Title: A SURGICAL AID FOR JOINTS

Abstract: A surgical aid for joints which allows the positioning of mono-compartment or three-compartment prosthetic components so that the isometry of the capsular-ligamentous tissues of the knee is maintained during the entire range of motion. Such surgical aid comprises: a first element (10) intended to be positioned in contact with a first bone of a joint; a second element (20), intended to be positioned in contact with a second bone of the joint; the first and second element (10, 20) being movable relatively to one another along at least a first direction (X); a displacement sensor (30) predisposed for measuring a relative displacement between the first and second element (10, 20); an actuator/motor (50) predisposed for exerting a force that tends to move the first element (10) and second element (20) away from one another; a pressure sensor (40) which measures the force that is exerted between the first and second bone; a processing module (60) arranged to control the actuator/motor (50) so as to calculate the variation of the slope arising from the relationship between distance and force; the processing module (60) receives in input the signal emitted by the displacement sensor (30), the force sensor (10) and the pressure sensor (40).
A surgical aid for joints

DESCRIPTION

The invention relates to a surgical aid for joints.

The invention particularly relates to a surgical aid that helps to determine the orientation and extent of bone resections for implant of a mono-compartmental or three-compartmental prosthetic joint by keeping the periarticular or intra-articular capsule-ligamentous tissues in isometric tension during the entire range of motion. The device quantifies the distance between femur and tibia medially and/or laterally in the arthritic knee affected by mono- bi- or tri-compartmental osteoarthritis during the full range of motion, with the capsule-ligamentous structures being isometric and the extensor mechanism reduced.

The invention is particularly useful in the surgery intended for mono-bi- and three-compartmental knee implants.

In brief, a total mono-compartmental, bi- or tri-compartmental prosthesis for the knee joint comprises a femoral element intended to be applied medially and/or laterally at the distal end of the femur, and a tibial element, intended to be applied medially and/or laterally to the proximal end of the tibia. When implementing the new knee joint, the osteo-cartilaginous ends of femur and tibia are replaced by the prosthetic femoral and tibial components.

The prosthetic tibial and femoral components are designed along geometrical criteria which promote stability and mobility of the new joint, without this causing any pain to the patient and enabling him/her to perform usual locomotor activities. The geometry of the prosthetic components and their three-dimensional alignment to the femur and the tibia have been recently defined via CT scan or MRI images in order that the anatomy of the knee joint is complied with.

To allow application of prosthetic femoral and tibial components, the corresponding femur and tibia ends must be resected so that the
prosthesis becomes aligned with the mechanical or anatomical axis of the femur and tibia respectively. Little attention has been paid till so far to the importance of maintaining the geometry and physiological stress of the capsule-ligament peri-articular or intra-articular tissues throughout the range of motion of the knee, with consequent optimization of articular biomechanics and particularly of stability, kinematics and proprioception of the knee and of the entire lower limb. Traditional surgical techniques as well as innovative techniques such as patient-oriented techniques, are geared towards changing the bone components anatomy (with alignment to the mechanical or anatomical axis), which implies in fact alteration of the soft tissue tension and change of the joint surfaces geometry. As a result, the kinematics and kinetics joint are completely altered as well as tension in the capsular ligamentous tissues. The femoral and tibial bone resections are made such as to ensure that the lower limb mechanical axis is passing through the center of the knee. The medial and lateral condylar bone resections are different in thickness due to the patients’ anatomical variations and because they are aligned to the mechanical axis of the femur and tibia. Asymmetrical bone resections as well as modification of the geometry of articular surfaces of femur and polyethylene insert, inevitably result in an altered tension of the soft tissues, which soft tissues, when excessively tensioned, are often released surgically to their insertion or along the course. In other words, the knee prosthesis implant surgery changes the anatomy of the femoral and tibial epiphysis in terms of alignment and surface geometry, regardless of the capsule-ligamentous tissues tensioning. All this can lead to unsatisfactory clinical results, accompanied by pain and difficulty on the part of the patient, not only in performing normal daily activities, but also in connection to locomotor activities desired by the patient.

It is an object of the device herein disclosed to enable positioning of the prosthetic components by maintaining the capsule-ligamentous tissues in
isometric conditions.

It is an aim of the present invention to further provide a surgical aid, which allows to position the prosthetic elements accurately, by maintaining the isometry of the peri-articular or intra-articular capsule-ligament structures according to the prosthetic design used.

An advantage of the surgical aid according to the present invention is to be compact and consequently little invasive, thus being positionable in a compartment or in both compartments with the extensor apparatus being reduced.

A further advantage of the surgical aid according to the present invention is that lengthening of the intervention time is not required. Further characteristics and advantages of the present invention will better emerge from the detailed description that follows of a preferred embodiment of the invention, illustrated by way of non-limiting example in the accompanying figures in which:

- Figure 1 shows a schematic view of the surgical aid according to the present invention;
- Figure 2 shows a schematic view of the surgical aid of figure 1 in a configuration of use;
- Figure 3 shows the surgical aid of figure 1 in side view;
- Figure 4 shows the surgical aid of Figure 3 in use configuration;
- Figure 5 shows an example of force/elongation curve for tendons and ligaments;
- Figure 6 shows a qualitative example of an angle/shifting curve obtained with the surgical aid according to the present invention.

With reference to the figures listed above, the surgical aid according to the present invention comprises a first element (10) intended to be positioned in contact with a first bone of a joint. In the case of a knee prosthesis, the first bone is the femur (F). In particular, the first element (10) is intended to be positioned in contact with the lower end of the femur. The surgical aid further comprises a second element (20) intended to be positioned in
contact with a second bone of the joint. The second bone, in the case of knee implants, is the tibia (T). In particular, the second element (20) is intended to be positioned in contact with the tibia upper end, preferably following performance of a minimal tibial resection.

The first and second element (10,20) are movable relatively to one another along at least a first direction (X). An actuator or motor (50) is arranged to exert a force which tends to move away the first element (10) and the second element (20) from one another. Such actuator or motor (50) may be interposed between the first and second element (10,20). In the illustrated embodiment, the actuator or motor (50) is associated to one between the first and second element (10,20), for example, the second element (10), and is acting on the second element (20) with an active portion. The actuator or motor (50) comprises for example a hydraulic cylinder and/or a screw mechanism or other system in order to axially space apart the two elements from one another. In this case, the actuator body or motor (50) is associated to the second element (20), whereas the stem or spindle nut is associated to the first element (10).

The surgical aid comprises a displacement sensor (30), which is predisposed for measuring a relative displacement between the first and second element (10,20). In particular, the displacement sensor (30) measures the relative displacement between the first and second element (10,20) with respect to zero or an initial pre-established position, wherein the first and second element (10,20) are located at a known distance. Essentially, this initial known distance is to be understood as the initial reference wherefrom the space between the tibia and femur is calculated during the entire range of motion. As shown in Figure 1, the displacement sensor may be associated to the actuator or motor (50), such that displacement between the first and second element (10,20) may be detected by measuring the stroke performed by the actuator or motor (50).

The surgical aid further comprises a force sensor (51), represented only
schematically and predisposed for measuring the force exerted by the actuator or motor (50).

Preferably the surgical aid further comprises a pressure sensor (40), arranged for detecting a pressure which is acting on the first element (10) and/or second element (20). For example, the pressure sensor (40) may be associated with the first element (10) in an area intended to come into contact with the first bone (F) of the joint. The pressure sensor (40) can be useful for detecting the presence of any peaks of pressure or a possible uneven distribution of pressure, both indicating an incorrect positioning or conformation of the joint. This data is therefore desirable for ascertaining the positioning performed during the full range of motion.

The displacement sensor (30), the force sensor (51) and the pressure sensor (40), if present, are connected to a processing module (60), which is predisposed for controlling the actuator or motor (50). In particular the processing module (60) in different angular positions or joint flexion-extension all along the range of motion of the knee, progressively increases the force exerted by the actuator/motor (50) by simultaneously detecting the displacement measured by the displacement sensor (30) and developing a force-displacement diagram.

The isometric tension of the soft tissues is detected by the processing module (60) through an analysis of the force-elongation diagram obtained by reading the force sensor (51), the pressure sensor (40), if present, and the displacement sensor (30) in different angular or flexion-extension positions of the joint. In any pre-determined angular position, the distraction essentially ceases as soon as the force-displacement diagram exhibits a net slope change indicating the end of the isometric condition. For each angular or flexion-extension position selected for the joint, the processing module traces the force/displacement diagram as described above, thereby detecting the critical displacement value based on which the change in the slope of the force/displacement diagram occurs. Such critical displacement, for each selected angular position, substantially
corresponds to the maximum distance between femur and tibia, wherein the capsule-ligamentous tissues are in isometric conditions. The number of angular positions or flexion-extension of the joint according to which the variation of the strength and development of the force/displacement diagram shall be performed, can be determined at will.

In each of the various selected angular positions, the processing module (60) then controls a variation of the force applied by the actuator/motor (50) up to the moment in which the variation of the slope of the force-displacement diagram is detected. At such time the processing module (60) detects the critical displacement between the first and second element (10, 20). In this way, for each of the angular positions which were selected for the purposes of detection, the space or maximum tibiofemoral distance is obtained, in which the capsule-ligamentous tissues are in isometric conditions.

During the range of motion of the knee, in the different selected angular or flexion-extension positions, the processing module (60) is arranged to detect the displacement signal sent by the displacement sensor (30), which corresponds to the critical displacement along the first direction (X), i.e. to the displacement value based on which the change of slope of the force-displacement diagram occurs. The displacement values recorded for each angular position are stored and subsequently processed by means of a pre-determined algorithm, such that an optimal displacement can be obtained which corresponds essentially to a maximum tibiofemoral distance in which the capsule-ligamentous tissues are maintained in conditions of isometric tension, i.e. under conditions in which the capsule-ligamentous tissues are not subjected to a tension higher than that based on which the change of slope of the force-displacement curve is determined. This optimal displacement measured along the first direction (X), basically corresponds to the ideal height of the prosthesis, or at least of the tibial prosthetic component which exhibits a substantially flat articular surface.
Moreover, once the femoral and/or tibial resection have been performed based on the optimal displacement value between femur and tibia, which value is calculated by the module (60), one may use the surgical aid in order to verify the isometry of tissues throughout the range of motion of the limb. After entering the trial femoral component, the surface of which is compatible with the geometry of the permanent prosthesis, the surgical aid is inserted on the final resection of the tibia, and by moving the knee throughout the range of motion, the force/displacement measurements mentioned above are repeated, and the pressure measured by the sensor (40) possibly detected. Cutting, insert thickness or size of the components may still be modified as a function of the detected measurements for the purposes of trying to get the isometry of the medial and/or lateral capsular-ligamentous tissues throughout the whole range of motion. On the contact surface with the trial component of the femur, the surgical aid preferably exhibits a geometry which is equal to the final one of the tibial insert.

For the implant of a medial or lateral mono-compartmental prosthesis, the surgical aid according to the invention can be used as detailed hereinafter. The limb is suspended with a grip being exerted on the femur in order that the weight of the thigh does not affect the detection of the force between the femur and tibia.

Before the definitive resections of the femur and tibia are performed, the surgical aid is inserted between the ends of the articular bones, with the first and second element (10,20) being arranged in contact with the ends of the bones themselves. In order to make this possible, a preliminary resection of the tibia is preferably carried out, by following the mechanical or anatomical axis of the tibia on the frontal and sagittal planes. The femur is retained intact (without bone resection).

The joint is then brought from full extension to full flexion, for example within a range between 0° (straight leg) and 150°. In a certain predetermined number of angular positions, the force applied by the actuator/motor (50) is varied and the first and second element (10,20) are
moved with respect to one another, up to the point in which the force-displacement curve processed by the processing module (60) is changed from a non-linear trend to a linear trend, wherein the tension value of the isometric capsule-ligamentous tissues is indicated, as well as the corresponding critical displacement value which is stored by the module (60) itself. In each of the angular positions in which the measurement is carried out, the processing module (60) stores the isometric force value (or isometric tension) as well, at which value the trend of the force/displacement curve is changed from a non-linear trend to a linear trend.

Once detections have been completed, or after completion of the articular rotation between the bones, an optimal displacement value (or space) between the femur and tibia is determined by the processing module (60), according to the algorithm already mentioned. The optimal displacement calculated, essentially corresponds to the overall thickness of the prosthesis or at least the prosthetic tibial component, and allows performance of a correct spatial orientation of the same. This enables to obtain a joint kinematics of the prosthetic components which is compatible with the isometry of the capsule-ligament intra and extra articular structures.

The surgical aid according to the present invention may be further provided with an angular measurement device (35), arranged to measure an angle of inclination between the two bones of the joint, which angular measurement device (35) is connected to the processing module (60). Such angular measurement device may be for example in the form of an inertial sensor. In a possible embodiment, the angular measurement device comprises a pair of inertial sensors (illustrated schematically in Figure 4), arranged to be associated respectively to the femur and the tibia. For example, a first sensor can be associated to the thigh (by means of a band or the like), whereas a second sensor can be associated to the tibia or to the patient's ankle.
The processing module (60) is predisposed for detecting the signals emitted by the displacement sensor (30) and the angular measurement device (35) and for tracing a variation of the displacement along the first direction (X), in function of the angle of inclination between the two bones of the joint. In other words, the processing module (60) is arranged to draw an angle/displacement diagram.

The angular measuring device (35) may be used advantageously to approximate or to obtain an articular surface of the prosthesis, or at least the prosthetic tibial component.

In a first possible method of use, after determining the optimal displacement and the isometric tension value according to the previously described mode, it is possible to maintain the force exerted by the actuator or motor (50) to a value corresponding to said isometric tension. By making the articular bones to rotate between two pre-determined angular positions, a displacement between the first and second element (10,20) is produced, which is detected by the displacement sensor (30). At the same time, by means of the angle measurement device (35), the angular displacement between the articular bones is detected. The processing module (60) is able to correlate the displacement between the articular bones along the first direction (X) with the angle of inclination between the articular bones by drawing a curve which is able to define, rather well, the profile of the articular surface of the tibial prosthesis seen in projection on the sagittal plane. The correlation angle/displacement curve thus obtained and illustrated only qualitatively in Figure 6, may be used to optimally select a ready-to-use prosthesis, or to shape ex novo a custom-made prosthesis.

In a second possible method of use, the angle of rotation between the articular bones is detected in any angular position based on which it is decided to perform the force-displacement measurement in the manner already described above. For example, starting from a substantially extended leg condition (angle close to 0°) and for a certain number of
angular positions up to an angle of 150°, the processing module (60) detects the critical displacement as already described, and puts the latter in correlation with the corresponding angle detected via the sensor (35). In this way, to each angle a respective critical displacement is associated, which critical displacement, as already mentioned, corresponds to the displacement wherein the change of slope of the force-displacement curve occurs; in this manner an angle/displacement trend is delineated which is shown in Figure 6, which approximates the profile of the articular surface of the tibial prosthesis seen in the sagittal plane.

In all the procedures herein disclosed, following resections and insertion of the trial femoral component, the surgical aid may be repositioned on the final resection of the tibia and the isometry of the capsule-ligamentous tissues in the medial or lateral compartment may be tested. This allows to make possible changes in bone resections, or to quantify and change the tension of the capsular ligamentous tissues.

In order that the orientation and extent definition of bone resections with respect to the femur and the tibia are accurate for the patient, relevant data shall be processed with a computer-assisted navigation and/or robotics system, wherein femur and tibia geometric images are obtainable via CT or NMR. The surgical aid may be further used by realizing cutting templates for the anatomical positioning of the femoral and tibial component via CT or NMR images, in order to optimize and possibly change the position of prosthetic components as a function of the optimal ligamentous tension.

The same technique may be applied in realizing mono-compartmental prosthesis, bi-compartmental-Cruciate-Retaining full prosthesis, as well as posterior-Cruciate-Retaining or replacing posterior-Cruciate full prosthesis, by employing two devices: one medial device and one lateral device. The surgical aid according to the present invention offers important advantages. It allows sizing and accurate positioning of the prosthetic elements, while maintaining the isometry of the capsule-ligamentous
tissues. In addition, the surgical aid according to the invention is compact and not invasive. A further important advantage is given by the fact that use of the surgical aid does not request to lengthen the intervention time, since it is enough to place the surgical aid between the ends of the articular bones and perform a complete joint movement for obtaining an optimal positioning and sizing of prosthetic components. The surgical aid may be further employed as an instrument for testing and adjusting orientation of the components and of bone thicknesses removed together with the trial components.
CLAIMS

1. A surgical aid for joints, characterized by comprising: a first element (10), intended to be positioned in contact with a first bone of a joint; a second element (20), intended to be positioned in contact with a second bone of the joint; the first and second element (10, 20) are movable relative to one another along at least a first direction (X); a displacement sensor (30) predisposed for measuring a relative displacement between the first and second element (10, 20); an actuator or motor (50) predisposed for exerting a force that tends to move away the first element (10) and second element (20) from one another; a force sensor (51) suitable for detecting the force exerted by the actuator or motor (50); a processing module (60) which receives in input the signals emitted by the displacement sensors (30) and pressure sensors (40) and which is predisposed for controlling the actuator or motor (50).

2. A surgical aid according to claim 1, wherein the processing module (60) is predisposed for detecting the signals of the displacement sensor (30) and the force sensor (51) and for processing a force/displacement diagram, which puts into correspondence a force value applied by the actuator or motor (50), which force is obtained from the value detected by the force sensor (51), with a corresponding displacement value detected by the displacement sensor (30).

3. A surgical aid according to claim 2, wherein the processing module (60) is arranged to store, in at least two bending positions, the force/displacement diagram by detecting the displacement wherein the diagram exhibits a change of slope.

4. A surgical aid according to claim 3, wherein the processing module (60) is arranged to detect on the force/displacement diagram in at least two bending positions, the displacement in which the diagram is changing from a non-linear to a substantially linear trend.
5. A surgical aid according to any preceding claim, wherein the processing module (60) is arranged to detect the signals emitted by the displacement sensor (30) and force sensor (51) and, based on the detected signals, to process said force/displacement diagram in pre-determined angular positions between the bones of the joint.

6. A surgical aid according to claim 5, wherein the processing module (60) comprises an algorithm for processing said points of the force/displacement diagrams in pre-determined angular positions in order that an optimal displacement is obtained, which is measured along the first direction (X) corresponding to the height of at least one prosthetic component.

7. A surgical aid according to any preceding claim, comprising a pressure sensor (40), which is predisposed for detecting a pressure acting on the first element (10) and/or on the second element (20).

8. A surgical aid according to any preceding claim, comprising an angular measurement device arranged to measure an angle of inclination between the two bones of the joint, which angle of inclination is connected to the processing module (60).

9. A surgical aid according to claim 8, wherein the processing module (60) is arranged to detect the signals of the displacement sensor (30) and the angular measurement device and to trace a variation of the displacement along the first direction (X) as a function of the angle of inclination between the two bones of the joint.

10. A method for determining the resection of a first and/or second bone for implantation of a joint prosthesis, comprising the following steps:

- inserting the surgical aid according to any preceding claim between the first and second bone, so that the joint end of the first bone is in contact with the first element (10) and the joint end of the second bone is in contact with the second element (20);
- varying the force exerted by the actuator/motor (50) in each of the
various pre-determined angular positions of the joint, and detecting the displacement measured by the displacement sensor (30) by developing a force-displacement diagram which puts in correspondence a value of force applied by the actuator/motor (50) with a corresponding displacement value detected by the displacement sensor (30);

- in each of said various pre-determined angular positions of the joint, detecting and storing the displacement values measured by the displacement sensor (30) and force sensor, wherein the force-displacement diagram is changing from a non-linear to a substantially linear trend, or wherein a first change of slope in the force/displacement curve occurs;

- processing the displacement values stored according to a pre-determined algorithm, in order that an optimal displacement is obtained, which is measured along the first direction (X), at which value an isometric tension of the capsule-ligament structures is produced, namely a tension which substantially does not exceed the tension value corresponding to the changing of the force-elongation curve slope, wherein said determined displacement corresponds to the height of at least one prosthetic component.

11. A method according to claim 10, wherein, after that said optimal displacement and isometric tension have been determined, the following steps are provided:

- maintaining the force exerted by the actuator or motor (50) at a value corresponding to said isometric tension of the capsule-ligament structures;

- rotating the articular bones between two pre-determined angular positions;

- tracing a variation of the displacement along the first direction (X), as a function of the angle of inclination between the two bones of the joint.
12. A method for implantation of a joint prosthesis, comprising the following steps:
   – determining the resection of the first and/or second bone by means of the method according to any one of claims 10 to 12;
   – performing resection of the first and/or second bone;
   – implanting the prosthetic joint.

13. A method according to claims 11 and 12, comprising the following steps:
    selecting or realizing at least one prosthetic component exhibiting a joint surface structured according to said displacement variation along the first direction (X) as a function of the angle of inclination between the two bones of the joint;
    implanting the prosthetic component.

14. A method according to claims 12 or 13, wherein, after implantation of the prosthetic joint, the following steps are provided:
    – re-inserting the surgical aid between the first and second bone, so that the prosthesis portion associated with the first bone is in contact with the first element (10) and the prosthesis portion associated with the second bone is in contact with the second element (20);
    – performing the steps according to claims 10 or 11, thereby obtaining a new set of points which approximate a resection;
    – removing the prosthesis and performing a new resection of the first and/or second bone in accordance with the new set of points that approximate a resection, if the new set of points deviates from the previous set of points beyond a pre-set threshold.
Fig. 5

Fig. 6
**INTERNATIONAL SEARCH REPORT**

**PCT/IB2016/051534**

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61F2/46 A61B17/02

ADD.

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61F A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

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

**E** earlier application or patent but published on or after the international filing date

**L** document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

**O** document referring to an oral disclosure, use, exhibition or other means

**P** document published prior to the international filing date but later than the priority date claimed

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

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

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

**&** document member of the same patent family

Date of the actual completion of the international search

30 May 2016

Date of mailing of the international search report

08/06/2016

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Storer, John

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INTERNATIONAL SEARCH REPORT

Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10-14
   because they relate to subject matter not required to be searched by this Authority, namely:

2. [ ] Claims Nos.
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)
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