Summary: Position Statement for Endoscopic Discectomy

Full endoscopic lumbar disc surgery should be a covered service. It allows for direct visualization of the surgical field and provides full access to the herniated disc with less trauma than more invasive techniques.

Indications for full endoscopic procedures are the same as those for open procedures. Appropriate diagnoses must be made based on patient history and physical exam, imaging studies, and patient response to conservative and other therapies. The diagnosis and therapeutic path should determine if the patient is an appropriate candidate for a full endoscopic procedure. In full endoscopic lumber surgery, as with open procedures, the physician has a wide range of instrumentation to inspect the anatomy, identify pathology, and to specifically address the patient's condition.

Endoscopic discectomy procedures should not be confused with or considered the same as percutaneous procedures that have no visualization during the operation and are limited by the use of a single, fluoroscopically guided, needle-based instrument to remove nucleus tissue. While some physicians may use an endoscope when performing a percutaneous procedure, these procedures are not performed under direct visualization as is the case with a full endoscopic procedure.

I. OVERVIEW:LUMBAR DISC HERNIATION

Intervertebral disc herniation (bulging with nerve root compression) occurs as the result of degenerative and/or traumatic weakening of the fibrous outer wall of the disc (annulus fibrosis). Most frequently seen in the lumbar spine, herniation can occur in escalating degrees of severity. In less severe cases, the annulus may weaken and bulge outward. As the disease progresses, the annulus may rupture and the nucleus may become extruded from the disc. In more severe cases, extruded disc material can become "sequestered", meaning that it no longer has continuity with the parent disc. In addition, herniation occurs in varying locations of the disc. This variability in herniation characteristics has important implications for medical management. When disc herniation causes nerve root irritation or compression, patients require treatment due to back pain which is often associated with discomfort and neuropathy in the lower extremities. Additionally, bony structures of the posterior spine, especially the facet joint, may compress the nerve root creating stenosis, and causing similar symptoms of pain and neuropathy.

II. Conventional "Open" Lumbar Surgery- Visualization

Much of the discussion around the different discectomy and laminotomy surgeries has to do with what kind of optics is used to view the anatomy. One previous opinion was that the anatomy had to be visible with the naked eye. However, most surgeons, when working around nerves, wear loupes (magnifying devices that are worn like eyeglasses) or use a surgical microscope. The definition of an open procedure has been expanded to include a minimally invasive procedure that uses a blade retractor or tube retractor system and a microscope, under the theory that the surgeon can still look down the tube and view the anatomy with the naked eye. However, it is unlikely that surgeons would perform the surgery through such a retractor system without loupes or a microscope.

A review of optic systems: microscope, loupes, naked eye, and endoscope

- The microscope has an objective lens that sits above the incision and refracts an image through the microscope housing, and through an ocular lens and into the eye of the operator. Optionally, the microscope can focus the image onto a video camera that will then display the image on a video monitor.
- The loupes have sets of magnifying lenses built into a pair of eyeglasses. Similarly to the microscope, the loupes sit above the incision and focus the image into the eye of the

operator. (The housing of the microscope is replaced by the shorter 2-6 cm telescope housings of the loupes.)

- Under direct vision, there are no external lenses (except the eye itself) and the image is focused directly onto the retina.

- **Visualization with an endoscope**

  With an endoscope, the objective lens is at the end of a thin tubular housing and is inserted into the patient's body. During use, the tip of the endoscope is located approximately 5-15 mm from the anatomy being viewed. The ocular lens is at the proximal end of the endoscope, which stays outside of the patient and through which the operator can look directly with the naked eye, or to which a video camera can be attached. In the very early days of spine endoscopy, a fiber optic endoscope and low resolution electronics were used that provided images inferior to microscopes and loupes. Users today employ a precision glass rod lens spine endoscope and a high definition video camera with a high definition video system that provide excellent visualization, allow freedom of movement while operating, and can simultaneously create a record of the procedure.

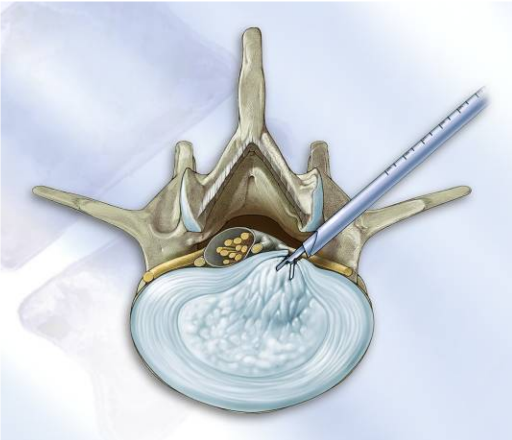
- **Comparison of the endoscope with other optic systems**

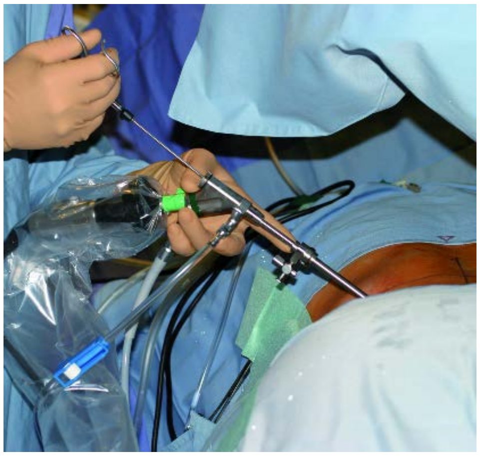
  a. The major difference between the endoscope, loupes, and the microscope is simply where the lenses are placed relative to the anatomy. Because the tip of the endoscope is only millimeters away from the anatomy, magnification is provided that is equivalent to that of loupes or a microscope.
  b. A notable difference between the endoscope and other methods is that the endoscope has only one image channel. A microscope, loupes, and vision with the naked eye provide two image channels, constituting binocular, or stereoscopic, vision which permits depth perception and gives the user a three dimensional view of the anatomy. However, while the endoscope provides only mono-ocular vision, the objective lens of the endoscope is angled by 25 degrees and its tip is located inside the anatomy so it allows the user to see around obstructions that would block the view of the other optical methods (i.e., the endoscope can "see around corners"). This allows the endoscopic system to view anatomy (such as the lateral recess of the spinal canal) that cannot be seen by any other optical system.
  c. The endoscope continuously irrigates the operative site, providing a significant visual advantage over open techniques. The visual field is free of blood and debris, so details of the anatomy, including tissue texture and color, is clearly visible. (This is in addition to the other advantages of continuous irrigation, including reduced blood loss and washout of debris and pathogens.)

II. Full Endoscopic Interlaminar and Transforaminal Lumbar Discectomy Compared to Traditional Open Surgery.

Endoscopic lumbar discectomy, as with open surgery, is indicated for those patients who fail conservative management and are diagnosed to have a demonstrated disc herniation. These patients present with radicular leg pain and, usually, an MRI and / or lumbar discogram that demonstrates a herniation. Based on the nature and location of the herniation, as well as anatomical considerations and the presence of other pathologies, a surgical plan is developed. The exact approach is selected so as to minimize trauma to the patient, while providing the highest likelihood of successfully addressing the pathology.

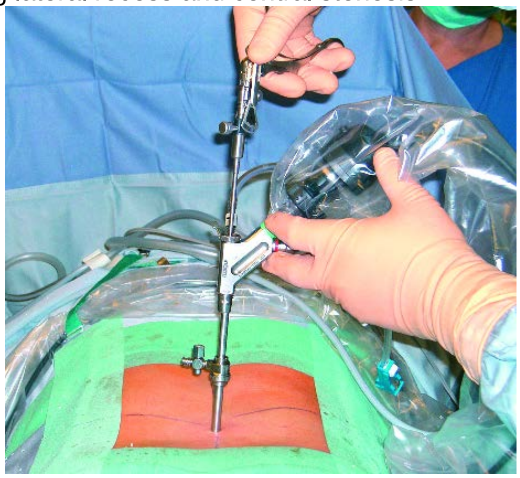
A transforaminal endoscopic discectomy is accomplished with a posterior-lateral approach that accesses the disc space through the intervertebral foramen. A needle, guide wire, and dilator are used to slightly spread the muscles and soft tissue in order to place a 7mm diameter working sleeve into the disc through Kambin's triangle. The endoscope is inserted through the working sleeve, and instruments are inserted through the working channel of the endoscope to resect disc material under direct visualization. The working sleeve and endoscope can be withdrawn slightly to access anatomy outside of the disc space, including the intervertebral foramen and epidural space. The transforaminal approach typically does not require resection of bone, and provides excellent access to foraminal, extraforaminal and paracentral herniations located at the L3-4 and L4-5 disc spaces, and may also be used to perform a foraminoplasy at these levels. More experienced users are able to access the L5-S1 disc space, the central canal, and sequestered herniation fragments.





Herniated disc removal using a spine endoscope through the transforaminal approach

An interlaminar endoscopic discectomy is more similar to a standard microdiscectomy and is accomplished with a posterior approach that traverses the interlaminar window. A dilator is inserted to spread the muscles and soft tissue in order to place a working sleeve into the interlaminar space. Sometimes a limited laminotomy is performed to accommodate the 8mm working sleeve. A small incision is made in the ligamentum flavum to permit access to the epidural space and posterior disc. This provides excellent access for removing central and paracentral herniations, and for addressing lateral recess and central stenosis.



Herniated disc removal using a spine endoscope through the interlaminar approach

Microdiscectomies and open discectomies are also performed via a posterior approach through the interlaminar space. An incision, 3 cm. or longer, is made in the skin, tissue is resected, and a retractor system is inserted. The muscles are resected and stripped from the lamina and, frequently, a laminotomy is performed. The ligamentum flavum is incised and, using a microscope or loupes, the surgeon identifies and removes the herniation. The size of the incisions and the amount of soft and bony tissue that is resected are significantly more than with the endoscopic approach. Many surgeons perform a "Minimally Invasive" discectomy in which a special tubular retractor system is used to reduce the incision size and the amount of dissection required, but the amount of tissue resected is still significantly more than with the endoscopic approach.

Despite their differences in approach and incision size, both open and full endoscopic discectomies are, functionally, very similar surgeries.

- Both techniques address the same pathology in the same way (e.g., the same herniated disc material is removed from its location pressing on the nerve root).
- Both provide the ability to visually inspect the anatomy and modify the surgical treatment plan, if necessary, during the procedure based on the observed pathology.
- Both permit the surgeon to select from a variety of instruments to perform a variety of surgical interventions (e.g., herniated disc removal, sequestered fragment removal, annuloplasty, foraminoplasty).
- Both allow the surgeon to visually confirm that the intervention has successfully treated the disease (e.g., visually verify that that nerve is decompressed).

While all of these are routinely performed during both open and endoscopic spine surgeries, they are difficult, if not impossible, to accomplish with a percutaneous procedure.

Full endoscopic surgery is less traumatic than more invasive surgical approaches

Conventional lumbar surgery has been associated with good results but the innate invasiveness associated with surgery, even microsurgery may result in significant tissue damage. Surgical techniques may be associated with blood loss; risks related to general anesthesia (especially in the elderly), failed back surgery syndrome (FBSS); soft tissue scarring, bone resection; and iatrogenic instability. Additionally, the amount of tissue damage also relates to the amount of post-operative pain and speed of recovery. While microsurgical techniques have reduced damage to the tissues, they too are associated with more trauma than less invasive approaches such as full endoscopic transforaminal and interlaminar lumbar discectomy. The length of the incision and the amount of muscle damage will contribute to the amount of blood loss, the amount of postoperative pain (and the need for pain medications). It will also affect the time that is required for healing and recovery, and return to work and everyday activities.

Additionally, the trauma from a microdiscectomy procedure generally leads to scarring of the soft tissues that make it very difficult to use the same surgical approach for future operations in the event that symptoms recur later on. In a similar manner, the amount of trauma to the epidural structures and the overlying tissues in a microdiscectomy can contribute to the development of epidural fibrosis, sometimes causing recurrence of pain.

It is typical during a microdiscectomy to remove some amount of bone in order to gain access to the epidural space and the herniated disc. The amount of bone removed to access the pathology is dependent on the size of the access device (tube or retractor), the size of the interlaminar window at the level being operated on, and the relative location of the pathology. If clinically significant stenosis (central, lateral recess, or foraminal) is present, then additional bone will need to be removed. If too much bone, especially the facet, is resected it can lead to an iatrogenic instability at that segment. Likewise, the ligamentum flavum must be resected to permit access to the epidural space, also contributing to trauma and potential instability.

Endoscopic procedures are significantly less traumatic than the microdiscectomy procedure. In the endoscopic interlaminar approach, the size of the working sleeve is only 8 mm and the muscle tissue is spread only a small amount. Likewise, the amount of bone resected and the size of the incision in the ligamentum flavum required for access is likewise much less for the endoscopic approach. In the endoscopic transforaminal approach, there is no incision in the ligamentum flavum, and bone is only resected for access if the foramen is unusually narrow. Additionally, with the option of either the interlaminar or transforaminal technique, stenosis can be addressed with the most advantageous approach, minimizing the amount of bone that has to be resected.

An endoscopic approach is preferred by many surgeons because it provides an equivalent success rate to microdiscectomy and causes less trauma to surrounding tissues. In addition to the immediate advantages to the patient, this reduced trauma provides a future benefit. Because of the minimal soft tissue scarring with the endoscopic approach, future surgeries to the same anatomy through the same approach are possible. Surgeons often use the phrase "not burning any bridges" when referring to the endoscopic techniques' minimal trauma and their preservation of future surgical options. Conversely, if a re-operation or other spine surgery is required after a microdiscectomy, it may be difficult to access the anatomy again through the same posterior approach. In this case, the transforaminal endoscopic approach may be used to avoid the scarred posterior soft tissue and reach the pathology from a posterolateral direction. Further, the transforaminal approach may be the most appropriate for reaching residual pathology, as one third of FBSS patients have residual foraminal stenosis (Spine J 2004).

Clinical Equivalence of Open Surgical and Full Endoscopic Approaches

Physicians who perform endoscopic procedures take the position (one supported in peer-reviewed publications) that, except for the approach, they are accomplishing the exact same surgical goal as those surgeons practicing open techniques. For example, they are removing the same fragment of herniated nucleus with an endoscope as other surgeons would with a microdiscectomy procedure. The only difference is that the surgeon performing a full endoscopic procedure makes a very small incision and accesses the anatomy through a 7mm working sleeve causing minimal trauma to the patient. By contrast, a surgeon performing a microdiscectomy will make a 20 mm, or larger, incision, and likely cut muscles, bone and ligaments to reach and remove the same herniation, in order to achieve the same decompression of the nerve.

<u>Advantages of Full Endoscopic Techniques</u>

Further, in the literature and in surgeons' experience, the full endoscopic techniques have demonstrated clinical outcomes equivalent to microdiscectomy, and have demonstrated several advantages over microdiscectomy:

- Smaller incision with less soft tissue damage and less scar tissue formation
- Less bone and ligament resection
- Less intracanal disruption and epidural fibrosis
- Less postoperative pain, and less need for pain medication
- Faster recovery and earlier return to work and ADLs
- Fewer surgical complications
- Visualizes anatomy not visible with a microscope (endoscope "sees around corners")
- Less operative blood loss
- Shorter operating time
- Does not require general anesthesia
- Feedback from awake patient helps monitor for neurological complications

<u>Advantage of Endoscopic Transforaminal Approach</u>

Among surgeons performing endoscopic procedures, the transforaminal approach is generally preferred over the interlaminar approach where possible. Advantages of the transforaminal approach include:

- Does not violate the posterior anatomy, including:
    - Multifidus and longissimus muscles
    - Ligamentum flavum
    - Laminae and facet joints
- Avoids the spinal canal and dura
- Permits access to extraforaminal and foraminal herniations
- More direct approach for treating foraminal stenosis

<u>Advantages of the interlaminar approach</u>

However, there are occasions when the interlaminar approach is more appropriate than the transforaminal approach. The advantages of the interlaminar endoscopic approach include:

- Allows easier access to the L5 S1 disc space (avoids the iliac crest)
- Provides potentially better access to certain pathology, including:
    - Central disc herniations
    - Central stenosis
    - Lateral recess stenosis
- Approach is similar to microdiscectomy (more familiar for surgeons to learn)

VI. Difference Between Endoscopic Surgery and Percutaneous Procedures

Differentiating Full Endoscopic from Percutaneous Procedures: "Percutaneous" means no visualization during the operation

The term "percutaneous" continues to be used inappropriately to apply to endoscopic spine techniques, which has created confusion in differentiating full endoscopic from true percutaneous procedures. "Percutaneous" is a term that most accurately and most frequently applies to procedures that involve needles or other small diameter devices that can be inserted through the skin (often by puncturing the skin) with no incision required and almost no trauma. These can include injections, needle biopsies, aspirations, etc.

Some devices, (e.g., catheters, tubes, and larger biopsy devices) may be of large enough diameter (over about 1-2 mm) to require a small stab incision from a scalpel. However, interventions performed with these devices, regardless of their larger diameter, are still properly considered percutaneous procedures because **they are performed with no visualization of the internal anatomy**. Either they are performed with indirect imaging, like fluoroscopy or ultrasound, or they are performed by only viewing external landmarks and palpating internal landmarks.

Functionally, there is a very significant difference between surgery performed with an optical system, such as an endoscope or microscope, and a percutaneous procedure performed using just fluoroscopy. This difference relates back to the inherent limitations of fluoroscopic imaging:

- Fluoroscopy is very poor at imaging soft tissue. Even when soft tissue can be identified, fluoroscopy cannot differentiate the tissue's color, texture, or fine details. Consequently, fluoroscopy cannot permit the user to determine the location and condition of nerves, nucleus material, or other soft tissue.
- Fluoroscopy does not provide any magnification of the anatomy at the surgical site.
- There is little possibility of inferring three-dimensional relationships using the fluoroscope. (Gross anatomical features can only be approximately localized by mentally correlating two orthogonal projections.)
- Instruments, and their interaction with the tissue, cannot be directly viewed.
- There is typically no continuous visualization of the instruments, and surgical progress is not monitored in real time. Typically, the fluoroscopic unit is used to take only infrequent "spot images".

- All imaging with a fluoroscopic unit comes at the expense of radiation exposure to the surgeon, the patient, and the OR staff. This fact tends to minimize the number of fluoroscopic images that are provided during a procedure.

These characteristics of the fluoroscope, while permitting a significant reduction in the size of instruments and the invasiveness of procedures, limit what can be accomplished during procedures that rely solely on fluoroscopic image guidance.

There are several discectomy systems on the market that are correctly considered percutaneous devices. Most of these devices involve the insertion of a cannula into the disc space under fluoroscopic guidance and then use an RF or mechanical system to remove some amount of the nucleus to effect a decompression. However, the anatomy is not directly visualized and the process of removing the nuclear tissue is not visually monitored. Sometimes, a small diameter endoscope may be inserted through the lumen of the access cannula, but this is done at the end of the procedure, not while the tissue is being modified. Again, **what makes these procedures percutaneous is not the diameter of the device per se, but the lack of direct visualization of internal structures during the operation.**

On the other hand, endoscopic spine surgery permits direct visualization of the anatomy while the surgeon uses miniature instruments to operate on the tissue. The spine endoscope is designed with a separate optic channel and instrument working channel so that visualization and surgery may occur simultaneously. The operative tips of the instruments emerge from the tip of the scope right next to, and in full view of, the objective lens and are kept in full view during surgery. (It should be noted that some authors, especially early in the development of spine endoscopic techniques, referred to endoscopy as “percutaneous” - but this was merely as a way to distinguish it from the well-known open techniques.)

Another major difference between endoscopic systems (such as the Richard Wolf system) and percutaneous systems, is that the endoscopic systems include a wide range of instrumentation intended to address a variety of conditions in specialized and optimum ways. Most of the percutaneous systems are designed only to be able to remove nucleus tissue from inside the disc. If there is other pathology (extruded fragments, sequestered fragments, annular tears, stenosis, adhesions, etc.,) the Wolf endoscopic system contains a wide range of instrumentation (including seven endoscopes, dozens of forceps, several RF probes, multiple powered burrs and shavers, and numerous other hand instruments) to address it. For example, if a fragment of herniated nucleus becomes sequestered in the epidural space, the Wolf system contains a flexible tip probe and articulating rongeurs to retrieve it. Similarly, if during a discectomy the surgeon sees that the facet joint is also impinging on the nerve root, the Wolf system contains high-speed burrs and bone punches to permit removal of the impinging bone. As opposed to percutaneous systems that have a “single purpose” tool that blindly removes nucleus tissue, endoscopic systems, such as the Richard Wolf system, permit the user to visually inspect the anatomy and identify pathology, and utilize different instruments intended to specifically address these conditions. It is a hallmark of all open surgery that the surgeon is able to inspect the anatomy, identify pathology, make intraoperative decisions on how to address problems, and select the most appropriate instruments to address it.

V. Conclusion:

Full endoscopic discectomy is a safe and effective surgical alternative to microsurgical discectomy and should be covered, particularly due to the option for either an interlaminar or transforaminal approach as well as a wide array of instrumentation available to address lumbar disc herniation and numerous other pathologies. Full endoscopic lumbar procedures allow direct visualization of internal structures while tissue is being modified - a hallmark of traditional surgical technique and should be covered by insurers. Full endoscopic discectomy should <u>not</u> be classified with or confused with percutaneous procedures from either a clinical perspective or a coverage and coding perspective.

VII. Literature Excerpt:

Full-endoscopic interlaminar and transforaminal lumbar discectomy versus conventional microsurgical technique: A prospective, randomized, controlled study.

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Abstract

Study Design: Prospective, randomized, controlled study of patients with lumbar disc herniations, operated either in a full-endoscopic or microsurgical technique.

Objective: Comparison of results of lumbar discectomies in full-endoscopic interlaminar and transforaminal technique with the conventional microsurgical technique.

Summary of Background Data: Even with good results, conventional disc operations may result in subsequent damage due to trauma. Endoscopic techniques have become the standard in many areas because of the advantages they offer intraoperatively and after surgery. With the transforaminal and interlaminar techniques, 2 full-endoscopic procedures are available for lumbar disc operations.

Methods: One hundred seventy-eight patients with full-endoscopic or microsurgical discectomy underwent follow-up for 2 years. In addition to general and specific parameters, the following measuring instruments were used: VAS, German version North American Spine Society Instrument, Oswestry Low-Back Pain Disability Questionnaire.

Results: After surgery 82% of the patients no longer had leg pain, and 14% had occasional pain. The clinical results were the same in both groups. The recurrence rate was 6.2% with no difference between the groups. The full-endoscopic techniques brought significant advantages in the following areas: back pain, rehabilitation, complications, and traumatization.

Conclusion. The clinical results of the full-endoscopic technique are equal to those of the microsurgical technique. At the same time, there are advantages in the operation technique and reduced traumatization. With the surgical devices and the possibility of selecting an interlaminar or posterolateral to lateral transforaminal procedure, lumbar disc herniations outside and inside the spinal canal can be sufficiently removed using the full-endoscopic technique, when taking the appropriate criteria into account. Full-endoscopic surgery is a sufficient and safe supplementation and alternative to microsurgical procedures.

Key Points:

The clinical results of the full-endoscopic technique are equal to those of the microsurgical technique. At the same time, there are advantages in the operation technique and reduced traumatization, including:

- No serious complications, fewer minor complications (dysesthesias)
- Less postoperative pain and faster return to work (25 vs. 49 days)
- Operative time faster (22 vs. 43 minutes)

With the surgical devices and the possibility of selecting an interlaminar or posterolateral to lateral transforaminal procedure, lumbar disc herniations outside and inside the spinal canal can be sufficiently removed using the full-endoscopic technique, when taking the appropriate criteria into account.

Full-endoscopic surgery is a sufficient and safe supplement and alternative to microsurgical procedures.

Open and maximally-invasive procedures are necessary in spinal surgery and must be mastered by surgeons so that they also overcome problems and complications encountered when performing full-endoscopic procedures.

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