Title: A METHOD FOR PRODUCING A CUSTOMISED ORTHOPAEDIC IMPLANT

Abstract: A method for producing a customised orthopaedic implant is provided. The method involves scanning a bone from which a diseased region of bone will be resected to obtain a three dimensional digital image of an unresected volume of bone; scanning the bone after a diseased region of bone has been resected to obtain a corresponding three dimensional digital image of a resected volume of bone; and comparing the three dimensional digital image of the unresected volume of bone to the corresponding three dimensional digital image of the resected volume of bone to estimate a volume of bone that has been resected. The estimate of the volume of bone that has been resected is used to design a customised orthopaedic implant that substantially corresponds to the configuration of the resected volume of bone, the implant being configured to substantially restore a biomechanical function of the bone. Finally the customised orthopaedic implant is manufactured and provided for insertion into the resected region of bone.
Published:

— with international search report (Art. 21(3))
A METHOD FOR PRODUCING A CUSTOMISED ORTHOPAEDIC IMPLANT

Technical Field

[0001] The present invention relates to methods for designing and manufacturing customised orthopaedic implants. More particularly, the method relates to design and production of patient-specific orthopaedic implants for insertion into a resected region of bone.

Background of Invention

[0002] Osteosarcomas are a class of cancer originating from the bone, mainly affecting children or young adults. Prior to the 1970s, amputation was the sole means of treatment available. Amputation results in poor outcomes for patients in terms of quality of life and accordingly current trends are directed toward trying to salvage the affected limb while resecting the tumour in its entirety to reduce the risk of local recurrence and to maximise the prospects of survival. Once the tumour is resected, further surgery is typically required to reconstruct the limb.

[0003] Efforts to salvage the limb often involve the insertion of orthopaedic implants to reconstruct the bone or replacement of natural joints with prosthesis. Conventional orthopaedic implants generally have a solid construction intended to structurally stabilise the resected bone to which they are attached. To stabilise small tumour resections, solid metallic plate type implants may be fixed to the bone tissue using multiple screws. These implants are available in standard shapes and sizes and the surgeon usually adjusts the implant contour to align with the bone during surgery using trial and error. For tumours located near joints, a total joint replacement prosthesis is used. These implants are substantial in design to improve fatigue life and accordingly require significant removal of bone tissue from the affected as well as the unaffected region to accommodate the prosthesis. In the case of young patients whose bones have not matured, an expandable prosthesis may be used requiring repeat visits to biomechanics laboratories for lengthening. Once the bones reach maturity the expandable prosthesis is replaced with permanent joint replacement prosthesis, resulting in further surgery and rehabilitation for the patient. For elderly patients, the chances of prosthesis failure are greater, due to reduced physical activity...
and other age related complications such as osteoporosis. Moreover, the placement strategy for such prosthesis tends to focus on the configuration of the standard orthopaedic implant and how the existing bone needs to be shaped to conform to the implant, rather than focusing on the anatomical function of the bone and what is required to maintain optimal biomechanical function of the limb.

[0004] The disparity in stiffness between the existing bone and the orthopaedic implant can lead to bone resorption and subsequent loosening of the orthopaedic implant. While in some cases, conventional orthopaedic implants do provide a satisfactory result that allow the patient to return to an active lifestyle, in others, use conventional orthopaedic implants has resulted in extended rehabilitation, pain, discomfort, and lack of mobility. Therefore, there is need for the development of customised orthopaedic implants that are optimised to loading conditions of the affected region, are affordable and can be rapidly produced.

[0005] It would therefore be desirable to be able to design and manufacture an orthopaedic implant which is customised for a patient and specific to a diseased skeletal element. In particular, it would be desirable to be able to automate design of orthopaedic implants which offer a suitable compromise to the bone’s inherent biomechanical function and enhance bone in-growth rate. Finally, it would be desirable to optimise the entire process of designing and manufacturing customised orthopaedic implants to enable orthopaedic implant design, manufacture and placement to take place within the time constraints of surgery.

**Summary of Invention**

[0006] According to an aspect of the present invention, there is provided a method for producing a customised orthopaedic implant, the method including the following steps: (a) scanning a bone from which a diseased region of bone will be resected to obtain a three dimensional digital image of an unresected volume of bone; (b) scanning the bone after a diseased region of bone has been resected to obtain a corresponding three dimensional digital image of a resected volume of bone; (c) comparing the three dimensional digital image of the unresected volume of bone to the corresponding three dimensional digital image of the resected volume of bone to estimate a volume of bone that has been resected; (d) using the estimate of the
volume of bone that has been resected to design a customised orthopaedic implant that substantially corresponds to a configuration of the resected volume of bone, the implant being configured to substantially restore a biomechanical function of the bone; (e) manufacturing the customised orthopaedic implant; and (f) providing the customised orthopaedic implant for insertion into the resected region of bone.

[0007] Design of the customised orthopaedic implant to substantially restore the biomechanical function of the bone involves consideration of one or more typical loading conditions on a bone type which corresponds to the bone that has been resected. For instance, this may involve a consideration of the anatomical function of the bone type in question and the anticipated bone loading during various typical activities.

[0008] Design of the customised orthopaedic implant preferably involves consideration of typical maximum stress and deflection to which the bone type which corresponds to the resected bone is subjected. That is, taking into account the physique of the patient, the loads incurred by the bone type during typical activities such as walking, running, jumping and external impact can be modelled.

[0009] In a particular embodiment, the customised orthopaedic implant includes a lattice-type geometry. The density of the lattice-type geometry is configured to enhance bone ingrowth and is optimised to neutralise stresses developed at the bone-implant interface. The lattice-type geometry is preferable since it offers a favourable strength to weight ratio, reduces stress shielding and can be manufactured using additive technology. In a more particular embodiment, the lattice-type geometry includes a periodic arrangement. Such an arrangement provides more predictable mechanical properties and behaviour and accordingly, provides greater control over the ultimate performance of the customised orthopaedic implant in-situ. That is, varying the porosity of the lattice structure at a bone/implant interface can be used to enhance bone ingrowth or increase implant stiffness.

[0010] The customised orthopaedic implant is preferably manufactured using additive manufacturing technology. The additive manufacturing technology may involve selective laser melting.
In one form of the invention, scanning a bone to obtain a three dimensional digital image involves obtaining a plurality of two dimensional digital images and constructing a three dimensional digital image therefrom.

Each three dimensional digital image may comprise a stereo lithography file (STL).

Scanning the bone to obtain one or more three dimensional digital images may involve the use of a medical imaging such as computed tomography (CT) scanner and Magnetic Resonance Imaging (MRI). Alternately, scanning the bone to obtain one or more digital images may involve use of a laser scanner.

Preferably, the three dimensional digital image is used to generate a three dimensional computer model of the customised orthopaedic lattice implant. The three dimensional computer model is subsequently transmitted to a three dimensional printer.

In one particular embodiment, the diseased region of bone is affected by osteosarcoma.

In a preferred form of the invention, the steps of the method for producing a customised orthopaedic implant occur consecutively during a period of time in which the patient is under anaesthesia.

According to another aspect of the present invention, there is provided a customised orthopaedic implant, the implant formed by a method including the following steps: scanning a bone from which a diseased region of bone will be resected to obtain a three dimensional digital image of an unresected volume of bone; scanning the bone after which a diseased region of bone has been resected to obtain a corresponding three dimensional digital image of a resected volume of bone; comparing the three dimensional digital image of the unresected volume of bone to the corresponding three dimensional digital image of the resected volume of bone to estimate a volume of bone that has been resected; using the estimate of the volume of bone that has been resected to design a customised orthopaedic implant substantially corresponding to a configuration of the resected volume of bone, the
implant being configured to substantially restore the biomechanical function of the bone; and manufacturing the customised orthopaedic implant.

**Brief Description of Drawings**

[0018] The invention will now be described in further detail by reference to the accompanying drawings. It is to be understood that the particularity of the drawings does not supersede the generality of the preceding description of the invention.

[0019] FIG. 1 is a flowchart showing the method for producing a customised orthopaedic implant according to an embodiment.

[0020] FIG.s 2A to 2C show a more detailed flowchart showing the method for producing a customised orthopaedic implant.

[0021] FIG. 3A is a schematic of a diseased bone showing the amount of tissue to be removed.

[0022] FIG. 3B is shows a 3D comparison between the diseased bone and a normal bone to assist in surgical planning.

[0023] FIG 3C shows the diseased bone of FIG. 3A with osteosarcoma tissue removed.

[0024] FIG.s 4A and 4B show the output of two different STL file comparisons to estimate the amount of tissue removed from diseased bone of different bone types.

[0025] FIG.s 5A to 5C show stepwise rendering of customised orthopaedic implant to replace the amount of tissue removed from the diseased bone shown in FIG.s 4B and 5A.

[0026] FIG.s 6A and 6B are schematic representations showing determination of loads and stresses incurred by a resected femur during walking.

[0027] FIG. 7A shows example of a lattice structure which is optimised for the loading conditions, but is not manufacturable using additive manufacturing.
FIG. 7B shows a lattice structure which is optimised for the loading conditions and further optimised for manufacture using additive manufacturing processes.

FIG.s 8A and 8B show an example of a periodic lattice structure generated using direct import of an STL file.

FIG.s 9A to 9D are exemplary lattice structure unit cells that may be used in a suitable periodic lattice structure.

FIG.s 10A and 10B show the application of a functionally gradient structure to the lattice geometry.

FIG.s 11A to 11C shows a series of schematics illustrating the customised orthopaedic implant inserted to replace the removed tissue.

Detailed Description

Referring firstly to FIG. 1, there is shown a flowchart illustrating the method 100 for producing a customised orthopaedic implant. At step 110, a bone from which a diseased region of bone will be resected is scanned to obtain a three dimensional digital image of an unsectected volume of bone. At step 120, the same bone from which a diseased region of bone has been resected is scanned to obtain a three dimensional digital image of a resected volume of bone. At step 130, a three dimensional digital image of the unsectected volume of bone is compared to the corresponding three dimensional digital image of the resected volume of bone to estimate the volume of bone that has been resected. At step 140, the estimate of the volume of bone that has been resected is used to design a customised orthopaedic implant which substantially corresponds to a configuration of the resected volume of bone. Modelling is performed to ensure proposed customised orthopaedic implant should substantially restore the biomechanical function of the bone. At step 150, the customised orthopaedic implant is manufactured. Finally, at step 160, the customised orthopaedic implant is provided for insertion into the resected region of bone.

It is to be understood that the steps of the method take place while the respective patient is in surgery and generally under anaesthesia. Moreover, the
invention is herein described in the context of designing and manufacturing orthopaedic implants to replace sections of tissue surgically resected to remove an osteosarcoma. However, it is to be understood that the method of producing customised orthopaedic implants may have broader application than that in the context of which the invention is herein described.

[0035] Manufacture of customised implants within surgical time constraints can be achieved using additive or three dimensional printing techniques as subsequently described.

[0036] The method will now be described in more detail with reference to the flowchart provided in FIG.s 2A to 2C. Referring now to FIG. 2A, at step 205, the surgical team acquires medical imaging data of the disease affected bone by scanning the bone using, for example, a laser or computed tomography (CT) scanner. Imaging a bone to obtain three dimensional models requires obtaining a plurality of two dimensional digital images and constructing a three dimensional digital image therefrom. Once scanning is complete, at step 210, the medical imaging data is processed in order to identify relevant features and attributes of the instant bone such as the anatomical position of the osteosarcoma within the bone, and the shape and size of the osteosarcoma. At step 215, the surgical team examines the medical imaging data of the diseased bone, as shown for example in FIG. 3A, to determine the region of bone to be resected to remove the osteosarcoma, using a three dimensional comparison of diseased and normal bone as shown for example in FIG. 3B. At this stage, the surgical team determines how the customised orthopaedic implant will be fixed to the bone, so that the preferred fixation strategy can be taken into account during orthopaedic implant design. Surgical data, as shown in FIG. 3C, is sent to the engineering team in real-time during the surgical procedure.

[0037] At step 220 the processed scan data is reviewed by an engineering team and the orthopaedic implant design process commences. The medical image data files typically comprise CT scan data that are converted into three dimensional stereo lithography (STL) files as shown for example in FIG. 3A. The STL files of the resected volume of bone can be imported directly into the design algorithm, avoiding any requirement for decimation of medical imaging data or the use of finite element
mesh creation software. This ultimately results in enhanced optimal geometric integrity of the customised implant and a more precise fit.

[0038] The resulting virtual three dimensional model is used compare models of the unresected volume of bone with the models of the resected volume of bone to provide an estimate of the volume of bone that will be resected as shown for example in FIG.s 4A and 4B.

[0039] FIG.s 5A to 5C further illustrate how the STL files can be used to model the amount of tissue to be resected 510, as shown in FIG. 5B. The resected region of bone 510 is then precisely filled using CAD modelling constrained by the pre-resection medical image data to provide a generalised shape of the proposed orthopaedic implant 520 as shown in FIG. 5C.

[0040] Since the aim of limb salvage surgery is to fill the resected region with a customised orthopaedic implant which substantially corresponds to not only to the configuration of the resected volume of bone, but also to ensure that the orthopaedic implant substantially corresponds to the biomechanical properties of the surrounding bone, the orthopaedic implant design must take into account the properties of the surrounding bone. These properties can be calculated using Young’s Modulus-bone density relationship using a bone density library and well established theoretical models at step 225.

[0041] Use of high resolution STL files enables accurate assignment of patient specific loads and boundary conditions such as tendon and ligament attachments that can be discerned from medical imaging data. The patient specific loads and boundary conditions are typically ascertained from magnetic resonance imaging (MRI) data or similar, whilst the resected bone volume determinations may be based on computed tomography (CT) data, laser scanner or the like.

[0042] At step 230, a variety of physical activities and movements are simulated whilst taking into account the patient’s age and physique, i.e. height, weight etc., in order to determine the loads that will be incurred by the customised orthopaedic implant post fixation. Such activities may include walking, running, jumping and external impact. Each activity will subject the orthopaedic implant to different load magnitudes and directions.
[0043] An example of a simulation is shown in FIG. 6A, wherein the loads on a femur whilst walking are illustrated. These loads may be estimated using OpenSim software tool (Delp SL, Anderson FC, Arnold AS, Loan P, Habib A, John CT, Guendelman E, Thelen DG. OpenSim: Open-source Software to Create and Analyze Dynamic Simulations of Movement. IEEE Transactions on Biomedical Engineering. (2007)) or similar. The estimated loads are applied to a three dimensional model of the femur to illustrate the loads on different areas of the femur as shown in FIG. 6B. Different activities will subject the orthopaedic implant to different load magnitudes and directions dependent on the physique of the patient.

[0044] Referring now to FIG. 2B, a digital model of the orthopaedic implant comprising of lattice structure that is conformal to the resected volume of the bone is developed at step 235. This step is carried out using a custom designed algorithm, which automatically imports the implant volume and converts it into a periodic lattice structure. At this stage features such as density gradient, choice of unit cell are interactively selected via a graphic user interface (GUI).

[0045] At step 240, the resulting digital model of the customised orthopaedic implant is adjusted to accommodate the requisite surgical features that are necessary to enable the orthopaedic implant to be suitably located and fixed to the bone. Such surgical features include custom surgical guides, fixation brackets and tailored screws.

[0046] Later at step 245, the proposed orthopaedic implant configuration is assessed to determine whether it can be manufactured using additive technology. Typical additively manufactured parts use structural supports to brace the part against the loads generated while laying and solidifying the preceding layers. These structures are difficult to remove, especially for complex geometries such as lattice structures. Hence it is desirable to avoid use of support structures within the part. If the proposed orthopaedic implant is not able to be manufactured without the use of support structures, using additive technology at 250, then the proposed orthopaedic implant configuration is modified to meet the manufacturing constraints at step 253. Some examples of suitable modifications include changing a feature thickness, modifying an inclination of a feature, adding or removing support features. Residual
stresses owing to the thermal gradient between the lattice and fixation brackets are compensated by generating additional removable struts.

[0047] Development and optimisation of the digital implant model takes into account the anatomical function of the bone, the properties of the bone, e.g. density gradient and corresponding variation in stiffness, and the anticipated load that the orthopaedic implant will be subject to during typical activities and movements.

[0048] Once the manufacturability of the implant is ensured at step 255, the lattice geometry or truss structure 700, 750 as generally shown in FIGs. 7A and 7B can be automatically optimised to take specified stresses, deflections and loading conditions as determined at step 230.

[0049] The lattice structure 750 shown in FIG. 7B is optimised to neutralise all possible forms of loading conditions and transmit the load to the load bearing bone and lends itself to manufacturing by additive technology. The lattice structure 700 shown FIG. 7A shows example of an optimised lattice structure that is not manufacturable using additive manufacturing and accordingly not suitable for rapid manufacture of customised orthopaedic implants within surgical time constraints.

[0050] A lattice structure with a periodic arrangement is preferred, i.e. a periodic layout of nodes and struts, since it results in predictable mechanical properties and behaviour. A periodic arrangement enables utilisation of a unit cell based topology wherein the user can assign different types of unit cells according to the structural requirements of the implant. An example of such a periodic lattice structure 800 is shown in Fig. 8A.

[0051] In contrast, aperiodic structures have non-organised arrangement of struts and nodes, making prediction of mechanical behaviour difficult. Currently, two strategies are employed to generate conformal lattice structures. Using the most common method, the organic volume to be filled is intersected by a periodic arrangement of lattice unit cells. Due to periodic nature of the lattice structure and aperiodic surface contour, intersection of lattice structure at nodes is not guaranteed. Accordingly, the structural integrity of such structures is compromised and the purpose of using a periodic structure is not fulfilled. Such structures are also difficult to optimise using available optimisation tools. Using another method of generating
conformal lattice structures, the organically shaped volume is decimated using STL processing software and the corresponding arrangement of nodes and vertices is converted into a lattice structure. Due to aperiodic placement of triangles on a STL file, the resulting structure is also aperiodic. Furthermore, as a result of shape deformation during decimation, accurate application of muscle loads and boundary conditions is difficult. The presently proposed algorithm takes into account the potential shortcomings and aforementioned issues. The ensuing lattice structure is generated directly from a high resolution STL file, enabling accurate assignment of loading conditions. Furthermore, all nodes are located on the surface of the STL, ensuring that the loads are applied at nodes and optimisation process for such structure is computationally efficient.

[0052] FIG.s 9A to 9D illustrate examples of unit cell types that can be applied to a periodic lattice structure 810 as shown in FIG.s 8A and 8B, for example. FIG. 9A shows a body centred cubic cell, FIG. 9B shows a face centred cubic cell with vertical struts, FIG. 9C shows a face and body centred cubic with vertical struts, and FIG. 9D shows face and body centred cubic with horizontal and vertical struts. The body centred cubic (BCC) type cells as shown in FIG. 9A are effectively employed in impact absorption applications due to their compliance. In contrast, the face centred cubic (FCC) type cells as shown in FIG. 9B are stiffer under compressive loading and accordingly useful for energy absorption. FCC type cells tend to be stronger when loaded in the Z direction, compared to the X and Y directions. This property makes them useful for load bearing implants since the resulting structure can exhibit increased stiffness in the loading direction, compared to other directions, enabling a reduction in the weight of the implant. The addition of horizontal elements to the unit cell, see for example the unit cell shown in FIG. 9D, increases the resistance of the structure to torsion and shear loading when compared with any of the other illustrated unit cell types.

[0053] Referring now to FIG.s 10A and 10B, periodicity of the lattice structure also enables application of a functionally gradient structure to permit regulation of stiffness and/or enhance osseointegration (bone-ingrowth) by varying the density of the lattice structure near the bone/implant interface. FIG. 10B FIG shows a change in density of the lattice structure towards the implant interface by employing different unit cell types.
and a larger strut diameter when compared to the rest of the structure. Varying the density in this way near the implant interface enables bone ingrowth to be enhanced whilst at the same time maintaining a lightweight structure. The periodicity of the lattice structure provides precise control over the pore geometry and size. Accordingly, porosity of the structure will be easy to vary depending on whether enhancement of bone ingrowth or controlling stiffness of the implant is prioritised.

[0054] The customised orthopaedic implant is passed through an iterative process of its design involving topological optimisation to identify the optimal geometry to fill the space left by the removed tissue within the constraints provided by the anatomical features of the instant bone and the physique of the patient for whom the orthopaedic implant is being customised from step 260 to 264. If the structure does not meet the stress and deflection criterion, the geometry is modified and the structure is reassessed until optimal solution is achieved. Modification of geometry includes either reduction or increase in strut diameter.

[0055] Once the structure is optimised based on loading conditions at step 264, the three dimensional computer model of the proposed orthopaedic implant configuration is processed for additive manufacture at step 265. Typically this will involve conversion to a file format suitable for transmitting direct to a three dimensional printer or selective laser melting machine. The orthopaedic implant is then manufactured at step 270 using additive technology.

[0056] At step 275, the manufacturing process is monitored to ensure that in-situ process control measures are met. For example, such in-situ control measures might include a check of the build temperature and the manufactured geometry. If the control measures are not within acceptable limits at 280, then the proposed geometry and/or processing is modified at step 285. Suitable modifications might include adding support structure(s), altering the location or orientation of the part on the machine platform or changing the processing parameters.

[0057] If the in-situ control measures are within acceptable limits at 290, then the manufactured customised orthopaedic implant is subject to post processing at step 295, as required. Necessary post-processing may include but is not limited to mechanical and/or chemical processing to enhance the surface finish of the
orthopaedic implant, removal of loose powder particles, and/or sterilisation of the customised orthopaedic implant in preparation for insertion into the patient.

[0058] Finally, at step 298, the manufactured customised orthopaedic implant is delivered to the surgical team together with the relevant instructions for implantation. Referring now to FIG.s 11A to 11C, there is shown in FIG. 11A the unresected bone 1110, in FIG. 11B the resected bone 1120 is shown with the customised orthopaedic implant comprising a periodic lattice structure 1130 fixed thereto and in FIG. 11C a “skin” 1140 is provided over the orthopaedic implant 1130 which has optimally sized pores to enable flow of essential nutrients and promote bone osseointegration i.e. bone in-growth.

[0059] Various software and tools may be employed in implementing the method for producing a customised orthopaedic implant and particularly during the design process. These may include but are not limited to Mimics, Geomagic Studio/VX Elements with laser scanning, Solidworks, Abaqus, Matlab, Haptic Device/Freeform Modelling Plus and Magics/Autofab.

[0060] It is a particular advantage of the present invention, that not only is it possible to provide a customised orthopaedic implant specific to a patient and specific to a particular bone and the manner in which that bone has been resected, within a relatively short time frame. In particular, it appears that the customised orthopaedic implant could be produced in accordance with the method described herein within a period of time in which the patient is under anaesthesia. This suggests a significant improvement over method for producing customised orthopaedic implants which often require multiple surgical interventions before the orthopaedic implant can be inserted and hence result in a much longer recovery and rehabilitation time for the patient as well as often sub-optimal outcomes owing to the difficulty of suitably customising the orthopaedic implant.

[0061] While the invention has been described in conjunction with a limited number of embodiments, it will be appreciated by those skilled in the art that many alternative, modifications and variations in light of the foregoing description are possible. Accordingly, the present invention is intended to embrace all such
alternative, modifications and variations as may fall within the spirit and scope of the invention as disclosed.
The claims defining the invention are as follows:

1. A method for producing a customised orthopaedic implant, the method including the following steps:
   a. scanning a bone from which a diseased region of bone will be resected to obtain a three dimensional digital image of an unresected volume of bone;
   b. scanning the bone after which a diseased region of bone has been resected to obtain a corresponding three dimensional digital image of a resected volume of bone;
   c. comparing the three dimensional digital image of the unresected volume of bone to the corresponding three dimensional digital image of the resected volume of bone to estimate a volume of bone that has been resected;
   d. using the estimate of the volume of bone that has been resected to design a customised orthopaedic implant that substantially corresponds to a configuration of the resected volume of bone, the implant being configured to substantially restore a biomechanical function of the bone;
   e. manufacturing the customised orthopaedic implant; and
   f. providing the customised orthopaedic implant for insertion into the resected region of bone.

2. A method for producing a customised orthopaedic implant according to claim 1, wherein design of the customised orthopaedic implant to substantially restore the biomechanical function of the bone involves consideration of one or more typical loading conditions on a bone type corresponding to the bone that has been resected.

3. A method for producing a customised orthopaedic implant according to claim 2, wherein design of the customised orthopaedic implant involves consideration of typical maximum stress and deflection to which the bone type which corresponds to the resected bone is subjected.

4. A method for producing a customised orthopaedic implant according to any one of claims 1 to 3, wherein the customised orthopaedic implant includes lattice-type geometry.
5. A method for producing a customised orthopaedic implant according to claim 4, wherein the lattice-type geometry includes a periodic arrangement.

6. A method for producing a customised orthopaedic implant according to claim 4 or 5, wherein the porosity of the lattice structure is varied at a bone/implant interface to enhance bone ingrowth.

7. A method for producing a customised orthopaedic implant according to any one of claims 1 to 6, wherein the customised orthopaedic implant is manufactured using additive technology.

8. A method for producing a customised orthopaedic implant according to claim 7, wherein the additive technology involves selective laser melting.

9. A method for producing a customised orthopaedic implant according to any one of claims 1 to 8, wherein scanning a bone to obtain a three dimensional digital image involves obtaining a plurality of two dimensional digital images and constructing a three dimensional digital image therefrom.

10. A method for producing a customised orthopaedic implant according to claim 6 or 8, wherein prior to manufacture the designed customised orthopaedic implant is assessed for suitability for additive manufacture.

11. A method for producing a customised orthopaedic implant according to claim 10, wherein a designed customised orthopaedic implant not considered suitable for additive manufacture is modified to meet additive manufacturing constraints.

12. A method for producing a customised orthopaedic implant according to any one of claims 1 to 11, wherein the three dimensional digital image is used to create a three dimensional computer model of the customised orthopaedic implant.

13. A method for producing a customised orthopaedic implant according to any one of claims 1 to 12, wherein the three dimensional computer model is transmitted to a three dimensional printer.
14. A method for producing a customised orthopaedic implant according to any one of claims 1 to 13, wherein the diseased region of bone is affected by osteosarcoma.

15. A method for producing a customised orthopaedic implant according to any one of claims 1 to 14, wherein steps a. to f. occur consecutively during a period of time in which the patient is under anaesthesia.

16. A customised orthopaedic implant, the implant formed by a method including the following steps:
   a. scanning a bone from which a diseased region of bone will be resected to obtain a three dimensional digital image of an unresected volume of bone;
   b. scanning the bone after which a diseased region of bone has been resected to obtain a corresponding three dimensional digital image of a resected volume of bone;
   c. comparing the three dimensional digital image of the unresected volume of bone to the corresponding three dimensional digital image of the resected volume of bone to estimate a volume of bone that has been resected;
   d. using the estimate of the volume of bone that has been resected to design a customised orthopaedic implant substantially corresponding to a configuration of the resected volume of bone, the implant being configured to substantially restore the biomechanical function of the bone; and
   e. manufacturing the customised orthopaedic implant.
100

Scanning a bone from which a diseased region of bone will be resected to obtain a 3D digital image of an unresected volume of bone

110

120

Scanning the same bone from which a diseased region of bone has been resected to obtain a 3D digital image of a resected volume of bone

130

Comparing a 3D digital image of the unresected volume of bone to the corresponding 3D digital image of the resected volume of bone to estimate the volume of bone that has been resected

140

Using the estimate to design a customised orthopaedic implant substantially corresponding to a configuration of the resected volume of bone to substantially restore the biomechanical function of the bone

150

Manufacturing the customised orthopaedic implant

160

Providing the customised orthopaedic implant for insertion into the resected region of bone

FIG. 1
MEDICAL IMAGING DATA AQUIRED BY SURGICAL TEAM

MEDICAL IMAGING DATA POST-PROCESSED TO IDENTIFY RELEVANT ATTRIBUTES

SURGICAL TEAM ADDS VALUE TO SCAN DATA

ENGINEERING TEAM EVALUATES THE DATA AND VIRTUALLY RECREATES THE AFFECTED BONE IN THREE DIMENSIONS

BONE PROPERTIES ARE CALCULATED USING YOUNG'S MODULUS-BONE DENSITY RELATIONSHIP ESTABLISHED USING BONE DENSITY LIBRARY AND THEORETICAL MODELS

VARIOUS PHYSICAL ACTIVITIES ARE VIRTUALLY SIMULATED BASED ON PATIENT ANATOMY TO DETERMINE LOADS THAT WILL BE TRANSFERRED TO THE IMPLANT POST FIXATION

(cont’d in FIG. 2B)
PROPOSED DIGITAL MODEL IS PROCESSED FOR ADDITIVE MANUFACTURE

ADDITIVE MANUFACTURE IS COMPLETED

ARE IN-SITU PROCESS CONTROL MEASURES SATISFACTORY?

YES

MANUFACTURED PART IS POST-PROCESSED AS REQUIRED, INCLUDING:
MECHANICAL AND CHEMICAL PROCESSING TO ENHANCE SURFACE FINISH AND REMOVE LOOSE POWDER PARTICLES
STERILISATION OF IMPLANT

MANUFACTURED PART AND RELEVANT DOCUMENTATION IS DELIVERED TO THE SURGICAL TEAM FOR IMPLANTATION

FIG. 2C
PATENT COOPERATION TREATY
PCT
INTERNATIONAL SEARCH REPORT
(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference
1021353

FOR FURTHER ACTION
see Form PCT/ISA/220
as well as, where applicable, item 5 below.

International application No.
PCT/AU2015/000124

International filing date (day/month/year)
04 March 2015

(Earliest) Priority Date (day/month/year)
04 March 2014

Applicant
RMIT UNIVERSITY

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report
   a. With regard to the language, the international search was carried out on the basis of:
      ☑ The international application in the language in which it was filed.
      ☐ A translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
   b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).
   c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II).

3. ☐ Unity of invention is lacking (See Box No. III).

4. With regard to the title,
   ☑ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,
   ☑ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,
   a. the figure of the drawings to be published with the abstract is Figure No. 11B
      ☑ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/28 (2006.01)   A61F 2/30 (2006.01)   B29C 67/00 (2006.01)   A61B 17/56 (2006.01)

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)

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)


Google Patents: osteosarcoma, imaging, 3d, model, additive manufacturing, custom, second, reconstruct or applicant search= RMIT university

Google Patents: osteosarcoma, disease, bone, implant, imaging, additive manufacturing, 3d, print, load, reconstruct (in various combinations)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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Documents are listed in the continuation of Box C

- * Special categories of cited documents:
  - "A" document defining the general state of the art which is not considered to be of particular relevance
  - "E" earlier application or patent but published on or after the international filing date
  - "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  - "O" document referring to an oral disclosure, use, exhibition or other means
  - "P" document published prior to the international filing date but later than the priority date claimed

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

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

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

- "&" document member of the same patent family

Date of the actual completion of the international search: 30 March 2015
Date of mailing of the international search report: 30 March 2015

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
Email address: pct@ipaustralia.gov.au

Authorised officer

Emma Francis
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No. 0399359631

Form PCT/ISA/210 (fifth sheet) (July 2009)
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<td>US 5,370,692 A (FIN K et al.) 06 December 1994</td>
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<td>Unwin, Paul. &quot;Fabricating specialised orthopaedic implants using additive manufacturing.&quot; SPIE LASER. International Society for Optics and Photonics, 2014. See whole document</td>
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This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

Form PCT/ISA/210 (Family Annex)(July 2009)