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(54) IMPROVEMENTS IN OR RELATING TO BONE JOINT PROSTHESES

(71) We, ARAM DADURIAN, of 1 Knochenhauer Strasse 15, D-2800 Bremen, Germany and Günther Rehder, of Mümmelmannstrasse 10, D-2805 Stuhr 3, Germany and GÜNTHER REHDER, of public of Germany, do hereby declare the invention for which we pray that a Patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:

The present invention relates to improvements in or relating to bone joint prostheses. A preferred embodiment of the invention further relates to a knee endo prosthesis having a femur part and a tibia part which are adapted to be anchored, each by way of an intramedullary stem, in the femur and tibia respectively and which are pivotable relative to one another around a flexing-axis pin to an extent limited by abutments.

When it becomes necessary to replace a knee joint by a prosthesis as a result of damage due to accident or disease, the operating surgeon will endeavour to resect as little bone as possible and to select a prosthesis which is likely to be highly durable, so that the operation does not have to be repeated and the joint does not stiffen.

In the case of conventional total prostheses, it has been necessary to resect the widened heads from the femur and tibia, whereafter the intramedullary stems on the hinge-like prosthesis are introduced into the medullary cavity of the associated bones and anchored in place by bone cement. Considerable resection is necessary in this procedure and durability is limited since all that secures the prosthesis from turning in the bones is simply the bone cement. Consequently, impact torque loadings of the joint occasionally cause the prosthesis to loosen and the loosening is not only painful but makes a further operation necessary.

To obviate these problems, German Patent Specification No. 2,114,287 proposes that the joint zone of the prosthesis be so narrow that the joint can be implanted inside the femoral head. This step really does obviate the difficulties mentioned by making total resection of the condyle unnecessary. Also, implanting the prosthesis in a recessed part of the condyle provides extra securing against turning. Unfortunately, with the known joint construction two disadvantages arise because the prosthesis must be taken apart for implantation and because, after the intamedullary stems have been positioned, the prosthesis must be assembled by way of a hinge or pivot pin. Consequently, a bore or recess extending medially through the condyle is necessary for such pin, with a resultant reduction of the unresected part of the condyle. Yet another disadvantage is that for anatomical reasons the bore is required in a part of the condyle where the lateral ligaments are attached, so that such ligaments have to be removed, even though undamaged, and, therefore, become unavailable to damp forces and to provide additional guiding of the joint.

According to one aspect of the present invention, there is provided a bone joint prosthesis comprising a first part and a second part to be anchored, in use, to a respective bone to form a joint therebetween, a pivot pin provided on one of the first and second parts for allowing, in use, relative pivotal movement of the first and second parts, the pivot pin having a pivot axis generally parallel with a longitudinal axis of the part on which the pivot pin is provided, a rigid intermediate member mounted for rotation, in use, about the pivot axis of the pivot pin, the intermediate member having a recess or projection, and the other of the first and second parts having a corresponding projection or recess, the

recess being adapted to receive the projection such that the first and second parts can be interconnected by inserting the projection into the recess and means for enabling the projection to be secured in the recess.

According to a second aspect of the present invention, there is provided a knee endoprosthesis comprising a tibia part and a femur part, the parts adapted to be anchored, each by way of an intramedullary stem, in a tibia and a femur respectively and being pivotable, in use, relative to one another about a flexing axis pin to an extent limited by abutments, a pivot pin, the pivot pin being fixedly disposed on one of the tibia and femur parts, extending along the longitudinal axis of the said one part and extending, in use, from the said one part towards the other of the tibia and femur parts, and a rigid intermediate member having a projection and being mounted on the pivot pin for rotation about the pivot axis thereof, the said other part having a recess, the recess being adapted to receive the projection, and the said other part being provided with securing means for securing the projection in the recess, which securing means comprises the flexing axis pin.

The present invention enables the provision of a prosthesis wherein lateral ligaments do not normally have to be touched in the implantation operation - that is, the lateral ligaments can continue to perform their functions after the substitution of the prosthesis for the natural joint.

Preferably, the means for enabling the projection to be secured in the recess comprise a flexing axis pin and allow, in use, movement of the intermediate member relative to the said other part about a flexing axis, which is an axis in a plane substantially perpendicular to the pivot axis of the pivot pin.

It is further preferred that the degree of rotation of the intermediate member about the pivot axis of the pivot pin is, in use, limited by abutments. These abutments may be formed by the flexing axis pin; in one convenient embodiment, the abutments are formed by one or more adjustable eccentrics connected to the flexing axis pin, each of which may bear on a recessed part of the pivot pin, the eccentric or eccentrics being so positioned as to cause the rotation of the intermediate member about the pivot axis of the pivot pin to be restricted to different degrees when the joint is flexed by different amounts.

Advantageously, the flexing axis pin or the or an adjustable eccentric connected to the flexing axis pin is secured in fork arms of the said other part by means of one or more screw-threaded pins so as to secure against displacement and rotation.

A plastics bearing element may be provided between the flexing axis pin and the intermediate element and/or between the intermediate element and the first part.

Preferably, the degree of rotation of the flexing axis pin about the flexing axis is also limited by abutments, which may take the form of a plastics material runner or pad.

Because the degree of pivotal mobility of the joint about the pivot pin axis is dependent upon the flexing angle, there is simulation of the natural joint which, when the lower leg bone moves from the extended into the flexed position, permits rotation of the lower leg bone or tibia relative to the femur as well as the bending movement. In both the natural joint and in this preferred embodiment of the prosthesis according to the present invention, the amount of pivoting depends upon the angle between the femur and the lower leg bone.

According to further features of the present invention, the eccentric and that part of the pivot which is near the eccentric can be enclosed in dust-tight manner, and the securing element can comprise a screw which is preferably self-locking, and can be screwed into a projection of the intermediate element and to engage at its exposed end in an annular groove in the pivot or the bottom part thereof.

For a better understanding of the present invention and to show how the same may be put into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

Figure 1 shows, in diagrammatic form, an end view of knee endoprosthesis in accordance with the present invention in its extended position;

Figure 2 shows, also in diagrammatic form, a side view of the prosthesis of Figure 1;

Figure 3 shows a part cross-sectional view to an enlarged scale taken along the line 3-3 of Figure 1;
and

Figure 4 shows a partial cross-sectional view through the prosthesis taken along the line 4-4 of Figure 3 but showing the joint flexed.

Referring to the drawings, an implantable knee endoprosthesis to be described hereinafter is subdivided into a femur part F, an intermediate member Z and a tibia part T and can make a hinging movement around a flexing axis 15 between $-5°$ and $+145°$ and also, when flexed, is adapted to make a limited rotation in the region of $\pm 20°$ around the axis of the tibia. The joint embodying the flexing axis is disposed in an assembled state between the femur part F and the intermediate element Z, whereas the rotational bearing is provided between the element Z and the tibia part T and, as will become apparent from the following

description, is assembled in the course of the surgical operation.

The femur part F has an intramedullary stem 10 and a fork 12 which, as shown in Figure 2, engages around the flexing axis 15 in the form of a circle segment; the fork 12 is recessed at its centre and transversely of the axis 15 to provide two fork arms 12*a* and 12*b*. The two arms 12*a* and 12*b* are formed concentrically of the axis 15 with a bore 14.

The intermediate element Z has a lug 30 which is introducible into the recess of the fork 12 and has an outer periphery which is rounded, that is curved, around the axis 15 and has the same radius as that of the fork 12. A central bore which extends coaxially with the axis 15 and through the lug 30 has a diameter greater than the diameter of the bore 14 by an extent such that the difference between the two diameters allows sufficient space to receive a plastics bearing element subdivided into two bearing parts or shells 17 and 18 (see Figure 4). On assembly the two parts 17 and 18 are introduced into the central bore of the lug 30. Each part 17 and 18 has a side flange. The intermediate element Z then has its lug 30 pushed into the recess of the fork 12 of the femur part F and is secured rotatably by the introduction of a flexing-axis pin 20.

The lug 30 is connected *via* a neck 32 to a circular base 34 having a base surface 35 adapted to absorb the vertical forces arising in subsequent use.

As can be seen from Figures 3 and 4, the pin 20 is secured against turning, that is rotating, and sliding out laterally by means of two screw-threaded pins 27 screwed into corresponding bores in the fork arms 12*a* and 12b. At its centre the pin 20 takes the form of an eccentric 22 having an eccentric axis 23. As will be described in greater detail hereinafter, the position of the eccentric 22, that is the position of its axis 23, relative to the flexing axis 15 is a matter of considerable importance in assembly.

A plastics pad 36 pushed over the neck 32 of element Z is adapted to the curved outer diameter of the fork 12 and also, as can be seen from Figures 2 and 3, is rounded at both ends. The rounded ends serve as resilient abutments limiting the hinging movement of the prosthesis around the flexing axis 15. As previously stated, in the present embodiment, the hinging movement can extend over a region of from −5° to + 145°. The range of hinging movement can be varied readily by using a differently shaped runner 36.

The surface 35 bears rotatably on a correspondingly shaped end plate 40 of the tibia part T *via* a bearing element 38 of plastics material. A circular base 43 arising from the centre of end plate 40 and merging into a circular pivot-like pin 42 serves to centre the intermediate element Z, the same having provision for limited rotation relative to the tibia part T. The elements 40, 43 and 42 are disposed concentrically of a pivot axis 50 which corresponds to the tibia axis and which, as can be seen in Figures 3 and 4, is offset from the flexing axis 15, the axis 50 intersecting a horizontal axis (see Figure 3) which passes through the flexing axis 15 at right angles thereto.

As shown in Figure 3, the bearing element 38 which separates the surface 35 of element Z from the tibia part end plate 40 has a stepped sleeve-like extension which engages intimately around the outer contours of the pivot pin 42 and the base 43 and which is preassembled during the combination of the intermediate element Z and the femur part F. The stepped extension is received in a corresponding recess in the element Z and retained by means of a screw 46 screwed into a tapped bore in a projection 33 of the next 32. The screw 46 may be a self-locking screw. The inner end of the screw 46 extends through a lateral bore of the bearing element 38, the main function of the screw 46 being to serve as a releasable connecting element between the members Z and T. The inner end of the screw 46 engages in an annular groove 44 in the base 43. After the femur part F and tibia part T have been introduced into appropriate cavities, recesses or the like in the femur and tibia and embedded with bore cement or the like, all that the operating surgeon need do is to connect the tibia part T to the intermediate element Z by pushing the pivot pin 42 with the base 43 into the corresponding recess of the bearing element 38 and tightening the screw 46. The length thereof is such that when its head is in contact with the outside surface of the projection 33, the free or inner end of the screw engages in the groove 44 but does not contact the base thereof. This ensures that the tibia part T remains rotatable relative to the intermediate element Z.

As can be seen in Figures 3 and 4, the top end of the member 42 is formed on one side with a recess 45 which, with the prosthesis is assembled, is near the eccentric 22 of the flexing-axis pin 20. When the prosthesis is in the extended position shown in Figure 3, the recess 45 engages with the correspondingly adjusted eccentric 22 without clearance, that is when the joint is in the extended position the tibia part T cannot rotate around the axis 50 relative to the femur part F. However, when the joint is flexed through for example 90° in the manner shown in Figure 4, there is a gap *d* between the eccentric 22 and the recess 45, the gap enabling the whole tibia part T to turn in either direction until the outside edges of the recess 45 abut the eccentric 22. The

angle of rotation can be adapted to the rotatability, when flexed of a natural knee joint by appropriate adjustment of the eccentric 22 and is in the region of ± 20°.

All the bearing areas of the knee endoprosthesis, hereinbefore described are lined with an appropriate plastics material to ensure freedom from wear and a long working life. The risk of metal abrasion is, therefore, completely obviated so there is no risk of metallosis. The only metal parts which engage directly with one another are the eccentric 22 and the surfaces of the recess 45. However, these metal parts are completely enclosed, and, therefore, any metal abrasion which may occur cannot be washed out into the organism.

The subassembly comprising the femur part F and intermediate element Z with the flexing joint, such sub-assembly being adapted to be implanted in the completely prefabricated state, is narrow near the fork 12 and can be completely received in a prepared condylar cavity.

WHAT WE CLAIM IS:-

1. A bone joint prosthesis comprising a first part and a second part to be achored, in use, to a respective bone to form a joint therebetween, a pivot pin provided on one of the first and second parts for allowing, in use, relative pivotal movement of the first and second parts, the pivot pin having a pivot axis generally parallel with a longitudinal axis of the part on which the pivot pin is provided, a rigid intermediate member mounted for rotation, in use, about the pivot axis of the pivot pin, the intermediate member having a recess or projection, and the other of the first and second parts having a corresponding projection or recess, the recess being adapted to receive the projection such that the first and second parts can be interconnected by inserting the projection into the recess, and means for enabling the projection to be secured in the recess.

2. A bone joint prosthesis according to Claim 1, wherein the means for enabling the projection to be secured in the recess comprise a flexing axis pin and allow, in use, movement of the intermediate member relative to the said other part about a flexing axis, which is an axis in a plane substantially perpendicular to the pivot axis of the pivot pin.

3. A bone joint prosthesis according to Claim 1 or 2, wherein the degree of rotation of the intermediate member about the pivot axis of the pivot pin is, in use, limited by abutments.

4. A bone joint prosthesis according to Claim 3, wherein the abutments are formed by the flexing axis pin.

5. A bone joint prosthesis according to Claim 3, wherein the abutments are formed by one or more adjustable eccentrics connected to the flexing axis pin, each of which may bear on a recessed part of the pivot pin, the eccentric or eccentrics being so positioned as to cause rotation of the intermediate member about the pivot axis of the pivot pin to be restricted to different degrees when the joint is flexed by different amounts.

6. A bone joint prosthesis according to Claim 4 or 5, wherein the flexing axis pin or the or an adjustable eccentric connected to the flexing axis pin is secured in fork arms of the said other part by means of one or more screw-threaded pins so as to secure against displacement and rotation.

7. A bone joint prosthesis according to any one of Claims 2 to 6, which prosthesis comprises a plastics bearing element between the flexing axis pin and the intermediate element.

8. A bone joint prosthesis according to any one of the preceding claims, which comprises a plastics bearing element between the intermediate element and the first part.

9. A bone joint prosthesis according to Claim 7 or 8 wherein the bearing element is removable.

10. A bone joint prosthesis according to Claim 9 when dependent on Claim 7 wherein the bearing element is a flanged sleeve formed of two parts.

11. A bone joint prosthesis according to any one of Claims 2 to 10, wherein the degree of rotation of the flexing axis pin about the flexing axis is limited by abutments.

12. A bone joint prosthesis according to Claim 11, wherein the abutments take the form of a plastics material runner or pad.

13. A bone joint prosthesis according to any one of Claims 2 to 12, wherein at least part of the flexing axis pin is enclosed in a dust-tight manner.

14. A bone joint prosthesis according to any one of the preceding Claims, wherein the intermediate member is secured to the first or tibia part by means of a screw screwed or to be screwed into a projection so as to engage in an annular groove in the pivot pin or the bottom part thereof.

15. A bone joint prosthesis according to Claim 14, wherein the screw is a self-locking screw.

16. A knee endoprosthesis comprising a tibia part and a femur part, the parts adapted to be anchored, each by way of an intramedullary stem, in a tibia and a femur respectively and being pivotable, in use, relative to one another about a flexing axis pin to an extent limited by abutments, a pivot pin, the pivot pin being fixedly disposed on one of the tibia and femur parts, extending along the longitudinal axis of the said one part and extending, in use, from

the said one part towards the other of the tibia and femur parts, and a rigid intermediate member having a projection and being mounted on the pivot pin for rotation about the pivot axis thereof, the said other part having a recess, the recess being adapted to receive the projection, and the said other part being provided with securing means for securing the projection in the recess, which securing means comprises the flexing axis pin.

17. A bone joint prosthesis, substantially as hereinbefore described with reference to, and as shown in, the accompanying drawings.

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2 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 1

Fig. 1

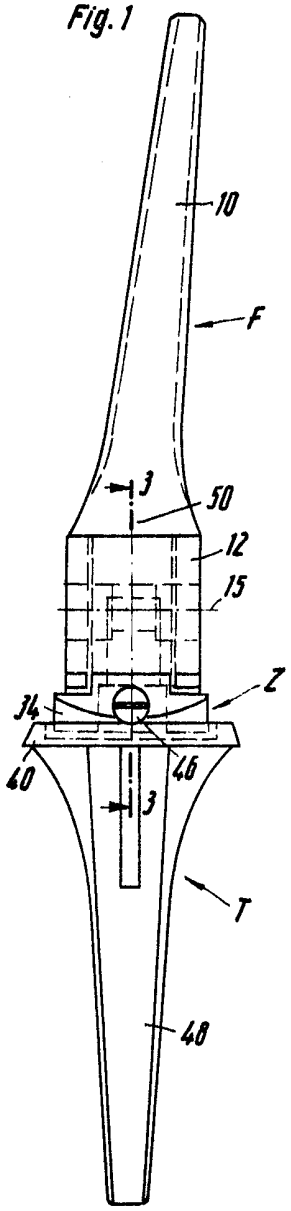

Fig. 2

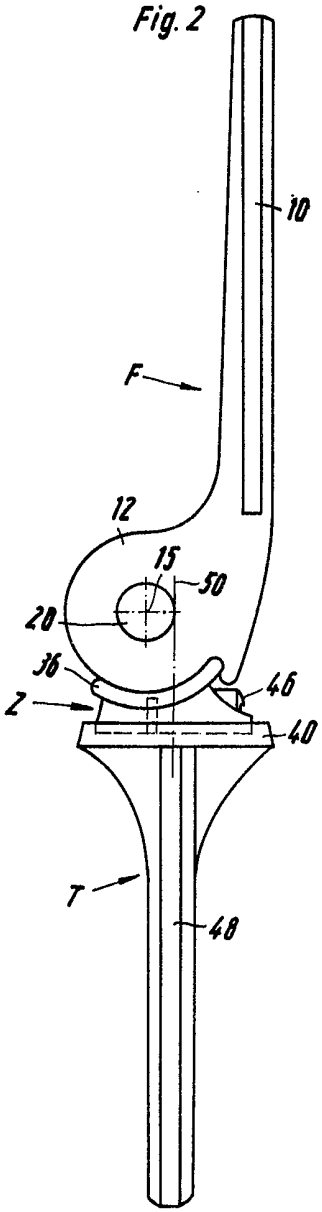

Fig.3

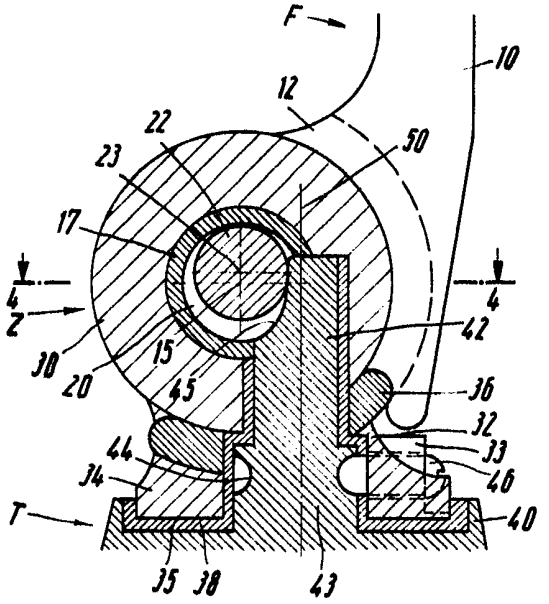
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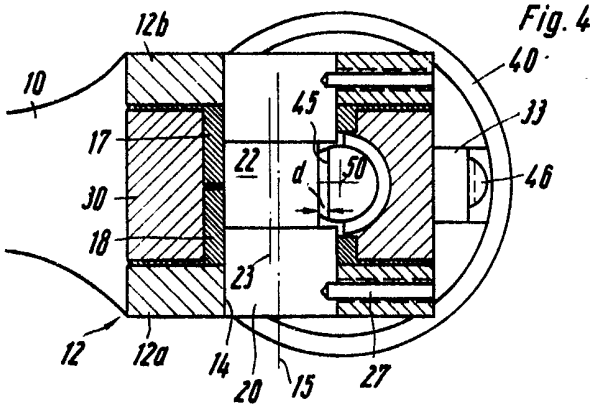
Fig. 4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