the German-speaking (n=20) and UK (n=28) studies. However, while the average difference between bilateral and better ear scores was not significant in the US study (n=30), significant individual differences were found for some recipients.

In the German-speaking centers, a significant bilateral advantage was found for the Oldenburger (OLSA) sentence test, six months after bilateral implantation (n=20). The average improvement in SNR using bilateral implants over a single implant in the better ear was 1.4 dB.

In the UK sequential bilateral study, it was also important to compare bilateral scores

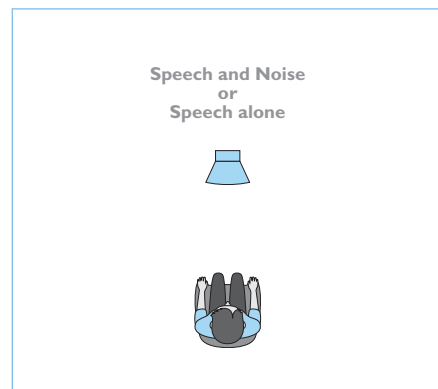


FIGURE 2. Setup for testing in spatially coincident speech and noise, and in quiet. The signal was from a loudspeaker in front of the subject.

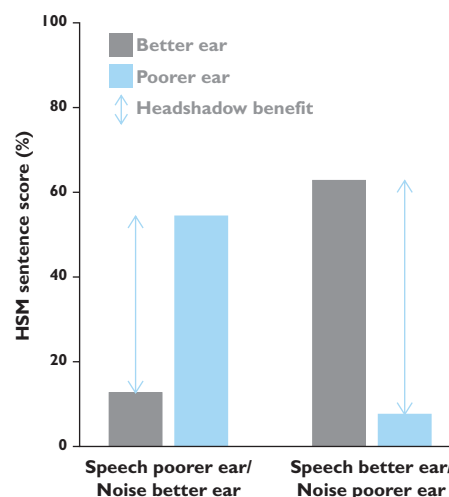


FIGURE 3. The average bilateral headshadow benefit for HSM sentences in noise, from the German-speaking centers. Recipients had six months of bilateral experience (n=23). Significantly higher scores were found for the ear with the better SNR in both test setups.

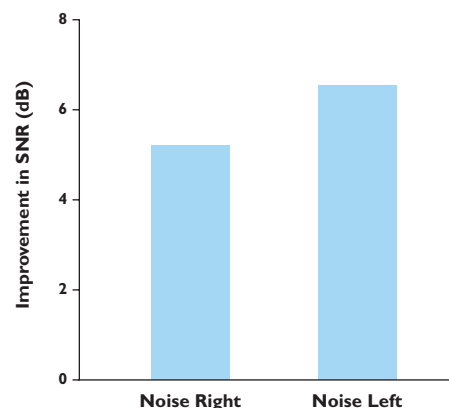


FIGURE 4. The average bilateral advantage from using bilateral implants over a single implant in the ear closest to the noise source for BKB-SIN sentences, expressed as improvement in SNR. Recipients had six months of bilateral experience (n=30). When noise was on the right, this is the difference between bilateral and right ear, and when noise was on the left, this is the difference between bilateral and left ear. Both improvements were significant.

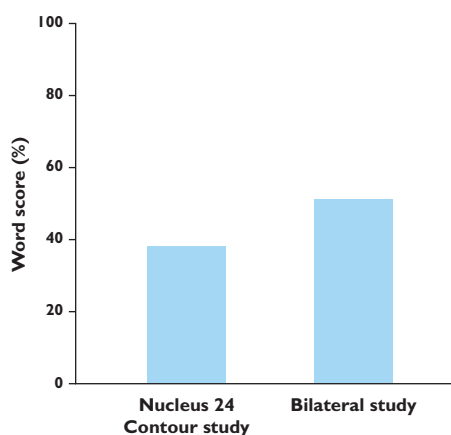


FIGURE 5. Scores for CNC monosyllabic words in quiet at three months comparing the outcomes from two US multi-center studies. The first bar shows the average score from recipients in the Nucleus® 24 Contour™ clinical study (n=56) and the second bar shows the average bilateral score from simultaneous bilateral recipients (n=30).

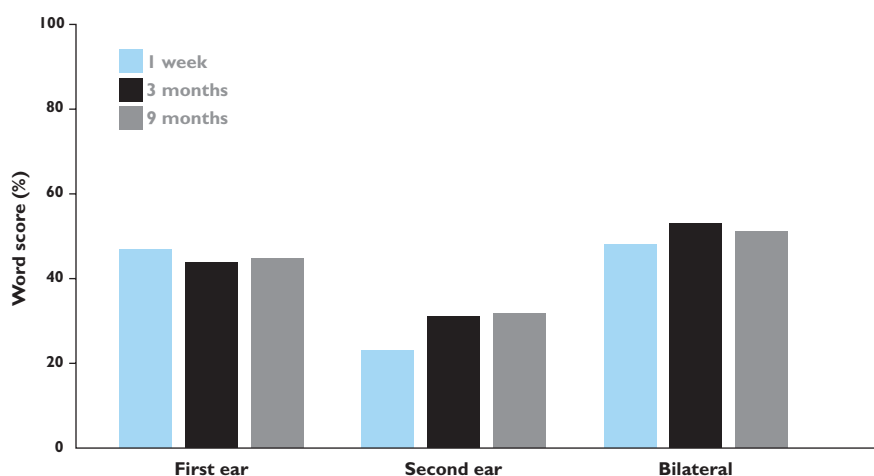


FIGURE 6. Scores for CNC monosyllabic words in quiet showing changes in performance over time in the UK study (n=28). A significant improvement was found between one week and three months for the second ear and bilateral conditions, but there was no significant improvement between three and nine months. There were no significant changes for the first ear.

with scores using a single implant in the first ear as this demonstrates a bilateral advantage from receiving the second implant. A significant improvement of 12.6% was found for CUNY sentences in noise, nine months after receiving the second implant (n=28).

## GUARANTEEING THE BETTER EAR

It is often difficult to accurately predict pre-operatively which ear will give the better post-operative monaural performance. Bilateral implants ensure that the recipient will always be able to take advantage of the better performing ear. In the US study for instance, one third of subjects had a significant difference between ears for CNC monosyllabic words. The average bilateral word score (n=30) for CNC words in quiet was 51% at three months post-operative in this study. This was 13% higher than the average word score from monaurally implanted adults (n=56) who participated in the clinical trial of the Nucleus® 24 Contour™, 38% at three months post-operative<sup>6</sup> (Figure 5). Thus bilaterally implanted recipients will, on average, be able to gain significant benefit because the better ear has been implanted.

## WHAT ARE THE OUTCOMES FROM THE SECOND EAR IN SEQUENTIAL BILATERAL IMPLANTS?

Sequential bilateral implants, where the second ear is implanted some time after the first, was an important focus of the UK multi-center study. This study tested whether there was any consistent asymmetry between the ears, whether performance changed over time, and the contributions from the second ear.

In the UK study the second surgery was on average 36 months after the first surgery, with a range of 12 to 84 months. The first implanted ear was often the better ear when each ear was tested separately. The average difference between the first and second ears was 14% for CNC words in quiet, nine months after bilateral implantation (n=28).

These sequentially implanted adults already have considerable experience with an implant in the first ear. Consequently, there was no significant improvement in speech scores for the first ear when tested over the nine month interval after receiving the second implant (Figure 6). Small but significant improvements in scores were found within the first three months after

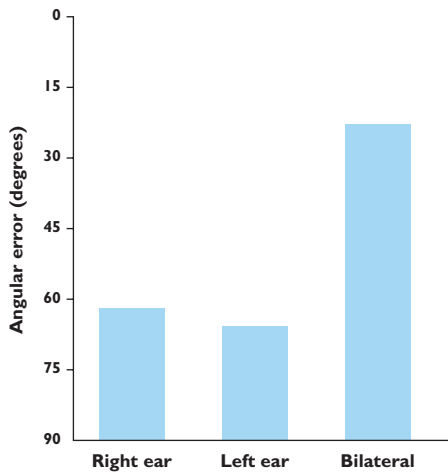


FIGURE 7. Average sound localization scores, expressed as angular error. The localization error for the bilateral condition was significantly smaller than for the other conditions. Data were collected at nine months (n=10).

receiving the second implant for the second ear alone and in the bilateral condition. However, there was no significant further improvement at nine months.

The second ear made significant contributions to bilateral outcomes in both the spatially separated speech and noise and spatially co-incident speech and noise test environments. Therefore, even though the second ear was often the poorer performing monaural ear, it provided considerable benefit to bilaterally implanted recipients. Only one subject in the UK study was not able to integrate the signals from each ear and withdrew from the study, and now does not use the second implant.

### WHAT ARE THE BENEFITS FOR SOUND LOCALIZATION?

It is very difficult to locate the person speaking or the source of sounds in the environment without binaural hearing. Outcomes from these studies have shown significant improvements in sound localization when using bilateral implants over a unilateral implant in adults.

Figure 7 shows the average sound localization results (n=10) from the UK multi-center study.<sup>7</sup> An array of 11 equally spaced loudspeakers were located in the horizontal plane in front of the subject. The stimuli consisted of speech with and without reverberation, pink noise at 60 and 70 dB SPL, short transients, and 1 KHz tone bursts.

The significantly smaller angular error for the bilateral condition clearly showed the benefit of binaural hearing for sound localization. Performance in the monaural conditions was close to chance (67.5°).

Sound localization results have also been reported for a group of 17 adults who received simultaneous bilateral implants in the US<sup>8</sup>. An array of eight loudspeakers spanning -70° to +70° in front of the subject was used. Localization errors were significantly lower using bilateral implants compared with a single implant in either ear. Similar results were found in the German-speaking study, with significantly lower localization error scores (n=16) using bilateral implants for an array of 12 loudspeakers at 30° intervals in a full circle around the subject.

### DOES DUAL MICROPHONE INPUT TO THE ONE EAR GIVE A SIMILAR BENEFIT?

Bilateral input to a monaural implant can be achieved by summing the outputs of two separate microphones, one on each ear, and delivering this signal to the implanted ear. This might provide benefits to monaurally implanted recipients and was investigated in early bilateral studies in Iowa<sup>9</sup> and the UK sequential bilateral study.

In the Iowa study with bilaterally and unilaterally implanted adults (n=5), subjects were tested in spatially separated speech and noise, with speech from the front and noise on the implant side. The second implant was not used by the bilaterally implanted subjects. The satellite microphone was worn on the opposite ear. For the BKB-SIN sentence test there was a significant improvement in SNR using dual microphone input. Thus providing a speech signal from the microphone on the opposite ear with the better SNR was of benefit when noise was on the implanted ear side.

Figure 8 shows the average scores from the UK study for CUNY sentences in spatially separated speech and noise at three months (n=28). There was no significant benefit from the dual microphone when noise was on the first ear side, differing from the findings in the Iowa study. However, there was a significant decrement in performance when noise was on the second ear side. In this situation, the dual microphone adds additional noise from the second ear which is closest to the noise source.

In spatially coincident speech and noise, there was no significant benefit from dual microphone input to the test ear in the Iowa study and to the first ear and UK study.

Dual microphone input was of no benefit for sound localization in the Iowa and UK studies. Important cues for localization, such as interaural intensity differences between the ears, would not be available from dual microphones.

### ARE BILATERAL IMPLANTS COST EFFECTIVE?

Improvements in the quality of life of bilaterally implanted recipients are being investigated as part of the UK sequential study measuring the incremental benefit of

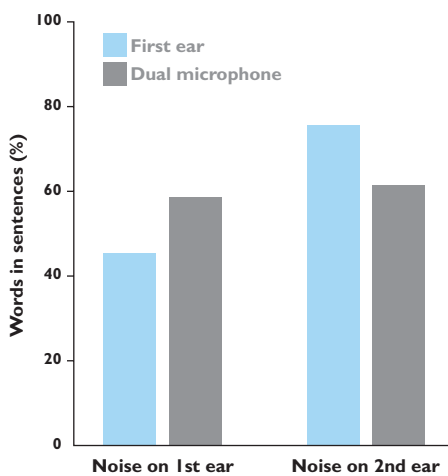


FIGURE 8. Average scores for CUNY sentences in spatially separated speech and noise comparing the first ear alone and dual microphone input to the first ear from the UK study (n=28). When noise was on the first ear side, there was no significant benefit from the dual microphone. When noise was on second ear side, scores were significantly poorer using dual microphone input to the first ear.

the second device. Four areas of benefit are being investigated: spatial hearing and speech perception in noise, otologically relevant quality of life, generic quality of life, and a health utility index.<sup>10</sup>

Early findings have shown that receiving the second implant has significant incremental beneficial effects on spatial hearing and otological aspects of quality of life, but not for the more generic quality of life and health utility.<sup>10</sup>

Bilateral implants will improve quality of life at least as much as a unilateral implant in the better ear. If the overall cost of bilateral implants could be made only 10% to 20% greater than the current cost of a single implant, then the cost-effectiveness of bilateral implants would be acceptable within the cost-effectiveness framework in the UK.<sup>11</sup>

This analysis did not consider some factors which may improve overall cost-effectiveness. These include simultaneous bilateral implantation, which would reduce costs as there is a single hospital stay, and streamlining bilateral speech processor fitting methods which may reduce clinical contact time.

## PROGRAMMING BILATERAL IMPLANTS

- Fitting two speech processors was typically uneventful. It is important to evenly balance the loudness of both devices so that recipients hear sounds with equal loudness in both ears. Sounds will lateralize to the louder ear if loudness is unbalanced. Global adjustments of the C-levels in each MAP was a quick and effective method.
- Some recipients may experience an initial binaural loudness summation when both devices are activated together. While in most cases this was a very small effect, care may be needed in the first fitting session. Over time, minor changes to the MAPs were no longer needed as the recipients adjusted to the loudness. Collaborative studies at the Cooperative Research Centre for Cochlear Implant and Hearing Aid Innovation, Melbourne, Australia, and Medizinische Hochschule Hannover, Hannover, Germany, have also shown that lowering C- and T- levels can result in a reduction in bilateral performance.<sup>12</sup>

- Many recipients in the UK sequential bilateral study commented that the overall pitch of the MAPs differed across the two devices. In most cases, this did not hinder integration of information from both ears. In some cases, adjustment of the Frequency Allocation Tables in the MAPs may be useful, and in extreme cases, where electrode insertion depths are very different, it may be helpful switch off some electrodes to facilitate easier adaptation in the early stages. These electrodes can be gradually introduced after experience.

## WILL SIMILAR BENEFITS BE FOUND WITH CHILDREN?

Cochlear is collaborating in further studies to measure the benefits of bilateral implants in children. These studies will measure the long-term development of binaural hearing for speech perception and localization, language development, and the cost-effectiveness of bilateral implants.

Early findings from a US multi-center sequential bilateral study have shown that children, aged three to 13 years at the time of the second surgery, achieved bilateral advantages in spatially separated speech and noise. In addition, there was some evidence that the second ear improved over time and that the difference between the first and second ears diminished with experience.<sup>13</sup> However, no significant benefit from bilateral implants for sound localization was found within the first 12 months.<sup>8,13</sup> With further bilateral experience, performance has improved, suggesting that localization abilities may take longer to develop in children who were born with bilateral profound hearing loss.<sup>14</sup>

In the US pediatric study, younger children appeared to adapt more quickly to bilateral implants. The older age-group's longer duration of deafness in the second ear appeared to correlate with their subjective difficulty in adapting to the second implant. Yet, even this group showed incremental improvement over time.

Medizinische Hochschule Hannover, Hannover, Germany, is investigating the benefits of simultaneous bilateral implants in children implanted before two years and between two and six years of age.<sup>15</sup> The

preliminary results, at 12 and 24 months post implant, suggested a trend towards better performance on age-appropriate open-set speech measures for bilaterally implanted children compared to unilaterally implanted children of comparable age.

A retrospective study at three centers in Germany<sup>16</sup> examined the benefits of sequential bilateral implants in a group of 21 children, between three and 9.5 years of age, with an average inter-implant interval of 3.5 years. The average bilateral experience was 1.5 years at the time of testing. The first ear was better than the second ear when tested separately for almost two thirds of the children. Significant bilateral advantages were found in spatially separated speech and noise for closed set speech perception. Lateralization ability, measured in an identification task with three loudspeakers at  $-90^\circ$ ,  $0^\circ$  and  $+90^\circ$ , showed significantly better performance in the bilateral condition compared to either the first or second ear alone conditions.

## NEW DIRECTIONS IN BILATERAL STUDIES

In collaboration with leading research centers, Cochlear will continue to investigate the benefits of bilateral cochlear implants. Some important topics include:

- Is there an optimum time period between surgeries when sequential bilateral implantation is being considered, and does this differ for adults and children?
- Can performance be further enhanced by advanced bilateral speech coding?
- Can improvements in microphone technology and noise canceling techniques, such as beam-forming, provide additional benefits to bilaterally and unilaterally implanted recipients?
- When is a hearing aid in the second ear not enough, and a second implant be considered as a viable option? In other words, how much benefit can be provided by a hearing aid in the second ear and will bilateral implantation provide more benefit?

## IN SUMMARY

These collaborative global multi-center studies have clearly shown:

- Bilateral implants provide significant benefits to postlingually deaf adults for speech perception particularly when speech and interfering noise are from different locations. This is a typical everyday listening situation for most recipients.
- Bilaterally implanted adults were able to better localize sound.
- Bilateral implantation ensures that the better performing ear, post-operatively, is always implanted.
- Bilateral fitting was an uncomplicated procedure.
- Dual microphone input delivered to a unilateral implant was of limited benefit, and in some environments resulted in poorer performance.
- Postlingually deafened adult cochlear implant candidates can be considered for bilateral implantation, keeping in mind that reimbursement for the second implant is an issue that must be addressed.
- Early outcomes from children are encouraging, suggesting that children may receive significant benefit from bilateral cochlear implants.

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