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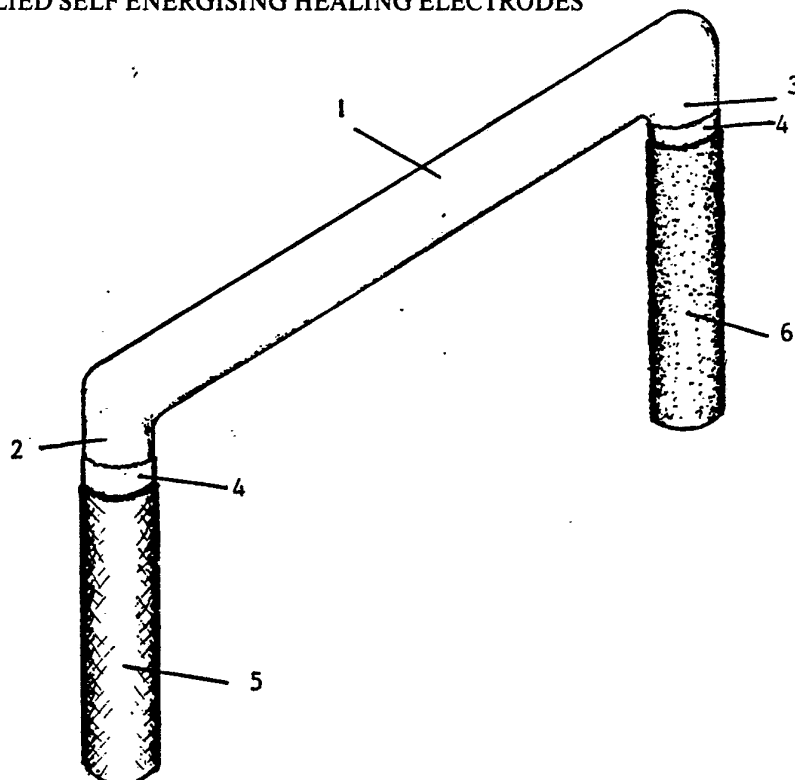
(71)(72) Applicant and Inventor: GRAY, Noel, Desmond
[AU/AU]; 3 Clive Crescent, Bayview, NSW 2104 (AU).(74) Agent: BARKER, BLENKINSHIP & ASSOCIATES;
P.O. Box 34, Chatswood, NSW 2067 (AU).

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(54) Title: INTERNALLY APPLIED SELF ENERGISING HEALING ELECTRODES



(57) Abstract

A healing aid comprising two or more conductive or semiconductive physiologically compatible electrodes adapted for insertion at least partly into living tissue, including bones; the first electrode comprising or being coated with a first material (5) one or more adjacent electrodes comprising or being coated with a different material (6) such that when the electrodes are placed in living tissue adjacent each other a potential difference exists between the electrodes. The electrodes may be integral with staples (1), pins or screws commonly used in surgical procedures.

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INTERNALLY APPLIED SELF ENERGISING HEALING ELECTRODES

The present invention relates to living tissue regeneration and pain reduction and to apparatus for achieving such ends by use of electrical energy.

5 The human body and indeed those of animals have quite remarkable inbuilt healing mechanisms whereby flesh wounds of quite substantial proportions may display substantial tissue regeneration within say seven days such that the risk of infection is minimised as is discomfort to the patient. As however in
10 many instances infection in a surgically created wound or a trauma wound may be life threatening any product or process which may enhance or speed up tissue regeneration and hence reduce the risk of infection would be an important advance. Such a product or process may be of particular use in conjunction with
15 patients who, due to age, diet or other factors, have a sub-standard ability to regenerate tissue.

Research indicates that small electronic currents in the vicinity of a flesh wound enhance tissue regeneration and hence healing of the wound even in cases where the patients natural
20 healing ability may be sub-standard. Research furthermore indicates that such current in the vicinity of a wound has the effect of reducing pain perceived by the patient as emanating from the wound.

Bone growth stimulators wherein electrodes with external power sources are utilised to generate current flow adjacent a

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fracture in order to promote osteogenesis are also known.

It is the object of the present invention to provide a method and apparatus for applying a small electronic current proximal to a wound utilising internally applied conductive or semi-conductive electrodes without an external power source.

According to the present invention there is provided two or more conductive or semi-conductive physiologically compatible electrodes adapted for insertion at least partly into living tissue; the first electrode comprising or being coated with a first material and an adjacent electrode comprising or being coated with a different material such that when the two electrodes are placed in living tissue adjacent each other a potential difference exists between the two electrodes which causes a small current to flow through tissue between the electrodes.

The present invention has application not only in the field of encouraging osteogenesis in the case of fractured bones but additionally has application in cases where it is desired to enhance the healing of soft tissue wounds.

In order that the invention may be better understood two embodiments of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a perspective view of a pair of electrodes in accordance with the present invention formed as a surgical staple;

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Figure 2 is a side elevation of a segment of a human long bone incorporating electrodes in accordance with the present invention formed as pins; and

Figure 3 is a cross-section through a human long bone incorporating electrodes in accordance with the present invention formed as pins.

Figure 1 discloses a surgical staple 1 having a first leg 2 and a second leg 3. Both legs are coated with a layer of plastic insulating material 4. Leg 2 is additionally provided with a gold coating 5 whereas leg 3 is additionally provided with a zinc coating 6.

In use the legs 2 and 3 of the staple would penetrate the soft tissue of say a flesh wound (not shown) either side of the wound line (not shown) in the conventional manner. The legs would then remain embedded in the flesh for some period of time.

Once embedded in human tissue legs 2 and 3 begin to operate as electrodes, the fluids present in the body serving as an electrolyte. Leg 2 will act as an inert electrode due to its coating of gold whilst the zinc coating 6 on leg 3 will cause that leg to operate as the active or sacrificial electrode. In this example utilising gold and zinc will create a potential difference of 2.12 volts between legs 2 and 3 causing a current to flow across the wound line (not shown). Several combinations of physiologically compatible electrode materials are available and in this regard it is contemplated that the coatings which result in the potential

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difference causing the current flow need not necessarily be metallic but may be any other elements or chemical compounds which result in a potential difference. Naturally the metals, elements or compounds must be physiologically compatible although as much work
5 has been done in this area in recent years a number of alternative combinations will be readily apparent to those skilled in this art. Lithium iodide cells for example are well known and may have application in certain embodiments of the present invention.

The rate of decay of the active electrode may be impeded by
10 the inclusion of an inert substance in the coating 6 or by other means.

Present research indicates that where one is trying to stimulate healing in soft tissue currents in the order of 40 to 300 microamps give good results whereas with embodiments intended
15 for use as bone growth stimulators currents in the range of 5 to 100 microamperes may be more appropriate. It should also be appreciated that as the conductivity of bone is generally less than that of flesh greater potential differences may be necessary in the case of bone growth stimulators in order to generate a given
20 current than would be the case with soft tissue.

It is envisaged that electrodes in accordance with the present invention should be capable of delivering currents in the range of 1 to 500 microamps being the range within which satisfactory accelerated healing appears to occur. Potential differences in
25 the order of .01-3 volts should be readily achievable provided the

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electrode materials are correctly chosen in accordance with a galvanic table or like reference.

Figure 1 depicts an example where two legs of a staple are coated with different materials so as to cause a single staple to generate a current when implanted in flesh. It should be appreciated that a similar result could be achieved by insertion of multiple staples with say alternate staples being fabricated from or coated with different materials such that a potential difference will arise between such adjacent staples.

10 A second embodiment of the present invention is depicted at figures 2 and 3 wherein there is depicted proximal 7 and distal 8 parts of a human long bone either side of a fracture 9. It is common practice to pin the proximal and distal parts of the bone in their correct relationship in order to ensure correct alignment of the bone after osteogenesis. To this end holes 10 are drilled into the bones in order to facilitate insertion of pins 11 and 12.

In accordance with the principles of the present invention these pins are comprised of or coated with dissimilar materials displaying a potential difference which in the environment of the human body forms a battery causing a current to flow along the fracture 8 in the area between the pins 11 and 12. The pins may be wholly or merely partially sacrificial electrodes. An embodiment as lastmentioned consequently renders the installation of mechanical fixing means such as pins, screws or the like and the installation of a bone growth stimulator a single operative

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procedure little more complex than the mere installation of mechanical fixing means themselves. Previously it was the case that if adequate osteogenesis had not occurred within six weeks a separate surgical procedure was required in order to install
5 electrodes and necessary wires to communicate with an external power source. Naturally these electrodes furthermore required yet another surgical procedure in order that they may be removed. These two additional surgical procedures in addition to the surgical procedure necessary to install the mechanical fixing
10 means necessarily result in additional risk to the patient as well as unnecessary expense.

The two embodiments above described should not be considered exhaustive of the applications of the present invention. Indeed it is not essential that the electrodes of the present invention
15 be incorporated with mechanical fixing means or other articles used in the human body such as pins, screws, discs, wires, plugs or staples. For example the electrodes of the present invention may comprise washers used in conjunction with say conventional screws or alternatively the electrodes may be implanted entirely
20 independently of any other device.

The term living tissue where used herein shall include bone.

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The claims defining the invention are as follows:

1. A healing aid comprising two or more conductive or semi-conductive physiologically compatible electrodes adapted for insertion at least partly into living tissue; the
5 first electrode comprising or being coated with a first material and an adjacent electrode comprising or being coated with a different material such that when the electrodes are placed in living tissue adjacent each other a potential difference exists between the electrodes
10 which causes a small current to flow through tissue between the electrodes.
2. A healing stimulator in accordance with claim 1 wherein the materials from which the electrodes are fabricated or with which they are coated are selected such that when implanted
15 in the body the electrodes will set up a current of between 1 and 500 microamps.
3. A healing stimulator in accordance with any one of the preceding claims wherein one or more of the electrodes is integral with traditional bone fixing means such as pins or screws.
- 20 4. A healing stimulator in accordance with any one of claims 1 - 2 wherein the electrodes are integral with articles traditionally used in soft tissue such as staples.
5. A healing stimulator in accordance with any one of claims 1 - 2 hereof wherein at least one of the electrodes is a

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washer adapted for use in conjunction with a conventional surgical screw.

6. A method of implanting a bone growth stimulator in accordance with the present invention comprising the steps of:

- 5 a) selecting at least two electrodes in accordance with any one of claims 1-5 hereof.
- b) implanting the electrodes at least partially within the body adjacent the wound site such that a current of between 1 and 500 microamps flows between the electrodes and
- 10 proximate the wound site.

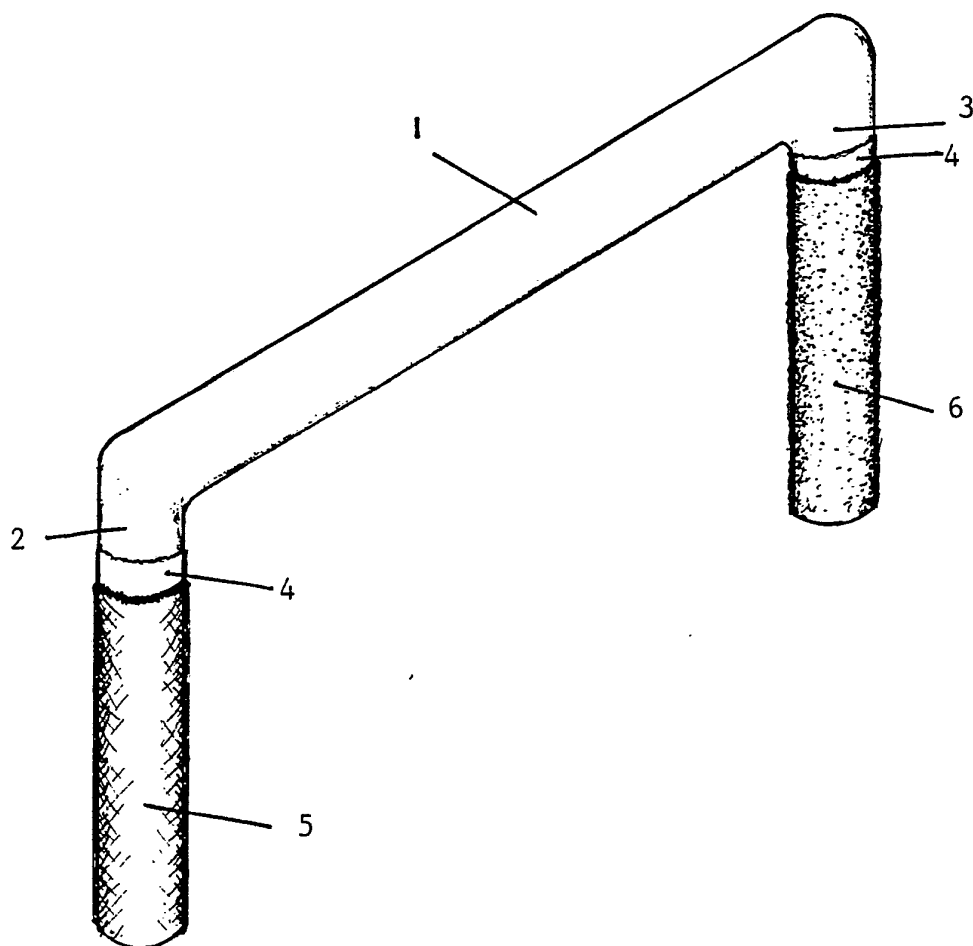
FIGURE 1

FIGURE 2

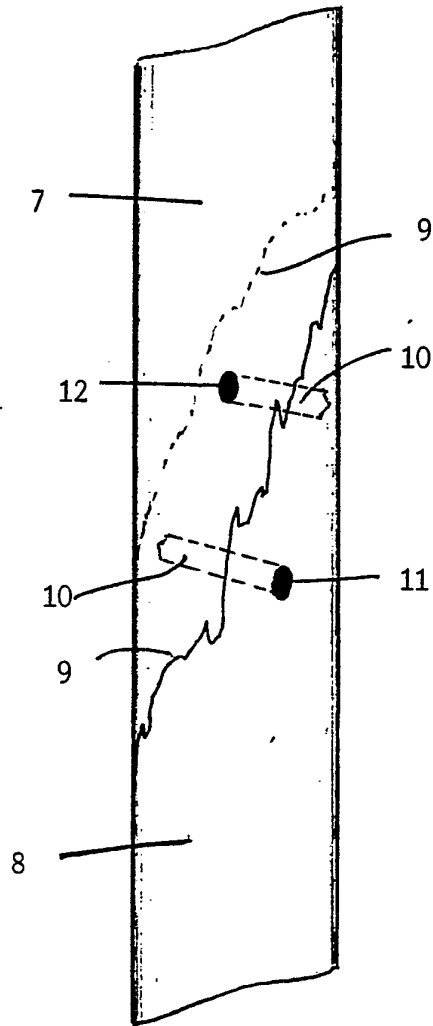
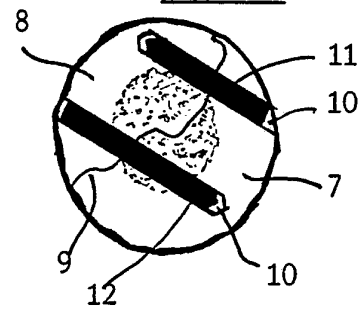


FIGURE 3



INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 86/00178

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. ⁴ A61N 1/05		
II. FIELDS SEARCHED		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
IPC	A61N 1/05, 1/04	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
AU : IPC as above; IPC A61B 17/08, 17/18, 17/58		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	AU,A, 2731/66 (PARKE, DAVIS AND COMPANY) 14 September 1967 (14.09.67)	1,4
X	AU,B, 3168/36 (100626) (OLIVER) 23 March 1937 (23.03.37)	1
A	US,A, 4506674 (C.T. BRIGHTON, J. BLACK) 26 March 1985 (26.03.85)	3
A	US,A, 4461300 (J.M. CHRISTENSEN) 24 July 1984 (24.07.84)	3
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
25 August 1986 (25.08.86)	4 SEPTEMBER 1986 (04.09.86)	
International Searching Authority	Signature of Authorized Officer	
Australian Patent Office	 J.I. WELSH	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 86/00178

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document
Cited in Search
Report

Patent Family Members

US 4506674

US 442846

END OF ANNEX