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(56) Documents Cited:
GB 2499316 A **GB 2495775 A**
WO 2015/057814 A1 **WO 2001/066021 A1**

(58) Field of Search:
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Other: **Online: WPI, EPODOC**

(54) Title of the Invention: **Tool**
Abstract Title: **Femoral jig for testing in flexion and extension before resection**

(57) The present invention provides a femoral jig 1 for use in knee surgery, said jig comprising a component shaped to indicate the profile of a femoral prosthesis, and at least one component which is capable of being mounted or demounted, and which component can comprise one or more spacers 19, a footplate (102, see figure 16) and/or an anterior proximal reference arm (12, see figure 5). The jig allows for the size and position of the femoral prosthesis to be tested, in flexion and extension, prior to any femoral bone resections. The jig may comprise a series of attachment holes for the dismountable component.

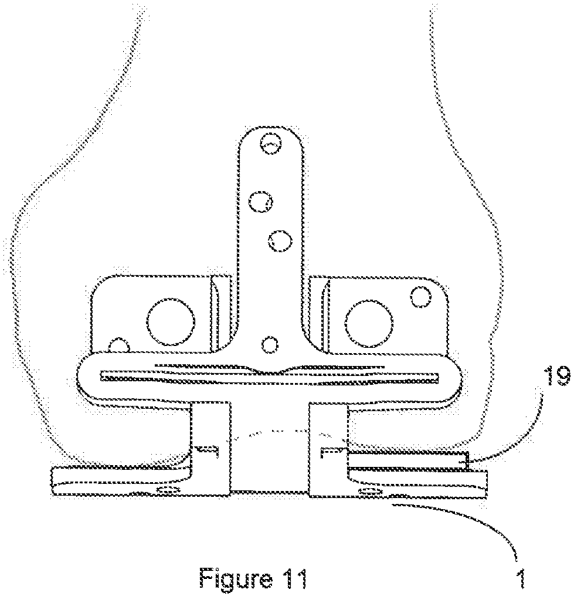

Figure 11

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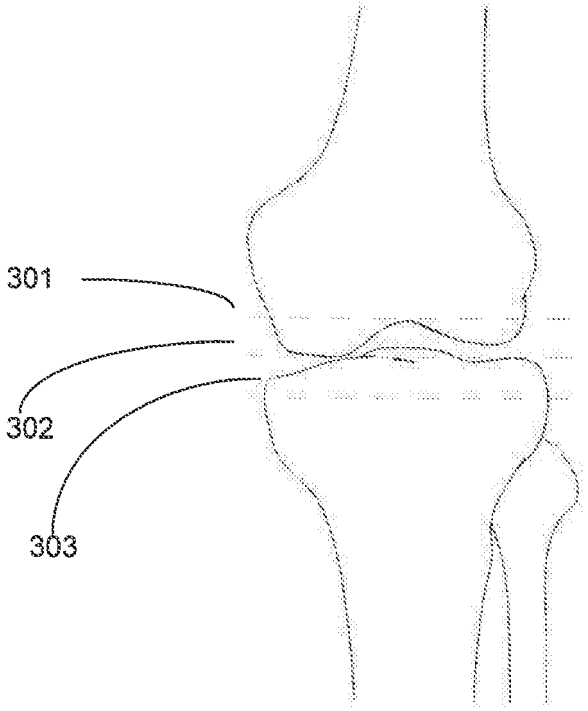


Figure 1

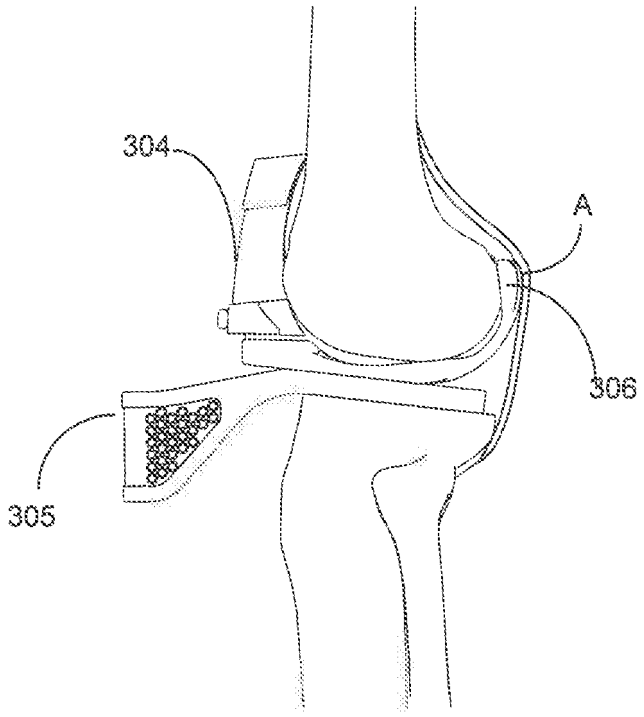
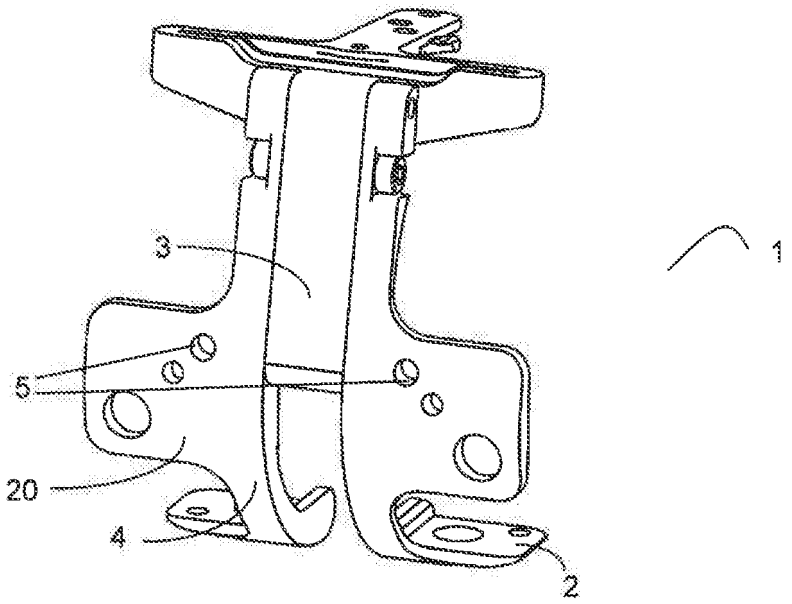


Figure 2



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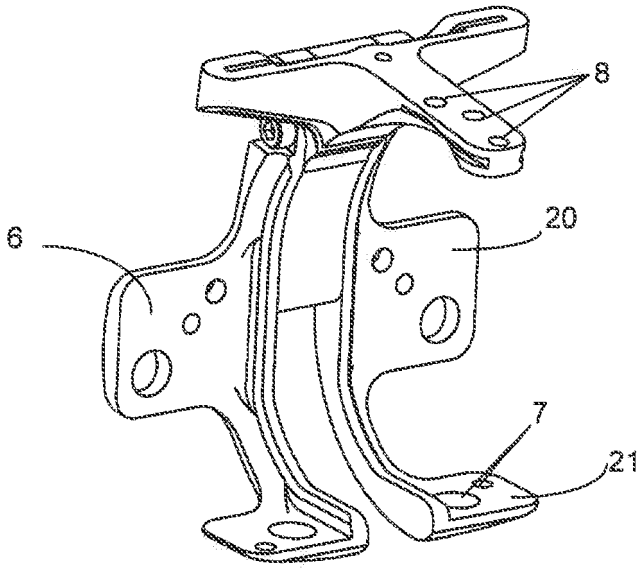

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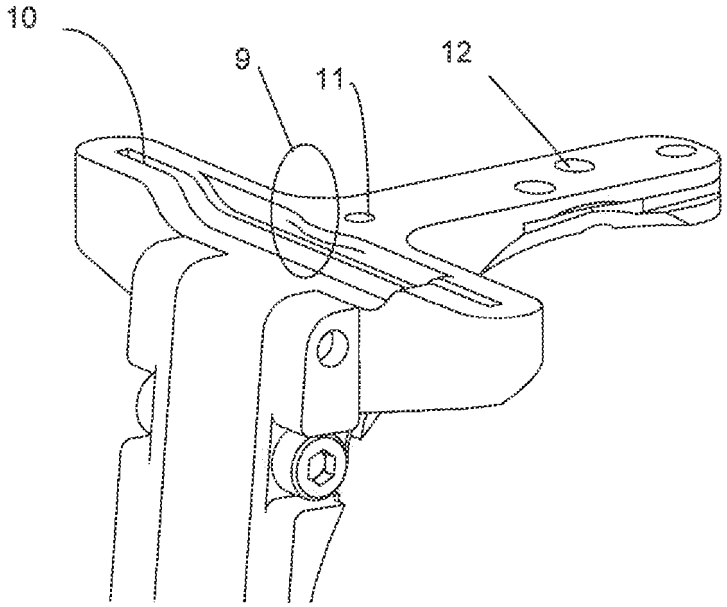

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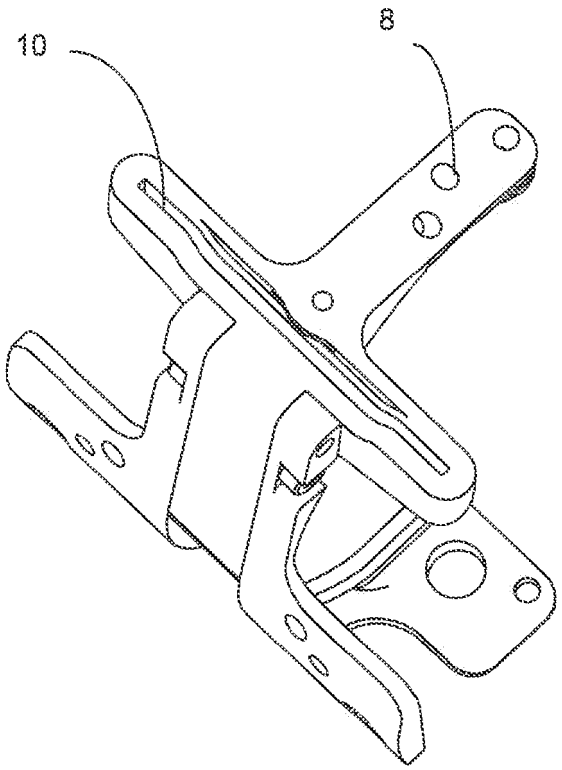

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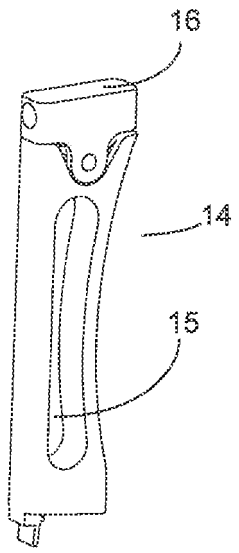

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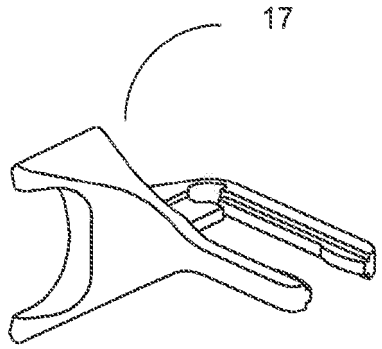

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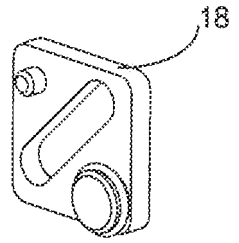

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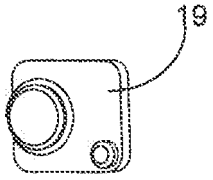

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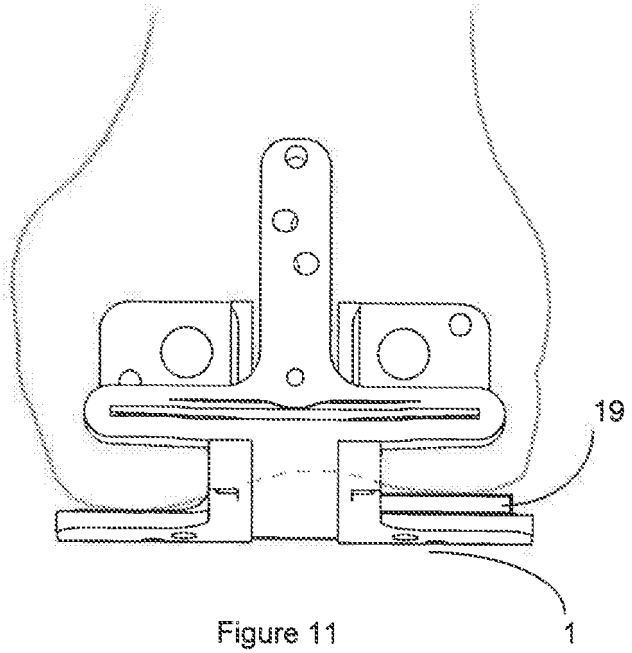

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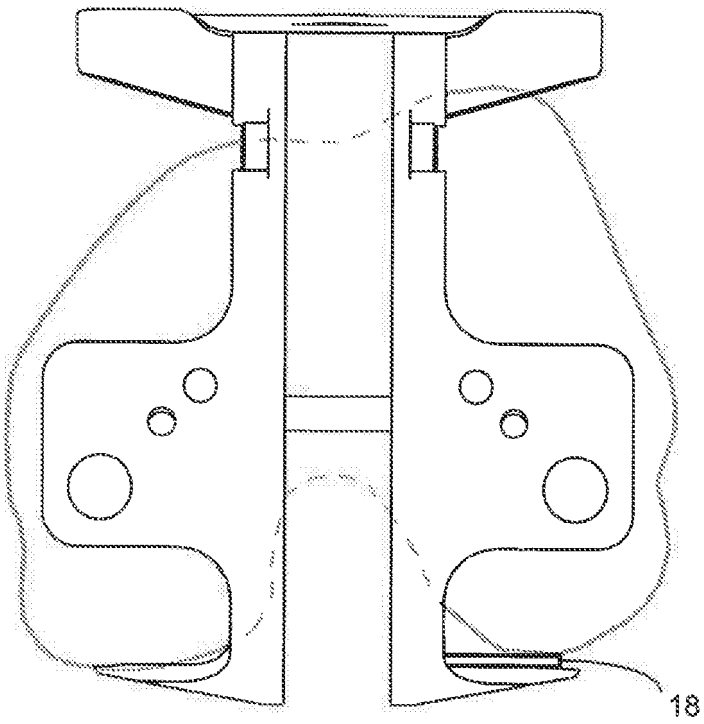

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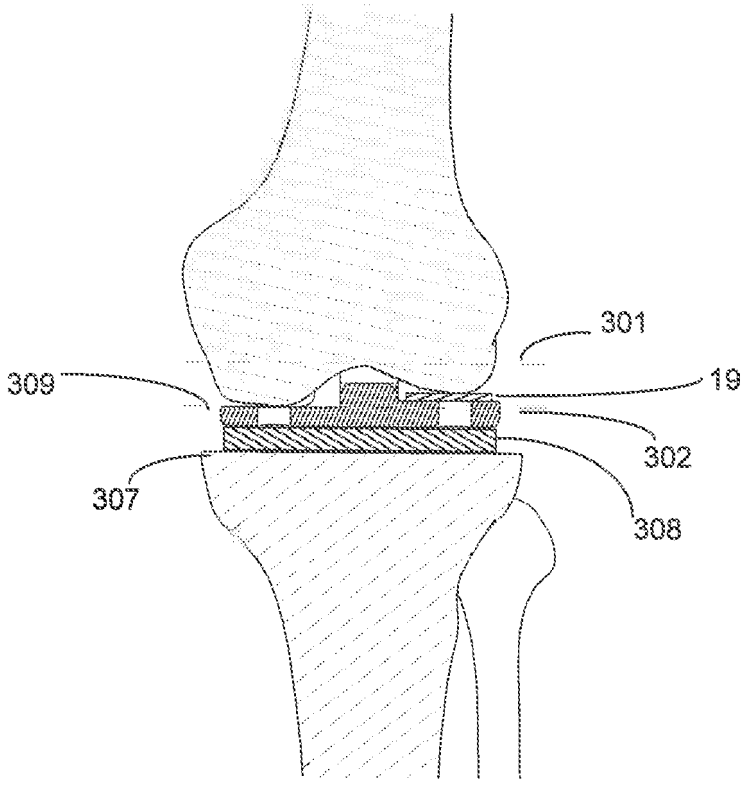

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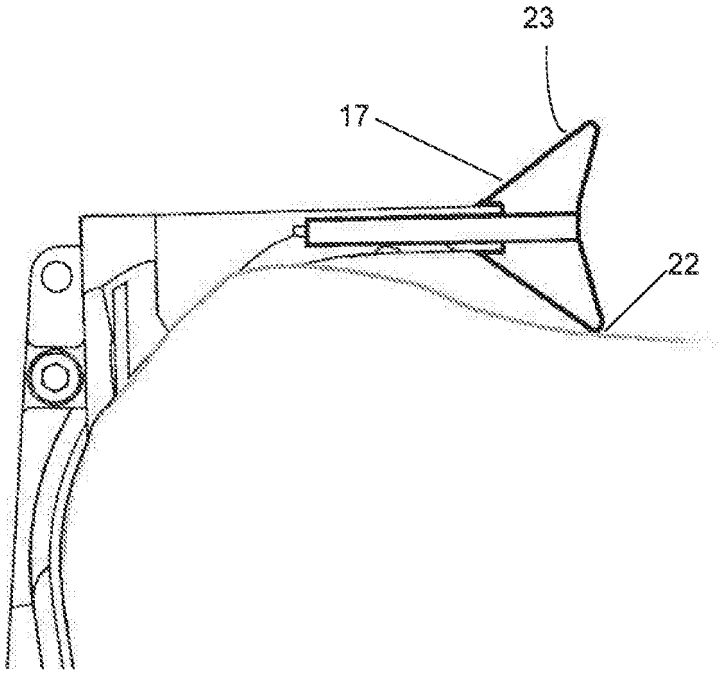

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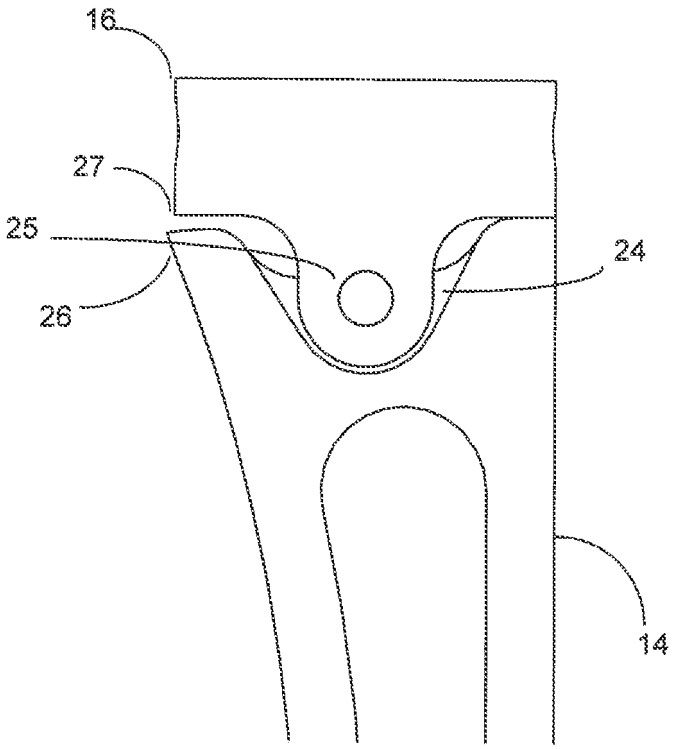

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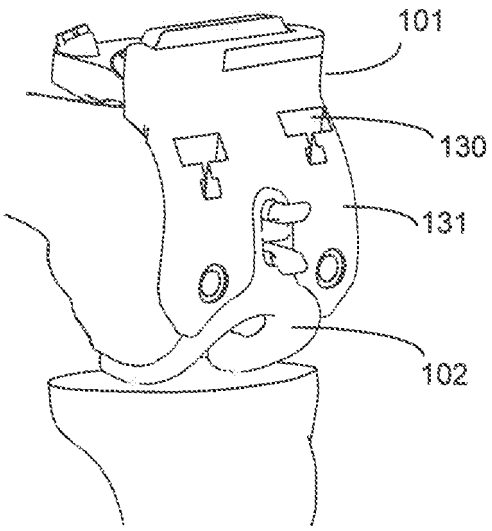

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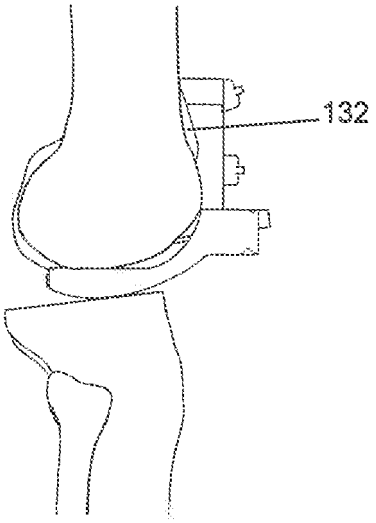

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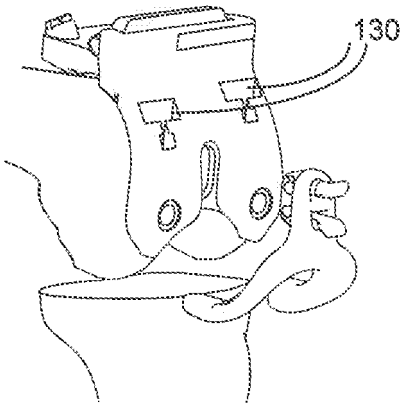

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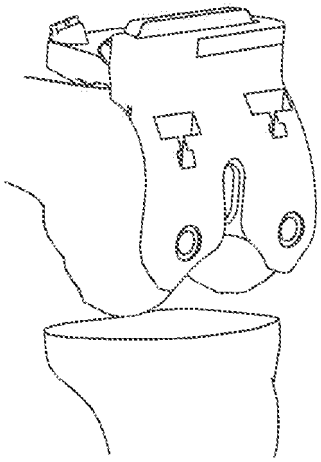
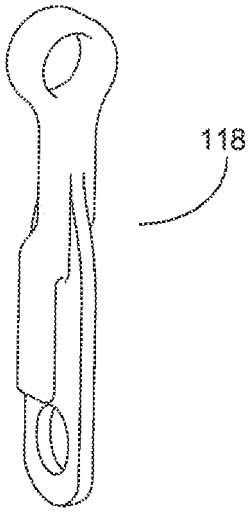
Figure 19





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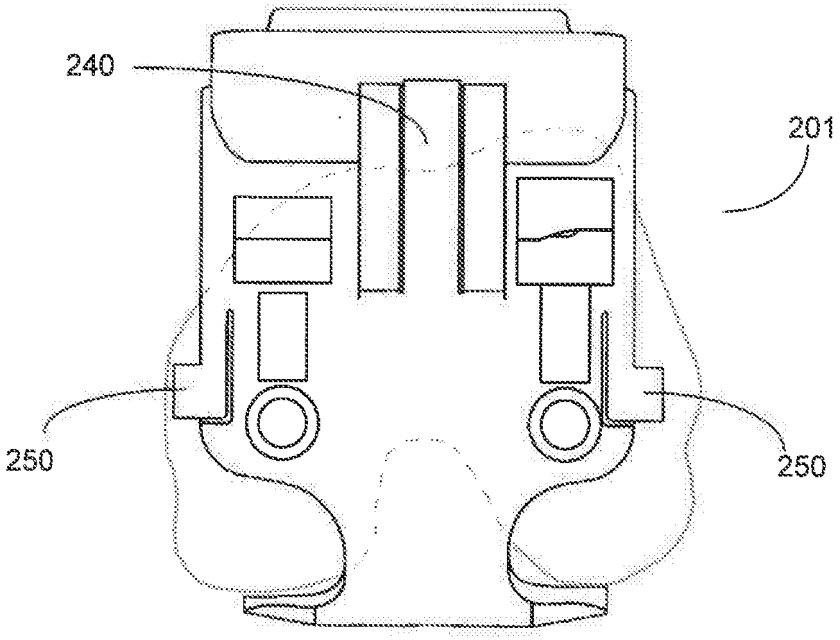

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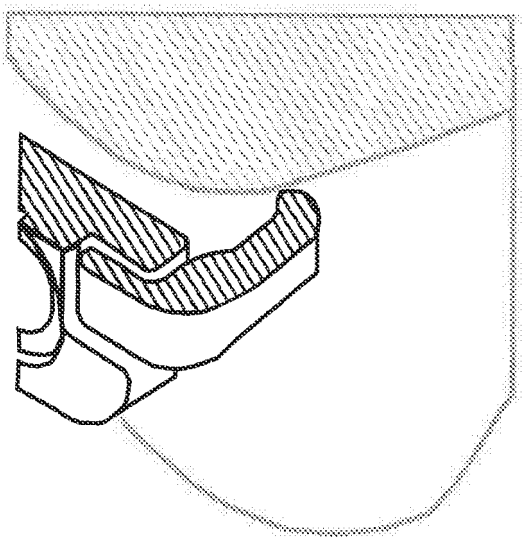

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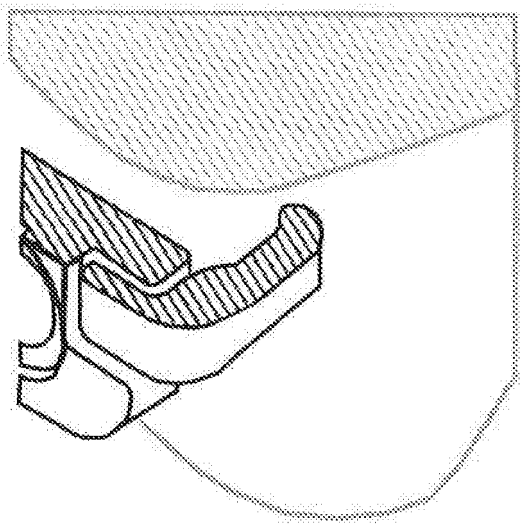

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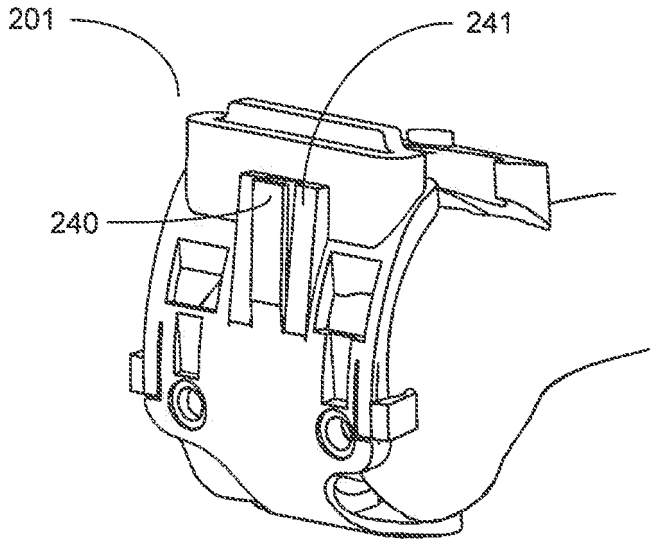

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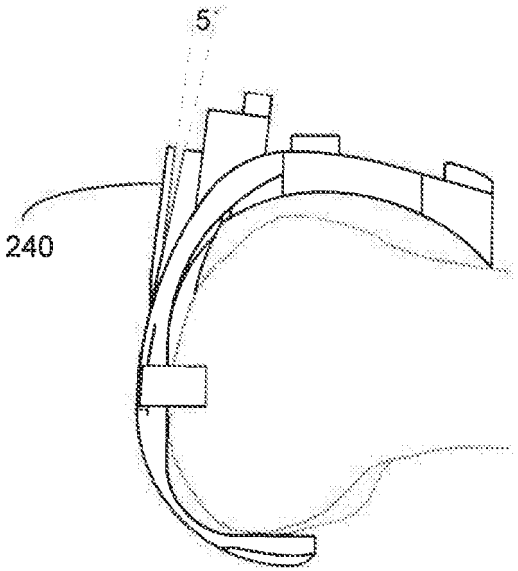

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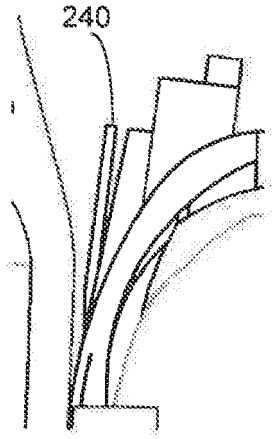

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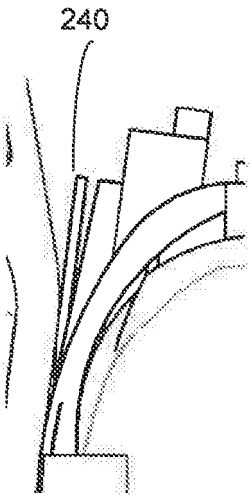

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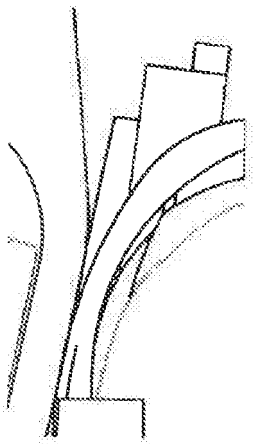

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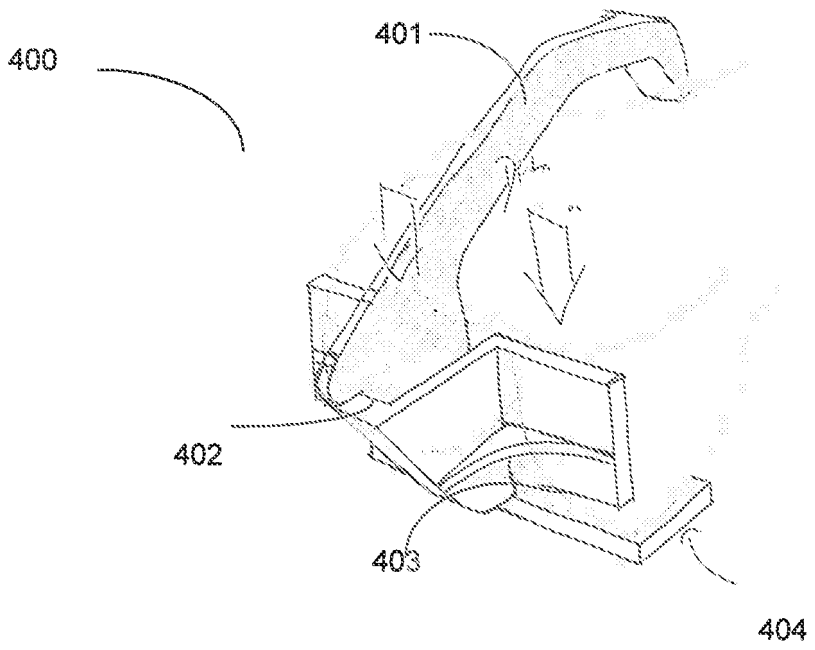

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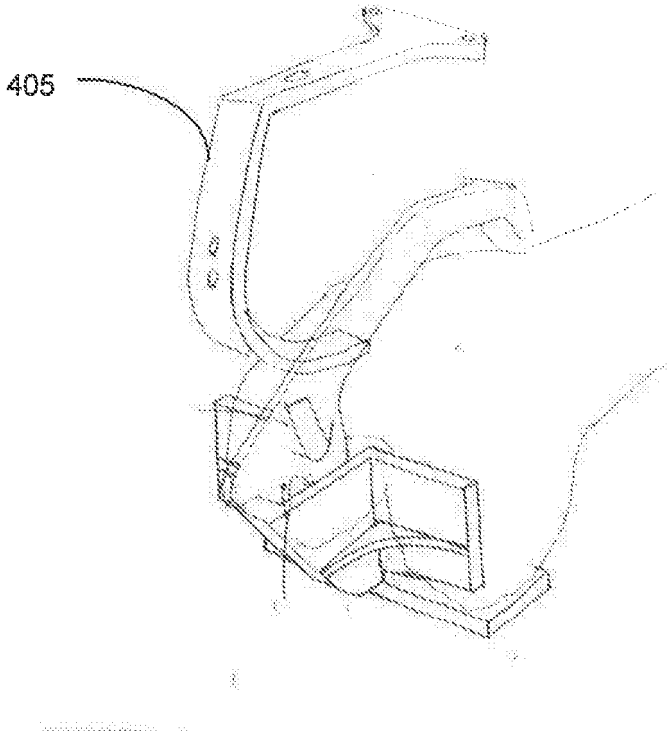

Figure 30

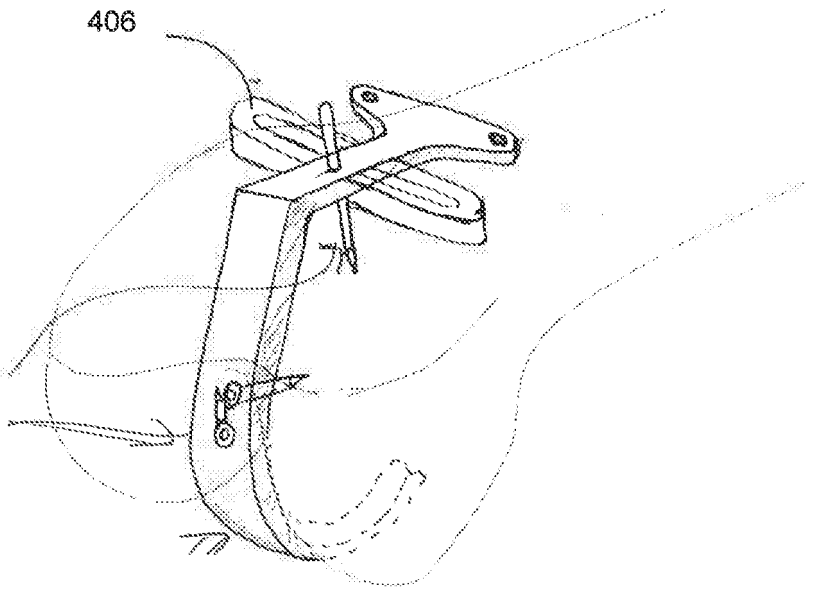

Figure 31

Tool

The present invention relates to a tool for use in knee replacement operations. In particular, it relates to a femoral jig for use in knee replacement operations. The jig may be for use in total knee replacement operations. The invention also relates to a system or kit for use in knee replacement operations and to a method of carrying out such operations.

The knee joint is formed by the distal end of the femur, the proximal end of the tibia, a meniscus located there-between and a patella. A plurality of ligaments is also present. These not only hold these components in the correct alignment, but also allow them to move relative to one another as the knee is flexed and extended. These ligaments also allow for some rotation. Since the knee supports several multiples of the entire weight of the body, and is subjected to various stresses as the body moves, it is vulnerable to damage through injury, disease or through the development of osteoarthritis. This damage causes loss of joint surface and hence pain.

When the knee has become damaged, the mobility of the body can be severely compromised. Various prostheses have therefore been suggested to replace the damaged natural joint. Whilst hinged components were initially suggested it was realised that components which mimic the structure of the natural knee would be more appropriate.

Initial prostheses of this kind comprised a femoral component for location on the resected distal end of the femur and a tibial component for location on the proximal end of the resected tibia. Whilst these prostheses allow for some articulation, the range of motion, and in particular the normal rotation and function of a healthy natural joint, was not achieved. With time, improved prostheses were suggested to address these problems.

For example, a so-called 'total' knee prosthesis has been produced which comprises a tibial plate and a femoral component with an intervening meniscal bearing component which may be configured to have medial and lateral sides. Typically the tibial plate and femoral component are made from a suitable metal or metal alloy, such as an alloy of cobalt and chromium, whereas the meniscal bearing component is made from a synthetic plastics material, for example ultra-high molecular weight polyethylene. In some designs the meniscal bearing component is fixed to the tibial plate. However, in other designs it is free to float at least to some extent with respect to the tibial plate in an attempt to mimic more closely the natural movement of the knee. In some arrangements the meniscal component may allow rotary and/or sliding motion on the tibial plate.

A schematic representation of the knee joint without the patella is illustrated in Figure 1. Lines 301 and 303 illustrate the typical point at which the femur and tibia will be resected in for total knee replacement operations. The space between lines 301 and 302 represents the typical femoral bone thickness replaced by the metal femoral implant, and the space between lines 302 and 303 represent the typical tibial bone thickness replaced by the metal tibial implant and a polyethylene bearing.

Whilst total knee implants are generally used, partial replacements are also known.

Generally, the equipment required to enable surgeons to perform these knee operations required to insert the prosthesis comprises several trays of metal and plastic components. These components include a variety of sizes of femoral and tibial components for the prosthesis and a large number of discrete and complex instruments which are required for the operation. Meniscal bearing components may also be present. Since the majority of the instruments are made of metal they are extremely heavy. This causes problems for theatre staff in moving them around. Further the trays in which they are provided, which are also made of metal so that they can be sterilized, have to be strong to support the weight of the components and thus they too are heavy which increases the overall weight needed to be handled with every case.

The trays also take up a large amount of space and are generally arranged and sterilized as a complete set that can be used in knee operations for any case of left or right knee from sizes small to large. As discussed above, the trays also contain trial components of the prosthesis. These components are provided by the manufacturing company in complete sets to cover all sizes and both knees. Thus any one set of trays can contain up to sixty components. The need for nursing staff to be able to quickly find the appropriate component for the particular need of the patient may be hampered by the number of components in the tray.

It will therefore be understood that a full set of the implant components and instruments must be provided for each operation to be carried out. These need to be cleaned and sterilized between each operation. Where hospitals carry out their sterilization on site, the time when the instruments are not available can be minimized but it is still significant. However, it is becoming increasingly common for sterilization to be carried out offsite which increases the time when the trays are not available for theatre use. The removal of the trays offsite may also lead to elements becoming misplaced or even mislaid. It will therefore be understood that the number of times each set of instruments and prosthesis can be used each week is decreased either meaning that additional sets have to be provided or that fewer operations

can be carried out per week. However, since the cost of providing additional sets is often borne by the manufacture, this represents an economic burden for the manufacturer. The storage of additional bulky sets can be problematic for the hospital.

The systems currently available are quite complex and need the surgeon and nursing staff to be familiar with them. Conventional femoral and tibial guides include a large number of adjustable components. This makes them difficult to use as the surgeon has to remember which adjuster carries out which function. The complexity of the guide, and the ability to adjust a large number of different components of the guide, can result in it being incorrectly positioned. Since the guide is used to guide the position of the cuts in the bone, incorrect positioning of the guide has serious consequences.

In addition to problems associated with the operation itself which may stem from unfamiliarity with the components and tools, the unfamiliarity may mean that the operation may take a lot longer than it should otherwise. The main disadvantage of this is to the patient but a further disadvantage relates to the longer use of expensive operating theatre time.

One problem which adds to the increase in operating time is the difficulty in finding which of 5 to 8 sizes of femoral component and a similar number of tibial components to use. Generally the selection of a size for the femoral component is carried out using jigs which take the position and size from the basic bony landmarks. This gives the nearest fit.

Since it is not possible to provide an infinite number of components there are inevitably steps between the sizes. Generally this is of the order of 3 to 4 mm. Unless a prosthesis is an exact fit, which is not common, the surgeon will have to select the closest size. These step differences between sizes have to be accommodated in the bone and it is therefore necessary for a compromise to be made on size and fit.

Once an appropriately sized prosthesis is selected, it must be inserted with the correct alignment to provide correct functionality of the knee post-operatively.

Computer navigation systems have been suggested as a means to address some of the problems. It has been suggested that the use of such systems may lead to greater accuracy of leg alignment. However, these systems generally rely on a rod being inserted into the femoral canal to "find" its orientation. Whilst this process may go some way to addressing some of the alignment issues, insertion of the rod into the femur has various disadvantages and drawbacks. First the insertion of the rod into the femur provides a risk of damage to the femur. In addition the insertion of the rod into the femur risks pressurizing fat into the blood stream and opening a risky cavity for infection. A further problem with the rod arrangement

is that unless it is aligned completely accurately and it is correctly related to hip position, it can lead to false alignments being taken.

An additional drawback with computer navigation systems is that they are expensive, cumbersome and take more time to use then the conventional systems. In addition, an equivalent level of accuracy of alignment can be found by aligning with the hip centre by simple manual means.

More recently it has been suggested that so-called "Patient Specific Instruments" (PSI) may offer an improved arrangement. In PSI systems the patient is required to have an MRI scan, a CT scan, or both an MRI and a CT scan of the leg pre-operatively. In this connection it should be noted that whilst the cheaper X-ray can provide information as to the damage to the bone, little information relating to orientation can be gathered from an X-ray. It is therefore necessary in PSI systems for the expensive CT scans to be carried out.

The data from the scan is fed into computer software which also has details of the components for the manufacturer's implant. Whilst the next stage may be carried out by the surgeon, generally, a technician receives the patient's scan data and using the computer software chooses and aligns the correct components for the operation from the manufacturer's product. The technician is generally employed by the manufacturer and may be located anywhere in the world. The technician will generally not meet the surgeon or the patient.

The computer software enables a software plan to be developed. This is sent to the surgeon for review and sign-off. The manufacturer then uses the data which is now patient specific to create three-dimensional rapid prototype models of the patient's bones in the knee and guides for each bone. The guide model once made should fit and engage on the bone to provide lock on for the guide which is then pinned and provides a route to make the cuts on the two bones to provide most of the steps required in the operation.

The benefit of this system is that the manufacturer only has to supply the planned parts for use. This has the benefit of avoiding stock being tied up and also reduces the amount of space which is taken up in the operating theatre. In addition, operation time is reduced as selection of components from a set is not required. All of the PSI parts are disposed of post operation therefore obviating the requirement for post-operative sterilisation.

The main advantage of the PSI system to the hospital and patient is that fewer instruments are required for the operation and the time required for their use is potentially reduced and

hence the whole operation takes less theatre time. Further a better accuracy of alignment is perceived and there is no requirement for a rod to be inserted into the femur.

The system also offers an advantage to the manufacturer in that a simpler instrument set can be provided. Further it locks the hospital and/or surgeon into using systems provided by the particular manufacturer. It also provides a new economic model for the company and the charging structure to the hospital.

Whilst PSI systems are finding favour and are being developed by a number of companies, there are various drawbacks and disadvantages. The first drawback is that the patient has to have an expensive MRI or CT scan or even both scans which is not required for conventional systems.

A more serious problem is that a mistake somewhere in the data from the scan, or the analysis of the data by the technician could lead to problems which may not be noted until the operation is underway and at that time alternative equipment will not be available in the operating theatre or even in the hospital. A further problem may relate to the lock on of the guides which can lead to problems with alignment accuracy.

In any event, the surgeon still needs some of the old style instruments to carry out the operation and therefore the instruments have to be managed as part sets and as such many of the problems associated with conventional systems such as weight, sterilisation down time etc. apply equally here.

A serious issue is that one fundamental skill of the surgeon is being derogated to the technician. Whilst the surgeon will retain responsibility for the soft tissue work and responsibility for the patient, the surgery outcome relating to the implant is abrogated to the manufacturing company. Whilst surgeon sign-off of the plan is required there is a risk of a longer term shift of the reality of the responsibility and ability to do the operation without the technical help.

A further problem is that the PSI system does not readily allow balancing of the knee during the operation. In an optimum system, the fit of the components should be assessed with the knee in both full extension and in flexion. If the knee is fitted so that the fit is optimized when extended then it may be too tight or unstable when in flexion which will mean the patient is unsteady when walking. The ability to assess and adjust the soft tissue is also removed. It is to assess this issue that knee balancing is carried out. Knee balancing can only be done during the operation and the effect of the balancing can be a requirement to make a change from the pre-operative plan. This is difficult with the PSI system because it is essentially

completed pre-operatively. There is a likelihood therefore that the required balancing step will be omitted from the operation which may lead to reduced outcomes for the patient.

Whilst PSI planning may better optimize the sizing of a fixed femur implant increment by adjusting the component to fit 3-dimensionally to the bone, it is unlikely that manufacturers will utilize this fully.

Further the knee is a complex joint and there is a subtlety of knee proportions anterior to posterior and medial to lateral. The PSI system is unlikely to be able to address these subtle differences.

Even with PSI, once the bones have been cut it is still necessary to use a trial component to see whether the components are properly aligned and how thick any meniscal part of the tibial component needs to be. Thus the number of components required is still relatively high.

A still further problem with the PSI system is that at any particular time the operating theatre is prepared for a specific patient and for the specific knee on which the operated is to be performed. With conventional systems, if the surgeon decides to do the other leg first he can. Similarly if a patient is unable to have the operation for any reason, the surgeon can simply move to the next patient. However, with PSI this cannot be done and due to the long lead time in having the PSI equipment produced it may be some time before another patient can be seen.

One alternative approach to carrying out knee surgery is proposed in GB2499316. In particular a femoral jig is described which is shaped to have the overall profile of a femoral prosthesis. The jig comprises a component which is shaped to represent the overall profile of a femoral prosthetic component of a specific side and size. The jig has an anterior reference arm which has a cutting guide located on it or it has means located on it to which a cutting guide may be attached. One particular benefit of this jig is that it can be applied to the femoral joint prior to making definitive bone cuts. Thus the surgeon is able to assess sizing and positioning before the femur is resected since the jig allows the size of the femoral component to be tested in flexion and extension and between the two positions prior to making definitive bone cuts.

Whilst the jig described in GB2499316 offers substantial advantages over prior art arrangements, and does not have the drawbacks noted for PSI systems, there is still a need for an improved jig which allows a full range of motion of the knee to be carried out while the jig is in position such that full testing of size, position and balancing can be achieved.

In permitting movement between flexion and extension, the knee joint goes through a complex movement. Not only is there the movement about a virtual transverse axis, there is also internal and external rotation about the axis of the femur in the flexed position. It is desirable that the jig which is used for trialling the size of a prosthesis and/or for assessing the position of the eventual prosthesis can be fully utilised in both flexion and extension and in positions in-between to ensure the best outcome for the patient.

Whilst the jig described in GB2499316 offers various advantages, in some circumstances, it has now been found that as the patient's leg is moved to take the knee from flexion to full extension, the soft tissues at the rear of the knee can impinge on the jig preventing the joint from reaching full extension while the jig is in place. As the knee is extended the soft tissue, which is relaxed when the knee is in flexion, can tighten around the posterior condyles. In one arrangement described in GB2499316, the jig, which sits on the posterior condyles of the femur, is of a thickness to represent the amount of tibial resection and to aid correct balancing. However, as the knee is extended, the soft tissue can tighten around such a jig at these condyles thereby restricting the knee from reaching full extension. This is illustrated schematically in Figure 2. In this illustration, one arrangement of the jig described in GB2499316, 304, is in position on the femur and a tibial spacer 305 is present on the resected tibia. As the leg is placed in extension, the footplate 306 of the jig interferes with the soft tissue in the area A.

It will be understood that the knee joint on which the operation is being conducted is damaged and therefore will be of a non-ideal configuration and thus a further problem is ensuring that the non-ideal nature of the distal end of the femur does not adversely affect the operation of any jig. It is therefore desirable to provide a jig which can accommodate the deficiencies/deformities found at the distal end of the femur. These deficiencies/deformities may be wear and/or the presence of bony deposits. In particular, there may be wear and/or deposits on one or both of the condyles and as such is desirable to provide a jig which can accommodate this non-normal anatomy.

A further problem associated with the design of jigs for use in knee surgery relates to locating the correct orientation for the prosthesis which is to be introduced. There has been substantial discussion in the orthopaedic community as to whether the correct orientation to which the surgeon should be aiming is the optimum orientation for the hypothetical anatomically perfect skeletal structure or whether the orientation of the prosthesis to be introduced should mimic the patient's pre-operative bone orientation, such that the patient experiences minimal perturbation of their natural, total body, alignment. On the latter

approach, it has been suggested that adjusting the orientation of the knee joint from the patient's natural orientation may adversely affect connected joints and associated soft tissue. Whichever philosophy for orientation is adopted, it is desirable to provide a jig which allows the surgeon the maximum flexibility to adjust varus/valgus orientation and/or rotational changes such that the orientation of the prosthesis which is to be introduced can be optimised.

It may also be desirable that the jig allows the surgeon to utilise alignment checking devices such that whichever philosophy of alignment he adopts, he can assess whether the desired orientation has been achieved.

It is therefore desirable to provide an improved femoral jig which addresses at least one or more, and preferably all of the above problems while providing the patient with a satisfactory, and preferably optimised, outcome to the surgery.

Thus according to a first aspect of the invention there is provided a femoral jig for use in knee surgery, prior to any femoral bone resections, said jig comprising a component shaped to indicate at least a part of the profile of a femoral prosthesis, said jig allowing for the size and position of the femoral prosthesis to be tested in flexion and extension prior to any femoral bone resections, said jig comprising at least one component which is capable of being mounted or demounted between testing in flexion and extension.

It will be understood that whilst the jig of the present invention is for use prior to any femoral bone resections, minor shaping of the femoral bone may be carried out prior to the use of the jig such as to remove osteophytes which may be present.

One of the main advantages of the present invention is that by optimising the configuration of the jig the size and position of the eventual femoral prosthesis that is to be used can be tested in flexion and full-extension, as well as at positions in between. The demountable components allow for testing of the thickness of the eventual prosthesis in flexion and in extension in order to ensure a good fit, and enable account to be taken of one or more of varus/valgus angle, external rotation angle, bone defects, and cartilage loss, before resection of the bone is carried out.

The testing of the size and orientation of the eventual prosthesis may be based on the jig of the present invention alone or in combination with a tibial protector spacer or jig mounted on a resected tibia.

Of particular advantage to the patient is that passive mid-stance laxity may be tested and ideal soft tissue balance can be tested and corrected. The patients therefore have more consistent outcomes whatever the implant type.

The jig indicates at least part of the profile of a femoral prosthesis. In one arrangement, the indication may be achieved by the shape of a portion of the jig. That is to say the jig may be configured such that at least a portion of the jig represents at least part of the femoral prosthesis once implanted. In an alternative arrangement, the shape of the jig may not itself represent at least part of the profile of the femoral prosthesis, in contrast other means for indicating at least part of the profile of the femoral prosthesis may be provided on the jig and these are discussed in more detail below.

While the jig is described as indicating at least part of the profile of the femoral prosthesis, it will be understood that the jig does not have to be of the same shape as the at least part of the femoral prosthesis which is represented, provided that the jig represents the prosthesis sufficiently that the intended size of the prosthesis can be checked to see if it is appropriate and the orientation and/or alignment of the prosthesis can be tested before cuts are made to the femur.

The jig of the present invention may be of any suitable size and thickness but will generally be of a thickness equivalent to the gap created by the cartilage and bone removed by the resection of the tibia either alone or when a tibial spacer is present. This will maintain the soft tissue gap.

Generally the jig itself will be relatively thin with the thickness being adjustable by means of the mountable/demountable components. In one arrangement the jig itself may have a thickness of from about 2mm to about 12mm, or from about 5mm to about 10mm, or from about 7mm to about 9mm. It may be necessary to provide the jig with one or more ribs to provide inherent strength to the jig. However, it will generally be configured such that when the knee is in extension, the thickness of the jig which extends around the posterior condyles is sufficiently thin to minimise interference with the posterior soft tissue.

In one arrangement, the jig is configured such that the or each component which is capable of being mounted or demounted, hereinafter the mountable/demountable component, is present while the knee is in flexion thereby enabling the surgeon to utilise the jig to verify the size of prosthesis required and to orientate the jig in the correct position such that when the bone cuts are made the prosthesis will be located in the correct position. Once the surgeon is happy with the orientation of the jig in flexion, one or more of the mountable/demountable

components may be mounted or removed as appropriate to allow the leg to be moved to put the knee in extension such that the selected size, and/or the orientation, can be checked with the knee in extension. This will also enable the surgeon to consider the alignment of the knee in relation to the hip and/or ankle and adjust it as appropriate.

The removal of the at least one mountable/demountable component may facilitate the rotation between flexion and extension. Additionally or alternatively, the removal may simply remove components necessary for some size checks, orientation checks, or size and orientation checks but which are not required for other size checks, orientation checks, or size and orientation checks and the removal of which may improve the visualisation for the other size checks, orientation checks, or size and orientation checks.

In an alternative arrangement, at least one mountable/demountable component may be present when the knee is in full extension but removed when the knee is to be moved to flexion. Conversely, where the jig is first applied in extension, the mountable/demountable component may be absent initially and then mounted when the knee is in flexion.

Where more than one mountable/demountable component is present, which may be the same or different, one or more may be utilised when the knee is in flexion and one or more may be utilised when the knee is in extension. Thus different mountable/demountable components may be used in flexion and extension. In one other arrangement, the same mountable/demountable components may be used in flexion and extension but removed as the knee is moved between the two positions. In a still further arrangement where more than one mountable/demountable component may be used, at least one may be maintained in position in flexion and extension and at least one may be absent in one of flexion and extension.

The, or each, mountable/demountable component may be able to be repeatedly mounted and demounted. This is particularly advantageous where the surgeon may, for example, want to repeatedly test the knee in one or both of flexion and extension.

The jig will generally comprise lateral distal, medial distal, lateral posterior and medial posterior reference surfaces. In use, the posterior of the jig will be placed against the surface of the femur. The jig may be configured to be suitable for use on either leg in which case the location of the lateral and medial reference surfaces will be identified by the positioning of the jig. In the alternative, the jig may be configured such that is only suitable for application to either the left or right leg in which case the lateral and medial reference surfaces are defined by the configuration of the jig.

In one arrangement the mountable/demountable component or at least one of the mountable/demountable components may be one or more spacers.

The one or more spacers may be placed in any suitable position on the jig. Spacers may be added to one or more of the lateral distal, medial distal, lateral posterior and medial posterior reference surfaces.

The mounting or demounting of one or more spacers on the lateral distal, medial distal, or the lateral distal and medial distal reference surfaces may enable the surgeon to set the jig at the appropriate varus/valgus angle. Setting the jig at the appropriate angle will mean that cuts made at the position directed by the jig will result in the prosthesis being located in the correct appropriate varus/valgus angle. Additionally or alternatively, the mounting or demounting of spacers on lateral distal, medial distal, or lateral distal and medial distal reference surfaces may allow the surgeon to adjust for bone, cartilage, or bone and cartilage damage and/or loss.

The mounting or demounting of one or more spacers on the lateral posterior, medial posterior, or the lateral posterior and medial posterior reference surface, may enable the surgeon to set the appropriate femoral internal or external rotation angle. Additionally or alternatively, the mounting or demounting of spacers on the lateral posterior reference surface, the medial posterior reference surface, or both the lateral posterior and the medial posterior reference surfaces may enable the surgeon to adjust for bone, cartilage or bone and cartilage damage and/or loss.

The spacers may be of any suitable size. Spacers for use on the lateral distal, medial distal, lateral posterior and medial posterior reference surfaces may be of the same or similar sizes. In an alternative arrangement they may be of different sizes. Similarly, the spacers may be of any suitable configuration. Spacers for use on the lateral distal, medial distal, lateral posterior and medial posterior reference surfaces may be of the same or similar configuration. In an alternative arrangement they may be of different configurations.

In one arrangement, spacers for use on the distal reference surfaces may be of any suitable thickness but will generally be about 10mm thick or less. They may be provided in a range of thicknesses enabling the surgeon to select the appropriate thickness of spacers. The spacers for use on the medial/lateral distal reference surfaces may be provided in a range of thickness at 1mm intervals from about 1mm to about 10mm. For example, spacers for use on the distal reference surface may be provided at thicknesses of 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm and/or 8mm. However, spacers of any appropriate thicknesses may be

provided. In an alternative arrangement, more than one spacer can be used at a particular position to provide the desired thickness of spacer. Thus in one arrangement a number of 1mm thick spacers can be combined to provide the desired thickness. Alternatively, a combination of 1 and 2 mm thick spacers may be combined to provide the desired thickness. In this arrangement, the spacers may be mounted to and/or demounted from the jig separately or may be connectable such that it is a single unit which is mounted/demounted.

Spacers for use on the posterior reference surfaces may be of any suitable thickness but will generally be about 8mm thick or less. They may be provided in a range of thicknesses enabling the surgeon to select the appropriate thickness of spacers. The spacers for use on the medial/lateral posterior reference surfaces may be provided in a range of thickness at 1mm intervals from about 1mm to about 8mm. For example, spacers for use on the distal reference surface may be provided at thicknesses of 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, and/or 7mm. However, spacers of any appropriate thicknesses may be provided. In an alternative arrangement, more than one spacer can be used at a particular position to provide the desired thickness of spacer. Thus in one arrangement a number of 1mm thick spacers can be combined to provide the desired thickness. Alternatively, a combination of 1 and 2 mm thick spacers may be combined to provide the desired thickness. In this arrangement, the spacers may be mounted to and/or demounted from the jig separately or may be connectable such that it is a single unit which is mounted/demounted.

In an alternative arrangement, the, or each, spacer may include a piezoelectric actuator such that once in position, the activation of the actuator may assist the surgeon to orientate the jig.

The spacers may be mounted on the jig by any suitable means. In one arrangement, the spacers may fit into a corresponding clip or onto a corresponding peg on the jig. Where appropriate the spacer may be configured to facilitate interaction with the jig. In one arrangement, the, or each, spacer may be a snap fit with the jig. Additionally or alternatively, separate connection means may be required to attach the spacers in position on the jig. Such connection means may include clips, pins, screws or magnets.

In one arrangement, the spacers may be inserted into pockets in the jig such that the spacers cause at least one wall of the pocket to expand.

In a further arrangement, the spacer may be held in position by being passed through a surface of the jig. Thus in one arrangement, the spacer which is to be located on the posterior reference surface may be located in position by being passed through an aperture in the jig from the distal side of the jig. In this arrangement, the spacer will generally be

shaped so that a portion of the spacer will pass through the aperture and an enlarged head portion of the spacer will prevent it passing totally through the aperture.

In one alternative arrangement the, or each, spacer may be integral with the jig and is demounted by breaking the connection between the spacer and the jig. Thus, for example, the, or each, spacer may be connected to the jig by a frangible flange.

Additionally or alternatively, the demountable component may be a footplate. When in position, the footplate will generally extend over the condyles of the femur and may have a thickness such that when the joint is in flexion the thickness of at least the portion of the footplate which extends over the condyles may generally correspond to the thickness of the tibial resection. In one arrangement the footplate may be of different thicknesses on the lateral and medial side.

The footplate may be mounted to the jig by any suitable means. For example the footplate may be screwed, clipped, pinned onto the jig. In an alternative arrangement, a portion of the jig will be a snap fit with a cooperating arrangement on the jig. Although a physical connection will generally be used, it is possible that the footplate may be held in place by other means such as by friction.

In this arrangement, the footplate will generally be in position on the jig while the knee is in flexion and assists in the verification that the correct size of the prosthesis has been selected and in verifying its orientation. However, the footplate may be demounted such that it does not impact on the ability of the joint to be moved to extension with the jig in position.

Although the footplate may be demounted prior to extending the joint, it may be mounted once the joint has been extended. However with some configurations of the jig it will not be necessary to have a demountable footplate.

Whatever mountable/demountable component is used, the thickness of the jig of the present invention may be of any suitable size. However, in one arrangement, with the demountable component attached, the femoral jig may have a posterior and distal thickness that is the same as the thinnest tibia component in an equivalent size less about 2mm to about 3mm on the medial side although this will/may change with the size of the jig to reflect sizing changes/variances of the femoral implant. Additionally or alternatively, the jig may have both posterior and distal thicknesses corrected to adjust for a neutral tibial varus/valgus angle. Thus it will be approximately 3mm thicker lateral than medial in flexion and extension. This means that sitting the component on unaffected cartilage distal and poster (medial or lateral) will provide correction of bone it replaces that has been cut from the tibia.

The femoral jig may optionally comprise an anterior proximal reference arm shaped to sit at the ideal proximal lateral femoral component position on the femur ridge. Thus it is designed to be at the position that will be subsequently taken up by the femoral implant. In one arrangement, the reference arm may include adjustment means. The adjustment means may enable the surgeon to visualize the fit of a prosthesis that is of a differing size to the one which the jig is designed to represent. Any suitable adjustment means may be used. In one arrangement, the adjustment means may be a screw. Alternatively, a range of lengths of the anterior reference arm may be supplied. This may be by way of different length anterior reference bars which may be interchangeably introduced to the anterior reference arm. Preferably a range of lengths between 0mm (neutral) and 15mm are provided. For example, anterior reference bars may have 0mm (neutral), 5mm, 10mm, or 15mm lengths.

In one arrangement the anterior reference arm may be integral with the jig. Alternatively the anterior reference arm may be mountable/demountable on the jig. This detachment may be made by any suitable means. The demounted anterior reference arm may be remountable. In another arrangement, the arm may be flipable such that by flipping the reference arm it is moved away from the femur, providing access to the bone.

The anterior reference arm may be suitable for left hand use, for right hand use or for either left or right hand use. Optionally, the reference arm may be adjustable for either left or right hand use.

The jig of the present invention may optionally include one or more pressure sensors which when present will provide the surgeon with information as to the interaction between the jig and the tibia as the knee is moved from flexion to extension. Pressure sensors may also be used to assist the surgeon to assess the pressure between the jig and the distal end of the femur at various points such that he can assess whether adjustment of orientation of the jig is required. Thus for example, pressure sensors between the jig and the distal end of the femur may assist the surgeon to assess whether the jig and hence the prosthesis is appropriately tensioned against the condyles. Additionally or alternatively, the sensors will enable the surgeon to assess whether the medial and lateral collateral ligaments are balanced or need surgical correction. The presence of the pressure sensors will generally enable the surgeon to measure soft tissue tensions in the knee joint that can effect alignment and kinematics.

Whatever the configuration of the jig, it will generally include one or more holes. These may allow pins to be introduced to lock the jig into position on the femur once the correct

orientation for the femur has been located. In one arrangement the jig may be provided with captured pins located in position which can be activated once the jig is in the correct position.

Additionally or alternatively the jig may include holes through which a drill may be operated in order to drill appropriate holes for the machining of the femur.

Additionally or alternatively, the jig may include one or more cutting guides through which, once the jig is in position, the femur can be cut. However, in one arrangement, the one or more cutting guides may not be integral with the jig but may be provided as mountable components on the jig which may be located in position once the surgeon is happy with the position of the jig and is ready to make femoral cuts.

The jig may include a demountable or a fixed handle. The handle may be useful in assisting the surgeon to adjust the orientation of the jig. Generally, the handle will extend upwardly from the jig. In one arrangement in which the handle is demountable, it will fit, generally as a snap fit, into a cutting slot on the jig. In one arrangement the handle may be formed integrally with the arm but may be demounted by breaking a frangible flange.

The jig may include one or more means to assist the surgeon to orientate and/or align the jig. By 'orientate' we mean the positioning of the jig relative to the distal end of the femur. By 'align' we mean positioning the jig relative to some external reference. The external reference may be, for example, one or both of the long bones, one or both of the ankle and the hip joint, external references, data obtained from x-ray or scans, and the like. For ease of reference, 'orientating' and/or 'aligning' the jig will be individually and/or collectively referred to as 'positioning'. Words such as 'position' and the like should be construed accordingly. Further, means to assist the surgeon to position the jig will be referred to as 'positioning means'.

The positioning means will generally enable varus and valgus orientation to be measured, adjusted or measured and adjusted. It will be understood that in one arrangement the position means may enable the varus and valgus orientation and other means, such as by use of the spacers, may be used to achieve the adjustment.

The positioning means may be integral with the jig or may be mountable/demountable thereon. In one arrangement, the positioning means may be mountable on the handle.

In one arrangement, the positioning means may include an alignment rod. The rod may be connected to the jig by any suitable means. In one arrangement, it may be attached to the handle. In an alternative arrangement, the alignment rod may be connected to the jig at

another suitable position. In either arrangement, the connection between the rod and the handle or jig will allow the rod to transcribe an arc. Generally, the transcription of the arc will be constrained to be between 0 and 5° to permit flexion and extension. This will generally encompass the range to which the prosthesis can be safely flexed and extended. In an alternative arrangement rather than the connection allowing the rod to describe an arc, a plurality of anchoring points may be provided, such as a plurality of holes in the handle into which the rod may be inserted. The holes are positioned such that the selection of one enables the surgeon to choose flexion/extension angles which are between about 0 and about 5°.

In one arrangement, the use of the rod will enable the surgeon to adjust the valgus/varus position of the jig with reference to the hip centre. In one arrangement, the hip centre may be that identified using the so-called Freeman 9 cm rule. However, alternative techniques may be used to locate the hip centre. These include reference to x-ray, CT scan data, MRI scan data, the use of gyroscopes and/or accelerometers and the like.

In one arrangement, the connection between the positioning means and the handle, may enable the positioning means to describe an arc. This will enable the surgeon to choose flexion/extension angles which are between about 0 and about 5°.

In an alternative arrangement, the connection between the positioning means and handle is fixed and the ability to describe an arc is provided within the body of the handle or at the point of connection between the handle and the jig.

In a still further arrangement the varus-valgus position may be found by use of an intermedullary alignment rod inserted through the femoral jig and into the femoral canal.

Additionally or alternatively to the use of an alignment rod, a laser or other non-mechanical pointing means may be used to assist in the positioning of the jig. In one arrangement, the laser or alternative pointing means may be located on the handle. Alternatively, a separate mounting means may be provided. The laser or alternative pointing means may be swivelable relative to its mounting position. This may allow the laser or alternative pointing means to transcribe a flexion arc of about 0 to about 5°. Additionally or alternatively, the laser or alternative pointing means enables the hip centre to be referenced.

In addition to the physical alignment means described above, or as an alternative thereto, an electronic imaging and/or alignment means may be used. In one embodiment electronic imaging of the jig may be performed. This will allow the surgeon to electronically view the jig relative to images of the bone. The electronic system may also allow the surgeon to

electronically visualise the prosthesis in the position defined by the jig thereby providing a further check of the positioning of the jig before definitive cuts are performed. To assist interaction between the electronic imaging systems and the jig, the jig may be formed of material which is visible to such electronic imaging systems, or may have sensors or other markers located at key points thereon. In this arrangement, sensors, or other markers, may also be placed at suitable points on the patient.

For optimum benefit, the visualisation of the jig will be carried out interoperatively. Suitable computer hardware and software will enable the visualisation and overlay with the bones to be carried out. The visualisation may be displayed on a visual display unit but will preferably be displayed on a handheld device such as a tablet.

The jig may additionally comprise a distal leaf spring. This spring may be able to aid the surgeon in determining whether the jig is the right size and/or is in the correct flexion position. The spring may be positioned on the distal face of the femoral jig, such that then the joint is in extension the spring is located at the interface between the femur and the tibia. The spring may be positioned such that when the leg is in full extension and the jig is in the correct position, the spring will contact the plate located on the top of the resected tibia. If the jig is under rotated, such as when it is not correctly positioned, the spring will not contact the tibial plate. However, if the knee including the jig is at an acceptable level of flexion then the tibial plate will contact the spring. In one arrangement, when the jig is at an acceptable position, the spring will contact the tibial template, and may be partially depressed. Generally, an acceptable position will be when the amount of flexion is between 0° and 5°.

It is acknowledged that if the jig is positioned such that over rotation has occurred, the spring will still contact the tibial plate. However, the spring is generally configured such that when the jig is in this position, the spring is fully compressed. The jig may be considered to be over-rotated if it has a corresponding level of flexion greater than 5°.

In one arrangement, when the knee is in extension and the jig is in the correct position, the spring will be parallel with at least a part of tibial plate, and may be able to be compressed by between 0 to 5° flexion. The spring may spring back to a non-compressed position if the knee is subsequently flexed. However, in an alternative arrangement, the spring may remain in its compressed position when the knee is subsequently flexed providing a clear visual indication of how far the spring was depressed during extension of the joint.

As indicated above, one purpose of the jig of the present invention is to assist the surgeon in assessing the correct size of prosthesis to be used. In one arrangement, the size of the jig

itself may correspond to a particular size of prosthesis. Thus, the surgeon can place the jig in position and if it appears to be the wrong size, try a smaller or larger jig as appropriate until the most appropriate jig is identified.

In an alternative, a jig may include markings to identify different sizes of prosthesis such that the surgeon can read off the required size of prosthesis from the markings in a similar manner to effectively using a ruler. An alternative use of markings may be to simply indicate an acceptable range for a size. Thus, markings may indicate two positions and the jig and hence the corresponding prosthesis, is of the correct size if the edge of the femur falls between the two markings.

Additionally, or alternatively, the jig may include medial-lateral arms which may be used to indicate whether an implant corresponding to the size of the selected jig will overhang the femur in the medial-lateral plane. The medial-lateral arms may be able to contact the femoral head at one or more positions in line with where the distal cut is to be made. In one arrangement, the arms may contact the bone if the jig is of an appropriate size and no overhang of the corresponding prosthesis will occur. However, if the jig is too large in the medial-lateral direction and would thus result in the corresponding prosthesis overhanging the resected femur, the medial-lateral arms may not be in contact with the bone.

In a particular arrangement, the medial-lateral arms may be sprung. In this arrangement, when contact occurs between the bone and the arms, the arms may move distally away from the bone, while remaining in contact with said bone. The force with which the arms move away from the bone is not sufficient to displace the jig.

The jig may be made of any suitable material. The mountable/demountable components of the jig may be made of the same or different materials to the body of the jig. In one arrangement, the jig may be made of a plastics material. This is particularly advantageous when the jig is to be single use as it is cost-effective to produce. In an alternative arrangement, at least the body of the jig may be made of metal. This is particularly advantageous when the jig is intended for multiuse such that repeated sterilisation is required.

Without wishing to be bound by any particular method of use, in one arrangement where the jig is available in a plurality of sizes, the surgeon will first select the most likely size of jig required. This can be done by reference to an x-ray or scan data or simply by assessing the patient's knee either pre-operatively or once the appropriate soft tissue dissections have been performed. The size of mountable/demountable components may also be selected in

this way. By this means it may be sufficient that the operating theatre be provided with only the selected jig and its mountable/demountable components, optionally with one size smaller or larger in case the surgeon wants to check whether a smaller or larger size would be suitable. By this means, the amount of equipment required to be available in theatre and sterilised is reduced.

Generally, following the access of the knee joint by cutting/releasing the soft tissues, the first step will be the resection of the tibia with the knee in flexion. A tibial protector spacer may be placed on the resected tibia to facilitate the process of testing in flexion through to extension. The tibial protector spacer, which may be of any suitable configuration, prevents the femoral condyles indenting the tibial cut bone surface. The tibial protector spacer is generally formed from plastics or metal such as stainless steel. The tibial protector spacer will generally be finished to achieve a low surface friction on its bearing surface. Thus the tibial protector spacer will reduce the friction during the testing.

The jig of the present invention can then be placed in position on the end of the femur.

Once the jig is in position, the surgeon can check whether the selected jig is of the appropriate size and if appropriate change it. Where a single size jig is used for multiple prostheses, the surgeon may, at this stage, note the size of prosthesis indicated by, for example, markings and/or arms. The femoral jig will generally allow an assessment of whether a particular sized prosthesis is appropriate. Where a tibial protector spacer is used, the combination of the femoral jig of the present invention and the tibial protector spacer will enable the surgeon to assess whether the combination of the implant selected for the tibia and the femur are of the correct size since it is the combination of both implants which will make up the space.

Spacers may be added or removed as appropriate to test the fit with the femur and to adjust the valgus/varus angle. The surgeon can readily choose to change the size of the prosthesis or a component thereof as appropriate, adjust the positioning of the jig and hence the eventual prosthesis on the bone and if appropriate make decisions on treatment of the ligaments to correct any deformity.

The optional anterior reference bar may be mounted on the jig. With the jig in relative flexion, the jig is rotated on the femoral bone until the anterior reference bar contacts the anterior cortex, thereby providing a further verification of the positioning of the jig.

The surgeon will generally now wish to place the knee into extension. In advance of this, some or all of the mountable/demountable components of the jig may be removed. In an

alternative, one or more mountable/demountable components may be added. Where a demountable footplate is present, this will generally be removed before the knee is placed into extension.

As the knee is placed into extension, flexion and extension space between the femur and the tibia can be evaluated. Optionally, one or more of the checks may be repeated with one or more of the demountable spacers being re-attached or removed from the jig as necessary.

In one arrangement, a spacer representing a tibial prosthesis may be in position prior to flexion. Optionally, a sensor may be located on the tibia such that interaction with the jig can be readily identified and if appropriate recorded.

Positioning means can be used throughout the operation to verify the correct positioning of the jig until the surgeon is happy with his position. At this point, it will be fixed in position, such as by use of the captive pins were present. Where appropriate, cutting guides can then be added to the jig such that the femoral cuts may be made.

As part of the operation, the surgeon may use a tibial jig. This may assist in positioning a saw blade to correctly resect the tibia. Any suitable tibial jig may be used. One example of a tibial cutting guide is described in GB2499316.

According to a second aspect of the present invention there is provided a kit comprising one or more of a femoral jig according to the above first aspect of the present invention, and optionally one or more mountable components. In one arrangement the mountable components include a selection of different sized and/or shaped spacers. Additionally or alternatively, one or more positioning means may be included in the kit.

In one arrangement the kit may additionally comprise one or more of a tibial jig, a multi-cut block, a re-cut block, a laser and a drill. Any suitable tibial jig may be included in the kit. In one arrangement, the tibial guide may be that described in GB2499316 the contents of which are incorporated herein by reference.

Even if all components are present the kit comprises far fewer components than were required in prior art arrangements. The components may be packed in a single sterile pack. Some components, such as, for example, a laser when used, may be packed separately. In one arrangement components of a particular size will be colour coded.

With this arrangement theatres can have the pre-operative selected size available and other sides and sizes available outside theatre in single side and size packed in case they are

required. Opening two or even three packs will not have a substantial cost implication. In one arrangement, a kit may be provided with small variation in sizes.

A further advantage of the present invention is that the size and position of the components can be carried out by the surgeon during the operation. Since the surgeon is using his judgement, de-skilling is avoided. However, the decisions that the surgeon has to make are made easier by the function of the instruments of the present invention. Whilst pre-operative templating may be recommended it is not essential.

In one arrangement, the jig once located in the optimum position can be used to locate a femoral spacer. Further flexion through to extension testing of the spacer can be carried out and once the orientation is acceptable, its position can be fixed for example by means of pins. A cutting guide can then be attached to the femoral spacer so that the required cuts can be made. In an alternative arrangement, the femoral spacer may include an integral cutting guide. Where the further testing indicates that the position is not correct, the jig of the present invention can be reattached to the femur so that angles can be checked.

The present invention will now be described by way of example with reference to the following figures in which:

Figure 1 is a schematic representation of the knee joint illustrating the amount of bone resected;

Figure 2 is a schematic representation of a jig of the prior art;

Figure 3 is a perspective view of a femoral jig of one aspect of the present invention from the front;

Figure 4 is a perspective view of the femoral jig of the Figure 3 from the rear;

Figure 5 is a perspective view of a portion of the jig of Figure 3;

Figure 6 is a perspective view of the jig of Figure 3 from above;

Figure 7 is one arrangement for a handle which may be mounted on a jig of the present invention;

Figure 8 is one arrangement for an anterior reference bar which may be mounted on a jig of the present invention;

Figure 9 is one example of a posterior spacer;

Figure 10 is one example of a distal spacer;

Figure 11 is a schematic representation of the jig of Figure 3 in position on the femur illustrating the function of a distal spacer;

Figure 12 is a schematic representation of the jig of Figure 3 in position on the femur illustrating the function of a posterior spacer;

Figure 13 is a schematic cross-section illustrating the relative spacing taken up with respect to the typical bone replacements;

Figure 14 is a schematic representation of the jig of Figure 3 in position on the femur illustrating the function of the anterior reference bar;

Figure 15 illustrates one arrangement for connecting a position means to the handle;

Figure 16 is a perspective view of a femoral jig of a second aspect of the present invention from the front;

Figure 17 is a perspective view of a femoral jig of a second aspect of the present invention from the side;

Figure 18 illustrates the femoral jig of Figure 16 with the footplate being removed;

Figure 19 illustrates the femoral jig of Figure 16 with the footplate removed;

Figure 20 is a perspective view of a spacer for use with the femoral jig of Figure 16;

Figure 21 is a view of a femoral jig of a third aspect of the present invention from the front;

Figure 22 is a close up of the arms of the femoral jig indicating that no overhang will occur;

Figure 23 is a close-up of the arms of the femoral jig indicating that overhang will occur;

Figure 24 is a perspective view of the femoral jig of Figure 20 from the side;

Figure 25 is a close-up of the jig from the side illustrating the spring before contact with the tibia;

Figure 26 is a close-up of the jig of Figure 24 with the knee in full extension with the jig under-rotated;

Figure 27 is a close-up of the jig of Figure 24 with the knee in full extension with the jig at the correct rotation;

Figure 28 is a close-up of the jig of Figure 24 with the knee in full extension with the jig over-rotated;

Figure 29 is a perspective view of an alternative jig of the present invention;

Figure 30 is a perspective view of the jig of Figure 29 illustrating the introduction of the femoral spacer; and

Figure 31 illustrates the femoral spacer in place on the femur.

As illustrated in Figure 3, the femoral jig 1 comprises a component shaped to indicate at least a part of a femoral prosthetic component of a specific size. The component may be suitable for use with a left or right knee joint or may be handed. This configuration of jig may be particularly suitable when the jig is made of metal.

In use, the jig 1 will be placed on the end of the femur. The feet 2 of the jig will sit against the condyles. The jig comprises a tibial extension limiter surface 3 and a flexion/extension bearing surface 4.

The jig will generally include a plurality of holes which provide a number of functions. Holes 5 may enable a multicut block, not shown, to be connected to the jig 1.

As further illustrated in Figure 4, distal spacer attachment holes 6 may be provided on the flexion/extension bearing surface 4. Posterior spacer attachment holes 7 may be provided on the feet 2.

In one arrangement, the width of the flexion/extension bearing surface may represent the size of the eventual prosthesis and so can be used to check the width of the prosthesis. In one alternative the flexion/extension bearing surface may be wider than one or more prosthesis and have markings to enable the correct size of prosthesis to be selected.

Stabilising pin holes 8 may also be present.

A close up of a part of the jig is illustrated in Figure 5. One example of handle attachment means 9 is illustrated. In this arrangement, the attachment is a combination of a portion of the cutting slot 10 in combination with a well 11. An anterior reference bar attachment feature 12 may also be present. These features are also illustrated from above in Figure 6.

One example of a mountable/demountable handle 14 is illustrated in Figure 7. In the illustrated arrangement a hand hole 15 is present. However, this hole may be absent and the surgeon may simply grasp the handle 14 as a hole. An alignment rod mounting point 16 may be located on the top of the handle.

A mountable/demountable anterior reference bar 17 is illustrated in Figure 8.

Once the jig is in position on the femur, one or more spacers may be mounted to the jig. In the illustrated arrangement, the spacers of Figures 9 and 10 are made of plastic. The spacer 18 illustrated in Figure 9 is of a suitable configuration to be used as a posterior spacer whilst the spacer 19 illustrated in Figure 10 is of a suitable configuration to be used as a distal spacer.

The distal spacer 19 may, for example, the attached to a lateral distal reference surface 20 and is used to set the appropriate varus/valgus angle and/or to account for bone defects and/or cartilage loss. In one arrangement, to cover possible range of angles and defects, 8 thickness is of distal spacer 19 may be provided at from 1 mm to 8 mm in 1 mm increments. The function of the distal spacer 19 is illustrated in Figure 11.

The posterior spacer 18 may, for example, be attached to the lateral posterior reference surface 21. This may be used to set the appropriate external rotation angle and/or account for bone defects and/or cartilage loss. To account for the possible range of angles and defects, 6 different thicknesses may be provided from 1 mm to 6 mm in 1 mm increments. The function of the proximal spacer 18 is illustrated in Figure 12.

As discussed in more detail above the tibia will generally have been resected before the jig of the present invention is located in position. The space taken up by the jig of the present invention when located on the femur is illustrated in Figure 13 together with its relationship to lines 301 and 302 which correspond to those illustrated in Figure 1. In Figure 13, the resected tibial surface 307 has a tibial spacer 308 located thereon. The femoral jig of the present invention 309, together with the tibial spacer 308 takes up the space which will finally be filled by the metal tibial impant and the polyethylene bearing.

The anterior reference bar 17 may be connected to the most anterior proximal part of the jig via the anterior reference bar attachment feature 12. The anterior reference bar 17 is used to provide the anterior reference which drives the anterior posterior fit of the femoral component. The anterior reference bar 17 in position on the femur is illustrated in Figure 14. The interaction between the anterior reference point 22 and the ridge on the femur enables

the surgeon to consider the anterior posterior fit. The flag 23 will help the position of the anterior reference point 22 to be visualised.

As discussed above, the jig of the present invention may be used in combination with positioning means. In one arrangement, the positioning means may be an alignment rod, not shown. The alignment rod mounting point 16 may be positioned on at the top of the handle 14 as illustrated in Figure 7. In one arrangement, the alignment rod mounting point 16 may be rotatable about the point of connection 25 with the handle 14. One example of this is illustrated in Figure 15. In this arrangement, the end of the handle 14 includes a well 24, in which a portion of the alignment rod mounting point 16 can rotate. The amount of rotation available is restricted by the interaction between the top of the handle 26 and the underside 27 of the alignment mod mounting point 16. The amount of rotation will generally be between 0 and 5°.

An alternative jig 101 is illustrated in Figure 16. In this arrangement, the jig includes a demountable footplate 102. Once the surgeon is happy with the orientation of the jig 101, the footplate 102 can be removed as illustrated in Figures 18 and 19. Once the footplate 102 has been removed, the need to be moved to extension. As illustrated in Figure 17, the removal of the footplate does not impact the interaction between the jig and the tibia such that the feet do not interact with soft tissue, including the ligaments and posterior capsule, during rotation from flexion to extension.

An alternative means for introducing spacers is illustrated in Figures 16 to 19. It will be understood that the spacers illustrated in connection with the arrangement of Figures 3 to 15 may be used with the jig of Figure 16 and equally that the means connecting spacers illustrated in Figures 16 to 19 can be used in connection with the arrangement illustrated in Figures 3 to 15.

In this arrangement, apertures 130 may enable elongate spacers to be inserted from the distal face 131 of the jig such that they extend into the proximal side 132 of the jig.

One example of a spacer 118 which may be used with the jig of Figures 16 to 19 is illustrated in Figure 20.

It will be understood that the jig of this arrangement can include some or all of the mountable/demountable components discussed in connection with the jig described in Figures 3 to 15.

A further example of a jig 201 is illustrated in Figure 21. This jig is illustrated in perspective in Figure 24. It will be understood that the arrangements illustrated specifically in connection with this jig may also be used in combination with the jig described above and similarly components discussed in connection with the jig discussed above, may be used in combination with this jig.

The jig 201 illustrated in Figures 21 and 24, includes a spring 240. The spring 240, which is located at the front of the jig 201 provides the surgeon with a visual indication as to the suitability of the flexion of the jig relative to the mechanical axis. In its starting position, the spring 240 is positioned parallel with the distal part of the tibia and represents 0° flexion. The spring can move up to 5° backwards into an enclave 241 of the jig 201. When the spring 240 is fully within the enclave 241, the hyperextension limit is reached. The angle of the spring 240 can be seen in the side view of Figure 25.

The effect of the spring 240 is noted when the leg is in full extension and interacting with the resected top of the tibia or a tibial spacer, plate or the top of a tibial jig. This is illustrated in Figures 26 to 28. If the femoral jig has been positioned such that it is under rotated, i.e. less than 0°, which may indicate a larger size is required than is being used, the spring 240 will not make contact with the tibial template in full extension. This is the arrangement illustrated in Figure 26. If the jig is at an acceptable level of flexion, generally between 0 and 5°, the spring 240 will contact the tibia, but will not be fully compressed. This is the arrangement illustrated in Figure 27. If the jig is over rotated/flexed, the spring will be fully compressed within the femoral jig as illustrated in Figure 28.

The jig illustrated in Figure 21 additionally includes medial lateral arms 250, which, when the jig is in position on the femur, will indicate whether and implant corresponding to the size of the selected jig will overhang medially/laterally. The sprung arms 250 sit against the femur in line with the position of the eventual distal cut thereby sitting where the final implant will sit. If the arms contact the femur as illustrated in Figure 22, the surgeon knows that no medial/lateral overhang will occur. If the arms do not contact the femur as illustrated in Figure 23, this will indicate that medial/lateral overhang will occur. The arms may also act as an aid to medial/lateral positioning. For example, if one arm contacts the femur that the other does not, it will be understood that the jig will need to be shifted toward the connecting side until the femur is centrally between the arms preferably such that they are both contacting. When contacted occurs, as the answer preferably likely sprung, they move away distally while maintaining contact.

An alternative arrangement of the jig 400 of the present invention is illustrated in Figure 29. Although this jig has a different configuration to that illustrated in earlier Figures it will be understood that it may also be of a similar shape to that illustrated in the other figures. In the illustrated configuration, a demountable reference arm 401 is located in a socket 402 on the body 403. The body 403 is shaped to define the varus/valgus external rotation and flexion angles together with the medial/lateral width. In the illustrated arrangement, the feet 404 may include a built-in angle of external rotation of 3°. Distal spacers may be added as indicated by the arrows to achieve varus/valgus position and address bony defects and/or cartilage loss. An alignment rod may be suitably attached to the jig to assess the orientation relative to the femoral mechanical axis, as previously described, so that this can be accepted or further adjusted accordingly.

Once the desired position has been achieved, the demountable reference arm 401 can be removed and a femoral spacer 405 attached into the socket 402. The insertion of the spacer into the socket 402 means that it will take up the same orientation as the jig. This spacer which may of a C-shaped configuration would be an offset of the implants condylar surface. This spacer can then be pinned into position and the jig 400 removed. The range of motion in flexion and extension can then be tested in a similar manner to that described for previous arrangements. This testing may be with or without a tibial spacer. Once the optimum position is achieved, then a cutting block may be mounted on the spacer or as illustrated in Figure 31 a cutting slot 406 may be present on the spacer.

Modifications, replacements and the like may be made to the jigs described herein without departing from the scope of the present invention.

Claims

1. A femoral jig for use in knee surgery prior to any femoral bone resections said jig comprising a component shaped to indicate at least a part of the profile of a femoral prosthesis, said jig allowing for the size and position of the femoral prosthesis to be tested in flexion and extension prior to any femoral bone resections, said jig comprising at least one component which is capable of being mounted or demounted between testing in flexion and extension.

2. The femoral jig according to Claim 1 wherein the, or one or more of the, component which is capable of being mounted or demounted is configured to be repeatedly mounted and demounted.

3. The femoral jig according to Claim 1 or 2 wherein the, or at least one of the, component(s) which is capable of being mounted or demounted is one or more spacers.

4. The femoral jig according to Claim 3 wherein the spacers are configured to be added to one or more of lateral, medial, posterior and distal reference surfaces.

5. The femoral jig according to Claim 3 or 4 wherein the, or each, spacer may be about 10mm thick or less.

6. The femoral jig according to any one of Claims 3 to 5 wherein a plurality of spacers may be combined.

7. The femoral jig according to Claim 3 or 4 wherein the spacer includes a piezoelectric actuator.

8. The femoral jig according to any one of Claims 1 to 7 wherein the, or one of the, components which is capable of being mounted or demounted is a footplate.

9. The femoral jig according to any one of Claims 1 to 8 wherein the jig additional includes an anterior proximal reference arm.

10. The femoral jig according to any one of Claims 1 to 9 wherein the jig additional includes one or more pressure sensors.

11. The femoral jig according to any one of Claims 1 to 10 wherein the jig additional includes one or more cutting guides.

12. The femoral jig according to any one of Claims 1 to 11 wherein the jig additional includes a handle.

13. The femoral jig according to any one of Claims 1 to 12 wherein the jig additional includes means to assist the surgeon to position the jig.

14. The femoral jig according to Claim 13 wherein the means to assist the surgeon to position the jig is an alignment rod.

15. The femoral jig according to Claim 14 wherein the means for connecting the alignment rod enable it to be adjusted between 0 and 5° flexion/extension.

16. The femoral jig according to Claim 15 wherein the means for connecting the alignment rod comprises a plurality of holes.

17. The femoral jig according to Claim 15 wherein the means for connecting the alignment rod is movable to allow adjustment.

18. The femoral jig according to Claim 13 wherein the means to assist the surgeon to position the jig is a laser.

19. The femoral jig according to any one of Claims 1 to 18 wherein the jig additionally comprises electronic imaging and/or alignment means.

20. The femoral jig according to any one of Claims 1 to 18 wherein the jig additionally comprises a distal leaf spring.

21. A kit comprising one or more of a femoral jig according to any one of Claims 1 to 20, and optionally one or more mountable and/or demountable components.

22. The kit according to Claim 21 additionally including a tibial protector spacer.

Intellectual Property Office

Application No:	GB1519654.6	**Examiner:**	Emily Jones
Claims searched:	1-22	**Date of search:**	30 March 2016

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-20	GB2499316 A (MATORTHO LTD et al) See whole document, in particular Figure 17 and page 9 lines 12 to 16
X	1-20	WO01/66021 A1 (SMITH & NEPHEW INC et al) See whole document, and page 13 lines 4-10 in particular
X	1-20	GB2495775 A (EMSLIE et al) See whole document
X	1-20	WO2015/057814 A1 (XPANDORTHO INC) See whole document

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X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61B; A61F

The following online and other databases have been used in the preparation of this search report

WPI, EPODOC

International Classification:

Subclass	Subgroup	Valid From
A61B	0017/15	01/01/2006
A61F	0002/46	01/01/2006