Bipolar Stimulation/Recording Device With Widely Spaced Electrodes

[01] This application claims the benefit of prior co-pending U.S. provisional application Serial No. 60/834,184, filed July 31, 2006.

BACKGROUND OF THE INVENTION

[02] Bipolar stimulator probes attachable to an electrical stimulator device or an electromyographic (EMG) device are commercially available for surface stimulation of peripheral nerves. Such apparatus provide both a stimulation electrode and a reference electrode on a single device. There are also bipolar bar electrode configurations, and sets of separate (individual) electrodes, for surface recording of nerve and muscle action potentials, and that can also serve to provide electrical muscle stimulation.

[03] These types of devices can be used in surface stimulation for eliciting muscle twitches of the type sought in a muscle pain and discomfort relieving method developed by the present inventor, referenced herein as Surface Applied Electrical Twitch Obtaining Intramuscular Stimulation (SA-ETOIMS^{TM}). This methodology is described in U.S. provisional patent application Serial No. 60/715,137, entitled "Intramuscular Stimulation Therapy Using Surface-Applied Localized Electrical Stimulation," filed September 9, 2005, and corresponding regular U.S. patent application No. 11/470,757, filed September 7, 2006. This technique involves the provision of brief electrical stimulation at multiple motor end-plate zones (twitch-points) in many muscles. It is important that the stimulation method be "user friendly," to both patient and treating clinician. That is, the stimulation should not cause significant additional discomfort to the patient and the method should be easy to apply for the clinician.

[04] Commercially available standard bipolar stimulating probes have an inter-probe distance of 2 cm or less between the active and reference electrodes. This type of bipolar stimulation induces significant stimulation pain making it undesirable for use in the SA-ETOIMS^{TM} procedure. In addition, due to the close proximity of the active and reference

electrodes, twitches that may be elicited with such devices are small and have low forces, and therefore do not provide significant pain relieving effects. Similarly, as mentioned, surface electrodes that can be used for recording as well as stimulation purposes are available in the form of a bar electrode pair. Such devices have an inter-electrode distance of about 3-4 cm, and thus the same problem of inducing stimulation pain arises if these devices are used to perform SA-ETOIMS™. Stimulation/recording electrodes are also available as separate (individual) electrodes. However, separate individual electrodes are less than ideal for use in the SA-ETOIMS™ procedure, since both the active and reference electrodes have to be moved in bi-manual fashion to multiple stimulus and reference sites, thus slowing down and encumbering the SA-ETOIMS™ procedure and making the procedure more difficult for the clinician. These difficulties are alleviated to some extent by use of a monopolar stimulation tool, as is explained below.

[05] The present inventor has performed SA-ETOIMS™ using monopolar stimulation, that is, with a generally pen-like tool having a single electrode mounted on its tip, which is used in conjunction with a separate reference electrode. Providing the stimulation electrode in the form of a stiff, pen-like tool gives the clinician a firm place to hold the tool in order to easily move the electrode to different stimulation sites in a rapid and efficient manner. The pain or discomfort relieving therapeutic effects are substantially achieved only when such sites with large force twitches are stimulated. SA-ETOIMS is performed in a time-based fashion, i.e. in incremental treatment segments of 10-15 minutes sessions to one hour sessions. For therapeutic effects to be substantial, it is essential that many large force twitch sites be sought, located and treated within the limits of timed sessions which are affordable and paid for by the patient as fee-for-service performed. To be able to search for as many large force twitch sites as possible within a given time-frame, the electrode needs to be moved to another site as soon as the twitch is elicited, i.e., within a fraction of a second. Therefore, it is crucial that the stimulation probes and reference electrodes allow expedient performance of the SA-ETOIMS procedure. However, a stimulation electrode provided in the form of a known-type adhesively applied disposable

electrode has no firm place for the clinician to hold onto effectively, and is also impractical for efficient use in a treatment method involving electrode relocation every fraction of a second. The monopolar stimulation probe, similar in size and length to that of a pen, is very useful in SA-ETOIMS procedure and can be easily applied onto the skin surface for stimulation to evoke muscle twitches and to facilitate the search for large force twitch sites. However, the monopolar stimulation method requires use of a separate remote surface reference electrode, which is typically a known-type adhesively applied disposable electrode. The treatment is less painful than with bipolar stimulation with electrodes that are spaced 2-4 cm or less apart. However, monopolar stimulation has disadvantages.

[06] With monopolar stimulation, moving the stimulating probe to different stimulus points has to be accompanied by relocating the disposable separate reference electrode to different body sites, multiple times, to avoid repetitive unnecessary stimulation and induced pain at the reference site. This type of surface reference electrode is not conducive to rapid movements, e.g., every second. Therefore, in practice, the electrode is moved after every minute or so. This bimanual work wastes time for the treating clinician since the disposable reference electrode will lose its adhesiveness, dislodge and/or fall off when subjected to multiple re-positioning and re-application onto the skin surface.

[07] To avoid skin irritation from repetitive stimulation at one reference site only, and to avoid having to often move the single, separate reference electrode from place to place, several reference electrodes can be placed at different sites on the skin. By rotating the activation of different reference electrodes, there is better and more even distribution of the stimulus to different reference sites. This reduces the number of times any single reference electrode is subjected to removal and relocation. However, to activate a reference electrode placed at a different site, the clinician has to detach an alligator clip from the first reference electrode and re-attach it onto the next reference electrode with one hand, since the other hand holds onto the monopolar probe used for treatment. This creates inconvenience for the clinician since the alligator clip might not attach well when

performed single-handedly. If bimanual attachment is required, it is disruptive to the treatment. It is also cumbersome since the multiple electrodes still need to be physically removed and rotated for placement at other skin sites to avoid discomfort at sites that have undergone previous repetitive stimulation. In prolonged treatments necessitating multiple different site placements of the reference electrodes, the electrodes can eventually lose their adhesiveness also causing them to fall off the skin surface. Additionally, when the reference electrode does not stick properly to the skin, the reduction in contact area of the reference electrode to the skin induces more treatment pain.

[08] For optimal pain relieving results with SA-ETOIMS^{TM}, it is desirable to search for as many muscle motor points that can produce large force twitches as quickly as possible in a time-based treatment. Stimulation can be enhanced, and the yield of large force twitches made easier, when the surface reference electrode is placed at a distance from the stimulating probe. If the reference electrode is placed close to the stimulating probe, the treatment is painful and the twitches are small. The further the reference electrode is placed away from the stimulating probe, e.g., by as much 2-3 feet, the easier it is to elicit the sought-after large force twitches from deeply situated motor end plate zones (twitch-points). As one example, the reference electrode can be on the mid or low back region while stimulating calf muscles or arm muscles, but this creates a problem for the clinician if the reference electrode is at a site not within easy reach. The clinician then has to temporarily stop the treatment every time he/she has to reach over to the reference electrode or has to move closer to re-position the remote reference electrode to another location within reach.

[09] Additional disadvantages of the monopolar stimulation approach (with separate reference electrode) include the fact that the lengthy separated wires of the stimulating and reference electrodes tend to get tangled, requiring that the clinician stop the treatment to untangle the wires. Additionally, there is a difficulty in finding a suitable site for reference electrode placement on the ventral (front) surface of the body where the skin is more sensitive to electrical stimulation, especially those associated with repetitive

stimulation to one site. Also, if the clinician forgets to remove the reference electrode from the back of the body while treating muscles on the front of the body or the chest, a trans-thoracic current may be induced and adversely affect heart rhythm.

SUMMARY OF THE INVENTION

[10] With the foregoing in mind, the present inventor recognized that there is a need for a bipolar stimulator probe, wherein the active stimulator electrode and the reference electrode are provided as part of a single tool, and the separation between the electrodes is fixable at a set, e.g., standardized, distance which is significantly greater than the electrode separation of known bipolar stimulator probes and bipolar bar electrode configurations. As a general principle, to obtain large force twitches and to simulate the monopolar stimulating condition with the bipolar tool, the distance between the active and reference electrodes should be spaced far apart as possible. Ideally, the two electrodes could be spaced as far apart as possible (perhaps by 2-3 feet or more), but it may not be clinically practical to have this type of very wide spacing provided by a bipolar electrode tool. Such a device may be too heavy, bulky, and /or awkward for practical use. Also, the uneven contours of the intervening tissues may prevent the reference electrode from touching the skin surface. For practical utility, an electrode spacing of 15-16 cm (6 inches) may be provided between the stimulating and reference electrodes. However, it is advantageous to have an option for increasing or decreasing the spacing between the two electrodes. The probe tool may be configured to permit adjustment of the fixed relative position of the electrodes within a given range, such as by slideable or otherwise movably mounted electrodes similar to the principle used in a sliding gauge such as a Vernier caliper. A bipolar probe tool providing a wide spacing between the two electrodes will approximate the effect of monopolar stimulation with a separate reference electrode, with the electrical stimulus producing less pain to the patient compared to bipolar stimulation where the two electrodes are spaced apart by only 2-4 cm or less. The ability to reduce the inter-electrode distance is essential for treating small muscles in the face, hands and feet.

BRIEF DESCRIPTION OF THE DRAWINGS

[11] Fig. 1 is a diagrammatic depiction of a bipolar stimulation probe in accordance with the invention.

[12] Fig. 1a is a diagrammatic depiction of a variation on the Fig. 1 embodiment, with the handle moved to one end of the tool (Vernier caliper-style).

[13] Fig. 2 is a diagrammatic depiction of a further bipolar embodiment stimulation probe tool.

[14] Fig. 3 is a diagrammatic depiction of a further exemplary probe tool in accordance with the invention.

[15] Fig. 4 is a diagrammatic depiction of yet another exemplary probe tool embodiment.

[16] Fig. 5 is a perspective view depicting a prototype probe tool in accordance with the invention, corresponding to the diagrammatic representation of Fig. 1.

[17] Fig. 6 is a perspective view of another prototype probe tool in accordance with the invention, corresponding to the diagrammatic depiction of Fig. 3.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[18] Referring now to the appended drawings, Fig. 1 is a diagrammatic depiction of a bipolar stimulation probe 1 in accordance with the invention. Handle 2 is preferably about 3-6" or so in length. Wires 3 lead to the two spaced electrodes 5, 7 of the probe tool, and connect to a suitable stimulator/recording device, such as the commercially available electrical stimulation unit, Model DS 7, from Digitimer Limited (Herforthshire, England). As illustrated, electrode 5 may be the stimulating electrode, and electrode 7 may be the reference electrode. Electrodes 5, 7 are mounted on the ends of spaced arms or prongs 9, 11, attached to each other by a connection cross member 12, which may extend between the stimulating prongs 9, 11 at right angles to the prongs, as shown in Fig. 1. Prongs 9, 11 preferably have a length of about 2.5 " (50 mm) and are spaced from each other to

provide a separation of distance "A" between electrodes 5 and 7, which is preferably at least 6" center to center, and with an upper limit of 24-36". Electrodes 5, 7 may be of a known type. For stimulation applications, the electrodes may be covered by a wad of wet cotton or wool soaked in water, but it is preferable to use hypertonic 9-10% saline to facilitate electrical conduction. The stimulating electrodes can be provided in the form of disposable felt pads manufactured for SA-ETOIMS. They can be pre-packaged already pre-soaked or immersed in hypertonic 9-10% saline to facilitate use in treatment. For recording purposes, the recording surface is made preferably with stainless steel or another known conductive metallic surface of suitable type.

[19] A trigger button may be mounted on probe tool 1, to permit a clinician to conveniently activate the probe for stimulation applications. The switch is preferably touch-sensitive, activated by a pressure on the patient contact surface of the stimulating electrode or activated by a push-button on the handle, on its side or end, for on/off control triggered by the clinician. The probe may also be activated via a separate hand button that can be triggered by the patient or another person.

[20] The stimulating probe should be light-weight, preferably weighing about 2-4 oz or less, e.g., preferably the approximate weight of a writing pen. However, the materials used for the connection cross member 12 should be sturdy enough to withstand breakage upon being subjected to repetitive use and receiving significant impacting forces along the attached prongs from the forceful twitches. The circumference of the handle or stem 2 of probe 1 is preferably about 4 cm, or on the order of the diameter of a writing pen, for ease of grasp and comfort for the clinician. Handle 2 preferably has a length of 3-6 inches to avoid wobbling of the electrodes on the surface of the skin by virtue of hand movements. Alternatively, instead of a stem-like handle, the connection cross member 12 may also be of a thickness that can allow it to be used as a handle in the same fashion commonly in use with steam irons (see Fig. 2, discussed below). Also, the handle may be placed at one end of the connection cross member 12, similar to the handle of a Vernier caliper. This is illustrated in Fig. 1a, wherein the tool has a repositioned handle 2'. In such a design, the handle may be tilted up at an obtuse angle relative to the connection

cross member 12 (as commonly seen in the handle of a frying pan or sauce pan), such that the handle will, in use, avoid touching the patient's skin and muscle tissue. Such a handle is shown in dotted lines in Fig. 1a (labeled 2"). The handle should be of a girth comfortable for gripping for long periods of time. The control for changing the inter-electrode distance can be suitably placed on the handle for thumb manipulation. The control may be a wheel or button that can also lock-in the chosen inter-electrode distance. Both electrode surfaces in contact with the patient will preferably be circular in shape and have a diameter of 1-2 cm.

[21] Fig. 2 is a diagrammatic depiction of a further embodiment, probe tool 13, wherein the spaced electrode mounting structure is provided in the form of an arched/semi-lunar shaped arm 14, with the active and reference electrodes 5, 7 mounted on the ends, e.g., with a spacing "A" of about 6". This embodiment also has a handle 2, as in the first embodiment, which attaches to a central portion of arm 14. Stem-like handle 2 may be omitted, in which case the arched/semi-lunar shaped arm 14 can be used as the handle with a girth comfortable for prolonged gripping, similar to that of a steam iron.

[22] On uneven body regions, the stimulation and reference electrodes may not be able to easily reach to touch the skin surface simultaneously. Simply re-positioning the stimulating electrode in treating these areas can overcome this difficulty. Also, fashioning the connector piece between the active and reference electrodes to be in the shape of an arc or semi-lunar shape, as shown in Fig. 2, will help with this issue, by fitting better over the contour of a muscle. Also, the probe arms could be made movable or bendable to permit the probe ends to reach to touch the skin surface. This concept is similar to that of the flexible stem of a reading lamp that can be bent to supply the optimal angle for providing the correct amount of light for reading. The probe device arms and handle should be made of, or shielded by, plastic or other insulative material to electrically isolate the stimulation and reference electrodes and prevent a short of the electrodes or electrical impulses passing to the clinician.

[23] Fig. 3 is a diagrammatic depiction of a further exemplary embodiment, probe tool 15, wherein the spaced electrode mounting structure is provided in the form of an essentially flat bar 16, to which the active and reference electrodes 5, 7 may be mounted, directly, or in very short arms or prongs, e.g., with an arm length of 0.5" or less, and an inter-electrode spacing of about 6". This embodiment also has a handle 2, as in the first embodiment, which attaches to a central portion of flat bar 15. This type of bar electrode is more suitable for recording or stimulation purposes over flat and even surfaces. Probe tool 15 is not so well suited for use where there is a need for rapid search and location of large force twitch sites in performing SA-ETOIMS therapy. This is due to the short length of the prongs of the bar electrode that interfere with placement of both electrodes in contact with the skin surface over contoured muscles.

[24] Fig. 4 is a diagrammatic depiction of yet another exemplary embodiment, probe tool 17, wherein the spaced electrode mounting structure is provided in the form of a pair of arms 19 which converge to form an obtuse angle. Similar to the previous embodiments, the active and reference electrodes 5, 7 may be mounted on the end of the arms, e.g., with an inter-electrode spacing of about 6". This embodiment also has a handle 2, as in the first embodiment, which in this case attaches to the central apex portion of the structure formed by the angled (converging) arms 19.

[25] SA-ETOIMS^{TM} related advantages potentially realizable a wide-spaced bipolar probe tool in accordance with the invention are described below.

[26] The bipolar probe tool allows SA-ETOIMS^{TM} treatment to be performed faster since bi-manual work is not required of the clinician as with the monopolar stimulation method that requires moving the stimulating electrode, in addition to the separate time and attention required to move the reference probe during the treatment procedure.

[27] The paired movement of the reference electrode together with the active stimulating probe prevents any one site over which the reference has been placed, from prolonged excessive stimulation and unnecessary discomfort to the patient.

[28] Having a fixed or limited adjustable distance between the stimulator and the reference electrodes allows the reference electrode to be in the same area of the muscle treated and the stimulus is localized to the one muscle of interest. This stimulus isolation to one muscle is possible in treating large muscles of the buttock and lower limbs. The stimulus can also be isolated to one side of the body since both stimulus and reference electrodes can be moved together for performing such purposes. This substantially eliminates the possibility of accidental placement of the reference electrode on the back of the body while treating muscles on the front of the body, and the attendant risk of inducing trans-thoracic current that can interfere with heart rhythm.

[29] With the bipolar probe tool, there need only be one cable leading to the stem of the tool, making the tool more user friendly by avoiding the need for two separate wires extending to separate reference and stimulator electrodes. This avoids the entanglement of wires during treatment and leads to better utilization of treatment time.

[30] The present inventor has used prototype probes similar to those depicted in Figs. 5 and 6 to provide SA-ETOIMS treatments with a fixed interelectrode distance of 15-16 cm or 6" and found the electrode spacing to be sufficient to allow large force twitches to be elicited. The treatments with such a probe is faster, more efficient and decidedly less painful at the reference site compared to monopolar stimulation using static reference electrode placement. With certain muscles, such as the buttocks of overweight patients, in certain instances, this spacing may not be sufficient to elicit large force twitches. This situation can be overcome by a slideable or otherwise moveable mechanism to increase the distance between the active and reference electrodes to more than 6" and possibly up to 24"-36", or more. Such an arrangement can be used to facilitate the positioning of the bipolar probe such that the active stimulation electrode is positioned on the muscle of interest, and the reference electrode is positioned to lie on a different muscle. This advantageously simulates monopolar stimulation conditions to a great extent, due to the wide spacing distance between the two electrodes. A slidable movement of the electrodes along the cross-arm 20, to adjust the electrode spacing, is diagrammatically depicted by arrows B_1 and B_2 in Fig. 5. Flexible joints, allowing the cross-arm 20 to

bend in order to reposition/reorient the electrodes, are diagrammatically depicted at 21. Also depicted in Fig. 5 is a handle-mounted user activated push-button 23 that may be associated with a trigger switch of the tool, as previously described. (The illustrated slidable movement, flexible joints and push-button are optional features not present in the prototype probes used by the inventor.)

[31] The bipolar probe devices of the present invention also have utility beyond their advantageous use for SA-ETOIMS™ stimulation purposes. Such devices can also be used for other stimulation procedures, wherein it may be necessary or desirable for the reference and active electrodes to be widely spaced apart, or in situations wherein it is desired to simulate monopolar stimulation conditions for stimulating nerve and/or muscle.

[32] This same type of probe can also be used for recording compound muscle action potentials and sensory nerve action potentials for performing nerve conduction study (NCS) recordings, using an electromyographic (EMG) machine. For motor nerve conduction studies with recording from large muscles, the active electrode is placed over the motor point of the muscle of interest and the reference electrode is placed over the tendon of the recorded muscle or in an electrically inactive region such as the bone on which the tendon of interest inserts. Similarly, for recording sensory nerve action potentials, the active and reference electrodes are placed over the line of distribution of the sensory nerve.

[33] In order to obtain better electrical readings for recording procedures, the probe electrodes that are placed in contact with the patient's skin are preferably made of metal or other disposable metallic conducting material, such as those routinely used in electrocardiographic (EKG) and nerve conduction study (NCS) recordings, instead of the disposable wet felt pads that are preferably used for stimulating purposes. The active and reference leads of the tool will preferably be of a compatible type that can fit into the appropriate receptacles of the pre-amplifier of the EMG machine. The spaced electrode pairing provided by the present invention is useful in facilitating the search for the best

motor point from which to record for a given muscle. This is due to the ease in repositioning the recording and reference electrodes, and the use of a fixable or standardized distance between the two electrodes. When the spacing between the active and reference electrodes is not held constant (fixed), the shape and amplitude of the recorded potential changes in relationship to the distance between these two electrodes; this variability is especially notable with sensory nerve action potentials recordings. The bar electrode style probe as shown in Figure 3, is suitable for recording of sensory and muscle action potentials.

[34] It will be understood that while the invention has been described in conjunction with various embodiments and details thereof, the foregoing description and examples are intended to illustrate, but not limit the scope of the invention. Numerous other variations and arrangements are within the scope of the invention.

CLAIMS:

1. A bipolar stimulator probe comprising an active stimulator electrode, a reference electrode and a user handle provided as part of a single tool, wherein the positions of the electrodes are substantially fixed with respect to each other such that the inter-electrode spacing is at least 15 cm center to center.

2. The bipolar stimulator probe according to claim 1, wherein the probe tool is configured to permit adjustment of the fixed relative position of the electrodes within a given range.

3. The bipolar stimulator probe according to claim 1, wherein the electrodes are mounted on the ends of spaced arms which are attached to each other by a connection member extending cross-wise between the arms.

4. The bipolar stimulator probe according to claim 3, wherein the handle is placed at one end of the connection member.

5. The bipolar stimulator probe according to claim 4, wherein the handle is tilted up at an obtuse angle relative to the connection member.

6. The bipolar stimulator probe according to claim 1, further comprising a trigger switch to permit a user to conveniently activate the probe for stimulation applications.

7. The bipolar stimulator probe according to claim 6, wherein the trigger switch is a touch-sensitive switch activated by pressure exerted on a patient contact surface of the stimulating electrode.

8. The bipolar stimulator probe according to claim 6, wherein the trigger switch is activated by a push-button provided on the handle.

9. The bipolar stimulator probe according to claim 1, wherein both electrodes have surfaces for contact with the patient that are circular in shape and have a diameter of 1-2 cm.

10. The bipolar stimulator probe according to claim 1, wherein both electrodes comprise metallic patient contact surfaces.

11. The bipolar stimulator probe according to claim 1, wherein both electrodes comprise felt pads providing patient contact surfaces.

12. The bipolar stimulator probe according to claim 1, further comprising a spaced electrode mounting structure provided in the form of an arched arm with the active and reference electrodes mounted on the ends thereof.

13. The bipolar stimulator probe according to claim 1, further comprising a spaced electrode mounting structure in the form of a generally flat bar to which the active and reference electrodes are mounted.

14. The bipolar stimulator probe according to claim 1, further comprising a spaced electrode mounting structure in the form of a pair of arms which converge to form an obtuse angle.

15. A bipolar stimulator probe comprising an active stimulator electrode, a reference electrode and a user handle provided as part of a single tool, wherein the probe tool is configured to permit the positions of the electrodes to be fixed with respect to each other and to permit adjustment of the fixed relative positions of the electrodes within a given range.

16. The bipolar stimulator probe according to claim 15, wherein at least one of the electrodes is slideably mounted on the tool to permit position adjustment thereof.

17. The bipolar stimulator probe according to claim 15, further comprising a spaced electrode mounting structure which is movable or bendable to permit adjustment of the relative positions of the active and reference electrodes in order to reach to touch uneven skin surfaces.