Title: DEVICE AND METHOD FOR ELECTRICALLY INDUCING OSTEOGENESIS IN THE SPINE

Abstract: A technique and associated device for stimulating multiple electrodes with multiple electrical signals in multiple regions of the spine without injury to the patient. The electrodes are applied to respective sides of the patient's spine, and a first electrical signal is applied to any electrodes in a treatment area of the lumbar region of the patient's spine, a second electrical signal is applied to any electrodes in a treatment area of the thoracic region of the patient's spine, and a third electrical signal is applied to any electrodes in a treatment area of the cervical region of the patient's spine to induce osteogenesis in at least one of the respective treated area's of the patient's spine. The first, second, and third electrical signals respectively generate different electrode currents in the respective treated areas and are ideally selected to create current densities that are approximately equal in respective treatment areas. The electrodes may include electrode pairs or strip electrodes placed either side of the patient's spine in the respective treatment areas.
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DEVICE AND METHOD FOR ELECTRICALLY INDUCING OSTEOGENESIS IN THE SPINE

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a device and method for fusing multiple spine levels and otherwise increasing the stability of the spine through selective application of electrical signals.

Description of the prior art

U.S. Patent No. 4,535,775 demonstrated that an appropriate capacitively coupled electric signal applied to a single pair of surface electrodes placed on the skin on each side overlying a bone defect, nonunion fracture, delayed union, fresh fracture, or fracture at risk produced an internal electric field in the bone that resulted in healing of the bone. This technology has also been successfully applied to the treatment of fracture nonunions and delayed unions and as an adjunct to the treatment of localized spine fusion (Fusion of 1-2 vertebral levels; for example L₁-L₂ and L₂-L₃). There continues to be a great need to be able to use electricity in its various forms to fuse multiple spinal levels as in spinal scoliosis, degenerative disk disease at multiple levels, spine instability secondary to trauma of any cause, spinal stenosis, osteoporosis and tumor, including pain symptoms associated with the above. The present invention addresses these needs.

SUMMARY OF THE INVENTION

The present invention addresses the above-mentioned needs in the art by determining the proper electric field amplitude and electrode placement for application of electric signals in the human spine to aid in spine fusion at multiple levels. To date, no animal or human data exists for
such applications, and in order to obtain such data, a model was developed in the rat and then reconfigured for use in humans. The present invention relates to this model and its application to a human spine for electrically induced osteogenesis.

In particular, the present invention relates to a device and method of electrically inducing osteogenesis in the spine by placing electrodes on either side of the patient’s spine and applying at least one of a first electrical signal to any electrodes in a treatment area of the lumbar region of the patient’s spine, a second electrical signal to any electrodes in a treatment area of the thoracic region of the patient’s spine, and a third electrical signal to any electrodes in a treatment area of the cervical region of the patient’s spine effective to induce osteogenesis in at least one of the respective treatment areas of the patient’s spine. In accordance with the invention, the first, second, and third electrical signals respectively generate different electrode currents in the respective treatment areas and create current densities that are approximately equal in the respective treatment areas when applied simultaneously. The electrodes may comprise respective pairs of electrodes placed in each of the treatment areas or strip electrodes that are applied to a single treatment area or across two or more treatment areas that run vertically along the patient’s spine.

In a preferred embodiment, the current stimulated by the first electrical signal in the lumbar region is greater than the current stimulated by the second electrical signal in the thoracic region, and the current stimulated by the second electrical signal in the thoracic region is greater than the current stimulated by the third electrical signal in the cervical region. Preferably, the current stimulated by the second electrical signal is approximately 2/3 the current stimulated by the first electrical signal, and the current stimulated by the third electrical signal is approximately 2/3 the current stimulated by the second electrical signal. For example, the electrode current stimulated by the first electrical signal may be in the current range of 7-10mA, the electrode current stimulated by the second electrical signal may be in the current range of 4.7-6.7mA, and
the electrode current stimulated by the third electrical signal may be in the current range of 3.1-4.5mA.

The power source of the invention generates the first, second and third electrical signals and further comprises at least one switch that selectively applies the first, second or third electrical signals to respective electrode pairs in accordance with the treatment area of the spine in which the respective electrode pairs are placed. In the case of strip electrodes, the strip electrodes may be discontinuous whereby each two vertebra length of strip electrode receives one of the first, second and third electrical signals from the power source based on whether the two vertebra length is placed in the lumbar, thoracic, or cervical region, respectively, of the patient's spine. In one embodiment of strip electrodes, the strip electrodes are arranged to be used in more that one region of the patient's spine, each of the strip electrodes including a graded conductivity strip that causes voltage drops along the respective electrode strips so as to cause a decrease in voltage as the current moves along strip electrodes from the lumbar to the thoracic and/or from the thoracic to the cervical regions of the patient's spine.

BRIEF DESCRIPTION OF THE DRAWINGS

A system and method for electrically inducing osteogenesis in the spine in accordance with the invention is further described below with reference to the accompanying drawings, in which:

Figure 1 illustrates the percentage decrease in mean electric field in trabecular bone of a neighboring vertebral body as a function of n, the number of vertebral bodies away from a single pair of transverse electrodes. For example, if the electrode (transverse pair) is over L_1, then n=1 describes L_2, n=2 describes L_3, etc.

Figure 2 illustrates that the computed value of any given electric field amplitude, as a function of the volume of trabecular bone tissue with that amplitude, is characterized by a
distribution function with a half width of 43% of the mean value of the electric field amplitude experienced by the trabecular bone.

Figure 3 illustrates the electric field $E$ generated by a pair of electrodes in the transverse configuration centered about one vertebra ($L_3$, for instance) for use in fusing $L_2$-$L_3$ and $L_3$-$L_4$ with at least 94.6% of the mean $E$ field.

Figure 4 illustrates the mean current density in the trabecular bone of the human model of the vertebrae as a function of vertebral position for current applied to different types of electrodes.

Figure 5 illustrates electrode placement for a 4-level fusion using two electrode pairs in accordance with a first embodiment including electrode pairs in accordance with the invention.

Figure 6 illustrates strip electrode placement for multiple spine level fusion in accordance with a second embodiment including strip electrodes in accordance with the invention.

**DETAILED DESCRIPTION OF THE INVENTION**

**Rat Model**

A finite element study of Carter, Vresilovic, Pollack and Brighton was used to develop a rat model for the case of a single pair of electrodes in a transverse configuration. Using these results, the percent change in mean electric field amplitude in the trabecular bone of vertebral bodies was calculated as a function of distance from the transverse pair of electrodes. The result is shown in Figure 1.

The computed value of any given electric field amplitude, as a function of the volume of trabecular bone tissue with that amplitude, is characterized by a distribution function with a half width of 43% of the mean value of the electric field amplitude experienced by the trabecular bone. This is shown in Figure 2.

If one imposes a constraint such that the mean electric field amplitude must remain within 5.4% of the value of the mean $E$ field to be effective, then vertebral bodies could not be treated
where the E field decreased below 5.4% of the mean E field (Figure 2). In the rat model, that means that if the mean E field (E) value decreases by more than 5.4%, the technology will not be effective. As shown in Figure 1, this means that if an electrode pair is adjacent to L₄ then the fields in trabecular bone of L₄ and S₁ will be 5.4% lower than in L₅, while the fields in trabecular bone of L₃ and S₁ will be reduced by 19%. Nineteen percent reduction in the mean electric field (E) is too great a reduction for clinical use. However, a reduction of 5.4% is acceptable as per the proposed constraint.

Accordingly, the result in the rat suggests that a pair of electrodes in the transverse configuration centered about one vertebra (L₁, for instance) could be used to fuse L₂-L₃ and L₅-L₆ with at least 94.6% of the mean E Field. However, if one wants to fuse multiple vertebral levels (3-10 or more, depending on the disease state), one pair of electrodes obviously will not work. The inventors considered two possible ways to increase the extent of an effective E field in the human vertebra: one is to use multiple electrode pairs with each pair powered by its own power supply but phased locked; the other solution is to use strip electrodes, one on each side of the spine, running the length of the vertebral segments to be fused.

Human Model

For the human model, the present inventors have developed a finite element modeling and analysis approach. In the human model, if a pair of electrodes is placed at the level of the Tₙ vertebra, with the electrodes being on opposite sides of the spine and the center of each electrode being 5 cm from the midpoint of the underlying vertebral body, for 1.0 mA current input into the electrodes, the current density (mean value) is 1.10 µA/cm² ± 0.4 µA/cm² (half width of mean current density value) for the inner cortical bone at Tₙ. At Tₙ, the value of the current density is reduced to 0.6 µA/cm² ± 0.2 µA/cm² (half width of mean current density value) for the inner cortical bone. This result shows that for the human vertebrae that are two vertebrae away from the electrode the E field falls outside the half width of the treated vertebrae and, as in the rat model, the success rates may drop substantially if only a single pair of electrodes is used. For the
above case, for outer cortical bone, the results are as follows: for the T₉ vertebra the mean current density for 1.0mA current input into the electrodes is 1.5 μA/cm² ± 0.5 μA/cm² half width, while at T₉ the mean current density is 1.0 μA/cm² ± 0.5 μA/cm² half width. This reduction in the current density exceeds the 5.4% constraint and therefore will not work.

The effect of the location of the electrodes on the human body also has been considered by the inventors. For example, the inventors considered whether the same electric fields are equally effective in different parts of the body or, in this instance, the same in the lumbar versus the thoracic versus the cervical spine. The inventors discovered that the answer is no because current flow to the lumbar vertebra, for instance, will be reduced compared to that in the thoracic vertebrae because more current will flow to the abdominal region since its conductivity is higher. This can be seen below from actual finite elements studies.

Thoracic and Lumbar Vertebrae Current Densities:

In the L₃ lumbar vertebrae overlying the abdomen, for 1.0mA current input into the electrodes, the current density in the abdomen is 4x10⁻⁶ μA/cm² ± 1x10⁻⁶ μA/cm², while for T₇ thoracic vertebrae overlying the lungs, the same current input into the electrodes would produce a current density in the thorax of 0.9x10⁻⁶ μA/cm² ± 0.3x10⁻⁶ μA/cm². However, the mean value of the current density in the vertebrae would be as follows:

\[
\text{L₃ mean current density} = 1.25 \text{ μA/cm}^2 \text{ for 1mA input}
\]
\[
\text{T₇ mean current density} = 1.9 \text{ μA/cm}^2 \text{ for 1mA input}
\]

This is a reduction in current density at L₃ of:

\[
\frac{1.9 - 1.25}{1.9} \times 100 = 34\%
\]
This reduction is due to the excess current that flows to the more conductive abdomen as seen above. The inventors conclude from this that the analysis must be separated between the abdomen ($L_1$-$L_3$) and the thorax $T_1$-$T_{12}$. Due to the presence of the lungs and ribs, the thorax has a higher resistivity. Therefore, for a given input current, more current flows near the back (spine) in the thorax than in the case of the abdomen. As a result, for a given input current to the lumbar vertebrae, the mean current that flows in the cortical bone of the vertebrae is about 34% lower than for the thorax.

The cervical (neck) spine will look more like the thorax but even more so because it has an even smaller volume through which current can flow in parallel with the current near the spine. Therefore, for a given current input from the electrodes at the cervical vertebra more current will flow in the vertebrae than in the thorax. For example, for a chest size of 36" and a neck size of 16" (circumference) the volume ratio per unit length is $(2.025)^3=4.1$. If the lungs occupy approximately half the volume of the thorax, this would reduce the ratio to 2.05. Taking cross sectional areas per unit length in the direction of current flow for transverse electrodes, this results in an increase in current to the bone portions of the spine in the neck by a factor of 1.5 over that in the thorax. Therefore, for the mean electric field to be the same in vertebrae in the three different regions (cervical, thoracic, lumbar), the input signal to the electrodes would have to vary as follows: for a 1.5mA current input into an electrode pair with a transverse symmetric placement over the lumbar vertebrae, the electric input into electrodes with a transverse symmetric placement over thoracic vertebrae would be 1mA current and overcervical vertebrae would be 0.67mA. In this way the same current densities are produced in cortical and trabecular bone of vertebrae regardless of their anatomical location (cervical, thoracic, or lumbar).

If one wants to treat multiple vertebral levels and/or vertebral levels extending across more than one region of the spine (i.e., thoracolumbar), one has two choices: 1) use multiple pairs of electrodes (one pair for every 2 levels fused: thus, to fuse $L_1$ to $L_4$, two electrode pairs would be used with one pair centered over $L_2$ and one pair centered over $L_4$). The power unit
would power multiple sets of electrodes and independently control the power output to reflect the number of vertebral levels fused and the location in the spine (i.e., lumbar, thoracic or cervical) where the fusion is desired; or 2) use strip (continuous) electrodes, one strip electrode running vertically along the back on one side of the spine, and the other strip electrode running vertically along the back on the other side of the spine. The distance between the strips would be 10 cm (center to center).

Figure 4 demonstrates several things. The first is that discrete electrodes and strip electrodes with the same total current result in similar trabecular bone current densities in the vertebral bodies. The decrease in current density at L₁ and L₂ is the result of the above-described phenomenon associated with the lower over all electrical resistance of the abdomen relative to the thorax. As a result, the multiple pair device concept offers the opportunity to adjust the current level, say, in the pair over L₂ (see Figure 4), increasing its value by approximately 40%, thereby achieving a nearly flat distribution (see Figure 4) of current density values. Similar results obtain for cortical bone current densities. The remaining question is what current should be used for the various electrode types i.e. multiple pairs, strips of various length, regions that span multiple vertebral regions.

From the finite element study the present inventors know that placing a pair of electrodes over every other vertebra keeps within 5.4% of the mean field. The values for the mean current densities in the cortical bone and trabecular bone at L₄ with an electrode pair having a surface area of 6 cm² per electrode with a current of 1mA are $1.14 \times 10^6$ A/cm² and $1.54 \times 10^6$ A/cm², respectively. Therefore, the clinical current density values using 7mA to 10mA are:

- **Cortical Bone:** $7.98 \times 10^6$ A/cm² to $11.4 \times 10^6$ A/cm²
- **Trabecular Bone:** $10.8 \times 10^6$ A/cm² to $15.4 \times 10^6$ A/cm²

The design of the power unit using multiple pairs should scale the current range for every second vertebra such that these values obtain. This will require a step-down of 33% in the current range to obtain the thorax value and a further 33% step-down from the thorax value to
obtain the value appropriate for the neck. The clinical values for electrode current (with an electrode pair centered over every second vertebra area) follow:

- **Lumbar region**: 7-10mA
- **Thoracic region**: 4.7-6.7mA
- **Cervical region**: 3.1-4.5mA

Of course, if the region to be treated is all the same, then only the currents for that region would be applied to the electrodes to achieve uniform current densities.

When using strip electrodes, one must consider whether all the vertebrae being treated are in the same region or whether the vertebrae being treated are from different regions. If all the vertebrae being treated are in the same region (i.e., lumbar region), then uniform (high) conductivity strip electrodes would have to increase in length as the number of vertebral levels to fuse increase. For example, in the lumbar region a two level fusion would require an input current of 7-10mA to the electrode strips, a four level fusion would require an input current of 14-20mA, a six level fusion of 21-30mA, etc. However, this amount of current flow in these strip electrodes may be too dangerous to use clinically: any break or current leak in the electrodes might irritate or burn the patient’s skin. To get around this unlikely but possible hazard, the electrode strips would be designed such that only 7-10mA of current would be delivered to every two vertebra length of strip electrode. In other words, the electrode would be discontinuous, with every two level segment having its own current supply of 7-10mA (for the lumbar region for example).

For strip electrodes to be used in more than one region, a graded conductivity strip is used so that the voltage drop along the electrode would result in a decrease in voltage as the current moved from the lumbar to the thorax or from the thorax to the neck region. In this configuration the input electrodes would enter the strip at the end of the electrode placed at the lumbar side (for lumbar-thorax fusion) or on the thorax side (for a thorax-neck fusion).
If pairs of individual electrodes are used rather than strip electrodes, the electronics must be designed so that the signal to all of the electrodes on a given side of the body are phase locked to assure that one side, say the right side, is all positive while the left side is all negative and vice versa. In addition, the amplitude of the current should be adjusted as per the above analysis depending upon the location on the body of each pair of electrodes used.

Device Design:

Multiple Electrode Pairs

Figure 5 illustrates electrode placement for a 4-level fusion using two electrode pairs 110a, 110b and 120a, 120b in accordance with a first embodiment of the invention. Each electrode 110a, 110b, 120a, 120b has a surface area of 6 cm² and is self-adherent. The power device 130 is run on one 9-volt battery and has resistors/transistors or current chip so designed that each pair of electrodes plugged into the device delivers the pre-selected amount of current as set by a switch on the device (C or cervical, T for thoracic, and L for lumbar). For example, when switched to C, the electrode pair delivers 3.4-4.5 mA of current, when switched to T it delivers 4.7-6.7 mA, and when switched to L it delivers 7-10 mA of current. The device may include multiple ports, each a plug-in for an electrode pair, and each controlled by a switch to indicate region of treatment. In Figure 5, the first pair of electrodes 110a, 110b are shown as centered over L₁ for fusing T₁₂-L₁ and L₁-L₂. For this purpose, 7-10 mA of current is provided at port 1. Similarly, the second pair of electrodes 120a, 120b are shown as centered over L₃ for fusing L₂-L₃ and L₃-L₄. For this purpose, 7-10 mA of current is provided at port 2. A switch (not shown) within the power device 130 may be used to select the appropriate current to be applied to each port based on the treatment area to which the inserted electrode pair is applied.

Strip electrodes

Figure 6 illustrates strip electrode placement for multiple spine level fusion using strip electrodes 140a, 140b in accordance with a second embodiment of the invention. Each strip
electrode 140a, 140b is 2.5 cm wide. The length varies according to the number of vertebral levels to be fused (3 to 15), allowing 3 cm per vertebral level. Thus, the electrode strips 140a, 140b may vary from 9 cm to 45 cm long. Strip electrodes for each region (lumbar, thoracic, cervical spine) may be separate and plug into the appropriately marked port on the power device 150. The power device 150 is designed such that each region would receive the amount of current for that region (e.g., 7-10 mA for L, 4.7-6.7 mA for T, and 3.4-4.5 mA for C). The power device 150 runs on a 9-volt battery and has resistors, transistors, and/or circuit chips such that the region treated may be selected by switch as well as the number of vertebral levels, keeping in mind that every 6 cm of strip length would receive only those current levels designated for each region above. In other words, every 6 cm of strip length would be a complete circuit and would deliver one of the current levels cited above, depending on the region. As illustrated, power device 150 may produce a current of 4.7-6.7 mA at port T for generation of an electric field for application to the thoracic vertebrae (T₁-T₁₂) and a current of 7-10 mA at port L for generation of an electric field for application to the lumbar vertebrae (L₁-L₂). A port C may also be provided on power device 150 for generating current to apply to cervical vertebrae. A switch (not shown) within the power device 150 may be used to select the appropriate current to be applied to each port based on the area of the spine treated by that port.

The description provided herein deals specifically with the current values to the multiple electrodes or strip electrodes. As in the afore-mentioned patent, the voltage and signal characteristics are the 20 kHz to 100 kHz, 60 kHz, 5 to 10 volts peak to peak sine wave (symmetric) and non-symmetric variations of these quantities. Those skilled in the art will appreciate that other variations in these values may also lead to useful clinical results.

Although exemplary implementations of the invention have been described in detail above, those skilled in the art will readily appreciate that many additional modifications are possible in the exemplary embodiments without materially departing from the novel teachings
and advantages of the invention. Any such modifications are intended to be included within the scope of this invention as defined by the following exemplary claims.
We claim:

1. A method of electrically inducing osteogenesis in the spine, comprising the steps of: placing electrodes on either side of the patient’s spine; and applying at least one of a first electrical signal to any electrodes in a treatment area of the lumbar region of the patient’s spine, a second electrical signal to any electrodes in a treatment area of the thoracic region of the patient’s spine, and a third electrical signal to any electrodes in a treatment area of the cervical region of the patient’s spine effective to induce osteogenesis in at least one of the respective treatment areas of the patient’s spine, wherein the first, second, and third electrical signals respectively generate different electrode currents in the respective treatment areas.

2. The method of claim 1, wherein the first, second and third electrical signals are simultaneously applied to the respective electrodes in the respective treatment areas to create current densities that are approximately equal in the respective treatment areas.

3. The method of claim 1, wherein the electrodes are placed on the patient’s skin.

4. The method of claim 1, wherein the electrodes comprise respective pairs of electrodes placed in each of said treatment areas in said placing step.

5. The method of claim 1, wherein the electrodes comprise respective strip electrodes each placed in said placing step so as to run vertically along the back on respective sides of the patient’s spine.
6. The method of claim 1, wherein a current stimulated by the first electrical signal is greater than the current stimulated by the second electrical signal, and the current stimulated by the second electrical signal is greater than the current stimulated by the third electrical signal.

7. The method of claim 6, wherein the current stimulated by the second electrical signal is approximately 2/3 the current stimulated by the first electrical signal, and the current stimulated by the third electrical signal is approximately 2/3 the current stimulated by the second electrical signal.

8. The method of claim 7, wherein the electrode current stimulated by the first electrical signal is in the current range of 7-10 mA, the electrode current stimulated by the second electrical signal is in the current range of 4.7-6.7 mA, and the electrode current stimulated by the third electrical signal is in the current range of 3.1-4.5 mA.

9. A device for electrically inducing osteogenesis in the spine, comprising:

a pair of electrodes for application on either side of the patient’s spine in each treatment region of the patient’s spine; and

a power source that selectively applies a first electrical signal to any electrode pair in a treatment area of the lumbar region of the patient’s spine, a second electrical signal to any electrode pair in a treatment area of the thoracic region of the patient’s spine, and a third electrical signal to any electrode pair in a treatment area of the cervical region of the patient’s spine effective to induce osteogenesis in the respective treatment areas of the patient’s spine, wherein the first, second, and third electrical signals respectively generate different electrode currents in the respective treatment areas.
10. The device of claim 9, wherein the first, second and third electrical signals are simultaneously applied to the respective electrode pairs in the respective treatment areas by the power source to create current densities that are approximately equal in the respective treatment areas and such that all electrodes on one side of the patient's spine are all positive while all electrodes on another side of the patient's spine are all negative.

11. The device of claim 9, wherein the electrode pairs are adapted to be attached to the patient's skin and to apply the electrode currents to the patient's spine through capacitive coupling.

12. The device of claim 9 wherein a current stimulated by the first electrical signal is greater than the current stimulated by the second electrical signal, and the current stimulated by the second electrical signal is greater than the current stimulated by the third electrical signal.

13. The device of claim 12, wherein the current stimulated by the second electrical signal is approximately 2/3 the current stimulated by the first electrical signal, and the current stimulated by the third electrical signal is approximately 2/3 the current stimulated by the second electrical signal.

14. The device of claim 13, wherein the electrode current stimulated by the first electrical signal is in the current range of 7-10 mA, the electrode current stimulated by the second electrical signal is in the current range of 4.7-6.7 mA, and the electrode current stimulated by the third electrical signal is in the current range of 3.1-4.5 mA.

15. The device of claim 9, wherein the power source generates said first, second and third electrical signals and said device further comprises at least one switch that selectively applies
said first, second or third electrical signals to respective electrode pairs in accordance with the treatment area of the spine in which the respective electrode pairs are placed.

16. The device of claim 15, further comprising a plug-in port for each electrode pair, each electrode pair controlled by a switch that is adjusted inaccordance with the treatment area to which the electrode pair is to be applied.

17. A device for electrically inducing osteogenesis in the spine, comprising:

respectively strip electrodes for application on either side of the patient’s spine so as to run vertically along the patient’s back on respective sides of the patient’s spine; and

a power source that selectively applies a first electrical signal to the strip electrodes when placed in a treatment area of the lumbar region of the patient’s spine, a second electrical signal to the strip electrodes when placed in a treatment area of the thoracic region of the patient’s spine, and a third electrical signal to the strip electrodes when placed in a treatment area of the cervical region of the patient’s spine effective to induce osteogenesis in the respective treatment areas of the patient’s spine, wherein the first, second, and third electrical signals respectively generate different electrode currents in the respective treatment areas.

18. The device of claim 17, wherein the strip electrodes are arranged such that a selected amount of current is delivered to every two-vertebra length of strip electrode.

19. The device of claim 18, wherein the strip electrodes are discontinuous and each two vertebra length of strip electrode receives one of the first, second and third electrical signals from the power source based on whether the two vertebra length is placed in the lumbar, thoracic, or cervical region, respectively, of the patient’s spine.
20. The device of claim 17, wherein the strip electrodes are arranged to be used in more that one region of the patient’s spine, each of said strip electrodes including a graded conductivity strip that causes voltage drops along the respective electrode strips so as to cause a decrease in voltage as the current moves along strip electrodes from the lumbar to the thoracic and/or from the thoracic to the cervical regions of the patient’s spine.

21. The device of claim 17, wherein the electrode strips are adapted to be attached to the patient’s skin and to apply the electrode currents to the patient’s spine through capacitive coupling.

22. The device of claim 17, wherein a current stimulated by the first electrical signal is greater than the current stimulated by the second electrical signal, and the current stimulated by the second electrical signal is greater than the current stimulated by the third electrical signal.

23. The device of claim 22, wherein the current stimulated by the second electrical signal is approximately 2/3 the current stimulated by the first electrical signal, and the current stimulated by the third electrical signal is approximately 2/3 the current stimulated by the second electrical signal.

24. The device of claim 23, wherein the electrode current stimulated by the first electrical signal is in the current range of 7-10 mA, the electrode current stimulated by the second electrical signal is in the current range of 4.7-6.7 mA, and the electrode current stimulated by the third electrical signal is in the current range of 3.1-4.5 mA.

25. The device of claim 17, wherein a separate pair of strip electrodes is provided for the lumbar, thoracic and cervical regions of the patient’s spine, the power source comprising
respective ports and at least one switch that selectively applies said first, second or third electrical signals to said respective ports in accordance with the treatment area of the spine in which the respective electrode pairs are placed.
**Figure 1**

![Graph showing percentage decrease in E with E field amplitude](image)

**Figure 2**

\[
\text{Effective Range Constrained Condition} \pm 5.4\% \text{ of Mean } E \text{ Field}
\]

\[
\frac{\text{Half Width at } E}{E} = 4.3\% \text{ (for single pair of transverse electrodes in rat model)}
\]
FIG. 3

MEAN CURRENT DENSITY IN THE TRABECULAR BONE OF THE VERTEBRA OF THE HUMAN MODEL AS A FUNCTION OF POSITION FOR CURRENT APPLIED TO DIFFERENT TYPES OF ELECTRODES

ELECTRODE TYPE

○ = 3 PR TRANSVERSE AT T7, T11, L3-1MA EACH
+
= STRIP ELECTRODE WITH CU, T7, TO L3-3MA

FIG. 4

SUBSTITUTE SHEET (RULE 26)