Title: METHOD OF USING A COMPUTING DEVICE FOR PROVIDING A DESIGN OF AN IMPLANT

Abstract: A patient-specific implant, based on a bottom-up approach, treats patients with bone defects. The defect bone is reconstructed. In the configuration step, parameters that influence fixation of the implant are calculated. Specifications of the surgeon may be incorporated to steer the implant configurations. Different configuration proposals are calculated with different values for a first number of parameters. Via the evaluation step, different implant geometries are numerically simulated to determine the biomechanical impact and strength of the implant. A suitable implant design is chosen if it meets certain quality criteria. If the implant design fails to meet the quality criteria, the number of parameters calculated for creating different configuration proposals is iteratively increased in an optimization process, and evaluation is repeated to find a suitable implant design. This optimization process continues until an implant configuration is found that complies with implant quality criteria and the surgeon's specifications.

FIG. 1
Method of using a computing device for providing a design of an implant

The present invention relates to a method of using a computing device for providing a design of an implant to treat a defect in a bone. The invention further relates to a non-transitory computer readable medium comprising instructions that when executed by a computing device, cause the computing device to perform the method and a computing device arranged to perform the method.

Procedures for treating bone defects, such as, for example, hip revision surgeries are becoming more common, as the general population ages and younger patients become more demanding with regard to the need for improved quality of life as they age. Larger bone defects may be treated using patient specific approaches including highly customized implants. However, smaller bone defects are currently treated with standard components, such as non-customized implants, with no or minimal preoperative planning. Unfortunately, though not as complex, treatment using standard components results in sub-optimal treatment of bone defects. Despite this issue, highly customized implants for small bone defects are not currently used because the time, complexity, and cost of current patient-specific approaches do not justify the possible better outcome. For example, current patient specific approaches may require significant manual intervention for the design of the implant (e.g., manual characterization of the bone defect, manual configuration of implant parameters such as placement, size, shape, etc.) making the process labor intensive. Accordingly, techniques for better treating bone defects that can reduce time, complexity, and cost are needed.

Extensive planning is currently needed in order to design custom implants. Computer-aided design techniques, such as statistical shape models ("SSM"), may be used to help in the planning process for custom implant design in order to treat bone defects. For example, SSM may be used in automatic segmentation methods and 3D representations using X-Ray images. Further, the use of SSM to virtually reconstruct bone defects, though still an uncommon application, has shown promising results in studies detailing different SSM-based reconstruction methods. For example, utilizing gender-specific SSMs to reconstruct pelvic bones with oncologic defects has in some cases led to improved outcomes including a faster created and more objective base from which to design an implant. Such SSM-based reconstruction methods can be useful for helping to automate reconstruction of bone defects to form a model of the bone defect (e.g., digital model). Using the model the surgeon and/or implant designers can more quickly design an implant. This still, however, requires significant manual configuration for design of the implant itself.

The current SSM reconstruction methods alone have not solved the current issues with bone defect treatment methods. There remains an unmet need for a bone defect treatment method that reduces
design time for customized implants while also providing a unique implant fit, improving implant fixation, and improving initial mechanical stability to provide a long-term optimal biological fixation (bone ingrowth), as compared to methods using standard implant components.

It is therefore a goal, amongst other goals, of the present invention to provide an improved method for designing and preferably manufacturing an implant and/or to provide an improved implant. This goal, amongst other goals, is met by a method according to claim 1. More specifically, this goal, amongst other goals, is met by a method of using a computing device for providing a design of an implant to treat a defect in a bone, the method comprising:

- generating one or more implant configurations of a patient-specific implant for optimization; and
- performing, on the computing device, a simulation implant process for each of the one or more implant configurations to generate one or more results;
- evaluating the one or more results to determine whether each of the one or more implant configurations complies with a quality criteria; and
- selecting, based on an optimization criteria, an optimum implant configuration from the one or more implant configurations that comply with the quality criteria as the design of the implant.

According to the invention, a plurality of implant configurations are generated, preferably in an automated manner, wherein these multiple configurations may be generated to have at least one different parameter value from each other, for instance in terms of parameters of the implant that influence implant fixation. These generated configurations are subsequently analysed by simulation, such that each of the configurations can be evaluating. An optimum implant configuration can be selected on the basis of these results, wherein the selected configuration can be selected as the design for the implant, or can be used as starting point for the design of an implant.

An implant configuration is preferably at least partially representative for a design of an implant. An implant configuration may for instance contain the digital three-dimensional design of the device and/or may describe the device in more general terms using configuration parameters. Based on these parameters, for instance in combination medical images as will be explained later on, a design of the device can be generated, and preferably in automated form. Each of the one or more implant configurations is hereby preferably defined by one or more parameters comprising one or more of the following: implant screw length, screw diameter, screw orientation, and screw
position. These parameters and their values may be used as part of creating a design (e.g., 3D CAD model of an implant).

According to a preferred embodiment, generating one or more implant configurations comprises:

- generating a first set of implant configurations having a first complexity; and
- generating a second set of implant configurations having a second complexity that is greater than the first complexity based on each of the first set of implant configurations failing to meet the quality criteria. At first, implant configurations having relative low complexities are generated. If these configurations however fail to meet the requirements, the complexity of the configurations is increased. This prevents creating needlessly complex implant configurations, while ensuring the quality thereof. Preferably, the complexity comprises at least one of: a number of screws, a span of the implant configuration, and an amount of congruency surface.

A reliable evaluating of the implant configurations is obtained if according to a further preferred embodiment, the quality criterion is at least one of: a fatigue threshold of a material of the implant, a maximum stress in a bone, a minimum stress in the bone, and a maximum implant micromotion.

According to a further preferred embodiment the one or more implant configurations are generated based on at least one of the following design constraints: surgical window, muscle insertions, screw-screw intersections, cup positioning, cup insertion, and surgical preference. This ensures that the generated configuration meet the requirements for the intended use and thereby limits the number of generated configurations, thereby increasing the efficiency of the method.

A reliable selection of an optimal configuration is obtained if the optimization criteria comprises at least one of: a measure of implant fixation, an optimal screw length, an optimal fixation potential, an optimal shape, and an optimal congruence to a bone.

A particularly reliable selection is obtained if the optimization criteria comprises the measure of implant fixation comprising an amount of implant displacement. Implant displacement is an important factor having a large impact on the success rate of the treatment of the bone defect using an implant.

The displacement can for instance be predicted on the basis of a simulation of displacements of the implant in implanted situation. This simulation may for instance include Finite Elements Analysis (FEA) using a model of the implant and the bone onto which the implant is to be connected. The model of the implant may be based on the implant configuration, while the model of the bone may
be based on medical images of the bone. The implant may then be subjected to loading conditions mimicking the situation in daily life to estimate the implant displacement.

The step of providing a three-dimensional model of the bone comprises the step of obtaining an image of the bone and defect therein. Digital patient-specific image information can be provided 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.

For example, the step of obtaining an image of the bone and the defect therein may for example comprise the steps of obtaining 2D datasets of the bone and reconstructing a 3D virtual bone model from said 2D datasets. Indeed, the first step in a planning is the construction of a 3D virtual model of the bone. This reconstruction starts with sending a patient to a radiologist for scanning, e.g. for a scan that generates medical volumetric data, such as a CT, MRI scan or the like. The output of the scan can be a stack of two-dimensional (2D) slices forming a 3D data set. The output of the scan can be digitally imported into a computer program and may be converted using algorithms known in the field of image processing technology to produce a 3D computer model of a relevant bone. Preferably, a virtual 3D model is constructed from the dataset using a computer program such as Mimics(TM) as supplied by Materialise N.V., Leuven, Belgium. Computer algorithm parameters are based on accuracy studies, as for instance described by Gelaude at al. (2008; Accuracy assessment of CT-based outer surface femur meshes Comput. Aided Surg. 13(4): 188- 199). A more detailed description for making a perfected model is disclosed in U.S. Patent No. 5,768, 134 entitled 'Method for making a perfected medical model on the basis of digital image information of a part of the body'. The three-dimensional model of the bone is reconstructed for instance as disclosed in Gelaude et al. (2007; Computer-aided planning of reconstructive surgery of the innominate bone: automated correction proposals Comput. Aided Surg. 12(5): 286-94).

As an alternative, it is possible to us a spring model. Therefore, according to a further preferred embodiment, the simulation implant process comprises:

- characterizing each of the one or more implant configurations based on a spring model; and
- estimating a total displacement of each of the one or more implant configurations based on the spring model, wherein the displacement is iteratively calculated by adjusting one or more spring constants of the spring model based on whether tension or compression is allowed for one or more springs associates with the one or more spring constants.
To allow efficient customization to the bone of the patient having the defect, a further preferred embodiment of the method according to the invention further comprises:

- obtaining a medical image of the bone;
- segmenting the bone based on the medial image;
- reconstructing the bone as a model based on the segmented bone, wherein at least one of generating the one or more implant configurations and the simulation implant process is based on the reconstructed bone model. The medical image is preferably a volumetric medical image.

A particularly reliable reconstruction is obtained if the reconstructing is performed using statistical shape modelling (SSM). For creating such a SSM, a model set of healthy bones, (e.g., hemipelvises) may be collected. For example, a database of images of healthy bones may be generated by taking images of patients with healthy bones. In some embodiments, the database may include both male and female patients. The database may be generated to account for natural variations in bones among different groups of individuals such as by age, gender, race, etc. The images may then be segmented into segmentation masks. For example, segmentation of volumetric images in the form of CT-scans may be performed using Mimics software made by Materialise NV, Belgium as mentioned above for the generation of the thee-dimensional models. From the segmentation masks, a triangular mesh may be calculated, for example, using the Marching Cubes algorithm. The triangular meshes may be remeshed, for example, in 3-Matic software by Materialise NV, Belgium to obtain a smooth and uniform triangulation.

Preferably, to create an SSM that captures shape variations of bones, all entities of the model set need to have corresponding points. For triangular meshes, this means that vertices on similar anatomic regions need to be corresponding and that the number of vertices in each mesh is equal (i.e., the corresponding point problem). After fulfilling these two conditions an SSM is calculated using principal component analysis ("PCA"). In some embodiments, the corresponding point problem is solved using the template based method. The method comprises registering a template (e.g., one data entry) to all the meshes of the dataset. The transformed template meshes are then used directly to build up the data matrix for PCA. The registration may be done using a combination of manually indicated anatomical features (e.g., landmarks and ridges) and an iterative nonlinear morphing algorithm based on a thin plate splines (TPS) kernel.

In some embodiments, the SSM may be directly fitted to the healthy parts of the patient's bone. The parameters of the SSM may therefore be varied to minimize the distance from the patient's bone to the sample of the SSM. The idea behind this approach is that the remaining healthy parts of
the patient's bone are predictors for the missing anatomical parts. In some embodiments, before fitting the SSM to the bone anatomy, a defect part of the bone may be manually cut out or automatically detected. Disregarding the defect part guarantees that the shape of the SSM may be fitted as close as possible to the remaining healthy parts of the bone. For example, in some embodiments, a rigid iterative closest point registration (ICP) with the mean SSM-shape is used to initialize the SSM-fit using the healthy parts of the patient's bone. Afterwards, in some embodiments, the fitting process is performed, which optimizes the distance from each point in the patient's bone to the sample of the SSM by varying the different modes of variation one by one. For each mode of variation, a bisection algorithm is used to find the minimum distance from the patient's bone to the SSM-sample. After calculating the minimum distance of each mode of variation, a rigid ICP registration optimizes the translation and rotation of the SSM-fit.

A further preferred embodiment of the method according to the invention further comprises the step of manufacturing an implant based on the optimum implant configuration. To be able to reliably and accurately manufacture the implant in accordance with the design thereof, the step of manufacturing preferably comprises using a three-dimensional printing technique, also referred to as rapid manufacturing technique, layered manufacturing technique, additive manufacturing technique or material deposition manufacturing technique.

Rapid manufacturing includes all techniques whereby an object is built layer by layer or point per point by adding or hardening material (also called free-form manufacturing). The best known techniques of this type are stereo lithography and related techniques, whereby for example a basin with liquid synthetic material is selectively cured layer by layer by means of a computer-controlled electromagnetic beam; selective laser sintering, whereby powder particles are sintered by means of an electromagnetic beam or are welded together according to a specific pattern; fused deposition modelling, whereby a synthetic material is fused and is stacked according to a line pattern; laminated object manufacturing, whereby layers of adhesive-coated paper, plastic, or metal laminates are successively glued together and cut to shape with a knife or laser cutter; or electron beam melting, whereby metal powder is melted layer per layer with an electron beam in a high vacuum.

In particular embodiments, Rapid Prototyping and Manufacturing (RP&M) techniques are used for manufacturing the implant of the invention. Rapid Prototyping and Manufacturing (RP&M) can be defined as a group of techniques used to quickly fabricate a physical model of an object typically using three-dimensional (3-D) computer aided design (CAD) data of the object. Currently, a multitude of Rapid Prototyping techniques is available, including stereo lithography (SLA),
Selective Laser Sintering (SLS), Fused Deposition Modeling (FDM), foil-based techniques, etc. A common feature of these techniques is that objects are typically built layer by layer.

Stereo lithography (SLA), a common RP&M technique, utilizes a vat of liquid photopolymer "resin" to build an object a layer at a time. On each layer, an electromagnetic ray, e.g. one or several laser beams which are computer-controlled, traces a specific pattern on the surface of the liquid resin that is defined by the two-dimensional cross-sections of the object to be formed. Exposure to the electromagnetic ray cures, or, solidifies the pattern traced on the resin and adheres it to the layer below. After a coat had been polymerized, the platform descends by a single layer thickness and a subsequent layer pattern is traced, adhering to the previous layer. A complete 3-D object is formed by this process.

Selective laser sintering (SLS) 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 (FDM) 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 RP&M techniques start from a digital representation of the 3-D object to be formed, in this case the design of the implant. 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 RP&M 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 implant of the invention may be manufactured in different materials. Typically, only materials that are biocompatible (e.g. USP class VI compatible) with the human body are taken into account. Preferably the implant is formed from a heat-tolerable material allowing it to tolerate high-temperature sterilization. In the case SLS is used as a RP&M technique, the implant 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.

The invention further relates to a non-transitory computer readable medium comprising instructions that when executed by a computing device, cause the computing device to perform the method according to the invention.

The invention further relates to a computing device comprising:
- a memory; and
- a processor coupled to the memory, the processor being configured to execute the method according to the invention.

The present invention is further illustrated by the following Figures, which show a preferred embodiment of the device according to the invention, and are not intended to limit the scope of the invention in any way, wherein:

- Figure 1 illustrates a flowchart of an example process for a bottom-up approach to custom implant design.
- Figure 2A illustrates a graphical example of a top-down approach to custom implant design.
- Figure 2B illustrates a graphical example of a bottom-up approach to custom implant design as shown in Figure 1.
- Figure 3 illustrates a schematic example of a spring model for implant fixation that can be used for custom implant design according to the process of Figure 1.
- Figure 4A illustrates a finite element model for a screw in the spring model of Figure 3.
- Figure 4B illustrates a finite element model for a contact in the spring model of Figure 3.
- Figure 5 illustrates one example of a system for designing and manufacturing an implant designed using the process of Figure 1.
- Figure 6 illustrates a more detailed view of a computer of the system of Figure 5.
- Figure 7 illustrates a general process for manufacturing an implant, designed using the process of Figure 1, using an additive manufacturing apparatus of Figure 5.

Traditionally, patient-specific implants have been created using a top-down approach to implant design. A top-down approach targets the most complex bone defects and are designed using significant manual intervention. In particular, an implant designer (e.g., technician and/or surgeon) may use analyzing tools (e.g., bone quality map) to help characterize the defect. Using that
characterization, the implant designer then manually designs/ selects all the various parameters of the implant (e.g., screw position). This manual top-down approach works, for example, for larger bone defects that are extremely complex, so the number of different implant designs and parameters considered for those designs may be constrained based on the fact that only a small number of designs would fit the complex bone defect. This top-down approach is typically ill-suited for fully automated implant design for smaller defects where many different designs and parameters need to be considered, as by starting with maximal complexity, the number of parameters that need to be optimized becomes uncontrollable as the search space (i.e., choice set) for each parameter value may be too large and it would be difficult to determine manually among all the design choices, which one is best as manual qualitative judgment may not give that answer.

Described herein are unique embodiments of a bottom-up approach, which is better suited for automated custom implant design, because it gradually builds complexity and allows for the number of parameters and the size of the search space (e.g., number of candidate solutions for each parameter) to be controlled. Figure 1 is a high level flow chart showing an example process 100 for a bottom-up approach to implant design, which may be used for different types of implants (e.g., hip joint). In some embodiments, the process 100 is performed on a computing device. The process begins at block 102, where one or more medical images (e.g., volumetric images, 3D images based on a biplanar x-ray, etc.) are obtained from a patient. Typically, the medical images of the patient take the form of CT-scans or MRI scans, although other types of scans may be used. Next, the process moves to block 104, where a 3D surface model of the pathological (i.e., defective) bone is segmented. Typically, the defective bone contains a defect due to bone loss, bone malunion, or fracture, but other bone defects may be present and observed.

Using a reconstruction algorithm, the defective bone is reconstructed as a model (e.g., digital model, triangular mesh, STL file, mathematical model, etc.), for example, in some embodiments, using healthy contralateral, a database of healthy bones, or a mathematical model of healthy bones. This reconstruction is shown at block 106, and it may serve as the base for eventual automatic configuration determination (i.e., design) of the implant and determination of the position and orientation of the screws or other fixation means for fixing the implant in the patient (e.g., to the bone of the patient). For example, the reconstructed model of the bone defect may be defined by or itself be indicative of certain properties of the patient's bone such as bone thickness, cortical thickness, etc. In some embodiments, the defective bone is reconstructed using SSM.

The process then moves to block 108, where multiple configurations for the implant design are generated automatically. These multiple configurations may be generated to have at least one (but
sometimes more than one) different parameter value from each other for parameters of the implant that influence implant fixation. In some embodiments, such parameters may include one or more of implant screw length, screw diameter, screw orientation (e.g., angle screw is placed in 3D space), screw position (e.g., area in 3D space in which screw is inserted), cup position, cup orientation, congruency, shape of the implant, guide stability on a bone surface, and other parameters of the implant. These parameters and their values may be used as part of creating an implant model/design (e.g., 3D CAD model of an implant).

In some embodiments, the number of parameters considered at block 108 (i.e., calculated to have different parameter values for each of the multiple configurations) starts small (e.g., 1 or 2 parameters) for a first pass at the implant design and is increased if a suitable implant design is not found using the initial number of parameters. For example, an additional 1 or 2 parameters may be considered on a second pass at generating multiple configurations for the implant design. The number of parameters considered my increase with each pass until a suitable implant design is found as discussed further herein. The increase in the number of parameters considered, is an increase in complexity of the implant design. In some embodiments, the number of parameters considered may include the number of flanges, number of features, span of the device, an amount of congruency surface, and/or the number of fixation means such as screws considered for the implant design.

The parameter values for each of the multiple configurations may be calculated based on certain properties, such as those discussed herein, of the reconstructed model of the patient's bone. For example, in some embodiments, a cup position/orientation may be initialized by using an analysis based on the patient-specific musculoskeletal model, the leg length difference, the defect geometry, and/or contralateral cup properties.

These parameters values for each of the multiple configurations for the implant design may also incorporate and/or consider one or more design constraints specified or provided by a third party such as the surgeon performing the procedure, for example. In particular, the parameter values may be restricted to certain values based on such design constraints. In some embodiments, the design constraints may include one or more of the following: surgical window, muscle insertions, screw-screw insertions, cup positioning, cup insertion, and other surgical preferences.

In some embodiments, the parameter values for each of the multiple configurations of the implant design may be calculated using known software and/or mathematical techniques such as algorithms related to computer graphics and mathematical solid geometry. For example, in some
embodiments, a ray intersection algorithm may be used where rays are defined in many different directions starting from possible screw insertion points for the implant design. For each ray, the point where the ray comes out of the bone is calculated. This calculation gives information about possible screw length in the direction of each ray. One example a ray intersection algorithm is described in the reference MÖLLER, Tomas; TRUMBORE, Ben. Fast, minimum storage ray-triangle intersection. *Journal of graphics tools, 1997. 2.1: 21-28*, which is incorporated by reference herein.

The process then moves to block 110, where a simulation implant process is performed to determine different aspects of an implant design, such as the likely biomechanical impact, bone and implant-bone strength (e.g., strength of the reconstruction), and/or outcome-power-effectiveness of an implant design of each of the multiple configurations having the generated parameter values for each of the parameters. For example, the numerical simulation may measure stresses in the implant and/or bone, and/or the implant fixation (e.g, measure implant displacement) for each of the multiple configurations of the implant design, such as through performance of a finite element analysis (FEA). The numerical simulation may take into account certain measured patient-specific properties (e.g., bone thickness, cortical thickness, patient-specific material properties, patient-specific muscle forces, patient-specific geometry, etc.). In some embodiments, the numerical simulation is calculated based at least in part on one or more of the parameter values of the following parameters of the reconstruction (i.e., implant and bone): cortical thickness, trabecular thickness, trabecular young's modulus, cortical young's modulus, screw length, screw diameter, screw position, and screw orientation. In some embodiments, information of the stresses in the implant and bone are calculated in a numerical simulation that includes a complete biomechanical evaluation that is based on an FEA, patient-specific muscle forces (MSM), patient-specific geometry, and patient-specific material properties.

Once the simulation is complete, the process moves to decision block 112, where the simulation results are evaluated to determine whether each of the multiple configurations of the implant design complies with defined quality criteria (e.g., threshold for maximum occurring stress in the implant under one or more physiological conditions (e.g., fatigue threshold of the implant material (e.g., titanium)), maximum/minimum stresses in the bone to prevent bone overloading and stress shielding, maximum implant micromotion, etc.). For example, the simulation result may show that an implant design for one configuration either complies or does not comply with the defined quality criteria. Therefore, a compliant configuration is one that results in an implant design that complies with the defined quality criteria. Any configurations that are not compliant, are not considered further. In some embodiments, the results of the numerical simulations are interpreted
automatically and objectively, without the need for human input. If no configurations are compliant, the process returns to block 108, and additional configurations of the implant design are generated wherein the complexity of the implant design is increased (e.g., a greater number of parameters are considered for the multiple configurations of the implant design as discussed above). In some embodiments, the results of the simulation evaluation may help inform to what degree and direction the parameter values should be adjusted, the search space that should be used for the parameter values for the additional configurations of the implant design, and/or the additional parameters that should be adjusted. From there, the process returns to block 110, and the simulation is performed again using the generated additional configurations of the implant design, and the results of the simulation are again analyzed at block 112. This sub-process continues until one or more compliant implant designs are identified.

If, at decision block 112, one or more implant configurations are found to be compliant/acceptable, the process moves to block 114. At block 114, an optimum implant design is selected from the one or more compliant implant configurations and the implant design is finalized. For example, the optimum implant design may be the configuration with the best implant fixation (e.g., lowest measured implant displacement), the optimal screw length, optimal fixation potential (e.g., optimal screw fixation), optimal shape, optimal congruence to the bone, or some combination of one or more of these optimization criteria or additional optimization criteria. In some embodiments, the selection of the optimum implant design is performed automatically and objectively, without the need for human input. In some embodiment, the process 100 may additionally validate the implant design when finalizing by a complete patient-specific finite element analysis (including e.g., muscle forces, implant, scaffold, bone quality, screws, etc.) for an objective analysis to determine whether or not to move forward with the implant production. Ultimately, this bottom-up approach produces an implant model (e.g., 3D CAD model) of an implant that may be produced using additive manufacturing techniques or traditional techniques such as casting, or CNC for example.

Turning now to Figures 2A and 2B, graphical examples illustrate the differences between a top-down approach to custom implant design and a bottom-up approach such as the approach described in connection with Figure 1. In both Figure 2A and 2B, the y axis 220 represents complexity, e.g., the number of parameters that need to be optimized. High on the y axis 220 is a MAX value 222. The MAX value is indicative of the maximum complexity for an implant design. The corresponding x axis 224 represents the size of the search space (shown in size as the distance of the horizontal line from the vertical line representing complexity to the next vertical line to the right) for parameter values for the parameters that need to be optimized.
Turning specifically to Figure 2A, the graph shows a prior art technique for customizing an implant design. The approach shown here is referred to as a "top-down" approach. This approach is often used in connection with very complex bone defects. These types of bone defects typically require consideration of many implant configuration parameters including all possible fixation means, all possible touch down regions on the surrounding healthy host bone for the implant, and maximal contact (congruency) between implant (porous portions) and the host bone must be considered. In this top-down approach, the design process starts with maximal complexity as shown with line 226, where all such parameters are considered. As discussed above, this may work for very complex bone defects where the number of parameters to be considered and their values is very limited by the complexity of the bone defect. In particular, human assistance is used to reduce complexity by manually selecting values for the parameters as shown by line 228. Ultimately, a solution 229 can be obtained. This top-down approach is typically ill-suited for fully automated implant design for smaller defects where many different designs and parameters need to be considered, as by starting with maximal complexity, the number of parameters that need to be optimized becomes uncontrollable as the search space (i.e., choice set) for each parameter value may be too large and it would be difficult to determine manually among all the design choices, which one is best as manual qualitative judgment may not give that answer.

Figure 2B is a graphical representation of the bottom-up approach which contrasts with the top-down approach represented in Figure 2A. In this example, the bottom-up approach gradually builds complexity, by first identifying a select number of parameters that influence implant fixation, and then automatically generating an implant configuration considering those parameters. The implant configuration is then tested for compliance with quality criteria, as discussed herein. Multiple configurations are generated, and the optimum configuration according to an optimization criteria is selected as the implant design. If a suitable/optimal implant design is not found among the multiple configurations using the select number of parameters, additional configurations are generated using an increased number of parameters. These additional configurations are evaluated based on the optimization criteria to see if a suitable/optimal implant design is found. The process continues iteratively, with additional parameters being considered for configurations until a suitable/optimal implant design is found. Thus, the complexity of the implant design increases gradually with each iteration. As shown, a first configuration is considered introducing a first amount of complexity, with a select number of parameters considered, as represented by line 230. The search space for the value for the first configuration is small as represented by line 232. Further, a next configuration is considered introducing a next amount of complexity, where an increased number of parameters are considered, as represented by line 234. The search space for the value for the next configuration is slightly larger due to the increased number of parameters.
considered, as represented by line 236. As shown, the solution 250 is achieved with significantly reduced complexity, which allows for a more automated process that avoids the need for a specialist's involvement and the resulting labor-intensive manual aspects of the implant design optimization process. In some embodiments, the solution 250 using the bottom-up approach is the same or even a better outcome than the solution 229 using the top-down approach. In particular, as discussed above, for small bone defects, the manual top-down approach for implant design may not allow for a proper assessment of all the possible implant designs and thus lead to a sub-optimal implant. As a result, using the techniques described above, this improved design methodology significantly reduces the design time and provides a better implant design.

In some embodiments, the simulation implant process described with respect to block 110 of Figure 1 involves measuring implant fixation as an estimated displacement of the implant when a given force (e.g., a force with a magnitude and direction correlating to use of the implant after implantation) is acting on the implant. In some such embodiments, the implant fixation may be used as the optimization criteria described with respect to block 114 of Figure 1. A larger displacement of the implant for a given force corresponds to a lower implant fixation. Therefore, the simulation implant process may, in some embodiments, involve selecting configurations for implant design that lower the overall or local (e.g., displacement of a particular area, such as a flange, of the implant) displacement of the implant for a given force. In some embodiments, the implant displacement is measured as overall displacement of the bone and implant reconstruction and/or locally at the interface between the implant and the bone.

In some embodiments, the displacement of the implant design can be estimated by defining a spring model based on the simulated fit of the implant design to the bone of the patient. A schematic of an example of such a spring model is shown in Figure 3. As shown, the spring model 300 includes parameters for the shape and position of the implant 310 with respect to the bone 320 of the patient, the shape of the bone 320 of the patient, and the screw(s) 330 (or other fixation elements) that couple (e.g., connect) the implant 310 to the bone 320 of the patient. Further, contact points 340 are shown where the implant 310 comes into contact with the bone 320. Each contact point 340 can be characterized as a spring that will resist compression (i.e., a force that moves the implant 310 and bone 320 together), but has no resistance to tensile forces (i.e., a force that moves the implant 310 and the bone 320 apart) as there is no force applied by the bone 320 on the implant 310 at the contact point 340 when forces move them apart. In some embodiments, there may be bone ingrowth near the contact point 340 that provides some resistance to tensile forces and the contact point 340 may be characterized accordingly. Further, each screw 330 can be characterized as a spring that will resist tensile forces (i.e., a force that moves the implant 310 and
the bone 320 apart), but has no resistance to compression (i.e., a force that moves the implant 310 and bone 320 together) as the screw 330 would push out a screw hole in the implant 310 so no force is applied by the bone 320 on the implant 310 at the screw 330 when forces move them together. The stiffness of each spring (e.g., contact point 340 and/or screw 330) can be characterized by an individual spring constant k, which may be unique to each spring. In particular, the stiffness of the spring is a characterization of the local resistance to indentation for contact points 340, and to pull-out for screws 330. Some springs may have the same k value. Based on these k values and the other characteristics of the spring model 300 described herein, the displacement of the implant 310 with respect to the bone 320 can be estimated/calculated for any given force vector G 360 applied to the implant 310 as described herein.

In some embodiments, the characterization of the spring constant k may be performed using experimental data of biomechanical bone tests. In some embodiments, the spring constant k may be calculated based on measured patient-specific properties (e.g., bone thickness, cortical thickness, etc.) local to the area of implantation of the implant 310 and/or parameter values of parameters of the implant 310. In some embodiments, the spring constant k of a given screw 330 is calculated based at least in part on one or more of the parameter values of the following parameters of the implant 310: cortical thickness, trabecular thickness, trabecular young's modulus, cortical young's modulus, screw length, screw diameter, screw position, and screw orientation. In some embodiments, the spring constant k of a given contact point 340 is calculated based at least in part on one or more of the parameter values of the following parameters of the implant 310: cortical thickness, trabecular thickness, trabecular young's modulus, and cortical young's modulus.

The calculation of the spring constant k based on the patient-specific properties and implant parameters may in some embodiments be performed using finite element analysis (FEA). In some embodiments, the spring constant k for each screw 330 can be represented as a finite element model (FEM) as shown in Figure 4A. Further, the calculated spring constant k for each contact point 340 can be represented by a FEM as shown in Figure 4B. The calculated spring constant $k_i$ for each spring i can be characterized by the following equation:

$$ k_i = F_s / U_s $$

wherein:

$F_s$ is a force applied to the spring i; and

$U_s$ is the displacement of the spring i based on the force $F_s$. 
Accordingly, it is shown that the parameter values of the implant 310 can affect the spring constant $k$, which is used to calculate implant displacement. Therefore, selecting a configuration of the implant design with a different parameter value of the implant 310, changes the implant displacement, which is an example of an optimization criteria for selecting a configuration of the implant design.

In some embodiments, the displacement of the implant 310 in the spring model 300 can be calculated using the following equations and the below described iterative process:

\[
\begin{align*}
\Delta \bar{u} &= K^{-1} \cdot \bar{G} \\
W^i &= \gamma_{P_i} \times n_i^- \\
W &= [w_1, w_2, \ldots, w_N] \\
K &= W \cdot \begin{bmatrix} k_1 & \cdots & 0 \\ \vdots & \ddots & \vdots \\ 0 & \cdots & k_N \end{bmatrix} \cdot W^T
\end{align*}
\]

wherein:
- $u$ is the displacement of the implant 310;
- $K$ is the stiffness matrix of the spring model 300;
- $k_i$ is the spring constant of the spring $i$ of the spring model 300;
- $w_i$ is the moment and force direction vector of the spring $i$ of the spring model 300;
- $G$ is an applied force on the spring model 300;
- $P_i$ is the position of the spring $i$ (e.g., in an xyz axis); and
- $n_i$ is the force direction vector of the spring $i$.

According to the above equations, the total displacement $u$ of the implant 310 is calculated through a matrix multiplication of the inverse stiffness-matrix $K^{-1}$ and the applied force $G$ 360. For each applied $G$ 360 (e.g., each force the implant 310 is expected to have applied during normal operation after implantation in the patient), the displacement $u$ can be calculated, but this induces spring tension/compression in the model that cannot happen in reality as screws 330 cannot have compression force and contact points 340 cannot have tensile force as discussed herein. Therefore, the displacement $u$ for a given $G$ 360 is iteratively calculated using the above equations until all springs $i$ have allowed/possible tension/compression. To ensure that all springs $i$ have allowed/possible tension/compression, the elongation/shortening of each spring $i$ is calculated and
assessed to verify if the elongation/shortening is allowed for the type of spring (i.e., contact points cannot be elongated and screws 330 cannot be shortened). For each impossible spring i, the spring constant $k_i$ is set to zero. This produces a new K matrix and therefore new calculations for elongation/shortening of each spring i. This process is iterated, as long as there are any calculated elongation/shortening of any spring that is not allowed. When the elongation/shortening calculations for each spring is found to be allowed, the process ends and the resulting value for displacement of the implant 310 for the given G 360 according to the values found through the iterative process is considered the estimated displacement of the implant design. As discussed above, the estimated displacement can be used as an optimization criteria in assessing implant design.

For example, in some embodiments of the bottom-up approach to implant design described herein, to optimize the implant fixation, parameters of the implant (e.g., the implant outline and/or the screw positions/directions) may be adjusted or varied in different configurations as described with respect to process 100. For each configuration, the implant displacement may be calculated as an indicator of implant fixation as discussed above and compared with one another. Further, additional conditions may restrict the search space for parameter values of the parameters of this optimization as discussed above (e.g., surgical window, muscle insertions, surgical preferences, screw-screw intersections, cup positioning, etc.).

In some embodiments, the bone defect reconstruction process described with respect to block 106 of Figure 1 involves is done using SSM. Some embodiments for SSM-based reconstruction that may be used to decrease implant design time and/or create less user dependency in implant design creation are described further herein. In some such embodiments, the SSM is not gender-specific and thus captures the anatomical variation of both males and females in one model.

In some embodiments, a model set of healthy bones, (e.g., hemi-pelvises) may be collected to build a SSM. For example, a database of images of healthy bones may be generated by taking images of patients with healthy bones. In some embodiments, the database may include both male and female patients. The database may be generated to account for natural variations in bones among different groups of individuals such as by age, gender, race, etc. The images may then be segmented into segmentation masks. For example, segmentation of images in the form of CT-scans may be performed using Mimics software made by Materialise NV, Belgium. From the segmentation masks, a triangular mesh may be calculated, for example, using the Marching Cubes algorithm. The triangular meshes may be remeshed, for example, in 3-Matic software by Materialise NV, Belgium to obtain a smooth and uniform triangulation.
In some embodiments, to create an SSM that captures shape variations of bones, all entities of the model set need to have corresponding points. For triangular meshes, this means that vertices on similar anatomic regions need to be corresponding and that the number of vertices in each mesh is equal (i.e., the corresponding point problem). After fulfilling these two conditions an SSM is calculated using principal component analysis ("PCA"). In some embodiments, the corresponding point problem is solved using the template based method. The method comprises registering a template (e.g., one data entry) to all the meshes of the dataset. The transformed template meshes are then used directly to build up the data matrix for PCA. The registration may be done using a combination of manually indicated anatomical features (e.g., landmarks and ridges) and an iterative nonlinear morphing algorithm based on a thin plate splines (TPS) kernel.

In some embodiments, the SSM may be directly fitted to the healthy parts of the defect bone. The parameters of the SSM may therefore be varied to minimize the distance from the defect bone to the sample of the SSM. The idea behind this approach is that the remaining healthy parts of the defect bone are predictors for the missing anatomical parts. In some embodiments, before fitting the SSM to the bone anatomy, the defect part of the bone may be manually cut out or automatically detected. Disregarding the defect part guarantees that the shape of the SSM may be fitted as close as possible to the remaining healthy parts of the bone. For example, in some embodiments, a rigid iterative closest point registration (ICP) with the mean SSM-shape is used to initialize the SSM-fit using the healthy parts of the defect bone. Afterwards, in some embodiments, the fitting process is performed, which optimizes the distance from each point in the defect bone to the sample of the SSM by varying the different modes of variation one by one. For each mode of variation, a bisection algorithm is used to find the minimum distance from the defect bone to the SSM-sample.

After calculating the minimum distance of each mode of variation, a rigid ICP registration optimizes the translation and rotation of the SSM-fit.

Figure 5 illustrates one example of a system 500 for designing and manufacturing an object by additive manufacturing, including, for example, an implant designed using the bottom-up approach described herein. The system 500 may be configured to support the techniques described herein. In some embodiments, the system 500 may include one or more computers 502a-502d. The computers 502a-502d may take various forms such as, for example, any workstation, server, or other computing device capable of processing information. The computers 502a-502d may be connected by a computer network 505. The computer network 505 may be, for example, the Internet, a local area network, a wide area network, or some other type of network capable of digital communications between electronic devices. Additionally, the computers 502a-502d may
communicate over the computer network 505 via any suitable communications technology or protocol. For example, the computers 502a-502d may share data by transmitting and receiving information such as software, digital representations of 3D objections, commands and/or instructions to operate an additive manufacturing device, and the like. Further, the computers 502a-502d may be configured to perform any of the embodiments of the bottom-up approach to implant design described herein. For example, the computers 502a-502d may have specialized hardware and/or software designed to perform any such embodiments.

The system 500 further may include one or more additive manufacturing devices 506a and 506b. These additive manufacturing devices may comprise 3D printers or some other manufacturing device as known in the art. In the example shown in FIG. 5, the additive manufacturing device 506a is directly connected to the computer 502d. The additive manufacturing device 506a is also connected to computers 502a-502c via the network 505, which further connects computers 502a-502d. Additive manufacturing device 506b is also connected to the computers 502a-502d via the network 505. A skilled artisan will readily appreciate that an additive manufacturing device such as devices 506a and 506b may be directly connected to a computer, connected to a computer, and/or connected to a computer via another computer.

Although a specific computer and network configuration is described in FIG. 5, a skilled artisan will also appreciate that the additive manufacturing techniques described herein may be implemented using a single computer configuration which controls and/or assists the additive manufacturing device 506, without the need for a computer network.

Figure 6 illustrates a more detailed view of computer 502a illustrated in FIG. 5. The computer 502a includes a processor 610. The processor 610 is in data communication with various computer components. These components may include a memory 620, an input device 630, and an output device 640. In certain embodiments, the processor may also communicate with a network interface card 660. Although described separately, it is to be appreciated that functional blocks described with respect to the computer 502a need not be separate structural elements. For example, the processor 610 and network interface card 660 may be embodied in a single chip or board. The processor 610 may be a general purpose processor, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, a discrete gate or transistor logic, discrete hardware components, or any suitable combination thereof designed to perform the functions described herein. A processor may also be implemented as a combination of computing devices, e.g., a combination of a DSP and
a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with
a DSP core, or any other such configuration.

The processor 610 may be coupled, via one or more data buses, to read information from or write
information to memory 620. The processor may additionally, or in the alternative, contain memory,
such as processor registers. The memory 620 may include processor cache, including a multi-level
hierarchical cache in which different levels have different capacities and access speeds. The
memory 620 may further include random access memory (RAM), other volatile storage devices, or
non-volatile storage devices. The storage can include hard drives, optical discs, such as compact
disks (CDs) or digital video discs (DVDs), flash memory, floppy discs, magnetic tape, Zip drives,
USB drives, and others as are known in the art.

The processor 610 may also be coupled to an input device 630 and an output device 640 for,
respectively, receiving input from and providing output to a user of the computer 502a. Suitable
input devices include, but are not limited to, a keyboard, a rollerball, buttons, keys, switches, a
pointing device, a mouse, a joystick, a remote control, an infrared detector, a voice recognition
system, a bar code reader, a scanner, a video camera (possibly coupled with video processing
software to, e.g., detect hand gestures or facial gestures), a motion detector, a microphone (possibly
coupled to audio processing software to, e.g., detect voice commands), or other device capable of
transmitting information from a user to a computer. The input device may also take the form of a
touch-screen associated with the display, in which case a user responds to prompts on the display
by touching the screen. The user may enter textual information through the input device such as the
keyboard or the touch-screen. Suitable output devices include, but are not limited to, visual output
devices, including displays and printers, audio output devices, including speakers, headphones,
earphones, and alarms, additive manufacturing devices, and haptic output devices.

The processor 610 further may be coupled to a network interface card 660. The network interface
card 660 prepares data generated by the processor 610 for transmission via a network according to
one or more data transmission protocols. The network interface card 660 may also be configured to
decode data received via the network. In some embodiments, the network interface card 660 may
include a transmitter, receiver, or both. Depending on the specific embodiment, the transmitter and
receiver can be a single integrated component, or they may be two separate components. The
network interface card 660, may be embodied as a general purpose processor, a DSP, an ASIC, a
FPGA, or other programmable logic device, discrete gate or transistor logic, discrete hardware
components, or any suitable combination thereof designed to perform the functions described
herein.
The processor 610 and/or memory 620 may be configured to perform any of the embodiments of the bottom-up approach to implant design described herein. For example, the process for the bottom-up approach, such as described with respect to Figure 1, may be designed to run as specialized hardware in the form of the processor 610. Additionally or alternatively, the process may be programmed and stored in software on the memory 620 and executed by the processor 610 so that the computer 502a performs any of the processes described herein. In some embodiments, embodiments of the process for the bottom-up approach for implant design described herein are stored in memory and the memory comprises a non-transitory computer readable medium (e.g., RAM, hard drive, flash drive, etc.).

Figure 7 illustrates a general process 700 for manufacturing an object, such as an implant designed using the bottom-up approach described herein, using an additive manufacturing apparatus, such as 506a or 506b in Figure 5.

The process begins at step 705, where a digital representation of the device to be manufactured is designed using a computer, such as the computer 502a in Figure 5. In some embodiments, a 2D representation of the device may be used to create a 3D model of the device. Alternatively, 3D data may be input to the computer 502a for aiding in designing the digital representation of the 3D device. The process continues to step 710, where information is sent from the computer 502a to an additive manufacturing device, such as additive manufacturing devices 506a and 506b. Next, at step 715, the additive manufacturing device begins manufacturing the 3-D device by performing an additive manufacturing process using suitable materials, as described above. Using the appropriate materials, the additive manufacturing device then completes the process at step 720, where the 3D object is completed.

Various specific additive manufacturing techniques may be used to produce objects using a method like that shown in FIG. 7. As explained above, these techniques include SLA, SLS, and SLM, among others.

The invention disclosed herein may be implemented as a method, apparatus, or article of manufacture using standard programming or engineering techniques to produce software, firmware, hardware, or any combination thereof. The term "article of manufacture" as used herein refers to code or logic implemented in hardware or non-transitory computer readable media such as optical storage devices, and volatile or non-volatile memory devices or transitory computer readable media such as signals, carrier waves, etc. Such hardware may include, but is not limited
to, FPGAs, ASICs, complex programmable logic devices (CPLDs), programmable logic arrays (PLAs), microprocessors, or other similar processing devices.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention without departing from the scope of the invention as broadly described in the claims. The above described embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.
Claims

1. A method of using a computing device for providing a design of an implant to treat a defect in a bone comprising:
   - generating one or more implant configurations of a patient-specific implant for optimization; and
   - performing, on the computing device, a simulation implant process for each of the one or more implant configurations to generate one or more results;
   - evaluating the one or more results to determine whether each of the one or more implant configurations complies with a quality criteria; and
   - selecting, based on an optimization criteria, an optimum implant configuration from the one or more implant configurations that comply with the quality criteria as the design of the implant.

2. The method of claim 1, wherein generating one or more implant configurations comprises:
   - generating a first set of implant configurations having a first complexity; and
   - generating a second set of implant configurations having a second complexity that is greater than the first complexity based on each of the first set of implant configurations failing to meet the quality criteria.

3. The method of claim 2, wherein the first complexity comprises at least one of: a number of screws, a span of the implant configuration, and an amount of congruency surface.

4. The method of claim 1, 2 or 3, wherein the quality criteria is at least one of: a fatigue threshold of a material of the implant, a maximum stress in a bone, a minimum stress in the bone, and a maximum implant micromotion.

5. The method according to any of the preceding claims, wherein the one or more implant configurations are generated based on at least one of the following design constraints: surgical window, muscle insertions, screw-screw intersections, cup positioning, cup insertion, and surgical preference.

6. The method according to any of the preceding claims, wherein each of the one or more implant configurations is defined by one or more parameters comprising one or more of the following: implant screw length, screw diameter, screw orientation, and screw position.
7. The method according to any of the preceding claims, wherein the optimization criteria comprises at least one of: a measure of implant fixation, an optimal screw length, an optimal fixation potential, an optimal shape, and an optimal congruence to a bone.

8. The method of claim 7, wherein the optimization criteria comprises the measure of implant fixation comprising an amount of implant displacement.

9. The method of claim 8, wherein the simulation implant process comprises:
   - characterizing each of the one or more implant configurations based on a spring model; and
   - estimating a total displacement of each of the one or more implant configurations based on the spring model, wherein the displacement is iteratively calculated by adjusting one or more spring constants of the spring model based on whether tension or compression is allowed for one or more springs associates with the one or more spring constants.

10. The method according to any of the preceding claims, further comprising:
    - obtaining a medical image of the bone;
    - segmenting the bone based on the medial image;
    - reconstructing the bone as a model based on the segmented bone, wherein at least one of generating the one or more implant configurations and the simulation implant process is based on the reconstructed bone model.

11. The method of claim 10, wherein the reconstructing is performed using statistical shape modeling (SSM).

12. Method according to any of the preceding claims, further comprising the step of manufacturing an implant based on the optimum implant configuration.

13. Method according to claim 12, wherein the step of manufacturing comprises using a three-dimensional printing technique.

14. A non-transitory computer readable medium comprising instructions that when executed by a computing device, cause the computing device to perform the method according to any of the preceding claims.
15. A computing device comprising:
   - a memory; and
   - a processor coupled to the memory, the processor being configured to execute the
     method according to any of the preceding claims.
102

OBTAINT VOLUMETRIC IMAGE FROM PATIENT

104

SEGMENT 3D SURFACE MODEL OF PATHOLOGICAL BONE

106

RECONSTRUCT HEALTHY BONE USING MODEL OF
HEALTHY BONES

108

CALCULATE PARAMETERS THAT INFLUENCE IMPLANT
FIXATION

110

SELECT PARAMETER FOR CONSIDERATION

112

PERFORM SIMULATION

114

PARAMETER COMPLIES WITH QUALITY
CRITERION AND SURGEON SPECIFICATION?

116

NO

ADJUST PARAMETER VALUE BASED ON SIMULATION RESULT

118

SAVE COMPLIANT PARAMETER VALUE TO IMPLANT
MODEL

120

ADDITIONAL PARAMETERS TO TEST?

122

NO

FINALIZE IMPLANT DESIGN

FIG. 1
FIG. 2A (PRIOR ART)

FIG. 2B
FIG. 6
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/30

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
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*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

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"F" document member of the same patent family

Date of the actual completion of the international search
26 August 2015

Date of mailing of the international search report
09/09/2015

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Authorized officer
Fernandez Ari llo, J

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