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(71) Applicant and

(72) Inventor: SACHS, Dan [US/US]; 1936 Irving Avenue S.,
Minneapolis, MN 55403 (US).

(74) Agents: JAMES, Stephanie, J. et al.; Beck & Tysver,
P.L.L.C., 2900 Thomas Avenue S., Suite 100, Minneapolis,
MN 55416 (US).

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Fig. 1A

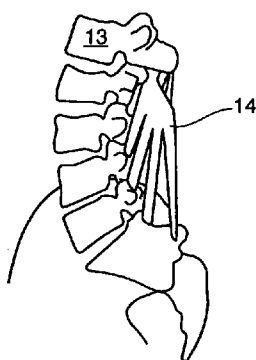


Fig. 1B

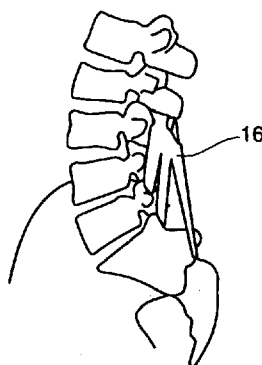
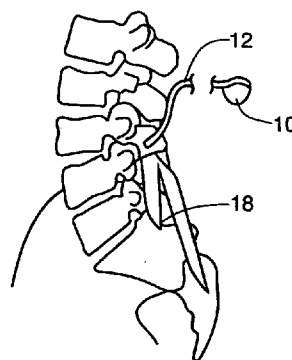


Fig. 1C



(57) Abstract: An implantable medical device for treating the back of a patient. Stimulation energy is delivered to muscles or joint capsules or ligaments or nerve fibers to improve the health of the back.

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MUSCLE STIMULATOR

Field of the Invention

The present invention relates to medical devices and more particularly to a stimulator for treating muscles and neural pathways in the back.

Background of the Invention

The human back is a complicated structure including bones, muscles, ligaments, tendons, nerves and other structures. The spinal column consists of interleaved vertebral bodies and intervertebral discs. These joints are capable of motion in several planes including flexion-extension, lateral bending, axial rotation, longitudinal axial distraction-compression, anterior-posterior sagittal translation, and left-right horizontal translation. The spine provides connection points for a complex collection of muscles that are subject to both voluntary and involuntary control.

Back pain is common and recurrent back pain in the lower or lumbar region of the back is well documented. The exact cause of most back pain remains unproven. One common notion is that some cases of back pain are caused by abnormal mechanics of the spinal column. Degenerative changes, injury of the ligaments, acute trauma, or repetitive microtrauma may lead to back pain via inflammation, biochemical and nutritional changes, immunological factors, changes in the structure or material of the endplates or discs, and pathology of neural structures.

The spinal stabilization system was conceptualized by Manohar Panjabi to consist of three subsystems: 1) the spinal column, to provide intrinsic mechanical stability; 2) spinal muscles surrounding the spinal column to provide dynamic stability; and 3) the neuromotor control unit to evaluate and determine requirements for stability via a coordinated muscle response. In patients with a functional stabilization

system, the three subsystems work together to provide mechanical stability.

The spinal column consists of vertebrae and ligaments (e.g. spinal ligaments, disc annulus, and facet capsules). There is an abundance of in-vitro work in explanted cadaver spines and models evaluating the relative contribution of various spinal column structures to stability, and how compromise of a specific column structure will lead to changes in the range of motion of spinal motion segments.

The spinal column also has a transducer function, to generate signals describing spinal posture, motions, and loads via mechanoreceptors present in the ligaments, facet capsules, disc annulus, and other connective tissues. These mechanoreceptors provide information to the neuromuscular control unit, which generates muscle response patterns to activate and coordinate the spinal muscles to provide muscle mechanical stability. Ligament injury, fatigue, and viscoelastic creep may corrupt signal transduction. If spinal column structure is compromised, due to injury, degeneration, or viscoelastic creep, then muscular stability is increased to compensate and maintain stability.

Muscles provide mechanical stability to the spinal column. This is apparent by viewing cross section images of the spine, as the total area of the cross sections of the muscles surrounding the spinal column is much bigger than the spinal column itself. Additionally, the muscles have much larger lever arms than those of the intervertebral disc and ligaments

Under normal circumstances, the mechanoreceptors generate signals to the neuromuscular control unit for interpretation and action. The neuromuscular control unit produces a muscle response pattern based upon several factors, including the need for spinal stability, postural control, balance, and stress reduction on various spinal components.

It is believed that in some patients with back pain, the spinal stabilization system is dysfunctional. With soft tissue injury,

mechanoreceptors may produce corrupted signals about vertebral position, motion, or loads, leading to an inappropriate muscle response. In addition, muscles themselves may be injured, fatigued, atrophied, or lose their strength, thus aggravating dysfunction of the spinal stabilization system. Conversely, muscles can disrupt the spinal stabilization system by going into spasm, contracting when they should remain silent, or contracting out of sequence with other muscles. As muscles participate in the feedback loop via mechanoreceptors in the form of muscle spindles and golgi tendon organs, muscle dysfunction could further compromise normal muscle activation patterns via the feedback loops.

Trunk muscles may be categorized into local and global muscles. The local muscle system includes deep muscles, and portions of some muscles that have their origin or insertion on the vertebrae. These local muscles control the stiffness and intervertebral relationship of the spinal segments. They provide an efficient mechanism to fine-tune the control of intervertebral motion. The lumbar multifidus, with its vertebra-to-vertebra attachments is an example of a muscle of the local system. Another example is the transverse abdominis, with its direct attachments to the lumbar vertebrae through the thoracolumbar fascia.

The multifidus is the largest and most medial of the lumbar back muscles. It consists of a repeating series of fascicles which stem from the laminae and spinous processes of the vertebrae, and exhibit a constant pattern of attachments caudally. These fascicles are arranged in five overlapping groups such that each of the five lumbar vertebrae gives rise to one of these groups. At each segmental level, a fascicle arises from the base and caudolateral edge of the spinous process, and several fascicles arise, by way of a common tendon, from the caudal tip of the spinous process. Although confluent with one another at their origin, the fascicles in each group diverge caudally to assume separate attachments to the mamillary processes, the iliac crest, and the sacrum. Some of the deep fibers of the fascicles which attach to the mamillary processes attach to the capsules of the facet joints next to the mamillary

processes. All the fascicles arriving from the spinous process of a given vertebra are innervated by the medial branch of the dorsal ramus that issues from below that vertebra.

The global muscle system encompasses the large, superficial muscles of the trunk that cross multiple motion segments, and do not have direct attachment to the vertebrae. These muscles are the torque generators for spinal motion, and control spinal orientation, balance the external loads applied to the trunk, and transfer load from the thorax to the pelvis. Global muscles include the oblique internus abdominis, the obliquus externus abdominis, the rectus abdominis, the lateral fibers of the quadratus lumborum, and portions of the erector spinae.

Normally, load transmission is painless. Over time, dysfunction of the spinal stabilization system will lead to instability, resulting in overloading of structures when the spine moves beyond its neutral zone. The neutral zone is the range of intervertebral motion, measured from a neutral position, within which the spinal motion is produced with a minimal internal resistance. High loads can lead to inflammation, disc degeneration, facet joint degeneration, and muscle fatigue. Since the endplates and annulus have a rich nerve supply, it is believed that abnormally high loads may be a cause of pain. Load transmission to the facets may also change with degenerative disc disease, leading to facet arthritis and facet pain.

For patients believed to have back pain due to instability, clinicians offer treatments intended to reduce intervertebral motion. Common methods of attempting to improve muscle strength and control include core abdominal exercises, use of a stability ball, and Pilates. Spinal fusion is the standard surgical treatment for chronic back pain. Following fusion, motion is reduced across the vertebral motion segment. Dynamic stabilization implants are intended to reduce abnormal motion and load transmission of a spinal motion segment, without fusion. Categories of dynamic stabilizers include interspinous process devices, interspinous ligament devices, and pedicle screw based structures. Total disc replacement and artificial

nucleus prostheses also aim to improve spine stability and load transmission while preserving motion.

There are a number of problems associated with current implants that aim to restore spine stabilization. First, it is difficult to achieve uniform load sharing during the entire range of motion if the location of the optimum instant axis of rotation is not close to that of the motion segment during the entire range of motion. Second, cyclic loading of dynamic stabilization implants may cause fatigue failure of the implant, or the implant-bone junction (e.g. screw loosening). Third, implantation of these systems requires surgery, which may cause new pain from adhesions, or neuroma formation. Moreover, surgery typically involves cutting or stripping ligaments, capsules, muscles, and nerve loops which will interfere with the spinal stabilization system.

Summary of the Invention

It is the conjecture and surmise of the inventor that one source of pain results from mechanical instability of the back. Reaction to pain may in fact induce further instabilities within the back, setting up an overall decline in back health. It is the conjecture and surmise of the inventor that episodic electrical stimulation of particular groups of muscles and associated nerves, ligaments, or joint capsules within the lower back can both reduce the severity of pain and reduce the frequency of pain exacerbations by enhancing stability of the mechanical structures of the lower back. The stimulation may serve to "train" the muscles and improve the tone, endurance, and strength of the muscles. The stimulation may also alter the stiffness of the back acutely during stimulation. The stimulation may also improve voluntary or involuntary motor control of muscles involved in spinal stabilization. The stimulation may also improve reflex arc activity between mechanoreceptors embedded within muscles, ligaments, or joint capsules, and the spinal cord, thereby enabling quick stabilization of the spinal column in the event of unexpected loads or movements. The stimulation may also be used to inhibit muscle spasticity and

muscle spasm. Protocols have been developed for the use of muscle stimulation to accomplish each of these objectives to treat a variety of clinical disorders.

The device will be at least partially implanted and include a lead system that may be coupled to a boney structure within the back to provide stable placement of the lead. The lead or leads will likely be placed in muscle and the electrical stimulation will activate the nerves associated with the muscle. In another embodiment, the lead will directly stimulate target muscles which attach directly to the spinal column, without causing intentional activation of efferent nerve fibers. Target muscles for lead placement include muscles associated with local segmental control of a motion segment, including the deep multifidus, and transversus (or transverse) abdominis. Target muscles may also include muscles such as the diaphragm or pelvic floor muscles, that when stimulated, cause contraction of local segmental muscles.

The optimal location is not known. It is expected that some muscle fibers will be activated and that some nerve fibers will be activated. An induced contraction is expected to activate stretch receptors in the back. This may cause further muscle contractions via intact neural pathways. The result of a neuromuscular stimulus is expected to trigger a cascade of reactions.

In another embodiment, leads may be placed adjacent to receptors which, when stimulated, result in reflex contraction or increased tone of the local segmental control muscles. Target sites for stimulation include the disc annulus, facet capsule, interspinous ligament, supraspinous ligament, and sacro-iliac joint. Electrical stimulation may be used to activate monosynaptic stretch reflexes, which involve stretch of a muscle spindle generating an afferent impulse from the receptor region of the spindles to excite the alpha motoneurons in the same muscle, resulting in contraction. Electrical stimulation may be used to activate short-latency reflexes in the paraspinal muscles, which activate the paraspinal muscles en-masse.

Electrical stimulation may be used to stimulate afferent fibers of distant musculoskeletal structures, such as the limbs, which may result in contraction of local segmental muscles in the spine. Electrical stimulation may be used to activate long-loop reflexes, which involve information processing at higher levels of the nervous system, including transcortical mechanisms.

Stimulation parameters for restoring muscle endurance, strength, or motor control are known in the field of physical medicine and rehabilitation, where electrical stimulation is used as a therapeutic tool to preserve or restore muscle function during immobilization, or in diseased, deinnervated, or atrophied muscle. It is anticipated that embodiments of our device may use stimulation parameters (e.g. pulse amplitude, frequency, width, duration, duty cycle, shape, ramp times, wave forms, voltage) that have been previously used in these other applications.

Electrical stimulation has been used to help patients improve their own voluntary control of apparently paralyzed muscles. For example, muscle stimulation has been used to improve motor control of limbs and swallowing function in patients following stroke or head injury. Facilitation is a term used to describe a treatment program aimed at enhancing volitional motor control for a patient who is experiencing dysfunction in the central nervous system. In patients recovering from central nervous system insult or partial denervation of muscle, the ability of the patient to “find” and contract the muscle is compromised. Neuromuscular facilitation implies the use of stimulation to augment voluntary efforts. One embodiment of a device for facilitation of spinal stabilization would use a sensor of multifidus activity (or activity of another muscle of the local muscle system) that would trigger a piggyback stimulation on top of a patient’s native contraction. Stimulus amplitudes may be set to achieve a strong muscle contraction, or may be used simply as a sensory reminder. As the patient’s motor control improves, stimulation amplitude may be

decreased to provide only a sensory cue as to when the multifidus should contract.

Reeducation is a term used to describe a treatment program to enhance motor control for those patients who have altered voluntary recruitment of the muscular system due to some peripheral change, such as pain or disuse. Motor facilitation and reeducation are basically the same stimulation program, applied to a different patient population. Surgery, pain, trauma, disc herniation, or edema may make it difficult for a patient with an intact central nervous system to recruit a local stabilization muscle, such as the multifidus. This difficulty may be attributed to active inhibition of the motoneurons of the affected muscles through pain afferents. Inhibition, from whatever source, may lower the excitability of the motoneurons sufficiently to make them difficult to recruit. Electrical stimulation activates the large nerve fibers, preferentially. Thus stimulation near the nerve supply to the multifidus will recruit the large, Ia spindle afferents before visible muscle contraction is achieved. The effect of this Ia activation is to facilitate the motoneurons of the same motor pool, increasing excitability of the motor neuron pool through partial depolarization of the hyperpolarized, inhibited motoneurons. In addition, electrical stimulation can be used to supply sensory input about how a desired multifidus muscle contraction should feel, so that eventually a patient can do so voluntarily. It is anticipated that embodiments of our device may use stimulation parameters to improve motor control of spine stabilization muscles.

It is believed that some patients with back pain have inappropriately active global muscles, and that restoration of normal spine stabilization will require that these global muscles remain quiet, unless needed for the generation of torque. One embodiment of the invention involves use of stimulation parameters to inhibit contraction of global muscles through direct stimulation of the target muscle, or indirect stimulation via its motor nerve fiber. Another embodiment of the invention would stimulate antagonist muscles for the inhibition of

agonist muscle contraction. This reciprocal inhibition is due to stimulation of the Ia afferents, which subsequently inhibit antagonist motoneurons. Another embodiment of the invention to inhibit abnormal contraction may rely on the phenomenon known as sensory habituation. Low amplitude stimulation given repeatedly has been reported to reduce muscle spasticity, given at either low frequency or high frequency. It is believed that the central nervous system allows repetitive information to be suppressed, and in the process, other related neural systems also come under inhibition. Stimulation is done at sensory levels only, for several hours at a time, on either the side of the muscle spasm, or the opposite side.

EMG sensing may be included in the implanted device to monitor and to modulate the degree of muscle activity of specific muscles of the back, and the training protocol for specific muscle groups. Other sensors may be used, such as pressure sensors, motion sensors, and nerve conduction sensors. The therapy can be titrated to obtain ideal support or control of the back to alleviate pain. The net result of the therapy is the restoration of muscle and motor control function to improve stability, and reduce the severity and recurrence of otherwise chronic or recurring back pain, or leg pain in the case of spinal stenosis. The device can be used as a standalone therapy or adjunctive to other procedures. In this context the inventor notes that disectomy and fusion operations, and procedures to insert medical device implants weaken, displace, and injure the muscles, ligaments, and nerves near the surgical site.

Brief Description of the Drawings

Fig. 1 is a schematic view of the muscle and nerve stimulation targets within the back of a patient. The figure is divided into three panels Fig. 1A , Fig. 1B and Fig. 1C.

Fig. 2 is a schematic view of an exemplary implementation of a system to carry out the invention.

Fig. 3 is a graph depicting potential observable mechanical improvements to back function as a result of the therapeutic stimulation regime.

Fig 4 is a flow chart representing a step wise method of carrying out an exemplary embodiment of the invention.

Fig. 5 is a schematic view of potential stimulation sites on ligaments, which may lead to increased tone of the spine stabilization muscles.

Detailed Description

Fig. 1 shows a schematic representation of the back and in particular shows the connection of three sets of multifidus (MF) muscle fascicles labeled 14, 16 and 18 in panel of Fig. 1A, Fig. 1B and Fig. 1C respectively. In each panel the identified multifidus muscles are portrayed in a lateral view attached to a set of spinal vertebrae. Note that MF fascicles 14 arising from the spinous process and common tendon of L1 (the first lumbar vertebra) 13 insert into the mamillary processes of L4, L5, and S1, and the posterior superior iliac spine. Likewise MF fascicles 16 arising from the base of the spinous process and common tendon of L2 insert into the mamillary processes of L5 and S1, the posterior superior iliac spine, and the iliac crest. MF fascicles 18 arising from the base of the spinous process and common tendon of L3 insert into the mamillary process of the sacrum, and a narrow area extending caudally from the caudal extent of the posterior superior iliac spine to the lateral edge of the sacrum.

Although shown in isolation the MF fascicles overlap and cooperate to impose stability and strength to the back. It is recognized that the spinal stabilization system consist of three subsystems: 1) the spinal column consisting of sets of vertically stacked vertebral bodies typified by vertebrae and the associated ligaments and intervertebral discs (not shown), to provide intrinsic mechanical stability; 2) spinal muscles surrounding the spinal column to provide dynamic stability; and 3) the neuromotor control unit to evaluate and determine

requirements for stability via a coordinated muscle response. In patients with a functional stabilization system, the three subsystems work together to provide mechanical stability. In panel Fig. 1C the implanted pulse generator 10 is shown near the lead system 12 that places electrodes (not shown) within the multifidus muscle structures.

Fig. 3 is a graph displaying displacement as a function of load for a spine. The stability of a spinal motion segment may be measured and presented as seen in Fig. 3. With a load applied to the spinal column the normal motion segment exhibits a range of motion (ROM) 30. The response is non linear overall but at a neutral point a neutral zone (NZ) 32 of the response is approximately linear. The neutral zone is a region of laxity around the neutral resting position of a spinal motion segment, where little resistance is offered.

The applicant believes that the neutral zone is a parameter that correlates well with instability of the spinal system. It has been found to increase with back injury, muscle weakness, and degeneration. The goal of the therapy is to drive this measured load response to a narrower NZ by improving muscle function. The applicant surmises that the displacement of vertebrae can be detected correlating to normal and abnormal NZ using presently available motion tracking or position sensing devices that are well known in the art.

It is the goal of the therapy to stimulate these MF muscles to train them. This training should lead to a more normal NZ. For example, a pretreatment NZ 32 should improve to a more normal NZ 37 post treatment.

In Figure 1C, a representative implementation of the invention may be carried out with a fully implanted pulse generator (IPG) 10 coupled to an implanted lead system 12. Together the IPG 10 and lead system 12 stimulate the MF muscle, as shown in the panels of the figure.

Fig. 2 shows a percutaneous lead placement with a lead system attached to a boney structure of a vertebra, more particularly on the spinous process 24 although the transverse process, the lamina or the

vertebral body are candidate anchor points as well. It is expected that the transverse process will be the optimal location since the medial branch of the dorsal root of the spinal nerve courses over the transverse process. Although the primary targets of the stimulation are the deep fibers of lumbar multifidus 26, there are complicated mechanical and neural relations between this relatively large muscle group and companion groups. For this reason it is possible that additional candidate targets will include alone or in combinations other muscle groups including the quadratus lumborum, the erector spinae, psoas major, and transverse abdominis, or connective tissue such as the annulus or facet capsule that when stimulated will cause reflex contraction of a spinal muscle. In Fig. 2 a fully implanted IPG based system is shown with a pulse generator 10 coupled to an implanted lead system 12. As an alternative a hybrid system is shown. In the hybrid system an external transmitter 20 couples to an implanted receiver stimulator 22.

Although direct implantation of stimulation electrodes in muscle tissue is anticipated, the purpose of the stimulation is to depolarize innervated sections of the muscle that will then propagate a depolarization stimulus along the nerve fibers recruiting muscle tissue remote from the site of stimulation. Induced motions and tensions in muscle may activate stretch receptors and result in a cascade response of related muscle groups. Transvenous stimulation may be possible as well, however vessels of a suitable size for lead placement are not always found in desirable locations near the target stimulation site.

Stimulation electrodes may be used to modulate nerve activity, including inhibiting nerve conduction, improving nerve conduction, and improving muscle activity. It is expected that stimulation parameters will be developed experimentally with animal models and most likely human studies. The literature and clinical studies suggest that the energy levels for stimulation are well within the energy levels produced by modern pacing devices. The strength of the stimuli and duration of the stimulation are expected to improve the strength,

endurance, or motor control of the muscles, thereby reducing instability of the back.

Fig. 4 shows a flowchart describing a process or method carried out with the implantable pulse generator. Modern programmable devices are well known and the flowchart is sufficient to enable one to carry out this embodiment of the invention. In step 50 the patient is diagnosed with a defect in the spinal muscle or motor control system. The patient may exhibit an inappropriate response as depicted by curve 33 in Fig. 3. At step 52 electrical stimulation is given to the muscle fascicles and related structures. The timing, magnitude and duration of the treatment will need to be titrated for the patient. In step 54 the patient is tested and if the dysfunction is resolved as indicated perhaps by MRI, ultrasound, EMG, physical examination, tissue biopsy or improved stability evidenced by curve 31 of Fig. 3 then the stimulation and train is stopped. Otherwise the treatment continues.

Fig. 5 shows the location of ligaments coupling bony structures of the spine. It is expected that electrical stimulation of these elements via lead system 12 will facilitate the therapy. As can be seen in the figure the ligaments lie close to the bone. The lead system 12 is placed along the bony structures and in an embodiment is anchored to the bone. Both active and passive fixation anchors are contemplated as well as glue based fixation features. Each of the ligaments and joint capsules enumerated in Figure 5 are targets for stimulation.

Definitions

There is no well accepted metric for expressing all of the physical changes brought about by the therapeutic stimulation regime disclosed herein. For this reason the following terms are defined herein as follows:

Stiffness is a measure of resistance to displacement when a force is applied.

Strength is the force generating capacity of a muscle.

Endurance is resistance to fatigue.

Motor control is the ability of a patient to activate a muscle.

Muscle function refers to strength, endurance, or motor control.

Improving one of these three variables, alone or in combination, can improve muscle function to accomplish a specific task.

It is desirable to provide real time therapy in an ambulatory patient. This is best achieved by a fully implantable system.

Alternatively, a hybrid system with an implanted component communicating with an external stimulator may be best suited for intermittent use for example with supine patients at times of rest.

What is Claimed is:

1. A method of treating a patient's back comprising:
generating a current within in a muscle of a patient at a location and of an amplitude sufficient to cause at least -one muscle of the local spine stabilization system to contract;
thereby, improving the function of the local spine stabilization muscle.
2. The method of Claim 1, wherein said muscle of the local spine stabilization system is the multifidus.
3. The method of Claim 1, wherein said muscle of the local spine stabilization system is the transverse abdominis.
4. The method of Claim 1, wherein the muscle function improvement includes strength or endurance, or motor control.
5. A method of treating a patient's back comprising:
generating a current within in a ligament of a patient at a location and of an amplitude sufficient to cause at least one muscle of the local spine stabilization system to contract;
thereby, improving the muscle function.
6. The method of Claim 5, wherein said muscle of the local spine stabilization system is the multifidus.
7. The method of Claim 5, wherein said muscle of the local spine stabilization system is the transverse abdominis.
8. The method of Claim 5, wherein the muscle function improvement includes strength or endurance, or motor control.

9. A method of treating a patient's back comprising:
generating a current within in a joint capsule of a patient
at a location and of an amplitude sufficient to cause at least one
muscle of the local spine stabilization system to contract;
thereby, improving the muscle function.
10. The method of Claim 9, wherein said muscle of the local spine
stabilization system is the multifidus.
11. The method of Claim 9, wherein said muscle of the local spine
stabilization system is the transverse abdominis.
12. The method of Claim 9, wherein the muscle function
improvement includes strength or endurance, or motor control.
13. A method of treating a patient's back comprising:
generating a current within in a muscle of a patient at a
location and of an amplitude sufficient to cause at least one
muscle of the local spine stabilization system to contract;
thereby, increasing the stability of the back.
14. The method of Claim 13, wherein said muscle of the local spine
stabilization system is the multifidus.
15. The method of Claim 13, wherein said muscle of the local spine
stabilization system is the transverse abdominis.
16. A method of treating a patient's back comprising:
generating a current within in a ligament of a patient at a
location and of an amplitude sufficient to cause at least one local
spine stabilization muscle to contract;
thereby, increasing the stability of the back.

17. The method of Claim 16, wherein said muscle of the local spine stabilization system is the multifidus.
18. The method of Claim 16, wherein said muscle of the local spine stabilization system is the transverse abdominis.
19. A method of treating a patient's back comprising:
 - generating a current within in a joint capsule of a patient at a location and of an amplitude sufficient to cause at least one local spine stabilization muscle to contract;
 - thereby, increasing the stability of the back.
20. The method of Claim 19, wherein said muscle of the local spine stabilization system is the multifidus.
21. The method of Claim 19, wherein said muscle of the local spine stabilization system is the transverse abdominis.
 - i) MF
 - ii) Transv Abd
22. A method of treating a patient's back comprising:
 - generating a current in a muscle in the back of a patient at a location and of an amplitude sufficient to generate an action potential within at least some of the afferent nerve fibers from at least one muscle of the local spine stabilization system;
 - thereby, increasing the motor control of said muscle.
23. The method of Claim 22, wherein said muscle of the local spine stabilization system is the multifidus.
24. The method of Claim 22, wherein said muscle of the local spine stabilization system is the transverse abdominis.
 - i) MF

ii) Transv Abd

25. A method of treating a patient's back comprising:
implanting a lead system at a target location placing one or more electrodes in tissue within at least one muscle of the local spine stabilization system;
generating a current on said electrodes sufficient to stimulate said muscles causing it to contract, thereby modulating the stability of the back.
26. The method of Claim 25, wherein said muscle of the local spine stabilization system is the multifidus.
27. The method of Claim 25, wherein said muscle of the local spine stabilization system is the transverse abdominis.
28. The method of Claim 13 wherein said generating step is carried out with an implanted pulse generator.
29. A system to treat a patient's back comprising:
one or more leads including stimulation delivery electrodes anchored to a vertebra (or vertebrae) of the spine to allow electrical stimulation of tissue proximate said vertebra (or vertebrae);
a pulse generator for delivering electrical stimulation to said leads, at a stimulation level and duration sufficient to cause increases in post stimulation muscle function;
thereby improving stability of the back after the cessation of delivery of stimulation.
30. The method of Claim 29 wherein said tissue is muscle.
31. The method of Claim 29, wherein said tissue is nerve fibers.

32. The method of Claim 29, wherein said tissue is a ligament.
33. The method of Claim 29, wherein said tissue is a joint capsule.

AMENDED CLAIMS

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1. A method of improving the spine stabilization system comprising:
generating electrical current to the efferent or afferent or both efferent and afferent nervous system associated with the spine stabilization system, at an amplitude sufficient to cause at least one impaired muscle that contributes to segmental spine stability to contract; and repeating said generation of electrical current episodically over a period of time sufficient to induce a neuromuscular physiological adaptation of said impaired muscle, thereby improving said spine stabilization system.
2. The method of claim 1, wherein said neuromuscular adaptation is selected from the group comprising one or more of the following: reduction of atrophy, reduction of fatty infiltration, increase in strength, increase in endurance, increase in neural drive, improvement in motor control, preservation of muscle mass, prevention of fatty infiltration, preservation of strength, preservation of endurance, preservation of neural drive, or preservation of motor control.
3. A method of improving the spine stabilization system comprising:
generating electrical current within an impaired muscle that contributes to segmental spine stability at an amplitude sufficient to cause said muscle to contract; and repeating said generation of electrical current episodically over a period of time sufficient to induce a neuromuscular physiological adaptation of said impaired muscle, thereby improving said spine stabilization system.
4. The method of claim 3, wherein said neuromuscular adaptation is selected from the group comprising one or more of the following: reduction of atrophy, reduction of fatty infiltration, increase in strength, increase in endurance, increase in neural drive, improvement in motor control, preservation of muscle mass, prevention of fatty infiltration, preservation of

strength, preservation of endurance, preservation of neural drive, or preservation of motor control.

5. A method of improving the spine stabilization system comprising:
generating electrical current in tissue that attaches to portions of two or more bones of the spinal column, at an amplitude sufficient to cause at least one impaired muscle that contributes to segmental spine stability to contract; and repeating said generation of electrical current to said tissue episodically over a period of time sufficient to induce a neuromuscular physiological adaptation of said impaired muscle, thereby improving said spine stabilization system.
6. The method of claim 5, wherein said neuromuscular adaptation is selected from the group comprising one or more of the following: reduction of atrophy, reduction of fatty infiltration, increase in strength, increase in endurance, increase in neural drive, improvement in motor control, preservation of muscle mass, prevention of fatty infiltration, preservation of strength, preservation of endurance, preservation of neural drive, or preservation of motor control.
7. A method of improving the spine stabilization system comprising:
implanting a lead system with at least one electrode at a target location in tissue associated with the spine stabilization system;
and implanting a pulse generator, such that the lead system and pulse generator together result in the generation of electrical currents, of sufficient magnitude and duration to cause at least one impaired muscle that contributes to segmental spine stability to contract; and repeating said generation of electrical current episodically over a period of time sufficient to induce a neuromuscular physiological adaptation of said impaired muscle, thereby improving said spine stabilization system.
8. The method of claim 7, wherein said neuromuscular adaptation is selected from the group comprising one or more of the following: reduction of

atrophy, reduction of fatty infiltration, increase in strength, increase in endurance, increase in neural drive, improvement in motor control, preservation of muscle mass, prevention of fatty infiltration, preservation of strength, preservation of endurance, preservation of neural drive, or preservation of motor control.

9. An implantable system to improve the spine stabilization system comprising:
 - one or more implantable leads with at least one electrode at a target location in tissue associated with the spinal stabilization system,
 - a pulse generator that results in the generation of electrical currents, in said one or more leads, of sufficient magnitude and duration to cause at least one impaired muscle that contributes to segmental spine stability to contract, such that said electrical current is generated episodically over a period of time sufficient to induce a neuromuscular physiological adaptation of said impaired muscle, thereby improving said spine stabilization system.
10. The method of claim 9, wherein said neuromuscular adaptation is selected from the group comprising one or more of the following: reduction of atrophy, reduction of fatty infiltration, increase in strength, increase in endurance, increase in neural drive, improvement in motor control, preservation of muscle mass, prevention of fatty infiltration, preservation of strength, preservation of endurance, preservation of neural drive, or preservation of motor control.

(1/5)

Fig. 1A

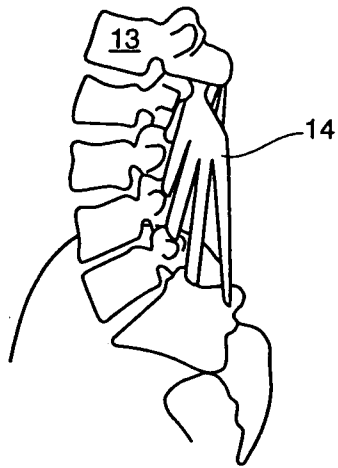


Fig. 1B

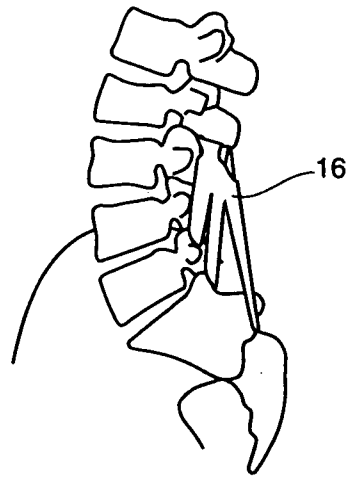
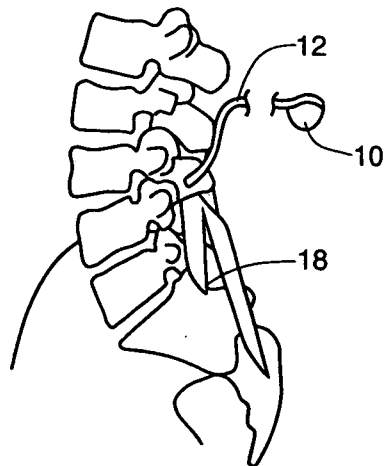
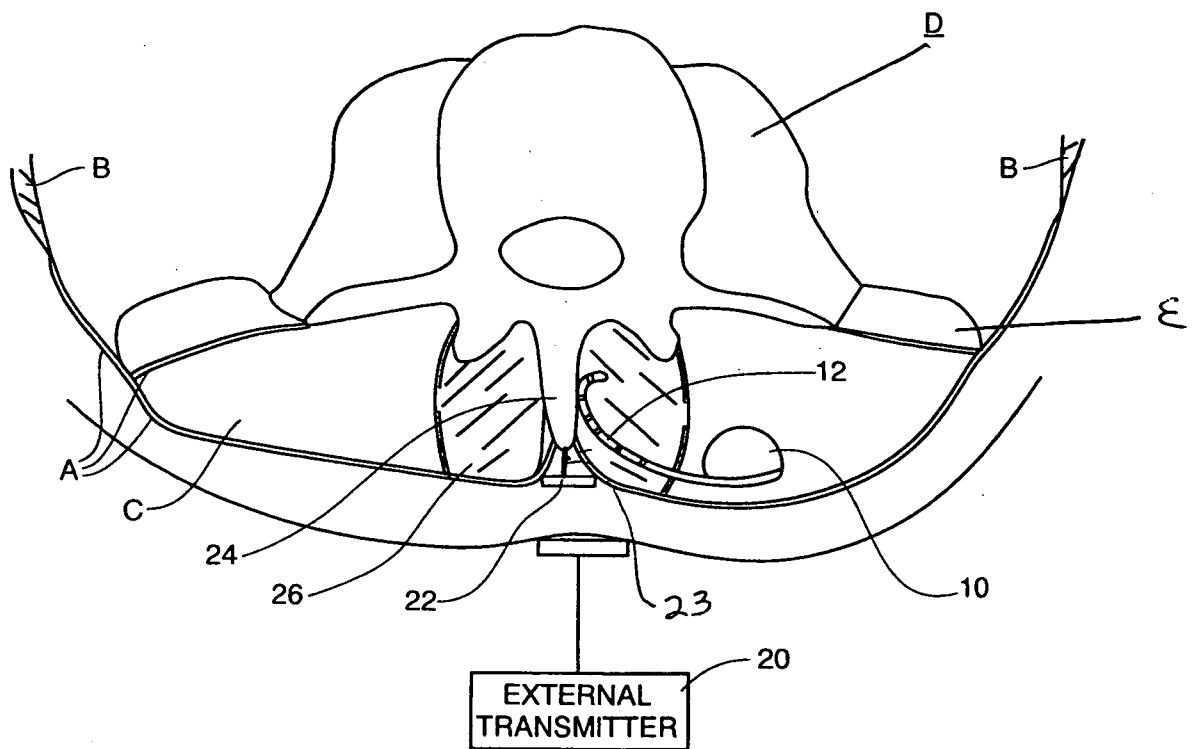


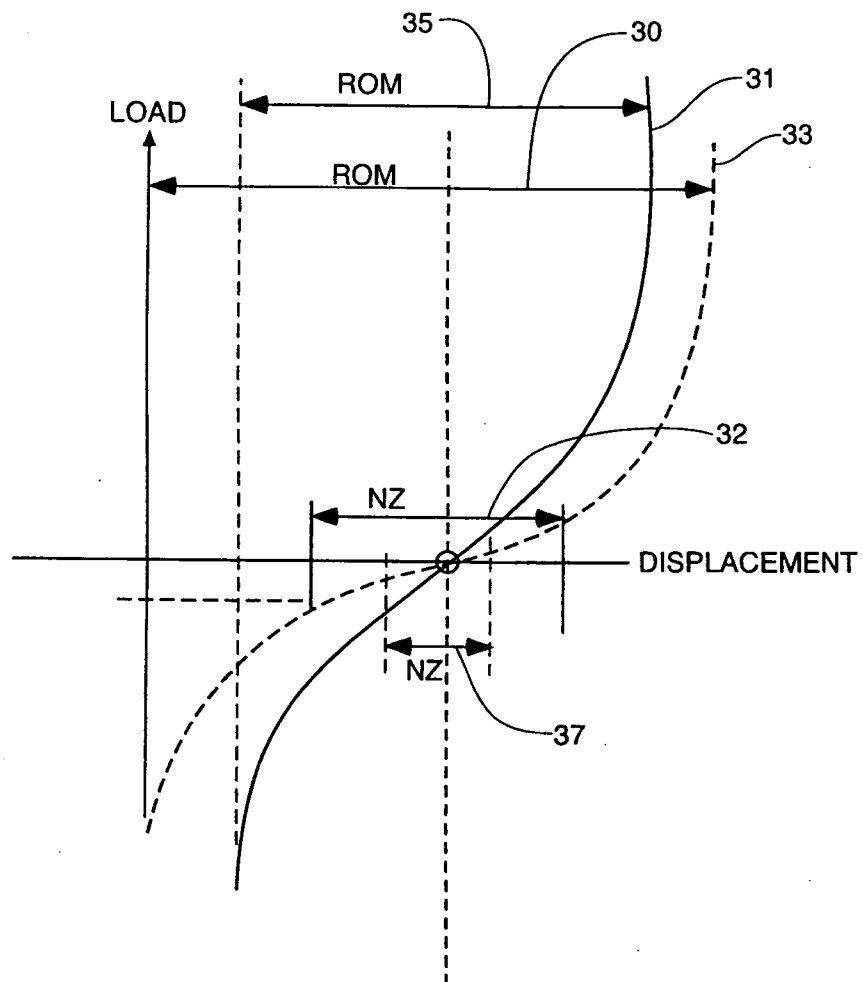
Fig. 1C



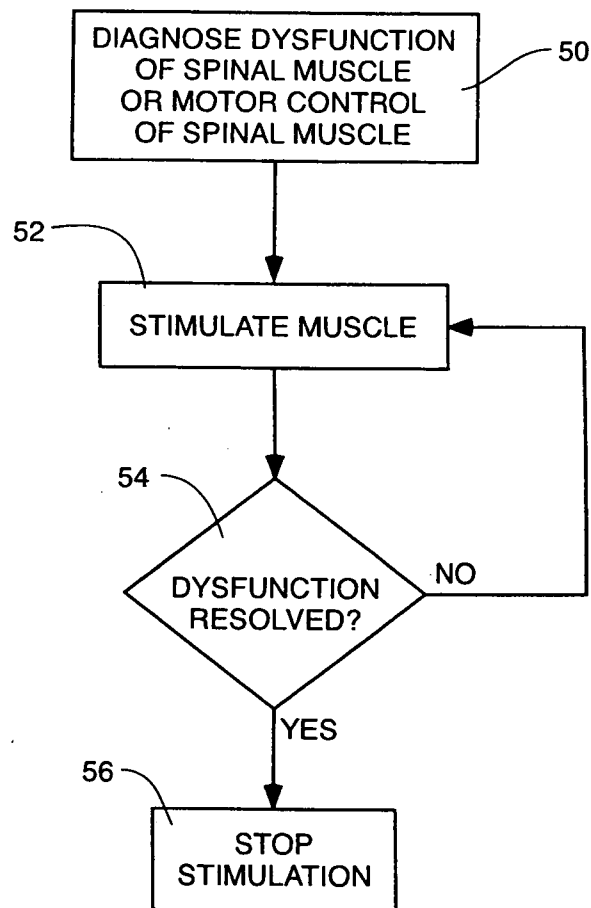
(2/5)

Fig. 2

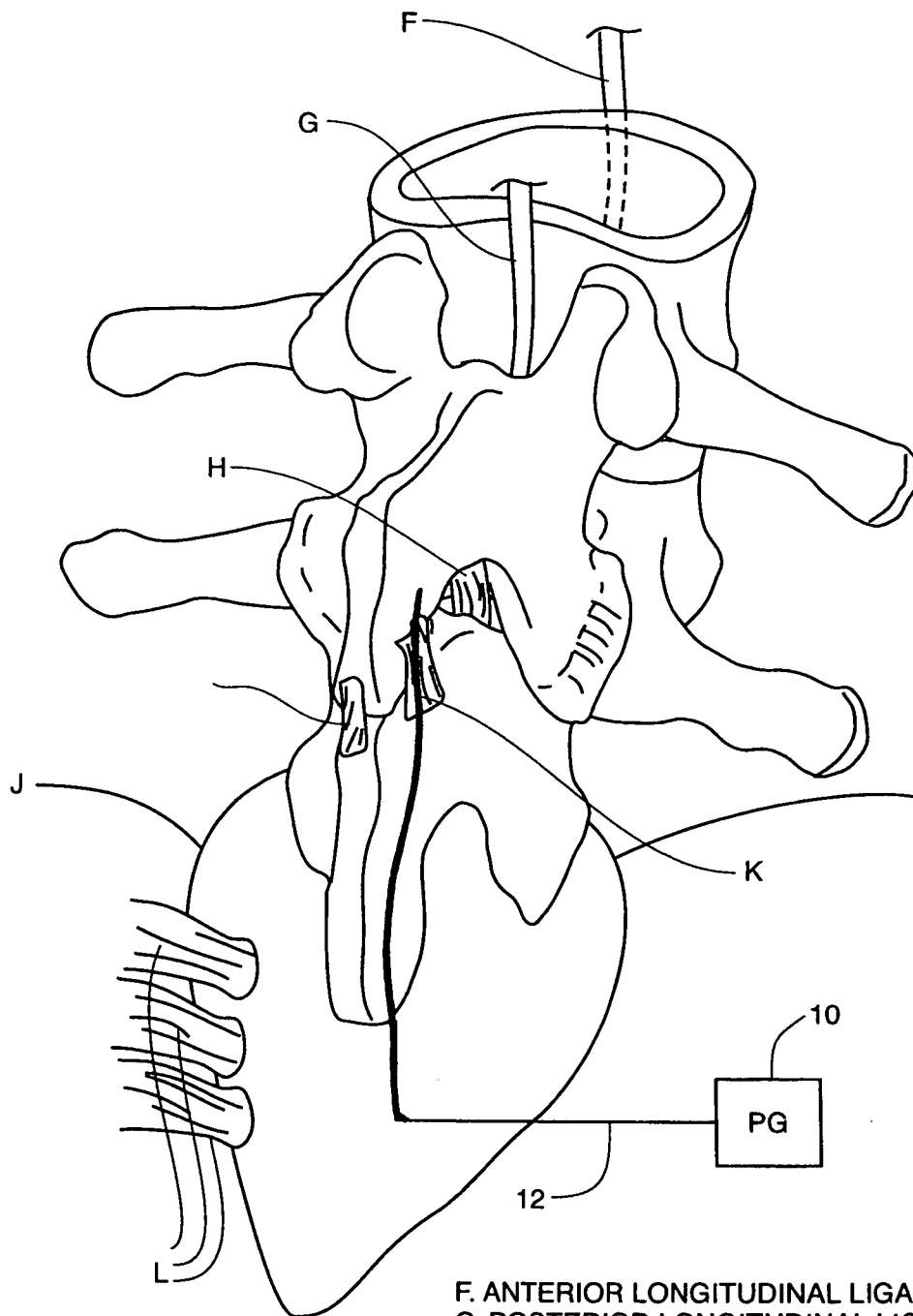
- A. THORAROLUMBAR FASCIA
- B. TRANSVERSE ABDOMINIS
- C. ERECTOR SPINEE
- D. PSOAS MAJOR
- E. QUADRATUS LUMBORUM

Fig. 3

(4/5)

Fig. 4

(5/5)

Fig. 5

F. ANTERIOR LONGITUDINAL LIGAMENT
G. POSTERIOR LONGITUDINAL LIGAMENT
H. LIGAMENTUM FLAVUM
J. SUPRASPINOUS LIGAMENT
K. INTERSPINOUS LIGAMENT
L. SACROILIAC LIGAMENT

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/03126

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/00 (2008.04)

USPC - 607/48

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)

IPC(8) - A61N 1/00 (2008.04)

USPC - 607/48

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

USPC - 607/48, 2, 1, 117, 43

(Text Search)

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

PubWEST (PGPB, USPT, USOC, EPAB, JPAB), DialogPRO (Enigeering) And Google Scholar

Search Terms: back pain, current, muscle, spine, contract, contraction, multifidus, transverse abdominis, spine stabiliz\$, ligament, joint capsule, lead, stable, stability, spinal, afferent nerve, action potential, median nerve, pulse generator

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2004/0236383 A1 (YELIZAROV) 25 November 2004 (25.11.2004) para [0052], [0055]-[0057], [0063], [0073], [0081], [0093], [0105].	1, 2, 4, 13, 14, 25 and 26 3, 5-12, 15-24 and 27-33
Y	US 5,916,172 A (HODGES et al.) 29 July 1999 (29.07.1999) col 1, ln 65-67; col 2, ln 1-7; col 3, ln 56-63; col 5, ln 59-60.	3, 7, 11, 15, 18, 21, 24 and 27
Y	US 2006/0111746 A1 (FOREMAN et al.) 25 May 2006 (25.05.2006) para [0303], [0312].	5-8, 16-18 and 32
Y	US 5,501,452 A (HALVORSON) 26 March 1996 (26.03.1996) col 2, ln 4-17.	9-12, 19-21 and 33
Y	US 5,522,854 A (IDEKER et al.) 04 June 1996 (04.06.1996) col 3, ln 1-3, 6-20; col 4, ln 25-36, 41-58; col 7, ln 12-15.	22-24 and 28-33

☐ Further documents are listed in the continuation of Box C.


* Special categories of cited documents:

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"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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 novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search

13 June 2008 (13.06.2008)

Date of mailing of the international search report

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Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774