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(54) **METHOD AND SYSTEM FOR GUIDING AN OSTEOTOMY PROCEDURE**

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A61B 17/15 (2006.01)

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CPC ***A61B 17/1764*** (2013.01); ***A61B 34/10*** (2016.02); *A61B 17/155* (2013.01)

(58) **Field of Classification Search**
CPC .. A61B 17/155; A61B 17/157; A61B 17/1764
See application file for complete search history.

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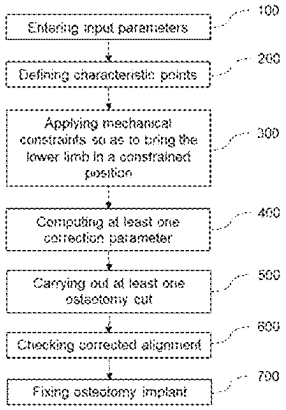
(57) **ABSTRACT**

The present disclosure relates to a method for guiding an osteotomy procedure on at least one bone selected from a tibia and a femur pertaining to a patient's lower limb to correct a misalignment of said lower limb, wherein a tibial tracker is fixed to the tibia and a femoral tracker is fixed to the femur, comprising:

- receiving at least one target alignment parameter of the lower limb;
- determining a position of a set of characteristic points on at least one of the tibia and the femur relative to at least one of the tibial tracker and the femoral tracker;
- applying mechanical constraints to the lower limb to bring the lower limb in a constrained position simulating laxities and/or soft tissues influence
- tracking positions of said characteristic points relative to at least one of the tibial tracker and the femoral tracker based on localization data of the set of characteristic points during application of said mechanical constraints,
- determining at least one alignment parameter of the lower limb in said constrained position, based on the positions of the characteristic points;
- based on the at least one target alignment parameter and on the at least one alignment parameter of the lower limb in the constrained position, determining at least one correction parameter of the osteotomy procedure to be applied to the lower limb to achieve the target alignment parameter.

32 Claims, 9 Drawing Sheets



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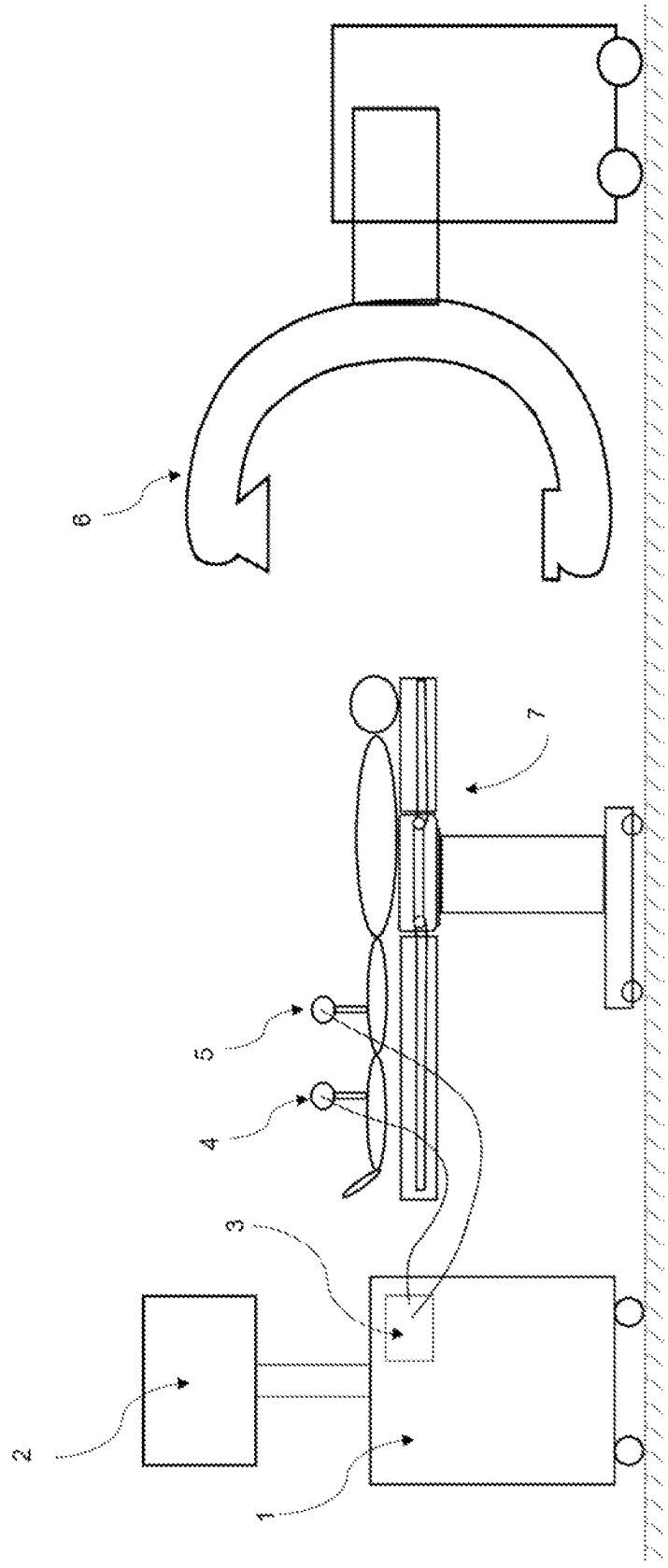

FIGURE 1

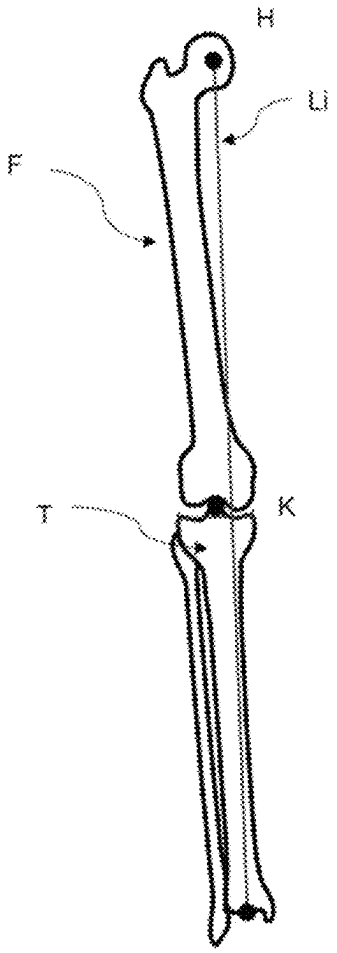

FIGURE 2A

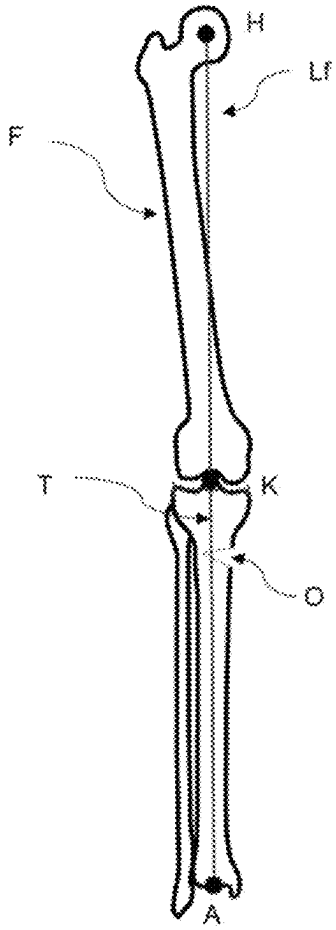

FIGURE 2B

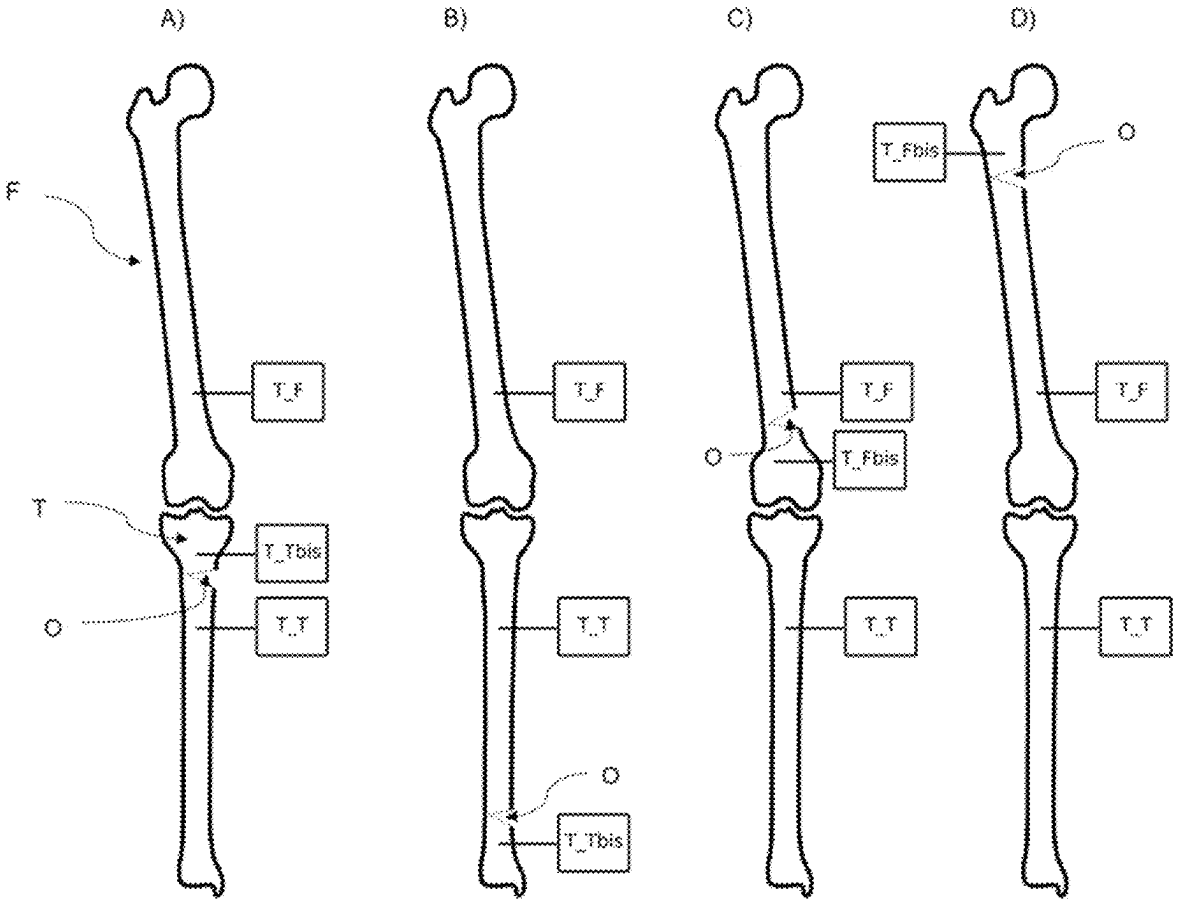

FIGURE 3

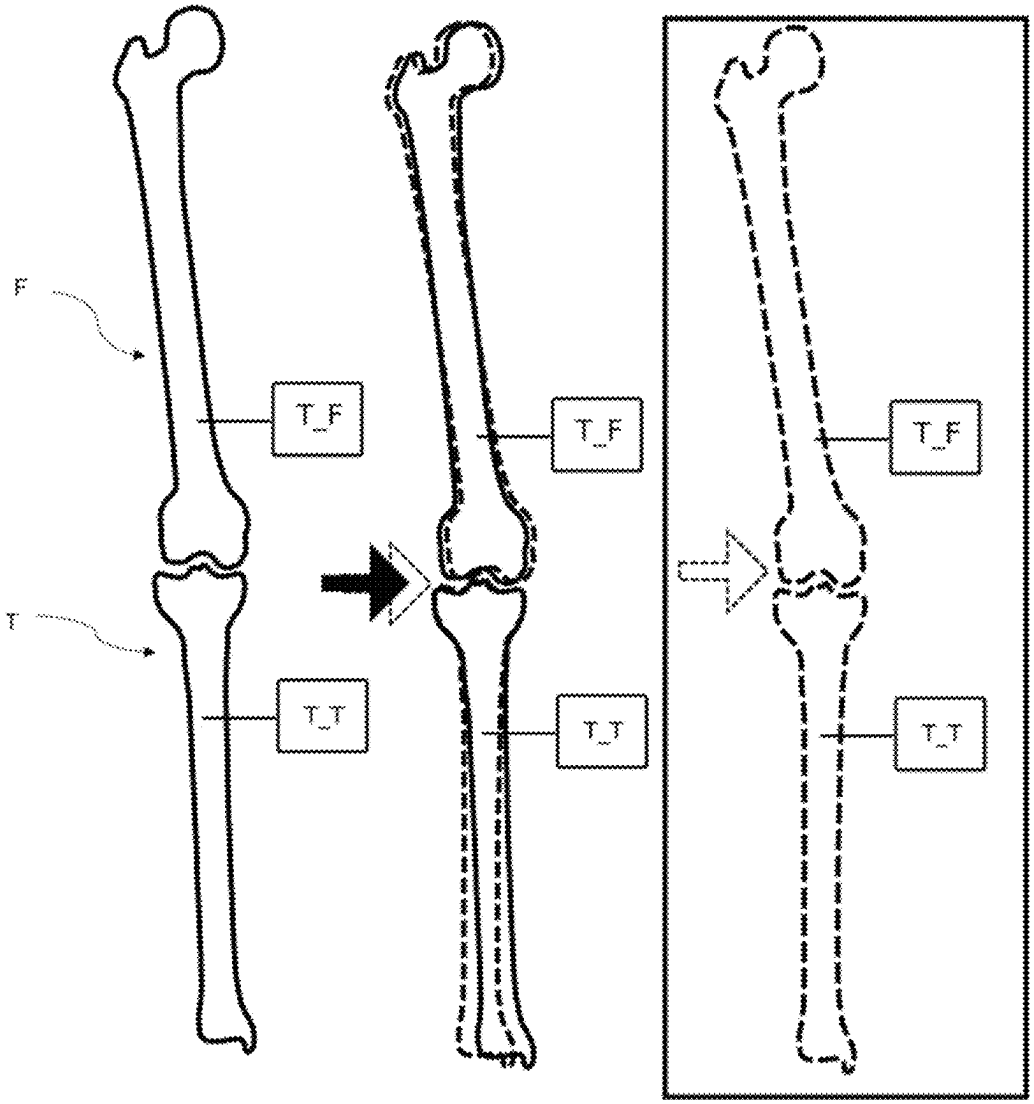

FIGURE 4

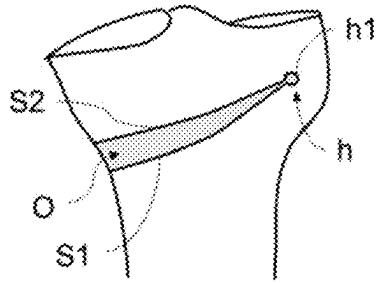

FIGURE 5A

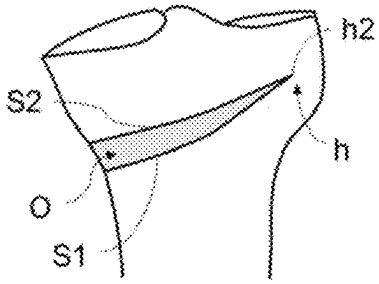

FIGURE 5B

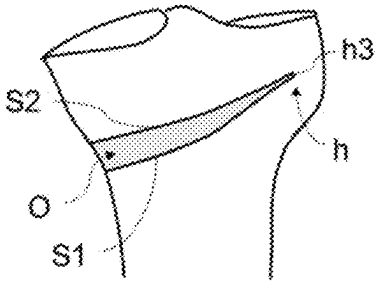

FIGURE 5C

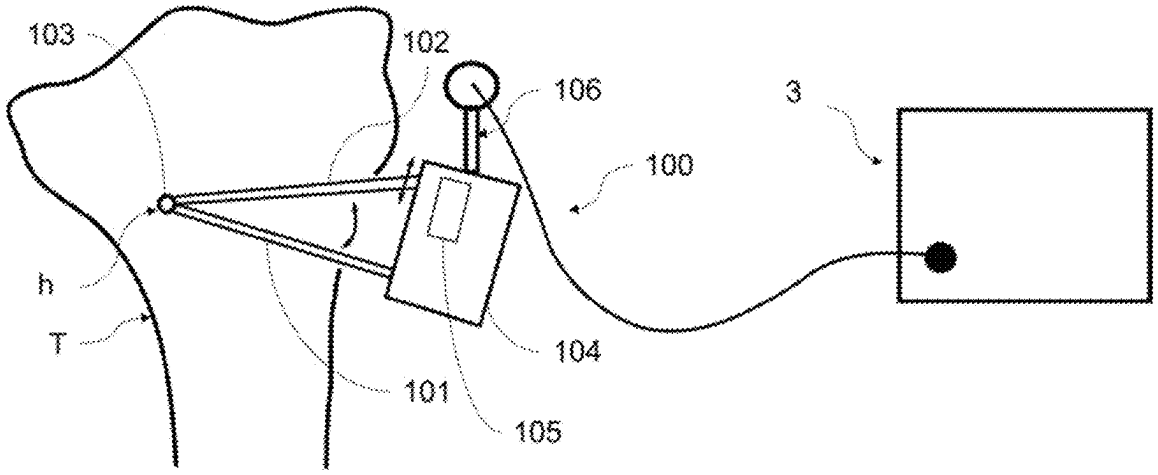

FIGURE 6

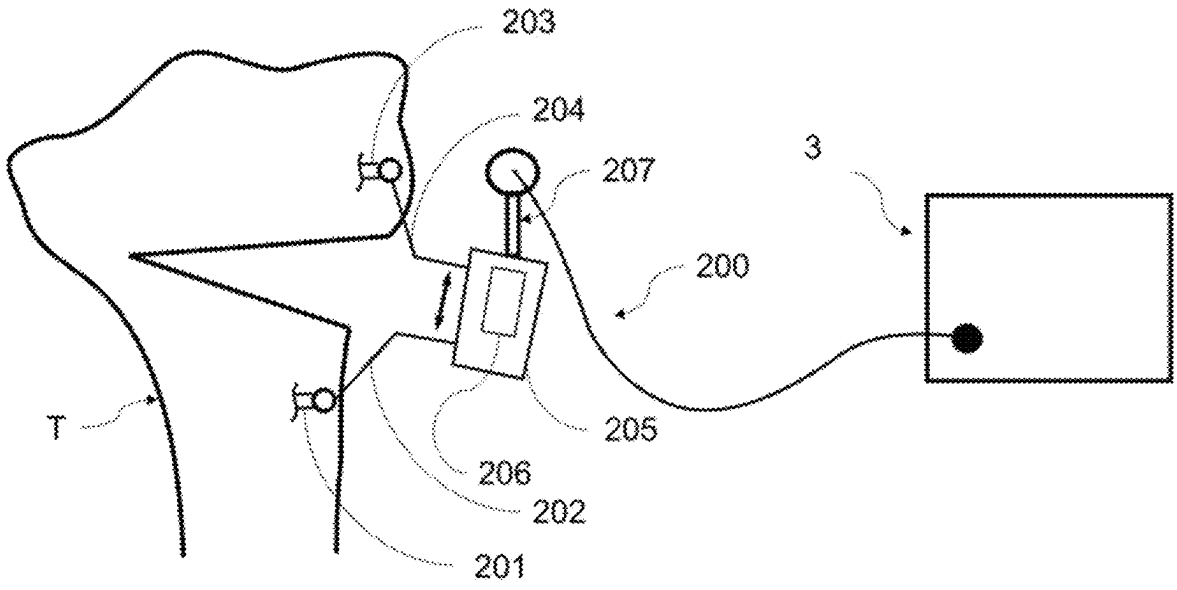

FIGURE 7

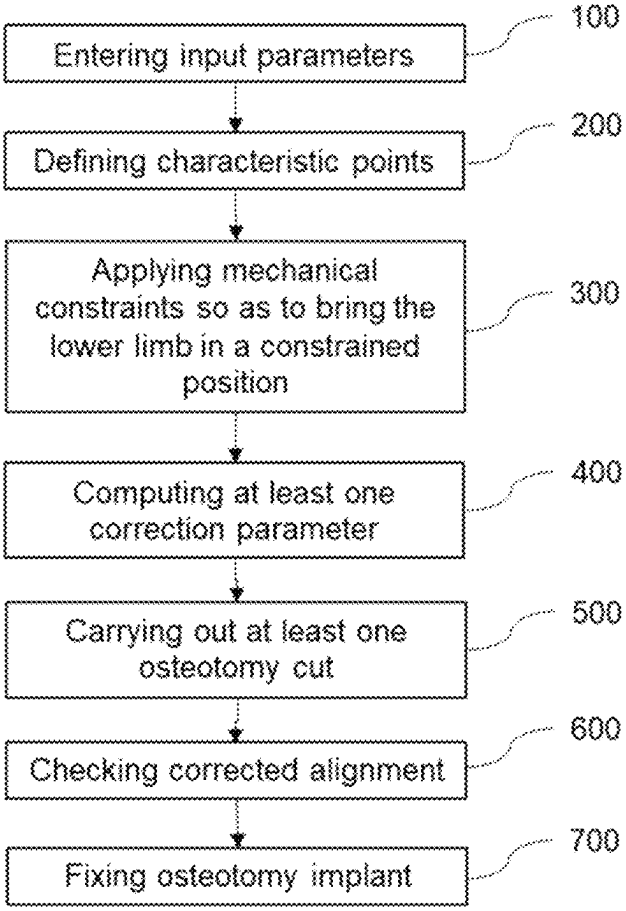

FIGURE 8

FIGURE 9A

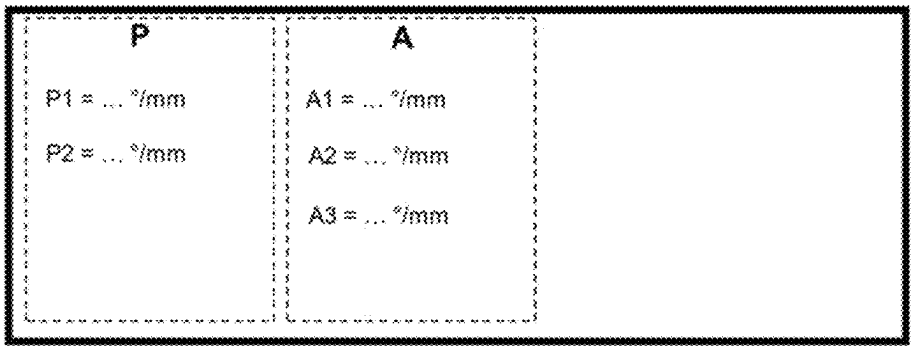

FIGURE 9B

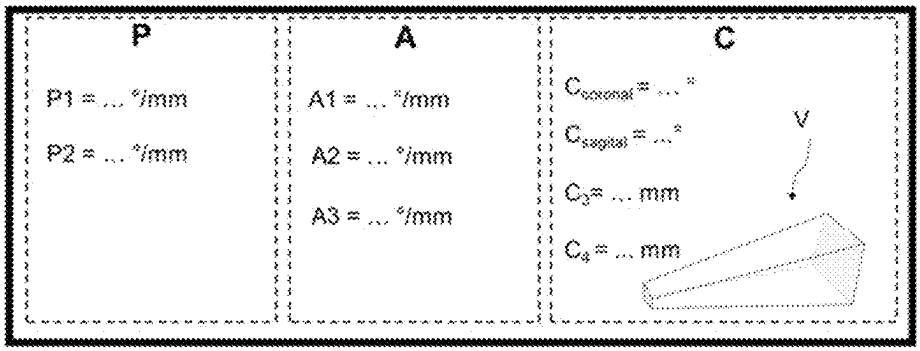

FIGURE 9C

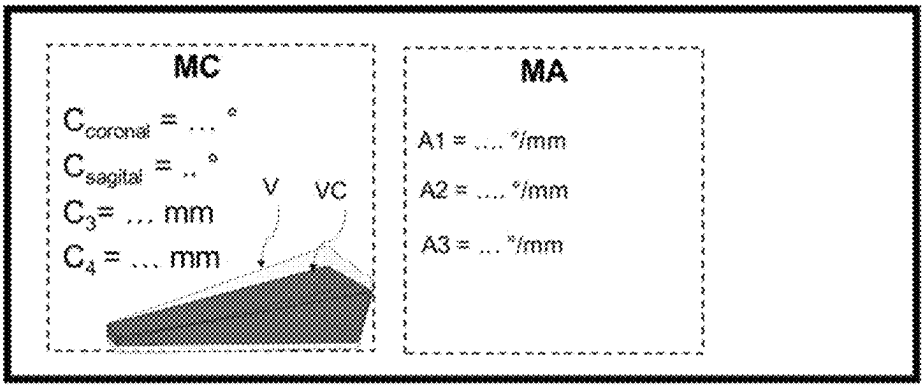

FIGURE 9D

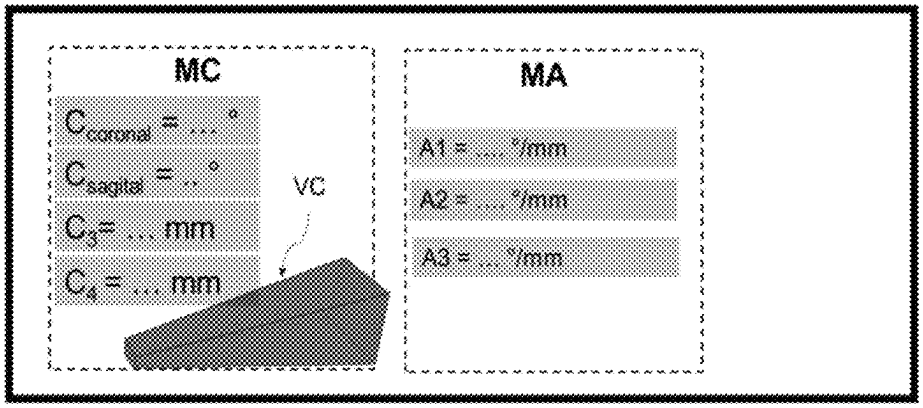

FIGURE 9E

METHOD AND SYSTEM FOR GUIDING AN OSTEOTOMY PROCEDURE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of EP Application No. EP 21306135.1 filed Aug. 23, 2021, which is hereby incorporated by reference herein in its entirety.

TECHNICAL FIELD

The present disclosure relates to a method and a system for guiding an osteotomy procedure.

TECHNICAL BACKGROUND

Osteotomy is a surgical procedure used to correct a misalignment of a limb, in particular a lower limb (leg). To that end, an osteotomy procedure comprises cutting at least a portion of a bone of said limb to create a bone hinge and moving the bone ends around the hinge to achieve a better alignment of the limb. Once said alignment has been achieved, an implant is placed between the bone ends to maintain them in said position.

Osteotomy of a lower limb is complex and requires not only a precise diagnosis of the misalignment but also an accurate control of the surgical procedure itself.

Generally, the diagnosis of a misalignment is made based on a preoperative 2D X-ray image, in particular according to a frontal view, acquired in the standing position of the patient. The surgeon analyses said X-ray image and draws lines between characteristic points to determine alignment measurements. Based on said measurements, in particular the analysis of the hip-knee-ankle (HKA) alignment, a tibial and/or femoral cut is deduced, either open or closed. An open-wedge or closed-wedge osteotomy procedure is decided by the surgeon. This osteotomy cut will allow reorienting the bone in a three-dimensional space. The cut is generally wedge-shaped, with position and dimensions that can be determined from the 2D X-ray image.

During surgery, the patient lies down onto an operating table. Intraoperative X-ray images may be acquired to guide the surgical procedure. However, said intraoperative X-ray images are acquired in a different configuration of the patient's limb on the operating table, which in particular differs from the standing position due to the laxity of the joints and the influence of soft tissues surrounding the bones.

In order to properly diagnose the alignment problem, plan the osteotomy and achieve the corrected alignment, the surgeon must be able to assess the contribution of laxity and soft tissue to the correction of alignment and the differences between standing and lying positions, and also be able to control the surgical gesture throughout the course of the surgical plan.

Currently, navigation stations used for osteotomies around the knee offer laxity measurements, however, they do not offer automatic planning based on these measurements and a defined leg position. Indeed, the initial alignment measurements are performed with a sedated patient's leg simply placed on the operating table. These measurements therefore have uncertainties, of the order of several degrees according to the literature [Stulberg et al.] [Jud et al., 2020].

Once the surgical gesture for forming the opening or closing of the patient's bone has been achieved, and before fixing the implant to maintain the bone in the corrected position, the surgeon checks the alignment of the leg by placing a radiopaque cable along the patient's leg and acquiring an X-ray image allowing measuring the corrected alignment of the leg. If the expected correction has not been achieved, the surgeon carries out a new surgical gesture to improve the correction, and then checks again the achieved alignment with an X-ray image. The surgeon fixes the implant once he considers that a sufficient correction has be achieved. However, when the patient is in a standing position post-operatively, the laxity of the joints and the influence of the soft tissues generally modify the alignment of the leg, and may reveal an over- or an under-correction of the initial misalignment.

[Kim et al.] teach an open-wedge osteotomy procedure taking into account the laxity of the patient's leg. In this method, a preoperative X-ray image with the patient in standing position is acquired. Based on said X-ray image, the surgeon estimates an angle of opening and carries out the surgical gesture to obtain said angle. Then, the surgeon checks the alignment of the leg by placing a radiopaque cable along the patient's leg and acquiring an X-ray image allowing measuring the corrected alignment of the leg. During the acquisition of the X-ray image, the surgeon applies a valgus stress to the knee in order to simulate the effect of laxity and thus checks the alignment when the leg is in this constrained position. If the expected correction has not been achieved, the surgeon carries out a new surgical gesture to improve the correction, and then checks again the achieved alignment with an X-ray image, with the leg in the constrained position. The surgeon fixes the implant once he considers that a sufficient correction has be achieved. Since the corrected alignment is checked with the leg in constrained position, the risk of an over- or under-correction is reduced. However, this method may require a plurality of surgical gestures and intraoperative checks based on X-ray images to achieve a satisfactory alignment. As a result, the osteotomy procedure may be lengthy and expose the patient to a large dose of X-rays.

SUMMARY OF THE DISCLOSURE

The present disclosure relates to a method and a system for guiding an osteotomy procedure that allows taking into account the laxity of the joints and the influence of soft tissues to determine and monitor a surgical plan.

To that end, the present disclosure presents a method for guiding an osteotomy procedure on at least one bone selected from a tibia and a femur pertaining to a patient's lower limb to correct a misalignment of said lower limb, wherein a tibial tracker is fixed to the tibia and a femoral tracker is fixed to the femur, comprising:

- receiving at least one target alignment parameter of the lower limb;
- determining a position of a set of characteristic points on at least one of the tibia and the femur relative to at least one of the tibial tracker and the femoral tracker;
- applying mechanical constraints to the lower limb to bring the lower limb in a constrained position simulating laxities and/or soft tissues influence
- tracking positions of said characteristic points relative to at least one of the tibial tracker and the femoral tracker based on localization data of the set of characteristic points during application of said mechanical constraints,
- determining at least one alignment parameter of the lower limb in said constrained position, based on the positions of the characteristic points;

based on the at least one target alignment parameter and on the at least one alignment parameter of the lower limb in the constrained position, determining at least one correction parameter of the osteotomy procedure to be applied to the lower limb to achieve the target alignment parameter.

The method may further comprise carrying the osteotomy procedure, said procedure comprising performing at least one osteotomy cut into the bone so as to form a hinge connecting two sides of the bone and moving said sides around the hinge.

In some embodiments, the method further comprises monitoring an evolution of the at least one alignment parameter based on localization data of the set of characteristic points during the osteotomy procedure.

In some embodiments, the method further comprises determining, based on the at least one target alignment parameter and localization data of the set of characteristic points during the osteotomy procedure, whether each target alignment parameter is achieved.

In some embodiments, the method further comprises monitoring an evolution of a geometric feature of a volume being removed or created by the at least one osteotomy cut relative to the at least one correction parameter.

In some embodiments, the method further comprises:

fixing an additional tibial or femoral tracker to the bone so that two tibial or femoral trackers are fixed to the bone on both sides of the osteotomy cut; and

computing an evolution of the osteotomy cut based on localization data of said two tibial or femoral trackers.

Alternatively, the method may comprise:

inserting a mechanical device into the osteotomy cut and expanding or retracting said mechanical device as a user moves the sides of the osteotomy cut farther or closer to each other;

measuring in real time an expansion or a retraction of the mechanical device by at least one sensor; and

computing an evolution of the osteotomy cut based on measurement data from said at least one sensor.

In other embodiments, the method may comprise:

fixing two mechanical devices to both sides of the osteotomy cut, said mechanical devices being connected by an adjustable link;

expanding or retracting the adjustable link as a user moves the sides of the cut farther or closer to each other;

measuring in real time an expansion or a retraction of the adjustable link by at least one sensor; and

computing an evolution of the osteotomy cut based on measurement data from said at least one sensor.

The method may further comprise displaying each alignment parameter and/or correction parameter.

In addition, the method may comprise displaying an indication that the at least one target alignment parameter is achieved.

The at least one target alignment parameter may comprise at least one of: a mechanical femorotibial angle (mFTA), a mechanical medial proximal tibial angle (mMPTA), a mechanical lateral distal femoral angle (mLDFA), a lateral tibial plateau inclination (LTPI), a medial tibial plateau inclination (MTPI), a hip-knee-ankle angle (HKA), a joint line convergence angle (JLCA), a posterior tibial slope (PTS), a hip abduction angle (HAA), a tibial plafond inclination (TPI), a talar inclination angle (TIA), a lateral patellar tilt (LPT) and a lateral patellar shift (LPS).

In some embodiments, the at least one correction parameter comprises a geometric feature of a part to be removed from the bone to form the hinge and a geometric feature of a space created around the hinge to appear during distraction of the bone sides.

In some embodiments, the position of the set of characteristic points on at least one of the tibia and the femur relative to at least one of the tibial tracker and the femoral tracker is determined based on at least one of the following methods:

segmenting at least one 2D and/or 3D medical image of the patient's limb and determining the set of reference characteristic points on said segmented image;

adjusting a bone model comprising the set of characteristic points to the tibia or femur in at least one 2D and/or 3D image of the patient's limb using a bone morphing technique;

obtaining localization data of a pointer tracker fixed to a pointer palpating characteristic points on the tibia and/or the femur; and

obtaining localization data of the femoral and tibial trackers as a user moves the limb about at least one joint.

The method may further comprise acquiring 2D images of the lower limb of the patient and determining the at least one target alignment parameter based on 2D X-ray images.

Additionally, the present disclosure presents a surgical system for guiding an osteotomy procedure on at least one bone selected from a tibia an a femur pertaining to a patient's lower limb to correct a misalignment of said lower limb according to the above-mentioned method, wherein a tibial tracker is fixed to the tibia and a femoral tracker is fixed to the femur, said system comprising a control unit configured to be coupled to a localization system adapted to track a position and orientation of the tibial tracker and the femoral tracker, wherein the control unit is configured to:

receive at least one target alignment parameter of the lower limb provided by a user;

determine a position of a set of characteristic points on the tibia and/or the femur relative to the tibial tracker and/or the femoral tracker;

track the positions of said characteristic points relative to the tibial tracker and/or the femoral tracker based on localization data of the set of characteristic points during application of mechanical constraints by the user to bring the lower limb in a constrained position simulating laxities and/or soft tissues influence,

determine at least one alignment parameter of the lower limb in said constrained position, based on the positions of the characteristic points;

based on the at least one target alignment parameter and on the at least one alignment parameter of the lower limb in the constrained position, determine at least one correction parameter of the osteotomy procedure to be applied to the lower limb to achieve the target alignment parameter.

By taking into account the laxity and influence of soft tissues for planning the surgical gesture, the correction parameter computed by the control unit is more accurate and more adapted to the patient's physiology. As a result, the risk of over- or under-correction of the misalignment is reduced, and the desired correction can be achieved directly, thereby reducing the number of iterations of surgical gestures and checks before fixing the osteotomy implant.

In some embodiments, the control unit can be configured to monitor an evolution of the at least one alignment parameter based on localization data of the set of characteristic points during the osteotomy procedure.

Advantageously, the control unit can be further configured to determine, based on the at least one target alignment

parameter and localization data of the set of characteristic points during the osteotomy procedure, whether each target alignment parameter is achieved.

In some embodiments, the control unit can be further configured to monitor an evolution of a geometric feature of a volume being removed or created by the osteotomy cut relative to the at least one correction parameter.

In some embodiments, an additional tibial or femoral tracker is fixed to the bone so that two tibial or femoral trackers are fixed to the bone on both sides of the osteotomy cut and the control unit is configured to compute the evolution of the osteotomy cut based on localization data of said two trackers.

In other embodiments, the system further comprises a mechanical device adapted to be inserted within the osteotomy cut and designed to expand or retract as the sides of the cut are moved farther or closer to each other, and at least one sensor coupled to the control unit and configured to measure in real time an expansion or a retraction of the mechanical device, and the control unit is configured to compute the evolution of the osteotomy cut based on measurement data from said at least one sensor.

Alternatively, the system can further comprise two mechanical devices adapted to be fixed to sides of the osteotomy cut, an adjustable link connecting said mechanical devices and designed to expand or retract as the sides of the cut are moved farther or closer to each other, and at least one sensor coupled to the control unit and configured to measure in real time an expansion or a retraction of the adjustable link, and the control unit can be configured to compute the evolution of the osteotomy cut based on measurement data from said at least one sensor.

The surgical system advantageously comprises a user interface coupled to the control unit and configured to display each alignment parameter and/or correction parameter.

Said user interface can be further configured to display an indication that the at least one target alignment parameter is achieved.

The at least one target alignment parameter comprises: a mechanical femorotibial angle (mFTA), a mechanical medial proximal tibial angle (mMPTA), a mechanical lateral distal femoral angle (mLDFA), a lateral tibial plateau inclination (LTPI), a medial tibial plateau inclination (MTPI), a hip-knee-ankle angle (HKA), a joint line convergence angle (JLCA), a posterior tibial slope (PTS), a hip abduction angle (HAA), a tibial plafond inclination (TPI), a talar inclination angle (TIA), a lateral patellar tilt (LPT) and/or a lateral patellar shift (LPS).

The at least one correction parameter can typically comprise a geometric feature of a bone part to be removed from the tibia and/or femur and a geometric feature of a space created around a hinge formed by an osteotomy cut to appear during distraction of the tibia and/or femur during distraction of bone sides around the hinge.

The control unit can be configured to determine the position of the set of characteristic points on the tibia and/or the femur relative to the tibial tracker and/or the femoral tracker based on at least one of the following methods:

- segmenting at least one 2D and/or 3D medical image of the patient's limb and determining the set of reference characteristic points on said segmented image;
- adjusting a bone model comprising the set of characteristic points to the patient's tibia or femur in at least one 2D and/or 3D image of the patient's limb using a bone morphing technique;
- obtaining localization data of a pointer tracker fixed to a pointer palpating characteristic points on the tibia and/or the femur; and
- obtaining localization data of the femoral and tibial trackers as a user moves the limb about at least one joint.

In some embodiments, the control unit is configured to be coupled to an X-ray imaging system adapted to acquire 2D and/or 3D images of the lower limb of the patient.

BRIEF DESCRIPTION OF THE FIGURES

Further features and advantages of the invention will appear in the following detailed description of embodiments, based on the appended drawings, in which:

FIG. **1** illustrates a general overview of the surgical system;

FIG. **2**A schematically illustrates a varus alignment of a patient's leg before an open-wedge high tibial osteotomy;

FIG. **2**B schematically illustrates the leg alignment after an open-wedge high tibial osteotomy;

FIG. **3** schematically illustrates various embodiments of trackers placement for an osteotomy procedure;

FIG. **4** schematically illustrates the measurement of the alignment parameters with the leg in a constrained position;

FIGS. **5**A to **5**C illustrate various geometric shapes of the space created around the hinge formed by an osteotomy cut;

FIG. **6** schematically illustrates a mechanical device allowing monitoring the retraction or distraction of the bone;

FIG. **7** schematically illustrates a mechanical assembly allowing monitoring the retraction or distraction of the bone;

FIG. **8** is a flowchart of the osteotomy procedure carried out with the system;

FIGS. **9**A to **9**E illustrate a screen of the user interface at successive stages of the osteotomy procedure.

For the sake of legibility of the figures, the drawings have been simplified and may not illustrate the whole patient's anatomy or all the structural details of the system.

DETAILED DESCRIPTION OF EMBODIMENTS

The osteotomy procedure is planned and guided by a computer-assisted surgery system. In some embodiments, the system may be a navigation system.

The procedure can comprise a preoperative step in which the patient is in a standing position and an intra-operative step in which the patient is in a lying position.

The intra-operative step is not limited to the surgical gesture itself but also includes the determination of a surgical plan based on target alignment parameters.

The target alignment parameters can be defined in the preoperative step.

However, the preoperative step is optional; in particular such a preoperative step can be omitted if the surgeon uses data known in the art to determine a surgical plan. In such case, the target alignment parameters are defined in the intra-operative step.

General Overview of the Surgical System

The surgical system comprises a control unit which comprises at least one processor configured to implement algorithms, and a localization system, configured to track in real time the position and orientation of trackers fixed to the bones (tibia and femur) of the patient's limb.

Any localization technology may be used. In some embodiments, the localization system may include at least one camera and the trackers each comprise a respective set of markers with a unique geometry that can be detected by the camera. Said markers may be passive markers, such as

disks or balls comprising a reflective surface adapted to reflect light from an infrared camera. Alternatively, the markers may be active markers that are themselves adapted to emit light, such as LEDs. In other embodiments, the localization system may include at least one electromagnetic emitter and receiver and the trackers may each comprise an electromagnetic receiver or emitter coupled to the localization system. In other embodiments, the localization may comprise accelerometers, gyroscopes and/or magnetometers, in particular IMU (Inertial Measurement Unit) sensors.

The control unit is coupled to the localization system so as to receive localization data regarding the trackers.

The surgical system may also comprise a user interface allowing a user to interact with the control unit, in particular to enter data. The user interface can include at least one screen to display information computed by the control unit or/entered by the user.

The osteotomy procedure can also involve an X-ray imaging system, which may be in particular a C-arm. However, such an X-ray imaging system is optional.

In case an X-ray imaging system is used, the control unit is coupled to the X-ray imaging system so as to receive 2D or 3D images acquired by the X-ray imaging system. Such a coupling allows placing in a common frame of reference the 2D or 3D images, the trackers and the characteristic points seen on the 2D or 3D images and tracked by the surgical system.

FIG. **1** illustrates a general overview of a preferred embodiment of the surgical system.

In the operating room, the patient lies on an operating table **7**. A tibial tracker **4** is fixed to the patient's tibia and a femoral tracker **5** is fixed to the patient's femur.

Next to the operating table **7**, a navigation station **1** comprises a control unit **3** and a display **2** for the user interface. In some embodiments, the display may be tactile.

For example, the tibial and femoral trackers **4**, **5** are electromagnetic trackers and belong to an electromagnetic localization system. The trackers are linked to the control unit **3** to provide the control unit with localization data. If additional electromagnetic trackers are used, as explained below, they are also linked to the control unit.

In some embodiments, the surgical system also comprises a 2D and/or 3D intra-operative X-ray imaging system **6** that can be brought next to the patient to acquire 2D and/or 3D images. For example, the X-ray imaging system is a C-arm.

The localization system and the X-ray imaging system are known per se and will not be described in detail in the present text. In particular, localization systems and X-ray imaging systems currently available on the market can be used for carrying out the osteotomy procedure.

The description will thus be focused on the configuration of the control unit that allows implementing the osteotomy procedure.

Osteotomy Procedure

An osteotomy procedure consists in realizing a tibial and/or a femoral osteotomy with the aim to correct a misalignment of a limb (the limb comprising a tibia and a femur).

FIGS. **2**A and **2**B schematically illustrate the principle of an open-wedge high tibial osteotomy on a patient's right leg including a tibia T and a femur F seen according to a frontal view.

The knee joint has a knee center K. There are commonly multiple definitions of the knee center. The knee center can be defined, for instance, as the center of the apex of the femoral notch, the midpoint of the femoral condyles, the center of tibial spines, the midpoint of soft tissue outline or the midpoint of tibial plateau. The femur F has a proximal joint, the hip joint and a center located in the hip ball (hereafter hip center H) which makes the interface with the pelvis (not shown). The tibia T has a distal joint, the ankle joint and a center (here after ankle center A) which makes the interface with the foot (not shown). As for the knee center, there are commonly multiple definitions of the ankle center. The ankle center can be defined, for instance, as the center of soft tissue near both the malleoli, the center bones near both the malleoli or the center of talus.

The present application is applicable to each of the above definitions.

In FIG. **2**A, before osteotomy, one can observe a varus alignment of the leg. Indeed, the initial weight-bearing line Li (also called Mikulicz line) which passes through the hip and ankle centers H, A is located inwardly with respect to the knee center K. To correct this misalignment, an open-wedge osteotomy has been carried out to cut the higher part of the tibia to form a hinge and space apart the two parts of the tibia about said hinge. The space created by the distraction is designated by O in FIG. **2**B. One can observe that, after osteotomy, the final weight-bearing line Lf passes through the hip, knee and ankle centers H, K and A. Of course, other types of osteotomies exist and the skilled person knows what type of osteotomy should be used for a given type of misalignment.

The osteotomy procedure requires the determination of target alignment parameters. Said target alignment parameters may be determined in a preoperative step or in the intra-operative step.

Determination of the Target Alignment Parameter(s)

Various target alignment parameters may be used and may be selected by the surgeon depending on the specific condition of the patient.

For example, but not limitatively, the target alignment parameter may be:

- a mechanical femorotibial angle (mFTA),
- a mechanical medial proximal tibial angle (mMPTA),
- a mechanical lateral distal femoral angle (mLDFA),
- a lateral tibial plateau inclination (LTPI),
- a medial tibial plateau inclination (MTPI),
- a hip-knee-ankle angle (HKA): angle between the mechanical axes of the femur and the tibia,
- a joint line convergence angle (JLCA): angle made by a tangential line between the femoral condyles and the tibial plateau,
- a posterior tibial slope (PTS),
- a hip abduction angle (HAA),
- a tibial plafond inclination (TPI),
- a talar inclination angle (TIA),
- a lateral patellar tilt (LPT), and/or
- a lateral patellar shift (LPS).

The target alignment parameter(s) may be determined by various techniques.

In some embodiments, the target alignment parameters can be determined based on 2D X-ray images, by measurements of specific features representative of the alignment of the leg.

Said 2D X-ray images can be acquired pre-operatively. In such case, the patient is generally in standing position. The pre-operative step can thus allow diagnosing directly a misalignment of the patient's leg and consequently determining the target alignment parameter(s) to be achieved by the osteotomy procedure to provide a correct alignment of the leg.

Alternatively, said 2D X-ray images can be acquired intra-operatively. In such case, the patient is generally lying on the operating table. In order to take into account laxities and influence of soft tissues, the surgeon applies mechanical constraints to the leg in order to achieve an alignment similar to the alignment that would be observed in the standing position. The surgeon uses his/her professional expertise and knowledge of patients' anatomy to apply suitable mechanical constraints and thus simulate the alignment in the standing position. As mentioned for the pre-operative step, the surgeon can then determine the target alignment parameter(s) to be achieved by the osteotomy procedure to provide a correct alignment of the leg.

Due to the length of the leg, it may not be possible or suitable to obtain a single X-ray image of the whole leg. Thus, several images of different parts of the leg can be acquired and recorded to allow determining target alignments of the leg.

However, the use of X-ray images is not compulsory to determine the target alignment parameters in the intra-operative step. For example, thanks to the localization system, the surgical system alone can be sufficient to determine the relative positions of the femur and the tibia in all directions of a three-dimensional space, diagnose a misalignment of the leg and determine the target alignment parameter(s) to be achieved by the osteotomy procedure to provide a correct alignment of the leg. This allows reducing the patient's exposure to X-rays.

The target alignment parameter(s) is(are) used as an input for planning the surgical gesture in the intra-operative step.

Preparation of Intra-Operative Step

In the intra-operative step, the patient is placed lying down on an operating table of a surgical room and sedated.

At least two trackers are fixed to the lower limb: at least one tracker is fixed to the tibia and at least one tracker is fixed to the femur. By "fixed" is meant a temporary (the tracker being intended to be removed after the surgical procedure) but rigid fixation of the tracker to the respective bone, so as to avoid any movement of the tracker relative to the bone during the surgical procedure. For example, each tracker may be implanted into the respective bone using a pin or a screw. A coordinate system is attached to each tracker and is thus tracked in real time by the localization system.

In addition, one additional tracker may be fixed to the bone to be cut, so that one tracker is fixed to a respective side of the osteotomy cut. Thanks to the additional tracker, the control unit can follow in real time the degree of opening or closing of the wedge formed by the osteotomy. However, as mentioned below, other devices can be used to follow the advancement of the osteotomy, and the use of such an additional tracker is thus optional.

FIG. **3** illustrates various embodiments of trackers placement.

In embodiment a), which corresponds to high tibial osteotomy, one tracker T_F is fixed to the femur F and two trackers T_T and T_Tbis are fixed to the tibia. The tracker T_Tbis is fixed to the upper part of the tibia, above the space O opened by osteotomy, and the tracker T_T is fixed to the lower part of the tibia, below the space O.

In embodiment b), which corresponds to distal tibial osteotomy, one tracker T_F is fixed to the femur F and two trackers T_T and T_Tbis are fixed to the tibia. The tracker T_Tbis is fixed to the lower part of the tibia, below the space O opened by osteotomy, and the tracker T_T is fixed to the upper part of the tibia, above the space O.

In embodiment c), which corresponds to distal femoral osteotomy, one tracker T_T is fixed to the tibia T and two trackers T_F and T_Fbis are fixed to the femur. The tracker T_Fbis is fixed to the lower part of the femur, below the space O opened by osteotomy, and the tracker T_F is fixed to the upper part of the femur, above the space O.

In embodiment d), which corresponds to high femoral osteotomy, one tracker T_T is fixed to the tibia T and two trackers T_F and T_Fbis are fixed to the femur. The tracker T_Fbis is fixed to the upper part of the femur, above the space O opened by osteotomy, and the tracker T_F is fixed to the lower part of the femur, below the space O.

These embodiments can be combined if appropriate, for example if an osteotomy cut has to be made on both the femur and the tibia (double level osteotomy).

The trackers T_Tbis and T_Fbis can be omitted if another device is used to track the advancement of the osteotomy procedure.

Determination of Characteristic Points

A set of characteristic points on the tibia and/or the femur is defined, with the position of said characteristic points in the coordinate system of at least one tracker being known.

Various methods for determining said set of characteristic points may be used.

In some embodiments, the characteristic points may be acquired by palpation using a pointer carrying a tracker tracked by the localization system. In such a way, the position of each palpated point relative to at least one of the tibial and femoral trackers can be determined.

In other embodiments, the characteristic points may be determined on at least one 2D (bi-dimensional) or 3D (three-dimensional) X-ray image whose position in the coordinate system of at least one tracker is known. Preferably, said 2D or 3D X-ray image is acquired in the intra-operative step. Alternatively, the 2D or 3D X-ray image can be acquired pre-operatively. In such case, the control unit computes a registration between the pre-operative 2D or 3D X-ray image and the coordinate system of at least one of the tibial and femoral trackers.

The characteristic points can be identified based on a segmentation of the 2D or 3D X-ray image(s). For instance, the knee joint center can be located in at least one 2D or 3D image of the knee, via the analysis of one or more characteristic point(s) found on the images. In particular, different characteristic points of the image can be used to define the knee center. For instance, the knee center can be the average of two or more points: the midpoint of the femoral condyles or the center of the soft tissue outline.

Otherwise, the characteristic points may be present on a model of the bone and said model may be adjusted to the patient's bone using known bone morphing techniques, so as to register the characteristic points with a 2D or 3D X-ray image of the patient's bone.

Some characteristic points (for example, the center of a joint) may also be determined by moving the limb or a part of the limb about a joint. For example, the knee joint center can be located by using a morpho-functional method using flexion-extension movements. In such a morpho-functional method, 3D positions and orientations of the femoral and tibial trackers are recorded during the motion by the surgical system. An average rotation axis representing the flexion/extension is estimated.

Said methods are known by the skilled person and will not be described in detail in the present case.

Of course, the above methods can be combined to determine the characteristic points. For example, the hip, knee or ankle center can be obtained via the morpho-functional

method and be adjusted via the information of the position of other characteristic points on a 2D or 3D X-ray image. In other situations, a partial determination of the characteristic points based on an incomplete segmentation or an incomplete bone morphing can be supplemented by the palpation of other characteristic points with a tracked pointer.

Determination of Alignment Parameter(s) in Free Position

Initially, the leg is in a free position, i.e. it lies on the operating table without any constraint. As mentioned in the introduction, the alignment of the bones is different from the standing position, due to the laxity of the joints and the influence of the soft tissues surrounding the bones.

The determination of the alignment parameters in said free position can be done based on the positions of the characteristic points. These characteristic points can be found and located with a method or a combination of methods described in the previous paragraph ("Determination of characteristic points").

In some embodiments, at least one X-ray image of the leg in said free position is acquired by the X-ray imaging system coupled to the control unit. Said X-ray imaging system may be the same as the X-ray imaging used in the preoperative step, or it may be a different X-ray imaging system. Based on said at least one X-ray image, at least one alignment parameter can be computed and recorded by the control unit. Preferably, alignment parameters are computed in a 3D frame of reference in order to take into account more accurately the patient's condition.

For example, a preoperative 3D image of the leg may be acquired, either in free or in constrained position. In this preoperative imaging step, the patient may be in a standing position. Then, when the patient lies on the operating room with the trackers fixed to the tibia and the femur, at least one X-ray image of the patient's leg may be acquired. The alignment parameter(s) can be determined thanks to the trackers and the localization system.

However, the determination of the alignment parameter(s) in the free position is optional and could thus be omitted.

Determination of Alignment Parameter(s) in Constrained Position

Whether or not there have been acquisitions and measurements of alignment parameters of the leg in the free position, the present step aims to measure the alignment parameters from a continuous tracking of the characteristic points (said characteristic points being determined with one or more of the methods previously described), when the leg is positioned by the surgeon in a constrained position.

To that end, the surgeon manipulates the leg to apply mechanical constraints so as to bring the lower limb in a constrained position simulating laxities and/or soft tissues influence. For example, the surgeon may apply a valgus stress if he considers that the valgus stress applied is representative of the inherent laxity that influences the patient's gait (i.e. with weight bearing). Of course, the surgeon may apply any type of mechanical constraints that he/she considers to be relevant for the patient based on his/her professional skills.

Since the position of the characteristic points is known in the coordinate system of at least one of the trackers, it is possible to track the position of said characteristic points over time when the surgeon manipulates the leg.

In particular, the position of the characteristic points in the constrained position of the leg is determined and recorded by the control unit.

Thus, at least one alignment parameter of the lower limb in said constrained position can be determined and recorded by the control unit. Preferably, alignment parameters are computed in all directions in order to take into account more accurately the patient's condition.

FIG. **4** schematically illustrates the application of the mechanical constraints and the computation of a correction in the frontal plane, for an open-wedge high tibial osteotomy.

From the left to the right of the figure:

- the leg is in the free position, at least one tibial and femoral tracker T_T, T_F being fixed to the tibia and the femur, respectively;
- the surgeon applies mechanical constraints to the leg in order to simulate the effect of laxities and soft tissues: the position of the leg in the constrained position is illustrated in dotted lines, superimposed with the free position (solid line); said mechanical constraints may be defined by known clinical tests. Such clinical tests include, but are not limited to: the valgus stress test—or medial stress test, in which the surgeon holds the patient's femur and pushes or pulls the tibia; and the Lachman test, in which the patient's knee is flexed to about 20°, the surgeon holds the distal part of the femur with one hand and exerts an anterior traction of the tibia with the other hand.
- at the final constrained position, the position of the characteristic points is determined and recorded by the control unit. Said final constrained position can be indicated by the surgeon to the control unit for example by pressing a button or a pedal when he/she considers that said constrained position is representation of the effect of laxities and soft tissues.

Computation of Surgical Plan

Then, the surgical plan can be automatically computed by the control unit.

To that end, the control unit receives the target alignment parameter(s) input by the surgeon. For example, said target alignment parameters may be entered by the surgeon through a user interface coupled to the control unit. The target alignment parameter(s) can be determined by the surgeon as explained above, based on measurements on 2D or 3D X-ray images, or based on data provided by the surgical system. Alternatively, the target alignment parameter(s) can be set arbitrarily by the surgeon, based on his/her own experience and the clinical state of the art.

The surgeon can also decide the bone(s) to be cut and the number of cuts to be performed to achieve the desired correction. Indeed, for open-wedge osteotomy, the bone can typically be cut according to one or two planes (formed by one or two cuts, respectively). For closed-wedge osteotomy, the bone can typically be cut according to one or two planes (formed by two or three planes, respectively. However, the surgeon may choose to carry out a more complex osteotomy, requiring additional planes and cuts.

The surgeon can then input the type of osteotomy he intends to implement (open-wedged, closed-wedge or more complex) and the number of cutting planes (one plane, two planes or more complex). For a complex osteotomy, the surgeon can indicate on a model displayed by the user interface the location and geometry of the planes and cuts.

Based on the input type of osteotomy and number of bone cuts, on the target alignment parameter(s) and on the alignment parameter(s) measured in the constrained position, the control unit computes at least one correction parameter. Such a correction parameter generally corresponds to an amount of bone distraction or removal to achieve in order to obtain the desired alignment of the limb. More precisely, for each bone cut, the planning provides the geometry and the correction angle to be achieved:

- geometry and angle of the bone part to be removed by the osteotomy cut(s), in the case of a closed-wedge osteotomy;
- geometry and angle of the space created around the hinge that will appear during distraction in the case of an open-wedge osteotomy.

FIGS. **5**A-**5**C illustrate various shapes of the hinge h that can be obtained after cutting the bone and distracting the two sides S**1**, S**2** of the bone to create the space O. In the embodiment of FIG. **5**A, after cutting the bone with a saw, an additional drilling is made at the junction between the two sides S**1**, S**2** in order to form a tunnel h**1** having a circular cross section. In the embodiment of FIG. **5**B, the hinge is in the form of a line h**2** obtained at the junction of the two sides S**1**, S**2** cut by the saw. In the embodiment of FIG. **5**C, after cutting the bone with the saw, an additional milling is made at the junction between the two sides S**1**, S**2** in order to form a flat end surface h**3**. Additional shapes such as h**1** and h**3** may allow reducing the risk of breaking the bone remaining around the hinge. Of course, the skilled person may choose any other shape if more appropriate.

If the correction requires several bone cuts, the planning provides the geometry and correction angle for each bone cut.

The final alignment parameters that should be obtained after the surgical procedure that would take into account the contribution of laxity and soft tissues can be predicted by applying the computed correction parameter(s) on the leg.

The surgeon can validate the surgical plan or modify it based on his/her professional skills and experience. The modification of the surgical plan may be made through the user interface mentioned above.

Implementation of Surgical Gesture

Once the surgical plan has been finalized, the surgeon can carry out the surgical gesture in accordance with the surgical plan. To that end, he/she may be assisted by a robot, by the surgical system, and/or by intra-operative X-ray imaging. During the surgery, the mechanical constraints (e.g. valgus stress) may be maintained or released.

In any case, the surgeon may monitor in real time the progress of the surgical intervention, for example thanks to a screen coupled to the control unit and displaying the evolution of the current correction relative to the correction parameter for each bone cut.

In some embodiments, said evolution can be monitored using two trackers fixed to the bone being cut, on both sides of the cut. To that end, an additional femoral or tibial tracker is fixed to the bone, on the other side of the cut with respect to the previously mentioned femoral or tibial tracker (see examples in FIG. **3**). Based on localization data of said trackers, the control unit can determine in real time the relative position of both parts of the bone being cut.

In other embodiments, a mechanical device may be inserted within the cut, and be designed to expand or retract as the parts of the bone being cut are moved farther or closer to each other. Said mechanical device may include at least one sensor coupled to the control unit and configured to measure in real time an expansion or a retraction of the mechanical device.

FIG. **6** schematically illustrates an embodiment of such a medical device.

The mechanical device **100** comprises two plates **101**, **102** connected to a mechanical hinge **103**. The plates **101**, **102** are coupled to a body **104**. The plates are pivotable relative to each other about the mechanical hinge **103**.

The angle between the two plates **101**, **102** is precisely measured with an angle sensor **105** arranged in the body **104**. The measurement data from the sensor **105** is sent to the control unit **3**.

The mechanical device **100** further includes a tracker **106** belonging to the same localization system as the tibial and femoral trackers (that are not represented in FIG. **6** for sake of legibility of the figure). For example, the tracker **106** is an electromagnetic tracker and is linked to the control unit **3** in order to provide to the control unit localization data regarding the mechanical device **100** during its operation.

In case of closed-wedge osteotomy, the plates **101**, **102** are inserted into the resected bone wedge so that the mechanical hinge **103** coincides with the bone hinge h, in order to monitor how the bone is retracted. Indeed, closing the wedge about the hinge h causes the plates **101**, **102** to be moved toward each other, thereby decreasing the angle between the plates **101**, **102**, which is measured by the sensor **105**.

In case of open-wedge osteotomy, the plates **101**, **102** are inserted into the slot of the osteotomy bone cut, so that the mechanical hinge **103** coincides with the bone hinge h, in order to monitor how the bone is distracted. Indeed, distracting the bone parts about the hinge h causes the plates **101**, **102** to be moved away from each other, thereby increasing the angle between the plates **101**, **102**, which is measured by the sensor **105**.

Although illustrated in the tibia T in FIG. **6**, the mechanical device **100** may be used in a similar way in case of femoral osteotomy.

In other embodiments, two mechanical devices may be fixed to both parts of the bone being cut, and linked by an adjustable link that is designed to expand or retract as the parts of the bone being cut are moved farther or closer to each other. Said link may include at least one sensor coupled to the control unit and configured to measure in real time an expansion or a retraction of the link.

FIG. **7** schematically illustrates an embodiment of such mechanical devices.

The mechanical assembly **200** comprises a body **205** and two plates **202**, **204** connected to the body **205** by a hinge inside the main body.

Each plate **202**, **204** is rigidly fixed to a respective part of the bone (e.g. the tibia T) around the osteotomy cut by a pin **201**, **203** implanted into the bone.

The plates are movable relative to each other, thereby allowing moving the parts of the bone (and thus the pins **201**, **203**) closer or farther to each other about the hinge h.

The distance between the two pins **201**, **203** is precisely measured with a displacement sensor **206** arranged in the body **205**. The measurement data from the sensor **105** is sent to the control unit **3**.

The mechanical assembly **200** further includes a tracker **207** belonging to the same localization system as the tibial and femoral trackers (that are not represented in FIG. **7** for sake of legibility of the figure). For example, the tracker **207** is an electromagnetic tracker and is linked to the control unit **3** in order to provide to the control unit localization data regarding the mechanical assembly **200** during its operation.

In case of closed-wedge osteotomy, the mechanical assembly is fixed below and above the resected bone wedge, so as to monitor how the bone is retracted.

In case of open-wedge osteotomy, the mechanical assembly is fixed below and above the slot of the osteotomy bone cut, so as to monitor how the bone is distracted.

The mechanical devices may be used in a similar way in case of femoral osteotomy.

Verification of the Alignment Parameter(s)

The planned correction is monitored until the end of the surgical procedure. Before fixing the implant, a difference between the planned correction and the correction actually performed by the surgeon can be displayed.

If said difference is considered by the surgeon to be clinically acceptable, the surgeon can then proceed with the final positioning and fixation of the osteotomy implant.

If said difference is considered by the surgeon to be not clinically acceptable, the surgeon can then proceed to further bone distraction or removal, until the difference between the planned correction and the actual correction is considered to be acceptable.

When the planned bone distraction or removal has been achieved, but before fixing the osteotomy implant, the surgeon may also check the final alignment parameter(s). Hence, optionally, the surgeon applies the same mechanical constraints as previously and measures, thanks to the surgical system, the alignment parameter(s), preferably in all directions. The control unit then computes differences between the achieved alignment parameters and the target alignment parameters.

If said differences are considered by the surgeon to be clinically acceptable, the surgeon can then proceed with the final positioning and fixation of the osteotomy implant.

If said differences are considered by the surgeon to be not clinically acceptable, the surgeon can then proceed to further bone distraction or removal, until the final alignment parameter(s) achieve(s) the desired target.

Summary of the Osteotomy Procedure

The osteotomy procedure is summarized in the flow chart of FIG. **8**.

In step **100**, input parameters are entered by the surgeon into the surgical system via the user interface to be used as input for the intra-operative step.

As mentioned above, the input parameters can include in particular:

- the bone(s) to be cut (tibial osteotomy, femoral osteotomy, or double level osteotomy),
- the type of osteotomy (open-wedged, closed-wedge or more complex),
- the number of cuts,
- one or more target alignment parameter(s).

In step **200**, characteristic points of the tibia and/or the femur are defined and localized such that the position of said characteristic points in the coordinate system of at least one tracker is known.

In step **300**, the surgeon manipulates the leg to apply mechanical constraints so as to bring the lower limb in a constrained position simulating laxities and/or soft tissues influence. The position of the characteristic points in the constrained position of the leg is determined and recorded by the control unit. Alignment parameters are computed from the monitoring of said characteristic points and recorded by the control unit.

In step **400**, the surgical plan is computed. Said surgical plan can be automatically computed based on the target alignment parameter(s) given by the surgeon. Based on the target alignment parameter(s) and on the alignment parameter(s) measured in the constrained position, the control unit computes at least one correction parameter. Such a correction parameter generally corresponds to an amount of bone distraction or removal to achieve in order to obtain the desired alignment of the limb. More precisely, for each bone cut, the planning provides the geometry and the correction angle to be achieved.

In step **500**, the surgical gesture is carried out. The osteotomy cut(s) is(are) done to achieve bone distraction or bone removal, depending on the type of correction decided by the surgeon. The surgeon may monitor in real time the progress of the surgical intervention, e.g. the evolution of the at least one correction parameter.

In step **600**, which is optional, the surgeon may check the corrected alignment of the leg. At a fixed bone distraction position or bone closure position, updated measurement of the alignment parameter(s), in free or constraint position, can be displayed.

In step **700**, the bone distraction or closure is fixed with a dedicated osteotomy implant when target alignment parameters are reached or when the surgeon decides the correction is achieved.

FIGS. **9**A to **9**E illustrate examples of a screen of the user interface at successive stages of the method.

FIG. **9**A represents the screen in an initial step of the intraoperative procedure, comprising the entry of target alignment parameters in a region P of the screen (see step **100** of the flow chart of FIG. **7**). In the illustrated example, two target alignment parameters P**1**, P**2** are set, that can each be expressed as an angle (unit: °) or as a distance (unit: mm). Of course, only one target alignment parameter, or more than two target alignment parameters could be set. Besides, the target alignment parameter(s) can be expressed in any other suitable unit, such as % for example.

FIG. **9**B represents the screen in a further stage of the intraoperative procedure, in which the position of the characteristic points in the constrained position of the leg has been determined and recorded by the control unit, and the alignment parameter(s) have been calculated based on the position of the characteristic points at this constraint position (see steps **200** and **300** in the flow chart of FIG. **8**). The alignment parameters are displayed in a region A of the screen, distinct from the region P. In this way, the surgeon can see simultaneously the target alignment parameters and the measured alignment parameters. In the illustrated example, three alignment parameters A**1**, A**2**, A**3** are displayed, that can each be expressed as an angle (unit: °) or as a distance (unit: mm). Of course, only one or two alignment parameters, or more than three alignment parameters could be computed and displayed. As mentioned above, the target alignment parameter(s) can be expressed in any other suitable unit, such as % for example.

FIG. **9**C represents the screen in a further stage of the intraoperative procedure, in which the control unit has computed at least one correction parameter (corresponding to step **400** in the flow chart of FIG. **8**). Such a correction parameter generally corresponds to an amount of bone distraction or removal to achieve in order to obtain the desired alignment of the limb. More precisely, for each bone cut, the planning provides the geometry and the correction angle to be achieved. The correction parameters are displayed in a region C of the screen, distinct from regions P and A. In this way, the surgeon can see simultaneously the target alignment parameters, the measured alignment parameters and the correction parameters. In the illustrated example, four correction parameters are displayed, two parameters $C_{coronal}$ and $C_{sagittal}$ expressed as angles (in °) and two parameters C_3, C_4 expressed as distances (in mm). Of course, additional and/or different correction parameters could be computed and displayed.

Advantageously, the volume of bone to be distracted or removed is computed by the control unit and displayed on the screen as a volume V that has a substantially wedge shape. The geometry of said volume V is correlated with the

correction parameters; in particular, each correction parameter can be a geometric feature of the volume, such as a length of a side of the volume or an angle between two sides or faces of the volume. Generally, it is possible to establish a relationship between angles and distances. Thus, if the volume is defined by angle values, one can also define the volume by distance (e.g. length, width, height) values, and conversely.

FIG. **9**D represents the screen at a further stage of the intraoperative procedure, during the surgical gesture (see step **500** in the flow chart of FIG. **7**). During the realization of the osteotomy cuts, bone distraction or bone removal, the surgeon may monitor in real time the progress of the surgical intervention, e.g. the evolution of the at least one correction parameter and the corresponding alignment parameters. In the illustrated example, the current correction parameters, as measured in real time, are displayed in a region MC of the screen, and the corresponding current alignment parameters are displayed in another region MA of the screen, distinct from the region MC.

Advantageously, the control unit also computes in real time the geometry of the volume of bone being distracted or removed, and displays it on the screen as a current volume VC superimposed with the target volume V. In this way, the surgeon can visualize easily a degree of progress of the opening or closing of the osteotomy.

FIG. **9**E represents the screen at the end of the surgical gesture, when the target alignment parameters have been achieved. In such situation, the control unit warns the surgeon by displaying the current correction parameters and alignment parameters with a specific color, e.g. green (schematically represented by the grey background) when they have reached the target value. Besides, the surgeon can observe that the current volume VC coincides with the target volume V.

Of course, the illustration of the screen in FIGS. **9**A to **9**E is only given as an example and any other aesthetic or functional way of displaying information allowing the user to monitor the progress of the osteotomy procedure could be used without departing from the scope of the present disclosure.

As compared to the method of [Kim et al], the method described above allows computing correction parameters suited to the leg in the intraoperative position but taking into account laxities and influence of soft tissues, and monitoring in real time the progress of the surgical gesture. In this way, a correct alignment of the leg can be achieved directly, without the need to rework the bone to adjust the correction and remedy to an over- or under-correction of the alignment.

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The invention claimed is:

1. A method for guiding an osteotomy procedure on at least one bone selected from a tibia and a femur pertaining to a patient's lower limb to correct a misalignment of said lower limb, wherein a tibial tracker is fixed to the tibia and a femoral tracker is fixed to the femur, comprising:

receiving at least one target alignment parameter of the lower limb;

determining a position of a set of characteristic points on at least one of the tibia and the femur relative to at least one of the tibial tracker and the femoral tracker;

applying mechanical constraints to the lower limb to bring the lower limb in a constrained position simulating laxities and/or soft tissues influence

tracking positions of said characteristic points relative to at least one of the tibial tracker and the femoral tracker based on localization data of the set of characteristic points during application of said mechanical constraints,

determining at least one alignment parameter of the lower limb in said constrained position, based on the positions of the characteristic points;

receiving at least one input comprising at least one of: at least one bone among the tibia and the femur in which a hinge has to be formed by an osteotomy cut, a type of osteotomy to be implemented, and a number of osteotomy cuts to be performed;

based on the at least one input, on the at least one target alignment parameter and on the at least one alignment parameter of the lower limb in the constrained position, computing a surgical plan by determining at least one correction parameter of the osteotomy procedure to be applied to the lower limb to achieve the target alignment parameter.

2. The method according to claim **1**, further comprising carrying out the osteotomy procedure, said procedure comprising performing at least one osteotomy cut into the bone so as to form a hinge connecting two sides of the bone and moving said sides around the hinge.

3. The method according to claim **2**, further comprising monitoring an evolution of the at least one alignment parameter based on localization data of the set of characteristic points during the osteotomy procedure.

4. The method according to claim **2**, further comprising determining, based on the at least one target alignment parameter and localization data of the set of characteristic points during the osteotomy procedure, whether each target alignment parameter is achieved.

5. The method according to claim **2**, further comprising monitoring an evolution of a geometric feature of a volume being removed or created by the at least one osteotomy cut relative to the at least one correction parameter.

6. The method according to claim **2**, further comprising:

fixing an additional tibial or femoral tracker to the bone so that two tibial or femoral trackers are fixed to the bone on both sides of the osteotomy cut; and

computing an evolution of the osteotomy cut based on localization data of said two tibial or femoral trackers.

7. The method according to claim **1**, further comprising displaying each alignment parameter and/or correction parameter.

8. The method according to claim **7**, further comprising displaying an indication that the at least one target alignment parameter is achieved.

9. The method according to claim 1, wherein the at least one target alignment parameter comprises at least one of: a mechanical femorotibial angle (mFTA), a mechanical medial proximal tibial angle (mMPTA), a mechanical lateral distal femoral angle (mLDFA), a lateral tibial plateau inclination (LTPI), a medial tibial plateau inclination (MTPI), a hip-knee-ankle angle (HKA), a joint line convergence angle (JLCA), a posterior tibial slope (PTS), a hip abduction angle (HAA), a tibial plafond inclination (TPI), a talar inclination angle (TIA), a lateral patellar tilt (LPT) and a lateral patellar shift (LPS).

10. The method according to claim 1, wherein the position of the set of characteristic points on at least one of the tibia and the femur relative to at least one of the tibial tracker and the femoral tracker is determined based on at least one of the following methods:

segmenting at least one 2D and/or 3D medical image of the patient's limb and determining the set of reference characteristic points on said segmented image;

adjusting a bone model comprising the set of characteristic points to the tibia or femur in at least one 2D and/or 3D image of the patient's limb using a bone morphing technique;

obtaining localization data of a pointer tracker fixed to a pointer palpating characteristic points on the tibia and/or the femur; and

obtaining localization data of the femoral and tibial trackers as a user moves the limb about at least one joint.

11. The method of claim 1, further comprising acquiring 2D images of the lower limb of the patient and determining the at least one target alignment parameter based on 2D X-ray images.

12. A system for guiding an osteotomy procedure on at least one bone selected from a tibia and a femur pertaining to a patient's lower limb to correct a misalignment of said lower limb according to the method of claim 1, wherein a tibial tracker is fixed to the tibia and a femoral tracker is fixed to the femur, said system comprising a control unit configured to be coupled to a localization system adapted to track a position and orientation of the tibial tracker and the femoral tracker, wherein the control unit is configured to:

receive at least one target alignment parameter of the lower limb provided by a user;

determine a position of a set of characteristic points on the tibia and/or the femur relative to the tibial tracker and/or the femoral tracker;

track the positions of said characteristic points relative to the tibial tracker and/or the femoral tracker based on localization data of the set of characteristic points during application of mechanical constraints by the user to bring the lower limb in a constrained position simulating laxities and/or soft tissues influence,

determine at least one alignment parameter of the lower limb in said constrained position, based on the positions of the characteristic points;

receive at least one input comprising at least one of: at least one bone among the tibia and the femur in which a hinge has to be formed by an osteotomy cut, a type of osteotomy to be implemented, and a number of osteotomy cuts to be performed;

based on the at least one input, on the at least one target alignment parameter and on the at least one alignment parameter of the lower limb in the constrained position, compute a surgical plan by determining at least one correction parameter of the osteotomy procedure to be applied to the lower limb to achieve the target alignment parameter.

13. The system according to claim 12, wherein the control unit is configured to monitor an evolution of the at least one alignment parameter based on localization data of the set of characteristic points during the osteotomy procedure.

14. The system according to claim 13, wherein the control unit is further configured to determine, based on the at least one target alignment parameter and localization data of the set of characteristic points during the osteotomy procedure, whether each target alignment parameter is achieved.

15. The system according to claim 12, wherein the control unit is further configured to monitor an evolution of a geometric feature of a volume being removed or created by an osteotomy cut relative to the at least one correction parameter.

16. The system according to claim 15, wherein an additional tibial or femoral tracker is fixed to the bone so that two tibial or femoral trackers are fixed to the bone on both sides of the osteotomy cut and the control unit is configured to compute the evolution of the osteotomy cut based on localization data of said two trackers.

17. The system according to claim 15, further comprising a mechanical device adapted to be inserted within the osteotomy cut and designed to expand or retract as the sides of the cut are moved farther or closer to each other, and at least one sensor coupled to the control unit and configured to measure in real time an expansion or a retraction of the mechanical device, wherein the control unit is configured to compute the evolution of the osteotomy cut based on measurement data from said at least one sensor.

18. The system according to claim 15, further comprising two mechanical devices adapted to be fixed to sides of the osteotomy cut, an adjustable link connecting said mechanical devices and designed to expand or retract as the sides of the cut are moved farther or closer to each other, and at least one sensor coupled to the control unit and configured to measure in real time an expansion or a retraction of the adjustable link, wherein the control unit is configured to compute the evolution of the osteotomy cut based on measurement data from said at least one sensor.

19. The system according to claim 12, further comprising a user interface coupled to the control unit and configured to display each alignment parameter and/or correction parameter.

20. The system according to claim 19, wherein the user interface is further configured to display an indication that the at least one target alignment parameter is achieved.

21. The system according to claim 12, wherein the at least one target alignment parameter comprises: a mechanical femorotibial angle (mFTA), a mechanical medial proximal tibial angle (mMPTA), a mechanical lateral distal femoral angle (mLDFA), a lateral tibial plateau inclination (LTPI), a medial tibial plateau inclination (MTPI), a hip-knee-ankle angle (HKA), a joint line convergence angle (JLCA), a posterior tibial slope (PTS), a hip abduction angle (HAA), a tibial plafond inclination (TPI), a talar inclination angle (TIA), a lateral patellar tilt (LPT) and/or a lateral patellar shift (LPS).

22. The system according to claim 12, wherein the at least one correction parameter comprises a geometric feature of a bone part to be removed from the tibia and/or femur and a geometric feature of a space created around a hinge formed by an osteotomy cut to appear during distraction of bone sides around the hinge.

23. The system according to claim 12, wherein the control unit is configured to determine the position of the set of characteristic points on the tibia and/or the femur relative to

the tibial tracker and/or the femoral tracker based on at least one of the following methods:

segmenting at least one 2D and/or 3D medical image of the patient's limb and determining the set of reference characteristic points on said segmented image;

adjusting a bone model comprising the set of characteristic points to the patient's tibia or femur in at least one 2D and/or 3D image of the patient's limb using a bone morphing technique;

obtaining localization data of a pointer tracker fixed to a pointer palpating characteristic points on the tibia and/or the femur; and

obtaining localization data of the femoral and tibial trackers as a user moves the limb about at least one joint.

24. The system according to claim **12**, wherein the control unit is configured to be coupled to an X-ray imaging system adapted to acquire 2D and/or 3D images of the lower limb of the patient.

25. A method for carrying out an osteotomy procedure on at least one bone selected from a tibia and a femur pertaining to a patient's lower limb to correct a misalignment of said lower limb, wherein a tibial tracker is fixed to the tibia and a femoral tracker is fixed to the femur, comprising:

receiving at least one target alignment parameter of the lower limb;

determining a position of a set of characteristic points on at least one of the tibia and the femur relative to at least one of the tibial tracker and the femoral tracker;

applying mechanical constraints to the lower limb to bring the lower limb in a constrained position simulating laxities and/or soft tissues influence

tracking positions of said characteristic points relative to at least one of the tibial tracker and the femoral tracker based on localization data of the set of characteristic points during application of said mechanical constraints,

determining at least one alignment parameter of the lower limb in said constrained position, based on the positions of the characteristic points;

based on the at least one target alignment parameter and on the at least one alignment parameter of the lower limb in the constrained position, determining at least one correction parameter of the osteotomy procedure to be applied to the lower limb to achieve the target alignment parameter,

performing at least one osteotomy cut into the bone so as to form a hinge connecting two sides of the bone and moving said sides around the hinge.

26. The method according to claim **25**, further comprising monitoring an evolution of the at least one alignment parameter based on localization data of the set of characteristic points during the osteotomy procedure.

27. The method according to claim **25**, further comprising determining, based on the at least one target alignment parameter and localization data of the set of characteristic points during the osteotomy procedure, whether each target alignment parameter is achieved.

28. The method according to claim **25**, further comprising monitoring an evolution of a geometric feature of a volume being removed or created by the at least one osteotomy cut relative to the at least one correction parameter.

29. The method according to claim **25**, further comprising:

fixing an additional tibial or femoral tracker to the bone so that two tibial or femoral trackers are fixed to the bone on both sides of the osteotomy cut; and

computing an evolution of the osteotomy cut based on localization data of said two tibial or femoral trackers.

30. The method according to claim **25**, further comprising:

inserting a mechanical device into the osteotomy cut and expanding or retracting said mechanical device as a user moves the sides of the osteotomy cut farther or closer to each other;

measuring in real time an expansion or a retraction of the mechanical device by at least one sensor; and

computing an evolution of the osteotomy cut based on measurement data from said at least one sensor.

31. The method according to claim **25**, further comprising:

fixing two mechanical devices to both sides of the osteotomy cut, said mechanical devices being connected by an adjustable link;

expanding or retracting the adjustable link as a user moves the sides of the cut farther or closer to each other;

measuring in real time an expansion or a retraction of the adjustable link by at least one sensor; and

computing an evolution of the osteotomy cut based on measurement data from said at least one sensor.

32. The method according to claim **25**, wherein the at least one correction parameter comprises a geometric feature of a part to be removed from the bone to form the hinge and a geometric feature of a space created around the hinge to appear during distraction of the bone sides.

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