

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 December 2006 (21.12.2006)

PCT

(10) International Publication Number
WO 2006/134343 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/GB2006/002158

(22) International Filing Date: 13 June 2006 (13.06.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

0511964.9	13 June 2005 (13.06.2005)	GB
0607302.7	11 April 2006 (11.04.2006)	GB
0607441.3	12 April 2006 (12.04.2006)	GB

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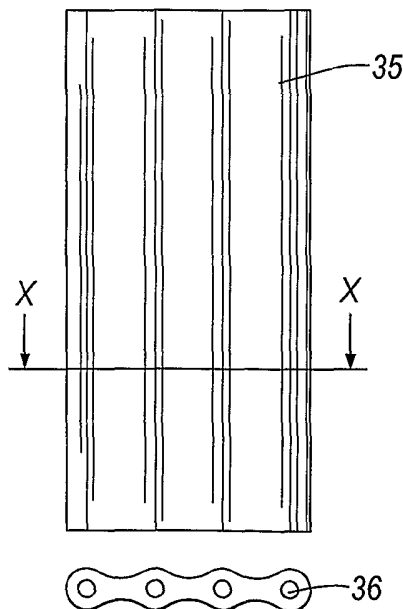
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,

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(54) Title: METHOD AND APPARATUS FOR FIXING BONE FRACTURES



(57) Abstract: Carbon fibre-filled biocompatible thermoplastic is mouldable at 60 °C and rigid at body temperature. A bone fracture fixation system has a plate of the thermoplastic, to go around a fracture site. The mouldable plate can be held in place by removable clips of superelastic material.



RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *without international search report and to be republished upon receipt of that report*

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Method and Apparatus for Fixing Bone Fractures

The present invention relates to fixation of bone fractures in birds, animals and humans including apparatus and method for fixing fractured bones of small animals or birds so they can heal.

It is known to use various devices for fixing bones to maintain their alignment and relative position during the healing process. Fractures of the long bones may be treated by means of internal fixation devices such as pins, plates and screws. These are applied to the broken bones after the fragments have been properly aligned and fixed to maintain that alignment. In fractures of the long bones, pins or nails are sometimes driven along the intramedullary canal to provide good axial alignment. Such devices do not however provide torsional control of the fragments.

More commonly plates are fitted to the periosteal surface of the bone bridging the fracture, providing resistance to torsional, axial and bending forces. Plates are usually made of metal and may be contoured to approximate to the bone surfaces. These are usually fixed in place by screws that pass through holes in the plate and through both the cortices of the bone. A variety of sizes and shapes are required to suit the different bones. They have to have a plurality of holes so that enough holes will occur at suitable sites on both sides of the fracture. Some may be supplied with a degree of contouring and others may be contoured to a limited degree with the use of bending equipment. Metal plates are also known with multiple protruding arms that can be hand-crimped into position around the bone. These can be adapted for use with a range of different sized and shaped bones.

Alternatively, external fixation devices can be used, such as splints, plaster casts and external fixators. With external fixators transfixion pins are screwed into the bone on either side of the fracture site and left protruding through the skin and are then clamped onto a rigid connecting bar outside the body that bears the load.

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A general problem in the field is how to improve bone fixation for humans. Another problem in this field is that there are no good bone fixation materials for small animals or birds. External fixators are in general not suitable for small animals or birds, which tend not to tolerate such devices. Using external fixators has the additional disadvantage that the pins tend to protrude at different angles and a complex series of clamps in combination with a fixator bar is needed to hold the fracture site secure. This applies to use on humans, too.

Biodegradable internal fixing plates are known for human use; but these are generally not used for bones that bear weight. Another problem is that it is impractical to manufacture contoured devices designed for internal use for the wide range of animals, from large dog to small bird, typically treated in a normal veterinary practice. Whilst metal plates can be used for several different sized bones, any crimping required e.g. for the known "Mennen plate" is subject to the insensitivity of the practitioner who may easily crimp the arms too tightly, or not tightly enough.

A further problem with plates is that a large inventory is required to ensure a suitable configuration is available in all cases. Holes where screws are not fitted constitute weaknesses in the device and screws usually prevent the simultaneous use of intramedullary nails. Lastly, bones may be too small or too fragile to accept bone screws, which may create a weakness in the uninjured regions.

An object of the invention is to solve or at least ameliorate the above-identified problems. An object of specific embodiments of the invention is to provide improved fixation of bone fractures.

Accordingly, the present invention provides a method of fixing a bone having a fracture, comprising locating a support member along the bone and extending either side of the fracture; and attaching the support member to the bone using a plurality of clips, at least one clip either side of the fracture.

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It is hence an advantage of the invention that the clips can be separate from and not integral to the support member, which can be a plate or other fixation device that can run longitudinally along a bone, either side of a fracture site, supporting the fracture during healing.

Suitable clips are substantially C-shaped or substantially horseshoe-shaped and comprise one or more teeth to grip the bone. There are usually several teeth, say 2, 3, 4 or even more on each of two arms. The teeth can be designed to bite into the bone, and this gripping holds them in place and by action of the clip on the support member holds that in place. They extend around the bone, partly encircling it, but have to be placed around a bone *in vivo* so do not generally go fully around the bone as it would be harder to fit these during an operation and also harder to remove them in the future after the fracture has healed – preferred clips being separate from the support member and removable. In addition, few materials have the necessary resilience to allow deformation for location fully around a bone and also spring back with sufficient force to hold the plate or support member in situ. Clips are preferably one-piece, preferably without any screws or fasteners or moving parts.

The clips preferably comprise one or more teeth to grip the support member. Generally these are located on an inside or underside of the clip, lying in use against the support member which in turn lies along and preferably against the bone. There are usually several teeth, say 2, 3, 4 or even more. The teeth can be designed to bite into the support member, and this gripping holds them in place with respect to the support member. Action of teeth positioned on arms of the clip in turn holds the unit in situ against and around the bone. The teeth can also be designed to cooperate with the external shape of the support member – thus teeth can fit into grooves or ridges on a bone plate and can but do not need to bite into it.

Clips used in an embodiment of the invention comprise a body, a first arm extending from an upper portion of the body and a second arm extending from a lower portion of the body, the first arm, second arm and body forming a C-shaped or horseshoe-shaped opening wherein the clip can be resiliently deformed between a first position

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in which the opening is enlarged so that the clip fits around the bone and the support member and a second position in which the clip holds the support member onto the bone. In use, a surgeon can flex the clip so that the mouth is large enough to fit over the bone and when the clip is in the right place, relax the flexing, allowing the clip to return towards an unflexed state, gripping onto the bone as it does so. In practice, clips of different sizes are available and if one clip is too small and e.g. even when fully flexed it will not go over the bone another larger clip can be tried. If a clip is too large then when relaxed it will not grip, and a smaller one can be tried. The cross-section of bones can vary along their length, so for fixation of a given fracture bone clips of different sizes can be expected to be needed.

It is preferable for teeth of the bone clip to embed into the bone to a significant degree but not to bury themselves completely.

According to the well known principle of Wolff's Law, bone is laid down where needed and resorbed where not needed. This idea has since been further elaborated by other workers in the field, who have described the phenomenon as a response to strain induced by activity. Bone resorption as a result of low strain is described as disuse osteolysis. A higher than normal strain will result in bone being laid down (osteosynthesis) so as to increase the structure's stiffness and thereby reduce the strain to normal levels. There is a limiting range of strain over which this mechanism is effectuated and bone is not completely resorbed in the absence of strain and resorption rather than osteosynthesis can also be initiated by excessive strain. To illustrate the effect it is observed that pressure on the bark of a tree induced by a supporting tie can result in a progressive resorption of the bark so the tie becomes embedded and subsequent healing of the bark to cover the offending device. In the same way high pressure applied to bone will result in resorption of bone to relieve this pressure to tolerable level with a subsequent healing or remodelling to control the stress distribution.

In the case of the device described in this application, a sharp point on the clip will result in theoretically infinite transient stress and the resultant strain is bound to

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exceed the normal strain levels expected and tolerated by bone. Some resorption will occur, causing embedding of the tapered spike and an increase in area of contact with a commensurate reduction in contact stress until a tolerable level of stress is achieved. Remodelling of bone around these teeth will occur to accommodate the loading that occurs in subsequent activity.

The teeth, therefore, have to be sharp enough to initiate this process but of an included angle that allows equilibrium conditions to be re-established before the elastic strain within the clip has relaxed completely.

Preferably, the teeth are sufficiently sharp that local contact pressure induced in the bone by the elastic strain in the clip is sufficient to cause localised osteolysis and bone resorption.

In preferred embodiments, the teeth have a geometry that, as bone resorption progresses, the contact area increases to reach a level that results in contact stress falling below that which causes resorption, leaving sufficient residual elastic strain in the clip to grip the plate.

The teeth are preferably able to be sufficiently embedded in the bone to provide sufficient resistance to shearing movement so as to secure the clip to the bone.

When considering the strain limits in the clips of the present invention, it is important to consider that stress induced through bending. Stress is induced in a material by the application of a force and is defined as the force applied per unit of cross sectional area of material to which the force is applied. The material deforming elastically in the direction of the applied force causes stress. This deformation is strain, which is defined as the change in dimension as a proportion of the original dimension resulting from the application of a unit of stress. The ratio of the stress and strain is the Young's modulus of the material normally denoted by E. Metals such as Nitinol can be deformed elastically up to a limit (elastic limit) when further deformation is

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irreversible or plastic. When the load is removed the elastic part of the deformation is recovered but the plastic part is not.

When formed into a structure, which is subjected to a deforming force, the material in different areas of the structure are subjected to different degrees of strain. The elastic limit of the structure is reached when the strain at any point reaches the elastic limit of the material from which the structure is composed.

When a beam is bent, the material on the outside of the bend is stretched (put under tension) and that on the inside is compressed. The material near or at the middle of the section does not deform. A line drawn through this zone of no deformation is called the neutral axis. At the neutral axis there is no stress or strain and the material within the plane of bending which is furthest away from the neutral axis is subjected to the greatest stress and strain. The stress and strain is proportional to the distance from the neutral axis and the greater this distance is, the greater is the stiffness (resistance to bending) of the beam.

It follows that a beam that has a greater dimension in the plane of bending is stiffer than one with a smaller but also cannot be bent so far before the elastic limit is reached in the outermost level. Therefore a thinner clip will bend more elastically but will provide a smaller clamping force. Widening the clip adds to clamping force without affecting the amount of deformation that can be achieved elastically.

Thus, clip dimensions can be designed which provide the maximum clamping force commensurate with sufficient opening of the clip.

There are advantages in use of the support and clips of the invention: the clips can be used at different positions along the support according to the location of the fracture and where there is good access to the bone for the clips to grip, thus there is flexibility for the user to position the clips in the best locations. The support member does not need to be provided with existing holes (which would weaken it). The clips can be rapidly located, reducing operating time.

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Various support members can be used with the invention, provided they can support the fracture during healing. An advantage of the clips that grip into the bone is that in combination with the support member they can provide torsional support to the fracture site.

Examples of suitable support members are selected from a bar, a plurality of bars, a plate and a reinforced plate. When a single bar is used, say of metal or alloy, torsional support is less, but the bar can be thin and take advantage of metal strength relative to bone. Bars or rods can be useful in particular for fractures of very small bones, including bird bones and also bones where torsional resistance is not so required. Bars can be grouped together to form a raft, either loose prior to application of the clips or linked into a cohesive unit. A bone plate is particularly suitable for operation of the invention. A plate has a surface that can be gripped by teeth on the clips. A plate can lie flatter against the bone fracture site – which is important for the necessary support during healing. Plates can be made of metal or plastics material or (as for all support members) any other material that is biocompatible.

In a preferred embodiment of the invention, the support member is mouldable. Referring to a specific embodiment of the invention, a bone plate can be used which is mouldable at high temperatures but rigid at patient body temperature. Typically the plate will be mouldable above about 60°C but set hard at 35-40°C. This enables a user to heat the plate e.g. by immersion in hot water, mould the plate in situ onto and around the fracture and then cool the plate by application e.g. of water or saline, setting the plate in situ. Clips can then be applied, and can be applied to a cooling plate. Alternatively, as described below, a mouldable bone plate can be used alone, i.e. without the application of clips or with fixing devices other than clips, e.g. using screws, cerclage ties and/or wires around the bone.

Support members can be reinforced, e.g. with bars or rods or with fibre, e.g. fibre-reinforced thermoplastic.

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Hence a particularly preferred support member comprises a reinforced, mouldable plate which is rigid at body temperature but which can be heated to a temperature at which it can be moulded. The support member can be reinforced with one or more longitudinal bars. The support member can be a reinforced, mouldable plastic. The support member can be a mouldable plastic reinforced with carbon fibre.

Plates can also be prepared with one or more pre-existing holes. Plates can then be attached by a combination of clips and screws, or screws alone. Another option is that, in use, a hole is formed in the plate, e.g. whilst it is heated and soft enough to be moulded. In this way a hole for a screw can be formed at the time of the operation and in the position required, without the plate having to have many pre-existing holes which are not all used. For certain bone fixations, including in humans, the dimensions of the damaged bones are sufficiently similar between different patients that plates are prepared in advance with holes in given positions.

Support members of the invention that contain carbon fibres are not biodegradable. Generally, the life span of a non-human animal is such that biodegradable polymers would outlive the animal anyway. Polycaprolactone filled with glass fibre is biodegradable, and the speed of biodegrading can be varied by varying the polymer and fibre composition. Biodegradable screws are also known and can be used with the invention.

Examples of sizes for plates of the invention are 5mm x 20mm x 50 – 500mm, 4mm x 12mm x 40 – 300mm, 3mm x 10mm x 30 – 150mm, 2mm x 8mm x 20 – 120mm, 1.4mm x 5mm x 6 – 15mm and 1mm x 5mm x 6 – 15mm. Bigger plates are provided for use on bigger bones. Generally, the width of the plate will be approximately one third to two thirds the bone diameter. In use plates can be cut to desired size, and this is conveniently done when plates are of mouldable thermoplastic.

Clips of the invention preferably can flex between wide open positions so they can be put in place and closed, resting or relaxed positions. In holding a plate onto a bone the clips would not return fully to such a position – as they would not provide much grip

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in that case – but would return towards that position. Metals and alloys are generally suitable. Particularly suitable are materials that are superelastic. A preferred clip is made of superelastic metal or alloy.

Clips of the invention can also be designed such that they attach directly onto the bone, and the support member is attached to an external face of the clips. In this way the clips attach the support member to the bone but with the support member outside them.

In more detail, a method of the invention comprises locating the support member along the bone and extending either side of the fracture; selecting a clip to hold the support member in place; flexing the clip so as enlarge the clip mouth and moving the clip into position around the bone and support member; allowing the clip to return towards an un-flexed state, the clip gripping the bone and holding the support member in place. Support is needed either side of the fracture, though the support member need not be located so that equal portions lie either side – there should just be enough for support each side. A surgeon carrying out the method may select different clips according to the size and shape of the bone at any given desired clip location. Generally several clips are used either side of the fracture, so generally at least 4 clips in total, and there can be more.

Another method of the invention comprises selecting a clip to hold the support member in place; flexing the clip so as enlarge the clip mouth and moving the clip into position around the bone; allowing the clip to return towards an un-flexed state, the clip gripping the bone and being held in place; repeating these steps with at least one further clip so that there are a plurality of clips in place; locating the support member along the bone, extending either side of the fracture and over the clips; attaching the support member to the clips, the clips thus holding the support member in place.

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The plate plus clips are optionally left in situ thereafter. It is also optional for the clips or plate plus clips to be removed after healing. It is optional for just the clips to be removed.

Some fractures are not clean breaks but result in an area where there are bone fragments or other pieces of bone that should be tied in. Prior to applying the mouldable plate, it is an option for the surgeon to tie in a fragment of bone to a fracture site. This is conveniently done using a clip of the invention. After this, the plate can be moulded over the clip (or clips if more than one is needed) hardened and attached to the bone with further clips. The mouldability of the plate of embodiments of the invention hence gives a further advantage.

The invention also provides a clip as described above for use in the invention. The clip is for holding a support member along a bone having a fracture as described. Hence, the clips are preferably substantially C-shaped or substantially horseshoe-shaped and comprise one or more teeth to grip the bone, with optionally one or more teeth to grip the support member. Particular clips comprise a body, a first arm extending from an upper portion of the body and a second arm extending from a lower portion of the body, the first arm, second arm and body forming a C-shaped or horseshoe-shaped opening wherein the clip can be resiliently deformed between a first position in which the opening is enlarged so that the clip fits around the bone and the support member and a second position in which the clip holds the support member onto the bone. Preferred clips are made of a superelastic material. Further features of preferred clips are as described elsewhere herein.

To enable positioning and other manipulation of a clip during a method of the invention, there is further provided a clip tool, adapted for location of a clip of the invention in situ to hold a support member onto a bone. A particular clip tool is described in more detail below in use for locating a clip around a bone so as to hold a support member in place along the bone, the clip having a body, a first arm extending from an upper portion of the body and a second arm extending from a lower portion of the body, the body, first arm and second arm forming a substantially C-shaped or

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horseshoe-shaped clip with an opening or mouth, wherein the clip tool comprises upper and lower jaws that engage respective upper and lower arms of the clip and which jaws can be moved apart so as to move apart the respective upper and lower arms so as to enlarge the clip mouth.

Suitably, there are hinged upper and lower jaws moveable between a first position in which the clip can be placed into or released from the jaws and a second position in which the clip is flexed to open the clip mouth so that the clip can be located around a bone. The clip tool can have upper and lower jaws which each comprise at their distal ends first and second fingers joined at their tip by a joining bar, forming a hook which engages respective catches on upper and lower arms of the clip. In use, a surgeon can hold the tool in the first position and locate a clip in the jaws, moving it such that projections on the clip arms, which can be ends of the arms or separate projections, engage with the hooks, so that action to urge apart the jaws acts to urge apart the arms of the clip. The hooks and projections may also be reversed – i.e. the hooks can be on the clip – but this can lead to the clip having portions which stick out and into flesh or tissue post operation. The surgeon operates the tool, urging the jaws apart to open the clip, locates the clip and closes the jaws to attach the clip. The jaws are closed a little further and the tool can be removed, leaving the clip in place. Alternatively, the surgeon pushes down on the clip, the hooks of the tool slide out of engagement with the projections on the clip and the tool jaws can be opened to withdraw the tool.

As a safety feature, tools for their respective clips – different sized tools typically being needed for different sized clips – are such that when the clip tool is fully opened the clip is not deformed beyond its superelastic limit. This has the advantage that clips are not damaged in use. Also, the likelihood of using the correct sized clip increases as a wrong size clip can not be pushed beyond its limit by operator error.

In another embodiment, a disposable tool is provided loaded with a clip. This tool does not have to include the specific features of other tools, though typically it will comprise jaws which engage respective ends of the clip and can hold the clip in a flexed, open position. In use the surgeon selects this from a rack of such tools,

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applies the clip and then disposes of the (now empty) tool. Tools of plastic are suitable for this. A rack of many tools having a clip in each can be provided e.g. as part of surgery apparatus.

A surgical kit is also provided, comprising a clip tool according to the invention and at least one clip according to the invention. Preferably a kit comprises a tool plus a plurality of clips, especially at least 4. More preferably a kit comprises a plurality of tools of different sizes with a corresponding plurality of clips. In addition, the kit can include one or more support members, optionally of different sizes and/or types, as described throughout herein.

A bone fracture support member of the invention and for use in the invention is provided, made of mouldable, thermoplastic which is rigid at body temperature and which can be moulded at a temperature above 60°C. In an example of the invention, near boiling water is used to heat the thermoplastic which is mouldable at a temperature of about 80°C. Reference to body temperature is to that generally of mammals and birds, the invention in all aspects being suitable for application to animals, including humans, and birds, including small animals and birds. The support member can be made mouldable by use of heat and then moulded around a fracture site longitudinally the length of the bone and also partly or fully around the bone. Generally, the support member will wrap around the bone to a varying degree, depending upon the human, animal or bird being treated and the type of support member. A rod or a plurality of rods or a raft of rods will typically lie alongside the bone, rather than wrap around the bone. A plate will typically be wrapped around the bone, encircling at least say one third of the bone, preferably at least one half and conveniently more, even up to two-thirds. Whilst there is no technical difficulty in making plates which will entirely encircle a bone, these are harder to fit in an operation and that degree of encirclement goes beyond the support needed.

Preferred support members comprise a reinforced thermoplastic, more preferably reinforced with fibre, optionally carbon fibre.

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Other support members are reinforced with one or more longitudinal bars made of metal or alloy. The bars are suitably titanium or stainless steel.

In another aspect there is provided an internal fracture support member, for location inside a fractured bone. This is made of mouldable thermoplastic, rigid at body temperature and soft enough when heated to be moulded. In one use of this aspect, a bar of the polymer is heated to make it soft. It is then flexed so that, whilst still soft, one end can be pushed into the lumen of a bone one side of the fracture and again whilst still soft the other end can be pushed into the lumen of the bone on the other side of the fracture. The bone is then set, e.g. straightened, which in turn straightens (at least partially) the support member in situ, inside the bone. The bar cools and hardens, providing support to the fracture. Screws can then be driven through the bone and into the now internal bar to fix the fracture. A support member of the invention can then be attached externally with or without the use of clips, as described elsewhere herein. Prior to pushing in the bar, the lumen can be enlarged or cleared e.g. using a tool to provide space for the bar.

Still further provided by the invention is a new material, namely, a carbon fibre – filled mouldable thermoplastic. This preferably comprises polycaprolactone, with suitably from 5-80% weight carbon fibres. In a specific embodiment, the invention provides carbon fibre – filled polycaprolactone.

Filled polycaprolactone containing carbon fibres can be prepared by known methods. In a typical method, polycaprolactone from a commercial source is melted and poured over a mat of carbon fibres, suitably at from 5 to 80% more suitably to 50%, preferably 10 to 40% by weight, which are hence incorporated into the reinforced polymer matrix. The carbon fibres can be a mixture of short and/or long fibres. Fibres can be woven for increased strength e.g. to resist torsional, axial and/or bending forces, especially at +/- 45 degrees. A specific polymer for use in the invention can be prepared in accordance with the methods disclosed in US-A-20040054372, the contents of which is incorporated herein, using carbon fibres instead of glass fibres.

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The carbon fibre – filled mouldable thermoplastic is preferably built up from laminated layers of carbon fibre mat. Each mat preferably has fibres running in two directions, further preferably at right angles to each other, for example, longitudinal and horizontal. Every second layer is preferably laid at about 45 degrees to the layer below. In other words, fibres in the first layer preferably run longitudinal and horizontal, in the second layer the fibres preferably run at about 45 degrees in both directions in relation to the first layer, in the third layer the fibres preferably run in substantially the same direction as the first layer, and in the fourth layer the fibres are again preferably at about 45 degrees, and so on. This pattern has been shown to be particularly effective, however, it will be envisaged that other patterns may be suitable. In particular, the carbon fibre – filled mouldable thermoplastic could be built up from carbon fibre mat having more horizontal and longitudinal layers, or more about 45 degree layers, or no about 45 degree fibres.

As detailed above, the polymer is preferably polycaprolactone. However, other suitable alternatives may be used, for example biocompatible polyethylene or nylon. Use of these polymers will result in a higher softening temperature and will be cheaper to manufacture.

In preferred embodiments, the bone fracture support member comprises up to twelve layers or more of carbon fibre mat, preferably between 5 and 7 layers of carbon fibre mat. The number of layers used depends upon the size of the support member required. In this connection, more layers will be used for larger, stronger support members and maybe fewer layers for smaller support members.

In preferred embodiments, the strength of the carbon fibre – filled thermoplastic is tailored to the required strength of its application. For example, if the carbon fibre – filled thermoplastic is to be used in a bone plate for a fractured bone which would normally bear a high weight, the carbon fibre – filled thermoplastic will be provided with a greater strength than that required for a fractured bone which would normally bear a low weight.

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In general, the carbon fibre – filled thermoplastic preferably has a longitudinal strength of about 50 to 90 GPa, more preferably about 70 GPa.

Preferably, the carbon fibre – filled thermoplastic has a minimum lateral strength of about 20 to 40 GPa, more preferably about 30 GPa.

Preferably, the carbon fibre – filled thermoplastic has a shear strength of about 20 to 40 GPa, more preferably about 30 GPa.

Preferably, the carbon fibre – filled thermoplastic has a minimum ultimate tensile strength (UTS) of about 130 to 170 MPa, more preferably about 150 MPa.

Preferably, the carbon fibre – filled thermoplastic has a minimum fatigue strength of about 120 to 160 MPa, more preferably about 140 MPa.

Preferably, a support member comprising the carbon fibre – filled thermoplastic has a minimum bending stiffness about 1 to 5Nm per degree of movement, more preferably about 2Nm per degree of movement.

Preferably, a support member comprising the carbon fibre – filled thermoplastic has a fatigue strength of about 1 million cycles bending at a minimum of about 6Nm.

Preferably, a support member comprising the carbon fibre – filled thermoplastic has a strength sufficient to allow about a 20 to 40 degree bend, more preferably a 30 degree bend, in the plane of the minimum section of the support member.

Preferably, a support member comprising the carbon fibre – filled thermoplastic has a strength sufficient to allow about a 20 to 40 degree twist, more preferably a 30 degree twist, over a length of 10mm along the longitudinal axis of the support member.

The above discussed strength parameters are preferably achieved at below about 40°C and about 100% humidity in physiological saline.

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Preferably, the carbon fibre – filled thermoplastic is manually bendable at below about 100 °C.

Preferably, the carbon fibre – filled thermoplastic is manually bendable at between about 50°C and about 100°C.

The support member preferably comprises a cross sectional profile to suit the bone on which it is to be used. For example, a cat femur support member preferably has a cross sectional profile to fit a 7mm diameter circle.

Preferably, the support member comprises screw holes.

Preferably the support member is substantially straight. Alternatively, the support member comprises a pre-determined shape for fitting the shape of a specific bone. For example, a support member for the canine humerus will be S –shaped. Other bones that could have a shaped plate are the radius, the distal femur and the mandible. It is also envisaged that the support member can be moulded into the correct shape immediately prior to placement around a fracture site.

In preferred embodiments of the present invention, the thickness of the support member is tailored to the weight of the animal and the bone that is fractured. For example, in typical domestic veterinary use, a preferred thickness is between 1mm and 5mm. However, for larger animals, for example an exotic animal (say in a zoo) the support member may have a thickness of up to 10mm or more.

The width of the support member is preferably tailored to the size of the bone having a fracture. For example, in typical domestic veterinary use, a preferred width is between 1mm and 12mm. However, for larger animals, for example an exotic animal (say in a zoo) the support member may have a width of up to 40mm or more.

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The length of the support member is preferably tailored to the length of the fractured bone and the fracture. In preferred embodiments, the support member is provided at a standard length and can then be cut to size by a surgeon.

As described herein, bone plates comprising the support member of the present invention can be softened to a point where the plate can be manually shaped to the contours of the fractured bone. Then when it cools to body temperature (37-41 degrees C) the plate regains its strength and stiffness.

Methods of softening the plate preferably include by electricity conducted along the carbon fibres, e.g. with electrodes attached to each end of the plate and connected to a diathermy machine, by hot water, by hot air, or by other methods known in the art.

The fibres in the carbon mat are preferably prepared by burning off their proprietary coating in preparation of a wetting out process. This 'wetting out' of the fibres is a chemical process well known in the art. The support member may be prepared using compression moulding.

Alternative methods of manufacture may also be used and may depend upon the amount of support member to be produced. For example, when it comes to bulk manufacture, the 'wetting out' process may be modified, or an alternative method used, and compression moulding may be replaced by another method such as pultrusion, which is cheaper than compression moulding.

Further, different methods of manufacture may preferably be used depending upon the nature of the bone plate being produced. For example, pultrusion may preferably be used for straight plates, with another method such as compression moulding preferably used for shaped plates.

As described herein, the plates of the present invention are preferably attached to a fractured bone by clips, screws, ties, wires, or a combination of two or more.

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Alternatively, the bone plates of the present invention may be used alone, i.e. without the use of clips, screws, ties or wires, for supporting bone fractures.

According to an aspect of the present invention, there is, therefore, provided a method of fixing a bone having a fracture, comprising:-

- identifying the bone,
- aligning the bone in a fixing position,
- applying to the bone in the fixing position a thermoplastic, wherein the thermoplastic is biocompatible and in a mouldable state,
- moulding the thermoplastic around the fracture,
- cooling the thermoplastic to render it rigid, and
- fixing the thermoplastic to and/or around the bone.

In use of an example of the invention, the bone is identified and a bone plate of suitable dimension, made of the thermoplastic, selected. If no suitably sized plate is available then a larger plate can be cut down to size. It is hence not necessary to provide to the surgeon a large inventory of differently sized plates. Instead, a larger section of the thermoplastic can be cut once the size of the plate needed for the particular fracture is known, and this can be done during the course of an operation. The thermoplastic is applied to the bone, around the fracture, in a mouldable state. Typically, the thermoplastic is heated during the operation, or it can be heated prior to the operation and then maintained in a mouldable state. The thermoplastic may cool to some extent during handling and whilst it is being positioned and moulded in situ. However, the thermoplastics, once heated to a temperature at which they can be moulded, will retain mouldability as their temperature decreases. If the temperature drops such that the thermoplastic can no longer be moulded then the thermoplastic can be removed from the fracture site, reheated to increase the mouldability, for example using hot water, and then re-applied to the fracture site so the surgeon can complete the process of locating the moulded plate around the fracture. The thermoplastic plate once correctly positioned can be allowed to cool or can actively be cooled, for example using a cooling liquid such as water or saline solution or other

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solution suitable for use during surgery. The plate then becomes rigid and is rigid and sufficiently strong to support the bone at body temperature. The plate can be fixed to the bone using screws and/or clips and/or other fixing devices.

The invention also provides a bone fixation plate comprising a plurality of screw holes, wherein the plate is made of mouldable, biocompatible thermoplastic, optionally reinforced.

Hence the invention specifically provides a new material for veterinary and human use – e.g. polycaprolactone, reinforced with carbon fibres - and a new means of fixing bones using:-

- (1) polymer plate reinforced with fibre, optionally held in place with clips,
- (2) polymer plate reinforced with rods, optionally held in place with clips.

The invention thus provides a new material for use in the veterinary field, exemplified as a carbon-fibre-reinforced mouldable, biocompatible polymer. It can be used in a bone plate held in place by bone clips, screws, ties and/or wires, or by the moulded shape of the plate alone.

The plates may be combined with other methods of fixation to strengthen the fixation, for example, combined with an intramedullary pin or intramedullary biocompatible composite rod, or with an external fixator. The plates have the potential to be used on any fracture and provide a more accurate plating system, particularly with plates shaped for specific bones, which is quicker to apply, lighter than metal plates and is radiolucent.

According to a further aspect of the present invention, there is provided use of a thermoplastic, mouldable, biocompatible polymer in manufacture of a bone fixation plate.

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According to another aspect of the present invention, there is provided use of a thermoplastic, mouldable, biocompatible polymer in the manufacture of an intramedullary support member.

In another aspect of the present invention there is provided a bone fracture support member adapted for insertion into the intramedullary canal of a fractured bone.

There is also provided an intramedullary support member comprising the thermoplastic as detailed above.

A particular material for clips on the invention is Nitinol (more correctly, NiTiNOL or NiTinol), the name for the family of shape memory alloys (SMAs) which contain a nearly equal mixture of nickel (about 55 wt. %) and titanium. Nitinol is an acronym for "Nickel Titanium Naval Ordnance Laboratory," after where its shape-memory behaviour was discovered.

Nitinol displays two distinct crystal structures in the solid phase – martensite and austenite. The martensite is the "soft" phase, and the austenite is the rigid phase. The particular crystal structure that Nitinol possesses at any given time depends on its temperature and the amount of force (stress) to which it is being subjected. Because the transformations between crystal structure occur over temperature ranges, scientists use the following naming conventions:

As = austenite start temperature (where Nitinol starts transforming to austenite during heating)

Af = austenite finish temperature (where Nitinol has finished transforming to austenite during heating)

Ms = martensite start temperature (where Nitinol starts transforming to martensite during cooling)

Mf = martensite finish temperature (where Nitinol has finished transforming to martensite during cooling)

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Martensite exists at lower temperatures and is the phase in which Nitinol can be easily deformed into any shape. As long as the temperature does not change, Nitinol will remain deformed. When Nitinol is heated, it transforms into the austenite phase, where it “remembers” the shape it had before it was deformed. In the austenite phase, Nitinol is rigid and does not deform easily.

Nitinol’s ability to spring back after being deformed in the austenite phase - its superelastic property is about 10 times greater than that of stainless steel. Said differently, Nitinol can be bent more than stainless steel without permanent damage. This property exists within the superelastic limit which is generally for deformations producing a level of strain of up to about 8% within the material. Beyond this limit deformations become at least partially permanent.

For the present invention, metals and alloys having superelastic properties are preferred. These may also have shape memory metal properties, but these are not necessary for the invention. The composition of the alloys or metals is preferably chosen such that the superelastic property is exhibited at body temperature, in some case this varying from the animal or bird to be treated.

There now follows a detailed description of specific embodiments of the invention illustrated by the accompanying drawings in which:

Fig. 1 shows a side view of a clip;

Fig. 2 shows a view from the front of a clip on its own and a similar clip inside a clip tool, the clip being in a flexed, open position;

Fig. 3 shows another clip on its own and a clip located in a clip tool in a non-flexed position;

Fig. 4 shows a view from above and the front of a clip tool with a clip inside;

Fig. 5 shows a view of a clip tool being used to locate a clip around a bone;

Fig. 6 shows a view of clips and rods illustrating a use of the invention;

Fig. 7 shows a schematic view of a plate of the invention and a cross-section thereof;
and

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Fig. 8 shows schematic views of a support member held in place on a bone by clips.

Parts List

1. Clip
2. Body
- 2a Upper portion
- 2b Lower portion
3. First arm
4. Second arm
5. Mouth of clip
6. Inside edge
7. Teeth
8. Inside of first arm
9. Teeth
10. Inside of second arm
11. Teeth
- 12, 13 Catch
20. Clip tool
21. Upper jaw
22. Lower jaw
23. Hinge
24. Upper handle
25. Lower handle
- 26, 27 Hook
28. Tool mouth
29. Finger
30. Finger
31. Joining bar
32. Bone
33. Length of wood
34. Break
35. Bone plate
36. Bar

Referring to Fig. 1, a clip 1 made of Nitinol has a middle body 2 with upper portion 2a and lower portion 2b. A first arm 3 extends from the lower body portion and a second arm 4 extends from the upper body portion forming clip mouth 5. Located on an inside edge 6 of the body 2 are teeth 7. Located on respective inside edges 8 and 10 of the first and second arms are teeth 9 and 11. At the distal ends of the first and second arms 3 and 4 are respective first arm catch 12 and second arm catch 13.

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Referring to figures 2-7, whilst these show a clip according to an alternative embodiment of the invention, for convenience the same numbering system is used.

An un-flexed clip 1 is shown at the bottom of fig. 2. Above it is a clip tool 20 which has been loaded with a clip 1 in a flexed, open position. The tool 20 has an upper jaw 21, a lower jaw 22 and a hinge 23, allowing pivoting of the upper and lower jaws so as to open and close the mouth of the clip. An operator holds the tool using upper handle 24 and lower handle 25. Each jaw is divided into respective fingers 29 and 30, joined at their distal ends by a joining bar 31 forming a hook portion 26 or 27.

It is seen that, comparing fig. 2 and fig. 3, the tool in fig. 2 is in a position which holds the clip open, as the hooks 27 of the tool engage the catches 12 and 13 of the clip, the upper and lower handles 24, 25 being held together. The extent of opening of the mouth 5 is limited by the handles being brought together, this preventing over flexing of the clip beyond its superelastic limit. In fig. 3, the upper and lower handles 24, 25 are spaced apart, and the clip is in an un-flexed position, and can be released from the tool by pushing it towards the hinge, at which point catches 12 and 13 no longer engage on the hooks 26 and 27. The upper and lower handles can then be closed whilst not engaging the clip and the clip can then be removed from the front of the jaws.

Fig. 4 shows in more detail how the fingers 29 and 30 surround the clip and enable it to be engaged with hooks on the jaws. In fig. 5, a clip is shown being located around bone 32. This figure is for illustration only. In use, a support or reinforcing member would be located along the length of the bone so that it can be held in place by the clips.

Fig. 6 illustrates an embodiment of the invention in which support for a fracture is provided by four longitudinal bars 31 held to a length of wood 33 (used to represent a bone) by a plurality of clips, the clips being spaced either side of a break 34 in the wood.

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A plate 35 is shown schematically in fig. 7. The cross-section on x-x shows reinforcing metal rods 35 longitudinally arranged inside the plate.

In use of plate plus clips of the invention, the plate is separate from the clips for fixation of a fracture, avoiding e.g. the hand crimping of known devices. Superelastic clips are used to retain the plate in situ, and are designed to fit over the contours of the bone plate (if reinforced with rods). Clips are contoured to fit the bone plate (when fibre-reinforced). Teeth on the body of the clips mean the clips don't slide along the plate. Clips have teeth on their arms to grip the bone and hold the plate in situ.

Referring to figure 8, which uses the same number scheme as previous figures, there is shown a support member 31 held in place along a bone 32 having fracture 34 by four clips 1 of the invention to illustrate the invention in use. Whilst only four clips are shown more can be used in practice. Teeth 9, 11 grip the bone to lesser and greater degrees according to the respective positions of the clip and the particular geometry of the bone at that point. Views a – d show cross-sections on the four clips along the bone. Views e – I are, respectively, anterior, antero-lateral, posterior and two straight plate views.

Example I: Protocol for bone fixation (using bone plate and clips)

Equipment required

- Bone plate
- Clips
- Clip tool(s)
- Boiling water in a sterile container such as a kidney dish.
- Heating electrodes and a diathermy machine (if desired)
- Routine instruments for orthopaedic surgery

Select a bone plate that is appropriate for the fractured bone and the load it is likely to carry. Select a plate that is at least two thirds the width of the bone to which it is being applied.

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Assess whether, after alignment of the fractured bone ends, the bone is likely to take some of the load immediately post surgery.

- If the bone plate is expected to take the entire load, select a plate with maximum thickness and reinforcement for the appropriate plate width.
- Select superelastic clips appropriate to the bone width and plate reinforcement. Plates reinforced with metal rods require a different clip shape than those with carbon fibre reinforced plates.

Surgery

- Use routine exposure techniques to visualise the fracture site.
- Apply traction to co-apt the fractured bone ends and orientate the proximal and distal joints in correct alignment.
- Secure the fractured bone in this correct position with clamps, a bone distractor, or with manual help.
- Select appropriate plate for the fracture.
- Cut the plate with scissors or a plate cutter to the required length.
- Decide where clips are to be applied to the bone. Aim for at least three clips into normal bone each side of the fracture site.
- Measure the bone width at these points and select the appropriate clip for that width and for the type of bone plate.
- If the surgeon thinks extra support will be needed for the clip plate in the form of an intramedullary pin or nail, this should be inserted before the plate and clips are applied.
- Or bone clips may be placed onto the bone, before the plate is applied, to tie in bone fragments at the fracture site to give extra support
- Place the bone plate into hot water until it is mouldable, and/or heat the bone using electrodes.

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- Remove the plate from the water and let it cool until it is comfortable to handle. Then place the plate along the fractured bone in the appropriate position and mould it to the bone surface.
- With a clip in the clip tool, expand the clip to no more than 8% of its width. The tool prevents expansion further than 8%.
- Place the clip over the bone plate and bone at the predetermined site.
- Push down on the clip with the tool to engage the bone plate and sides of the bone.
- Once the clip is fully seated on the plate and bone, relax and release the tool from the clip, whereupon the tool can be withdrawn.
- Place all the clips on their predetermined sites.
- Cool the composite plate with cool saline so the plate becomes firm.
- Test if the secured plate is giving adequate support. If required, add more clips and / or consider adding other support systems such as an external fixator.
- Close the fracture site in a routine fashion.
- After the bone heals, the plate and clips may be removed at the surgeon's discretion.

Example II: Protocol for bone fixation (using bone plate without clips)

Equipment required

- Bone plate
- Boiling water in a sterile container such as a kidney dish.
- Heating electrodes and a diathermy machine (if desired)
- Routine instruments for orthopaedic surgery

Select a bone plate that is appropriate for the fractured bone and the load it is likely to carry. Select a plate that is at least two thirds the width of the bone to which it is being applied.

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Assess whether, after alignment of the fractured bone ends, the bone is likely to take some of the load immediately post surgery.

- If the bone plate is expected to take the entire load, select a plate with maximum thickness and reinforcement for the appropriate plate width.

Surgery

- Use routine exposure techniques to visualise the fracture site.
- Apply traction to co-apt the fractured bone ends and orientate the proximal and distal joints in correct alignment.
- Secure the fractured bone in this correct position with clamps, a bone distractor, or with manual help.
- Select appropriate plate for the fracture.
- Cut the plate with scissors or a plate cutter to the required length.
- If the surgeon thinks extra support will be needed for the plate in the form of an intramedullary pin or nail, this should be inserted before the plate is applied.
- Place the bone plate into hot water until it is mouldable, and/or heat the bone plate using electrodes.
- Remove the plate from the water and let it cool until it is comfortable to handle. Then place the plate along the fractured bone in the appropriate position and mould it to the bone surface.
- Cool the composite plate with cool saline so the plate becomes firm.
- Test if the secured plate is giving adequate support. If required, consider adding other support systems such as an external fixator.
- Close the fracture site in a routine fashion.
- After the bone heals, the plate may be removed at the surgeon's discretion.

Methods and apparatus for human, animal and bird bone fixation are hence provided.

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CLAIMS

1. Carbon fibre – filled mouldable biocompatible thermoplastic.
2. A thermoplastic according to claim 1, comprising polycaprolactone.
3. A thermoplastic according to claim 1 or 2 comprising from 5-80% by weight carbon fibres.
4. A thermoplastic according to claim 3 comprising 5-50% by weight carbon fibres.
5. A thermoplastic according to any of claims 1 to 4 comprising one or more layers of carbon fibre mat.
6. A thermoplastic according to claim 5, wherein the carbon fibre mat comprises fibres running in at least two different directions.
7. A thermoplastic according to claim 6, comprising two or more layers of carbon fibre mat, wherein the fibres of at least one layer lie in different directions to the fibres of at least one other layer.
8. Carbon fibre – filled polycaprolactone, rigid at body temperature and mouldable at 60°C.
9. A bone fracture support member, made of mouldable, biocompatible thermoplastic which is rigid at body temperature and which can be moulded at a temperature above 60°C.
10. A support member according to claim 9, comprising a reinforced thermoplastic.

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11. A support member according to claim 10, reinforced with fibre.
12. A support member according claim 11, reinforced with carbon fibre.
13. A support member according to any of claims 9 to 12, reinforced with one or more longitudinal bars made of metal or alloy.
14. A support member according to claim 13 comprising bars of titanium or stainless steel.
15. A bone fracture support member according to any of claims 9 to 14 adapted for insertion into the intramedullary canal of a fractured bone.
16. An intramedullary support member comprising a thermoplastic according to any of claims 1 to 8.
17. A clip for holding a support member along a bone having a fracture.
18. A clip according to claim 17, wherein the clips are substantially C-shaped or substantially horseshoe-shaped and comprise one or more teeth to grip the bone.
19. A clip according to claim 17 or 18, wherein the clips comprise one or more teeth to grip the support member.
20. A clip according to any of claims 17 to 19, wherein the clips comprise a body, a first arm extending from an upper portion of the body and a second arm extending from a lower portion of the body, the first arm, second arm and body forming a C-shaped or horseshoe-shaped opening wherein the clip can be resiliently deformed between a first position in which the opening is enlarged so that the clip fits around the bone and the support member and a second position in which the clip holds the support member onto the bone.

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21. A clip according to any of claims 17 to 20, wherein the clip is made of a superelastic material.

22. A clip tool for locating a clip around a bone so as to hold a support member in place along the bone, the clip having a body, a first arm extending from an upper portion of the body and a second arm extending from a lower portion of the body, the body, first arm and second arm forming a substantially C-shaped or horseshoe-shaped clip with an opening,

wherein the clip tool comprises upper and lower jaws that engage respective upper and lower arms of the clip and which jaws can be moved apart so as to move apart the respective upper and lower arms so as to enlarge the clip mouth.

23. A clip tool according to claim 22, comprising hinged upper and lower jaws moveable between a first position in which the clip can be placed into or released from the jaws and a second position in which the clip is flexed to open the clip mouth so that the clip can be located around a bone.

24. A clip tool according to claims 22 or 23 wherein the upper and lower jaws each comprise at their distal ends first and second fingers joined at their tip by a joining bar, forming a hook which engages respective catches on upper and lower arms of the clip.

25. A clip tool according to any of claims 22 to 24 adapted for use with a clip such that when the clip tool is fully opened the clip is not deformed beyond its superelastic limit.

26. A surgical kit, comprising a clip tool according to any of claims 22 to 25 and at least one clip according to any of claims 17 to 21.

27. A kit according to claim 26, comprising a support member.

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28. A kit according to claim 27, comprising a support member according to any of claims 9 to 14.
29. A method of fixing a bone having a fracture, comprising:-
 locating a support member along the bone and extending either side of the fracture;
 attaching the support member to the bone using a plurality of clips, at least one clip either side of the fracture.
30. A method according to claim 29 wherein the clips are substantially C-shaped or substantially horseshoe-shaped and comprise one or more teeth to grip the bone.
31. A method according to claim 30 wherein the clips comprise one or more teeth to grip the support member.
32. A method according to any of claims 29 to 31 wherein the clips comprise a body, a first arm extending from an upper portion of the body and a second arm extending from a lower portion of the body, the first arm, second arm and body forming a C-shaped or horseshoe-shaped opening wherein the clip can be resiliently deformed between a first position in which the opening is enlarged so that the clip fits around the bone and the support member and a second position in which the clip holds the support member onto the bone.
33. A method according to any of claims 29 to 32 wherein the support member is selected from a bar, a plurality of bars, a plate and a reinforced plate.
34. A method according to claim 33 wherein the support member is mouldable.
35. A method according to claim 33 or 34 wherein the support member comprises a reinforced, mouldable plate which is rigid at body temperature but which can be heated to a temperature at which it can be moulded.

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36. A method according to claim 35 wherein the support member is reinforced with one or more longitudinal bars.

37. A method according to claim 36 wherein the support member is a reinforced, mouldable plastic.

38. A method according to claim 37 wherein the support member is a mouldable plastic reinforced with carbon fibre.

39. A method according to any of claims 29 to 38 wherein the clip is made of a superelastic material.

40. A method according to any of claims 29 to 39 comprising:-

- locating the support member along the bone and extending either side of the fracture;
- selecting a clip to hold the support member in place;
- flexing the clip so as to enlarge the clip mouth and moving the clip into position around the bone and support member;
- allowing the clip to return towards an un-flexed state, the clip gripping the bone and holding the support member in place.

41. A method of fixing a bone having a fracture, comprising:-

- identifying the bone and fracture;
- aligning the bone in a fixing position;
- applying to the bone a mouldable support member;
- moulding the support member at least partially around the fracture; and
- cooling the support member to render it rigid and supportive of the bone.

42. A method according to claim 41, wherein the support member is selected from a support member according to any of claims 9 to 14.

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43. A method according to claim 41 or 42, wherein the mouldable support member is fixed to the bone using screws, cerclage ties and/or wires.

44. Use of a clip according to any of claims 17 to 21 in holding a support member to a bone.

45. Use of a support member according to any of claims 9 to 14 in bone fracture fixation.

46. Use of a thermoplastic, mouldable, biocompatible polymer in the manufacture of a bone fixation plate.

47. Use of a thermoplastic, mouldable, biocompatible polymer in the manufacture of an intramedullary support member.

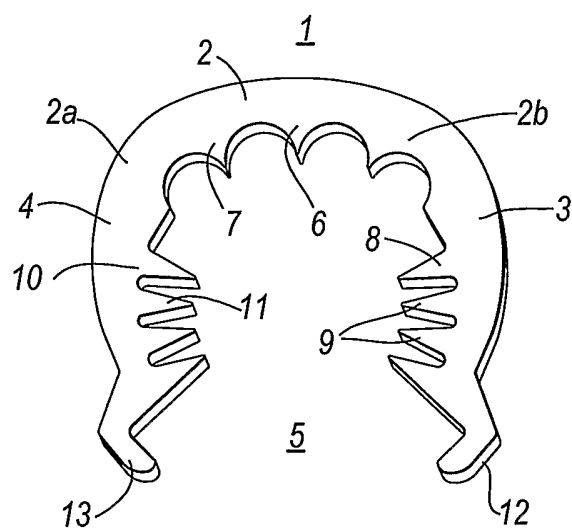


Fig.1

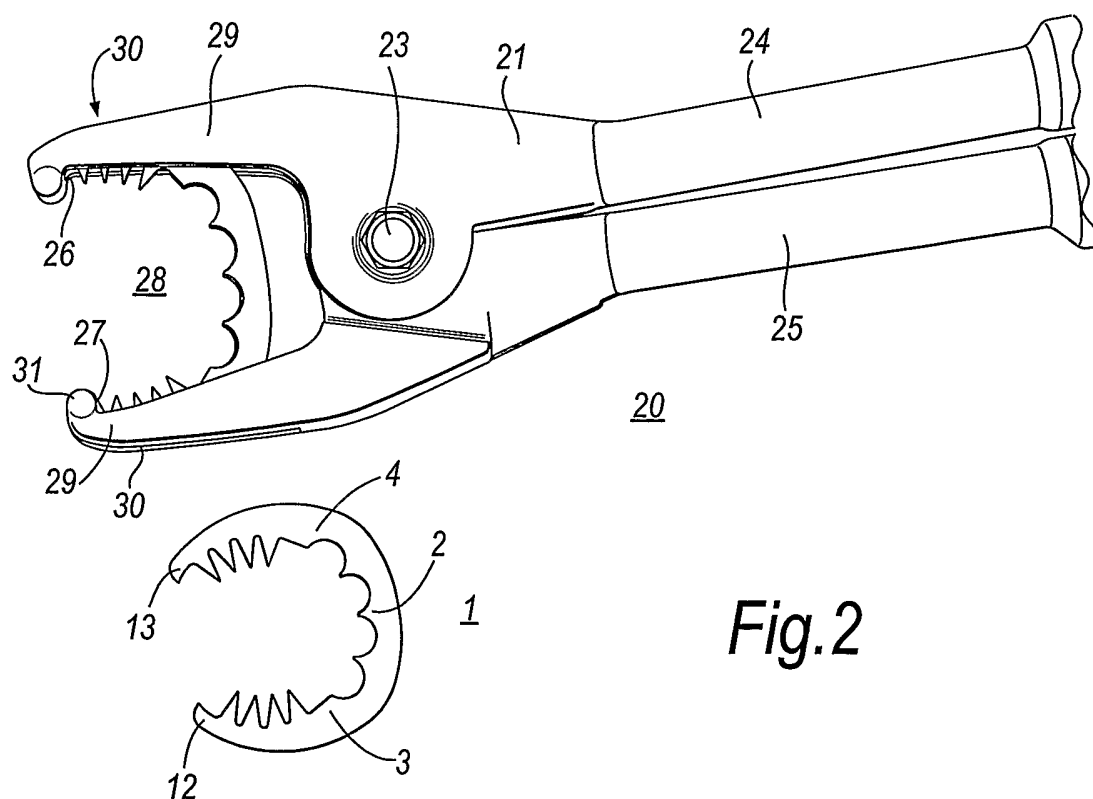


Fig.2

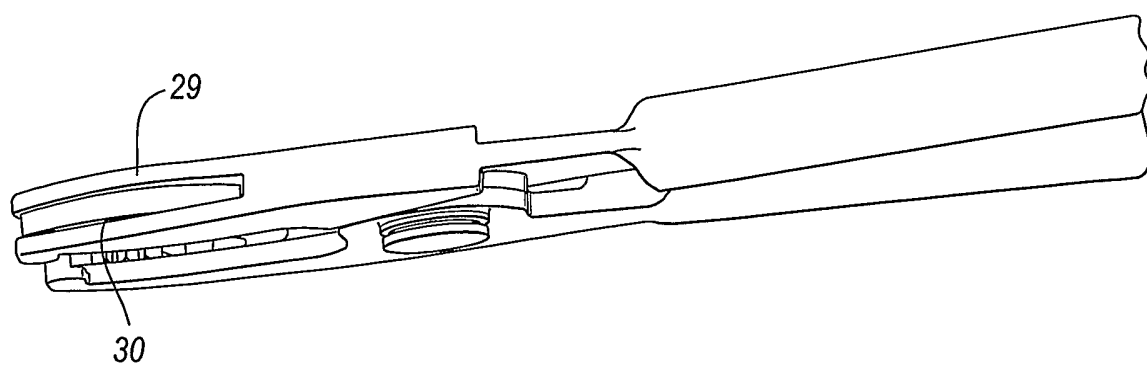
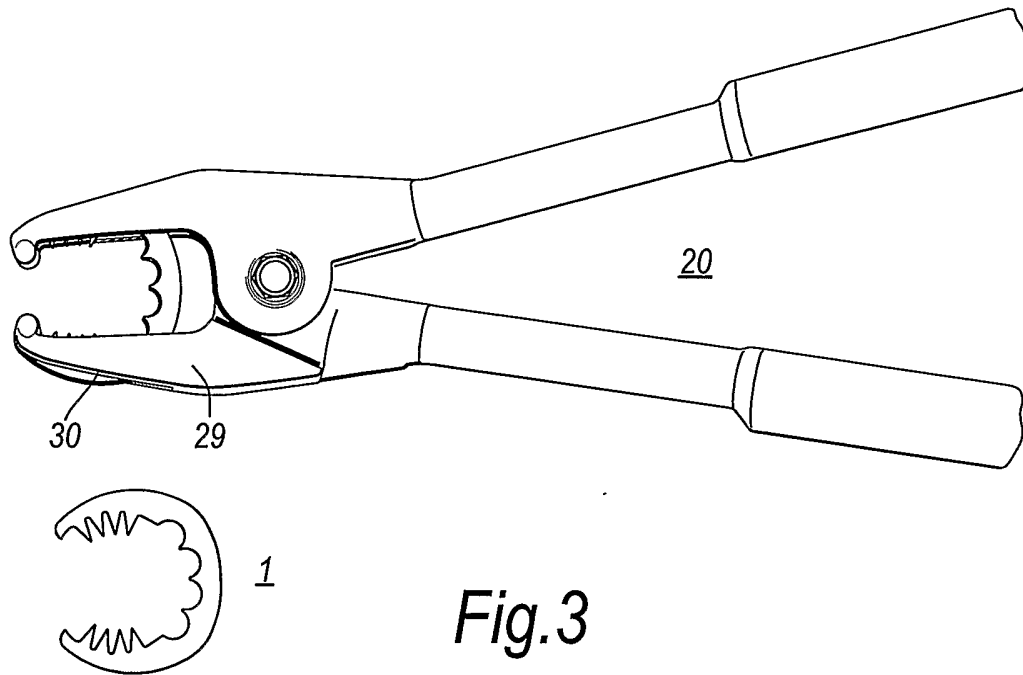


Fig.4

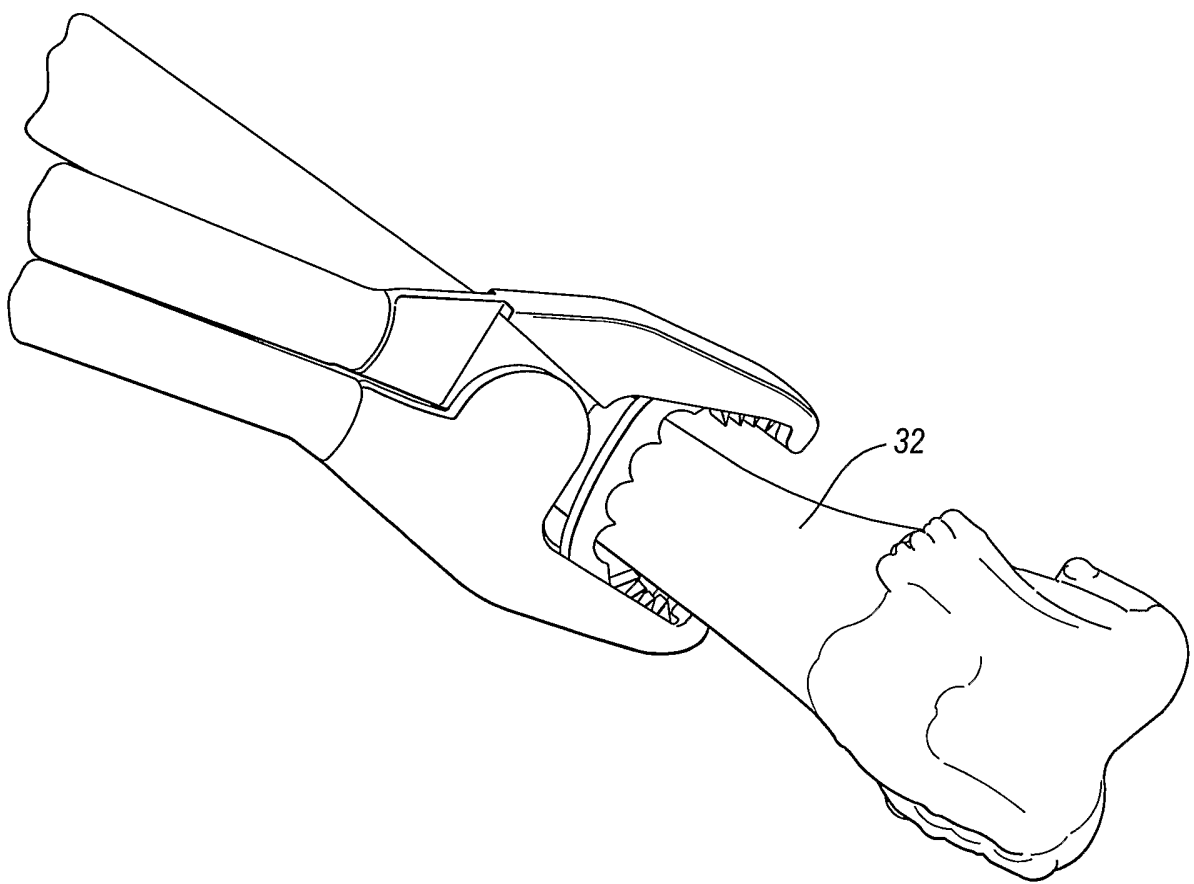


Fig.5

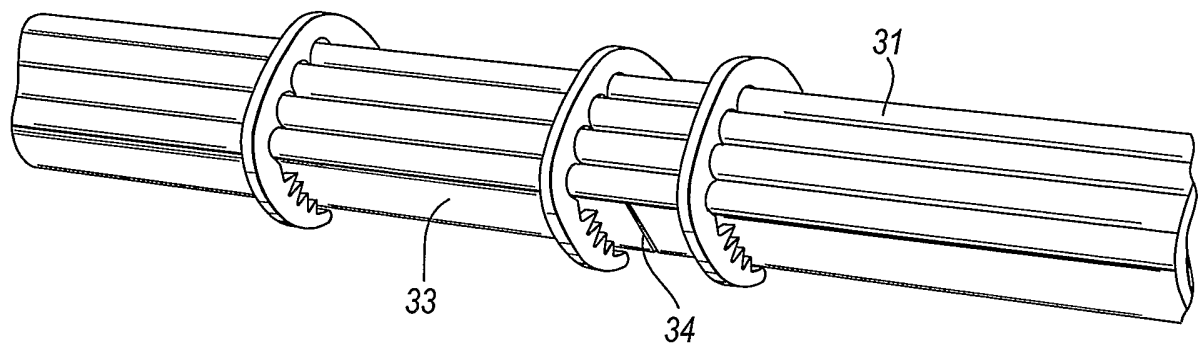


Fig. 6

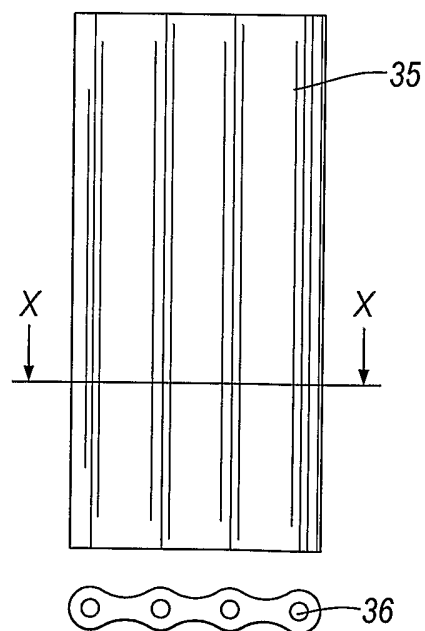


Fig. 7

Fig.8

