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A5R RFB RX4

(56) Documents Cited
GB 1253389 A **EP 0755658 A1** **EP 0201905 A2**
WO 97/05836 A1 **US 5250049 A** **US 4688561 A1**
US 4289124 A

(58) Field of Search
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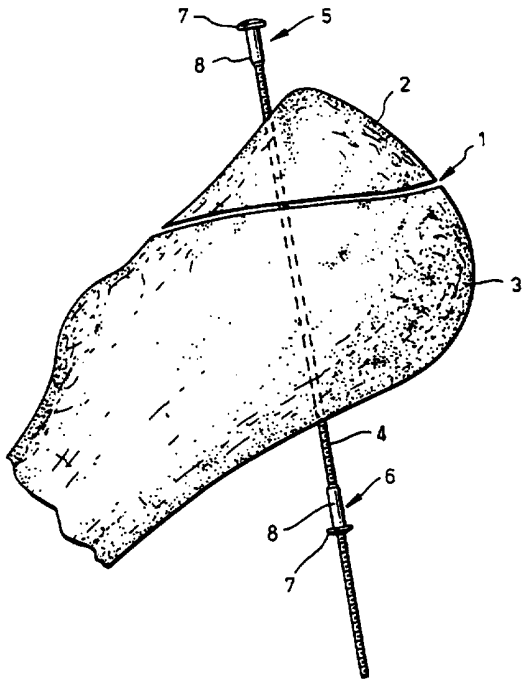
INT CL^6 **A61B 17/58 17/68 17/84 17/86**
Online:WPI,CLAIMS

(54) Abstract Title
Bone fixation device

(57) A bone fixation device comprising a threaded wire 4 which extends through a hole drilled in pieces 2,3 of bone to be joined at a break 1, and on which are threaded a pair of nuts 5,6. The nuts are generally T-shaped, having a head portion 7 and a shank portion 8. In use, the nuts 5,6 are threaded towards one another so that the shank portions are tight within the hole and the head portions bear against the outside surface of the bone 2,3 and thus keep the wire 4 in tension.

Fig.1.



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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1995

Fig.1.

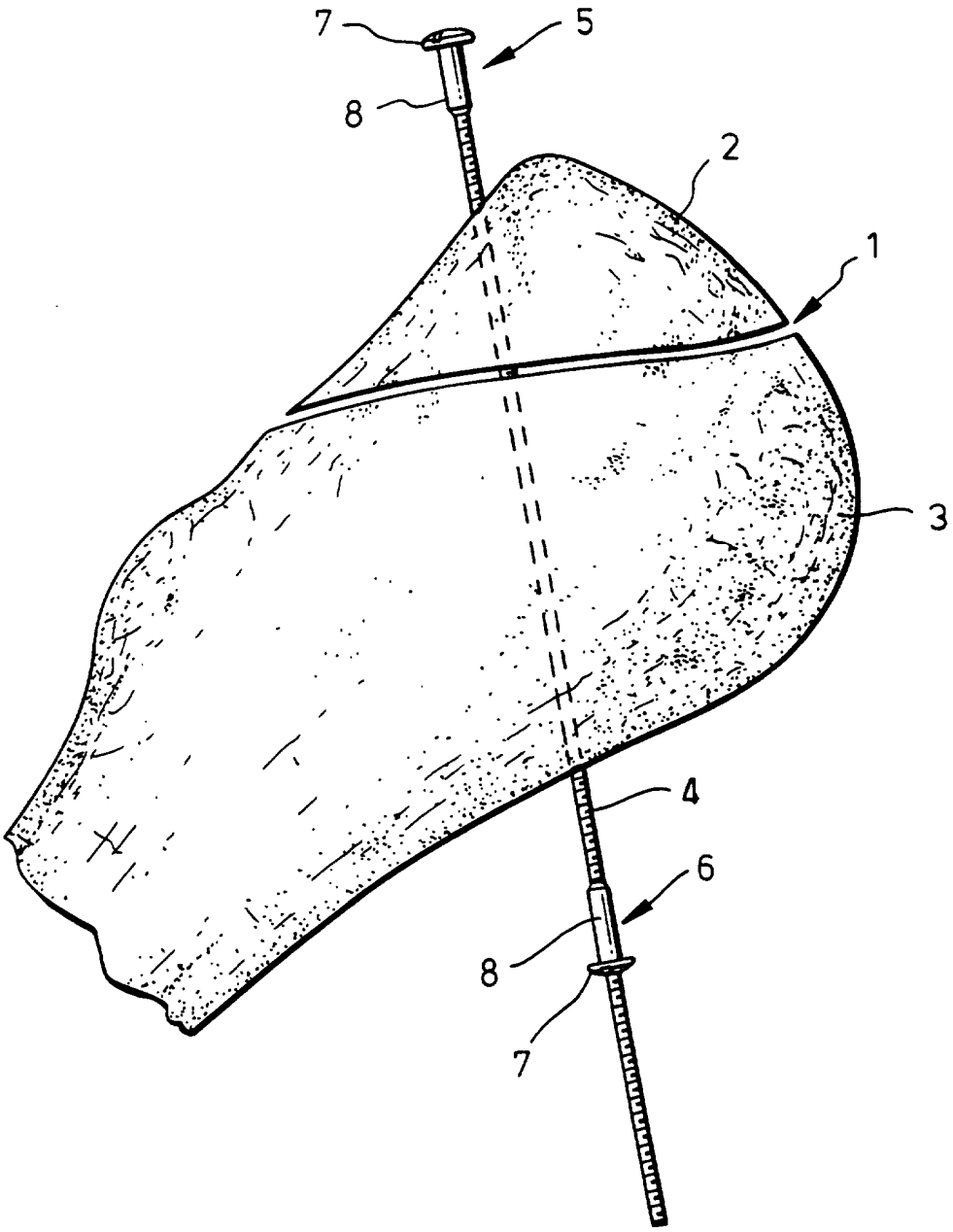


Fig.2.

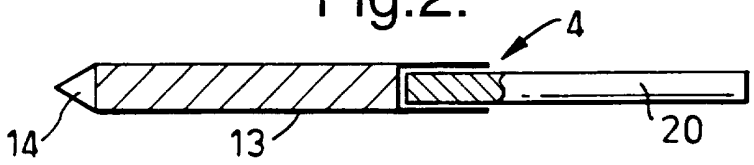


Fig.3A.

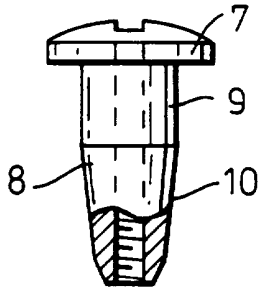


Fig.3B.

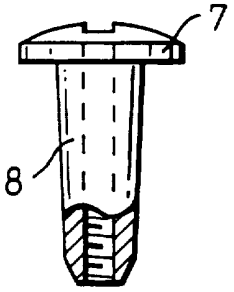


Fig.3C.

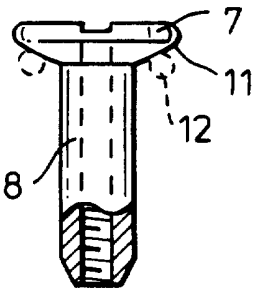
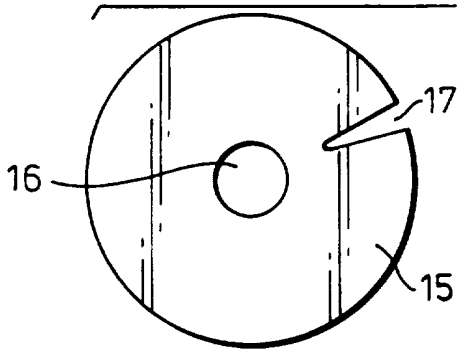


Fig.4A.



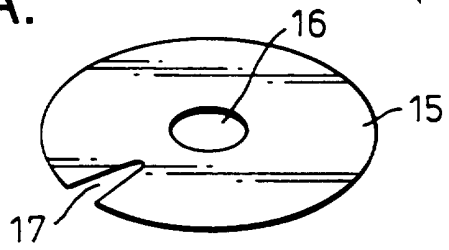


Fig.4B.

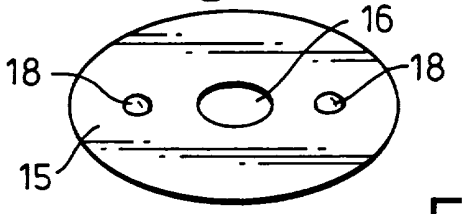


Fig.4C.

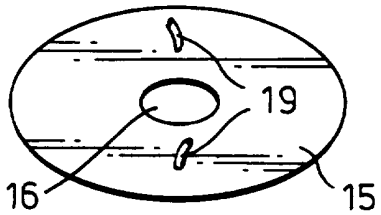
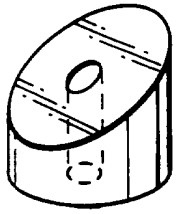


Fig.5.



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"FIXATION SYSTEM FOR FRACTURED BONES"

This invention relates to a bone fixation device and method.

The treatment of fractured bones has changed radically in the last 25 years. Before then, patients with broken bones were put on traction in bed, or in plaster while the break mended; in both cases, healing could take months.

More recently a technique known as internal fixation has been used. This involves the use of plates and screws which hold the bones relatively tightly together so that the patient can lead a reasonably normal life while the bones are healing. One such system, designed by a Swiss group, comprises a set of interchangeable plates and screws for fixing fractures. The system is well designed and has improved the success rate of internal fixation. However, these systems have been designed primarily for fixation in relatively young bone and are intended for injuries sustained typically in sports, for example skiing, or road accidents. Because these systems rely on a screw connection primarily into the medulla, they are at their best on strong young bone. However, in practice most fractures occur in the elderly who may have thin weak bone with almost no trabecular pattern. As a result, the screws do not hold as well as they might and the system is thus not as reliable as it should be. In addition, the known widely used systems for internal fixation tend to be quite expensive, and can be tricky to use.

Also known are a number of external fixation methods, which involve some form of gantry or scaffolding placed on the outside of the broken limb. In one system the bones are transfixed by means of thin wires which are fixed in tension to a circular frame which fits around the limb. This frame can then be fixed externally to a further similar frame fitted on the other side of the fracture, thus holding the bone while the patient continues to use the limb. Whilst effective, this technique has

obvious disadvantages for the patient because of the bulk and inconvenience of the external fixture.

In the present invention the idea of wires in tension is taken up, but adapted to the internal fixation technique thus combining the best of both ideas.

According to a first aspect of the present invention, there is provided a bone-fixation device comprising a thin wire for extending through a hole made through two pieces of bone to be affixed, said wire being of sufficient length to extend right through the pieces of bone from one side to the other, a first and a second securing device, means for attaching each securing device on said wire at a particular position along its length. In practice the two securing devices are attached on respective opposite surfaces of the bone at the point at which the wire emerges from the bone. The securing devices are positioned so that the wire joining them is in tension, thus drawing the two securing devices firmly onto the bone surfaces at opposite sides of the break. As a result, the two pieces of bone are themselves firmly drawn together and are laterally fixed due to the presence of the wire extending across the break. The fixation forces are applied mainly to the cortex of the bone, which is the strongest part of the bone and which may, in older people, be the only part of the bone which has a significant holding strength.

In order to spread the load and prevent crushing of the cortex, washers may be placed under the securing devices. Shaped washers may also be used for special purposes, for example where the wire emerges from the bone surface at an angle.

Various means may be used for attaching the securing devices to the wire. For example, they may be crimped in place, with the protruding ends of wire cut off. Alternatively the wire itself may be threaded, and the securing devices take the form of nuts which are screw threaded onto the wire. If a very fine thread is used, it is possible that the

thread itself will form a sufficient means for attaching it to the wire; however, various thread locking techniques could be used, such as suitable thread locking compounds, a plastic insert or a split nut.

The wire itself could be made of a suitable metal, for example surgical grade stainless steel, or could be made from a suitable plastics material. The wire could be made of a biodegradable plastics material such as DEXON, polylactate or polydioxone sulphate (PDS). In order to reduce to the minimum possible the size of the hole needed to accommodate the wire, the wire is made as small as possible consistent with its duty to hold the pieces of bone together securely during healing. Typically the wire might have an outside diameter in the range 0.9 to 3 mm.

During fitting of the wire a suitable hole has to be drilled through the bone, from one piece of bone to be joined to the other across the break. This hole can be drilled by means of a conventional surgical drill, after which the wire is inserted. However, there are advantages, to be discussed in more detail below, to using the wire itself as a drill. To be suitable for this purpose, the wire needs to be rigid, and preferably reasonably tough also so that its end can be sharpened to form a drill point. An equivalent effect can be obtained by using a short length of rigid wire, sharpened at one end as noted above, which draws through the hole as it drills a length of flexible wire such as wire made of plastics (for example biodegradable plastics) material.

The securing devices may take various forms, according to the manner in which they are to be attached to the wire, as discussed above. In a preferred embodiment, the security device has an enlarged head portion, which acts to spread the load (possibly in conjunction with a washer) on the exterior surface of the bone, and a shank portion which, when fitted, surrounds the wire. In use the securing devices are orientated on the wire such that the two shank portions face one another. The shank portions are of such size that, when the securing devices are

drawn towards one another during assembly (either by tensioning the wire or by screw threading), the shank portions are drawn into the hole occupied by the wire to give a tight fit in the hole and thus assist securement of the whole device with respect to the bone. These shank portions may be chamfered at their ends, and possibly tapered at a shallow angle along all or part of their length to assist assembly. The shank portions may also be provided with a roughened, serrated or fluted exterior surface to assist gripping of the securing device in the bone.

The head portion is of a size suitable to prevent it being drawn in to the bone during fitting and, in this function, may be assisted by a washer, as mentioned. A countersunk head may also be used if a low profile fitting against the bone is desirable; note however that the tendency of a countersunk head to form a corresponding countersunk hole in the bone surface will weaken the bone surface at this point and may for this reason be unacceptable if the bone is weak. One particular arrangement which is felt might be useful is a countersunk head in which the underside surface of the countersink is rounded and used in association with a suitably-shaped washer, for example an 0-ring washer, to give an arrangement which will give a secure fixing even if the wire emerges from the bone surface at an angle (a common occurrence).

The bone fixation device of the present invention enables the use of a particularly advantageous method for bone fixation.

According to a second aspect of the invention there is provided a bone fixation method comprising the steps of temporarily holding pieces of bone to be attached together in the positions they are to occupy, drilling a hole through from a first surface, being a surface of one of said pieces, across the join between the two pieces, to emerge at a second surface, being a surface of the other of said pieces, inserting through said hole a thin wire, said wire being of sufficient length to extend right through the pieces of bone from said first surface to said second

surface, and attaching to said wire a respective one of first and second securing devices at the point at which the wire emerges onto each of said first and second surfaces respectively to thereby effect a secure attachment as between the two pieces of bone when the temporary hold is released.

In a preferred embodiment of the method, the flesh covering the bone is cut back to reveal the bone only on that side of the break at which the drill is to enter the bone - in other words, to reveal said first surface. The wire is then pushed through the hole in the manner described until it reaches the remote side of the bone whereupon the wire is pushed through the flesh at the remote side of the bone until it emerges from the skin surface. At this point, the second securing device is attached to the protruding wire, whereupon the wire can be drawn back again, thus pulling said second securing device through the flesh until it reaches the surface (said second surface) of the bone. The first securing device may then be fitted against the first surface to effect the required secure attachment between the pieces of bone. By using this technique the flesh needs to be disturbed to a significant extent only on one side of the break. Preferably, said second securing device is attached at the end of the wire; if it is not attached at the end, the end must be trimmed before the second securing device is drawn into the flesh on the remote side.

In a preferred embodiment the wire is sharpened at one end to enable its use as a drill; in this event there is no need for separate steps of drilling the hole and inspecting the wire therethrough: both steps are effectively combined into one. This has the significant advantage that withdrawal of the drill and subsequent insertion of the wire with a time interval (albeit short) in between does not occur and this considerably reduces the possibility of accidental relative movement between the pieces of bone during this process.

In order that the invention may be better understood, several

embodiments thereof will now be described by way of example only and with reference to the accompanying drawings in which:-

Figure 1 is a general perspective view of a bone fixation device in accordance with the invention;

Figure 2 is a side view of a flexible wire for use with the device of Figure 1, having a rigid end for drilling;

Figures 3 A to C are side views showing various shapes of nut for use with the device of Figure 1;

Figures 4 A to C are diagrams of various buttons for use with the device of Figure 1; and

Figure 5 is a diagrammatic view of an angled washer for use with the device of Figure 1.

Figure 1 shows a bone which has fractured along a break line 1 into two pieces 2,3. The fixation device is intended to hold the two pieces 2,3 together reasonable tightly so that the patient can go about his normal life while the bones heal. The fixation device comprises a threaded wire 4 having two securing devices in the form of nuts 5,6 threaded on to it. All components are made from surgical grade stainless steel. The wire may comprise, for example, threaded Kirschner wires and have an outside diameter of 2 mm.

The nuts comprise a head portion 7, typically of 5 mm outside diameter and a narrower shank portion 8. The shank portion has a chamfered end remote from the head, to aid insertion into the bone. The nut 5 is a blind nut and fits tightly on the end of the wire 4. The head portion of both nuts is equipped with a straight or hex screwdriver slot or equivalent formation to enable the nut to be rotated on the wire 4 by a cannulated screwdriver (not shown) or similar tool. A washer (also not shown) may be placed around the shank portion under the head portion of one or both nuts to spread the load.

That end of the wire 4 which is covered by the nut 5 is

sharpened to form a drill point whereby the wire itself may be used to drill the necessary hole through the bone pieces 2,3.

In order to use the device, the flesh is first cut away to expose the bone on one side of the break to allow the parts to be temporarily clamped together while the fixation device is installed. Installation commences by fitting the wire 4 into the chuck of a conventional surgical drilling machine and using the wire itself, with its sharpened end, to drill through the piece 3 of bone, across the break 1 preferably at as near a right angle as possible, and thence through the piece 2 of bone. When the wire 4 emerges from the other side, the blind nut 5 is fitted and tightened onto the sharpened end and the wire 4 is then drawn back to pull the nut 5 towards the surface of piece 2. Pressure is continued to pull the shank 8 of the nut 5 into the hole formed by the wire 4 until further movement is stopped by the abutment of the head portion 7 of nut 5 (or any washer thereunder) on the surface of the piece 2. At this point, the shank of the nut 5 is firmly gripped by the drilled hole and this, together with the abutment of the head portion against the bone surface, firmly locates the remote end of the wire 4. At this point, the nut 6 is threaded onto the wire (nut 6 may be pre-threaded onto wire 4, if convenient, and left positioned out of the way during the early operations), and is tightened onto the surface of piece 3 using a cannulated screwdriver (not shown). As with nut 5, the nut 6 is moved until its shank portion 8 is firmly located in the hole drilled by the wire 4, and the head portion 7, or a washer thereunder, abuts the bone surface. The action of tightening up the nut 6 draws the two bone pieces together and places the wire 4 extending between the nuts 5 and 6 in slight tension to maintain the joint. Once fully tightened, the end of the wire 4 emerging from nut 6 is cut off using special pincers (not shown). This cutting off operation may be designed to additionally distort the cut end to prevent the nut 6 from unscrewing itself.

It will be seen that, once completed, the fixation device leaves only a very small protrusion on the bone surface and even this can be avoided, at least in bone with a reasonably thick and healthy cortex, by use of nuts in which the head portion 7 is countersunk, thus enabling the head portion to be drawn into the bone surface so that it is substantially flush with the surface. This low profile arrangement is desirable where there is only a small amount of flesh covering the bone at the point at which the nut is placed.

Although only one wire is shown, for clarity, it will be clear that multiple wires, and associated nuts could be used in more complicated or extensive breaks, or where greater strength is required.

In the basic installation, described above, it is necessary to gain access to the bone surface at both sides of the break in order to attach the nuts 5,6 and tighten them up. However, in some circumstances it is possible to avoid the need to gain access to the remote side and this can reduce tissue injury. If it is assumed therefore that access to the bone surface is obtained only on one side of the break (the lower side in Figure 1), then the drilling operation proceeds as before, except that, upon emerging from the piece 2, drilling is continued through the covering of flesh and other body components on the remote side of the break until the drill emerges from the skin surface. A small nick is made on the skin surface to let the wire out. The nut 5 is then fitted and secured, as before, and the wire 4 moved back, thus drawing the wire, and its attached nut 5 into and through the flesh until it meets the surface of bone piece 2. The nut 5 is then drawn into the bone surface in the manner described above, and the remainder of the procedure is as before. By using this technique, the tissue damage on the remote side is kept to a minimum.

In order to give reasonably close control of the nuts 5,6 on the wire 4, and also to minimise the requirements for nut locking, a fine thread is preferably used for the wire and nuts, for example a B.A. thread.

In order to ensure that the nut to wire connection can withstand the forces necessary, the nuts are made reasonably long so that the number of interengaging threads can be maximised. A torque wrench mechanism can be used to prevent overtightening. Although not apparent from the drawings, it is desirable, if not essential, to provide some form of thread locking mechanism to prevent the nuts loosening after fitting. The fine thread will help here, as will the tight fitting of the shank portions 8 into the hole drilled out by the wire 4. However, if this is felt to be insufficient, further measures known in industry, may be used. For example, the use of a nylon or similar nut insert, or the use of a suitable thread locking compound (cleared for surgical use).

Various alternative shapes of nuts 5/6 are shown in Figure 3. The drawings all illustrate a through-nut (i.e. nut 6), but the same principles apply to blind nut 5. In Figure 3A, the shank portion 8 is formed as a first part 9 with parallel sides and a second part 10 with slowly tapering sides. In Figure 3B, the whole shank portion 8 is given a slow taper. The tapered or semi-tapered nuts ease the passage of the nuts 5,6 into the bone during the fitting operation. Figure 3C shows a nut with a countersunk head portion 7 in which the undersurface 11 is curved and co-acts with an 0-ring washer 12 as shown to enable the nut to seat firmly against the bone surface even if the wire 4 emerges at an angle. For extreme cases, a wedge-shaped washer, such as illustrated diagrammatically in Figure 5, may be used. The nut shown in Figure 3C may also be used by itself (as a conventional countersunk - headed nut) or with alternative shapes of washer or load-spreading plates, according to the circumstances of use.

It was mentioned above that the wire 4 could be made of flexible material, for example biodegradable plastics materials, which would not in itself be able to act as a drill, neither would it be tough enough to be successfully threaded, for use with threaded nuts. In these circumstances a different technique may be used. Referring to Figure 2, there is shown a

wire 4 which has a major portion 20 made of flexible material, as aforesaid, but having an end section 13 made of a rigid material, such as stainless steel, joined thereto. The section 13 is sharpened at its end 14 to a drill point. During installation, the rigid section 13 is fitted into a drill chuck and the necessary hole drilled through the bone pieces in the manner described above. When the rigid section 13 emerges from the remote side, it is pulled to draw the flexible section 20 through so that a suitable securing device, in place of nut 5, can be attached thereto before trimming the flexible section to remove unwanted length, including the (now redundant) rigid section 13. The wire 4 may now be moved backwards to draw the securing device against the remote bone surface, as described above, before fitting a further securing device, in place of nut 6, against the surface of bone piece 3. Prior to attaching this latter securing device, the wire 4 should be placed in tension so that, after fitting the second securing device, this tension can be released to draw the two securing devices together, thus forming a tight joint between the bone pieces 2 and 3. After fitting the second securing device, any excess wire 4 can be trimmed off, as before.

As already mentioned, it is unlikely that threaded nuts could be used as securing devices because the flexible material would probably not be strong enough to form reliable threads. However, alternative fixing devices are possible, for example a sleeve or collar of similar shape to nuts 5,6 could be crimped onto the wire 4 using a special crimping tool. Even a quick-setting adhesive might be used. A further alternative is illustrated in Figure 4.

Figure 4 shows three different possible alternatives for a washer-like securing device. In each case, the washer shown under reference 15, has a centrally-located aperture 16 through which, in use, the flexible wire 4 will pass. In Figure 4A, the washer is equipped with a V-shaped slit 17 in its periphery into which the wire 4, having passed through

aperture 16 may be inserted and trapped, and the end trimmed off. In Figure 4B the washer is equipped with small hoops 18 through which the end of the wire 4 may be inserted to trap same before it is trimmed off. In Figure 4C, small hooks 19 are used for the same purpose.

An important advantage of the present invention is that, unlike other commonly-used systems, the wire itself does not grip the bone and the securing devices at each side bias against the cortex of the bone, which is its strongest part. This differentiates the above-described fixation device from those which use cortical screws which bite on the cortex and medulla of the bone with the threads of the screws and then have a nut put on the end to give extra security. As with most of the known systems, the intention is that, once fitted, the fixation device will remain in the body, even after healing has taken place; however, it is of course possible to remove the whole or part of the device subsequently should this be necessary.

CLAIMS

1. A bone-fixation device comprising a wire for extending through a hole made through two pieces of bone to be affixed, said wire being of sufficient length to extend right through the pieces of bone from one side to the other, a first and a second securing device and means for attaching each securing device on said wire at a particular position along its length.

2. A bone-fixation device as claimed in claim 1 wherein said attaching means comprises means for crimping the securing devices to the wire.

3. A bone-fixation device as claimed in claim 1 wherein the wire is threaded and the securing devices take the form of nuts which are screw threaded onto the wire.

4. A bone-fixation device as claimed in any one of claims 1 to 3 further including washers which are placed between the securing devices and the bone in order to spread the load.

5. A bone-fixation device as claimed in claim 4 wherein at least some of said washers are shaped to accommodate particular shapes of bone.

6. A bone-fixation device as claimed in any one of the preceding claims wherein each securing device is of generally T-shape, having a head portion and a narrower shank portion.

7. A bone-fixation device as claimed in claim 6 wherein the end of the shank portion remote from the head portion is chamfered to aid insertion into the bone.

8. A bone-fixation device as claimed in either one of claims 6 or 7 wherein the shank portion is tapered at a shallow angle along all or part of its length.

9. A bone-fixation device as claimed in any one of claims 6,7 or

8 wherein the outside surface of the shank portion is roughened, serrated or fluted to assist gripping of the security device in the bone.

10. A bone-fixation device as claimed in any one of claims 6 to 9 wherein the head portion of the securing device is countersunk.

11. A bone-fixation device as claimed in claim 10 wherein the underside surface of the countersunk head portion is rounded, and rests in a washer situated against the bone.

12. A bone-fixation device as claimed in any one of the preceding claims wherein one end of the wire is sharpened to enable its use as a drill.

13. A bone-fixation device as claimed in claim 12 wherein the wire is made of flexible material and wherein said one end thereof is made of rigid material for a length sufficient to enable its use as a drill.

14. A bone fixation method comprising the steps of temporarily holding pieces of bone to be attached together in the positions they are to occupy, drilling a hole through from a first surface, being a surface of one of said pieces, across the join between the two pieces, to emerge at a second surface, being a surface of the other of said pieces, inserting through said hole a wire, said wire being of sufficient length to extend right through the pieces of bone from said first surface to said second surface, and attaching to said wire a respective one of first and second securing devices at the point at which the wire emerges onto each of said first and second surfaces respectively to thereby effect a secure attachment as between the two pieces of bone when the temporary hold is released.

15. A method as claimed in claim 14 wherein the securing devices are positioned so that the wire is in tension.

16. A method as claimed in either one of claims 14 or 15 wherein, prior to drilling the bone, the flesh covering the bone is cut back to reveal the bone on the side that the drill enters, but not on the remote side and wherein, after pushing the wire through said hole until it emerges from the other side, thence pushing the wire through the flesh at the remote side

of the bone until it emerges from the skin surface, then attaching said second securing device, and drawing same back through the flesh to the bone surface at the remote side.

17. A method as claimed in any one of claims 14 to 16 wherein drilling is carried out by said wire which is sharpened at one end for the purpose.

18. A method as claimed in any one of claims 14 to 17 wherein said securing devices are generally T-shaped, having a head portion and a narrower shank portion, and wherein the securing devices are attached in such a way that the shank portion of each securing device enters and is gripped by said hole and wherein the head portion bears against the outside surface of the bone.

19. A method as claimed in claim 18 wherein said security devices are threaded to the wire and are drawn towards one another to effect said secure attachment as between the two pieces of bone.

20. An assembly comprising two pieces of bone to be joined, said pieces being butted against one another in desired relative positions, with a line of abutment therebetween, said pieces having a through-hole which passes from a first surface, being a surface of one of said pieces, through said one of said pieces, across said line of abutment and through the other of said pieces to emerge at a second surface, being a surface of said other of said pieces, a wire extending through said hole, and first and second securing devices, each attached to said wire at a respective one of the points at which the wire emerges onto each of said first and second surfaces, the arrangement being such that said bone pieces are held in abutment by said wire.

The Patent Office

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Application No: GB 9709362.9 **Examiner:** Peter Davey
Claims searched: 1-20 **Date of search:** 26 August 1998

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.P): A5R (RFB)

Int Cl (Ed.6): A61B 17/58 17/68 17/84 17/86

Other: Online: WPI, CLAIMS

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 1253389	(HALLORAN), see eg. Fig.4	1, 14 and 20 at least
X	WO 97/05836 A1	(COMBS), see eg. Fig. 4	"
X	EP 0755658 A1	(GROUPE LEPINE), see eg. Fig. 4	"
X	EP 0201905 A2	(HAUER), see eg. Fig. 4	"
X	US 5250049	(MICHAEL), see eg. Fig. 5	"
X	US 4688561	(REESE), see eg. Fig. 4	"
X	US 4289124	(ZICKEL), see eg. Fig. 1	"

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.