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Martinez

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[54] **KNEE IMPLANT PROSTHESIS**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 356,816, May 3, 1973, Pat. No. 3,848,276.

[52] **U.S. Cl.** ..... **3/1.911;** 128/92 C

[51] **Int. Cl.²** **A61F 1/24**

[58] **Field of Search** ..... 3/1, 1.9–1.911, 3/22; 128/92 C

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Primary Examiner—Ronald L. Frinks

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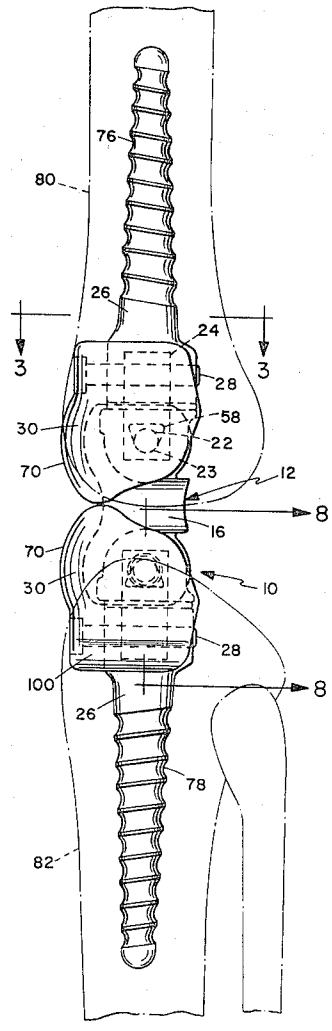
[57] **ABSTRACT**

A knee prosthesis for replacing the functions of the natural knee including the ability of the natural knee to rotate, abduct-adduct and flex. The device incorporates spaced pivot bearings mounted in a pivot body. The pivoting structure is connected to the natural bone structure by a connector screw received in the bone, and a connector shield received in a cavity surgically prepared in the bone. Resilient plastic material provides a resistance restoring force for the abduction-adduction and rotation modes.

14 Claims, 8 Drawing Figures



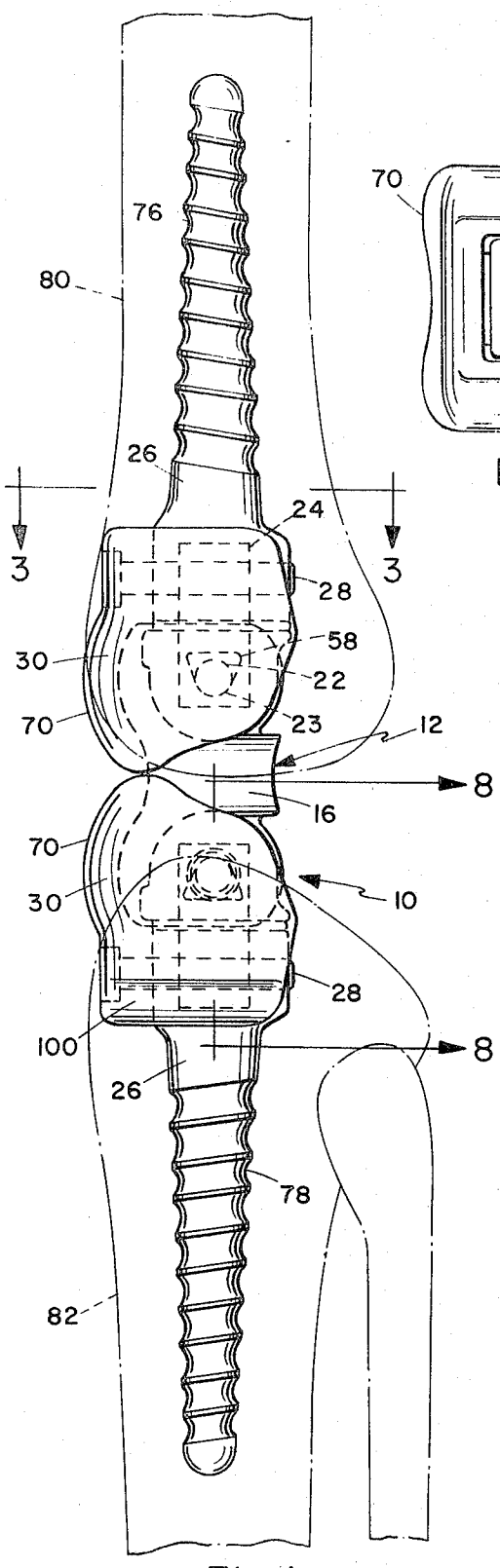


Fig. 1

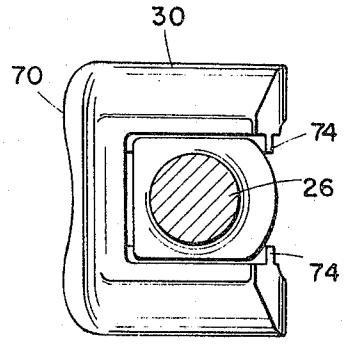


Fig. 3

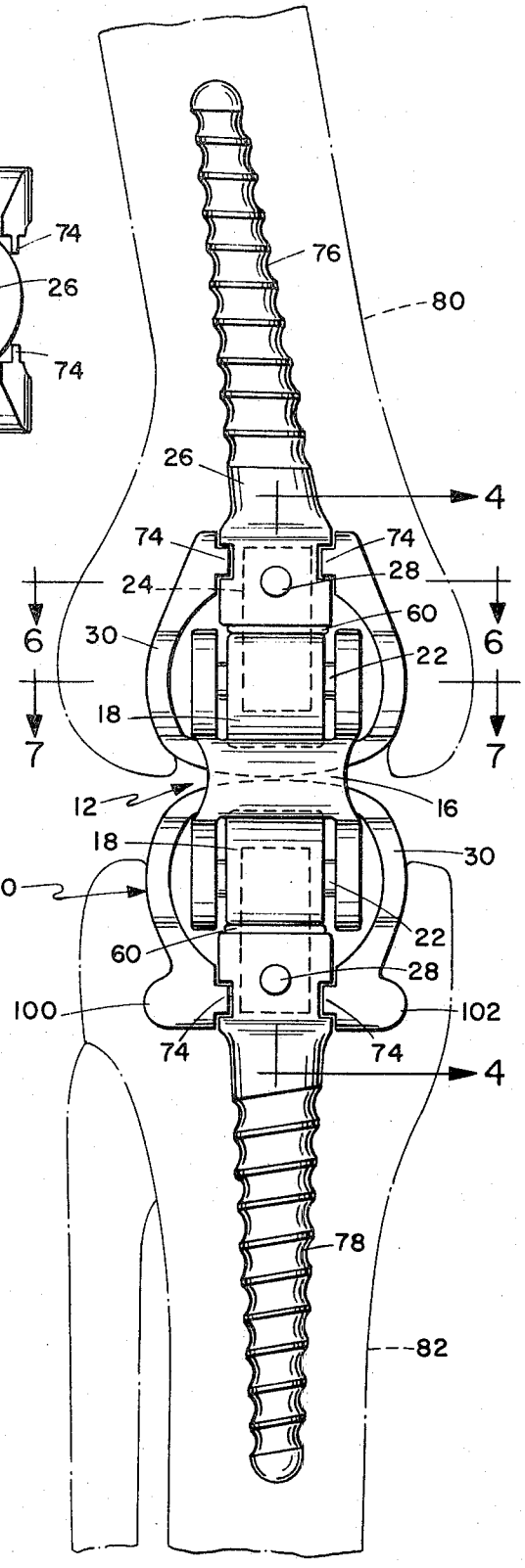


Fig. 2

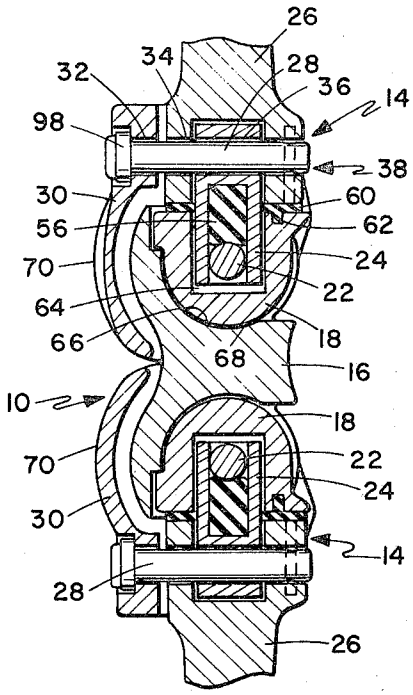


Fig. 4

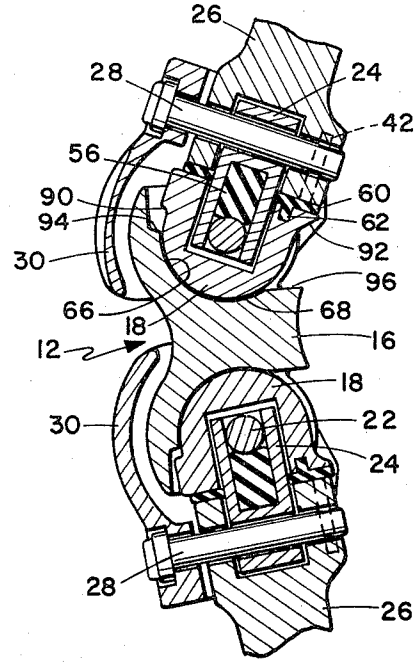


Fig. 5

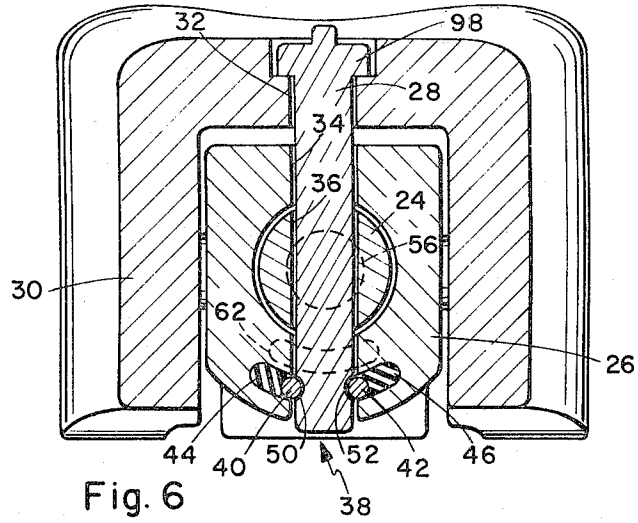


Fig. 6

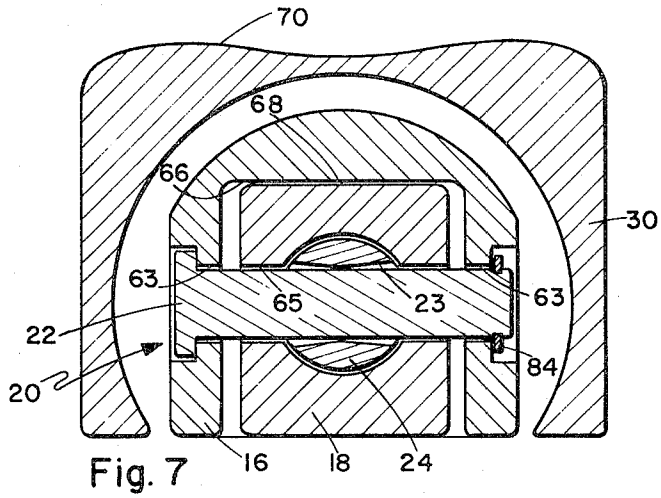


Fig. 7

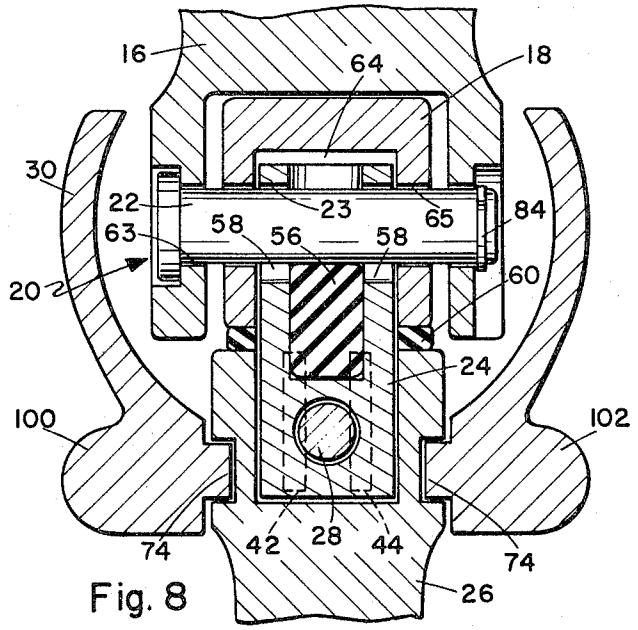


Fig. 8

KNEE IMPLANT PROSTHESIS

RELATION TO OTHER APPLICATIONS

This application is a continuation-in-part of patent application, Ser. No. **356,816,** filed May **3, 1973** and issued as U.S. Pat. No. **3,848,276** on Nov. **19, 1974.**

BACKGROUND OF THE INVENTION

Prior art knee implant prosthesis devices have generally not provided for a natural knee action or have utilized unduly complex structures to obtain the complex motion that is accomplished by a natural knee. Further deficiencies of such prior art devices included their inability to provide for materials and structures that are compatible with bodily tissues and fluids and which therefore promote infection and other side effects after implantation. Such devices have typically not been of sufficient strength to permit the user to walk normally or to engage in the other activities that produce substantial stress on the knee joint. Prior art devices have typically been of such a size that an excessive amount of bone and surrounding tissue must be removed for implantation. The trauma from such excessive bone removal can lead to complications in the operation or to an unsuccessful adaptation to the prosthesis.

The structures utilized by the prior art are covered in more detail in the co-pending application identified herein. The background of the invention is such application as well as the specification therein are hereby incorporated by reference. One approach to the problem of body tissue and body fluid contamination and infection by the knee prosthesis is set forth in this co-pending application. In this configuration, the knee prosthesis is encapsulated to prevent the entrance of body tissues and fluids to the joint. Such a configuration avoids contamination and entrapment of body tissues during knee flexion, however, encapsulation adds to the overall size of the device and increases the complexity of its installation.

It is therefore desirable to have a knee implant prosthesis that closely duplicates the motions obtainable in a natural knee especially where such a device may be implanted with a minimum of disturbance to tissues and bone structure, and wherein the device will not contaminate the body tissues and fluids nor entrap body tissues during knee flexion.

SUMMARY OF THE INVENTION

An exemplary embodiment of the invention incorporates a pivot structure having a relatively large pivot center spacing between dual pivot bearings but which has a small overall size, so that a full **135°** of knee flexion may be obtained without entrapment of body tissues. The main flexure pivots are trapped for rotation against a surface of the pivot body to which they are rotatably secured thereby increasing the rigidity and stability of the prosthesis in flexure. The pivot body also cooperates with the pivot roller elements to form stops in the straight leg and fully flexed positions.

The attachment means for connecting the pivoting structure to the natural bone structure includes a connector screw and a connector shield. The connector screw is self-tapping in the soft central bone is locked in place by the connector shield. The connector shield is received in a cavity surgically prepared in the bone to have a locking undercut. The undercut cooperates with an enlarged portion on the connector shield to lock the connector shield and connector screw in position. Adhesives may also be employed to further secure the attachment means in position.

The movements of the natural knee referred to as rotation and adduction-abduction are accommodated in the interconnection between the attachment means and the pivot roller element. The connector screw and pivot roller element have facing axial bores into which is received an axial rotation post. The rotation post has sufficient clearance from the walls of the bore in the connector screw so that it may rotate about a connector assembly pin. The connector assembly pin is on a fore and aft transverse axis so that rotation about the connector assembly pin will be in the adductionabduction rotational mode. A layer of resilient plastic material is interposed between the faces of the connector screw and pivot roller element to accommodate the adduction-abduction movement and to exert a resilient bias on the joint tending to restore the joint to its aligned orientation. The inner end of the rotation post is secured to the roller block element through the same flexure pivot pin which, in association with the roller block element, forms the flexure pivot bearing. However, the bore through the rotation post that receives the flexure pivot pin is enlarged and asymmetrical. The enlarged opening permits limited relative rotation about the overall axis of the prosthesis corresponding to the rotation of the natural knee joint. The asymmetrical configuration of the hole permitting rotation causes a "screw-in" action which corresponds to the "screw-in" effect in the natural knee occuring, for example, during normal walking. Such movement compresses the resilient plastic material received in an axial bore in the rotation post. The resilient plastic thereby exerts a restoring force tending to return the knee to its normal or aligned rotational position.

The implantation of the device is simplified by a locking mechanism utilized to secure the connector screw and connector shield to the pivot structure after the connector screw has been inserted in the bone. The connector assembly pin includes a pair of transverse surface recesses near one end. The recesses are positioned to cooperate with locking pawls in the terminal portion of the connector screw. The insertion of the pin with a proper rotational orientation will bias the locking pawls over the surface of the connector pin. Then, the bias of the pawls will cause the pawls to be forced into the surface recesses, locking and holding the pin, connector shield, connector screw, and rotation post in assembled relations. For removal, the pin is first rotated **90°** to bias the locking pins out of the recesses and then the pin may be withdrawn.

It is therefore an object of the invention to provide a new and improved knee implant prosthesis.

It is another object of the invention to provide a new and improved knee implant prosthesis that reduces the complexity of surgical implantation.

It is another object of the invention to provide a new and improved knee implant prosthesis that requires the removal of a relatively small amount of bone structure.

It is another object of the invention to provide a new and improved knee implantt prosthesis that protects against entrapment of body tissues during knee flexion and other movement.

It is another object of the invention to provide a new and improved knee implant prosthesis that closely duplicates the movement capabilities of the natural knee.

It is another object of the invention to provide a new and improved knee implant prosthesis that has high strength.

It is another object of the invention to provide a new and improved knee implant prosthesis that eliminates voids that could otherwise promote body fluid contamination.

It is another object of the invention to provide a new and improved knee implant prosthesis that provides for a natural movement of the patella and surrounding tendons.

It is another object of the invention to provide a new and improved knee implant prosthesis that is inert to body fluids and tissues.

It is another object of the invention to provide a new and improved knee implant prosthesis that provides for a high strength interconnection to the natural bone structure.

It is another object of the invention to provide a new and improved knee implant prosthesis with a high degree of rotational stability.

Other objects and many attendant advantages of the invention will become more apparent upon the reading of the following detailed description together with the drawings in which like reference numerals refer to like parts throughout and in which:

FIG. 1 is a side elevational view of the improved knee implant prosthesis.

FIG. 2 is a rear elevational view of the knee implant prosthesis.

FIG. 3 is a sectional view taken along line 3—3 of FIG. 1.

FIG. 4 is a sectional view taken along line 4—4 of FIG. 4.

FIG. 5 is a view similar to FIG. 4 showing knee flexure action.

FIG. 6 is a sectional view taken along line 6—6 of FIG. 2.

FIG. 7 is a sectional view taken along line 7—7 of FIG. 2.

FIG. 8 is a sectional view taken along line 8—8 of FIG. 1.

Referring now to the drawings there is illustrated a knee implant prosthesis **10.** The pivot structure **12** includes a pivot body **16** which mounts and supports pivot roller elements **18** through pivot bearings **20.** The pivot bearings **20** comprise pivot pins **22** received through transverse bores **63** in the pivot body **16** and bores **65** through the pivot roller elements **18.** The pins **22** are retained by spring retainer **84.** The upper and lower halfs of the prosthesis are identical except where noted therefore the prosthesis will be described in connection with the upper portion thereof.

The pivot body **16** and pivot roller element **18** have cooperating arcuate surfaces **66** and **68** which, in the preferred embodiment are lapped to closely conform to one another so that the curved surfaces supplement and stabilize the action of the pivot bearing **20.** It should be noted that it is also within the scope of the invention to incorporate cylindrical bearing rollers in recesses along the arcuate surfaces **66** or **68.**

An axial rotation post **24** is also carried on the pivot pin **22** through an enlarged transverse bore **23.** The post **24** interconnects the pivot structure **12** with the attachment means **14.** Post **24** is received in an axial bore in the connector screw **26** and is pinned, together with the connector screw **26,** and the connector shield **30,** by a connector assembly pin **28.** The pin **28** has a head with a flange **98** and is received in a bore **32** through the frontal portion of the connector shield **30,** and through a transverse bore **34** in the connector screw **26,** and transverse bore **36** through the rotation post **24.**

Assembly of the device during implantation is facilitated by the lock means **38** for the connector assembly pin **28.** The connector assembly pin **28** has a pair of diametrically opposed transversed recesses **50** and **52** near its end, which recesses receive biased locking pawls **40** and **42.** The pawls are biased into engagement with the surface of the connector assembly pin **28** by resilient material **44** and **46.** The assembly and disassembly of the structure of the invention through the use of the connector assembly pin **28** and lock means **38** will be described more fully hereinafter.

The rotation **24,** in addition to providing for the structural interconnection of the attachment means **14** and pivot structure **12,** provides for relative rotation between the femur and tibia corresponding to the rotation capability of the natural knee. The rotation is accommodated on the pivot pin **28** through the mechanism of an enlargement in the transverse bore **23** in the rotation post **24.** The enlargement produces an asymmetrical enlargement on the outer portion **58** of the transverse bore **23.** Thus rotation between the upper and lower leg members will cause a camming action of the pivot pin **22** on the inclined walls of the transverse bore **23,** drawing the pivot pin **22** up into the enlarged outer portion **58** of the bore **23,** limiting the total rotation, and causing the compression of a resilient snubber **56.** The snubber **56** is received in a bore in the rotation post **24** and serves the functions of cushioning the rotation action and providing a resistence to rotation for the purpose of introducing "feel" to the user, and for providing a return bias to the aligned orientation. A clearance space **64** provides necessary axial movement of the rotation post **24** during the aforedescribed rotation.

Rotation about the axis referred to as the adduction-abduction axis is accomplished through the provision of a resilient pad **60.** Pad **60** is positioned between the connector screw **26** and roller block element **18.** A protruding tab **62** is received in a slot on the roller block element to hold the pad **60** in position. The combined effect of the upper and lower pads **60** produces the **8°** of total adduction-abduction (left, right rocking motion) which is a necessary and normal part of natural knee action.

Both adduction-abduction and rotation are accommodated throughout the range of flexion since the generally spherical (see FIGS. **4** and **7**) upper and lower portions of the pivot body **16** cannot be drawn into conflict with the generally sphereical cavity formed by the connector shield.

Referring now specifically to FIG. **5,** the configuration of the knee prosthesis during flexion is illustrated. It will be noted that the arcuate surfaces of the pivot roller element and pivot body have moved in a sliding frictional engagement to a rotationally displaced position. The maximum arc of rotation permitted by the device is determined by the stops **90** and **92** on the pivot roller element, which cooperate with the stops **94** and **96** on the pivot body to limit overall rotation. The lower terminal portions of the connector shield **30** contact during the straight legged or knee locked posi-

tion as an additional stop. The total arc of rotation is limited to 135° which corresponds to that of the normal knee and which prevents the entrapment of body tissues between the pivoting structures.

Referring now to specifically to FIGS. 1 through 3, the installation of the knee prosthesis 10 according to the invention is illustrated. The prosthesis is illustrated as being implanted in a femur 80 and tibia 82. The lower pivot shield is locked into the tibia 82 by the provision of interlock protrusions 100 and 102 which fit into corresponding cavities surgically provided in the upper portion of the tibia. A connector screw 26 with a straight shank 78 is received in the soft central portion of the bone and is locked against rotation by the relationship of tabs 74 on the connector shield received in corresponding diametrically opposed slots on the connector screw 26. The installation of the upper connector screw 26 and connector shield 30 is similar, with the exception that the upper connector screw 26 has a canted shank 76 to correspond to the inclination of the femur 80. Further, since the connector shield 30 is nearly totally retained within the lower terminate portion of the tibia, the use of interlock protrusions is not required.

OPERATION

In use, the knee prosthesis 10 according to the invention is implanted by first cutting into the condyles of the tibia and femur to create a cavity that closely conforms to the exterior configuration of the connector shield 30. The connector screws 26 are than screwed into the soft central bone structure until they are fully inserted as illustrated in FIG. 2. The connector shields 30 are then inserted over the connector screws 26, which has the effect of locking the screws in rotational position by the action of the tabs 74. The connector assembly pins 28 perform the dual functions of securing the connector shield-connector screw relationship, and securing the combinations of connector screw 26 and connector shield 30 forming the attachment means 14 to the pivot structure 12. The pins 28 are inserted through the bores 32 in the connector shield 30, the transverse bores 34 in the connector screws and the transverse bores 36 in the rotation posts 24. When the pin 28 encounters the lock means 38 in the form of the biased pawls 40 and 42 additional pressure will force the pawls against the bias of the resilient material 44 and 46 and cam the pawls over the surface of the pin 28 and into the recesses 50 and 52. The rotational orientation of the connector pin is maintained with the flange 73 in a vertical orientation to align the recesses 50 and 52 with the pawls 40 and 42.

After implantation and convalescense, the patient is able to utilize the full rnage of normal knee movements without undesirable affects. The pivot body provides for sufficient spacing between the pivot axes about the pivot pins 60 so that at the maximum arc of rotation of 135° there is no pinching of tissue between the upper and lower portions of the device. At the same time, the use of the interconnection structure in the form of the rotation post being received in a female recess in the connector screw minimizes the overall size of the device so that the strength and resiliency of the device itself is enhanced by the natural support given by tendons and muscles. The front face 70 of the connector shield on the tibia corresponds generally to the surface of the bone structure removed and thus the connector shield forms a patellar slide retaining the desirable patellar functions. The smooth surfaces 70 of the connector shields 30 also serve to provide a surface on which the tendons may move during flexion of the knee.

In normal activity such as in walking, which exercises all of the movements of which a natural knee is capable, the abduction-adduction, and rotation capabilities of a joint are utilized. The use of resilient plastic material such as silastic for the snubber pad and insert 56 and 60 provides a desirable resistence to movement to give the user a feel for leg position and also biases the knee joint back to its nominal orientation after displacement. Plastic resilient material is found to be advantageous over other resilient means in that it fills voids as well as providing the resilient effect and thereby avoids excessive entrapment of body fluids. The joint is designed to provide sufficient strength without creating concentrated areas of stress so that the device may be constructed of pyrolytic carbon, silicon nitride or boron nitride, which materials have the desirable properties of inertness to the body system, while having high strength. These materials have a tendency toward brittleness and could not be employed, where it not for the stress design and configuration of the device, and the use of snubbers to reduce impact stresses.

If it should ever become necessary to remove the implanted prosthesis or to replace it, after the device has been surgically exposed, the connector assembly pins are merely rotated 90°. The rotation cams the locked pawls 40 and 42 onto the smooth outer surface of the pin and permits the pin to be withdrawn. The separate parts can then be disassembled.

Having described my invention, I now claim:

1. A knee prosthesis comprising joint means for controlled flexion, rotation, and abduction-adduction movements:
   - attachment means for securing said joint means between relatively movable skeletal members,
   - said joint means comprising two relatively spaced apart flexure pivot bearings journaled in a common pivot body and upper and lower pivot roller elements carried by said flexure pivot bearings,
   - said pivot body and said pivot roller elements having cooperating arcuate surfaces in relatively sliding engaging relationship,
   - each of said attachments means being secured to each of said pivot rollers for a limited relative rotation about an abduction-adduction axis and a rotation axis, which axes are mutually orthogonal with the axis of said pivot bearing.

2. The knee prosthesis according to claim 1, further including:
   - first resilient means for exerting a restoring force against relative displacement of said attachment means and said pivot roller element toward misallignment in said abduction-adduction axis.

3. The knee prosthesis according to claim 2, wherein:
   - said first resilient means comprises a resilient pad between said attachment means and said pivot roller element.

4. The knee prosthesis according to claim 1, wherein:
   - said attachment means is secured to said pivot roller element by an axial rotation post,
   - said axial rotation post being pinned by a connector assembly pin into a recess in said attachment means,

said rotation post having a transverse bore with an asymmetrical cross-section,

said pivot bearing comprising a pivot pin received through said transverse bore.

5. The knee prosthesis according to claim **4**, further including:

an axial bore extending beyond said transverse bore,

a quantity of resilient material in said bore bearing against pivot pin.

6. The knee prosthesis according to claim **1**, wherein:

said pivot roller element and said pivot body having cooperating stop members for limiting the maximum arc of relative rotation between said pivot roller element and said pivot body.

7. The knee prosthesis according to claim **1**, further including:

a connector shield secured to said attachment means,

said connector shield having at least one enlargement forming an interlock for interlocking said connector shield into bone structure.

8. The knee prosthesis according to claim **7**, wherein:

said connector shield includes a depending portion which overlies and substantially surrounds the frontal and side portions of said pivot body in the aligned orientation of said pivot roller elements.

9. The knee prosthesis according to claim **8**, wherein:

the lower terminal edges of said depending portion of said connector shield are in contact in the aligned orientation.

10. The knee prosthesis according to claim **1**, wherein:

said attachment means comprises elongated connector screws.

11. The knee prosthesis according to claim **1**, wherein:

said attachment means is secured to said pivot roller element through a connector assembly pin received in a transverse bore in said attachments means,

said connector assembly pin comprising an elongated pin,

locking means for holding said connector assembly pin within said transverse bore.

12. The knee prosthesis according to claim **11**, wherein:

said locking means comprises at least one transverse recess in the surface of said connector assembly pin and cooperating biased lock pawl positioned in said attachment means for engaging said recess when said connector assembly pin is fully inserted in said transverse bore.

13. The knee prosthesis according to claim **12**, wherein:

said lock pawl is substantially cylindrical.

14. The knee prosthesis according to claim **12**, wherein:

said lock pawl is biased by resilient plastic material.

* * * * *