April 2, 1963 C. F. WOODHOUSE 3,083,706

APPARATUS AND METHOD FOR MEASURING OXYGEN TENSION IN BONE

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FIG. 1

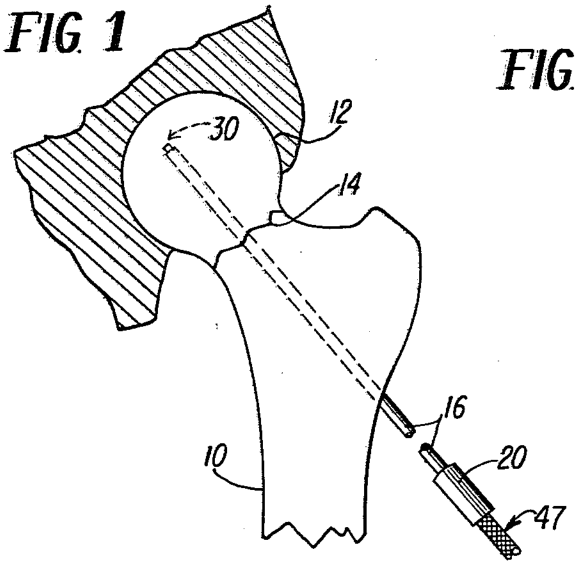


FIG. 2

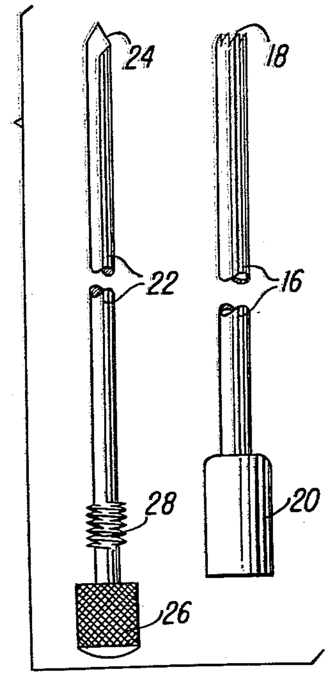


FIG. 3

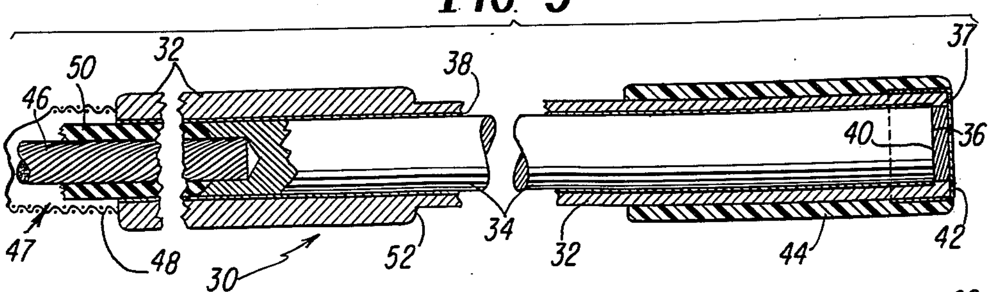


FIG. 4

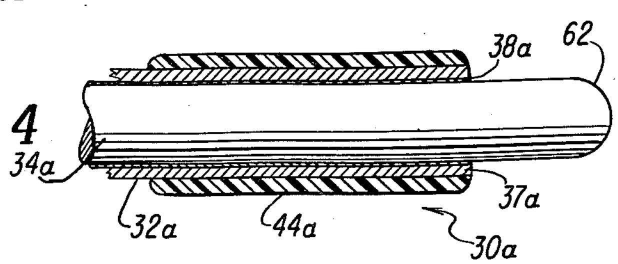
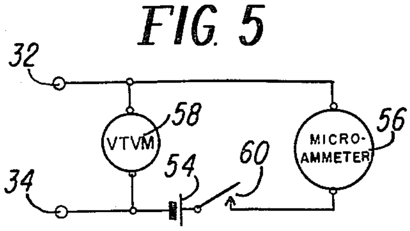


FIG. 5



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APPARATUS AND METHOD FOR MEASURING OXYGEN TENSION IN BONE

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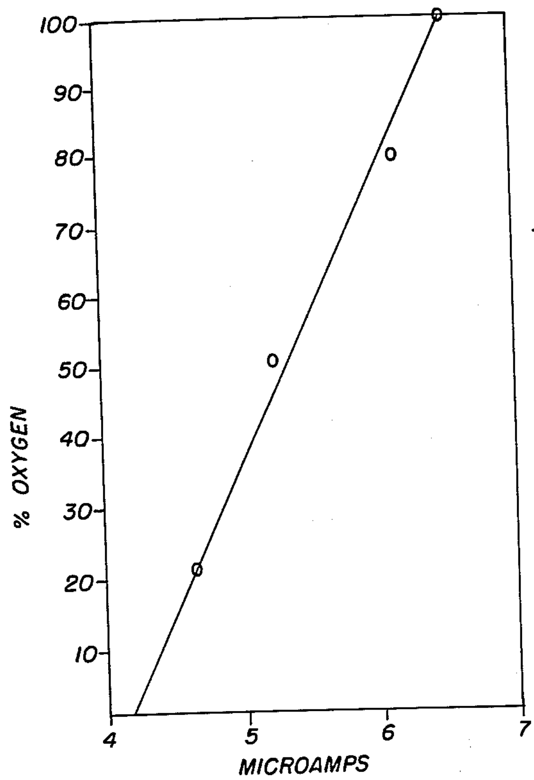

FIG. 6

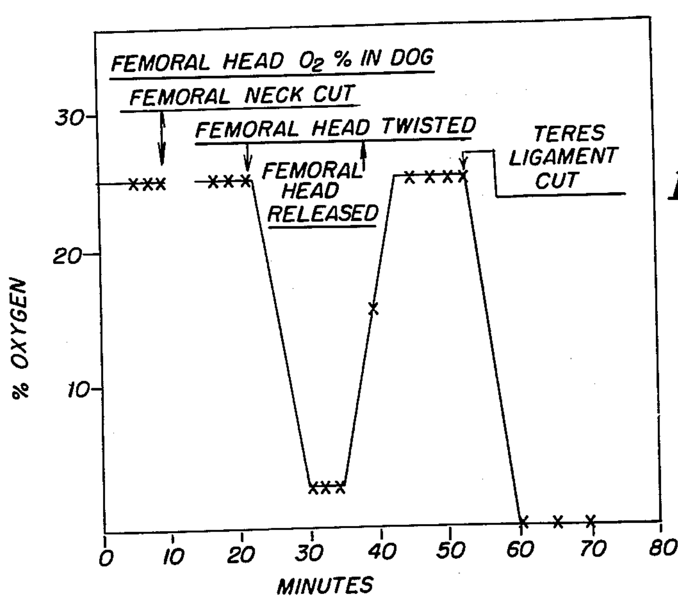

FIG. 7

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APPARATUS AND METHOD FOR MEASURING OXYGEN TENSION IN BONE

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This invention relates generally to medical test apparatus and more particularly to apparatus and a method for determining immediately and directly at the time of surgery whether a bone is dead or alive.

One of the serious and heretofore insoluble problems which has long plagued the medical profession was the fact that the state of viability of a fractured bone could not be determined immediately at the time of reduction of the fracture. It is well known that certain bone fractures frequently result in the death of a portion of the affected bone so that the reduction of such a fracture is futile. This is particularly true of fractures of the hip or femur wherein the femoral head is affected. Of course, if the femoral head is in fact dead as a result of the fracture, the reduction thereof is not only useless, but further necessitates a second operation at a later date to reconstruct or remove the dead head and prosthetically replace the same.

Until fairly recently, the clinically accepted procedure was to pin or reduce all hip fractures. After a period of some four to six months of invalidism and crutches, the affected femur was examined by X-ray. Only at that late date was it possible to determine whether the fracture had satisfactorily knit or whether the femoral head was dead. In the latter case, a second operation was required for reconstruction or prosthetic replacement of the dead head. Countless patients were thus subjected to additional and unnecessary surgery, expense, pain and invalidism. Of course, in elderly patients, such a second operation was often an extremely serious procedure.

More recently, however, statistics have shown that in approximately 80% of all hip fractures, the femoral head is dead. As a consequence, the modern trend in all hip fractures involving elderly people, is to initially remove and replace the femoral head. It will thus be appreciated that in a significant number of cases a viable head is removed for the sake of avoiding a second operation which might overtax the recuperative powers of the elderly patient. In younger patients, the described practice of pinning all hip fractures is still followed. In either case, the seriousness of the problems attendant the present procedure "in the dark," is manifest.

It is, of course, well known that if the head of the fractured femur has a normal blood supply, then the same is alive and satisfactory healing of the bone is assured. Similarly, if the femoral head has no blood supply, then the same is dead and the reduction of the bone is doomed to fail. It thus follows that if the presence or absence of blood supply to the fractured femoral head could be determined at the time of initial surgery, the suitable surgical procedure would automatically be determined in every case. To the applicant's knowledge there is at the present time no method or test for determining at the time of surgery whether the head of a fractured femur has a blood supply and is alive.

It is therefore an important object of this invention to provide apparatus for determining immediately and directly, at the time of surgery, whether a fractured bone has a blood supply and is therefore alive.

Another important object of the invention is to afford apparatus of the character described which operates electrically to measure the oxygen tension in the affected bone. In this regard, the invention utilizes the knowledge that oxygen is carried through the body by the blood. Thus, if there is no oxygen, or only a negligible amount, in the affected femoral head, then there is no blood supply and the head is dead. Similarly, if, on increasing the oxygen that the anesthetized patient is breathing, the oxygen in the femoral head increases in response to the general blood oxygen increase, the blood supply to the head must be intact and the head alive.

Hip fractures are invariably reduced by pinning with what is commonly known as a "Smith-Peterson" nail. Before such a reduction can be achieved it is of course necessary to drill a hole through the bone into which the nail may be inserted. For the purpose of drilling such a guide hole, there is commonly employed a form of drilling cannula and removably insertable bit. Thus, the primary procedure in every hip fracture case is to drill a guide hole as described.

A further object of the invention is to provide apparatus of the character described which requires no special bone drilling equipment or the like. In this regard, the invention employs a novel electrical probe which may be readily inserted into the ordinary drilling cannula which has already been positioned in the bone.

Still another object is to afford apparatus of the character described which is small and conveniently portable so that the same may be readily carried from place to place and used under virtually any operating conditions.

Still a further object is to provide apparatus of the character described which is completely accurate in measuring the presence or absence of a blood supply in the affected bone.

Yet another object is to afford apparatus of the character described which is immediately responsive and gives a direct reading so that a determination of the condition of the affected bone may be accomplished within a matter of seconds.

Yet a further object is to provide apparatus of the character described which is relatively inexpensive to manufacture and yet is most efficient and simple to operate.

With the foregoing and other objects in view which will appear as the description proceeds the invention consists of certain novel features of construction, arrangement and a combination of parts hereinafter fully described, illustrated in the accompanying drawings, and particularly pointed out in the appended claims, it being understood that various changes in the form, proportion, size and minor details of the structure may be made without departing from the spirit or sacrificing any of the advantages of the invention.

For the purpose of facilitating an understanding of my invention, I have illustrated in the accompanying drawings preferred embodiments thereof, from an inspection of which, when considered in connection with the following description, my invention, its mode of construction, assembly and operation, and many of its advantages should be readily understood and appreciated.

Referring to the drawings in which the same characters of reference are employed to indicate corresponding or similar parts throughout the several figures of the drawings:

FIG. 1 is a fragmentary view of a fractured femur showing the invention operationally inserted into the femoral head through a standard drilling cannula;

FIG. 2 is an exploded fragmentary view of the drilling cannula and associated drilling bit;

FIG. 3 is a greatly enlarged fragmentary sectional view of a preferred form of the novel electrical probe of the invention;

FIG. 4 is a similar view of another embodiment of the probe;

FIG. 5 is a schematic view of the electrical circuitry of the invention;

FIG. 6 is a graph illustrating the direct relationship between current flow and the presence of oxygen in the blood; and

FIG. 7 is a graph illustrating the accuracy of the invention under laboratory controlled known conditions of the femoral head in a dog.

Turning first to FIG. 1 of the drawings, a typical application of the invention is illustrated. A femur 10 having a femoral head 12 is fractured as at 14. As already indicated above, the initial procedure in every such case is to drill a guide hole through the femur 10 and head 12 into which may be inserted a "Smith-Peterson" nail, or the like, for pinning or reducing the fracture 14.

Referring to FIG. 2, the instrument commonly employed for drilling the said guide hole comprises a hollow drilling cannula 16. The cannula 16 has a sharp serrated drilling edge 18 and an internally threaded enlarged diameter rear portion 20. Cooperating with the cannula 16 and insertable therethrough is a drilling bit 22. The drilling bit 22 has a drilling tip 24, a handle 26 and an intermediate threaded portion 28 for cooperating with the enlarged diameter cannula portion 20. It should be noted that the bit 22 is slightly longer than the cannula 16 so that when the same is operationally positioned within the cannula, the top 24 projects out beyond the edge 18. When the guide hole has been drilled as indicated in FIG. 1, the bit 22 may of course be readily removed leaving the cannula 16 positioned within the bone. At this stage in the normal operating procedure, the subject invention may now be employed to quickly and efficiently determine the condition of the femoral head 12, thereby indicating the proper surgical procedure.

The means for accomplishing the aforesaid determination comprises a novel electrical probe indicated generally by the reference character 30 (see FIG. 3). The probe 30 comprises an outer electrode in the form of an elongated silver tube 32. In actual practice, the tube 32 is approximately 8 inches in length and of an outer diameter which will permit the same to be readily inserted into the cannula 16 in a manner which will be subsequently described.

Positioned within the tube 32 is an inner electrode 34 which comprises a piece of fine platinum wire approximately one-half inch in length. It will be noted that the inner electrode 34 is positioned so that the front face 36 thereof is slightly recessed from the front edge 37 of the outer electrode 32. The inner electrode 34 is electrically insulated along the sides thereof from the outer electrode by any suitable means such as a coat of varnish of lacquer 38. A varnish found to be ideally suited for this purpose is "Formvar." A circular piece of "Millipore" filter paper 40 may be positioned in abutment with front face 36 to fill the recess in the tube 32, and a cup-like membranous member 42 is positioned over the front edge of the tube 32. Before insertion, the filter paper 40 may be soaked in a .9 normal sodium chloride solution to approximate the salinity of the blood. The membranous member 42 is extremely thin (on the order of .00025 inch) and is adapted to permit the passage of a gas therethrough while being nonetheless impervious to liquids. The reason therefor will become apparent as the description proceeds. The member 42 must of course also be capable of complete sterilization, and I have found that a fine film of tetrafluoroethylene is ideally suited for the purposes described.

Positioned over the member 42 and tube 32 is a tight-fitting sleeve 44 which is adapted to securely hold the member 42 in place. For this purpose, the sleeve 44 may comprise any suitable heat shrinkable material capable of complete sterilization, and the plastic tetrafluorethylene has been found to be ideal for this purpose also.

Connected to the inner electrode 34 by any suitable means such as soldering is the inner conductor 46 of a coaxial wire indicated generally by the reference numeral 47. An outer conductor or shield 48 of the coaxial wire

47 is connected to the tube 32 as by soldering or the like. The conductors 46 and 48 are of course electrically insulated by any suitable insulation 50. The coaxial wire 47 may be of any convenient length such as 6–8 feet, and the free end thereof is provided with a connector (not shown) for connecting the same to a source of electrical energy. The tip of the tube 32 may be crimped as at 52 to insure the immovable retention of the inner electrode 34 therein.

Referring now to FIG. 5 of the drawings, it will be seen that the electrical circuit comprises generally a means for applying a low voltage (from .1 to 1.5 volts) across the electrodes 32 and 34 and measuring the resulting current flow. Thus, the electrodes 32 and 34 are connected in series with a voltage source 54 and a microammeter 56. A high impedance instrument such as a vacuum tube voltmeter 58 is connected across the electrodes 32 and 34 to provide a means for controlling the voltage applied as desired. A switch such as 60 may likewise be employed.

The operation of the apparatus may now be described in the following manner. As already described, the cannula 16 is positioned in the bone as illustrated in FIG. 1. The probe 30 is now inserted into the cannula 16 until the front edge 37 thereof projects out of the cannula. In this condition, the membranous member 42 is of course in direct contact with the blood in the femoral head 12. The switch 60 is now closed and the vacuum tube voltmeter adjusted to give the desired voltage; for example, 1 volt.

It may be theorized that the presence of any oxygen in the blood of the femoral head 12 causes some of said oxygen to pass through the membranous member 42 so that the same is in contact with the outer electrode 32 and the front face 36 of the inner electrode 34. Since this oxygen is in solution in the water of the blood and in the vaporized phase thereof there is thus provided an electrical conductor according to the known principles of polarography. There will thus be a flow of current and corresponding reading on the microammeter if any oxygen is present in the femoral head 12.

The amount of current which flows is directly proportional to the amount of oxygen present in the blood of the femoral head 12, and is thus a function of the bone's oxygen tension. This phenomenon is readily proven by the graph shown in FIG. 6 which illustrates an actual patient determination wherein .65 volt was applied and the amount of oxygen being breathed by the patient varied at 20.9% (atmosphere), 50%, 80% and 100%. The percentage of oxygen being breathed may of course be readily and accurately controlled by employing any of the oximeters currently in use.

It will thus be appreciated that if the patient is initially breathing atmosphere and there is no flow of current or only an extremely small current flow, then there is no blood supply to the femoral head 12 and reconstruction or prosthetic replacement thereof is the indicated surgical procedure. On the other hand, if the initial current flow is within the known normal range as indicated in the above graph, then the head 12 is viable and the fracture 14 should be successfully reduced. The reason for the aforementioned extremely small current flow in a dead femoral head is due to the fact that some residual oxygen may be present even though the blood supply to the head has been cut off.

Where the initial current flow is not clearly definitive of the viability of the head, then the procedure indicated in the foregoing graph is followed. Thus, the percentage of oxygen being breathed by the patient is increased. If, after about 60 seconds (the aproximate time for the generalized blood oxygen to appear) there is a corresponding increase in current flow, the head 12 has a normal blood supply and is alive. Conversely, if there is no increase in current flow, then the head 12 is now definitely proven dead. Of course, after the described determination is made, the probe 30 is simply withdrawn from the cannula 16 and the indicated surgical procedure resumed.

The complete accuracy and infallibility of the apparatus have been conclusively verified both clinically and in the laboratory. Thus, for example, all possible known conditions of the femoral head have been simulated in animals such as dogs.

Illustrative of such experimental verification is the graph shown in FIG. 7 wherein the amount of oxygen in the femoral head of a dog as measured by the subject invention, is shown to be a direct function of various induced blood supply conditions. In this experiment, as indicated by the various legends on the graph, the neck of the femur and the capsule were completely cut and the femoral head then twisted. The oxygen in the head decreased as the blood supply was interrupted and cell metabolism extracted the available oxygen. Upon release of the occlusion, blood flowed again and the oxygen saturation returned to normal. Upon section of the remaining blood supply, achieved in dogs by cutting the teres ligament, the available oxygen fell to zero.

Similarly, the apparatus has been employed with complete accuracy in numerous human cases. In a number of cases, for example, the apparatus indicated that the femoral head was dead or alive and this determination was confirmed in every case in the laboratory by microscopic section. In other cases, the apparatus determined that the head was alive, and a successful reduction resulted in every case.

Turning to FIG. 4 of the drawings, a second embodiment of the probe **30** is illustrated with similar parts bearing similar reference characters with the suffix "*a*" added thereto. It will thus be seen that the probe **30*a*** comprises an outer electrode **32*a*** having a front edge **37*a***, an inner electrode **34*a*** and a sleeve **44*a*** positioned over the outer electrode **32*a***. The electrodes are electrically insulated from each other by a suitable coat of varnish or the like **38*a***. It will be noted, however, that the tip **62** of the inner electrode **34*a*** is rounded and projects uncovered from the outer electrode **32*a*** a distance of about .250 inch. Thus the membranous member **42** and the filter paper **40** are absent. In all other respects, the probe **30*a*** is the same as the probe **30**.

The operation of the probe **30*a*** is substantially the same in that the current flow is a function of the oxygen tension of the blood in the bone. However, since the bare tip **62** and front edge **37*a*** are in direct contact with the blood in the bone, it has been found that this form of probe is not quite as stable and accurately responsive as the preferred embodiment. This characteristic probably results from the fact that the blood itself is an electrical conductor.

From the above description and drawings it should be apparent that I have provided a novel apparatus for immediately determining the viability of a fractured bone. The correct surgical procedure may thus be followed in

every case. The apparatus is portable, simple to operate and completely accurate. In addition, a determination may be made in a matter of only seconds, and auxiliary drilling instruments or the like are not required.

It is believed that my invention, its mode of construction and assembly, and many of its advantages should be readily understood from the foregoing without further description, and it should also be manifest that while preferred embodiments of the invention have been shown and described for illustrative purposes, the structural details are nevertheless capable of wide variation within the purview of my invention as defined in the appended claims.

What I claim and desire to secure by Letters Patent of the United States is:

1. A method for determining the viability of a femoral head in a fractured femur characterized by the steps of: drilling a nail-guide hole through said femur and into said femoral head with a drilling cannula and cooperating drilling bit; removing said bit from said cannula; and inserting electrical means into said cannula to measure the amount of oxygen present in said femoral head.

2. A method for determining the viability of a femoral head in a fractured femur characterized by the steps of: drilling a nail-guide hole through said femur and into said femoral head; inserting a slender, elongated electrical probe having two coaxial electrodes of silver and a noble metal respectively into said femoral head through said nail-guide hole; applying an electrical potential to said electrodes; and measuring the flow of current through said probe as a function of the amount of oxygen present in said femoral head.

3. A probe for measuring oxygen tension in a bone by slidable insertion thereinto comprising: a slender smooth elongated anode; a relatively short cathode positioned within said anode and being electrically insulated therefrom, said cathode having a bare tip projecting out beyond the front edge of said anode; and electrical conductor means connected to said anode and cathode for connecting said probe to a source of electrical energy, said anode comprising a smooth silver tube, said cathode comprising a noble metal wire and said conductor means comprising a coaxial conductor connected to said tube and wire.

4. The probe of claim 3 in which the electrical insulation between said tube and wire comprises a coating of non-conductive varnish.

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