United States Patent [19]

Ersek

[11] **3,710,789**

[45] **Jan. 16, 1973**

[54] **METHOD OF REPAIRING BONE FRACTURES WITH EXPANDED METAL**

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[22] Filed: **Dec. 4, 1970**

[21] Appl. No.: **95,240**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 35,815, May 8, 1970, Pat. No. 3,657,744.

[52] **U.S. Cl.**.....**128/92 BC,** 128/92 D, 128/92 G

[51] **Int. Cl.**.....**A61f 5/04**

[58] **Field of Search**..128/92 R, 92 BA, 92 BC, 92 D, 128/92 G, 89 R, 334 R

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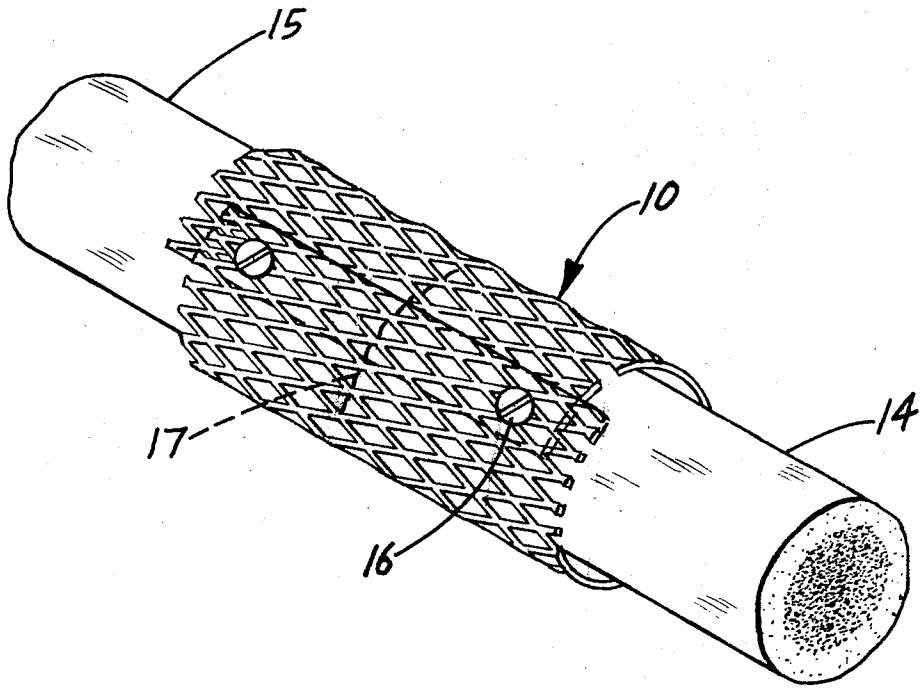
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[57] **ABSTRACT**

A method of repairing fractures of the bone utilizing expanded metal or similar openwork metal sheeting as a fracture fixation device. Where possible the sheeting is wrapped around the bone, extending on opposite sides of the fracture site, and fastened. For other fractures a strip of the sheet material is secured to the bone on opposite sides of the fracture site or inserted within the medullary cavity. The fixation device holds the bone immobilized while permitting knitting and, at the same time, the surrounding tissue grows into and through the many fenestrations of the metal sheeting to permanently fix the device to the fractured bone.

9 Claims, 6 Drawing Figures



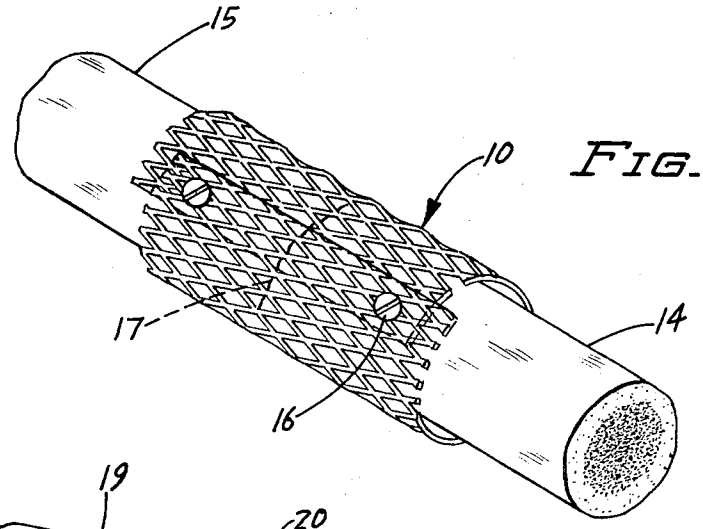


FIG. 3

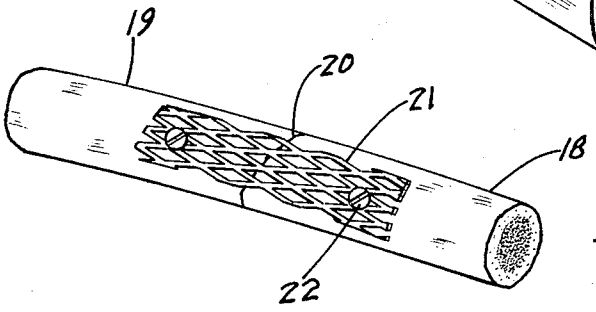


FIG. 4

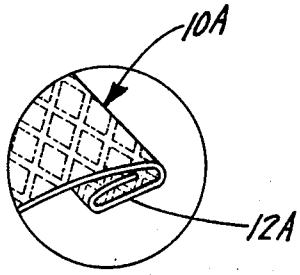
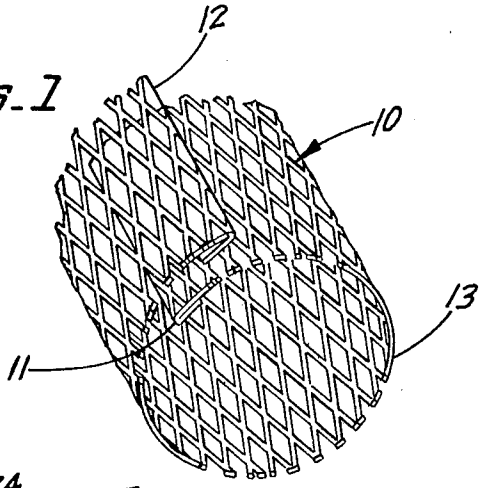


FIG. 2

FIG. 1



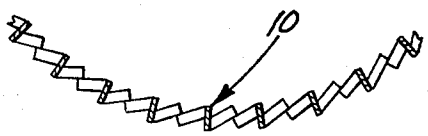


FIG. 6

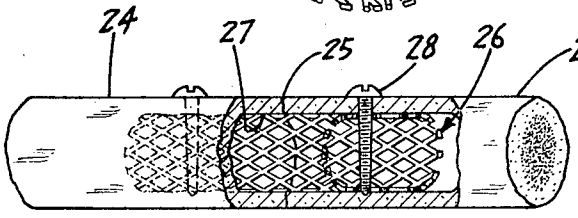


FIG. 5

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METHOD OF REPAIRING BONE FRACTURES WITH EXPANDED METAL

This application is a continuation-in-part of my copending application Ser. No. 35,815, filed May 8, 1970, entitled Method For FIxing Prosthetic Implants In A Living Body, now U.S. Pat. No. 3,657,744.

This invention relates to a new system for the repair of fractures of the bone utilizing expanded metal or similar openwork metal sheeting as a fracture fixation device.

Expanded metal has been used successfully according to the teachings of my copending application Ser. No. 35,815 as an implant device into the aorta of several animals including dogs, calves and pigs. In that use total success with the implantation of the expanded metal has been achieved. That is to say, there is no rejection phenomenon, there is no foreign body reaction and there is no measurable corrosion of the expanded metal, thus implying that it is biologically accepted.

In the past fractures of bones in the human or lower animals have been repaired by strict immobilization of the opposing fracture surface. This immobilization has been achieved in two principal ways. Firstly, by external fixation with splints, baskets, plaster casts, and other similar means to maintain alignment and immobilization. This has worked well for simple fractures in which the bone is not completely severed. It has worked less well, but satisfactorily, for those simple fractures where the bone is completely severed. It has worked poorly in those cases where there are more than two bone fragments, several of which may be unstable.

Secondly, immobilization has been achieved by internal fixation wherein metal plates have been used to secure the two or more fractured ends to each other with long bone screws passing through two surfaces of the bone and thus securing the unstable ends. Internal fixation has also been employed in the form of nails, wires, pins and intramedullary rods. In this application a metal piece is passed through the soft center of the bone to maintain longitudinal alignment and some rotational stability. Often these intramedullary rods in place have been secured with bone plates that are applied to the outside of the bone and sometimes attached by screws and bolts to the inside of the bone.

In the prior art some attempts at transplantation of bone have been made wherein a step is cut in each end of the opposing bone surfaces and a transplanted piece of bone from a cadaver donor or from another species is then cut to size to fit in the two corresponding steps. Screws have been used to fix these steps of the similar bone to each other.

Defects in the cranium and maxillae and mandible have been repaired by solid plates of stainless steel, silver and other metals. Wire and silicone rubber have also been used to make up such contour defects.

In the case of multiple fractured ribs, where a loose segment of the thoracic cage existed from several ribs being broken in more than one place, a condition known as flail chest, the fixation of the flailing portion of the chest has been achieved by securing towel clips to an overhanging orthopedic frame and partially hanging the patient by his chest. In this way the loose segment of the thorax can be stabilized so that the patient is able to breathe adequately.

In the prior art, bone screws and intramedullary pins have served well in many cases. However, long range results are less gratifying and removal of bone plates and screws and pins is often recommended because the passage of time often allows these devices to minutely work loose. In cases where multiple fragments of bone have resulted from gunshot wounds, or multiple breaks, there has been no convenient way to stabilize many small fragments of bone. In the prior art there is no totally satisfactory method of bridging a gap where a segment of a few inches of bone has been destroyed, to allow the packing of autogenous bone chips to grow long enough to form new bone and bridge the gap.

The use of solid plates for cranium wounds prevents the later use of diagnostic X-rays in the area for a tumor or the like. The use of large bone plates to repair smaller bones has often been a cumbersome procedure and erosion of the bone plate through the thinner overlying muscles and skin has taken place. Attempts to repair ribs in flail chest with large bone plates would result in erosion of the plates and screws through the thin overlying skin and in their present configuration most of the prior art screws would pierce through the rib and possibly pierce the lung.

This invention relates to fracture fixation means and more specifically to expanded metal as a means for the fixation of fractures. In the case where a simple fracture exists with only one crack or break through the bone, the expanded metal is wrapped around the bone and small truss head screws are placed through the lapped seam and into one cortex of bone, in this way giving longitudinal, rotational and length stability. In the application where there are two or more bone fragments, the unstable members are encased within the cylinder of expanded metal and the screws secured to the more stable end members.

The invention is illustrated in the accompanying drawings in which:

FIG. 1 is a fragmentary perspective view of a cylinder of expanded metal;

FIG. 2 is a fragmentary perspective view of one edge of the sheet material forming the cylinder, showing a preferred form of structure;

FIG. 3 is a schematic perspective view of a fractured bone repaired with an expanded metal cylinder and affixed with screws;

FIG. 4 is a schematic perspective view of a fractured rib having been repaired with expanded metal and small screws;

FIG. 5 is a schematic elevation, partly in section, of a fractured bone repaired with an expanded metal cylinder inserted into the medullary cavity; and

FIG. 6 is a schematic representation of a portion of the perimeter of the devices of FIGS. 1 and 3 shown in transverse section.

Referring to FIG. 1, there is shown a portion of a sheet of expanded metal 10 formed generally into the shape of a cylinder. The longitudinal edges 11 and 12 are provided with a hem by folding the sheet material over and crimping flat. The end edges 13 are desirably also provided with a hem in the same manner. Preferably, as shown in FIG. 2, a double hem is produced at leading edge 12A so that it may pass easily over the other portions of mesh and will tend to lock it in place.

In FIG. 3 there is shown schematically a repair in which the proximal end **14** of fractured bone fragment and the distal end **15** of the bone are joined together by the circumferentially applied cylinder of overlapped expanded metal **10**, the cylinder of expanded metal having been secured to these bone fragments, as by the previous drilling of holes and the installation of truss head screws **16**. Alternatively, the expanded metal sleeve can be secured by wire or metal straps or bands passed around the sleeve. The fracture site **17** is completely encased in the expanded metal and will get its blood supply from its uninterrupted medullary blood supply since no long screws protrude through the cortex of the bone, and through the myriad of tiny windows in the expanded metal.

The repair of a fractured rib is shown in FIG. **4**. The proximal segment **18** and distal segment **19** of rib are here joined at the fracture site **20** by a rectangular section of expanded metal **21** that has secured the two loose ends and is held by truss head screws **22**.

In FIG. **5** there is illustrated the use of a cylinder of expanded metal as an internal fracture fixation device. The proximal segment **23** and distal segment **24** of the bone are joined at the fracture site **25** by a cylinder **26** of expanded metal positioned within the medullary cavity **27** and secured by truss head screws **28**. The fixation device may be forced through the soft spongy cellular material within the bone cavity, or, if necessary, a rod or similar tool may be used to initiate a passage for insertion of the expanded metal cylinder. The resiliency of the rolled cylinder as it tends to unwind urges the fixation device into contact with the cavity wall. If desired, both internal and external fixation devices may be used, particularly in the case of fractures where the multiple bone fragments are present. These may be packed around an internal cylinder as a core and enveloped by an outer cylinder holding the chips and fragments in place.

Preferably the openwork fixation device, whether in the form of a flat strip of shaped sheet or a sleeve is formed from so-called "expanded metal" sheeting which is produced by forming a series of staggered parallel slits in an impervious metal sheet and then stretching the sheet in a direction perpendicular to the slits to open the slits into apertures and expand the metal sheet in that direction while contracting it slightly in the opposite direction. The stretching operation by which the metal sheet is expanded imparts a twist or bend to the undulating flat ribbon-like portions of the metal sheet separating the diamond-shaped apertures which are generally uniformly sized and distributed. This twisting or bending of the metal members between adjacent apertures imparts an angle or direction to the apertures themselves and to the ribbon-like members.

The expanded metal sheeting is desirably not flattened prior to forming into a fixation device of appropriate shape. The result, as seen schematically in FIG. **6**, is that the ribbon-like portions of the sleeve extend angularly relative to the perimeter of the sleeve providing multitude of narrow projecting edges which embed themselves into the tissue wall. The edges may be cuffed if desired or simply smoothed to facilitate entry. The fixation devices are formed to be a size appropriate for the repair being made. The strands and apertures are sized proportionately. It has been found convenient to hem the edges with a few millimeter bend of the expanded metal on all exposed edges. This enables the expanded metal to be passed around the bone and over the muscle and fascia layers. Desirably the surface is sandblasted to provide maximum surface area and mechanical roughness to enable the surrounding biological tissues to adhere to it. Because of the twisted relation of the ribbon-like portions of the sleeve, protrusion of the surrounding tissue is facilitated.

The fixation device is made of deformable material such that it retains its expanded dimensions. It is formed from a non-toxic material compatible with blood and other body fluids, such as stainless steel. Its walls desirably have a large percentage of open area so as to permit proliferation of the tissues through the openings and over the intervening strand-like or ribbon-like members. The stainless steel expanded metal has great strength and yet is easily worked. Sheet material with multiple fenestrations produced by other means may be used, for example perforated sheet material in which many closely spaced openings are produced by drilling or stamping.

Expanded metal mesh such as is herein described is especially useful in the repair of cranial and maxillary defects where molding must take place at the operating site by the surgeon. This material is easily stretched and bent to form any three-dimensional shape and easily attached to the surrounding bone by fine screws of the same metal. The great surface area of this substance and the many windows allow for total tissue ingrowth so that it acts in a manner similar to the reinforcing rods in reinforced concrete and it is anticipated that this stainless steel substance can remain within the body permanently without adverse effect. The use of expanded metal provides a simple unobtrusive means for the fixation of multiple fractures of ribs, where microscrews are used to fasten a small section of expanded metal right over the fractured site and in this way gaining stability.

Expanded metal has been shown to be useful at the University of Minnesota Hospitals laboratory where 304 stainless steel expanded metal as is herein described has been implanted in canine, porcine and bovine experimental animals. It has been found that the material is well accepted for long periods of implantation with no appreciable change in geometry, with no foreign body reaction and with no rejection and with minimal infection.

A series of experiments has been performed with 10 dogs wherein their radius was sawed through at approximately its midpoint and the surrounding muscle and subcutaneous tissue was separated from the bone. A piece of expanded metal was then wrapped around the bone at the site of the fracture for a distance of approximately 1 inch on each side of the fracture and overlapping about one-half inch. The overlapping ends were then secured with small truss head screws. Of the 10 dogs, one died of infection, one died of anesthesia overdose 22 days after the operation, and the other eight are alive and well and living in Minneapolis. An autopsy was done on the dog that died of anesthesia overdose and it was found that tissue had grown in all the many little windows and that the bone was very well

fixed. Movies were made of this dog running across the lawn at the end of 11 days. The eight dogs which are alive several months after the operation are being studied for long term effects. All dogs performed some weight bearing on their broken leg within a week after the operation.

It is apparent that many modifications and variations of this invention as hereinbefore set forth may be made without departing from the spirit and scope thereof. The specific embodiments described are given by way of example only and the invention is limited only by the terms of the appended claims.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A method of rapidly and positively repairing a fractured bone in a living body which comprises:

A. separating the surrounding muscle and subcutaneous tissue from the fractured bone on opposite sides of the fracture site and bringing the ends of the fractured bones together into normal relation,

B. shaping a fixation device into conformity with the bone surfaces to stabilize the broken segments of the fractured bone, said device comprising:

1. a thin expanded metal openwork member of strong easily deformable material capable of being shaped into conformity with the surfaces of the fractured bone, and formed from inert non-toxic material compatible with body fluids and tissues,

2. said member including a plurality of longitudinally extending ribbon-like undulating portions interconnected to define a plurality of staggered closely spaced uniformly sized and distributed apertures, the ribbon-like portions being disposed to extend angularly with respect to the bone surfaces, thereby being adapted for mechanical attachment to the fractured bone and for attachment to the surrounding tissue in a living host body,

C. positioning the device against the exposed bone surfaces on opposite sides of the fracture site,

D. bringing the ends of the fractured bones together into normal relation, and

E. while the ends of the bone are held in fixed position, securing the fixation device to the bone on opposite sides of the fracture site, and then restoring the separated muscle and tissue around the fixation device.

2. A method according to claim 1 further characterized in that the fixation device is formed into a cylinder surrounding the bone and spanning the fracture site.

3. A method according to claim 2 further characterized in that said fracture is a multiple fracture, the unstable bone fragments are encased within the cylinder of expanded metal and the cylinder is secured to the stable end bone members on opposite sides of the fracture site.

4. A method according to claim 1 further characterized in that the fixation device is formed into a rolled resilient cylinder, said cylinder is inserted in the medullary cavities of the fractured bone ends and permitted to unwind into contact with the cavity walls, and secured by fastening means extending into the cylinder from the external bone surface.

5. A method according to claim 1 further characterized in that:

A. said fracture is a multiple fragmented fracture,

B. a first fixation device is formed into a rolled resilient cylinder, inserted into the medullary cavities of the stable end bone members and permitted to unwind into contact with the cavity walls as a core,

C. bone fragments are packed around the first core cylinder, and

D. a second fixation device is formed into an outer cylinder enveloping the bone fragments and core cylinder.

6. A method according to claim 1 further characterized in that said openwork member is generally rectangular, and at least one of the edges of said member is hemmed by being folded back upon itself prior to being shaped into conformity with the bone surfaces.

7. A device according to claim 6 further characterized in that all of the edges of the member are hemmed.

8. A method according to claim 1 further characterized in that the fracture is a simple fracture and the fixation device is a rectangular strip extending longitudinally along the fractured bone.

9. A method according to claim 1 further characterized in that said device is secured to said bone by truss head screws.

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