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(54) Abstract Title
Vertebral body replacement

(57) A spinal prosthesis (1) comprises a hollow strut (2) terminated by a pair of end caps (10, 12) which are adapted to engage respective vertebrae. Each end cap (10, 12) may have a flange (20, 22) which is closely received within and supports a respective end (6, 8) of the strut (2). Alternatively, or in addition, each end cap (10, 12) may be substantially kidney shaped and may be provided with a kidney shaped recess (16, 18) which provides access to the interior of the strut (2). Preferably, the end caps (10, 12) are provided with respective shoulders (28, 30) which are adapted to cover the ends of the strut (2) to prevent the strut damaging soft tissue during implantation. A porous titanium plasma coating may be applied to the end caps (10, 12) to enhance bone fixation and to resist anterior translation and rotation of the prosthesis (1).

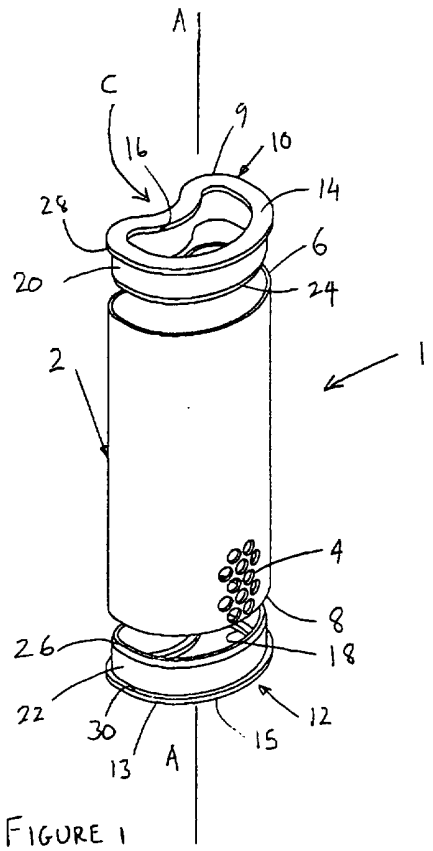

FIGURE 1

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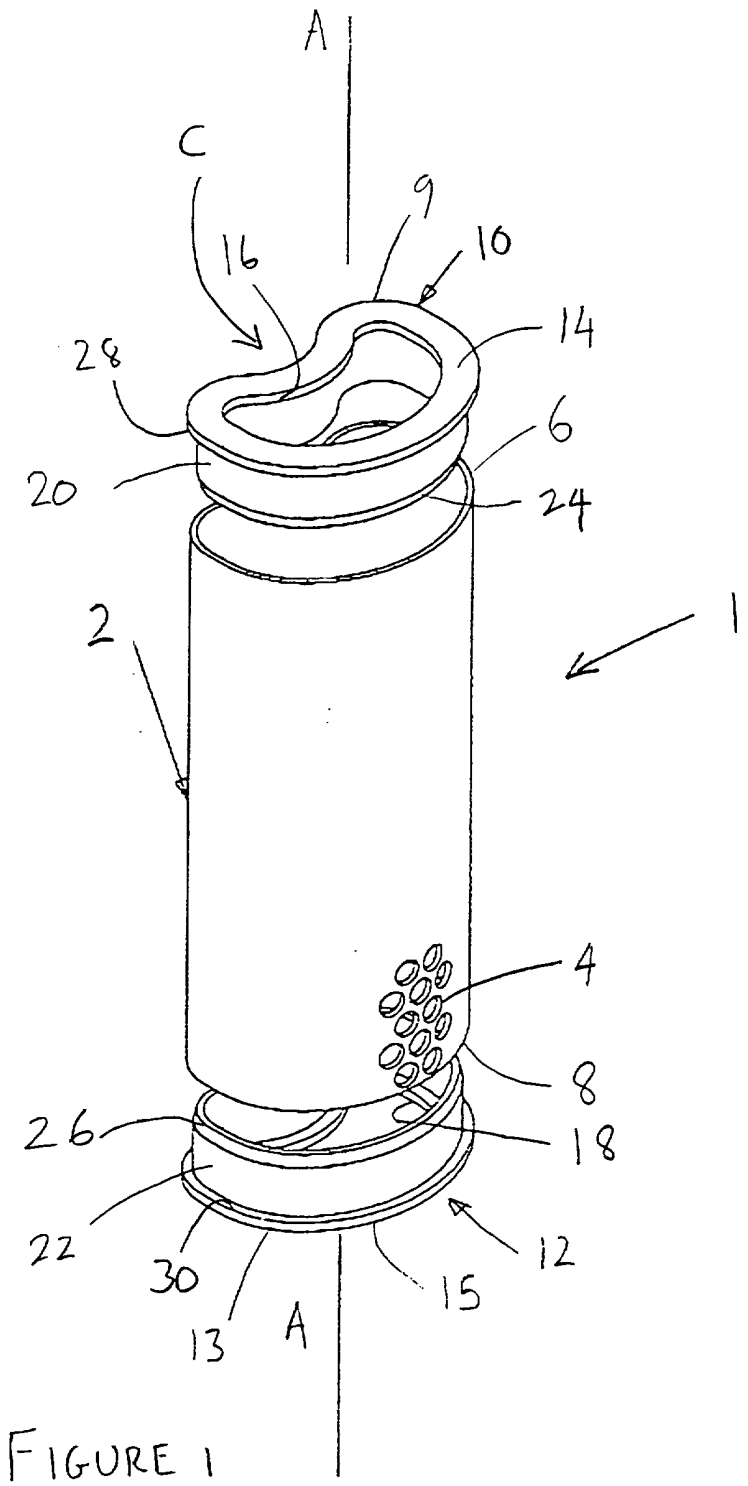

FIGURE 1

VERTEBRAL BODY REPLACEMENT

This invention relates to a spinal prosthesis for supporting or replacing all or part of one or more vertebral bodies.

The treatment of spinal fractures and tumours often requires the implantation of a prosthesis capable of substituting for the affected vertebra.

In the absence of any commercially available implants, spinal surgeons used bone cement as a crude spacer. PMMA cement has sufficient compressive strength to replace bone for the space of one vertebra. If more than two vertebrae are involved, then the cement must be reinforced with metal rods which function as compression struts.

Although PMMA cement was widely used in this application, it does have disadvantages. More specifically, it is difficult to prepare a cement bridge which is dimensionally accurately enough to restore correct spinal alignment and to install easily. Intraoperatively, soft tissues have a tendency to fold or curl over the edge of the anterior rim and enter the intervertebral space, thus causing the anterior rim to be insufficiently supported. This can lead to displacement of the cement bridge. There is also a high risk of infection with cement struts. The infection risk is increased partly because of the longevity of the surgery, and because of biological reaction with cements which contain antibiotics. Cements have been developed specifically for this type of procedure, to reduce the incidents of infection. The cement in these procedures is mixed to a dense paste and is fitted into the spine. This then cures in vivo. As it cures it generates heat, risking thermal damage to the neural pathways. A 4 to 12°C rise in tissue temperature at the dural sac has been measured in experiments in cadavers. Although this technique is

still in use today, it is confined to end stage patients.

Alternative systems have also been proposed and current commercially available instrumentation includes, among other systems, bracing devices and sophisticating jacking devices. These jacking devices all follow the same basic pattern, although to different levels of sophistication. Each uses opposite handed thread arrangements to adjust the implant height and can be locked off once the correct height and position is achieved. They only differ in the fixing to the vertebrae, and in the degree of anatomic accuracy. These existing systems have been partially successful, but there have been reports of subsidence or anterior translation with attendant problems of hyperkyphosis and pain. The present invention has therefore been developed to address the problems associated with the existing systems of corporectomy based spinal reconstruction.

According to a first aspect of the present invention there is provided a prosthesis comprising a hollow strut terminated by a pair of end caps which are adapted to engage respective vertebrae, each end cap having a flange which is closely received within and supports a respective end of the hollow strut.

To ensure long term stability and resistance to subsidence, the end caps are preferably substantially kidney shaped so that they approximate to the anatomic shape of the hard outer cortex of the vertebral bodies of the vertebrae.

According to a second aspect of the present invention, there is provided a prosthesis comprising a strut having a pair of end caps which are adapted to engage respective vertebrae, each end cap being substantially kidney shaped in a plane substantially perpendicular to the longitudinal axis of the strut.

Preferably the strut is substantially kidney shaped in cross-section, so that the prosthesis as a whole has a posterior concavity which, when implanted, accommodates the spinal cord.

Any spinal prosthesis is subject to compression, torsion and cyclic fatigue loads. By far the largest component of force is a cyclic compressive component which must be transmitted at the interface between the end plate of the adjacent vertebral body and the prosthesis. The anatomy of the vertebral body end plate is well documented and is not discussed in detail here. Put simply, the end plate is approximately kidney shaped and has a soft cancellous centre and a hard outer cortex of bone capable of withstanding compressive loading. Therefore, in a preferred embodiment of the invention, the end caps have a large cutout which corresponds in shape to the outer rim, and allows contact between bone graft packed inside the implant and the vertebral body end plate, or in cases where the device has been packed with cement, to allow for any excess to escape and be removed.

According to a third aspect of the present invention there is provided a prosthesis comprising a strut having a pair of end caps which each have an end wall which is adapted to engage a respective vertebra, the periphery of each end wall extending further from the strut than the remainder of the end wall.

Preferably, the end caps are a press fit into the hollow strut. Preferably, the leading edge of each flange is chamfered, which assists alignment of the end cap with the hollow strut and facilitates assembly.

Preferably, the strut comprises a tube. The tube may be seam welded or extruded.

Preferably, the tube is made of titanium and may be heat treated. Preferably, the tube has a 0.9 mm thick wall.

The strut may be provided with a plurality of through holes. Preferably, the hole pattern is configured to enable trimming to length to suit individual patient need, such as to allow for a degree of lordosis and kyphosis.

Preferably, in a region away from the periphery, the end wall is provided with a kidney shaped recess.

Preferably, the recess comprises a through hole which provides access to the interior of the strut.

Preferably, each end cap is provided with a shoulder which is adapted to cover the end of the strut and to prevent the end of the strut damaging the surrounding soft tissue.

Preferably, the prosthesis is stabilised by rods and bone screws. For example, 5mm diameter transvertebral rods and 6.5mm diameter bone screws may be used. These screws and rods are preferably based on a top loading collet locking system such as the Webb-Morley system. The screws and rods are preferably used anteriorly to bridge the prosthesis and may also be used posteriorly to further strengthen the total assembly.

Preferably a porous titanium plasma coating is applied to the end caps to enhance bone fixation and to resist anterior translation and rotation of the prosthesis by biting into the subcondral bone. When the prosthesis is implanted and under a compression load, there will be intimate contact between the porous coating and the bone. This helps enhance primary stability and encourages osseointegration.

According to a fourth aspect of the present invention there is provided a prosthesis comprising a strut, the ends of the strut being adapted to engage respective vertebrae, the strut comprising a tube.

Preferably each end of the strut is provided with an end cap which is adapted to engage a respective

vertebra.

The wall of the tube may be perforated, but otherwise is preferably continuous to enhance its strength. The tube may, for example, be seam welded or extruded.

For a better understanding of the present invention and to show how it may be carried into effect, reference will now be made, to the accompanying drawing, which is a perspective view of a prosthesis in accordance with the present invention.

Figure 1 shows a prosthesis for use in the treatment of spinal tumours and fractures. The prosthesis 1 comprises a strut 2 formed from a heat treated titanium tube in which are formed a plurality of perforations 4. The ends 6, 8 of the strut 2 are terminated by respective end caps 10, 12 which are a push fit into the ends 6, 8.

The strut 2 and end caps 10, 12 have a substantially kidney shaped cross-section and the internal diameter of the strut is sized such that the end caps 10, 12 are closely received within the ends 6, 8 of the strut 2.

Each end cap 10, 12 comprises an end wall 9, 13 having a bone engaging surface 14, 15 which is disposed in a plane substantially perpendicular to the longitudinal axis AA of the strut 2. A kidney shaped central opening 16, 18 is formed in each end wall 9, 13 and limits the bone engaging surface 14, 15 to the periphery of the end wall 9, 13 of the respective end cap 10, 12. A continuous flange 20, 22 projects at right angles from the end wall 9, 13 and forms the main body of each end cap 10, 12. The free end 24, 26 of each flange 20, 22 is chamfered to ease insertion into the strut 2.

The end wall 9, 13 of each end cap 10, 12 extends radially outwardly beyond the respective flanges 20, 22

to form shoulders 28, 30.

In a vertebral body replacement operation, the damaged or tumorous vertebral body (not shown) is cut away and the strut 2 is trimmed, so that the prosthesis as a whole will be of the correct length to replace the excised vertebral body. The end caps 10, 12 are then pushed into the open ends of the strut until the respective shoulder 28, 30 abuts the respective end 6, 8 of the strut 2. As will be appreciated, the shoulders 28, 30 cover the otherwise exposed ends 6, 8 of the strut 2, which may be rough or jagged, following the trimming operation.

Following assembly, the prosthesis is inserted into the space left by the excised vertebral body, such that the spinal cord is accommodated by the posterior concavity C generated by the kidney shaping of the end caps 10, 12 and the strut 2 and such that the bone engaging surfaces 14 engage the end plates of the adjacent vertebral bodies. As discussed above, the vertebral body end plates are approximately kidney shaped and have a soft cancellous centre and hard outer cortex of bone capable of withstanding compression loading. In the implanted condition, the kidney shaped bone engaging surfaces 14 of the end caps 10, 12 are aligned with the hard outer cortex of bone of the vertebral body end plates and the openings 16, 18 are aligned with the soft cancellous centre of the end plates, so that the compressive loading on the spine is carried directly from the hardest part of the end plates into the bone engaging surfaces 14, 15 of the respective end cap 10, 12.

Prior to insertion of the prosthesis, bone graft or bone cement may be packed inside the interior of the strut 2 through the openings 16, 18 in the end caps 10, 12. If the interior of the strut 2 and end caps 10, 12 is completely filled with bone cement, the adjacent

vertebral bodies will impinge directly on the bone cement which fills the openings 16, 18, so that there will be direct contact not only between the bone engaging surfaces 14 and the hard outer cortex of the end plate but also between the bone cement and the soft cancellous centre of the end plates. Any excess bone cement will be squeezed to the outside of the prosthesis and can be removed, so that once the bone cement has set, the prosthesis is an exact fit between the adjacent vertebral bodies and is therefore resistant to dislocation. Furthermore, as the load is transferred into the strongest parts of the adjacent vertebral bodies, post-operatively, the patient's spine will be able to withstand substantially the same compressive loads that it could withstand pre trauma or disease.

In order to improve the stability of the prosthesis, the bone engaging surfaces 14, 15 are provided with a porous titanium plasma coating which roughens the bone engaging surfaces 14, 15 and causes them to bite into the subcondral bone. The titanium porous coating acts as a host media for bony ingrowth, so long term fixation is also improved.

It will be appreciated that a single prosthesis in accordance with the present invention may be used to replace or support all or part of more than one vertebral body.

CLAIMS

1. A prosthesis comprising a strut terminated by a pair of end caps which are adapted to engage respective vertebrae, each end cap having a flange which is closely received within and supports a respective end of the hollow strut.

2. A prosthesis as claimed in claim 1, in which the leading edge of each flange is chamfered.

3. A prosthesis as claimed in claim 1 or 2, in which the end caps are substantially kidney shaped.

4. A prosthesis comprising a strut having a pair of end caps which are adapted to engage respective vertebrae, each end cap being substantially kidney shaped in a plane substantially perpendicular to the longitudinal axis of the strut.

5. A prosthesis as claimed in any one of the preceding claims, in which the strut is substantially kidney shaped in cross-section.

6. A prosthesis comprising a strut having a pair of end caps which each have an end wall which is adapted to engage a respective vertebra, the periphery of each end wall extending further from the strut than the remainder of the end wall.

7. A prosthesis as claimed in claim 6, in which in a region away from the periphery, each end wall is provided with a kidney shaped recess.

8. A prosthesis as claimed in claim 7, in which the recess comprises a through hole which provides access to the interior of the strut.

9. A prosthesis as claimed in any one of the preceding claims, in which each end cap is provided with a shoulder which is adapted to cover the end of the strut

10. A prosthesis as claimed in any one of the preceding claims, in which a porous titanium plasma coating is applied to the end caps.

11. A prosthesis as claimed in any one of the preceding claims, in which the end caps are a press fit into the strut.

12. A prosthesis as claimed in any one of the preceding claims, in which the strut comprises a tube.

13. A prosthesis as claimed in any one of the preceding claims, in which the tube is made from titanium.

14. A prosthesis as claimed in claim 12 or 13, in which the tube is heat treated.

15. A prosthesis as claimed in any one of claims 12 to 14, in which the tube is seam welded.

16. A prosthesis as claimed in any one of the preceding claims, in which the strut is provided with a plurality of through holes.

17. A prosthesis as claimed in claim 16, in which the through holes are aligned in rows substantially perpendicular to the longitudinal axis of the strut.

18. A prosthesis substantially as described herein, with reference to, and as shown in, the accompanying drawings.

The Patent Office

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Claims searched: 1-3 at least **Date of search:** 21 September 1998

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.P): A5R (RAS)

Int Cl (Ed.6): A61F 2/44

Other:

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	WO 96/17564 A1	(SOFAMOR DANEK), see eg. Fig. 3	1 at least
X	WO 91/06261 A1	(SURGICAL DYNAMICS), see eg. Figs. 1 and 5	"
X	EP 0369603 A1	(CEDAR SURGICAL), see eg. Fig. 1	"
X	EP 0356112 A1	(JOHNSON & JOHNSON ET AL), see eg. Figs. 1 and 2	1 and 3 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.