

April 11, 2011

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Coverage and Analysis Group, OCSQ
S3-02-01
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Dear Ms. Ellis:

Cochlear Americas, together with its parent and affiliate companies, is the global leader in implantable hearing solutions. Cochlear Americas appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Medicare Evidence Development & Coverage Committee (MEDCAC) May 11th public meeting on the review of Cochlear Implantation for Sensorineural Hearing Loss .

The CMS meeting notice states that the purpose of convening this MEDCAC meeting is to review the evidence on health outcomes attributable to unilateral and bilateral cochlear implantation for Medicare beneficiaries. Subsequent to the meeting notice, CMS published a list of questions upon which the MEDCAC meeting panel will review and vote based on the technology assessment conducted by AHRQ.

Cochlear Americas would like to offer a response to the panel voting questions, with particular attention to the following:

Bilateral Implantation

- While bilateral benefits of cochlear implantation to speech perception and quality of life on the elderly is not the sole subject of the majority of published literature on bilateral CI implantation, that age group is widely represented and, in some cases, performance compared to their 'younger' peers.
- Noble, Tyler, Dunn and Bhullar (2009) compared the domains of disability/handicap, speech perception and localization between younger and older groups of hearing impaired adults utilizing unilateral cochlear implants (1) bilateral CI, (2) and (3) CI + hearing aid in non-implanted ear. Significant benefit after implantation was found with all groups with no significant age-related differences observed within groups 1 and 3. In the bilateral CI recipients (group 2) the younger cohort showed very substantial increases in both performance and self-rated abilities while the older cohort exhibited more modest outcomes. The mixed outcome observed in the older CI + CI group might be due to individual differences in interaction between effects of aging and the ability to integrate binaural cues.

- It is well documented that unilateral cochlear implantation provides significant and substantial benefit to adults with severe to profound hearing loss as compared to a hearing aid. Available in the U.S. commercial market place for close to 30 years for adults, it is fair to say that cochlear implantation as a treatment modality has come to be considered the “standard of care” for those individuals meeting its indications. The transition into bilateral implantation has naturally evolved as did the practice of unilateral hearing aid fitting to bilateral hearing aid fittings over 20 years ago. The recognition of binaural hearing advantages is not disputed and individuals meeting indications for treatment of mild to moderately severe bilateral hearing disability are routinely fitted with bilateral hearing aids. A company review of over 100 articles specifically addressing the use of bilateral cochlear implants was completed last year (currently pending publication). In the review, the psychoacoustic benefits of binaural hearing (e.g. squelch effect, binaural summation and head shadow effect) was well supported.
- The lack of study outcomes indicating a bilateral advantage in speech perception “in quiet” is not an indication of the lack of effectiveness. Generally, speech tests in quiet are not sensitive to differences between monaural and binaural hearing nor are they representative of “real world hearing.” The study outcomes as summarized in the AHRQ report “Discussion and Conclusion” sections support the benefit in speech perception “in noise” with bilateral implantation as compared to unilateral
- The discussion of whether there are data supporting improvements in the psychoacoustic processes of squelch and binaural summation is misplaced. It is primarily an academic argument. The individual patient does not care nor benefit from the underlying physiological mechanism by which binaural listening provides benefit. It matters only that the patients are doing better with two ears rather than one. In fact, head-shadow effects are a very large issue in real world listening situations with background noise and the large benefits received via the second implant even if an individual patient receives less benefit attributable to binaural squelch.
- Omission from the study literature review conducted by AHRQ failed to examine studies on the restoration of the ability to localize sound direction with bilateral implantation. The hearing science literature strongly supports the improvement in localization ability for individuals receiving bilateral hearing treatment (e.g. two hearing aids or two cochlear implants). This has significant safety implications in the “real world” (i.e. identifying the direction of emergency vehicular sirens, identifying the direction of a call for assistance) for all ages.
- The need for longer-term follow-up with bilateral patients does not appear to be supported with data. There is nothing in the evidence that suggests that the incidence and types of adverse events would be any different with bilateral vs unilateral implant patients over time. The majority of adverse events are perioperative or immediate postoperative with the exception of those attributable to device malfunctions (e.g. internal device failure).

Quality of Life

- Well known and recognized experts in the field have studied and addressed the quality of life improvements associated with cochlear implantation and hearing loss. Age-related bilateral sensorineural hearing loss, more prominent in the higher frequencies, is most commonly known in the hearing care professions as presbycusis. This disorder is correlated with decreased quality of life (QoL) and depression and according to the World Health Organization, is a leading cause of years lived with disability in the adult years. While mild to severe disorders are treated with hearing aids, those individuals with more significant losses of hearing audibility or discrimination are treated with cochlear implants. Very positive QoL and speech perception outcomes have been documented in treating severe-profound presbycusis with CIs. In some studies, QoL outcomes have even exceeded expectations of elderly patients.
- In a 2010 publication in Gerontology, researchers reported on the surgical and speech perception outcomes over 12 months on 20 patients over the age of 65 at the time of implantation with a cochlear implant. Major complications such as facial nerve paralysis and foreign body reaction were rare ($n = 2$) with minor complications [disequilibrium ($n = 5$) and wound problems ($n = 5$)] resolving spontaneously or successfully managed conservatively. No significant correlations were found between the background data: unaided thresholds, aided thresholds, duration of profound deafness, duration of hearing aid use prior to CI. Significant differences ($p < 0.01$) between the pre- and post-speech perception categories were found. It was strongly recommended that every CI candidate be informed about possible complications associated with the procedure, especially related to the vestibular system. At the same time, it should be made clear that life-threatening conditions are rare and that the surgery is usually safe.
- In 2008 at the University of Massachusetts, researchers evaluated the impact of cochlear implantation on speech understanding, depression, and loneliness in the elderly. They reported on 17 CI users (9 over 70 years of age and 8 under 60 years of age) and 9 elderly HA users. No perioperative complications were reported in either group of CI users nor significant differences in speech understanding ability in quiet or in noise between elderly and younger CI patients. As for depression, it was found that cochlear implantation decreased perceived depression in both the elderly recipients and loneliness in both elderly and younger recipients and finally, it was found that elderly CI users were no more depressed or lonely than their age-matched peers with mild-to-moderate hearing loss who use HA.
- Earlier studies have also supported improvement in QoL in speech perception with CIs in the younger and older populations. In 1995, Kelsall, Shalloo and Burnelli reported on 28 patients older than 60 years and with profound bilateral sensorineural hearing loss implanted with a CI. Significant improvement of bi-syllabic words and sentences scores (postimplantation) was noted. The patients who were over 70 years performed as well as those who were younger with the surgical procedure well tolerated in all patients with the exception of one patient that developed a postoperative vertigo due to a peri-lymphatic fistula. Their conclusion was that

cochlear implantation offers improvement in speech perception to the elderly population, as in the younger population.

- Bichey and Miyamoto (2008) illustrated the cost-utility and quality of life improvements for bilateral compared unilateral implantation. (Bichey BG, Miyamoto, RT. Outcomes in Bilateral Cochlear Implantation. Otolaryngol Head Neck Surg 2008; 138(5):655-661)
- Litovsky et al. (2006) identified a large group of subjects representing typical U.S. patients and demonstrated a significant improvement across questionnaire measures of hearing and perceived benefit with patients with bilateral implantation vs unilateral

Thank you very much for your consideration of our comments.

Sincerely,

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Cochlear Americas

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