Abstract: The problem of attaching a donor nerve stump to a recipient nerve for an end-to-side coaptation is solved by the use of a tissue connector. The tissue connector can have a body for receiving the donor nerve stump and one or more overlaps for attaching the tissue connector with the donor nerve stump therein to the epineurium on the side of the recipient nerve. Sutures can also be used to secure the tissue connector and nerves in place.

Title: CONNECTOR AND WRAP FOR END-TO-SIDE NERVE COAPTATION
DESCRIPTION

CONNECTOR AND WRAP FOR END-TO-SIDE NERVE COAPTATION

CROSS-REFERENCE TO A RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application Serial No. 62/251,901, filed November 6, 2015, the disclosure of which is hereby incorporated by reference in its entirety, including all figures, tables and drawings.

BACKGROUND OF INVENTION

The current gold standard for nerve repair is autologous nerve grafting, particularly in the presence of major loss of nerve tissue; however, there are situations in which this technique may not be feasible, such as when there is a limited amount of available graft tissue, when a proximal nerve stump is not available, when nerve is transected too far from target organ, or when there is excessive morbidity at the donor site. Surgical alternatives have been proposed, such as the use of synthetic and biological tubulization, the application of cultured Schwann cells, and the use of end-to-side neurorrhaphy techniques (M. G. Lykissas, "Current concepts in end-to-side neurorrhaphy," World Journal of Orthopaedics, vol. 2, no. 11, pp. 102-106, 2011.)

The end-to-side neurorrhaphy technique has been known by surgeons for over a hundred years. This technique entails grafting the distal nerve stump of a damaged nerve to the side of a healthy neighboring nerve. This technique can aid in maintaining the integrity and viability of the distal nerve to prevent loss of function and atrophy. There has been increased interest in this technique and numerous recent studies have been conducted in order to further understand the mechanisms of nerve regeneration with this technique and how to improve clinical applications and positive patient results. The end-to-side neurorrhaphy technique is being accepted as a feasible alternative for regaining nerve function when the proximal stump of the donor damaged nerve is not available or injury has occurred too distal to the target organ. The technique has also been used to avoid symptomatic (painful) neuroma formation by grafting a proximal sensory nerve stump into a small branch motor or sensory nerve.

The technique is based on the concept that collateral axonal sprouting from a healthy, local recipient nerve can occur with a distal stump of a donor transected nerve, if the distal
stump is sutured in end-to-side fashion to the local recipient nerve. Studies have also shown that it is not necessary to create an epineural window, or opening, in the recipient nerve site to encourage collateral axonal sprouting. However, when the raw or open distal nerve stump is attached to the recipient site, axonal growth may not be limited to the recipient and donor nerves and random axon growth can occur outside the nerves causing a variety of symptoms, including soft tissue attachments and painful neuromas.

The ability to cover and isolate a coaptation site between a recipient nerve and a donor nerve stump can reduce or eliminate undesired axonal growth into surrounding areas. It can also decrease healing time by directing axonal growth towards the preferred nerve regeneration site, instead of into non-target areas. Covering the coaptation site can also provide reinforcement to the area and inhibit separation of the coapted nerves. The use of implant devices to cover and isolate the nerve ends in end-to-end procedures is known. An implant capable of providing the same or similar benefits for end-to-side procedures could make this technique more acceptable by reducing or eliminating undesirable side effects and improving patient outcomes.

**BRIEF SUMMARY**

The subject invention provides advantageous novel nerve connectors. More particularly, the subject invention provides nerve connectors for facilitating end-to-side nerve repairs. The device and methods of the subject invention can provide improved healing with fewer side effects in patients in need of such treatment. Covering the coaptation site can also provide protection to the repair by detensioning the sutured nerves and preventing avulsion of the repair should sudden tension occur.

The subject invention successfully addresses the above described side effects associated with the end-to-side surgical nerve technique and provides certain attributes and advantages, which can improve nerve repair and increase positive patient outcomes. In particular, the embodiments of the subject invention provide novel and highly effective methods and devices for convenient and effective coaptation of a donor distal nerve stump to the side of a healthy, sufficiently intact neighboring recipient nerve.

One embodiment of the subject invention is a nerve sleeve or tube device that has at least two lateral splits or lateral cut-outs at one end. This provides at least two overflaps, such that the end of the tube resembles something reminiscent to a V- or U-shape or like the mouth of a fish. The nerve stump of a damaged or a healthy donor nerve can be introduced
into the end of the tube with the overflaps extending past the nerve stump. The overflaps can be placed around the outside or epineurium of either a living or dead recipient nerve, so that the donor nerve is positioned on the side of the recipient nerve. In some instances, a cut or opening, referred to as an "epineurial window," can be made in the epineurium of the recipient nerve where the donor nerve stump is to be placed and secured by suture or other means such as fibrin derived products or equivalents, to facilitate axonal growth between the nerves. Once the nerve tube is in place, sutures can be used to secure the nerve tube and overflaps on the donor and recipient nerves.

Another embodiment is a nerve wrap device of expandable diameter. One end of the wrap device can have two or more lateral splits or lateral cut-outs, as described above, to create at least two overflaps. With this embodiment, the tube is a wrapped material that can be opened or expanded to be placed around the distal nerve stump, again, with the overflaps extending past the end of the donor nerve stump. The overflaps can be utilized, as described above, to secure the distal nerve stump to the outside or epineurium of a recipient or neighboring nerve.

BRIEF DESCRIPTION OF DRAWINGS

In order that a more precise understanding of the above recited invention can be obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. The drawings presented herein may not be drawn to scale and any reference to dimensions in the drawings or the following description is specific to the embodiments disclosed. Any variations of these dimensions that will allow the subject invention to function for its intended purpose are considered to be within the scope of the subject invention. Thus, understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered as limiting in scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 is an illustration of one embodiment of the subject invention with a donor nerve therein and placed against a recipient nerve.
Figure 2 is an illustration of one embodiment of the subject invention with a donor nerve therein and placed against a recipient nerve, with overflaps secured around the recipient nerve, and secured with sutures.

Figure 3 is a photograph showing one embodiment of a nerve wrap device with overflaps at one end.

Figures 4A-4F show non-limiting examples of different shaped slots that can be used with the embodiments of a nerve wrap device according to the subject invention.

Figure 5 is a photograph illustrating one embodiment of a nerve wrap device with the overflaps at one end utilized to attach a donor nerve stump to the side of a recipient neighboring nerve. Also illustrated is the advantageous transparency and flexibility of a nerve wrap device manufactured with small intestine submucosa (SIS) material, which allows easy and visual placement for improved accuracy. Birth tissues, such as, for example, amnion derived products could also be used. Note that in this example the over flap does not wrap all the way around the periphery of the recipient nerve.

Figure 6 illustrates how the donor nerve enters the nerve wrap device at the distal end and is brought into close proximity with the recipient nerve, which is situated within the slots on the proximal end of the nerve connector. Also shown is how one or more sutures can be used at strategic locations on the nerve wrap device to secure the donor nerve and the recipient nerve in position with each other. Fibrin glue can also be used to effect nerve attachment or to reinforce suture attachments.

DETAILED DISCLOSURE

The subject invention provides an implant useful for coaptation of tissues. More specifically, the subject invention provides nerve connectors, or similar devices, for use in coapting nerves in a patient in need of such treatment. Still more specifically, the embodiments of the subject invention provide nerve connector implants useful for end-to-side nerve coaptation, in particular end-to-side nerve repair procedures.

In the description that follows, a number of terms related to medical devices and nerve repair are utilized. In order to provide a clear and consistent understanding of the specification and claims, including the scope to be given such terms, the following definitions are provided.

The term "patient" as used herein, describes any animal, including mammals, to which the devices and methods of the present invention are applied. Mammalian species that
can benefit from the disclosed systems and methods include, but are not limited to, humans, apes, chimpanzees, orangutans, monkeys; domesticated animals (e.g., pets) such as dogs, cats, guinea pigs, hamsters; veterinary uses for large animals such as cattle, horses, goats, sheep; and any wild animal for veterinary or tracking purposes. Human or non-human animal patients can range in age from neonates to elderly.

The term "surgeon" as used here is merely for literary convenience. The term should not be construed as limiting in any way. The devices, apparatuses, methods, techniques and/or procedures of the subject invention could be utilized by any person desiring or needing to do so and having the necessary skill and understanding of the invention.

The terms "nerve" and "nerve tissue" as used herein are merely for literary convenience. Any tissue to which the embodiments of the subject invention can be applied and useful is considered to be encompassed by these terms. By way of non-limiting example, the embodiments of the subject invention could be utilized with vascular or urological tissue, tendons, or muscle tissue.

The term "suture" is also used herein merely for literary convenience. This term should not be construed as limiting in any way. The embodiments of the subject invention could be utilized with any of a variety of devices, substances, and techniques useful for securing and/or connecting tissues, including nerve tissue. This can include, but is not limited to, sutures, staples, vascular clips, hydrogels, fibrins, urethane-based adhesives, and other medical adhesives, or combinations thereof.

Any reference in this specification to "one embodiment," "an embodiment," "example embodiment," "further embodiment," "alternative embodiment," etc., is for literary convenience. The implication is that any particular feature, structure, or characteristic described in connection with such an embodiment is included in at least one embodiment of the invention. The appearance of such phrases in various places in the specification does not necessarily refer to the same embodiment. In addition, any elements or limitations of any invention or embodiment thereof disclosed herein can be combined with any and/or all other elements or limitations (individually or in any combination) or any other invention or embodiment thereof disclosed herein, and all such combinations are contemplated with the scope of the invention without limitation thereo.

Finally, reference is made throughout the application to the "adjoining end" and "insertion end" of the embodiments of the subject invention. As used herein, the adjoining end of the device is that end that is placed closest to, or that can be affixed to, a recipient
tissue or nerve. Conversely, the "insertion end" of the device is that end into which the stump of a donor nerve is inserted and is typically but not exclusively furthest away from the adjoining end.

The present invention is more particularly described in the following examples that are intended to be illustrative only since numerous modifications and variations therein will be apparent to those skilled in the art. As used in the specification and in the claims, the singular for "a," "an" and "the" include plural referents unless the context clearly dictates otherwise.

Both natural and synthetic biomaterials can be used to manufacture the devices of the subject invention. In certain embodiments, the biomaterial is a homogenous material. Examples of biomaterials for use in manufacturing the subject invention include, but are not limited to, high density polyethylene (HDPE), polyethylene glycol (PEG) hydrogel, purified proteins from human or animal sources (e.g., membrane of purified collagen or fibrin), cellularized and decellularized tissue constructs (e.g., demineralized bone, small intestine submucosa (SIS), dermis, muscle, fascia, or birth tissue, such as amnion). An HDPE or PEG device can comprise or consist of a cylinder of porous HDPE or PEG surrounded by a layer of non-porous HDPE or PEG. Biomaterials which can form a fluid material, such as soluble purified collagen or particulate SIS and dermis, can be directly cast to form the device without a membrane as an intermediate.

It can be advantageous for embodiments of the subject invention to be flexible and transparent or at least semi-transparent or translucent. In a particular embodiment, small intestine submucosa (SIS) material is utilized. The SIS material can provide sufficient transparency, flexibility, and strength to a nerve connector of the subject invention. During a procedure, a surgeon can usually see the donor nerve stump through the SIS material, which is advantageous for positioning the nerve stump at an appropriate distance from the recipient nerve and aligning the nerve stump with an epineurial window, or opening in the epineurium, if utilized. The flexibility of the material also allows it to be bent or wrapped around the nerve, without breaking or causing damage to the nerve. The SIS material is also amenable for use with sutures for holding it in place once positioned on the nerve.

Reference will be made to the attached Figures on which the same reference numerals are used throughout to indicate the same or similar components. With reference to the attached Figures, which show certain embodiments of the subject invention, it can be seen in Figure 1 that a nerve connector 20 of the subject invention has an insertion end 100 and an
adjoining end 200. In general, a nerve connector includes a body 30 with a lumen 35 therethrough, for receiving a donor nerve stump, and is open to both the adjoining end and insertion end. The adjoining end can further have at least one overlap 40. Alternative embodiments can include two or more overlaps 40 separated by slots 45 into which a recipient nerve can be received. Each of these general components can have one or more sub-components, which will be discussed in detail below.

One embodiment of the subject invention has a hollow body 30 that is generally tubular, such that the body is a continuous tubular construct. There can further be a lumen 35 through the longitudinal length of the body with openings 36 at both the insertion end 100 and the adjoining end 200. With this embodiment, a donor nerve stump 5 can be inserted into the insertion end 100 and pushed or pulled towards the adjoining end 200. Figures 1, 2, and 6 illustrate examples of a donor nerve within the lumen.

In one embodiment, the diameter of the lumen 35 is generally constant along the length of the continuous body, such that the openings 36 have the same or approximately the same diameter. In an alternative embodiment, shown in Figure 4D, the diameter of the lumen 35 gradually increases towards the insertion end 100, such that the opening 36 at that end is larger than the opening at the opposite end, which can make inserting the donor nerve stump easier and can allow for an end-to-side connection of nerves having different diameters. The flexibility of the material allows the material around the opening to be pulled, gathered, or crimped around the epineurium 7 of the donor nerve and closed off or secured with sutures 250, if necessary.

In another embodiment, the diameter of the lumen 35 is substantially consistent along a portion of the body 30 at the adjoining end 200, for example, along at least one half of the length of the body from the adjoining end, and then the body and lumen can flair towards the insertion end 100, as shown, for example, in Figure 4C. This can make insertion of the donor nerve stump easier at the insertion end and that portion of the lumen that is narrower and is not flaired can aid in holding the nerve stump within the lumen. The flaired opening can be gathered or crimped around the epineurium 7 of the donor nerve and secured with one or more sutures to help hold the nerve connector 20 in place.

In one embodiment, the body of the device is made by rolling a sheet of biomaterial to form a tubular construct, one example of which is shown in Figure 4F, where the body of the device is a "roll" of overlapping, or partially overlapping, layers that form a tubular construct of biomaterial, such that the body is a non-continuous tubular construct. The layers of the
roll can expand to accommodate nerves, or other tissue, of different diameters. In specific
related embodiments, the layers of the rolled biomaterial are overlapped sufficiently to
maintain the wall of the tubular construct, when the internal diameter of the device is
expanded to accommodate larger diameter nerves.

The length of a body can vary depending upon a variety of factors that are understood
by those with skill in the art, including, but not limited to, the length of the donor nerve, the
diameter of the donor nerve, the integrity of and/or amount of injury to the donor nerve,
where and how many sutures can be used, and the in vivo location of the recipient nerve, as
well as other factors. In one embodiment, the length of the body 30 is between
approximately 0.5 cm. and approximately 3.0 cm. In a more particular embodiment, the
length of the body is between approximately 0.75 cm and approximately 2.0 cm. In a
specific embodiment, a body has a length of approximately 1.0 cm.

Likewise, the diameter of the lumen can vary depending upon a variety of factors
understood by those with skill in the art, including, but not limited to those factors listed
above. In one embodiment, the diameter of the lumen is between approximately 0.25 cm and
approximately 0.5 cm. In a more specific embodiment, the diameter of a lumen is
approximately .3 cm.

At the adjoining end 200, there can be one or more overflaps 40 that are continuous
with the body 30 and extend out from, or extend around, the opening at the adjoining end 200
of the body. In one embodiment, there is a single overlap 40, as shown, for example, in
Figure 4A. This embodiment can be useful when only a portion of the recipient nerve
epineurium 15 is accessible. With this embodiment, for example, the nerve connector 20
with a donor nerve therein can be brought into proximity to the recipient nerve and the single
overlap placed across or around the accessible portion of the recipient nerve epineurium 15
and sutured in place.

Figures 3 and 4B through 4E illustrate examples of other embodiments where there
are two overlaps 40 that are continuous with the body 30 and extend out from, or extend
around, the opening at the adjoining end 200 of the body. With this embodiment, the
overflaps can be placed on either side of the epineurium 15 of the recipient nerve 10, such
that the overflaps can encircle or at least partially encircle the periphery of the recipient
nerve, such as shown, by way of example, in Figures 2 and 6. The overflaps can be
positioned at or about 180 degrees apart or on approximately opposite sides of the opening,
such that they resemble the open mouth of a fish, as demonstrated in Figure 5. However, this
is not a required configuration and in some circumstances it can be beneficial for the overflaps to be offset or not directly opposite to each other around the opening. Further, the overflaps can be of different sizes and/or lengths, an example of which is shown in Figure 4B.

In an alternative embodiment, there can be more than two overflaps 40. This embodiment can be useful when the recipient nerve 10, or, perhaps, the donor nerve, has an irregular shape or location that makes the use of just two overflaps difficult, inefficient, or ineffective. Multiple overflaps can have the same characteristics and variations as described above for single and two overlap embodiments. A person with skill in the art, having benefit of the subject disclosure, would understand how to incorporate more than two overflaps with a nerve connector 20, according to the subject invention. Thus, examples have not been included in the Figures herein.

The two or more overflaps 40 can have separations 41 therebetween that define the shape or configuration of the overflap. The separation can be any shape or size and creates a point or line at which the overflaps can be separated or spread apart. In one embodiment, a separation is one or more cuts 42 between overflaps, so that they can be separated for placement around or to either side of the recipient nerve, as described above. Typically, a cut is a very narrow separation with minimal or no loss of material between the overflaps. Such a cut can extend from the opening at the adjoining end 200 towards the insertion end 100, an example of which is shown in Figure 4F. The cut can further be made at an angle relative to the body. For example, the cut 42 can be substantially collinear with the body 30, as shown in Figure 4F or it can be angled or non-collinear with the body, as exampled by the dotted lines in Figure 4F.

In one embodiment, the separations between two or more overflaps 40 can be more like slits 45, which are larger and provide more open space, and less material, between the overflaps than a cut. A slit can further have any of a variety of configurations to facilitate placement of the overflaps on or around a recipient nerve 10. The slits can have straight edges, curved edges, or some combination thereof that facilitates attachment or wrapping around a recipient nerve. Figures 4B through 4E illustrate a few examples of slits with different shapes that can be employed with the embodiments of the subject invention. Preferably, the length and shape of the slit is such that it can wrap around or over a recipient nerve sufficiently that sutures can be used to secure the overlap. The slit could also be of sufficient length to allow the overflaps to extend completely around the periphery of a
recipient nerve such that at least one suture could be used to secure the adjoining ends of the overflaps, as shown, for Example, in Figure 2.

The length of a slit and conversely the length of the overflaps can vary depending upon any of a variety of factors understood by a person with skill in the art. For example, a connector to be used on sciatic nerve tissue can be larger than a connector intended to be used with nerve tissue in the hand or face. In one embodiment, the length of an over flap is between approximately 0.1 cm and approximately 4.0 cm. In another embodiment, the length of an over flap is between approximately 0.2 cm and 2.0 cm. In a more specific embodiment, the length of an over flap is between approximately 0.3 cm and approximately 0.7 cm. In a specific embodiment, the length of an over flap is approximately 0.5 cm.

Utilization of a tissue connector 20, according to the subject invention, can include installing a donor nerve stump 5 into the lumen, usually by inserting or pushing it into the lumen from the insertion end 100 of the body 30. The terminal end 8 of the donor nerve stump can be brought into proximity to the opening 36 at the adjoining end. It can be advantageous to ensure that there is at least some space between the epineurium of the recipient nerve and the terminal end of the donor nerve. Thus, the terminal end 8 of the donor nerve can be positioned just behind the cuts 42 or slots 45. The one or more overflaps 40 of the tissue connector can then be partially or entirely wrapped around the side of the recipient nerve 10, such that the terminal end 8 of the donor nerve stump 5 is sufficiently close to the side of the recipient nerve to form an end-to-side attachment.

In some situations, a cut or opening, often referred to as an epineurial window 17, can be created in the epineurium 15 of the recipient nerve to encourage or enhance axonal growth between the nerves. As mentioned above, it can be helpful if the material of the tissue connector is transparent or semi-transparent or translucent, allowing a surgeon to see the position of the donor nerve stump within the lumen 35 and so that the position of the donor nerve stump relative to the recipient nerve and/or the epineurial window can be seen as well. This can help the surgeon position the terminal end 8 accurately and ensure that the nerves are not positioned too closely or distorted in shape, before attaching the tissue connector to the nerves with sutures.

Once the terminal end of the donor nerve stump 5 is positioned correctly in relation to the recipient nerve 10, one or more sutures can be used between the donor nerve stump and the tissue connector as well as between the recipient nerve and the one or more overflaps and/or just between the overflaps, if they completely surround the recipient nerve.
Alternatively, the overlaps 40 at the adjoining end 200 can be attached to the recipient nerve and the donor nerve placed within the lumen 35 after the overflaps are attached. This can permit the surgeon to place the opening 36 at the adjoining end 200 in the optimal location on the recipient nerve, ensuring that the terminal end 8 of the donor nerve, when emplaced in the lumen will be properly located as well.

In another alternative, one or some of the overflaps can be attached to the recipient nerve to aid in optimal placement. The donor nerve can then be inserted into the lumen and positioned, such that when the remaining one or more overflaps are attached, the donor nerve is properly placed relative to the recipient nerve. Additional sutures can be used to secure the remaining one or more overflaps and the donor nerve.

The nerve repair technique of attaching a donor nerve stump from a damaged peripheral nerve to the side of a neighboring, usually undamaged, recipient nerve is useful in some cases. Attaching the donor nerve to a recipient nerve can keep the donor nerve viable and ensure that the tissue enervated by the damaged peripheral nerve does not atrophy. Nerve repair devices used for end-to-end nerve repair may not be applicable for end-to-side nerve repairs when a donor nerve stump is attached to the side of a recipient nerve.

The embodiments of the subject invention provide new, biocompatible devices that can make end-to-side nerve repairs easier to perform, inhibit undesirable axonal outgrowth, and provide improved patient outcomes. The tissue connector devices and techniques of the subject invention can help in the attachment of a donor nerve to a recipient nerve and, when formed from appropriate materials, can allow a surgeon to actually see the nerves through the device during placement, for improved accuracy.

The scope of the invention is not limited by the specific examples and suggested procedures and uses related herein since modifications can be made within such scope from the information provided by this specification to those skilled in the art.

The invention has been described herein in considerable detail, in order to comply with the Patent Statutes and to provide those skilled in the art with information needed to apply the novel principles, and to construct and use such specialized components as are required. However, the invention can be carried out by specifically different equipment and devices, and various modifications, both as to equipment details and operating procedures can be effected without departing from the scope of the invention itself. Further, although the present invention has been described with reference to specific details of certain embodiments thereof and by examples disclosed herein, it is not intended that such details
should be regarded as limitations upon the scope of the invention except as and to the extent that they are included in the accompanying claims.
We claim:

1. A nerve connector device for connecting two nerves, the connector device comprising:
   - a hollow body having an insertion end and an adjoining end and a lumen therebetween that extends through the body,
   - one or more overflaps that extend from the adjoining end and are continuous with the body, and
   - at least one separation between the one or more overflaps that allows the one or more overflaps to be separated.

2. A nerve connector device, according to claim 1, wherein the body comprises a biocompatible material that is transparent or translucent.

3. A nerve connector device, according to claim 2, comprising a biomaterial selected from the group consisting of: high density polyethylene (HDPE), polyethylene glycol (PEG) hydrogel, and purified proteins from human or sources.

4. A nerve connector device, according to claim 2, comprising a biomaterial selected from the group consisting of small intestine submucosa (SIS), amnion, dermis, collagen and decellularized fascia.

5. A nerve connector device, according to claim 2, comprising porous HDPE or PEG surrounded by a layer of non-porous HDPE or PEG.

6. A nerve connector device, according to claim 2, wherein the body is a continuous tubular construct.

7. A nerve connector device, according to claim 2, wherein the body is a non-continuous tubular construct of rolled material.
8. The nerve connector device, according to claim 6, wherein the separation is cut.

9. The nerve connector device, according to claim 6, wherein the separation is a slit.

10. A method for connecting a donor nerve stump to a recipient nerve in a patient in need of such treatment, the method comprising:

   utilizing a nerve connector device having,
   a hollow body having an insertion end and an adjoining end and a lumen therebetween that extends through the body,
   one or more overflaps that extend from the adjoining end and are continuous with the body, and
   at least one separation between the one or more overflaps that allows the one or more overflaps to be separated;

   installing the donor nerve stump through the insertion end and for a distance into the lumen;

   wrapping the one or more overflaps around the recipient nerve, such that the donor nerve stump is at least directed towards an epineurium around the recipient nerve; and

   using one or more sutures to secure the one or more overflaps to the recipient nerve and one or more sutures to secure the body to the donor nerve.

11. The method, according to claim 10, further comprising creating an epineurial window in the recipient nerve.

12. The method, according to claim 10, further comprising installing the donor nerve stump into the lumen until a terminal end of the donor nerve stump is at or near the insertion end of the at least one separation.

13. The method, according to claim 10, further comprising wrapping the overflaps around the periphery of the recipient nerve such that the adjoining ends of the overflaps can be sutured to each other.
5 - 7 mm bilateral cuts 180 degrees apart

FIG. 3

"Fishmouth" covers recipient nerve to secured end-to-side transfer.

FIG. 5
Secured with interrupted stitches at wrap around and donor nerve

FIG. 6
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/ll(2006.01)i, A61L 27/16(2006.01)i, A61L 27/24(2006.01)i, A61B 17/04(2006.01)i

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)
A61B 17/1 ; A61L 27/24; A61F 204; A61L 27/54; A61B 17/08; A61B 17/04; A61L 27/16

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

Japanese utility models and applications for utility models
Korean utility models and applications for utility models

Electronic data base consulted during the international search (name of database and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: nerve, connector, hollow, overlap, slit

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>A</td>
<td>US 2014-0336681 AI (UNIVERSITY OF UTAH RESEARCH FOUNDATION) 13 November 2014</td>
<td>1-9</td>
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<tr>
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<td>See paragraphs [0022] - [0073] ; claims 1-32 ; and figures 1A-4 .</td>
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<td>See paragraphs [0045]-[0120] ; claims 1-29 ; and figures 1-24 .</td>
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<td>A</td>
<td>US 4778467 A (STENSAAS , LARRY J. et a1.) 18 Oct ober 1988</td>
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<td>US 4920962 A (PROULX, CLAUDE) 01 May 1990</td>
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
  "A" document defining the general state of the art which is not considered to be of particular relevance
  "E" earlier application or patent but published on or after the international filing date
  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  "O" document referring to an oral disclosure, use, exhibition or other means
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T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered new or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

& document member of the same patent family

Date of the actual completion of the international search 09 February 2017 (09.02.2017)

Date of mailing of the international search report 16 February 2017 (16.02.2017)

Name and mailing address of the ISA/KR International Application Division
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Form PCT/ISA/210 (second sheet) (January 2015)
**INTERNATIONAL SEARCH REPORT**

**Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 10-13
   because they relate to subject matter not required to be searched by this Authority, namely:
   Claims 10-13 pertain to methods for treatment of the human body by surgery, and thus relate to a subject matter which the International Searching Authority is not required to search, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).

2. **☐** Claims Nos.:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. **☐** Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. **☐** As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. **☐** As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. **☐** As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. **☐** No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

**☐** The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

**☐** The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

**☐** No protest accompanied the payment of additional search fees.

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