33rd Annual International Conference of the IEEE EMBS
Boston, Massachusetts USA, August 30 - September 3, 2011

An integrated vestibular-cochlear prosthesis for restoring balance and hearing

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***Abstract*—An integrated vestibular-cochlear implant can be rapidly prototyped and clinically tested by modifying an existing modern cochlear implant. The modifications include addition of gyroscope sensors and reallocation of several electrodes that are normally used for auditory nerve stimulation to the semicircular canals, while sharing the external DSP processor and the internal receiver/stimulator. This paper discusses the validation issues related to hardware and software design that arise in integrating electric hearing and balance onto a single device. The device's initially targeted population will be deaf individuals who also have vestibular impairment since there is a strong ethical justification for vestibular implantation along with minimal additional surgical risk. Because of widespread usage of ototoxic drugs and unique genetic mutations, the patient population with both impaired hearing and balance function is especially prevalent in Asian countries such as China and India. Should such an integrated vestibular-cochlear implant be verified, it could be used to restore balance or treat a wide array of vestibular disorders.**

Keywords- vestibular; cochlear; semicircular canals; electric stimulation

I. Introduction

There is an urgent need to improve the quality of life for patients that have lost vestibular function due to disease or injury. For example, falling is one of the major reasons for emergency room visits, sometimes even causing fatal injuries, particularly for the elderly population [1-3]. So far patients mostly rely on sensory substitution and physical therapy to overcome their impaired vestibular function [4-6]. Despite extensive research, no vestibular implants (VI) are commercially available at present.

In contrast to a cochlear implant (CI), which is mature and in widespread clinical use to restore hearing [7], the VI is still in its infancy. This is due in part to gyroscopic sensing technology lagging behind acoustic microphones and digital signal processing in terms of size and cost. Otherwise, both the technology and theory for electrical stimulation of vestibular nerves are solidly established [8-10] as is vestibular nerve survival under varied pathologies [11-14]. Only with the recent miniaturization and mass production of gyroscopic sensors using micro-electromechanical systems (MEMS) have potential vestibular prosthetic systems become both feasible and affordable [15-19].

Since many individuals with vestibular impairment also have normal hearing, a VI may create an unnecessary risk, given that visual feedback is often sufficient for rudimentary balance. The potential risk of hearing loss, even if minimal, would not be acceptable in this patient population. However, deaf individuals who are candidates for CI but also have vestibular impairments would be ideally suited for an integrated vestibular-cochlear prosthesis. Because of the minimal additional surgical risk, the worst case scenario for such an integrated device in these already deafened patients is that, even if the VI does not work, they would still have use of a functional CI.

There are two patient populations that are susceptible to both balance and hearing impairment. Patients in the first group are those who have experienced ototoxicity due to aminoglycosides; approximately 20% of patients treated with aminoglycosides will result in some hearing loss. While not used commonly in the U.S., in developing countries such as China and India, aminoglycosides are still in widespread use because of its effectiveness and low cost. A mitochondrial genetic mutation (12S rRNA) in Asians results in hypersensitivity to this antibiotic, and even a single dose can cause both deafness and loss of vestibular function [20, 21]. This mutation has been found in more than 1:1000 of the general population in China [22]. The second population consists of elderly patients who are likely to suffer from both impaired balance and hearing functions. Severe high frequency hearing loss due to aging and other factors, can be treated by CIs with short electrodes that can restore high frequency hearing loss while preserving low frequency acoustic hearing [23].

For these hearing and balance impaired patients, an integrated vestibular-cochlear implant would allow for both hearing and balance to be restored in a single surgery with minimal additional risk. Should there be any failure or problem with the semicircular canal implantation, those specific electrodes can be turned off, and the system will operate as a normal cochlear implant. The potential benefits of such an integrated device can not only further our understanding of the vestibular system and function (as CIs have done for audition), but also help achieve clinical acceptance of the VI as a means to treat balance-related impairments.

Manuscript received April 14, 2011. This work was supported by NIH Grant P30 DC008369 (F.-G.Z) and Nurotron Biotechnology Inc.

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II. System Specificiations

A. Technical approach

An overview of the integrated vestibular-cochlear implant (VCI) is shown in Figure 1. Inputs from microphones and gyroscopic sensors are processed by a single DSP chip and translated into stimulation parameters appropriate for each sensory modality. These are encoded and transmitted over a radio frequency (RF) link where it is decoded by a single, surgically inserted implant. The implant then delivers current pulses through electrodes separately implanted in the cochlea and semicircular canals (SCCs).

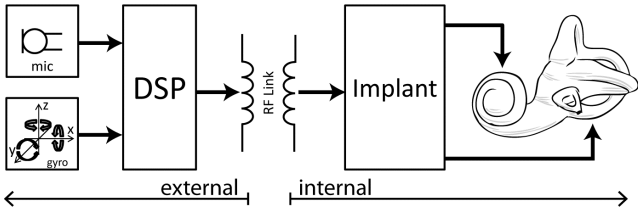

Fig. 1. Block diagram of an integrated vestibular-cochlear implant (VCI)

B. Vestibular prosthesis specifications

The design will allow for stimulation of all three SCCs. The characteristics of vestibular stimulation are modeled after that described in [16]. Because the SCCs normally operate as a bilateral push-pull pair, firing rates can either increase or decrease relative to a normal spontaneous rate of ~100 spikes/sec. The device will approximate the normal physiological responses of vestibular afferents, meaning that head rotations will be coded by changes in stimulation rate. Normal physiological adaptation of the vestibular nerve to constant input will be modeled with a high pass filter with a cut off frequency of 0.03 Hz. Stimulation levels will be comparable to those used in a cochlear implant, with maximum output levels <2000 μA for short biphasic pulses (25 μs/phase) with an interphase gap of about 8 μs, although there will be flexibility with durations of each phase and the gap between.

C. Auditory prosthesis specifications

The technical specifications for CI are well established. Stimulation strategies for modern cochlear implants typically use fixed rates of about 1000 pulses per second (pps) per channel, and rely on amplitude modulation of the pulses to convey auditory information. The total available number of electrodes for cochlear stimulation will be correspondingly reduced by the number of electrodes used for vestibular stimulation. For auditory function, 12 channels are sufficient for good speech understanding as evidenced by the clinical success of the CI from Med-El (Austria).

III. Implementation

A. Vestibular-Cochlear implant system

The combined vestibular-acoustic implant is based off of the Nurotron cochlear implant system (Fig 2), developed by Nurotron Biotechnology Inc. (USA) and manufactured by its facility in China. The system is similar to other products in the market, which consists of the external unit and the internal unit surgically implanted under the skin. The core of the external unit is a low-power 16-bit DSP processor that supports many standard interfaces such as I^2C, UART, SPI. The core of the internal unit is an ASIC chip that provides both forward and backward telemetry. The Nurotron device consists of 24 intra-cochlear electrodes, of which up to 6 can be reallocated to stimulation of the three SCCs. The remaining 18 electrodes are used for intracochlear stimulation. Four current sources and two electrode networks are implemented with the capability of generating stimulation simultaneously at an overall rate of 40,000 pps. The Nurotron device is in clinical trials carried out in five major hospitals in China. Sixty patients are currently being evaluated for 1 year starting from the day of the switch-on of the device. Since this integrated prosthesis is based on an existing cochlear implant, three modifications are necessary to the hardware. The first is the addition of a gyroscopic sensor to the external hardware. The second is that several electrodes for cochlear stimulation are repurposed toward vestibular stimulation. The third is reprogramming the DSP to concurrently process gyroscopic data and apply appropriate vestibular stimulation pulses along with normal CI function.

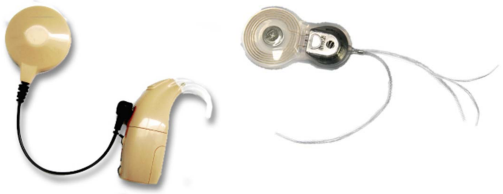

Fig. 2. An integrated vestibular-cochlear implant system with additional leads for semicircular canal stimulation

B. Gyroscopic Sensors

Sensors to detect rotational movement consist of gyroscopes based on MEMS technology. These are now manufactured small enough to be flexibly placed in a number of different locations. They can operate at 2-3V and draw <7mA of current while active. Compared to the power requirements in current CI speech processors, there will be a limited impact on battery life. Using three #675 batteries (600mAH each) with auditory function alone, the typical CI processor can last 30-50+ hours. Adding gyro sensors would reduce the runtime to an estimated 24-35 hrs.

The gyros will be mounted on the headpiece to provide the most stable location. The headpiece contains the RF transmitting coil and is held in place by a magnet directly over the receiving coil of the implanted device. Communication from the sensor to the DSP is through an analog signal from the MEMS gyro. Calibration of the gyros will occur once the RF link is activated to account for variations in the placement angle of the headpiece.

C. Electrode array design

Up to three separate leads from the implant will go to the SCCs. They will be physically separate from the cochlear electrode array in order to eliminate any potential complications during surgical implantation due to tugging

between SCCs leads and cochlear electrode array. Each lead will consist of two electrodes for stimulation. The second electrode will provide redundancy as well as the option for flexible stimulation options, such as bipolar stimulation, in order to restrict current spread. Increasing pulse amplitude increases the current spread and is implicated in shifting the axis of eye movement [24]. Furthermore bipolar stimulation modes may help in the cases where there is potential and inadvertent stimulation of the facial nerve.

The two electrode arrays (auditory and vestibular) can be configured with two return electrodes separately so that two completely independent current paths can be generated simultaneously. One return electrode is a ring-type located at the end of electrode array close to the case. The other one is a plate-type return located on the top the case. The area of the plate-type return is much bigger than the ring-type return. Two returns can be shorted together or operated separately by the internal circuit configuration.

D. Software integration

Although the hardware is integrated to produce vestibular and cochlear stimulation, the signal processing routines are handled independently by a single DSP processor with two processing threads. In one thread, audio input from the microphone is frequency analyzed into different bands. The band-specific envelopes are extracted and used to amplitude-modulate current pulses delivered to the cochlea. On the other thread, data from the gyro sensor are also low-pass filtered and processed to determine head motion. The result is used to determine the stimulation rate according to a pre-calculated lookup table.

In order for these two processing threads to run together and produce their respective outputs, two problems need to be addressed. First, stimulation of the vestibular system occurs at a much lower rate than the cochlear system. Second, the vestibular system relies on frequency modulated pulse rates. To address these problems, two stimulation schemes are possible: simultaneous or non-simultaneous. The Nurotron cochlear implant system is able to deliver currents simultaneously on two electrodes, i.e., one electrode to the cochlear and one electrode to SCC. Since the stimulation rate for the cochlea is much higher than that for SCC, it is possible to stimulate the SCC electrode on every n^{th} pulse of cochlear while keeping the stimulation resolution needed for SCC stimulation. Furthermore, we can use one return electrode for CI stimulation and the other one for SCC stimulation, which will physically overcome the possible interaction of stimulation between these two current paths. Alternatively with non-simultaneous stimulation, stimulation pulses to the SCC can be delivered between CI stimulation pulses. Although the stimulation rate of CI and the pulse width of SCC will be limited with this method, the electrical interactions between cochlea and SCCs should be greatly reduced due to the interleaved pulses.

E. Verification

The output of the vestibular-cochlear prosthesis will be verified by mounting the device on a mannequin head and recording the SCC pulse rate as a function of angular velocity. The results will be compared to the physiological data [8-10] as well as other VIs [15-18].

IV. Surgical Approach and clinical fitting

A. Vestibular and cochlear electrode implantation

The surgical approach for the combined vestibular-cochlear implant is similar to the current mastoidectomy facial recess approach used for cochlear implantation. Once the horizontal canal and facial recess have been identified, additional exposure of the posterior and superior canals is performed. A small opening is made in each semicircular canal close to the ampulated end of each canal. The electrode is threaded into the canal with the electrode contact point near Scarpa's ganglion in the ampulla.

An additional 15 minutes per semicircular canal will be necessary for placement of the VI, depending on the pneumatization of the temporal bone. The electrodes will be stabilized using bone cement. The cochlear implant electrode is placed after placing the vestibular electrodes. Electrically-evoked vestibular nerve potentials will be used for verification of electrode placement [25].

B. Clinical fitting and testing

The device can be fit to the patient using eye motion tracking. Calibration of the gyro to the subject's range of head motion will be recorded and the values stored for use with a look up table to determine stimulation pulse rate. Clinical assessments will be performed before and after implantation. These include vestibular autorotation testing, rotation chair testing, and dynamic visual acuity testing. Cochlear implant function will be assessed using standard methods and include speech understanding performance.

The device will also be tested to ensure that there are no interactions between cochlear and vestibular stimulation. Tests include auditory threshold measurements in the presence of vestibular input and checking for vestibular-ocular reflex activity in response to auditory inputs in a darkened room.

C. Safety Considerations

Because the normal vestibular system has a 100 spikes/s signal, the loss of stimulation may be perceived as a sudden rotation possibly causing blurred vision, nystagmus, and even falls. There has been neurophysiological evidence that training can help the user to adapt to such a situation, but it remains a risk. Several studies have shown that humans can adapt to vestibular stimulation [17, 26-29]. Accidental rotation of the headpiece could also be source of perceptual confusion.

V. Summary

The engineering and clinical issues surrounding integrating vestibular stimulation with cochlear stimulation in the same prosthesis were discussed. This integrated device has the potential to restore both hearing and balance function to deaf individuals with vestibular impairment. Because the technology is available off-the-shelf and affordable, the

device can be rapidly prototyped and put into clinical trials. Once this integrated vestibular-cochlear implant is verified, it could be used to restore balance or treat a wide array of vestibular related disorders.

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