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Title: DEVICE FOR RESECTING SPINAL TISSUE

Abstract: A device for excising tissue. In an embodiment, the device comprises an outer sleeve. In addition, the device comprises an inner tubular member slidingly received within the outer sleeve. Further the device comprises a cutting head connected to a distal end of the inner tubular, wherein the cutting head comprises at least three arms extending axially from the inner tubular. Still further, the device has an open position in which the cutting head extends from the outer sleeve, and a closed position in which the cutting head is at least partially disposed within the sleeve.
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DEVICE FOR RESECTING SPINAL TISSUE

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable.

BACKGROUND

Field of the Invention

The present invention relates generally to minimally invasive methods, devices and systems for treating spinal disorders using imaging guidance. More particularly, the present invention relates to devices and methods to reduce stenosis and increase the cross-sectional area of the spinal canal available for the spinal cord. Still more particularly, the present invention relates to devices and methods to percutaneously excise portions of an enlarged ligamentum flavum.

Field of the Invention

The present invention relates generally to a minimally invasive method, device and system for treating spinal disorders using imaging guidance. More particularly, this invention relates to devices and tools that provide a percutaneous portal to tissues in a region of interest. Still more particularly, this invention relates to devices and tools that provide percutaneous portals to tissue through bone.

Background of the Invention

The vertebral column (spine, spinal column, backbone) forms the main part of the axial skeleton, provides a strong yet flexible support for the head and body, and protects the spinal cord disposed in the vertebral canal, which is formed within the vertebral column. The vertebral column comprises a stack of vertebrae with an intervertebral disc between adjacent vertebrae. The vertebrae are stabilized by muscles and ligaments that hold the vertebrae in place and limit the movements of the vertebrae.

As illustrated in Figure 1, each vertebra includes a vertebral body that supports a vertebral arch. A median plane generally divides vertebra into two substantially equal lateral sides. Vertical body has the general shape of a short cylinder and is anterior to the vertebral arch. The vertebral arch together with vertebral body encloses a space termed the vertebral foramen. The succession of vertebral foramen in adjacent vertebrae along the vertebral column define the vertebral canal (spinal canal), which contains the spinal cord.

Vertebral arch is formed by two pedicles which project posteriorly to meet two laminae. The two laminae meet posteriorly to form the spinous process. At the
junction of pedicles 24 and laminae 16, six processes arise. Two transverse processes 20 project posterolateral, two superior articular processes 22 project generally superiorly and are positioned superior to two inferior articular processes 25 that generally project inferiorly.

The vertebral foramen 15 is generally an oval shaped space that contains and protects the spinal cord 28. Spinal cord 28 comprises a plurality of nerves 34 surrounded by cerebrospinal fluid (CSF) and an outermost sheath/membrane called the dural sac 32. The CSF filled dural sac 32 containing nerves 34 is relatively compressible. Posterior to the spinal cord 28 within vertebral foramen 15 is the ligamentum flavum 26. Laminae 16 of adjacent vertebral arches 14 in the vertebral column are joined by the relatively broad, elastic ligamentum flavum 26.

In degenerative conditions of the spine, narrowing of the spinal canal (stenosis) can occur. Lumbar spinal stenosis is often defined as a dural sac cross-sectional area less than 100 mm² or an anteroposterior (AP) dimension of the canal of less than 10-12 mm for an average male.

The source of many cases of lumbar spinal stenosis is thickening of the ligamentum flavum. Spinal stenosis may also be caused by subluxation, facet joint hypertrophy, osteophyte formation, underdevelopment of spinal canal, spondylosis deformans, degenerative intervertebral discs, degenerative spondylolisthesis, degenerative arthritis, ossification of the vertebral accessory ligaments and the like. A less common cause of spinal stenosis, which usually affects patients with morbid obesity or patients on oral corticosteroids, is excess fat in the epidural space. The excessive epidural fat compresses the dural sac, nerve roots and blood vessels contained therein and resulting in back and leg pain and weakness and numbness of the legs. Spinal stenosis may also affect the cervical and, less commonly, the thoracic spine.

Patients suffering from spinal stenosis are typically first treated with exercise therapy, analgesics and anti-inflammatory medications. These conservative treatment options frequently fail. If symptoms are severe, surgery is required to decompress the canal and nerve roots.

In some conventional approaches to correct stenosis in the lumbar region, an incision is made in the back and the muscles and supporting structures are stripped away from the spine, exposing the posterior aspect of the vertebral column. The thickened ligamentum flavum is then exposed by removal of a portion of the vertebral arch, often at the laminae, covering the back of the spinal canal (laminectomy). The thickened ligamentum flavum ligament can then be excised by sharp dissection with a scalpel or punching instruments such as a Kerison punch that is used to remove small chips of tissue. The procedure is performed under general anesthesia. Patients are usually admitted to the hospital for approximately five to seven days depending on the age and overall condition of the patient. Patients usually require between six weeks and three months to
recover from the procedure. Further, many patients need extended therapy at a rehabilitation facility to regain enough mobility to live independently.

Much of the pain and disability after an open laminectomy results from the tearing and cutting of the back muscles, blood vessels, supporting ligaments, and nerves that occurs during the exposure of the spinal column. Also, because the spine stabilizing back muscles and ligaments are stripped and detached from the spine during the laminectomy, these patients frequently develop spinal instability post-operatively.

Minimally invasive techniques offer the potential for less post-operative pain and faster recovery compared to traditional open surgery. Percutaneous interventional spinal procedures can be performed with local anesthesia, thereby sparing the patient the risks and recovery time required with general anesthesia. In addition, there is less damage to the paraspinal muscles and ligaments with minimally invasive techniques, thereby reducing pain and preserving these important stabilizing structures.

Various techniques for minimally invasive treatment of the spine are known. Microdiscectomy is performed by making a small incision in the skin and deep tissues to create a portal to the spine. A microscope is then used to aid in the dissection of the adjacent structures prior to discectomy. The recovery for this procedure is much shorter than traditional open discectomies. Percutaneous discectomy devices with fluoroscopic guidance have been used successfully to treat disorders of the disc but not to treat spinal stenosis or the ligamentum flavum directly. Arthroscopy or direct visualization of the spinal structures using a catheter or optical system have also been proposed to treat disorders of the spine including spinal stenosis, however these devices still use miniaturized standard surgical instruments and direct visualization of the spine similar to open surgical procedures. These devices and techniques are limited by the small size of the canal and these operations are difficult to perform and master. In addition, these procedures are painful and often require general anesthesia. Further, the arthroscopy procedures are time consuming and the fiber optic systems are expensive to purchase and maintain.

Still further, because the nerves of the spinal cord pass through the spinal canal directly adjacent to and anterior to the ligamentum flavum, any surgery, regardless of whether open or percutaneous, includes a risk of damage to the nerves of the spinal cord.

Hence, it remains desirable to provide simple methods, techniques, and devices for treating spinal stenosis and other spinal disorders without requiring open surgery. It is further desired to provide a system whereby the risk of damage to the dural sac containing the spinal nerves may be reduced.
SUMMARY OF THE INVENTION

These and other needs in the art are addressed in one embodiment by a device for excising tissue. In an embodiment, the device comprises an outer sleeve. In addition, the device comprises an inner tubular member slidingly received within the outer sleeve. Further the device comprises a cutting head connected to a distal end of the inner tubular, wherein the cutting head comprises at least three arms extending axially from the inner tubular. Still further, the device has an open position in which the cutting head extends from the outer sleeve, and a closed position in which the cutting head is at least partially disposed within the sleeve.

These and other needs in the art are addressed in another embodiment by a method for treating stenosis in a spine of a patient having a median plane, the spine including a spinal canal having a posterior surface, a dural sac and an epidural space between the posterior surface and dural sac, the location of the stenosis determining a region of interest in the spine. In an embodiment, the method comprises the step of positioning a tissue excision device adjacent the region of interest, wherein the tissue excision device comprises an outer sleeve, an inner tubular member slidingly received within the outer sleeve, and a cutting head connected to a distal end of the inner tubular, the cutting head including at least three arms extending axially from the inner tubular. In addition, the method comprises the step of opening the tissue excision device by extending the cutting head from the outer sleeve. Further, the method comprises the step of inserting the tissue excision device into tissue in the region of interest. Still further, the method comprises the step of closing the tissue excision device by advancing the outer sleeve over the cutting head. Moreover, the method comprises the step of retracting the tissue excision device from the tissue in the region of interest.

These and other needs in the art are addressed in another embodiment by a kit for performing a procedure on a spine, the spine including an epidural space containing a dural sac. In an embodiment, the kit comprises an insertion member for accessing the epidural space. In addition, the kit comprises a volume of a contrast medium adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space. Further, the kit comprises a tissue excision device comprising an outer sleeve, an inner tubular member slidingly received within the outer sleeve, a cutting head connected to a distal end of the inner tubular, wherein the cutting head comprises at least three arms extending axially from the inner tubular.

Thus, embodiments described herein comprise a combination of features and advantages intended to address various shortcomings associated with certain prior devices. The various characteristics described above, as well as other features, will be readily apparent to those skilled in the art upon reading the following detailed description of the preferred embodiments, and by
referring to the accompanying drawings. It should be appreciated by those skilled in the art that
the conception and the specific embodiments disclosed may be readily utilized as a basis for
modifying or designing other structures for carrying out the same purposes of the embodiments
described herein. It should also be realized by those skilled in the art that such equivalent
constructions do not depart from the spirit and scope of the invention as set forth in the appended
claims.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the invention, reference is made to the
accompanying drawings, wherein:

Figure 1 is cross-section of the spine viewed from the space between two vertebrae,
showing the upper surface of one vertebra and the spinal canal with the dural sac and a normal
(un-stenosed) ligamentum flavum therein;

Figure 2 is an illustration of the same section as Figure 1, showing the spinal canal with
the dural sac and a thickened ligamentum flavum therein;

Figure 3 is an enlarged cross-section of a vertebral foramen, showing a safety zone
created by compression of the dural sac;

Figure 4 is the cross-section of Figure 3, showing a tissue excision tool positioned in the
ligamentum flavum;

Figures 5-9 are a series of illustrations showing tissue excision by a tissue-excision tool
constructed in accordance with a first embodiment of the invention;

Figures 10-14 are a series of illustrations showing tissue excision by a tissue-excision tool
constructed in accordance with a second embodiment of the invention;

Figures 15 and 17 are sequential illustrations showing removal of tissue from a tissue-
excision tool by a tissue-removal device constructed in accordance with an embodiment of the
invention;

Figures 16 and 18 are end views of the tissue-removal device of Figures 15 and 17,
respectively;

Figure 19 shows an alternative embodiment of a grasping needle with a corkscrew shape;

Figure 20 is a perspective view of a tissue-excision tool constructed in accordance with a
third embodiment of the invention;

Figures 21 and 22 are enlarged cross-sectional and perspective views, respectively, of the
grasping device of Figure 20 in its retracted position;

Figures 23 and 24 are enlarged cross-sectional and perspective views, respectively, of the
grasping device of Figure 20 in its extended position;
Figure 25 is a schematic illustration of one embodiment of a double-ended ligament anchor being deployed in a ligamentum flavum;

Figure 26 shows the device of Figure 25 after full deployment;

Figures 27 is a perspective view of an entire tool constructed in accordance with preferred embodiments;

Figure 28 is an enlarged cross-sectional view of the distal tip of the tool of Figure 27 with the aperture partially opened;

Figure 29 is a cross-sectional view of the handle end of the tool of Figure 27;

Figure 30 is cross-section of another embodiment of a tissue-removal device;

Figure 31 is a perspective view of the distal portion of an embodiment of a tissue excision device in an open position;

Figure 32 is an end-view of the tissue excision device of Figure 31;

Figure 33 is a perspective view of the tissue excision device of Figure 31 transitioning from the open position to the closed position; and

Figures 34 and 35 are sequential schematic illustrations showing the excision of tissue by the tissue excision tool illustrated in Figure 31.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following discussion is directed to various embodiments of the invention. Although one or more of these embodiments may be preferred, the embodiments disclosed should not be interpreted, or otherwise used, as limiting the scope of the disclosure, including the claims. In addition, one skilled in the art will understand that the following description has broad application, and the discussion of any embodiment is meant only to be exemplary of that embodiment, and not intended to intimate that the scope of the disclosure, including the claims, is limited to that embodiment.

For purposes of this discussion, the x-, y-, and z-axes are shown in Figures 1 and 3 to aid in understanding the descriptions that follow. The x-, y-, and z-axes have been assigned as follows. The x-axis is perpendicular to the longitudinal axis of the vertebral column and perpendicular to the coronal/frontal plane (i.e., x-axis defines anterior vs. posterior relationships). The y-axis runs substantially parallel to the vertebral column and perpendicular to the transverse plane (i.e., y-axis defines superior vs. inferior relationships). The z-axis is perpendicular to the longitudinal axis of the vertebral column and perpendicular to the median/midsagittal plane (i.e., z-axis defines the lateral right and left sides of body parts). The set of coordinate axes (x-, y-, and z-axes) are consistently maintained throughout although different views of vertebrae and the spinal column may be presented.
It is to be understood that the median/midsagittal plane passes from the top to the bottom of the body and separates the left and the right sides of the body, and the spine, into substantially equal halves (e.g., two substantially equal lateral sides). Further, it is to be understood that the frontal/coronal plane essentially separates the body into the forward (anterior) half and the back (posterior) half, and is perpendicular to the median plane. Still further, it is to be understood that the transverse plane is perpendicular to both the median plane and coronal plane and is the plane which divides the body into an upper and a lower half.

**The Spinal Canal and Spinal Stenosis**

Referring again to Figure 1, vertebral foramen 15 contains a portion of the ligamentum flavum 26, spinal cord 28, and an epidural space 27 between ligamentum flavum 26 and spinal cord 28. Spinal cord 28 comprises a plurality of nerves 34 surrounded by cerebrospinal fluid (CSF) contained within dural sac 32. Nerves 34 normally comprise only a small proportion of the dural sac 32 volume. Thus, CSF filled dural sac 32 is somewhat locally compressible, as localized pressure causes the CSF to flow to adjacent portions of the dural sac. Epidural space 27 is typically filled with blood vessels and fat. The posterior border of the normal epidural space 27 generally defined by the ligamentum flavum 26, which is shown in its normal, non-thickened state in Figure 1.

Figure 2 illustrates a case of spinal stenosis resulting from a thickened ligamentum flavum 26. Since vertebral foramen 15 is defined and surrounded by the relatively rigid bone its volume is substantially constant. Thus, thickening of ligamentum flavum 26 within vertebral foramen 15 can eventually result in compression of spinal cord 28. In particular, the thickened ligamentum flavum 26 may exert a compressive force on the posterior surface of dural sleeve 32. In addition, thickening of ligamentum flavum 26 may compress the blood vessels and fat occupying epidural space 27.

Compression of spinal cord 28, particularly in the lumbar region, may result in low back pain as well as pain or abnormal sensations in the legs. Further, compression of the blood vessels in the epidural space 27 that houses the nerves of the cauda equina may result in ischemic pain termed spinal claudication.

In order to relieve the symptoms associated with a thickened or enlarged ligamentum flavum 26, methods, techniques, and devices described herein may be employed to reduce the compressive forces exerted by the thickened ligamentum flavum on spinal cord 28 and the blood vessels in epidural space 27 (e.g., decompress spinal cord 28 and blood vessels in epidural space 27). In particular, compressive forces exerted by the thickened/enlarged ligamentum flavum 26 may be reduced by embodiments of a minimally invasive ligament decompression (MILD) procedure described herein. In some embodiments, the MILD procedure may be performed
percutaneously to reduce the size of ligamentum flavum 26 by excising portions of ligamentum flavum 26. In particular, in some embodiments of the MILD procedure, the ligamentum flavum 26 is accessed, cut and removed ipsilaterally (i.e., on the same side of vertebral arch 14) by a percutaneous cranial-caudal approach. Such an embodiment of the MILD procedure may be described hereinafter as Ipsilateral Approach MILD Procedure (ILAMP).

Creation of Safety Zone

As shown in Figures 1 and 2, ligamentum flavum 26 is posteriorly apposed to spinal cord 28. Thus, placement of tools within ligamentum flavum 26 to excise portions of ligamentum flavum 26 creates a risk of for inadvertent damage to the spinal cord 28, dural sac 32, and/or nerves 34. Thus, in preferred embodiments of the procedures described herein, prior to insertion of tissue removal tools into the ligamentum flavum 26, a gap is advantageously created between ligamentum flavum 26 and spinal cord 28 to provide a safety zone between ligamentum flavum 26 and spinal cord 28.

Figure 3 illustrates an enlarged cross-sectional view of a vertebral foramen 15 within a vertebra. Vertebral foramen 15 includes epidural space 27 and spinal cord 28 containing nerves 34 and CSF within dural sac 32. Further, a thickened/enlarged ligamentum flavum 26 extends into vertebral foramen 15. To reduce the risk of damage to dural sac 32 and spinal cord 28, a safety zone 40 is created between ligamentum flavum 26 and dural sac 32.

As previously described, spinal cord 28 comprises nerves 34 surrounded by CSF and is contained within dural sac 32. Since more than 90% of the volume of dural sac 32 in the lumbar region is filled by CSF, dural sac 32 is highly compressible. Thus, even when stenosis is causing compression of spinal cord 28, in most cases it is possible to temporarily compress spinal cord 28 further. Thus, according to preferred embodiments, dural sac 32 is further compressed in the region of interest by injecting a fluid into epidural space 27 to create safety zone 40. The presence of the injected fluid comprising safety zone 40 gently applies an additional compressive force to the outer surface of dural sac 32 so that at least a portion of the CSF within dural sac 32 is forced out of dural sac 32 in the region of interest, resulting in safety zone 40 between dural sac 32 and ligamentum flavum 26.

According to some embodiments, dural sac 32 is compressed by injecting a standard radioopaque non-ionic myelographic contrast medium or other imagable or non-imagable medium into epidural space 27 in the region of interest. This is preferably accomplished with a percutaneous injection. Sufficient injectable fluid is preferably injected to displace the CSF out of the region of interest and compress dural sac 32 to at least a desired degree. The injected medium is preferably substantially contained within the confines of epidural space 27 extending to the margins of the dural
sac 32. The epidural space is substantially watertight and the fatty tissues and vascularization in epidural space 27, combined with the viscous properties of the preferred fluids, serve to substantially maintain the injected medium in the desired region of interest. This novel method for protecting spinal cord 28 column may be referred to hereinafter as "contrast-guided dural protection."

Once a safety zone 40 has been created, a tool 100, such as the tissue excision devices and tissue retraction devices described below, may be inserted into the ligamentum flavum 26, as illustrated in Figure 4. Tool 100 may comprise any suitable device, tool, or instrument for relieving stenosis caused by the thickened/enlarged ligamentum flavum 26 including without limitation, embodiments of tissue excision devices and tissue retraction devices described in more detail below. Further, as best illustrated in Figure 4, tool 100 is positioned in the ligamentum flavum 26 on the opposite side of median plane 210 as tool 100 percutaneously accesses the body, such that tool 100 crosses median plane 210. In another embodiment, tool 100 is inserted and positioned in the ligamentum flavum 26 on the same side (ipsilateral) of median plane 210 as tool 100 percutaneously accesses the body, such that tool 100 does not cross median plane 210.

While it is preferred that the tip of tool 100 remain within ligamentum flavum 26 as shown, the presence of safety zone 40 reduces the likelihood that dural sac 32 will be damaged, even if the tool breaks through the anterior surface of ligamentum flavum 26.

For insertion of tool 100, a fluoroscopic window of access (FWA) is defined by the inferior margin of the lamina (contra lateral to the point of instrument entry in the soft tissues) and the dorsal margin of the contrast material that defines the epidural space. This FWA is roughly orthogonal to the long axis of the cutting instrument, which parallels the inferior surface of the lamina as in Figure 4. The fluoroscopic plane of projection is preferably but not necessarily oriented 20-45 degrees from normal (AP projection).

Because the present techniques are preferably performed percutaneously, certain aspects of the present invention may be facilitated by imaging. In this context, the spine can be imaged using any suitable technology, including without limitation, 2D fluoroscopy, 3D fluoroscopy, CT, MRI, ultrasound or with direct visualization with fiber optic or microsurgical techniques. Stereotactic or computerized image fusion techniques are also suitable. Fluoroscopy is currently particularly well-suited to the techniques disclosed herein. Fluoroscopic equipment is safe and easy to use, readily available in most medical facilities, relatively inexpensive. In a typical procedure, using direct biplane fluoroscopic guidance and local anesthesia, epidural space 27 is accessed for injection of contrast media adjacent to the surgical site.

If the injected medium is radio-opaque, as are for example myelographic contrast media, the margins of the expanded epidural space will be readily visible using fluoroscopy or CT imaging. Thus, the safety zone created by the present contrast-guided dural compression
techniques can reduce the risk of damage to the spinal cord during procedures to remove or displace portions of the ligamentum flavum and/or laminae in order to treat spinal stenosis.

Injectable Medium

If desired, the injected medium can be provided as a re-absorbable water-soluble gel, so as to better localize safety zone 40 at the site of surgery and reduce leakage of this protective layer from the vertebral/spinal canal. An injectable gel is a significant improvement on prior epidural injection techniques. The gel is preferably substantially more viscous than conventional contrast media and the relatively viscous gel preferably tends to remain localized at the desired site of treatment as it does not spread as much as standard liquid contrast media that are used in epidurography. This may result in more uniform compression of dural sac 32 and less leakage of contrast out of the vertebral/spinal canal. In addition, preferred embodiments of the gel are re-absorbed more slowly than conventional contrast media, allowing for better visualization during the course of the surgical procedure.

In some embodiments, a contrast agent can be included in the gel itself, so that the entire gel mass is imagable. In other embodiments, an amount of contrast can be injected first, followed by the desired amount of gel, or an amount of gel can be injected first, followed by the desired amount of contrast. In this case, the contrast agent is captured on the surface of the expanding gel mass, so that the periphery of the mass is imagable.

Any standard hydrophilic-lipophilic block copolymer (Pluronic) gel such as are known in the art would be suitable and other gels may be used as the injectable medium. The gel preferably has an inert base. In certain embodiments, the gel material is liquid at ambient temperatures and can be injected through a small bore (such as a 27 gauge needle). The gel then preferably becomes viscous when warmed to body temperature after being injected. The viscosity of the gel can be adjusted through the specifics of the preparation. The gel or other fluid is preferably sufficiently viscous or viscous at body temperature to compress and protect the thecal sac in the manner described above and to remain sufficiently present in the region of interest for at least about 30 minutes. Thus, in some embodiments, the injected gel attains a viscosity that is two, three, six or even ten times that of the fluids that are typically used for epidurograms.

In certain embodiments, the injected medium undergoes a reversible change in viscosity when warmed to body temperature so that it can be injected as a low-viscosity fluid, thicken upon injection into the patient, and be returned to its low-viscosity state by cooling. In these embodiments, the injected medium is injected as desired and thickens upon warming, but can be removed by contacting it with a heat removal device, such as an aspirator that has been provided
with a cooled tip. As a result of localized cooling, the gel reverts to its initial non viscous liquid state and can be easily suctioned up the cooled needle or catheter.

An example of a suitable contrast medium having the desired properties is Omnipaque® 240 available from Nycomed, New York, which is a commercially available non-ionic iodinated myelographic contrast medium. Other suitable injectable media will be known to those skilled in the art. Because of the proximity to spinal cord 28 and spinal nerves 34, it is preferred not to use ionic media in the injectable medium. The preferred compositions are reabsorbed relatively rapidly after the procedure. Thus any residual gel compression on dural sac 32 after the MELD procedure dissipates relatively quickly. For example, in preferred embodiments, the gel would have sufficient viscosity to compress dural sac 32 for thirty minutes, and sufficient degradability to be substantially reabsorbed within approximately two hours.

The injected contrast medium further may further include one or more bioactive agents. For example, medications such as those used in epidural steroid injection (e.g. Depo medrol, Celestone Soluspan) may be added to the epidural gel to speed healing and reduce inflammation, scarring and adhesions. The gel preferably releases the steroid medication slowly and prolongs the anti-inflammatory effect, which can be extremely advantageous. Local anesthetic agents may also be added to the gel. This prolongs the duration of action of local anesthetic agents in the epidural space to prolong pain relief during epidural anesthesia. In this embodiment the gel may be formulated to slow the reabsorption of the gel.

The present gels may also be used for epidural steroid injection and perineural blocks for management of acute and chronic spinal pain. Thrombin or other haemostatic agents can be added if desired, so as to reduce the risk of bleeding.

In some embodiments, the gel may also be used as a substitute for a blood patch if a CSF leak occurs. The gel may also be used as an alternative method to treat lumbar puncture complications such as post-lumbar puncture CSF leak or other causes of intracranial hypotension. Similarly, the gel may be used to patch postoperative CSF leaks or dural tears. If the dural sac were inadvertently torn or cut, then gel could immediately serve to seal the site and prevent leakage of the cerebral spinal fluid.

**Percutaneous Tissue Excision**

After safety zone 40 has been created, the margins of epidural space 27 are clearly demarcated by the injected medium and can be visualized radiographically if an imagable medium has been used. As mentioned above, percutaneous procedures can now safely be performed on ligamentum flavum 26 and/or surrounding tissues without injuring dural sac 32 or nerves 34 and the spinal canal can be decompressed using any of several techniques. Suitable
decompression techniques include removal of tissue from the ligamentum flavum, laminectomy, laminotomy, and ligament retraction and anchoring.

In some embodiments, all or a portion of ligamentum flavum 26 and/or lamina 16 are excised using a percutaneous tissue excision device or probe 100, which may hereinafter be referred to as the MILD device. As shown schematically in Figure 4, a device 100 may be placed parallel to the posterior and lateral margin of the safety zone 40 with its tip in the ligamentum flavum 26.

Preferred embodiments of the present tissue excision devices and techniques can take several forms. In the discussion below, the distal ends of the tools are described in detail. The construction of the proximal ends of the tools, and the means by which the various components disclosed herein are assembled and actuated, will be known and understood by those skilled in the art.

By way of example, in the embodiment shown in Figure 4 and as illustrated in Figure 5, device 100 may be a coaxial excision system 50 with a sharpened or blunt tip that is placed obliquely into the thickened ligamentum flavum 26 posterior to safety zone 40 under fluoroscopic guidance. The needle is preferably placed parallel to the posterior margin of the canal. Excision system 50 is preferably manufactured from stainless steel, titanium or other suitable durable biocompatible material. As shown in Figures 5-10, an outer needle or cannula 51 has an opening or aperture 52 on one side that is closed during insertion by an inner occluding member 54. Aperture 52 is readily visible under imaging guidance. Once needle 51 is positioned in the ligamentum flavum or other tissue removal site, inner occluding member 54 is removed or retracted so that it no longer closes aperture 52 (Figure 6). Aperture 52 is preferably oriented away from the epidural space so as to further protect the underlying structures from injury during the surgical procedure. If it was not already present in the tool, a tissue-engaging means 56 is inserted through outer needle 51 to aperture 52 so that it contacts adjacent tissue, e.g. the ligamentum flavum, via aperture 52.

Tissue-engaging means 56 may be a needle, hook, blade, tooth or the like, and preferably has at least one flexible barb or hook 58 attached to its shaft. The barb 58 or barbs may extend around approximately 120 degrees of the circumference of the shaft. Barbs 58 are preferably directed towards the proximal end of the tool. When tissue-engaging means 56 is retracted slightly, barbs 58 allow it to engage a segment of tissue. Depending on the configuration of barbs 58, the tissue sample engaged by tissue-engaging means 56 may be generally cylindrical or approximately hemispherical. Once needle 56 has engaged the desired tissue, inner occluding means 54, which is preferably provided with a sharpened distal edge, is advanced so that it cuts the engaged tissue section or sample loose from the surrounding tissue. Hence occluding means
54 also functions as a cutting means in this embodiment. In alternative embodiments, such as Figures 10-14 discussed below, a cylindrical outer cutting element 60 may extended over outer needle 51 and used in place of occluding member 54 to excise the tissue sample.

Referring still to Figures 5-9, once the tissue sample has been cut, tissue-engaging needle 56 can be pulled back through outer needle 51 so that the segment of tissue can be retrieved and removed from the bars (Figure 8). The process or engaging and resecting tissue may be repeated (Figure 9) until the canal is adequately decompressed.

Referring briefly to Figures 10-14, in other embodiments, a tissue-engaging hook 64 can be used in place of needle 56 and an outer cutting member 60 can be used in place of inner occluding member 54. Hook 64 may comprise a length of wire that has been bent through at least about 270°, more preferably through 315°, and still more preferably through about 405°. Alternatively or in addition, hook 64 may comprise Nitinol™, or any other resilient metal that can withstand repeated elastic deflections. In the embodiment illustrated, hook 64 includes at least one barb 58 at its distal end. In some embodiments, hook 64 is pre-configured in a curvilinear shape and is retained within tool 100 by outer cutting member 60. When cutting member 60 is retracted, the curved shape of hook 64 urges its outer end to extend outward through aperture 52. If desired, hook 64 can be advanced toward the distal end of tool 100, causing it to extend farther into the surrounding tissue. In some embodiments, hook 64 is provided with a camming surface 66. Camming surface 66 bears on the edge of opening 52 as hook 64 is advance or retracted and thereby facilitates retraction and retention of hook 64 as it is retracted into the tool. In these embodiments, hook 64 may not extend through aperture 52 until it has been advanced sufficiently for camming surface 66 to clear the edge of the opening. Hook 64 may alternatively be used in conjunction with an inner occluding member 54 in the manner described above. As above, hook 64 can be used to retrieve the engaged tissue from the distal end of the tool.

In still other embodiments, the tissue-engaging means may comprise a hook or tooth or the like that engages tissue via aperture 52 by being rotated about the tool axis. In such embodiments (not shown) and by way of example only, the tissue-engaging means could comprise a partial cylinder that is received in outer cannula 51 and has a serrated side edge. Such a device can be rotated via a connection with the tool handle or other proximal device. As the serrated edge traverses aperture 52 tissue protruding into the tool via the aperture is engaged by the edge, wherein it can be resected and retrieved in the manner disclosed herein.

In preferred embodiments, the working tip of tool 100 remains within the ligamentum flavum and does not penetrate the safety zone 40. Nonetheless, safety zone 40 is provided so that even an inadvertent penetration of the tool into the epidural space will not result in damage to the thecal sac. Regardless of the means by which the tissue is engaged and cut, it is preferably
retrieved from the distal end of the tool so that additional tissue segments can be excised without requiring that the working tip of the tool be repositioned. A tissue-removal device such as that described below is preferably used to remove the tissue from the retrieval device between each excision.

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Tissue Removal

Each piece of tissue may be removed from barbs 58 by pushing tissue-engaging means 56 through an opening that is large enough to allow passage of the flexible barbs and supporting needle but smaller than the diameter of the excised tissue mass. This pushes the tissue up onto the shaft, where it can be removed with a slicing blade or the like or by sliding the tissue over the proximal end of the needle. Alternatively, needle 56 can be removed and re-inserted into the tool for external, manual tissue removal.

It is expected that in some embodiments, approximately 8-10 cores or segments of tissue will be excised and pushed up the shaft towards the hub during the course of the procedure. Alternatively, a small blade can be used to split the tissue segment and thereby ease removal of the segment from the device. If desired, a blade for this purpose can be placed on the shaft of needle 56 proximal to the barbs.

In an exemplary embodiment, shown in Figures 15-18, the tissue removal device may include a scraper 120 that includes a keyhole slot having a wide end 122 and a narrow end 124. To remove a tissue sample from needle 56 or hook 64, the tissue-engaging device with a mass of excised tissue 110 thereon can be refracted (pulled toward the proximal end of the tool) through wide end 122 of the slot and then re-inserted (pushed toward the distal end of the tool) through narrow end 124 of the slot. Narrow end 124 is large enough to allow passage of the barbed needle, but small enough to remove the tissue mass as the needle passes through. The removed tissue can exit the tool through an opening 113 in the tool body. By shuttling the tissue-engaging device through scraper 120 in this manner, each excised segment of tissue 110 can be removed from the device, readying the device for another excision.

In an alternative embodiment shown in Figure 30, the tissue removal device may be constructed such that tissue is removed from the tissue-engaging device by refracting the tissue-engaging device through narrow end 124 of the slot. As above, narrow end 124 is large enough to allow passage of the shaft of the tissue-engaging device, but small enough to remove the tissue mass as the needle passes through. If the tissue-engaging device is constructed of a tough material, the barbs or the like will cut through the tissue and/or deform and release the tissue. As above, the removed tissue can exit the tool through an opening 113 in the tool body. By shuttling
the tissue-engaging device through scraper 120 in this manner, each excised segment of tissue 110 can be removed from the device, readying the device for another excision.

In another alternative embodiment (not shown) an alternative mechanism for removing the tissue segment from needle 56 includes an adjustable aperture in a disc. After the tissue-bearing needle is pulled back through the aperture, the aperture is partially closed. Needle 56 and flexible hooks 58 then can pass through the partially closed aperture but the larger cylinder of tissue cannot. Thus the tissue segment is pushed back onto the shaft. The tissue segment can either be pulled off the proximal end of the shaft or cut off of it. A small blade may be placed just proximal to the barbs to help cut the tissue segment off the shaft. The variable aperture can formed by any suitable construction, including a pair of metal plates with matching edges that each define one half of a central opening. The two pieces may be held apart by springs. The aperture may be closed by pushing the two edges together. In other embodiments, this process can be mechanically automated by using a disc or plate with an opening that is adjustable by a variety of known techniques, including a slit screw assembly or flexible gaskets.

**Alternative Tissue Excision Devices**

Other cutting and/or grasping devices can be used in place of the system described above. For example, embodiments of the grasping mechanism include but are not limited to: needles with flexible barbs, needles with rigid barbs, corkscrew-shaped needles, and/or retaining wires. The corkscrew-shaped needle shown in Figure 19 works by screwing into the ligamentum flavum in the manner that a corkscrew is inserted in a cork. After the screw engages a segment of tissue, outer cutting element 60 slides over the needle, cutting a segment of tissue in a manner similar to that of the previous embodiment. In some embodiments, the cutting element can be rotated as it cuts.

In other embodiments, shown in Figures 20-22, cannulated scalpel 51 houses a grasping device 70 that includes at least one pair of arcuate, closable arms 72. Closable arms 72 may be constructed in any suitable manner. One technique for creating closable arms is to provide a slotted sleeve 74, as shown. Slotted member 74 preferably comprises an elongate body 75 with at least one slot 76 that extends through its thickness but does not extend to either end of the body. Slot 76 is preferably parallel to the longitudinal axis of the sleeve. On either side of slot 76, a strip 77 is defined, with strips 77 being joined at each end of sleeve 74. It is preferred that the width of each strip 77 be relatively small. In some embodiments, it may be desirable to construct slotted member 74 from a portion of a hollow tube or from a rectangular piece that has been curved around a longitudinal axis. The inner edge of each strip that lies along slot 76 forms an opposing edge 78. The width of the piece is the total of the width of strips 77 and slot 76.
Advancing one end of sleeve 74 toward the other end of sleeve 74 causes each strip 77 to buckle or bend. If strips 77 are prevented from buckling inward or if they are predisposed to bend in the desired direction, they will bend outward, thereby forming arcuate arms 72, which extend through aperture 52 of cannulated scalpel 51, as shown in Figure 21. As they move away from the axis of body 75, arms 72 move apart in a direction normal to the axis of body 75. Likewise, moving the ends of sleeve 74 apart causes arms 72 to straighten and to move together and inward toward the axis of the device, as shown in Figure 22. As the arms straighten, opposing edges 78 close and a segment of tissue can be capture between them. Tissue within the grasping device may then be resected or anchored via the other mechanisms described herein.

Closable arms 72 may include on their opposing edges 78 ridges, teeth, or other means to facilitate grasping of the tissue. In other embodiments, edges 78 may be sharpened, so as to excise a segment of tissue as they close. In these embodiments, closable arms 72 may also be used in conjunction with a hook, barbed needle, pincers or the like, which can in turn be used to retrieve the excised segment from the device.

Once arms 72 have closed on the tissue, if arms 72 have not cut the tissue themselves, the tissue can be excised using a blade such as cutting element 60 above. The excised tissue can be removed from the inside of needle 51 using a tissue-engaging hook 64 or other suitable means. The process of extending and closing arms 72, excising the tissue, and removing it from the device can be repeated until a desired amount of tissue has been removed.

If desired, this cycle can be repeated without repositioning the device in the tissue. Alternatively, the tool can be rotated or repositioned as desired between excisions. It is possible to rotate or reposition the tool during an excision, but it is expected that this will not generally be preferred. Furthermore, it is expected that the steps of tissue excision and removal can be accomplished without breaching the surface of the ligament, i.e. without any part of the device entering the safety zone created by the injected fluid. Nonetheless, should the tool leave the working zone, the safety zone will reduce the risk of injury to the thecal sac.

**Ligament Retraction**

In some embodiments, the spinal canal may also be enlarged by retracting the ligamentum flavum, either with or without concurrent resection. Retraction is preferably but not necessarily performed after dural compression has been used to provide a safety zone. In addition, the dural compression techniques described above have the effect of pressing the ligamentum flavum back out of the spinal canal and thereby making it easier to apply a restraining means thereto.

Thus, in preferred embodiments, after a safety zone is created by epidural injection of contrast medium or gel, a retraction device 90 as shown in Figure 23 is used to retract and
compress the thickened soft tissues around the posterior aspect of the spinal canal, thereby increasing the available space for the dural sac and nerves. In the embodiment shown, retraction device 90 is a double-headed anchor that includes at least one distal retractable tissue-engaging member 91 and at least one proximal tissue-engaging member 92, each of which are supported on a body 94. Retraction device 90 is preferably constructed from an implantable, non-biodegradable material, such as titanium or stainless steel, but may alternatively be polymeric or any other suitable material. In certain preferred embodiments, body 94 is somewhat flexible. In some instances, flexibility in body 94 may facilitate the desired engagement of barbs 91, 92. Barbs 91, 92 may comprise hooks, arms, teeth, clamps, or any other device capable of selectively engaging adjacent tissue. Barbs 91, 92 may have any configuration that allows them to engage the ligamentum flavum and/or surrounding tissue. Similarly, barbs 91, 92 may be covered, sheathed, pivotable, retractable, or otherwise able to be extended from a first position in which they do not engage adjacent tissue to a second position in which they can engage adjacent tissue.

Figure 23 shows schematically the distal and proximal retractable arms 91, 92 of a preferred ligament anchor 90. The proximal end of the anchor preferably includes a threaded connector 96 or other releasable mechanism that attaches to a support rod 100. Ligament anchor 90 may be attached to a support shaft 112 and sheathed in a guide housing 114. The distal and proximal barbs 91, 92 are prevented by guide housing 114 from engaging surrounding tissue. Housing 102 is preferably a metal or durable plastic guide housing.

The distal end of the device is preferably positioned in the ligamentum flavum under fluoroscopic guidance. If desired, an accessway through the lamina may be provided using an anchored cannula or the like. The device is held in position by support shaft 112. Distal barbs 91 are unsheathed and optionally expanded by pulling back guide housing 102, as shown in Figure 23. Distal barbs 91 are secured in the ligamentum flavum by pulling back on the support shaft 112. With barbs 91 engaging the tissue, the ligamentum flavum is retracted posteriorly by pulling back on support shaft 112. While maintaining traction on the now-retracted ligament, proximal barbs 92 are uncovered and expanded by retracting guide housing 114, as shown in Figure 24. Barbs 92 are preferably positioned in the soft tissues 116 in the para-spinal region so that the device is firmly anchored behind the posterior elements of the spinal canal. Once the proximal end of the anchor is engaged, support shaft 112 may be detached from body 94 as shown in Figure 24. In this manner, the posterior margin 95 of the ligamentum flavum can be held in a retracted position, thereby expanding the canal. The procedure can then be repeated on adjacent portions of the ligamentum flavum until it is sufficiently retracted.

In an alternative embodiment, the proximal end of ligament anchor 90 may be adapted to engage the lamina. This may be accomplished by having the arm posterior to the lamina or by
using the laminotomy and suturing the device to the lamina there. A knotted or knotless system or a suture plate can be used.

A second embodiment of the present method uses a plurality of retraction devices 90. In this embodiment, the retraction device is inserted through one lamina in an oblique fashion, paralleling the opposite lamina. After the distal anchor is deployed, the retraction device is pulled back and across the ligamentum flavum, thereby decompressing the opposite lateral recess of the spinal canal. This is repeated on the opposite side. This same device can also be deployed with a direct approach to the lateral recess with a curved guide housing.

While retraction device 90 is describe above as a double-headed anchor, it will be understood that other devices can be used. For example sutures, barbed sutures, staples or the like can be used to fasten the ligament in a retracted position that reduces stenosis.

Using the percutaneous methods and devices described herein, significant reductions of stenosis can be achieved. For example, a dural sac cross-sectional area less than 100 mm² or an anteroposterior (AP) dimension of the canal of less than 10-12 mm in an average male is typically considered relative spinal stenosis. A dural sac cross-sectional area less than 85 mm² in an average male is considered severe spinal stenosis. The present devices and techniques are anticipated to cause an increase in canal area of 25 mm² per anchor or 50 mm² total. With resection and/or retraction of the ligamentum flavum, the cross-sectional area of the dural sac can be increased by 10 mm², and in some instances by as much as 20 mm² or even 30 mm². Likewise, the present invention can result in an increase of the anteroposterior dimension of the canal by 1 to 2 mm and in some instances by as much as 4 or 6 mm. The actual amount by which the cross-sectional area of the thecal sac and/or the anteroposterior dimension of the canal are increased will depend on the size and age of the patient and the degree of stenosis and can be adjusted by the degree of retraction of the ligament.

**MILD**

The minimally invasive ligament decompression (MILD) devices and techniques described herein allow spinal decompression to be performed percutaneously, avoiding the pain and risk associated with open surgery. Through the provision of a safety zone, the present devices and techniques offer reduced risk of spinal cord damage. In addition to improving nerve function, it is expected that decompression of the spinal canal in the manner described herein will result in improved blood flow to the neural elements by reducing the extrinsic pressure on the spinal vasculature. For these reasons, it is believed that spinal decompression performed according to the present invention will be preferable to decompression operations performed using currently known techniques.
Dural Shield

In some embodiments (not shown), a mechanical device such as a balloon or mechanical shield can also be used to create a protective guard or barrier between the borders of the epidural space and the adjacent structures. In one embodiment a durable expandable device is attached to the outside of the percutaneous laminectomy device, preferably on the side opposite the cutting aperture. The cutting device is inserted into the ligamentum flavum with the expandable device deflated. With the aperture directed away from the spinal canal, the expandable device is gently expanded via mechanical means or inflated with air or another sterile fluid, such as saline solution, via a lumen that may be within or adjacent to the body of the device. This pushes the adjacent vital structures clear from the cutting aperture of the device and simultaneously presses the cutting aperture into the ligament. As above, the grasping and cutting needles can then be deployed and operated as desired. The balloon does not interfere with tissue excision because it is located on the side opposite the cutting aperture. The cutting needle may be hemispherical (semi-tubular) in shape with either a straight cutting or a sawing/reciprocating blade or may be sized to be placed within the outer housing that separates the balloon from the cutting aperture.

In another embodiment, a self-expanding metal mesh is positioned percutaneously in the epidural space. First the epidural space is accessed in the usual fashion. Then a guide catheter is placed in the epidural space at the site of the intended surgical procedure. The mesh is preferably compressed within a guide catheter. When the outer cover of the guide catheter is retracted, the mesh expands in the epidural space, protecting and displacing the adjacent dural sheath. At the conclusion of the surgical procedure, the mesh is pulled back into the guide sheath and the assembly removed. The mesh is deformable and compresses as it is pulled back into the guide catheter, in a manner similar to a self-expanding mesh stent. There are many commercially available self-expanding stents approved and in use in other applications. However, using a self-expandable mesh as a device within the epidural space to protect and displace the thecal sac is novel.

Tissue Excision Devices

Embodiments of tissue excision tools, devices, and methods disclosed herein may take several forms and may be used in accordance with the MELD method described above, or used according to alternative procedures such as the ipsilateral approach minimally invasive ligament decompression procedure (ILAMP method) disclosed in U.S. Application Serial Number 11/382,349, which is hereby incorporated herein by reference in its entirety.
In the descriptions of the tissue excision devices below, the distal portions of the devices are described in detail, distal referring to positions that are relatively closer to the region of interest (e.g., the thickened portion of the ligamentum flavum to be decompressed). An exemplary embodiment of a proximal end for the tissue excision devices, including an actuation means, is also described below. However, it is to be understood that embodiments of tissue extraction devices described herein may be used with a variety of proximal ends and a variety of actuation means that are known and understood by those skilled in the art.

Figures 31-33 illustrate the distal portion of an embodiment of a tissue excision device 200 in an open position. Tissue excision device 200 comprises an inner tubular 230 coaxially disposed within and slidingly engaging an outer sleeve 210. Inner tubular 230 and sleeve 210 both share a central longitudinal axis 250. Sleeve 210 has an inner radius $R_1$ (not shown), as measured from axis 250, and inner tubular 230 has an outer radius $R_2$ (not shown), as measured from axis 250. In this embodiment, outer radius $R_2$ is substantially the same or slightly less than inner radius $R_1$ such that the outer surface of inner tubular 230 slidingly engages the inner surface of sleeve 210. Thus, sleeve 210 and inner tubular 230 are permitted to move axially (i.e., along axis 250) relative to each other. Sleeve 210 and inner tubular 230 may be formed from any suitable hollow bodies including without limitation a hypotube, cannula, or catheter. Although sleeve 210 and inner tubular 230 shown in Figures 31-33 generally have a circular cross-section, in general sleeve 210 and inner tubular 230 may have any suitable shape and cross-section including without limitation circular, oval, or rectangular.

Inner tubular 230 includes a central cavity or through bore 240 (Figure 32) that runs the length of inner tubular 230. In addition, a cutting head 250 is disposed at the distal end of inner tubular 230. In this embodiment, cutting head 250 is formed integrally with inner tubular 230 such as by casting, molding, or machining. However, in different embodiments, cutting head 250 may be manufactured separately from inner tubular 230 and then fixed to the distal end of inner tubular 230 by any suitable means, such as welding.

Cutting head 250 preferably comprises a body 252 and three cutting arms 253 extending axially from body 252. In this embodiment, body 252 is integral with and essentially an extension of inner tubular 230. Since each arm 253 extends axially from body 252, each arm 253 may be described as including a fixed end 253a integral with body 252 and a free end 253b generally distal to body 252. Although each of the embodiments illustrated herein show cutting head 250 with three cutting arms 253, in different embodiments, cutting head 250 may include any suitable number of cutting arms 253 including without limitation two, three, four, or more.

Arms 253 are preferably integral with body 252 and inner tubular 230. In such embodiments, arms 253 may be formed by any suitable means including without limitation casting.
or molding, laser cutting, machining, or combinations thereof. However, it should be understood that arms 253 may alternatively be distinct components that are mechanically coupled to body 252 and inner tubular 230 generally at fixed end 253a. In such alternative embodiments, arms 253 may be connected to inner tubular 230 by any suitable means, including without limitation welding, pins, or combinations thereof.

As best shown in Figure 32, bore 240 is contiguous with a tissue-receiving space 263 defined between arms 253 inside cutting head 250. Tissue-receiving space 253 and bore 240 accommodate tissue excised by device 200 (e.g., excised pieces of ligamentum flavum). In some embodiments, one or more of the surfaces that define tissue-receiving space 263 inside cutting head 250 may include ridges, knurling or other textured surface features 264 thereon so as to further improve grasping and retention of tissue between arms 253. Textured surface feature 264 may be formed by any suitable means including without limitation knurling, sand blasting, bead blasting, plasma etching, or combinations thereof. Likewise, the inner surface of inner tubular 230 may be roughened to enhance the ability of inner bore 240 to enhance grasping and retention of excised portions of tissue.

Referring again to Figures 31-33, each arm 253 preferably terminates in a cutting or tissue-grasping member. In the embodiment shown in Figures 31 and 32, two arms terminate in cutters 251 and a third arm terminates in a sharp anchoring tip 154 that extends beyond the distal ends of cutters 251. Each cutting edge 251 preferably has a sharpened or beveled edge adapted to slice through tissue. In addition, in this embodiment, anchoring tip 154 includes a tissue grasping member 257 that extends radially inward and helps grasp tissue and retain tissue within tissue-receiving space 263. In this embodiment, tissue grasping member 257 is a tooth. However, in different embodiments, one or more tissue grasping members may comprise teeth, barbs, or the like. Tooth 257 preferably has sharpened edges to enhance cutting of tissue. In general, arms 253 may be any desired length.

Cutting head 250 is constructed so that arms 253 can be brought together so as to grasp tissue therebetween, termed herein as a "closed position", and moved apart so as to release tissue and/or allow the entry of tissue between arms 253, termed herein as an "open position". As shown in Figures 31 and 32, cutting head 250 is in an open position. Specifically when cutting head 250 is in an open position, cutting head 250 is extended from sleeve 210 and free ends 253b of each arm 253 are radially spaced apart. Consequently, any tissue within tissue-receiving space 263 is not pinched or firmly grasped by arms 253 and tissue is allowed to enter tissue-receiving space 263 via the gap between free ends 253b of arms 253.

Referring now to Figures 31 and 33, cutting head 250 is transitioned to a closed position by advancing sleeve 210 axially relative to cutting head 250 toward cutting ends 253b of arms 253 in
the direction of arrow 270. Specifically, each arm 253 preferably includes a frustoconical chamfer 255 on its outer surface. The surface of each frustoconical chamfer 255 extends radially beyond inner radius R_i of sleeve 210. In the opened position (Figure 31), cutting head 250 is extended from sleeve 210 and thus sleeve 210 does not engage frustoconical chamfer 255. Thus, each frustoconical chamfer 255 is generally free to extend radially beyond inner radius R_1 of sleeve 210 (i.e., sleeve 210 does engage chamfers 255 nor restrict arms 253). However, when sleeve 210 is advanced toward cutting ends 253b it engages the portions of frustoconical chamfer 255 that radially extend beyond inner radius R_1 of sleeve 210, thereby tending to force arms 253 together. As sleeve 210 is advanced further towards cutting ends 253b, sleeve 210 continues to bear on chamfers 255 and arms 253 are brought closer together. Cutting head 250 achieves the closed position when arms 253 contact each other and/or when each radially outermost portions or ridge 260 of each frustoconical chamfer 255 is disposed within inner tubular 230. At this point, cutting ends 253b of each arm 253 are at their closest relative to each other. In some embodiments, cutting ends 253b may engage adjacent cutting ends 253b.

In the reverse manner, device 200 and cutting head 250 can be transitioned from the closed position to the open position. In general, sleeve 210 may be moved axially relative to cutting head 250 by any suitable manner including without limitation a threaded engagement with inner tubular 230, a trigger mechanism, or combinations thereof.

In the embodiments described herein, arms 253 are normally open. In other words, arms 253 are biased to the open position such that cutting head 250 will assume the open position when no forces are acting to push arms 253 together. Thus, to transition device 200 and cutting head 250 to the closed position, compressive forces, namely sleeve 210 acting on each frustoconical chamfer 255, are necessary to push arms 253 together. Further, since arms 253 are biased open, cutting head 253 will automatically assume the open position illustrated in Figure 31 as sleeve 210 is retracted and cutting head 253 extends from sleeve 210. However, in other embodiments (not illustrated), arms 253 may be biased closed and transitioned to an open position by providing an inner wedge between each arm 253 that urges the arms apart as it moves axially relative to arms 253.

Tissue Excision and Removal

Figures 34 and 35 schematically illustrate the excision of a portion of tissue 126 by device 200. In some embodiments, a portal or cannula (not shown) may be employed to provide percutaneous access to tissue 126. For instance, tissue excision device 200 maybe inserted into and advanced through such a portal or cannula to reach tissue 126. U.S. Application Serial No. 11/461,020 filed concurrently herewith, which is hereby incorporated herein by reference in its entirety, discloses several tools, devices and methods for employing a portal to provide
percutaneous access to a tissue of interest. If a portal or cannula is used to guide device 200, device 200 may be passed through such cannula in the opened position or closed position.

Regardless of the manner in which tissue excision device 200 reaches the tissue of interest (e.g., by portal or otherwise), prior to insertion into the tissue to be excised, device 200 is configured in the open position as shown in Figures 31 and 32. With device 200 in the opened position, the distal portion of tissue excision device 200 is advanced into tissue 126, as best shown in Figure 34. Tissue 126 may be any type of tissue to be excised and removed from a patient including without limitation, soft tissue, fat, muscle, or bone. When used to treat spinal stenosis caused by a thickened ligamentum flavum, cutting head 250 of device 200 is preferably inserted into the stenotic ligamentum flavum 26, preferably posterior to a safety zone 40, in order to safely cut and remove portions of the thickened ligamentum flavum 26 (see Figures 2 and 3), thereby reducing the stenosis.

Still referring to Figures 34 and 35, as device 200 is inserted and advanced into tissue 126, portions of tissue 126 slide into and fill at least a portion of tissue-receiving space 263 between arms 253 within cutting head 250. It is to be understood that the farther device 200 is advanced into tissue 126, the greater the amount of tissue 126 that will occupy tissue-receiving space 263. As tissue-receiving space 263 fills, some excess tissue within tissue-receiving space 263 may be pushed into bore 240 of inner tubular 230. Arms 253 are preferably rigid such that cutting head 250 does not inadvertently transition to the closed position as device 200 is advanced through the tissue.

In other words, arms 253 are preferably rigid so that the forces exerted on the outer surface of arms 253 by the surrounding tissue 126 as device 200 is advanced do not tend to move arms 253 towards each other.

Once a desired amount of tissue has filled tissue-receiving space 263 and bore 240, device 200 may be transitioned to the closed position by advancing sleeve 210 toward cutting ends 253b and over cutting head 250 as previously described. As arms 253 move towards each other, the portions of tissue 126 within tissue-receiving space 263 and bore 240 are severed from the surrounding tissue 126. Specifically, the sharpened or beveled edges of cutters 251 and tooth 257 slice tissue extending axially from tissue-receiving space 263, while an annular cutting edge 211 of sleeve 210 slices tissue extending radially from tissue-receiving space 263 between arms 253.

Cutting edge 211 of sleeve 210 is preferably sharpened to enhance the cutting ability of sleeve 210 as it moves relative to cutting head 250. In addition, the severed tissue 126 contained within tissue-receiving space 263 is grasped by arms 253. Specifically, arms 253 exert compressive forces on the tissue 126 within tissue-receiving space 263, the textured surface features 264 on the inner surface of arms 253 grips the tissue 126 within tissue-receiving space 263, and tooth 257 grasps tissue 126
within tissue-receiving space 263 and restricts it from sliding axially out of cutting head 250 between cutting ends 253b.

Once device 200 has achieved the closed position, device 200 may be retracted from tissue 126 as best shown in Figure 35. The portion of tissue 126 contained within tissue-receiving space 263 and bore 240 is removed along with device 200. Once device 200, including a portion of tissue 126 within tissue-receiving space 263 and bore 240, has been completely removed from the patient, resected tissue within tissue-receiving space 263 and bore 240 is removed from device 200 so that device 200 may be reinserted into tissue 126 to continue to the cutting and removal of portions of tissue 126.

Pieces of tissue 126 captured within tissue-receiving space 263 and bore 240 may be removed by simply opening device 200 and pulling the pieces of tissue from tissue-receiving space 263 and bore 240. Device 200 may be opened from the closed position by retracting sleeve 210 from cutting head 250 as previously described. As device 200 transitions to its opened position, arms 253 will separate, allowing the user to access tissue-receiving space 263 and inner bore 240.

In an alternative embodiment, a plunger or tissue ejector may be included with device 200 to physically eject the excised tissue 126 from tissue-receiving space 263 and inner bore 240. For instance, a plunger (not shown) may be included within device 200 to push cut tissue in tissue-receiving space 263 and inner bore 240 axially out through the opening between cutting ends 253b of arms 253.

The process of inserting device 200 into tissue 126 in the opened position, closing device 126, retracting device 200 in the closed position, opening device 200, emptying tissue-receiving space 263 and bore 240, and reinserting device 200 may be repeated until the desired amount of tissue 126 has been excised and removed. Referring briefly to Figure 3, when device 200 is employed to remove portions of thickened ligamentum flavum 26, this process may be repeated until the spinal canal is adequately decompressed. Further, when device 200 is employed to remove portions of thickened ligamentum flavum 26, the cutting ends 253b of each arm 253 of device 200 are preferably controlled to remain within ligamentum flavum 26 and not penetrate safety zone 40. Nonetheless, safety zone 40 is preferably provided so that even an inadvertent penetration into epidural space 27 by device 200 will not result in damage to the dural sac 32 or nerves 34.

The components of tissue excision device 200 (e.g., arms 253, tooth 257, etc.) may comprise any suitable material(s) including without limitation metals (e.g., stainless steel, titanium, etc.), non-metals (e.g., polymer, composites, etc.) or combinations thereof. The components of tissue excision device 200 are preferably manufactured from a durable biocompatible material such as titanium or stainless steel, but may alternatively be polymeric. In addition, arms 253 each preferably comprise a relatively rigid material(s) capable of maintaining their shape and
configuration when inserted into and advanced through tissue. Further, arms 253 preferably
comprises a resilient material having the ability to be repeatedly flexed between the open position
and closed position without cracking or otherwise being damaged. Such a resilient material also
enables each arm 253 to return to its original configuration once external forces (e.g., force applied
by sleeve 210) are removed.

In addition, the components of tissue excision device 200 may be manufactured by any
suitable methods. Examples of suitable methods include casting or molding, machining, laser
cutting, EMD, or combinations thereof. In some embodiments, cutting edges or tips may be electro
polished to for sharpening. The components of tissue excision device 200 may be assembled by
any suitable method including without limitation welding, press fitting, or combinations thereof.

While preferred embodiments of this invention have been shown and described,
modifications thereof can be made by one skilled in the art without departing from the scope or
teaching of this invention. For example, the means by which the safety zone is formed may be
varied, the shape and configuration of the tissue excision devices may be varied, and the steps used
in carrying out the technique may be modified. Accordingly, the invention is not limited to the
embodiments described herein, but is only limited by the claims that follow, the scope of which
shall include all equivalents of the subject matter of the claims. Likewise, the sequential recitation
of steps in a claim, unless explicitly so stated, is not intended to require that the steps be performed
in any particular order or that a particular step be completed before commencement of another step.
CLAIMS

What is claimed is:

1. A device for excising tissue, comprising:
   a. an outer sleeve;
   b. an inner tubular member slidingly received within the outer sleeve;
   c. a cutting head on a distal end of the inner tubular;
   wherein the cutting head comprises at least three arms extending axially from the inner tubular;

2. The device of claim 1 wherein the device has an open position in which the cutting head extends from the outer sleeve, and a closed position in which the cutting head is at least partially disposed within the sleeve; and wherein the arms are biased away from each other when the device is in the opened position.

3. The device of claim 2 wherein the inner surface of the outer sleeve engages a radially outermost portion of the frustoconical surface when the device is in the closed position.

4. The device of claim 1 wherein each arm has a fixed end integral with the inner tubular and a free end.

5. The device of claim 4 wherein the free end of at least one arm includes a tissue grasping member.

6. The device of claim 5 wherein said tissue grasping member comprises a tooth extending radially inward.

7. The device of claim 5 wherein the free end of at least one arm comprises a cutter having a beveled edge adapted to slice tissue.

8. The device of claim 6 wherein each arm has an axial length from the fixed end to the free end, and wherein the axial length of the at least one arm comprising the tooth is greater than the axial length of the other arms.

9. The device of claim 1 wherein at least one arm has an inner surface that includes a textured surface feature.

10. The device of claim 9 wherein the textured surface feature comprises ridges or knurling.

11. The device of claim 1 wherein the at least three arms define a tissue receiving space that is contiguous with a through bore of the inner tubular.
12. The device of claim 1 wherein each arm has a fixed end and a free end and wherein the
free end of each arm engages the free end of at least one other arm when the device is in the
closed position.

13. A method for treating stenosis in a spine of a patient having a median plane, the spine
including a spinal canal having a posterior surface, a dural sac and an epidural space between the
posterior surface and dural sac, the location of the stenosis determining a region of interest in the
spine, comprising the steps of:
a) positioning a tissue excision device adjacent the region of interest, wherein the tissue
excision device comprises:
   an outer sleeve;
   an inner tubular member slidingly received within the outer sleeve;
   a cutting head connected to a distal end of the inner tubular;
   wherein the cutting head comprises at least three arms extending axially from the inner
tubular;
   wherein the device has an open position in which the cutting head extends from the outer sleeve,
and a closed position in which the cutting head is at least partially disposed within the sleeve.
b) opening the tissue excision device by extending the cutting head from the outer sleeve;
c) inserting the tissue excision device into tissue in the region of interest;
d) closing the tissue excision device by advancing the outer sleeve over the cutting head; and
e) retracting the tissue excision device from the tissue in the region of interest.

14. The method of claim 13 wherein a portion of the patient's ligamentum flavum occupies
the region of interest, and wherein step c) comprises inserting the tissue excision device into the
ligamentum flavum in the region of interest, step d) comprises cutting at least a portion of the
ligamentum flavum in the region of interest, and step e) comprises removing at least a portion of
the cut ligamentum flavum.

15. The method of claim 13 further comprising the steps of compressing the dural sac in the
region of interest by injecting a fluid to form a safety zone and establish a working zone in the
region of interest, the safety zone lying between the working zone and the dural sac.

16. The method of claim 13 further comprising the step of emptying the cut tissue from the
tissue excision device.

17. A kit for performing a procedure on a spine, the spine including an epidural space
containing a dural sac, the kit comprising:
an insertion member for accessing the epidural space;
a volume of a contrast medium adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space; and

a tissue excision device comprising:

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an outer sleeve;

an inner tubular member slidingly received within the outer sleeve;

a cutting head connected to a distal end of the inner tubular;

wherein the cutting head comprises at least three arms extending axially from the inner tubular;

wherein the device has an open position in which the cutting head extends from the outer sleeve,

and a closed position in which the cutting head is at least partially disposed within the sleeve.
Fig. 3

Fig. 4

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