The contributions of William F. House to the field of implantable auditory devices

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Research paper

William F. House was a pioneer in the evolving field of cochlear implants and auditory brainstem implants. Because of his vision, innovation and perseverance, the way was paved for future clinicians and researchers to carry on the work and advance a field that has been dedicated to serving adults and children with severe to profound hearing loss. Several of William House's contributions are highlighted in this prestigious volume to honor the recipients of the 2013 Lasker-DeBakey Clinical Medical Research Award. Discussed are the early inventive years, clinical trials with the single-channel cochlear implant, the team approach, pediatric cochlear implantation, and the auditory brainstem implant. Readers may be surprised to learn that those early contributions continue to have relevance today.

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List of abbreviations: ABI, auditory brainstem implant; CAP, Categories of Auditory Performance; CDaCI, Childhood Development after Cochlear Implantation; CI, cochlear implant; FDA, Food and Drug Administration; Hz, hertz; kHz, kilohertz; NF2, Neurofibromatosis Type 2; NIDCD, National Institute on Deafness and Other Communication Disorders; NIH, National Institutes of Health.

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prototype in 1961, one of whom was implanted with a multiple-electrode device. The first “take-home” wearable device, a single-electrode CI, became available in 1972 (House and Urban, 1973; Danley and Fretz, 1982). Dr. House’s original motivation for instigating this work was based on a deep desire to help children with profound hearing loss. In his memoir he writes.

“... I had seen deaf children with some residual hearing who could hear a degraded signal with a hearing aid and could learn lipreading. It seemed possible that if an implant could give totally deaf children some hearing, they could learn lipreading, be successful in an oral school, understand the English language and learn to read” (House, 2011, p. 67).

Cochlear implantation of the first humans in the United States became a source of heated debate between the early CI surgeons and their peers in basic science about the ultimate value and potential risks of human experimentation (House and Berliner, 1991; Levitt, 2008). Even the National Institutes of Health (NIH) imposed itself into the dispute by issuing a request for proposals to conduct an independent study on patient outcomes with the first wearable CIs. The University of Pittsburgh was selected as the site to carry out this study. The eventual results were published in a supplement (Bilger et al., 1977), which came to be known as “The Pittsburgh report”. Thirteen patients from two sites in California, the House Ear Institute in Los Angeles (n = 11) and the University of California, San Francisco (n = 2), traveled to Pittsburgh to be assessed on a number of test protocols. To the surprise of many the results of the study were generally positive, reflecting findings similar to those that the early clinicians had been reporting: 1) detection thresholds were improved across a broad frequency range with the implant activated, and 2) lipreading and voice monitoring were improved with use of the implant, as was quality of life. There also were two negative findings from the Pittsburgh study; noise was bothersome and postural instability was increased on some of the balance test conditions.

This finding of postural instability surprised the Los Angeles group because balance had not been problematic for their CI patients. In response to this negative finding, Dr. House and his team conducted a study to investigate potential adverse vestibular effects. Surprisingly, the results from the House vestibular study were found to be quite the opposite of the Pittsburgh findings. It was discovered that postural stability actually improved with electrical stimulation on some test conditions (Eisenberg et al., 1982). This positive finding was later verified in a study by Buchman and his colleagues (Buchman et al., 2004).

The Pittsburgh study was to become a turning point in the evolution of CI technology. The generally positive findings gave the early investigators a green light to move forward in human cochlear implantation. As a consequence, auditory scientists began to work hand in hand with clinicians in a synergistic relationship to study performance outcomes. Engineers were inspired to develop new electrode designs and advanced speech processors. Today clinical and research studies on the CI enjoy a strong presence in journals dedicated to hearing research, otology, audiology, speech-language pathology, and deaf education. We have Dr. House and the other pioneers to thank for their perseverance and fortitude to meet those early challenges and to not be deterred by them.

2. Clinical trials and the team approach

The single-channel CI was the first auditory implantable device to undergo a multicenter clinical trial in adults with official oversight from the United States Food and Drug Administration (FDA). Manufactured by the 3 M Company in 1982 and based on the 1972 single-electrode processing algorithm (Danley and Fretz, 1982), the single-channel device became known as the 3 M House CI (Fig. 2). The processing scheme was fairly simplistic; the incoming stimulus was band-pass filtered (340–2700 Hz) which amplitude modulated a 16-kHz sinusoidal carrier wave (Fretz and Fravel, 1985). Following the clinical trial, an advisory panel of experts convened by the FDA reviewed the adult data to determine safety and efficacy. The data confirmed that the CI was feasible in adults and that the procedures could be carried out safely in different clinical settings (Berliner and House, 1982). In November, 1984, the 3 M House CI became the first CI to receive marketing approval by the FDA. Formal approval by a regulatory agency represented another important milestone in the evolution of the CI.

The design and implementation of multicenter clinical trials necessitated the formation of clinical teams. Thus, another major contribution from the early CI trials was the establishment of the multidisciplinary team. During the original development of the CI,
even before the first human trials, Dr. House worked primarily with engineers. When the first group of adults with profound hearing loss was implanted with a wearable device, professionals from clinical disciplines become integral to the project.

The CI clinical program saw the teaming of the otolaryngologist and the audiologist as equal partners in this endeavor. Before the availability of the CI, audiologists typically worked directly for the physician, or provided a service to the physician through a hospital clinic or private practice. From the very inception of the CI, the audiologist came to play a vital role on the CI team. Today, the audiologist conducts assessments to determine candidacy, activates and programs the speech processor, carries out aural rehabilitation, and tracks speech perception through regular test intervals.

Dr. House’s first clinical team consisted of audiologists, a speech-language pathologist, clinical psychologists, and an engineer (see House et al., 1976). Initiation of the pediatric CI program in 1980 saw the team expand with the support of pediatric specialists in audiology, speech-language pathology, psychology, and education of the deaf. Today, other team members may include radiologists, electrophysiologists, neurosurgeons, pediatric anesthesiologists, social workers, physical and occupational therapists. The multidisciplinary team has become the standard of care for clinical CI programs and now clinical ABI programs. The field of implantable auditory devices has Dr. House to thank for being the first to recognize the importance of the team approach.

3. Pediatric cochlear implantation

William House is credited with being the first surgeon to implant children with profound hearing loss. Most will therefore be surprised to learn that Dr. House was not the first surgeon to implant children. Although it is a fact that William House implanted a 10.8-year-old child in the summer of 1980, Dr. Claude-Henri Chouard from Paris reported implanting teens as early as 1976 (Chouard et al., 1983). Regardless of this technicality, William House does deserve credit for being the first surgeon to implant very young children. He implanted a 3-year-old deaf child in 1981 (Eisenberg and House, 1982). The decision to implant children was neither trivial nor capricious. At that time results from postlingually deafened adults who were implanted with the single-channel system were showing modest performance gains on closed-set speech perception tests (Thielemier et al., 1982). Moreover, the availability of rare earth magnets removed a major obstacle for aligning the external transmitter and internal receiver across the skull, ensuring a consistent transmission of the signal (Dormer et al., 1980).

The decision to implant children created a maelstrom of criticism, with even greater vitriol than what had been experienced with implants in adults. The CI professional community at large remained unimpressed by the incremental improvements that resulted from the single-channel device, particularly when the first-generation multichannel devices were beginning to show evidence of open-set speech recognition by postlingually deafened adults.

Dr. House and his team did not carry out the pediatric CI trials in a vacuum. At a relatively early point in the trials Dr. House organized two workshops, inviting leading practitioners and researchers in the field of deaf education and aural rehabilitation to help guide the pediatric CI team. Some of those experts were antagonistic and turned down the offer to participate. Others, though skeptical, chose to attend and learn more about this technology and its potential use for children with hearing loss. Among the attendees were Mary Joe Osberger, Arthur Boothroyd, Daniel Ling, Julia Davis, and Norm Erber. Despite the hostile culture, William House and his team initiated the first pediatric CI trial in the United States (Eisenberg et al., 1983). By 1985, a supplement to Ear and Hearing was published, detailing the results from the first 164 children with the 3 M House single-channel CI (Berliner et al., 1985). The findings from this report confirmed that the medical/surgical risk was minimal (House et al., 1985; Luxford and House, 1985), and that small but significant gains were attained from pre- to post CI on closed-set, auditory-only speech perception tests (Thielemier et al., 1983) and speech production and language measures (Kirk and Hill-Brown, 1985).

It is important to recognize that the average age at implantation for the group of 164 children was approximately 8 years. Thus, the relatively low levels of auditory functioning observed with the single-channel system would not seem so surprising today when one considers that early access to sound is essential for successful auditory development in children with congenital deafness. However, most of the clinical and basic scientists at that time were convinced that the incremental gains by children were explicitly due to the limited auditory information delivered from the single-channel system.

In fact, those of us working with the first group of implanted children were in agreement with this opinion. Imagine how surprised and delighted we were to have been proven wrong. In a paper that posed the question “... have we erred in our expectations?”, we presented the first evidence of open-set speech recognition by a small group of children using the single-channel CI (Berliner and Eisenberg, 1987). In this paper, 9 of 10 children recognized words presented in an open-set format and 10 of 19 children comprehended simple sentences presented in an open-set format. This startling finding of open-set speech recognition in children with the single-channel CI was later analyzed in a larger sample consisting of 51 children with the single-channel CI (Berliner et al., 1989). In that second report, 52% of the sample achieved open-set word recognition and 41.5% attained open-set sentence comprehension. By the late 1980s, we were beginning to understand that performance with the CI was attributed to more than the device characteristics. Other influences, such as child factors, family involvement, and intervention type, interacted in ways to support overall performance outcomes of the developing deaf child.

Many investigators and clinicians chose to ignore or even refute those rather remarkable findings. In response, Dr. House invited well-known investigators in the area of pediatric hearing loss to test those high-performing children on measures of their choosing. Ann Geers and Jean Moog from the Central Institute for the Deaf accepted the invitation. They verified open-set speech recognition in 7 of the 12 children they tested (Geers and Moog, 1988).

The 3 M House single-channel device was the first CI to undergo FDA clinical trials in children. The data from 265 children collected through September, 1987 were submitted to the FDA for marketing approval (Berliner et al., 1990). The FDA advisory panel of experts evaluated the data and recommended that the device be approved for use in children. However, before formal marketing approval was officially granted by the FDA, the 3 M House device was sold to another CI company and essentially “shelved” due to the growing interest in multichannel technology.

Today, most professionals engaged in the field of implantable auditory devices believe that William House was strongly resistant to the multichannel CI and that he held firm to the concept of single-channel implants. What most may not realize is that Dr. House was the first surgeon in the United States to implant a young child with the Nucleus multichannel device (see Luxford et al., 1988, Case #1).
It is true that in his later years Dr. House focused his complete attention on single-channel technology. Many of his peers believed that such steadfastness to the simpler type of implant diminished his stature and perhaps his legacy. Alternatively, one could view this resolve from a different perspective. William House’s commitment to the single-channel concept was not tied to financial gain or fame, but to a sense of personal integrity he maintained throughout his life (comments attributed to Bob Shannon in a memorial to William House at the 2013 Cochlear Implant Auditory Prosthesis [CIAP] meeting).

To my knowledge, at least one family that participated in the early pediatric single-channel trial chose not to upgrade to the newer, multichannel technology because of strong loyalty to William House. This child, now an adult, had been able to develop spoken language and achieve open-set speech recognition with the single-channel system. Thus, it is particularly poignant that this now-adult CI recipient and his mother traveled to Oregon to visit William House as he was nearing the end of his life. During that visit, Dr. House gave the young man his blessing to upgrade to multichannel technology. The young man went home, began to research multichannel devices, and is now a multichannel user.

4. Auditory brainstem implants

With the recent media attention surrounding the ABI in children, many are under the impression that this technology is of recent origin. This couldn’t be further from the truth. In 1979, Dr. House with neurosurgeon William Hittsberger implanted an electrode on the cochlear nucleus of an adult with Neurofibromatosis Type 2 (NF2) (Edgerton et al., 1982). Results from a series of psychoacoustic experiments led the investigators to conclude that performance with the ABI was similar to that of the single-channel CI.

This first case was soon followed by a small group of patients as part of an early trial of ABIs in adults with NF2. Notably, results indicated that speech perception scores were either on par with single-channel CI performance or lower (Eisenberg et al., 1987). To our amazement, the early ABI experiments in humans were not subjected to the same level of controversy or enmity as had been experienced during the early CI trials; the scientific community seemed to embrace the notion of direct stimulation of the cochlear nucleus in patients with NF2. In 1986, the ABI team was awarded the International Bioengineering Prize for the outstanding paper presented at the International Symposium on Artificial Organs, Biomedical Engineering and Transplantation, held in Salt Lake City Utah (Eisenberg et al., 1988).

During the late 1980s, Bob Shannon took the helm of the ABI project at the House Ear Institute. He and his team set out to develop a more technologically advanced ABI (Brackmann et al., 1993; Shannon et al., 1993). In partnership with Cochlear Corporation, this new multichannel ABI underwent FDA clinical trials. The Nucleus multichannel ABI received marketing approval by the FDA in the year 2000 for individuals 12 years and older with NF2.

As an aside the “other William”, Dr. Hittsberger, was ostracized by his own neurosurgical colleagues because of his partnering with a neurotologist for acoustic tumor surgery. Fortunately the FDA approval of the ABI restored Dr. Hittsberger to good standing with his peers. William Hittsberger died on February 13, 2014 at the age of 83 years, a little over a year after the death of William House.

Today, FDA safety trials of the ABI are presently underway in young non-NF2 children at several locations in the United States, including our own clinical trial in Los Angeles, which received official approval by the FDA on December 7, 2012. Another recent milestone came in the summer of 2013, when the National Institute on Deafness and Other Communication Disorders (NIDCD) of the NIH awarded the first pediatric ABI clinical trial grant to our Los Angeles-based team. These pediatric trials have been long in coming.

The fact that we are even considering pediatric ABI clinical trials in the United States can be attributed to the efforts of a more recent pioneer in this field—Vittorio Colletti, M.D. from Italy. Professor Colletti is the first to show improved performance outcomes with the ABI in non-NF2 adults and children when compared to outcomes of adult ABI recipients with NF2; (Colletti et al., 2005).

Once again history may be repeating itself with the ABI in children. Just as we had formed low expectations for children with the single-channel CI, similarly low expectations were first considered for children with ABIs. As before, we are becoming pleasantly surprised by the data coming out of Italy and by our own experiences testing several children with ABIs during a time when the FDA was not receptive to a pediatric ABI clinical trial. Our group had an opportunity to assess performance in several children with cochlear nerve deficiency who had traveled to Italy for ABI surgery. In two of those children, we were able to track speech recognition development on the same battery of tests administered to children participating in the NIH-supported Childhood Development after Cochlear Implantation (CDaCI) national study (Eisenberg et al., 2006; Fink et al., 2007; Niparko et al., 2010). We also were able to compare both children’s speech recognition outcomes against those of the CDaCI sample population. Results demonstrated that the two pediatric ABI recipients progressed at a slower rate than that observed for the CI group (Eisenberg et al., 2012). Impressively, one of the two children achieved open-set word recognition on formal assessments after four years of experience with the ABI (Eisenberg, 2013). Evidence of open-set speech recognition is similarly being reported for pediatric ABI users with cochlear nerve deficiency by the Verona group (Colletti et al., in press), as documented on the Categories of Auditory Performance (CAP) scale (Archbold et al., 1995).

As a young audiologist who worked alongside William House during the first pediatric CI trials and the first adult ABI trials, the pediatric ABI clinical trial represents my coming full circle after almost 40 years working in the field of implantable auditory devices. Dr. House did not live to see the fruits of his labor make it to this point in the evolution of the ABI. Indeed, there is some irony to the fact that our Los Angeles-based team received formal approval by the FDA to conduct an ABI safety trial in children on December 7, 2012—the exact date of William House’s death.

5. Final thoughts

Levitt (2008), in a guest editorial, aptly referred to the CI as the “enfant terrible of auditory rehabilitation,” characterizing the evolution of this technology in the following way:

“Born in controversy
Raised in dogged determination
Matured in grace and glory” (p. ix)

The first two of these statements easily could point to the efforts of William House in the early development of implantable auditory devices. On the evolutionary timeline of this technology, the single-channel CI and the first ABI device were to be short-lived and replaced by multichannel technology that surpassed the early devices both in technological sophistication and patient outcomes. As Dr. House faded into the background in the CI and ABI worlds, the path became paved for the new innovators. Today, young people...
working in the field of implantable auditory technology may not be familiar with the history of the CI and ABI, or the literature that chronicles those endeavors. Indeed, it is the early literature that stands as a testament to the hardships encountered by William House and the other pioneers. Dr. Bill bucked the system. We’re glad he did.

Acknowledgment

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References


House, W.F., 2011. The Struggles of a Medical Innovator. Cochlear Implants and Other Ear Surgeries. William F. House D.D.S., M.D., All rights reserved.


