

**SPINAL PLUG FOR A MINIMALLY INVASIVE
FACET JOINT FUSION SYSTEM**

Technical Field

The present invention relates generally to minimally invasive spine surgery and, more particularly, to using an arthroscopic type portal or open facet joint fusion surgical instrumentation for insertion of either pre-made, pre-shaped synthetic cortical bone or harvested and compacted iliac crest grafts, autologous or cadaveric allografts. The graft and fusion system is limited to the forty-eight facet joints located on the spine, C1-C2 through L5-S1.

Background Art

In the United States alone, about 10% of the entire population will suffer from back pain sometime in the next twelve months. More people will contract back pain in the next year than any other injury or disease except the common cold and flu. About one-third will not recover and have to live with persistent, disabling symptoms. The number is cumulative year after year.

One of the root causes of back pain, particularly the persistent and disabling kind, are facet joints, small joints located behind adjacent vertebrae in the spine that allow for spinal motion.

Present surgical solutions available for the millions of people with facet joint dysfunctions are complex, invasive,

pedicle screw based high-risk operations with prolonged recovery times, from 6 to 24 months, and uncertain outcomes. High risk equates to frequent litigation, which forces non-surgical symptomatic treatment while the disease or consequences of injury progressively worsen. Some of these efforts provide intervertebral fusion described in U.S. Patent Number 6,485,518 and U.S. Patent Application Serial Number 2003/0032960. Numerous patents have been granted for general fusion of the spine that may or may not involve the facet joint by proximity or design.

With the advent of new, safer and less invasive surgical techniques and technology, the growth of spine surgery now outpaces every other orthopedic surgery segment. Its growth is further fueled by an enormous demand.

Disclosure of Invention

The use of pre-shaped, harvested or synthetic bone as a structural fixation for facet joint fusion offers three distinct advantages over pedicle or compression screws, which are presently used in facet fusion procedures; i.e., (1) using bone instead of metal allowing for natural bone ingrowth and a stronger, permanent fusion; and (2) the natural or synthetic graft cannot work its way loose over time, a concern with screw type fixation.

The grafts and system are specifically designed for use in a minimum invasive or an arthroscopic type portal for stand-

alone procedures and provide a stronger, unique and superior fusion when used as an adjunct to instrumented vertebral fusion by greatly reducing risk of facet joint pain resulting from persistent facet joint motion.

The minimally invasive facet joint fusion for the treatment of a diseased or painful facet joint that is not appropriate for resurfacing or replacement, involves the use of instrumentation and autograft, cadaveric allograft or FDA approved pre-made, pre-shaped synthetic cortical bone graft for use in minimally invasive, outpatient, arthroscopic spine surgery or classic open surgery and, more specifically, to fuse spinal facet joints from C1-C2 through L5-S1. This system serves as a primary or a revision surgery.

The present invention accomplishes a superior spinal facet joint fusion by providing a grafting alternative to facilitate fusion using arthroscopic portal or open surgical techniques of the C1-C2 through L5-S1 spinal facet joints.

According to one broad aspect of the present invention, the arthroscopic facet joint fusion system comprises a punch or drill that creates a hole through both sides of the facet joint in a conical pattern. The hole is filled with either the patient's own harvested and compacted bone plug using iliac crest autograft, pre-made, pre-shaped cortical cadaveric allograft (the autograft or allograft formed by bone plug press

or machining) or FDA approved pre-made, pre-shaped synthetic grafts.

The punch or drill includes any number of components capable of performing the creation of a hole through both sides of the spinal facet joint using an arthroscope or similar portal to access the joint or during classic open surgery. By way of example only, the punch/drill includes a hand actuator that will create sufficient pressure to create a specific sized hole through both sides of the spinal facet joint using a mechanical arrangement similar to that of common pliers resized to work through an arthroscopic opening. Additionally, a drill guide can be placed and a specifically sized and shaped drill head can be used to create the opening, either in a horizontal or vertical direction through the facet joint.

The bone plug press (graft forming or compression instrument) includes any number of components capable of using harvested autograft, cadaveric allograft cortical bone or a synthetic alternative to match the bone tunnel made by the punch or drill. By way of example only, the bone plug press includes a mechanism similar to common pliers or a more standard hand press that will transfer sufficient force to form bone plugs by squeezing the handles together to form the bone plug and compress the bone or synthetic alternative to the proper density and shape.

The impactor or tamp includes any number of components capable of pushing and compressing the bone plug into the bone tunnels. A suture or metallic overlay also can be applied to provide additional structural stability to the joint during graft incorporation.

Brief Description of Drawings

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

Figure 1 shows a frustum shaped bone plug of this invention for employment in a facet joint fusion;

Figure 2 shows a tapered drill used to prepare for the bone plug;

Figure 3 shows a hole prepared for the bone plug;

Figure 4 shows a bone plug inserted in the hole of Figure 3 and with an application tube for inserting synthetic or biologic material;

Figure 5, is a cross-section along line 5-5 of Figure 4;

Figure 6 is a cross-section along line 6-6 of Figure 4;

Figure 7 is a cross-section according to Figure 6 showing synthetic or biologic material cementing the bone plug in place;

Figure 8 shows a first alternative frustum shaped bone plug;

Figure 9 shows a cross-section of the frustum shaped bone plug of Figure 8 along lines 9-9; and

Figure 10 shows a second alternative frustum shaped bone plug.

Best Mode for Carrying Out the Invention

Referring to Fig. 1, the bone plug of this invention is an inverted frustum shaped device 10 having a vertical central channel 12 for insertion of a synthetic or biologic material to assist in fusing the bone plug 10 in place in a spinal joint 15. The bone plug 10 has multiple side parts 14 and 16 for excretion of the synthetic or biologic material from the central channel 12. A pair of opposed flanges 18 and 20 on the same plane partially circumvent the bone plug 10 near bottom end 22 having a smaller diameter than the top end 24.

In order to fuse a spinal facet joint, a tapered drill 26, shown in Fig. 2, is employed to prepare a hole 28 shown in Fig. 3 between two bones 30 and 32. As seen in Fig. 4, an application tube 34 is inserted in channel 12 to permit insertion of a synthetic or biologic material 36 into bone plug 10. The biologic material 36 flows down channel 12 as shown in Fig. 5, and excess biologic material flows out of side parts 14 and 16 through channels 42 and 44, respectively, into a space 38 between the bones 30 and 32, and an exterior side wall 40 of

the bone plug 10. The flanges 18 and 20 act as detents to hold the bone plug 10 in place within hole 28. As seen further in Fig. 7, the biologic material 36 flows outwardly from openings 14 and 16 into a space 38 to cement the plug 10 in place.

An alternative plug 10a is shown in Figs. 8 and 9. A central channel 12a feeds biologic material to side channels 46, 42 and 44a. In like manner, biologic material 36 flows out through openings 52, 14a and 16a and promotes bonding to the bone. A second parallel pair of flanges 48 and 50 are added to flanges 18a and 20a to increase the strength of the plug 10a in the hole 28. Side wall 40a in like manner to plug 10 is narrower in diameter at a bottom end 22a than its top end 24a.

If the joint is determined to be too badly damaged or diseased for present replacement methods or prospective methods such as facet joint hemi-arthroplasty, minimally invasive facet joint fusion is prospectively a superior alternative for three primary reasons:

- (1) It is minimally invasive surgery that can be performed in an outpatient setting as opposed to major surgery performed in a hospital. This procedure can also be performed during open surgery if the facet joints need to be fused as determined by a physician particularly in conjunction with instrumented vertebral fusion;

- (2) Recovery times are estimated to be a few weeks as opposed to 6 to 12 months; and

(3) It takes full advantage of advances in biomaterials and synthetic alternatives.

The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art by achieving the following:

- Reversal of the cost/benefit ratio of present procedures versus the invention;
- A minimally invasive procedure versus major open surgery;
- Outpatient versus inpatient surgery (about 20 minutes per joint versus hours). Note: this procedure may also be performed during open surgery at the discretion of the physician;
- Can be used to augment present open fusion techniques to lessen the need for bone stimulation especially in high risk groups such as smokers and multi-level cases;
- Reduced morbidity;
- Reduced blood loss;
- Reduced time under anesthesia;
- Reduced risk;
- Recovery time dramatically reduced;
- Minimal scarring that decreases the risk of failed back syndrome and improves revision surgery outcome;

- Reduced risk of post operative infection by significantly reducing operating room time and soft tissue destruction;
- No preclusion of other surgical or non-invasive treatment options; and,
- Projected high success rate by utilizing accepted arthroscopic procedures employing a new technique and taking advantage of either existing cortical bone harvesting procedures in combination with unique instrumentation to shape and prepare the bone or new pre-shaped, pre-made synthetic cortical bone alternatives as they are made generally available by FDA approval.

It is anticipated that the availability of this system and graft alternatives will dramatically increase the number of surgeries performed because they offer the first safe outpatient surgical solution to the predominant cause of spinal joint pain. It is expected that virtually all patients receiving this procedure will be able to walk out the same day and be fully functional within a few weeks. Present surgical solutions require hospitalization of about three days and six to twenty-four months recovery.

Aside from the obvious positive clinical outcome, the significant favorable financial impact on disability, worker's compensation and health care insurers is considerable.

Spinal facet implant units are calculated per joint. Each patient has two joints per spinal segment and twenty-four segments, C1-C2 through L5-S1 for a total of forty-eight facet joints. Each surgery is likely to involve multiple joints.

The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art.

In inserting the plug 10, the tapered drill is specifically used through an arthroscopic type portal allowing access to the joint through a small incision and progressive dilation of the intervening soft tissue. The instrument design does not preclude its use in a classic open surgery or by access to the facet joint through an otherwise limited incision. The opening 28 is marginally smaller than the bone plug 10 to create proper fixation of the plug 10 and the joint.

Referring again to Figures 1 and 8, a fused facet joint plug 10, 10a or 10b is shown with one shaped autograft, cadaveric allograft or FDA approved synthetic pre-made, pre-shaped cortical bone plug. The anterior end 22 or 22a of the plug 10 or 10a is 3 - 8mm and the posterior end 24 or 24a of the plug 10, 10a or 10b is 4 - 12mm in diameter in a frustum shape with the wider portion located in the posterior portion to facilitate fixation during bone graft incorporation. The procedure is envisioned to require only one bone plug per facet joint and two per level. Permanent fixation occurs when bone

in-growth occurs into the joint itself and into the plug over time.

The frustum shaped bone graft 10b, as shown in Fig. 10, can be employed when no additional biologic material is required.

Other equivalent elements can be substituted for the elements disclosed herein to produce substantially the same results in substantially the same way.

Claims:

1. A facet joint fusion plug comprising:

a substantially solid frustum shaped body having an aperture in a top surface and a pair of first opposed apertures in a side surface and a pair of second opposed apertures in the side surface, both the first and second opposed apertures positioned in a lower portion of the body distal from the top surface;

a vertical channel directed downwardly from the aperture in the top surface, the vertical channel intersecting with a first horizontal channel connecting the first opposed pair of apertures and terminating at a second horizontal channel connecting the second opposed pair of apertures;

at least one pair of flanges partially surrounding a bottom portion of an exterior surface of the body; and

the body formed from a material selected from the group consisting of synthetic cortical bone, a harvested synthetic cortical and compacted iliac crest graft and a cadaveric allograft.

2. The facet joint fusion plug according to Claim 1, wherein there is a third pair of opposed apertures in a side surface of the body and the vertical channel intersects with a third horizontal channel connecting the third pair of apertures.

3. The facet joint fusion plug according to Claim 1, wherein a second pair of flanges partially surrounds a bottom portion of the exterior surface of the body.

4. The facet joint fusion plug according to Claim 2, wherein a second pair of flanges partially surrounds a bottom portion of the exterior surface of the body.

5. The facet joint fusion plug according to Claim 1, wherein the first and second horizontal channels are on parallel horizontal planes.

6. The facet joint fusion plug according to Claim 2, wherein the third horizontal channel is on a parallel horizontal plane above the first and second horizontal channels.

7. The facet joint fusion plug according to Claim 1, wherein the body is formed from synthetic cortical bone.

8. The facet joint fusion plug according to Claim 1, wherein the body is formed from a harvested and compacted iliac crest graft.

9. The facet joint fusion plug according to Claim 1, wherein the body is formed from a cadaveric allograft.

10. A plug mounted in a hole between bones forming a facet joint, the plug comprising:

a substantially solid frustum shaped body having an aperture in a top surface, the top surface having a greater diameter than a bottom surface;

a first pair of opposed apertures in a side surface of the body, the first pair of apertures connected by a first horizontal channel;

a second pair of opposed apertures in a side surface of the body, the second pair of apertures connected by a second horizontal channel in a parallel plane to the first horizontal channel;

a vertical channel directed downwardly from the aperture in the top surface, the vertical channel intersecting with the first horizontal channel and terminating in the second horizontal channel;

at least one pair of flanges partially surrounding a bottom portion of an exterior surface of the body; and

a synthetic or biologic material compatible with bone passing through the top aperture and exiting from the first and second pair of apertures in the side surface of the body.

11. The plug mounted in a hole between bones forming a facet joint according to Claim 10, wherein a third pair of opposed apertures are connected by a third horizontal channel intersecting with the vertical channel, the synthetic or biologic material exiting from the third pair of apertures.

12. The plug mounted in a hole between bones forming a facet joint according to Claim 10, wherein there are two pair of

flanges spaced apart partially surrounding a bottom portion of an exterior surface of the body.

13. The plug mounted in a hole between bones forming a facet joint according to Claim 10, wherein the body is formed from a material selected from the group consisting of a synthetic cortical bone, a harvested and compacted iliac crest graft and a cadaveric allograft.

14. The plug body according to Claim 13, formed from a synthetic cortical bone.

15. The plug body according to Claim 13, formed from a harvested and compacted iliac crest graft.

16. The plug body according to Claim 13, formed from an iliac cadaveric allograft.

17. A method of mounting a plug in a facet joint C1-C2 and L5-S1, the method comprising:

cutting an arthroscopic type portal in the tissue of a patient outside a diseased or damaged facet joint;

creating a hole between two opposed bones forming the facet joint;

inserting a frustum preshaped plug into the hole, the plug having a shape substantially the same as the hole;

providing the plug with an aperture on a top surface, the top surface diameter being greater than a bottom surface diameter;

providing the plug with at least one pair of flanges partially surrounding an outside side wall and at least a first and second opposed pair of side apertures in the side wall of the plug;

providing an internal cortical channel from the top surface aperture to a first horizontal channel connecting the first pair of apertures and a second horizontal channel connecting the second pair of apertures;

inserting an applicator tube into the aperture in the top surface;

inserting a synthetic or biologic material compatible with bone into the applicator tube; and

providing sufficient pressure on the synthetic or biologic material to cause egress of the material from the side wall apertures.

18. The method according to Claim 17, wherein the preshaped plug is provided as a synthetic cortical bone.

19. The method according to Claim 17, wherein the preshaped plug is provided as a compacted iliac crest graft.

20. The method according to Claim 17, wherein the preshaped plug is provided as a cadaveric allograft.

21. A solid plug mounted in a hole between bones forming a facet joint, the plug consisting of a substantially frustum shaped body having a posterior end with a diameter of 4 to 12mm

and an anterior end with a diameter less than the posterior end.