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(54) Title: POROUS DENTAL IMPLANT

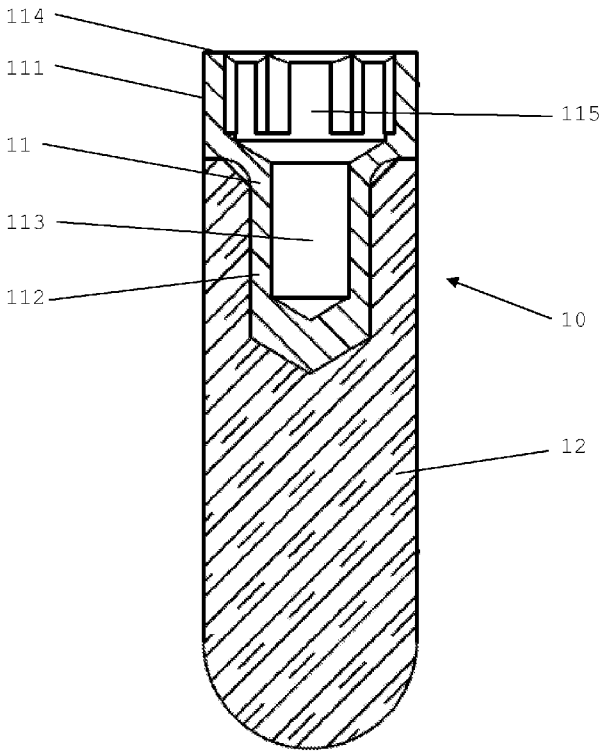


FIG 1

(57) Abstract: The present invention is related to a dental implant (10) comprising a unitary dense member (11) made of a biocompatible material and a porous body (12) made of a porous biocompatible material and having a compressive strength higher than 40 MPa. A portion (112) of the dense member is surrounded by the porous body. The remainder portion (111) projects out of the porous body. The porous body comprises open interconnected pores. The biocompatible material is preferably Ti or a Ti-alloy. The invention is equally related to a method of manufacturing a dental implant comprising the steps of : producing a dense member of a biocompatible material, producing a porous body of a porous biocompatible material and bonding the porous body to the dense member. The bonding is performed by sintering.

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POROUS DENTAL IMPLANT

Field of the Invention

[0001] The present invention is related to a dental implant and a method of manufacturing the implant.

State of the Art

[0002] Titanium and Ti-alloys are commonly used for the production of surgical implants, because of their strength/weight ratio, their high resistance to corrosion and relatively low elasticity modulus, and their biocompatibility. Therefore, Ti and Ti-alloys are already used in a large number of implant materials in a dense form, e.g. for dental implants, shoulder-, hip-, finger-implants, etc.

[0003] Dense titanium implant materials have the disadvantage to loose their fixation after some time due to their higher strength and higher E-modulus compared to trabecular bone. This phenomenon is known as "stress shielding" [1,2]. A conventional way of improving the fixation is to increase the roughness of the surface or to coat it with a calcium phosphate layer.

[0004] Nevertheless, many implant materials are loosing their fixation with the bone by "stress shielding" with extra painful operations and high costs as a result.

[0005] References:

1. Garrett Ryan, Abhay Pandit, Dimitrios Panagiotis Apatsidis, “Fabrication methods of porous metals for use in orthopaedic applications”, Biomaterials 27 (2006), pp. 2651-2670

2. P. Habibovic, J. Li, C.M. vanderValk, G. Meijer, P. Layrolle, C.A. Van Blitterswijk, K. de Groot, Biomaterials 26 (2005), pp. 23-36

[0006] Patent application WO 02/34155 discloses a porous TiNi dental implant of cylindrical shape. The pores are permeable so as to allow osseointegration of the implant into the bone. As the porous body has not sufficient strength and is elastically deformable, the implant is reinforced by at least one wire of dense TiNi running along the entire length of the implant. The porous body and the reinforcing wires are manufactured simultaneously, in the same process by an agglomeration technique. However, in order to avoid infections, a polymer coating has to be provided on the neck and the supporting head. Another disadvantage of this implant is that the dental crown is fastened onto the polymer coating with no contact with the metal parts of the implant.

[0007] US patent 5344457 discloses an implant to which a dental bridge may be connected. The implant comprises a lower bone-engaging region and an upper bone attachment region. The lower region is provided with a porous surface into which bone may grow. The porous surface is comprised of a network of discrete particles. The upper region has a surface suitable for bone attachment which is different from the surface of the lower region.

Aims of the Invention

[0008] The present invention aims to provide a dental implant which overcomes the drawbacks of prior art implants. It is an aim of the invention to provide at least an alternative dental implant having at least a same and preferably an improved functionality compared with dental implants of the prior art. The present invention equally aims to provide a method of manufacturing the implant.

Summary of the Invention

[0009] Aims of the invention are achieved by providing a dental implant and a method of manufacturing said implant as set out in the appended claims. According to the invention, there is provided a dental implant comprising (or consisting of) a porous body made of a porous biocompatible material and a dense member made of (or consisting of) one biocompatible material (i.e. a single material, not multiple, different materials). The dense member is arranged for accepting a dental crown. The dense member is preferably arranged for removable connection of a dental crown. In dental implants of the invention, a first portion of the dense member is surrounded by the porous body and a second, remaining portion of said dense member projects out of the porous body. The first portion and the second portion of the dense member together constitute the dense member. In the present context, dense bears the meaning of air-tight.

[0010] According to the invention, the porous body is made of a porous biocompatible material having a compressive strength higher than 40 MPa, preferably falling in the range between 50 MPa and 75 MPa, more preferably, between 55 MPa and 75 MPa.

[0011] The dense member is preferably a unitary piece. It is made of one material. The dense member can be made from a powder material.

[0012] Said first portion of the dense member can extend along the entire length of the porous body. Said first portion can also project out of the porous body, at an end remote from said second portion.

[0013] Preferably, the porous body comprises open interconnected pores. More preferably, the pores have a mean size in the range between 100 µm and 500 µm.

[0014] Preferably, the porous body is made of porous titanium or a porous Ti-alloy. Preferably, the dense member is made of titanium or a Ti-alloy.

[0015] Preferably, the porous body surrounding said first portion of the dense member has a thickness larger than or equal to 0.5 mm.

[0016] Preferably, the outer size of the second, remaining portion of the dense member is larger than the outer size of said first portion of the dense member, the outer sizes measured in planes perpendicular to the longitudinal axis of the dental implant. Preferably, said outer size of the second portion is equal to or larger than the outer size of the porous body, the outer sizes measured in planes perpendicular to the longitudinal axis of the dental implant.

[0017] Preferably, the dense member comprises a blind hole. The blind hole preferably extends into said first portion of the dense member. The blind hole can comprise thread. The thread is preferably smaller than M2. The blind hole can comprise a portion having a hexagonal form, which is preferably comprised in the second portion.

[0018] The second portion of the dense member can have a conical shape.

[0019] Preferably, dental implants of the invention comprise at least one additional dense member. The dense member is bonded to the porous body.

[0020] According to a second aspect of the invention, there is provided a method of manufacturing a dental implant comprising the steps of: producing a dense member from a biocompatible material, preferably a metal, producing a porous body of a porous biocompatible material, preferably a metal and bonding the porous body and the dense member.

[0021] Preferably, the step of producing a porous body comprises using a gelcasting technique. Equally preferably, the step of producing a porous body comprises using a 3D fibre deposition technique. A rapid prototyping technique can be used as well for producing the porous body.

[0022] The bonding step can comprise the step of partially introducing the dense member into the porous body. Preferably, the bonding step comprises bringing the porous body and the dense member in intimate contact followed by a sintering step. More preferably, the bonding step comprises applying sinter-active powder to the dense member, the porous body, or both.

[0023] Preferably, one or more of the steps of: producing a dense member, producing a porous body and the bonding step comprise applying a thermal treatment. The thermal treatment can comprise a sintering step. The thermal treatment preferably comprises a pre-sintering step. The thermal treatment more preferably comprises a calcining step.

Brief Description of the Drawings

[0024] Figure 1 represents a cross-section of a dental implant of the invention, comprising a dense member acting as an implant base and a porous body.

[0025] Figure 2 represents different views of the implant of figure 1.

[0026] Figure 3 represents a block of porous titanium with dental roots fixed to it.

Detailed Description of the Invention

[0027] The dental implant of the invention comprises a porous body and a dense member. The dense member is arranged for accommodating a dental crown. The porous body

ensures a strong fixation of the dental implant to the surrounding bone. The dense member and the porous body are bonded to each other. The porous body is made of a porous biocompatible material, preferably a metal. The dense member is made of a dense biocompatible material, preferably a metal. More preferably, the porous body is made of a porous titanium or Ti-alloy, and the dense member is made of titanium or Ti-alloy.

[0028] Dental implants according to the invention are envisaged to be implanted in humans for tooth reconstruction. Dental implants according to the invention are equally well envisaged to be implanted in animals, such as dogs and horses.

[0029] The dense member is preferably made of a biocompatible metal, preferably titanium or a Ti-alloy, in particular an alloy with aluminium and vanadium (e.g. Ti-6Al-4V). Other metals that can alternatively be used are stainless steel and alloys of cobalt, chromium and molybdenum (Co-Cr-Mo alloys).

[0030] The porous body can be made of a (porous) biocompatible material as indicated hereinabove (for the dense member). The porous body can be made of a material different from the material of the dense member. Preferably, the dense member and the porous body are made of a same material. This is advantageous for preventing disparate thermal expansion coefficients.

[0031] Embodiments of the present invention will now be described in detail with reference to the attached figures, the invention is not limited thereto but only by the claims. The drawings described are only schematic and are non-limiting. In the drawings, the size of some of the elements may be exaggerated and not drawn on scale for illustrative purposes. The dimensions and the relative dimensions do not necessarily correspond to actual

reductions to practice of the invention. Those skilled in the art can recognize numerous variations and modifications of this invention that are encompassed by its scope. Accordingly, the description of preferred embodiments should not be deemed to limit the scope of the present invention.

[0032] Furthermore, the terms first, second and the like in the description and in the claims are used for distinguishing between similar elements and not necessarily for describing a sequential or chronological order. It is to be understood that the terms so used are interchangeable under appropriate circumstances and that embodiments of the invention described herein are capable of operation in other sequences than described or illustrated herein.

[0033] Moreover, the terms top, bottom, left, right, over, under and the like in the description and the claims are used for descriptive purposes and not necessarily for describing relative positions. The terms so used are interchangeable under appropriate circumstances and embodiments of the invention described herein can operate in other orientations than described or illustrated herein. For example, "left" and "right" of an element indicates being located at opposite sides of this element.

[0034] It is to be noticed that the term "comprising", used in the claims, should not be interpreted as being restricted to the means listed thereafter; it does not exclude other elements or steps. Thus, the scope of the expression "a device comprising means A and B" should not be limited to devices consisting only of components A and B. It means that with respect to the present invention, A and B are relevant components of the device.

[0035] Where numerical values are given with regard to limitations of a quantity, or the outcome of a measurement, for the assessment of those values, account

shall be taken of variations due to impurities, methods used to determine measurements, human error, statistical variance, etc.

[0036] Where a range of numerical values is defined as extending between a lower limit and an upper limit, the range is to be construed as including said lower limit and said upper limit, unless otherwise noted.

[0037] By way of example, an implant 10 is shown cross-sectionally in figure 1. Dental implant 10 is a tooth root implant. The implant's shape is essentially cylindrical, but other shapes for the implant are equally envisaged by the present invention and the shape of the implant of figure 1 is merely used for illustrative purposes.

[0038] Dental implant 10 comprises a member 11 of a dense biocompatible material (e.g. titanium or a Ti-alloy). Dental implant 10 also comprises a porous body 12 of a porous biocompatible material (e.g. porous titanium or a porous Ti-alloy). The dense member 11 and the porous body 12 are preferably manufactured separately and are bonded to each other afterwards.

[0039] The dense member 11 is a unitary piece and is made of one (kind of) material. A first portion 112 is immersed into the porous body so as to be surrounded by the porous body 12. A second portion 111 (i.e. the remaining portion of the dense member 11) projects out of the porous body, at an end of the implant.

[0040] The second portion acts as an implant base 111, being a seat for a dental crown. The first portion has the shape of a pin 112 and projects from the base 111 into the porous body. Both the base and the pin have preferably an essentially cylindrical outer shape. Other geometries are however possible. The outer size (diameter) of the base 111 is larger than the outer size (diameter) of the pin

112. The base 111 and the porous body 12 hence can have the same outer diameters. According to a preferred embodiment, the base 111 of the dense member has a size larger than or equal to the size of the porous body 12. In another, preferred embodiment, the implant base (111) has a conical shape.

[0041] The particular design of the dental implant 10 of the invention allows to prevent infections of the bone tissue without the need to provide the implant with special air-tight coatings. It is important for dental implants that the bone tissue is shielded from contact with the oral ambient (air), as this can transmit infections to the bone. The dental implant 10 is envisaged to be completely immersed in bone. Alternatively, an upper part of the second portion (base) 111 of the dense member is envisaged to project out of the bone and to be surrounded by gingival tissue. An air path towards the bone in which the implant is fixed is avoided because the porous body 12 is shielded from contact with air by the dense member 11. At an end, distal from the bone, the porous body abuts against the dense member. The porous body 12 is arranged to be completely immersed in the bone tissue. In addition, the implant 10 may not provide any air path through the dense member 11 communicating between the oral ambient and the porous body 12. Therefore, the term dense is used here to mean air-tight.

[0042] Preferably, the dense member does not comprise open porosity (no connected or "through" pores).

[0043] Base 111 acts as a seat for a dental crown. The dental crown can be fastened to the tooth root 10 according to various ways known in the art. In the example of figure 1, the dense member 11 comprises a blind hole 113, arranged to accept a fastening element. The fastening element can be a bolt, in which case hole 113 is provided

with internal thread. The thread can be e.g. M 1.6 or M 1.8. Hole 113 extends from the base 111 into the pin 112.

[0044] An upper portion 115 of the blind hole 113 (i.e. a portion of the hole 113 comprised in the second portion or implant base) can have a hexagonal shape for fitting a dental crown. Other polygonal shapes are possible as well.

[0045] Porous body 12 is permeable for bone cells. The pores of porous body 12 should have a size so as to allow bone cell growth within the porous structure of porous body 12. The growth of bone cells within a porous structure of a biocompatible material has been found to occur for pores having a size of 50 µm and more. Preferably, the pores of the porous body 12 are tortuous and are open interconnected pores.

[0046] Preferably, the pore size distribution of the porous body 12 can be customized with a pore size lying in the range between 50 µm and 1500 µm, more preferably in the range between 50 µm and 1000 µm and most preferably in the range between 50 µm and 500 µm. Pore size can be measured by image analysis.

[0047] Preferably, the mean pore size of the porous body preferably falls in the range between 100 µm and 500 µm, which is generally recognized as ideal for allowing bone in-growth. More preferably, the mean pore size of the porous core part falls in the range between 200 µm and 400 µm, most preferably in the range between 200 µm and 300 µm.

[0048] The porosity of the porous body 12 preferably falls in the range between 25 % and 95 % of the theoretical density (TD), with the range between 60% and 90% TD being preferred and the range between 70% and 80% TD being more preferred. Porosity ranges as indicated constitute an optimal compromise between open structure and mechanical strength of the porous body. Hence, bone can grow into the

porous structures of the porous body 12, improving the fixation of the implant. The enhanced bone in-growth creates a biological fixation and minimizes the problem of stress shielding.

[0049] The portion of porous body 12 which surrounds pin 112 has preferably a thickness equal to or larger than 0.5 mm for mechanical strength. The diameter of the dental implant 10 can be on the order of 4 mm. It is important to note that the porous body 12 is not a coating that is applied onto the dense member 11, as is known in the prior art. The porous body 12 is a bulk porous part to which a dense member is bonded.

[0050] The compressive strength of the porous material used for the porous body 12 is higher than 40 MPa. For porous Ti or Ti-alloys having a porosity of about 70% TD, the compressive strength is on the order of 50-60 MPa. Most ideal for the porous body is to have a compressive strength between 55 MPa and 75 MPa. For a given porous material, the compressive strength is dependent on the amount of porosity. The higher the porosity, the lower the compressive strength will be. A high strength of the porous body obviates the need of reinforcing the porous body with dense material, such as rods or wires. An optimal implant hence results from a trade-off between porosity and strength of the porous body.

[0051] The bond strength between dense member and porous body is of primary importance for a good and long-lasting implant. Preferably, the bond strength between dense member and porous body is higher than the strength of the material of the porous body.

[0052] Figure 2 shows a few views of the dental implant of figure 1. Typically, a tooth root implant is of a cylindrical shape with a spherical ending 20 at the

bottom. Blind hole 113 is arranged for accepting a dental crown and corresponding fixation element.

[0053] Advantageously, the upper surface of the dense member forms a seat (base) for a dental crown. Said upper surface preferably does not comprise projections extending above said upper surface. The upper surface is preferably formed of a flat plane.

[0054] A second aspect of the invention is related to a method of manufacturing the dental implant of the invention.

[0055] In a step of the method of manufacturing, the porous body 12 is produced. Porous bodies are preferably produced by a foam technique (e.g. by gel-casting or tape-casting foamed suspensions). They can be produced by a 3D fibre deposition technique. They can be produced by a other rapid prototyping technique. These techniques allow to manufacture porous titanium or Ti-alloy. Reference is made here to patent application WO 2006/130935, describing the use of gel-casting to produce porous bodies in titanium or a Ti-alloy, and to the paper "Porous Ti6Al4V scaffold directly fabricating by rapid prototyping: preparation and in vitro experiment", Jia Ping Li et al., Biomaterials 27 (2006) pp. 1223-1235, describing the use of rapid prototyping for that purpose.

[0056] The porous body is preferably produced by gel-casting.

[0057] Careful control of the production process parameters in the manufacture of the porous body allows to obtain a wide variety in (micro)structural characteristics (porosity, pore size distribution, etc.) of the porous body. These production process parameters can be chosen out of the group comprising: powder quality, viscosity of the suspension, loading, composition, gelling agent and concentration thereof, foaming agent, mixing time,

calcination parameters (temperature, heating rate, vacuum pressure and time period), sintering parameters (temperature, heating rate, vacuum pressure and time period), etc. Hence, the mechanical properties and the porosity of the porous body can be tuned within a wide range, avoiding a large discrepancy in mechanical properties of the porous body with these of the surrounding bone.

[0058] In another, distinct step, the dense member 11 is produced. The dense member 11 can be machined into a desired form starting from a bulk part, or can be manufactured based on a powder material which is then brought into a desired form and sintered. In the latter case, the green (not sintered) or sintered part can be machined to the required tolerances.

[0059] In case the dense member is produced based on a powder material (by powder metallurgy), the final (sintered) dense member has preferably a density of at least 95% TD. Preferably, the surface pores of the dense member are smaller than 1 µm. Those pores are not open pores.

[0060] At this stage of the manufacturing procedure, the porous body 12 can be in green (not sintered), pre-sintered (having undergone a thermal treatment at e.g. 1000°C, but not sintered), or sintered state. The dense member 11 can be in a green, a pre-sintered or a dense (in case of machining from bulk material) state. Next, the porous body 12 is prepared (machined) for accepting the dense member 11. Subsequently, the dense member 11 is (partially) introduced into the porous body 12. Dense member 11 and porous body 12 are brought into contact and are sintered together, preferably under high vacuum (pressures of 10^{-4} mbar or smaller - higher vacuum) and preferably at temperatures between 1200°C and 1500°C.

[0061] In the case of a green porous body, the sintering step is preceded by a calcination step, preferably at temperatures between 400°C and 600°C. A slow heating until temperatures as indicated is preferred, such as with a heating rate smaller than or equal to 25°C per hour, more preferably smaller than or equal to 20°C per hour. Calcination is preferably performed in vacuum (at pressures around 10^{-3} mbar, preferably between 10^{-5} mbar and 10^{-3} mbar) and/or in an argon atmosphere. The calcination step is necessary in order to burn out organic components which are still present in the green state. The burning of these organic components during sintering would otherwise produce gasses which would induce cracks and damage the structure.

[0062] In order to improve the fixation between porous and dense members by the sintering step, the dense member and the porous body have to be brought in close contact. The bonding between dense member and porous body can be improved by adding fine sinter-active powder (e.g. Ti-powder in case of Ti or Ti-alloys) on one or both surfaces that are brought into contact, or by sandblasting the surfaces in order to remove the TiO_2 layer.

[0063] According to a particular embodiment of the invention, titanium (Ti) or a titanium alloy are used as preferred materials for the porous body and the dense member. Other biocompatible metals as identified above can alternatively be used.

[0064] Conventional machining techniques can be used to give the porous body the right dimension or to bring the combined component (porous body and dense member) after the sintering step to the specified tolerances.

[0065] An advantage of the design of the dental implant 10 of figure 2 is that the machining to the specified tolerances of the upper surface 114 of base 11

can be deferred until the end of the manufacturing process, i.e. until after the sintering step in which porous body 12 and dense member 11 are bonded. The sintering and the other thermal treatments may induce small deformations to the geometry of the dental implant. As the upper surface 114 acts as a seat for a dental crown, it is important to keep this surface flat. By having a base 111 of the same outer diameter, or even a bit larger than the outer diameter of the porous body, final machining of the surface 114 can be accomplished readily by clamping the dental implant at the base 111. Hence there is no problem of damaging the porous body due to clamping.

[0066] The co-sintering of dense and porous Ti or Ti-alloy parts creates the possibility to develop a large number of improved medical components. Furthermore, the separate manufacturing of the dense member and the porous body allows to tailor the manufacturing processes of dense member and porous body individually.

Description of a Preferred Embodiment of the Invention

[0067] The dense member is manufactured from Ti or Ti-6Al-4V (or another Ti alloy) and is machined following a typical design as shown in figure 1.

[0068] The porous Ti, Ti-6Al-4V or other Ti-alloy part is manufactured by gelcasting. A suspension is prepared using 300g Ti (T-1147, Cerac, -325 mesh), 201 H_2O, 6g Agar (3.18% on H_2O), 6g Tergitol TMN10 (2% on Ti), 3g Triton (1% on Ti) and 0.36 g Ammonium alginate (0.18% on H_2O). It is mixed during 6 minutes at 70°C to obtain a fluid foam. The foam is cast into a mould and cooled down until the structure is gellified. After demoulding, the structure is dried at atmospheric pressure and room temperature. The structure is calcined (10^{-3} mbar, 25°C/hour up to 500°C), pre-sintered at 1000°C (2 hours

isotherm) and sintered at 1350°C in a vacuum of 10^{-5} mbar (heating rate 5°C/min to 1350°C). After sintering, a block of porous Ti (or a Ti alloy) is obtained.

[0069] Holes with dimensions of the dental root (i.e. the dense member 11) are drilled in the porous Ti-block. The holes in the Ti-block are placed so that their interdistance is large enough to allow further machining later on.

[0070] The dense roots 11 are placed in the holes of the porous block and fixed by a second sintering during 2 hours at 1350°C. Figure 3 shows the porous Ti block 32 with the fixed tooth root implants 11. After a machining step to flatten the surface, the block is cut in parts, each part comprising one or more dental roots. Each part will eventually constitute an implant, after being machined individually until the porous body has the designed geometry to fit in the bone. Hence, in an embodiment of the invention, a dental implant can comprise more than one dense members, bonded to one and the same porous body.

[0071] While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be obvious to those skilled in the art that various changes and modifications may be made therein without departing from the spirit and scope of the present invention.

CLAIMS

1. A dental implant (10) comprising a porous body (12) made of a porous biocompatible material and a dense member (11) made of one biocompatible material, the dense member arranged for accepting a dental crown, wherein:

- a first portion (112) of the dense member is surrounded by the porous body,
- a second portion (111) of said dense member projects out of the porous body and
- the porous biocompatible material has a compressive strength higher than 40 MPa.

2. The dental implant according to claim 1, wherein the porous biocompatible material has a compressive strength falling in the range between 50 MPa and 75 MPa, preferably in the range between 55 MPa and 75 MPa.

3. The dental implant according to claim 1 or 2, wherein the porous body (12) comprises open interconnected pores.

4. The dental implant according to claim 3, wherein the pores have a mean size in the range between 100 µm and 500 µm, preferably between 200 µm and 400 µm.

5. The dental implant according to any one of the preceding claims, wherein the porous body (12) is made of porous titanium or a porous Ti-alloy and the dense member (11) is made of titanium or a Ti-alloy.

6. The dental implant according to any one of the preceding claims, wherein the outer size of said second portion (111) of the dense member is:

- larger than the outer size of said portion (112) of the dense member and
- at least equal to the outer size of the porous body (12),

the outer sizes measured in one or more planes perpendicular to the longitudinal axis of the dental implant.

7. The dental implant according to any one of the preceding claims, wherein the dense member comprises a blind hole (113).

8. The dental implant according to claim 7, wherein the blind hole comprises a portion (115) having a hexagonal form.

9. The dental implant according to any one of the preceding claims comprising at least one additional dense member as in any one of the preceding claims.

10. A method of manufacturing a dental implant comprising the steps of:

- producing a dense member (11) from a biocompatible material,
- producing a porous body (12) of a porous biocompatible material and
- bonding the porous body and the dense member,

wherein the bonding step comprises bringing the porous body and the dense member in intimate contact followed by a sintering step.

11. The method according to claim 10, wherein the bonding step comprises applying sinter-active powder to the dense member, the porous body, or both.

12. The method according to claim 10 or 11, wherein the step of producing a porous body (12) comprises using a gelcasting technique, 3D fibre deposition technique or a rapid prototyping technique to produce the porous body.

13. The method according to any one of the claims 10 to 12, wherein one or more of the steps of: producing a dense member (11), producing a porous body (12)

and bonding step comprise applying a thermal treatment comprising one or more of the steps of: calcining, pre-sintering and sintering.

14. The method according to any one of the claims 10 to 13, wherein the porous body (12) is made of a metal and wherein the dense member (11) is made of a metal.

15. The method according to claim 14, wherein the porous body is made of titanium or a Ti-alloy and the dense member is made of titanium or a Ti-alloy.

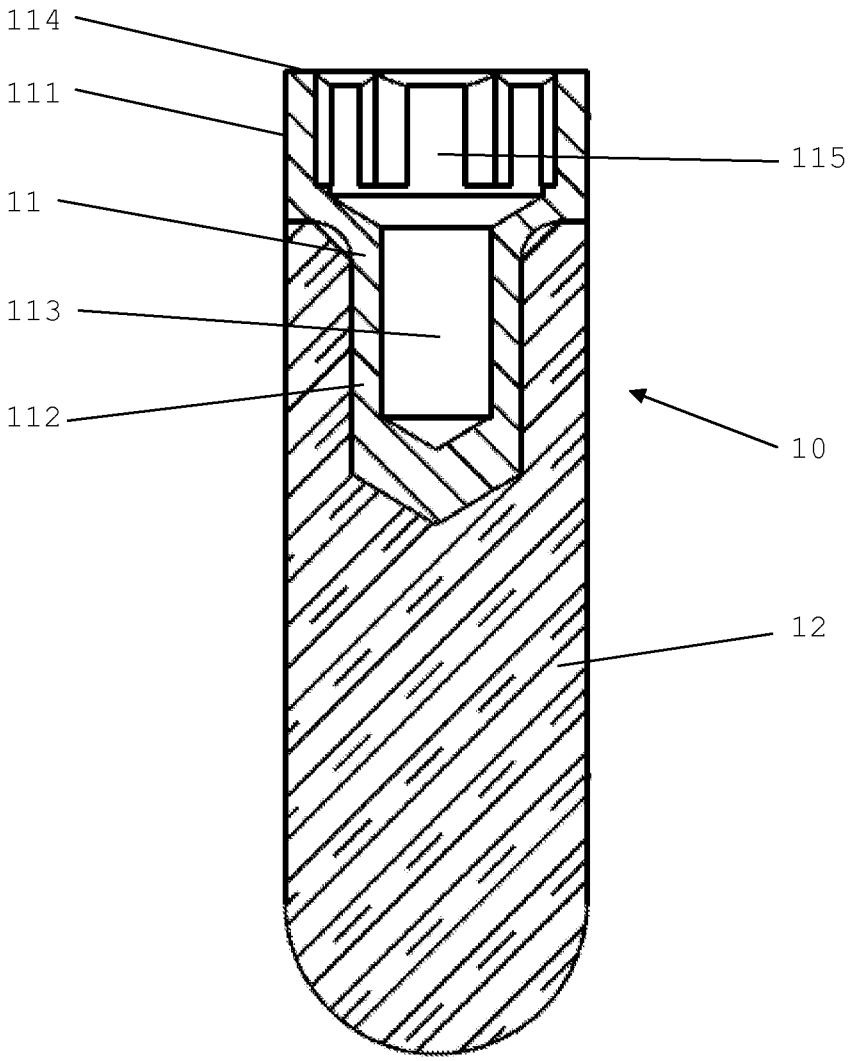


FIG 1

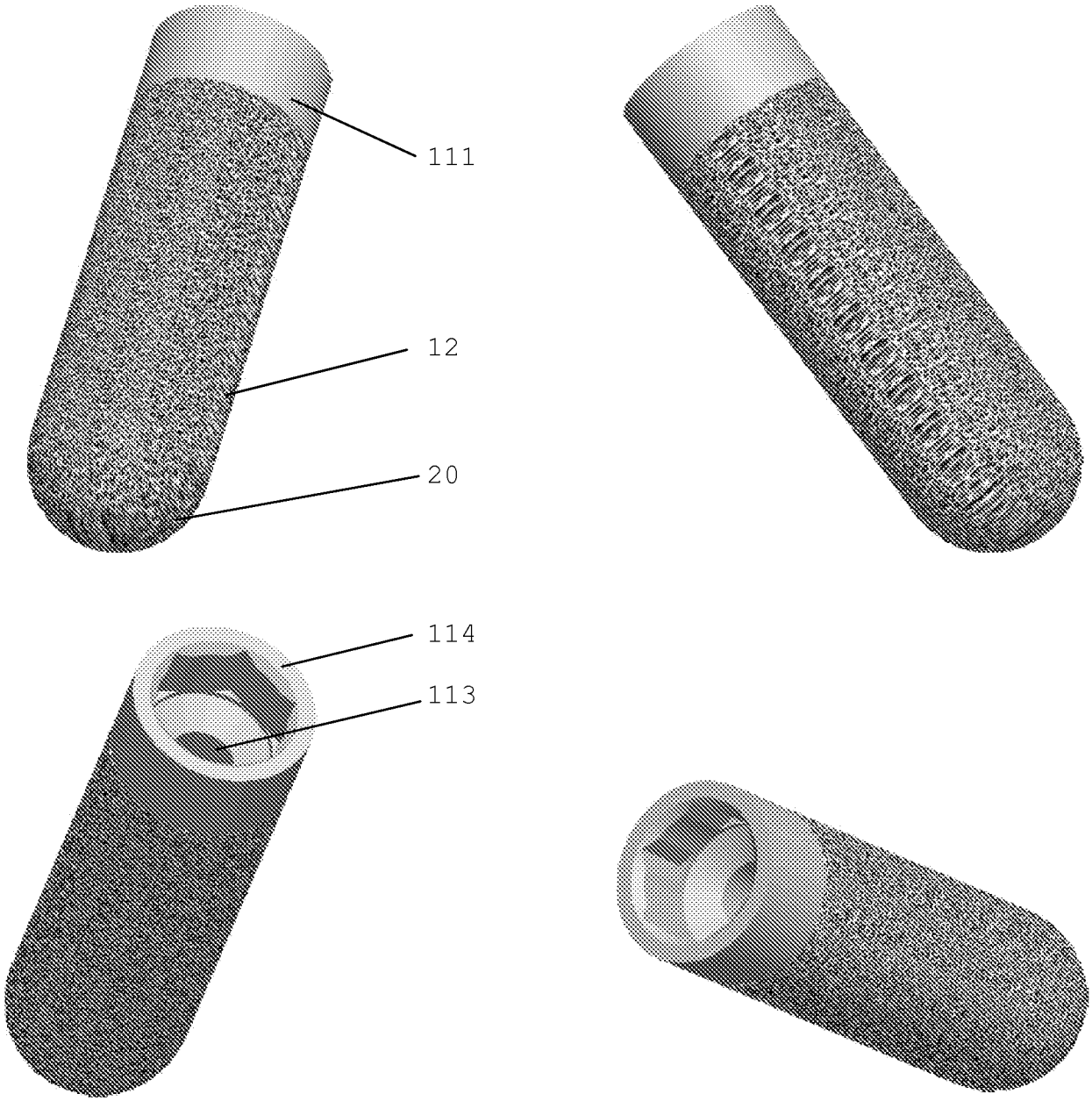


FIG 2

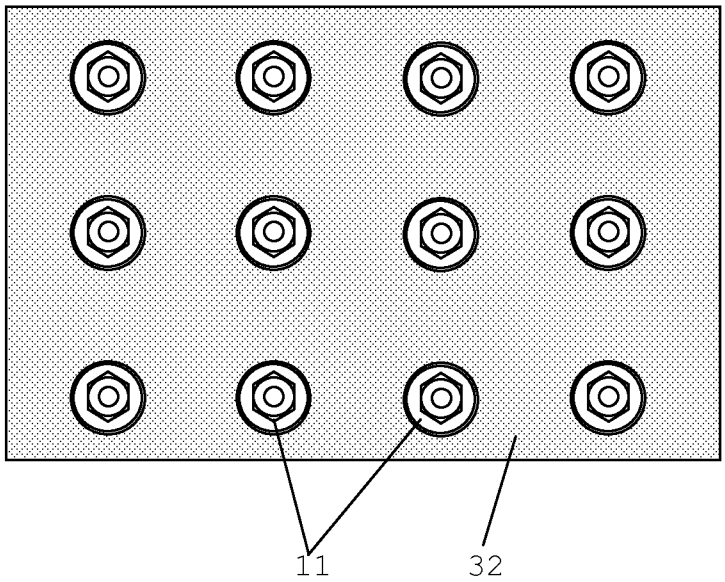


FIG 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/058623

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61C8/00

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)
A61C

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2004/121290 A1 (MINEVSKI ET AL.) 24 June 2004 (2004-06-24)	1
A	paragraph [0025] paragraph [0035] paragraph [0042] - paragraph [0043] paragraph [0054] - paragraph [0055]; claims 1,28,30,34,68,76,82,84,85,95	3-5
Y	US 2005/251267 A1 (WINTERBOTTOM ET AL) 10 November 2005 (2005-11-10) paragraph [0097] paragraph [0117]	1
X	US 4 259 072 A (HIRABAYASHI ET AL.) 31 March 1981 (1981-03-31)	10-15
A	column 2, line 63 - column 3, line 11 column 4, line 50 - line 57 figures 1-7,11	3,4,6,7

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

* Special categories of cited documents :

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

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"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	Date of mailing of the international search report
7 November 2008	19/11/2008

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/058623

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 344 457 A (PILLIAR ET AL.) 6 September 1994 (1994-09-06) cited in the application	10-15
A	column 4, line 66 - column 6, line 9 column 8, line 61 - column 9, line 13 claims 1,5,13	3-7

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2008/058623

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004121290 A1	24-06-2004	AU 2003272451 A1	30-04-2004
		EP 1542738 A1	22-06-2005
		WO 2004024202 A1	25-03-2004
US 2005251267 A1	10-11-2005	AU 2005240145 A1	17-11-2005
		CA 2540969 A1	17-11-2005
		EP 1742595 A2	17-01-2007
		JP 2007534348 T	29-11-2007
		KR 20070028286 A	12-03-2007
		WO 2005107651 A2	17-11-2005
US 4259072 A	31-03-1981	NONE	
US 5344457 A	06-09-1994	NONE	