A surgical instrument for inserting an implantable electrode carrier includes a housing having a proximal end and a distal end. The proximal end is configured to hold the implantable electrode carrier. The instrument also includes a vibration generator positioned within the housing. The vibration generator is configured to generate vibrations in at least a portion of the electrode carrier.
FIG. 4A

FIG. 4B

Section A-A
INSTRUMENT FOR INSERTING IMPLANTABLE ELECTRODE CARRIER

CROSS REFERENCE TO RELATED APPLICATIONS


FIELD OF THE INVENTION

[0002] The present invention generally relates to surgical instruments for medical implants and, more particularly, the invention relates to surgical instruments for implantable electrode carriers that improve the insertion process of the electrode carriers.

BACKGROUND OF THE INVENTION

[0003] For many patients with severe to profound hearing impairment, there are several types of middle-ear and inner-ear implants that can restore a sense of partial or full hearing. For example, cochlear implants can restore some sense of hearing by direct electrical stimulation of the neural tissue of the inner ear or cochlea. The cochlear implant typically includes an electrode carrier having an electrode lead and an electrode array, which is threaded into the cochlea. The electrode array usually includes multiple electrodes on its surface that electrically stimulate auditory nerve tissue with small currents delivered by the electrodes distributed along the electrode array. These electrodes are typically located toward the end of the electrode carrier and are in electrical communication with electronics that produce an electrical stimulation signal for the implanted electrodes to stimulate the cochlea.

[0004] One of the important steps in cochlear implant surgery is the insertion of the electrode array into the scala tympani of the cochlea. In some cases, this insertion process can be disrupted when the continuous movement of the electrode carrier into the cochlea gets disturbed due to increased frictional forces between the cochlea wall and the electrode array, or due to small obstacles preventing the electrode carrier from smoothly moving along the insertion path. In both cases, the electrode carrier may become damaged if it is excessively bent when being pushed further inside the cochlea while the tip or other parts of the electrode carrier are prevented from moving forward. Furthermore, x-ray microscopy studies by Hüttenbrink et al. allowed a visualization of the frictional behavior of electrodes in the inner ear and revealed that in some cases there might be the danger of kinking of the electrode carrier inside of the scala tympani. A subsequent contact pressure between electrode and basilar membrane which may lead to rupture of the basilar membrane is very likely to damage anatomical structures of the inner ear and destroy residual hearing. Such damage is not acceptable with the latest trends in Electric Acoustic Stimulation (EAS) technology and cochlear implant surgery to preserve any residual hearing.

[0005] To minimize these problems, lubricating substances are sometimes used on the electrode carrier to reduce the frictional forces between electrode carrier and the cochlea. However, it is questionable whether these lubricating substances are able to prevent typically occurring problems during the insertion process and currently have not become a commonly accepted clinical practice.

[0006] Another issue which is observed in cochlear implant surgery is the floppiness of the electrode carrier in the mastoidectomy and posterior tympanotomy which may make it difficult to guide the electrode carrier to the cochleostomy or round window without picking up blood or other fluids from the surrounding tissues. A contamination of the electrode carrier with blood represents another potential hazard to the residual hearing of patients.

[0007] U.S. Patent Application Publication No. 2007/0225787 to Simaan et al. ("Simaan") teaches active-bending electrodes and corresponding insertion systems for inserting same. In this context, an electrode applicator is mentioned which reduces the frictional forces as the electrode traverses the inner ear by applying vibrations to the electrode array. However, the insertion systems disclosed therein include a controller located remotely, making the systems bigger and more unwieldy. In addition, Simaan fails to provide any teachings on how, and by what mechanism, the insertion system generates the vibrations in the electrode array.

SUMMARY OF THE INVENTION

[0008] In accordance with one embodiment of the invention, a surgical instrument for inserting an implantable electrode carrier includes a housing having a proximal end and a distal end. The proximal end is configured to hold the implantable electrode carrier. The instrument also includes a vibration generator positioned within the housing. The vibration generator is configured to generate vibrations in at least a portion of the electrode carrier.

[0009] In related embodiments, the vibration generator may be positioned within the distal end and/or the proximal end of the housing. The instrument may further include a power supply coupled to the vibration generator and positioned within the housing, such as the distal end of the housing. The power supply is configured to supply energy to the vibration generator. The vibration generator may include a floating mass transducer. The floating mass transducer may include a bushing having an inner area, a permanent magnet positioned within the inner area of the bushing, and an electromagnetic coil adjacent to a portion of the bushing. The electromagnetic coil is configured to move the permanent magnet within the inner area of the bushing. The floating mass transducer may further include one or more springs positioned between the permanent magnet and one end of the bushing so that the spring(s) are configured to move the permanent magnet back to a neutral position after the electromagnetic coil moves the permanent magnet within the inner area of the bushing. The permanent magnet may be cylindrical or spherical in shape.

[0010] The vibration generator may include an electromotor connected to a gear, and a mass connected to the gear. The mass is configured to produce at least a portion of the vibrations generated by the vibration generator when the gear moves the mass. Alternatively, or in addition, the vibration generator may include an electromotor connected to a gear having an unbalanced mass. The unbalanced mass is configured to produce at least a portion of the vibrations generated by the vibration generator when the gear moves the unbalanced mass. The instrument may further include one or more sensors positioned near the distal end of the housing. The sensor(s) may be configured to sense a force applied to the instrument, and the vibration generator may be configured to
control vibrations parameters based on the sensed force. The vibration generator may impart longitudinal oscillations, transverse oscillations and/or rotational oscillations to the proximal end of the housing. The vibration generator may include a piezoelectric actuator, a pneumatic actuator, an hydraulic actuator, an electrodynamic actuator and/or a mechanical actuator. The housing may have a longitudinal axis from the proximal end to the distal end of the housing, and the vibration generator may be concentric to the longitudinal axis or offset from the longitudinal axis.

In accordance with another embodiment of the invention, a method of making a surgical instrument for inserting an implantable electrode carrier includes providing a housing having a proximal end and a distal end, and providing a vibration generator positioned within the housing. The proximal end is configured to hold the implantable electrode carrier, and the vibration generator is configured to generate vibrations in at least a portion of the electrode carrier.

In related embodiments, the method may further include providing a power supply coupled to the vibration generator and positioned within the housing. The power supply is configured to supply energy to the vibration generator. The vibration generator may include a floating mass transducer that has a bushing having an inner area, a permanent magnet positioned within the inner area of the bushing, and an electromagnetic coil adjacent to a portion of the bushing. The electromagnetic coil is configured to move the permanent magnet within the inner area of the bushing. The vibration generator may include an electromotor connected to a gear having an unbalanced mass, and the unbalanced mass may be configured to produce at least a portion of the vibrations generated by the vibration generator when the gear moves the unbalanced mass. The method may further include providing one or more sensors positioned near the distal end of the housing. The one or more sensors are configured to sense a force applied to the instrument, and the vibration generator is configured to control vibration parameters based on the sensed force.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

FIG. 1 schematically shows a typical human ear which includes a cochlear implant system;
FIG. 2 schematically shows an exemplary surgical instrument with an integrated vibration generator according to embodiments of the present invention;
FIG. 3 schematically shows an electrodynamic vibration generator that permits axial vibrations according to embodiments of the present invention;
FIGS. 4A and 4B schematically show a bushing for an electrodynamic vibration generator that permits axial and torsional vibrations according to embodiments of the present invention;
FIG. 5 schematically shows an electromotor vibration generator that permits multidimensional vibrations according to embodiments of the present invention;
FIG. 6A schematically shows one portion of a gear with an unbalanced mass that permits multidimensional vibrations according to embodiments of the present invention;
FIG. 6B schematically shows a cross-sectional view along lines B-B of FIG. 6A; and
FIG. 7 schematically shows a portion of an instrument holding an implantable electrode carrier according to embodiments of the present invention.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Various embodiments of the present invention provide a surgical instrument for inserting an implantable electrode carrier, methods of making same, and methods of inserting the electrode carrier, that improves the current implantation process for electrodes. The surgical instrument may include a housing and a vibration generator which is integrated into the housing. The vibration generator is configured to generate vibrations in at least a portion of the electrode carrier. Details of illustrative embodiments are discussed below.

FIG. 1 schematically shows the anatomy of a normal human ear and some components of a typical cochlear implant system. As shown, the cochlear implant system includes an external microphone (not shown) that provides an audio signal input to an external signal processor where various signal processing schemes may be implemented. The processed signal is then converted into a stimulation pattern by an external transmitter/stimulator, and the stimulation pattern/signal is transmitted through connected wires (not shown) to an implanted electrode carrier. The electrode carrier has an electrode lead and an electrode array. Typically, the electrode array has multiple electrodes on its surface that provide selective stimulation to the cochlea.

FIG. 2 schematically shows an illustrative embodiment of a surgical instrument with an integrated vibration generator that may be used to implant an electrode carrier. The instrument includes a housing having a proximal end and a distal end. The proximal end is configured to hold the implantable electrode carrier (not shown in FIG. 2). The instrument also includes a vibration generator positioned within the housing, in the distal end and/or proximal end of the housing. The vibration generator is configured to generate vibrations in at least a portion of the electrode carrier. The housing has a longitudinal axis from the proximal end to the distal end of the housing, and the vibration generator may be concentric to the longitudinal axis or offset from this axis. For example, the vibration generator may be coupled to, or adjacent to, an inner surface of the housing in one or more locations so that the vibration generator is relatively equally spaced from the sides of the housing. Alternatively, the vibration generator may be coupled to, or adjacent to, one portion of the inner surface of the housing so that the vibration generator is closer to one side of the housing than the other. The vibration generator will be described in more detail below.

Embodiments of the instrument may include a power supply positioned within the housing and coupled to the vibration generator. Preferably, the power supply is positioned within the distal end of the housing. The power supply supplies energy to the vibration generator. The instrument may include a standard instrument handle-handle at the distal end of the instrument which allows a surgeon to grip the instrument, guide it and the cochlear implant electrode carrier to the cochleo-
stomy, and insert the electrode array into the cochlea. Although one configuration of the instrument 120 is shown, any standard instrument geometry may be used, e.g., forceps, tweezers, or surgical claws, that allows an integrated vibration generator 124.

Embodyings of the instrument 120 may also include one or more sensors (not shown) positioned on or in the housing 122. The sensor(s) may be used to detect a force which is applied to the instrument 120, and the sensed force may be used as an input for the vibration generator 124. The sensor(s) may be used to give surgeons the ability to control various vibration parameters generated by the vibration generator 124 (e.g., an increased pressure on the handle of the instrument by the surgeon may increase the amplitude and/or frequency of the vibrations). This may allow surgeons to implement the instrument and its vibrations in a much more controlled way. A stopper (not shown) may also be used with the instrument 120 to prevent overloading of the electrode carrier caused by any high closing forces of the instrument 120.

Embodyings of the vibration generator 124 are configured to couple vibrations to at least a portion of the electrode carrier. The frequency and amplitude of the vibrations produced by the vibration generator 124 are preferably chosen such that the oscillations produced in the electrode carrier help to overcome the friction effects and obstacles encountered when inserting the electrode carrier into the cochlea, reducing possible insertion trauma. In addition, or alternatively, the vibrations may be adapted to the vibration characteristics of one or more portions of the electrode carrier such that any large amplitude deflections of the electrode carrier may be suppressed or substantially suppressed. The instrument 120 may have one or more different vibration modes to provide optimal behaviour of the electrode carrier inside and outside the cochlea. The vibration parameters may be optimized to improve the electrode carrier movement, to improve the stability of the electrode carrier (e.g., to avoid transversal oscillations of a floppy electrode carrier), and/or to improve the smoothness of the electrode carrier insertion process. Vibration parameters may include amplitude, frequency, ascending and descending slope of the vibration signal and its waveform in general. Modes of vibrations may include sinusoidal, triangular, square-wave, saw-tooth-like signals or a combination of two or more of these modes.

Various types of systems may be used for the vibration generator 124. For example, the vibration generator 124 may include electrodynamic actuators, piezoelectric actuators, pneumatic actuators, hydraulic actuators, and/or mechanical systems, although other systems may also be used. Preferably, the frequency of the vibrations may range between 0 to about 100 kHz and the amplitude of the vibrations may range between 0 to about 5 mm. Longitudinal, transverse and/or rotational oscillations may be applied by the vibration generator 124 to the electrode carrier depending on the configuration of the vibration generator 124.

For example, FIG. 3 schematically shows an exemplary floating mass transducer 130 that may be used as a vibration generator 124 to generate longitudinal or transverse oscillations within the electrode carrier 106 depending on the orientation of the transducer 130 in the instrument 120. As shown, the floating mass transducer 130 includes a bushing 132 having an inner area 134 and a permanent magnet 136 positioned within the inner area 134. Preferably, the permanent magnet is cylindrical (shown) or spherical (not shown) in shape. The bushing 132 allows the permanent magnet 136 to move within the inner area 134 toward either end 132a, 132b of the bushing 132, and generally along axis, a, as shown. The floating mass transducer 130 further includes at least one electromagnetic coil 138 adjacent to a portion of the bushing 132. As known by those skilled in the art, a current may be passed through the electromagnetic coil 138, which creates a magnetic field within the inner area 134 of the bushing 132. In response to this magnetic field, the permanent magnet 136 moves within the inner area 134 of the bushing 132 either toward end 132a or end 132b, depending on the direction of the magnetic field. As known by those skilled in the art, the direction of the magnetic field may be changed depending on the direction of the current flow within the electromagnetic coil 138. The movement of the permanent magnet 136 within the inner area 134 of the bushing 132 causes vibrations to be produced by the floating mass transducer 130.

The floating mass transducer 130 may optionally include one or more springs or dampers 140 positioned between the permanent magnet 136 and either end 132a, 132b of the bushing 132. After the electromagnetic coil 138 has moved the permanent magnet 136 within the inner area 134, the spring(s) 140 provide a restoring force to the permanent magnet 136 and move the permanent magnet 136 back to a neutral position within the inner area 134. The bushing 132 may be hermetically sealed so as to prevent corrosion and/or leakage of material into or out of the bushing 132. Preferably, the bushing 132 is made of a non-ferromagnetic material and may be made of a biocompatible material, e.g., stainless steel, titanium, aluminum, platinum, nylon and/or a ceramic material.

Although FIG. 3 shows a floating mass transducer 130 that generates axial vibrations, the configuration of the inner area 134 within the bushing 132 may be modified to permit axial and torsional vibrations according to embodiments of the present invention. For example, FIG. 4A schematically shows a longitudinal cross-section of a bushing 142 and its inner area 144, and FIG. 4B schematically shows a transverse cross-sectional view along line A-A of FIG. 4A that may be used within a floating mass transducer to generate both axial and torsional vibrations. As shown, the permanent magnet 156 may move generally along axis a and axis b (shown as dashed lines in FIG. 4A) as well as rotate or turn within the inner area 144. An advantage of adding rotational vibrations to translational rotation is that rotational vibrations may be especially effective when trying to overcome obstacles during electrode carrier insertion.

Another configuration of a vibration generator 124 that may be used is a miniaturized electromotor. For example, FIG. 5 schematically shows an electromotor 150 that permits multidimensional vibrations according to embodiments of the present invention. As shown, the electromotor 150 may include a motor 152 connected to a gear 154, which in turn is connected to a mass 156 that may move back and forth generally in the direction shown with arrows. As shown in FIGS. 6A and 6B, the gear 154 may have an unbalanced mass 158, which when the gear rotates, may generate multidimensional vibrations. An advantage of a mechanical gear solution is that the individual parts are generally inexpensive, simple and reliable.
Some embodiments may provide improved methods of inserting the electrode carrier into the cochlea. For example, as shown in FIG. 7, the instrument 120 may be configured so that the vibrations generated impart an axial motion to the housing 122 (as shown by the double-sided arrow), which may cause the electrode carrier 106 to move forward (as shown by the arrow) with a constant, incremental movement. This may produce an adjustable feed rate of the electrode carrier 106 into the cochlea which may result in a constant, slow and atraumatic insertion process. This automated insertion method may eliminate the need to have the surgeon repeatedly grip the electrode carrier 106 with the instrument 120 or apply mechanical force to the electrode carrier 106. This approach may further reduce the trauma associated with implanting the electrode carrier into the cochlea since the constant, slow insertion process may automatically choose the path of lowest resistance. The instrument 120 may also be configured with a mode which allows moving the electrode carrier 106 in the reverse direction, reducing the forces occurring during explantation of electrode carriers.

Accordingly, various embodiments of the present invention improve the electrode insertion process by applying vibrations to the electrode carrier. Embodiments should not produce any negative effects on hearing preservation since the motions which are introduced by the vibrations are negligible in comparison to the overall electrode insertion trauma.

Although the above discussion discloses various exemplary embodiments of the invention, it should be apparent that those skilled in the art can make various modifications that will achieve some of the advantages of the invention without departing from the true scope of the invention.

1. A surgical instrument for inserting an implantable electrode carrier, the instrument comprising:
   a housing having a proximal end and a distal end, the proximal end configured to hold the implantable electrode carrier and the distal end configured to allow a surgeon to grip the housing; and
   a vibration generator positioned within the housing, the vibration generator configured to generate vibrations in at least a portion of the electrode carrier.

2. The instrument of claim 1, wherein the vibration generator is positioned within the distal end of the housing, the proximal end of the housing, or both.

3. The instrument of claim 1, further comprising a power supply coupled to the vibration generator and positioned within the housing, the power supply configured to supply energy to the vibration generator.

4. The instrument of claim 3, wherein the power supply is positioned within the distal end of the housing.

5. The instrument of claim 1, wherein the vibration generator includes a floating mass transducer.

6. The instrument of claim 5, wherein the floating mass transducer comprises:
   a bushing having an inner area;
   a permanent magnet positioned within the inner area of the bushing; and
   an electromagnetic coil adjacent to a portion of the bushing, the electromagnetic coil configured to move the permanent magnet within the inner area of the bushing.

7. The instrument of claim 6, wherein the floating mass transducer further includes at least one spring positioned between the permanent magnet and one end of the bushing so that the at least one spring is configured to move the permanent magnet back to a neutral position after the electromagnetic coil moves the permanent magnet within the inner area of the bushing.

8. The instrument of claim 6, wherein the permanent magnet is cylindrical or spherical in shape.

9. The instrument of claim 1, wherein the vibration generator includes an electromotor connected to a gear, and a mass connected to the gear, wherein the mass is configured to produce at least a portion of the vibrations generated by the vibration generator when the gear moves the mass.

10. The instrument of claim 1, wherein the vibration generator includes an electromotor connected to a gear having an unbalanced mass, wherein the unbalanced mass is configured to produce at least a portion of the vibrations generated by the vibration generator when the gear moves the unbalanced mass.

11. The instrument of claim 1, further comprising one or more sensors positioned near the distal end of the housing, the one or more sensors configured to sense a force applied to the instrument, wherein the vibration generator is configured to control vibration parameters based on the sensed force.

12. The instrument of claim 1, wherein the vibration generator imparts longitudinal oscillations, transverse oscillations, rotational oscillations, or a combination thereof, to the proximal end of the housing.

13. The instrument of claim 1, wherein the vibration generator includes a piezoelectric actuator, a pneumatic actuator, a hydraulic actuator, an electromagnetic actuator, a mechanical actuator, or a combination thereof.

14. The instrument of claim 1, wherein the housing has a longitudinal axis from the proximal end to the distal end of the housing, and the vibration generator is concentric to the longitudinal axis.

15. The instrument of claim 1, wherein the housing has a longitudinal axis from the proximal end to the distal end of the housing, and the vibration generator is offset from the longitudinal axis.

16. A method of making a surgical instrument for inserting an implantable electrode carrier, the method comprising:
   providing a housing having a proximal end and a distal end, the proximal end configured to hold the implantable electrode carrier and the distal end configured to allow a surgeon to grip the housing; and
   positioning a vibration generator within the housing, the vibration generator configured to generate vibrations in at least a portion of the electrode carrier.

17. The method of claim 16, further comprising:
   providing a power supply coupled to the vibration generator and positioned within the housing, the power supply configured to supply energy to the vibration generator.

18. The method of claim 16, wherein the vibration generator includes a floating mass transducer comprising:
   a bushing having an inner area;
   a permanent magnet positioned within the inner area of the bushing; and
   an electromagnetic coil adjacent to a portion of the bushing, the electromagnetic coil configured to move the permanent magnet within the inner area of the bushing.

19. The method of claim 16, wherein the vibration generator includes an electromotor connected to a gear, and a mass connected to the gear, wherein the mass is configured to
produce at least a portion of the vibrations generated by the vibration generator when the gear moves the mass.

20. The method of claim 16, wherein the vibration generator includes an electromotor connected to a gear having an unbalanced mass, wherein the unbalanced mass is configured to produce at least a portion of the vibrations generated by the vibration generator when the gear moves the unbalanced mass.

21. The method of claim 16, further comprising: providing one or more sensors positioned near the distal end of the housing, the one or more sensors configured to sense a force applied to the instrument, wherein the vibration generator is configured to control vibration parameters based on the sensed force.