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(54) **Title:** MULTIFUNCTIONAL PATIENT - SPECIFIC GUIDES

(57) **Abstract:** The application provides patient-specific surgical guiding instruments, and methods for the manufacture thereof. The methods comprise the steps of i) obtaining volume information of an anatomical part of a patient; ii) providing a first surgical plan for performing a surgical operation on said anatomical part, and a second surgical plan for performing an alternative surgical operation on said anatomical part; and iii) designing a surgical guiding instrument based on the information obtained in steps i) and ii).

MULTIFUNCTIONAL PATIENT - SPECIFIC GUIDES

FIELD OF THE INVENTION

Patient-specific surgical guiding tools are provided which allow for different applications depending on the necessity determined during surgery, and to methods for designing and manufacturing such guiding tools.

BACKGROUND

In order to improve the accuracy of surgical procedures various custom made, patient-specific orthopaedic guides are available, which help the surgeon in accurately positioning place pins, guide bone cuts, and insert implants during orthopaedic procedures.

Patient-specific guides are available for surgical operations on various parts of the human or animal anatomy, for example the spine, hip, knee or radius. Specific examples of surgical guides include, but are not limited to patient-specific femoral and tibial cutting blocks, and distal radius drilling and cutting templates.

Typically, the patient-specific guides are made from a pre-operative plan formed from an MRI or CT scan of the patient and rely on the matching of a subcutaneous anatomic feature for correct positioning of the guide according to pre-operational planning. The patient-specific guides further have a custom design to transfer the pre-operative planning and are generally compatible with one standard set of instruments.

The planning of the surgical operation, and therefore the properties of the patient-specific guide, is typically based on the pre-operative pathological condition of the patient. However, situations might occur in the operating room where the surgeon needs to switch to another procedure than planned. For example a unicondylar knee replacement can be aborted intra-operatively and changed to a bicondylar knee replacement when the surgeon finds the cruciate ligaments or cartilage on the lateral plateau are severely damaged. This type of information cannot always be gathered based upon the used imaging technique. It can even occur that the ligaments are damaged during the procedure and therefore a switch to the bicondylar replacement is necessary after some resections already have been made. Alternatively, it may occur that the pre-operatively selected procedure is appropriate, but the selected parameters need to be adjusted. In spine surgery, for example sacropelvic fixation, screws are placed. It is critical to guide these screws in the

correct position in order not to hit critical body parts. However, the surgeon might want to select the appropriate screw diameter intra-operatively.

The patient-specific surgical guides currently available offer little or no flexibility to make changes intra-operatively. Therefore, the surgeon cannot change the pre-operatively determined parameters intra-operatively, or has to make freehanded adjustments of these parameters. Therefore, most or all of the benefit of the surgical guide, i.e. ensuring an optimal execution of the procedure, is lost. Alternatively, separate patient-specific guides may be provided for each possible scenario. However, this is expensive and significantly prolongs the duration of a surgical procedure.

Accordingly, there is a need for improved surgical guiding tools, for example for guiding the positioning of implants in joint surgery or for guiding osteotomies or other surgical operations. Moreover, there is a need for methods for the designing and manufacturing of such guiding tools.

SUMMARY OF THE INVENTION

The application provides patient-specific surgical guiding tools which allow for different applications depending on the necessity determined during surgery, and to methods for designing and manufacturing such guiding tools. More particularly the disclosure provides for combinations of surgical guiding tools which allow the surgeon to make the required intervention independent of the conditions encountered intra-operatively.

Disclosed herein are methods for designing a patient-specific surgical guiding instrument. These methods comprise:

i) obtaining volume information of an anatomical part of a patient;

ii) providing a first surgical plan for performing a surgical operation on said anatomical part, and a second surgical plan for performing an alternative surgical operation on said anatomical part;

iii) designing a surgical guiding instrument based on the information obtained in steps i) and ii), wherein said surgical guiding instrument comprises:

1) a support structure for positioning onto said anatomical part, comprising an anatomy engagement surface which anatomically matches at least a part of the surface of said anatomical part; and

2) at least one independent guiding element comprising a body which is provided with one or more guiding features corresponding to said second surgical plan;

wherein one or more guiding features corresponding to said first surgical plan are provided on said support structure or an a further independent element.

In particular embodiments of the methods described herein, the surgical guiding instrument comprises:

1a) a support structure for positioning onto said anatomical part, comprising

- an anatomy engagement surface which anatomically matches at least a part of the surface of said anatomical part; and
- one or more coupling features;

2a) first and second independent guiding elements provided as insertion elements, each comprising:

- a body which is provided with one or more guiding features; wherein said first insertion element is provided with one or more guiding features corresponding to said first surgical plan, and said second insertion element is provided with one or more guiding features corresponding to said second surgical plan; and
- a coupling feature which allows a removable coupling of said insertion elements to said support structure.

In further embodiments, the coupling features of said first insertion element differ in shape and/or size from the coupling features of said second insertion element, and wherein said support structure is provided with a dedicated coupling feature for each of said insertion elements.

In particular embodiments of the methods described herein, the surgical guiding instrument comprises:

1b) a support structure for positioning onto said anatomical part, comprising:

- an anatomy engagement surface which anatomically matches part of the surface of said anatomical part;
- one or more guiding features for guiding a surgical operation according to said first surgical plan; and

- a reference positioning feature;

2b) at least one independent guiding element comprising:

- one or more guiding features guiding a surgical operation according to said second surgical plan; and
- a reference positioning feature;

wherein said reference positioning feature of said support structure and said reference positioning feature of said independent guiding element are adapted to the same reference tool.

Further described herein is a kit comprising a patient-specific surgical guiding instrument, comprising:

1c) a support structure for positioning onto an anatomical part, comprising

- an anatomy engagement surface which anatomically matches at least a part of the surface of said anatomical part; and
- one or more coupling features;

2c) first and second independent guiding elements provided as insertion elements, each comprising:

- a body which is provided with one or more guiding features; wherein said insertion elements differ from each other in the number of guiding features and/or in the location, shape and/or size of at least one of said one or more guiding features;
- a coupling feature which allows a removable coupling of said insertion elements to one or more of said coupling features of said support structure.

Further described herein is a kit comprising a patient-specific surgical instrument for guiding an operation according to a first or second operational plan, wherein said patient-specific surgical instrument comprises:

1d) a support structure for positioning onto said anatomical part, comprising:

- an anatomy engagement surface which anatomically matches part of the surface of said anatomical part;
- one or more guiding features for guiding a surgical operation according to said first surgical plan; and

- a reference positioning feature;

2d) one or more independent guiding element comprising:

- one or more guiding features guiding a surgical operation according to said second surgical plan; and
- a reference positioning feature;

wherein said reference positioning feature of said support structure and said reference positioning feature of said independent guiding element are adapted to a common reference tool.

Disclosed herein are patient-specific surgical guiding instrument which comprise:

- a support structure for positioning onto an anatomical part of a patient, comprising an anatomy engagement surface which anatomically matches part of the surface of said anatomical part and one or more coupling features;
- two or more independent insertion elements, each comprising a body which is provided with one or more guiding features and a coupling feature which allows a removable coupling of said insertion elements to said support structure, via the one or more coupling features of said support structure;

wherein said insertion elements differ from each other in the number of guiding features and/or in the location, shape and/or size of at least one of said one or more guiding features.

In particular embodiments, said one or more guiding features are selected from the group consisting of a cutting slot, a drill guide, a pin hole and a screw hole.

In certain embodiments, said support structure is provided with two or more coupling features and each of said insertion elements comprises a coupling feature which allows a removable coupling of said insertion elements to one of said coupling features of said support structure. In particular embodiments, said coupling features of said insertion elements differ in shape and/or size, and wherein said support structure is provided with a dedicated coupling feature for each of said insertion elements. In certain embodiments, said coupling features comprise elements or combinations of elements selected from the group consisting of interlocking features, a snap-fit system, a dovetail system, a pinned system and a magnetic system. In particular embodiments, the coupling feature(s) of the independent insertion elements form(s) an extension of the body of the element. Typically

the body of the element extends over part of an anatomical part of said patient close to or adjacent to the part onto which the support structure is matched. The body of the insertion element may optionally also comprise a patient specific surface.

In particular embodiments, at least one of said one or more coupling features is patient-specific and/or located on a patient-specific position on said support structure.

In particular embodiments, said support structure is provided with at least one guiding feature selected from the group consisting of a cutting slot, a drill guide, a pin hole and a screw hole.

The anatomical part is preferably an animal or human bone, with or without cartilage or other soft tissues. In certain embodiments, the anatomical part is a femur, tibia or pelvic bone.

In particular embodiments, the surgical guiding instruments envisaged herein are manufactured via additive manufacturing, more particularly each of the elements is manufactured as a one-piece element.

The present application further provides a method for performing a surgical operation on an anatomical part, said method comprising:

a) obtaining volume information of said anatomical part;
b) selecting one or more pre-operative plans for performing said surgical operation;
c) designing and manufacturing a surgical guiding instrument as described hereabove, based on the information obtained in steps a) and b);
d) positioning said support structure on said anatomical part;
e) selecting one of said insertion elements, and coupling said insertion element to said support structure;
f) performing said surgical operation guided by said one or more guiding features of said insertion element.

Further disclosed herein is a method for manufacturing the patient-specific surgical guiding instrument as described hereabove, said method comprising:

a) obtaining volume information of said anatomical part;
b) selecting one or more pre-operative plans for performing said surgical operation;

c) designing and manufacturing a surgical guiding instrument as described hereabove, based on the information obtained in steps a) and b).

Further disclosed herein is a patient-specific surgical guiding instrument which comprises:

- a support structure for positioning onto an anatomical part of a patient, comprising an anatomy engagement surface which anatomically matches part of the surface of said anatomical part and one or more guiding features and further comprising a reference positioning feature;
- an independent guiding element, comprising one or more guiding features and a reference positioning feature;

wherein said reference positioning feature of said support structure and said reference positioning feature of said independent guiding element are adapted to the same reference tool.

In particular embodiments, said reference tool is a pin and said reference positioning feature on said support structure and said independent guiding instrument is a hole or slot adapted to the size of said pin.

In certain embodiments, said one or more guiding features are selected from the group consisting of a cutting slot, a drill guide, a pin hole and a screw hole.

The anatomical part is preferably an animal or human bone, with or without cartilage or other soft tissues. In certain embodiments, said anatomical part is a femur or tibia.

In particular embodiments, said support structure comprises at least four guiding features selected from the group consisting of a cutting slot, a drill guide, a pin hole and a screw hole.

In certain embodiments, at least two guiding features of said support structure are provided with a tapered hole.

In particular embodiments, the surgical guiding instrument envisaged herein are manufactured via additive manufacturing.

Further disclosed herein is a method for manufacturing the patient-specific surgical guiding instrument as described hereabove, comprising:

A) obtaining volume information of anatomical parts in the knee region of a patient;

B) making pre-operative plans for performing a total knee replacement and for performing a patella femoral replacement;

C) designing a surgical guiding instrument as described hereabove, based on the information obtained in steps A) and B);

D) manufacturing said surgical guiding instrument.

The present application further provides a method for performing a total knee replacement or a patella femoral replacement, comprising the steps of:

A) obtaining volume information of anatomical parts in the knee region of a patient;

B) making pre-operative plans for performing a total knee replacement and for performing a patella femoral replacement;

C) designing a surgical guiding instrument as described hereabove, based on the information obtained in steps A) and B);

D) positioning said support structure on said anatomical part;

E) performing a total knee replacement guided by said support structure, or

E') using said support structure for positioning of said guiding element, and performing a patella femoral replacement guided by said guiding element.

The present application further provides a patient-specific surgical guiding instrument comprising:

- a support structure provided with:
  - an anatomy engagement surface which anatomically matches part of the surface of an anatomical part of a patient;
  - a rail with a u-shaped transversal section, wherein the wall of said rail is provided with two or more holes, and wherein the outer side of said rail is provided with locking features;
- at least one guiding element comprising a first portion connected to a threaded cylindrical second portion, wherein said first portion has a circular section along the direction perpendicular to the longitudinal axis of said second portion, and further has a shape fitting said rail.

In particular embodiments, the surgical guiding instrument envisaged herein further comprises a fixation element provided with

- a threaded cylindrical hole matching said threaded cylindrical second portion of said guiding element; and
- locking features matching said locking features of said rail.

In particular embodiments, said locking features provided on the outer side of said rail comprise hook-shaped extensions on the wall of said rail.

In certain embodiments, said guiding element is provided with a hole along its longitudinal axis.

In particular embodiments, said fixation element is further provided with one or more guiding features selected from the group consisting of a cutting slot, a drill guide, a pin hole and a screw hole. In certain embodiments, said fixation element is further provided with a cutting slot.

In particular embodiments, said first part of said guiding element has a substantially spherical shape. In certain embodiments, said guiding element is a drill guide.

In particular embodiments, the position of said holes provided onto said rail is patient-specific.

In certain embodiments, said rail follows a three dimensional path. More particularly, in certain embodiments, said rail is curved in three dimensions.

The anatomical part is preferably an animal or human bone, with or without cartilage or other soft tissues. In particular embodiments, said anatomical part is a femur or tibia.

In particular embodiments, said surgical guiding instrument is able to guide drilling in two or more different directions and/or on different locations of said anatomical part.

In certain embodiments, the surgical guiding instrument, envisaged herein i.e. each of the elements thereof, is manufactured via additive manufacturing.

The present application further provides a guiding element as described hereabove, for use in a surgical guiding instrument as described hereabove.

The present application further provides a locking element as described hereabove, for use in a surgical guiding instrument as described hereabove.

The present application also provides a method for guiding drilling in two or more different locations of an anatomical part, comprising the steps of:

(i) obtaining volume information of said anatomical part;

(ii) selecting one or more positions directions for drilling;

(iii) designing and manufacturing a surgical guiding instrument according as described hereabove, based on the information obtained in steps (i) and (ii);

(iv) positioning said support structure on said anatomical part;

(v) moving said guiding element to a first hole provided on a first location of said rail, and optionally fixing said guiding element using said fixation element;

(vi) drilling a hole in said anatomical part on said first location;

(vii) moving said guiding element to a second hole provided on a second location of said rail, and fixing said guiding element using said fixation element;

(viii) drilling a hole in said anatomical part on said second location.

The present application further describes a method for manufacturing the patient-specific surgical guiding instrument as described hereabove, said method comprising:

(i) obtaining volume information of said anatomical part;

(ii) selecting one or more positions directions for drilling;

(iii) designing and manufacturing a surgical guiding instrument as described hereabove, based on the information obtained in steps (i) and (ii).

In the methods and instruments described herein, the patient may be an animal or human patient. In particular embodiments, the patient is a human patient.

According to particular embodiments, the surgical guides designed by the methods described herein have the advantage that the choice between two or more surgical procedures no longer needs to be made pre-operatively, while still ensuring an accurate guidance for each of said two or more surgical procedures. This is important because the information obtained pre-operatively, e.g. via CT or MRI scans, is often insufficient to predict which procedure will give the best results. The guiding instruments designed using the methods described herein solve this problem by allowing the surgeon to decide which procedure to follow intra-operatively, when a maximal amount of information is available to the surgeon. Furthermore, these surgical guides may further provide to the surgeon the flexibility to change certain parameters intra-operatively in a certain range based on pre-operative planning.

BRIEF DESCRIPTION OF THE DRAWINGS

The following description of the figures of specific embodiments of the methods and surgical instruments described herein is merely exemplary in nature and is not intended to limit the present teachings, their application or uses. Throughout the drawings, corresponding reference numerals indicate like or corresponding parts and features.

Figure 1 Surgical guiding instrument (1) according to a particular embodiment of the instruments described herein, positioned on an anatomical part (6). The surgical instrument comprises a support structure (2) which can be coupled to a first insertion element (4) (A) and to a second insertion element (4') (B).

Figure 2 A: Surgical guiding instrument (1) according to a particular embodiment of the instruments described herein, comprising a support structure (2) and an insertion element (5). B: Support structure (2) of a surgical guiding instrument according to a particular embodiment of the concepts described herein.

Figure 3 Surgical guiding instrument (7) according to a particular embodiment of the instruments described herein, comprising a support structure (8) and an independent guiding element (11).

Figure 4 A : Surgical guiding instrument (12) according to a particular embodiment of the instruments described herein, comprising a support structure (13), a guiding element (17) and a fixation element (21). B: Side view of a guiding element (17) and fixation element (21) according to a particular embodiment of the guides envisaged herein. C: Section view of a guiding element (17) and fixation element (21), mounted on the rail (14) of a support structure according to a particular embodiment envisaged herein.

DETAILED DESCRIPTION

The concepts are described herein with respect to particular embodiments but these concepts are not limited thereto but only by the claims. Any reference signs in the claims shall not be construed as limiting the scope thereof.

As used herein, the singular forms "a", "an", and "the" include both singular and plural referents unless the context clearly dictates otherwise.

The terms "comprising", "comprises" and "comprised of" as used herein are synonymous with "including", "includes" or "containing", "contains", and are inclusive or open-ended and do not exclude additional, non-recited members, elements or method steps. The terms

"comprising", "comprises" and "comprised of when referring to recited members, elements or method steps also include embodiments which "consist of said recited members, elements or method steps.

Furthermore, the terms first, second, third and the like in the description and in the claims, are used for distinguishing between similar elements and not necessarily for describing a sequential or chronological order, unless specified. It is to be understood that the terms so used are interchangeable under appropriate circumstances and that the embodiments described herein are capable of operation in other sequences than described or illustrated herein.

The term "about" as used herein when referring to a measurable value such as a parameter, an amount, a temporal duration, and the like, is meant to encompass variations of +/-10% or less, preferably *+1-5%* or less, more preferably +/-1% or less, and still more preferably +/-0.1% or less of and from the specified value, insofar such variations are appropriate to perform as envisaged herein. It is to be understood that the value to which the modifier "about" refers is itself also specifically, and preferably, disclosed.

The recitation of numerical ranges by endpoints includes all numbers and fractions subsumed within the respective ranges, as well as the recited endpoints.

All documents cited in the present specification are hereby incorporated by reference in their entirety.

Unless otherwise defined, all terms used in disclosing the concepts described herein, including technical and scientific terms, have the meaning as commonly understood by one of ordinary skill in the art to which these findings belongs. By means of further guidance, definitions for the terms used in the description are included to better appreciate the teaching of the present application. The terms or definitions used herein are provided solely to aid in the understanding of the concepts described herein.

Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment envisaged herein. Thus, appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment, but may. Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to a person skilled in the art from this disclosure, in one or more embodiments. Furthermore, while some embodiments described herein

include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the concepts envisaged herein, and form different embodiments, as would be understood by those in the art. For example, in the following claims, any of the claimed embodiments can be used in any combination.

The present application provides a method for designing patient-specific surgical guiding tools which allow for different applications depending on the necessity determined during surgery. More particularly the present application provides for combinations of surgical guiding tools which allow the surgeon to make the required intervention independent of the conditions encountered intra-operatively.

The surgical guiding instruments designed using the methods described herein can be used for guiding surgical procedures on an anatomical part of a human or animal patient.

Examples of surgical operations which may be guided by the surgical instruments described herein include cutting, drilling, screwing, reshaping, reaming, and implant positioning. In preferred embodiments, the anatomical part is a bone, with or without cartilage or other soft tissues. In further embodiments, the anatomical part comprises a femur, a tibia, or a pelvic bone.

The methods for designing a patient-specific surgical guiding instrument described herein comprise the following steps:

i) obtaining volume information of an anatomical part of a patient;

ii) providing a first surgical plan for performing a surgical operation on said anatomical part, and a second surgical plan for performing an alternative surgical operation on said anatomical part;

iii) designing a surgical guiding instrument based on the information obtained in steps i) and ii).

These steps will be explained in more detail herein below.

<u>i) Obtaining volume information of an anatomical part</u>

In a first step of the methods for designing surgical instruments as described herein, volume information is obtained of an anatomical part on which a surgical operation is envisaged. It is not necessary that volume information of the complete anatomical part is

obtained. Indeed, volume information related to a specific region of interest relevant to the envisaged surgical procedures can be sufficient.

The step of obtaining volume information of the anatomical part typically comprises obtaining digital patient-specific image information which can be done by any suitable means known in the art, such as for example a computer tomography (CT) scanner, a magnetic resonance imaging (MRI) scanner, an ultrasound scanner, or a combination of Roentgenograms. A summary of medical imaging has been described in "Fundamentals of Medical imaging", by P. Suetens, Cambridge University Press, 2002. In particular embodiments, the collected data is used to construct a digital, three dimensional model of the anatomical part.

ii) Providing a first and a second surgical plan

In a further step of the methods described herein, a first surgical plan for performing a surgical operation on the anatomical part is provided. For example, this may be a surgical plan which, based on the information available prior to surgery, is likely to be the most beneficial to the patient. The plan is typically based at least partially on the volume information of the anatomical part, as described above.

However, often not all parameters relevant to the surgery are available during pre-operational planning. As a result, it may turn out during surgery that the first surgical plan will not provide the best results, or cannot be performed at all.

Therefore, in the methods described herein, also a second surgical plan is provided, for performing an alternative surgical operation on said anatomical part. The second surgical plan can provide a reliable back-up for the surgeon, such that the surgeon can intra-operatively decide to follow the second surgical plan in case it is not desirable or possible to perform the operation according to the first surgical plan.

In particular embodiments also a third surgical plan may be provided, for performing further alternative surgical operation on the anatomical part. In certain embodiments, four, five, six, seven, eight, nine, ten or more surgical plan may be provided, each plan corresponding to an alternative surgical operation on the anatomical part.

For example, if the anatomical part is a knee bone (e.g. a femur or tibia), the surgical operation (first surgical plan) and alternative surgical operation (second surgical plan), and optionally a further alternative surgical operation (third surgical plan) may be selected from

the list consisting of bicruciate retaining arthroplasty, total knee arthroplasty, and unicondylar arthroplasty.

iii) Design of the surgical guiding instrument

In a further step of the methods described herein, a surgical guiding instrument is designed. Typically, the instrument is designed after the surgeon has approved the first and second surgical plans, and optionally further surgical plans, as described above. The instrument is designed based on the volume information obtained in step i) and the surgical plans provided in step ii), as described above.

In particular embodiments, the instrument comprises:

1) a support structure for positioning onto said anatomical part, comprising an anatomy engagement surface which anatomically matches at least a part of the surface of said anatomical part;
2) at least one independent element comprising a body which is provided with one or more guiding features corresponding to the second surgical plan;

wherein one or more guiding features corresponding to the first surgical plan are provided on said support structure or a further independent element i.e. other than said independent element comprising one or more guiding features corresponding to the second surgical plan. Thus, in particular embodiments, the instrument further comprises a further independent element comprising a body which is provided with one or more guiding features corresponding to the first surgical plan. Additionally or alternatively, the support structure may be provided with one or more guiding features corresponding to the first surgical plan.

The guiding feature(s) provided on the independent element(s) and optionally on the support structure typically provide an opening in the independent element(s) and/or support structure. The shape of such opening is typically dependent on the nature of the surgical operation to be guided. For example, the opening may be a cylindrical hole, a threaded hole, a planar slit, etc. In particular embodiments, each guiding feature is selected from the list consisting of a cutting slot, a drill guide, a pin hole, and a screw hole. The design of surgical instruments according to further embodiments of the methods described herein are described in more detail herein below (iiia) and iiib)).

iiia) Surgical instruments comprising a support structure and two or more insertion elements

In particular embodiments, the surgical guiding instrument designed via the present methods comprises:

1a) a support structure for positioning onto the anatomical part of the patient; and

2a) first and second independent elements which are insertion elements.

The features of the support structure and the insertion elements will be discussed in more detail herein below.

The support structure of the surgical guiding instrument is designed for positioning on the anatomical part for which the surgical plans were provided in step ii) as described above. To achieve this, the support structure comprises an anatomy engagement surface which at least partially matches the surface of the anatomical part. The anatomy engagement surface ensures that the patient-specific surgical instrument can be accurately positioned on an anatomical part according to pre-operational planning. The engagement surface may be located anywhere on the alignment element. In particular embodiments, the support structure may comprise at least two engagement surfaces.

In certain embodiments, the support structure further comprises one or more guiding features for guiding a surgical operation, preferably selected from the list consisting of a cutting slot, a drill guide, a pin hole, and a screw hole.

The surgical guiding instrument further comprises first and second independent elements which are referred to herein as "insertion elements", as they can be inserted onto/into the support structure. Thus, the support element, the first insertion element, and the second element form three separate pieces, but which can be interconnected by coupling elements. Each of the insertion elements comprises one or more guiding features for guiding a surgical operation. More particularly, the first insertion element is provided with one or more guiding features corresponding to the first surgical plan, and the second insertion element is provided with one or more guiding features corresponding to said second surgical plan. Thus, the insertion elements may differ from each other in the number of guiding features and/or in the location, shape and/or size of at least one of said

one or more guiding features, depending on the nature of the surgical plan corresponding to each insertion element.

In particular embodiments, the insertion elements are patient-specific, i.e. designed for a particular anatomical part of a certain patient. In other embodiments, the insertion elements are standard elements. The design of the patient-specific guiding instruments according to the methods described herein may then involve selecting standard insertion elements from a database.

The nature of the guiding features depends on the envisaged surgical operation(s). In particular embodiments, the one or more guiding features are selected from the list consisting of a cutting slot, a drill guide, a pin hole, and a screw hole.

In particular embodiments, the surgical guiding instrument further comprises a third independent insertion element, which is provided with one or more guiding features corresponding to a third surgical plan, as described above. In particular embodiments, the surgical guiding instrument comprises a dedicated insertion element for each surgical plan provided in step ii).

The support structure and the insertion elements each comprise one or more coupling features, which allow a removable connection between the support structure and the insertion elements. As the insertion elements correspond to alternative surgical operations, it is not required that the insertion elements can both be connected to the support structure at the same time. In preferred embodiments, the coupling features ensure that the relative position of the support structure and an insertion connected thereto is constrained according to the pre-operationally planning. This ensures that the insertion elements can be accurately positioned relative to the anatomical part according to pre-operational planning, via the support structure (which is accurately positioned on the anatomical part according to pre-operational planning via the anatomy engagement surface(s)). Additionally or alternatively, one or more of the insertion elements may comprise an anatomy engagement surface which at least partially matches the surface of the anatomical part. This allows for a further verification whether the relative position of the insertion element and the anatomical part is according to pre-operational planning.

Different types of coupling features are envisaged in the context of the guides described herein. In particular embodiments, the coupling features comprise elements or

combinations of elements selected from the group consisting of interlocking features, a snap-fit system, a dovetail system, a pinned system and a magnetic system.

In certain embodiments, the support structure is provided with two or more coupling features, and each insertion element comprises a coupling feature which allows a removable coupling of the insertion elements to one of said coupling features of the support structure. In particular embodiments, the coupling features of said insertion elements differ in shape and/or size, wherein the support structure is provided with a dedicated coupling feature for each of the insertion elements.

In particular embodiments, the coupling feature(s) of at least one insertion element form(s) an extension of the body of the element. For example, the body of the element may extend over a part of the anatomical part close to or adjacent to the part onto which the support structure is matched.

In specific embodiments, at least one of the coupling features is patient-specific (e.g. a patient-specific shape) and/or located on a patient-specific position on the support structure.

iiib) Surgical instruments comprising a support structure and two insertion elements

In particular embodiments, the surgical guiding instrument designed via the present methods comprises:

1b) a support structure for positioning onto the anatomical part, comprising:
- an anatomy engagement surface which anatomically matches part of the surface of the anatomical part;
- one or more guiding features for guiding a surgical operation according to the first surgical plan; and
- a reference positioning feature;

2b) an independent guiding element comprising:
- one or more guiding features guiding a surgical operation according to said second surgical plan; and
- a reference positioning feature;

wherein said reference positioning feature of said support structure and said reference positioning feature of said independent guiding element are adapted to the same reference tool. This implies that each of the positioning features can make use of the same reference tool to ensure positioning of the support structure and independent guiding element

respectively and/or that a reference tool of which the position is determined by the positioning feature present on the support structure can be used to guide the position of the independent guiding element.

The support structure according to this embodiment of the present methods comprises an anatomy engagement surface which at least partially matches the surface of the anatomical part, as described above. In particular embodiments, the support structure may comprise at least two engagement surfaces.

The support structure further comprises one or more guiding features for guiding a surgical operation according to the first surgical plan, preferably selected from the list consisting of a cutting slot, a drill guide, a pin hole, and a screw hole. Optionally, the support structure may further comprise one or more guiding features for guiding a surgical operation according to the second surgical plan. In particular embodiments, the support structure comprises at least four guiding features selected from the group consisting of a cutting slot, a drill guide, a pin hole, and a screw hole. In certain embodiments, at least two guiding features of the support structure are provided with a tapered hole.

The support structure further comprises at least one reference positioning feature. The reference positioning feature allows for the positioning of a reference tool, which can, if needed, be used for the correct positioning of the guiding element relative to the anatomical part according to the surgical planning (see further).

The independent guiding element comprises at least one guiding feature guiding a surgical operation according to the second surgical plan. Exemplary guiding features include a cutting slot, a drill guide, a pin hole, and a screw hole.

The guiding element further comprises at least one reference positioning feature, wherein the reference positioning feature of the support structure and the reference positioning feature of the guiding element are adapted to the same reference tool. This allows for the correct positioning of the guiding element relative to the anatomical part according to the surgical planning via the reference tool, even if the support structure has been removed from the anatomical part. This avoids the need of connecting the support structure and the guiding element via coupling features as described above, and can reduce the volume of the surgical guide during surgery.

In particular embodiments, the reference tool is a pin, and the reference positioning feature on the support structure and the reference positioning feature provided on the guiding element are adapted to the same reference tool. In certain embodiments, the reference tool may be a (laser) beam. The use of a beam may eliminate the need of inserting a reference tool into the anatomical part.

In particular embodiments, the reference positioning feature comprises a cylindrical hole. This allows the use of a pin or laser beam as reference tool. The diameter of the cylindrical hole can then be adapted to the diameter of the pin or laser beam.

In preferred embodiments, the guiding element is patient-specific.

If there more than two surgical plans were provided in step ii), the surgical instrument can comprise a dedicated independent guiding element for each of these surgical plans. Preferably, each of these guiding elements comprises a reference positioning feature adapted to the same reference tool.

iiic) Surgical instruments comprising an adjustable guiding feature.

In particular embodiments, the surgical guiding instrument comprises:

1) a support structure provided with:
   - an anatomy engagement surface which anatomically matches part of the surface of an anatomical part of a patient;
   - a rail with a u-shaped transversal section, wherein the wall of said rail is provided with two or more holes, and wherein the outer side of said rail is provided with locking features;
2) at least one guiding element comprising a first portion connected to a threaded cylindrical second portion, wherein said first portion has a circular section along the direction perpendicular to the longitudinal axis of said second portion, and further has a shape fitting said rail.

The support structure according to these embodiments of the present methods comprises an anatomy engagement surface which at least partially matches the surface of the anatomical part, as described above. In particular embodiments, the support structure may comprise at least two engagement surfaces.

The support structure further comprises a rail with a u-shaped transversal section. This allows accommodating one or more movable guiding elements. The wall of the rail is

provided with two or more holes. The positions of the holes can be in accordance with the first and second surgical plans as described above, and allow the positioning of the guiding element according to these plans. More particularly, the position of the holes provided onto the rail can be patient-specific. Also the shape of the rail typically depends on the surgical planning. In certain embodiments, the rail follows a three dimensional path. More particularly, in certain embodiments, the rail is curved in three dimensions.

The outer side of the rail is provided with locking features, which ensure that the position of the guiding element relative to the rail (and therefore also relative to the anatomical part) can be locked. In particular embodiments, the locking features provided on the outer side of said rail comprise hook-shaped extensions on the wall of the rail.

The guiding element comprising a first portion, which is connected to a threaded cylindrical second portion. The first portion has a shape fitting the rail, such that the rail can accommodate the guiding element. Furthermore, the first portion has a circular section along the direction perpendicular to the longitudinal axis of said second portion.
This allows for rotation of the guiding element along this longitudinal axis while accommodated in the rail. Such rotation may, for example, be required for locking the position of guiding element. In further embodiments, the first portion has a substantially spherical shape.
The second portion has a threaded cylindrical shape, such that other elements, such as a fixation element, can be screwed on the guiding element.
In certain embodiments, the guiding element is provided with a hole along its longitudinal axis. This can be used for guiding a drill or a pin, or can be used for connecting a surgical guide to the guiding element.

In particular embodiments, the surgical guiding instrument according to these embodiments further comprises a fixation element provided with:

- a threaded cylindrical hole matching the threaded cylindrical second portion of the guiding element; and
- locking features matching the locking features of the rail.

In particular embodiments, the fixation element is further provided with one or more guiding features selected from the group consisting of a cutting slot, a drill guide, a pin hole

and a screw hole. In certain embodiments, the guiding feature comprises a drill guide. In certain embodiments, the fixation element is further provided with a cutting slot.

In particular embodiments, the surgical guiding instrument is able to guide drilling in two or more different directions and/or on different locations of the anatomical part.

iv) Manufacture of the surgical guiding instrument

In particular embodiments, the methods described herein further comprise manufacturing the surgical guiding instruments, or at least a part thereof, according to the obtained design. In a particular embodiment, Additive Manufacturing (AM) techniques are used for manufacturing the surgical guiding instruments described herein, or parts thereof. In particular embodiments, at least the support structure is manufactured via AM.

AM techniques are particularly useful to manufacture patient-specific contact surfaces, or to produce the surgical guiding tools in one piece. As an example, the manufacturing of medical-image-based patient-specific surgical instruments via AM is described in US Pat. No. 5.768.134 (Swaelens et al).

AM can be defined as a group of techniques used to fabricate a tangible model of an object typically using three-dimensional (3-D) computer aided design (CAD) data of the object. Currently, a multitude of Additive Manufacturing techniques is available, including stereolithography, Selective Laser Sintering, Fused Deposition Modeling, foil-based techniques, etc.

Selective laser sintering uses a high power laser or another focused heat source to sinter or weld small particles of plastic, metal, or ceramic powders into a mass representing the 3-dimensional object to be formed.

Fused deposition modeling and related techniques make use of a temporary transition from a solid material to a liquid state, usually due to heating. The material is driven through an extrusion nozzle in a controlled way and deposited in the required place as described among others in U.S. Pat. No. 5.141 .680.

Foil-based techniques fix coats to one another by means of gluing or photo polymerization or other techniques and cut the object from these coats or polymerize the object. Such a technique is described in U.S. Pat. No. 5.192.539.

Typically AM techniques start from a digital representation of the 3-D object to be formed. Generally, the digital representation is sliced into a series of cross-sectional layers which

can be overlaid to form the object as a whole. The AM apparatus uses this data for building the object on a layer-by-layer basis. The cross-sectional data representing the layer data of the 3-D object may be generated using a computer system and computer aided design and manufacturing (CAD/CAM) software.

The surgical guiding tools envisaged herein may be manufactured in different materials. Typically, only materials that are biocompatible (e.g. USP class VI compatible) with the animal or human body are taken into account. Preferably the surgical guiding tool is formed from a heat-tolerable material allowing it to tolerate high-temperature sterilization. In the case selective laser sintering is used as an AM technique, the surgical template may be fabricated from a polyamide such as PA 2200 as supplied by EOS, Munich, Germany or any other material known by those skilled in the art may also be used.

Further provided herein is a kit comprising a surgical instrument obtained or obtainable by the methods described herein.

In certain embodiments, the kit comprises a patient-specific surgical guiding instrument comprising:

1c) a support structure for positioning onto an anatomical part, comprising
- an anatomy engagement surface which anatomically matches at least a part of the surface of said anatomical part; and
- one or more coupling features;

2c) first and second independent insertion elements, each comprising:
- a body which is provided with one or more guiding features; wherein said insertion elements differ from each other in the number of guiding features and/or in the location, shape and/or size of at least one of said one or more guiding features;
- a coupling feature which allows a removable coupling of said insertion elements to said support structure.

In particular embodiments, the kit comprises a patient-specific surgical instrument comprising:

1d) a support structure for positioning onto an anatomical part, comprising:
- an anatomy engagement surface which anatomically matches part of the surface of said anatomical part;

- one or more guiding features for guiding a surgical operation according to said first surgical plan; and
- a reference positioning feature;

2d) an independent guiding element comprising:

- one or more guiding features guiding a surgical operation according to said second surgical plan; and
- a reference positioning feature;

wherein said reference positioning feature of said support structure and said reference positioning feature of said independent guiding element are adapted to the reference tool. In further embodiments, the reference tool is a pin.

The methods and instruments described hereabove will now be illustrated by the following, non-limiting illustrations of particular embodiments.

EXAMPLES

Example 1: surgical guiding instrument for knee arthroplasty.

The present example relates to knee replacements. According to a particular embodiment of the guides envisaged herein, the surgeon selects a patient for knee replacement and takes a scan of the patient's anatomy, for example using magnetic resonance imaging (MRI) or computed tomography (CT). Based on this scan a three dimensional model of the patient's anatomy is made. Then, pre-operative plannings for two or more knee procedures (for example bicruciate retaining arthroplasty, total knee or partial, i.e. unicondylar, knee arthroplasty) are reviewed. The surgeon approves the pre-operative plans but does not need to select a procedure. A patient-specific surgical guiding instrument (1) is then developed based on the approved plans of the surgeon. The device consists of a support structure (2) and two independent insertion elements (4, 4'); each insertion element transferring a different type of knee replacement according to each pre-operatively determined plan, as shown in Figure 1 A and B. Figure 1 A shows a support structure (2), comprising guiding features, i.e. a proximal pin positioning for total knee replacement and cutting slots (5'') for bicruciate retaining knee replacement. The support structure further comprises a female coupling feature (3), which mates with the coupling feature (3') of an insertion element (4). The coupling feature (3) provided on the support structure may also

mate with the coupling features of other insertion elements. Indeed, Figure 1 B shows the same support structure (2), coupled to another insertion element (4') via the same coupling feature (3).

Alternatively, the support structures could be provided with two female coupling features, wherein each coupling feature on the support structure matches with the coupling feature of a different insert for a different surgical procedure. A further option is to provide one female coupling feature on the support structure, wherein this coupling feature has a complex shape as to provide a unique lock fit for differently shaped male parts on the insertion elements.

Each insertion element (4, 4') comprises guiding features, more particularly pin holes (5, 5'), which allow the mounting of cut blocks for each procedure. The resection level and flexion/extension angle are preoperatively planned for each procedure and are contained in the insertion element.

Due to the different insertion elements, the guiding instrument allows intra-operative switching between different pre-operatively planned surgical procedures.

Example 2: surgical guiding instrument for sacro-iliac fixation procedures.

The present example relates particularly to sacro-iliac fixation procedures. In a particular embodiment of the guides envisaged herein, the surgeon selects a patient for a specific procedure and performs an MRI or CT. Based on this image a three dimensional model of the patient's anatomy is made. A pre-operative plan is reviewed by the surgeon and the appropriate planning parameters are selected.

Figure 2 A shows a surgical guiding instrument (1) according to a particular embodiment, which can be of use in sacro-iliac fixation procedures. In sacro-iliac fixation, the pin diameter is crucial in order to establish stable fixation: the chosen pin diameter should allow capture the cortical bone without penetrating it. Figure 2 A shows that the surgical guiding instrument (1) comprises a support structure (2) and an independent insertion element (4). The insertion element (4) is provided with guiding features (5) which can be used to guide a pin. Figure 2 B shows the support structure without insertion element. The support structure (2) is provided with coupling features (3), in casu holes, which allow mounting of an insertion element (4). Different insertion elements may be provided, each

offering the same pre-operatively planned pin location, but allowing different pin diameters to be inserted.

Thus, according to particular embodiments, methods and a patient-specific guiding instrument are provided which allow flexibility to change certain parameters intra-operatively in a certain range.

Example 3: surgical guiding instrument for total knee arthroplasty or patella femoral replacement procedures.

In a particular embodiment of the guides provided herein, the surgeon selects a patient for which two specific procedures (A and B) might be applicable, although intra-operative information is needed to decide which procedure is to be followed. The surgeon performs an image acquisition of CT or MRI data of the patient's anatomy. Based on this data a three dimensional model of the patient's anatomy is made. A pre-operative plan of both procedures (A and B) is reviewed by the surgeon and the appropriate planning parameters are selected.

A patient-specific guiding instrument is manufactured according to the approved plans. In some cases, one of the procedures (B) is as such that the anatomy only provides a limited engagement surface area. A referencing pin on the patient specific guiding instrument for procedure A is needed to correctly position the patient specific guiding instrument of procedure B. For example, this situation can occur when a patient might be selected for a patella femoral replacement (PFR) in the best case and otherwise needs total knee replacement (TKA).

Figure 3 shows a surgical guiding instrument (7) according to a particular embodiment of the guides referred to herein, which is particularly useful for use in total knee arthroplasty or patella femoral replacement procedures. The guiding instrument (7) comprises a support structure (8) and an independent guiding element (11). The support structure (8) is provided with three distal pinholes (9', 10), of which one (10) is not used if intra-operatively the surgeon decides to have TKA surgery. In the other case, when PFR is selected by the surgeon, the guiding element (11) is used. The guiding element (11) does not comprise an engagement surface which is sufficient for accurate positioning of the guiding element, but requires a pin reference set by the support structure. The pin reference is positioned using pinhole (10). The guiding element (11) is provided with two guiding features (9") and one reference positioning feature (10').

Thus, according to particular embodiments, guiding instruments and methods are provided which allow intra-operative switching of surgical procedure.

Example 4: surgical fixture with multiple contact elements.

The present example illustrates particular embodiments of methods and surgical guiding instruments as envisaged herein. The method and guide allow switching between pre-operatively planned surgical procedures intra-operatively by means of patient specific instruments. The present example relates to knee replacements, more in particular total and partial knee replacements. However, the concepts described herein are not limited thereto, and may be used for surgical procedure involving multiple drilling angles.

According to particular embodiments of the guides and methods envisaged herein, the surgeon selects a patient for knee replacement and takes a scan of the patient's anatomy (for example MRI or CT). Based on this scan a three dimensional model of the patient's anatomy is made. Pre-operative plannings for one or more knee procedures (for example total knee or partial, i.e. unicondylar knee arthroplasty) are reviewed. The surgeon approves the pre-operative plans but does not need to select a procedure. A patient specific guiding instrument is manufactured based on the approved plans of the surgeon. Such a guiding instrument (12) is shown in Figure 4 A, and comprises a support structure (13) provided with at least one surface mating a patient's bone at the inner surface. The support structure (13) is further provided with a rail (14) between two or more guidance positions. The rail (14) follows a path which is curved in three dimensions.

The surgical guiding instrument (12) further comprises a guiding element (17) which can be moved along the rail of the support structure. The guiding element (17) comprises a spherical body (19) with a cylindrical threaded projection (20), as shown in Figure 4 B and C. The surgical guiding instrument (12) further comprises a fixation element (21) which is provided with a threaded cylindrical hole, such that it can be screwed onto the guiding element (17). The fixation element (21) is further provided with locking features (23), more particularly protruding arms which interlock with the locking features (16) provided on the rail (14) into a certain desired position and orientation along the rail. Once the desired position of the guiding element (17) is obtained, the guiding element (17) can be used for

guiding a drill bit, or another surgical tool. Optionally, the fixation element (21) may be provided with a guiding feature, for example a cutting slot for guiding a saw blade.

CLAIMS

1. A method for designing a patient-specific surgical guiding instrument, said method comprising:

   i) obtaining volume information of an anatomical part of a patient;

   ii) providing a first surgical plan for performing a surgical operation on said anatomical part, and a second surgical plan for performing an alternative surgical operation on said anatomical part;

   iii) designing a surgical guiding instrument based on the information obtained in steps i) and ii), wherein said surgical guiding instrument comprises:

      1) a support structure for positioning onto said anatomical part, comprising an anatomy engagement surface which anatomically matches at least a part of the surface of said anatomical part; and

      2) at least one independent guiding element comprising a body which is provided with one or more guiding features corresponding to said second surgical plan;

   wherein one or more guiding features corresponding to said first surgical plan are provided on said support structure or an a further independent element.

2. The method according to claim 1, wherein said surgical guiding instrument comprises:

   1a) a support structure for positioning onto said anatomical part, comprising

      - an anatomy engagement surface which anatomically matches at least a part of the surface of said anatomical part; and
      - one or more coupling features;

   2a) first and second independent guiding elements provided as insertion elements, each comprising:

      - a body which is provided with one or more guiding features; wherein said first insertion element is provided with one or more guiding features corresponding to said first surgical plan, and said second insertion element is provided with one or more guiding features corresponding to said second surgical plan; and

- a coupling feature which allows a removable coupling of said insertion elements to said support structure.

3. The method according to claim 2, wherein said coupling features comprise elements or combinations of elements selected from the group consisting of interlocking features, a snap-fit system, a dovetail system, a pinned system and a magnetic system.

4. The method according to claim 2 or 3, wherein the coupling features of said first insertion element differ in shape and/or size from the coupling features of said second insertion element, and wherein said support structure is provided with a dedicated coupling feature for each of said insertion elements.

5. The method according to any one of claims 1 to 4, wherein said insertion elements are patient-specific.

6. The method according to any one of claims 1 to 4, wherein said insertion elements are standard elements.

7. The method according to claim 1, wherein said surgical guiding instrument comprises:

1b) a support structure for positioning onto said anatomical part, comprising:

- an anatomy engagement surface which anatomically matches part of the surface of said anatomical part;
- one or more guiding features for guiding a surgical operation according to said first surgical plan; and
- a reference positioning feature;

2b) at least one independent guiding element comprising:

- one or more guiding features guiding a surgical operation according to said second surgical plan; and
- a reference positioning feature;

wherein said reference positioning feature of said support structure and said reference positioning feature of said independent guiding element are adapted to the same reference tool.

8. The method according to any one of claims 1 to 7, wherein said support structure is provided with at least one guiding feature selected from the group consisting of a cutting slot, a drill guide, a pin hole, and a screw hole.

9. The method according to any one of claims 1 to 8, further comprising manufacturing said surgical guiding instrument via additive manufacturing.

10. A kit comprising a patient-specific surgical guiding instrument, comprising:

1c) a support structure for positioning onto an anatomical part, comprising

- an anatomy engagement surface which anatomically matches at least a part of the surface of said anatomical part; and
- one or more coupling features;

2c) first and second independent guiding elements provided as insertion elements, each comprising:

- a body which is provided with one or more guiding features; wherein said insertion elements differ from each other in the number of guiding features and/or in the location, shape and/or size of at least one of said one or more guiding features;
- a coupling feature which allows a removable coupling of said insertion elements to one or more of said coupling features of said support structure.

11. A kit comprising a patient-specific surgical instrument for guiding an operation according to a first or second operational plan, wherein said patient-specific surgical instrument comprises:

1d) a support structure for positioning onto said anatomical part, comprising:

- an anatomy engagement surface which anatomically matches part of the surface of said anatomical part;
- one or more guiding features for guiding a surgical operation according to said first surgical plan; and

- a reference positioning feature;

2d) one or more independent guiding element comprising:

- one or more guiding features guiding a surgical operation according to said second surgical plan; and
- a reference positioning feature;

wherein said reference positioning feature of said support structure and said reference positioning feature of said independent guiding element are adapted to a common reference tool.

12. The kit according to claim 11, wherein said reference tool is a pin.

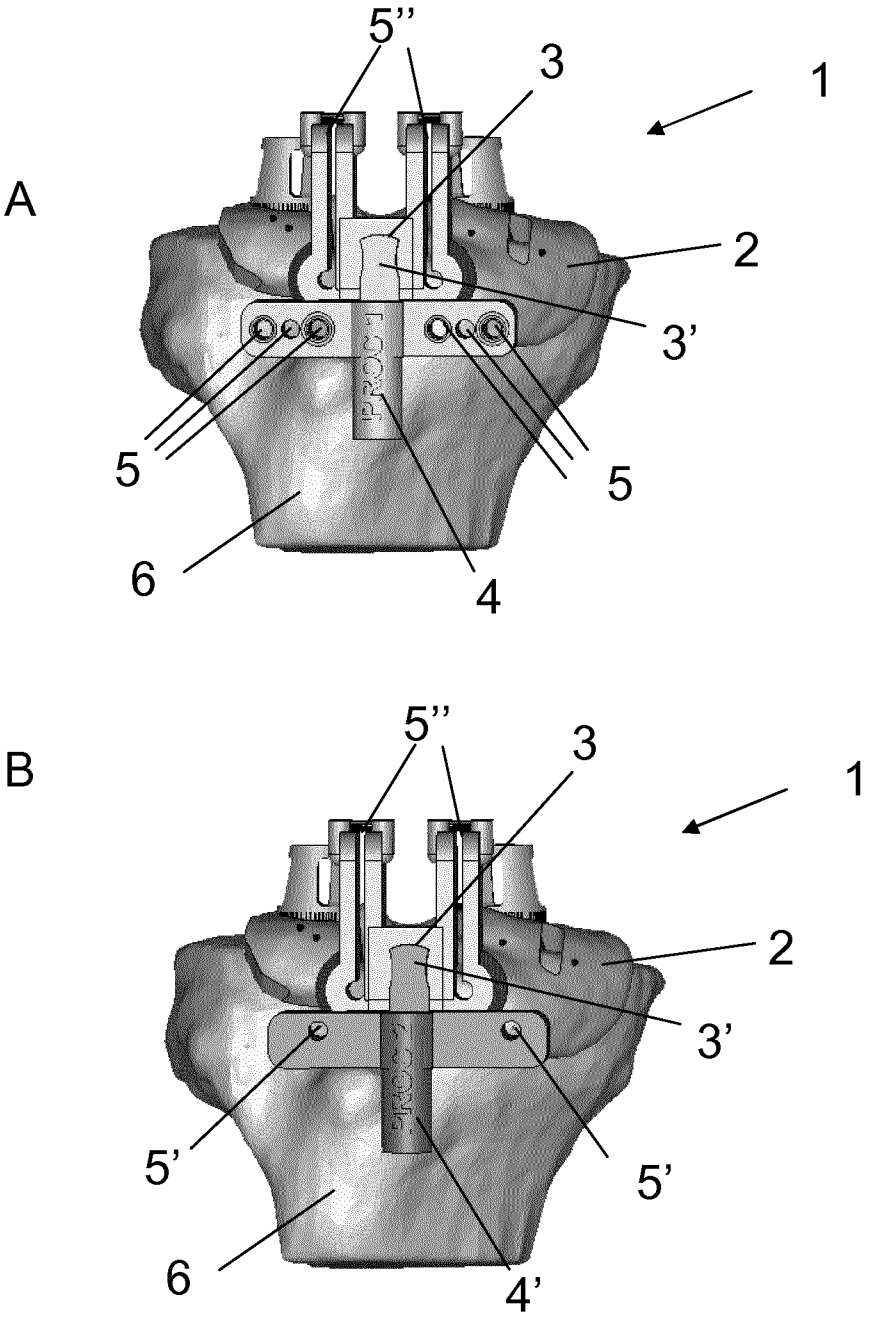

Figure 1

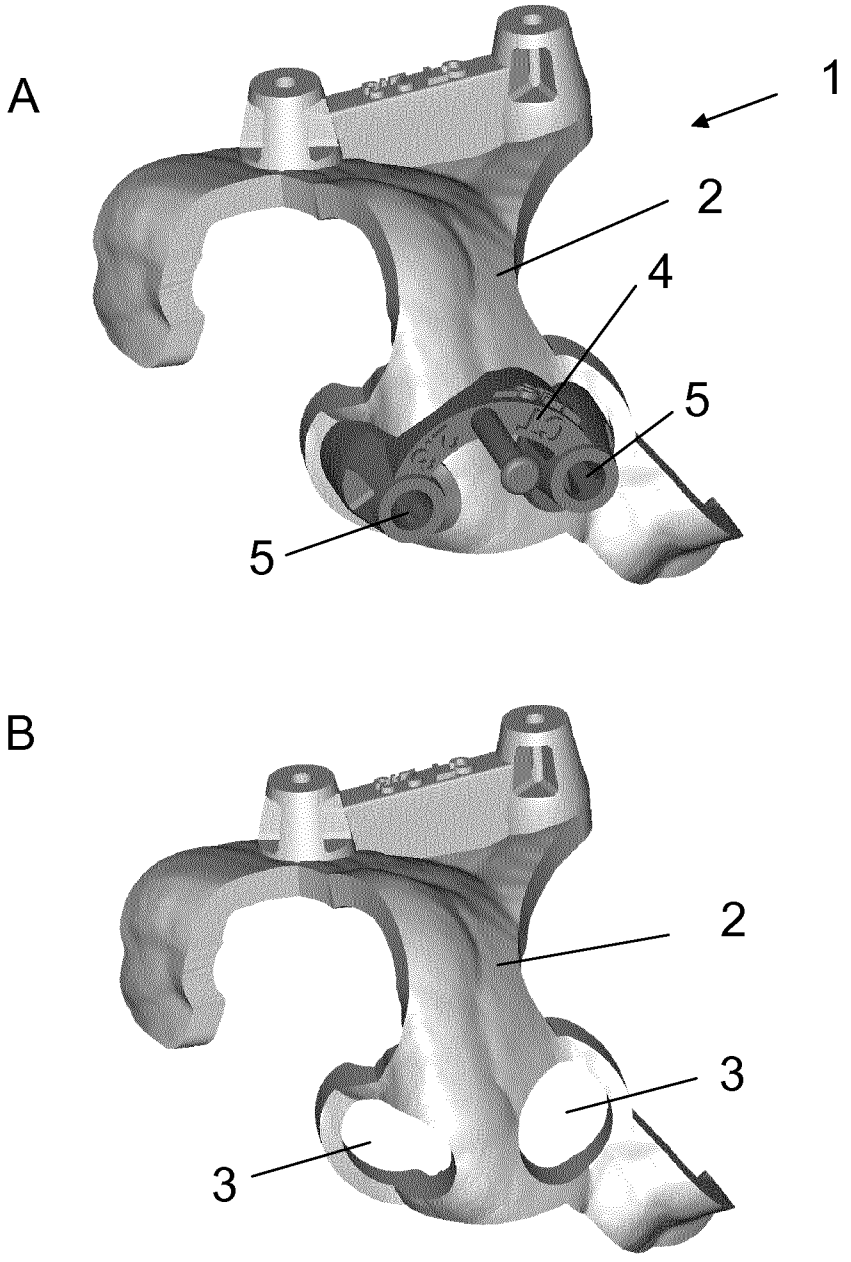

Figure 2

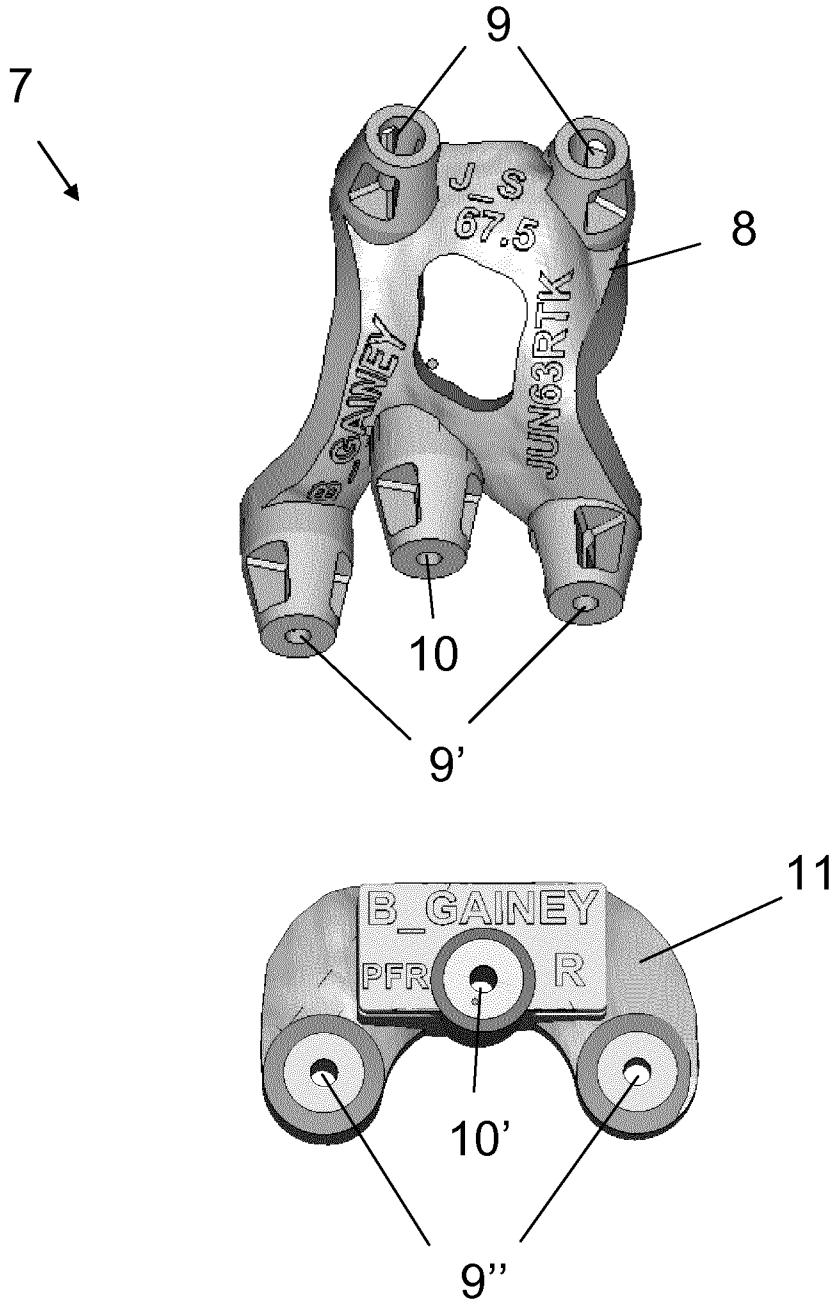

Figure 3

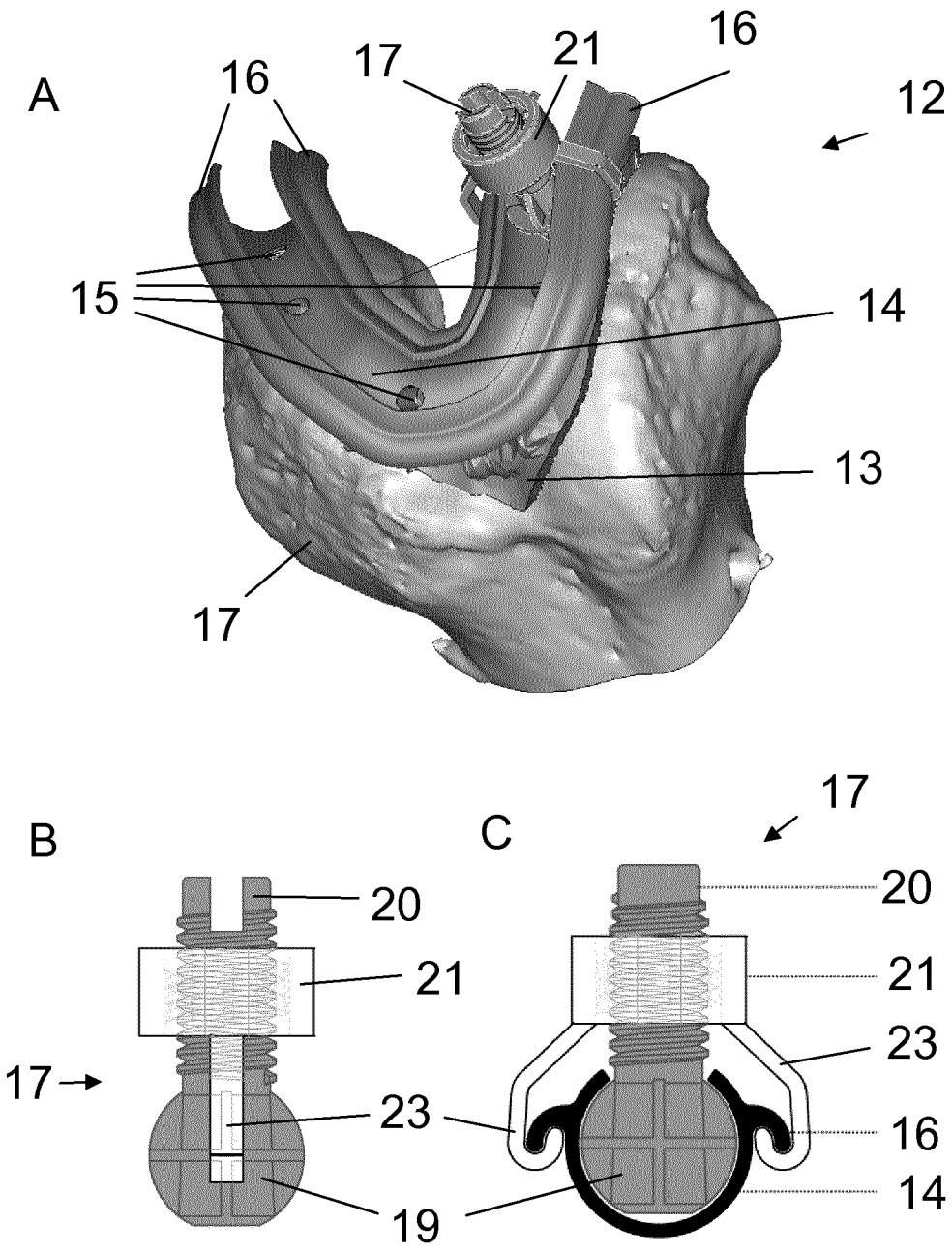

Figure 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/068534

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/17
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)
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/106093 A1 (ROMANO ANTHONY P [US] ET AL) 5 May 2011 (2011-05-05) paragraph [0046] ; figure 14	1-6, 10
X,P	WO 2012/024317 A2 (SMITH & NEPHEW INC [US] ; JORDAN JASON S [US] ; NADZADI MARK E [US] ; MEH) 23 February 2012 (2012-02-23) the whole document	1-6, 10
X	US 2011/172672 A1 (DUBEAU SERGE [US] ET AL) 14 July 2011 (2011-07-14) paragraphs [0027] , [0035]	11, 12

☐ 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" documentwhich may throw doubts on priority claim(s) orwhich 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	Date of mailing of the international search report
16 January 2013	25/01/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Hamann , Joachim

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2012/068534

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011106093 A1	05-05-2011	CA 2778057 A1	19-05-2011
		EP 2493396 A1	05-09-2012
		US 2011106093 A1	05-05-2011
		WO 2011059641 A1	19-05-2011
WO 2012024317 A2	23-02-2012	WO 2012024317 A2	23-02-2012
		WO 2012024318 A2	23-02-2012
US 2011172672 A1	14-07-2011	NONE	