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(54) **INTERVERTEBRAL PROSTHESIS**

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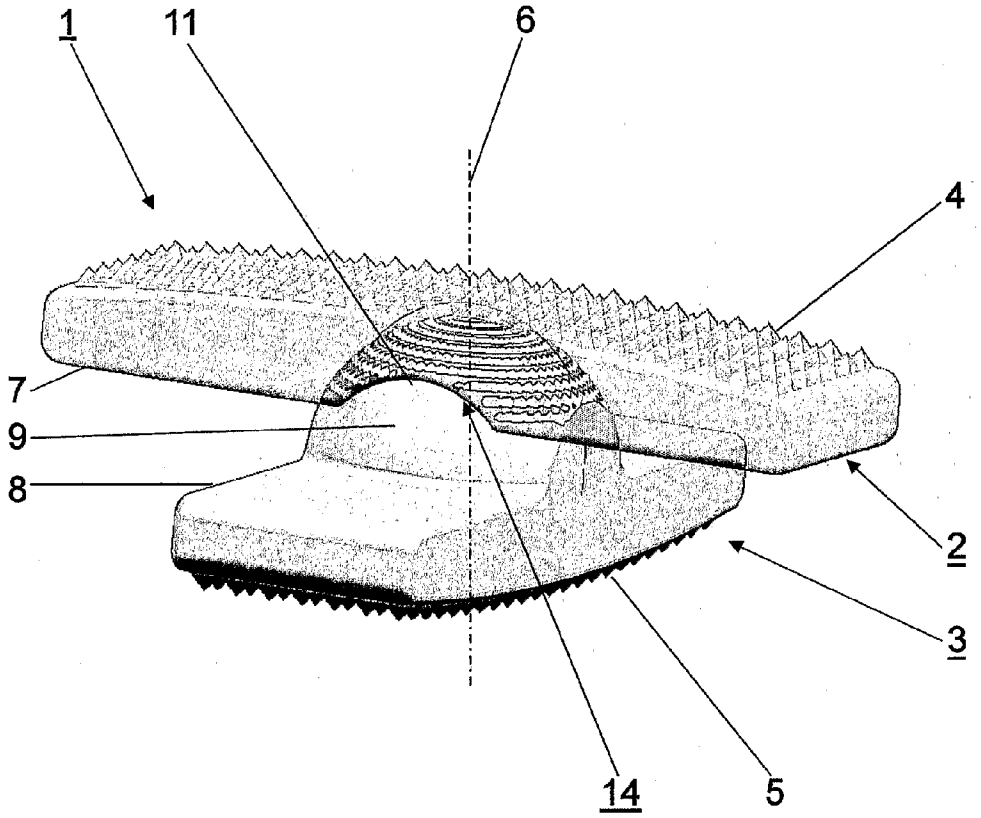
(57) **ABSTRACT**

Intervertebral prosthesis (**1**), in particular intervertebral disk prosthesis, with a central axis (**6**) and comprising A) a first prosthetic component (**2**) having a first apposition surface (**4**) and a first inner surface (**7**), both being disposed transversely to the central axis (**6**) and having a spherical recess (**11**); B) a second prosthetic component (**3**) having a second apposition surface (**5**) and a second inner surface (**8**) both being disposed transversely to the central axis (**6**) and having a calotte (**9**) congruent with said recess (**11**); C) the first and second prosthetic components (**2**;**3**) being connectable in an articulated manner by means of the calotte (**9**) which may be slidably received in the recess (**11**); whereby D) the first and second prosthetic components (**2**;**3**) have a width B and a length H each being transverse to the central axis (**6**), said first and second prosthetic components (**2**;**3**) further comprise a longitudinal axis L_1, respectively L_2 extending parallel to the respective length H; and whereby E) the length H is greater than the width B, such that the prosthetic components (**2**;**3**) may be put into a position in the intervertebral space in which the two longitudinal axes L_1 and L_2 intersect each other at an angle $\alpha > 0°$ when being projected in a plane being orthogonal to the central axis (**6**).



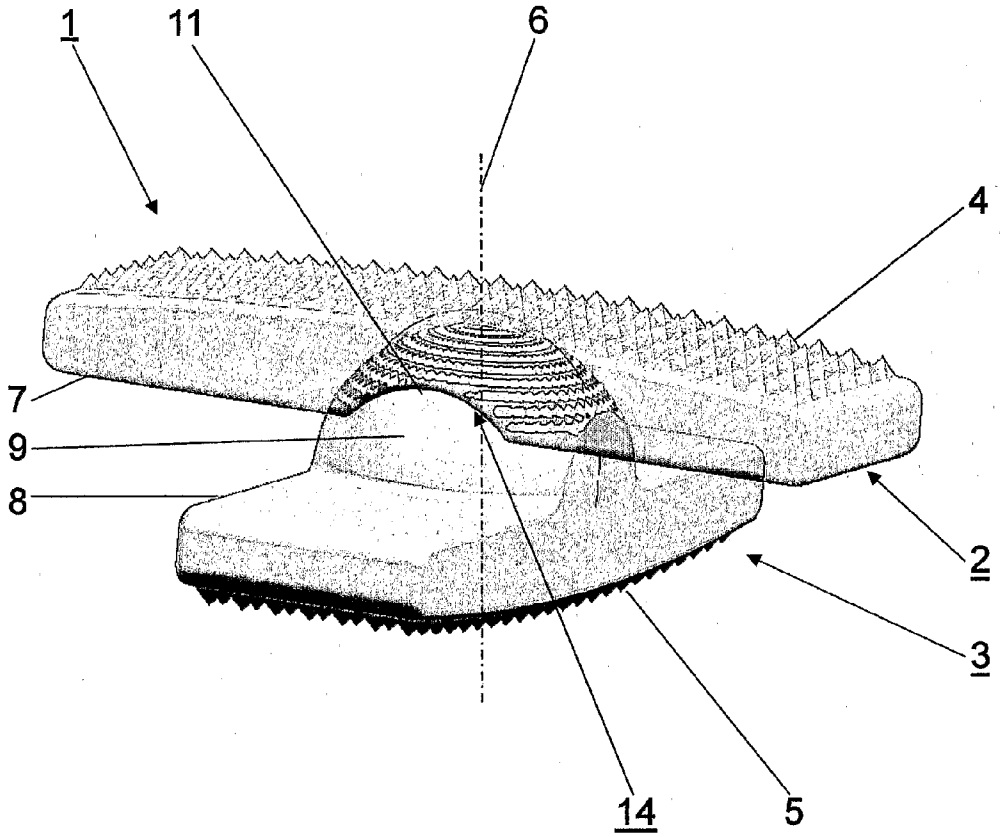


Fig. 1

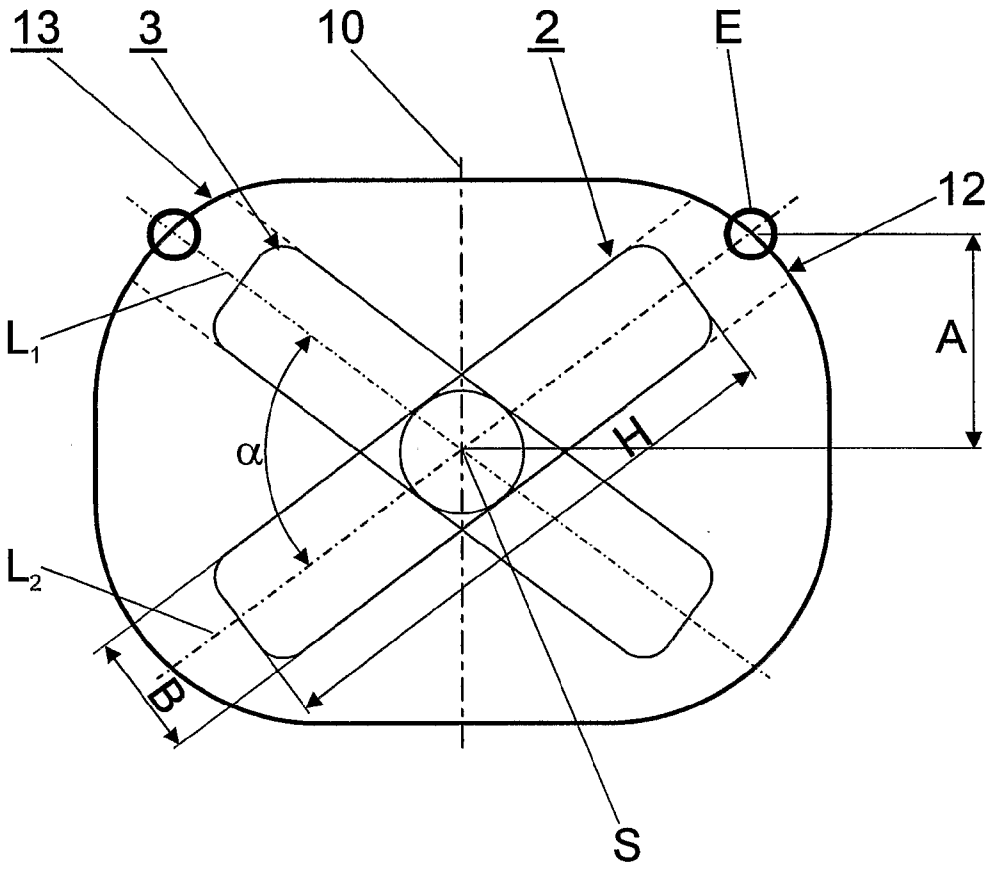


Fig. 2

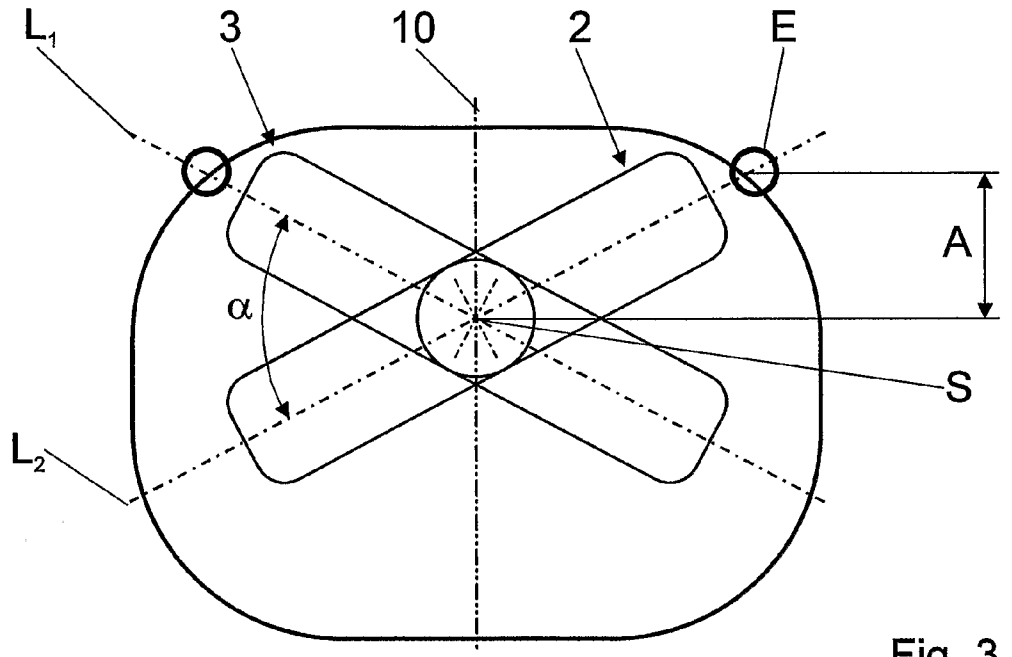


Fig. 3

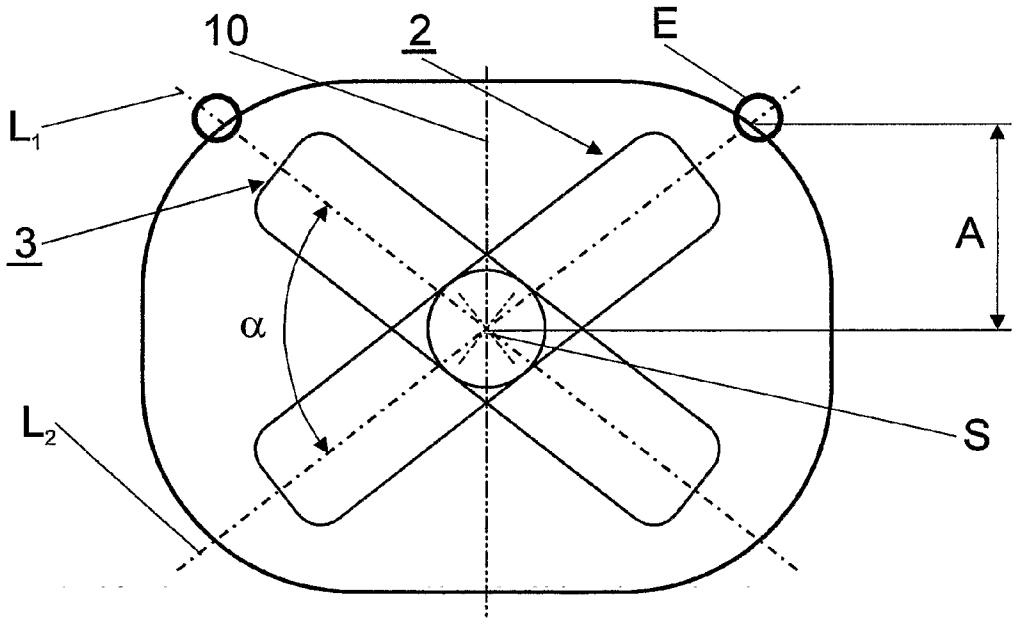


Fig. 4

INTERVERTEBRAL PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

[0001] This Application is a national stage application under 35 U.S.C. 371 based on International Application Serial No. PCT/CH2005/000774 filed on Dec. 27, 2005 for "INTERVERTEBRAL PROSTHESIS".

FIELD OF INVENTION

[0002] The invention relates to an intervertebral prosthesis, in particular to an intervertebral disk prosthesis.

DESCRIPTION OF RELATED ART

[0003] In recent years, intervertebral prostheses have gained wide acceptance in vertebral column surgery. These prostheses are inserted anteriorly or antero-laterally between the vertebral bodies in place of the intervertebral disk. This implantation technique represents a certain risk, as the access leads through the abdominal region. There is a risk that greater vessels in the region of the anterior lumbar column may be injured. From a biomechanical point of view, the anterior access has the disadvantage that the anterior longitudinal ligament of the vertebral column has to be partially or entirely dissected in order to enable the insertion of the prosthesis. This dissection will result in a certain instability of the vertebral column and may, in the worst case, facilitate a ventral migration of the prosthesis. In order to reduce the risk of a migration of the prosthesis, different anchoring means are used which fix the prosthesis on the cover plates of the adjacent vertebral bodies.

[0004] An intervertebral prosthesis of this type is known from WO 01/01893 MARNAY. This known prosthesis comprises two plates having a ball-and-socket joint and two differently shaped projections for anchoring the prosthesis in two vertebrae. In said document it is also proposed to minimize the height of the prosthesis during insertion in that the two components are made to engage with each other. Despite the provided fixation means, there is a risk for the prosthesis to migrate back along the insertion channel.

SUMMARY OF THE INVENTION

[0005] The invention is intended to provide a remedy for this. The present invention is directed to an intervertebral prosthesis which for implantation purposes is decomposable into two parts and which is inserted into the intervertebral space via transforaminal and/or extraforaminal accesses. The articulation of the intervertebral prosthesis preferably consists of a spherical calotte and a corresponding spherical recess. During the implantation of the two prosthetic components, which are implanted separately into the intervertebral space via the two separate accesses, the two longitudinal axes of the prosthetic components cross each other in the intervertebral space. By freely selecting the angle α between the longitudinal axes of the two prosthetic components, the position of the point of intersection can be adjusted in a sagittal direction with the insertion points remaining unchanged. This adjustment may be planned preoperatively by means of CT or X-ray photographs or may be defined intraoperatively by means of guide wires and/or templates.

[0006] The advantages achieved by the invention reside essentially in the fact that due to the intervertebral prosthesis of the invention:

[0007] an individual adjustment of the intervertebral prosthesis for any pair of vertebral bodies is possible. Thus, an individual anatomy of the motion element can be taken into account;

[0008] the individual segmental motion sequences may be preoperatively taken into account and defined by the surgeon;

[0009] an uncomplicated and secure operation technique is made possible compared to implants which are inserted into the intervertebral space in a completely assembled state;

[0010] the risk of an antero-posterior and/or lateral migration of the prosthesis due to flexion/extension or lateral bending of the spinal column is minimized;

[0011] the natural intervertebral disk has to be only partially removed, i.e. in order to implant the two prosthetic components in the intervertebral space (intervertebral disk) it is only necessary to clear two paths of a width B and a length H, so that only the apposition surfaces of the two prosthetic components are in bone contact with the respective end plates. The rest of the intervertebral disk remains in situ and prevents the intervertebral prosthesis from migrating laterally and/or antero-posteriorly once the two prosthetic components have been implanted.

[0012] In a preferred embodiment, the ratio of the length H of the prosthetic components to the width B thereof is between 3:1 and 5:1. The advantages of this design essentially are that in order to implant the two prosthetic components in the intervertebral space (intervertebral disk) it is only necessary to clear two narrow paths of a width B and a length H.

[0013] In another embodiment, the intervertebral prosthesis is realized in two pieces, i.e. the calotte is made in one piece with one of the two prosthetic components.

[0014] In a further embodiment, the intervertebral prosthesis is realized in three pieces, so that the calotte forming the third piece is connectable with one of the two prosthetic components. The advantage of this design is to be seen essentially in the fact that the plate and the calotte may be realized by using different materials, so that it is possible to achieve optimal sliding properties for the articular surfaces. Preferred materials for the plates are titanium or a titanium alloy as well as PEEK or coated variants, and for the calotte highly crosslinked polyethylene (X-UHMWPE), an alloy of cobalt and chrome, or a ceramic material.

[0015] In again a further embodiment, the intervertebral prosthesis is realised in at least three pieces and comprises an articular shell including the recess, whereby said articular shell is attachable to one of said first and second prosthetic components as a third piece. The advantage of this design is to be seen essentially in the fact that the plate and the calotte may be realised using different materials, so that it is possible to achieve optimal sliding properties for the articular surfaces.

[0016] In a further embodiment, the calotte and the articular shell consist of a material combination made of metal and plastic. The advantages of this embodiment are that it is possible to use proven combinations of joint replacement materials such as, for example, highly crosslinked polyethylene (X-UHMWPE) and an alloy of cobalt and chrome. Further advantages are to be seen in the fact that low frictional forces are achievable for the relative displacement of the articular surfaces and that a compensation of axial impact loads can be achieved.

[0017] In yet another embodiment a ceramic-to-ceramic articulation is used.

[0018] In a further embodiment the surfaces of the calotte and the recess are coated with titanium carbide or with amorphous carbon (ADLC) therewith permitting a substantial reduction of the coefficient of friction.

[0019] In another embodiment, at least the calotte is made of a memory metal or of a material capable of swelling (e.g. hydrogels).

[0020] In still another embodiment at least the calotte is made of a flowable, thermosetting material. The monomers, comonomers, homopolymers, oligomers, or mixtures which contain such thermosetting, flowable substances may suitably be selected from the group of:

[0021] a) polyethylene glycols, preferably polyethylene glycol(di)-acrylates;

[0022] b) n-vinylpyrrolidones; and

[0023] c) vinyls, preferably vinyl alcohols; and

[0024] d) styrenes.

[0025] The polymers thus obtained may be widely varied as regards to their elasticity. The advantages of these designs are to be seen essentially in the fact that due to the reduced volume of the joint, the insertion of the intervertebral prosthesis becomes less invasive, the increased volume being best suited for achieving an optimal articular function.

[0026] In a further embodiment the first prosthetic component is selected from a first kit of at least $M \geqq 2$ first prosthetic components and the second prosthetic component is selected from a second kit of at least $N \geqq 2$ second prosthetic components. Said first and second kit may comprise first and second prosthetic components being provided with different heights, articulation radii or locations of the center of the respective radii, i.e. the center of rotation. By means of this embodiment the following advantages may be achieved

[0027] the position of the center of rotation is adjustable in height as the two component parts may be arranged in a modular manner;

[0028] the components which may also vary in the radius of the calotte, which makes it possible to adjust the center of rotation of the intervertebral prosthesis;

[0029] the position of the center of rotation, the angulation, and the portion of translatory motion of the intervertebral prosthesis may be freely selected within a relatively wide range, the portion of translatory motion being the portion of movement measured transversely to the central axis of the prosthetic components relative to each other;

[0030] the prosthetic components may also take into account the articulation requirements of the motion segment in that it is possible to include calottes having different radiuses. Greater calotte radiuses have a higher portion of translatory motion during deflection, which on the flexion of a patient's spine puts increased pressure on the facet joints and leads to an accelerated degeneration thereof;

[0031] the heights of the prosthetic components and the corresponding radiuses of the articulating calotte of the intervertebral prosthesis may vary and are thus adaptable to the dimensions of different intervertebral spaces.

[0032] The method of implanting an intervertebral prosthesis into the intervertebral space according to the invention comprises the steps of:

[0033] A) implanting a first prosthetic component via a first access into the intervertebral region transversely to the central axis of the intervertebral prosthesis;

[0034] B) implanting the second prosthetic component of the intervertebral prosthesis via a second access, which is different from the first access, into the intervertebral region transversely to the central axis of the intervertebral prosthesis, whereby the two prosthetic components, when measured transversely to the central axis each have a width B and a length $H>B$ and the longitudinal axes L_1 and L_2 of the first and second prosthetic components which extend parallel to the length H intersect each other at an angle $\alpha>0$; and

[0035] C) coupling the second prosthetic component to the first prosthetic component in an articulated manner during the implantation.

[0036] Depending on the type of embodiment of the method of the invention, at least one access is located transforaminally or extraforaminally. The transforaminal access is known and established in vertebral column surgery. Due to the extraforaminal access it is possible to have large openings towards the intervertebral disk space without adversely affecting the ventral or the dorsal ligaments or the neural structures.

[0037] In a preferred embodiment the two accesses are located posteriorly.

[0038] In another embodiment the first access is located transforaminally.

[0039] In still another embodiment the second access is located extraforaminally.

[0040] In a further embodiment the intervertebral disk located in the spacing between the two vertebral bodies is removed only to such an extent that the entire apposition surfaces of the two prosthetic components designed for abutment onto the bone have full bone contact with the end plate of the respective vertebral body.

[0041] In yet a further embodiment the two accesses each have one entrance point E which is spaced apart from the sagittal axis extending centrally in an antero-posterior direction in such a way that the longitudinal axes L_1 and L_2 of the two implanted prosthetic components form an angle α. Preferably, the angle α is in a range of between 25° and 120°.

[0042] In the following, the invention and improvements of the invention will be illustrated in greater detail with reference to the partially diagrammatic representations of a plurality of embodiments of the intervertebral prosthesis according to the invention.

[0043] In the drawings:

[0044] FIG. **1** is a perspective view of one embodiment of the intervertebral prosthesis of the invention;

[0045] FIG. **2** is a top view of the embodiment of the intervertebral prosthesis of the invention shown in FIG. **1**;

[0046] FIG. **3** is a top view of the embodiment of the intervertebral prosthesis of the invention shown in FIG. **1** similar to FIG. **2** yet with different angles α, different distances A and a point of intersection S dislocated along the sagittal axis **10**.

[0047] The embodiment shown in FIG. **1** comprises essentially an intervertebral prosthesis **1** which consists of two prosthetic components **2**;**3** having rectangular apposition surfaces **4**;**5**. Said two prosthetic components **2**;**3**, which have a length H and a width B, are releasably connected with each other by means of a joint **14**. The joint **14** consists of a calotte **9** and a corresponding recess **11**. In this embodiment, the radius of the calotte **9** is greater than the width B of the prosthetic component **3** but smaller than the length H of said prosthetic component **3**, the length H being four to five times longer than the width B. This design feature leads to different overall inclinations of the longitudinal axes L_1;L_2 of the two

prosthetic components **2**;**3** relative to each other, depending on the magnitude of the angle α (α=the angle between the longitudinal axes L_1;L_2 in a plane extending orthogonally to the central axis **6**). The optimal articular function is achieved at an angle α of 90 degrees. With said angle α being 90 degrees, the angle of inclination is twice as great as with an angle α of 0 degrees.

[0048] The embodiment shown in FIG. **2** comprises a first and a second prosthetic component **2**;**3**, which are longitudinal members having longitudinal axes L_1 and L_2, and a sagittal axis **10**. The longitudinal axes L_1;L_2 of the two prosthetic components **2**;**3** have a point of intersection S and form an angle α. The distance A between the entrance points E, which are disposed symmetrically with respect to the sagittal axis **10** and which mark the points of insertion of the two prosthetic components **2**;**3** into the intervertebral space, and the point of intersection S varies for different angles α formed by the longitudinal axes L_1 and L_2 (FIGS. **3** and **4**).

[0049] The two cross-sections shown in FIGS. **3** and **4** each comprise two prosthetic components **2** and **3** with their respective longitudinal axes L_1 and L_2. Due to the different angles α caused by the modification of the positions of the longitudinal axes L_1 and L_2 relative to each other, the point of intersection S is displaced along the sagittal axis **10**, whereas the positions of the entrance points E remain unchanged as the distance A increases. According to the appreciation given in specialised literature, the variant shown in FIG. **3** having a point of intersection S disposed dorsally with respect to the center of the end plates of the vertebral bodies is advantageous as compared to the variant shown in FIG. **4** having a point of intersection S disposed frontally with respect to the center of the end plates.

Description of the Surgical Method:

[0050] In the following the surgical method permitting the implantation of an intervertebral prosthesis **1** will be described with reference to FIG. **2**:

[0051] a) Prior to the implantation, the intervertebral disk is prepared as required by the size of the prosthetic components **2**;**3**. Instead of removing the entire intervertebral disk, it is only necessary to clear two paths which are large enough so that the two apposition surfaces **4**;**5** of the intervertebral prosthesis **1** may be in direct contact with the cover plates of the vertebral bodies. To this effect, the intervertebral space (intervertebral disk) is removed only to such an extent that the entire application surfaces of the two prosthetic components have bone contact with their respective end plate. The rest of the intervertebral disk remains in situ and prevents the intervertebral prosthesis from migrating laterally once the two prosthetic components **2**;**3** have been implanted.

[0052] b) Subsequent to the preparation of the two implantation canals in the intervertebral disk the implantation of the two prosthetic components **2**;**3** is performed via the two postero/lateral accesses **12**;**13**. It is preferred to first implant one prosthetic component **2**;**3**, whereupon the implantation of the other prosthetic component **2**;**3** is carried out. As soon as the two corresponding articulation centers (calotte **9**-recess **11**) are located in the point of intersection S of the two longitudinal axes L_1 and L_2, the two prosthetic components **2**;**3** may be connected with each other by means of the joint **14** which is composed by the calotte **9** and the recess **11**. Due to the intervertebral disk portions remaining laterally of the two prosthetic components **2**;**3** and the coupling of the calotte **9** with the recess **11**, the intervertebral prosthesis **1** is securely lodged in the intervertebral space. The center of rotation is located in the central sagittal plane and may vary anteriorly or posteriorly, the central sagittal plane being the plane extending antero-posteriorly through the patient's body and intersecting said body centrally.

[0053] For the implantation, two transforaminal or extraforaminal accesses **12**;**13** may be used, which are known and established in vertebral column surgery. Once the coupling has been effected, the two prosthetic components **2**;**3** form a unit which admits inclinations of the end plates of adjacent vertebral bodies relative to each other.

[0054] Due to the posterior implantation technique of the intervertebral prosthesis **1**, the ventral ligament structures of the vertebral column remain intact and are not impaired in their function of stabilising the vertebral column. In addition, the intact ventral ligament structure reduces the risk of a ventral migration of the intervertebral prosthesis **1** and of endangering ventral structures in the region of the vertebral column. The same technique of surgical treatment may also be applied anteriorly, in particular in the higher lumbar and thoracolumbar regions. Anatomical circumstances preclude a strictly anterior insertion, as the access is obstructed by the aorta and the vena cava. Also in this case, the ventral structures of the fibrous ring as well as the anterior longitudinal ligament remain intact.

1. An intervertebral disk prosthesis comprising:

a first prosthetic component with a first width, a first length and a first longitudinal axis, the first prosthetic component comprising a first apposition surface disposed transversely to a central axis for contacting an end plate of a first adjoining vertebral body and further comprising a first inner surface disposed transversely to the central axis and having a spherical recess;

a second prosthetic component with a second width, second length and a second longitudinal axis, the second prosthetic component comprising a second apposition surface disposed transversely to the central axis for contacting an end plate of a second adjoining vertebral body and further comprising a second inner surface disposed transversely to the central axis and having a calotte congruent with said recess wherein the calotte can be slidably received in the recess; wherein:

the first and second prosthetic components are connectable in an articulated manner by means of the calotte being slidably received in the recess; and

the first length is greater than the first width such that the first and second prosthetic components are in position in the intervertebral space in which the first and second longitudinal axes intersect each other at an angle greater than zero degrees when being projected in a plane being orthogonal to the central axis.

2. The intervertebral prosthesis as claimed in claim **1**, wherein the ratio of the first length to the first width is between 3:1 and 5:1.

3. The intervertebral prosthesis as claimed in claim **1**, wherein one of the first and second prosthetic components and the calotte consist of one piece.

4. The intervertebral prosthesis as claimed in claim **1**, wherein said intervertebral prosthesis consists of at least three pieces with the calotte being the third piece attachable to one of said first and second prosthetic components.

5. The intervertebral prosthesis as claimed in claim **1**, wherein said intervertebral prosthesis consists of at least three

pieces and comprises an articular shell including the recess which is attachable to one of said first and second prosthetic components as a third piece.

6. The intervertebral prosthesis as claimed in claim **5**, wherein the calotte and the articular shell consist of a material pairing of metal and plastic.

7. The intervertebral prosthesis as claimed in claim **5**, wherein the calotte and the articular shell consist of a ceramic-to-ceramic material pairing.

8. The intervertebral prosthesis as claimed in claim **1**, wherein the surfaces of the calotte and of the recess are coated with titanium carbide or with an amorphous carbon.

9. The intervertebral prosthesis as claimed in claim **1**, wherein at least the calotte is made of a memory metal.

10. The intervertebral prosthesis as claimed in claim **1**, wherein at least the calotte is made of a material capable of swelling.

11. The intervertebral prosthesis as claimed in claim **1**, wherein at least the calotte is made of a flowable, thermosetting material.

12. The intervertebral prosthesis as claimed in claim **11**, wherein at least the calotte is made of a monomer, comonomer, homopolymer, oligomer, or mixture which contains a thermosetting, flowable substance.

13. The intervertebral prosthesis as claimed in claim **12**, wherein the thermosetting, flowable substance is selected from the group of:

a) polyethylene glycols;

b) n-vinylpyrrolidones;

c) vinyls; and

d) styrenes.

14. The intervertebral prosthesis as claimed in claim **1**, wherein said first prosthetic component is selected from a group of at least two first prosthetic components.

15. The intervertebral prosthesis as claimed in claim **1**, wherein said second prosthetic component is selected from a group of at least two second prosthetic component.

16. A method of implanting an intervertebral disk prosthesis into an intervertebral space, which comprises a first and a second prosthetic component articulately connectable with each other and which presents a central axis extending coaxially or parallel to the longitudinal axis of a vertebral column, comprising the steps of:

implanting the first prosthetic component via a first access into a first intervertebral region that is transverse to the central axis of the intervertebral prosthesis, the first prosthetic component having a first width and a first length, wherein the first length is greater than the first width;

implanting the second prosthetic component via a second access into a second intervertebral region that is transverse to the central axis of the intervertebral prosthesis; the second prosthetic component having a second width and a second length, the second length being greater than the second width; wherein the longitudinal axes of the first and second prosthetic components extend parallel to the first length and intersect each other at an angle greater than zero degrees; and

coupling the second prosthetic component to the first prosthetic component in an articulated manner during the implantation.

17. The method as claimed in claim **16**, wherein the two accesses are located posteriorly.

18. The method as claimed in claim **16**, wherein the first access is located transforaminally.

19. The method as claimed in claim **16**, wherein the second access is located extraforaminally.

20. (canceled)

21. The method as claimed in claim **16**, wherein the first access and second access each have one entrance point that is spaced apart from the sagittal axis extending centrally in an antero-posterior direction in such a way that the longitudinal axes of the two implanted prosthetic components form an angle greater than zero degrees.

22. The method as claimed in claim **21**, wherein the angle is in a range of between 25° and 120°.

* * * * *