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[54] **CONSTANT CURRENT POWER PACK FOR BONE HEALING AND METHOD OF USE**

[75] Inventors: **Carl T. Brighton; Zachary B. Friedenberg; William Redka,** all of Philadelphia, Pa.

[73] Assignee: **The United States of America as represented by the Secretary of the Navy,** Washington, D.C.

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[52] **U.S. Cl.** .... **128/419 R,** 128/82.1

[51] **Int. Cl.** **A61n 1/20**

[58] **Field of Search** .... 128/419 R, 421 D, 422, 128/2.1 P, 2.1 R, 82.1, 92 R; 307/297, 304, 251; 323/4, 16; 3/1

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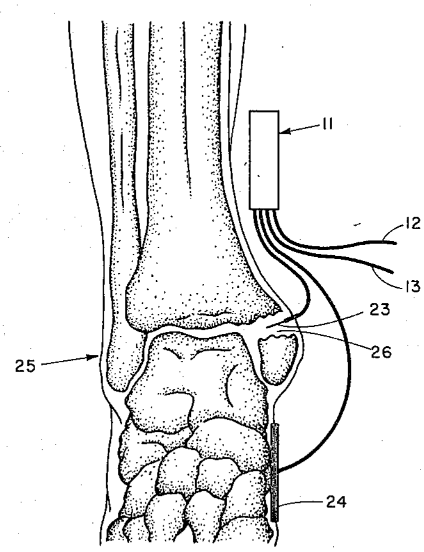
Primary Examiner—William E. Kamm

Attorney, Agent, or Firm—R. S. Sciascia; C. E. Vautrain, Jr.

[57] **ABSTRACT**

Bone fracture healing through use of direct current of from 5 to 20 microamperes applied between a cathode inserted into a fracture or the site of a bone defect and an anode taped to the skin near the cathode implantation site is disclosed. A power source capable of delivering such current constantly despite increasing tissue resistance also is provided.

13 Claims, 3 Drawing Figures



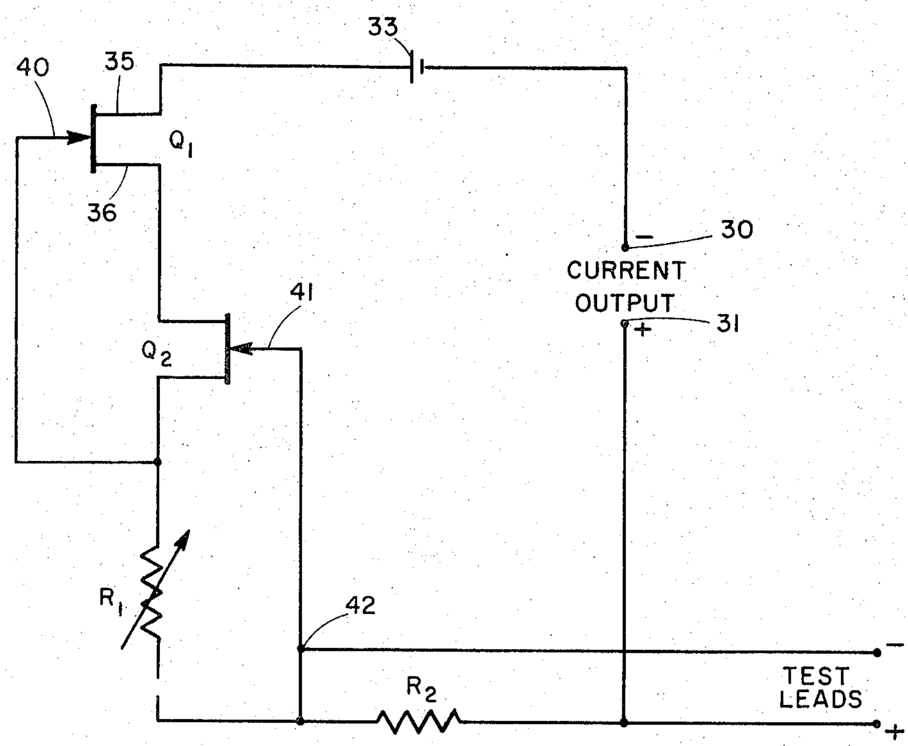


Fig. 2

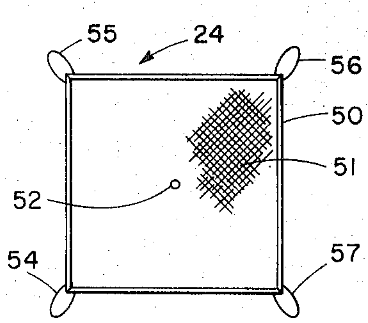


Fig. 4

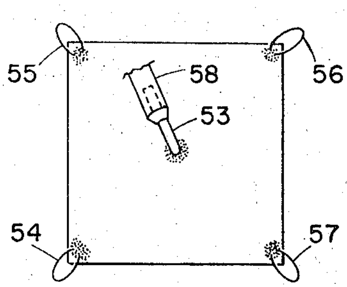


Fig. 5

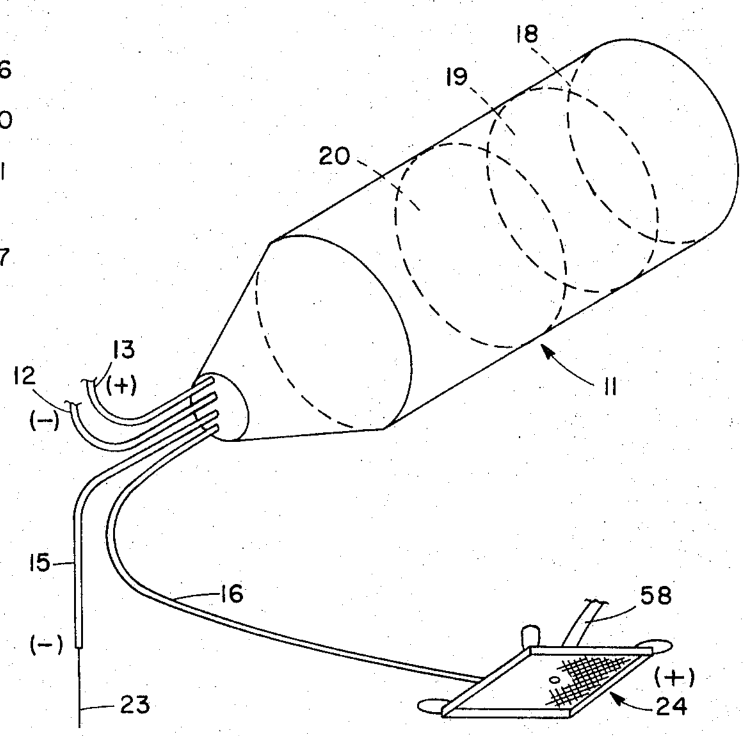


Fig. 1

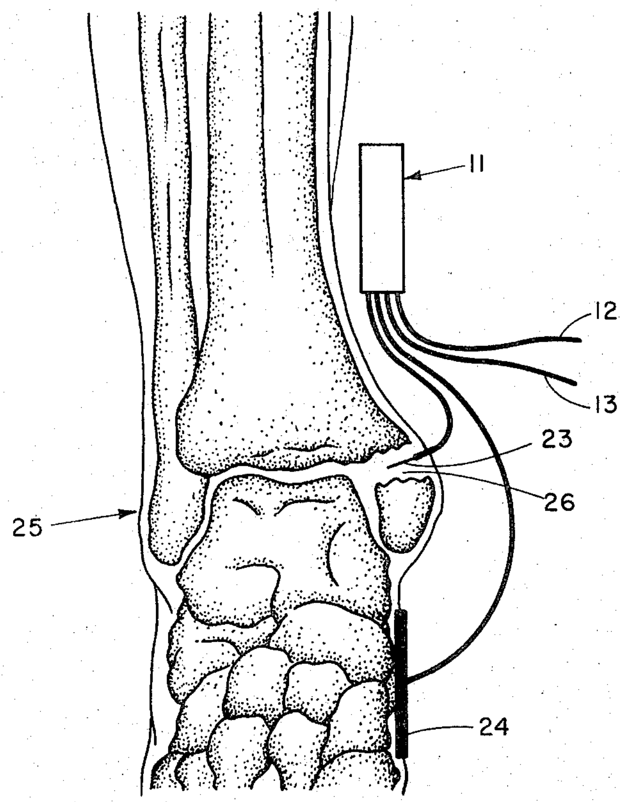


Fig. 3

CONSTANT CURRENT POWER PACK FOR BONE HEALING AND METHOD OF USE

The present invention concerns bone healing with the assistance of electric current and, more particularly, bone fracture healing through the use of direct current from a portable power source.

The application of direct current to a bone fracture in an effort to influence regeneration has been the subject of several past efforts. Among early efforts, a 1 microampere current was passed through the femur for a period of 3 weeks with the result that a ridge of callus was formed from pole to pole. More callus was noted at site of the cathode than at that of the anode. Bony callus developed with amperages between 1 and 100 microamperes, and cartilaginous callus appeared when the current exceeded 100 microamperes. Bone destruction resulted when currents greater than 1,000 microamperes were passed through the femur. A subsequent effort resulted in bone production from a current actually delivered to the bone of from 0.7 microampere to slightly more than 3 microamperes, this production reaching a peak within 2 weeks after which no significant increase in bone formation occurred. These and other efforts, however, were inconclusive because a constant current source to the bone was not available, current provided to the bone decreasing as tissue resistance developed at the electrode sites. The need for using a constant current as well as wider range of current to study the galvanometabolic behavior of bone was recognized. The present invention is the result of an attempt to study the galvanometabolic behavior of bone with a constant current source that was not influenced by tissue resistance in vivo. Such a power pack heretofore was not available.

The present invention is a practical application of the use of direct current to influence bone formation, the current being maintained constant by a portable direct current source. The entire device is encapsulated in silicone and includes a power pack of a plurality of batteries, appropriate electronics to assure that a constant direct current is provided and a silicone seal to protect both the device and the person using it. The device is sufficiently compact to be strapped or taped to the leg, arm or body of the user. Current is delivered to the fracture source by implantation of the power pack cathode lead into the body near the fracture and the application of the anode to the skin on the remote side of the fracture from the cathode preferably by means of a surface electrode.

Accordingly, it is an object of the present invention to provide a method of and means for promoting the healing of bone fractures and bone defects.

It is another object of the invention to provide a method of and means for portable bone fracture healing and bone defect healing which supplies a constant current throughout the time current is delivered to the fracture region.

A further object of the invention is to provide a method of and means for for supplying a constant current to healing fractures and bone defects to promote and/or accelerate healing by means which may be taped to and worn by the person during those normal activities which are permitted by the nature of the fracture.

Other objects, advantages and novel features of the invention will become apparent from the following detailed description thereof when considered in conjunction with the accompanying drawing in which like numerals represent like parts throughout and wherein:

FIG. 1 is a perspective view of the power pack and its external appendages;

FIG. 2 is a schematic diagram of a constant current power supply;

FIG. 3 is a schematic diagram of a fractured ankle bone showing placement of electrodes;

FIG. 4 is a top plan view of a surface anode; and

FIG. 5 is a bottom plan view of the anode of FIG. 4.

FIG. 1 is a view in perspective of the complete fracture healing device **11** having a pair of test leads, or wires, **12** and **13** and a pair of leads **15** and **16** with healing electrodes **23** and **24** extending therefrom. The pack contains, not necessarily in the succession recited, a battery or batteries in a compartment **18**, necessary electronics to provide a constant current supply source in a compartment **19** and a silicone seal and miscellaneous connections in a compartment **20**. The entire pack may be encapsulated in methacrylate plastic or a like substance. Test leads **12** and **13** are connected to test equipment, not shown, so that the operation of the device may be constantly monitored. Lead **15** ends in a bare-wire region **23** which comprises a cathode which is implanted in the region of the fracture by the insertion of bare wire region **23**, while lead **16** is connected to an anode **24** which, in this embodiment, is shown as a wire mesh which is to be applied to the surface of the skin on the remote side of the fracture from the position where cathode wire **23** is inserted.

FIG. 2 schematically illustrates a power supply which may be used to produce the desired constant DC current flow across the bone fracture. Electrodes **15** and **16** are adapted to be connected across output terminals **30** and **31** respectively, and the impedance across these electrodes, which changes during the bone healing process, is automatically compensated for by the control circuit to maintain a present, constant, microampere current level through the treatment site tissue.

The control elements of the power supply are a pair of n-channel field-effect transistors, Q1 and Q2. These transistors are effectively connected in series with a resistive network, R1 and R2, across the output electrodes and a bias source **33**. More specifically, the drain electrode **35** of Q1 is connected to the positive terminal of battery **33** while the source electrode **36** of this transistor is directly connected to the drain **37** of Q2. The source electrode **38** of this second transistor is connected to one side of the resistance network, the other side of which is connected to the positive side of the output terminal **31**. The gate electrode **40** of Q1 is directly tied to the source electrode **38** of Q2, and the gate electrode **41** of Q2 is connected to the junction **42** of R1 and R2. For calibration and monitoring purposes, voltage output readings may be taken across R2 via test leads **12** and **13**.

FIG. 3 is a schematic view of an X-ray of the lower leg and foot **25** of a person in which a fracture exists in the region indicated in **26**. The fracture area is enlarged on the order of two or more times to more clearly illustrate the placement of healing electrode **23** therein. Electrode **23** is inserted in the fracture opening with the conductive part of the electrode, i.e., the exposed bared wire, preferably being placed within the periphery of the bone sections. Anode **24** is applied to the skin, in this case along the vertical surface of the instep, while power pack **11** is positioned and carried by the user above the ankle. The power pack may be attached to the person by tape, strap or other conventional means. Test electrodes **12** and **13** are shown available for connection as desired to a monitoring device for reviewing the operation of the power source.

The operation of this circuit is such that the variations in the impedence of the load, i.e., of the fracture tissue, connected across the output terminals **30** and **31**, will not change the predetermined current level. The field-effect transistor (FET) because of its characteristic is readily applicable as a constant current element. As shown in FIG. **2**, Q1 and Q2 are cascaded to decrease the circuit output conductance as the voltage across the transistor or the load impedence change, the key consideration in operation of the constant current source. Resistor R_1 adjusts current output level, provides bias for the circuit, and develops feedback to further decrease output conductance. As long as the voltage across the field-effect transistor is larger than the pinch-off voltage, the FET is operating in the constant current region of its characteristic, thus a change in the load impedence will change the load circuit by only a small factor because of the low output conductance of the circuit. R2 is in series with the load and is used merely to develop monitoring voltage across it.

In order to set the current level, R1 may be adjusted to an appropriate value as determined by the voltage reading across R2. In one practical embodiment, **33** was a 7 volt battery, R2 = 1,000 ohms and R1 = 3×10^6 ohms, 8×10^5 ohms 4×10^5 ohms 15×10^4 ohms for currents of 1 microampere, 5 microampere, 10 microampere and 20 microampere outputs.

FIGS. **4** and **5** are front and back plan views, respectively, of one embodiment of an anode **24** which may be used with the device. This embodiment is preferably made of a face plate **50** of metal to which is soldered a stainless steel mesh **51**. This form of anode may be constructed by cutting a square of stainless steel sheathing preferably 0.7 mm. thick to a size slightly greater than 2 cm. × 2 cm. The additional material in excess of 2 cm. is then turned up to form a shallow well. A small hole **52** preferably 1/64 inch in diameter is then drilled in the center of the well and thereafter stainless steel mesh **51** is cut to size, inserted in the well and then soldered along all **4** edges of the plate. A tube **53** is then soldered to the hole in the back of the plate with the end flush against the plate. Four small wire eyelets **54** - **57** may be soldered to the corners of plate **50** to permit fixing the plate against the skin of a person. A polyethelene tubing **58** is then attached to tube **53** to permit the instillation of electrolytic paste into the well through tubing **58**.

In practice, compartment **18** preferably houses 5½ volt batteries connected in series with field-effect transistors Q1 and Q2. The entire capsule is sealed with silicone, methacrylate plastic or similar sealing compounds while the multi-strand stainless steel wires **12**, **13**, **15** and **16** are covered with Teflon insulation. Anode **24**, shown in FIG. **1**, is one form of anode which is to be placed on the surface of the skin, with the wire mesh attached thereto in such a manner as to permit a conductive paste, not shown, to be installed therein in order to make an effective circuit with the implanted cathode. If the anode is to be implanted, it, like electrode **23**, is bared of its cover for the last ¼ inch or more.

In animal experiments, the entire power pack, except for the two monitoring wires, was implanted under the skin on the back of the animal. The cathode and anode wires were run subcutaneously along the limb to the fracture or bone defect site. The cathode was inserted into the fracture or bone defect site and held there with chromic sutures. The anode was fastened in the nearby soft tissue with chromic sutures. Current output was monitored at will by means of the monitoring leads protruding through the skin.

In human subjects, the entire power pack is sterilized in a gas autoclave, or, if replaceable cathodes are used, only the cathode is sterilized. Only the cathode is inserted into the patient at the fracture, nonunion, or bone defect site. The anode is taped to the surface of the skin near the cathode implantation site, and the power pack is strapped to the limb or to the outside of a cast encasing the limb. The cathode may be modified such that the multi-strand stainless steel wire is replaced by a more rigid stainless steel pin covered with Teflon. If the multi-strand cathode is used, a small incision must be made in the skin and underlying subcutaneous tissue in order to insert the cathode into the fracture or bone defect site. If the stainless steel pin cathode is used, no incision is made. The pin is simply pushed through the skin and soft tissue into the underlying bony fracture or defect. Placement and location of the pin is determined by X-ray evaluation.

The present invention has been successful in promoting bone growth in rabbits which were divided into three groups, one in which 1 to 5 microamperes current were applied, another in which 10 to 20 microamperes were applied and another where 50 to 100 microamperes were applied. In the 1 to 5 microampere group, little reaction was noted at the implant site at either the anode or the catode site. In the 10 to 20 microampere group, a dark discoloration was noted around the anodal site but no discoloration was noted in the vicinity of the cathode. At 50 to 100 microamperes, marked discoloration occurred at both electrode sites.

Microscopic examination showed that bone formation occurred predominately around the cathode site. The optimum range of current for such formation was 5 to 20 microamperes with diminution of bone production above 20 microamperes. The bone formed appeared to be predominantly osteoblastic in type, with some areas of fibro-osseous metaplasia. The areas of bone formation were contiguous with, and surrounded areas of, cartilage which, in turn, surrounded the electrode sites. Cartilage production, which appeared to be hyaline in type, occurred around both poles to a limited extent, with the optimum production again being reached between 5 to 20 microamperes at the cathode. No appreciable change was noted in the capillaries or blood vessels. There was a reversal of electrodal relationships relative to fibrous tissue formation, with the greatest production occurring at the anode. A gradual increase of anode fibrous tissue formation was seen up to 10 microamperes, after which there was a sharp decline at the higher microamperages. Tissue destruction was markedly prevalent at the anode in virtually every instance, with a maximum being attained at 20 microamperes and persisting through 100 microamperes. Tissue destruction at the cathode was minimal until 100 microamperes, when the severity approached that found at the anode. Tissue destruction was that of fibrinoid necrosis, extending from the immediate area around the electrode to destruction of the entire marrow content between the two electrodes, and involved the cortical endosteum, with many of the lacunae being empty. Bone formation ranged from a thin shell rimming the cathode to a filling of the medullary cavity between the two electrodes.

It will be appreciated that the present invention provides a novel method of treating both delayed and non-union fractures as well as bony defects by use of constant current as described herein. The invention has produced accelerated fracture healing. The bony healing promoted by the present invention is accomplished without any requirement for surgery whereas methods presently available for achieving bony union require bone graft surgery.

The foregoing is accomplished through the use of a constant **10** microampere current which is available regardless of changing tissue resistance. This current may be obtained from portable power pack **11** which is sterilizable and therefore readily usable. The preferred electrodes are an implantable cathode and a surface anode. The individual components of the power pack may be varied as to construction materials so long as the output of the unit is a constant current regardless of changing resistance. Further research, utilizing power packs with greater current outputs and cathodes with a much greater surface area, may indicate a use of this system in the treatment of large bone defects. Although the cathode must be placed in the fracture, non-union or bony defect site, the anode, though described as preferably being placed on the remote side of the site from the cathode, may be placed anywhere so long as it completes a circuit with the cathode. Obviously, other modifications and variations of the present invention are possible in the line of the above teachings.

What is claimed is:

1. A system for expediting the healing of bone fractures and bone defects in a living being comprising:
- constant current source means for providing a constant value of current despite changes in load;
- means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect,
  - said connecting means including further means for application internally of said living being at the fracture or defect site,
  - said constant current being a selected value within a predetermined microampere range so as to promote bone formation at the fracture or bone defect site and avoid fibrous tissue formation in other areas of the living being.

2. The system as defined in claim **1** wherein said connecting means includes means for external application to the skin surface, the internal means being a cathodic electrode,

the external means being an anodic electrode.

3. The system as defined in claim **1** wherein said constant current means comprises miniature solid state means suitable for mounting on the living being in close proximity to said fracture or defect.

4. The system as defined in claim **1** wherein said cathodic electrode is positionable within said fracture or defect.

5. The system as defined in claim **1** wherein said current is in the range of from substantially **5** microamperes to substantially 20 microamperes.

6. A system for supplying a constant current within a selected amperage range to a bone fracture or a bone defect in a living being to promote healing thereof comprising:
- a pair of *n*-channel field-effect transistors, each having a source, drain and gate electrode;
- a dc power source, having a positive and a negative terminal,
  - the drain electrode of one of said transistors being connected to the positive terminal of said power source and the source electrode of said one transistor being connected to the drain electrode of the other of said transistors;
- a variable resistor;
  - the gate electrode of said one transistor and the source electrode of said other transistor being connected to one side of said variable resistor;
- means for connecting the negative terminal of said power source to the site of a bone fracture or bone defect; and
- means for completing the electrical circuit through the living being to a junction of the gate electrode of said other transistor and the other side of said variable resistor, the value of said variable resistor being adjusted for the desired current value of the cascaded transistors and the current valve being maintained notwithstanding changes in impedance across the fracture or defect tissue.

7. The system as defined in claim **6** wherein said means for connecting the negative terminal comprises a cathodic electrode for implantation in the fracture or defect and said means for completing the electrical circuit comprises an anodic electrode for application to the skin of the living being.

8. The system as defined in claim **6** wherein said power source is a 7-volt battery, and said battery, said field-effect transistors and said variable resistor can provide a current output in the range of from 1 to 20 microamperes.

9. The system as defined in claim **6** wherein the current through said fracture or defect site is constant at a selected value in the range of from 5 microamperes to 20 microamperes to promote bone formation in the region of said cathodic electrode and avoid fibrous tissue formation in the region of said anodic electrode.

10. The system as defined in claim **6** wherein said power source is suitable for mounting on the living being in close proximity to said fracture or defect.

11. The method of promoting the healing of a bone fracture or bone defect in a living being comprising:
- inserting a first electrode into a site within the fracture or defect;
- applying a second electrode to the skin surface of the living being at a location in the vicinity of said fracture or defect;
- connecting constant dc current means across said electrodes, thereby producing a constant flow of current therebetween, regardless of load changes; and
- adjusting said current flow to a predetermined value between 5 and 20 microamperes.

12. The method of claim **11** including the step of mounting the current means on the living being in close proximity to the fracture or defect.

13. The method claim **11** wherein said first electrode is connected to the negative terminal of said current source.

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