

COMPACT HEARING AIDS

BACKGROUND

Field

[0001] Embodiments of the present disclosure generally relate to assistive hearing devices and methods of implantation thereof. More particularly, embodiments of the present disclosure are related to compact hearing aids mounted internally into an ear canal, for example, into or across the tympanic membrane, which provide vibration transduction to modulate the velocity or the position of the tympanic membrane.

Description of the Related Art

[0002] Hearing aids are well known and typically include a microphone, an amplifier, and a speaker. Typically, the microphone receives a sound wave and converts the wave into an electrical signal, the amplifier amplifies the electrical signal, and the speaker converts the amplified signal into amplified sound waves that impart vibrations to the tympanic membrane or ear drum in the ear. Traditionally, hearing aids are mounted outside the ear canal, particularly around the outer ear. The externally mounted hearing aid has the advantage of accessibility to change batteries and to adjust the volume of sound. However, many users find such externally mounted hearing aids to be relatively bulky and objectionable for cosmetic and comfort reasons.

[0003] An alternative to externally mounted hearing aids are internally mounted hearing aids disposed in an ear canal of a user. Conventional internally mounted hearing aids offer better cosmetic appearance, but have disadvantages as well. For instance, the typical internally mounted hearing aid blocks the majority, if not all, of the ear canal diameter. Such blockage can cause the body of the user to produce an excessive amount of ear wax in the ear canal and can cause ear infections. Further, the blocking of the ear canal obstructs the natural transmission of sound waves through the ear canal and negatively impacts the hearing quality. Unless a user is totally hearing impaired, any ability of the tympanic membrane to register the natural

occurring sound waves is reduced or eliminated. Thus, the user is substantially dependent upon the sound fidelity of the hearing aid. Still further, the typical internally mounted hearing aids may still be somewhat visible in the ear canal.

[0004] Some hearing systems deliver audio information to the ear through electromagnetic transducers. A microphone and amplifier transmit an electronic signal to a transducer that converts the electronic signal into vibrations. The vibrations vibrate the tympanic membrane or parts of the middle ear that transmit the sound impulses without reconvert to audio sound waves. Historically, a separate magnet, or any suitable actuator, was remotely mounted at or near the tympanic membrane. The interaction between the magnetic fields of the transducer receiving the electronic signal and the magnet mounted at or near the tympanic membrane causes the magnet to vibrate and thus mechanically transmits the sound through the vibration to the ear at the cochlea. Typically, however, the remainder of the hearing aid is inserted into the ear canal or on the outer ear and can cause the problems discussed above. Still further, the transducers and/or magnets of the hearing aids are mounted in a relatively invasive procedure. For instance, one contact transducer having a magnet is installed by drilling through the mastoid bone, cutting through the tympanic membrane, microscopically drilling a bone structure, and screwing the magnet to any one or more of the middle ear bones. Such procedures are often painful and expensive, and can have serious complications.

[0005] As described above, there are various types of hearing aids that are used to amplify and transmit sound waves to the hearing center of the brain resulting in the perception of sound. However, conventional hearing aids do not selectively suppress sound waves generated by background noise and excessively loud noises while simultaneously transmitting normal speech and other desirable acoustic signals. Noise suppression could be used by astronauts on long duration missions such as the International Space Station or a Mars mission that want to selectively suppress background noise created

by rotating machinery, air handling systems, and environmental control systems while still allowing the astronaut to hear the sound waves generated by other astronauts and other desirable acoustic signals. Amplification of selective frequencies could be used in a military operation, wherein sound waves generated by enemy combatants could be amplified and sent to the hearing center of the brain while all other sound waves are transmitted in a normal manner. Additionally, the traditional types of hearing aids do not allow a user to receive signals or sound waves that are not audible to a normal person, such as in covert communication.

[0006] Therefore, there is a need in the art for improved hearing aids, which can be inserted in the ear canal and/or through the tympanic membrane using minimally-invasive surgical procedures.

SUMMARY

[0007] The present disclosure relates to compact hearing aids, components thereof, and support systems therefor, as well as methods of insertion and removal thereof. The compact hearing aids generally include a sensor, such as a microphone, an actuation mass, an energy source for providing power to the compact hearing aid, a processor, and an actuator enclosed in a housing that is designed to be inserted through the tympanic membrane during a minimally-invasive outpatient procedure. In operation, the microphone receives sound waves and converts the sound waves into electrical signals. A processor then modifies the electrical signals and provides the electrical signals to the actuator. The actuator converts the electrical signals into mechanical motion, which actuates the actuation mass to create inertia internal to the housing, and the housing is configured to modulate the velocity or the position of the tympanic membrane.

[0008] In one embodiment, a tympanic membrane actuation assembly is disclosed. The tympanic membrane actuation assembly includes at least one mass configured to be disposed on at least one of a medial side or a lateral side of a tympanic membrane of a user, and at least one actuator coupled

to the mass and configured to be disposed on at least one of a medial side or a lateral side of the tympanic membrane or through the tympanic membrane of a user, the actuator being configured to convert electrical signals into mechanical motion to move the mass and modulate the tympanic membrane.

[0009] In another embodiment, a hearing aid, which is insertable through a user's tympanic membrane to amplify certain frequencies and cancel other frequencies, is disclosed. The hearing aid includes a tympanic membrane actuation assembly, which includes at least one mass configured to be disposed on at least one of a medial side or a lateral side of the tympanic membrane of a user, and at least one actuator coupled to the mass and configured to be disposed on at least one of a medial side or a lateral side of the tympanic membrane or through the tympanic membrane of a user, the actuator being configured to convert electrical signals into mechanical motion to move the mass and modulate the user's tympanic membrane.

[0010] In yet another embodiment, a hearing aid, which is insertable through a user's tympanic membrane to amplify certain frequencies and cancel other frequencies, is disclosed. The hearing aid includes a housing having a first flange and a second flange having a groove therebetween, the housing encloses a microphone, a processor coupled to the microphone, and a tympanic membrane actuation assembly, which includes a mass, the mass having a first battery disposed in the first flange, and a second battery disposed in the second flange, the first battery being configured for placement on a lateral side of the tympanic membrane, the second battery being configured for placement on a medial side of the tympanic membrane, a connecting member coupling the first battery to the second battery, the connecting member being configured for placement through the tympanic membrane, and an actuator coupled to the mass and disposed within the connecting member, the actuator being configured to convert electrical signals into mechanical motion to move the mass and modulate the user's tympanic membrane.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] So that the manner in which the above recited features of the present disclosure can be understood in detail, a more particular description of the disclosure, briefly summarized above, may be had by reference to embodiments, some of which are illustrated in the appended drawings. It is to be noted, however, that the appended drawings illustrate only exemplary embodiments and are therefore not to be considered limiting of its scope. The disclosure may admit to other equally effective embodiments.

[0012] FIG. 1 is a cross-sectional schematic view of the anatomy of an ear having a hearing aid inserted through the tympanic membrane thereof.

[0013] FIG. 2 is a schematic plan view of a right tympanic membrane.

[0014] FIG. 3 is schematic perspective view of a compact hearing aid.

[0015] FIG. 4 is a cross-sectional view of the compact hearing aid of FIG. 3.

[0016] FIG. 5 is a plan view of an actuator.

[0017] FIG. 6 is a plan view of an alternative embodiment of an actuator.

[0018] FIG. 7 is a schematic perspective view of an alternative embodiment of a compact hearing aid.

[0019] FIG. 8 is a schematic perspective view of an alternative embodiment of a compact hearing aid.

[0020] FIGS. 9A-9C depict an alternative embodiment of a compact hearing aid.

[0021] FIG. 10 is a process flow of a method for inserting a compact hearing aid.

[0022] FIGS. 11A-11B depict the compact hearing aid of FIGS. 9A-9C with a portion of an implantation tool at various stages of implantation.

[0023] FIG. 12 is a block diagram of an ASIC processor.

[0024] FIG. 13 is a cross-sectional view of a compact hearing aid having an alternative embodiment of an actuator.

[0025] FIG. 14 is a cross-sectional view of a compact hearing aid having an alternative embodiment of an actuator.

[0026] FIGS. 15A-15B depict an alternative embodiment of an implantation tool.

[0027] FIGS. 16A-16C depict an alternative embodiment of a compact hearing aid.

[0028] FIG. 17 depicts a schematic cross-sectional view of an actuation assembly of a compact hearing aid.

[0029] FIG. 18 depicts a schematic cross-sectional view of a compact hearing aid.

[0030] FIG. 19 depicts a schematic cross-sectional view of an actuation assembly of a compact hearing aid.

[0031] FIG. 20 depicts a schematic cross-sectional view of an actuation assembly of a compact hearing aid.

[0032] FIG. 21 depicts a top-down cross-sectional view of a portion of an actuation assembly of a compact hearing aid.

[0033] FIG. 22 depicts a top-down cross-sectional view of a portion of an actuation assembly of a compact hearing aid.

[0034] FIGS. 23A-23D depict an alternative embodiment of a compact hearing aid.

[0035] FIGS. 24A-24F depict an alternative embodiment of a compact hearing aid.

[0036] FIG. 25 depicts a cross-sectional view of an alternative embodiment of a compact hearing aid.

[0037] To facilitate understanding, identical reference numerals have been used, where possible, to designate identical elements that are common to the figures. It is contemplated that elements and features of one embodiment may be beneficially incorporated in other embodiments without further recitation.

DETAILED DESCRIPTION

[0038] The present disclosure relates to compact hearing aids, components thereof, and support systems therefor, as well as methods of insertion and removal thereof. The compact hearing aids generally include a sensor, such as a microphone, an actuation mass, an energy source for providing power to the compact hearing aid, a processor, and an actuator enclosed in a housing that is designed to be inserted through the tympanic membrane during a minimally-invasive outpatient procedure. In operation, the microphone receives sound waves and converts the sound waves into electrical signals. A processor then modifies the electrical signals and provides the electrical signals to the actuator. The actuator converts the electrical signals into mechanical motion, which actuates the actuation mass to modulate the velocity or the position of the tympanic membrane.

The Anatomy of the Ear

[0039] FIG. 1 is a cross-sectional schematic view of the anatomy of an ear 100 having a hearing aid inserted through the tympanic membrane thereof. The ear includes an outer ear 110, an ear canal 112 coupled to the outer ear 110, a tympanic membrane 114 disposed near a proximal end of the ear canal 112 from the outer ear 110. The structure of the outer ear 110 provides a "funnel" to direct and amplify the amplitude of the sound waves into the ear canal 112. An ossicular chain 115, located in a middle ear and disposed on a medial side of the tympanic membrane 114 from the outer ear 110, couples and amplifies vibrations from the tympanic membrane 114 to an inner ear

having a spiral structure known as the cochlea 120. The cochlea 120 converts the vibrations into impulses to the brain.

[0040] Hearing aids, such as hearing aid 122, of the present disclosure can be inserted through the outer ear 110 into the ear canal 112 and at least partially through the tympanic membrane 114. The hearing aid 122 generally includes a sensor, such as a microphone, and at least one eardrum stimulating member described in more detail below. The hearing aid 122 generally receives sound waves conducted from the outer ear 110 through the ear canal 112, converts the sound waves into electrical or electromagnetic signals, and converts the electrical signals into mechanical motion, which is typically called a feed-forward system. The mechanical motion is used to impact the tympanic membrane 114, and/or portions of the middle and inner ear, to vibrate the ossicular chain 115, specifically the malleus 118, the incus 117, and the stapes 116. These three bones in the ossicular chain 115 act as a set of levers that amplify the amplitude of the vibrations received by the tympanic membrane 114. The stapes 116 is coupled to the entrance of a spiral structure known as the cochlea 120 that contains an inner ear fluid. The mechanical vibrations of stapes 116 cause the fluid to develop fluid impulses that cause small hair-like cells (not shown) in the cochlea 120 to vibrate. The vibrations are transformed into electrical impulses, which are transmitted to neuro-pathways in the hearing center of the brain resulting in the perception of sound.

[0041] FIG. 2 is a schematic plan view of the tympanic membrane 114 (a right tympanic membrane is shown as an example). The tympanic membrane 114 is generally an oval shape, which is slightly drawn inwards at its center, called the umbo 202, which is where the handle of malleus (shown in FIG. 1 and described above) is attached. The tympanic membrane is conceptually divided into four quadrants: the anterior superior quadrant 204, the anterior inferior quadrant 206, the posterior inferior quadrant 208, and the posterior superior quadrant 210.

Compact Hearing Aids and Components Thereof

[0042] The present disclosure relates to compact hearing aids, components thereof, and support systems therefore. The embodiments described herein provide exemplary configurations of compact hearing aids contemplated by the present disclosure. However, any other suitable configurations for hearing aids that modulate the velocity or the position of the tympanic membrane, by direct or indirect modulation, are also contemplated. The embodiments that follow discuss inserting the disclosed compact hearing aids through the tympanic membrane, as an example; however, the compact hearing aids are also disposable in other locations within the ear.

[0043] FIG. 3 is a schematic perspective view of a compact hearing aid 300. FIG. 4 is a cross-sectional view of the compact hearing aid 300 of FIG. 3. As shown in FIGS. 3 and 4, the compact hearing aid 300 is encompassed in a housing 301, which includes two flange portions 302 coupled by a connecting portion 304. When implanted, the two flange portions 302 are positioned on opposite sides of the tympanic membrane (*i.e.*, one flange portion is in the outer ear and the other portion is in the middle ear) and the connecting portion 304, shown as a narrow tube as an example, transverses the tympanic membrane. The connecting portion 304 is generally positioned along the center axis of the compact hearing aid 300 or parallel to the center axis of the compact hearing aid 300.

[0044] As used herein the term flange refers to a portion of the disclosed compact hearing aids, which is lateral or peripheral to a central portion thereof, such as the connecting portion 304.

[0045] The one or more flanges and the connecting member generally make up the body of the compact hearing aid. As used herein, the term body generally refers to the one or more flanges and the connecting portion as a unit.

[0046] As shown in FIG. 4, the compact hearing aid 300 is enclosed by the housing 301, which houses the various components of the compact hearing aid 300. The various components generally include at least a sensor 408,

such as a microphone configured to detect the sound to be processed, a mass which is shown as an energy source 410, an actuator 412 configured to convert electrical signals into mechanical motion, and a processor 414 configured to aid with signal processing and power conversion by modifying electrical signals and transmitting the electrical signals to the at least one actuator, as well as to drive the actuator 412 to move the mass, which is the energy source 410 in this example. Together, the mass and the at least one actuator make up a tympanic membrane actuation assembly. In embodiments in which the energy source 410 is a rechargeable energy source, the compact hearing aid 300 generally also includes a recharging circuit 416.

[0047] The sensor 408 is generally fixed within the housing 301 and is configured to receive the sound to be amplified by the compact hearing aid 300 and convert the sound waves or acoustic signals into electrical or electromagnetic signals. The present disclosure contemplates a microphone as the sensor 408 as an example; however, it is contemplated that the sensor 408 is generally any suitable sensor. Suitable sensors include, but are not limited to, high sensitivity microphones, piezoelectric micro-electro-mechanical systems (MEMS) microphones, electrostatic microphones, accelerometers, gyroscopes, and optical sensors. Other suitable sensors include sensors, which may be used to sense otoacoustic emissions (OAEs) or pressures to diagnose ear infections, or other changes in the user or in the performance and device health of the compact hearing aid 300 itself.

[0048] While one sensor 408, which is a microphone, is shown as an example, further embodiments of the compact hearing aids described herein include multiple microphones or other sensors, which may be disposed about the lateral aspect of the compact hearing aid, about the medial aspect of the compact hearing aid, or on both the medial and lateral aspects of the compact hearing aid. In yet further embodiments, one microphone, such as sensor 408 is disposed in the compact hearing aid, and one or more other microphones are disposed elsewhere, such as in the ear canal. In such

embodiments, the one or more external microphones are directly connected or, or otherwise communicate with, the compact hearing aid 300.

[0049] In another embodiment, the sensor 408 may be disposed outside of the housing. In another embodiment, the compact hearing aid 300 may include a second actuator to ensure that the sensor 408 does not move with the housing or the first actuator. In yet another embodiment, the compact hearing aid 300 may further include a passive mechanical coupler to isolate the sensor 408 from the movement of the housing or the first actuator.

[0050] The mass is any suitable mass material, component, or combination of components, which may be actuated to modulate the velocity or the position of the tympanic membrane, and may include any suitable number of portions, such as a first portion and a second portion. The mass is generally between about 5 milligrams (mg) and about 40 mg in total. For example, in embodiments comprising a first portion and a second portion, each portion being a battery, the weight is generally between about 10 mg per battery and about 15 mg per battery (totaling between about 20 mg and about 30 mg, respectively).

[0051] The energy source 410 is generally any suitable energy source of any suitable configuration, such as a single mass, a thin film battery having multiple, vertically-stacked layers (for example, between 5-20 layers), a radio thermal generator, a super capacitor, a thick film battery, or a traditional lithium (Li) ion battery. As shown in FIG. 4, the mass is the energy source 410, which is dumbbell shaped and disposed centrally within the compact hearing aid 300. In such an embodiment, the energy source 410 itself can be used as the mass to modulate the velocity or the position of the tympanic membrane. In further embodiments, the energy source 410 is disposed medially or laterally within the compact hearing aid and on one side of the tympanic membrane. In yet further embodiments, such as FIGS. 13, 14, 16A-C, 17, and 18, one or more mass portions, such as batteries, are disposed on both the medial and lateral sides of the tympanic membrane and may be connected by a connection member disposed in the housing 301 that

traverses the tympanic membrane. In still further embodiments, an energy source and a counter mass, which are connected across the tympanic membrane, are used. The counter mass is generally an inert or inactive mass.

[0052] In one embodiment, the diameter of the energy source 410 is less than or equal to 2.5 millimeters (mm) and the height is less than or equal to 1.5 mm. The mass of the energy source 410 is selected to maximize the safety of holding the compact hearing aid in the tympanic membrane and/or based on a passive noise transmission attenuation level, for example less than or equal to 10 decibels (dB). In one embodiment, the mass is generally less than or equal to about 15 milligrams (mg). As described below, the energy source 410 is generally rechargeable. In such embodiments, the charging time is generally less than or equal to about 3 hours and can be charged more than 1,000 times.

[0053] The actuator 412 is generally any actuator mechanism, or any plurality of actuator mechanisms, suitable to convert the electrical signals into mechanical motion by moving the mass such that the mass modulates the velocity or the position of the tympanic membrane, and may be disposed on the medial side, the lateral side, both sides of the tympanic membrane, or across the tympanic membrane. The actuator 412 is configured to push the mass, and to retrieve, or pull, the mass, relative to the coupling to the tympanic membrane.

[0054] FIG. 5 is a plan view of an actuator 500 according to one embodiment, which may be used as the actuator 412. The actuator 500 includes at least an outer ring 502 and an inner ring 504, the outer ring 502 being connected to the housing 301 and the inner ring 504 being connected to the mass, such as the energy source 410. The outer ring 502 has a plurality of piezoelectric actuators 506 that can be excited to create the force needed to modulate the inner ring 504 axially and to ultimately modulate the velocity or the position of the tympanic membrane. In another embodiment, the

plurality of piezoelectric actuators 506 are individually addressable to provide non-axial modulation of the velocity or the position of the tympanic membrane.

[0055] FIG. 6 is a perspective side view of an actuator 600 according to another embodiment, which may be used as the actuator 412. The actuator 600 includes a first disk 602 and a second disk 604, which are coupled together by a plurality of piezoelectric actuators 606 sandwiched therebetween. At least one of the first disk 602 or the second disk 604 is movable to modulate the velocity or the position of the tympanic membrane. In another embodiment, the plurality of piezoelectric actuators 606 are individually addressable to provide non-axial modulation of the velocity or the position of the tympanic membrane.

[0056] FIG. 13 is a cross-sectional view of a compact hearing aid, such as compact hearing aid 300, having an alternative embodiment of an actuator. In the embodiment shown in FIG. 13, the actuator is a piezoelectric stack actuator 1320 that actuates linearly. The base 1324 of the piezoelectric stack actuator 1320 is fixed. As shown, one or more connecting members 1322, shown as disposed around the outside of the piezoelectric stack actuator 1320, connect a first mass 1328 to a trailing mass 1326. The first mass 1328 is displaced by the piezoelectric stack actuator 1320 and the trailing mass 1326 generally follows the movement of the first mass 1328 to move the masses in phase.

[0057] FIG. 14 is a cross-sectional view of a compact hearing aid, such as the compact hearing aid 300, having an alternative embodiment of an actuator. In the embodiment shown in FIG. 14, the actuator is a piezoelectric microtube 1420. The base 1424 of the piezoelectric microtube 1420 is fixed. In operation, the piezoelectric microtube 1420 lengthens linearly to displace the first mass 1426. One or more connecting members 1422 connect the first mass 1426 and the second mass 1428. The one or more connecting members 1422 lie in an inner diameter of piezoelectric microtube 1420.

[0058] In still further embodiments, the actuator 412 is a linear actuator. For example, the actuator 412 may be a voice coil having a central mass, generally a magnet, with an outer coil wrapped there around, which modulates the force on the mass by energizing the outer coil. Alternatively, the voice coil may be centrally disposed with the magnet disposed therearound. The linear actuator may traverse the tympanic membrane within the compact hearing aid, which when energized, oscillates and creates a modulating force to the tympanic membrane. In another embodiment, the actuator 412 includes a plurality of actuators coupled to the housing 301 and/or the energy source 410. In yet another embodiment, the actuator 412 is a plurality of concentric actuators that create linear movement. In yet another embodiment, the actuator 412 is a rotary actuator that creates a wave that extends radially from the compact hearing aid. In yet another embodiment, the actuator 412 includes a piezo MEMS device or an electrostatic MEMS device with a stepper motor, for example. In yet another embodiment, an actuator may be formed through the combination of two or more of the above-mentioned actuators.

[0059] As discussed herein, the disclosed compact hearing aids include one or more actuators. When more than one actuator is used, all of the actuators may be the same type of actuator or more than one type of actuator. When more than one type of actuator is used, the stimulation of the actuators may be in different or similar planes. In one embodiment, the different types of actuators are configured to actuate in different planes at the same time, for example, to grow in length and/or diameter. Additionally, and as discussed further below, the actuator may utilize an impedance matching component, such as a MEMs lever arm depending on the energy and displacement ranges needed to improve the user's hearing.

[0060] As shown in FIGS. 4, 13, and 14, the compact hearing aid 300 may also include a movement mechanism 418, such as bearings or a linear slide, which confines the movement of the mass to the direction of the actuation.

The Operation of the Hearing Aid

[0061] The processor 414, which is generally an Application Specific Integrated Circuit (ASIC) chip, takes an electrical signal from the sensor 408 that represents the acoustic signals and converts the signals into an electrical signal to drive the actuator 412 and move the mass (e.g., the energy source 410) to modulate the position of the tympanic membrane and thus provide impulses to the user's brain. The mass generally moves a distance of less than or equal to about one millimeter. The direct or indirect modulation of the position of the tympanic membrane improves the hearing of the user.

[0062] In addition to converting the signals for modulating the mass, the processor 414 may also bias the sensor 408, and provide safety functions, such as internal temperature and current monitoring.

[0063] In some embodiments, the processor 414 encompasses the safety circuitry for the energy source 410, including for appropriately charging and discharging the energy source 410 safely and efficiently.

[0064] In even further embodiments, the processor 414 also performs communication functions such that the compact hearing aid can send information to, and receive information from, the external world. For example, the processor 414 generally includes circuitry allowing the compact hearing aid to communicate information about the state of the compact hearing aid, and even the state of the user's ear, to an external recipient.

[0065] In even further embodiments, the processor 414 is configured to modify acoustic input to allow for frequency shifting. This frequency shifting processing is useful to optimize the mechanical output, address various frequency responses and transfer functions ultimately to provide the user a superior acoustic experience. For example, certain frequencies or nodes that the device may miss, which have been preidentified, may be captured and shifted so that the user will hear the missed frequency at a different, shifted frequency.

[0066] FIG. 12 depicts a block diagram of an ASIC processor 1200. The ASIC processor 1200 may be used as the processor 414. The ASIC

processor 1200 generally includes a wireless communications component 1202, a safety circuit component 1204, a nonvolatile memory component 1206, a microphone preamplifier component 1208, a signal processing component 1210, an actuator driver component 1212, an energy source management component 1214, a power supply component 1216, and a wireless power component 1218. Wireless communications include, but are not limited to, optical, acoustic, and radio frequency communications.

[0067] In one embodiment, the ASIC processor 1200 uses analog signal processing to reduce power needs and minimize digital components. Additionally, the ASIC processor 1200 may be configured to minimize power consumption via programming and/or estimating responses, while maintaining acceptable processing. In another embodiment, the ASIC processor 1200 may be configured to perform frequency communication and/or registration via an audio device, such as a smart phone. For example, the ASIC processor 1200 may be configured to turn the compact hearing aid on and off via an acoustic profile signature. The ASIC processor 1200 may also be configured to change the intensity mode, for example by controlling the amplitude when in uncomfortable acoustic environments, using the acoustic profile signature, to limit amplitude of all frequencies, and/or to provide noise cancellation. Even further, the ASIC processor 1200 may be configured to recognize emergency tones that automatically turn the compact hearing aid on, such as fire alarms, door bells, and glass breaking sounds.

[0068] In further embodiments, the ASIC processor 1200 uses digital signal processing.

[0069] In another embodiment, the ASIC processor 1200 is wirelessly controlled by radiofrequency (RF) signals. The RF signals may be used to turn the compact hearing aid on and off, to change the intensity mode to control amplitude in uncomfortable acoustic environments, and to provide for tuning and verification tone responses for diagnostics.

[0070] The ASIC processor 1200 may also be configured to filter certain frequencies. For example, the disclosed compact hearing aids may further or alternatively include a feed-forward system to control feedback by changing frequencies of certain ranges of input to avoid certain resonance frequencies. The disclosed compact hearing aids may also or alternatively include a system with learning algorithms to adjust frequency responses when unique environments produce unique resonance frequencies. OAEs are sounds produced by the inner ear. More specifically, there are hair cells in the inner ear that respond to signals by vibrating. The vibration produces a very quiet sound that reverberates back into the middle ear. It is thought that OAEs help to selectively amplify certain frequencies. Similarly, the compact hearing aids disclosed herein are also configurable to produce a low decibel and patentable frequency signal that will help to amplify the incoming sounds. This extra background sound will help with improving the signal-to-noise (STN) ratio, or it will be uniquely helpful at certain frequencies. This background sound could be a simple single frequency sound, it could be a single complex sound made up of multiple different frequencies, or it could be several sounds, which are fractions of a second apart, or it could generate any of these sounds at specific times depending on the frequency being processed.

[0071] The disclosed compact hearing aids are also configurable to self-diagnose by recognizing the OAEs and making adjustments in the device itself to optimize hearing for that particular user.

[0072] Additionally, the disclosed compact hearing aids produce an output, to which the inner ear responds and produces a unique OAE, which is correlated with the degree of hearing loss at those frequencies.

Additional Device Components and Configurations

[0073] In the embodiment shown in FIG. 4, the compact hearing aid 300 includes a separate recharging circuit 416; however, as discussed above, in other embodiments, much, and sometimes all, of the recharging circuit can be

included in the processor 414. The recharging circuit 416 recharges the energy source 410.

[0074] In one embodiment, one or more coil arrays for recharging are disposed in or about the flange(s). In another embodiment, one or more coil arrays for recharging are disposed in or about the lateral portion of the compact hearing aid. In yet another embodiment, one or more coil arrays for recharging are disposed in or about the medial portion of the compact hearing aid. In yet another embodiment, one or more coil arrays for recharging are disposed in both the medial and lateral portions of the compact hearing aid. In yet another embodiment, one or more of the coil arrays for recharging may be the same coil that powers the voice coil actuator described above.

[0075] FIGS. 16A-16C depict an alternative embodiment of a compact hearing aid 1600. The compact hearing aid 1600 includes an enclosure housing 1601 that houses at least a microphone 1608, a first mass, shown as a first battery 1626, as an example, a second mass, shown as a second battery 1628, as an example, coupled to the first battery 1626 by a connecting member 1621, and a processor 1614. The connecting member 1621 includes, or is surrounded by, an actuator 1620. The actuator 1620 is generally a tubular or cylindrical stacked piezoelectric actuator having a hole therein to allow the connecting member 1621 to pass therethrough. The height of the actuator 1620 is generally between about 1 mm and about 4 mm, and the outer diameter of the actuator 1620 is generally between about 1 mm and about 2 mm.

[0076] The compact hearing aid 1600 also includes a recharging coil antenna 1616 disposed around the microphone 1608. The recharging coil antenna 1616 is used to recharge the first battery 1626 and the second battery 1628 daily. When positioned within the ear, the first battery 1626 and the second battery 1628 are disposed on opposite sides (i.e., the medial and lateral sides) of the tympanic membrane and the connecting member 1621 is disposed through the tympanic membrane.

[0077] Factors considered in the design of the various components, such as the actuator, of the compact hearing aids described herein are the amount of force to be applied to, and the amount of displacement of, the tympanic membrane to improve the user's hearing. The amount of force may vary based on the modulating mass or masses of between about 20 mg and about 30 mg, between about 0.05 microns and about 5.0 microns of displacement with a force of between about 0.001 Newtons (N) and about 0.05 N, across the audible frequency range.

[0078] As shown in FIG. 17, the compact hearing aid includes an actuation assembly 1700, which may also include a displacement multiplier 1725 in conjunction with the actuator 1723 to amplify the actuation of the first mass, shown as a first battery 1726, as an example, and the second mass, shown as a second battery 1728, as an example. The displacement multiplier 1725 is shown as a piezo coupling arm lever, as an example. The arm lever displacement multiplier 1725 includes an actuator leg portion, a pivot on case portion, and a mass, shown as a battery, leg portion. As shown in FIG. 19, the actuation assembly 1900 may also include a fixed coupling 1925 in conjunction with the actuator 1923. The fixed coupling 1925 is shown as a fixed coupling to the top of the actuator, as an example. As shown in FIG. 20, the actuation assembly 2000 may also include a rigid coupler 2025 in conjunction with the actuator 2023. The rigid coupler 2025 is shown as a rigid coupler between the first battery 2026 and the second battery 2028 and positioned around the outside of the actuator 2023, as an example.

[0079] As shown in FIGS. 21 and 22, the various piezo couplings, including the arm lever displacement multiplier, the fixed coupling, and the rigid coupler, may include any suitable number of components surrounding or otherwise coupled to the actuator 2123 and 2223, respectively. The actuator 2123 is shown as a rectangular prism as an example, and the actuator 2223 is shown as a cylindrical tube as an example. The actuators 2123, 2223 are surrounded by a plurality of any suitable number and combination of rigid

coupler portions 2131, 2231, fixed coupling portions 2135, 2235, and arm lever displacement multiplier portions 2137, 2237.

[0080] In addition to the aforementioned components, the disclosed compact hearing aids may also include additional components, such as sensors for detecting a change in the biological conditions of the ear, for example, infections, inflammation, scar tissue, or epithelial cell migration.

[0081] The housing 301 is generally any suitable covering which encloses and provides a sealed compartment for the device components. Suitable casings including, for example, biocompatible materials, such as silicon, fluoropolymers, polyethylene, stainless steel, and titanium. The housing 301 is either a solid or a porous material. In one embodiment, the housing 301 has micro holes to allow for venting. In another embodiment, the housing 301 is solid such that it does not have any venting holes therethrough. In another embodiment, the housing 301 is solid such that it does not have any venting holes therethrough and utilizes dead space to allow for compression created by internal movement. In some embodiments, the housing 301 includes linear channels to allow for internal pressure balancing due to internal movement of the actuator and mass (e.g., the battery). The linear channels also provide compensation for epithelial migration about the compact hearing aid 300. Even further, the linear channels provide mechanical benefits, such as improved stabilization.

[0082] FIG. 18 depicts a schematic cross-sectional view of a compact hearing aid 1800. The compact hearing aid 1800 includes a housing 1801 which encloses a stack of components, which includes a microphone 1808, a processor 1814, a first portion 1826, shown as a first battery, a second portion 1828, shown as a second battery, and a connecting member 1820 having an actuator disposed therein.

[0083] The housing 1801 is between about 5 mm and about 10 mm in length, such as about 6 mm. The housing 1801 generally has two diameters, a first diameter 1815 and a second diameter 1817. The first diameter 1815,

which generally corresponds to the flanged portions that rest on either side of the tympanic membrane, is between about 1 mm and about 5 mm, such as about 3mm. The second diameter 1817, which corresponds to the portion of the compact hearing aid 1800 to be disposed through the tympanic membrane, is between about 0.5 mm and about 3 mm, such as about 1.5 mm. The notched portion 1829, in which the tympanic membrane is to be disposed is generally between about 0.15 mm and about 0.5 mm, such as about 0.25 mm, to provide sufficient space for the tympanic membrane without pinching the tympanic membrane such that it would cause necrosis.

[0084] Each of the microphone 1808 and the processor 1814 is between about 0.25 mm and about 1.0 mm thick, such as about 0.5 mm. Each of the first portion 1826, and the second portion 1828 is between about 1 mm and about 2 mm in height, such as about 1.5 mm, and has an outer diameter of between about 2 mm and about 3 mm, such as about 2.5 mm. The connecting member 1820, having an actuator disposed therein in some embodiments, or coupled thereto, is between about 0.5 mm and about 3 mm in height, such as about 1 mm, and has an outer diameter between about 0.5 mm and about 2 mm, such as about 1 mm. Similarly, in some embodiments, the actuator may be between about 0.5 mm and about 3 mm in height, such as about 1 mm, and have an outer diameter between about 0.5 mm and about 2 mm, such as about 1 mm.

[0085] As discussed above, the compact hearing aid can be of any suitable size and shape with components of various size and shape; however, each configuration generally requires the same various components, for example, the microphone, energy source, actuator, and processor.

[0086] FIG. 7 is a schematic perspective view of an alternative embodiment of a compact hearing aid 700. As shown in FIG. 7, at least one flange 702, generally the medial flange, is interrupted by a pie-shaped notch 704 therein. The notch 704 is useful for insertion of the compact hearing aid 700 through the tympanic membrane because the notch 704 acts as an

Archimedes screw, making it easier to fit the flange 702 through a smaller incision.

[0087] FIG. 8 is a schematic perspective view of an alternative embodiment of a compact hearing aid 800. The compact hearing aid 800 includes at least one flange 802, generally the medial flange, which is conical and acts as a dilator when inserted through an incision in the tympanic membrane.

[0088] In further embodiments, at least one of the first flange and the second flange of the compact hearing aid is otherwise tapered from a first end to a second end thereof, such that the first flange or the second flange acts as a dilator when inserted through an incision in the tympanic membrane.

[0089] FIGS. 9A-9C depict various views of an alternative embodiment of a compact hearing aid 900. The compact hearing aid 900 includes a first flange 902 and a second flange 904. The first flange 902 has a plurality of first flange tabs 906 coupled thereto, and the second flange 904 has a plurality of second flange tabs 908 coupled thereto. The plurality of second flange tabs 908 are offset from the plurality of first flange tabs 906. As shown in FIG. 9B, and described further below, the first flange tabs 906 and the second flange tabs 908 generally lie flat against the compact hearing aid 900 until after the compact hearing aid 900 has been inserted through the tympanic membrane. After the compact hearing aid 900 is inserted, the plurality of first flange tabs 906 and/or the plurality of second flange tabs 908 are opened such that they lie parallel to the surface of the tympanic membrane to stabilize the compact hearing aid 900, as shown in FIG. 9C.

[0090] The mounting region of the disclosed compact hearing aids generally includes one or more flanges, such as the first flange 902 and the second flange 904, which are positioned to optimize energy transfer to the tympanic membrane, with a space 909 therebetween configured for the tympanic membrane to be disposed therein. The mounting region provides for retention of the compact hearing aid, such as compact hearing aid 900, in

the tympanic membrane. In addition, the mounting region provides for balance and stabilization of the compact hearing aid 900 in the tympanic membrane. In further embodiments, the one or more flanges may deliver actuation or modulation to the tympanic membrane. In some embodiments, the one or more flanges contain a charging coil or charging array. In addition, in some embodiments, the one or more flanges include predesigned features to provide offset forces to avoid pinching or clamping of the tympanic membrane since such pinching or clamping often causes necrosis of, or a hole in, the tympanic membrane.

[0091] In further embodiments, at least one of the first flange and the second flange is compressible and can be deployed or released into its final shape or position once inserted through the tympanic membrane.

[0092] The above-described embodiments provide exemplary shapes and configurations of the one or more flanges. However, the present disclosure contemplates further shapes and configurations, including but not limited to, circular flanges resembling a top hat, circular flanges resembling a top hat having a brim turned up about the outer edge, a skirt that flairs away from the body that curls up around its edges, a circular flange that is undercut on the side that faces the tympanic membrane, while the outer ring is turned upward distributing the clamping force to the outer rim of the flange, and a flange that is created by a micro-wire form that is covered by a thin film of material or polymer and can also be used as the recharging coil for inductive recharging. In some embodiments, the surface of the brim may a multiplane surface, such as a wavy surface or a stepped surface.

[0093] In some embodiments, the flanges which stabilize the compact hearing aid are juxtaposed across the tympanic membrane to avoid opposing pressure maintaining vascular perfusion about the tympanic membrane and avoiding necrosis. Such flanges generally include tabs arranged around the circumference of the flange that individually flare away from the flange and body of the compact hearing aid. The tabs can be various shapes, including but not limited to, pie shaped, lobes, dual lobes, or clover shaped.

[0094] In yet another embodiment, the mounting region includes an array of intermittent flanges that is undercut on the side that faces the tympanic membrane, while the outer edge of the intermittent flanges may be turned upward to distribute the force to the outer rim of the flange. The array can be placed on the medial and lateral sides to sandwich the tympanic membrane therebetween, or offset radially to ensure the tympanic membrane is not pinched between stabilizing flanges.

[0095] In further embodiments, the flanges are designed to stabilize the compact hearing aid and are positioned to, or have features to, mitigate the challenges of epithelial migration on the lateral side of the tympanic membrane. The flanges can be juxtaposed with retention and stabilizing features on the medial side. Suitable features include, but are not limited to, bump patterning, bi-lateral hatching, linear tracks or channels, axial tracks, patterning of tear drop shaped raised portions, and boat hull-shaped configurations. In still further embodiments, these features may additionally or alternatively be patterned on other portions of the disclosed compact hearing aids, such as the body.

[0096] In still further embodiments, at least one of the one or more flanges includes an actuator component, which extends from the compact hearing aid to modulate the malleus or umbo directly. In still further embodiments, an actuator may extend from other portions of the compact hearing aid, such as the body, to modulate the malleus or umbo directly.

[0097] The flanges disclosed herein, alone or in any combination, may interact with the body of the compact hearing aid and/or with the tympanic membrane in any suitable manner.

[0098] FIGS. 23A-23D depict an alternative embodiment of a compact hearing aid 2300. The compact hearing aid 2300 is similar to other embodiments described herein, but utilizes bending mode actuators 2322, 2324 to actuate one or more masses for modulation of velocity and/or position of a tympanic membrane.

[0099] Note that, herein, a medial end, side, or surface of a component refers to the end, side, or surface that is closer to the tympanic membrane when implanted. On the other hand, the lateral end, side, or surface of a component refers to the end, side, or surface that is further from the tympanic membrane when implanted.

[0100] The compact hearing aid 2300 generally includes a first enclosure housing 2301 having a first medial wall 2350 (shown in FIG. 23B) and a first lateral shell 2370. Together, the medial wall 2350 and lateral shell 2370 encase at least a microphone 2308, a processor 2314 coupled to the microphone 2308, a first active or inactive mass, shown as a first battery 2326 coupled to the processor 2314 in this example, and first actuator 2322 coupled to the first battery 2326. In certain embodiments, a recharging coil antenna 2316 is disposed around the microphone 2308 to enable daily recharging of the compact hearing aid 2300. In certain embodiments, the recharging coil antenna 2316 and the microphone 2308 are independent of the first battery 2326, which is indirectly coupled to the first medial wall 2350. The compact hearing aid 2300 further includes a second enclosure housing 2302 having a second medial wall 2352 (shown in FIG. 23B) and a second lateral shell 2372 that together encase at least a second active or inactive mass, shown as a second battery 2328, and second actuator 2324 coupled to the second battery 2328. The first enclosure housing 2301 is coupled to the second enclosure housing 2302 by a connecting member 2320 disposed between the adjacent medial walls 2350, 2352 of the first and second enclosure housings 2301, 2302, respectively.

[0101] When implanted, the medial walls 2350, 2352, which may be planar in morphology, are positioned on and contacting (i.e., disposed against) opposing sides of the tympanic membrane while the connecting member 2320, shown as a tubular-like structure as an example, transverses the tympanic membrane along or parallel to a central axis of the compact hearing aid 2300. In addition to providing mechanical support, the connecting member 2320 enables routing of electrical signal connections between the

enclosure housings 2301, 2302 (e.g., for recharging and actuation of the masses).

[0102] Note that although the masses in Figures 23A-23D are depicted and described as batteries 2326, 2328, the bending mode actuators 2322, 2324 may modulate any suitable type of mass or mass material other than a battery in certain embodiments. For example, the masses may be any suitable mass material, component, or combination of components, which may be actuated to modulate the velocity or the position of the tympanic membrane.

[0103] As shown in FIGS. 23A-23D, the actuators 2322, 2324 are indirectly coupled to the medial walls 2350, 2352 within the enclosure housings 2301, 2302, respectively, and on opposing sides of the connecting member 2320. In certain other embodiments, however, the actuators 2322, 2324 are indirectly coupled to the lateral shells 2370, 2372, which may have a dome-like morphology. The actuators 2322, 2324 are each held in place by one or more brackets 2354 (shown in FIG. 23B) extending from the medial walls 2350, 2352 or lateral shells 2370, 2372, which provide slots in which the actuators are secured at distal ends thereof. The brackets 2354 further provide clearances 2356 between each actuator 2322, 2324 and the corresponding medial wall 2350, 2352 to facilitate deflection of the actuators during operation. As shown, the actuators 2322, 2324 are further indirectly coupled to at least the batteries 2326, 2328, via extensions 2380, 2382, respectively, thus enabling internal displacement of the batteries by the actuators within each enclosure housing 2301, 2302.

[0104] An enlarged view of the second actuator 2324 within the second enclosure housing 2302 is depicted in FIG. 23C for reference. Unless otherwise specified, description of the components of the second actuator 2324 and second enclosure housing 2302 may apply to the first actuator 2322 and first enclosure housing 2301.

[0105] As described above, the second actuator 2324 is a bending mode actuator, such as a unimorph-type actuator, bimorph-type actuator, dome-type actuator, or the like. For purposes of clarity and not to be limiting, the second actuator 2324 is herein depicted and described as a unimorph-type actuator having at least one inactive layer 2360 and at least one active layer 2362. Each of the inactive and active layers 2360, 2362 comprises a thin film-like layer configured to be controllably deformed upon application of an electric field to the active layer. Accordingly, one or more electrodes 2364 may be disposed at either end of the second actuator 2324 and contacting at least the active layer 2362. In certain examples, the one or more electrodes 2364 are formed of gold (Au), platinum (Pt), copper (Cu), or any other suitable conductive material.

[0106] As shown in FIG. 23C, the inactive layer 2360 of actuator 2324 is disposed between the active layer 2362 and the medial wall 2352 of enclosure housing 2302. The medial wall 2352 is generally less than 1 mm thick and is formed of a biocompatible material, similar to the lateral shell 2372. Brackets 2354 extend from the medial wall 2352, or the lateral shell 2372, and at distal ends of inactive layer 2360 to clamp the inactive layer in place while also providing clearance 2356 to facilitate deformation of the actuator. In certain embodiments, the inactive layer 2360 is formed of titanium (Ti) or titanium oxide (TiO_2) and have thicknesses between about 0.02 mm and about 0.1 mm, such as between about 0.02 mm and about 0.03 mm, such as about 0.02 mm.

[0107] The active layer 2362 is coupled to the inactive layer 2360 opposite of the medial wall 2352 and generally has a thickness greater than that of the inactive layer, such as between about 0.05 mm and about 0.2 mm, such as between about 0.065 mm and about 0.085 mm, such as about 0.075 mm. The active layer 2362 may be formed of a piezoelectric-type material having a perovskite crystal structure, such as lead zirconate titanate (PZT), barium titanate (BaTiO_3), strontium titanate (SrTiO_3), or other ferroelectric materials. In certain embodiments, the inactive layer 2360 and the active layer 2362

each have a length between about 1 mm and about 4 mm, such as between about 2 mm and about 3 mm, and a width less than about 3 mm, such as less than about 2 mm.

[0108] As previously mentioned, the active layer 2362 is also indirectly coupled to at least battery 2328 via extension 2382 (active layer 2362 within the first enclosure housing 2301 is coupled to at least battery 2326 via extension 2380). The extensions 2380, 2382 may be similar in structure and material to the connecting member 2320 disposed between medial walls 2350, 2352. In certain embodiments, as depicted in FIGS. 23A-23C, the extensions 2380, 2382 are coupled between aligned and centrally-disposed positions on lateral surfaces of the active layers 2362 and medial surfaces of the batteries 2326 and 2328, thus facilitating axial motion of the batteries during operation. In such embodiments, the inactive layers 2360 may be secured to the medial walls 2350, 2352, or lateral shells 2370, 2371, by two brackets 2354 at opposing ends thereof. In certain other embodiments, however, the extensions 2380, 2382 are coupled between oblique (e.g., non-central) and non-axial (e.g., unaligned) positions on the lateral surfaces of the active layers 2362 and medial surfaces of the batteries 2326 and 2328, as shown in FIG. 23D. In such embodiments, the coupling of the active layers 2362 and batteries 2326, 2328 facilitates rotational (e.g., nonlinear) motion of the batteries during operation. Accordingly, the inactive layers 2360 may be secured to the medial walls 2350, 2352 or lateral shells 2370, 2371 by only one bracket 2354 at a distal end of each inactive layer 2360, enabling greater deflection of the actuators 2322, 2324. In some examples, the single bracket 2354 is secured to each inactive layer 2360 at an end opposite the end of the active layer 2362 coupled to the extension 2380 or 2382.

[0109] In operation, the microphone 2308 or any other suitable sensor receives a sound to be amplified and the processor 2314 converts the soundwaves or acoustic signals into an electrical signal that is applied to the first and/or second actuators 2322, 2324. The electrical signal is transmitted to the active layers 2362 thereof by the one or more electrodes 2364, causing

the active layers to morph (e.g., deform) in a desired direction. For example, the active layers 2362 of the first and second actuators 2322, 2324 may be similarly or inversely energized to morph in a similar or inverse directions as desired. The deformation of the active layers 2362 modulates the positions of the batteries 2326 or 2328 (e.g., masses) relative to the tympanic membrane and connecting member 2320 disposed therebetween, thereby modulating the tympanic membrane which provides impulses to the user's brain via the ossicular chain and cochlea.

[0110] In certain embodiments, the active layers 2362 have a capacitance of less than about 300 pico- Farads (pF), such as less than about 200 pF. The active layers 2362 may be driven by a 40 volt (V) alternating current (AC) to a frequency between about 7500 to about 10500 Hertz (Hz), such as between about 8000 to about 10000 Hz. In further embodiments, each of the active layers 2362 displaces the medial walls 2350, 2352 and/or the batteries 2326, 2328 by a distance of about 1 μm to about 5 μm , such as about 2 μm , and produces a blocking force between about 0.02 to about 0.1 N, such as between about 0.04 N to about 0.07 N.

[0111] Utilization of the compact hearing aid 2300 depicted in FIGS. 23A-23D may facilitate more controlled tympanic membrane modulation as the first and second actuators 2322, 2324 enable better utilization of hearing aid internal mass. For example, including two separate actuators 2322, 2324 enables each mass (e.g., battery 2326 or 2328) to be modulated independently of the other, thereby reducing energy losses resulting from modulating both masses together. Furthermore, the structure and bending mode functionality of the actuators 2322, 2324 enables free movement of internal components, such as the masses, within the enclosure housings 2301, 2302. Thus, the actuators 2322, 2324 may provide a more stable internal environment with a reduction of undesired micro-movement of the connecting member 2320 and connections disposed therein.

[0112] FIGS. 24A-24F depict yet another embodiment of a compact hearing aid 2400 that utilizes bending mode (e.g., unimorph-type) actuators

2422, 2424 for modulation of velocity and/or position of a tympanic membrane. The hearing aid 2400 is substantially similar to hearing aid 2300, and thus, similar components between the hearing aid 2400 and the hearing aid 2300 have been labelled with the same reference numerals for clarity.

[0113] Unlike the hearing aid 2300, the masses of hearing aid 2400, shown as batteries 2326, 2328 in this example, are not directly coupled to the actuators 2422, 2424, and are instead directly or indirectly coupled to the lateral shells 2370, 2372, respectively. Accordingly, the batteries 2326, 2328 in FIGS. 24A-24C are shown separated from the actuators 2422, 2424 by clearances 2446. In certain embodiments, the first battery 2326 is directly and/or indirectly coupled to the first lateral shell 2370 via the microphone 2308 and/or the processor 2314. In such embodiments, the microphone 2308 and/or the processor 2314 may be attached to the lateral shell 2370 via any suitable coupling mechanism, such as a bonding adhesive or other support structure. In certain embodiments, the second battery 2328 is directly coupled to the second enclosure housing 2302 opposite of the medial wall 2352. Similar to the microphone 2308 and processor 2314, the second battery 2328 may be attached to the second lateral shell 2372 via a suitable coupling mechanism, such as a bonding adhesive or other support structure.

[0114] Furthermore, the first and second actuators 2422, 2424 of the hearing aid 2400 are formed of a flexible membrane such as polymer or silicone and are disposed along or integrated with the medial walls 2350, 2352, respectively, and so no clearance is present therebetween. For reference, enlarged views of the second enclosure housing 2302 and the actuator 2424 are depicted in FIGS. 24C-24F. Unless otherwise specified, description of the components of the second enclosure housing 2302 and second actuator 2424 may apply to the first first enclosure housing 2301 and first actuator 2422.

[0115] As shown in FIGS. 24C-24F, in certain embodiments, a medial surface 2461 of the inactive layer 2360 is coupled directly to the medial wall 2352. Thus, the inactive layer 2360 forms a direct barrier between the medial

wall 2352 and the active layer 2362. In certain examples, the inactive layer 2360 is disk-shaped and extends along an entire lateral side 2453 of the medial wall 2352, separating the medial wall from the lateral shell 2372 as shown in FIG. 24D. In certain examples, the inactive layer 2360 is beam- or strip-shaped and linearly extends along a diameter of the corresponding medial wall 2352, intersecting the lateral shell 2372 at ends thereof. In still other examples, a disk- or beam-shaped inactive layer 2360 only extends along portions of lateral side 2453 of the medial walls 2352, as shown in FIGS. 24E and 24F. In such examples, the inactive layer 2360 may either form a partial separation between the medial wall 2352 and the lateral shell 2372 (FIG. 24E), or no separation therebetween (FIG. 24F).

[0116] In still other embodiments, the active layer 2362 of the actuator 2422 has a medial surface directly coupled to the medial wall 2352 (not shown), and the medial wall 2352 itself functions as an inactive layer for the actuator 2442. Accordingly, the medial wall 2352 may be formed of a thin and flexible material layer such as polymer or silicone and is configured to be controllably deformed upon application of an electric field to the active layer 2362. In some examples, the medial wall 2352 is formed of Ti or TiO₂ and has a thickness between about 0.02 mm and about 0.1 mm, such as about 0.025 mm, similar to the inactive layer 2360. In such examples, the active layer 2362 may be formed of PZT, BaTiO₃, SrTiO₃, or other ferroelectric materials, and have dimensions similar as described above with reference to FIGS. 23A-23C.

[0117] In operation, the application of electrical signal to the active layers 2362 causes deformation thereof, thereby modulating the medial walls 2350, 2352 along which the active layers 2362 are disposed. Accordingly, the modulation of the medial walls 2350, 2352 modulates the positions of lateral shells 2370, 2372 and batteries 2328, 2328 coupled thereto relative to the tympanic membrane, thereby modulating the tympanic membrane which sends impulses to the user's brain via the ossicular chain and cochlea. By utilizing the first and second enclosure housings 2301 and 2302 as moving

masses themselves, the hearing aid 2400 enables better utilization of total mass and reduces the movement of internal components thereof. Thus, the hearing aid 2400 may provide a more stable internal environment with reduced undesired micro-movement, while further improving mass utilization by modulating the enclosure housings 2301, 2302.

[0118] FIG. 25 depicts a schematic cross-sectional view of an alternative compact hearing aid 2500. The compact hearing aid 2500 includes a housing 2501 with an internal profile shaped to house and support a stack of components, including a microphone 2508, a processor 2514, a first portion 2526, shown as a first battery, and a second portion 2528, shown as a second battery, coupled to the first battery 2526 by a rigid connecting member 2520. The compact hearing aid 2500 further includes an actuator 2522 coupled to a lateral side of the second battery 2528 opposite the connecting member 2520, and a battery support 2536 disposed on a proximal side of the first battery 2526 that functions as a modulation guide and force to push against. The compact hearing aid 2500 is substantially similar to the hearing aids described above, but for the actuator 2522 being disposed on the lateral end of the second battery 2528 and coupled to an internal surface of a lateral end of the housing 2501.

[0119] As discussed above, the compact hearing aid can be of any suitable size and shape with components of various size and shape; however, each configuration generally requires the same various components, for example, the microphone, energy source, actuator, and processor.

[0120] The actuator 2522 generally comprises a tubular or cylindrical stacked piezoelectric actuator with a mechanical amplifier. For example, as shown in FIG 25, the actuator 2522 comprises a piezoelectric stack 2542 coupled to a mechanical amplifier 2540. The piezoelectric stack 2542 may include any suitable number of layers (e.g., disks) formed of piezoelectric materials. For example, the piezoelectric stack 2542 may include between one and ten layers, such as between two and eight layers, such as five layers, formed of piezoelectric materials. In certain embodiments, one or more of

layers of the piezoelectric stack 2542 are formed of PZT or similar ferroelectric materials, such as lead magnesium niobate-lead titanate (PMN-PT) and the like. Generally, the piezoelectric stack 2542 has a height H between about 0.5 mm and about 4 mm, such as between about 1 mm and about 2 mm. Each layer of the piezoelectric stack 2542 may have a diameter or width D between about 0.5 mm and about 2.5 mm, such as between about 0.5 mm and about 2 mm.

[0121] The mechanical amplifier 2540 may include any suitable type of displacement amplifier. For example, the mechanical amplifier 2540 may include a two-stage flexure-based displacement amplifier. The mechanical amplifier 2540 is configured to transform an input mechanical energy provided by the piezoelectric stack 2542 to an enlarged output mechanical energy for modulation of the second battery 2528 and thus, the first battery 2526 coupled thereto. Accordingly, the mechanical amplifier 2540 may transform a relatively small displacement of the piezoelectric stack 2542 to a desired larger displacement applied to the batteries 2526, 2528 for effective modulation thereof. In certain embodiments, the mechanical amplifier provides a displacement amplification between about 20x and about 100x, such as between about 25x and about 35x.

[0122] Factors considered in the design of the mechanical amplifier 2540 include the amount of force and displacement generated by the piezoelectric stack 2542, and the amount of force to be applied to, and the amount of displacement of, the tympanic membrane to improve the user's hearing. The amount of force may vary based on the modulating mass or masses of between about 20 mg and about 30 mg, between about 0.05 microns and about 5.0 microns of displacement with a force of between about 0.001 Newtons (N) and about 0.05 N, across the audible frequency range.

Methods of Implantation

[0123] The disclosed compact hearing aids are implantable by any suitable implantation method. FIG. 10 is a process flow of one such method 1000.

[0124] Prior to the method 1000, an optional cleaning may be performed to clean the tympanic membrane and the proximal external auditory canal.

[0125] The method 1000 generally includes identifying the optimal location for placement of the compact hearing aid at operation 1010, anesthetizing the location for placement at operation 1020, making an incision, or any other puncture, at the location for placement at operation 1030, and inserting the compact hearing aid through the incision at operation 1040. The method 1000 generally further includes confirming the placement and the functionality of the compact hearing aid at operation 1050.

[0126] In one embodiment, the optimal location is the anterior inferior quadrant of the tympanic membrane. Accordingly, the method includes anesthetizing a portion of the anterior inferior quadrant, making a small incision, such as less than or equal to about 2 mm, for example less than or equal to about 1 mm, and inserting the compact hearing aid through the incision to position the compact hearing aid in the user's anterior inferior quadrant of the tympanic membrane.

[0127] As discussed above, some embodiments of the compact hearing aids include configurations that are adapted for easier insertion through the tympanic membrane. For example, at least one of the one or more flanges may include a slotted or interrupted flange, such as the compact hearing aid 700 shown in FIG. 7, to aid in placement across an incision in the tympanic membrane by rotating the compact hearing aid through the incision.

[0128] In another embodiment, such as the compact hearing aid 800 of FIG. 8, at least one of the one or more flanges, such as the medial flange, or the body of the compact hearing aid itself, is conically-shaped such that it serves as a dilator, which provides a profile to be pushed through the incision in the tympanic membrane to dilate the incision and allow the medial portion of the compact hearing aid to pass therethrough.

[0129] In yet another embodiment, at least one of the medial and lateral flange is a self-expanding flange that is insertable through the incision and

expandable in the middle ear such that it will lie against the medial side of the tympanic membrane once expanded. In still further embodiments, the distance between the flanges, or intermittent portions thereof, is predetermined to allow for implantation and for providing adjustment for variable thickness of the tympanic membrane and/or variable force.

[0130] In even further embodiments, the compact hearing aid includes multiple pieces, which can be coupled together to form the entire compact hearing aid. In such embodiments, the medial and lateral flanges are generally connected by an array of connectors that are fixed in one or both halves and that couple to corresponding receptacles on one or both halves. After one piece of the compact hearing aid is inserted through the incision, for example through the tympanic membrane, then the second piece is coupled to the already inserted piece, for example, by piercing the tympanic membrane with the array of pins that mate with the already inserted piece. In still further embodiments, one piece is inserted through the incision to the medial side of the tympanic membrane and a second piece is coupled to the first piece across the tympanic membrane at a location a distance away from the initial placement incision. In such embodiments, the initial placement incision will heal up.

Methods of Removal for Emergency or Safety Reasons

[0131] The disclosed compact hearing aids can be quickly and safely removed for safety and emergency reasons. For example, as discussed above, embodiments of the compact hearing aids are configured to turn off upon recognition of a particular audio signature frequency. If the particular audio signature fails to turn off the compact hearing aid, or if the compact hearing aid needs to be removed for emergency reasons, then the device may be inactivated and/or removed by physical means.

[0132] In one embodiment, the lateral flange of the disclosed compact hearing aids includes a switch, a pressure switch, a contact point, a slide, or any combinations thereof. A medical professional may contact the switch, the

pressure switch, the contact point, the slide, or the combinations thereof using basic medical tools in an emergency room or other medical setting to inactivate the compact hearing aid after the compact hearing aids fails to turn off in response to the audio signature frequency. In some embodiments, the lateral flange of the disclosed compact hearing aids incorporates a feature to assist in the removal of the compact hearing aid that can be grasped or connected with general medical tools such as tweezers, probes, and forceps.

[0133] In still further embodiments, users of the disclosed compact hearing aids are provided with a custom configured inactivation or retrieval tool that can be used by a medical professional to remove or inactivate the device in emergency situations.

Devices for Implantation and Retrieval

[0134] The disclosed compact hearing aids can be implanted into a patient's ear during a minimally-invasive, outpatient procedure. In one embodiment, the disclosed compact hearing aids are inserted using a scalpel, or any suitable cutting instrument, to create a small incision, or any other puncture, and a tool is used to hold the compact hearing aid and position the contact hearing aid through the tympanic membrane. In another embodiment, an implantation tool, which generally includes an elongate rod having a cutting tool on a distal end thereof, is inserted through the ear canal to the appropriate position on the tympanic membrane. The cutting tool positions the compact hearing aid at the location for placement using a distal alignment ring guide, advances a cutting instrument, such as a blade or a needle, of a predetermined, suitable size to create an incision at the location for placement, and then advances the compact hearing aid across the tympanic membrane to dispose the compact hearing aid therethrough.

[0135] The configuration of the device for implantation and retrieval may be varied to more easily insert specific configurations of the disclosed compact hearing aids. For example, FIGS. 11A-11B depict the compact hearing aid 900 of FIGS. 9A-9C with a portion of an exemplary implantation

tool. As shown in FIGS. 11A-11B, the implantation tool 1100 includes a sheath 1102 and an advancement rod 1104. In operation, the sheath surrounds the compact hearing aid 900 and keeps the plurality of first flange tabs 906 and the plurality of second flange tabs 908 in their non-expanded position such that they lie flat alongside the compact hearing aid 900, as shown in FIG. 11A.

[0136] A portion of the sheath 1102 is generally inserted through the incision made in the tympanic membrane and once the sheath 1102 has been inserted through the tympanic membrane, then at least a portion of the sheath 1102 is withdrawn. The compact hearing aid 900 is thus disposed through the tympanic membrane, such that a first portion of the compact hearing aid 900 is disposed on the medial side of the tympanic membrane and a second portion of the compact hearing aid 900 is disposed on the lateral side of the tympanic membrane. Once the portion of the compact hearing aid 900 having the plurality of first flange tabs 906 is released from the sheath 1102, the advancement rod 1104 maintains its position while the sheath 1102 is withdrawn. The first flange tabs 906 expand, flare out, or otherwise deploy, and form a flange alongside the tympanic membrane, as shown in FIG. 11B.

[0137] In another embodiment, one or more tools, such as cupped forceps, are inserted through a primary opening for accessing the medial side of tympanic membrane, thereupon the two or more components are joined across the tympanic membrane through various mechanisms, such as pins or snaps. The one or more tools, such as the cupped forceps are then removed.

[0138] FIGS. 15A-15B depict an alternative embodiment of an implantation tool 1500. The implantation tool 1500 includes a distal cup 1501, a proximal cup 1502, a connecting member 1503, an advancing member 1504, a handle 1505 and an actuating trigger 1506. The implantation tool 1500 is configured to hold one or more devices to be implanted.

[0139] The operation of the implantation tool 1500 will be described in the context of inserting a compact hearing aid through the tympanic membrane.

However, it is contemplated that the implantation tool 1500 is useful to implant any suitable device in any suitable location throughout the body.

[0140] As shown in FIG. 15B, the implantation tool is configured to hold a first portion 1508 and a second portion 1510 of a compact hearing aid, such as the compact hearing aids disclosed herein.

[0141] In operation, the distal cup 1501 holding the first portion 1508 is advanced through an incision in the tympanic membrane such that the distal cup 1501 and the first portion 1508 are disposed on the medial side of the tympanic membrane while the proximal cup 1502 and the second portion 1510 are disposed on the lateral side of the tympanic membrane. The actuating trigger 1506 can then be used to actuate the distal cup 1501 and/or the proximal cup 1502 to snap the first portion 1508 and the second portion 1510 of the compact hearing aid together through the tympanic membrane at a distance away from the incision. Once the compact hearing aid has been snapped together and implanted through the tympanic membrane, the implantation tool 1500 is withdrawn through the incision and the hearing aid is left in place through the tympanic membrane.

Devices and Systems for Recharging

[0142] The present disclosure further contemplates recharger devices and systems for providing a user interface to recharge the implanted compact hearing aids easily. The recharger devices and systems interact with the charging circuitry to recharge the disclosed compact hearing aids. The recharger devices and systems are generally disposed in the ear canal, over the ear, around the ear, or in the vicinity of the user's head. Exemplary rechargers include ear buds, inner ear canal inserts, ear muffs, over-the-ear clips, glasses stem clips, devices in or around a pillow, and devices in or around the vicinity of the user's head, that can be placed in the ear canal, over the ear, around the ear, or in the vicinity of the user's head to interact with the recharging circuit. In some cases, the recharger device itself will need to be recharged. In one embodiment, the recharging system is a cradle

system that provides a support cradle for the recharge device, which is coupled to a power source such as, an outlet, a USB port, or an automobile power source. In another embodiment, the recharge device itself may be directly connected to a power source through a connector, such as prongs. It is also contemplated that the recharging system can be modular such that a head set would provide holders for the ear components and hold them in place while they are being worn by the patient and additional holders for holding them while they are recharging. The charging components that are placed in the ear canal can be disconnected from the head set system to be more discreet and to allow for mobile recharging.

Docking Devices

[0143] The present disclosure also contemplates docking devices for docking one or more devices in a user's ear, such as through the tympanic membrane. Like embodiments of the compact hearing aids described herein, the docking devices may also include any suitable configurations of a first flange and a second flange connected by a connecting member. However, the docking devices generally do not include the components of the hearing aid described above. Instead, the docking devices generally include a hollow portion therethrough, which is predesigned to dock another device therein. Much like the disclosed compact hearing aids, the docking devices can be inserted during a minimally-invasive outpatient procedure. The procedure generally includes identifying the optimal location for placement of the docking device, anesthetizing the location for placement, making an incision, or any other puncture, at the location for placement, and inserting the docking device through the incision. The procedure may also include cleaning the location for placement, as well as confirming the placement and the functionality of the docking device after the docking device has been placed.

[0144] Suitable devices to be docked include, but are not limited to, biometric devices, diagnostic instruments, entertainment modules, covert communication modules, therapeutic devices, fitness tracking devices, health tracking devices, tissue stimulating devices, and assistive hearing devices.

These docking devices beneficially provide a docking station in the ear, such as through the tympanic membrane, which allows for various devices to be placed therein over time. Since the docking device has already been placed at the predetermined location for placement, an additional incision does not need to be made at the placement location when the device is docked in the docking device.

Stimulating and/or Modulating Devices

[0145] While the present disclosure discusses the disclosed devices being used as compact hearing aids. The present disclosure also contemplates stimulating and/or modulating devices, which are positionable, for example, in any tissue throughout the user's body. Such tissue stimulating devices similarly include a housing with various components therein, such as one or more sensors, one or more masses, one or more energy sources, which may be used as the one or more masses, one or more processors, and one or more actuators. The one or more sensors are generally any suitable sensors to provide a predetermined output, the predetermined output being based on the desired effect on the user's body. Exemplary output includes, but is not limited to, mechanical, electrical, and thermal output. In operation, the stimulating and/or modulating devices are useful to effect change on a number of different tissues in the body, such as muscles, ligaments, membranes, bones, and cartilage.

Conclusion

[0146] Embodiments of the present disclosure provide improved compact hearing aids that use vibration transduction to directly or indirectly modulate the velocity or the position of the tympanic membrane. This direct or indirect modulation of the velocity or the position of the tympanic membrane significantly improves sound quality for the user. The disclosed compact hearing aids are more compact, more comfortable, and less cosmetically noticeable. Indeed, since the disclosed compact hearing aids may be disposed in the ear canal and across the tympanic membrane, the disclosed

compact hearing aids are invisible from the outside observer. In addition, because of the compact design of the disclosed compact hearing aids, the compact hearing aids do not totally block the ear canal. Instead, the disclosed compact hearing aids leave the ear canal unobstructed and thus provide a more natural and improved sound quality for the user. Additionally, the disclosed compact hearing aids provide additional functionality, such as avoiding the canal occlusion effect and hearing aid feedback associated with conventional hearing aids. Moreover, the disclosed compact hearing aids can be inserted and removed during a minimally-invasive outpatient procedure.

[0147] While the foregoing is directed to embodiments of the present disclosure, other and further embodiments of the disclosure may be devised without departing from the basic scope thereof, and the scope thereof is determined by the claims that follow.

What is claimed is:

1. A tympanic membrane actuation assembly, comprising:
at least one mass configured to be disposed on at least one of a medial side or a lateral side of a tympanic membrane of a user; and
at least one bending mode actuator coupled to the mass and configured to be disposed on at least one of a medial side or a lateral side of the tympanic membrane, the bending mode actuator configured to convert electrical signals into mechanical motion to move the mass and modulate the tympanic membrane.
2. The actuation assembly of claim 1, wherein the at least one bending mode actuator comprises a piezoelectric active layer.
3. The actuation assembly of claim 2, wherein the piezoelectric active layer has a perovskite crystal structure.
4. The actuation assembly of claim 3, wherein the piezoelectric active layer comprises lead zirconate titanate (PZT).
5. The actuation assembly of claim 2, wherein the at least one bending mode actuator comprises an inactive layer formed of titanium (Ti) or titanium oxide (TiO₂).
6. The actuation assembly of claim 1, wherein the at least one mass comprises a battery directly coupled to the at least one bending mode actuator.
7. The actuation assembly of claim 6, further comprising:
a sensor configured to detect and convert sound waves into electrical signals;
and
a processor in communication with the sensor and the at least one bending mode actuator, the processor configured to modify the electrical signals from the sensor and provide the modified electrical signals to the at least one bending mode actuator.

8. The actuation assembly of claim 7, wherein the sensor comprises a microphone.
9. A tympanic membrane actuation assembly, comprising:
at least one housing configured to be disposed on at least one of a medial side or a lateral side of the tympanic membrane of a user;
at least one mass disposed within the at least one housing; and
at least one bending mode actuator coupled to the at least one housing, the at least one bending mode actuator configured to convert electrical signals into mechanical motion of the housing to modulate the user's tympanic membrane.
10. The actuation assembly of claim 9, wherein the at least one bending mode actuator is coupled to a planar membrane of the at least one housing, the planar membrane configured to be disposed against the medial side or lateral side of the user's tympanic membrane.
11. The actuation assembly of claim 10, wherein the at least one bending mode actuator comprises a piezoelectric active layer.
12. The actuation assembly of claim 11, wherein the piezoelectric active layer has a perovskite crystal structure.
13. The actuation assembly of claim 12, wherein the piezoelectric active layer comprises lead zirconate titanate (PZT).
14. The actuation assembly of claim 11, wherein the piezoelectric active layer is directly coupled to the planar membrane of the at least one housing.
15. The actuation assembly of claim 11, wherein the at least one bending mode actuator comprises an inactive layer formed of titanium (Ti) or titanium oxide (TiO₂), the inactive layer disposed between the piezoelectric active layer and the planar membrane of the at least one housing.

16. The actuation assembly of claim 11, wherein deformation of the piezoelectric active layer causes modulation of the planar membrane of the at least one housing.
17. A hearing aid, which is insertable through a user's tympanic membrane to amplify certain frequencies and cancel other frequencies, comprising:
a tympanic membrane actuation assembly, comprising:
at least one housing configured to be disposed on at least one of a medial side or a lateral side of the tympanic membrane of a user;
at least one mass disposed within the at least one housing; and
at least one bending mode actuator coupled to a planar membrane of the at least one housing, the at least one bending mode actuator configured to convert electrical signals into mechanical motion of the housing to modulate the user's tympanic membrane.
18. The hearing aid of claim 17, wherein the at least one bending mode actuator comprises a piezoelectric active layer formed of lead zirconate titanate (PZT).
19. The hearing aid of claim 18, wherein the at least one bending mode actuator further comprises an inactive layer formed of titanium (Ti) or titanium oxide (TiO₂), the inactive layer disposed between the piezoelectric active layer and the planar membrane of the at least one housing.
20. The hearing aid of claim 18, wherein the piezoelectric active layer is coupled directly to the planar membrane of the at least one housing.