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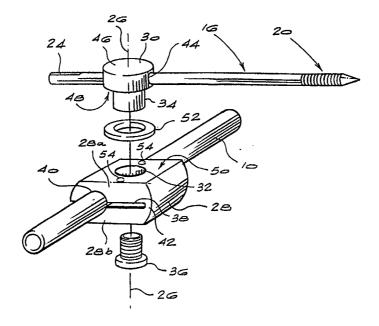
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(54) Title: MEANS FOR ANTI-ROTATIONALLY FIXING TWO COMPONENTS TOGETHER, PARTICULARLY OF AN OSTEOSYNTHETIC FIXATOR



#### (57) Abstract

Fixation means comprising first and second jaws, at least one of which has an opening passing therethrough, the two jaws having opposed generally planar faces. A clamping shank for connecting the two jaws together passes through the opening so that the shank defines a rotation axis about which the two jaws are rotatable relative to each other. A deformable shim is located between the two jaws and is adapted to be clamped therebetween. A nut engages with the shank in order to clamp the two jaws together and the arrangement is such that the nut is used to draw the two jaws together to clamp the shim therebetween, causing deformation of the shim, and thereby affixing the two jaws together. The fixation means is particularly suitable for use as an external fixator system employed in orthopaedic operations.

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MEANS FOR ANTI-ROTATIONALLY FIXING TWO COMPONENTS TOGETHER, PARTICULARLY OF AN OSTEOSYNTHETIC FIXATOR

#### BACKGROUND OF THE INVENTION

This invention relates to a fixing arrangement for fixing two components together. The invention will be specifically described with reference to a locking mechanism for external fixing of orthopaedic implants but it is to be understood that the invention will have wider application and is therefore not limited to the fixing of orthopaedic implants.

External fixator systems are used extensively in orthopaedic practice, particularly for fixing together broken or damaged bones, but also in other situations such as bone elongation procedures and the like. An external fixator system generally comprises a beam which is aligned generally parallel to the length of the bone to be fixed and a series of implant pins which are aligned generally perpendicular to the length of the beam and are screwed into the bone and then fixed to the beam so that the two or more parts of the bone are held aligned and rigid by the beam via the implant pins.

It will be appreciated that the external fixation of bone parts is an extremely delicate and precise operation. Any small angular variation or rotational stress that is placed on the bone parts will result in imperfectly aligned knitting of the bone which can cause ongoing complications for the patient and necessitate the breaking and resetting of the partially knitted bone. Clearly it is desirable that this be avoided.

Prior art external fixator systems have included a relatively complex clamp formed in two parts, one part of which clamps to the beam and the other part of which clamps to the implant pin. A threaded shank connects the two WO 98/32385 PCT/EP97/00293

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clamp parts together, the two parts being rotatable about the shank axis to allow for rotation of the implant pin relative to the beam. When the threaded shank is tightened it anti-rotationally fixes the implant pin to the beam to ensure that there is no rotational slippage between the implant pin and the beam. The opposed faces of the two clamp parts have co-operant formations formed thereon which interact with each other to prevent rotation. These co-operant formations can take various forms. For example, in one known system, the opposed faces have a series of radially extending grooves and ridges formed therein, in the manner of gear teeth, so that the ridges of one face located in the grooves of the opposed face, which, when clamped together, ensures that no relative rotation of the two clamp parts takes place. However, this system has the disadvantage in that clamping can only take place in discrete angular steps. Relatively fine grooves and ridges are formed in the two faces but it is still found that often it is desirable to clamp the two clamp parts together in an intermediate position which is not possible with the system. Another system employs a series of pins formed in one face and the opposed face has a series of holes formed therein and the two clamp parts can be rotated to positions where the pins are in register with the opposed holes. However, again, this system does not allow for clamping in intermediate positions.

A further problem with prior art arrangements is that they tend to be expensive. The machining of the opposed face of the clamp parts adds considerably to the cost of the clamp parts. Since the fixing of a single bone can require a large number of clamps and implant pins, the overall cost of the apparatus is high with a result that such external clamping procedures are frequently not used in situations where they would otherwise be appropriate or in communities which cannot afford the cost of the equipment.

### SUMMARY OF THE INVENTION

According to the invention there is provided a fixation means comprising:

first and second jaws, at least one of which has an opening passing therethrough, the two jaws having opposed generally planar faces;

a clamping shank for connecting the two jaws together said shank passing through said opening, such shank defining a rotational axis about which the two jaws are rotatable relative to each other;

a deformable shim located between the two jaws and adapted to be clamped therebetween;

at least one of said generally planar faces having one or more fixing formations thereon; and

a clamping means associated with the clamping shank for drawing the two jaws towards each other in a clamping action;

the arrangement being such that as the clamping means is used to draw the two jaws together to apply the clamping action the shim is clamped between the opposed planar faces and the fixing formation or formations deform the shim to thereby anti-rotationally fix the two jaws together.

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The clamping shank and clamping means may conveniently comprise a nut and bolt assembly. The nut may be in a form of a internally threaded sleeve in which the bolt is screwable.

The first and second jaws may themselves have other components connected or connectable thereto. Either one or both of the jaws may employ the clamping action provided by the clamping shank and clamping means to secure said other components thereto. At least one of the said other component may engage with the deformable shim to secure that component in position. In a preferred arrangement at least one of the said other components is an elongate rigid member which slidably locates in a passage formed in one of the jaws, said passage having an axis which is generally perpendicular to the rotational axis and is arranged to be clamped within that passage when the clamping action is applied.

The jaw with the opening therethrough may be split or cut at least part way therethrough along a plane generally perpendicular to the axis of rotation, and a transverse passage, the axis of which lies parallel to said plane, may pass through said jaw so that opposite sides of said split lie on opposite sides of said passage, the arrangement being such that when the clamping force is applied the split will be urged to close thereby decreasing the diameter of the transverse passage to thereby clamp a component located in the passage.

There is preferably at least one fixing formation formed in one of the opposed planar faces, and preferably there will be a plurality of fixing formations. An alternative arrangement there will be for the planar faces simply to be of non-polished or slightly roughened finish so that when the clamping action is applied micro-deformation of the deformable shim takes

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place.

The deformable shim is preferably in the form of an annular washer which locates around the shank. An annealed copper or like material is suitable for the manufacture of this shim although it is envisaged that a suitable plastics material could also be used.

One particularly suitable application for fixing means is for external fixing of orthopaedic implants, wherein the fixing means is employed to fix an implant pin to a beam, and generally there will be a plurality of fixing means spaced apart along a single beam, each fixing mean leaving an implant pin fixed thereto.

These are the further features of the invention will be made up in the description of an embodiment thereof given below by way of example. In the description reference is made to the accompanying drawings but the specific feature shown in the drawing should not be construed as limiting on the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows, diagrammatically, an external fixator system

according to the invention securing two parts of a

broken bone together;

Figure 2 shows an exploded perspective view of a fixing means

according to the invention;

Figure 3 shows a side view of a fixing means depicted in Figure 2 in the assembled condition;

Figure 4 shows a similar view to that of Figure 3 at right angles to the view depicted in Figure 3; and

Figure 5 shows a cross sectional view along lines V-V depicted in Figure 1.

### **DETAILED DESCRIPTION**

Referring initially to Figure 1, an external fixator system for orthopaedic purposes is shown comprising a beam 10 which will be of circular cross section and is of a length which accords with the length of the bone 12 which is to be held in alignment. The bone 12 has a break 14 along its length and the beam 10 is aligned with the length of the bone. A series of implant pins 16 are secured to the beam 10 by fixing clamps 18 which are described in more detail herebelow. The implant pins have a sharpened and threaded inner end 20 and the outer end 22 of the pins have a series of flats 24 thereon to enable the pins to be screwed into the bone 12. Implant pins of this type are well known.

Each of the pins 16 is rotatable relative to the beam 10 about an axis 26 which is generally perpendicular to the axis of the beam 10 and allows the implant pins 16 to be inserted into the bone 12 at whatever angle is most appropriate for the fixation of the bone. Thus, the clamps 18 are formed in two parts, one part 28 which fixes to the beam 10 and the second part 30

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which fixes the implant pins in position. The two parts 28 and 30 are themselves clamped together once the alignment of the beam and implant pins has been achieved so that the implant pin is rotationally fixed to the beam 10. These aspects are described in more detail below.

Turning now to Figures 2 to 5 of the drawings, a clamping arrangement is shown in more detail. The first part 28 of the clamp has an opening 32 therethrough adapted to receive a shank 34 which forms part of the second part 30 of the clamp. The shank 34 is of hollow cylindrical form and is internally threaded to receive a screw or bolt 36 in order to clamp the parts 28 and 30 together. The first clamp part 28 a split is indicated at numeral 38 and a transverse passage 40 which is orthogonal to the opening 32 is provided. The transverse passage 40 is dimensioned to receive the beam 10 in a sliding fit and the split 38 intersects the passage 40. The split 38 thus divides the first clamp part 28 into two halves, 28a and 28b, which are joined together along an edge as indicated at numeral 42, the edge 42 forming a hinge between the two parts 28a and 28b. The second clamp part 30 also has a transverse passage therethrough indicated at numeral 44 adapted to receive the implant pin 16 in a sliding fit.

The second clamp part 30 has a circular head 46 the undersurface 48 of which faces the upper surface 50 of the first clamp part. A deformable shim 52, in the form of a washer, is adapted to be interposed between the phases 48 and 50 in order to anti-rotationally fix the two clamp parts 28 and 30 together.

The washer 52 may conveniently be formed of a malleable metal, such as annealed copper, which will stress harden on deformation. Thus, when clamped in position, the washer will deform slightly, as described below, and the deformations will be plastically fixed in the washer once deformation has taken place.

The upper surface 50 of the first clamp part 28 has a pair of protrusions 54 thereon which face towards the surface 48 on the second clamp part 30. These protrusions 54 will bed themselves in the washer 52 when the washer is clamped between the surfaces 48 and 50. In so doing, the protrusions will cause plastic deformation of the washer 52.

It will also be noted that the passage 44 in the second clamp part 30 intersects the undersurface 48 of the second clamp part 30. Thus, the implant pin 16, when in the passage 44, forms a pair of protrusion which stand proud of the surface 48 on opposite sides of the shank 34. These protrusions, as indicated at numeral 56 in Figure 4 also serve to plastically deform the washer 52 under the clamping action provided by the nut 36. When all fixing means have been properly aligned and positioned the nut 36 will be tightened thereby affectively clamping the two clamp parts together and fixing the implant pins in position. In so doing, the implant pin will be securely fixed to the beam 10 in both a longitudinal direction and with respect to the axis of the rotation 26 thereby securely fixing the bone 12 to the beam 10.

It is envisaged that the external fixator system described herein will be relatively inexpensive and simple to use. More particularly, the malleable washer provides an infinitely variable anti-rotational fixation device which can be used for fine adjustment and does not depend on inter engagement of interlocking formations. Thus, it is envisaged, a relatively precise angular

fixation can be achieved. Since the faces 48 and 50 do not require special machining the fixation system can be made to be relatively inexpensive and should prove to be ideally suited for primary fixation in emergency and conflict situations as well as being useful for orthopaedic fixations conducted in less affluent communities.

It is important to note that the invention is not limited to that described herein. One advantage of the system described herein is that a single screw and nut assembly is used to fix the clamp to the beam, fix the implant pin to the clamp, and fix the two clamp parts together in a single tightening operation. Whilst this is considered to be advantageous, it may be more preferable in certain applications to have one or other of these fixing operations conducted by a separate fixing means. What is, however, considered to be important is that the deformable washer or shim provides for the infinitely variable rotation and fixing of the two clamp parts.

#### **CLAIMS:**

## 1. A fixation means comprising:

first and second jaws, at least one of which has an opening passing therethrough, the two jaws having opposed generally planar faces;

a clamping shank for connecting the two jaws together said shank passing through said opening, such shank defining a rotational axis about which the two jaws are rotatable relative to each other;

a deformable shim located between the two jaws and adapted to be clamped therebetween;

at least one of said generally planar faces having one or more fixing formations thereon; and

a clamping means associated with the clamping shank for drawing the two jaws towards each other in a clamping action;

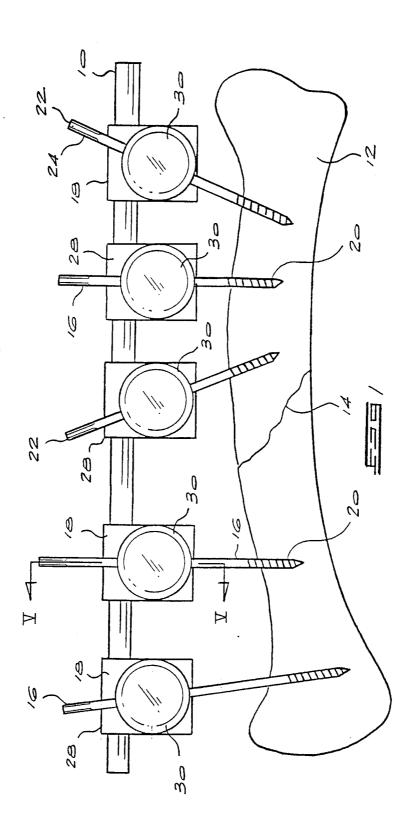
the arrangement being such that as the clamping means is used to draw the two jaws together to apply the clamping action the shim is clamped between the opposed planar faces and the fixing formation or formations deform the shim to thereby anti-rotationally fix the two jaws together.

- 2. Fixation means according to claim 1 wherein the clamping shank and clamping means comprise a nut and bolt assembly.
- 3. A fixation means according to claim 2 wherein the nut is in the form of an internally threaded sleeve into which the bolt is screwable, the sleeve defining said clamping shank.
- 4. A fixation means according to any of the proceeding claims wherein the first and second jaws have other components connected or connectible thereto.
- 5. A fixation means according to claim 4 wherein either one or both of the jaws employs the clamping action provided by the clamping shank and clamping means to secure said other component thereto.
- 6. A fixation means according to claim 5 wherein at least one of the said other components engages with the deformable shim to secure that component in position.
- 7. A fixation means according to any one of claims 4 to 6 in which at least one of the other components is an elongate rigid member which slidably locates in a passage formed in one of the jaws, said passage having an axis which is generally perpendicular to the axis of rotation of the clamp and is arranged to be clamped within that passage when the clamping action is applied.
- 8. A fixation means according to any preceding claim wherein the jaw with the opening therethrough is split or cut, at least part way

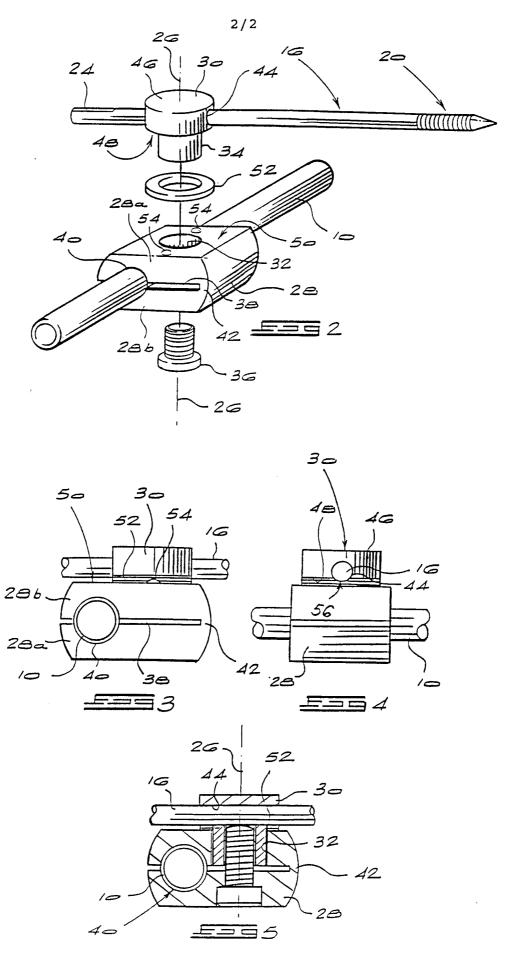
therethrough, along a plane which is generally perpendicular to the axis of rotation, and a transverse passage, the axis of which lies generally parallel to said plane, passes through said jaw so that opposite sides of said split lie on opposite sides of said transverse passage, the arrangement being such that when the clamping action is applied, the split will be urged to close under the clamping action, thereby decreasing the diameter of the transverse passage to thereby clamp a component located in the transverse passage.

- 9. A fixation means according to any preceding claim wherein each of the opposed planar faces has at least one fixing formation formed thereon.
- 10. A fixation means according to claim 9 wherein there are a plurality of fixing formations located in at least one of the planar faces.
- 11. A fixation means according to any one of claim 1 to 8 wherein fixing formations on the planar faces are achieved by providing a non-polished, or slightly roughened, finish to the faces so that when the clamping action is applied, micro-deformation of the deformable shim takes place.
- 12. A fixation means according to any preceding claim wherein the deformable shim is in the form of an annular washer which locates around the shank.
- 13. A fixation means according to claim 12 wherein the deformable shim is formed of an annealed copper or like performing deformable material.

- 14. A fixation means according to any preceding claims specifically adapted for external fixing of orthopaedic implants.
- 15. An external fixator system comprising a beam, a plurality of fixation means according to any preceding claims mountable on said beam, and a plurality of implant pins adapted to be secured by said fixation means to said beam.
- 16. A fixation means substantially as herein before described with reference to the accompanying drawings.
- 17. An external fixator system substantially as herein before described with reference to the accompanying drawings.



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# INTERNATIONAL SEARCH REPORT

Inter onal Application No
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A. CLASSI IPC 6	FICATION OF SUBJECT MATTER A61B17/64			
According t	o International Patent Classification (IPC) or to both national classi	fication and IPC		
B. FIELDS	SEARCHED			
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C. DOCUM	MENTS CONSIDERED TO BE RELEVANT			
Category °	Citation of document, with indication, where appropriate, of the re	elevant passages	Relevant to claim No.	
X	DE 90 05 149 U (G.SCHMIDT) 12 Ju see page 5, line 32 - line 36; c figures 1,2		1-17	
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Furt	ther documents are listed in the continuation of box C.	.    X   Patent family members are listed	in annex.	
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