(54) Title: LEAD FOR A COCHLEAR IMPLANT

(57) Abstract: Disclosed is a lead for a cochlear implant modified so as to provide increased robustness to the lead. In one aspect, the lead has a helix region having an increased length such that it extends into a mastoid cavity of a patient when in situ. Also disclosed is a cochlear implant having a lead as described herein. In another aspect, the lead has an increased lead angle between the helix region and the transition region.
LEAD FOR A COCHLEAR IMPLANT

TECHNICAL FIELD

The present invention relates to cochlear implants and in particular, to a lead of a cochlear implant.

PRIORITY

The present application claims priority from Australian Provisional Patent Application No. 2007906283 entitled "Lead For A Cochlear Implant". The entire content of this provisional application is hereby incorporated by reference.

INCORPORATION BY REFERENCE

The following documents are referred to in the following description:

- US Patent No. 6,421,569;

The entire content of each of these documents is hereby incorporated by reference.

BACKGROUND

Medical implants are used in many areas of medicine to enhance the length and/or quality of the life of the implant recipient. Such implants include pacemakers, controlled drug delivery implants and cochlear implants.

A cochlear implant allows for electrical stimulating signals to be applied directly to the auditory nerve fibres of the patient, allowing the brain to perceive a hearing sensation approximating the natural hearing sensation. These stimulating signals are applied by an array of electrodes implanted into the patient’s cochlear.

The electrode array is connected to a stimulator unit (by way of a lead) which generates the electrical signals for delivery to the electrode array. The stimulator unit in turn is operationally connected to a signal processing unit which also contains a microphone for receiving audio signals from the environment, and for processing these signals to generate control signals for the stimulator.

The signal processing unit is in practice, located externally to the patient and the stimulator is implanted within the patient, usually near the mastoid on the patient’s skull and underneath the surrounding tissue. The processor and stimulator may communicate by various wireless means including by a radio frequency link.
Figure 1 shows a typical structure of a cochlear implant 100 defining the different regions. Shown there is the stimulator 10, to which is connected lead 20. Lead 20 includes helix region 21, transition region 22, proximal region 23 and intra-cochlear region 24 including the electrode contacts which in use are inserted into the patient's cochlea.

The stimulator 10 generates the electrical signals that are applied to the patient's auditory nerves in the cochlea via the lead and through the electrode wires and respective electrode contacts of the electrode array.

The helix region 21 contains the electrode wires of the lead (for example 22 wires). These wires are wound in a helical arrangement in this region.

The transition region is the region between the helix and the proximal region. This is the region proximal to the facial recess / posterior tympanotomy.

The proximal region 23 is, when in situ, outside of the cochlea (proximal to cochleostomy). It is defined as the region between the ribs (which are at the cochleostomy) and the stylet exit. The stylet exit is just outside of the posterior tympanotomy.

The intra-cochlear region 24 is the active portion of the electrode array that contains the electrode contacts. The whole of this portion is intra-cochlear, i.e. apical to the cochleostomy.

A typical length of the helix region 21 is about 45mm, and a typical length of the transition region 22 is about 24mm.

Figure 2 shows the implant 100 being implanted into a patient. Shown there is the stimulator 10 lying in a bed 51 formed in the skull 50 of a patient with a skin flap 51a of the scalp of the patient's head folded back. The bed 51 provides a space for location of the stimulator 10 to retain it in place in the patient's skull and to minimise protrusion of the stimulator package from the skull when in place. A gutter 52 is also provided to accommodate the lead 20 coming from stimulator 10. A hole is drilled into the mastoid bone to allow the lead 20 to enter the middle ear and provide access to the round window of the cochlea 55. The area of bone that is removed to provide access to the cochlear 55 is referred to as the mastoid region 53. Figure 2 shows that the lead 20 is provided long enough to assist the surgeon in manipulating the lead 20 into the cochlea, as well as to take account for any growth in the patient's skull, if implanted at a young age. Accordingly, the surgeon typically forms a loop in the transition region 22 of the lead 20 that is then placed in the mastoid region 53, to account for any excess lead length.
The wires connecting the electrodes to the stimulator are very thin and can be easily damaged during manufacture of the lead, transport, storage, surgical insertion or even when in situ in the patient, through either external impact to the patient's head or simply by movement of the lead due to growth of the patient's skull or diurnal activities, such as chewing.

Damage to the wires can eventually result in the wires or insular coating of the wires breaking due to fatigue, which typically cause faults such as open or short circuits to develop in or between the wires of the lead. These faults can cause insufficient stimulation at some nerves and overstimulation at others. Furthermore, the damage that causes faults to develop in the lead is difficult to detect and may only be evident after the lead is implanted due to deteriorating performance of the implant. As a consequence, frequent remapping of the implant is often required in order to correct, or at least mitigate, the progressive malfunction or loss of electrodes caused by these faults.

It is an object of the present invention to provide a lead that is less susceptible to damage.

**SUMMARY**

In one aspect, the present invention provides a lead for a cochlear implant for implantation into a patient, the lead comprising:

- a helix region;
- a transition region following the helix region;
- a proximal region following the transition region; and
- an intra-cochlear region following the proximal region; wherein, an interface of the helix region and the transition region is located so as to lie within a mastoid region of the patient when the cochlear implant is in situ.

In one form, the length of the helix region is greater than about 1000% of the length of the transition region.

In one form, the length of the helix region is between about 1000% and about 1300% of the length of the transition region.

In one form, the length of the helix region is about 63mm and the length of the transition region is about 5mm.

In one form, the transition region tapers from the helix region to the proximal region.
In one form, the diameter of the transition region at the interface of the helix region and the transition region is about 1.2mm.

In one form, the diameter of the transition region at the interface of the transition region and the proximal region is about 0.8mm.

In one form, a lead angle between the transition region and the proximal region is greater than about 4 deg.

In one form, the lead angle between the transition region and the proximal region is about 10 deg.

According to another aspect of the present invention, there is provided a lead for a cochlear implant for implantation into a patient, the lead comprising:

- a helix region;
- a proximal region following the helix region; and
- an intra-cochlear region following the proximal region; wherein,

the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

According to an alternate aspect of the present invention, there is provided a lead for a cochlear implant for implantation into a patient, the lead comprising:

- a helix region;
- a transition region following the helix region; and
- an intra-cochlear region following the transition region; wherein,

the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

According to another aspect of the present invention, there is provided a cochlear implant comprising a lead, the lead comprising:

- a helix region;
- a transition region following the helix region;
- a proximal region following the transition region; and
an intra-cochlear region following the proximal region; wherein the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

According to another aspect of the present invention, there is provided a cochlear implant comprising a lead, the lead comprising:
a helix region;
a proximal region following the helix region; and
an intra-cochlear region following the proximal region; wherein,
the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

According to an alternate aspect of the present invention, there is provided a cochlear implant comprising a lead, the lead comprising:
a helix region;
a transition region following the helix region; and
an intra-cochlear region following the transition region; wherein,
the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

15 DRAWINGS
Various aspects of the present invention will now be described in detail with reference to the following drawings in which:
Figure 1 - shows an example of a conventional lead for a cochlear implant;
Figure 2 - shows an example of a cochlear implant with the conventional lead of Figure 1 being implanted in a patient;
Figure 3 - shows a lead modified according to one aspect of the present invention;
Figure 4 - shows a close-up of the lead of Figure 3;
Figure 5 - shows an example of a cochlear implant with a lead according to the lead of Figures 3 and 4 being implanted in a patient;
Figures 6A—shows a conventional lead with lead angle;
Figure 6B - illustrate a further aspect of the present invention relating to lead angle;
Figure 6C - shows the combination of increased lead angle and tapered transition region; and
Figure 7 - shows an alternative configuration of the lead of Figure 3 according to another aspect of the present invention.

30 DETAILED DESCRIPTION
It has been discovered that the conventional lead 20 of Figure 1 is vulnerable to damage at the transition region 22 due to its location on the lead 20. As shown in Figure 2, the transition region 22 is located on the conventional lead 20 to lie outside the mastoid region 53 when implanted in a patient such that it is exposed to external impact or movement. According to one aspect of the present invention, the lead 20 has been redesigned so that the interface between the helix region 21 and the transition region 22 lies within the mastoid region 53 when the implant is in situ, the helix region 21 being the only part of the
lead 20 that lies outside the mastoid region 53. This reduces the risk of damage to the wires of the lead from external impact to the patient's skull post implantation, and/or damage from other activities such as chewing due to the ability of the helix region to distribute force evenly along its length and elastically stretch without the wires breaking.

Figure 3 shows a lead 20 as shown in Figure 1, but modified according to one aspect of the present invention. In Figure 3, it can be seen that although the lead 20 is the same length as the lead 20 of Figure 1, the length of the helix region 21 is greater, and conversely, the length of the transition region 22 is reduced.

In one form, the length of the helix region 21 is greater than about 1000% of the length of the transition region. In one form, the length of the helix region 21 is between about 1000% and about 1300% of the length of the transition region 22. In one form, the length of the helix region 21 is about 63mm and the length of the transition region 22 is about 5mm. However, a skilled addressee will appreciate that the length of the helix region 21 allows it to extend into the mastoid region 53 in order to provide greater protection to the lead and will depend on the distance between the implantation site selected for implantation of the stimulator 10 and the mastoid region 53. Accordingly, the length of the helix region 22 may range anywhere from 5mm to 250mm.

Figure 4 shows a close-up view of lead 20 as shown in Figure 3 designed according to this aspect of the present invention. As can be seen, the transition region 22 has been greatly shortened to about 5mm in this example. As can also be seen, the transition region 22 has also been designed to taper from the helix region 21 to the proximal region 23. This tapering provides increased robustness over prior art leads as there is no "step" or discontinuity that would otherwise result in a stress concentrator between the helix region 21 and the transition region 22.

Another aspect of the new design provides for a transition region 22 with a greater minimum cross-sectional area than in previous designs. For example the diameter of the transition region 22 in Figure 4 tapers from about 1.2 mm at the interface with the helix region 21 down to about 0.8mm at the interface with the proximal region 23. This provides a minimum cross-sectional area of about 0.8 x 0.9 mm. A greater diameter or thickness contributes to increased robustness.

In one example, the silicone chosen for the transition region 22 is Nusil Med 4860, available from suppliers such as Nusil or Dow Corning. This has a Shore A hardness of 60. In another example, the silicone chosen for the transition region is Dow Corning Silastic 7-4860, biomedical grade LSR.
Figure 5 shows the implant 100 having a lead 20 designed according to the various aspects of the present invention, being implanted into a patient. Shown there is the stimulator 10 lying in a bed 51 formed in the skull 50 of a patient with a skin flap 51a of the scalp of the patient's head folded back. The bed 51 provides a space for location of the stimulator 10 to retain it in place in the patient's skull and to minimise protrusion of the stimulator package from the skull when in place. A gutter 52 is also provided to accommodate the lead 20 coming from stimulator 10. A hole is also formed in the mastoid bone to allow the lead 20 to enter the mastoid region 53 for access to the round window of the cochlea 55.

In this arrangement, it can be seen that the helix region 21 extends into the mastoid region 53, such that the interface between the helix region 21 and transition region 22 is protected from external impact or other stresses that may contribute to breakage of wires.

According to a further aspect of the present invention, the new design provides for a greater lead angle between the transition region 22 and the proximal region 23 as can also be seen in Figures 6A and 6B. Figure 6A shows a conventional lead 20 for comparison with the new design shown in Figure 6B. The lead angle has increased to 10° in the new lead design as shown in Figure 6B, from the conventional design having a lead angle of 3.5° as shown in Figure 6A.

The greater lead angle allows the helix region 21 to be located within the mastoid region 53, without having the larger outer diameter of the helix region 21 negatively affecting access to the stylet and or surgical visibility during insertion of the intra-cochlear region 24 into the cochlea 55.

It will be understood that the increased angle can take on any desired value, including 4°, 5°, 6°, 7°, 8°, 9°, 10°, 1, 2°, 13°, 14°, 15° etc. Alternatively, the "angle" could be replaced by a curve.

Figure 6C shows the option of combining the feature of the increased lead angle as shown in Figure 6B with the feature of the tapered transition region as shown in Figure 4.

The following description provides instructions as to how to manufacture one example of a lead according to an aspect of the present invention.

Welding of Electrode Contacts (as known for example in US 6, 421, 569)

a) The 22 contacts are formed by slicing 0.3mm wide sections of Platinum Tube

b) The contacts are placed in a Welding Jig and squashed to a U shape

c) A bundle of 22 wires is placed in the Welding Jig.

d) Each wire is connected to a contact (e.g. by welding). (The strand travels from the contact proximally in bottom of all the proximal U-shaped contacts)
Formation of Welded Sub-assembly (as known for example in US 6, 421, 569)

a) A droplet of silicone is then placed in the trough of each electrode contact to secure the wires.
b) The production stylet (PTFE coated wire) is pressed on top of the strands and silicone in the troughs of the electrode contacts (this stylet is removed later and forms the lumen).

c) Each electrode trough is then partially filled with more silicone.
d) The sub-assembly is then placed in an oven to cure the silicone.
e) The assembly is then removed from the straight die

Moulding of electrode array (as known for example in US 6, 421, 569)

a) The sub-assembly is carefully curved to match the shape of a curved moulding die. The assembly is then placed in the curved moulding die with the contacts being located closer to the medial side (inside of the curve).
b) The space in the die is packed with silicone material.
c) A matching die cover is placed over the assembly and pressed down.
d) The die is then placed in an oven to cure the silicone.
e) The die is then open to allow the resulting electrode array to be removed from the die.

The new Transition Region is made by the "overmoulding" technique, as follows:
a) The wires in the transition region are coated with a thin layer of RTV (silicone adhesive)
b) The thin coating is placed in the oven and the silicone cured.
c) The wire bundle is then placed in a transition region moulding die
d) Silicone is injected into the moulding die
e) The moulding die is placed in the oven and the silicone is cured

A helix is then formed (as known in the art)
a) The wires in the helix region are coated in a thin layer of silicone
b) The thin coating is placed in the oven and the silicone cured.
c) The wires are wound around a mandrel
d) The mandrel is removed
e) A silicone tube is threaded over the helixed wires
f) The tube is injected with silicone
g) The silicone is cured in an oven.

Forming the new transition region 22 using the above described "overmoulding" technique, as compared to making the transition region 22 using the conventional technique of threading the wires through a silicone tube and then backfilling the tube with silicone compound (known in the prior art as "tube
injection” moulding), creates better quality silicone curing and thus more robust silicone to protect the wires from damage that may occur during handling, transport, and insertion of the cochlear implant 100.

As shown in Figure 7, in another form of the present invention, the lead 20 is formed with no transition region at all, with the helix region 21 interfacing directly with the proximal region 23. However, it should be appreciated that the proximal region 23 can be omitted from the design of the lead 20 instead of the transition region, such that transition region 22 as shown in Figure 3, extends further along the lead 20 to interface directly with the intra-cochlear region 24.

While various embodiments of the lead 20 have been discussed comprising at least a transition region 22 and/or a proximal region 23 between the helix region 21 and the intra-cochlear region 24, it will be appreciated that the lead 20 can also be formed without a transition region 22 and a proximal region 23, such that the helix region 21 interfaces directly with the intra-cochlear region 24.

In yet a further modification of the invention as shown in Figure 3, the lead 20 can include undulating wires (not shown) in the transition region 21 to provide a strain relief component to the transition region 21.

Disclosed herein is a lead design having a number of different features, which together, or in isolation, provide significant advantages over prior art leads. These advantages include:

A more robust electrode, resulting in higher manufacturing yield rates (due to less damage to the lead during manufacturing; a lower failure rate during surgery; a lower failure rate in situ; a more flexible transition region which is beneficial during surgery (facilitating manipulation of the array by the surgeon during surgery).

It will be understood that while the various aspects of the present invention have been described in relation to a specific embodiment, many variations and modifications may be made within the scope of the appended claims. For example, while the following features:

- Shorter transition region (any size down to zero, i.e. no transition region)
- Larger diameter transition region
- Tapered Transition region
- Larger lead angle
- Harder silicone
- Longer Helix (could lengthen, completely into the proximal region)
- Overmoulding transition region
have been described in combination, it will be understood that each feature could be taken on its own to provide an improved lead design, or two or more of the features could be combined to provide an improved lead design.

For example a lead 20 could be provided having a tapering transition region from the helix region to proximal region, with no change in length of the helix or transition region; a thicker diameter transition region could be provided with no other dimensional changes; a larger lead angle could be provided with no other changes; a harder silicone could be used for the transition region with no other changes; the transition region could be overmoulded with no other changes; the lead could have a combination of a tapered transition region and a greater lead angle with no other changes; or any other combination of the features referred to above.

Furthermore, it will be understood that the lead described above can be used in the standard Cochlear Surgical Technique, as well as other techniques including the Suprameatal Approach (SMA), as described in the paper entitled "The Suprameatal Approach in Cochlear Implant Surgery: Our Experience with 80 Patients", published in ORL 2002;64:403-405, previously incorporated by reference.

Throughout the specification and the claims that follow, unless the context requires otherwise, the words "comprise" and "include" and variations such as "comprising" and "including" will be understood to imply the inclusion of a stated integer or group of integers, but not the exclusion of any other integer or group of integers.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement of any form of suggestion that such prior art forms part of the common general knowledge.
CLAIMS:
1. A lead for a cochlear implant for implantation into a patient, the lead comprising:
   a helix region;
   a transition region following the helix region;
   a proximal region following the transition region; and
   an intra-cochlear region following the proximal region; wherein,
   the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

2. A lead as claimed in claim 1 wherein the length of the helix region is greater than about 1000% of the length of the transition region.

3. A lead as claimed in claim 1 wherein, the length of the helix region is between about 1000% and about 1300% of the length of the transition region.

4. A lead as claimed in claim 1 wherein the length of the helix region is about 63mm and the length of the transition region is about 5mm.

5. A lead as claimed in claim 1 wherein the transition region tapers from the helix region to the proximal region.

6. A lead as claimed in claim 5 wherein the diameter of the transition region at the interface of the helix region and the transition region is about 1.2mm.

7. A lead as claimed in claim 6 wherein the diameter of the transition region at the interface of the transition region and the proximal region is about 0.8mm.

8. A lead as claimed in claim 1 wherein a lead angle between the transition region and the proximal region is greater than about 4 degrees.

9. A lead as claimed in claim 8 wherein the lead angle between the transition region and the proximal region is about 10 degrees.

10. A lead for a cochlear implant for implantation into a patient, the lead comprising:
    a helix region;
    a proximal region; and
    an intra-cochlear region following the proximal region; wherein,
the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

11. A lead for a cochlear implant for implantation into a patient, the lead comprising:

5 a helix region;

' a transition region following the helix region; and

an intra-cochlear region following the transition region; wherein,

the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

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12. A cochlear implant comprising a lead, the lead comprising:

 a helix region;

 a transition region following the helix region; and

 an intra-cochlear region following the proximal region; wherein,

the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

13. A cochlear implant comprising a lead, the lead comprising:

20 a helix region;

 a proximal region following the helix region; and

 an intra-cochlear region following the proximal region; wherein,

the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.

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14. A cochlear implant comprising a lead, the lead comprising:

 a helix region;

 a transition region following the helix region; and

 an intra-cochlear region following the transition region; wherein,

the helix region is of a length such that it extends into a mastoid region of the patient when the cochlear implant is in situ.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.
A61N 1/05 (2006 01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI: USPTO: ESPACE: GOOGLE: IPC (A61F-01 I/C or A61N-001/IC) & keywords (COCHLEA+ OR LEAD OR CABLE OR WIRE OR HELI+ OR SPIRAL+ COIL+) & similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 2005/0267558 A1 (FRJNS et al.) 1 December 2005 See abstract; fig. 1</td>
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<td>A</td>
<td>US 6421569 B1 (TREABA et al.) 16 July 2002 See abstract; figs 1a-b; 7a-d</td>
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Further documents are listed in the continuation of Box C

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Date of the actual completion of the international search: 18 December 2008

Date of mailing of the international search report: 23 Dec 2008

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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX