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(54) Title: IMPLANTABLE PROSTHESIS, KIT AND DEVICE FOR MANUFACTURING THE SAME

(57) Abstract

An implantable prosthesis comprises a biocompatible, synthetic, substantially bioresorbable matrix material seeded with fibroblasts.

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IMPLANTABLE PROSTHESES, KIT AND DEVICE FOR MANUFACTURING THE SAME

The present invention relates to methods suitable for replacing or repairing broken or damaged connective tissue such as ligaments or tendons and to prostheses for use in such methods. Also disclosed is a device for use in forming such prostheses, as well as kits from which the prostheses can be formed.

It is known from United States Patent No. US5078744 to repair damaged ligaments such as the anterior cruciate ligament (ACL) by replacing part of the damaged ligament by a prosthetic ligament comprising purified connective animal tendon or ligament tissue fibres which are cross-linked and formed into groups of aligned fibres.

The most common method of repair or reconstruction of the ACL is to implant a prosthetic graft comprising autogenous tissues. Thus it is common surgical practice to harvest autogenous tissue eg. patellar tendon from the host and to form a prosthesis for implantation.

A number of synthetic non-bioresorbable materials have been used in the manufacture of prosthetic ligaments, the materials being chosen for their affinity for supporting or encouraging the ingrowth of fibroblasts, after implantation of the prosthesis.

According to the present invention there is provided an implantable prosthesis which, in a form prior to implantation in a host, comprises a biocompatible, synthetic, substantially bioresorbable matrix material seeded with fibroblasts.

By "synthetic", is merely meant a material which is not used naturally by the mammalian body in connective tissue repair or which is not a chemically modified form of such a material. Thus this term excludes collagen and artificially cross-linked collagen matrixes (although, if desired, collagen can be used in addition to the synthetic material).

The term "fibroblast" includes cells which are sometimes referred to as fibroblast, fibrocyte, tenocyte or synovioctye cells. This term also covers precursor cells to any of these cells.

By "substantially bioresorbable matrix material" is meant a three dimensional structure for supporting fibroblasts (which may be in the form of a scaffold, mesh or solid structure, for example) and which, in the implanted prosthesis, degrades substantially over time in a mammalian body, due to the chemical/biological action of body components (as opposed to simply breaking due to physical strain on to the prosthesis). Desirably after the prosthesis has been implanted in an adult human for five years (more preferably after only one year's implantation) the bioresorbable material will have degraded to such an extent so that it makes no substantial contribution to the structural integrity of the prosthesis.

Preferably the matrix may additionally comprise one or more of the following molecules: proteoglycans, glycosaminoglycans, fibronectin or its active binding domain, or one or more growth factors e.g. bone morphogenetic protein (BMP) fibroblast growth factor, angiogensis factor or other stimulatory factors.

In a further embodiment of the invention, the prosthesis or part thereof (e.g. area(s) of the prosthesis which will come into contact with bone after implantation), may be impregnated with osteoinductive or osteoconductive agents, to enable more easy infiltration by bone cells. Examples of suitable osteoinductive materials susceptible to infiltration include hydroxyapatite, freeze-dried or demineralised bone, growth factors (e.g. bone morphogenetic protein) etc. Impregnation may suitably be just before implantation of the prosthesis. Aptly such materials are incorporated into ends of the prosthesis.

In a further embodiment of the present invention, there is provided a method of repairing or replacing damaged connective tissue in a human or non-human animal comprising the steps of: incubating a biocompatible, synthetic, substantially bioresorbable

matrix material in the presence of a suitable culture medium and of fibroblasts under suitable conditions for fibroblast seeding on or in the matrix and thereafter implanting the seeded matrix into a host.

Examples of suitable substantially bioresorbable synthetic polymers include polylactide (PLA), polyglycolide (PGA), polydioxanone, poly caprolactone (PCL), polyhydroxybutyrate (ICI BIOPOL™), polyhydroxybutyrate-co-hydroxyvalerate (ICI BIOPOL™), polyanhydrides, polyorthoesters, polyorthocarbonates, polyaminocarbonates, polytrimethylene carbonate and co-polymers incorporating monomers from which the aforesaid polymers can be formed.

When the prosthesis according to the present invention comprises a copolymer, the copolymer may incorporate hydroxyvalerate and hydroxybutyrate monomers. In such copolymers the amount of hydroxyvalerate present may be from 1 to 47% mol. Other particularly suitable copolymers are PLA/PGA and PLA/PCL copolymers.

Composites of a plurality the above substantially bioresorbable materials may also be suitable as or as part of the matrix material.

The matrix be fabricated of two or more distinct materials (e.g. distinct fibre types) with different degradation rates, providing a two or more phase loss of mechanical properties with time. Also, the different fibre types may possess different mechanical properties. For example, highly extendable fibres may be combined with less extendable fibres. The matrix may be designed to elongate to a specified extent before the less extendable fibres prevent further extension. This design may be advantageous in exposing the cells to limited and controlled strain while protecting against damage to the forming tissue. For example, polycaprolactone fibres have a lower Young's modulus than polylactide fibres.

Furthermore, one polymer may be coated with another polymer. This is advantageous where the material of choice on the

basis of mechanical properties is not necessarily the material of choice for cell culture (unless it is modified). Here a more biocompatible polymer may be used to coat a less biocompatible base material. For example, polylactide provides a better substrate for fibroblast proliferation than polycaprolactone. Polycaprolactone fibres could be coated with polylactide to improve compatibility with fibroblasts.

As indicated above, copolymeric materials may be used. This can be advantageous where the copolymers possess degradation rates intermediate between the rates of the homopolymers of which they are composed. Therefore, the degradation rate may be controlled by controlling the composition of the copolymer. Also, production of copolymer fibres by fibre spinning or extrusion may yield fibres with mechanical properties superior to those of homopolymers. Polylactide-Polyglycolide copolymers are good examples of both of these points.

Suitable fibroblasts for use in seeding the matrix may be autogenic fibroblasts, allogenic fibroblasts or xenogenic fibroblasts. Preferably, the fibroblasts are autogenic. The fibroblasts may originate from for example the dermis, tendons or ligaments. The fibroblasts for use in seeding the matrix may comprise a mixture of one or more of the above types of fibroblasts. Where the fibroblasts are autogenic, it is preferable to isolate them from the dermis, as this avoids the need for extensive invasive surgery.

The fibroblasts may be obtained according to any suitable method. A preferred method is by carrying out a skin biopsy.

The matrix material may be seeded with fibroblasts by placing the matrix in a culture vessel containing an appropriate culture medium (e.g. DMEM), in the presence of fibroblasts and incubating under cell culture conditions. The fibroblasts may be suspended in the culture medium and the resultant suspension added to the culture vessel either before or after addition of the matrix. The

number of fibroblasts/ml of medium may be varied according to the degree of seeding it is desired to establish.

The prosthesis of the present invention may be used to either partially or totally replace a damaged ligament, tendon, cornea, dermis, dura (or other body part comprising connective tissue). Where the damage is substantial, the damaged ligament or tendon may be totally surgically replaced by the prosthesis. Where the damage is less substantial the matrix may be designed so as to be joined (e.g. by suturing) to the existing damaged ligament or tendon.

The matrix may be designed according to any one of a number of possibilities. Aptly the matrix is a fibrous structure. It may have loops or other structures at each end for aiding fixation to bone (using for example either the "two tunnel" or the "over-the-top" technique). It may be formed by any appropriate technique - e.g. braiding, knitting, weaving, crocheting etc. The matrix is desirably in elongate form and is preferably flexible.

The device may closely mimic the natural structure and fixation of the ligament or tendon. For example, for ACL reconstruction, the device could be composed of a hierarchy of fibres bundled together in fasicular units, passing directly from the femur to the tibia or taking a spiral path around the axis of the device. Fixation may be to the natural fixation areas of the ligament or tendon. Any appropriate fixation means may be used (e.g. screws, nails, staples or sutines). The fixation means may itself be bioresorbable, for example it may be formed of polyhydroxybutyrate.

The present invention further provides a kit for forming the prosthesis of the present invention comprising a synthetic biocompatible matrix material and a source of fibroblasts.

On incubation under suitable conditions, the fibroblasts will grow on and/or in the matrix, thus producing a matrix seeded with fibroblasts.

The kit may additionally comprise a suitable medium for the proliferation of fibroblasts.

Ideally the kit is presented in a sterile package. Alternatively the parts of the kit may be sterilised just before use. Prior to implantation, the components of the kit can be incubated together under appropriate culture conditions as above described to allow the fibroblasts to seed the prosthesis.

The fibroblasts may be in any suitable form ready for use. Thus aptly the fibroblasts may be cryopreserved.

The matrix, or components/precursors thereof, may be provided in lyophilised form.

In a preferred embodiment, the present invention comprises, an implantable prosthesis which in a form prior to implantation comprises a biocompatible synthetic substantially bioresorbable matrix material having a polymeric gel in intimate contact therewith, the gel having fibroblasts dispersed therein. This is advantageous in that the gel can support the cells in a true three-dimensional arrangement rather than merely supporting a monolayer on the surface of a material. The environment closely mimics the natural physiological environment of the cells. Also, incorporation of cells in a gel can provide for even cell distribution, preventing cells from pooling which might otherwise occur due to gravitational influence.

The present invention provides a method of repairing or replacing connective tissue in a human or other animal, comprising the steps of: incubating a biocompatible matrix material in the presence of a gel-forming composition and of fibroblasts under suitable conditions to form a prosthesis comprising a matrix contacting a polymeric gel, the gel having fibroblasts dispersed therein, and thereafter implanting the prosthesis into a host.

Suitable gel forming compositions include collagen gel forming compositions and fibrin gel forming compositions.

Fibroblasts in a collagen gel are capable of utilising the collagen and reorganising it. Under an appropriate mechanical stimulus they are capable of reorganising the fibrils into non-randomly orientated, organised structures resembling the natural ultrastructure of ligament and tendons. A mechanical stimulus may be the prevention of gel contraction which would otherwise occur over time by fixing the gel at two points. The matrix may be designed to achieve this. Alternatively, the gel on or in the matrix may be exposed to applied strain using a mechanised straining device to stimulate fibroblast alignment.

The method may comprise an additional step of incubating a gel-contacting matrix under suitable conditions for fibroblast proliferation in the gel and thereafter implanting the matrix into a host.

In the preferred embodiment of the present invention, the matrix is seeded by means of incubating the matrix in the presence of a suitable culture medium, a gel-forming composition and the fibroblasts to be seeded. An appropriate agent for causing gelation of the gel forming composition may also be used, if necessary.

Seeding the matrix in the presence of a gel-forming composition, fibroblasts (and a gelling agent, if required) results in a gel-coated or filled matrix, the gel having fibroblasts dispersed therein. The gel can be formed by the interaction of the gelling agent and the gel-forming composition. A preferred gel is a collagen gel. A Type I, II or III collagen solution may be prepared using an appropriate source of collagen. Thus for example a Type I collagen solution may be prepared from dermis (Type I collagen forms up to 70% of extracellular protein found in skin) as above described. Alternatively a Type I collagen solution may be prepared tendons, e.g. rat or bovine tendons, which comprise almost exclusively Type 1 collagen. The collagen may be extracted according to any of the standard methods known by those skilled in the art.

There are a number of suitable ways of incorporating the gel in or on the matrix. For example, the matrix may be suspended in such a manner that the gel-forming solution (optionally comprising fibroblasts) completely surrounds the matrix. A mould which surrounds the matrix may be used. Centrifugation or suction may alternatively be used to direct gel towards the matrix.

A kit for use in forming the prosthesis of the preferred embodiment can comprise a biocompatible matrix, a gel-forming composition and a source of fibroblasts.

Alternatively the kit may comprise a biocompatible matrix having a coating comprising a polymeric gel and/or having a polymeric gel incorporated therein and a source of fibroblasts. On incubation under suitable conditions the fibroblasts can invade the gel, thus producing a matrix bearing a gel having fibroblasts therein.

The prosthesis of the present invention offers an advantage over previously known prostheses which were designed to enhance ingrowth of fibroblasts after implantation and act as a scaffold through which fibroblasts can grow and form a new ligament, since it comprises fibroblasts prior to implantation. Thus the damaged tissue may be replaced by a prosthesis comprising viable fibroblasts which may be replicating. The fibroblasts may already substantially be aligned on implantation or at least oriented in a non-random manner. This process is speedier than previously known methods which rely on infiltration of prostheses by fibroblasts after implantation. It will be clear that the prosthesis may be implanted after an initial predetermined incubation period timed to result in seeding of the prosthesis with fibroblasts. Alternatively the prosthesis may be incubated for a longer incubation period than the initial incubation period so that the fibroblasts will be replicating and will have already started to secrete collagen fibrils when the prosthesis is implanted.

The prosthesis and method of the present invention offers other advantages over the common surgical practice or harvesting

host patellar tendon in that it avoids the need for carrying out an extensive surgical operation to harvest the tendon. A simple skin biopsy (a standard procedure which does not result in substantial scarring) can be used to obtain fibroblasts which can then be proliferated in culture. In addition, the prosthesis can be designed to optimise fibroblast orientation. The cumulative effect of these advantages can result in a reduction in the length of a hospital stay.

In one preferred embodiment of the present invention, where a collagen gel contacts the matrix, the prosthesis of the present invention provides a source of collagen which can be used by the fibroblasts. The collagen in the gel is preferably in a non-cross-linked form.

In another preferred embodiment of the present invention a fibrin gel is used.

According to a further aspect of the present invention there is provided a device for culturing cells for use in forming a prosthesis according to the present invention, comprising a chamber for maintaining fibroblasts in a viable condition, the chamber being provided with means for releasably securing the matrix material and means adapted for applying strain to the matrix material along a single axis only. Such a device can be included in a kit as aforesaid.

If several straining means are present, the device of the present invention can apply strain to a plurality of samples at any one time. Thus the device may have one or more chambers adapted to retain a culture medium and may be provided with means for releasably securing a plurality of matrix materials. This may be done simultaneously. Each of several chambers may be provided with means for releasably securing a plurality of matrix materials. Alternatively each chamber may be provided with means for releasably securing a single matrix material.

A chamber may be permanently fixed within the device. Alternatively the chamber may be releasably fixed so that it may be

removed from the device as desired, e.g. the chamber(s) may be removed to facilitate the securing and release of the matrix material.

A chamber may be made from any material which may be sterilised by suitable methods of sterilisation, e.g. gamma irradiation, steam sterilisation or ethylene oxide (ETO) sterilisation.

A chamber may have any desirable shape and size. Suitably the chamber may be cylindrical, cuboid or spherical. The dimensions of the chamber should be such that they enable the matrix material to be secured and to be subsequently extended on the application of strain. The device of the present invention can be adapted to apply a strain which causes e.g. up to 100% extension of the matrix material (relative to the material in unextended form). Generally speaking however, an extension of up to 10%, or of up to 5% may be sufficient.

Thus the dimensions of the chamber can be such that they enable the matrix material to be extended to the desired level.

The dimensions of a chamber are desirably such that the chamber has a capacity of up to $75cm^3$, e.g. up to $50cm^3$. The chamber may be made from any suitable material, e.g. stainless steel or Perspex™ material. Preferably the material is autoclavable to facilitate sterilisation.

Preferably the chamber is provided with a transparent or translucent window to enable the matrix material to be viewed during the time of culture. Examples of suitable materials include glass and polymethylmethacrylate (PERSPEX).

The chamber may comprise a closure, which may be removably or hingedly mounted to allow access to the inside of the chamber. Thus for example the chamber may comprise a glass cylinder wherein at least one of the ends is removable. Aptly the chamber may be collapsible or telescopic.

The chamber is desirably thermostatically controlled and may be heated via a water jacket or other heating means. It may be provided with various sensors e.g. sensors of the CO_2 content within a head space of the chamber. A CO_2 source may also be provided.

The matrix material may be releasably secured by securing means within the chamber.

The means for applying strain may compare two elements which are movable within the chamber so that the spacing between the elements can be varied. Alternatively one element may be movable but the other may be fixed.

The securing means may be any suitable means for releasably securing the matrix sample. The design of the securing means depends upon the design of the ends of the matrix material. Thus for example where the matrix material comprises looped ends the securing means may comprise a pair of clips or hooks. Suitably the securing means may comprise for example a chuck or a lathe or jaws which may screw together or be held by springs. Aptly the securing means may be in the form of a slot or other opening such that the ends of the matrix material are designed to fit thereon. Thus for example the ends of the matrix material may be embedded in a resin which may be retained in a slot. The opposite arrangement can be used in which the opening is in the matrix material and the securing means fit therein. A yet further way of releasably securing the matrix material is to provide a spool, which may be generally cylindrical, about which matrix material can be wrapped and held in position by friction. The spool may be held in place by a gripping device. Two such spools may be provided - one for each of two gripping devices.

The matrix material to which strain is to be applied by the device of the present invention may comprise any suitable material for supporting viable cells. Cells may be present in or along the entire length of the matrix material. Alternatively part of the matrix

material, e.g. the ends thereof, may have no cells. The cells may be applied to the matrix material either before or after the matrix material has been secured under extension. It is preferable however to apply the cells to the material before securing the material under extension in the chamber.

The matrix material may be designed in the form of a prosthetic ligament or tendon. Where for example the matrix material is in the form of a prosthetic ligament, the ligament when unstrained is preferably in the range of from 1 to 30cm long. The matrix material should be chosen so that it is suitable for withstanding the magnitudes of strain which it will be subjected to on implantation, e.g. in the knee.

The means for applying strain may act by pulling both ends or one end of the matrix material, resulting in an extension of the matrix material. This may be done by various means, e.g. mechanical, electrochemical, electrical, piezoelectric, pneumatic, hydraulic or other means. The matrix material may be releasably attached to a stationary element at one end of the chamber and the opposing end of the matrix material may be attached to a tension applying member (for example a winding device). Suitably strain may be applied to the matrix material by means of a diaphragm, one side of the diaphragm lying within the chamber and the opposing side lying outside the chamber. A pivotally mounted lever may be used to apply strain.

The present invention also provides a method of culturing cells under strain which method comprises the steps of releasably securing a matrix material having viable cells in intimate contact therewith in a chamber, the chamber comprising an adequate amount of culture medium to cover the matrix and cells, and applying strain to the matrix material along a single axis.

Materials suitable for use in a matrix of the present invention can be assessed as exemplified below:-

Assessment of Materials

In order to make an initial assessment of suitable materials for supporting fibroblast growth, various materials were obtained (which are not to be construed as limiting), as indicated in Table 1 below, and moulded into films for 5min at 2.5 Tons at the following temperatures: Polylactide 170°C; polyglycolide, 245°C; polyhydroxybutyrate, 185°C; and polycaprolactone, 65°C.

Table 1

Material	Supplier	Fig.
Polylactide	Medisorb, Cincinnati, Ohio, USA	1a
Polyglycolide	Medisorb, Cincinnati, Ohio, USA	1b
Polyhydroxybutyrate	Goodfellows, Cambridge, UK	1c
Polycaprolactone	Birmingham Polymers Inc. Alabama, USA	1d

Fibroblasts were seeded onto the surfaces of these materials at a density of 1×10^4 cells/cm^2 of material and incubated for 3 days under culture conditions.

After the incubation period, photomicrographs were taken of the cell-seeded samples. These are shown in Figs. 1a to 1d for the samples indicated in Table 1 above (photocopies of all of the photographs provided for this application are provided immediately after the relevant photographs).

Fibroblasts can be seen to be well adhered to the surfaces of all of the materials and to exhibit the morphology typical of healthy cultural fibroblasts.

One sample of fibroblasts was grown on polylactide as described above apart from the fact that a longer (16 day) culture period was used.

After this period the cells were stained with a viable stain (calcein AM (2μM)) and visualised by fluorescence microscopy using a fluorescein filter. A confluent monolayer of viable cells was observed, showing that polylactide is capable of supporting viable fibroblasts for extended periods of culture.

Figure 2 is a graph showing the relative rate of proliferation of fibroblasts on four examples of bioresorbable synthetic materials: polylactide (PLA); polyglycolide (PGA) polyhydroxybutyrate (PHB) and polycaprolactone (PCL) (all as described above) in comparison with a tissue culture treated polystyrene (TCP) control (since TCP is known to support good fibroblast growth).

Figures 2a) to e) show each of these materials on a single graph (for each of reference). Cells were seeded at 1 $x10^4$ cells.cm^{-2} in triplicate and the rate of proliferation determined by measuring the uptake of tritiated thymidine into cellular DNA at timepoints up to 7 days after incubation using standard cell culture techniques. The medium was changed at 2, 4 and 6 days. The points represent the mean of three determinations and the error bars represent the range. All polymers supported fibroblast proliferation.

Figure 3 is a photomicrograph of fibroblasts embedded within a three dimensional collagen gel after 15 days of culture. The cell-seeded gel was prepared as described in example 2 (which will be described later) apart from the fact that it was not used to contact a matrix. The gel provides a three-dimensional structure in which the cells are embedded and can form interactions with collagen molecules via membrane integrin receptors. The cells are randomly arranged, exhibit long processes and are capable of reorganising collagen fibrils within the gel.

Figure 4 is a photomicrograph of fibroblasts embedded within a three dimensional collagen gel as described for Fig. 3 above, apart from the fact that the gel has now been constrained from contracting in one direction by two stainless steel pegs glued to a culture dish with a tissue culture compatible adhesive. The cells are arranged in a highly orientated fashion, their long axes being parallel to the axis between the contraining pegs. The collagen fibrils align along the same axis. This effect is due to the pegs preventing the gel contracting, as would otherwise occur in the presence of fibroblasts in culture.

The following examples, which are not to be construed as limiting, illustrate how various cell-seeded matrixes can be produced.

Example 1 : Preparation of a fibroblast seeded polylactide matrix prosthesis

a) Preparation of Cells

A biopsy is washed three times in phosphate buffered saline (PBS), and rinsed in 70% alcohol. The rinsed biopsy is then dipped into Dulbecco's Modified Essential Medium (DMEM) and incubated at 37°C for 24 hours. After incubation, the biopsy is cut into small pieces under PBS. The cut pieces are transferred to a 50mm petri dish, containing about 5ml of collagenase solution to allow digestion. The epidermal sheets are removed from the collagenase solution. The resultant solution is centrifuged. The fibroblast cell pellet is resuspended in DMEM and thereafter seeded in a 35mm petri dish using DMEM. The cells may be confluent in from 2-4 days. Thereafter the cells may be cultured to provide an appropriate quantity of fibroblasts for seeding the matrix.

A suitable medium for culturing the isolated fibroblasts may comprise DMEM which may be supplemented with the following: glutamine, foetal calf serum, non essential amino acids and antibiotics. In addition the medium may have a buffering agent such as bicarbonate.

b) Preparation of matrix material

A polylactide matrix material suitable for use in a prosthesis for replacing a ligament can be prepared by obtaining polylactide fibres and then braiding them to form a braid of appropriate dimensions to replace the ligament.

Polylactide fibres can be obtained by extrusion, fibre spinning, melt-spinning, drawing, heat annealing etc.

Braiding of the fibres can be done by standard braiding techniques, the length and thickness of the braid, number of fibres present and diameter of fibres present being selected to form a braid with appropriate properties.

The ends of the device are constructed in a suitable way to aid fixation of the device by a screw or other fixation means. This is done by forming eyelets at the ends.

c) Seeding of matrix material with cells

The braided device is incubated in a medium containing 10% v/v serum for 24 hours and is then seeded with cells by pipetting a cell suspension over the surface of the matrix material until the latter is completely covered with cell suspension. (Alternatively the matrix may be incubated together with the cell suspension for a period of about six hours under conditions of agitation, e.g. on a bottle roller. Other alternatives are to seed the device by sucking cell suspension through it under vacuum (if it is porous) or by centrifuging cell suspension through the device).

d) Straining of the cell-seeded matrix

The cell seeded device is gripped at both ends in a straining apparatus which causes the device to be strained along a single longitudinal axis. This is done for sufficient time so as to cause the fibroblasts substantially to align along the general direction of the longitudinal axis, as can be assessed by microscopic analysis of the cells. The apparatus comprises a culture chamber so that straining can occur over several hours or even several days and yet the cells can remain viable. Typically the device is strained at 37°C.

During straining a culture medium is used to culture the cells under suitable conditions. This includes serum, ascorbate or stable analogues thereof, together with growth factors.

The ascorbate stimulates the fibroblasts to synthesise collagen; the serum contains factors promoting cell proliferation and cell adherence and the growth factors can stimulate cell proliferation, development and migration.

e) Implantation of the cell-seeded matrix

Once the cell-seeded device has been strained for a sufficient period to obtain a desired degree of alignment of fibroblasts, it is removed from the cell-straining device and implanted into a patient by any desired technique.

Minimal invasive surgery is preferred. For a prosthetic anterior cruciate ligament implantation be done utilising the "two-tunnel" or the "over the top" techniques. Fixation can be achieved by using screws (or other fixation elements) placed through the eyelets of the matrix. The screws are suitably formed of a biodegradable material, such as polyhydroxybutyrate.

Example 2 : Preparation of a fibroblast seeded polylactide matrix prosthesis comprising a collagen gel in which the fibroblasts are incorporated

This can be done in an analogous manner to the method described in Example 1, except for the inclusion of an alternative procedure whereby fibroblasts are incorporated in a collagen gel which is used to seed the polylactide matrix. This extra procedure is described below:-

a) Preparation of collagen

It is desired to form the collagen in a form which is acid soluble and which is not cross-linked. This can be done as follows:-

Type I collagen is prepared from tendon but could be from other tissue e.g. skin. The tissue is minced finely, disinfected in 70% (v/v) ethanol for at least 30 mins, dispersed in acetic acid (1% v/v) and incubated with agitation at 4°C. The supernatant is removed and neutralised by addition of an appropriate volume of 1.0M sodium hydroxide. The precipitated type I collagen is pelleted by centrifugation at 8,000 x g and the pellet resuspended in an appropriate volume of acetic acid (1% v/v). The collagen concentration of this solution is determined by any appropriate method (e.g. a total protein assay - the BCA assay) and the concentration of the collagen solution adjusted appropriately (e.g. $3mg.ml^{-1}$ can be used).

If the product is a kit, sterile collagen solution may be lyophilised and stored under vacuum or an inert gas (e.g. argon) to prevent cross-linking. A diluent (acetic acid) could also be provided. Alternatively, it could be provided as a solution and stored at 4°C to -20°C.

b) Seeding of matrix material with cells

Three components are typically used to seed the matrix:- cells suspended in an appropriate medium, collagen solution and a gelling agent - (e.g. 1M sodium hydroxide). The final collagen concentration may be approximately $1mg.ml^{-1}$ and the seeding density approx. $3x10^4$ cells per ml of gel (or volume within the matrix). The three components are maintained at 0°C to 4°C, mixed and added to the matrix. Once the matrix is fully impregnated, it is incubated at 37°C and gelling is initiated.

The impregnation of the matrix may be achieved by any suitable method. The matrix may be merely immersed in the solution within a mould. Alternatively the solution may be sucked into the scaffold by use of a vaccum or forced in by centrifugation (for example within a mould centrifuged at 500rpm for 5min at 0-4°C).

The rate of setting of the gel may be varied by varying the temperature.

Example 3 : Preparation of a fibroblast seeded polylactide matrix prosthesis comprising a fibrin gel in which the fibroblasts are incorporated

This can be done by an analogous method to that described in Example 2, except that a fibrin gel rather than a collagen gel is used.

Again, three components are used: cell suspension, fibrinogen solution and thrombin solution containing calcium chloride (mM). The final cell concentration may be $3x10^4$ cells per ml, the fibrinogen concentration may be 3mg/ml, the thrombin activity 2.5 Units/ml and the calcium chloride concentration 5mM. The reagents are mixed and then incubated with the matrix. Once impregnated with the solution, the matrix is incubated at 37°C to allow rapid gelling. Impregnation of the matrix may be conducted by any of the techniques described above.

The rate of gelling may be varied by varying the thrombin activity and/or the temperature.

The cell straining device referred to previously will now be described by way of example only with reference to Figs. 5 a), b), c), d), and e) which show various components which can be put together to form the device.

The device comprises a Perspex™ container 10 (shown in cut-away section) and lid 20 (see Figs. 5a) and 5e)). Container 10 can be used to contain an extensible material seeded with fibroblasts under cell culture conditions. For ease of reference thermostats, sensors, inlets for topping up culture media and other components which would be well known to those skilled in the art are not shown.

The device further comprises first and second grips 30 and 40, each of which has two parallel arms 45 bearing pegs 50 (see Figs. 5c) and e)).

One of the grips (grip 40) is provided with a support 60 which can be moved towards or away from the other grip 30 along a single longitudinal axis by a motor (not shown). The other grip 30 is fixedly mounted to an end wall 35 of the device.

The grips 30 and 40 function to receive and hold spools 70 and 80 (see Figs. 5c) and 5e)). This is achieved by pegs 50 fitting into grooves 90, thereby attaching the spools 70 and 80 to grips 30 and 40 in a manner which prevents rotation of the spools 70 and 80 relative to the grips 30 and 40 respectively.

Spools 70 and 80 function to hold an extensible material seeded with fibroblasts, indicated by cell seeded polylactide braid prosthesis 100.

This is achieved by threading opposite ends of the prosthesis 100 through apertures 110 and 120 and then rotating the spools 70 and 80 several times about axes A and B respectively so that the prosthesis 100 is secured to the spools 70 and 80 by friction (see Fig. 5b).

The spools 70 and 80 can then be slotted onto grips 30 and 40 as aforesaid (see Fig. 5c) and the prosthesis 100 can be extended by causing support 60 to retract within the container so that grips 30 and 40 become increasingly spaced. Once a desired degree of extension has been achieved support 60 can be held in position by a releasable locking device (not shown) and the extended prosthesis 100 can be incubated under culture conditions for as long as desired.

In order that the prosthesis 100 can be easily seen a window 130 is provided formed of a transparent on translucent material. This can be used for microscopic analysis of fibroblasts growing on the prosthesis 100 in order to determine when the prosthesis 100 is ready for implantation.

A grooved transparent or translucent block 140 is also provided for positioning at the bottom of container 10 (see Fig. 5d). The block is sized so that groove 150 can accommodate sufficient culture medium to cover the prosthesis 100 when positioned on spools 70 and 80 with the spools 70 and 80 being held by grips 30 and 40. This enables economical amounts of culture medium to be used.

The materials used to form the components of the straining device are autoclavable and sterilisable with alcohol. Typically the device is operated at a temperature of 37°C and with an atmosphere of 5% CO_2.

CLAIMS

1. An implantable prosthesis which in a form prior to implantation comprises a biocompatible, synthetic, substantially bioresorbable matrix material seeded with fibroblasts.

2. A prosthesis according to claim 1 wherein the bioresorbable matrix material comprises a polylactide, a polyglycolide, a polydioxanone, a poly caprolactone, a polyhydroxybutyrate, a polyhydroxybutyrate-co-hydroxyvalerate, a polyanhydride, a polyorthoester, a polyorthocarbonate, a polyaminocarbonate, a polytrimethylene carbonate or a co-polymer which incorporates monomers from which the abovementioned polymers are formed.

3. A prosthesis according to claim 1 or claim 2, further comprising a non-bioresorbable matrix material.

4. A prosthesis according to claim 3 wherein the non-bioresorbable matrix material is a polyester, a polyethylene, a polypropylene, PTFE, carbon fibre, or a composite of two or more of the aforesaid materials.

5. A prosthesis according to any preceding claims wherein the matrix further comprise one or more of the following:- proteoglycans, glycosaminoglylycans, fibronectin or its active binding domain, growth factors, osteoinductive or osteoconductive materials.

6. A prosthesis according to any preceding claim wherein the prosthesis comprises a gel in intimate contact with the bioresorbable matrix material, the gel having fibroblasts dispersed therein.

7. A prosthesis according to claim 6, wherein the gel is a collagen or fibrin gel.

8. A prosthesis according to claim 7 wherein the gel is in the form of a coating and/or a filling.

9. A prosthesis according to any of claims 6 to 8, wherein the bioresorbable matrix material is polyhydroxybutyrate or a copolymer incorporating a plurality of hydroxybutyrate monomers.

10. A prosthesis according to any preceding claim wherein the matrix is flexible.

11. A prosthesis according to any preceding claim which is in the form of a fibrous member.

12. A prosthesis according to any preceding claim which is in the form of a woven, knitted, crocheted or braided member.

13. A prosthesis according to any preceding claim comprising a plurality of bioresorbable matrix materials having different rates of bioresorbtion.

14. A prosthesis according to any preceding claim, wherein the fibroblasts are non-randomly oriented.

15. A prosthesis according to claim 14 wherein the fibroblasts are substantially aligned.

16. A kit for producing a prosthesis according to claim 1 comprising a fibroblast cell source or a device adapted for extracting fibroblasts from a mammalian body and a bioresorbable matrix material.

17. A kit for producing a prosthesis according to claim 6 comprising a fibroblast cell source or a device adapted for extracting fibroblasts from a mammalian body, a bioresorbable matrix material and a polymeric gel or a composition for forming the polymeric gel.

18. A device for use in manufacturing a prosthesis according to claim 14 or claim 15, wherein the device comprises a chamber for maintaining fibroblasts in a viable condition, the chamber being

provided with means for releasably securing the matrix material and means adapted for applying strain to the matrix material along a single axis only.

19. A method of repairing or replacing damaged connective tissue in a human or animal, comprising incubating a biocompatible synthetic substantially bioresorbable matrix material in the presence of a suitable culture medium and of fibroblasts under suitable conditions for fibroblast seeding on or in the matrix and thereafter implanting the matrix seeded with fibroblasts into a host.

20. A method according to claim 19 further comprising the step of applying strain to the matrix material when seeded with fibroblasts so as to cause non-random orientation of the fibroblasts.

21. A method according to claim 19 wherein the non-random orientation is a substantial alignment of fibroblasts.

22. A method according to claim 20 or claim 21 wherein the fibroblasts are incorporated in a gel.

23. A method according to claim 22 wherein the gel is a collagen gel or a fibrin gel.

Fig 1a

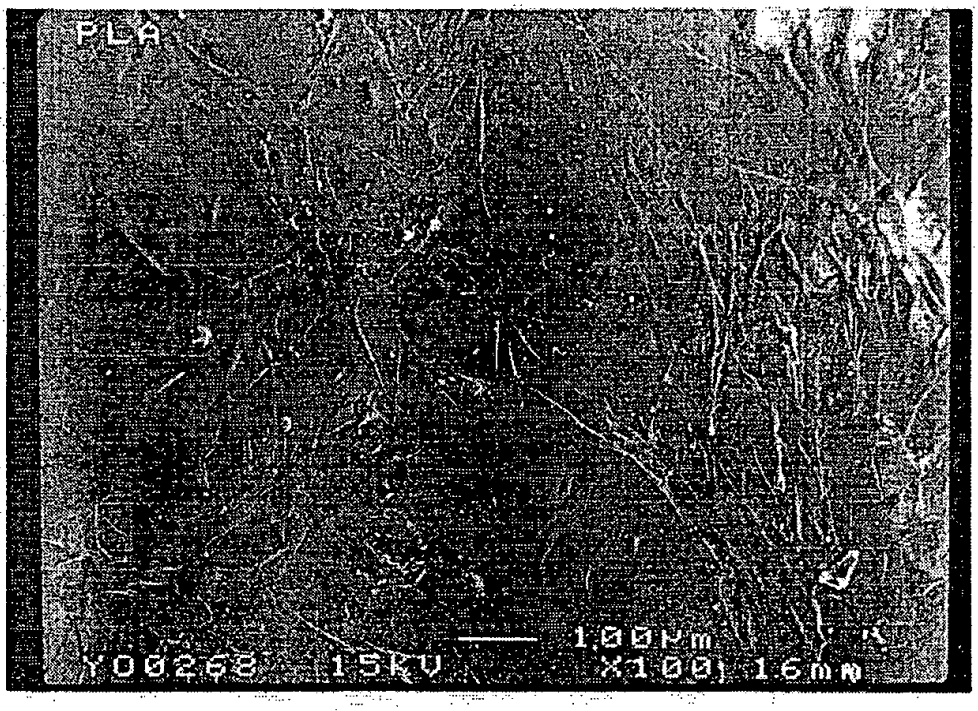


Fig 1b

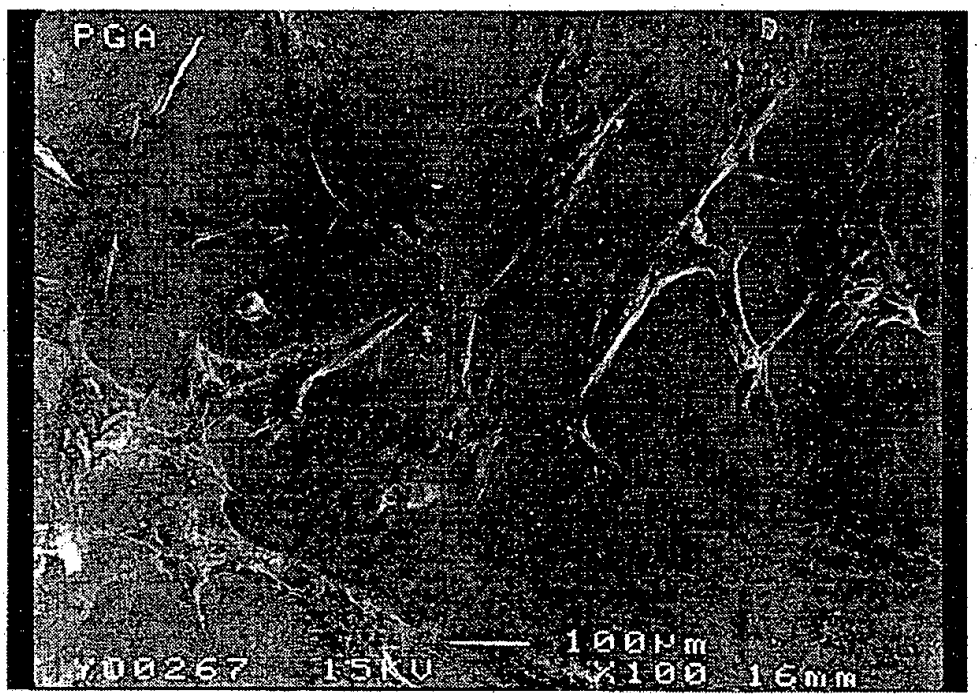


Fig 1c

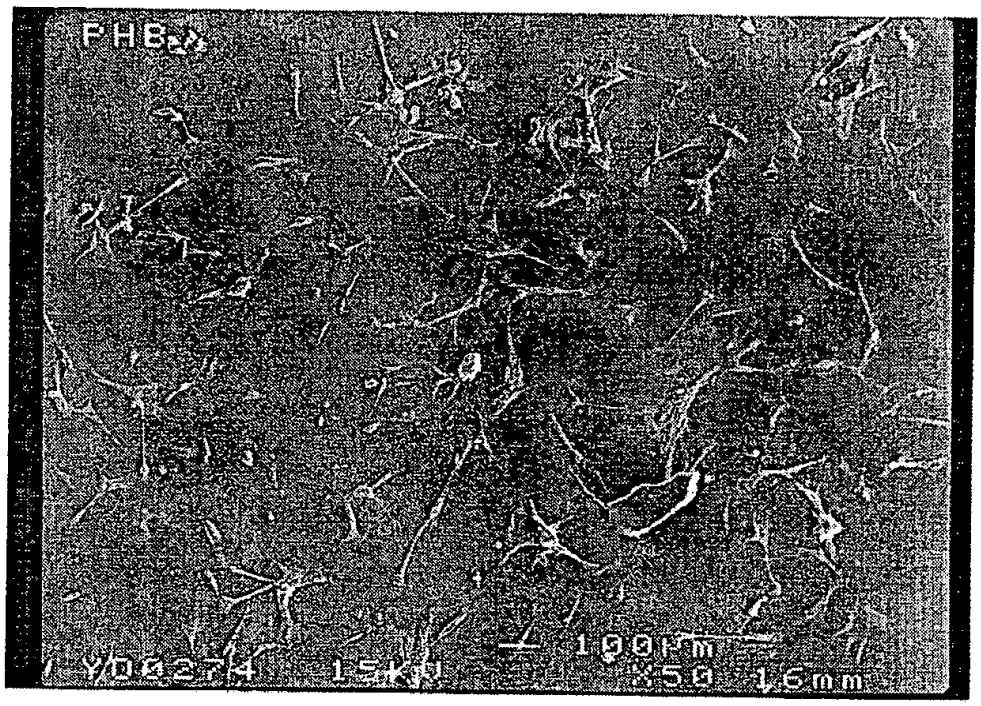


Fig 1d

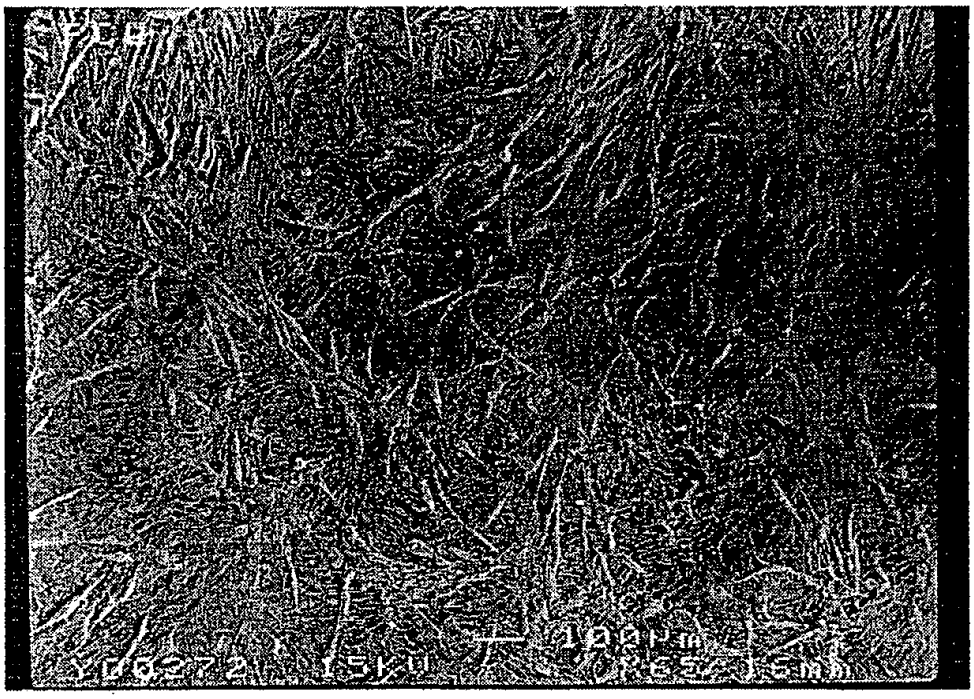


Fig 2a

Cell Proliferation on Tissue Culture Plastic

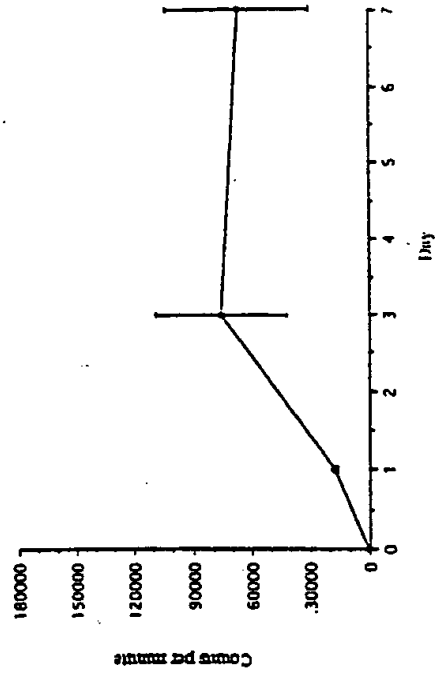


Fig 2c

Cell Proliferation on PHB

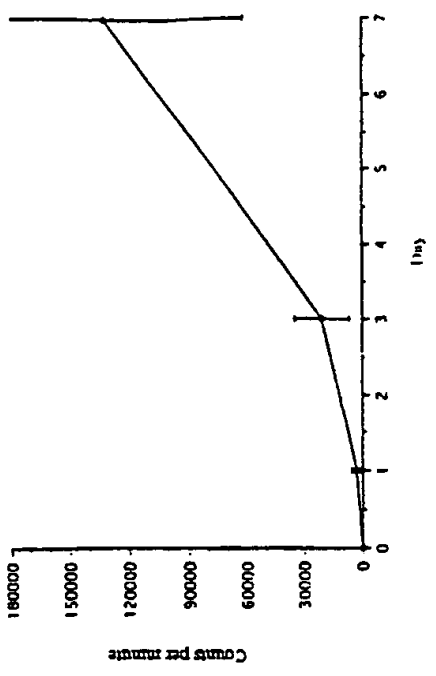


Fig 2

Cell Proliferation on a Range of Polymers

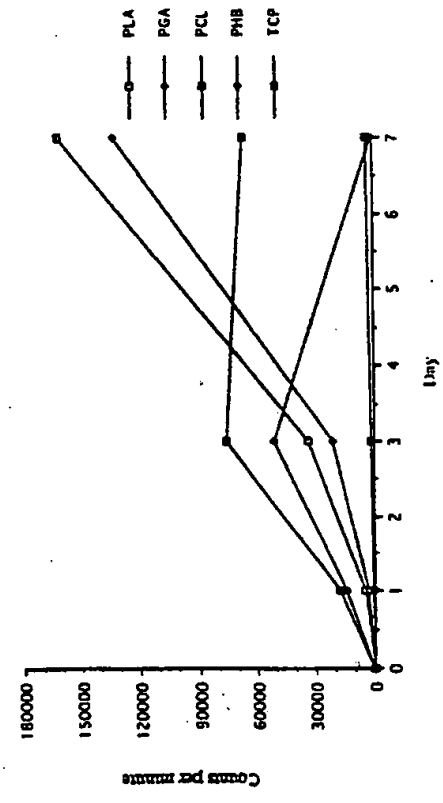
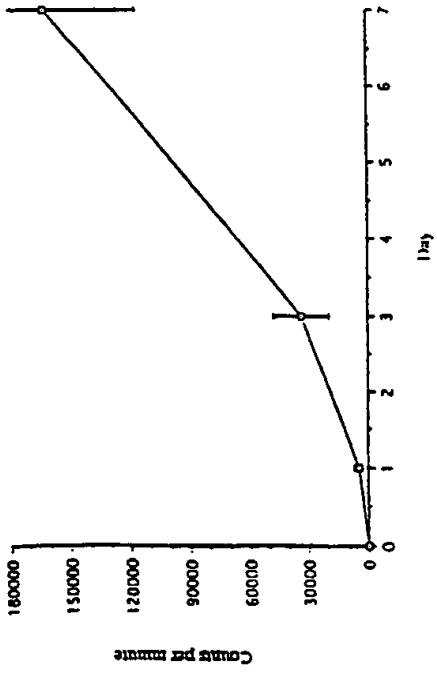


Fig 2b

Cell Proliferation on PLA



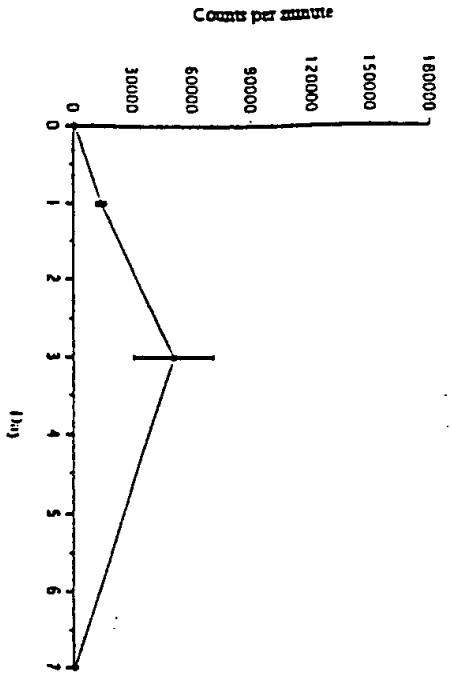


Fig 2d.

Cell Proliferation on FGA

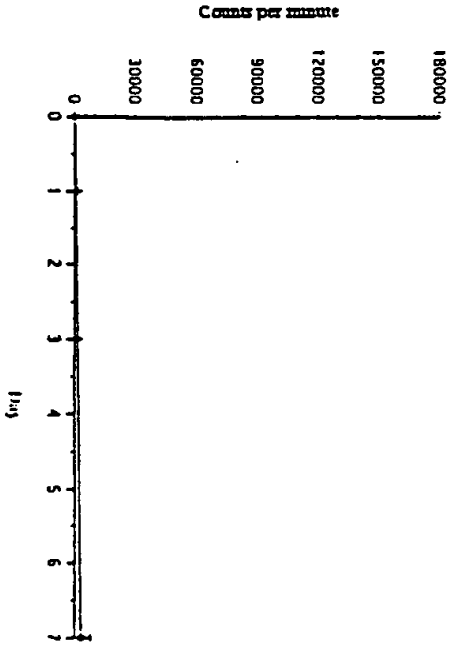


Fig 2e

Cell Proliferation on FCL

Fig 3

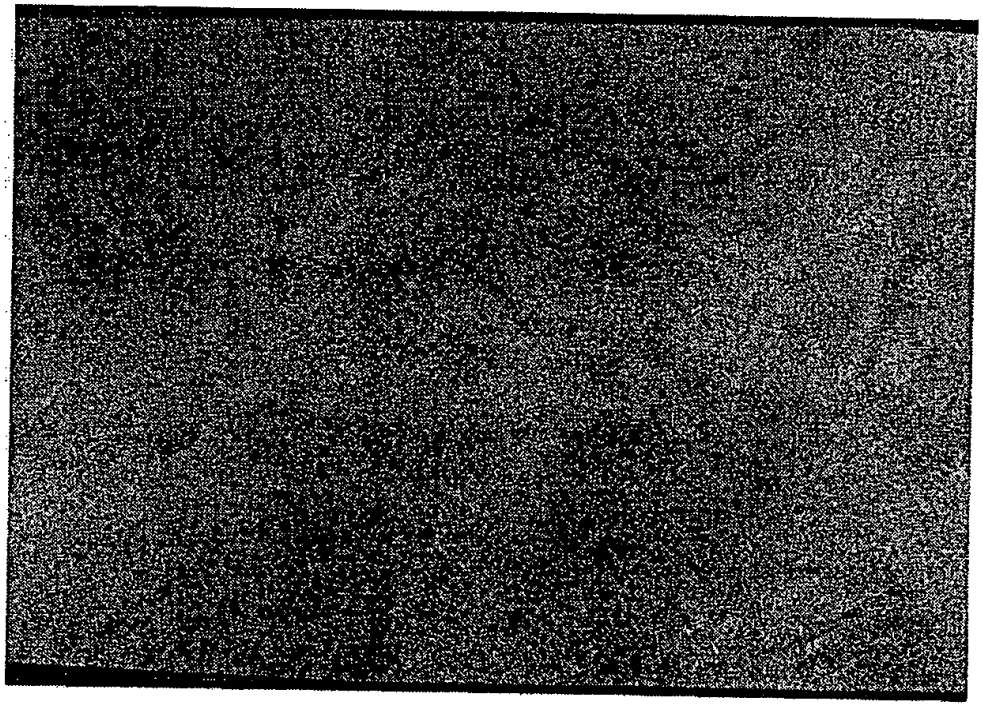


Fig 4

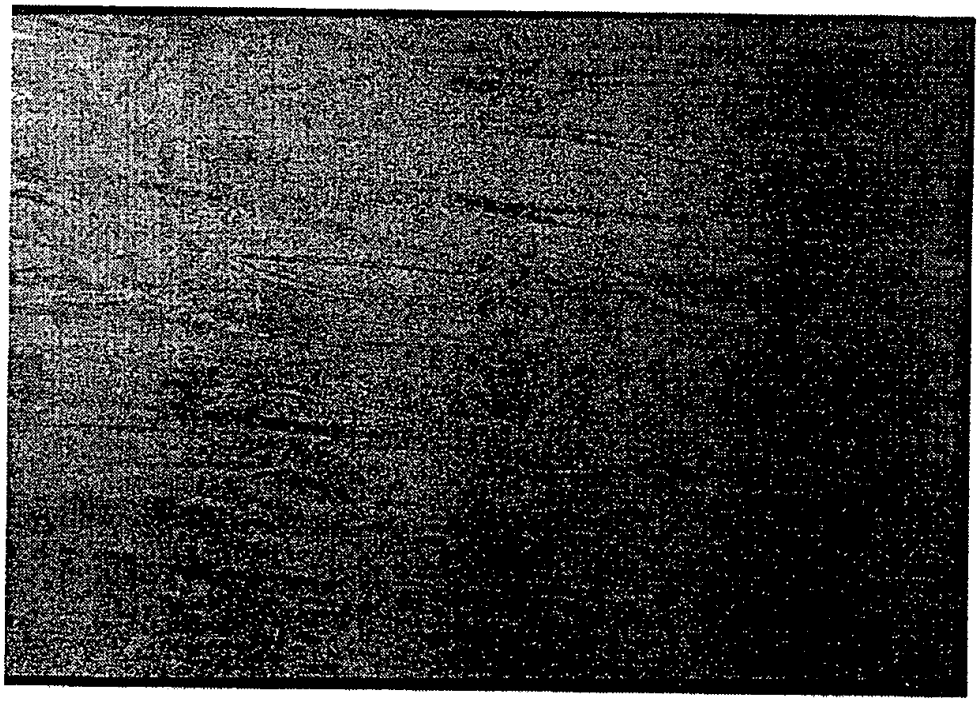
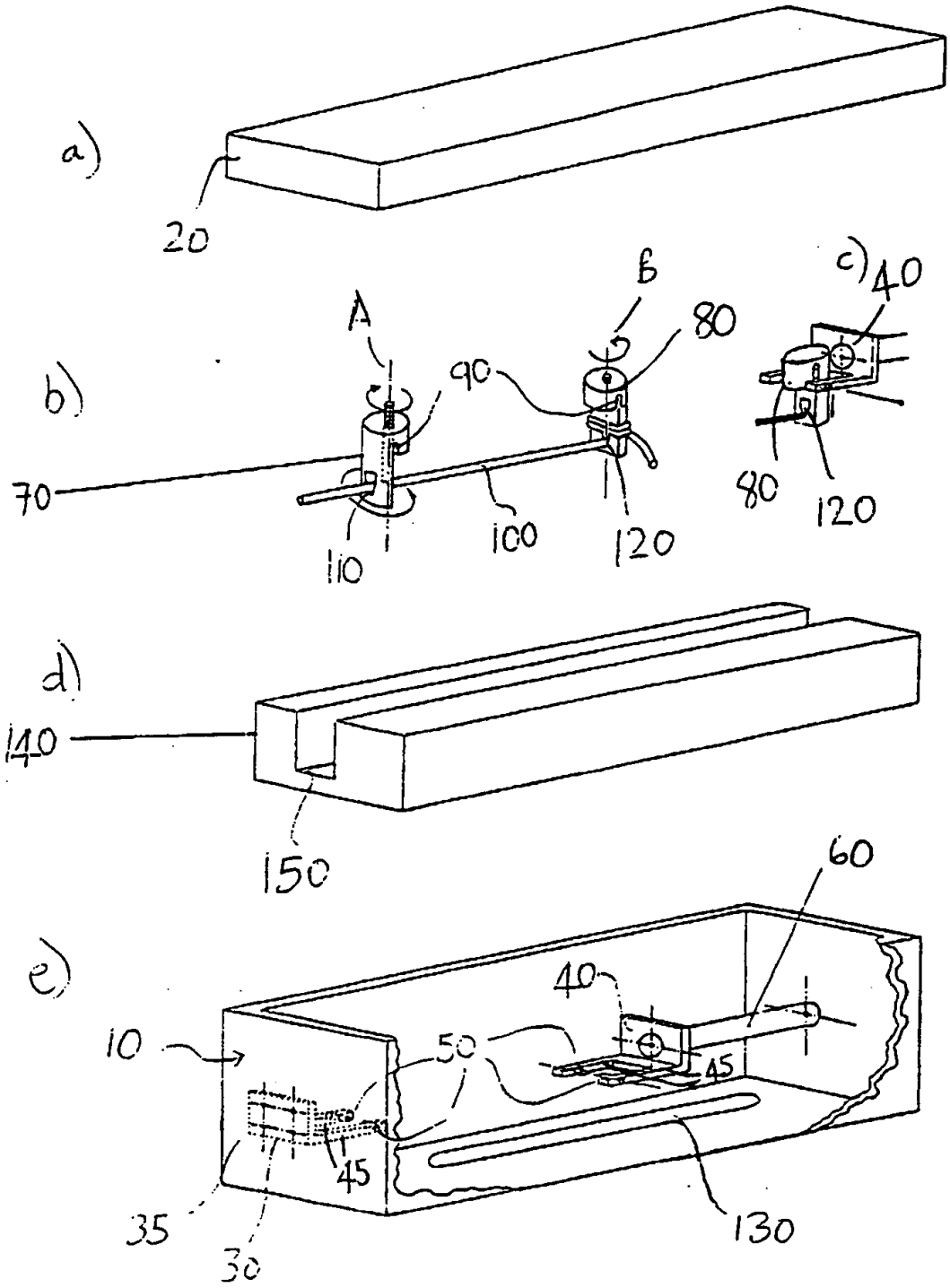


Fig 5


a)
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 94/01455

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L27/00 C12M3/04

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)
IPC 6 A61L C12M

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,90 12603 (VACANTI, JOSEPH, P. ET AL.) 1 November 1990 see page 6, line 9 - line 28 see page 8, line 13 - line 33 see page 11, line 23 - line 35 ---	1-15
X	WO,A,88 03785 (VACANTI JOSEPH, P. ET AL.) 2 June 1988 see page 22, line 14 - line 28; claims ---	1-3
X	WO,A,85 04185 (CAPLAN, ARNOLD, I.) 26 September 1985 see claims ---	1
Y	WO,A,92 15259 (COLORADO STATE UNIVERSITY RESEARCH FOUNDATION.) 17 September 1992 see claims --- -/--	1-23

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
12 October 1994	28. 10. 94
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Authorized officer ESPINOSA, M

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,93 07913 (CHILDREN'S MEDICAL CENTER CORPORATION.) 29 April 1993 see claims	1-23
P,Y	WO,A,93 19701 (BAXTER INTERNATIONAL INC.) 14 October 1993 see examples 1-3	1-23
A	WO,A,93 08850 (MASSACHUSETTS INSTITUTE OF TECHNOLOGY) 13 May 1993 see page 8, line 3 - line 26; claims	1

2

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB94/01455

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 19-23
because they relate to subject matter not required to be searched by this Authority, namely:
Remark: Although claims 19-23 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/GB 94/01455

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9012603	01-11-90	US-A-	5041138	20-08-91
		AU-B-	635025	11-03-93
		AU-A-	5556890	16-11-90
		CA-A-	2051663	18-10-90
		EP-A-	0469070	05-02-92
		JP-B-	6006155	26-01-94
		JP-T-	4505717	08-10-92
WO-A-8803785	02-06-88	EP-A-	0299010	18-01-89
		JP-T-	1501362	18-05-89
		US-A-	5041138	20-08-91
WO-A-8504185	26-09-85	US-A-	4609551	02-09-86
		AU-A-	4153985	11-10-85
		EP-A-	0175762	02-04-86
WO-A-9215259	17-09-92	US-A-	5192312	09-03-93
		AU-A-	1577792	06-10-92
		CA-A-	2105478	06-09-92
		EP-A-	0574527	22-12-93
WO-A-9307913	29-04-93	AU-A-	2900792	21-05-93
WO-A-9319701	14-10-93	NONE		
WO-A-9308850	13-05-93	CA-A-	2121040	13-05-93
		EP-A-	0610423	17-08-94

Form PCT/ISA/210 (patent family annex) (July 1992)

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(22) International Filing Date: 8 September 1995 (08.09.95)

(30) Priority Data:
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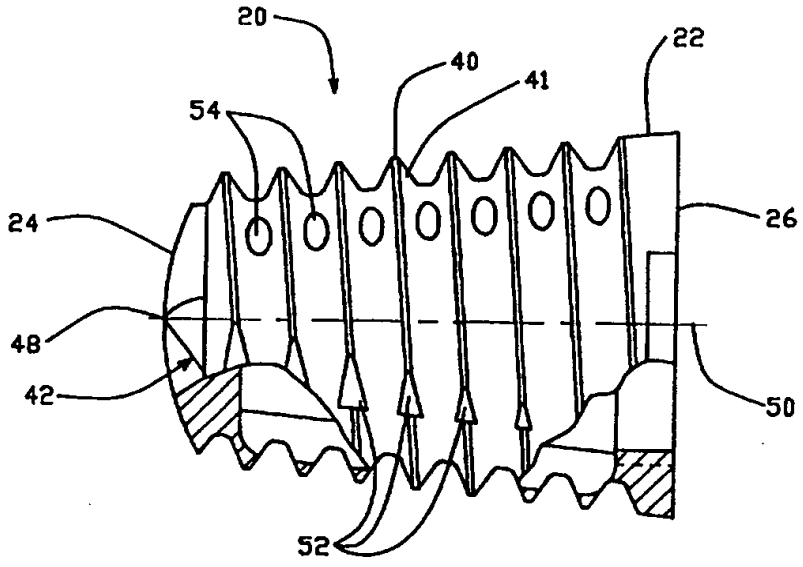
(74) Agent: MEYER, Sheldon, R.; Fliesler, Dubb, Meyer and Lovejoy, Suite 400, Four Embarcadero Center, San Francisco, CA 94111-4156 (US).

(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
With international search report.

(54) Title: CONICALLY-SHAPED ANTERIOR FUSION CAGE AND METHOD OF IMPLANTATION



(57) Abstract

A fusion cage (20) for anterior vertebral body fusion is conically shaped and includes a rounded distal end (24). A thread (40) is formed as part of the external conical surface of the fusion cage (20). The thread (40) defines one or more flutes (52) which enhance the ability of the fusion cage (20) to be self-tapping. Apertures (54, 206, 322) are defined through the fusion cage in order to provide for contact between the engaged vertebral bone structures and bone growth inducing substances packed within the fusion cage. The fusion cage (20) is introduced through an anterior procedure and maintains or increases the lordosis between adjacent vertebral bone structures.

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CONICALLY-SHAPED ANTERIOR FUSION CAGE AND METHOD OF IMPLANTATION

BACKGROUND

Field of the Invention

The present invention is directed to devices and methods for facilitating the fusing of bone structures and more particularly the fusing together of adjacent vertebral bodies or bone structures.

Background of the Invention

Technical literature and patent documents disclose a number of devices and methods for fusing bones together. One such device which has proven to be successful is disclosed in U.S. Patent 4,961,740, entitled "V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT," which patent has been assigned the present assignee and which patent is incorporated herein by reference. The referenced patent discloses a fusion cage which is preferably cylindrical and has a thread formed as part of the external cylindrical surface. The fusion cage defines an internal cavity and apertures through the wall of the cage which communicate the external cylindrical surface with the internal cavity. The apertures are formed in the valleys of the thread. Normally two such cages are used to stabilized and fuse together adjacent vertebral bodies or bone structures.

In practice, using a posterior approach, a patient's vertebral bone structures are exposed and degenerate disk material located between the vertebral bone structures is removed. A threaded tap is used to tap a complementary thread in the upper and lower vertebral bone structures preparatory to the insertion of the above fusion cage. Once such tapping has been accomplished, using an introduction tool, the fusion cage is screwed into the space between the adjacent vertebral bone structures. The thread bites into the bone of the upper and lower vertebral bone structures, stabilizing the bone structures, and preventing the fusion cage from working out of this position due to patient movement. Generally two

such fusion cages are applied using this technique. Once the two implants have been positioned, then bone growth inducing substances, such as bone chips, are packed into the internal cavity of the fusion cages. These bone growth inducing substances come into immediate contact with the bone from the vertebral bone structures which project into the internal cavity through the apertures. Such projection of bone is due to the fact that the apertures are formed in the valleys of the external thread of the fusion cage. Such immediate bone to bone contact between the vertebral bone structures and the bone pack within the fusion cages results in more rapid propagation of bone cells between the adjacent vertebral bone structures and thus a more rapid fusion of the adjacent vertebral bone structures.

Summary of the Invention

The present invention is directed to a fusion cage which has been designed to be implanted using an anterior approach to the vertebral bone structures.

In a first embodiment of the present invention, the fusion cage includes a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than the diameter of the proximal end. The distal end further is rounded with for example a bull nose in order to facilitate the insertion of the cage body relative to one or more bone structures. The conically-shaped cage body is particularly advantageous for use with an anterior approach to vertebral bone structure fusion. This is due to the fact that the normal lordosis of the vertebral bone structures defines a wedged-shape space for a vertebral disk between, for example, lumbar vertebrae. Accordingly, the conically-shaped body cage can be sized and selected in order to maintain or enlarge upon the normal lordosis.

In a second embodiment of the present invention, a fusion cage includes a conically-shaped cage body having a proximal end and a distal end with the distal end having a diameter which is smaller than the

diameter of the proximal end. The conically-shaped cage body has a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface. The flute acts as a relief much as the flute placed on self-tapping screws in order to facilitate the insertion of the fusion cage using a twisting motion between two vertebral bone structures.

In a third embodiment of the invention, a fusion cage includes a conically-shaped cage body having a proximal end and a distal end, the distal end having a diameter which is smaller than the diameter of the proximal end. The conically-shaped cage body has a conically-shaped outer surface and a thread formed as part of the conically-shaped outer surface. The thread allows the cage body to be inserted using an anterior approach. Due to the fact that the cage body is conically-shaped, the requirement for pretapping the vertebral bone structures to receive the fusion cage is eliminated with the fusion cage being self-tapping. Also the cage gradually spreads apart the vertebral bone structures as the cage is inserted in order to regain or enlarge the natural lordosis of the adjacent vertebral bone structures. As with other embodiments of the present invention, flutes can be provided through the thread in order to allow for enhanced thread tapping by the cage and for a smoother insertion of the fusion cage between the vertebral bone structures. Preferably two or three flutes would be formed spaced about the fusion cage in order that one flute would be engaging with or adjacent to an upper vertebral bone structures with another flute being engaging with or adjacent to a lower vertebral bone structure. Such a relationship maintains alignment of the fusion cage and prevent wandering as the fusion cage is introduced between the two vertebral bone structures. Without two or more flutes, wandering might occur due to the fact that the thread is only substantially engaged with the vertebral bone structures and not with the disk material between the vertebral bone structures, which disk material does not provide support to the thread.

In a further aspect of the invention, any of the above embodiments can be provided with a plurality of apertures through the fusion cage and an internal cavity with the apertures communicating between the internal cavity and the external surface of the fusion cage. Bone growth inducing substances, such as bone chips, can be packed into the internal cavity either before the fusion cage is inserted or after the fusion cage has reached a final insertion position. The bone chips come in contact with the vertebral bone structures through the apertures in order to facilitate fusion between the adjacent vertebral bone structures.

In another aspect of the invention which can be included in any of the above embodiments, the cage body can have a round or bull nose distal end with one or more flutes formed in the round or bull nose distal end in order to enhance the self-tapping nature of the fusion cage.

In yet another aspect of the invention, introduction tools allow the fusion cage to be accurately positioned between the vertebral bone structures.

The method of the present invention affords access to adjacent vertebral bone structures using an anterior approach and procedure. Such anterior approach and procedure can be preferably performed laparoscopically using an introduction set including a cannula. A laparoscopic procedure is minimally invasive as the abdomen muscle tissue can be spread using a set of cannula of increasing size and a small opening thereby developed through which a fusion cage can be inserted. Such a procedure is less traumatic to the tissue than an alternate anterior approach and procedure, also known as an anterior lumbar interbody fusion, where an incision, perhaps up to five inches long is made, through the abdomen muscle tissue. It is to be understood however that either anterior approach and procedure can be used with the fusion cage and fall within the scope of the invention.

After such access, using preferably a laparoscopic technique, degenerate disk material can be removed and, using a cannula and insertion tool, an appropriately shaped fusion cage can be screwed into

place between the vertebral bone structures in order to stabilize the vertebral bone structures and allow for fusion. Either preparatory to insertion of the fusion cage or after it has been inserted, bone chips or other bone growth inducing substances can be inserted into the fusion cage to promote bone to bone contact and subsequent fusion.

It is to be understood that although the above-embodiments have been described with respect to the fusion of adjacent vertebral bodies or bone structures, that the present invention can be used to fuse together a variety of bone structures, in addition to being fused to one bone structure and used as, for example, a base for an implant.

Other objects and advantages of the invention can be obtained through a review of the specification and the figures.

Brief Description of the Figure

Figure 1 is a partially sectional side view of an embodiment of the fusion cage of the invention.

Figure 2 depicts a left end (distal end) view of the fusion cage of Figure 1.

Figure 3 depicts a right end (proximal end) view of the fusion cage of Figure 1.

Figure 4 depicts a view through line 4-4 of the fusion cage of Figure 1.

Figure 5 depicts the fusion cage of Figure 1 in conjunction with an introduction tool.

Figure 6 depicts an alternative embodiment of the introduction tool.

Figures 7, 8, and 9 depict the progressive stages in the method of inserting the fusion cage between adjacent vertebral bone structures.

Figure 10 depicts a side view of an alternative embodiment of the fusion cage of the invention.

Figure 11 depicts the left end (distal end) view of the fusion cage of Figure 10.

Figure 12 depicts the right end (proximal end) view of the fusion cage of Figure 10.

Figure 13 depicts a side view of yet another embodiment of the fusion cage of the present invention.

Figure 14 depicts a left distal end (distal end) view of the fusion cage of the invention of Figure 13.

Figure 15 depicts a right end (proximal end) view of the fusion cage of the invention of Figure 13.

Figure 16 depicts a sectional view taken through line 16-16 of Figure 13.

Detailed Description of the Preferred Embodiment

With respect to the figures in a particular Figure 1, a side view of the preferred embodiment of the fusion cage 20 is depicted. Fusion cage 20 includes a fusion cage body 22 which in this preferred embodiment is provided in the shape of a cone. Fusion cage 20 includes a distal end 24 and a proximal end 26. The distal end 24 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 20 relative to one or more bone structures. The proximal end 26 includes an opening 28 which communicates with an internal cavity 30 defined by the fusion cage 20. The opening 28 in a preferred embodiment is threaded so that it can receive an end cap or plug 32 (Figure 5). End cap 32 is used to close off the proximal end 26 and retain bone growth inducing substances packed therein as described herein-below. As can be seen in Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, hex-shaped section 35 which can be used with a socket wrench to tightly position end cap 32 in opening 28. The proximal end 26 further define first and second peripheral indentations 36, 38. These peripheral indentations 36, 38 receive tangs from an insertion tool as described hereinbelow for facilitating the insertion of the fusion cage 20.

A thread 40 is defined as part of the outer cylindrical surface 41 of the body 22. It is to be understood that the thread can be replaced with a plurality of discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

The rounded distal end 24, and at least some of the turns of thread 40 defined flutes or relief grooves 42, 44, and 46. (Figures 1, 2.) In a preferred embodiment, flutes 42, 44, and 46 meet at a central point 48 of the distal end 24 on the longitudal axis 50 of the fusion cage 20. In other embodiments the flutes can be smaller and not extend all the way to the central point 48 on the longitude axis 50. Still in other embodiments, the flutes can be eliminated from the distal end 24 and such embodiments are still within the spirit and scope of the invention.

The flutes extend from the distal end 24 toward the proximal end 26 as shown in Figure 1 with respect to flute 42. These flutes are defined by the sections 52 which are removed from the thread. In a preferred embodiment, the flutes become narrower as they approach the proximal end 26 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

As can be seen in Figures 1, 4, a plurality of apertures 54 are provided through wall 56 of the fusion cage 20. In a preferred embodiment, these apertures 54 are formed by broaching grooves 58 in the internal surface 60 of the interna. cavity 30. The effect of such roaching is to remove material from the valleys between the turns of the thread 40, thus defining the aperture 54. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone

structures and the bone packed within the internal cavity 30 of the fusion cage 20.

The apertures 54 in a preferred embodiment increase in size from smaller apertures closer to the distal end 24 to a larger aperture closer to the proximal end 26. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 1, all the apertures are of the same size.

As can be seen in Figure 4, the apertures are clustered about a transverse axis 51, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 9) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral section of the fusion cage found along the other transverse axis 53 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

A preferred embodiment of the conically-shaped fusion cage 20 includes a fusion cage which is 23 millimeters in length having a distal end 24 with a diameter of 14 millimeters and a proximal end 26 with a diameter of 18 millimeters. The cage body is a right circular cone. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium material. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using an insertion tool 62 (Figure 5). Insertion tool 62 includes an inner handle 64 and an outer handle 66. The outer handle includes a bore 68 for receiving the inner handle 64. Handles 64, 66 include knobs 70, 72 respectively. The distal end of inner handle 64 defines a threaded shaft 74, having a reverse thread to facilitate easy removal, and the distal end of handle 66 define a cylindrical disk 76 which has first and second tangs 78, 80, projecting from the peripheral edge of the cylindrical disk 76. These tangs 78, 80

are designed to mate with the peripheral indentation 36, 38 of the fusion cage 20. For purposes of inserting the fusion cage between the vertebral bodies, the end cap 32 is inserted into the fusion cage 20 as shown in Figure 5. Then the threaded shaft 74 of the inner handle is introduced into the threaded bore 34 of the end cap 32. After this is accomplished, the outer handle 66 is slid over the inner handle 64 and the tangs 78, 80 are positioned into engagement with the indentations 36, 38. In this arrangement, the fusion cage 20 can be anteriorly inserted into the space between the vertebral body structure using the insertion tool 62.

An alternative embodiment of the insertion tool is shown in Figure 6. In this figure, insertion tool 82 includes a handle 84 with a knob 86. At the end of the insertion tool 82 distal from the knob 86 is a cylindrical disk 88 which has first and second tangs 90, 92, which have the same function as the above tangs 78, 80. Extending from the center of the cylindrical disk 88 along the centerline of the insertion tool 82 is a shaft 94 which has a ball detent 96. For use with insertion tool 82, the threaded bore 34 of the end cap 32 would be replaced with a bore having a lip which could engage with the ball detent 96 of the insertion tool 82.

The method for inserting the fusion cage 20 of Figure 1 using an anterior approach and procedure to the vertebral bodies is as follows. It is to be understood that although the focus of this discussion is on a laparoscopic procedure, that the anterior approach and procedure can also include a more invasive procedure where a long incision is made in the abdomen wall.

With an anterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. With the same or a larger diameter cannula, the

fusion cage 20 can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap 32 is affixed to the fusion cage 20. Insertion tool 62 is then secured to the fusion cage 20 and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 7, 8, 9, by upper body 98 and lower body 100. In the initial position as shown in Figure 7, the fusion cage 20 is adjacent to the anterior sections 102, 104 of the vertebral bodies 98, 100. As the introduction tool is turned, the thread 40 of the fusion cage 20 bites into the vertebral bodies 98, 100. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 8 to the final resting position shown in Figure 9, where the distal end 24 is moved adjacent to the posterior sections 106, 108 of the vertebral bone structures 98, 100. As this occurs, the fusion cage 20 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies and causing the vertebral bodies to pivot about the posterior sections 106, 108, with such posterior sections acting like a hinge. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distractions also occur at the posterior sections where the hinged effect is exhibited. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

Once the fusion cage 20 is appropriately positioned, the handle 64 of the insertion tool 62 is unscrewed from the cap 32 and the insertion tool 62 is pulled away from the fusion cage.

An alternative embodiment of a fusion cage 200 is shown in Figures 10, 11, and 12. Fusion cage 200 includes a distal end 202 and an a proximal end 204. Fusion cage 200 includes an internal cavity 206. End caps not shown can be used to close the ports 208, 210 of distal and

proximal ends 202, 204. A plurality of threads 212 is defined on the external conical surface 214 of the fusion cage 200. Defined by the thread 212 are first and second flutes 216, 218, which in this embodiment extend from the distal end 202 to the proximal end 204. These flutes provide thread relief allowing the fusion cage 200 to be self-tapping.

The fusion cage 200 includes a plurality of elongated apertures 220 which are formed through the side walls of a fusion cage 200. The elongated apertures 202 are formed in such a way that the internal conical surface 214 is spaced away from the internal surface 224 of the internal cavity 206 by the thickness of the sidewall 222.

A further embodiment of the invention is shown in Figures 13, 14, 15 and 16. In Figure 16 the fusion cage 300 has distal and proximal ends 302 and 304 respectively. The fusion cage 300 defines an internal cavity 306, and ports 308 and 310 defined through the distal and proximal ends 302 and 304 respectfully. A thread 312 is defined as part of the external conical surface 314 of the fusion cage 200. First, second and third flutes 316, 318, and 320, are defined in the thread 312 from the distal end 302 to the proximal end 304. These flutes give the fusion cage 300 an enhanced self-tapping advantage. These flutes are equally spaced about the fusion cage 300 in a manner similar to the flutes of the fusion cage embodiment 20 in Figure 1.

A plurality of aperture 322 is provided through the external conical surface 314 of the fusion cage 300 and through the side wall 324 opening into the internal cavity 306. Accordingly, at the location of the aperture 322 the external surface 314 is held away from the internal surface 326 by the thickness of the side wall 324.

Industrial Applicability

The present invention affords the advantages of a fusion cage which can be introduced through an anterior approach in order to maintain or increase lordosis between adjacent vertebral bodies. The fusion cage has the advantage of being conically-shaped and self-tapping through the

use of external flutes. The flutes additionally assist in keeping the fusion cage aligned and centered as the cage is being inserted between the vertebral bone structures.

Other advantages, aspects, and objects of the invention can be obtained through a review of the claims and the appended figures.

It is to be understood that additional embodiments of the invention can be constructed and fall within the spirit and scope of the claims.

We claim:

1. A fusion cage for promoting fusion with one or more bone structures comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

2. The fusion cage of claim 1 including:

said conically-shaped cage body having a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface.

3. The fusion cage of claim 2 including:

said conically-shaped cage body wherein said flute extends from the distal end toward the proximal end.

4. The fusion cage of claim 2 including:

at least three flutes formed in the conically-shaped outer surface.

5. The fusion cage of claim 4 including:

said three flutes are equally spaced about said distal end.

6. The fusion cage of claim 2 including:

said flute being additionally formed in the rounded distal end.

7. The fusion cage of claim 4 including:

said three flutes being additionally formed in the rounded distal end.

8. The fusion cage of claim 1 including:

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface.

9. The fusion cage of claim 8 including:

at least one flute formed in the thread.

10. The fusion cage of claim 8 including:

said conically-shaped cage body having a conically-shaped outer surface and an internal cavity; and

a plurality of apertures formed through the conically-shaped body which communicate said conically-shaped outer surface with said internal cavity.

11. The fusion cage of claim 1 including:

said conically-shaped cage body is a right circular cone.

12. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, said fusion cage comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace larger than the height of the posterior interspace; and

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface in

order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

13. The fusion cage of claim 12 including:

said distal end being rounded in order to facilitate insertion of the fusion cage between the vertebral bone structures, from the anterior interspace toward the posterior interspace.

14. The fusion cage of claim 12 including:

at least one flute formed in the thread.

15. The fusion cage of claim 14 including:

said flute extends from the distal end toward the proximal end.

16. The fusion cage of claim 12 including:

at least three flutes formed in the thread.

17. The fusion cage of claim 16 including:

said three flutes are equally spaced about said distal end.

18. The fusion cage of clam 13 including:

at least one flute being formed in the rounded distal end.

19. The fusion cage of claim 18 including:

three flutes being formed in the rounded distal end.

20. The fusion cage of claim 12 including:

said conically-shaped cage body having an internal cavity; and

a plurality of apertures formed through the conically-shaped body which communicate said conically-shaped outer surface with said internal cavity.

21. The fusion cage of claim 12 including:

said conically-shaped cage body is a right circular cone.

22. A fusion cage for promoting fusion with one or more bone structures comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said conically-shaped cage body having a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface.

23. The fusion cage of claim 22 including:

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

24. The fusion cage of claim 22 including:

said conically-shaped cage body wherein said flute extends from the distal end toward the proximal end.

25. The fusion cage of claim 22 including:

at least three flutes formed in the conically-shaped outer surface.

26. The fusion cage of claim 22 including:

three flutes equally spaced about said distal end.

27. The fusion cage of clam 23 including:

a flute formed in the rounded distal end.

28. The fusion cage of claim 25 including:

said distal end being rounded in order to facilitate insertion relative to the one or more bone structures;

and

said three flutes being additionally formed in the rounded distal end.

29. The fusion cage of claim 22 including:

a thread formed into said conically-shaped outer surface.

30. The fusion cage of claim 29 including:

said at least one flute formed in the thread.

31. The fusion cage of claim 22 including:

said conically-shaped cage body an internal cavity; and

a plurality of apertures formed through the conically-shaped body which communicate said conically-shaped outer surface with said internal cavity.

32. An anterior fusion cage for promoting fusion between vertebral bone structures comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, said distal end for initial insertion between vertebral bone structures from an anterior approach;

said conically-shaped cage body having a conically-shaped outer surface and a thread with a plurality of turns formed into said conically-shaped outer surface, and a flute formed in at least one said turns;

said conically-shaped cage body having an interior cavity; and

a plurality of apertures formed through the conically-shaped body which communicate said conically-shaped outer surface with said internal cavity.

33. The fusion cage of claim 32 including:

said distal end being rounded in order to facilitate insertion between the vertebral bone structures from an anterior location towards a posterior location.

34. The fusion cage of claim 32 including:

said conically-shaped cage body wherein said flute extends from the distal end toward the proximal end.

35. The fusion cage of claim 32 including:

at least three flutes formed in at least one of the turns.

36. The fusion cage of claim 32 including:

three flutes equally spaced about said distal end.

37. The fusion cage of clam 33 including:

said flute being additionally formed in the rounded distal end.

38. The fusion cage of claim 33 including:

three flutes are formed in the rounded distal end.

39. A fusion cage for promoting fusion with one or more bone structures comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface.

40. The fusion cage of claim 39 including:

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

41. The fusion cage of claim 39 including:

at least one flute formed in the thread.

42. The fusion cage of claim 41 including:

said flute extends from the distal end toward the proximal end.

43. The fusion cage of claim 39 including:
at least three flutes formed in the thread.

44. The fusion cage of claim 43 including:
said three flutes are equally spaced about said distal end.

45. The fusion cage of clam 40 including:
at least one flute being formed in the rounded distal end.

46. The fusion cage of claim 40 including:
three flutes being formed in the rounded distal end.

47. A fusion cage for promoting fusion with one or more bone structures comprising:
a cage body having a proximal end and a distal end; and
said cage body having an outer surface and at least one flute formed in the outer surface in order to facilitate the insertion of the fusion cage in the one or more bone structures.

48. The fusion cage of claim 47 including:
said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

49. The fusion cage of claim 47 including:
said flute extends from the distal end toward the proximal end.

50. The fusion cage of claim 47 including:
at least three flutes formed in the outer surface.

51. The fusion cage of claim 50 including:

three flutes are equally spaced about said distal end.

52. The fusion cage of clam 48 including:

said flute being additionally formed in the rounded distal end.

53. The fusion cage of claim 47 including:

said cage body having a thread formed into said outer surface.

54. The fusion cage of claim 53 including:

said flute formed in the thread.

55. The fusion cage of claim 1 in combination with an insertion tool, said fusion cage and said insertion tool including:

said proximal end having a opening which communicates with an internal cavity;

an end cap which can fit into said opening in order to close off said internal cavity;

said proximal end including at least one insertion tool receiving indentation;

said end cap including an insertion tool receiving threaded bore; and

said insertion tool having a tang for being received in said indentation and a threaded shaft for being received in said threaded bore. said insertion tool for being engaged with said fusion cage for inserting said fusion cage relative to the one or more bone structures.

56. The fusion cage of claim 10 including:

said apertures are elongated in order to increase the amount of communication between the internal cavity and the one or more bone structures.

57. A method for fusing together two spaced apart vertebral bone structures which have posterior sections and anterior sections and

with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, with the height of the anterior interspace being about the same as or larger than the height of the posterior interspace, the method comprising the steps of:

accessing the vertebral bone structures from the anterior sections;

selecting a fusion cage with a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace relative to the height of the posterior interspace, and said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface;

position the fusion cage body adjacent to the anterior sections of the vertebral bone structures;

causing said fusion cage to be inserted between the vertebral bone structures by moving the fusion cage from (1) a position with the distal end adjacent to the anterior section of the vertebral bone structures to (2) a position with the distal end adjacent to the posterior sections and the proximal end adjacent to the anterior sections of said vertebral body structures.

58. The method of claim 57 including:

said causing step includes turning the fusion cage so that the thread formed as part of the outer surfaces and engage the vertebral bone structures in order to hold the fusion cage in place and stabilize the vertebral bone structures.

59. The method of claim 57 including:

said causing step includes turning the fusion cage so that the thread self-taps a complementary thread in the vertebral bone structures.

60. A method of achieving a desired lordosis of the spinal column of a patient including the steps of:

accessing the vertebral bone structures from the anterior;

positioning a conically-shaped fusion cage adjacent to anterior sections of the vertebral bone structures using an anterior procedure;

urging the conically-shaped fusion cage into the disk space between adjacent vertebral bone structures in a direction from the anterior to the posterior of the vertebral bone structures in order to restore a desired lordosis.

61. The method of claim 60 including the step of:

preparatory to the positioning step, the step selecting a conically shaped fusion cage of an appropriate size in order to achieve the desired lordosis.

62. The method of claim 60 including the step of:

preparatory to the positioning step, the step of selecting a conically-shaped fusion cage of an appropriate size in order to stretch the anterior longitudinal ligaments in order to stabilize the vertebral bone structures about the fusion cage.

63. The fusion cage of claim 10 including:

said apertures increase in size from the distal end toward the proximal end.

64. A fusion cage (1) for promoting fusion between two spaced apart vertebral bone structures which have posterior sections and anterior sections with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior positions, and (2)

for achieving a desired lordosis as the fusion cage is implanted by urging the fusion cage from the anterior sections toward the posterior sections using an anterior approach, the fusion cage comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures as the conically-shaped cage body is urged using an anterior approach from an initial position where the distal end is positioned adjacent to the anterior sections to a final position where the proximal end is positioned in the anterior interspace and the distal end is positioned in the posterior innerspace.

65. The fusion cage of claim 64 including:

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer space in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

66. The fusion cage of claim 65 including:

said distal end of said cage body is rounded in order to facilitate insertion between the vertebral body structures.

67. The method of claim 57 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

68. The method of claim 57 including:

said causing step distracting the anterior sections more than the posterior sections, and for causing the vertebral bone structures to pivot about the posterior sections.

69. The method of claim 60 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

70. The method of claim 60 including:

said urging step for distracting the anterior sections more than the posterior sections of the vertebral bone structures, and for causing the vertebral bone structures to pivot about the posterior sections.

71. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

72. The fusion cage of claim 71 including:

said cage body having an outer surface and at least one flute formed in the outer surface.

73. The fusion cage of claim 72 including:

said cage body wherein said flute extends from the distal end toward the proximal end.

74. The fusion cage of claim 72 including:

at least three flutes formed in the outer surface.

75. The fusion cage of claim 71 including:

at least one flute formed in the rounded distal end.

76. The fusion cage of claim 71 including:

three flutes formed in the rounded distal end.

77. The fusion cage of claim 71 including:

said cage body having an outer surface and a thread formed into said outer surface.

78. The fusion cage of claim 77 including:

at least one flute formed in the thread.

79. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, said fusion cage comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace larger than the height of the posterior interspace; and

said cage body having an outer surface and a thread formed into said outer surface in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

80. The fusion cage of claim 79 including:

said distal end being rounded in order to facilitate insertion of the fusion cage between the vertebral bone structures, from the anterior interspace toward the posterior interspace.

81. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said cage body having an outer surface and at least one flute formed in the outer surface.

82. The fusion cage of claim 81 including:

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

83. A fusion cage for promoting fusion between vertebral bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, said distal end for initial insertion between vertebral bone structures from an anterior approach;

said cage body having an outer surface and a thread with a plurality of turns formed into said outer surface,;

said cage body having an interior cavity; and

a plurality of apertures formed through the body which communicate said outer surface with said internal cavity.

84. The fusion cage of claim 83 wherein:

a flute is formed in at least one of said turns.

85. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said cage body having an outer surface and a thread formed into said outer surface.

86. The fusion cage of claim 85 including:

said cage body being conically-shaped.

87. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end; and

said cage body having at least one flute formed in the distal end in order to facilitate the insertion of the fusion cage in the one or more bone structures.

88. The fusion cage of claim 87 including:

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

89. The fusion cage of claim 87 including:

said flute extends from the distal end toward the proximal end.

90. A method for fusing together two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, with the height of the anterior interspace being about the same as or larger than the height of the posterior interspace, the method comprising the steps of:

accessing the vertebral bone structures from the anterior sections;

selecting a fusion cage with a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior

interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace relative to the height of the posterior interspace, and said conically-shaped cage body having an outer surface and a thread formed into said outer surface;

position the fusion cage body adjacent to the anterior sections of the vertebral bone structures;

causing said fusion cage to be inserted between the vertebral bone structures by moving the fusion cage from (1) a position with the distal end adjacent to the anterior section of the vertebral bone structures to (2) a position with the distal end adjacent to the posterior sections and the proximal end adjacent to the anterior sections of said vertebral body structures.

91. A fusion cage (1) for promoting fusion between two spaced apart vertebral bone structures which have posterior sections and anterior sections with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior positions, and (2) for achieving a desired lordosis as the fusion cage is implanted by urging the fusion cage from the anterior sections toward the posterior sections using an anterior approach, the fusion cage comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures as the conically-shaped cage body is urged using an anterior approach from an initial position where the distal end is positioned adjacent to the anterior sections to a final position where the proximal end is positioned in the anterior interspace and the distal end is positioned in the posterior innerspace.

92. The fusion cage of claim 91 including:

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer space in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

93. The fusion cage of claim 91 including:

said posterior end of said cage body is rounded in order to facilitate insertion between the vertebral body structures.

94. The method of claim 90 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

95. The method of claim 90 including:

said causing step distracting the anterior sections more than the posterior sections, and for causing the vertebral bone structures to pivot about the posterior sections.

96. The method of claim 90 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

97. The method of claim 90 including:

said causing step for distracting the anterior sections more than the posterior sections of the vertebral bone structures, and for causing the vertebral bone structures to pivot about the posterior sections.

98. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, said fusion cage comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace larger than the height of the posterior interspace.

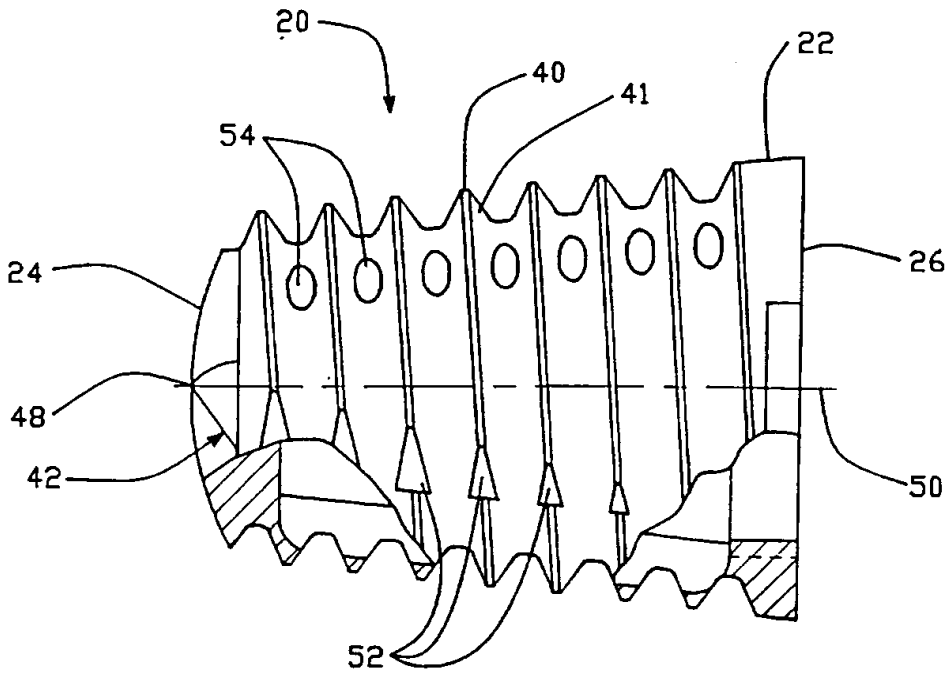

FIG.—1

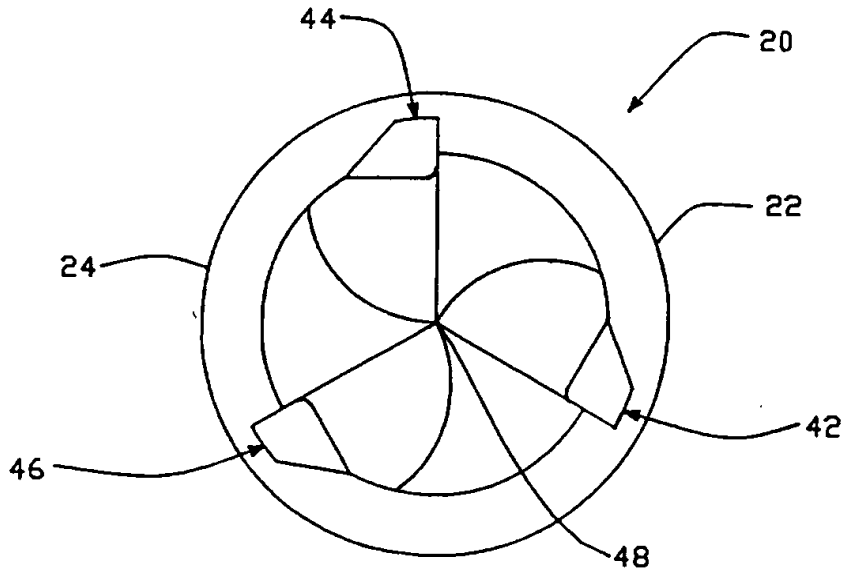

FIG.—2

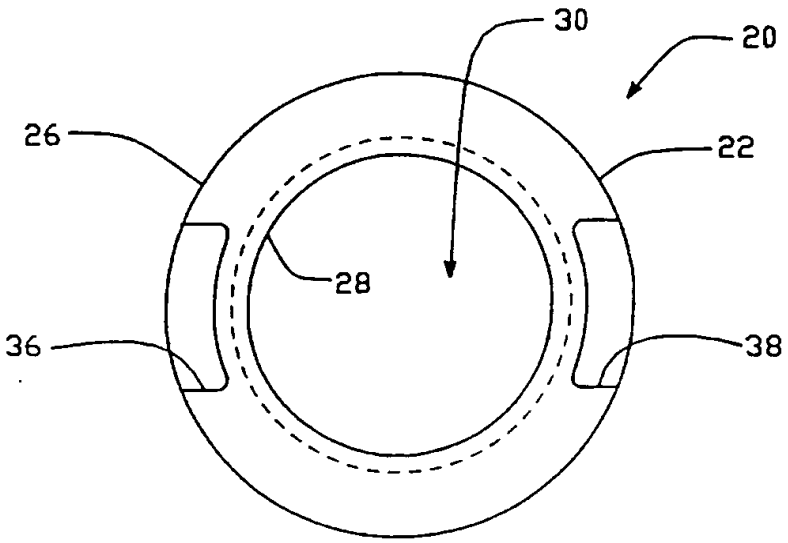

FIG.—3

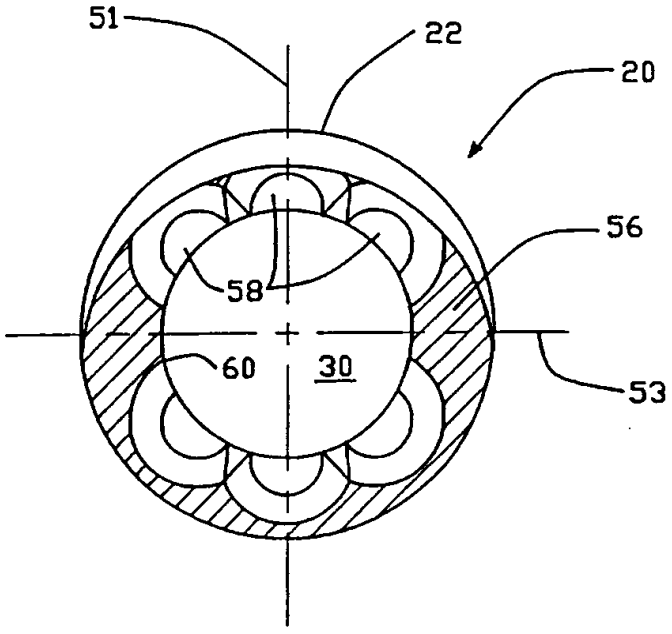

FIG.—4

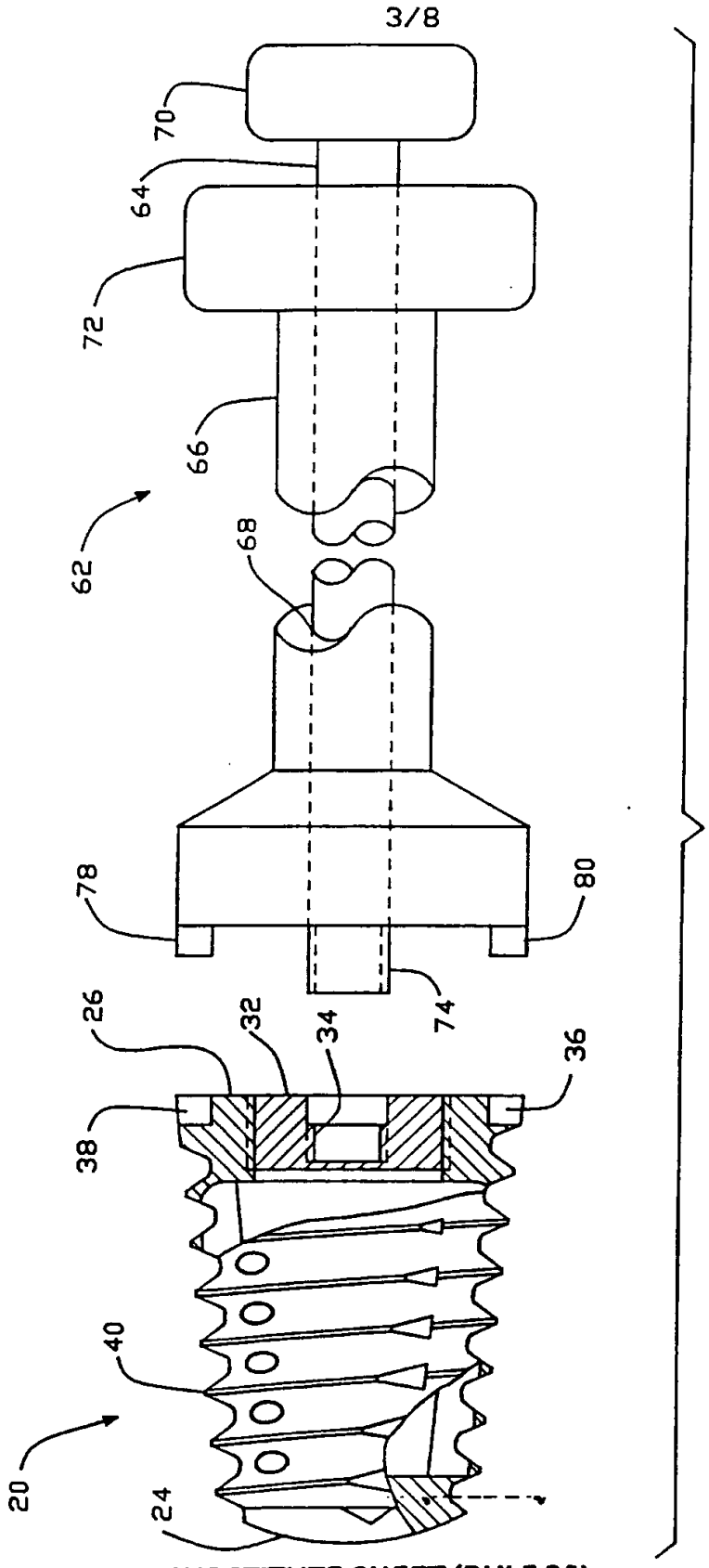

FIG.—5

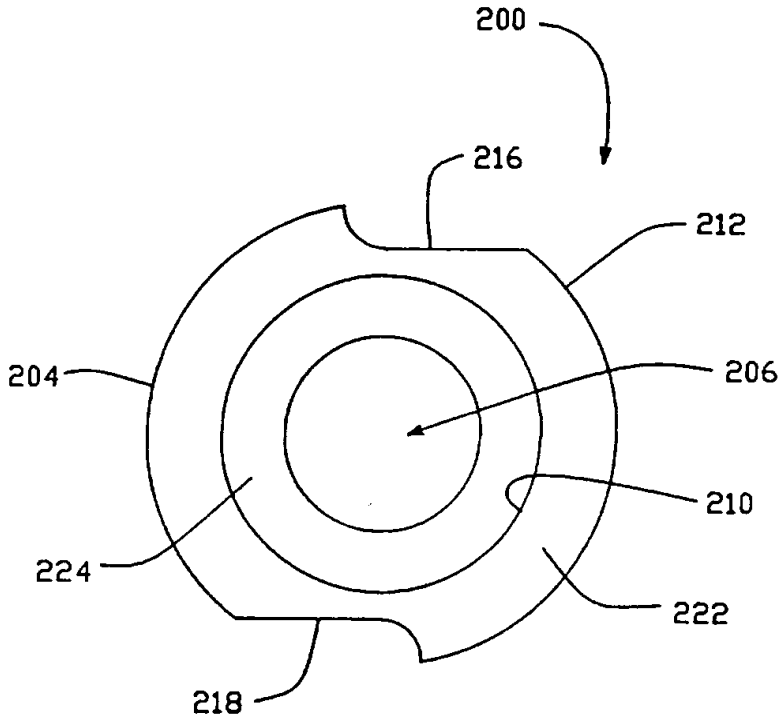

FIG.-12

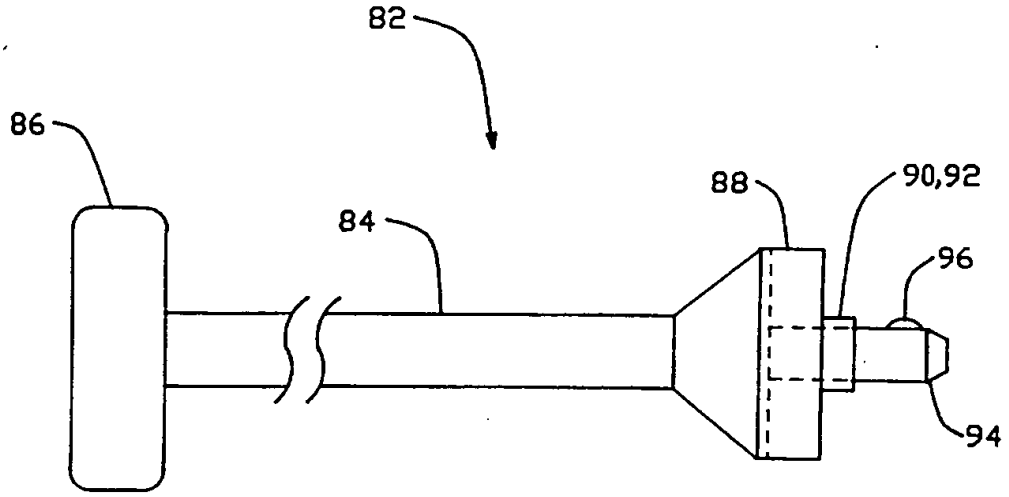

FIG.-6

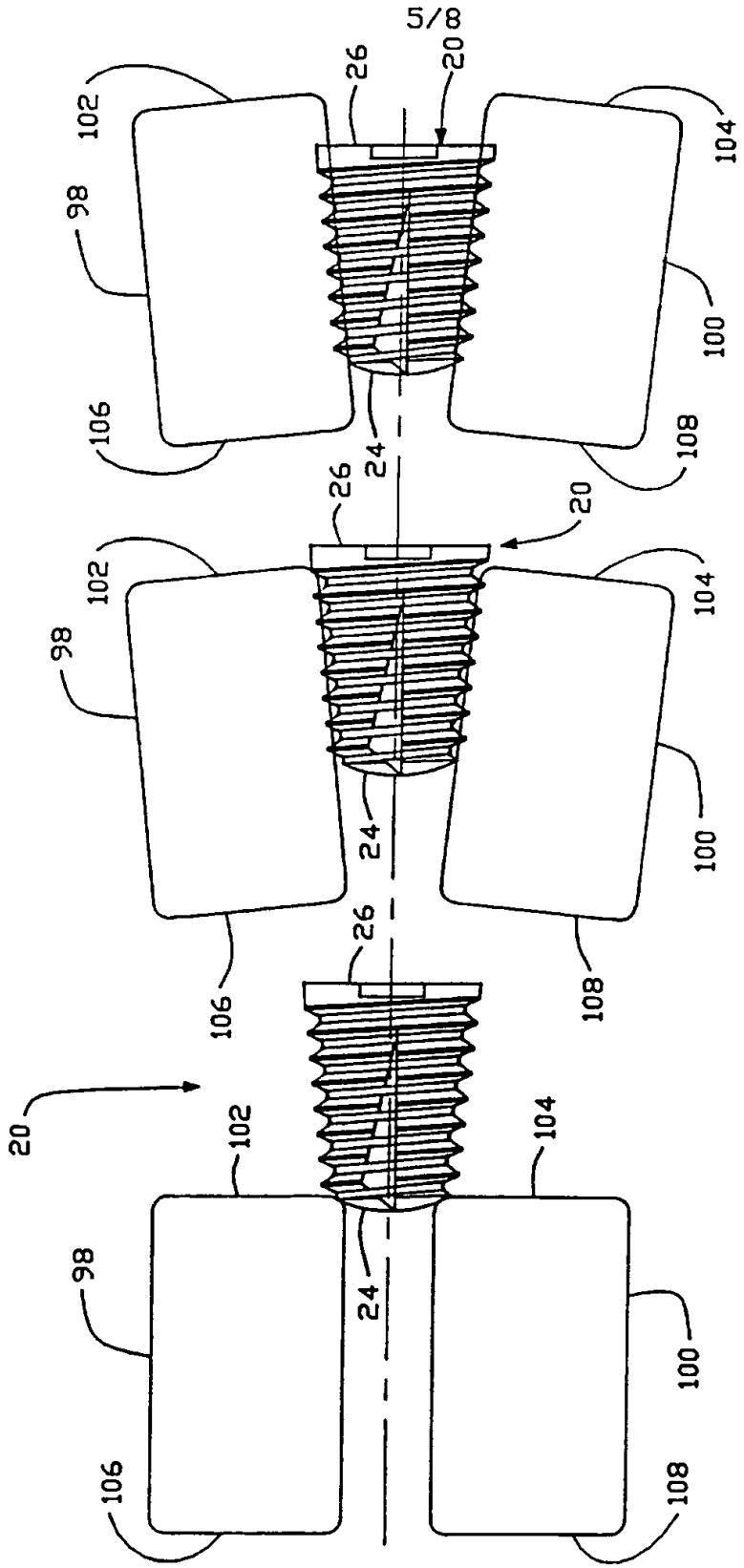
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FIG.—9
FIG.—8
FIG.—7

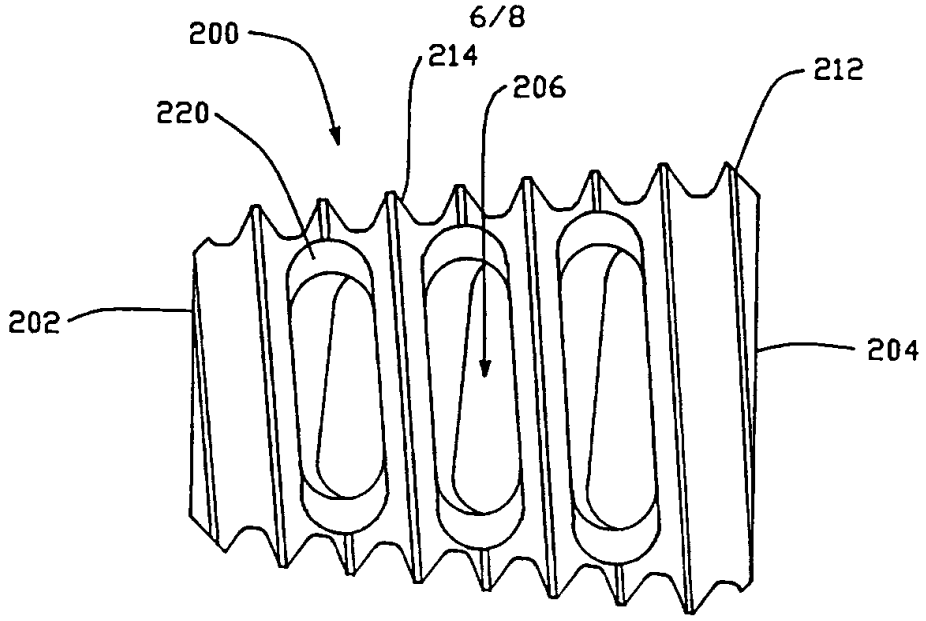

FIG.—10

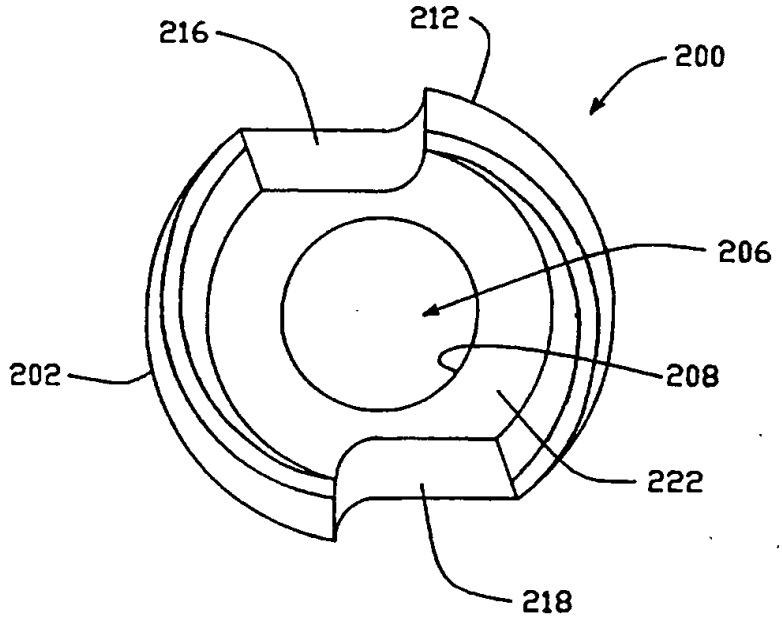

FIG.—11

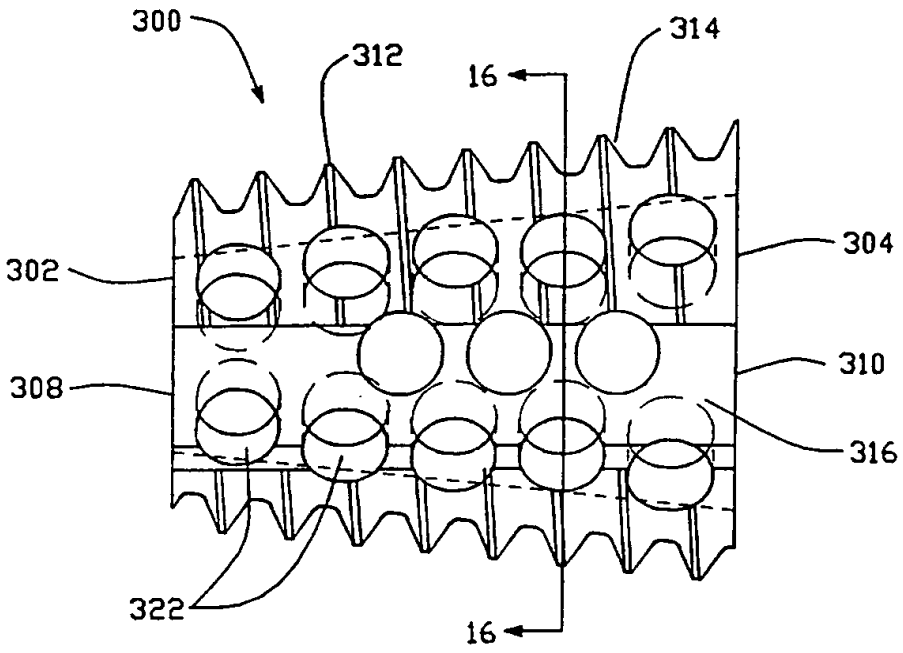

FIG.—13

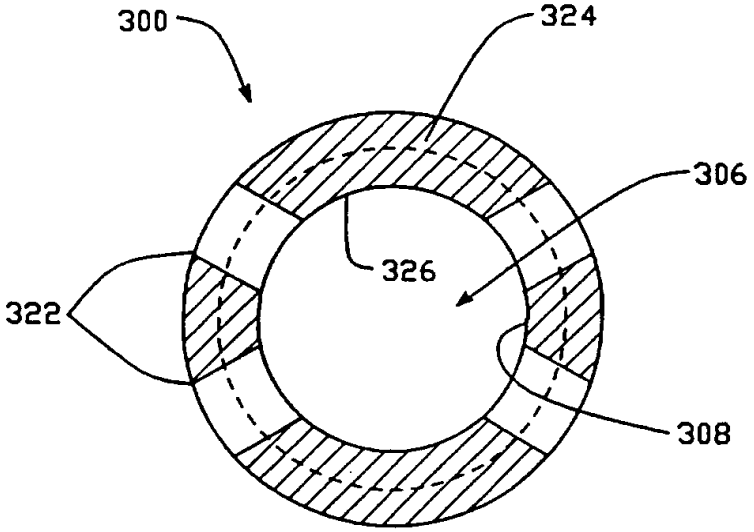

FIG.—16

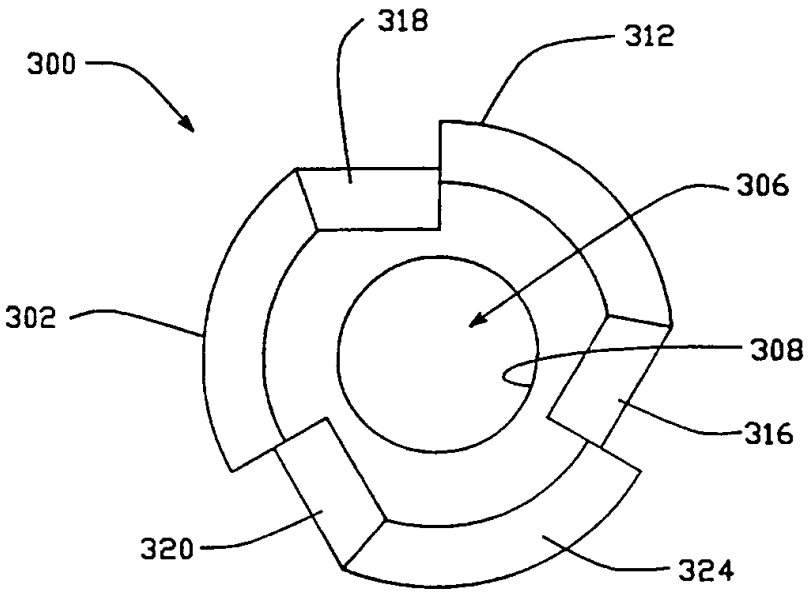
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FIG.—14

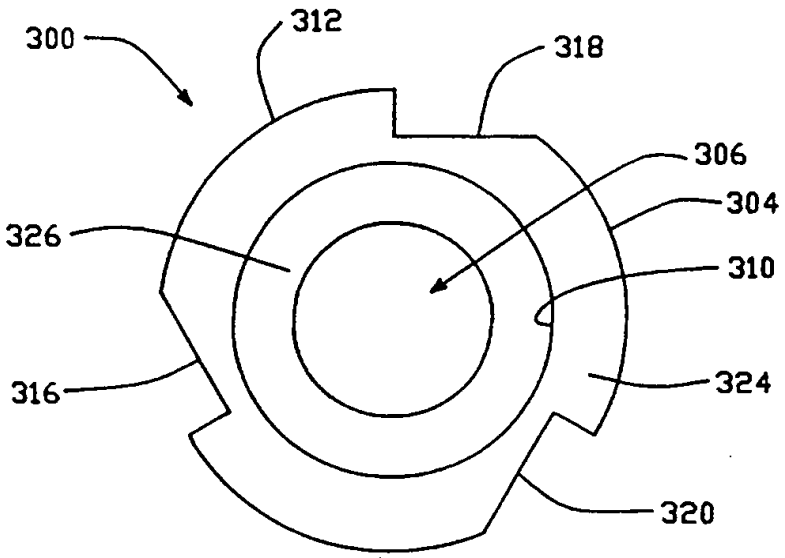
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FIG.—15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/11281

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/70
US CL :606/61

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)

U.S. : 606/61, 65, 66, 72, 73, 76, 90, 104; 623/17, 16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,950,270 (BOWMAN ET AL.) 21 August 1990, see Fig. 1.	1-3, 8, 9, 11-15, 18, 21-25, 27-30, 39-42, 45, 47-49, 52-54, 64-66, 71-73, 75, 77-82, 85-89, 91-93, 98 --- 4-7, 10, 16, 17, 19, 20, 26, 31-38, 43, 44, 46, 50, 51, 74, 76, 83, 84

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

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Date of the actual completion of the international search	Date of mailing of the international search report
16 OCTOBER 1995	05 DEC 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GUY TUCKER Telephone No. (703) 308-3271

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/11281

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,537,185 (STEDNITZ) 27 August 1985, see Fig. 2.	4-7, 16, 17 19, 26, 35, 36, 38, 43, 44, 46, 50, 51, 74, 76
Y	US, A, 4,484,570 (SUTTER ET AL.) 27 November 1984, see Fig. 3.	10, 20, 31-38, 83, 84
X	US, A, 4,349,921 (KUNTZ) 21 September 1982, see Fig. 4.	60
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Y		61, 62, 69

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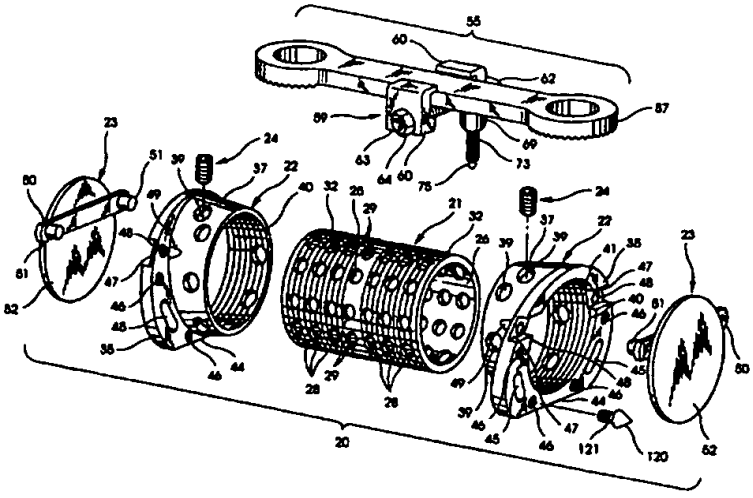
(81) Designated States: AU, CA, CN, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: ADJUSTABLE VERTEBRAL BODY REPLACEMENT



(57) Abstract

An adjustable vertebral boby replacement implant assembly (20) includes a thin-walled cylindrical body (21) configured to span over most of the length between intact vertebrae. The cylindrical body (21) defines a hollow interior (26) with a plurality of bone-ingrowth apertures (28, 29) communicating with the interior. The assembly further includes endplates (22) configured to contact the adjacent vertebra and to engage the cylindrical body therebetween. The cylindrical body and the endplates include mating threads (32, 40, 41) to permit adjustment of the overall height of the implant. In one embodiment is a set screw (24) for locking the cylindrical body to the endplates. In another embodiment, a crimping channel (100) and notch (101) are defined in the endplates to be crimped onto the cylindrical body. A means for connecting the replacement implant to a longitudinal member is provided, which is one embodiment contemplates a clamp and screw assembly (55) and another embodiment includes an arm (94) projecting from the endplates with an opening (95) to receive a longitudinal member (105) therethrough.

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ADJUSTABLE VERTEBRAL BODY REPLACEMENT

BACKGROUND OF THE INVENTION

The present invention concerns an implant for replacement of one or more vertebral bodies and their adjacent disks. More particularly, the vertebral body replacement is particularly well suited for implantation through an anterior approach.

The treatment of injuries to the spine has advanced significantly since the days of the first recorded surgical procedure for spinal cord injury in the late 7th Century. The techniques, instrumentation and implants have changed over the years and have been better adapted to address many forms of spinal injury and deformities that can occur due to trauma, disease or congenital effects. One type of spinal deformity, a kyphosis, involves a prolapse of the vertebral column towards the front of the body, often caused by the destruction of the vertebral body itself. This destruction can be in the form of a trauma type injury, such as a fracture or burst injury to the vertebral body, or a non-traumatic deformity caused by a tumor or a degeneration of the bone in the vertebral body.

Treatment of a kyphosis in the thoracic or lumbar spine appears now to be best achieved through an anterior approach, particularly in order to avoid some of the more severe complications associated with support or replacement of a damaged vertebral body. In most treatments of a kyphosis, a high degree of anterior reconstruction of the spine is required, most frequently involving total removal of the damaged vertebral body. In a typical anterior approach, partial or total ablation of the vertebral body and the two

adjacent vertebral disks is carried out. The remaining space is then distracted to manipulate the spine to its correct orientation.

In many cases, the space is filled with a polymerizable paste or a bone graft which is frequently modeled to give it the shape of the destroyed vertebral body. Frequently, autologous bone, such as that extracted from the ilium, is used to bridge the space. The polymerizable paste can include a PMMA bone cement. Once the cavity remaining after the removal of the original vertebral body has been filled, an osteosynthesis instrument is positioned between the adjacent unaffected vertebrae to prevent any relative movement therebetween. The osteosynthesis device is essential to restabilize the vertebral column, to support the loads to which the thoracic or lumbar spine is exposed, and to enhance the likelihood and quickness of union of the bone graft material with the adjacent vertebral bodies. Once the bone graft and material is sufficiently solid, the osteosynthesis device normally is not subjected to any further mechanical stresses.

A known osteosynthesis device is depicted in U.S. Patent No. 5,108,395 to Jean-Marie Laurain, the disclosure of which is incorporated herein by reference. This system is illustrated in FIGS. 1 and 2 of the present application. Referring first to FIG. 1, it can be seen that a damaged vertebra V_3 includes a destroyed vertebral body C_3. An interior implant 1 is provided for bridging between the two intact vertebrae V_2 and V_4 to permit removal of the damaged vertebra V_3 and its adjacent disks D_2 and D_3. The anterior implant 1 includes a pair of clamps 2 which are engaged to the intact vertebral bodies by way of a number of spikes 3. In addition, the clamps 2 are maintained in position by bone screws 5 extending through screw holes 11, lateral lugs 8 of the clamps. The implant 1 also includes a plate 6 which is configured to span between the intact

vertebrae and is strong enough to support the loads generated in the spinal column at that location.

Each clamp 2 includes a threaded post 12 projecting therefrom which is configured to pass through a corresponding opening 14 at each end of the plate 6. A nut 7 is adapted to engage the threaded post 12 to fix the plate 6 to each of the clamps 2. The surface of the clamps 2 include serrations 15 which mate with corresponding serrations 16 at each end of the plate 6, thereby permitting differing angular orientations of the plate relative to each of the clamps. An opening 9 is provided through the threaded post 12 of the clamps to receive another bone screw 5 for firm fixation of the clamp with the healthy vertebral bodies V_2 and V_4.

An important feature of the system described in the '395 patent is the provision of notches 18 in each of the clamps 2. The notches are configured to receive the tips of a forceps 19 which is used to provide a distraction force between the two vertebrae V_2 and V_4. As shown in FIG. 2, once the clamps 2 are fixed to the corresponding intact vertebrae, the forceps 19 are used to distract and permit room for placement of a bone graft G. Once the bone graft is in place, the anterior plate 6 can be attached to each of the clamps 2 in the manner previously described. Once the plate is in position, the distraction forceps 19 is removed and the nut 7 tightened to form a rigid construct.

The anterior construct shown in the '395 patent and in FIGS. 1 and 2 of this application is one system for providing anterior fixation with the use of autologous or allogenic bone graft material. Other implants have been devised which rely upon an additional element interposed between the adjacent vertebra, in lieu of or in addition to the traditional bone graft material. One such device is shown in the patent to Harms et al. no. 4,820,305, which is sold as the "Harms Cage" by the Biedermann-Motech Company. This device contemplates a hollow cylindrical mesh which is

inserted in the gap between adjacent vertebra, with bone graft material being disposed inside the hollow interior of the mesh.

The patent to Brantigan, No. 5,192,327, shows a device similar to the "Harms Cage" which is composed of a number of hollow oval-shaped implants within which bone graft material is disposed. European Patent No. 0 179 695 to Kehr shows a rigid inert body having a number of passageways extending between the intact vertebrae into which bone growth material can be implanted. In addition, the device shown in the Kehr European patent includes a plate spanning between the vertebrae having holes for receiving bone screws therethrough.

Another variety of implant devices particularly suited for replacement of vertebral bodies include components of generally solid construction which completely occupy the empty vertebral space. These devices are represented by the patents to Kapp et al., no. 4,554,914; Doty, no. 4,599,086; Ogilvie et al., no. 4,636,217; and Downey, no. 5,147,404. Each of these devices is provided with a spike or similar mechanism for engaging the end plates of the intact vertebrae to maintain the implant in position. A similar construction is followed in the U.S. Patent 5,062,850 to MacMillan et al., although this device includes open space between support columns of the axially fixed vertebral body prosthesis.

In each of the former patents, the implant device requires separate distraction of the intact vertebrae prior to insertion of the device. The following patents show vertebral prosthesis which include some feature for expansion of the device *in situ*. For example, the Main et al., no. 4,932,975, and Barber no. 5,236,460 show prostheses that telescope through the admission of a hydraulic fluid. The patents of Rezaian, no. 4,401,112; Wu, no. 4,553,273 and Daher, no. 4,657,550 show devices that expand *in situ* the manipulation of a threaded component. In addition, the

Rezaian patent shows a turnbuckle construct of this type with the addition of a spiked plate engaged in the opposite intact vertebrae to strengthen the construct.

In recent years, the application of anterior approaches to instrumenting the spine has become more prevalent. As these anterior approaches advance, it becomes of greater necessity to provide a vertebral body replacement that meets all of the benefits of anterior surgery without the detriments of the several prior devices. Each of the above-mentioned vertebral body replacements suffer from one or more disadvantages. For instance, some of the devices do not provide means for osteosynthesis between the intact vertebrae. These devices lack features that can either permit bone ingrowth or facilitate placement of bone graft between adjacent healthy vertebrae. It is recognized that a more permanent and stable correction of a kyphotic condition occurs with fusion of a bony mass in place of the replaced vertebra. Thus, any vertebral body replacement should accommodate this aspect. Other vertebral prosthesis offer no means for adjusting the size of the implant to accommodate the specific vertebral anatomy. Further, other of the devices do not contemplate some auxiliary fixation to help provide a stable construct. Each of these needs, and many others, are met by the vertebral body replacement according to the present invention.

SUMMARY OF INVENTION

The present invention contemplates a vertebral replacement implant and assembly for fixation of the implant in the space left by a removed vertebra between two intact vertebrae. In one aspect, the implant includes a thin-walled cylindrical body sized to occupy a substantial portion of the space between the intact vertebrae. The cylindrical body is hollow with a plurality of apertures through the wall of the body in communication with the interior, to permit bone ingrowth once the implant is implanted. The opposite ends of the cylindrical body carries continuous threads, preferably on the outer surface of the body.

The inventive implant further contemplates a pair of endplates having a surface directed against a corresponding one of the intact vertebrae when the prosthesis is implanted. The endplates each include a cylindrical portion extending from the end surface, which portion includes threads for mating with the threaded ends of the cylindrical body. Preferably, the threads of the endplates are internal to the cylindrical portion. In one aspect, the endplates are themselves hollow to provide communication between the hollow interior of the cylindrical body and the adjacent intact vertebrae. Alternatively, the invention contemplates the addition of an end cap to the implant to close the end surface of the endplates against the adjacent vertebrae in order to provide additional support for weak vertebrae.

Another feature of the invention resides in the provision of means for fixing the cylindrical body to each of the endplates to prevent unthreading of the mating threads of the three components of the implant. In one embodiment, the means for fixing includes apertures in the threaded portion of the endplates which are threaded to accept a set screw. Preferably, two set screws are threaded into two such apertures in the endplates to apply a clamping pressure

against the cylindrical body engaged with the endplate.

In another embodiment, the means for fixing contemplates a crimpable cylindrical portion of the endplates. In one aspect, the cylindrical portion includes an annular ring, dissected by a crimping notch. The application of a crimping force around the annular ring reduces the notch, and thereby reduces the circumference of the cylindrical portion so it is tightly engaged about the cylindrical body threaded therein.

Another inventive aspect resides in the provision of means for connecting the implant to a longitudinal member extending outside the space left by the removed vertebrae. The longitudinal member may be a plate or a rod that is fixed in a known manner to the adjacent intact vertebrae. Preferably, the longitudinal member can be used to assist in the distraction of the intact vertebrae for insertion of the vertebral replacement implant.

In one embodiment, the means for connecting includes a clamp configured to clamp onto the longitudinal member. The clamp supports a screw directed towards the replacement implant when it is interposed between the intact vertebrae. The cylindrical body of the implant includes a number of apertures threaded to receive the connecting screw. The clamp is preferably slidable along the length of the longitudinal implant to facilitate alignment of the screw with the number of threaded apertures of the cylindrical body. In addition, the clamp includes a spherical seat, and the screw includes a spherical head to permit varying angular orientations of the screw relative to the longitudinal member.

In another embodiment, the means for connecting includes an arm extending from a flange of the endplates. The free end of the arm defines an opening through which the longitudinal member extends. A set screw intersects the opening to provide fixation of the longitudinal member to the arm of the endplates.

One object of the present invention is to provide a

vertebral body replacement implant configured to support the space left by removal of a damaged or diseased vertebra. One objective is to provide an implant that can be easily adjusted to vary the overall length of the implant dependent upon the vertebral level into which the implant is interposed. A further objective of the inventive implant is to permit this length adjustment yet provide means for fixing the components to prevent disengagement or unthreading.

A further object is achieved by the present invention by the provision of means for connecting the vertebral replacement implant to a longitudinal member extending along the length of the spine between the adjacent intact vertebrae. The longitudinal member can be used for distracting the space left by the removed vertebra to facilitate insertion of the replacement implant. Yet another object is to provide an implant that can house bone growth material to facilitate fusion of the instrumented level.

One benefit of the vertebral body replacement of the present invention is that it provides a strong implant to support the spinal loads while awaiting fusion of bone growth material between the intact vertebrae. A further benefit is that the implant can be more easily adjusted to accommodate spaces at different vertebral levels.

Other objects and benefits of the invention can be gleaned from the following written description of the invention, considered together with the accompanying figures and claims.

DESCRIPTION OF THE FIGURES

FIG. 1 is an exploded perspective view of a spinal osteosynthesis implant according to the prior art patent 5,108,395.

FIG. 2 is a view showing a portion of the view of FIG. 1 with the addition of an instrument for permitting positioning of a graft between the vertebrae carrying the clamps associated with the prior device of the '395 patent.

FIG. 3 is an exploded perspective view of a vertebral body replacement assembly in accordance with one embodiment of the present invention.

FIG. 4 is an end elevational view of an endplate used in connection with the vertebral body replacement assembly shown in FIG. 3.

FIG. 5 is a side elevational view of an endplate used with the vertebral body replacement assembly of FIG. 3.

FIG. 6 is a perspective exploded view showing a component of the clamp assembly used with the vertebral body replacement assembly shown in FIG. 3.

FIG. 7 is a side elevational view of a vertebral body replacement assembly in accordance with another embodiment of the invention, particularly for use with an elongated rod spanning the vertebral sections.

FIG. 8 is an end elevational view of the vertebral body replacement assembly shown in FIG. 7, with the assembly shown in position on a intact vertebra.

FIG. 9 is a side elevational view of the assembly shown in FIG. 7 as engaged to an elongated rod.

FIG. 10 is a perspective view of the endplate used with the vertebral body replacement assembly shown in FIG. 7.

FIG. 11 is an end elevational view of one specific endplate used in connection with the vertebral body replacement assembly shown in FIG. 3 in the thoracic spine.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now to FIG. 3, a vertebral body replacement assembly 20 is shown in accordance with one embodiment of the present invention. The assembly 20 generally includes a threaded cylindrical body 21, threaded endplates 22 and end caps 23. A set screw 24 is also provided as one embodiment of a means for fixing each of the endplates 22 to a corresponding end of the cylindrical body 21. In one specific embodiment, the set screw 24 is a breakable locking screw in which the head of the screw shears off when the tightening torque limit is reached. Such a locking screw is disclosed in co-pending French patent application No. 94 10 377, filed on August 29, 1994.

The threaded cylindrical body 21 is formed from a cylindrical wall 25 which defines a hollow cavity 26 therein. The cavity is configured to receive bone osteosynthesis material, which may be in the form of autogenous or allograph material. The cylindrical wall 25 is provided with a plurality of apertures 28 in communication with the cavity 26. These apertures provide a path for bone or tissue ingrowth to further enhance the stability of the implant. The cylindrical wall 25 includes a second plurality of threaded apertures 29 generally in the middle of the

implant, which are configured to engage the support assembly 55 as described in more detail herein.

In one important feature of the cylindrical body 21, the opposite ends of the cylindrical wall 25 are formed into external threads 32. In one specific embodiment, the threads 32 extend from each opposite end over most of the total length of the threaded cylindrical body 21 and are configured to engage the threaded endplates 22. Each endplate includes a flange 35, which preferably assumes a shape to cover a substantial load-bearing area of the end plates of the adjacent intact vertebral bodies. A cylinder 37 is integrally formed with flange 35 to extend toward the threaded cylindrical body 21 when the endplates 22 are placed within the excised vertebral space. The cylinder 37 of each endplate includes a number of threaded openings 39 adapted to receive a set screw 24 therein.

The cylinder 37 and flange 35 of the endplates 22 define a bore 40 therethrough. The inside surface of the bore 40 is provided with internal threads 41 which are configured to mate with the external threads 32 of the cylindrical body 21. In the preferred embodiment, the threads 41 extend along at least the entire length of the cylinder 37 and preferably into the flange 35.

Further details of the endplates 22 can be seen in FIGS. 4 and 5. As shown in FIG. 5, the cylinder 37 is integrally formed with the flange 35 to define a lordosis angle 43. This angle is intended to permit use of the vertebral body replacement assembly 20 to replace a damaged vertebra, such as vertebra V_3 shown in FIG. 1, and still maintain the normal lordotic curvature of the spine at that level. The end face 36 of the flange 35 is provided with vascularization apertures 45 extending through the flange. These apertures 45 are intended to provide an avenue for vascularization of the space between the adjacent vertebrae. The end face 36 can be provided with four spikes, such as spikes 91 shown in

the embodiment of FIG. 7. Alternatively, spikes 120 (FIG. 3) can be provided that include a threaded stem 121 to be engaged in threaded apertures 46 defined in end face 36. In either case, the spikes (91, 120) are configured to penetrate the end plate of the adjacent vertebra to help maintain the position of the implant in situ.

The end face is further provided with a mounting slot 47 passing across the flange 35 and spanning along a chord of the internal bore 40. Within each mounting slot is an aperture 48 passing therethrough. The cylinder 37 of the endplate 22 is provided with a mounting notch 49 that is aligned with each aperture 48 in the mounting slot 47. This slot 47, aperture 48 and notch 49 are configured to support an end cap 23, as herein described. Referring back to FIG. 3, the end cap 23 includes a generally rectangular support bar 50 which is mounted to span across a chord of the flat circular plate 52 of the end cap. At each end of the support bar 50 is an outwardly projecting lug 51. Each lug 51 is sized to be received within a corresponding aperture 48, while the support bar 50 is itself configured to fit within the mounting slot 47 in the flange 35. Further, each lug 51 slides conveniently into a corresponding mounting notch 49 in the cylinder 37. In this manner, the end cap 23 is held in position, particularly when the replacement body assembly is disposed between the adjacent intact vertebrae V_2 and V_4.

The end cap 23 provides additional support for the implant between the adjacent intact vertebrae. The end cap can be eliminated if bone growth between the adjacent vertebrae and through the replacement body is preferred. Alternatively, the plate 52 of each end cap 23 can be perforated to permit bone ingrowth between the vertebral end plates and the bone growth material disposed within the threaded cylindrical body 21. In the preferred embodiment, the endplates are shown solid to provide the maximum load bearing capability for loads along the length of the vertebral column.

In the illustrated embodiment, the threads 32 on the cylindrical replacement body are external threads, while the threads 40 in the endplates are internal. Alternatively, the cylinder 37 of the endplates can carry external threads and the cylindrical replacement body carry internal threads in the cavity 26. In this latter instance, the inner diameter of the cylindrical body would naturally be slightly greater than the outer diameter of the cylinder of the endplates.

In the preferred embodiment, the cylindrical wall forming the implant 21 can be relatively thin, when compared against replacement bodies of the prior art. In one specific embodiment, the wall is one (1) mm. thick. Since the primary load endured by the implant will be axial compression, rather than bending, a thin-walled cylinder is appropriate and even desirable.

It is also preferred that the implant 21 include a large number of apertures 28, 29 to promote tissue ingrowth and vascularization, thereby enhancing the stability of the construct after fusion has occurred. In one specific embodiment, the total area of the plurality of apertures is at least twenty five percent (25%) of the surface area of the cylindrical body 21.

In use, the damaged vertebra, such as vertebra V_3 shown in FIG. 1, is removed. In one embodiment, the clamps 2 of the interior implant 1 shown in FIGS. 1 and 2 are engaged to the intact vertebral bodies in the manner shown in FIG. 2. Also shown in FIG. 2, the forceps 19 can be used to distract the intact vertebrae to permit implantation of a vertebral body replacement assembly 20. In the preferred method, the optimum vertebral height is determined and the threaded cylindrical body 21 and threaded endplates 22 are fitted together to achieve that proper height. Specifically, each of the end caps can be threaded onto the threaded cylindrical body 21 until the desired height is attained.

It is important that the bottom edge 44 of the flange 35

of each of the endplates be generally oriented in the same way between the two threaded endplates 22. This orientation is important because the replacement assembly 20 will be disposed between the two intact vertebrae, bearing against the end plates of those vertebrae. In order to maintain the maximum load bearing capability, the flanges 35, and particularly the end face 36, assume the shape of the vertebral body against which the endplates bear and are sized to occupy as much area of the intact vertebral body end plate as possible.

Preferably, three such shapes are provided to accommodate the anatomic variations of the vertebral bodies at the lumbar, thoraco-lumbar and thoracic levels. the configuration of the flange 35 shown in FIG. 4 is applicable to the thoraco-lumbar vertebrae. A smaller, more rounded, configuration can be provided for implantation at the thoracis level, such as the flange 35' shown in FIG. 11. The flange 35' is also shown as including a relief radius 38 to increase the clearance between the flange and the dural space housing the spinal cord. This relief radius 38 is preferably included in all three shapes of the endplate flanges.

In one specific embodiment, the external threads 32 on the threaded cylindrical body 21 are cut in opposite directions so that the endplates can be drawn together or apart by rotating only the cylinder. Thus, as the cylinder is rotated in one direction, the threads 32 at each of the ends engage the internal threads 41 of each of the end caps 23 in the right direction to draw the end caps together. Alternatively, the handedness of the threads 32 can be the same at each end so that it is necessary to individually thread each end cap in opposite directions onto the cylindrical body 21. The disadvantage of this arrangement is that it is more difficult to adjust the height of the total assembly 20 while maintaining the proper orientation of each of the lower edges 44 of the end face 36. An advantage is that *in situ* the assembly is unable to unthread itself.

Once the endplates and threaded cylindrical body have been engaged in the proper orientation for the correct height, the set screws 24 are threaded into an appropriate one of the threaded openings 39 in the cylinder 37 of the endplates 22, in order that the set screw 24 extend into contact with the threaded cylindrical body 21. The set screws 24 (which can be the breakable locking screws mentioned above) exert a clamping pressure against the body 21 to hold it in place. Thus, the set screws 24 provide a means for fixing the components together and prevent rotation of the cylindrical body 21 with respect to either of the endplates 22. Preferably, two set screws are used at each endplate 23 to firmly fix the associated ends of the threaded cylindrical body 21. To ensure that the set screws 24 achieve firm purchase on the body 21, the apertures 28 in the threaded body have a smaller diameter than the set screws 24.

With the cylinder and endplates thus fixed at their proper height dimension, bone graft material can then be inserted into the bore 40 of the endplates and cavity 26 of the cylindrical body 21. After the interior of these components has been completely filled with bone graft material, the endplates 23 are placed in position with the lugs 51 extending through apertures 48, and with support bar 50 passing through mounting slot 47 in each endplate. The replacement assembly 20 can then be disposed between the distracted vertebrae V_2 and V_4. Once the assembly is properly positioned with the end faces 36 of each of the endplates 22 properly oriented on the vertebral end plates, the distraction forceps 19 are removed so that the assembly 20 is clamped in place between the two vertebrae.

In order to further ensure that the replacement assembly 20 will not migrate or slip in its position between the intact vertebrae, a support assembly 55 may be provided. In the preferred embodiment, this support assembly 55 is configured to mate with the clamps 2 used with the anterior

implant system of the prior art shown in FIGS. 1 and 2. The support assembly 55 can also be used with other anterior plates, such as the Z-PLATE ATL* sold by Danek Medical, Inc., or rod systems such as the CD Hopf System of Sofamor, S.N.C.

In particular, the support assembly includes a stabilization plate 57, which can be configured substantially similar to the plate 6 shown in FIG. 1, including the serrations on the bottom face of the ends of the plate. Means for connecting the vertebral replacement body assembly 20 to the plate 57 includes a clamp assembly 59 is provided which firmly grips the plate 57 to support a locking screw 69. The clamp assembly 59 includes a pair of clamp halves 60 which are preferably in the shape of a C to grip and support the plate 57. Each of the clamp halves 60 include an aperture (not shown) which receives a threaded rod 63 of an adjustment plate 62. A nut 64 is threaded on the rod 63 to draw the clamp halves 60 together about the stabilization plate 57.

The details of the adjustment plate 62 are shown more clearly in FIG. 6. The adjustment plate includes the threaded rod 63 extending from a face 65 of the plate 62. The plate 62 also includes an aperture 67 therethrough having a spherical seat surface 68 into which a corresponding spherical head 70 of the locking screw 69 is received. The locking screw 69 includes a hex recess 71 in its head to accept a driving tool. The locking screw 69 also includes a threaded shank 73 which is adapted to engage one of the threaded apertures 29 in the threaded cylindrical body 21. To help guide the locking screw 69 into position, a guide nub 75 is provided having a smaller diameter than the threaded shank 73. The locking screw 69 preferably includes smooth shank 74 between the head 70 of the screw and the threaded shank 73.

In use, the clamp halves 60 can be tentatively attached

but not clamped to the stabilization plate 57. The stabilization plate 57 can then be engaged to the clamps 2 in each of the intact vertebral bodies and fixed in place by a corresponding nut, such as nut 7 shown in FIG. 1. With the stabilization plate 57 thus attached between the distracted vertebrae, the distraction forceps 19 can be removed so that the full load of the spinal column can be borne by the replacement assembly 20. Once the distraction forceps have been removed, the clamp halves 60 can be adjusted along the length of the plate 57 so that the locking screw 69 is aligned with an appropriate one of the threaded apertures 29 in the threaded cylindrical body 21. The spherical contact between the head 70 of the locking screw 69 and the spherical seat 68 of the adjustment plate 62 allows the locking screw to assume whatever angle is necessary to engage a threaded aperture 29. As so aligned, the locking screw 69 can then be easily threaded into one of the apertures 29 until it is locked between the adjustment plate 62 and the threaded cylindrical body 21. At this point then, the clamp halves 60 can be fully clamped onto the plate 57 by tightening the nut 64 on the threaded rod 63.

In another embodiment of the invention, a vertebral body replacement assembly 80 is configured for connection to an elongated distraction or compression rod. In this embodiment, the assembly 80 includes opposite endplates 83 which are configured to threadedly engage a cylindrical body 21. (This cylindrical body 21 is substantially identical in all respects to the cylindrical body 21 described with respect to FIG. 3). With this embodiment, the endplates 83 include a flange 85 and a cylinder 87 projecting therefrom. The cylinder 87 includes a threaded bore 88 which is threaded to accept the external threads 32 of the cylindrical body 21. Like the prior endplates, the endplate 83 includes a plurality of vascularization apertures 89 formed through the flange 85. The end face 86 of the flange 85 includes a

number of spikes 91 projecting therefrom. The spikes are configured to penetrate the end plate of the adjacent vertebral bodies to help maintain the position of the implant *in situ*.

As shown in FIGS. 7 and 8, the endplates 83 include an arm 94 projecting from the flange 85, which is a component of a means for connecting the implant to a longitudinal member, such as rod 105. A rod bore 95 is defined adjacent the free end 94a of the arm 94, with a set screw bore 96 intersecting the rod bore 95 from the free end of the arm 94. A set screw 98 is provided which is engaged within the set screw bore 96 to clamp a rod passing therethrough.

The manner of using the replacement assembly 80 in this embodiment is shown in FIGS. 8 and 9. In particular, the endplates 83 are engaged in the appropriate vertebrae by way of spikes 91. Again, the plates are configured to define an angle 115 to correspond to the proper spinal anatomy at the particular vertebral level. A distraction plate 107 is mounted into each of the intact vertebrae by way of bone screw 108. The plate 107 includes a collar 109 integrally formed thereon through which a distraction rod 105 passes. The distraction rod also extends through each of the rod bores 95 in the arms 94 of the endplates 83. With the rod extending through each of the bores, the set screws 98 fix the endplates in position. Distraction of the adjacent vertebrae can be achieved by an appropriately formed instrument that can engage the collars 109 of each of the distraction plates 107 mounted into the respective vertebrae. A set screw (not shown) can be provided to fix the rod 105 within each collar 109.

Referring to FIGS. 7, 9 and 10, details of the manner in which the endplates are fixed to the threaded cylindrical body is described. In particular, the endplates 83, and particularly the cylinder 87 of the endplates, is provided with a a means for fixing in the form of a crimping channel

100 around the diameter of the cylinder. At opposite sides of the cylinder, a crimping notch 101 is provided in the channel 100. In essence, this crimping notch is a gap in the outer circumference of the channel 100. This crimping notch provides a gap which can be closed by an appropriate crimping tool gripping the entire circumference of the crimping channel 100. As the crimping tool is tightened, the notches 101 close as the channel moves together in the direction of the arrows 102. It can be seen that this crimping aspect will replace the set screw 24 disclosed with the previous embodiment for fixing the endplates to the threaded cylindrical body.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A vertebral replacement implant for interposition in a space left by one or more removed vertebrae between adjacent intact vertebrae, comprising:

a replacement body with opposite ends sized to span a portion of the space between the intact vertebrae, said replacement body having first threads defined thereon at each of said opposite ends; and

a pair of endplates each having an end surface for contacting a respective one of the intact vertebrae when the implant is interposed in the space, each of said endplates having a cylindrical portion integrally extending from said end surface, said cylindrical portion having second threads defined thereon configured to threadedly engage the first threads on said replacement body, each of said endplates further defining a bore therethrough opening at said end surface and at said cylindrical portion.

2. The vertebral replacement implant according to claim 1, wherein said replacement body includes a cylindrical wall defining a hollow interior, said cylindrical wall defining a plurality of apertures therethrough, said apertures being in communication with said hollow interior of said replacement body to facilitate tissue ingrowth into said replacement body.

3. The vertebral replacement body according to claim 2, wherein said cylindrical wall defining said replacement body has a surface area and said plurality of apertures define an effective area greater than twenty five percent (25%) of said surface area.

4. The vertebral replacement implant according to claim 2, wherein the hollow interior of said replacement body is open at said opposite ends.

5. The vertebral replacement implant according to claim 1, wherein said replacement body includes a cylindrical wall defining a hollow interior and is open at said opposite ends.

6. The vertebral replacement implant according to claim 5, wherein each of said endplates defines a bore therethrough opening at said end surface and at said cylindrical portion.

7. The vertebral replacement implant according to claim 6, wherein said first threads on said replacement body are external threads and said second threads on said cylindrical portion of said pair of endplates are internal threads.

8. The vertebral replacement implant according to claim 1, further comprising an end cap for closing said bore of one of said endplates at said end surface thereof, said end cap having means for supporting the end cap on the endplate.

9. The vertebral replacement implant according to claim 1, wherein said first threads on said replacement body are external threads and said second threads on said cylindrical portion of said pair of endplates are internal threads.

10. The vertebral replacement implant according to claim 1, further comprising means for fixing said replacement body to each of said endplates to prevent unthreading of said first and second threads.

11. The vertebral replacement implant according to claim 10, wherein said means for fixing includes:

a number of openings defined in said cylindrical portion of each of said pair of endplates; and

a member extendable through one of said number of apertures into contact with said replacement body.

12. The vertebral replacement implant according to claim 11, wherein:

said member is a set screw; and

said number of openings is threaded to receive said set screw in threaded engagement.

13. The vertebral replacement implant according to claim 11, wherein said number of openings are defined in said endplates at said second threads.

14. The vertebral replacement implant according to claim 1, wherein each of said endplates includes a flange defining said end surface, said flange extending radially outwardly from said cylindrical portion and defining a shape generally corresponding to the shape of a portion of the intact vertebra against which the endplate is in contact.

15. The vertebral replacement implant according to claim 14, wherein said flange defines a number of vascularization apertures therethrough.

16. The vertebral replacement implant according to claim 15, wherein:

said end cap includes;

a plate shaped to correspond to said bore opening in said endplate; and

a support bar attached to said plate; and

said endplate includes a slot defined at said end surface for receiving said support bar so that said plate of said end cap resides flush with said end surface of said endplate.

17. The vertebral replacement implant according to claim 10, wherein:

said cylindrical portion of each of said endplates has a

length projecting from said end surface; and

said means for fixing includes a crimping notch formed along a portion of said length of said cylindrical portion, said cylindrical portion being deformable at said crimping notch to close said notch and thereby reduce the circumference of said cylindrical portion about said replacement body when said body is threadedly engaged to said endplate cylindrical portion.

18. The vertebral replacement implant according to claim 1, wherein each of said pair of endplates includes a number of spikes projecting from said end surface for implantation in a corresponding one of the adjacent intact vertebrae.

19. The vertebral replacement implant according to claim 18, wherein:

said end surface of each of said pair of endplates defines a number of threaded apertures therein; and

each of said number of spikes includes a threaded post configured for engagement with said threaded apertures in said end surface of each of said endplates.

20. The vertebral replacement implant according to claim 1, wherein said cylindrical portion of each of said endplates extends from said end surface at a non-perpendicular angle, said angle corresponding to the curvature of the spine at the space left by the removed vertebra.

21. The vertebral replacement implant according to claim 1, wherein each of said endplates includes a flange defining said end surface and extending outwardly from said cylindrical portion, said flange including an arm projecting away from said cylindrical portion, said arm having a free end configured to extend beyond the adjacent intact vertebrae for engagement to a longitudinal member disposed along the length of the spinal column.

22. The vertebral replacement implant according to claim 21, wherein said arm defines a bore at said free end for receiving the longitudinal member therethrough.

23. An assembly for fixation of adjacent intact vertebrae following removal of an intermediate damaged vertebra, comprising:

a vertebral replacement implant including;

a replacement body with opposite ends sized to span a portion of a space left by the removal of the damaged vertebra, said replacement body having first threads defined thereon; and

a pair of endplates each having an end surface for contacting a respective one of the intact vertebrae when the implant is interposed in the space, each of said endplates having a cylindrical portion integrally extending from said end surface, said cylindrical portion having second threads defined thereon configured to threadedly engage the threads on said replacement body;

an elongated longitudinal member sized to span between and fixedly engage the adjacent intact vertebrae outside the space left by the removal of the damaged vertebra; and

means for connecting said vertebral replacement implant to said longitudinal member.

24. The assembly for fixation of adjacent intact vertebrae according to claim 23, wherein:

said replacement body defines a number of threaded openings; and

said means for connecting includes:

a clamp for clamping said longitudinal member; and

a screw attached to said clamp, said screw having threads for engaging one of said number of threaded openings and having a length sufficient for said screw to engage said replacement body when said clamp is engaged to said longitudinal member.

25. The assembly for fixation of adjacent intact vertebrae according to claim 24, wherein:

said clamp includes a plate, said plate defining an aperture having a spherical seat; and

said screw includes a spherical head configured for engagement within said spherical seat.

26. The assembly for fixation of adjacent intact vertebrae according to claim 22, wherein:

each of said endplates includes a flange defining said end surface and extending outwardly from said cylindrical portion; and

said means for connecting includes an arm integral with said flange and projecting away from said cylindrical portion, said arm having a free end configured to extend beyond the adjacent intact vertebrae for engagement to the longitudinal member.

27. The assembly for fixation of adjacent intact vertebrae according to claim 26, wherein:

said arm defines a first bore at said free end for receiving the longitudinal member therethrough and a set screw bore at said free end intersecting said first bore; and

said means for connecting includes a set screw for threading into said set screw bore, said set screw having a tip for engaging a longitudinal member extending through said first bore.

28. A vertebral replacement implant for interposition in the space left by a removed vertebra between adjacent intact vertebrae, comprising:

a replacement body with opposite ends and having a length sized to span a portion of the space between the intact vertebrae;

a pair of endplates each having an end surface for contacting a respective one of the intact vertebrae when the implant is interposed in the space, each of said endplates having an engagement portion integrally extending from said end surface; and

means between said opposite ends of said replacement body and said engagement portion of each of said endplates for engaging said endplates to said replacement body at variable positions along the length of said replacement body.

29. The vertebral replacement implant according to claim 28, wherein said means for engaging includes mating threads defined on said opposite ends of said replacement body and each of said endplate engagement portions.

30. The vertebral replacement implant according to claim 28, further comprising means for fixing said replacement body to each of said endplates to prevent disengagement of said means for engaging.

31. A vertebral replacement implant for interposition in the space left by a removed vertebra between two intact vertebrae, comprising:

a thin-walled cylindrical body defining a hollow interior, the wall of the cylindrical body defining a plurality of apertures having a combined area at least equal to twenty-five percent (25%) of the outer surface area of the body, said body having opposite ends with continuous threads formed at each of said opposite ends; and

a pair of endplates, each endplate formed by a flange defining an end surface for contacting a respective one of the intact vertebrae when the implant is interposed in the space, and each endplate further including a cylindrical portion integrally projecting from said flange, said cylindrical portion defining a continuous thread for

engagement with the threads at the opposite ends of said thin-walled cylindrical body, each of said endplates defining a bore therethrough to communicate with the hollow interior of said thin-walled cylindrical body when said body is threadedly engaged with the endplate.

32. The vertebral replacement implant according to claim 31, wherein:

said cylindrical portion of each of said endplates has a length projecting from said end surface; and

said cylindrical portion defines a crimping notch formed along a portion of said length of said cylindrical portion, said cylindrical portion being deformable at said crimping notch to close said notch and thereby reduce the circumference of said cylindrical portion about said cylindrical body when said body is threadedly engaged to said endplate cylindrical portion.

33. The vertebral replacement implant according to claim 2, wherein some of said plurality of apertures extend through said first threads of said replacement body.

34. The vertebral replacement implant according to claim 7, wherein said replacement body includes a cylindrical wall defining a hollow interior, said cylindrical wall defining a plurality of apertures therethrough, said apertures being in communication with said hollow interior of said replacement body to facilitate tissue ingrowth into said replacement body.

35. The vertebral replacement implant according to claim 34, wherein some of said plurality of apertures extend through said external threads of said replacement body.

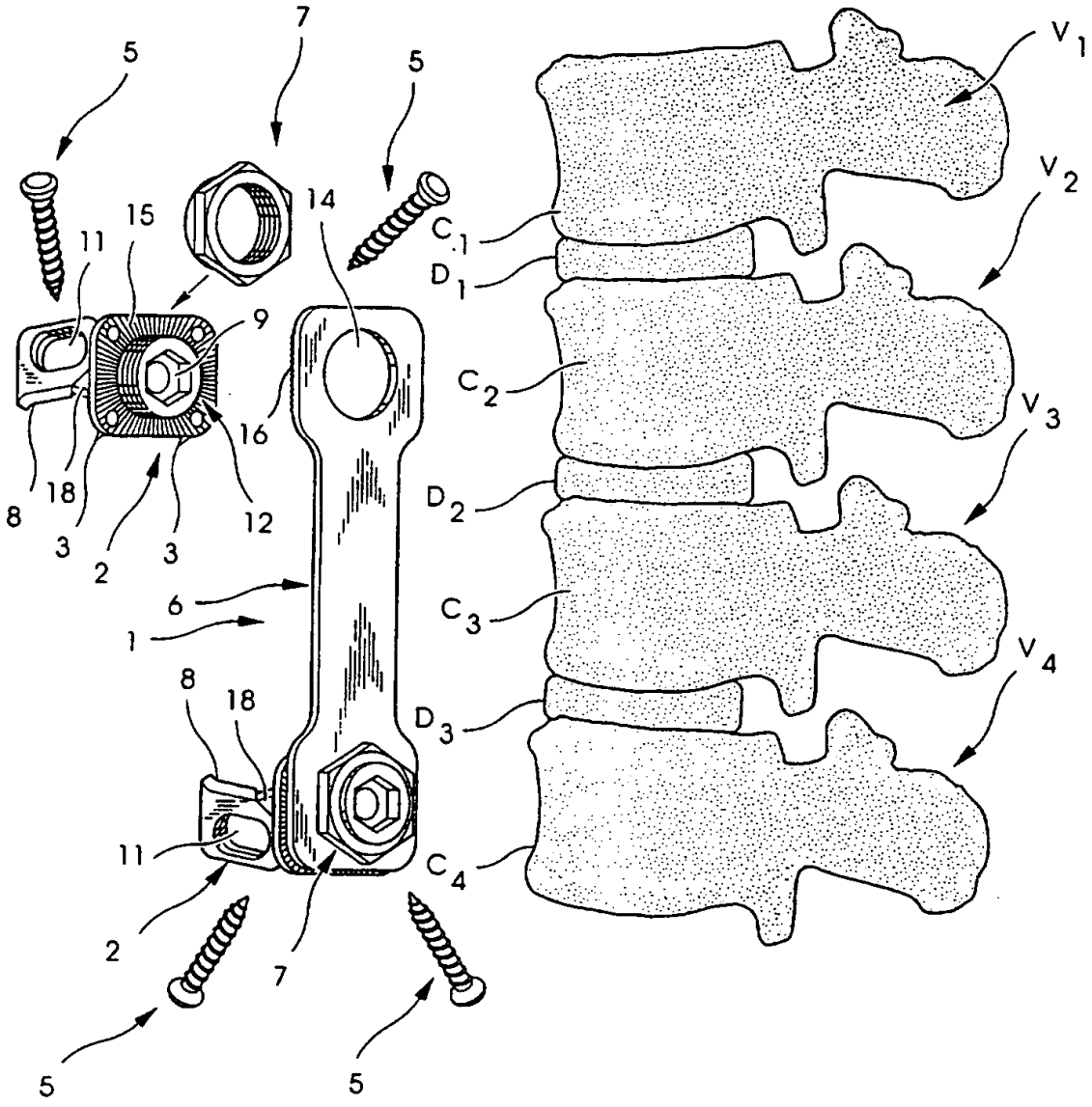

Fig. 1

(PRIOR ART)

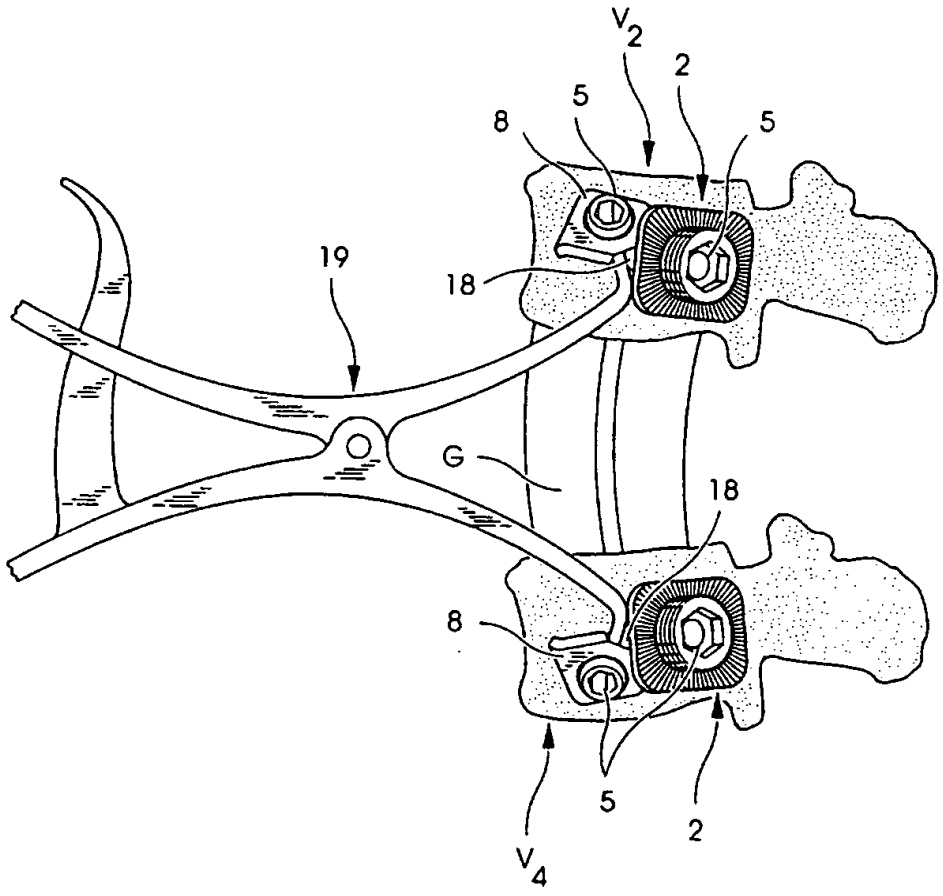

Fig. 2
(PRIOR ART)

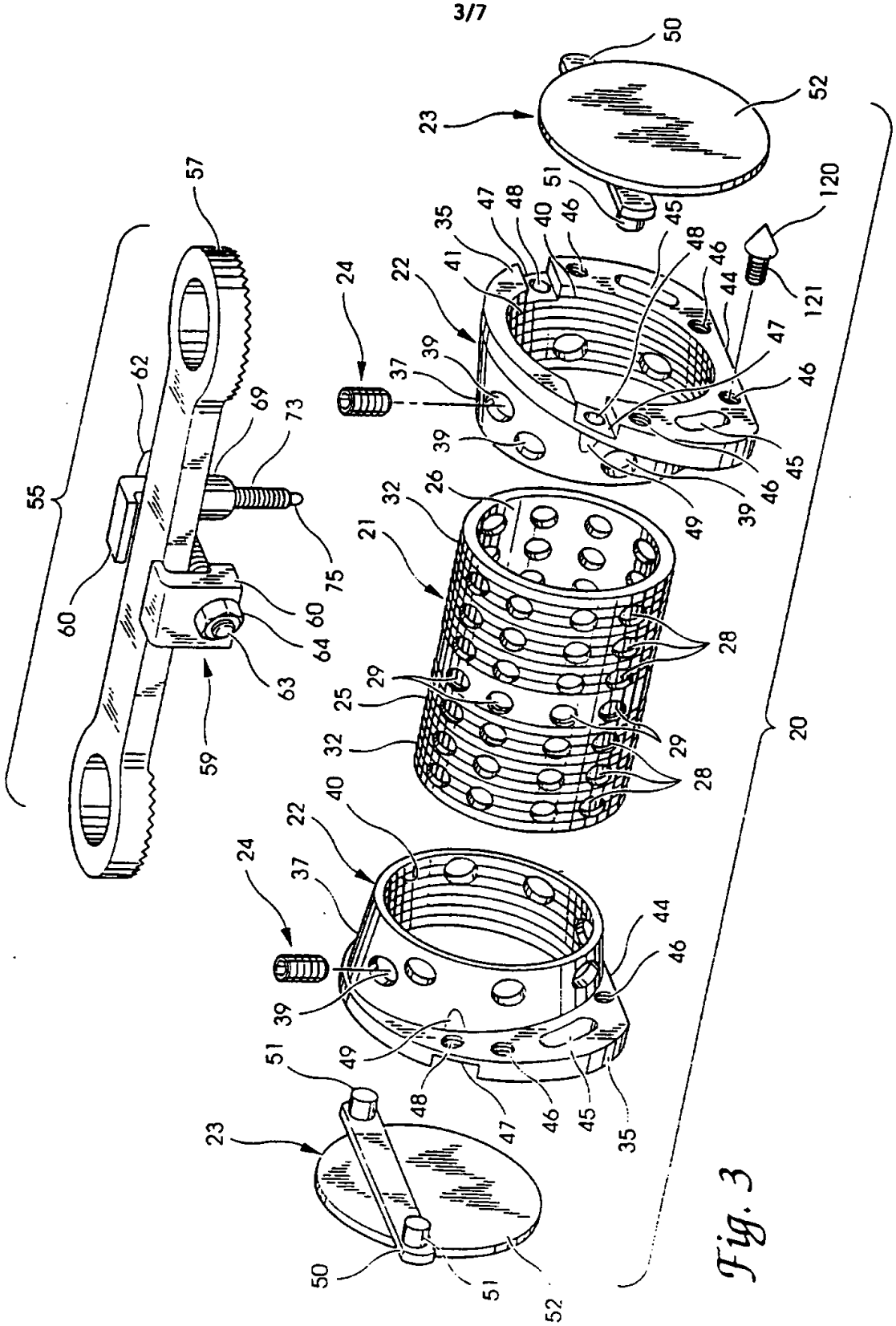
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Fig. 3

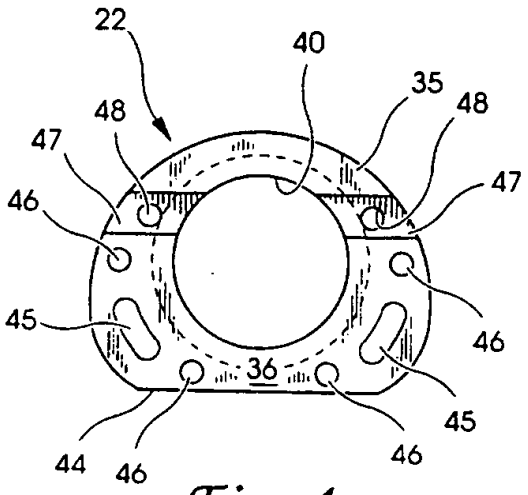

Fig. 4

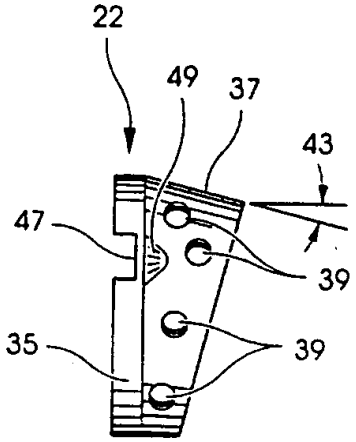

Fig. 5

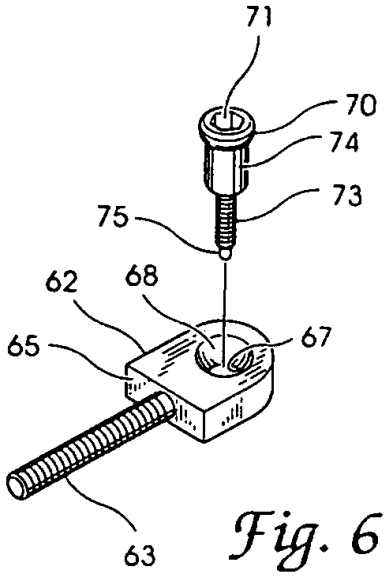

Fig. 6

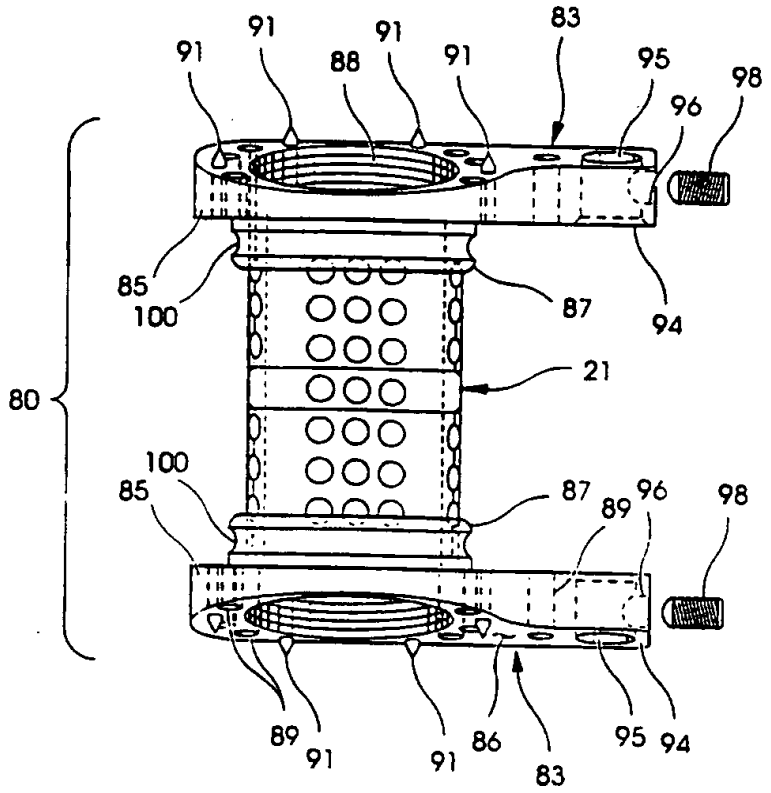
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Fig. 7

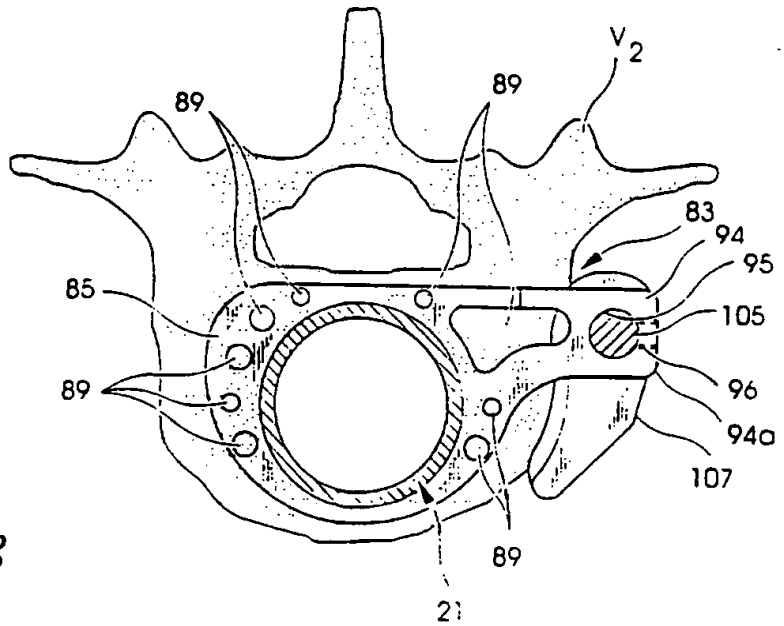
V2
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Fig. 8

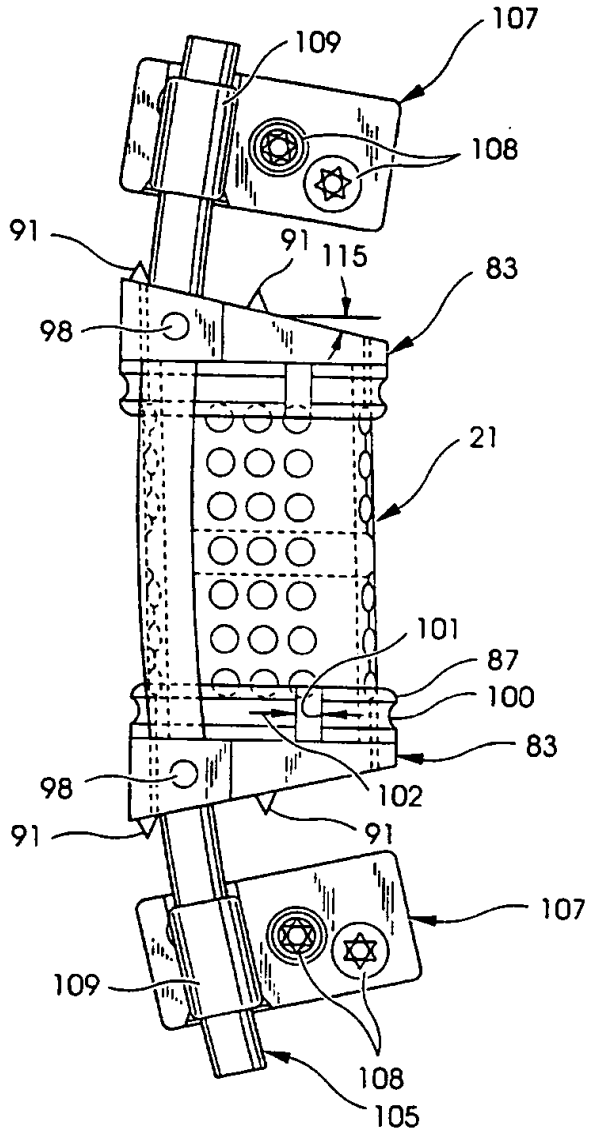
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Fig. 9

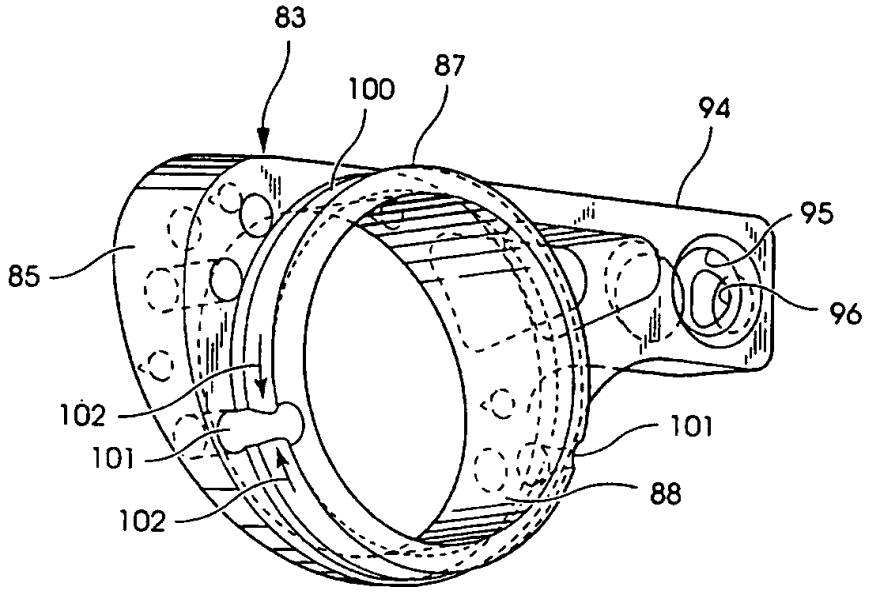

Fig. 10

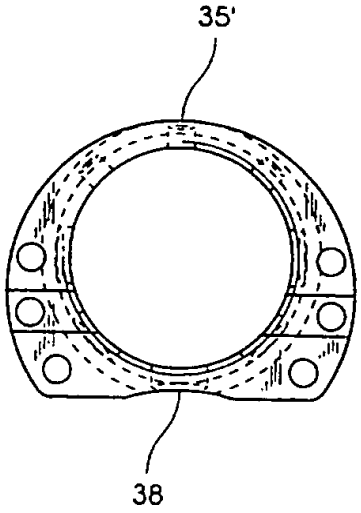

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/15654

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 2/44
US CL :623/17
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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/61, 71; 623/17, 22

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	EP, A, 567424 (APARICI ET AL.) 27 October 1993, entire document.	1, 2, 4-6, 10-12, 14, 28-30, 33, 34 --- 3, 7-9, 13, 15, 17-20
Y	US, A, 5,019,108 (BERTIN ET AL.) 28 May 1991, see entire document.	8
Y	US, A, 4,911,718 (LEE) 27 March 1990, see entire document.	15
Y	US, A, 4,553,273 (WU) 19 November 1985, see entire document.	7, 9, 13

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

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Date of the actual completion of the international search	Date of mailing of the international search report
05 FEBRUARY 1996	14 MAR 1996
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/15654

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,657,550 (DAHER) 14 April 1987, see entire document.	17-19
Y	Scientific Rationale, TITANIUM-MESH-CYLINDER, MOSS, July 1989, (J. HARMS ET AL.), pp. 106309 and 106312.	3, 31

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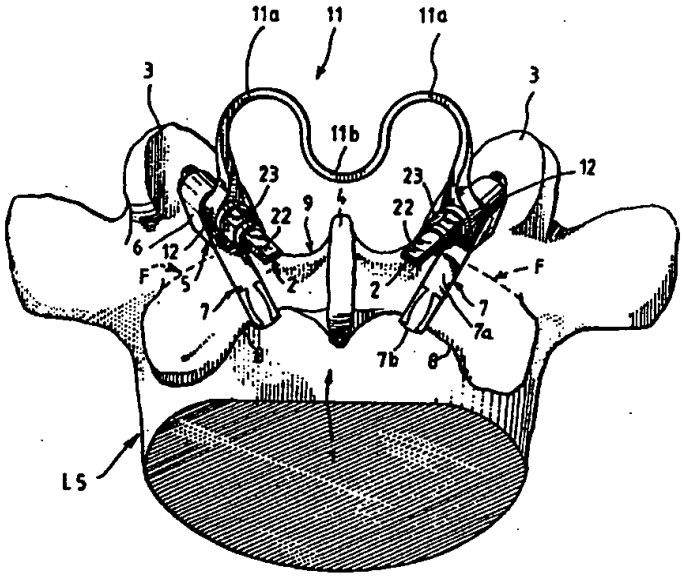
Publiée
Avec rapport de recherche internationale.

(54) Title: IMPLANT FOR SURGICALLY TREATING A VERTEBRAL ISTHMIC FRACTURE

(54) Titre: IMPLANT POUR LE TRAITEMENT CHIRURGICAL D'UNE FRACTURE ISTHMIQUE VERTEBRALE

(57) Abstract

An implant including a pair of screws (2) for screwing into respective vertebral facets (3), a pair of hooks (5) each consisting of a body (6) and a blade (7), said body having a through-bore for the screw, and said bore having a longitudinal axis at a suitable angle to the central longitudinal plane of the blade (7) such that the hook blade can suitably engage the posterior arch (9), a resilient connecting member (11) for holding apart the two screws and urging the blades (7) against the edges of the posterior arch, and nuts (23) for locking the connecting member and the hooks to the screws. Said implant takes up less space on the posterior side than known implants and thus avoids undesirable lumps under the skin, and the above-mentioned angular offset enables the hooks to engage a suitable area on the edges of the posterior arch, so that the surgeon is not required to perform preliminary cutting of the posterior arch.



(57) Abrégé

Cet implant comprend une paire de vis (2) destinées à être vissées chacune dans une facette vertébrale (3), une paire de crochets (5) constitués chacun d'un corps (6) et d'une lame (7), le corps étant percé d'un alésage de passage de la vis, dont l'axe longitudinal forme avec un plan longitudinal médian de la lame (7) un angle approprié pour permettre un appui convenable de la lame du crochet sur l'arc postérieur (9), un organe (11) de liaison élastique agissant en distraction entre les deux vis, et appliquant les lames (7) contre les bords de l'arc postérieur, et des écrous (23) de blocage de l'organe de liaison et des crochets sur les vis. Cet implant présente un encombrement postérieur réduit par rapport aux implants connus et évite donc ainsi des saillies gênantes sous la peau, et, grâce au décalage angulaire précité, les crochets peuvent prendre appui sur une zone adéquate des bords de l'arc postérieur sans qu'il soit nécessaire au chirurgien de tailler au préalable l'arc postérieur.

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Implant pour le traitement chirurgical d'une fracture isthmique vertébrale".

La présente invention a pour objet un implant pour le traitement chirurgical d'une fracture isthmique vertébrale. Plus précisément l'invention concerne le traitement chirurgical du spondylolisthésis du premier degré et de la spondylolyse par fracture isthmique.

Si cette anomalie rachidienne est très souvent découverte chez de jeunes patients dont la moyenne d'âge est de 11,5 ans et dont le pourcentage de cas le plus élevé (environ 73%) se trouve chez les jeunes filles, ce même traitement se rencontre aujourd'hui également chez les adultes. Ainsi, il est estimé que 5 à 7% de la population blanche présente une spondylolyse affectant le plus souvent la vertèbre L5, parfois L4 ou L3, et avec un listhésis dans seulement 60% des cas.

Il est généralement aujourd'hui admis que la spondylolyse est la conséquence d'une surcharge mécanique de l'isthme avec fracture de fatigue secondaire. Au stade préliminaire de cette évolution, on rencontre assez souvent une sclérose de l'isthme comme signe prémonitoire de la spondylolyse.

Cette surcharge résulte de deux mécanismes :

1 -Une hyperlordose (fonctionnelle, acquise ou congénitale) conduisant à un effet "casse-noisette" par hyperpression du processus articulaire cranial sur l'isthme, la fréquence de la spondylolyse dans les disciplines sportives conduisant à une hyperlordose (en particulier les gymnastes).

2 - La spondylolyse se rencontre aussi en l'absence d'une hyperlordose et est due, dans ce cas, à une anomalie de développement de la région isthmique : l'angle formé par la direction de la colonne articulaire inférieure de L5 par rapport au plan postérieur du corps vertébral est en moyenne de 168° à la naissance et de 145° chez l'adulte

européen. Il arrive que cette incurvation de 18 à 28° ne se produise pas en cours de développement. Il en résulte également un effet de "casse-noisette" de la part du processus articulaire proximal.

De fait, tant que cette surcharge articulaire existe sur l'isthme, cette fracture ne peut se consolider spontanément (pseudarthrose) et peut entraîner des douleurs lombaires, parfois sciatiques ou neurales par compression des éléments nerveux par le tissu au contact de la pseudarthrite. La fracture nécessite alors un traitement chirurugical au stade de la pseudarthrose.

Préalablement à toute intervention chirurgicale, un traitement probatoire doit être effectué. Les différents traitements possibles sont les suivants : physiothérapie, thérapeutiques médicamenteuses, infiltrations locales, gymnastique lombaire, corset. Cependant, malgré ces traitements certains cas demandent une indication opératoire.

On connaît actuellement plusieurs techniques de réparation isthmique associant une greffe osseuse et une instrumentation qui sont les suivantes :

- La première technique consiste à reconstruire la rupture des isthmus en insérant une vis dans la fracture. Ce procédé présente l'avantage de la simplicité, mais aussi des inconvénients sérieux : la vis diminue l'interface osseuse au niveau de la rupture, ce qui peut conduire à un nombre important de pseudarthrose. De plus, il exige une immobilisation externe post-opératoire avec port d'un corset par le patient et enfin on observe des ruptures des vis.

- La seconde technique consiste à combiner les vis avec des fils métalliques qui retiennent les transverses avec les lames postérieures. On réalise ainsi une fixation

plus stable, améliorant la guérison des ruptures. En revanche, ce procédé est compliqué et ne permet pas d'éviter des ruptures de vis. Chez l'adulte, la plupart (90%) des interventions faites sur lyse isthmique sont actuellement des arthrodèses plus ou moins étendues selon l'état des disques. Ceci signifie qu'on réalise des appuis sur les deux vertèbres voisines de la vertèbre fracturée, ce qui constitue un inconvénient évident puisque ces vertèbres ne sont pas endommagées.

- Selon une autre technique connue, l'isthmus est reconstruit par une vis insérée dans la façade supérieure et par un crochet positionné sur la lame de l'arc vertébral, la vis et le crochet étant dans le même plan médian général. Un ressort hélicoïdal est enfilé sur la vis derrière le crochet et mis en compression contre le crochet par un écrou, un second écrou vissé contre le premier assurant un contre blocage pour s'opposer à tout desserrage du premier écrou. Deux dispositifs identiques sont ainsi montés sur les facettes et les bords correspondants de l'arc postérieur de la vertèbre.

On obtient ainsi une fixation qui, quoique de volume relativement réduit, reste encore assez encombrante par la saillie en arrière de l'arc postérieur constituée par les deux écrous, le crochet et le ressort. Ces parties saillantes se traduisent par des proéminences gênantes sous la peau au niveau des épineuses. Ces proéminences sont accentuées par le fait que le corps du crochet est positionné en appui sur l'arc postérieur relativement près de l'épineuse.

Un second inconvénient de ce type d'implant provient du fait que la compression du ressort n'est pas maîtrisée par le chirurgien, ce qui signifie que celui-ci peut comprimer trop ou pas assez ce ressort. Dans tous les

cas, le ressort applique une charge axialement sur le crochet, qui presse les deux parties fracturées l'une contre l'autre. Lorsque la soudure de ces deux parties est terminée, le crochet ne peut plus être déplacé par la poussée du ressort et est donc bloqué. Par contre le ressort reste toujours comprimé et applique donc sa charge sur les écrous, ce qui à la longue provoque un arrachement de la vis de l'os de la facette, dû à une poussée axiale du dit ressort sur la vis de sorte que la vis recule. En fait la vis recule alors de deux façons, d'une part sous l'effet du ressort, et aussi parce qu'elle est libre en rotation, ce mouvement de rotation étant provoqué par les vibrations dans le corps du patient au cours de son activité. La vis tend alors à sortir plus ou moins complètement de la facette de la vertèbre, de sorte que la fracture du patient est ressoudée, mais avec une vis qui n'est plus maintenue en place et va donc se déplacer de la distance nécessaire à la décharge du ressort. Il peut en résulter une saillie importante au niveau de la peau du patient, qui nécessite une seconde intervention chirurgicale pour enlever l'implant.

La vis peut du reste également reculer alors que la soudure des deux bords de la fracture n'est pas terminée, en fonction de la résistance plus ou moins grande des vis à l'arrachement.

Pour réduire ce risque, le chirurgien impose au patient de ne pas s'asseoir pendant 3 mois ce qui nécessite un lit médical surélevé et une rehausse de toilette à domicile tout en portant un corset. Chez l'enfant ce type d'intervention se révèle assez satisfaisant, mais par contre de nombreux échecs sont rencontrés chez les adultes en raison des efforts appliqués.

Un autre inconvénient de cette technique connue

réside dans le fait que le chirurgien est obligé de tailler l'arc postérieur pour offrir une surface d'appui suffisante au crochet, à l'emplacement prévu pour celui-ci. En effet, à cet endroit, et à défaut d'une entaille appropriée , l'arc postérieur n'offrirait pratiquement qu'une zone d'appui limitée à un angle du crochet.

Enfin une autre technique connue dite "CD" (Cotrel-Dubousset), consiste à reconstruire l'isthmus par une vis insérée dans le pédicule et un crochet positionné sur la lame de l'arc postérieur, la vis et le crochet étant reliés par une tige. Ce montage est très stable, mais présente l'inconvénient d'être relativement volumineux, compliqué et onéreux.

L'invention a donc pour but de proposer un implant agencé de manière à éviter les inconvénients des différentes réalisations ci-dessus, notamment ayant un encombrement postérieur réduit.

Conformément à l'invention, l'implant pour le traitement chirurgical d'une fracture isthmique vertébrale comprend :

- un premier sous-ensemble et un second sous-ensemble comportant chacun un élément adapté pour être fixé à une partie antérieure de la vertèbre fracturée d'un côté d'une épineuse de cette vertèbre, et un organe adapté pour être fixé à une partie postérieure de la vertèbre, cet organe étant associé à l'élément précité, et les deux sous-ensembles étant orientés suivant des axes divergents de part et d'autre de l'épineuse,

- un organe de liaison entre lesdits premier et second sous-ensembles, monté de manière à pouvoir rapprocher l'un de l'autre ledit élément et ledit organe de chaque sous-ensemble,

- et chaque sous-ensemble est pourvu de moyens de

retenue aptes à éviter la dissociation desdits éléments et desdits organes adaptés pour être fixés à une partie postérieure de la vertèbre.

Selon un mode de réalisation de l'invention, l'organe de liaison est élastique, et agencé pour développer sur lesdits éléments des forces de distraction dirigées suivant les directions axiales des éléments et qui tendent à appliquer contre le bord d'un arc postérieur lesdits organes fixés à ladite partie postérieure de la vertèbre.

Suivant un mode de réalisation préféré lesdits éléments destinés à être fixés à la partie antérieure de la vertèbre sont des vis adaptées pour être vissées dans les facettes vertébrales, lesdits organes destinés à être fixés à une partie postérieure de la vertèbre sont des crochets monopièce comprenant chacun un corps et une lame, le corps étant percé d'un alésage de passage de la vis associée, et l'alésage du corps des crochets a un axe longitudinal qui forme avec un plan longitudinal médian de la lame un angle approprié pour permettre un appui convenable de la lame du crochet sur un bord correspondant de l'arc postérieur de la vertèbre.

Le fait de décaler angulairement l'axe longitudinal de la vis par rapport au plan longitudinal médian de la lame du crochet permet d'écarter de l'épineuse la zone d'appui de cette lame sur l'arc postérieur. Compte tenu de l'anatomie de l'arc postérieur du patient on obtient ainsi une surface d'appui convenable pour la lame du crochet sans devoir entailler l'arc postérieur, ou, le cas échéant, en l'entaillant très légèrement, ce qui constitue un avantage important par rapport à une des réalisations connues rappelées ci-dessus.

Par ailleurs, le fait de prévoir une liaison élastique entre les deux vis par un organe de liaison

agissant en distraction permet avantageusement, compte tenu en outre du fait que les deux vis sont orientées dans des directions divergentes, d'appliquer sur chaque crochet, par les extrémités de cet organe de liaison comprimé, des forces axiales aux vis et dirigées vers les facettes supérieures de la vertèbre. Ces forces maintiennent fermement les lames des crochets appliquées sur l'arc postérieur.

Suivant un mode de réalisation de l'invention, l'organe de liaison élastique a une forme sensiblement en double oméga ou en M à sommets arrondis, reliés par un raccord central arrondi autorisant le logement de l'épineuse d'une vertèbre supérieure adjacente, et les extrémités de cet organe de liaison sont constituées par des embouts ayant un profil complémentaire de celui de la partie correspondante de chaque vis.

Ainsi le profil de cet organe de liaison formant une lame élastique, lui permet de venir s'insérer entre les épineuses de deux vertèbres successives sans les toucher. D'autre part, ces embouts terminaux s'opposent à toute rotation des vis autour de leur axe, donc à tout recul de ces vis par rotation, grâce au profil conjugué des embouts et des zones d'appui correspondante des vis.

D'autres particularités et avantages de l'invention apparaîtront au cours de la description qui va suivre, faite en référence aux dessins annexés qui en illustrent une forme de réalisation à titre d'exemple non limitatif.

La figure 1 est une vue en perspective à échelle agrandie d'une vertèbre équipée d'une forme de réalisation de l'implant pour le traitement chirurgical d'une fracture isthmique de cette vertèbre.

La figure 2 est une vue en perspective éclatée à

échelle agrandie de l'implant de la Fig.1.

La figure 3 est une vue en perspective à échelle agrandie de l'implant des Fig.1 et 2 à l'état assemblé.

La figure 4 est une vue de dessus à échelle agrandie de la vis et du crochet de l'implant des Fig.1 à 3.

Les figures 5, 6 et 7 sont des vues en élévation latérale de trois autres modes de réalisation possible des éléments d'ancrage de l'implant dans les facettes vertébrales.

La figure 8 est une vue en perspective d'un second mode de réalisation des crochets.

La figure 9 est une vue en perspective d'un second mode de réalisation possible de l'organe de liaison entre les éléments d'ancrage de l'implant.

La figure 10 est une vue en perspective éclatée d'un troisième mode de réalisation possible de l'organe de liaison précité.

La figure 11 est une vue mi-coupe mi-élévation longitudinale d'un quatrième mode de réalisation de l'organe de liaison.

La figure 12 est une vue en perspective d'un cinquième mode de réalisation possible de l'organe de liaison entre les éléments d'ancrage de l'implant.

La figure 13 est une vue en perspective d'un second mode de réalisation possible des moyens de blocage de l'organe de liaison et des crochets sur les éléments d'ancrage.

L'implant est adapté, après une greffe osseuse d'une fracture isthmique F (Fig.1) d'une vertèbre, par exemple L5, pour le traitement chirurgical de cette fracture isthmique, sans devoir prendre appui sur des vertèbres adjacentes non endommagées. La fracture F

s'étend sur les isthmes de chaque côté de l'épineuse 4.

L'implant 1 représenté aux Fig.1 à 4 comprend :

a) une paire de vis 2 destinées à être vissées chacune dans une facette supérieure vertébrale 3 de manière à peu près symétrique de chaque côté de l'épineuse 4 et suivant des axes divergents,

b) deux crochets 5 constitués monopièce chacun d'un corps 6 et d'une lame 7, le corps 6 étant percé d'un alésage cylindrique 7 lisse de passage de la vis 2. L'axe longitudinal XX de cette dernière forme avec un plan longitudinal médian P de la lame 7 un angle A approprié pour permettre un appui convenable de la lame 7 de chaque crochet 5 sur un bord correspondant 8 de l'arc postérieur 9 de la vertèbre;

c) un organe de liaison élastique 11 entre les deux vis 2, agissant en distraction,

d) et des moyens de blocage de l'organe de liaison 11 et des crochets 5 sur les vis 2, constitués dans l'exemple représenté par des écrous 23.

Le corps 6 du crochet 5 est décalé vers l'avant par rapport à la lame 7 c'est-à-dire vers la facette 3. En d'autres termes, la lame 7 est constituée d'une branche rectiligne 7a et d'une partie incurvée 7b, la branche rectiligne reliant la partie incurvée 7b au corps 6.

L'organe de liaison 11 a une forme sensiblement en double oméga ou en M à sommets 11a arrondis reliés par un raccord central arrondi 11b définissant une ondulation avec les sommets arrondis 11a. La forme arrondie du raccord central 11b à l'opposé des sommets 11a permet à une épineuse d'une vertèbre contiguë de venir se loger à l'intérieur de la boucle définie par le sommet arrondi 11b sans toucher celui-ci. L'organe de liaison 11 peut ainsi être inséré entre deux épineuses contiguës sans les toucher.

L'organe de liaison est de préférence constitué par une lame métallique élastique dont les extrémités sont constituées par des embouts 12 ayant un profil complémentaire de celui de la partie correspondante de chaque vis 2. Par rapport au plan général du reste du ressort 11 les embouts 12 sont vrillés de façon à s'étendre, lorsque le ressort 11 est au repos, dans des plans décalés angulairement dudit plan général. Ce décalage angulaire est avantageusement réalisé dans un sens tel que, après montage du ressort 11, les embouts 12 exercent une poussée élastique sur les crochets 5. De préférence ce décalage est de 17 degrés, donc égal à un angle A qui sera défini ci-après en référence à la Fig.4.

Chaque embout 2 peut avantageusement présenter un profil polygonal 13, par exemple partiellement hexagonal, dont les méplats peuvent venir s'appliquer sur un tronçon 14 à profil polygonal conjugué du profil 13, donc par exemple hexagonal et présentant ainsi une succession de six méplats longitudinaux 15.

De ce fait les profils 13 des embouts terminaux 12 peuvent venir s'appliquer dans la position angulaire choisie sur les méplats 15 correspondants, et dans la position axiale recherchée compte tenu de la longueur du tronçon 14.

Le tronçon polygonal 14 de chaque vis 2 est prolongé d'un côté par une zone 16 à filets spongieux 17 et âme conique 18 de raccordement avec le tronçon 14. La partie filetée 17, de moindre diamètre par conséquent que la partie conique 18, se termine par un téton arrondi 19. La zone filetée 16 est destinée à pénétrer dans la facette supérieure 3 associée à l'ensemble constitué par la vis 2 et son crochet support 5 (Fig.1).

Du côté opposé à la zone filetée 16, le tronçon 14

se prolonge par une partie filetée métrique 21 sur laquelle, à partir de son extrémité, est formé au moins un méplat longitudinal 22. Dans l'exemple représenté la partie filetée 21 comporte deux méplats 22 symétriques par rapport à l'axe longitudinal de la vis, et qui interrompent donc le filet de la zone 21.

Chaque corps 6, dont la surface externe peut être partiellement cylindrique et partiellement plane sur ses côtés comme représenté, peut être enfilé d'abord sur la partie filetée 21 puis sur le tronçon lisse 14. Les écrous 23 peuvent être vissés chacun sur la partie filetée 21 correspondante. Ces écrous assurent le blocage des crochets 5 et de leur lame sur les zones choisies 8 des bords de l'arc postérieur 9, ainsi que le blocage des embouts 12 dans leur position représentée à la Fig.3, où ils coiffent partiellement les tronçons 14 respectifs et sont interposés entre les corps 6 et des rondelles 23a solidaires des écrous 23.

Les écrous de blocage 23 sont complétés par un dispositif anti-recul de ces écrous sur les tiges 2, constitué dans l'exemple illustré aux dessins par la combinaison d'une collerette cylindrique 24 lisse monopièce avec l'écrou correspondant 23, et du ou des méplats terminaux 22. En effet, l'implant étant posé sur la vertèbre L5 comme illustré aux Fig.1 et 3, après vissage des écrous 23 par le chirurgien sur les extrémités saillantes filetées 21 des tiges 2, chaque collerette 24 peut être déformée au moyen d'une pince appropriée pour venir s'écraser ou se plaquer sur le ou les méplats 22. Ainsi les collerettes écrasées 24 empêchent toute rotation ultérieure des vis 2 autour de leur axe, donc tout recul et tout arrachement de ces vis des facettes 3.

Le décalage angulaire A (Fig.4) est orienté dans

le sens qui écarte la zone d'appui des lames incurvées 7 de l'épineuse centrale 4, par rapport à la zone d'appui que ces lames auraient si le plan général P contenait l'axe XX des vis 2. A titre d'exemple numérique non limitatif, l'angle A peut être avantageusement de 17 degrés environ.

Pour procéder à la pose de l'implant qui vient d'être décrit, le chirurgien agit de la manière suivante:

a) il pratique une résection du tiers ou de la moitié inférieure de l'articulaire inférieure de la vertèbre sus-jacente à la facette supérieure 3 de la vertèbre fracturée, par exemple articulaire inférieure L_4 pour fracture isthmique de L_5.

b) il fixe chaque vis 2 sur la dite facette 3 après avoir pratiqué un trou de passage dans celle-ci au moyen d'un foret et d'un taraud, puis il enfile sur cette vis le corps 6 de chaque crochet 5 jusqu'à ce que la lame 7 de ce dernier soit en appui sur l'arc postérieur 9 à l'emplacement convenable, offrant une zone d'appui satisfaisante, compte tenu du décalage angulaire A entre l'axe XX et le plan longitudinal médian P. Cet appui peut être assuré soit sans pratiquer aucune entaille sur le bord visé 8, soit en y effectuant une très légère entaille ;

c) le chirurgien monte l'organe de liaison élastique 11 en rapprochant l'un de l'autre les embouts 12 pour mettre l'organe 11 en distraction, et coiffe les tronçons 14 par les embouts 12. Les méplats des profils 13 viennent s'appliquer sur des méplats correspondants 15 dans la position angulaire choisie, en réalisant un appui stable et solide des extrémités 12 de l'organe 11 sur les vis 2. Après sa mise en place, l'organe de liaison 11 est donc contraint en compression et exerce sur les corps 6, donc aussi sur les lames 7, des forces de distraction qui,

compte tenu de l'orientation divergente des vis 2, ont des composantes coaxiales aux vis 2 et qui tendent à maintenir fermement les lames 7 appliquées contre les bords 8 de l'arc 9, donc les deux parties fracturées l'une contre l'autre.

d) Le chirurgien visse les écrous 23 sur les parties filetées 21 afin de bloquer en place l'organe de liaison 11 et les crochets 5,

e) et enfin le chirurgien pince les collerettes 24 au moyen d'un outil approprié, afin de les écraser sur les méplats 22 et ainsi empêcher tout recul des écrous 23 par desserrage.

Outre les avantages techniques déjà mentionnés, l'invention présente les suivants :

a) Le décalage angulaire A supprime la nécessité de tailler l'arc postérieur 9.

b) Le fait que le corps 6 du crochet 5 soit décalé vers l'avant par rapport à sa lame incurvée 7, c'est-à-dire vers la facette 3, de telle sorte que sa branche 7a sensiblement rectiligne prolonge jusqu'au corps 6 la partie incurvée 7b de la lame 7, réduit l'encombrement de l'implant derrière l'arc postérieur 9 par rapport à celui des implants antérieurs décrits connus. En effet la saillie postérieure par rapport aux bords 8 de l'arc postérieur 9 est alors notablement diminuée, ainsi que la saillie sous la peau du patient.

c) Les vis 2 ne peuvent plus se dévisser et donc s'arracher des facettes 3. En effet les collerettes 24 s'opposent à toute rotation des vis 2 autour de leur axe, donc à tout recul de ces vis. De plus il a été exposé ci-dessus que les embouts 12 exercent sur les vis 2 des forces de distraction dont les composantes axiales aux vis sont dirigées vers les facettes 3 et maintiennent donc les

lames 7 fermement appliquées sur l'arc postérieur 9. Du fait que les écrous 23 ne peuvent se desserrer, les composantes axiales des forces de distraction précitées contribuent également à maintenir les vis 3 dans les trous correspondants des facettes 3, donc à s'opposer à leur recul par rotation.

d) Le fait de munir chaque vis 2 d'une zone 16 à filetage spongieux et à âme conique 18 permet d'assurer aux filets 17 une prise sur l'os largement supérieure à un filet habituel; de plus après percement des facettes (zone corticale, os spongieux puis nouvelle zone corticale) le trou de passage de la vis 2 a été légèrement agrandi, et le cône 18, en pénétrant dans ce trou, permet de bien appliquer la vis 2 contre les parois du trou et donc évite ainsi toute apparition de jeu. De ce fait la vis 2 est fermement bloquée sur l'os de la facette 3. Cette suppression de tout jeu résulte de la compression de la paroi osseuse du trou, grâce à l'âme conique 18, qui réduit la profondeur des filets par rapport à celle de la zone des filets 17.

e) Par rapport aux réalisations antérieures connues, l'encombrement derrière les lames ou bords 8 de l'arc postérieur 9 est encore réduit grâce à la mise en oeuvre des collerettes 24 anti-recul. En effet celles-ci sont moins encombrantes que des contre-écrous, le gain de longueur étant d'environ 1/2 écrou. Ainsi, dans la mesure où le chirurgien effectue un choix judicieux de la longueur des vis 2, les extrémités arrière de celles-ci débordent très peu par rapport aux bords postérieurs de l'arc 9.

La très bonne tenue de la vis d'ancrage 2 est obtenue grâce à la forme du filetage dans l'os, le filet spongieux 17 ayant en effet la particularité de présenter

une surface d'appui maximum dans un volume minimum. La fin de filet dont le noyau 18 est conique assure une meilleure résistance de la vis à la flexion, car des efforts dans ce sens sont appliqués lors de la mise en position de l'organe de liaison élastique 11. Ces efforts sont développés par la réaction de l'effet ressort lors de la mise en compression de cette lame 11.

La liaison entre vis 2 et crochet 5 est effectuée de manière à laisser une liberté de translation et de rotation du crochet 5 sur la vis 2, permettant au crochet de se positionner dans les meilleures conditions sur l'arc postérieur. Cette liaison a aussi pour fonction, par l'intermédiaire de la lame ressort 11 ainsi que par le positionnement angulaire des deux vis 2, de créer une action du type ressort sur les crochets (effet amortisseur) permettant à ces derniers d'être toujours en action sur la greffe osseuse.

Les corps des vis 2 étant de forme hexagonale dans leur partie centrale 14, ainsi que les profils 13 de préhension de l'organe élastique 11, cet agencement autorise un mouvement de translation entre ces deux éléments et ainsi permet l'effet amortisseur précité.

Par contre, ces deux pièces 2 et 11 sont bloquées en rotation, ce qui évite le dévissage de la vis à os 2 dans son encastrement osseux.

On a représenté aux Fig.5 à 13 diverses variantes de réalisation possibles de certains éléments constitutifs de l'implant selon l'invention.

La Fig.5 montre ainsi un élément d'ancrage dans une facette vertébrale constitué par une cheville 25 complétée par une tige filetée 27.

La Fig.6 illustre une troisième possibilité dans laquelle l'élément d'ancrage est constitué par un crochet

28 prenant appui sur la facette 3 et complété par une tige filetée 29, et enfin

La Fig.7 montre une quatrième variante dans laquelle l'élément d'ancrage est formé par une vis 31 équipée d'un écrou 32 prenant appui derrière la facette vertébrale 3.

Ces modes de réalisation sont toutefois moins avantageux que les vis 2 illustrées aux Fig.1 à 4 car leur mise en place présente des difficultés. De plus le démontage d'une cheville 25 et d'un écrou 32 n'est pas possible.

La Fig.8 montre un crochet 33 dont la lame 34 a un profil en V ou U arrondi et dont le corps 35 est décalé vers l'extrémité libre de l'une 34a des branches 34a, 34b de la lame 34, à savoir vers l'avant c'est-à-dire vers la facette correspondante 3. Dans le corps 35 est percé un alésage 36 de passage de la tige de l'élément d'ancrage tel que 2. Le corps 35 s'étend dans le plan moyen général de la lame 34 et ne présente donc pas le décalage angulaire A décrit ci-dessus en référence à la Fig.4. Il est percé d'un trou latéral 37 pour le passage d'une vis de fixation de l'élément d'ancrage traversant l'alésage 36. Le décalage du corps 35 vers l'avant présente l'avantage de diminuer l'encombrement postérieur du crochet au niveau de l'arc vertébral. Toutefois l'absence de décalage angulaire entre le corps 35 et son alésage 36 et le plan général de la lame 34 rend ce crochet moins avantageux que le crochet 5 du premier mode de réalisation décrit.

La Fig.9 montre une première forme de réalisation possible de l'organe de liaison entre les éléments d'ancrage 2, 27, 29, 31. Cet organe est ici constitué par une barrette 38 dans les extrémités de laquelle sont ménagés deux trous 39, 41 dont l'un (41) est oblong. Ces trous

sont adaptés pour le passage des éléments d'ancrage respectifs, le trou oblong 4 permettant, avant blocage, un réglage de la position transversale de l'élément d'ancrage correspondant au moyen d'une pince de distraction. La barrette 38 assure donc une liaison monobloc. Elle est relativement difficile à mettre en place et ne produit aucune action de ressort, contrairement à l'organe de liaison 11 décrit en référence aux Fig.1 à 4.

Le troisième mode de réalisation possible de l'organe de liaison, représenté à la Fig.10, est constitué par la combinaison d'un ressort lame 42 sensiblement en forme de U arrondi et à extrémités 43 recourbées, et de deux ressorts spirales tels que 44. Ces derniers sont associés chacun à une extrémité 43 de telle sorte que l'élément d'ancrage respectif puisse traverser l'extrémité recourbée 43 et le ressort spirale associé 44, lequel après blocage de l'ensemble est comprimé et exerce une poussée élastique sur le crochet 5 (ou 33). Cette variante de réalisation présente toutefois l'inconvénient d'être relativement encombrante en direction postérieure.

La Fig.11 illustre une troisième forme de réalisation possible dans laquelle l'organe de liaison est constitué par un cylindre 45 contenant un piston 46 pouvant coulisser à l'intérieur du cylindre 45, dans lequel est logé un ressort 47 qui sollicite élastiquement le piston 46 vers l'extérieur du cylindre 45. Sur les extrémités de ces derniers sont articulées des bagues respectives 48, pouvant être enfilées sur les éléments d'ancrage de l'implant et tournées d'un angle approprié, de préférence de 17° comme l'angle A. La liaison produite par ce dispositif est donc élastique grâce à la compression du ressort 47. Toutefois ce dispositif est d'une réalisation relativement complexe.

La Fig.12 illustre une cinquième forme de réalisation de l'organe de liaison ici constitué par un ressort 49 sensiblement en arc de cercle, dont les extrémités sont profilées pour constituer des embouts 51 complémentaires des parties correspondantes des éléments d'ancrage. Les embouts 51 sont avantageusement décalés angulairement du plan général du reste du ressort 49 lorsque ce dernier est au repos. Ce décalage angulaire est choisi dans un sens tel que, après montage du ressort 49 sur les éléments d'ancrage, les embouts 51 exercent une poussée élastique sur les crochets. De préférence, le décalage angulaire des embouts 51 est égal à l'angle A (Fig.4).

La Fig. 13 montre une seconde forme de réalisation possible des moyens de blocage de l'organe de liaison (11, 38...) : ces moyens sont ici constitués par des rondelles 52 dont les ouvertures centrales délimitent des pattes radiales flexibles 53, séparées par des oeillets 54. Les pattes radiales 53 sont dimensionnées de façon à définir entre elles un diamètre légèrement inférieur à celui de l'élément d'ancrage tel que 27 ou 29, de façon à pouvoir être enfilées par friction sur ces éléments d'ancrage et ensuite à interdire tout retour en arrière des rondelles 52. Ces dernières doivent être réalisées en un matériau biocompatible et qui ait une élasticité suffisante pour assurer un fonctionnement fiable, tel que l'acier inoxydable.

Il convient encore d'ajouter que le fait que les embouts 12 ou 51 de l'organe de liaison élastique 11, 59 soient vrillés, de préférence de 17 degrés par rapport au plan général du reste de cet organe, assure un excellent appui de ces embouts sur l'arrière des crochets 5 et permet un coulissement aisé sur les vis 2.

L'implant selon l'invention présente l'avantage

important qu'aucun effet de traction n'est exercé sur les éléments d'ancrage tels que les vis 2.

REVENDICATIONS

1. Implant (1) pour le traitement chirurgical d'une fracture isthmique vertébrale (F), caractérisé en ce qu'il comprend :

- un premier sous-ensemble et un second sous-ensemble comportant chacun un élément (2) adapté pour être fixé à une partie antérieure de la vertèbre fracturée d'un côté d'une épineuse (4) de cette vertèbre, et un organe (5) adapté pour être fixé à une partie postérieure de la vertèbre, cet organe étant asscié à l'élément précité, et les deux sous-ensembles étant orientés suivant des axes divergents de part et d'autre de l'épineuse,

- un organe (11) de liaison entre lesdits premier et second sous-ensembles, monté de manière à pouvoir rapprocher l'un de l'autre ledit élément et ledit organe de chaque sous-ensemble,

- et chaque sous-ensemble est pourvu de moyens de retenue (23) aptes à éviter la dissociation desdits éléments et desdits organes adaptés pour être fixés à une partie postérieure de la vertèbre.

2. Implant selon la revendication 1, caractérisé en ce que l'organe (11) de liaison est élastique, et agencé pour développer sur lesdits éléments (2) des forces de distraction ayant des composantes dirigées suivant les directions axiales des éléments et qui tendent à appliquer contre le bord d'un arc postérieur de la vertèbre lesdits organes (5) fixés à ladite partie postérieure de la vertèbre.

3. Implant selon la revendication 2, caractérisé en ce que lesdits éléments destinés à être fixés à la partie antérieure de la vertèbre sont des vis (2) adaptées pour être vissées dans les facettes vertébrales, en ce que lesdits organes (5) destinés à être fixés à une partie

postérieure de la vertèbre sont des crochets monopièce comprenant chacun un corps (6) et une lame (7), le corps étant percé d'un alésage (10) de passage de la vis associée, et l'alésage (10) du corps (6) des crochets (5) a un axe longitudinal (XX) qui forme avec un plan longitudinal médian (P) de la lame (7) un angle (A) approprié pour permettre un appui convenable de la lame du crochet sur un bord (8) correspondant de l'arc postérieur (9) de la vertèbre (L5).

4. Implant selon la revendication 3, caractérisé en ce que chaque crochet (5) a une forme en U ou en V avec une branche (7a) plus longue que l'autre (7b) et qui porte le corps (6) au voisinage de son extrémité libre.

5. Implant selon la revendication 4, caractérisé en ce que l'organe de liaison élastique (11) a une forme sensiblement en double oméga ou en M à sommets arrondis (11a) reliés par un raccord central arrondi (11b) autorisant le logement de l'épineuse d'une vertèbre supérieure adjacente, et les extrémités de cet organe de liaison sont constituées par des embouts (12) ayant un profil (13) complémentaire de celui de la partie correspondante (14) de chaque vis (2).

6. Implant selon la revendication 5, caractérisé en ce que, lorsque le ressort (11) est au repos, les embouts (12) s'étendent dans des plans décalés angulairement du plan général du reste du ressort, et ce décalage angulaire est réalisé dans un sens tel que, après montage du ressort sur les éléments d'ancrage (21), les embouts exercent une poussée élastique sur les crochets (5).

7. Implant selon la revendication 3, caractérisé en ce que ladite partie (14) des vis (2) recevant les embouts terminaux (12) dudit organe de liaison (11) a une section polygonale et constitue un tronçon conjugué d'un

profil polygonal interne (13) de chaque embout, lequel empêche ainsi toute rotation de la vis autour de son axe (XX).

8. Implant selon la revendication 7, caractérisé en ce que le tronçon polygonal (14) est prolongé d'un côté par une zone (16) à filet spongieux (17) et âme conique (18) destinée à pénétrer dans la facette associée (3) de la vertèbre (L5...), et du côté opposé par une partie filetée (21), et en ce que lesdits moyens de blocage de l'organe de liaison (11) comprennent des écrous (23) vissés chacun sur ladite partie filetée (21) afin de bloquer les embouts (12) de l'organe de liaison entre les corps (6) des crochets (5) et ces écrous.

9. Implant selon la revendication 5, caractérisé en ce que lesdits moyens (23) de blocage sont complétés par un dispositif anti-recul des écrous (23) sur les tiges (2).

10. Implant selon la revendication 7, caractérisé en ce que le dispositif anti-recul est constitué par la combinaison d'une collerette (24) monopièce avec chaque écrou (23) et d'au moins un méplat longitudinal (22) formé sur ladite partie filetée (21) de chaque tige (2), la collerette pouvant être déformée après vissage de l'écrou afin de venir se plaquer sur le méplat.

11. Implant selon la revendication 3, caractérisé en ce que l'angle (A) entre l'axe longitudinal (XX) de chaque vis (2) et le plan médian (P) de la lame (7) du crochet (5) est d'environ 17 degrés.

12. Implant selon la revendication 2, caractérisé en ce que les éléments de fixation dans les facettes vertébrales (3) sont des chevilles (25), équipées de vis (27) ou des crochets (28), prolongés par des vis (29), ou des systèmes vis-écrous (31, 32).

13. Implant selon la revendication 2, caractérisé en ce que les éléments de fixation à ladite partie postérieure sont des crochets (33) ayant un profil en U ou en V avec un corps (35) décalé vers l'extrémité de l'une (34a) des branches (34a, 35b) du U ou du V.

14. Implant selon la revendication 1, caractérisé en ce que l'organe de liaison est une barrette (38) dans les extrémités de laquelle sont ménagés deux trous (39, 41) dont l'un (41) est oblong, adaptés pour le passage des éléments de fixation respectifs, le trou oblong permettant un réglage de la position transversale de l'élément de fixation correspondant (2, 27, 29...).

15. Implant selon la revendication 1, caractérisé en ce que l'organe de liaison est formé par la combinaison d'un ressort lame (42) sensiblement en U et à extrémités recourbées (43) et de deux ressorts spirales (44) associés chacun à une extrémité recourbée de telle sorte que cette dernière et le ressort spirale correspondants puissent être traversés par l'élément de fixation respectif (2...) avec production d'une poussée élastique sur le crochet (5) par le ressort spirale comprimé.

16. Implant selon la revendication 1, caractérisé en ce que l'organe de liaison comporte un cylindre (45) contenant un piston (46) sollicité élastiquement vers l'extérieur du cylindre par un ressort (47) logé dans ce dernier, des bagues (48) étant articulées aux extrémités du cylindre et du piston.

17. Implant selon la revendication 3, caractérisé en ce que l'organe de liaison est un ressort (49) sensiblement en arc de cercle dont les extrémités (51) sont profilées pour être complémentaires des parties correspondantes desdits éléments de fixation (2...), et forment des embouts situés, lorsque le ressort est au repos, dans des

plans décalés angulairement du plan général du reste du ressort, ce décalage angulaire étant choisi dans un sens tel que, après montage du ressort sur les éléments d'ancrage, les embouts exercent une poussée élastique sur les crochets (5).

18. Implant selon la revendication 3, caractérisé en ce que lesdits moyens de butée de l'organe de liaison (11,...) et des crochets (5) sur les éléments de fixation (2) sont des rondelles (52) dont les ouvertures centrales délimitent des pattes radiales flexibles (53) de friction et de retenue des rondelles sur lesdits éléments de fixation.

19. Procédé de pose d'un implant (1) selon l'une des revendications 3 à 17, selon lequel :

a) on pratique une résection du tiers ou de la moitié inférieure de l'articulaire inférieure de la vertèbre sus-jacente à la facette supérieure (3) de la vertèbre fracturée (L5),

b) on fixe l'élément de fixation (2) sur ladite facette, on enfile sur cet élément le corps (6) du crochet (5) jusqu'à ce que la lame (7) de ce dernier soit en appui sur l'arc postérieur (9) de la vertèbre,

c) on monte l'organe (11) de liaison sur les éléments d'ancrage,

d) on met en place les moyens de butée (23...) sur les éléments de fixation.

20. Procédé selon la revendication 18, dans lequel l'organe de liaison (11) est élastique et a une forme sensiblement en double oméga ou en M à sommets arrondis (11a) reliés par un raccord central arrondi (11b) autorisant le logement de l'épineuse d'une vertèbre supérieure adjacente, et les extrémités de cet organe de liaison sont constituées par des embouts (12) ayant un profil (13)

complémentaire de celui de la partie correspondante (14) de chaque vis (2) constituant les éléments de fixation précités, et les moyens de butée comprennent des écrous (23) prolongés par des collerettes (24), procédé selon lequel :

a) on fixe la vis (2) sur ladite facette, on enfile sur cette vis le corps (6) du crochet (5) jusqu'à ce que la lame (7) de ce dernier soit en appui sur l'arc postérieur (9) de la vertèbre,

b) on monte l'organe (11) de liaison élastique en compression sur les vis en coiffant les parties correspondantes (14) des vis (2) par les embouts (12) dudit organe,

c) on visse les écrous (23) sur les parties filetées (21) des vis (2) afin de bloquer en place, l'organe de liaison et les crochets,

d) et on pince les collerettes (24) des écrous afin de les écraser sur les méplats (22) des vis afin d'empêcher tout recul des écrous par desserrage.

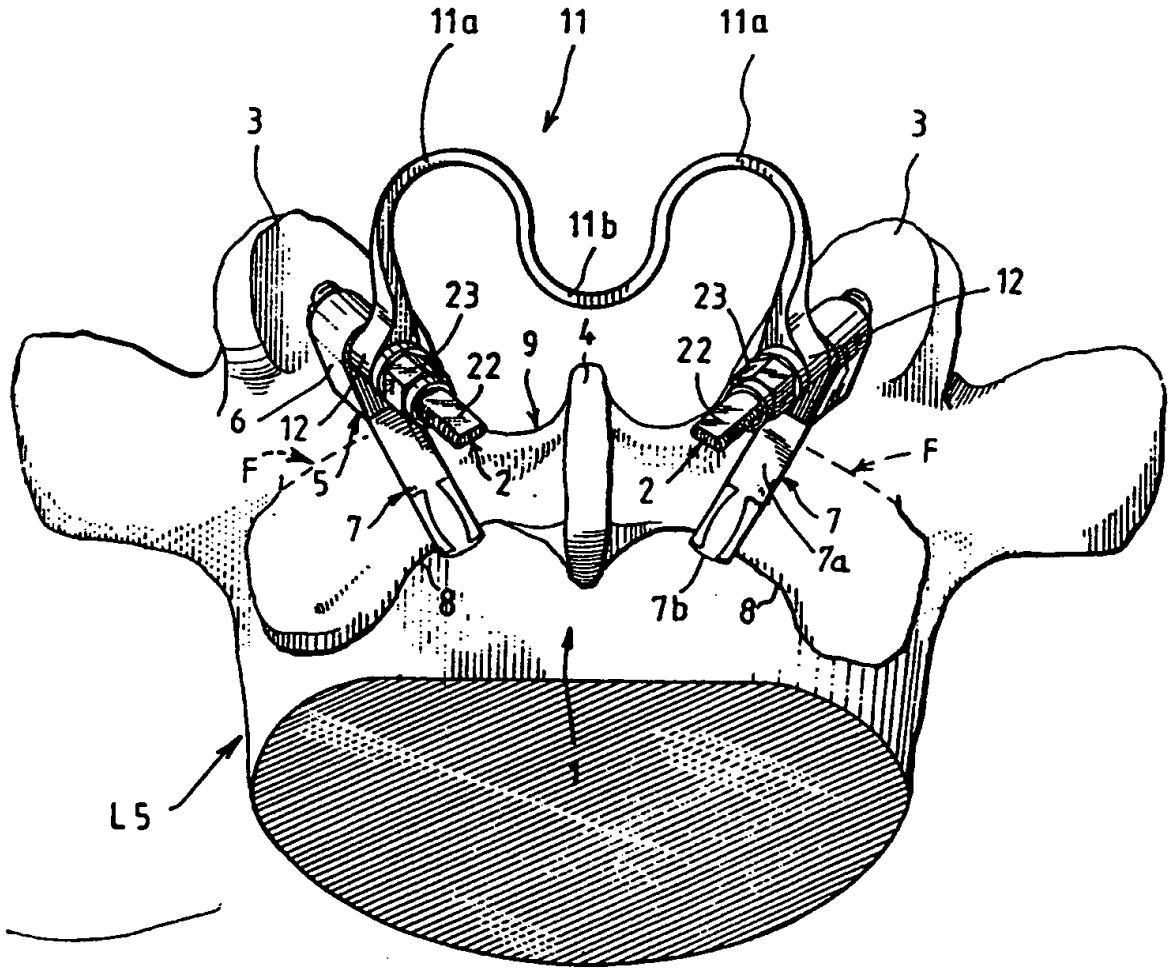
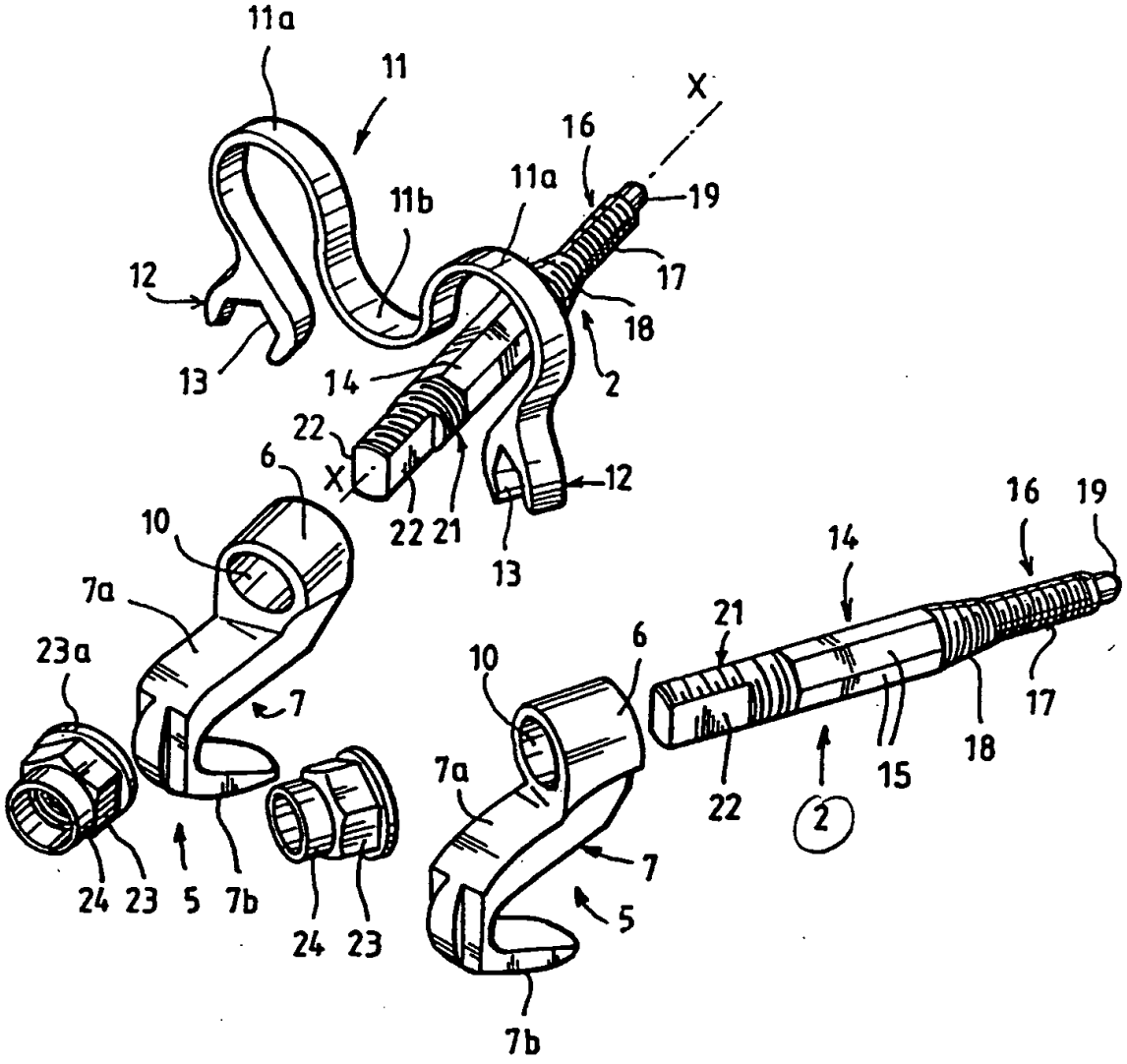


FIG.1


11a
11
X
16
19
11a
11b
17
12
18
13
14
2
22
X
6
12
22 21
13
10
7a
23a
7
24 23 5 7b
24 23
10
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7a
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7b
16 19
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22
2

FIG. 2

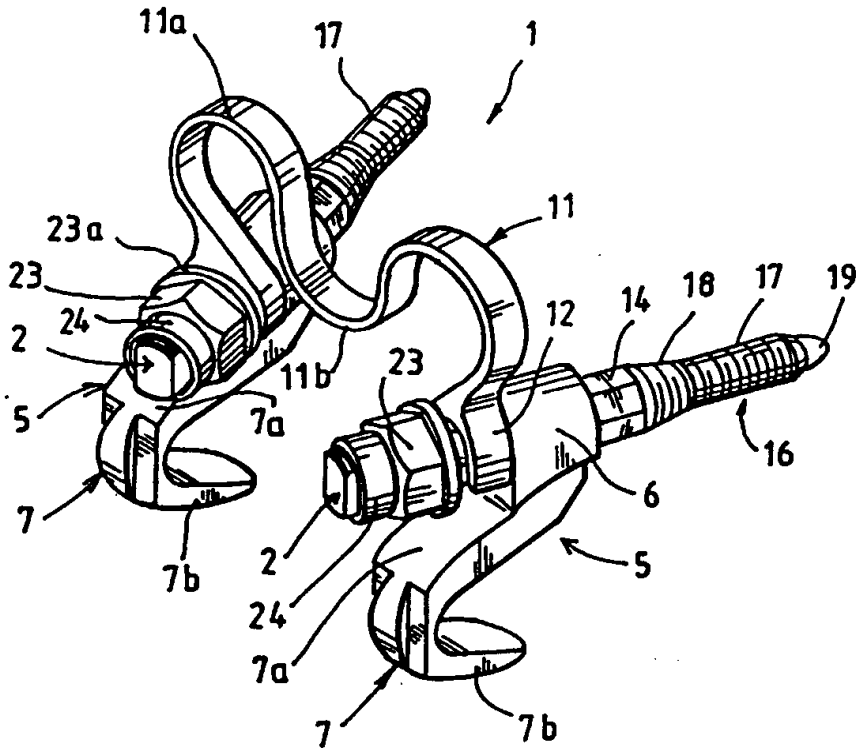

FIG.3

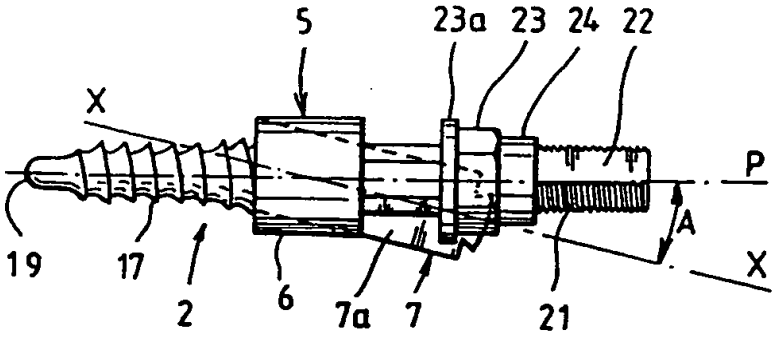

FIG. 4

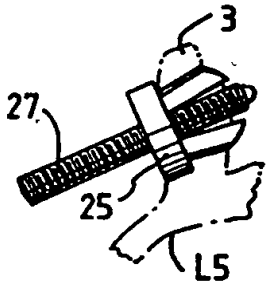

FIG. 5

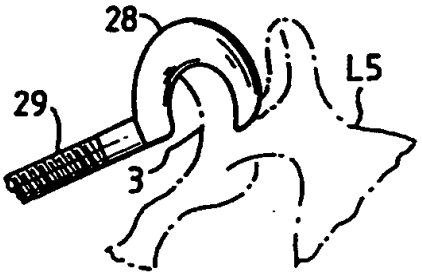

FIG. 6

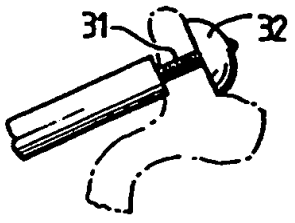

FIG. 7

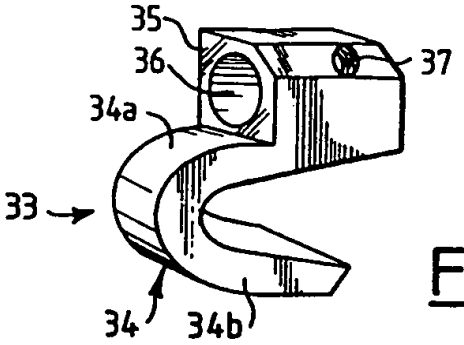

FIG. 8

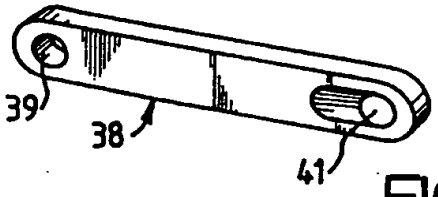

FIG. 9

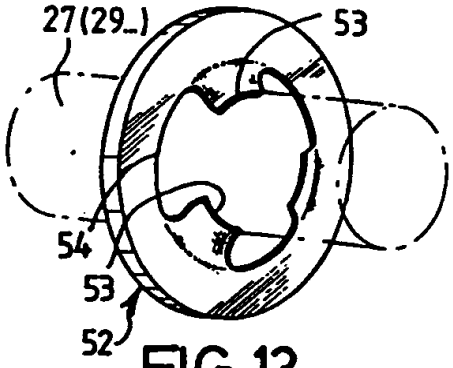

FIG. 13

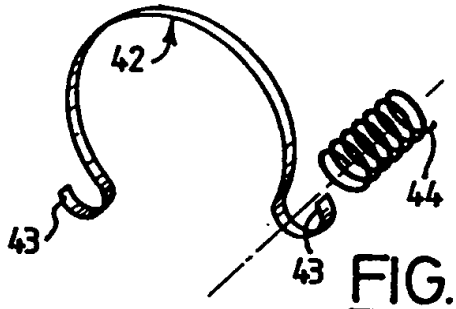

FIG. 10

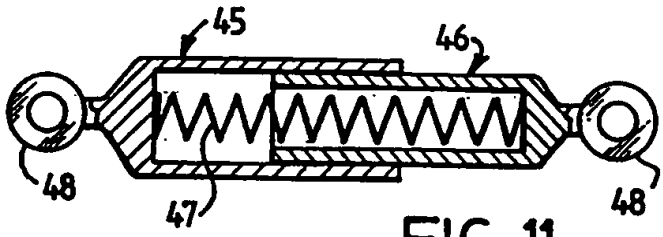

FIG. 11

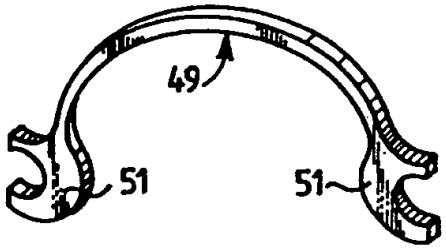

FIG. 12

INTERNATIONAL SEARCH REPORT

Internati Application No.
PCT/FR 96/00839

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/70

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)
IPC 6 A61B

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 352 225 (YUAN ET AL.) 4 October 1994 see column 2, line 63 - column 3, line 55; figures 1A-2C	1
A	EP,A,0 283 373 (SOFAMOR) 21 September 1988 see page 5, column 6-19; figure 10	1
A	DE,U,88 16 233 (DWORRAK ET AL.) 6 July 1989 see page 7, line 1-31; figures	1
A	WO,A,94 20048 (RAY) 15 September 1994 see abstract; figures	1
A	FR,A,2 697 428 (ALBY) 6 May 1994 see the whole document	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"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

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"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
9 September 1996	13.09.96
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer Giménez Burgos, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna[illegible] l Application No
PCT/FR 96/00839

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5352225	04-10-94	NONE		
EP-A-0283373	21-09-88	FR-A-	2612071	16-09-88
		AU-B-	599464	19-07-90
		AU-B-	1280088	15-09-88
		JP-A-	1076847	22-03-89
DE-U-8816233	06-07-89	NONE		
WO-A-9420048	15-09-94	US-A-	5470333	28-11-95
		AU-B-	6404494	26-09-94
		CN-A-	1121308	24-04-96
		EP-A-	0688198	27-12-95
		JP-T-	8507458	13-08-96
		US-A-	5531745	02-07-96
		US-A-	5531747	02-07-96
		ZA-A-	9404061	16-02-95
FR-A-2697428	06-05-94	NONE		

Form PCT/ISA/210 (patent family annex) (July 1992)

RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No
PCT/FR 96/00839

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 6 A61B17/70

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 6 A61B

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si cela est réalisable, termes de recherche utilisés)

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	US,A,5 352 225 (YUAN ET AL.) 4 Octobre 1994 voir colonne 2, ligne 63 - colonne 3, ligne 55; figures 1A-2C	1
A	EP,A,0 283 373 (SOFAMOR) 21 Septembre 1988 voir page 5, colonne 6-19; figure 10	1
A	DE,U,88 16 233 (DWORRAK ET AL.) 6 Juillet 1989 voir page 7, ligne 1-31; figures	1
A	WO,A,94 20048 (RAY) 15 Septembre 1994 voir abrégé; figures	1
A	FR,A,2 697 428 (ALBY) 6 Mai 1994 voir le document en entier	1

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Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
9 Septembre 1996	13.09.96

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
Office Européen des Brevets, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Giménez Burgos, R

Formulaire PCT/ISA/210 (deuxième feuille) (juillet 1992)

RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande internationale No PCT/FR 96/00839

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
US-A-5352225	04-10-94	AUCUN		
EP-A-0283373	21-09-88	FR-A-	2612071	16-09-88
		AU-B-	599464	19-07-90
		AU-B-	1280088	15-09-88
		JP-A-	1076847	22-03-89
DE-U-8816233	06-07-89	AUCUN		
WO-A-9420048	15-09-94	US-A-	5470333	28-11-95
		AU-B-	6404494	26-09-94
		CN-A-	1121308	24-04-96
		EP-A-	0688198	27-12-95
		JP-T-	8507458	13-08-96
		US-A-	5531745	02-07-96
		US-A-	5531747	02-07-96
		ZA-A-	9404061	16-02-95
FR-A-2697428	06-05-94	AUCUN		

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(51) Internationale Patentklassifikation 6 : A61B 17/80

A1

(11) Internationale Veröffentlichungsnummer: WO 97/20513

(43) Internationales Veröffentlichungsdatum: 12. Juni 1997 (12.06.97)

(21) Internationales Aktenzeichen: PCT/EP96/05355

(22) Internationales Anmeldedatum: 3. December 1996 (03.12.96)

(30) Prioritätsdaten:
195 45 612.2 7. December 1995 (07.12.95) DE

(71) Anmelder *(für alle Bestimmungsstaaten ausser US)*: AESCULAP AG [DE/DE]; Am Aesculap-Platz, D-78532 Tuttlingen (DE).

(72) Erfinder; und
(75) Erfinder/Anmelder *(nur für US)*: TADDIA, Lino [IT/DE]; Rosenstrasse 9, D-78573 Wurmlingen (DE). ZEPF, Rudolf [DE/DE]; Untere Hauptstrasse 14, D-78604 Rietheim-Weilheim (DE).

(74) Anwalt: BÖHME, Ulrich; Hoeger, Stellrecht & Partner, Uhlandstrasse 14 c, D-70182 Stuttgart (DE).

(81) Bestimmungsstaaten: US, europäisches Patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Veröffentlicht
Mit internationalem Recherchenbericht.
Vor Ablauf der für Änderungen der Ansprüche zugelassenen Frist. Veröffentlichung wird wiederholt falls Änderungen eintreffen.

(54) Title: ORTHOPAEDIC FIXING SYSTEM

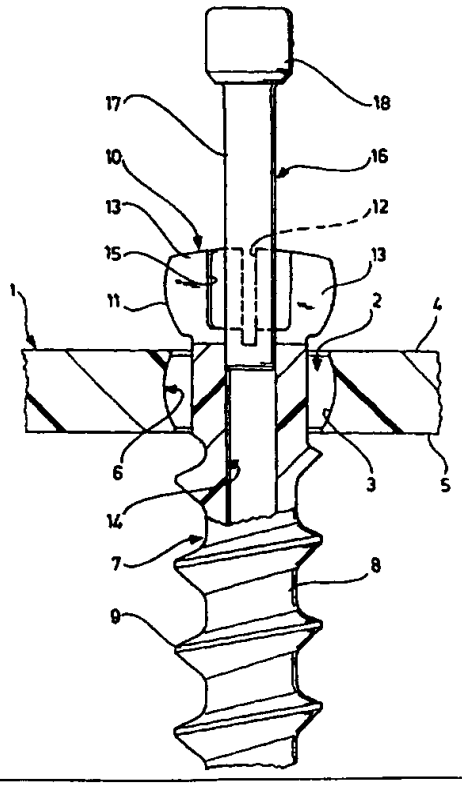
(54) Bezeichnung: ORTHOPÄDISCHES HALTESYSTEM

(57) Abstract

The invention concerns an orthopaedic fixing system with at least one implant part which comprises at least one through-opening, and with fixing elements which are inserted in the through-openings. The through-openings have widened portions which accommodate a head-shaped thickening on the fixing elements for securing the fixing elements in the axial direction in the implant part without hindering their rotatability. According to the invention, the head-shaped thickenings of the fixing elements can be compressed; the outer diameter of the widened portions is slightly smaller than the non-resiliently compressed head-shaped thickening; and the widened portions have undercuts in which the head-shaped thickening engages resiliently after insertion in the widened portion.

(57) Zusammenfassung

Um bei einem orthopädischen Haltesystem mit mindestens einem Implantatteil, das mindestens eine Durchstecköffnung aufweist, und mit Halteelementen, die in die Durchstecköffnungen eingesetzt werden, wobei die Durchstecköffnungen Erweiterungen aufweisen, die eine kopfförmige Verdickung der Halteelemente aufnehmen, die Halteelemente in dem Implantatteil in axialer Richtung festzulegen, ohne jedoch deren Verdrehbarkeit zu behindern, wird vorgeschlagen, daß die kopfförmigen Verdickungen der Halteelemente zusammendrückbar sind, daß die Erweiterungen einen Außendurchmesser aufweisen, der geringfügig kleiner ist als die nicht elastisch zusammengedrückte kopfförmige Verdickung, und daß die Erweiterungen Hinterschneidungen aufweisen, in die die kopfförmige Verdickung nach dem Einschieben in die Erweiterung elastisch eingreift.



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ORTHOPÄDISCHES HALTESYSTEM

Die Erfindung betrifft ein orthopädisches Haltesystem mit mindestens einem Implantatteil, das mindestens eine Durchstecköffnung aufweist, und mit stiftförmigen Halteelementen, die in die Durchstecköffnungen eingesetzt werden, wobei die Durchstecköffnungen Erweiterungen aufweisen, die eine elastisch zusammendrückbare kopfförmige Verdickung der Halteelemente aufnehmen, wobei die Erweiterungen einen Außendurchmesser aufweisen, der geringfügig kleiner ist als die nicht elastisch zusammengedrückte kopfförmige Verdickung, und wobei die Erweiterungen Hinterschneidungen aufweisen, in die die kopfförmige Verdickung nach dem Einschieben in die Erweiterung elastisch eingreift, und mit einem Sackloch im Bereich der kopfförmigen Verdickung des Halteelements, in das ein dieses ausfüllender Kern einschiebbar ist.

Derartige Haltesysteme werden zur Verbindung von Knochenfragmenten und zur Fixierung von Skeletteilen verwendet. Es kann sich dabei beispielsweise um Knochenplatten handeln, die mit Knochenschrauben in die Knochensubstanz eingeschraubt und dadurch gegen die Oberfläche des Knochens gedrückt und dort festgelegt werden. Es kann sich auch um Systeme aus mehreren Implantatteilen handeln, die untereinander verbunden werden müssen, beispielsweise verschiedene Knochenplatten oder Knochenplatten einerseits und Endoprothesen andererseits.

In der WO88/03781 ist eine osteosynthetische Vorrichtung beschrieben, bei welcher in eine Knochenplatte eine Knochenschraube elastisch eingerastet werden kann. Die Knochenplatte weist dazu eine Öffnung mit Hinterschneidungen auf, und der Kopf der Knochenschraube ist elastisch zusammendrückbar, so daß er elastisch in diese hinterschnittene Öffnung eingerastet werden kann. Nach dem Einschrauben der Knochenschraube in den Knochen wird die Knochenschraube bei dieser vorbekannten Konstruktion durch Einsetzen eines Verriegelungsstiftes so aufgeweitet, daß die Knochenschraube in der Durchstecköffnung der Knochenplatte im Klemmsitz gehalten wird, sie bildet also nach dem Einsetzen des Verriegelungsstiftes zusammen mit der Knochenplatte eine starre Einheit.

Es ist Aufgabe der Erfindung, ein gattungsgemäßes orthopädisches Haltesystem so auszubilden, daß eine Knochenschraube unverlierbar in der hinterschnittenen Durchstecköffnung der Platte festgelegt werden kann, wobei trotzdem die freie Verdrehbarkeit der Knochenschraube gegenüber der Platte erhalten bleibt.

Diese Aufgabe wird bei einem orthopädischen Haltesystem der eingangs beschriebenen Art erfindungsgemäß dadurch gelöst, daß der Kern so bemessen ist, daß er die kopfförmige Verdickung in seiner in das Sackloch eingeschobenen Stellung verriegelt ohne sie aufzuweiten.

Dieser einschiebbare Kern, der die Teile der kopfförmigen Verdickung nicht auseinanderdrückt, sondern nur das Sackloch ausfüllt, ohne es aufzuweiten, verhindert, daß

die elastisch verbiegbaren Teile der kopfförmigen Verdickung elastisch radial nach innen gebogen werden können, so daß allein das Einschieben dieses Kerns die kopfförmige Verdickung in der Erweiterung der Durchstecköffnung verriegelt, wenn die kopfförmige Verdikkung in die Hinterschneidung der Erweiterung eingreift. Da die kopfförmige Verdickung durch diesen Kern nicht aufgeweitet wird, bleibt die kopfförmige Verdickung frei drehbar in der Erweiterung, die Verriegelung erfolgt allein durch den Formschluß in axialer Richtung.

Diese freie Drehbarkeit der Verdickung in der Erweiterung führt dazu, daß bei Kombinationssystemen die Implantatteile eine gewisse Beweglichkeit gegenüber dem Knochensystem erhalten, obwohl die Halteelemente fest im Knochen oder an anderen Implantatteilen verankert sind. Dadurch wird bei Veränderungen, beispielsweise durch Knochenresorption, verhindert, daß die Implantatteile oder die Halteelemente durch eine ungewollte Krafteinwirkung brechen können.

Grundsätzlich können die Implantatteile die unterschiedlichste Form aufweisen. Beispielsweise kann es sich dabei um Knochenplatten handeln, die mit Hilfe eines Halteelements in Form einer Knochenschraube am Knochen durch Verschraubung gehalten sind und dadurch Knochenfragmente fixieren. Es können auch mehrere Implantatteile durch ein Halteelement unmittelbar miteinander verbunden werden, beispielsweise zwei Knochenplatten oder eine Knochenplatte einerseits und der Schaft einer Endoprothese andererseits.

Weiterhin versteht es sich, daß unter dem Begriff "Knochenplatte" nicht nur rein plattenförmige Bauteile verstanden werden, sondern auch anders geformte Implantate, die zur Festlegung und Stützung des Knochenapparates Verwendung finden. Ebenso umfaßt der Begriff "Knochenschraube" nicht nur im eigentlichen Sinne in Knochensubstanz einschraubbare Haltestifte, sondern stiftförmige Halteelemente mit kopfförmiger Verdickung allgemein, die die Knochenplatten durchsetzen. Diese könnten auch über eine aufgeschraubte Mutter oder andere Zugmittel am Knochenapparat festgelegt werden, sie müssen nicht unbedingt durch eigene Gewindegänge in der Knochensubstanz selbst verankert sein.

Bei einer bevorzugten Ausführungsform der Erfindung kann vorgesehen sein, daß die kopfförmige Verdickung durch mehrere elastisch radial nach innen biegbare Teile des Halteelements gebildet wird.

Dabei ist es vorteilhaft, wenn die elastisch nach innen biegbaren Teile durch radial verlaufende Einschnitte voneinander getrennte, einstückig mit dem Halteelement ausgebildete Abschnitte des Halteelements sind. Es genügt also grundsätzlich bereits, wenn ein Halteelement aus elastischem Material im Bereich der kopfförmigen Erweiterung einen oder mehrere radial verlaufende Einschnitte aufweist, die eine geringfügige Annäherung der Teile des Halteelements ermöglichen, um die geforderte Zusammendrückbarkeit zu realisieren.

Es kann vorgesehen sein, daß das Sackloch sich zum freien Ende des Halteelements hin stufig verengt. Dabei

kann sich das Sackloch bis in den Schaft des Halteelements erstrecken, wobei dann der Kern einen entsprechenden Verlängerungsstift trägt, der das Sackloch im wesentlichen vollständig ausfüllt.

Günstig ist es, wenn das Sackloch kreiszylindrisch ausgebildet ist.

Bei einer besonders bevorzugten Ausführungsform ist vorgesehen, daß die Erweiterung eine kugelringförmige Innenfläche und die kopfförmige Verdickung eine komplementäre kugelringförmige Außenfläche aufweisen, deren größter Durchmesser im Innern des Implantatteils im Abstand von dessen Außenfläche angeordnet ist.

Eine solche Ausgestaltung ermöglicht es, das Halteelement in der Erweiterung der Durchstecköffnung über einen bestimmten Winkelbereich zu verschwenken, so daß es schräg zum Implantatteil eingeschraubt werden kann. Trotzdem bleibt das Halteelement in dem Implantatteil gehalten. Dies gilt auch dann, wenn ein Kern in eine Sacklochbohrung eingesetzt ist, der das Halteelement gegen ein Herausziehen aus dem Implantatteil verriegelt. Eine freie Drehbarkeit um die Längsachse des Halteelements und um in der Ebene des Implantatteils liegende Drehachsen bleibt aber dabei voll erhalten.

Bei einer besonders bevorzugten Ausführungsform ist vorgesehen, daß das Halteelement eine Knochenschraube ist.

Bei einer abgewandelten Ausführungsform kann das Halteelement eine Schraube mit einem Maschinengewinde sein. Während sich die Knochenschraube zum Eindrehen in Knochensubstanz eignet, kann ein Halteelement mit einem Maschinengewinde verwendet werden, um zwei Implantatteile miteinander zu verbinden. Es ist dann günstig, wenn ein Implantatteil ein Innengewinde aufweist, in das das Halteelement eingeschraubt werden kann, während das andere Implantatteil in der beschriebenen Weise eine Durchstecköffnung mit einer hinterschnittenen Erweiterung für den Kopf des Halteelements aufweist. Beispielsweise können auf diese Weise zwei Knochenplatten miteinander verbunden werden. Es ist auch möglich, an einem Röhrenknochen den in diesen Knochen eingeführten Schaft einer Endoprothese mit einer außen am Knochen anliegenden Knochenplatte zu verbinden, wobei das Halteelement dann durch die Wand des Knochens hindurchtritt.

Die nachfolgende Beschreibung einer bevorzugten Ausführungsform der Erfindung dient im Zusammenhang mit der Zeichnung der näheren Erläuterung. Es zeigen:

Figur 1: eine seitliche Ansicht einer Knochenplatte und einer in einer Durchstecköffnung der Knochenplatte eingesetzten Knochenschraube mit Kern in einer Teilschnittdarstellung vor dem Eindrücken der Knochenschraube in die Durchstecköffnung;

Figur 2: eine Ansicht ähnlich Figur 1 der in die Knochenplatte eingedrückten, aber in axialer Richtung nicht verriegelten Knochenschraube der Figur 1 im Bereich der Knochenplatte und der kopfförmigen Verdickung in einem Schnitt längs Linie 2-2 in Figur 3;

Figur 3: eine Draufsicht auf die Knochenplatte und die eingesetzte Knochenschraube der Figur 2 und

Figur 4: eine Ansicht ähnlich Figur 2 mit eingesetztem Kern zur Verriegelung der Knochenschraube in axialer Richtung.

Das orthopädische Haltesystem wird nachstehend am Beispiel einer Knochenplatte beschrieben, die mit Hilfe von Knochenschrauben an Knochensubstanz festgelegt werden soll. Es versteht sich aber, daß die Erfindung nicht auf den Einsatz an Knochenplatten und die Verwendung von Knochenschrauben beschränkt ist, sondern allgemein auf orthopädische Haltesysteme gerichtet ist, bei denen Implantatteile mit Hilfe von Halteelementen am Knochensystem oder untereinander festzulegen sind.

Das in der Zeichnung dargestellte orthopädische Haltesystem umfaßt eine metallische Knochenplatte 1 mit mehreren Durchstecköffnungen 2, von denen in der Zeichnung nur eine dargestellt ist. Diese Durchstecköffnung hat eine kugelringförmige Innenwand 3, wobei der Bereich

des größten Durchmessers der Durchstecköffnung 2 etwa in der Mitte der Knochenplatte 1 angeordnet ist, so daß sich also die Durchstecköffnung 2 zur Oberseite 4 und zur Unterseite 5 hin jeweils verengt. Somit bildet die kugelringförmige Innenwand 3 eine Ausbauchung und damit eine Hinterschneidung 6 aus.

In die Durchstecköffnung 2 ist eine Knochenschraube 7 eingesetzt, die beispielsweise aus einem elastischen Kunststoff bestehen kann, insbesondere aus einem resorbierbaren Kunststoff.

Diese Knochenschraube 7 weist einen Schaft 8 mit einem Außengewinde 9 sowie eine kopfförmige Verdickung 10 auf, die seitlich begrenzt wird durch eine kugelringförmige Umfangsfläche 11, deren Abmessungen im wesentlichen den Abmessungen der ebenfalls kugelringförmigen Innenwand 3 der Durchstecköffnung 2 entsprechen. Die Umfangsfläche 11 ist also komplementär zur Innenwand 3 ausgebildet.

Zwei senkrecht zueinander angeordnete, diametrale Einschnitte 12, die von oben her über die gesamte Höhe der kopfförmigen Verdickung 10 in die Knochenschraube 7 eintauchen, teilen die kopfförmige Verdickung 10 in vier in Umfangsrichtung voneinander getrennte Abschnitte 13 und erzeugen somit eine gewisse Elastizität dieser Abschnitte 13, d.h. die Abschnitte 13 können elastisch radial nach innen gebogen werden.

In die Knochenschraube 7 ist eine zentrale Sacklochbohrung 14 eingearbeitet, die sich bis in den Schaft 8

hineinerstreckt und die im Bereich der kopfförmigen Verdickung 10 einen erweiterten Bereich 15 aufweist. Dieser erweiterte Bereich 15 erleichtert das elastische Zusammendrücken der kopfförmigen Verdickung 10, bei der die Abschnitte 13 elastisch nach innen gebogen werden. Durch dieses Zusammenpressen der kopfförmigen Verdikkung 10 ist es möglich, deren Außendurchmesser zu reduzieren, so daß die kopfförmige Verdickung 10 in die Durchstecköffnung 2 eingeschoben werden kann, obwohl diese an den engeren Übergangsstellen zur Oberseite 4 und zur Unterseite 5 einen Innendurchmesser aufweist, der kleiner ist als der Außendurchmesser der unverformten, nicht zusammengedrückten kopfförmigen Verdickung 10. Beim Einschieben dieser kopfförmigen Verdickung 10 wird diese elastisch zusammengepreßt und schnappt nach dem Eindrücken wieder elastisch auseinander, wobei die bauchige Umfangsfläche 11 in die Hinterschneidung 6 der Durchstecköffnung 2 eingreift. Dadurch wird die Knochenschraube 7 in der Durchstecköffnung 2 in axialer Richtung festgelegt, ohne allerdings die freie Drehbarkeit der Knochenschraube um ihre Längsachse und zusätzlich auch um in der Ebene der Knochenplatte 1 liegende Schwenkachsen zu beeinträchtigen. Damit wird eine drehgelenkartige Verbindung zwischen Knochenschraube 7 und Knochenplatte 1 hergestellt.

Die Knochenschraube 7 kann in geeigneter Weise durch ein Werkzeug verdreht werden, dieses kann beispielsweise in die Einschnitte 12 eingreifen oder in die Sacklochbohrung 14, die zu diesem Zweck einen unrunden Querschnitt haben kann, beispielsweise einen Sechskantquerschnitt.

In die Sacklochbohrung 14 ist ein Kern 16 einsetzbar, der so geformt ist, daß er die Sacklochbohrung 14 im wesentlichen vollständig ausfüllt. Der Kern 16 weist einen länglichen Stift 17 auf, der in den unteren, im Schaft 8 angeordneten Teil der Sacklochbohrung 14 eingreift, und eine zylindrische Verdickung 18, die in den erweiterten Bereich 15 der Sacklochbohrung 14 eintaucht. Dabei sind die Abmessungen so gewählt, daß der Kern 16 in die Sacklochbohrung 14 eintritt, ohne diese aufzuweiten.

Wenn der Kern 16 in dieser Weise in die Knochenschraube 7 eingesetzt ist, wird durch die vollständige Ausfüllung des erweiterten Bereichs 15 der Sacklochbohrung 14 die elastische Verbiegung der Abschnitte 13 radial nach innen behindert, d.h. es ist nicht mehr möglich, den Außendurchmesser der kopfförmigen Verdickung 10 der Knochenschraube 7 zu reduzieren. Wenn die Knochenschraube 7 in die Durchstecköffnung 2 eingesetzt ist, ist es daher nicht mehr möglich, die kopfförmige Verdickung 10 aus der Hinterschneidung 6 zu entfernen, man erhält auf diese Weise also eine Verriegelung der Knochenschraube 7 in der Knochenplatte 1, ohne daß jedoch eine Verklemmung erfolgt. Trotz dieser Verriegelung bleibt die Knochenschraube frei drehbar und frei verschwenkbar in der Durchstecköffnung 2 gehalten, so daß die Drehgelenkeigenschaft der Verbindung zwischen Knochenschraube 7 und Knochenplatte 1 in keiner Weise beeinträchtigt wird.

P A T E N T A N S P R Ü C H E

1. Orthopädisches Haltesystem mit mindestens einem Implantatteil, das mindestens eine Durchstecköffnung aufweist, und mit stiftförmigen Halteelementen, die in die Durchstecköffnungen eingesetzt werden, wobei die Durchstecköffnungen Erweiterungen aufweisen, die eine elastisch zusammendrückbare kopfförmige Verdickung der Halteelemente aufnehmen, wobei die Erweiterungen einen Außendurchmesser aufweisen, der geringfügig kleiner ist als die nicht elastisch zusammengedrückte kopfförmige Verdickung, und wobei die Erweiterungen Hinterschneidungen aufweisen, in die die kopfförmige Verdickung nach dem Einschieben in die Erweiterung elastisch eingreift, und mit einem Sackloch im Bereich der kopfförmigen Verdikkung des Halteelements, in das ein dieses ausfüllender Kern einschiebbar ist, dadurch gekennzeichnet, daß der Kern (16) so bemessen ist, daß er die kopfförmige Verdickung (10) in seiner in das Sackloch (14) eingeschobenen Stellung verriegelt ohne sie aufzuweiten.

2. Haltesystem nach Anspruch 1, dadurch gekennzeichnet, daß die kopfförmige Verdickung (10) durch mehrere elastisch radial nach innen biegbare Teile (13) des Halteelements (7) gebildet wird.

3. Haltesystem nach Anspruch 2, dadurch gekennzeichnet, daß die elastisch nach innen biegbaren Teile (13) durch radial verlaufende Einschnitte (12) voneinander getrennte, einstückig mit dem Halteelement (7) ausgebildete Abschnitte des Halteelements (7) sind.

4. Haltesystem nach einem der voranstehenden Ansprüche, dadurch gekennzeichnet, daß das Sackloch (14) sich zum freien Ende des Halteelements (7) hin stufig verengt.

5. Haltesystem nach einem der voranstehenden Ansprüche, dadurch gekennzeichnet, daß das Sackloch (14) kreiszylindrisch ausgebildet ist.

6. Haltesystem nach einem der voranstehenden Ansprüche, dadurch gekennzeichnet, daß die Erweiterung eine kugelringförmige Innenfläche (3) und die kopfförmige Verdickung (10) eine komplementäre kugelringförmige Außenfläche (11) aufweisen, deren größter Durchmesser im Innern des Implantatteils (1) im Abstand von dessen Außenflächen (4, 5) angeordnet ist.

7. Haltesystem nach einem der voranstehenden Ansprüche, dadurch gekennzeichnet, daß das Halteelement eine Knochenschraube (7) ist.

8. Haltesystem nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß das Halteelement eine Schraube mit einem Maschinengewinde ist.

9. Haltesystem nach einem der voranstehenden Ansprüche, dadurch gekennzeichnet, daß das Implantatteil eine Knochenplatte (1) ist.

10. Haltesystem nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß das Halteelement zwei oder mehr Implantatteile miteinander verbindet.

11. Haltesystem nach Anspruch 10, dadurch gekennzeichnet, daß die beiden Halteelemente plattenförmig ausgebildet sind.

12. Haltesystem nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, daß ein Implantatteil eine Knochenplatte ist und das andere eine Endoprothese.

FIG.1

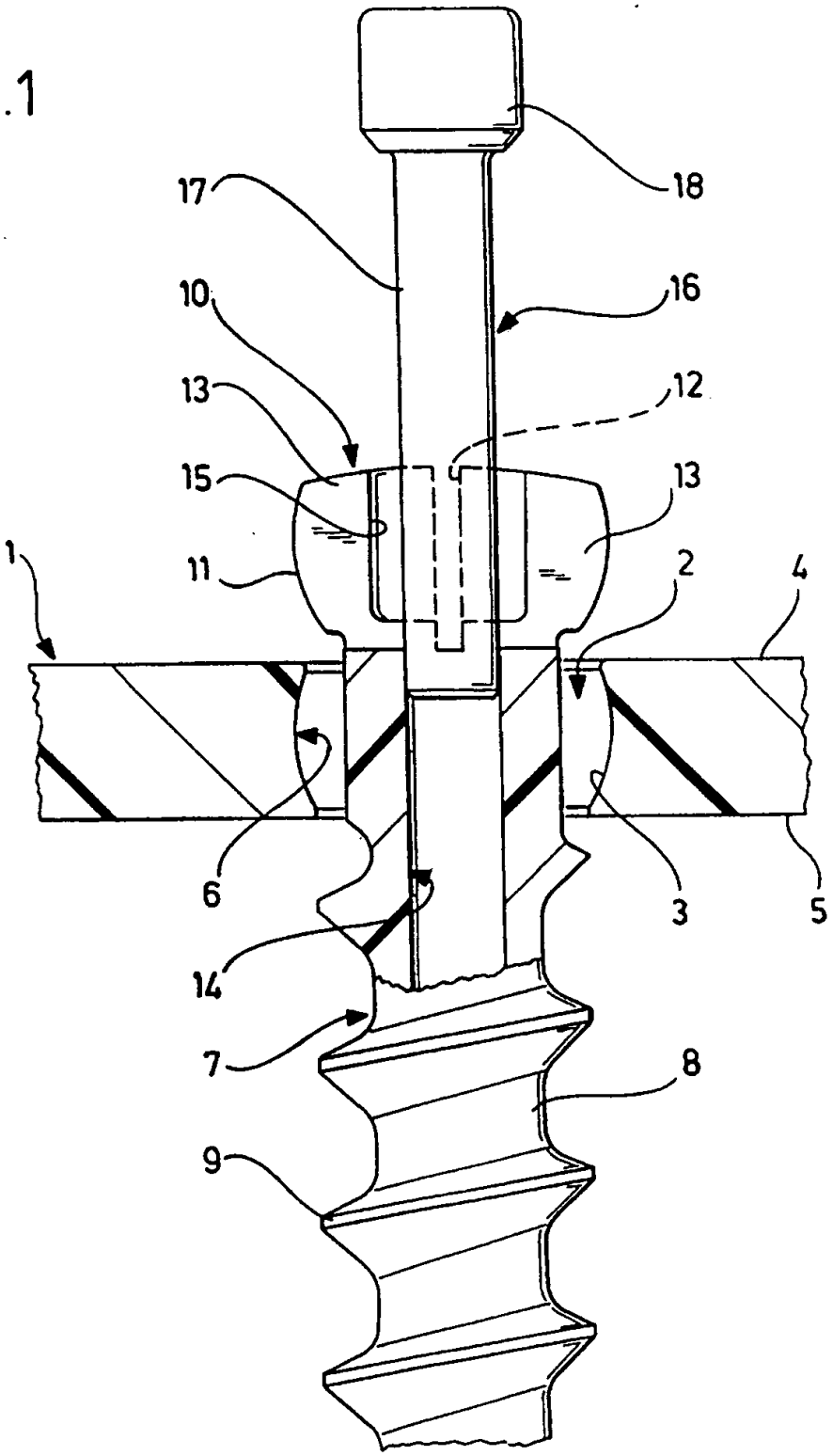


FIG. 2

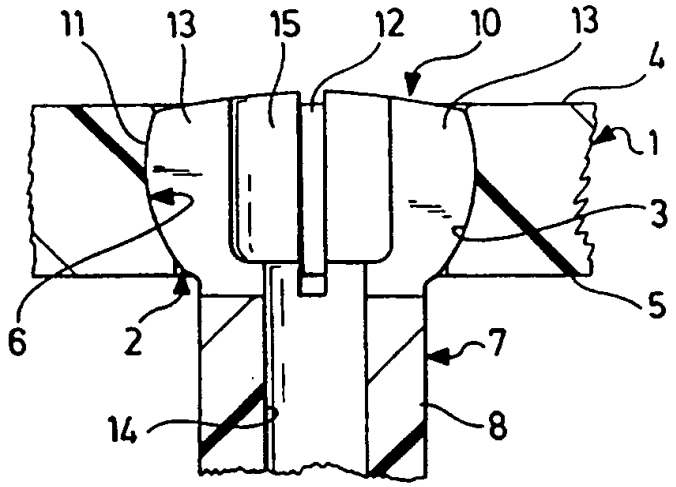


FIG. 3

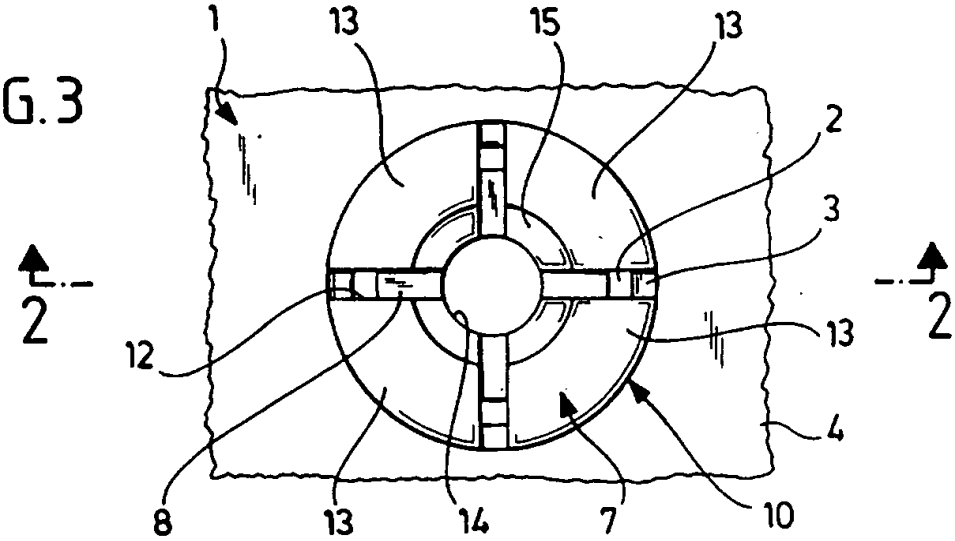
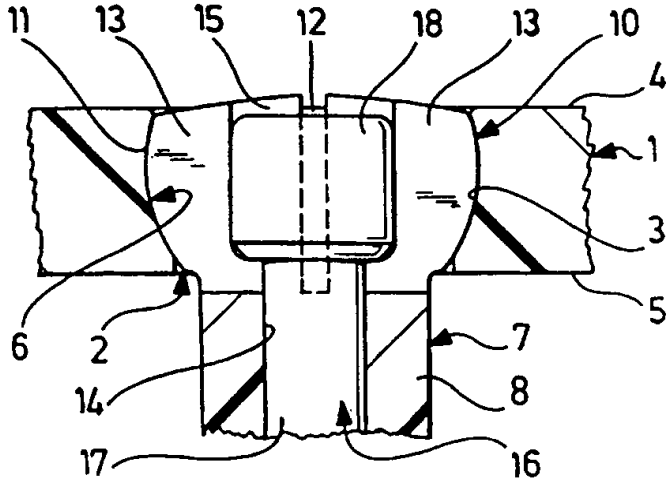


FIG. 4



INTERNATIONAL SEARCH REPORT

Inter ...nal Application No
PCT/EP 96/05355

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/80

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)
IPC 6 A61B

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 88 03781 A (J.RAVEH) 2 June 1988 cited in the application see page 4, line 26 - page 5, line 12; figures 1,7,26,27	1-3,5-7, 9
A	WO 94 26193 A (INDUSTRIEAB ELOS) 24 November 1994 see page 13, line 8 - page 14, line 12; figures 2,7	1-5,7,9

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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1

Date of the actual completion of the international search	Date of mailing of the international search report
7 April 1997	12.04.97

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, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Nice, P

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
PCT/EP 96/05355

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8803781 A	02-06-88	CH 672245 A	15-11-89
		CH 669105 A	28-02-89
		EP 0293411 A	07-12-88
		JP 2500490 T	22-02-90
WO 9426193 A	24-11-94	SE 501265 C	19-12-94
		SE 9301578 A	08-11-94

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INTERNATIONALER RECHERCHENBERICHT

Intern. ales Aktenzeichen
PCT/EP 96/05355

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 6 A61B17/80

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B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 6 A61B

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	WO 88 03781 A (J.RAVEH) 2.Juni 1988 in der Anmeldung erwähnt siehe Seite 4, Zeile 26 - Seite 5, Zeile 12; Abbildungen 1,7,26,27	1-3,5-7, 9
A	WO 94 26193 A (INDUSTRIEAB ELOS) 24.November 1994 siehe Seite 13, Zeile 8 - Seite 14, Zeile 12; Abbildungen 2,7	1-5,7,9

☐ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

☒ Siehe Anhang Patentfamilie

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Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
7.April 1997	12.04.97

Name und Postanschrift der Internationale Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Nice, P

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INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Inte. ...nales Aktenzeichen
PCT/EP 96/05355

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
WO 8803781 A	02-06-88	CH 672245 A	15-11-89
		CH 669105 A	28-02-89
		EP 0293411 A	07-12-88
		JP 2500490 T	22-02-90
WO 9426193 A	24-11-94	SE 501265 C	19-12-94
		SE 9301578 A	08-11-94