

This invention concerns a positioning device which, in implantations of condylar total knee prostheses, permits the surgeon to perform the osteotomies with extreme precision. This is a prerequisite for being able to carry
5 out the implantation in such a way that the correct mechanical axis of the leg is attained through the operation.

It has been demonstrated that achievement of the correct mechanical axis of the leg is one of the most
10 important prerequisites for long life of the knee prosthesis without loosening and pain (Bargren, J.H., Blaha, J.D., Freeman, M.A.R., "Alignment in Total Knee Arthroplasty", *Clinical Orthopaedics and Related Research*, No. 173 (1983), pp. 178-183).

15 In this connection it is not just a matter of bringing about the correct static knee structure (alignment), but it is likewise important for balanced tension of the knee ligaments to be present, insofar as they still exist, or the correct soft-tissue tension (Ewald, F.C., "Biomechanical Indications for Implant Selection III: Knee",
20 *Role of Ligaments and Alignment*, American Academy of Orthopaedic Surgeons, 54th Annual Meeting, San Francisco, January 22-27, 1987; Instructional Course Number 323).

Condylar knee prostheses consist of a component fixed
25 to the femur and a component fixed to the tibia. Unlike the hinge prosthesis, these components are not connected by artificial mechanical aids.

As in the natural knee joint, the flexible connection between the two components is made up of ligaments and
30 muscles insofar as they are preserved during implantation of the prosthesis. Before the prosthesis components can be attached to the femur and the tibia by means of clamping, wedging, or bone cement, the femur and tibia must be shaped to fit the prosthesis with the aid of bone saws and
35 other tools. The instruments generally offered by the

manufacturers of the knee prostheses serve primarily to carry out the required matching bone cuts on the femur and the tibia, the osteotomies, with the necessary accuracy.

An essential requirement in this connection is that the components of the knee prosthesis which slide against one another when the knee is bent and straightened must always occupy correct relative positions, i.e., the mechanical axis of the leg must not deviate from the physiological axis of the leg by more than 3° varus or 3° valgus, and that correct tension of the various ligaments must be achieved, which produces good stability of the knee joint during both extension and flexion.

As a rule, prior art instrumentaria for the implantation of condylar total knee prostheses comprise the following means:

- means for aligning the tibia with the femur for attaining the desired leg-axis position;
- means for carrying out osteotomies, in the form of cutting gauges serving to guide the saw; such cutting gauges are conformed to specific shapes of prostheses and can usually be used for various sizes of one type of prosthesis;
- means for producing the desired tension of the knee joint ligaments.

Such an instrumentarium is described in US-A-4 524 766. It comprises a guiding device which is fixed frontally to the tibia. A cutting block is adjustably disposed at the upper end of this guiding device for carrying out osteotomies. This arrangement has the disadvantage, however, that access to the operating area is hampered by the upper part of the guide device bordering the cutting block. Moreover a precise knee alignment is difficult as the point of reference for the operation is aligned with the pelvic bone on the operating table.

- Further instrumentaria are described, for example, in the following publications: Richards GmbH, Osterbrooksweg 69, 2000 Hamburg-Schenefeld: "TRICON-M^(R) Die zementfreie Kniegelenksendoprothese", *Operationstechnik mit dem*
- 5 *ProFitTM Instrumentarium*, undated. Pappas, M.J., et al.: "N.J. Knee Instrumentation System: Biomechanical and Surgical Rationale," Biomedical Engineering Corp., issue date 7/1984. "ZIMMER^(R) Intramedullary Surgical Technique for the Miller/Galante Total Knee System", undated.
- 10 Intermedics Orthopaedics, 1300 East Anderson Lane, Austin, Texas 78752: "The Intermedics Natural-KneeTM System," 1986. Howmedica, Inc., Orthopaedics Division, 359 Veterans Blvd., Rutherford, N.J. 07070: "The Howmedica^(R) Total Knee Instrument System," 1980. Interplanta GmbH,
- 15 Barkhausenweg 10, 2000 Hamburg 63: "SchalenKneelenkprothesen-System Modell Interplanta^(C)", Link, W., 1981.

The prior art instrumentaria have the drawback that the cutting gauge for the osteotomies has two positioning

20 systems, viz., one on the tibia for cutting thereon, and a second one on the femur for cutting on that bone. For determining the cutting planes and for carrying out the osteotomy with the saw on the tibia, measuring means and cutting gauge are first attached to the tibia, e.g., by

25 means of Steinmann's nails or bone-screws. After the tibia cut has been effected, the measuring means and cutting gauge are attached to the femur. During this changeover, an exact geometric relationship between the tibia-side and femur-side components of the prosthesis is

30 not ensured. Almost any surgeon who implants condylar total knee prostheses does, in fact, know of errors in this regard. Such errors are described; for instance in Lotke, P.A., Ecker, M.L., "Influence of Positioning of Prosthesis in Total Knee Replacement," *J. of Bone and*

35 *Joint Surgery* 55-A, 1977, pp. 77-79.

Steps have already been taken to avoid the aforementioned drawback, e.g., by fastening the knee to the operating table with a mechanical device, the saw also being connected to this device (cf. Cooke, T.D.V., Saunders, G.,
5 Siu, D., Yoshioka, Y., Wevers, W., "Application of Bench-Mounted Saws for Precision Arthroplasty of the Arthritic Knee [Questor Knee Jigs], "Abstract Book, Second European Congress of Knee Surgery and Arthroscopy, Basle, September 29 - October 4, 1986, pp. 110 - 111; *J. Biomed. Eng.*,
10 7/45 - 50, 1985.

The devices described in the aforementioned publications entail complicated mechanical structures which are time-consuming to use and also hamper access to the operating area.

15 Consequently it is an object of this invention to provide an instrumentarium which avoids the above-mentioned drawbacks of prior art instrumentaria.

It has been discovered that this object can be fulfilled by creating a positioning device for the
20 implantation of condylar total knee prostheses in which the measuring means and the cutting gauge for the tibial and femoral osteotomies are attached only to the tibia. The positioning device must also be so designed that it can remain screwed to the tibia during the whole operation
25 without significantly hampering access to the operating area and without preventing movement of the knee joint.

The subject matter of this invention is thus the positioning device defined in patent claim 1 for implantation of condylar total knee prostheses.

30 The positioning device according to the invention is an instrumentarium with which the cutting gauge for the tibial and femoral osteotomies can be set from the same point of reference. The positioning device is thus preferably fixed laterally to the tibia with modified Schanz
35 screws by means of two attachment arms. The basic element

of the instrumentarium is the measuring rod, which is attached by means of the aforementioned attachment arms preferably about 10 cm. away from the axis of the tibia. Movably affixed to this measuring rod on the guide rail is the cutting block which can be moved precisely into position in front of the opened knee. Likewise disposed on the measuring rod is a so-called alignment bar which is essentially the continuation of the measuring rod and which reaches into the region of the pelvic bone. Prior to the operation, the alignment element, disposed displacably relative to the alignment bar at the top thereof, is fixed, e.g. by a screw, in such a way that it is aimed at a certain point on the pelvic bone. This point is preferably a screw driven into the spina iliaca anterior superior perpendicular to the frontal plane. By means of the positioning device, the tibia can be brought into the correct position relative to the femur at any time, even during the operation. This is particularly necessary when cutting has to be performed on the femur and, at a late stage of the operation, for correct insertion of the condylar total knee prosthesis.

At the location where it is connected to the measuring rod, the alignment bar preferably has a hinge allowing it to be swung away so that good accessibility to the operating area remains ensured. For the osteotomy of the ventral and dorsal femoral condyles, the knee is brought into flexed position. This position, too, is possible when using the positioning device. If the osteotomy of the ventral and dorsal femoral condyles is performed in the first phase of the operation, the osteotomy of the tibia in the second phase, and the osteotomy of the distal condyles in the third phase, a tensor is inserted between the tibia and the femur before carrying out these second and third phases. In this state, the stretched ligaments and tissue pull the two bones together.

Hence auxiliary means are necessary for bringing the tibia into the correct position so that the osteotomies can be performed correctly on the tibia and femur with the joint flexed at 90° and on the femur with the leg

5 extended. Such an auxiliary means is the tenser. Its task is to press the joint surfaces of the tibia and the femur apart, it being possible to check this action by means of the positioning device.

In the following two different examples of tensers
10 are described, one for the osteotomies on the straightened knee, the other for osteotomies on the flexed knee.

The first tenser for the osteotomies on the straightened knee is preferably a block-shaped device which can be inserted between femur and tibia after the
15 osteotomy on the head of the tibia has been carried out. The block is preferably so designed that on the top, two movable plates can be displaced toward the femur independently of one another, parallel to a plate lying on the tibia, e.g., by tightening screws, so that various
20 spacings can be set between the medial and lateral femoral condyles and various forces exerted. In this way, it is possible to adjust the soft-tissue tension medially and laterally correctly and to check any axial correction possibly having to be made.

25 The second tenser is designed on the principle of expander-tongs and presents a number of advantages in conjunction with the inventive positioning device as compared with prior art instruments of this kind. The tenser can be inserted when the knee is flexed without
30 removing the cutting block. One arm of the tenser can be introduced through an aperture in such a way that it rests on the roof of the intercondylar notch. The other arm is formed so that it is braced against a bone screw driven into the tibia below the knee. This bone screw, a
35 modified Schanz screw, has already been driven in for

attaching the knee-side attachment arm. Bracing against this screw instead of against the tibia, osteotomy adjacent to the femur has the advantage that the osteotomy surface is not damaged by the action of force. The tensor presents the further advantage that it is not hampered by the rotation of the knee joint caused by the medially and laterally differing soft-tissue forces, so that such rotation can be checked and modified as desired by known operative procedures.

- 10 If this position is correct, the measuring carriage with the cutting block can, with the aid of the scale on the guide rail, be moved into the proper position for the osteotomy of the distal condyles. At this time, the spacing of the cuts on the tibia and the femur is adapted to the prosthesis to be implanted. The inventive positioning device is important not only for the osteotomies but also during implantation of the prosthesis components since their correct adaptation, including the proper axial relationships, can be checked at any time during this decisive phase of the operation.

- 20 The lateral placement of the positioning device lessens parallax errors during checking of the axial position. Such parallax errors are greater with frontal alignment bars of conventional instrumentaria since the neutral rotation position of the extended leg cannot be reliably established during the operation owing to the covering of sterile cloths.

- The correct leg-axis position with the knee joint straightened is checked by means of the alignment bar. For this purpose, the distance from the spine to the centre of the hip joint is measured pre-operatively on a pelvic survey radiograph and transferred at the distal end of the instrumentarium to the alignment element or spine pointer.

The positioning device is fundamentally suited to any desired sequence of osteotomies. This sequence is established by the operating surgeon according to the condition of the knee joint and the axial position present.

A preferred embodiment of the invention will now be described in detail with reference to the accompanying drawings in which:

Figure 1 is a perspective survey diagram of the inventive positioning device and of the portions of bone to which it is applied,

Figure 2 is an elevation of a knee joint to which the positioning device is applied, flexed at a 90° angle and distracted with the aid of a tensor,

Figure 3 is a perspective view of a caliper bracket,

Figure 4 is an elevation of the flexed knee joint with cutting block and caliper bracket of the positioning device, showing the osteotomies to be performed,

Figure 5 is a side view of the positioning device,

Figure 6 is a front view of the positioning device,

Figure 7 is an exploded view of a tensor for the straightened knee,

Figure 8 is a side view of the positioning device, illustrating the effect of the first tensor on the straightened knee, and

Figure 9 is a front view of the tensor for the straightened knee.

Figure 1 shows in a survey view the instrumentarium which comprises the essential components of the inventive positioning device. Also shown are a tibia T and a femur F to which the positioning device is to be applied. Disposed on a measuring rod 1 are lateral attachment arms 2 which are connected to measuring rod 1 by attachment means 3. Measuring rod 1 is attached to tibia T by means of Schanz screws 4 passing through holes 5 in arms 2.

Associated bores 5 for modified Schanz screws 4 are drilled in tibia T by means of a template 6 during the course of preparation for the operation, template 6 being fixed to the head of the tibia by a Steinmann's nail
 5 driven into the head through a bore 7.

Secured to measuring rod 1 by means of attachment means 8 is a guide rail 9 including a scale 10. Disposed on guide rail 9 is a measuring carriage 11 which can be slid in the region of scale 10 into the position necessary
 10 for the osteotomies. Alternatively, measuring rod 1 and guide rail 9 might be made in one piece. In the present embodiment, guide rail 9 is set back relative to the frontal plane so that the operating area is optimally liberated. Disposed on measuring carriage 11 is a movable
 15 pointer 12 by means of which the scale can be calibrated for each operation. Carriage 11 includes guide rods 13 for guiding a guide element 14 of a cutting block 15. Cutting block 15 can be displaced upward and downward on guide rods 13 and fixed. Cutting block 15 includes slits
 20 16 for insertion of a sawing instrument and various holes 17 for receiving Steinmann's nails. A hole 18 is intended for attaching a caliper bracket (see Figure 3) used for osteotomies on the femur with the knee in flexed position (cf. Figure 2). An alignment bar 20 is removably fastened
 25 to a pin 22 and a threaded connecting portion 23 of measuring rod 1 by means of a hinge part 21. It is shown detached in the drawing <Figure 1>. During the operation, alignment bar 20 can be swung away through 180° rotation about the hinge, thus allowing unhindered access to the
 30 operating area. In this embodiment, alignment bar 20 can be telescoped for easier handling and locked against rotation by a stud 24 entering a groove. An alignment element 26 is slidably attached by means of a removable mounting 25 and can be fixed by tightening a screw on this
 35 mounting. Sighting element 26 ends in a knob 27 which can

be aligned with the point of reference of the operation, namely, a screw B in the spina anterior superior of the pelvis.

In Figures 2 and 3, the position of cutting block 15, with caliper bracket 28 placed thereon, is shown relative to the flexed knee. Cutting block 15 is attached to femur F by two Steinmann's nails 29. Ventral condyles 30 are osteotomized through the uppermost saw slit 16, at which time the femur is pressed away from the tibia T by means of a tenser 31. An arm 49 of tenser 31 for flexed knee is inserted through an aperture 19 in cutting block 15. The arm of part 47 of tenser 31 is braced against the upper modified Schanz screw 4 in tibia T. A screw 32 fixes parts 47 and 48. The osteotomy 33 of the ventral femoral condyles is further indicated.

Figure 3 shows caliper bracket 28 in perspective, while Figure 4 indicates by means of a dot-dash cutting line 34 the position of the osteotomy of the dorsal condyles.

Figure 5 is a side view of the positioning device with the knee straightened. Here the attachment of measuring rod to tibia T by means of Schanz screws 4 is apparent. In the present embodiment, guide rail 9, on which measuring carriage 11 is guided, is set back relative to the part of measuring rod 1 fastened to the tibia, thus affording better access to the operating area. Affixed to the set-back part of measuring rod 1 is carriage 11, which includes movable pointer 12 for reading off scale 10. Guide rods 13, on which cutting block 15 is movably mounted by means of guide element 14, are attached to carriage 11. Alignment bar 20 is fastened to measuring rod 1 on threaded connecting portion 23 thereof; it can be swung back by means of hinge part 21 and, if necessary, removed by taking off a nut 23'. At the top of alignment bar 20 is mounting 25 by means of which alignment element

26 with press element 27 can be brought into the proper position.

Figure 6 shows the same arrangement from the front. Here the lateral connection of measuring rod 1 by means of attachment arms 2 is clearly apparent, these arms being fixed to the tibia by Schanz screws 4. The position of cutting block 15 in front of the knee is also made plain. Guide rail 9 on which measuring carriage 11 slides is so disposed that cutting block 15 can be moved into the correct position for all the necessary cutting. Furthermore, the function of alignment bar 20 with alignment element 26 and press element 27 can be deduced. If, prior to the operation, the position of alignment element 26 on alignment bar 20 and the distance between press element 27 and alignment bar 20 are determined, the position of the tibia can be corrected at any time during the operation by resting press element 27 against a screw in the spina iliaca anterior superior as the point of reference.

Figure 7 shows a tenser 35, the application of which is further elucidated by Figure 8. A part 36 includes support surfaces 37 for the osteotomized tibia. In guide grooves 38 there are parts 39 having support surfaces 40 for the femoral condyles. Disposed on each part 39 is a bolt 41 with a thread 42 at one end for receiving a nut 43 having a radial groove 44. Parts 39 and nuts 43 are held together on part 36 by a base plate 45 and a cover plate 46. Through this arrangement, parts 39 can be precisely moved relative to part 36 by turning nuts 43. Support surfaces 37 and 40 then remain parallel; only the spacing is changed.

Figure 8 depicts the application of tenser 35 in conjunction with the positioning device essentially as illustrated in Figure 5, the difference being that here the osteotomy of the tibia and of the dorsal and ventral femoral condyles has already been carried out. The

position of the instrumentarium corresponds to the preparation of the osteotomy of the distal femoral condyles. The tibia is pushed away from the femur by the pressure of support surfaces 37, 40. Once the correct
 5 position has been adjusted, cutting block 15 can be moved to the predetermined location and the osteotomy performed.

Figure 9 shows tensor 35 from the front. Here it is particularly apparent how support surfaces 40 of movable parts 39 act upon the femoral condyles. It will be seen
 10 that by turning grooved nuts 43, the space between the tibia and femur can be increased or decreased. Downwardly directed part 36 with cover plate 46 affords optimal access to the operating area for carrying out osteotomies on the femur.

15 One advantage of the inventive instrumentarium is that the surgeon may perform the osteotomies in any desired order. In the case of a joint having a significantly immobilized false frontal position, he will first perform the osteotomy of the proximal tibia and then
 20 correct the soft-tissue tension surgically. The osteotomy of the ventral and dorsal femoral condyles after correction of the ligaments then ensures a stable joint, both in extension and in flexion. In the case of joints with a largely correct axial position, osteotomy of the ventral
 25 and dorsal femoral condyles may be performed first.

When the cutting block is used in the flexed position of the knee, its position is determined by the Steinmann's nails and the caliper bracket. The osteotomy of the ventral condyles takes place through the uppermost sawing
 30 slit and that of the dorsal condyles through the middle sawing slit. The spacing of the bores in the cutting block for fixing by the Steinmann's nails corresponds to the various prosthesis sizes. The cutting block can be lifted off, displaced by the bore interval, and put back
 35 again on the two Steinmann's nails.

Inasmuch as the cutting block is additionally displaceable in sagittal direction at right angles to the measuring rod on guide rods of the measuring carriage, it can be moved into the optimal position for any osteotomy
5 on the tibia and the femur.

The position of the cutting block can be determined, according to the size of the components of the prosthesis, from a table accompanying the instrumentarium.

As already pointed out, the correct leg-axis position
10 with the knee straightened is checked using the alignment bar, the distance from the spina iliaca anterior superior to the center of the hip joint having been measured pre-operatively on a pelvic survey radiograph and transferred to the distal end of the alignment bar by means of the
15 press element or the iliac spine pointer.

The correct resection height is set on the measuring rod, and the cutting block is screwed to the osteotomized ventral condyles by a cortex screw having a diameter of 4.5 mm. The distal condyles are osteotomized through the
20 lowest slit of the cutting block, the correct ligament tension being established with the aid of the tenser and the axial position being repeatedly checked with the alignment bar.



Patent Claims

1. Positioning device for the implantation of condylar total knee prostheses using tension devices for the structures surrounding the knee, which relates to the tibia, comprising a sighting element (26, 27) for alignment of the leg axis, which is aimed at a landmark on the pelvic bone, characterized by a measuring rod (1) with at least two attachment arms (2) for lateral attachment on the tibia (T), parallel to the tibia longitudinal axis, a guide rail (9) of the measuring rod (1) having a fixible measuring carriage (11), which can be slid in longitudinal direction, its position in the longitudinal direction being exactly determinable by means of a graduated scale of length (10) next to the knee to be operated, on the side of the measuring carriage a removable cutting block (15) as a gauge for the osteotomies disposed in such a way that it can be put into position in front of the knee, movable at right angles to the frontal plane on guide pins (13) located on the measuring carriage (11) and parallel to the tibia longitudinal axis on the guide rail (9), and which can be fixed in a pre-determined position, attached to the measuring rod is an alignment bar (20), which forms the extension of the measuring rod (1) in the direction of the pelvis and has a length such that its end reaches to the pelvis, on the upper end on the alignment bar a movable sighting element (26, 27) being disposed, which element can be moved and fixed along the alignment bar and at a right angle to the sagittal plane for adjustment so that the correct position of the lower leg (T) can be set or checked during the operation by means of a certain point of reference (B) on the pelvic bone.

2. Positioning device according to claim 1, characterized in that on the measuring rod two lateral attachment arms (2) with a length of 8 to 15 cm and attachment



means (3, 3a) are provided, which are rotatable around the measuring rod (1) as an axis at 180 degrees for application on the left or right leg and can be fixed in the correct position by means of attachment screws (3a), and
5 on the attachment arms (2) several attachment holes (5) for bone screws (4) are provided on the side turned away from the measuring rod so that the distance of the measuring rod (1) from the tibia (T) can be adjusted in such a way that the cutting block lies concentrically in
10 front of the Fossa intercondylica.

3. Positioning device according to claim 1 or 2, characterized in that the alignment bar (20) is detachable and is fixed in a way that it cannot be twisted in relation to the guide rail (9) and is provided with a hinge,
15 so that it can be swivelled on the sagittal plane so that the operation site can be made more accessible if necessary.

4. Positioning device according to one of the claims 1 to 3, characterized in that the measuring carriage (11) has an adjustable indicator (12) for calibration of the positioning device.

5. Positioning device according to one of the claims 1 to 4, characterized in that the measuring carriage (11) has at least two guide pins (13), which are
25 arranged at a right angle to the frontal plane and the cutting block has a corresponding guide element (14) so that it can be pushed along the guide rod (13) and can be fixed in the desired position.

6. Positioning device according to one of the
30 claims 1 to 5, characterized in that the cutting block (15) has several slits (16), which serve as a gauge for a sawing instrument in carrying out osteotomies.



7. Positioning device according to one of the claims 1 to 6, characterized in that the cutting block (15) has an aperture (19), which is dimensioned in such a way that a tension device (31) can be introduced through it so that this tension device can be used on the flexed knee without the cutting block being removed.

8. Positioning device according to one of the claims 1 to 7, characterized in that a removable caliper bracket (28) on the cutting block (15) is provided, which serves to position the cutting block (15) to define the point as the landmark for osteotomies and for the osteotomies of the ventral and dorsal femur condyles..

9. Positioning device according to one of the claims 1 to 8, characterized in that the sighting element (26) is formed as a rod which has a knob-shaped press element (27) for placement on the spina iliaca anterior superior on its end and is attached to the alignment bar with a detachable fixing device (25).

10. Positioning device according to claims 1 to 9, characterized in that it comprises a tension device (31) for tensioning the genicular ligaments in the flexed knee joint to generate a force between the femur and the tibia in the course of an operation using the positioning device, the said tension device of pincers-like form, having two movable parts (47, 48) connected by an axis which parts can be regulated precisely and blocked in the desired position through a means, whereby the bent arm (49) of the part (48) on the roof of the fossa intercondylar can be applied to exert a force on the femur, and the part (47) also has an arm which is formed in such a way however that it can be braced against the upper bone screw (4), which has already been screwed in to fix the



lateral arm (2), the counterforce being necessarily taken up by the bone screw (4).

11. Positioning device according to one of the claims 1 to 9, characterized in that it comprises a hole gauge (6) for putting bores in the tibia for fastening the positioning device, the said bore gauge consisting of a flat stick which has holes at the correct position for fastening the attachment arms (2) of the measuring rod (1) and has in addition a further hole (7) through which the hole gauge can be provisionally fixed to the tibia with a nail.