

English translation of the publication of the International Patent Application No. PCT/CH02/00099 "Intervertebral Implant" in the name of Synthes AG Chur

INTERVERTEBRAL IMPLANT

The present invention relates to an intervertebral implant defined in the preamble of claim 1.

Such an intervertebral implant is known from the British patent document 2,207,607 A which discloses a horseshoe implant structure having a plurality of cylindrical holes. These holes are fitted with inner, smooth surfaces and comprise only one stop for the heads of the bone screws to be inserted into them. This design incurs the drawback that the inserted affixation screws may be anchored into the bone only by their shanks, a rigid connection with the horseshoe shaped intervertebral implant being lacking. As soon as the anchoring of the bone screw in the bone is weakened, the intervertebral implant becomes displaceable relative to the screw and the bone screws may then migrate while endangering the blood vessels. Moreover the loosening of the intervertebral implant may entail pseudoarthrosis.

The above cited state of the art is intended merely to elucidate the background of the present invention but it does not imply that the cited state of the art had actually been made public or was publicly known at the time of this application or at the time of its priority.

The objective of the present invention is palliation. This invention creates an intervertebral implant which is able to rigidly connect to bone affixation means in a manner that even in the event of bone structure weakening, loosening between the intervertebral implant and the bone affixation means shall be precluded.

The above problem is solved in the present invention by an intervertebral implant exhibiting the features of claim 1.

The advantages offered by the present invention substantially are attained by the rigid, that is by the firm connection between the intervertebral implant and the longitudinal affixing elements. Basically two different embodiment modes are available to attain said rigid connection.

In a first embodiment mode, at least one of the boreholes shall be internally threaded. In this case a matching bone screw fitted with a thread head may be rigidly screwed into the implant.

As regards a second embodiment mode, a front plate is mounted at the fore surface of the three dimensional (3D) implant structure so as to be configured vertically to the horizontal center plane of the intervertebral implant, said boreholes passing through said front plate and receiving the anchored longitudinal affixation elements. Compared to the state of the art of a two-part implant, wherein a front plate is implanted in a separate operational step, the above design of the present invention offers the advantage that the intervertebral implant shall be implanted in a single step and hence in simple and quicker manner. The invention offers a further advantage in that the intervertebral implant shall be affixed as frontally to the vertebra as possible, namely at a place where good bone material may be expected to be. As a result anterior displacement is restricted without thereby incurring greater danger to the surrounding structures than when using a state of the art intervertebral implant. The load still is being borne by the compressed vertebral implant, not by the front plate or the affixation screws.

In yet another embodiment mode of the present invention, the front plate is displaceably configured in the 3D implant structure in order that it may move vertically relative to this 3D implant structure. "Stress shielding" is attained in this manner (namely protection from or neutralization of mechanical stresses), and as a result the end plates may gradually match the intervertebral implant during the healing process.

As regards a further embodiment, the front plate is made of a material different from that of the 3D implant structure.

As regards a further embodiment of the present invention, at least one borehole tapers conically towards its underside and as a result a bone screw fitted with a matching conical head may be rigidly anchored in said borehole. Preferably the conical borehole exhibits a cone angle smaller than the resultant angle of friction. Appropriately the borehole's conicity shall be 1:3,75 to 1:20,00, preferably 1:5 to 1:15.

As regards a further embodiment mode of the present invention, the intervertebral implant side faces shall all be substantially convex.

Appropriately the intervertebral implant's top and/or undersides are not planar but convex. In this manner better matching to the end plates of the adjacent vertebrae may be attained.

The boreholes preferably shall not pass through the left and right intervertebral implant side faces. Preferably again no borehole shall run through the front surface.

As regards a further preferred embodiment mode of the present invention, at least two boreholes shall be mutually parallel. This features facilitates inserting the vertebral implant during implantation.

As regards another preferred embodiment mode of the present invention, at least two boreholes shall run in mutually divergent manner as seen from the front side. As a result the bone screws shall move into a vertebral region offering better bone quality than found at the vertebra's center. Appropriately the borehole axes subtend an angle of 25° to 70° , preferably 35° to 55° with the horizontal center plane. This feature offers improved access for screw insertion.

As regards a further embodiment mode of the present invention, the boreholes shall not cross the horizontal center plane.

Depending on circumstance, two, three, four or even more longitudinal affixation elements may rigidly connected to the intervertebral implant; appropriately at least one affixation element shall pass through the top side and at least one affixation element shall pass through the intervertebral implant side.

Preferably the longitudinal affixation elements shall be bone screws comprising a head and a shank, said head preferably being fitted with an external thread that matches the inner thread of the intervertebral implant's borehole. As regards a second appropriate connection, preferably a bone screw shall be used of which the head tapers conically in the direction of the shank, the head's conicity corresponding to that of the intervertebral implant's borehole.

Regarding a further embodiment mode, at least two longitudinal affixation elements pass through the top side and at least two longitudinal affixation elements pass through the underside. In this manner the intervertebral implant is optimally anchored into the adjacent vertebrae.

Preferably the screw-shaped longitudinal affixation elements exhibit a self-boring and self-tapping external thread. The longitudinal affixation elements also may be designed as unthreaded cylindrical pins fitted with a boring tip, preferably in the form of a trocar.

In another embodiment variation, the longitudinal affixation elements are spiral springs; lastly said longitudinal affixation elements also may be designed as single or multi-wing spiral blades.

In a further embodiment mode of the present invention, the longitudinal affixation element tip may be anchored in the structure of the intervertebral implant, as a result of which the head of the longitudinal affixation element may be anchored in the adjacent vertebra.

In a further embodiment mode of the present invention, the longitudinal affixation element head exhibits a widened diameter; also a support disk is provided for said head to rest against the vertebra.

The intervertebral implant may be made of any physiologically compatible material, though appropriately the implant structure shall consist of a physiologically compatible plastic, preferably an unreinforced plastic. The advantage offered by the invention over the already known, fiber-reinforced plastics used in implantology is that no reinforcing fibers will be bared -- an eventuality that would be clinically disadvantageous. Appropriately bone screws consisting of non-reinforced plastic of which the external threads exhibit load bevels of 11° to 14° , preferably 12° to 13° , may be used in such an implant structure. The relatively small slope of the load bevel implements high clamping forces, as a result of which radial elongation and danger of cracking of the plastic are reduced. Appropriately the bone screws' external thread exhibits the bones an angular pitch of 6° to 10° , preferably 7° to 9° . This particular angular pitch produces thread self-locking and prevents the bone screw from loosening on its own.

The borehole may be in the form of a metal bush fitted with an inner thread for the purpose of improving anchoring the bone screw in the plastic implant structure. The intervertebral implant also may be consist partly of plastic and, in the borehole zones, of metal. This design offers improved guidance and anchoring of the bone screw in the intervertebral implant.

As regards a further preferred embodiment mode, the inside borehole walls are smooth, the thread head of a metallic, longitudinal affixation element cutting or tapping into said smooth wall.

The present invention and further embodiment modes of it are elucidated below in relation to the partly schematic representation of two illustrative embodiments.

Fig. 1 is a perspective view including a partial section of the intervertebral implant with inserted bone screws,

Fig. 2 is a front view of the intervertebral implant of Fig. 1,

Fig. 3 is a sideview of the intervertebral implant of Fig. 1,

Fig. 4 is a topview of the intervertebral implant of Fig. 1,

Fig. 5 is a front view of the intervertebral implant with a front insert, in partial section,

Fig. 6 is a vertical, longitudinal section of the intervertebral implant of Fig. 5, and

Fig. 7 is a horizontal cross-section of the intervertebral implant of Fig. 5.

The intervertebral implant of Figs. 1 through 4 consists of a 3D structure 10 exhibiting both a convex top side 1 and a convex underside 2, the two sides each being designed to rest against the end plates of two adjacent vertebrae. To attain improved anchoring, the top side 1 and the underside 2 may be topographically shaped and be fitted with grooves, ribs or teeth, or their surfaces may be merely roughened.

The 3D implant structure 10 moreover comprises a left side face 3 and a right side face 4, also a front face 5 and a rear face 6. The implant structure 10 also may be hollow and its outer surface may comprise perforations.

The implant structure 10 comprises a plurality of boreholes 9 passing through it and receiving longitudinal affixation elements 20. Preferably four such boreholes 9 shall be provided.

At least one of the boreholes 9 is designed in a way that the longitudinal affixation element 20 received therein may be rigidly connected to the intervertebral implant. The boreholes 9 are conical for that purpose.

Preferably the affixation elements 20 are bone screws having a head 21 and a tip 22. The head 21 conically tapers toward the shank 23, the conicity of the head 21 corresponding to the conicity of the borehole 9. Moreover the four boreholes 9 may be fitted with inner threads 11.

As regards the embodiment variation shown in Figs. 5 through 7, the 3D structure 10 is fitted at its front face 5 with a preferably metallic insert 8 into which the affixation elements 20 may be anchored. The insert 8 is mounted in a vertically displaceable manner in the 3D structure 10.

CLAIMS

1. An intervertebral implant in the form of a three-dimensional (3D) structure (10), comprising

(a) a top side (1) and an underside (2) which are appropriate to rest against the end plates of two adjacent vertebrae,

(b) a left side face (3) and a right side face (4),

(c) a front face (5) and a rear face (6),

(d) a horizontal center plane (7) situated between the top side (1) and the underside (2), and

(e) a plurality of boreholes (9) passing through the implant structure (10) receiving longitudinal affixation elements (20) and comprising axes (19) that intersect the horizontal center plane (7), further

(f) at least one of the boreholes (9) is designed so that a longitudinal affixation element (20) received in it can be connected rigidly to the intervertebral implant,

characterized in that

(g) the 3D implant structure (10) comprises at its front face (5) a front plate (8) which is configured vertically to the horizontal center plane, the boreholes (9) passing through said plate (8) and the longitudinal affixation elements (20) being anchorable in it.

2. Intervertebral implant as claimed in claim 1, characterized in that the front plate (8) is configured in the 3D implant structure (1) to be vertically displaceable relative to the center plane (7).

3. Intervertebral implant as claimed in either of claims 1 and 2, characterized in that the front plate (8) is made of a material different from that of the 3D implant structure (10).

4. Intervertebral implant as claimed in claim 3, characterized in that the front plate (4) is metallic.

5. Intervertebral implant as claimed in one of claims 1 through 4, characterized in that at least one of the boreholes (9) comprises an inside thread.
6. Intervertebral implant as claimed in one of claims 1 through 5, characterized in that at least one borehole (9) tapers conically toward the underside (2).
7. Intervertebral implant as claimed in claim 6, characterized in that the cone angle of the conical borehole (9) is smaller than the resulting angle of friction.
8. Intervertebral implant as claimed in claim 7, characterized in that the conicity of the conical borehole (9) is in the range of 1:3.75 to 1:20.00, preferably in the range of 1:5 to 1:15.
9. Intervertebral implant as claimed in one of claims 1 through 8, characterized in that its side faces (1, 2, 3, 4, 5, 6) are all substantially convex.
10. Intervertebral implant as claimed in one of claims 1 through 9, characterized in that the top side (1) and/or the underside (2) are non-planar and preferably convex.
11. Intervertebral implant as claimed in one of claims 1 through 10, characterized in that the boreholes (9) do not pass through the left side face (3) nor through the right side face (4).
12. Intervertebral implant as claimed in one of claims 1 through 11, characterized in that the boreholes (9) do not pass through the front face (5).
13. Intervertebral implant as claimed in one of claims 1 through 12, characterized in that at least two of the boreholes (9) run mutually parallel.
14. Intervertebral implant as claimed in one of claims 1 through 13, characterized in that at least two of the boreholes (9) diverge from each other as seen from the front side (1).

15. Intervertebral implant as claimed in one of claims 1 through 4, characterized in that the axes (19) of the boreholes (9) subtend an angle in the range of 25° to 70°, preferably 35° to 55°, with the horizontal center plane.

16. Intervertebral implant as claimed in one of claims 1 through 15, characterized in that the boreholes (9) do not pass through the horizontal center plane (7).

17. Intervertebral implant as claimed in one of claims 1 through 16, comprising at least two longitudinal affixation elements (20) which are inserted into the boreholes (9) and which are fitted with a head (21) and a tip (22), characterized in that at least one longitudinal affixation element (20) passes through the top side (1) and at least one longitudinal affixation element (20) passes through the underside (2).

18. Intervertebral implant as claimed in claim 17, characterized in that the longitudinal affixation elements (20) are bone screws having a head (21) and a shank (23).

19. Intervertebral implant as claimed in claim 18, characterized in that the head (21) is fitted with an external thread (24) which matches the inner thread (11) of the borehole (9).

20. Intervertebral implant as claimed in either of claims 18 and 19, characterized in that the head (21) conically tapers toward the shank (23), the conicity of the head (21) preferably matching the conicity of the borehole (9).

21. Intervertebral implant as claimed in one of claims 17 to 20, characterized in that at least two longitudinal affixation elements (20) pass through the top side (1) and at least two longitudinal affixation elements (20) pass through the underside (2).

22. Intervertebral implant as claimed in one of claims 17 through 21, characterized in that the longitudinal affixation elements (20) are bone screws of which

the shanks are fitted with external threads (25) that preferably shall be self-boring and self-tapping.

23. Intervertebral implant as claimed in one of claims 17 through 22, characterized in that the longitudinal fixation affixation elements (20) are unthreaded cylindrical pins having a drilling tip preferably in the form of a trocar.

24. Intervertebral implant as claimed in one of claims 17 through 22, characterized in that the longitudinal fixation elements (20) are spiral springs.

25. Intervertebral implant as claimed in one of claims 17 through 22, characterized in that the longitudinal affixation elements (20) are single wing or multi-wing spiral blades.

26. Intervertebral implant as claimed in one of claims 17 through 25, characterized in that the tip (22) of the longitudinal affixation element (20) can be anchored in the implant structure (10) in a manner that the head (21) of the longitudinal affixation element (20) can be anchored in the adjacent vertebra.

27. Intervertebral implant as claimed in claim 26, characterized by the head (21) of the longitudinal affixation element (20) comprising a widened diameter and additionally by a support disk (30) designed to rest against the vertebra and being provided for said head.

28. intervertebral implant as claimed in one of claims 17 through 27, characterized in that the implant structure (10) consists of a plastic, preferably a non-reinforced plastic.

29. Intervertebral implant as claimed in claim 28, characterized in that the external thread (25) of the bone screws (20) comprise a lead bevel angle in the range of 11° to 14°, preferably of 12° to 13°.

30. Intervertebral implant as claimed in one of claims 17 through 29, characterized in that the external thread (25) of the bone screws exhibits an angular pitch in the range of 6° to 10° , preferably 7° to 9° .

31. Intervertebral implant as claimed in one of claims 1 through 30, characterized in that the borehole (9) comprises a metal bush with an inner thread (11).

32. Intervertebral implant as claimed in one of claims 1 through 31, characterized in that it is made partly of plastic and in that in the zone of the boreholes (9) it is made of metal.

33. Intervertebral implant as claimed in one of claims 28 through 32, characterized in that the boreholes (9) exhibit a smooth inner wall into which the threaded head of a metal, longitudinal affixation element (20) may be cut or integrated.

34. Intervertebral implant as claimed in one of claims 1 through 33, characterized in that its top side (1) and its underside (2) are shaped preferably in the form of teeth.

35. Intervertebral implant as claimed in one of claims 1 through 34, characterized in that it is in the form of a hollow structure of which the outside surfaces are preferably perforated.