PROSTHESIS WITH ARTIFICIAL LIGAMENT

Abstract: A prosthetic device comprising a bearing component (2, 4) for connection to a bone (3, 6), the bearing component (2, 4) replacing part or all of a human or animal joint, and a prosthetic ligament (8) which is connected to or passes through the bearing component (2, 4). Preferably, the joint comprises a human knee joint and the first and second bearing components comprise a tibial bearing component (4) and a femoral bearing component (2) respectively, and the prosthetic ligament (8) at one end is connected to or passes through the tibial component (4) and at the other end is connected to or passes through the femoral component (2). The present invention can be used with a fixed bearing prosthetic knee or a mobile bearing knee using a meniscal component (10).
SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
--- with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
PROSTHESIS WITH ARTIFICIAL LIGAMENT

BACKGROUND

In the normal knee, the anterior and posterior cruciate ligaments work in concert to guide the anterior/posterior translation of the femur on the tibia through the normal range of flexion of the knee.

The structure and kinematics of the natural knee are described in detail in the book "Surgery of the Knee" by John N Insall and Michael A Kelly. The attached Figures 1A, 1B, 2A and 2B are taken from that book.

Figure 1A shows the anterior cruciate ligament in extension and figure 1B shows the anterior cruciate ligament in flexion. Figure 2A shows the posterior cruciate ligament in extension and Figure 2B shows the posterior cruciate ligament in flexion.

With the exception of the Cloutier prosthesis described in US 4,207,627, all total knee replacements are designed to function without the anterior cruciate ligament. Some retain the posterior cruciate ligament in an attempt to get the femur to roll back on the tibia during flexion, whereas others encourage rollback with some kind of posterior cruciate substituting mechanism, eg a cam and post. A retained posterior cruciate ligament, or a cam and post, can help the femur to roll back in flexion, but cannot force the femur forward in extension.

There are several approaches to substituting for the action of the anterior cruciate ligament, and getting
the femur to roll forward as the knee extends. For example the prosthesis may be provided with two sets of articular surfaces. One set engages in full extension; the other set is located in a more posterior position, and engages as the knee is flexed (see US 5,658,342 Draganich & Pottenger). Alternatively, the articular surfaces can be shaped to encourage roll forward in extension, see EP 1121074 (Walker), or the knee prosthesis may be provided with a saddle shaped recess in the tibial bearing which engages with a centrally placed cam on the femoral component to force the femoral component forwards in extension.

It is known to replace ruptured anterior cruciate ligaments with prosthetic ligaments in the form of cords, such as the ABC ligaments from Surgicraft Limited (registered trademarks). As in the natural knee, the ligament is connected to the femur at one end and to the tibia at the other end.

SUMMARY OF THE INVENTION

A prosthetic device comprising a bearing component for connection to a bone, the bearing component replacing part or all of a human or animal joint, and a prosthetic ligament which is connected to or passes through the bearing component.

The bearing component may be provided with a peg or bollard to which the prosthetic ligament is connected. Preferably, the peg is integrally formed with the bearing component. Alternatively, the peg may be fixed to the bearing component. For example, the peg may be an interference fit in a tapered hole in the bearing
component or may be screwed into a threaded bore formed in the bearing component.

 Preferably, an end of the ligament is formed into a loop which fits over the peg. Alternatively a hole may be formed in the ligament, the peg being accommodated in the hole. Preferably, the hole is shaped like the eye of a needle.

 Preferably, an opening is formed in the bearing component, through which the prosthetic ligament passes. Preferably, the opening tapers outwardly at one or both ends, so that wear of the prosthetic ligament by abrasion against an inside wall of the opening is minimised.

 Preferably, means are provided for adjusting the length of the prosthetic ligament. The length may be adjusted so as to provide appropriate tension in the prosthetic ligament throughout the range of movement of the joint. The means may comprise a turnbuckle or a plurality of loops situated along the prosthetic ligament, the appropriate loop being selected to achieve the required tension in the ligament. The adjustment means ensures that the prosthetic ligament can work with a retained natural posterior cruciate ligament, such that it is neither stretched nor lax in any position over the entire range of motion of the knee.

 The required length of ligament may be determined intra-operatively by a "trial reduction", before fixation of some or all of the components. An artificial ligament of the required length can then be selected from a range of artificial ligaments of
different lengths which is made available to the surgeon.

Preferably the prosthetic ligament is formed from resilient material. Alternatively, the prosthetic ligament may be formed from rigid or semi-rigid material and may comprise, at least in part, a rigid strut which is able to resist compressive loads. The prosthetic ligament may be formed from Polyester and/or Daeron and/or Polyurethane and may be formed from one or more bundles of individual fibres. The fibres may be parallel or interlinked or a combination of the two to achieve a desired resilience characteristic.

Preferably, the bearing component comprises a first bearing component for connection to a first bone and a second bearing component for connection to a second bone, the prosthetic ligament being connected to or passing through the first and/or second bearing component. The prosthetic ligament may also be connected to the first and/or second bone.

Preferably, the joint comprises a human knee joint and the first and second bearing components comprise a tibial bearing component and a femoral bearing component respectively, and the prosthetic ligament at one end is connected to or passes through the tibial component and at the other end is connected to or passes through the femoral component. Preferably, the prosthetic ligament is connected at one end to the tibial component and at the other end to a femur, or at one end to the femoral component and at the other end to a tibia. Preferably, the prosthetic ligament is
adapted to bias the femur in an anterior direction as the joint extends.

A device in accordance with the present invention provides a means for substituting for the action of the anterior and/or posterior cruciate ligaments and reproduces more closely than existing prostheses the kinematics of the natural knee joint.

The present invention can be used with a fixed bearing prosthetic knee. It can also be used with a mobile bearing knee using a meniscal component. An opening for the prosthetic ligament may be provided through the meniscal component, so that the meniscal component is free to translate and rotate relative to the tibial component. Preferably, the opening tapers outwardly at both ends, so that wear of the prosthetic ligament by abrasion against an inside wall of the opening is minimised and so that translation and rotation of the meniscal component can be accommodated.

According to a second aspect of the present invention there is provided a knee prosthesis comprising a femoral component for attachment to a femur, a tibial component for attachment to a tibia and a meniscal component which is disposed between the femoral and tibial components, the tibial component having a projection to which is attached an artificial ligament, the projection engaging with a cooperating formation on the meniscal component to provide restraint of movement of the meniscal component relative to the tibial component.
For a better understanding of the present invention and to show how it may be carried into effect, reference will now be made by way of example, to the accompanying drawings, in which:

Figure 1A is a side view of a human femur and tibia showing the anterior cruciate ligament in extension;

Figure 1B is a side view of a human femur and tibia showing the anterior cruciate ligament in flexion;

Figure 2A is a side view of a human femur and tibia showing the posterior cruciate ligament in extension;

Figure 2B is a side view of a human femur and tibia showing the posterior cruciate ligament in flexion;

Figure 3A is a front perspective view of a fixed bearing knee prosthesis incorporating an artificial ligament;

Figure 3B is a side view of the prosthesis of Figure 3A;

Figure 3C is an enlarge view of the attachment of the artificial ligament to a condyle of the femoral component illustrated in Figure 3A;

Figure 3D is an enlarged view of an end of artificial ligament in the form of a loop of fibres;

Figure 3E is an enlarged view of an end of an artificial ligament in which is formed a fixing opening;
Figure 4 shows a fixed bearing knee prosthesis incorporating an artificial ligament which is attached externally to the tibia;

Figure 5 is a partial view of the prosthesis of Figure 4 in which the tibial component is provided with a "key-hole" shaped cut out to accommodate the artificial ligament;

Figure 6 shows a prosthesis as illustrated in Figure 5 in which an end of the artificial ligament is fixed to an edge of the tibial component of the prosthesis;

Figure 7A shows the preferred line of action of force applied by an artificial ligament to a ligament bollard;

Figure 7B shows a first stage in attaching an artificial ligament to a bollard;

Figure 7C shows the ligament in its installed position;

Figure 8A is a perspective view of a metal-backed fixed-bearing knee prosthesis in which the artificial ligament is attached to the tibial component of the prosthesis;

Figure 8B is a side view of the prosthesis illustrated in Figure 8A, showing one mode of attachment of the artificial ligament to the tibial component;

Figure 8C shows an alternative mode of attachment of the artificial ligament to the tibial component; and
Figure 9 is a perspective view of the tibial component and meniscal component of a mobile bearing knee prosthesis incorporating an artificial ligament.

Figures 3A to 3C show a fixed bearing prosthesis comprising a femoral component 2 which is implanted onto the distal end of a human femur 3, and a tibial component 4 which is implanted onto the proximal end of a human tibia 6. An artificial ligament 8 replaces the anterior cruciate ligament and is attached at one end to a bollard 10 formed on a lateral condyle 12 of the femoral component 2 and at the opposite end to the tibial component 4 or to the tibia 6. In order to reproduce as closely as possible the line of action of a natural anterior cruciate ligament, the artificial ligament 8 passes through aligned openings 14, 16 in the tibial component 4 and tibia 6 to the outside of the tibia 6 where it is attached to the tibia 6 or to the tibial component 4.

Figure 3D shows an end of an artificial ligament 8 comprising one or more bundles of fibres which are formed into a loop which fits over the bollard 10.

Figure 3E shows an alternative type of ligament comprising a band or strap in which is formed an eye 20 which fits over the bollard 10.

Figure 4 shows an arrangement in which the artificial ligament 8 is attached to the tibia 6 by a staple 22 which is driven directly into the tibia 6. In an alternative arrangement illustrated in Figure 6 the
artificial ligament 8 is attached to a bollard 24 fixed to the tibial component 4.

In the embodiment illustrated in Figures 5 and 6, the opening 14 through the tibial component 4 is substantially "key-hole" shaped so that during articulation of the knee joint, the artificial ligament 8 does not abrade itself on the tibial component throughout the entire range of movement.

In the Figure 5 embodiment, bearing surfaces are formed directly in the tibial component 4, whereas in the Figure 6 embodiment the bearing surfaces are formed in a meniscal component 26 which is attached to the tibial component 4.

Figure 7A is an enlarged view of a bollard 10, 24. The bollard has an enlarged head 28 and narrower stem 30. The head 28 of each bollard 10, 24 is substantially oval in shape and is attached to the femoral component 2 or tibial component 4 such that its longer axis A-A is substantially perpendicular to the direction of pull of the artificial ligament, indicated by arrow F.

Figure 7B shows how the artificial ligament 8 is attached to the bollard 10, 24. More specifically, the artificial ligament 8 is either provided with an elongated loop 18 or a substantially oval eye 20, which is fitted over the bollard 10, 24 in the orientation illustrated in Figure 7B. The ligament 8 is then twisted through 90 degrees until its longitudinal axis is aligned with the direction F in Figure 7A. This arrangement ensures that the artificial ligament 8 is
easy to attach to bollards 10, 24, but it is also
attached securely when under load.

Figure 8A shows a metal backed fixed bearing prosthesis
comprising a tibial component 4 to which is attached a
polyethylene bearing component 32 having bearing
surfaces which cooperate with a femoral component (not
shown). The bearing component 32 is provided with a
chamfered recess 34 which accommodates the artificial
ligament 8. In this embodiment, the bollard 24 is
fixed directly to a projection 36 formed on the tibial
component 4. In Figure 8A, the bollard 24 is connected
to an upper surface of the projection 36, whereas in
Figure 8C, the bollard 24 is fitted to a side surface
of a larger projection 38. It will be appreciated that
in the embodiment illustrated in Figure 8B, the
artificial ligament 8 is forced to bend during
flexion/extension as it comes into contact with the
bearing component 32, whereas in the arrangement
illustrated in Figure 8C the ligament 8 rotates during
flexion/extension about the bollard 24. Although this
rotation may cause local abrasion of the ligament 8
adjacent the bollard 24, this is considered preferable
to abrasion of the ligament 8 where it contacts the
bearing component 32, as in the Figure 8B embodiment.

Figure 9 shows a mobile-bearing prosthesis comprising a
tibial plateau 4 on which slides a polyethylene
meniscal component 40. The meniscal component 40 is
substantially unconstrained, but the projection 36 (of
the type shown in Figure 8C) which supports the bollard
24 operates in conjunction with a recess 42 formed in
the meniscal component 40, to resist dislocation of the
meniscal component. Thus the projection 38 serves the
dual function of anchoring the artificial ligament and providing limited constraint of the meniscal component.

In the illustrated embodiments, an artificial ligament 8 is used to replace the anterior cruciate ligament. However, it will be appreciated that similar fixation techniques could be used to attach an artificial posterior cruciate ligament. Furthermore, the present invention is applicable to any prosthesis used to replace all or part of a human or animal joint in which an artificial ligament is connected to or passes through a bearing component of the prosthesis.
CLAIMS

1. A prosthetic device comprising a bearing component for connection to a bone, the bearing component replacing part or all of a human or animal joint, and a prosthetic ligament which is connected to and/or passes through the bearing component.

2. A prosthetic device as claimed in claim 1, in which the bearing component is provided with a peg or bollard to which the prosthetic ligament is connected.

3. A prosthetic device as claimed in claim 2, in which the peg is integrally formed with the bearing component.

4. A prosthetic device as claimed in claim 2 or 3, in which the end of the ligament is formed into a loop which fits over the peg.

5. A prosthetic device as claimed in any one of the preceding claims, in which an opening is formed in the bearing component, through which the prosthetic ligament passes.

6. A prosthetic device as claimed in claim 5, in which the opening tapers outwardly at one or both ends.

7. A prosthetic device as claimed in any one of the preceding claims, in which means are provided for adjusting the length of the prosthetic ligament.
8. A prosthetic device as claimed in any one of the preceding claims, in which the prosthetic ligament is formed from one or more bundles of individual fibres.

9. A prosthetic device as claimed in claim 8, in which the fibres are parallel and/or interlinked, to achieve a desired resilience characteristic of the prosthetic ligament.

10. A prosthetic device as claimed in any one of the preceding claims, in which the bearing component comprises a first bearing component for connection to a first bone and a second bearing component for connection to a second bone, the prosthetic ligament being connected to or passing through the first and/or second bearing component.

11. A prosthetic device as claimed in claim 10, in which the prosthetic ligament passes through the first and/or second bearing components to be secured to the first and/or second bone respectively.

12. A prosthetic device as claimed in claim 10 or 11, in which the joint comprises a human knee joint and the first and second bearing components comprise a tibial bearing component and a femoral bearing component respectively, and the prosthetic ligament at one end is connected to or passes through the tibial component and at the other end is connected to or passes through the femoral component.

13. A prosthetic device as claimed in claim 12, in which the prosthetic ligament is adapted to bias a
human femur in an anterior direction as the joint extends.

14. A prosthetic device as claimed in any one of claims 10 to 13 further comprising a meniscal component, an opening for the prosthetic ligament being provided through the meniscal component.

15. A prosthetic device as claimed in claim 14, in which the opening tapers outwardly at one or both ends.

16. A prosthetic device as claimed in claim 14 or 15 in which the opening is substantially key-hole shaped.

17. A prosthetic device substantially as described herein, with reference to, and as shown in Figures 3A to 9.
## INTERNATIONAL SEARCH REPORT

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 7 A61F2/38 A61F2/08

According to international Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of database and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<td>WO 03/005914 A (ROGER GREGORY JAMES ;AUSTRALIAN SURGICAL DESIGN AND (AU))</td>
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**X** Special categories of cited documents:

*A* document defining the general state of the art which is not considered to be of particular relevance

*E* earlier document published on or after the international filing date

*L* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

*O* earlier document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

*P* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other documents, such combination being obvious to a person skilled in the art

**X** Patent family members are listed in annex.

**X** Special categories of cited documents:

*Y* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

**X** earlier document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

**Y** document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other documents, such combination being obvious to a person skilled in the art

**X** Document of the same patent family

**Date of the actual completion of the international search**

9 September 2004

**Date of mailing of the international search report**

17/09/2004

**Name and mailing address of the ISA**

European Patent Office, P.B. 5316 Patentlaan 2 NL - 2280 HV Rijswijk

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Authorized officer

Storer, J
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# INTERNATIONAL SEARCH REPORT

### Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [ ] Claims Nos.: 
   because they relate to subject matter not required to be searched by this Authority, namely:

2. [X] Claims Nos.: 17
   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:
   
   *see FURTHER INFORMATION sheet PCT/ISA/210*

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 III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International 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. [X] 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.:  

**Remark on Protest**

- [ ] The additional search fees were accompanied by the applicant's protest.
- [ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2004)
Continuation of Box II.2

Claims Nos.: 17

Present claim 17 relates to an extremely large number of possible apparatus. In fact, the claims contain so many possible permutations that a lack of clarity within the meaning of Article 6 PCT arises to such an extent as to render a meaningful search of the claims impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear, namely the apparatus of claims 1-16.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.
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