The New Horizon of Vestibular Implants for Ménière’s Disease

Gabrielle O’Brien

The patient was 56, male, and almost out of options. For the last eight years he had suffered from uncontrollable Ménière’s disease, plagued with disruptive and unpredictable episodes of vertigo. He had tried a low salt diet, diuretics, and a shunt to reduce pressure in his inner ear, but the attacks always returned. Limited choices remained: he could pursue an invasive line of treatment that would destroy parts of his ear to quell the symptoms, he could live with the frequent and debilitating episodes, or he could enroll in a clinical trial of an experimental device called a vestibular implant.

He became the first patient in the first clinical trial of a vestibular implant for Ménière’s disease. The idea behind the device was that electrical stimulation could relieve episodes of vertigo by sending an overriding signal to the brain. It was not intended as a replacement for the body’s natural sense of balance, but as an electrical pacemaker of sorts that could be dialed in until an attack subsided. The implant, in theory, would be no more risky or damaging than the traditional treatments for intractable Ménière’s disease, and might do far less permanent damage to the patient’s balance and hearing.

The device was developed at the University of Washington in a collaboration between Drs. Jay Rubinstein and James Phillips, experts in bioengineering and vestibular physiology respectively¹. They had accelerated the process of building, testing, and fabricating a novel implant by piggy-backing on the innovations of a prostheses already available on the market, the cochlear implant, which restores a degree of hearing to profoundly deaf individuals. The cochlear implant consists of a string of electrodes that sit inside the snail-shell shaped cochlea and stimulate the auditory nerve. A processor is worn outside the head that communicates to the implant when to let electrical current flow, and how much. Backed by a contract from the National Institute of Health, the Washington team paired with industry giant Cochlear Ltd. to hack the existing cochlear implant design. Instead of a chain of electrodes, it would have three branches, like a pitchfork, to suit the vestibular anatomy.

On the day of the operation, the surgical team exposed the patient’s vestibular organ and meticulously placed the device’s three branches of electrodes with a pair of jeweler’s forceps². Each branch was positioned to target a unique bundle of vestibular neurons, which would allow the device to signal three independent directions of head rotation. Previous surgeries done with rhesus macaque monkeys showed promise; the placement of the device had been close enough to the vestibular nerve to send signals to the brain. More importantly, the surgery seemed to leave normal vestibular function and hearing intact. This was especially important for the potential treatment of Ménière’s, since the symptoms are episodic. It was hoped that, like the macaques, the first human patient would not have to sacrifice balance or hearing in his quest for periodic relief.

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On activation day, the testing room brimméd with equal parts anxiety and hope. There were no guarantees that the device would work, that the electrodes would be in the right place, or that the brain would even be able to make sense of the new, foreign signal. Although device activation is normally an intimate moment shared between doctor and patient, this time the room was packed. A crowd gathered from the experimental team, including electrical engineers who had written the device’s software and electrophysiologists who had conducted the primate studies.

A very small amount of current was sent through one of the electrodes. The researchers were watching for nystagmus—an involuntary deflection of the eye, caused by the vestibular system, in the direction opposite the perceived rotation of the head. That would be proof that the device was stimulating its intended target. As the current flowing through the electrode increased, the eye movements began to appear, and then became faster. The patient even described feeling himself rotate to the right. At least one electrode was working as expected. When the second electrode was stimulated, he felt as if he was drifting towards the ground and to the left. When the researchers turned on the third, they could not elicit eye movements, but the patient felt the room spin. Never before had anyone been so relieved to experience vertigo.

It must have been an encouraging moment: if the device could make the patient experience phantom rotations, then maybe it could cancel a Ménière’s attack, too. The real test would come the next time he experienced an episode. He was given a processor to take home and instructed to push a button when he noticed symptoms. First a small amount of current would flow, then if the dizziness was unremitting, he could dial up the intensity, finding a sweet spot between ineffectively weak and overpoweringly strong. Six months after the operation, when he began to feel the onset of an attack, he turned on his device and experienced some relief using the device’s lowest setting.

As with all innovative devices, there were unexpected challenges and concerns. After the implantation, things were changing inside the patient’s ear. His score on a speech test dropped precipitously, from recognizing 40% of words to only 4% after a year with the implant. His normal everyday vestibular functioning was also declining. In a test 63 weeks after the surgery, two of the electrodes failed to elicit any eye movements, and the third could only do so to a diminished degree. The effects of the device were mysteriously fading away.

The same pattern occurred in the other three patients enrolled in the study. Puzzlingly, the primate study had shown far more long term success, with electrodes working long after the surgery and little permanent damage to hearing and balance. Why were the rhesus macaques so different? The researchers believed that it was unlikely to be a result of surgical trauma—macaques have a similar, but smaller, vestibular organ. If anything, the risk of surgical damage would have been greater in the animal study. Of course, the primates all had healthy ears to begin with, unlike the Ménière’s patients whose vestibular organs and cochleae had endured years of strain from the disease. Perhaps the damaged ears of the patients were less able to recuperate from the added insult of surgery. Another explanation would be that the primates were stimulated more regularly than the human patients, which may have helped their vestibular nerves thrive.

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The clinical trial ended after four patients, but the mission for a viable vestibular implant for the Ménière’s community continues. The next generation of the device has already been designed, tested in a macaque, and is currently awaiting federal approval for human use. This time, the electrode array will be more mechanically stable, and the electrodes have changed shape to allow higher stimulating currents. The biggest upgrade, though, is the inclusion of a cochlear implant in the device, which may prevent device recipients from becoming almost totally deaf in the implanted ear. The experience of listening with a cochlear implant still falls considerably short of natural hearing, but for many patients living with intractable Ménière’s disease, it may be a worthy trade for long-term relief.

Research is ongoing at a few other sites around the world: at Johns Hopkins University, a clinical trial of a vestibular implant that dynamically senses head motion has begun this year. And in Europe, a collaboration between groups in Maastricht and Geneva continues to investigate experimental vestibular implants in patients with bilateral loss of vestibular function. These projects are currently targeting individuals with severely degraded normal vestibular function, not episodic Ménière’s attacks. But all teams will have to grapple with the same questions: what should the electrical output of the device look like to be most easily interpreted by the brain? How much current is going to be needed to drive the device, and how will it change over time? What is needed to make the implants viable for years of success? What sorts of surgical and software innovations will it take? Who can be helped by such a device, and will it justify the personal and financial burdens?

For the clinicians and Ménière’s patients frustrated with the limited treatment options at their disposal, the vestibular implant represents an avenue of progress and hope. Although it is in its earliest stages now, available only to intractable cases where conservative treatments have been exhausted, one need only look to the cochlear implant to see a vision for the future. The cochlear implant, with humble origins as an experimental, last-resort device in the 1960s, is now a mainstream medical device that has improved the lives of hundreds of thousands of patients worldwide. It hardly seems radical, then, that its close cousin the vestibular implant could in our lifetimes become a viable solution for people whose relief is long overdue.
Bibliography


