United States Patent [19]

Brantigan

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[54] **PROSTHETIC IMPLANT**

[76] Inventor: **John W. Brantigan,** 2108 Bramblewood La., Fremont, Nebr. 68025

[21] Appl. No.: **173,928**

[22] Filed: **Mar. 28, 1988**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 5,785, Jan. 22, 1987, Pat. No. 4,743,256, which is a continuation of Ser. No. 784,112, Oct. 4, 1985, abandoned, and a continuation-in-part of Ser. No. 95,461, Sep. 11, 1987.

[51] **Int. Cl.**[4] **A61F 2/44**

[52] **U.S. Cl.** ..... **623/17;** 623/16; 128/92 YG; 128/92 YM

[58] **Field of Search** ..... 623/17, 16, 18, 21, 623/22, 23, 66; 128/92 YG, 92 YM, 92 YJ, 92 W, 305

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Primary Examiner—Richard J. Apley

Assistant Examiner—Alan W. Cannon

Attorney, Agent, or Firm—Hill, Van Santen, Steadman & Simpson

[57] **ABSTRACT**

Gauge blocks or plugs and permanent implant plugs are provided for surgical procedures to support and fuse together adjacent vertebrae in a vertebral column. The plugs are rectangular with tapered front ends and tool receiving rear ends. The gauge blocks are smooth faced for removal but the implant plugs have roughened surfaces to grip the vertebrae and provide channels for bone ingrowth. The plugs have recesses in the form of through slots to be packed with bone graft material. In the surgical procedure, undamaged annulus fibrosus disc tissue connecting the adjacent vertebrae is preserved and a pair of side-by-side roughened implant plugs are forced into side-by-side transverse channels in the adjoining vertebrae to stretch the remaining annulus disc tissue and form struts supporting the vertebrae. The plugs are bottomed in the channels on cortex bone and bone ingrowth is facilitated to fuse the plugs to the vertebrae.

11 Claims, 2 Drawing Sheets

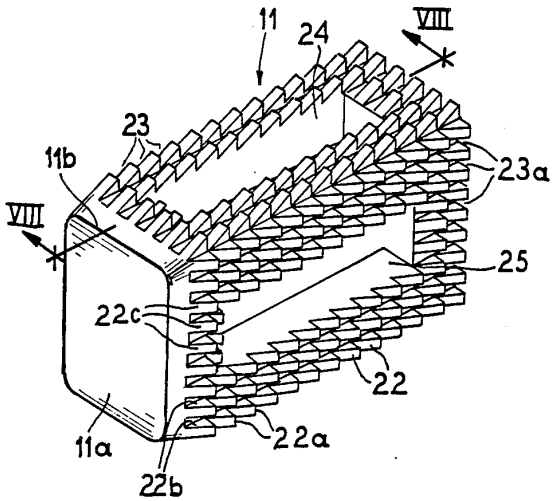


FIG. 1

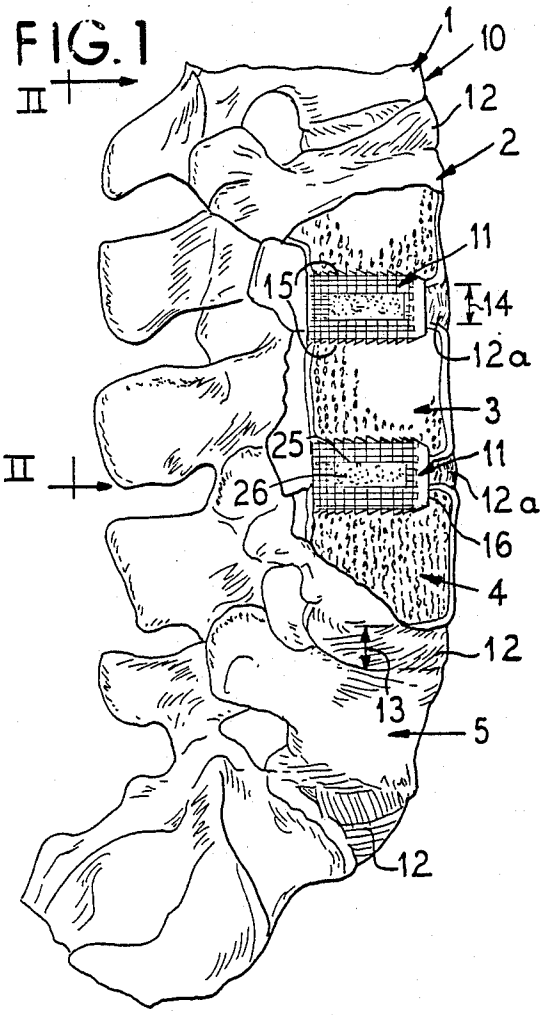


FIG. 2

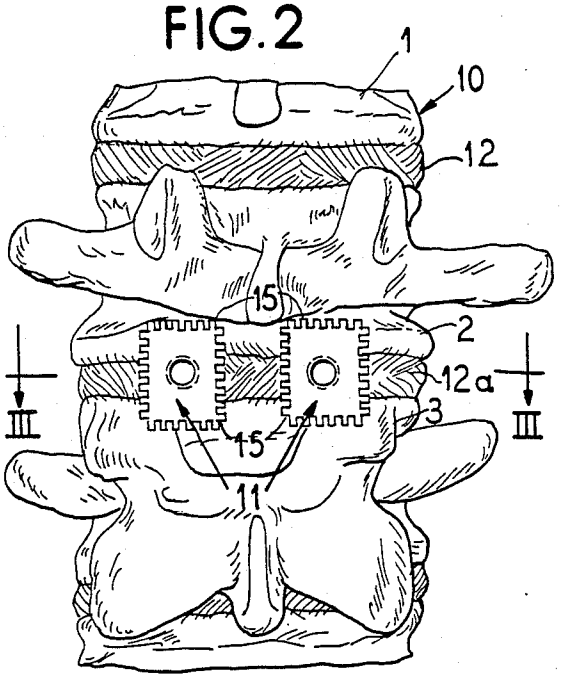


FIG. 3

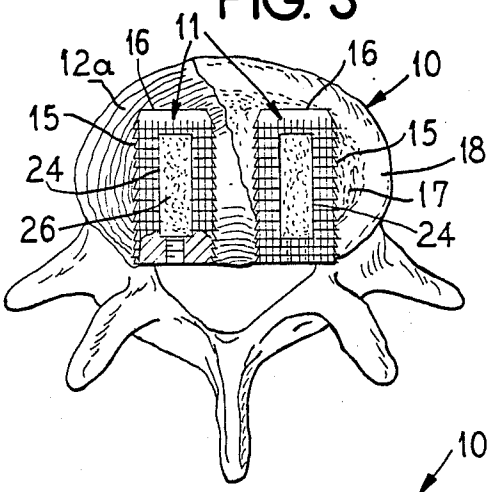


FIG. 4

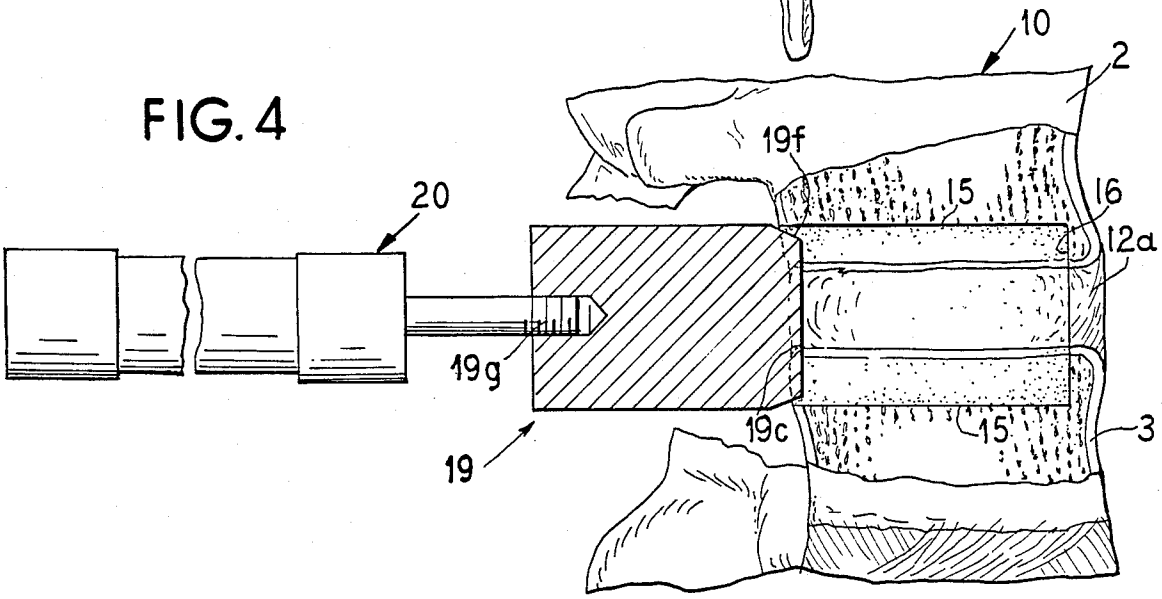


FIG. 5

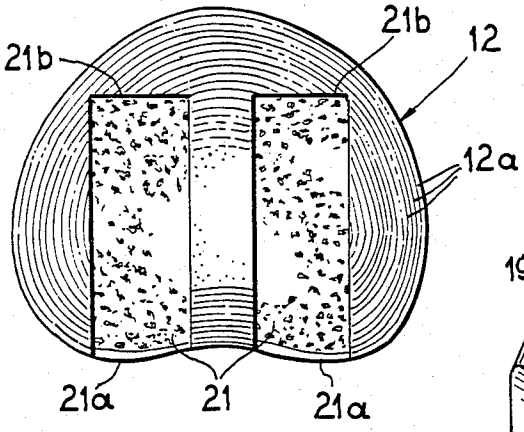


FIG. 6

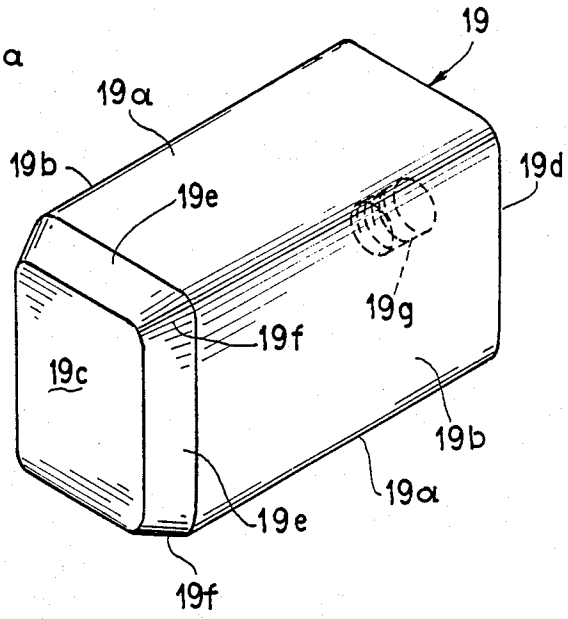


FIG. 7

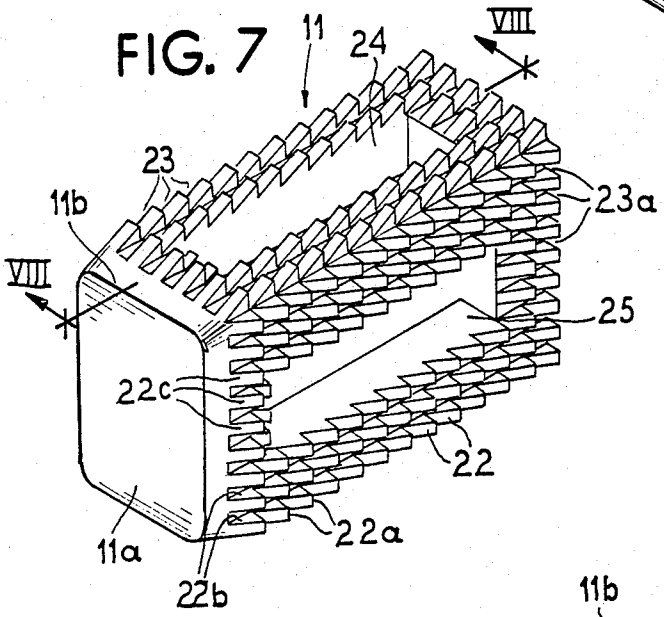
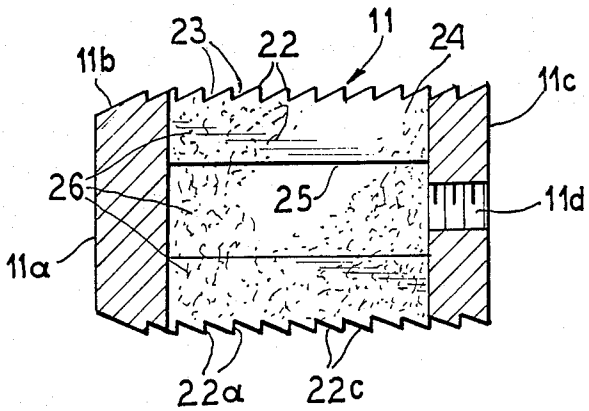


FIG. 8



PROSTHETIC IMPLANT

RELATED APPLICATIONS

This application is a continuation-in-part of Ser. No. 005,785, filed Jan. 22, 1987, now U.S. Pat. No. 4,743,256, which is a continuation of Ser. No. 784,112, filed Oct. 4, 1985, abandoned, and is also a continuation-in-part of Ser. No. 095,461, filed Sept. 11, 1987

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to the art of prosthetic devices and methods for implanting the devices between adjacent vertebrae to treat or prevent back pain in patients with ruptured or degenerated intervertebral discs. Specifically this invention deals with improvements in prosthetic strut forming plugs or blocks with roughened surfaces facilitating bone ingrowth from adjoining vertebrae wherein the blocks are shaped to fit in rectangular slots cut in the vertebrae, have heights which will stretch the remaining elastic annulus tissues of damaged discs between the adjoining vertebrae and have slots extending vertically, transversely or both vertically and transversely through the plugs to be packed with bone grafts to expedite the bone ingrowth.

More specifically the plugs or blocks fitting the rectangular slots in the adjoining vertebrae have tapered leading ends facilitating insertion into the slots between the vertebrae to stretch remaining disc tissue connecting the vertebrae and tool receiving trailing ends for forcing the plugs into position. A still further specific feature of the invention is the provision of plugs which are radiolucent for improved X-ray visualization of the bone healing post-operatively.

As pointed out in my aforesaid parent U.S. Pat. No. 4,743,256 its continuation-in-part application Ser. No. 095,461, the leading cause of low back pain arises from rupture or degeneration of lumbar intervertebral discs. Pain in the lower extremities of the back (sciatica) is caused by the compression of spinal nerve roots by damaged discs between the vertebrae and low back pain is caused by collapse of the disc and the adverse effects of bearing the majority of the body weight through a damaged unstable vertebrae joint. Surgical treatments for relief of the sciatic pain and lower back pain generally include the following:

(1) EXCISION OF THE RUPTURED SOFT DISC

This procedure removes the portion of the disc compressing the spinal nerve and is generally successful in relieving the sciatic leg pain but in more than half of the cases, there is a recurrence of back pain. Over a period of time the disc gradually loses height due to the rupture and this loss of height causes the posterior facet joints of the vertebrae to fit incorrectly resulting in arthritic change in all elements of the spinal segment. Recurrent nerve root compression due to bony encroachment (spinal stenosis) also develops. The continuing and recurring back pain from this source has created a leading source of pain and disability.

(2) DISC EXCISION WITH POSTERIOR FUSION

Traditional posterior fusion, creating bone growth between the bony laminae, or postero-lateral fusion between the transverse processes prevents motion between the adjacent vertebrae but does not alter the fact that approximately 90% of the body weight must be transmitted through degenerated discs causing pain. Further, posterior fusion tends to cause bony overgrowth leading to nerve root compression by spinal stenosis.

(3) DISC EXCISION WITH ANTERIOR INTERBODY FUSION

Interbody fusion techniques, in which the soft disc is completely excised and replaced with either the patient's own bone (autologous bone) or with transplant banked bone (homologous bone) are generally successful if solid fusion can be obtained between adjacent vertebrae bodies. Unfortunately, the success rate has only been about 50%.

(4) DISC EXCISION WITH POSTERIOR LUMBAR INTERVERTEBRAL FUSION (PLIF)

This procedure reconstructs the normal anatomic relationships between the bony and the neural structures and has many advantages. Weight bearing through a solid bony fusion mass between vertebral bodies relieves the mechanical pain of the traditional unstable degenerative disc and generally prevents long term disc collapse or further degenerative changes. The complete disc excision prevents recurrent herniation of the same degenerated disc.

However, this PLIF procedure has several serious disadvantages in that it is technically very difficult, and, therefore, not as successful or widely used as it might be. It entails large amounts of blood loss in a small deep hole causing physiological stress to the patient and psychological distress to the surgeon. Further, the use of autologous bone graft from the patient's own iliac crests extends the operation and creates a second painful operative site. Because it is difficult to obtain a large enough quantity of autogenous bone with sufficient strength, homologous bank bone is generally used.

Interbody bone grafting involves the problems of strength and that of bone incorporation. Strong cortex bone (the outer layer) is required as a strut in the interbody position to prevent collapse of the disc space while healing occurs. The surgeon has the unfortunate requirement of having to fashion the required struts with handheld tools during the operation and these cortex bone struts are not wide enough for optimum load bearing and they anchor themselves by healing process that occurs very slowly over a matter of years. Further, soft cancellous bone, which heals more reliably over a matter of 12 to 18 months, is also required for a traditional interbody fusion.

It is well understood in orthopaedic surgery, that grafted bone heals by a process called "creeping substitution" in which blood capillaries first grow into the grafted bone, the grafted bone is reabsorbed, and then new bone cells are laid down along the bony matrix of the graft. During the time that the structural bone grafts struts are being reabsorbed, motion must still be prevented in the involved segments and although a brace or cast is often used, the entire process has proven less reliable than desired. Homologous bank bone, being more "foreign", requires a much longer time to grow together and has a higher failure rate estimated at three times the failure as with the patient's own bone. In effect, neither source of bone is optimum for the fusion procedure.

My prior aforesaid U.S. Pat. No. 4,743,256 discloses an improved surgical procedure for eliminating spinal

back pain caused by ruptured or degenerated vertebral discs by spanning the disc space between adjacent vertebrae with rigid implants having surfaces facilitating bone ingrowth and bottomed on prepared sites of the vertebrae to integrate the implant with the vertebrae and to provide a permanent weight supporting strut maintaining the disc space.

My prior aforesaid patent application Ser. No. 095,461, filed Sept. 11, 1987, discloses a further improved surgical procedure by providing the rigid implants or blocks with tool receiving end faces facilitating their insertion onto the prepared sites and having geometric patterns of roughened surfaces on the peripheries of the implants enhancing the bone growth. Novel tools are releasably attached to the end faces of these implants.

The present invention now still further improves this art by providing a group of smooth faced trial or gauge blocks or plugs of different heights and widths for temporary insertion in the rectangular grooves or slots cut into the adjacent vertebrae to locate a plug that will tightly fit the slots and stretch the disc tissue a desired amount. This procedure permits the surgeon to select a permanent implant plug with a rough surface of a slightly larger size that can be force fitted into permanent position to further stretch the annulus tissue fibers of the disc still connecting the vertebrae placing them under tension thus facilitating their growth and also causing the vertebrae to tightly grip the plug. Further, the permanent impact plugs are provided with beveled or taped leading ends to spread the vertebrae apart and facilitate insertion into the rectangular channels or slots. Still further, the plugs may have vertical, horizontal, or both horizontal and vertical intersecting slots therethrough packed with bone grafts to expedite bone ingrowth. Also, the plugs can be made of radiolucent material to facilitate x-ray inspection of the bone growth.

SUMMARY OF THE INVENTION

The present invention now provides vertebral prosthesis implant plugs or blocks fitting rectangular transverse or perpendicular channels or grooves cut in the adjoining faces of vertebral bodies having heights that will stretch the remaining annulus tissue of the discs therebetween still connecting the vertebrae. According to this invention, parallelepiped blocks or plugs are provided to fit these transverse rectangular channels or slots and have beveled or tapered leading ends easily inserted into the open ends of the transverse slots to spread the vertebrae apart so that the top and bottom faces of each block or plug is tightly bottomed in the slot with the stretched disc tissues causing the vertebrae to grip the plugs. These plugs are inserted laterally or transversely of the vertebral column into the slots while mounted on the end of an insertion tool, have roughened surfaces to facilitate the bone ingrowth and also have vertical or horizontal slots therethrough or intersecting vertical and horizontal slots packed with bone graft material, such as strips of bone excised from the iliac crest of the pelvis. This implant material provides a block of living bone that grows all around and though the implant plug into the bone of the vertebrae.

Also, according to this invention, the blocks or plugs instead of being made of an inert metal, such as stainless steel, titanium, cobalt-chromium-molybdenum alloys and the like, can be made of a radiolucent material, such as a plastic of the nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone type, preferably filled with glass or carbon fibers. These plastics can be injection molded, are light in weight, have great load carrying strength and provide improved x-ray visualisation of bone healing. Fiber reinforced plastics composed of such materials filled with glass or carbon fibers are also desirable. Suitable carbon fiber composites are supplied under the tradename "VICTREX P.E.S." which is polyether sulfone filled with carbon fibers. Suitable grades are "4101 G.L.-30" which is a 30 percent fiber glass filled and "450 C.A.-30" which is a 30 percent carbon fiber filled. These materials are supplied from ICI Industries of Wilmington, Del. Carbon-carbon fiber plastics of the type sold by Fiber-Rite Corporation of Winona, Minn., are useful.

The roughened surfaces of the permanent implant plugs are non-yielding and have configurations to best grip the channels of the vertebral body and to permit bone ingrowth therebetween.

Preferred embodiments of the invention are illustrated in the annexed drawings in which:

FIG. **1** is a side-elevational view of the lower portion of a human vertebrae column with parts broken away and shown in section to illustrate flat-sided rectangular prosthetic implant plugs or blocks of this invention inserted in rectangular grooves or channels in the opposed faces of adjacent vertebrae to support the vertebrae in place of the human disc therebetween which has been partially excised to remove damaged and herniated tissue.

FIG. **2** is a posterior elevational view of a portion of FIG. **1** taken along the line II—II of FIG. **1**.

FIG. **3** is a transverse sectional view, with parts in elevation and broken away in section, along the line III—III of FIG. **2**.

FIG. **4** is an enlarged fragmentary side-elevational view with parts broken away and shown in vertical section illustrating the manner in which a trial or gauge plug or block of this invention is inserted in position in the transverse rectangular slots of adjoining vertebrae to stretch the remaining interposed disc tissue connected to these vertebrae and to gauge the sites for receiving a proper sized permanent implant.

FIG. **5** is a plan view of a vertebrae disc with the interior pulp removed and with disc tissue partially excised to provide gaps or slots aligned with channels cut in the vertebrae to receive the plugs therethrough.

FIG. **6** is a perspective view of a smooth faced trial or gauge plug or block for use as shown in FIG. **4**.

FIG. **7** is a perspective view of a preferred form of permanent implant plug or block of this invention.

FIG. **8** is a longitudinal vertical sectional view of the plug of FIG. **7** taken along the line VIII—VIII of FIG. **7**.

As Shown on the Drawings:

In FIGS. **1–3**, the reference numeral **10** illustrates generally the lower portion of a human vertebral column with adjacent vertebrae supported on prosthetic implant blocks or plugs **11** of this invention.

FIG. **4** shows the manner in which adjacent vertebrae are spread apart to stretch intervening disc tissue as a gauge or trial block of this invention is inserted laterally into transverse rectangular slots of adjoining vertebrae.

In FIG. **1**, the vertebral column **10** shows the five lower vertebrae Nos. **1–5**. Adjacent vertebrae Nos. **2**

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