A minimally invasive facet joint fusion including a method, instrumentation and autograft, cadaveric allograft or FDA approved pre-made, pre-shaped synthetic cortical bone grafts consistent with the description and Claims herein for use in minimally invasive, outpatient, arthroscopic spine surgery or classic open surgery and, more specifically, to fuse spinal facet joints from T12-L1 through L5-S1. This method serves as a primary or a revision surgery.
MINIMALLY INVASIVE FACET JOINT FUSION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

REFERENCE TO SEQUENCE LISTING, A TABLE, OR A COMPUTER PROGRAM LISTING
COMPACT DISK APPENDIX

[0003] Not Applicable

BACKGROUND OF THE INVENTION

[0004] 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 method, instrumentation and either pre-made, pre-shaped synthetic cortical bone or harvested and compacted iliac crest grafts, autologous or cadaveric allografts. The instrumentation, grafting and fusion method is limited to the forty-eight facet joints located on the spine, C1-C2 through L5-S1.

[0005] 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: (1) using bone instead of metal allows for natural bone ingrowth and a stronger, permanent fusion; (2) the natural or synthetic graft cannot work its way loose over time, a concern with screw type fixation; and, (3) the graft is self-leveling, which eliminates any concern of vertebral tilting.

[0006] The instrumentation, grafts and method are specifically designed for use in an arthroscopic type portal for stand-alone procedures and provides a stronger, secure and more stable fusion; it utilizes pre-shaped grafts to simulate bone growth and minimize the risk of collateral post-operative facet joint pain resulting from additional stress placed on facet joints by the instrumentation itself.

BRIEF SUMMARY OF THE INVENTION

[0007] A minimally invasive facet joint fusion for the treatment of a diseased or painful facet joint that is not appropriate for resurfacing or replacement comprises a method, 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 method serves as a primary or a revision surgery.

[0008] The present invention accomplishes a superior spinal facet joint fusion by providing a method, instrumentation and grafting alternatives to facilitate fusion using Arthroscopic portal or open surgical techniques of the C1-C2 through L5-S1 spinal facet joints.

[0009] According to one broad aspect of the present invention, the Arthroscopic Facet Joint Fusion method comprises a punch or drill that creates a hole through both levels 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 shaped cortical cadaveric allograft (the autograft or allograft formed by a unique bone plug press or machining) or FDA approved pre-made, pre-shaped synthetic grafts.

[0010] The punch or drill may include 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 may include 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 may be placed and a specifically sized and shaped drill head may be used to create the opening.

[0011] The bone plug press (graft forming or compression instrument) may include 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 may include 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.

[0012] The impactor or press may include any number of components capable of pushing and compressing the bone plug into the bone tunnels. A suture or metallic overlay may also be applied to provide additional structural stability to the joint during graft incorporation.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWING

[0013] 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:

[0014] FIG. 1 represents the punch and press mechanism described herein according to the present invention.

[0015] FIG. 3 represents a properly completed procedure and the resultant facet joint fusion.

DETAILED DESCRIPTION OF THE INVENTION

[0016] In the United States alone, about 10% of the entire population will suffer from back pain sometime in the next 12 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.

[0017] 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. Pat. No. 6,485,518 and U.S. Patent application Serial Number 2003/0032860. 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.

If the joint is determined to be too badly damaged or diseased for present replacement methods or prospectively 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 method, instrumentation 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. The inventor also expects 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.

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The Arthroscopic Facet Joint Fusion method, instrumentation and pre-made, pre-shaped natural or synthetic bone implants disclosed herein boast a variety of inventive features and components that warrant patent protection, both individually and in combination.

**FIG. 1** illustrates a bone punch instrument as an embodiment of the invention shown without representation of a press accessory, which can be attached to the punch tips (4) and used to press a bone plug more completely described in **FIG. 3** (6) into place. The instrument is specifically invented to be used through an arthroscopic type portal (1) 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. A separating handle (2) is specifically designed to provide sufficient mechanical advantage to the punch tips (4). Punch tips of different sizes to create an appropriate opening to receive the sized bone plug selected by a physician. The opening is marginally smaller than the bone plug to create proper fixation of the plug and the joint. Mechanical advantage created by pressure on the handle is transferred to the punch tips using an "X" type joint (3).

[0044] FIG. 2 illustrates a specially designed osteotome as an embodiment of the invention, which accesses the facet joint through an arthroscopic type portal (5) and is used to make a thin slice into the bone on each of the inner surfaces of the joint to prepare the surface to heal together in a permanent fusion. The osteotome is equipped with a specifically sized single use blade (6) shown in situ in the correct aspect into a facet joint (7). The osteotome is impacted with a slip-hammer (8) to make the cuts and is properly positioned using a loop (9) on the osteotome shaft. A protective stop (10) is provided to ensure that the osteotome blade does not penetrate to an unsafe depth.

[0045] FIG. 3 illustrates a fused facet joint (11) with one shaped autograft, cadaveric allograft or FDA approved synthetic pre-made, pre-shaped cortical bone plug (12). The posterior end of the plug is 2 mm to 3 mm (13) and the anterior end of the plug is 3 mm to 4 mm (14) in a conical shape with the wider portion located in the anterior portion to facilitate fixation during bone graft incorporation. The procedure is envisioned to require only one bone plug. Permanent fixation occurs when bone in-growth occurs into the joint itself and into the plug (15) over time.

1 claim:
1. A bone dowel or plug made of a pre-made, pre-shaped human cortical cadaveric allograft harvested from a femur or other suitable donation site machined, pressed or otherwise conically shaped in any size from 6 millimeters in width at the top to two millimeters in width at the bottom and 0.5 to 2.0 centimeters in length. The dowel or plug is conically shaped to be inserted into a punched or drilled hole through any or all of the forty-eight facet joints located vertebral segments C1-C2 through L5-S1. The dowel or plug is then pressed into place using an accessory to the bone punch/press described in claims 4 and 5.

2. The Device of claim 1 wherein said component is made of a pre-made, pre-shaped synthetic bone or bone substitute.
3. The device of claim 1 wherein said component is made of cortical bone allograft harvested from a patient's iliac crest, femur or other suitable donation site.
4. The device of claim 1 wherein said component is made of a pre-made, pre-shaped bovine cortical cadaveric allograft harvested from a femur or other suitable donation site.
5. The device of claims 1-4 wherein said component is structurally reinforced by adding a core of medical-grade high-density polyethylene.

6. The device of claims 1-4 wherein said component is structurally reinforced by adding a core of stainless steel.
7. The device of claims 1-4 wherein said component is structurally reinforced by adding a core of cobalt-chrome alloy.
8. The device of claims 1-4 wherein said component is structurally reinforced by adding a core of biocompatible metal.
9. The device of claims 1-4 wherein said component is structurally reinforced by inserting a screw comprised of biocompatible metal in the center of the device to provide additional compression and structural stability.
10. The device of claims 1-4 wherein said component is structurally reinforced by inserting a screw comprised of bio-compatible medical-grade high-density polyethylene in the center of the device to provide additional compression and structural stability.
11. The device of claims 5-9 wherein said component includes an outside surface coated with a porous coating.
12. The device of claim 11 wherein the said porous coating is the same material of said component.
13. A bone punch suitable for use through an arthroscopic type portal or in open surgery the same as or similar to the punch shown in FIG. 1. The punch includes attachments to create different sized holes to accommodate different sized devices of claims 1-4 to be used at the discretion of the physician.
14. The device of claim 13 wherein said device includes a press attachment suitable to compress said device of claims 1-4.
15. An osteotome as shown in FIG. 2 to strip away cartilage and bone on both inner edges of a facet joint to prepare the bone for in growth resulting in a permanent natural fusion.
16. Placement of said device of claims 1-9 in a vertebral facet joint segment in any of the facet joints from C1-C2 through L5-S1 the same as or similar to the placement described in FIG. 3 as a structural support until bone in growth occurs to create a permanent natural fusion.
17. Reinforcement of said device of claims 1-9 in a vertebral facet joint segment in any of the facet joints from C1-C2 through L5-S1 using a pin, suture, wire, tie, zip type tie, screw or any other type of reinforcing fixation of any bio-compatible construct or material, absorbable or non-absorbable.
18. In a human spinal facet joint wherein a human, whether allograft or autograft, bovine or synthetic bone or bone substitute, whether or not it is reinforced with a center insert of any absorbable or bio-compatible material, porous or non-porous, threaded or non-threaded, is inserted or pressed into a pre-made hole reaching through or partially through the anterior to the posterior joint segments so as to create a permanent or temporary fusion of said joint.

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