A method for the implantation of a device made of biodegradable materials between interspinous processes is described. The implant has a spacer that can be placed between adjacent spinous processes to limit the movement of the vertebrae. Once inserted between interspinous processes, the implant acts to limit extension (backward bending) of the spine without inhibiting the flexion (forward bending) of the spinal column. The device is used as an adjunct to remediation of an intervertebral disk.
FIG. - 1F
Accessing intervertebral space (810)
   ↓
Restoring damaged disk (820)
   ↓
One of implanting bioresorbable device and distracting adjacent spinous processes (830)
   ↓
The other of implanting bioresorbable device and distracting adjacent spinous processes (840)
   ↓
Tethering the spinous processes (850), or, tethering the spinous processes and bioresorbable device if said device has at least one of a first wing, and a first wing and a second wing (855)
   ↓
Fastening the ends of the tether (860)

Fig. 8
METHOD FOR REMEDIATION OF INTERVERTEBRAL DISKS

CROSS-REFERENCE TO RELATED APPLICATIONS


CLAIM OF PRIORITY


BACKGROUND

[0003] This field of art of this disclosure is an interspinous process implant.

[0004] The spinal column is a biomechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The biomechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and the nerve roots.

[0005] As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), and facet arthropathy. Spinal stenosis typically results from the thickening of the bones that make up the spinal column and is characterized by a reduction in the available space for the passage of blood vessels and nerves. Pain associated with such stenosis can be relieved by medication and/or surgery.

[0006] In addition, to spinal stenosis, and facet arthropathy, the incidence of damage to the intervertebral disks due to injury or degeneration is also common. The primary purpose of the intervertebral disk is as a shock absorber. The disk is constructed of an inner gel-like structure, the nucleus pulposus (the nucleus), and an outer rigid structure comprised of collagen fibers, the annulus fibrosus (the annulus). At birth, the disk is 80% water, and then gradually diminishes, becoming stiff. With age, disks may degenerate, and bulge, thin, herniate, or ossify. Additionally, damage to disks may occur as a result spinal cord trauma or injury.

[0007] Given an increasing need, there is increasing attention currently focused on devices and methods for remediation of conditions of the spine. Remediation includes replacement or repair, or both of an affected part or parts of the spine, as will be discussed in more detail subsequently. Regarding the evolution of remediation of damage to intervertebral disks, rigid fixation procedures resulting in fusion are still the most commonly performed, though trends suggest a move away from such procedures. Currently, areas evolving to address the shortcomings of fusion for remediation of disk damage include technologies and procedures that preserve or repair the annulus, that replace or repair the
nucleus, and that utilize technology advancement on devices for total disk replacement. The trend away from fusion is driven by both issues concerning the quality of life for those suffering from damaged intervertebral disks, as well as responsible health care management. These issues drive the desire for procedures that are minimally invasive, can be tolerated by patients of all ages, especially seniors, and can be performed preferably on an out patient basis.

Accordingly, there is a need in the art for innovation in technologies and methods that advance the art in the area of minimally invasive intervertebral disk remediation, thereby enhancing the quality of life for those suffering from the condition, as well as responding to the current needs of health care management.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A-1F. FIG. 1A is a front plan view of an embodiment of an assembled the disclosed device; FIG. 1B is a left side view of what is shown in FIG. 1A, and FIG. 1C is a front plan view of FIG. 1A including a distraction guide, spacer, a central body and a first wing; FIG. 1D is a left side view of the second wing of FIG. 1A; FIG. 1E is a front plan view of the second wing of FIG. 1A; FIG. 1F is an end view of the spacer of FIG. 1A.

FIG. 2 is a front plan view of a second embodiment of the disclosed device, including an end piece, a spacer, and a distraction guide.

FIG. 3 is a front plan view of a third embodiment of the disclosed device, which is an implant system including an insertion tool comprised of a distraction guide, a central body, a stop and a handle, with a spacer around the central body.

FIGS. 4A and 4B depict the use of the embodiment of FIG. 1A for distraction between vertebrae.

FIG. 5 depicts a further embodiment of the apparatus of the invention based on the embodiment in FIG. 2.

FIG. 6 depicts a further embodiment of the apparatus of the invention based on the embodiment in FIG. 1C.

FIG. 7 depicts a further embodiment of the apparatus of the invention based on the embodiment in FIG. 1A.

FIG. 8 depicts an embodiment of the method of the present invention.

DETAILED DESCRIPTION

What is disclosed herein is a device that limits spinal extension without limiting spinal flexion. More specifically, the embodiments of the device disclosed herein act to limit extension (backward bending) of the spine without inhibiting the flexion (forward bending) of the spinal column.

The disclosed device is made in part or entirely from biodegradable materials. The device is used to distract the spinous processes of adjacent vertebrae in order to increase the volume of the spinal canal, and concomitantly relieve intervertebral load. In this regard, the biodegradable device may be used in procedures where temporary increase in spinal canal volume and relief of intervertebral load is indicated for remediation of an adverse spinal cord condition. Such distraction as a part of surgical remediation of spinal disorders may be performed either before or after the remediation procedure is performed. Remediation includes replacement or repair, or both of an affected part or parts of the spine. For example, remediation of the intervertebral disk may include either disk replacement or disk repair, as well as repair of one part of the disk; the annulus for example, and replacement of another; the nucleus for example. One feature of a biodegradable device is that it does not require an additional surgery for removal after temporary use.

A biodegradable material is a material that is broken down by natural processes, and removed thereby. Classes of materials that are useful as biodegradable materials include polymers, ceramics, and glasses. Polymers of interest include polyesters, polyether esters, polycarbonates, polysaccharides, polyamides, polyurethanes, and polyanhydrides, including copolymers, composites, and blends thereof, as well as composites and blends with ceramics, glasses, and graphite, and the like. A copolymer is a polymer derived from more than one species of monomer. A polymer composite is a heterogeneous combination of two or more materials, wherein the constituents are not miscible, and therefore exhibit an interface between one another. A polymer blend is a macroscopically homogeneous mixture of two or more different species of polymer, the constituents of which are in principle separable by physical means. Fillers, which are solid extenders, may be added to a polymer, copolymer, polymer blend, or polymer composite. Fillers are added to modify properties, such as mechanical, optical, and thermal properties. For biodegradable materials, it may be desirable to add a filler that would reinforce the material mechanically to enhance strength for certain uses, such as load bearing devices. Biodegradable ceramics, glasses, and graphite are examples of classes of materials that are desirable for use as fillers to enhance polymer material strength. It may be desirable to add reinforcement elements to a biodegradable polymer matrix that have the same chemical composition as the polymer matrix. In this instance, the material is referred to as self-reinforced ("SR").

Polyesters are a diverse class of polymers with a number of biodegradable materials of interest. Poly ether esters are a closely related group, and due to the ester functionality, share many of the same properties of members of the polyester class. Since esters are a condensation polymer, they are easily degraded by hydrolytic processes. Moreover, the materials of interest are also biocompatible materials, meaning that they cause no untoward effect to the host; e.g., excessive inflammation, thrombosis, and the like. Additionally, these biodegradable polyethers are readily broken down in vivo and eventually excreted in a biocompatible fashion.

Polyesters meeting the criteria of biocompatible, biodegradable materials include polymers made from monomers of hydroxy acids such as the ω-hydroxylactic acid, ω-hydroxyglutamic acid, β-hydroxybutyric acid, γ-hydroxypropionic acid, and δ-hydroxyvaleric acid. Fumaric acid and hydroxylalkanes, such as propylene glycol, butylene glycol, etc., form copolymers that are also candidate biodegradable polyethers. An example of a biodegradable poly ether ester is poly(dioxanone).

Frequently, the starting materials are condensation products of the free acids, producing cyclized structures
used as the monomer starting materials. Poly(dioxanone) is formed from the cyclized monomer, \( \text{p-dioxanone} \). For the lower molecular weight hydroxy acids, two molecules of hydroxy acid may be condensed to form a cyclized monomer. In the case of lactic acid, the corresponding cyclized condensation product of two lactic acid molecules is referred to commonly as a lactide. In the case of glycolic acid, the resultant molecule is referred to commonly as a glycolide. In this regard, whether one starts with lactic acid, or forms thereof, or with lactide, the resultant polymer is a homopolymer of lactic acid. Similarly, in the case of glycolic acid, or forms thereof, and glycolide, regardless of the starting monomer, the resultant polymer is a homopolymer of glycolic acid. The higher molecular weight hydroxy acids can undergo an internal cyclization to form lactones that may be used as starting monomers, as can the uncyclized monomer forms. Examples of these include caproic acid, which forms caprolactone, and valeric acid, which forms \( \alpha \)-valerolactone. Again, whether the cyclized monomer, or the free acid monomer, or forms thereof are used as starting materials, homopolymers of the corresponding acids will result. In terms of the common nomenclature for designating these polymers, either form of the starting material may be used to refer to the polymer formed thereby. Hence, reference to polylactides is equivalent to poly(lactate), since both are homopolymers of lactic acid.

Stereoisomers of the lactic acid, and lactide exist. The properties of the copolymers formed from the stereoisomers of lactide may vary considerably. Interestingly, there is no linear relationship between properties of homopolymers, and their corresponding copolymers. In that regard, a 70:30 copolymer of poly-L-lactide with poly-D,L-lactide produces a material that has a degradation time of thirty-six months, while the degradation time of poly-D,L-lactide is about twelve months and that of poly-L-lactide is greater than twenty-four months. As another example, a 50:50 copolymer blend of glycolide with D,L-lactide produces a material that degrades in about two months, while the degradation of poly-D,L-lactide and polyglycolide is about twelve months.

Major suppliers of bulk biodegradable polyester materials include Boehringer Ingelheim, Purac, and Dow. Boehringer Ingelheim’s extensive RESOMER® line includes a variety of medical grade poly(\( L \)-lactide), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly([L-lactide-co-glycolide], poly([L-lactide-co-\( \epsilon \)-caprolactone], poly([L-lactide-co-trimethylene carbonate], and poly(dioxanone) resins for fabrication of the disclosed device. Similarly, Purac’s PURASOR® line includes lactide and glycolide monomers, as well as polylactide, polyglycolide, and polylactide/glycolide copolymer resins. Dow’s Tone™ products include high molecular weight polycaprolactone resins of high crystallinity. Metabolix Inc. is a supplier of a family of poly(hydroxybutyrate-co-valerate) copolymer resins under the trade name Biopol.

Polycarbonates have strength properties desirable for biocompatible, biodegradable load bearing implants. The copolymerization of lactide or glycolide with trimethylene carbonate produces poly(lactide-co-trimethylene carbonate) and poly(glycolide-co-trimethylene carbonate), respectively. These copolymers have been used to make a range of products from sutures to tacks and screws. Tyrosine derived polycarbonates such as poly(desaminotyrosyl-tyrosine ethyl carbonate) and poly(desaminotyrosyl-tyrosine hexyl carbonate) have also been used in orthopedic applications, such as bone pins and screws. As mentioned above, Boehringer Ingelheim is a bulk supplier of a poly(\( L \)-lactide-co-\( \epsilon \)-caprolactone) resin, RESOMER® LT 706. Additionally, Integra Life Sciences is a supplier of tyrosine polycarbonates.

Other examples of biocompatible, biodegradable classes of polymers are polysaccharides and polyanhydrides. Polysaccharides are a diverse class and include glucons and glycosaminoglycans. Glucans are any homopolymer of glucose, and include celluloses, starches, and dextrines. Starch blends have properties desirable for load-bearing biocompatible, biodegradable implants. Blends exhibiting good strength characteristics include starch/cellulose acetate blends, starch/polycaprolactone blends, as well as starch blended with copolymers of ethylene and vinyl alcohol. Glucosaminoglycans includes hyaluronates, dermatan sulfates, chondroitin sulfates, heparins, keratins, chitosans, and shittosans. The glucosaminoglycans are a ubiquitous class polysaccharides occurring naturally as structural materials, and show potential for as polymers and copolymers for biocompatible, biodegradable implants. Polyanhydrides are formed by the condensation of diacid molecules. One example of a biodegradable polyanhydride copolymer is the condensation of sebacic acid ("SA") with hexanedecandioic acid ("HAD") to form poly ("SA-co-HAD") anhydride.

It should be noted that there are two important phases of the process of bioresorption: time to complete loss of strength of the material, and time to complete resorption. There are several factors that affect the rate of degradation of biodegradable materials, and hence both the time to complete loss of strength, and time to complete resorption. In general, reduction in strength follows the reduction in molecular weight of a polymeric material as it degrades. Factors that affect degradation of biodegradable polymers include the crystalline nature of the starting material, the hydrophilic nature of the polymer backbone, whether or not the polymer has a reinforcing filler, the initial molecular weight of the polymer, the degree of porosity of the polymer material, the surface area to mass ratio of the device, and the degree of stress on the implanted device.

An example of how the crystalline vs. amorphous nature of the starting material impact degradation is illustrated in the comparing the properties of poly-L-lactide vs. poly-D,L-lactide. The time to complete loss of strength of poly-D,L-lactide is about 6 months, while that of poly-L-lactide is more than 12 months. Recalling from the above, poly-D,L-lactide degrades more rapidly (12 months) than poly-L-lactide (24 months). The racemic mixture of the stereoisomer produces significantly amorphous powders, which yield lower strength materials degrading more rapidly than polymers made from their highly crystalline counterpart. Still another example of how the crystalline versus amorphous nature of a material affects degradation time comes from the previously given example of a 50:50 copolymer blend of glycolide with D,L lactide. This copolymer exhibits a highly amorphous state, and produces a material that degrades significantly faster (two months) than the degradation of poly-D,L-lactide and polyglycolide (twelve months).

Concerning the hydrophilic nature of the polymer backbone, an example of how this property impacts degra-
dation is demonstrated through the comparison of the stability of poly-L-lactide against polyglycolide. Poly-L-lactide has an increased hydrophobic nature (decreased hydrophilic nature) compared with polyglycolide, due to the methyl group in the backbone structure, and is therefore less susceptible to hydrolysis. The time to complete loss of strength of poly-L-lactide is greater than twelve months, while that of polyglycolide is about two months. The comparative degradation times for poly-L-lactide and polyglycolide are twenty-four months versus about six to twelve months, respectively.

[0030] The impact of reinforcing filler on increasing material strength can be understood by comparing poly-L-lactide to SR poly-L-lactide properties. Time to complete loss of strength for poly-L-lactide is greater than twelve months, while for SR poly-L-lactide is about eighteen months, while the degradation times are about twenty-four months and seventy-two months, respectively. Other types of reinforcing fillers include ceramics, glasses, and graphite fibers. Ceramics including hydroxyapatite and tricalcium phosphate, and blends thereof are commonly used reinforcing biodegradable materials. Bioglasses are silicate glasses containing sodium, calcium, and phosphate as the main components. Ceramics, bioglasses, and bioglass/ceramic compositions have been used in numerous polymer and copolymer biodegradable material blends to add strength to these materials. The biodegradation of the inorganic ceramic and glass materials follows as the dissolution of the ions, and biodegradation thereof.

[0031] In addition to the molecular properties influencing material properties that impact degradation, bulk properties of the material, such as the porosity of material, as well as properties of the device, such as the surface area to mass ratio, affect degradation time, as well. As previously mentioned, there are two phases to the degradation process: time to complete loss of strength and time to complete resorption. These two phases of degradation correlate to two distinct processes: (1) water penetration into the material, with initial degradation of polymer chains, referred to as the hydrolysis phase; and (2) degradation of material strength and fragmentation, and process of enzymatic attack, phagocytosis, and metabolism. This phase is referred to as metabolism or bulk erosion. Increased porosity of a device and increased relative surface area to mass of a device will enhance the hydrolysis phase, and hence tend to hasten the overall degradation process.

[0032] Regarding the impact of degradative processes on the site of the implant, as loss of strength proceeds, the implant will begin to fragment. Increased stress on the implant, and increased vascularization may increase the degradation time. Stress may have a role in decreasing structural integrity, and the increase in the rate of water absorption thereby, and hence affect the rate of bulk erosion. Once the polymer has fragmented into small pieces, in vivo processes, such as phagocytosis, and enzymatic activity speeding up the hydrolysis process may proceed to hasten in the biodegradation process. Such in vivo processes are enhanced by increased vascularization. The presence of the small particles, as well as a local drop in tissue pH in the case of ester hydrolysis due to increased levels of free acid, induces an inflammatory response in the tissue. When biodegradation is complete, the inflammatory response subsides. In that regard, it may be desirable, depending on the use of the device, to fabricate devices from polymers that take longer to complete loss of strength, and have slower rates of degradation.

[0033] By what is disclosed of molecular properties, bulk material properties, device design, and factors at the site of implantation, it is therefore possible to design devices from selected materials accordingly.

[0034] The following description is presented to enable any person skilled in the art to make and use the disclosed device. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present disclosure as defined by the appended claims. Thus, the present disclosure is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

[0035] An embodiment of an implant 100 of the disclosed device is depicted in FIG. 1A. This implant 100 includes a first wing 104 and a spacer 150 and a lead-in tissue expander or distraction guide 110. This embodiment further can include, as required, a second wing 132. As can be seen in FIG. 1A, a central body 102 extends from the first wing 104 and is the body that connects the first wing 104 to the tissue expander or distraction guide 110. Also, as can be seen in FIG. 1A and 1B, the distraction guide 110 in this particular embodiment acts to distract the soft tissue and the spinous processes when the implant 100 is inserted between adjacent spinous processes. In this particular embodiment, the distraction guide 110 has an expanding cross-section from the distal end 111 to the area where the second wing 132 is secured to the distraction guide 110. In this embodiment the distraction guide 110 is wedge-shaped.

[0036] Additionally, as can be seen in FIGS. 1A, and 1F, the spacer 150 is elliptical shaped in cross-section. The spacer 150 can have other shapes such as circular, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other shapes, and be within the spirit and scope of what is disclosed. In this embodiment, spacer 150 includes a bore 152 which extends the length of spacer 150. The spacer 150 is received over the central body 102 of the implant 100 and can rotate thereon about the central body 102. In these embodiments, the spacer 150 can have minor and major dimensions as follows:

<table>
<thead>
<tr>
<th>MINOR DIMENSION (116A)</th>
<th>MAJOR DIMENSION (116 B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mm</td>
<td>13.7 mm</td>
</tr>
<tr>
<td>8 mm</td>
<td>14.2 mm</td>
</tr>
<tr>
<td>10 mm</td>
<td>15.2 mm</td>
</tr>
<tr>
<td>12 mm</td>
<td>16.3 mm</td>
</tr>
<tr>
<td>14 mm</td>
<td>17.8 mm</td>
</tr>
</tbody>
</table>

[0037] The advantage of the use of the spacer 150 as depicted in the embodiment of FIG. 1A is that the spacer 150 can be rotated and repositioned with respect to the first wing 104, in order to more optimally position the implant 100 between spinous processes. It is to be understood that the cortical bone or the outer bone of the spinous processes is stronger at an anterior position adjacent to the vertebral
bodies of the vertebra than at a posterior position distally located from the vertebral bodies. Also, biomechanically for load bearing, it is advantageous for the spacer 150 to be close to the vertebral bodies. In order to facilitate this and to accommodate the anatomical form of the bone structures, as the implant is inserted between the spinous processes and/or urged toward the vertebral bodies, the spacer 150 rotates relative to the wings, such as wing 104, so that the spacer 150 is optimally positioned between the spinous processes, and the wings 104 are optimally positioned relative to the spinous processes. Further, the broad upper and lower surfaces of the spacer 150 helps spread the load that the spinous processes place on the spacer 150.

Additionally, for the embodiments shown in FIGS. 2 and 3, the device may be secured in place via bioresorbable sutures or screws. The degradation times of sutures made from bioresorbable polymers are influenced by both the suture size and type of polymer. Suture products such as Maxon (Davis and Geck), a polyglyconate based suture material, and PDS (Ethicon), a polydioxanone based suture material, maintain tensile strength for four to six weeks, and may take up to six months to be resorbed completely. Depending on the material used, as detailed above, screws may have total time to resorption from six months to five years. Biologically Quite (Instrument Makar), a poly(D,L-lactide-co-glycolide) screw degrades in about six months, while Plusline (Plusis), a poly(L-lactide-co-D,L lactide) copolymer degrades in about five years, and Bioscrew (Linvatec), a ploy(D-lactide) screw degrades in the range of two to three years.

In another embodiment, the spacer 150 has a cross-section with a major dimension and a minor dimension, wherein the major dimension is greater than the minor dimension and, for example, less than about two times the minor dimension.

Implant 200 is depicted in FIG. 2. This implant is similar to the implants 100 of FIG. 1, except that this implant does not have either first or second wings. Implant 200 includes a distraction guide 210, spacer 220 which surrounds a central body just as central body 102 of implant 100 in FIG. 1, and endpiece 230. The distraction guide 210 in this preferred embodiment is cone-shaped, and is located in the previous embodiment's central body (not shown). At the other end is an endpiece 230. Endpiece 230 is used to contain the other end of the spacer 220 relative to the central body. This embodiment is held together with a bolt (not shown).

FIG. 3 depicts an implant system 300. Implant system 300 includes an insertion tool 310. Insertion tool 310 includes a distraction guide 320 which in a preferred embodiment is substantially cone-shaped. Distraction guide 320 guides the insertion of the spacer 330 and the insertion tool 360 between adjacent spinous processes. The insertion tool 310 further includes a central body 340, a stop 350, and a handle 360. The distraction guide 320 at its base has dimensions which are slightly less than the internal dimensions of the spacer 330 so that the spacer can fit over the distraction guide 320 and rest against the stop 350. The tool 310 with the distraction guide 320 is used to separate tissues and ligaments and to urge the spacer 330 in the space between the spinous processes. Once positioned, the distraction guide insertion tool 310 can be removed leaving the spacer 330 in place.

For the implants 200 of FIG. 2 and 300 of FIG. 3, such devices would be appropriate where the anatomy between the spinous processes was such that it would be undesirable to use either a first or second wing. However, these embodiment afford all the advantageous described hereinabove (FIGS. 1A-1F) with respect to the distraction guide and also with respect to the dynamics of the spacer.
connect with the second wing 632. Instead, the tether 670 fastens with an upper bore 605 in a first wing 604 and passes around an upper spinous process 710 and can then pass through a bore 615 in the distraction guide 610. The tether 670 then passes under the lower spinous process 720 and fastens with a lower bore 607 through the first wing 604. The tether 670 can be fastened at the upper bore 605 and lower bore 607 of the first wing 604 by an appropriate fastening means, such as a cuff made of biocompatible, biodegradable or bioresorbable material. Alternatively, the ends of the tether 670 fastened to the upper bore 605 and lower bore 607 can be knotted or tied off, or sewn with sutures.


FIG. 8 is a flowchart showing an embodiment of the method of the present invention. Regarding the disclosed devices used in conjunction with disk remediation implants and procedures like those described by the aforementioned incorporated references, load relief of the vertebral disks, either before or after a disk remediation procedure is done 820, is indicated either to assist in the process of disk remediation, or to allow for effective recovery of the surgical procedure, or both. Moreover, the disclosed devices, made in part or completely from the biocompatible, biodegradable materials described in this disclosure, require no additional surgical procedure for removal after recovery is complete.

The biodegradable load relief/spinal distraction devices disclosed above can be inserted laterally. The implanting physician, after accessing the intervertebral space 810 optionally can distract the spinous process before inserting the device 830, 840. Alternatively, the tissue expander can be used to distract the spinous processes while inserting the device 830, 840.

The spinous processes can be further stabilized by the use of a biodegradable tether together with the resorbable distracting device adapted to accept the tether 855, or with a biodegradable device which does not have wings and need not be adapted to accept the tether 855. If the device does not have a first or second wing, the tether is looped around the spinous processes and fastened, after the implant is positioned between the spinous processes 850.

Certain of the biodegradable devices are adapted to accept the tether so that the tether binds not only the spinous processes but also the implant, to maintain temporarily a minimum spacing between the spinous processes 855. The adaptations include an upper bore and a lower bore on the first wing, and a bore through the distraction guide. During the implantation, the device is inserted between the spinous processes with one first of the tether attached to the upper bore of the first wing. A curved needle or other tool can then be used to lead the second end of the tether over an upper spinous process, through the bore in the tissue expander, under a lower spinous process, and through the lower bore of the first wing, to fasten the second end to the lower bore of the first wing. The tether is tightened to the desired degree to maintain a minimal distraction of the spinous processes and the ends of the tether are fastened 860.

It is within the scope of the present invention to fasten the first end of the tether to the lower bore of the first wing, and to use a curved needle or other implement to lead the second end of the tether below the lower spinous process, through the bore in the tissue expander, over the upper spinous process, and through the upper bore on the first wing, to fasten the second end of the upper bore of the first wing.

Where the implant has a second wing, the same method is followed as for an implant with one wing, as the second wing need not engage the tether.

The foregoing description of embodiments of the present disclosure has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of this disclosure and its practical application, thereby enabling others skilled in the art to understand various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of this disclosure be defined by the following claims and its equivalence.
What is claimed:

1. A method for remediation of a damaged intervertebral disk, comprising the steps of:
   - accessing an intervertebral space;
   - restoring the damaged disk;
   - inserting a biodegradable device between spinous processes of the spinal column; and
   - wherein the steps of restoring and inserting are done in any order.

2. The method of claim 1 further comprising the step of tethering the spinous processes with a biodegradable tether.

3. The method of claim 2 wherein the tethering step further comprises threading the tether around the spinous processes and fastening the ends together.

4. The method of claim 1, wherein the step of inserting the device further comprises:
   - accessing adjacent first and second spinal processes of the vertebrae;
   - distracting the first and second spinous processes;
   - implanting the device between said spinous processes, said device comprising a spacer; and
   - where the distracting and implanting steps are done in any order or simultaneously.

5. The method of claim 4, wherein the step of implanting the spacer between the spinous processes further comprises:
   - assembling the spacer on an insertion tool with a distal end and proximal end, the tool comprising:
   - a distraction guide at the distal end of the insertion tool, a handle at the proximal end of the insertion tool; a central body proximal to the distraction guide, and a stop between the central body and the handle; and
   - wherein the spacer fits over the distraction guide and is disposed between the stop and the distraction guide;
   - separating tissues and ligaments with the distraction guide of the insertion tool;
   - urging the spacer into the space between the spinous processes;
   - removing the insertion tool, while leaving the spacer in place; and
   - where the distracting and implanting steps are done in any order or simultaneously.

6. The method of claim 1, wherein the step of inserting the device further comprises:
   - accessing adjacent first and second spinal processes of the vertebrae;
   - distracting the first and second spinous processes;
   - inserting a device between the spinous processes of the spinal column using the steps of:
     - a central body with a distal end and a proximal end, said central body having a longitudinal axis;
     - a spacer associated with the central body, wherein said spacer is adapted to be placed between spinous processes;
   - a tissue expander extending from the distal end of the body; and
   - where the distracting and inserting steps are done in any order or simultaneously.

7. The method of claim 1, wherein the step of inserting the device further comprises:
   - accessing adjacent first and second spinal processes of the vertebrae;
   - distracting the first and second spinous processes;
   - inserting a device between the spinous processes of the spinal column, the device comprising:
     - a central body with a distal end and a proximal end, said central body having a longitudinal axis;
     - a stop located at the proximal end of the central body;
     - a spacer associated with the central body, wherein said spacer is adapted to be placed between spinous processes;
     - a tissue expander extending from the distal end of the body; and
   - where the distracting and inserting steps are done in any order or simultaneously.

8. The method of claim 7, wherein the stop is a first wing.

9. The method of claim 8 further comprising tethering the spinous processes and the device wherein the device already is inserted between the spinous processes, and wherein the device has a biodegradable tether anchored at a first end to the device.

10. The method of claim 9 wherein the tethering step further comprises using a tool to guide a second end of the tether over an upper spinous process, through a bore through the tissue expander, under a lower spinous process, and through a lower bore in the first wing; and anchoring the second end of the tether to the lower bore in the first wing, the first end of the tether anchored to an upper bore in the first wing.

11. The method of claim 9 wherein the tethering step further comprises using a tool to guide a second end of the tether under a lower spinous process, through a bore through the tissue expander, over an upper spinous process, and through an upper bore in the first wing; and anchoring the second end of the tether to the upper bore in the first wing, the first end of the tether anchored to a lower bore in the first wing.

12. The method of claim 8, further comprising a second wing located at the distal end of the central body, wherein the spacer is between the stop and the second wing.

13. The method of claim 12 further comprising tethering the spinous processes and the device wherein the device already is inserted between the spinous processes, and wherein the device has a biodegradable tether anchored at a first end to the device.

14. The method of claim 13 wherein the tethering step further comprises using a tool to guide a second end of the tether over an upper spinous process, through a bore through the tissue expander, under a lower spinous process, and through a lower bore in the first wing; and anchoring the second end of the tether to the lower bore in the first wing, the first end of the tether anchored to an upper bore in the first wing.
15. The method of claim 13 wherein the tethering step further comprises using a tool to guide a second end of the tether under a lower spinous process, through a bore through the tissue expander, over an upper spinous process, and through an upper bore in the first wing; and anchoring the second end of the tether to the upper bore in the first wing, the first end of the tether anchored to a lower bore in the first wing.

16. A method for remediation of a damaged intervertebral disk, comprising:

accessing the intervertebral space;

inserting a device between the spinous processes of the spinal column using the steps of:

accessing adjacent first and second spinal processes of the vertebrae;

distracting the first and second spinous processes;

implanting the device between the spinous processes; and

where the distracting and implanting steps are done in any order or simultaneously; and

replacing the intervertebral disk; and

wherein the steps of inserting and replacing are done in any order.

17. A method for remediation of a damaged intervertebral disk, comprising:

accessing the intervertebral space;

inserting a device between the spinous processes of the spinal column using the steps of:

accessing adjacent first and second spinal processes of the vertebrae;

distracting the first and second spinous processes;

implanting the device between the spinous processes; and

where the distracting and implanting steps are done in any order or simultaneously; and

repairing the intervertebral disk; and

wherein the steps of inserting and repairing are done in any order.

18. In a method for remediation of an intervertebral disk, the improvement including the step of temporarily distracting spinous processes with the implantation of a bioresorbable spacer between the spinous processes.

19. In a method for remediation of an intervertebral disk, the improvement including the step of temporarily maintaining a minimum spacing between the spinous processes with the implantation of a bioresorbable spacer between the spinous processes.

20. The method of claim 16 wherein the inserting step includes inserting a bioresorbable device.

21. The method of claim 17 wherein the inserting step includes inserting a bioresorbable device.

22. A method for remediation of a damaged intervertebral disk, comprising the steps of:

accessing an intervertebral space;

restoring the damaged disk;

inserting a device between spinous processes of the spinal column; and

wherein the steps of restoring and inserting are done in any order.

23. The method as in claim 22 further comprising the step of tethering the spinous processes with a bioresorbable suture after the inserting step.

24. The method as in claim 22 further comprising the step of tethering the spinous processes and the device with a bioresorbable suture after the inserting step.

25. In a method for remediation of an intervertebral disk, the improvement including the step of temporarily distracting spinous processes with the implantation of a spacer between the spinous processes.

26. In a method for remediation of an intervertebral disk, the improvement including the step of temporarily maintaining a minimum spacing between the spinous processes with the implantation of a spacer between the spinous processes.

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