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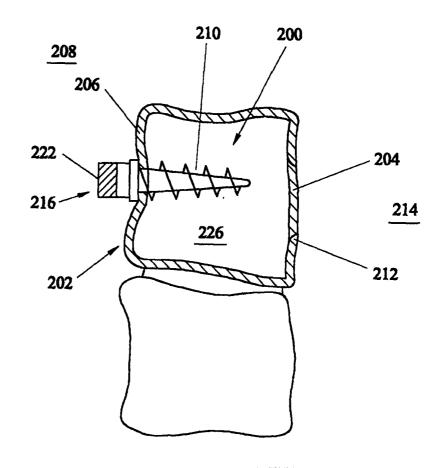
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: IMPROVEMENTS IN AND RELATING TO BONE FIXINS

(57) Abstract

The invention provides improved bone fixing system, use of bone fixing system and method for achieving fixation or anchor sites in The bone fixing deploys a first externally threaded component (200) of generally polymeric material which contacts the bone and a second component (216) of generally metallic material, which is provided in a bore in the first component, with a threaded engagement being provided between the first and second component. Insertion of the second component in the bore may cause the first component to expand in at least one lateral direction.



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IMPROVEMENTS IN AND RELATING TO BONE FIXINGS

This invention concerns improvements in and relating to bone fixings, and in particular, but not exclusively in relation to spinal fixations and trauma fixations.

In a wide variety of surgical applications, it is important to provide a firm fixing to the bone so as to enable other systems to be applied between two or more such fixings. Bone screws are commonly used to provide such anchor sites / fixations.

A particular example of such an application is the placement of bone screws in the vertebrae of the spine. Vertebrae are formed by a thin hard exterior, of cortical bone, surrounding a mass of less dense cancellous bone.

Fixations to vertebrae are required for a variety of applications, including correction of spinal deformities, where it is necessary to provide a fixing on a number of vertebrae and interlink the anchors with a rod designed to apply a corrective force to the spine. Due to the levels of force which must be applied and accommodated in use, the anchors must be very secure.

Despite best practice there is a tendency, particularly with the end anchors, for these fixations to pull from the vertebrae in use due to the high loads to which they are subjected. This is a particular problem with applications in the vertebrae as the thickness of cortical bone to which the anchors can be attached is very small and may vary.

In an attempt to provide a more secure anchor screws have been passed through the vertebrae so as to engage the cortical bone on both sides. Even so, problems with the anchors pulling out have been encountered.

The present invention aims to provide an improved anchor and improved fixation for a variety of systems. It is a particular aim of the invention to provide a fixing which

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needs a higher pull force and/or a higher energy input to pull the fixation from its location of use.

According to a first aspect of the invention we provide a bone fixing comprising a first component and a second component, the first component being provided with an internal bore to receive at least a portion of the second — component.

The first component may be made from polymeric and / or bioresorbable materials. Preferably the first component is made of a material with a modulus of elasticity in the range of 1GPa to 10GPa.

At least a portion of the external surface of the first component is provided with a screw thread. The thread may be continuous or discontinuous. Preferably the thread may extend over the majority of the length of the first component. Preferably the pitch of the screw thread is constant. The thread depth may be between 2 and 5mm, and more preferably between 3 and 4mm.

The first component may be provided with a constant dimension, for instance a constant diameter, or with different dimensions or diameters at two or more locations along its length. At least a portion of the half of the first component away from the initially inserted end is tapered. A constant taper may be provided. Preferably in one or more lateral directions, and most preferably diameter, the first component increases away from the initially inserted end.

Preferably the bore is an axial bore, most preferably the bore axis is aligned with the axis of insertion in use.

The first component may be provided with a bore closed at its end. The first component may be provided with a bore open at its end.

The bore may be provided with an internal screw thread. The screw thread may match the external screw thread of the second component. The bore may be provided with a self

tapping thread ability. Alternatively, the first component may have a plain bore and the second component provided with a self tapping ability.

The sides of the bore may be provided with openings, for instance slits. The slits may be provided intermediate to the ends. The slits may extend to the end of the first component, for instance to define arm portions. The first component may be provided with two or more arm portions, for instance four.

The first component may be provided with a pointed end. The first component may be provided with a threaded end portion.

The one or more parts of the first component may have a first and second state, the lateral extent of the one or more parts relative to the axis, in one or more directions, being greater in the second state than in the first state. Preferably insertion of the second component into the first causes the transition from the first to the second state. The parts may be or include the end of the first component.

The lateral extent may be greater than 25% bigger in the second state than the first. An at least 30% greater extent may be provided.

Improved contact between the bore and first component may be provided in this way, with increased retention as a result.

The first component may have intermediate portions, for instance defined by slits, which are deployed outwards by the transition of the first component from its first to second state.

The second component may be made of metal.

Preferably the second component comprises a head portion and a stem portion.

At least a portion of the external surface of the second component, preferably of the stem, is provided with a screw thread. The thread may be continuous or discontinuous.

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Preferably the thread extends over the length of the stem portion of the second component.

The head portion of the second component preferably has a greater dimension than the stem portion. The head portion may be provided with means for connection to another element, such as a plate, rod or the like. The head portion may be provided with a recess or groove. Preferably the groove or recess passes through the head portion, and most preferably is provided perpendicular to the axis of the second component. The groove or recess may be adapted to receive a rod, bar or other element in use. The external and/or internal surface of the head portion may be provide with a screw thread. The screw thread may be used to provide an engagement for a retaining element, for instance a retaining element for the rod, bar or other fixing.

The stem portion of the second component may be provided with a constant diameter or may have a taper. A constant taper may be provided. The diameter of the second component may increase away from the initially inserted end.

Preferably the axis of rotation of the second component corresponds with the axis of the bore and/or the axis of insertion.

According to a second aspect of the invention we provide a method of forming an anchor or fixation in a bone comprising inserting a first component of the fixing into the bone and inserting a second component of the fixing into the first component, the first component engaging the bone, the second component being inserted into a bore in the first component and engaging the first component.

The first and/or second component may be provided according to the features, options or details of the first aspect of the invention, and/or according to other features, options or possibilities set out elsewhere herein.

The first component may be pushed and/or rotated through the bone. The first component is preferably rotated

The bone may be cortical bone, into the cancellous bone. for instance of the vertebrae or acetabulum. The under lying tissue may be cancellous.

Preferably the second component is rotated to insert it in the first component.

Preferably the first component is inserted through the cortical bone on the side of insertion. The first component may be inserted through the cortical bone on the side opposing insertion. Preferably the first component is inserted into the cancellous bone.

Preferably the first component has a threaded engagement with the cortical bone or, preferably and, with the cancellous bone. The method may include providing a plurality of such fixings.

One or more such fixings may be attached to the components, such as rods, bars or plates of a spinal correction or trauma system or in a case of vertebral destruction.

According to a third aspect of the invention we provide the use of a bone fixing, the bone fixing may be provided according to the first aspect of the invention and/or used according to the method of the second aspect of the invention.

Various embodiments of the invention will now be described, by way of example only, and with reference to the accompanying figures in which:-

Figure 1 illustrates a prior art bone screw fixation in a vertebrae;

Figure 2 illustrates a first embodiment of the present invention, used in a spinal fixation, in partial cross section;

Figure 3a illustrates a second embodiment of the invention for use in trauma fixation; and

Figure 3b illustrates an alternative plug form.

A variety of surgical applications call for a fixation or anchor site to be provided on a bone. The anchor is then used for the attachment of additional pieces of equipment such as ligaments, bars, straps, screws or the like, to affect the surgical procedure desired.

Systems of the above mentioned type finds particular — application in correcting deformity of the spine where a series of anchor locations are connected by a bar pre-shaped to apply the desired corrective force application to the spine. The level of forces involved are high and as a consequence a very firm anchor is required. This is particularly so where the correction is applied anteriorly to the spine.

A further typical application is the fixation of plates or the like across a trauma injury such as a fracture. Here the anchors are used to provide a firm positional force for the two components either side of the fracture during healing. Again reliable anchors are necessary.

A particular problem in vertebrae, and in a number of other bones, is that the bone is formed of a thin exterior cortical bony portion enclosing a softer cancellous matrix. Conventional fixings rely predominantly on the exterior bone portion in gaining purchase. The limited thickness available, however, limits the resistive force that the fixings can provide.

As illustrated in Figure 1, a conventional bone screw comprises a stem 1 provided with a screw thread 3, and a head portion 5 provided with a recess 7 into which a bar (not shown) can be inserted and retained by a cap portion (not shown) which engages with the screw thread 9 on the head portion 5.

The bone screw is shown inserted through the cortical bone 11 on the insertion side 13, which is relatively thin, through the softer cancellous bone 15 inside the vertebrae and onward, through and out of the cortical bone 17 on the

opposing side 19. Both cortical bone portions 11, 17 are used to provide as much fixation as possible.

The thin nature of the cortical bone renders it susceptible to failure and pulling out of the fixing from its desired position during use. This will impair the effectiveness of the corrective technique and/or necessitate-further surgery to insert further fixings.

The first embodiment of the present invention illustrated in Figure 2 is also a vertebral fixation. this case, however, the technique involves introducing a self tapping plastics plug 200 into the fixing location 202 first. The plug 200 is provided with a pointed, closed end 204 which is used to pierce the cortical bone 206 on the insertion side 208. No drilling is thus necessary and reduced risk of damage to the bone may arise as a result. Rotation of the plug 200 advances it into the hole formed and engagement of the large depth screw thread 210 with the cancellous bone 206 causes further advance. The plug 200 is screwed into the vertebrae until it reaches the position shown in Figure 2. The use of a screw thread on the exterior surface gives improved retention through cooperation with the boNe. By rotation, however, the plug is introduced with minimal disturbance to the material surrounding it. The plug 200 may or may not pierce the cortical bone 212 on the opposing side 214.

With the plug 200 in position a bone screw type fixing 216 is introduced by rotation into the plug 200. The threaded portion of the screw 216 engages with a corresponding pre-formed screw thread in the plug 200 and leads to a firm engagement between the two components 200 and 216 as a result.

The screw 216 is provided with a head portion 222 incorporating a groove into which rods (not shown) can, for instance, be introduced to affect the desired corrective surgery.

The plug 200 provides a far greater depth of effective screw thread engagement between the fixing and the vertebrae than conventional bone screws as effective engagement is provided between the large depth screw thread portion 210 and the cancellous bone 226. Resistance to pull of the fixing arises from resistance from the cancellous material 226, therefore, in addition to the contribution made by the cortical bone 206.

As a plastic plug 200 is used, the modulus of elasticity is such that the threaded engagement formed between the bone 206 and plug 200, upon the plug's insertion, is also of a superior quality to that formed when a conventional screw is inserted. The deformable nature of the plugs screw thread 210 leads to a consistent, high quality thread being formed in the cortical bone 206, and minimises bone resorption due to stress shielding. The rigid metal vertebral body screws previously used have a modulus of elasticity less close to that of bone than the plastic plug, making bone resorption due to stress shielding more likely.

In the embodiment illustrated in Figure 3a a similar system is used but this time in a trauma type application. The bone 300 has been fractured, location 302. As with the vertebrae, the bone is formed of the relatively thin cortical bone exterior and softer cancellous tissue, interior. To assist healing a pair of anchors 304 are provided on either side of the fracture line 302. These anchors 304 are used to retain a plate 306 which provides strength to the fracture site during the healing process and/or during its subsequent life. Since the modulus of elasticity of the plastic plug is closer to that of bone than a metal cone screw this embodiment results that bone resorption due to stress shielding is less likely, and more micro motion occurs which aids fracture healing.

The plug 308 in this embodiment is provided with a self tapping portion to encourage engagement with the cortical

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bone 300 and ease its passage there through. The principal engagement between the plug 308 and the location stems from the constant pitch, high depth, screw thread 310 provided on the plug 308.

As with the initial embodiment of the invention the screw 316 introduced is inserted through one side 318 of the-cortical bone 300 but the opposing side 320 may or may not be left intact.

The head 312 of the plug 308 may have a tapering nature to ensure maximum engagement between the plug 308 and the cancellous material 314, see Figure 3b.

If desired, the open end may be provided for the plug so that the screw can be advanced so as to partially engage and/or pass through the cortical bone on the side opposing insertion. The screw can of course stop short of the cortical bone in the manner outlined above, however.

The plug and screw fixations of the present invention give substantial advantages in terms of performance over the conventional screws. In tests the following data was obtained.

Table 1

	Force at which	Energy input for
	fixing pulls from	pulling and fixing
	location	
Screw thread metal	0.78kN	Low
fixing		,
Plug and screw	0.85kN	High
fixing		

As can be seen, therefore, significant improvements over the prior art system are provided. The fixations provided enable higher strength, longer life fixings to be provided and enable correction of deformities, the treatment

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of other spinal problems and the fixing of trauma injuries in a highly reliable manner.

A number of fixings according to the present invention can be provided in an anterior manner on the spine. The anchors in each set are linked by a metal plate or rod(s) which in each case has been configured to the desired configuration for the spine. This applies a significant corrective force, therefore, once clamped in position on the heads of the various anchors.

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CLAIMS:

1. A bone fixing comprising a first component and a second component, the first component being provided with an internal bore to receive at least a portion of the second component, the external surface of the first component being provided with a screw thread on at least a portion thereof, a threaded engagement being provided between the first and second components.

- 2. A bone fixing according to claim 1 in which one or more parts of the first component have a first and second state, the lateral extent of the one or more parts relative to the axis, in one or more directions, being greater in the second state than in the first state.
- 3. A bone fixing according to claim 2 in which insertion of the second component into the first causes the transition from the first to the second state.
- 4. A bone fixing according to any of claims 1 to 3 in which the first component is provided with a pointed end and / or is self tapping.
- 5. A bone fixing according to any preceding claim in which the bore is provided with an internal screw thread to match the external screw thread of the second component.
- 6. A bone fixing according to any preceding claim in which the first component has a plain bore and the second component is provided with a self tapping ability.
- 7. A bone fixing according to any preceding claim in which the second component comprises a head portion and a stem portion, the head portion being provided with means for

connecting the bone fixing to another element, such as a plate or rod.

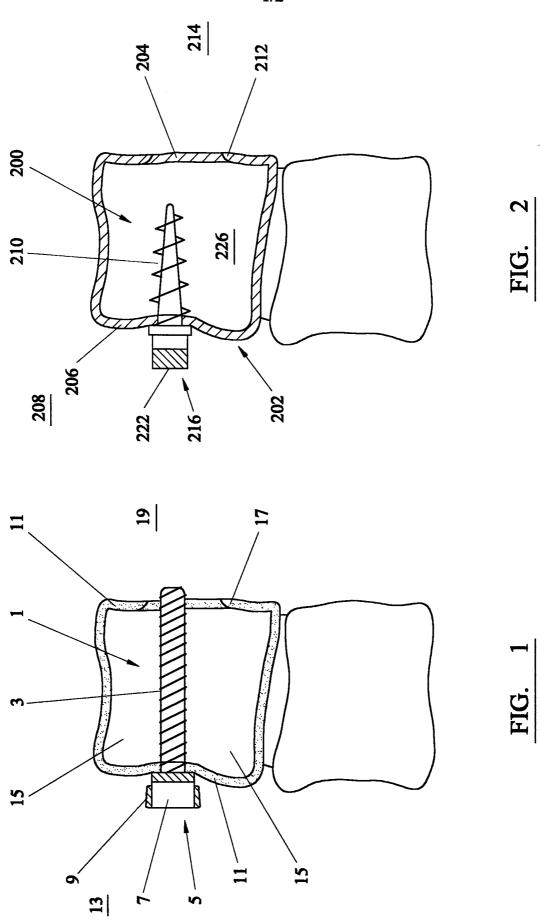
- 8. The use of a bone fixing, the bone fixing comprising a first component and a second component, the first component being provided with an internal bore to receive at least a portion of the second component, the first component engaging the bone.
- 9. The use of claim 8 in which the first component of the fixing is inserted into the bone and the second component of the fixing is inserted into the first component.
- 10. The use of claim 8 or claim 9 in which the second component is rotated to insert it in the first component.
- 11. The use of any of claims 8 to 10 in which the first component is inserted through the cortical bone on the side of insertion and the first component is inserted into the cancellous bone.
- 12. A method of forming an anchor or fixation in the bone comprising inserting a first component of the fixing into the bone and inserting a second component of the fixing into the first component, the first component engaging the bone, the second component being inserted into a bore in the first component and engaging the first component.
- 13. A method according to claim 12 in which the first component is rotated through the bone.
- 14. A method according to claim 12 or claim 13 in which the second component is rotated to insert it into the first component.

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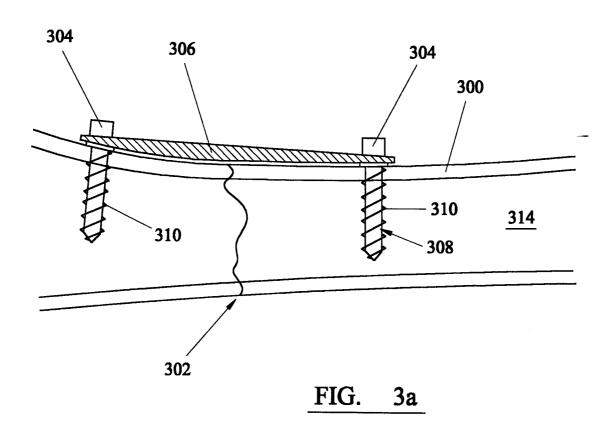
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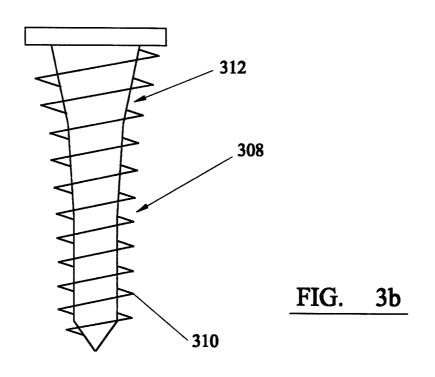
15. A method according to any of claims 12 to 14 in which the first component has a threaded engagement with the cortical bone and / or cancellous bone.

16. A method according to any of claims 12 to 15 in which a plurality of anchors or fixations are employed, the anchors—or fixations being attached to a rod, bar or plate of a spinal correction system or trauma injury system.



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INTERNATIONAL SEARCH REPORT

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Electronic d	ata base consulted during the international search (name of data bas	se and, where practical, search terms use	ad)
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Category °	Citation of document, with indication, where appropriate, of the rele	evant passages	Relevant to claim No.
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X	FR 2 691 626 A (ASA LABORATOIRES 3 December 1993 (1993-12-03) page 4, line 22 -page 5, line 2 page 5, line 10 - line 15 page 5, line 20 - line 23 figures	PROTHAID)	1-5
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X Furt	her documents are listed in the continuation of box C.	X Patent family members are liste	ed in annex.
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C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
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X	Figure 1 EP 0 340 413 A (FISCHERWERKE ARTUR FISCHER) 8 November 1989 (1989-11-08) column 3, line 20 - line 25 column 3, line 32 - line 36 figures 1,3	1-3,7

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INTERNATIONAL SEARCH REPORT

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Box i	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	ernational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: 8-16 because they relate to subject matter not required to be searched by this Authority. namely: Rule 39.1(iv) PCT- Method for treatment of the human or animal body by surgery
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Int	ternational Searching Authority found multiple inventions in this international application, as follows:
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Rema	The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

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Information on patent family members

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