The invention relates to a hearing instrument, comprising an audio signal source (28), an audio signal processing unit (34) for processing the audio signals provided by the audio signal source, and implantable stimulation assembly (18) for stimulating a round window (24) or an oval window of a patient according to the processed audio signals, wherein the stimulation assembly comprises an electromechanical actuator (20) for vibrating an output member (62) according to the processed audio signals, a support member (72) to be fixed at the patient's skull, and a lever element (22) having a proximal end portion (66), a distal end portion (64) and an intermediate portion (68) connecting the proximal end portion and the distal end portion, wherein the actuator is fixed at the support member, wherein the intermediate portion is supported by the support member in manner enabling a pivoting motion of the lever element, wherein the output member is arranged for imparting an pivoting motion to the lever element by acting on the proximal portion, and wherein the distal end portion arranged is for acting on the round or oval window in order to make the membrane (24) of the round or oval window vibrate according to the pivoting motion of the lever element.
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Hearing instrument for round or oval window stimulation

The present invention relates to a hearing instrument comprising an audio signal source (typically a microphone arrangement), an audio signal processing unit for processing the audio signals provided by the audio signal source and an implantable assembly for stimulation of the round window or oval window of the cochlea according to the processed audio signals.

Besides the stapes footplate and the oval window, the cochlea provides a second natural window for mechanical stimulation, namely the round window. In contrast to the oval window, the round window is closed by a compliant membrane and, besides other purposes, may serve for compensation of static pressures on the inner ear. Mechanical stimulation of the round window membrane is an approach particularly suitable in cases where normal middle ear structures are absent or are severely damaged and cannot be used.

US 2009/0306458 A1 relates to a partially implantable hearing aid comprising an electromechanical actuator acting via a coupling element on the round window. The coupling element may have an angled configuration, and it may include a ball and socket joint which can be locked in order to adjust the angle formed by the coupling element.

WO 2009/062172 A2 relates to a fully implantable hearing aid comprising an electromechanical actuator acting via a coupling element on the round window. The coupling element comprises a first rod being driven by the actuator in reciprocating manner, a second rod being fixedly connected to a stationary portion of the middle ear anatomy and a third rod touching the round window, with the three rods being connected to each other in a star-like fashion at a central joint which may be a mechanical joint, such as a hinge, or a flexible joint, such as an elastomeric member. The first and the third rod thereby are angled with regard to each other.

US 7,753,838 B2 relates to an implantable stimulation assembly which has a rod-like vibratory member which is driven to a reciprocating motion by a first electromagnetic driver acting on the proximal end of the vibratory member and which is driven by a second electromagnetic driver to a tilting/pivoting motion in a direction normal to the axial direction of the vibratory member, with the tip member of the vibratory member being coupled to an
ossicle. According to a variant, the vibratory member is driven at its proximal end by a motor, with a pivotal section, which is connected via a hinge member to a bellows, being provided at the distal end, and with the vibratory member comprising an eccentric rod having a distal end applying a force to the pivotal end section at a point displaced from the hinge member.

While it is a benefit of round window stimulation that it does not involve opening of the inner ear, so that the risk of infections resulting from implantation of the hearing aid is lower compared to oval window stimulation which requires opening of the stapes footplate, the round window is a technically difficult area to be accessed and transducers in this area are difficult to be stabilized. In particular, when an electromechanical actuator is fixed in the usual way within a cavity of the mastoid region, the direction in which the mechanical output member is reciprocating does not coincide with the direction in which reciprocating movement of the coupling element would be desirable for achieving efficient and save vibration/stimulation of the round window membrane.

It is an object of the invention to provide for a hearing instrument for direct mechanical stimulation of the round or oval window, wherein the electromechanical actuator should be mounted in a relatively simple manner while nevertheless efficient mechanical stimulation of the round window or oval window should be achieved.

It is a further object of the invention to provide for a corresponding method of providing hearing assistance.

According to the invention, these objects are achieved by a hearing instrument as defined in claim 1 and a method as defined in claim 40, respectively.

The invention is beneficial in that, by providing the stimulation assembly with a lever element supported by a support member which is fixed at the patient’s skull and at which also the actuator is fixed, with the actuator driving the lever element to a pivoting motion, the angle of the direction used for stimulation of the round or oval window can be adjusted relative to the direction of the output motion of the actuator, thereby achieving efficient stimulation of the round or oval window; in addition, by using such pivoting lever element for stimulation, the force applied by the lever element to the round or oval window can be adjusted.
Preferred embodiments of the invention are defined in the dependent claims.

Hereinafter, examples of the invention will be illustrated by reference to the attached drawings, wherein:

Fig. 1 is a cross-sectional view of an example of a hearing instrument according to the invention after implantation;

Fig. 2 is a block diagram of the system of Fig. 1;

Fig. 3 is a schematic view of an example of a stimulation assembly of a hearing instrument according to the invention;

Fig. 4 is a perspective view of an example of a stimulation assembly of a hearing instrument according to the invention, being shown together with the cochlea and the ossicular chain;

Fig. 5 is a perspective side view of an example of a stimulation assembly of a hearing instrument according to the invention;

Figs. 6 to 8 show a perspective view of various examples of a pivot element of the stimulation assembly of a hearing instrument according to the invention;

Fig. 9 is a perspective view of an example of a stimulation assembly when connected to a fixation system allowing three-dimensional adjustment;

Fig. 10 is a perspective view of an example of a stimulation assembly of a hearing instrument according to the invention when connected to a single axis fixation system;

Fig. 11 is a longitudinal sectional view of the components of Fig. 10;

Fig. 12 is a perspective view of a modified embodiment of the components shown in Figs. 10 and 11;
Fig. 13 is a schematic view of an example of a stimulation assembly comprising an angled lever element; and

Fig. 14 is a perspective view of an example of a stimulation assembly of a hearing instrument according to the invention, being shown together with the cochlea and the ossicular chain, when connected to a fixation system allowing three-dimensional adjustment.

Fig. 1 shows a cross-sectional view of the mastoid region, the middle ear and the inner ear of a patient after implantation of an example of a hearing instrument according to the invention, wherein the hearing instrument is shown only schematically. The system comprises an external unit 10 which is worn outside the patient's body at the patient's head, typically close to the ear, and an implantable unit 12 which is implanted under the patient's skin 14, usually in an artificial cavity created in the user's mastoid. The implantable unit 12 is connected, via a cable assembly 16, to a stimulation assembly 18 comprising an electromechanical actuator 20 for stimulating the round window 24 of the cochlea 26 via a lever element 22.

The external unit 10 is fixed at the patient's skin 14 in a position opposite to the implantable unit 12, for example, by magnetic forces created between at least one fixation magnet provided in the external unit 10 and at least one co-operating fixation magnet provided in the implantable unit 12 (the magnets are not shown in Fig. 1).

An example of a block diagram of the system of Fig. 1 is shown in Fig. 2. The external unit 10 includes a microphone arrangement 28, which typically comprises at least two spaced-apart microphones 30 and 32 for capturing audio signals from ambient sound, which audio signals are supplied to an audio signal processing unit 34, wherein they undergo, for example, acoustic beam forming. The processed audio signals are supplied to a transmission unit 36 connected to a transmission antenna 38 in order to enable transcutaneous transmission of the processed audio signals via an inductive link 40 to the implantable unit 12 which comprises a receiver antenna 42 connected to a receiver unit 44 for receiving the transmitted audio signals. The received audio signals are supplied to a driver unit 48 which drives the actuator 20.
The external unit 10 also comprises a power supply 50 which may be a replaceable or rechargeable battery, a power transmission unit 52 and a power transmission antenna 54 for transmitting power to the implantable unit 12 via a wireless power link 56. The implantable unit 12 comprises a power receiving antenna 58 and a power receiving unit 60 for powering the implanted electronic components with power received via the power link 56.

Preferably, the audio signal antennas 38, 42 are separated from the power antennas 54, 58 in order to optimize both the audio signal link 40 and the power link 56. However, if a particularly simple design is desired, the antennas 38 and 42 and the antennas 54 and 58 could be physically formed by a single antenna, respectively.

In Fig. 3 an example of the structure of a stimulation assembly is shown schematically. The stimulation assembly 18 comprises an electromechanical actuator 20 (which may be formed, for example, by electromagnetic transducer) for driving an output member formed by a rod 62 in a reciprocating manner, a lever element 22 having a first, distal end portion 64 acting on the round window membrane 24, a second, proximal end portion 66 driven by the output member 62 and an intermediate portion 68 connecting the distal end portion 64 and the proximal end portion 66 and being supported by a pivot element 70, and a support member 72 for supporting the actuator 20 via an adjustable actuator fixation portion 74 and for supporting the pivot element 70 (hereinafter, "distal" designates directions towards the round or oval window, and "proximal" designates directions away from the round or oval window towards the skin). In operation of the device, both the pivot element 70 and the actuator 20 are fixed relative to the support member 72. The free end of the output rod 62 is provided with a rounded tip 76 for touching a contact area of the proximal end portion 66 of the lever element 22, with the output rod 62 moving in a direction substantially perpendicular to the direction into which the proximal end portion 66 of the lever element 22 extends.

The distal end portion 64 is provided with a rounded contact element 79 extending into a radial direction of (i.e. laterally from) the distal end portion 64 and acting on the round window membrane 24. The contact element 79 of the lever element 22 preferably has a mushroom-like spherical head, with the front surface area of the head being substantially equal to the area of the round window membrane 24. Preferably, the contact element 79 is made of or coated with a pyrocarbon material. The pyrocarbon material typically has a
Vickers hardness of 150 to 250. Preferably, the surface roughness Ra of the contact element 79 is less than 0.02 µm.

By action of the output rod 62 a pivoting motion is imparted to the lever element 22 with regard to the intermediate portion 68 (see arrows 78 in Fig. 3), whereby the round window membrane 24 is made to vibrate according to such pivoting motion. Since, by action of the lever element 22, the actuator 20 is driven according to the processed audio signals, the round window 24 is made to vibrate according to the processed audio signals received from the external unit 10.

The support member 72 comprises a first portion 80 for holding the actuator 20 via the actuator fixation portion 74 and a second portion 82 for holding the pivot element 70, with the first portion 80 and the second portion 82 extending in directions which are essentially perpendicular with regard to each other. Preferably, the first portion 80 and the second portion 82 of the support member 72 have an essentially tubular, preferably cylindrical design, wherein the first portion 80 houses the actuator 20, and the second portion 82 houses the proximal end portion 66 and the intermediate portion 68 of the lever element 22.

In Figs. 4 and 5 an example of a stimulation assembly 18 is shown, wherein the support member 72 comprises an essentially cylindrical second portion 82 and an essentially cylindrical first portion 80 which are oriented perpendicular to each other. The position of the actuator 20 relative to the support member 72 is axially adjustable with regard to the actuation direction (i.e. the direction of the reciprocating movement) of the output rod 62 in order to adjust the loading of the contact element 79 of the distal end portion 64 of the lever element 22 on the round window membrane 24. This may be realized, as shown in Figs. 5 and 9 to 12, by a rotatable adjustment member 84 engaging with a thread provided at the first portion 80 of the support member 72. In the example shown in Figs. 5 and 9 to 12, the adjustment member 84 is a nut-like element which is screwed onto an outer thread 86 provided at the periphery of the first portion 80 of the support element 72. Thus, the axial position of the actuator 20 with regard to the first portion 80 of the support member 72 may be adjusted by rotating the nut 84 accordingly, with the corresponding axial movement of the nut 84 causing the actuator 20 to move axially.
The outer surface of the actuator 20 preferably is provided with a structure engaging with a mating counter-structure provided at the actuator fixation portion 74 of the support member 72 in manner that the actuator is axially moveable in the actuation direction of the output member 62, but is prevented from rotation. Such engagement may be provided in a rib-and-groove fashion, for example by providing the outer surface of the actuator 20 with an axially extending rib and providing the inner surface of the actuator fixation portion with a corresponding groove for receiving the rib.

Preferably, the nut-like element 84 is provided with an axially extending lateral slot 85 (see Fig. 9) for allowing the cable assembly 16 connecting the actuator 20 to the implantable unit 12 to pass into a central portion of the the nut-like element 84.

The pivot element 70 is constructed in a manner so as to have a torsion of the central portion 90 due to the pivoting motion of the lever element 22, while avoiding friction on materials in order to keep wearing of the materials small.

As shown in the examples of Figs. 6 to 8, the pivot element 70 may be designed in a hub-like manner to be torsioned by the pivoting motion of the lever element 22, with the pivot element 70 being made of a sufficiently elastic material. In particular, the pivot element 70 comprises two end portions 88 which are fixed at the support member 72 and a central portion 90 which extends between the end portions 88 and at which the intermediate portion 68 of the lever element 22 is fixed. The end portions 88 of the pivot element 70 are fixed in corresponding holes in the wall of the second portion 82 of the support member 72. The central portion 90 of the pivot element 70 comprises a central opening 92 in which the intermediate portion 68 of the lever element 22 is fixed.

In the example shown in Fig. 6, the pivot element 70, or at least the central portion 90 thereof, may be made of silicone, with the central portion 90 of the pivot element 70 having a rod-like shape.

In the example shown in Fig. 7, the central portion is made of a suitable metal material and has a wireless design.

In the example of Fig. 8, the central portion 90 of the pivot element 70 has a blade-like shape.
According to the example shown in Fig. 3, the lever element 22 is substantially straight. However, according to an alternative embodiment, the distal end portion 64 and the proximal end portion 66 of the lever element 22 may be angled with regard to each other, thereby introducing an additional design parameter, namely the angle between the portions 64 and 66, which can be adjusted for achieving optimal coupling to the round window membrane 24 (when using a straight lever, the movement of the output rod 62 of the actuator 20 is anti-parallel to the movement of the contact element 79 of the lever element 22; by selecting an appropriate angled configuration of the lever element 22, the angle between the movement of the output rod 62 and the movement of the contact element 79 can be adjusted as desired). A schematic example of a stimulation assembly using such a angled lever element 22 is shown in Fig. 13.

The support member 72 preferably is made of titanium.

The support member 72 is fixed at the patient's skull via an adjustable fixation system 94 by bone screws (in Figs.4 and 9-12 only the bone screw openings 96 of the fixation system 94 are shown, but not the bone screws themselves).

In the embodiment shown in Fig. 9, the fixation system 94 comprises a linearly driven slide element 92, at which the support member 72 is fixed, and a lockable ball joint 100 at which the slide element 92 is supported. The ball joint 100 forms part of a flange element 102 comprising the bone screw opening 96. By using such fixation system, the position of the stimulation assembly 18 may be adjusted in three dimensions during implantation. Once the ball joint 100 and the linearly driven slide element 92 have reached their final position, the loading on the round window 24 may be adjusted by adjusting the nut 84.

In the alternative embodiment shown in Fig. 14, the slide element 92 is replaced by a clamp element 105 which is attached to the ball of the ball joint 100 and which comprises two legs 103, 106 for surrounding a cylindrical proximal portion 108 of the support member 72 in manner so as to connect the support member 72 to fixation system 94 in an adjustable manner. To this end, the legs 103, 106 are connected at one end by a screw 109 which can be turned by the surgeon so as to adjust the clamping force exerted by the legs 103, 106 onto the proximal portion 108 of the support member 72. When the screw 109 is loosened, the support member
72 may be axially moved and/or rotated relative to the clamp element 105 in order to adjust the position and orientation of the support member 72 relative to the fixation system 94, thereby also adjusting the position of the contact element 79 with regard to the cochlea 26. By tightening the screw 109, the support member 72 can be fixed with regard to the fixation system 94.

An alternative embodiment of a fixation system fixation system 194 is shown in Figs. 10 and 11. In this case, the second portion 82 of the support element 72 carries a stopper plate 104 which is adjustable in the axial direction with regard to the support member 72 in order to determine the position of the support member 72 during implantation. To this end, the cylindrical second portion 82 of the support member 72 is provided with an outer thread 106, with the stopper plate 104 having a central opening provided with an inner thread 108 engaging with the outer thread 106. Thereby the axial position of the stopper plate 104 can be adjusted by rotating the stopper plate 104.

The support member 72 comprises a third portion 110 which forms an axial extension of the second portion 82 beyond the region where the first portion 80 and the second portion 82 are connected to each other. A fixation plate 112 comprising bone screw openings 96 for being fixed at the patient's skull is connected to the third portion 110 of the support member 72 in a manner so as to be axially movable but not rotatable with regard to the third portion 110. To this end, the fixation plate 112 comprises a base portion 114 which is slidably received in a receptacle 116 in the third portion 110 of the support member 72. In order to prevent rotation between the fixation plate 112 and the third portion 110 of the support member 72, the base portion 114 and the receptacle 116 have a non-circular symmetry, for example, by providing axial grooves engaging with corresponding projections.

The fixation system 194 shown in Figs. 10 and 11 allows for adjustment of the position of the stimulation assembly 18 in one direction only, namely along the axial direction of the second portion 82 of the support member 72. Such linear adjustment is achieved by adjusting the axial position of the stopper plate 104 by rotating the stopper plate 104 accordingly. Such design of the fixation system is much simpler than that of Fig. 9. However, it requires a much more precise drilling of the cavity into which the stimulation assembly 18 is to be inserted. An
appropriate drilling/implantation method is described in WO 2010/061006 A2 and
international application No. PCT/EP2010/056749.

The axial position of the stopper plate 104 is adjusted prior to inserting the stimulation
assembly into the drilled cavity by using a fork-shaped tool (not shown) engaging with
radially extending openings 105 of the stopper plate 104, with the support member 72 being
held by hand. After the stimulation assembly 18 has been inserted into the cavity, the stopper
plate 104 is fixed to the bone.

In Fig. 12, a modification of the embodiment of Figs. 10 and 11 is shown, wherein the fixation
plate 112 includes a compartment 118 for electronic components, whereby the electronic
components can be brought close to the main axis of the stimulation assembly 18.

While the examples described so far relate to stimulation of the round window, it is to be
understood that the above examples of the stimulation assembly 18 in principle also could be
used for stimulation of the oval window.
Claims

1. A hearing instrument, comprising an audio signal source (28), an audio signal processing unit (34) for processing the audio signals provided by the audio signal source, and implantable stimulation assembly (18) for stimulating a round window (24) or an oval window of a patient according to the processed audio signals, wherein the stimulation assembly comprises an electromechanical actuator (20) for vibrating an output member (62) according to the processed audio signals, a support member (72) to be fixed at the patient's skull, and a lever element (22) having a proximal end portion (66), a distal end portion (64) and an intermediate portion (68) connecting the proximal end portion and the distal end portion, wherein the actuator is fixed at the support member, wherein the intermediate portion is supported by the support member in manner enabling a pivoting motion of the lever element, wherein the output member is arranged for imparting an pivoting motion to the lever element by acting on the proximal portion, and wherein the distal end portion arranged is for acting on the round or oval window in order to make the membrane (24) of the round or oval window vibrate according to the pivoting motion of the lever element.

2. The hearing instrument of claim 1, wherein the stimulation assembly (18) comprises a pivot element (70) supported by the support member (72), with the pivot element supporting the intermediate portion (68) of the lever element (22).

3. The hearing instrument of claim 2, wherein the pivot element (70) is fixed at the support member (72).

4. The hearing instrument of claim 3, wherein the pivot element (70) is made of elastic material and is designed in hub-like manner to be torsioned by the pivoting motion of the lever element (72).

5. The hearing instrument of claim 4, wherein the pivot element (70) comprises two end portions (88) which are fixed at the support member (72) and an central portion (90) which extends between the end portions and at which the intermediate portion (68) of the lever element (22) is fixed.
6. The hearing instrument of claim 5, wherein the central portion (90) of the pivot element (70) comprises a central opening (92) in which the intermediate portion (68) of the lever element (22) is fixed.

7. The hearing instrument of claim 6, wherein the pivot element (70) comprises silicone.

8. The hearing instrument of claim 7, wherein the central portion (90) of the pivot element (70) has a rod-like shape.

9. The hearing instrument of claim 6, wherein the pivot element (70) comprises a metal material.

10. The hearing instrument of claim 9, wherein the central portion (90) of the pivot element (70) has a blade-like shape.

11. The hearing instrument of one of the preceding claims, wherein the lever element (22) is substantially straight.

12. The hearing instrument of one of claims 1 to 10, wherein the proximal end portion (66) and the distal end portion (64) are angled with regard to each other.

13. The hearing instrument of one of the preceding claims, wherein the position of the actuator (20) relative to the support member (72) is adjustable with regard to the actuation direction of the output member (62) in order to adjust the loading of the distal end portion (64) of the lever element (22) on the round or oval window membrane (24).

14. The hearing instrument of claim 13, wherein the position of the actuator (20) is adjustable by a rotatable adjustment member (84) engaging with a thread (86) provided at the support member (72).

15. The hearing instrument of claim 14, wherein the adjustment member is a nut-like element (84) which is adapted to advance the actuator (20) upon being rotated.

16. The hearing instrument of claim 15, wherein the nut-like element (84) is provided with an axially extending lateral slot (85) for allowing a cable assembly (16) fixed at the actuator (20) to pass into a central portion of the the nut-like element (84).
17. The hearing instrument of one of claims 13 to 16, wherein the outer surface of the actuator (20) is provided with a structure engaging with a mating counter-structure provided at the support member (72) in manner that the actuator is axially moveable in the actuation direction of the output member (62), but is prevented from rotation.

18. The hearing instrument of claim 17, wherein the structure and the counter-structure are designed for engagement in a rib-and-groove fashion.

19. The hearing instrument of one of the preceding claims, wherein the output member (62) of the actuator (20) comprises a rounded tip (76) for touching a contact area of the proximal end portion (66) of the lever element (22).

20. The hearing instrument of claim 19, wherein the output member (62) is designed to move in a direction substantially perpendicular to the direction into which the proximal end portion (66) of the lever element (22) extends.

21. The hearing instrument of claim 20, wherein the contact area has a concave shape.

22. The hearing instrument of one of the preceding claims, wherein the distal end portion (64) of the lever element (22) is provided with a contact element (79) for acting on the round or oval window membrane (24).

23. The hearing instrument of claim 22, wherein the contact element (79) has a mushroom-like spherical head.

24. The hearing instrument of claim 23, wherein the front surface area of the head (79) is substantially equal to the area of the round window membrane (24).

25. The hearing instrument of one of claims 22 to 24, wherein the contact element (79) comprises a pyrocarbon material.

26. The hearing instrument of one of claims 22 to 24, wherein the surface roughness $Ra$ of the contact element (79) is less than 0.02 $\mu$m.

27. The hearing instrument of one of the preceding claims, wherein the support member (72) comprises a first portion (80) for holding the actuator (20) and a second portion (82) for holding the pivot element (70), wherein the first portion and the second portion extend in directions which are essentially perpendicular with regard to each other.
28. The hearing instrument of claim 27, wherein the first portion (80) and the second portion (82) of the support member (72) have a tubular shape, wherein the first portion of the support member houses the actuator (20) and wherein the second portion of the support member houses the proximal end portion (66) and the intermediate portion (68) of the lever element (22).

29. The hearing instrument of claim 27, when depending from claim 5, wherein the end portions (88) of the pivot element (70) are fixed in holes of a wall of the second portion (82) of the support member (72).

30. The hearing instrument of one of the preceding claims, wherein the support member (72) is to be fixed at the patient's skull via an adjustable fixation system (94, 194) by bone screws.

31. The hearing instrument of claim 30, wherein the fixation system (94) comprises a linearly driven slide element (98), at which the support member (72) is fixed, and a lockable ball joint (100), at which the slide element is supported.

32. The hearing instrument of one of claims 1 to 29, wherein the second portion (82) of the support member (72) is carried a stopper plate (104) which is adjustable in the axial direction with regard to the support member in order to determine the position of the support member during implantation.

33. The hearing instrument of claim 32, wherein the second portion (82) of the support member (72) is provided with an outer thread (106) and the stopper plate (104) has a central opening provided with an inner thread (108) engaging with the outer thread of the stopper plate.

34. The hearing instrument of one of claims 32 and 33, wherein the support member (72) comprises a third portion (110) which forms an axial extension of the second portion (82) of the support member into a proximal direction, wherein a fixation plate (112) to be fixed at the patient's skull is connected to the third portion of the support member in a manner so as to be axially moveable but not to be rotatable with regard to the third portion of the support member.
35. The hearing instrument of claim 34, wherein the fixation plate (112) comprises a base portion (114) which is slideably received in a receptacle (116) in the third portion (110) of the support member (72).

36. The hearing instrument of one of the preceding claims, wherein the actuator (20) comprises an electromagnetic transducer.

37. The hearing instrument of one of the preceding claims, wherein the audio signal source is formed by a microphone arrangement (28) for capturing audio signals from ambient sound.

38. The hearing instrument of claim 37, wherein the microphone arrangement (28) and the audio signal processing unit (34) form part of external unit (10) to be fixed at the patient's head and comprising means (36, 38) for transmitting the processed audio signals via a wireless subcutaneous link (40) to the stimulation assembly (18).

39. The hearing instrument of claim 30, wherein the fixation system (94) comprises a lockable ball joint (100) supporting a clamp element (105) having two legs (103, 106) which surround a proximal end portion (108) of the support member (72) in a detachable manner.

40. A method of providing hearing assistance to a patient, comprising

providing audio signals from an audio signal source (28) and processing the audio signals provided by the audio signal source,

vibrating an output member (62) of an electromechanical actuator (20) fixed at the patient's skull according to the processed audio signals,

exiting a pivoting motion of a lever element (22), which is supported in an intermediate portion (68) thereof, with regard to the intermediate portion, by the output member acting on a proximal end portion (66) of the lever element, and

vibrating the membrane (24) of the round or oval window of the patient according to the pivoting motion of the lever element (22), by a distal end portion (64) of the lever element acting on the round or oval window, thereby stimulating the round window or oval window according to the processed audio signals.