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CERVICAL IMPLANT

Abstract

The present invention provides cervical implant (**30**) comprising an upper surface (**38**), a lower surface (**40**), a posterior portion (**34**) and an anterior portion (**36**) and including a perimeter (**42**) and one or more apertures (**44,46**) within said anterior portion for receiving securing means, said apertures having respective longitudinal axes M**1**, M**2**, characterised in that said axes extend in a direction substantially through said anterior portion (**36**) and converge at a point in a plane outside of said perimeter (**42**).

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. patent application Ser. No. 18/082,031 filed Dec. 15, 2022, which is a continuation of U.S. patent application Ser. No. 16/742,103 filed Jan. 14, 2020, which is a divisional of U.S. patent application Ser. No. 14/282,315 filed May 20, 2014, which is a divisional of U.S. patent application Ser. No. 11/938,476 filed Nov. 12, 2007, now U.S. Pat. No. 8,728,165, which claims benefit of U.S. provisional No. 60/867,727 filed Nov. 29, 2006, the contents of all of which are incorporated by reference in their entirety for all purposes.

FIELD
[0002] The present invention relates to orthopaedic implants and prostheses and relates particularly but not exclusively to implants and prostheses for bone structures, particularly in the cervical region.
BACKGROUND ART
[0003] Bones and related structural body parts, for example spine and/or vertebral bodies and/or inter-vertebral discs, may become crushed or damaged as a result of trauma/injury, or damaged by disease (e.g. by tumour, auto-immune disease), or damaged as a result of degeneration through an aging process. In many such cases the structure can be repaired by replacing the damaged parts (e.g. vertebra and/or discs) with a prosthesis or implant. A method of repair is to remove the damaged part(s) (e.g. vertebra and/or partial vertebra and/or disc and/or partial disc) and replace it with an implant or prosthesis such that the implant or prosthesis is free standing or fastened in position between adjacent undamaged parts (e.g. adjacent vertebral bodies).
[0004] Associated with this method of repair, is fusion of the bone structure where the implant or prosthesis is placed. Typically an implant or prosthesis may consist of a central space surrounded by a continuous wall that is open at each end (e.g. superior and inferior). This form of implant or prosthesis is thought to allow bone to develop within the central space, developing from each extremity of the implant or prosthesis towards the centre. Typically an implant or prosthesis is secured directly to a bone structure by mechanical or biological means.
[0005] Many current implants and prostheses are hollow to allow bone growth within the hollow space. One problem, when replacing large structural sections, is that the relationship of length (or height) to cross sectional area of the central space is large. The larger this relationship, the more problems arise in providing an adequate blood and nutrient supply to allow fusion and or bone growth into the hollow centre, either in a timely manner, or at all. One solution to this problem is to make the central space with as large a cross section as possible. However, this is limited by the wall thickness and the material used for the implant or prosthesis, which determines its mechanical strength. For this reason, orthopaedic surgeons often pack the space within the implant or prosthesis with an injectable or mouldable bone growth encouraging material or with fragments of bone taken from other parts of the patients body i.e. autograft or bone from biocompatible sources, for example allograft or synthetic bone. Even then there may not be complete fusion of the implant or prosthesis into the bone structure.
[0006] The implant or prosthesis is attached to the adjacent vertebral body using a fixing e.g. a screw. A problem generally with such fixing or fixing systems is that, after insertion into the vertebral body, the fixing can work itself loose and/or back-out i.e. withdraw from the vertebral body. The consequence of back-out or loosening of the implant or prosthesis includes loss of

stability, potential risk to the patient and a separate costly and often painful operation.
[0007] One of the applicant's own well known product is protected under U.S. Pat. No. 4,904,261 and provides a generally horse shoe shaped implant for use between vertebrae in the lower spine area. The arrangement includes a plurality of screws extending therethrough and into the adjacent vertebra so as to ensure the implant is securely located once positioned by a surgeon. The screw arrangement in this design is such as to cause the screws to converge at a point within the boundary of the implant when viewed form above.
[0008] Cervical implants are particularly problematic to design as their positioning dictates a very small size and requires good security of location once implanted and a low profile so as to reduce any portions thereof that may otherwise extend beyond the boundary of the implant. The small dimensions of such implants make achieving these goals somewhat difficult and the market demand does not appear to have been adequately met.
[0009] It is an object of the present invention to provide an improved cervical implant that may address one or more of the above-mentioned issues.

SUMMARY

[0010] Accordingly, the present invention provides a cervical implant comprising an upper surface, a lower surface, an anterior portion and a posterior portion and including a perimeter and one or more apertures within said anterior portion for receiving securing means, said apertures having respective longitudinal axes M**1**, M**2**, wherein said axes extend in a direction substantially through said anterior portion and converge at a point in a plane outside of said perimeter.
[0011] Advantageously, one or more of said apertures include guide portions for engagement with corresponding guide portions on corresponding securing means and wherein said guide portions maintain said securing means substantially within a 3 degree cone angle. Preferably, the centre lines of the apertures as shown on the plan view the (ref axes M**1**, M**2**) converge at an angle of between 13 and 15 degrees.
[0012] The implant includes a horizontal plane and said axes M**1**, M**2** extend at an angle of between Y and Z from said horizontal plane and may be provided with an interior portion for receiving bone growth material and said axes M**1**, M**2** may extend through said interior portion.
[0013] Preferably, the implant includes a retaining means for retaining one or more securing means within said implant. Said retaining means may include a plate portion securable to said implant and covering one or more of said apertures when secured, thereby to prevent removal of one or more securing means.
[0014] In one arrangement the retaining means comprises a rotatable plate portion secured to said implant at a rotation mount and wherein said plate portion is rotatable between a first position in which it acts to obturate one or more apertures and a second position in which it acts to unbturate one or more of said apertures.
[0015] Preferably, the plate portion includes one or more projections for engagement with one or more of said securing means and includes apertures for fixation devices which connect to vertebrae.
[0016] Advantageously, the implant includes a frictional engagement portion for frictionally engaging the implant and the plate such as to resist rotation of the plate once in its obturation mode.
[0017] Preferably, the implant includes one upwardly projecting aperture and one downwardly projecting aperture. Alternatively, the implant includes two apertures extending generally in a first direction and one aperture extending in a second direction.
[0018] Preferably, the implant includes one or more securing means, such as a screw or the like and one or more of said one or more securing means includes an anti-back out feature.
[0019] In one arrangement one or more of said surfaces comprises a domed surface but in an alternative arrangement, said surfaces extend in convergent planes.
[0020] The implant may include one or more location markers and may be provided as a kit comprising a selection of different height implants.

[0021] Although the following discussion focuses on spinal implants or prostheses, it will be appreciated that many of the principles may equally be applied to other bone structures within the human or animal body.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The present invention will now be more particularly described by way of example with reference to the accompanying drawings in which:

[0023] FIGS. **1** and **2** are respective plan and side elevations of a prior art arrangement;

[0024] FIG. **3** is a general view of a first arrangement of the present invention;

[0025] FIG. **4** is a general view of a second arrangement of the present invention;

[0026] FIGS. **5** and **6** are respective plan and cross-sectional views of the arrangement of FIG. **3**;

[0027] FIGS. **7** and **8** are respective plan and cross-sectional views of the arrangement of FIG. **4**; and

[0028] FIGS. **9** to **12** illustrate a further modification of a locking mechanism that may be employed to secure any screws within the implant and prevent what is commonly referred to as "back-out".

DETAILED DESCRIPTION

[0029] Referring to FIG. **1** which illustrates the prior art, a spinal implant or prosthesis **10** comprises a cage portion **12** for insertion between vertebrae and including posterior and anterior portions **14**, **16** and upper and lower surfaces **18**, profiled to correspond with the profile of any bone material to which they are to be secured. An outer perimeter **22** is defined by the surface extending between the upper and lower surfaces **18**, **20** and when viewed from above defines a generally "horse-shoe" shape. One or more holes **24**, **26**, **28** are provided through which securing means (not shown) may be inserted so as to secure the device to respective superior and inferior vertebral bodies (not shown). The securing means may be screws, pins, staples, bollards or any other suitable fastening device.

[0030] FIG. **2** is a cross-sectional view taken through one of the holes in FIG. **1** and illustrates the angle of attack for any screw placed therein. In practice, the angle is substantially 39 degrees and each hole is circumferentially displaced relative to its neighbour such that any screws placed therein and emerging therefrom converge at a point within the boundary of the cage, when viewed from above.

[0031] The arrangement of the present invention is shown in FIGS. **3** to **8** and the implant itself comprises a spinal implant or prosthesis **30** suitable for use in the cervical region of the spine and which includes a cage portion **32** for insertion between vertebrae and further includes a posterior and anterior portions **34**, **36** and upper and lower surfaces **38**, **40** profiled to correspond with the profile of any bone material to which they are to be secured. An outer perimeter **42** is defined by the surface extending between the upper and lower surfaces **38**, **40** and when viewed from above defines a generally wedge shaped structure. One or more holes **44**, **46**, **48** are provided through which securing means (not shown) may be inserted so as to secure the device to respective superior and inferior vertebral bodies (not shown). The securing means may be screws, pins, staples, bollards or any other suitable fastening device. FIG. **4** illustrates a two hole arrangement discussed in more detail later herein.

[0032] In contrast with the arrangement of FIGS. **1** and **2**, the arrangement of FIGS. **3** and **4** is generally much flatter and less circular in form and includes a sidewall portion **50** which extends in the direction of arrow W. The reader will also appreciate the aperture arrangement of this implant differs from the above in that a upwardly extending hole **48** is provided along with one or more generally downwardly extending holes **44**, **46** and those holes extend in a direction and at an angle

which results in them converging at a point X in a plane outside of the perimeter **42** thereof. The plan view of FIG. **5** aptly illustrates the angular relationship between the two holes **44**, **46** and from which the reader will appreciate that the holes are angled at an angle θ**1** of 7 degrees from a longitudinal axis L and the hole axes H cross each other outside of the perimeter **42** and below the implant itself. The vertical angular relationship is shown in FIG. **6** which illustrates the hole axes H extend at an angle θ**2** of approximately 45 degrees when measured from the neutral horizontal plane N. The angles θ**1** and **02** may be varied from the above so long as the arrangement still converges outside of the perimeter and as long as the vertical angle θ**2** is such as to maintain any screw within the vertebral body into which it is inserted. In practice, it has been found that for relatively small cervical cages it is desirable to maintain angle θ**1** at between 5 and 10 degrees and preferably between 6 and 8 degrees and maintain angle θ**2** at between 40 and 50 degrees and preferably between 44 and 46 degrees. The central hole **48** in FIG. **5** extends upwardly at the angle shown in FIG. **6** and as modified above and in practice any screw positioned therein will pass between downwardly extending screws of an implant positioned between lower vertebral bodies. Thus, it will be appreciated that the angular positioning of the holes is important to the effective operation of the implant and the ability to "stack" implants in adjacent multilevel procedures without the securing means interfering with each other. This is a particular problem in the cervical region as space is at a premium and the security of any implant is of particular concern.

[0033] FIGS. **7** and **8** illustrate another arrangement **60** the present invention in which only two holes **52**, **54** are provided for receiving appropriate screws or the like (not shown). These holes have centre lines or axes M**1** and M**2** which are angled relative to longitudinal axis L by an angle θ**3** of 20 degrees and, again, the arrangement is such as to cause the hole centre lines or axes M**1** and M**2** to cross at a point X in a plane outside of the perimeter **42** of the implant itself. The vertical angular relationship is shown in FIG. **7** and is the same for both holes which extend at an angle θ**4** of 45 degrees from the horizontal and vertical planes. It will be appreciated that the angles θ**3** and θ**4** may be varied slightly so long as the same basic principle of the axes crossing outside of the boundary is observed. For example θ**3** could be between 18 and 22 degrees depending on the depth of the implant and angle θ**4** could be varied as discussed above.

[0034] FIGS. **9** to **12** illustrate a further feature of the present invention which helps secure any screws in the implant once they have been screwed into the surrounding vertebral body. From FIG. **9** it will be appreciated that the locking mechanism includes a rotatable blocking plate **70** which rotates about mounting pin **72** secured to the implant itself. In one position of the mechanism it acts to unobturate the holes whilst in a second position it acts to obturate them and prevent any screw inserted therein from reversing out of the implant or suffering from "back-out". FIGS. **9** and **11** shows the plate **70** in the obturating mode but it will be appreciated that the unobturated mode is achieved by simply turning the plate in the direction of arrow U such that it extends substantially vertically rather than substantially horizontally. An additional feature of the locking mechanism is one or more projections **74** which extend from the plate **70** and towards any screw **76** that might be inserted within an associated hole. These projections assist with the securing of the screws by virtue of the fact that they reduce the distance that any screw can back-out before they engage with the plate. Indeed, these projections could be sized such as to positively engage with the head of any screw.

[0035] A still further possible feature of this plate arrangement is a frictional engagement portion **78** comprising a minor detent **80** on an inner surface **82** of the plate which, in operation, is sized such that it engages on an edge **84** of an associated hole when the plate **70** is in its obturating position and is caused to ride over said edge when the plate is moved but the force required to complete such a displacement is greater than the plate would experience in normal use of the insert but less than can be generated by a surgeon whilst installing or removing the insert, particularly if a tool of some type is employed. Such a feature may be provided in association with one or other or both holes.

[0036] Common to all the arrangements shown herein and discussed above is the additional but optional feature of curved surfaces **90**, **92** or edges on the posterior portion and **94**, **96** on the anterior portion. Such curved surfaces help reduce frictional interference with adjacent body portions. Additional to this feature is the provision of curved edges **98**, **100** around the upper and lower surfaces **38**, **40** as they adjoin the perimeter **42**. One or other or both of the upper and lower surfaces **38**, **40** may be domed as shown by dotted lines **102** and **104** of FIG. **12**, thereby to more accurately conform to some patient vertebrae profiles.
[0037] It will be appreciated that the implant may be formed of a radio-translucent material, such as polyether-etherketone (PEEK), which means that the cage will not obscure inspection of the degree of bone growth inside the cage when imaged by x-rays. Additionally, they may be formed of a bio-resorbable material. The bio-resorbable material is preferably osteo-conductive or osteo-inductive (or both). The implant may be formed of a bio-resorbable material. The bio-resorbable material is preferably osteo-conductive or osteo-inductive (or both).
[0038] Some practitioners prefer to allow some degree of movement between the implant and the adjacent vertebral body after implantation. In that case the screws would not be fully tightened. Others prefer a more rigid implant, which is firmly locked to the adjacent vertebral body. This implant allows either preference.
[0039] The implant described above is a unitary device that is inserted in one plane and is self centering, is conformable to surrounding anatomy, matches anatomical geometry, and matches natural anterior anatomical load constraints.
[0040] It will be appreciated that, instead of having one superior hole and two inferior holes in the implant as shown in the drawings, the implant may have two superior and one inferior holes, or may be adapted to have two superior holes and one inferior holes.
[0041] It will also be appreciated that the angular positioning of the various holes, as described above, allows the present insert to be of a relatively small size and therefore insertable within the inter vertebral space in the cervical region, where space is at a premium, whilst still allowing for the securing of said implant by conventional means. Thus, it will be appreciated that the angular positioning of the holes is important to the effective operation of the implant and the ability to "stack" implants in adjacent multilevel procedures without the securing means interfering with each other, which can be of major significance in some situations.
[0042] The locking plate provides a means for ensuring the security and location of the implant once inserted but may be reversed so as to allow removal of the securing screws if a revision is required.

Claims

1. A cervical implant comprising: a single cage portion comprising an upper surface having a contact area configured for engaging an inferior surface of a first cervical vertebral body and a lower surface having a contact area configured for engaging a superior surface of a second cervical vertebral body, wherein the second cervical vertebral body is at an immediate adjacent level inferior to the first cervical body, an opening formed through the upper and lower surfaces to define an interior portion for receiving bone growth material, an outer perimeter surface extending in between said upper and lower surfaces, said outer perimeter surface including an anterior side and an opposite posterior side, one upwardly projecting aperture that extends through said anterior side and said upper surface and projects upwardly towards the first cervical vertebral body, two downwardly projecting apertures that extend through said anterior side and said lower surface and project downwardly towards the second cervical vertebral body for receiving fastening devices, each of said downwardly projecting apertures having proximal and distal openings and a channel extending therebetween, the proximal openings of said downwardly projecting apertures lying within angled planes relative to said outer perimeter surface, each of said downwardly projecting

apertures further comprising a longitudinal axis that extends at an angle between about 5 degrees and about 10 degrees from the midline to converge at a point outside of the posterior side of said outer perimeter surface.

2. The cervical implant of claim 1, wherein the longitudinal axes of the two downwardly projecting apertures extend at an angle between about 6 degrees and about 8 degrees from the midline.

3. The cervical implant claim 1, wherein the anterior and posterior sides have superior and inferior curved edges that adjoin said outer perimeter surface to the upper and lower surfaces, respectively, and are configured to reduce frictional interference with adjacent body portions.

4. The cervical implant system of claim 1, wherein the upper and lower surfaces of the cervical implant further include ridges for engaging the first and second cervical vertebral bodies.

5. The cervical implant of claim 1, wherein the fastening devices comprise screws, pins, staples, or bollards.

6. The cervical implant of claim 1, wherein at least one of the upper and lower surfaces is a domed surface.

7. The cervical implant claim 1, wherein the upwardly projecting aperture is centrally located on the anterior side.

8. The cervical implant of claim 1, wherein one or more of the apertures comprises guide portions configured for engagement with corresponding guide portions of a fastening device.

9. The cervical implant of claim 8, wherein the guide portions each comprise a substantially annular projection between the proximal and distal openings, the substantially annular projection extending outward into the channel and being configured to maintain the fastening device substantially within a three degree cone angle.

10. A cervical implant comprising: an upper surface having a contact area configured for engaging an inferior surface of a first cervical vertebral body, and a lower surface having a contact area configured for engaging a superior surface of a second cervical vertebral body, an opening formed through the upper and lower surfaces to define an interior portion for receiving bone growth material; an outer perimeter surface extending in between said upper and lower surfaces, said outer perimeter surface including an anterior side and an opposite posterior side; one upwardly projecting aperture that extends through said anterior side and said upper surface and projects upwardly towards the first cervical vertebral body; and two downwardly projecting apertures that extend through said anterior side and said lower surface and project downwardly towards the second cervical vertebral body for receiving fastening devices, each of said downwardly projecting apertures having proximal and distal openings and a channel extending therebetween, the proximal openings of said downwardly projecting apertures lying within angled planes relative to said outer perimeter surface, each of said downwardly projecting apertures further comprising a longitudinal axis that extends at an angle between about 40 degrees and about 50 degrees from an axis extending perpendicularly through the cervical implant.

11. The cervical implant of claim 10, wherein the longitudinal axis of the two downwardly projecting apertures extends at an angle between about 44 degrees and about 46 degrees from said axis extending perpendicularly through the cervical implant.

12. The cervical implant of claim 10, wherein the outer perimeter surface includes two opposing sides connecting the anterior side to the posterior side, and wherein the outer perimeter surface comprises superior and inferior curved edges that adjoin said two opposing sides to the anterior and posterior sides, respectively, and are configured to reduce frictional interference with adjacent body portions.

13. The cervical implant of claim 12, wherein the superior and inferior curved edges comprise a continuous curve between the anterior and posterior sides and the two opposing sides.

14. The cervical implant of claim 10, wherein one or more of the apertures comprises guide portions configured for engagement with corresponding guide portions of a fastening device.

15. The cervical implant of claim 14, wherein the guide portions each comprise a substantially

annular projection between the proximal and distal openings, the substantially annular projection extending outward into the channel and being configured to maintain the fastening device substantially within a three degree cone angle.

16. The cervical implant of claim 10, wherein the second cervical vertebral body is at an immediate adjacent level inferior to the first cervical body.

17. The cervical implant of claim 10, wherein the anterior and posterior sides have superior and inferior curved edges that adjoin said outer perimeter surface to the upper and lower surfaces, respectively, and are configured to reduce frictional interference with adjacent body portions.

18. The cervical implant of claim 10, wherein the upper and lower surfaces of the cervical implant further include ridges for engaging the first and second cervical vertebral bodies.

19. The cervical implant of claim 10, wherein the fastening devices comprise screws, pins, staples, or bollards.

20. The cervical implant of claim 10, wherein at least one of the upper and lower surfaces is a domed surface.