A method for determining an effectual placement of an electrode array during a surgical procedure to implant the lead is provided. This method involves placing a lead having electrodes in a first location in a patient then (1) activating electrical stimulation to produce paresthesia, (2) "electro-mechanically" varying the length of the electrode array and (3) determining whether the paresthesia is in an effective location. If the paresthesia is not in an effective location to match the location of the pain, the lead is moved to a different location, and steps (1) through (3) are repeated. The process of electro-mechanically varying involves moving the electrical stimulation along the electrode array so that all regions of the electrode array provide stimulation. This method reduces or eliminates the need to move the lead during the implant procedure and thus simplifies the implant procedure compared to the currently used physical trolleying method, reducing the risks to the patient. Additionally, this method saves time and improves outcomes by allowing multiple electrode combinations to be tested in a relatively short amount of time.
START

1. Position lead epidurally in patient

2. Activate stimulation

3. Electronically troll electrode array

4. Is paresthesia in approximately the same location as pain?
   - NO: Optionally deactivate stimulation
   - YES: End trolling and secure lead

5. Determine effectual stimulation parameter sets

FIG. 4
METHOD FOR OPTIMIZING LOCATION OF IMPLANTED ELECTRODE ARRAY DURING IMPLANT SURGERY

[0001] This application is a continuation-in-part of, and claims the benefit of priority to, U.S. application Ser. No. 10/355,955, filed Jan. 31, 2003, which claims the benefit of and priority to U.S. Provisional Application Ser. No. 60/354,098, filed Feb. 4, 2002. These prior applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to Spinal Cord Stimulation (SCS) systems and more particularly to methods for efficiently searching for an effective SCS system stimulation parameter sets. An SCS system treats chronic pain by providing electrical stimulation pulses through the electrodes of an electrode array placed epidurally next to a patient’s spinal cord. The stimulation parameter set determines the characteristics of the stimulation pulses provided through the electrode array, and the electrodes used to provide the stimulation pulses. The optimal stimulation parameter set for a specific patient may be determined from the response of the patient to various sets of stimulation parameters. There is, however, an extremely large number of possible combinations of stimulation parameters, and evaluating all possible sets is very time consuming, and impractical.

[0003] Spinal cord stimulation is a well accepted clinical method for reducing pain in a portion of patients. An SCS system typically includes an Implantable Pulse Generator (IPG), electrodes, electrode lead, and electrode lead extension. The electrodes are implanted along the dura of the spinal cord, and the IPG generates electrical pulses that are delivered, through the electrodes, to the dorsal column and dorsal root fibers within the spinal cord. Individual electrode contacts (“electrodes”) are arranged in a desired pattern and spacing in order to create an electrode array. Individual wires within one or more electrode leads connect with each electrode in the array. The electrode leads exit the spinal column and generally attach to one or more lead extension. The electrode lead extensions, in turn, are typically tunneled around the torso of the patient to a subcutaneous pocket where the IPG is implanted.

[0004] Spinal cord stimulators and other stimulation systems are known in the art. For example, an implantable electronic stimulator is disclosed in U.S. Pat. No. 3,646,940 issued Mar. 7, 1972 for “Implantable Electronic Stimulator Electrode and Method” that provides timed sequenced electrical impulses to a plurality of electrodes. As another example, U.S. Pat. No. 3,724,467 issued Apr. 3, 1973 for “Electrode Implant For The Neuro-Stimulation of the Spinal Cord,” teaches an electrode implant for the neuro-stimulation of the spinal cord. A relatively thin and flexible strip of physiologically inert plastic is provided as a carrier on which a plurality of electrodes are formed. The electrodes are connected by leads to an RF receiver, which is also implanted.

[0005] In U.S. Pat. No. 3,822,708, issued Jul. 9, 1974 for “Electrical Spinal Cord Stimulating Device and Method for Management of Pain,” another type of electrical spinal cord stimulation device is taught. The device disclosed in the ’708 patent has five aligned electrodes, which are positioned longitudinally on the spinal cord. Electrical pulses applied to the electrodes block perceived intractable pain, while allowing passage of other sensations. A patient operated switch allows the patient to adjust the stimulation parameters.

[0006] Most of the electrode arrays used with known SCS systems employ between 4 and 16 electrodes. Electrodes are selectively programmed to act as anodes, cathodes, or left off, creating a stimulating group. The number of stimulation groups available, combined with the ability of integrated circuits to generate a variety of complex stimulation pulses, presents a huge selection of stimulation parameter sets to the clinician. When an SCS system is implanted, a “fitting” procedure is performed to select an effective stimulation parameter set for a particular patient.

[0007] A known practice is to manually test one parameter set, and then select a new stimulation parameter set to test, and compare the results. Each parameter set is painstakingly configured, and ramped up in amplitude gradually to avoid patient discomfort. The clinician bases their selection of a new stimulation parameter set on their personal experience and intuition. There is no systematic method to guide the clinician. If the selected stimulation parameters are not an improvement, the clinician repeats these steps, using a new stimulation parameter set, based only on trial-and-error. The combination of the time required to test each parameter set, and the number of parameter sets tested, results in a very time consuming process.

[0008] In order to achieve an effective result from spinal cord stimulation, the lead or leads should be placed in a location such that the electrical stimulation will affect the targeted nerves and cause paresthesia. The paresthesia perceived by the patient and induced by the stimulation should be located in approximately the same place in the patient’s body as the pain that is the target of treatment. If a lead is not correctly positioned, it is possible that the patient will receive little or no benefit from an implanted SCS system. Thus, correct lead placement can mean the difference between effective and ineffective pain therapy.

[0009] Presently, surgeons use various methods in order to determine if a lead is correctly positioned during the surgical implant procedure. One method involves providing stimulation using one electrode combination and then physically moving the electrode array along the spinal cord dura with the stimulation remaining “on.” This method is known as “trolling.” The patient provides feedback as to the effectiveness of the stimulation as the electrode array is moved. Once an approximately effective location is identified, the electrode array is fixed in that position. This method has several disadvantages, including the fact that only one electrode combination is used and the possible benefits of different electrode combinations are not explored. Additionally, this method involves a more complicated surgical procedure that presents additional risks to the patient.

[0010] Another method for determining whether an electrode array is correctly positioned during a surgical procedure involves testing a variety of combinations of electrodes, one at a time. In this method, the lead is implanted in a location that the surgeon believes will be effective. Stimulation is activated and then painstakingly ramped up for one electrode combination. The patient then provides feedback as to the effectiveness of that combination. The stimulation is then ramped down to zero, and the process is
repeated for another electrode combination. If no combinations produce a satisfactory result, the surgeon moves the electrode array and the process is repeated. This method can result in a time consuming and frustrating surgical procedure for the patient.

[0011] What are needed are methods for selection of trial stimulation parameter sets that guide the clinician towards an effective stimulation parameter set(s). What are also needed are methods for quickly and simply determining whether an electrode array is correctly positioned during a surgical procedure.

SUMMARY OF THE INVENTION

[0012] The present invention addresses the above and other needs by providing a method for selecting trial Spinal Cord Stimulation (SCS) stimulation parameter sets, which method guides a clinician towards an effective set of stimulation parameters.

[0013] In accordance with one aspect of the invention, there is provided a table, or equivalent, of a small number of trial stimulation parameter sets (a coarse table) that define a starting point for selecting a stimulation parameter set. There is also provided a larger table (a fine table), or equivalent, of predetermined stimulation parameter sets to guide the search for a local optimum. Any method for finding an effective stimulation parameter set that uses a combination of a small coarse table, or equivalent, and a large fine table, or equivalent, is intended to come within the scope of the invention.

[0014] In accordance with another aspect of the invention, the clinician first evaluates the effectiveness of a small number of trial stimulation parameter sets from a Simplified Measurement Table comprising for example, four stimulation parameter sets. Based on the patient’s assessment, the trial stimulation parameter sets are ranked. Then the clinician selects a starting row in a Simplified Steering Table corresponding to the highest ranked trial stimulation parameter set. The clinician moves either up or down from the starting row, testing consecutive parameter sets. The clinician continues as long as the patient indicates that the stimulation results are improving. When a local optimum is found, the clinician returns to the starting row, and tests in the opposite direction for another local optimum. If an acceptable set of stimulation parameters is found, the selection process is complete. If an acceptable set is not found, a new starting row in the Simplified Steering Table is selected based on the next best trial stimulation parameter set, and the process of searching for local optima is repeated.

[0015] In accordance with yet another aspect of the invention, there is provided a method for searching for an effective set of stimulation parameters for an SCS system. The method improves the efficiency of the search by organizing the search based on predetermined stimulation parameter sets. A clinician first ranks the effectiveness of a very small set of trial stimulation parameter sets, and then searches for an optimum stimulation set around the highest ranked trial stimulation parameter set.

[0016] It is thus a feature of the present invention to provide a method for determining a locally optimum SCS system stimulation parameter set without requiring exhaustive testing of a multiplicity of stimulation parameter sets. Millions of possible stimulation parameter sets exist, and it is therefore impossible to test all possible sets. Therefore the clinician must be satisfied by finding an effective stimulation parameter set. By providing a systematic method for searching for an effective stimulation parameter set, a locally optimum stimulation parameter set is found, which locally optimum stimulation parameter set is associated with a best trial stimulation parameter set.

[0017] In accordance with another aspect of the invention, there is provided a method for determining an effectual placement of an electrode array during a surgical procedure to implant the lead. This method involves placing a lead having electrodes in a first location in a patient then (1) activating electrical stimulation to produce paresthesia, (2) “electronically trolling” the length of the electrode array and (3) determining whether the paresthesia induced by the stimulation is in an effective location. If the paresthesia is not in an effective location to match the pain, the lead is moved to a different location and steps (1) through (3) are repeated. The electrical stimulation is defined by parameters specified by software, which may include a steering table used for trolling. The steering table may include multiple rows arranged so that the electric field properties of adjacent rows are similar. The process of electronically trolling involves moving the electrical stimulation along the electrode array so that all regions of the electrode array provide stimulation. This may involve moving from a first end of the electrode array to the opposite end of the electrode array, and may involve moving “up” and/or “down” through a steering table.

[0018] This method reduces or eliminates the need to continually move the lead and electrode array during the implant procedure while still allowing the electric field produced by the stimulating electrodes to be moved. This method thus simplifies the implant procedure compared to the physical trolling method and reduces the risks to the patient. Additionally, this method saves time by allowing multiple electrode combinations to be tested in a shorter amount of time than the known method of painstakingly ramping stimulation up and down to test a single electrode combination.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The above and other aspects of the present invention will be more apparent from the following more particular description thereof, presented in conjunction with the following drawings wherein:

[0020] FIG. 1 shows a Spinal Cord Stimulation (SCS) system;

[0021] FIG. 2 depicts the SCS system of FIG. 1 implanted in a spinal column; and

[0022] FIG. 3 depicts a stimulation parameter set flow chart according to one embodiment of the present invention.

[0023] FIG. 4 depicts an electronic trolling flow chart according to one embodiment of the present invention.

[0024] Corresponding reference characters indicate corresponding components throughout the several views of the drawings.

[0025] Appendix A, comprising 2 pages including a cover, is an example of a Simplified Measurement Table.
Appendix B, comprising 13 pages including a cover, is an example of a Simplified Steering Table.

Appendices A and B are incorporated herein by reference.

DETAILED DESCRIPTION OF THE INVENTION

The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

The method of the present invention provides a systematic approach for selecting a Spinal Cord Stimulation (SCS) stimulation parameter set. The method leads a clinician through a selection process that efficiently locates locally optimum stimulation parameter sets.

A typical Spinal Cord Stimulation (SCS) system 10 is shown in FIG. 1. The SCS system 10 typically comprises an Implantable Pulse Generator (IPG) 12, a lead extension 14, an electrode lead 16, and an electrode array 18. The IPG 12 generates stimulation current for implanted electrodes that make up the electrode array 18. A proximal end of the lead extension 14 is removably connected to the IPG 12 and a distal end of the lead extension 14 is removably connected to a proximal end of the electrode lead 16, and electrode array 18 is formed on a distal end of the electrode lead 16. The in-series combination of the lead extension 14 and electrode lead 16, carry the stimulation current from the IPG 12 to the electrode array 18.

The SCS system 10 described in FIG. 1 above, is depicted implanted in the epidural space 20 in FIG. 2. The electrode array 18 is implanted at the site of nerves that are the target of stimulation, e.g., along the spinal cord. Due to the lack of space near the location where the electrode lead 16 exits the spinal column, the IPG 12 is generally implanted in the abdomen or above the buttocks. The lead extension 14 facilitates locating the IPG 12 away from the electrode lead exit point.

A more detailed description of a representative SCS system that may be used with the present invention is described in U.S. Pat. No. 6,516,227, issued Feb. 4, 2003, incorporated herein by reference. It is to be emphasized, however, that the invention herein described may be used with many different types of stimulation systems, and is not limited to use only with the representative SCS system described in the 6,516,227 patent.

A flow chart representing one embodiment of a method for stimulation parameter set selection in accordance with the present invention is depicted in FIG. 3. As with most flow charts, each step or act of the method is represented in a “box” or “block” of the flow chart. Each box or block, in turn, has a reference number associated with it to help explain the process in the description that follows.

At the start 22 of the method, a measurement table, or equivalent, and a steering table, or equivalent, are provided. The measurement table typically comprises rows, with each row defining one set of stimulation parameters. In a preferred embodiment, each row specifies the polarity on each electrode of the electrode array 18 (FIGS. 1 and 2) that the stimulation system determines should be applied to the patient for a particular purpose. The electrode array 18 preferably comprises eight or sixteen electrodes, but the measurement table may only utilize a subset of the electrode array 18, for example four electrodes. Those skilled in the art will recognize that a measurement table may include stimulation parameter sets with various variations, such as pulse duration or pulse frequency, and a measurement table with such other variations is intended to come within the scope of the present invention. An exemplary simplified measurement table that may be used with the invention is found in Appendix A.

The steering table, or equivalent, typically includes a larger number of rows than does the measurement table. An exemplary steering table, containing 541 rows, that may be used with the invention is found in Appendix B. The rows in the steering table typically reflect the same variation as the rows in the measurement table, however, those skilled in the art will recognize that the steering table may also include other degrees of variation not included in the measurement table, and these variations are also intended to come within the scope of the invention. At least one row in the steering table will however correspond to one of the rows in the measurement table, as will be made apparent by the following description.

The rows in the steering table are arranged in order based on the physical characteristics of the stimulation provided by each stimulation parameter set, so that moving from one row to the next in the steering table represents a gradual, and somewhat uniform, change in stimulation. In other words, stepping from one row to an adjacent row in the steering table causes the stimulation applied to the tissue through the individual electrodes of the electrode array 18 to gradually move in a desired direction. This type of current steering is described more fully in U.S. Pat. No. 6,393,325, incorporated herein by reference.

Once the desired measurement table and steering table have been provided, the first step in the method is selection of a trial stimulation parameter set (block 24). Generally, the first row of the measurement table will be tested first, followed in order by the remaining rows. However, the order of row selection is not essential, and the rows may be selected in any order. Next, the selected stimulation parameter set is used to provide stimulation to the patient (block 26). Generally, to avoid uncomfortable “jolting” and over-stimulation, the amplitude of the stimulation provided is initially set to a relatively low level, i.e., below the level that will result in the patient perceiving paresthesia. The amplitude is then gradually increased. The stimulation level at which the patient begins to perceive paresthesia is called the perception or perceptual threshold. See e.g., U.S. Pat. No. 6,393,325, noted above. The stimulation is then increased until it begins to become uncomfortable for the patient. This level is called the maximum or discomfort threshold. See e.g., U.S. Pat. No. 6,393,325, noted above. These pre-steering measured thresholds may be noted and used later in the steering process. Alternatively, these thresholds may be determined based on pre-established values, or based on previously-measured thresholds for the patient.

The patient provides feedback as to the effectiveness of the stimulation that has been applied using the trial
stimulation parameter set. Alternative means (e.g., objective measurements of various physiological parameters of the patient, such as perspiration, muscle tension, respiration rate, heart rate, and the like) may also be used to judge the effectiveness of the applied stimulation. A determination is then made if all of the trial sets have been tested (block 28). The steps of selecting a trial set of stimulation parameters (block 24) and providing stimulation in accordance with the selected trial set of stimulation parameters (block 26) are repeated until all of the trial stimulation parameter sets have been tested.

After all of the trial stimulation parameter sets have been tested, the trial stimulation parameter sets are ranked (block 30) based upon the patient's evaluation (and/or based upon alternative evaluation of selected physiological parameters of the patient) of the effectiveness of each trial stimulation parameter set.

The testing and ranking of the trial stimulation parameter sets provides a coarse approximation of the stimulation which may be most effective. Because the trial stimulation parameter set is only a coarse approximation, the implication is that fine adjustments of such parameter sets may also be effective, and perhaps even more effective. Hence, once the trial stimulation parameter sets have been ranked, the highest ranked trial stimulation parameter set becomes a first specified ranked set that functions as a first “benchmark,” or starting point, for a much finer search for the most effective stimulation parameter set. The finer search for a stimulation parameter set begins by selecting a row in the steering table that corresponds to the highest ranked set in the measurement table (block 32a). This selected highest ranked trial stimulation parameter set is then used to provide stimulation (block 34a) to the patient. Again, the patient evaluates the effectiveness of the stimulation, and/or alternative means (e.g., measuring physiological parameters of the patient) are used to evaluate the effectiveness of the stimulation. Then, a row next to the row just tested, e.g., moving in a first direction in the steering table, such as down, is selected as a possible new stimulation parameter set (block 36), and this new row is then used to provide stimulation (block 34b). The results of the new stimulation are then compared to the results of the previous stimulation (block 38a). If the results improve (YES branch of block 38a) the steps set forth in blocks 36 and 34b are repeated, i.e., the row in the steering table adjacent to the most recently used row, moving in the same direction in the table as before, is used to define a new stimulation parameter set (block 36) and that stimulation parameter set is used to provide stimulation (block 34b). As long as the stimulation results continue to improve, this process of stepping to the next row in the steering table and retesting is continued, thereby fine tuning the stimulation parameter set until no further improvements are detected.

As soon as the results fail to improve (NO branch of block 38), the method goes back to the “benchmark” parameter set, i.e., that row in the steering table corresponding to the highest ranked set (block 32b) and stimulation is again provided (block 34c). This is actually a repeat of the stimulation performed at blocks 32a and 34a, but inasmuch as one or more stimulation parameter sets have been provided since the benchmark stimulation was provided at steps 32a and 34a, this repeat stimulation provides the patient with a reminder or refresher of what the benchmark stimulation was like. (Alternatively, of course, this repeat of the benchmark stimulation could be skipped.) Then, a process almost identical to that described above is performed to again fine tune the benchmark stimulation parameter set, only in the other direction. That is, the row adjacent to the row that defines the benchmark stimulation parameter set is selected as the row that defines the stimulation parameter set (block 40), moving in the opposite direction, e.g., up, from the direction used in the step performed at block 36. Once a row is selected, stimulation is provided using the parameters of the selected row (block 34d). Thus, the fine tuning that occurs at steps 40 and 34d in FIG. 3 occurs while moving in the opposite direction in the steering table than was used previously.

The results of the new stimulation applied at step 34d are compared to the results of the previous stimulation (block 38b). If the results improve (YES branch of block 38b), the steps set forth in blocks 40 and 34d are repeated, i.e., the row in the steering table adjacent to the most recently used row, moving in the same direction in the table as before, are used to define a new stimulation parameter set (block 40), and that stimulation parameter set is used to provide stimulation (block 34d). As long as the stimulation results continue to improve, this process of stepping to the next row in the steering table, and retesting is continued, thereby fine tuning the stimulation parameter set until no further improvements are detected.

Hence, it is seen that thus far in the method, two sets of effective stimulation parameters have been identified: one by moving in a first direction from the benchmark row (of the specified ranked set) in the steering table (determined using the steps at blocks 36, 34b and 38a), and another by moving from the benchmark row in a second direction in the steering table (determined using the steps at blocks 40, 34d and 38b). These two possible stimulation sets are then evaluated to see if one comprises the most effective stimulation set (block 42). If so (YES branch of block 42), then that set is selected as the best parameter stimulation set for the stimulation that is to be provided (block 46) whenever the operating program of the SCS system (or other neural system) determines stimulation is needed. If not (NO branch of block 42), then the search continues for the most effective stimulation set by selecting the row in the steering table corresponding to the next highest ranked set (block 44), e.g., the second ranked stimulation set. The next highest ranked set thus defines a new specified “benchmark” stimulation set from which additional fine tuning is performed as described above (blocks 32a through 38b).

It is thus seen that unless an effective stimulation parameter set is found at block 42, the process described in FIG. 3 is repeated for the next highest ranked trial stimulation parameter set, until the most effective stimulation parameter set is identified.

By way of a simple example, consider the Simplified Measurement Table found in Appendix A and the Simplified Steering Table found in Appendix B. After testing each of the stimulation parameter sets defined by the rows in the Simplified Measurement Table in Appendix A, the following “coarse” ranking in effectiveness of the stimulation sets is found.
Starting with the highest ranked Stimulation Set (from the Simplified Measurement Table in Appendix A), which uses Electrode Number 3 as an anode (+) and Electrode Number 5 as a cathode (−) to provide a stimulus to the patient, a corresponding row in the Simplified Steering Table (in Appendix B) is found to be Stimulation Set No. 301, which shows that the current flow from Electrode 3 is “1” and the current flow from Electrode 5 is “−1”. This means that all of the current applied by the stimulator is applied from Electrode 3 as an anode to Electrode 5 as a cathode. (The amplitude of the current applied may, of course, be adjusted as required.) Thus, the coarse adjustment provided by the measurement table leads one to Stimulation Set No. 301 in the Simplified Steering Table. Stimulation Set No. 301 thus serves as the first “benchmark” stimulation set.

Once the first benchmark stimulation set is identified, the method then fine tunes this selection by applying the stimulation set(s) adjacent the benchmark set. For example, going “down” in the Simplified Steering Table, Stimulation Set No. 302 is applied, then No. 299, then No. 298, and so on, until the patient (or other means) determines that no further improvement results. In this example, Stimulation Set No. 302 is found to be the most effective set.

In a similar manner, going “up” in the Simplified Steering Table from the benchmark set (No. 301), Stimulation Set No. 300 is applied, then No. 299, then No. 298, and so on, until the patient (or other means) determines that no further improvement results. In this example, Stimulation Set 298 is found to be the most effective set to use.

Once the two Stimulation Sets No. 298 and 302 have been identified, then a determination is made as to which one is the most effective to use for stimulation. If one of these two is the most effective, e.g., Stimulation Set No. 298, then that Stimulation Set is selected as the best one to use for stimulation in this instance, and the search ends. If, however, neither is found to be the most effective, then the process continues by locating the third-highest ranked benchmark stimulation set (corresponding to Stimulation Set No. 2 in the Simplified Measurement Table) in the Simplified Steering Table, and the process continues as described.

Those skilled in the art will recognize that various variations exist to the method described herein. For example, a gradient method may be utilized to evaluate the slope of stimulation parameter set effectiveness around each trial stimulation parameter set. A combination of the relative effectiveness of each trial stimulation parameter set, and the slope of the effectiveness in the neighborhood of the trial stimulation parameter set may be used to select which trial stimulation parameter set to test around. The basic core of the present invention is to use a table, or equivalent, of a small number of trial stimulation parameter sets (a coarse table) to determine a starting point, and a larger table (a fine table), or equivalent, of predetermined stimulation parameter sets to guide the search for a local optimum. Any method for finding an effective stimulation parameter set that uses a combination of a small coarse table, and a large fine table, is intended to come within the scope of the invention.

Related methods may be used to ensure an effectual lead placement during a surgical procedure to implant a lead. A flow chart depicting one embodiment of these methods is shown in FIG. 4.

Using normal surgical techniques, a lead 16 containing an electrode array 18 is placed epidurally next to a patient’s spinal cord in a location believed to be the correct location for effective treatment (block 50). This location may be estimated based on, for instance, mapping the location of the pain to spinal segments via dermatome maps. Once the lead is in place, it is connected to a pulse generator. The pulse generator may be an external trial stimulator (ETS), an implantable pulse generator (IPG) 12 or another source of stimulation. The lead may be connected directly to the pulse generator, or may be electrically connected, for instance, via a lead extension 14 and/or an operating room (OR) cable. The ETS, IPG, lead extension and OR cable are described in more detail in U.S. Pat. No. 6,516,227, discussed above.

Once the lead is in place and connected to the pulse generator, stimulation is activated (block 52). In one embodiment, a steering table such as the steering table shown in Appendix B is used to define the stimulation parameters. In such a table, the table entries are arranged so that the electric field properties of the stimulation defined by parameters in adjacent rows are similar. This is accomplished by having the rows arranged in order based on the characteristics of the stimulation provided by each stimulation parameter set, so that moving from one row to an adjacent row in the steering table causes a gradual change in stimulation. For example, rows 21 to 41 of the table in Appendix B define stimulation parameters representing a gradual transition of an anode from electrode 3 to electrode 4. The electric field properties of the stimulation defined by the parameters in these rows are similar, such that a transition from row 21 to row 41 has the effect of gradually moving the anode from electrode 3 to electrode 4.
Once the stimulation has been activated, the process of “electronic trolling” (block 54) can begin. In one embodiment, the steering table is arranged such that stimulation is first provided by an electrode located at one end of the electrode array. The entries of the table are arranged so that the stimulation is gradually transitioned to an adjacent electrode, then another adjacent electrode, and so on, until the stimulation has been transitioned along the entire length of the array. The number of steps used to transition along the entire array, and thus the number of entries in the steering table used for trolling, depends on many factors. These factors include the number of electrodes in the array and the maximum step size that will not produce an uncomfortable “jolt” to the patient. Additionally, the amount of time the surgeon and/or patient wants to spend trolling and the amount of time the patient can tolerate trolling must be weighed against the desired electric field shift resolution. If too large of a step size is selected, the group of effective stimulation parameter sets might be inadvertently skipped during the trolling process and the location of the lead may be incorrectly judged to be ineffective. The number of steps or step size may be programmable and selectable by the surgeon and/or clinician, or may be pre-programmed in software. Once the number of steps or step size is determined, a steering table for use in trolling can be created or can be selected from an existing table. Alternatively, particular rows from a larger steering table may be selected for use in the trolling process.

In another embodiment, the stimulation is first provided by an electrode or set of electrodes that is not at the end of the array. For example, several electrodes in the middle of the array may be used to provide stimulation. The stimulation is then transitioned in one direction along the array to one end of the array. The stimulation may then be transitioned back to the middle of the array and to the opposite end of the array. In this way, stimulation is provided from electrodes located in different regions of the array. Any combination or pattern in which stimulation is transitioned along the length of the array is intended to fall within the scope of these methods.

Furthermore, the methods discussed above are not limited to use with a steering table. Any method in which stimulation is transitioned along the electrode array may be used. For example, stimulation may be defined by parameters specified by software, which may define multiple sets of stimulation parameters. As another example, stimulation may be activated in one portion of an array and an algorithm may be used to transition stimulation from that portion of the electrode array to another or from one end of the array to the other without the use of a steering table. Fixed step sizes may be used to transition stimulation, or a method such as the method disclosed in co-pending U.S. application Ser. No. #######, filed Dec. 30, 2004 entitled “Method for Optimizing Search for Spinal Cord Stimulation Parameter Settings” and incorporated herein by reference, may be used to determine the appropriate step sizes to use for electronic trolling.

In order to maximize the benefit of the methods discussed above, the electronic trolling process preferably involves electrodes from all regions of the array. If the trolling process involves less than the entire array, then a relatively smaller region of the patient’s spinal cord is stimulated during the trolling process and the lead may have to be repositioned a greater number of times. To avoid this less efficient result and to gain the maximum benefit of the methods discussed above, a representative number of sets of stimulation parameters are preferably used during the trolling process. This means that sets of stimulation parameters defining stimulation in all regions of the electrode array are preferably used, and that a sufficient number of sets are preferably used. The number of sets required depends on several factors, including the number and size of electrodes, the inter-electrode spacing, the patient’s anatomy and the location(s) and total area of the patient’s pain. This number is preferably chosen so that the electric field and the resulting paresthesia do not shift too much with each transition in the trolling process, and so that stimulation is provided from all regions of the electrode array.

Similarly, in order for electronic trolling to be most effective, the electrical stimulation should be of a strong enough intensity to produce paresthesia along the entire length of the array. Any method that accomplishes this can be used, including giving the patient the ability to manually adjust the intensity of the stimulation up and down as the stimulation is transitioned. Alternatively, an algorithm, such as the SEQ algorithm described in co-pending U.S. application Ser. No. #######, discussed above, may be used to maintain a relatively constant stimulation intensity as the stimulation is transitioned. As the electric field produced by the stimulation is shifted, the location on the patient’s body where paresthesia is sensed will also shift. The goal of the trolling process is to ensure the effective placement of an electrode array such that the location of the induced paresthesia is effective, i.e., so that the location of the induced paresthesia matches the location of the pain when the electrode array is located in a particular place.

Thus in the next step of the method, the patient reports whether the paresthesia generated by the stimulation is located in approximately the same location as the pain (block 56). The patient may provide feedback during the trolling process, or may be asked at the conclusion of the trolling process whether the location of the paresthesia matches the location of the pain at any time during the process. If the location of the paresthesia sufficiently matches the location of the pain, then the lead is in an effective position and the trolling process is complete (block 58). The surgeon then secures the lead in position, using a lead anchor or other means. The process of determining effective stimulation parameter sets, for example as shown in FIG. 3 and described above, may then begin (block 64).

If the patient reports that the area(s) of paresthesia generated by stimulation do not sufficiently overlap the area(s) of pain, then the stimulation may optionally be deactivated (block 60), the lead is repositioned in the epidural space (block 62) and the steps shown in blocks 52-56 are repeated. This process of optionally deactivating stimulation, repositioning the lead, and repeating the steps in blocks 52-56 is repeated until the patient reports that the paresthesia generated by the stimulation sufficiently matches the location of the pain.

Thus, electronic trolling has a similar effect as physical trolling in that the location of the electric field produced by the stimulation moves with respect to nerves in the spinal cord. However, unlike physical trolling, the lead need not be moved while the stimulation is active. Instead,
the stimulation provided by the electrode array is moved along the array electronically by changing which electrode or electrodes are providing stimulation. Also unlike physical trolling, the lead is not moved unless the patient reports that the paresthesia produced by the stimulation does not sufficiently match the location of the pain. This results in a simpler surgical procedure with less risk of damage to tissue surrounding the lead or to the spinal cord itself. Additionally, because stimulation is not deactivated between testing each electrode combination, electronic trolling saves time over conventional methods which require stimulation to be ramped up and down in order to test each combination.

While the invention herein disclosed has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims. For example, the methods discussed above are not limited to spinal cord stimulation systems and may be used with many kinds of stimulation systems such as cochlear implants, cardiac stimulation systems, peripheral nerve stimulation systems, brain stimulation systems and microstimulators.

1-15. (canceled)

16. A method for determining an effectual placement of an electrode array during a surgical implant procedure comprising:

(a) placing a lead having electrodes in a first location in a patient;
(b) activating electrical stimulation to produce paresthesia;
(c) electronically trolling the length of said electrode array;
(d) determining whether the paresthesia is in an effective location;
(e) if the paresthesia is not in an effective location, moving the lead to a different location and repeating steps (b) through (d).

17. The method according to claim 16, wherein the electrical stimulation is defined by parameters specified by software.

18. The method according to claim 17, wherein the software comprises a steering table.

19. The method according to claim 18, wherein the steering table comprises multiple rows containing stimulation parameters for one or more electrodes.

20. The method according to claim 19, wherein the rows are arranged so that the electric field properties of adjacent rows in said steering table are similar.

21. The method according to claim 20, wherein electronically trolling comprises:

moving the electrical stimulation from a first position on the electrode array to a second position on the electrode array.

22. The method according to claim 16, wherein electronically trolling comprises:

electronically moving the electrical stimulation from a first position on the electrode array to a second position on the electrode array.

23. A method for determining an effectual placement of an electrode array during a surgical implant procedure comprising:

(a) placing a lead having electrodes in a first location in a patient;
(b) providing electrical stimulation to produce paresthesia, the electrical stimulation defined by a first set of stimulation parameters specified by software;
(c) determining whether the paresthesia is in an effective location;
(d) providing electrical stimulation defined by a different set of stimulation parameters specified in software;
(e) determining whether the paresthesia is in an effective location;
(f) repeating steps (d) and (e) until effective paresthesia is obtained or all sets of stimulation parameters specified by software have been provided;
(g) if effective paresthesia is not obtained, moving the lead to a different location; and

24. The method according to claim 23, wherein the software comprises at least one steering table containing rows corresponding to sets of stimulation parameters.

25. The method according to claim 24, wherein the rows are arranged so that the electric field properties of adjacent rows in said steering table are similar.

26. The method according to claim 23, wherein the software comprises at least one algorithm specifying sets of stimulation parameters.

27. The method according to claim 23, wherein repeating step (d) results in a gradual transition of stimulation from a first position on the electrode array to a second position on the electrode array.

28. A method for determining an effectual placement of an electrode array for the treatment of pain comprising:

(a) placing a lead having electrodes in a first location in a patient;
(b) providing electrical stimulation to produce paresthesia, the electrical stimulation defined by a first set of stimulation parameters contained in a steering table;
(c) determining whether the location of the paresthesia effectively matches the location of the pain;
(d) if it does not, providing electrical stimulation defined by a different set of stimulation parameters contained in said steering table;
(e) repeating steps (c) and (d) until effective paresthesia is obtained or electrical stimulation defined by a representative number of sets of stimulation parameters has been provided;
(f) if the location of the paresthesia still does not effectively match the location of the pain, moving the lead to a different location; and

(g) repeating steps (b) through (f) until the location of the paresthesia effectively matches the location of the pain.
29. The method according to claim 28, wherein the first set of stimulation parameters are contained in a first row of the steering table.

30. The method according to claim 28, wherein the rows of the steering table are arranged so that the electric field properties of adjacent rows in said steering table are similar.

31. The method according to claim 28, wherein providing electrical stimulation defined by a different set of stimulation parameters comprises:

   providing electrical stimulation defined by stimulation parameters contained in an adjacent row of the steering table.

32. The method according to claim 31, wherein the first row of the steering table contains stimulation parameters that define stimulation to be provided at a first end of the electrode array and the row of the steering table farthest from the first row contains stimulation parameters that define stimulation to be provided at a second end of the array.

33. The method according to claim 28, wherein repeating step (d) results in a gradual transition of stimulation from a first position on the electrode array to a second position on the electrode array.

34. The method according to claim 33, wherein repeating step (d) results in a gradual transition of stimulation from the first end of the electrode array to the second end of the electrode array.