Evolving Methodology in the Treatment of Discogenic Back Pain by SED

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ABSTRACT

Objective: to describe the developing changes in Selective Endoscopic Discectomy™ (SED™) to correlate endoscopic spinal surgery with the disc pathology identified by Evocative Discography™ (ED™) and direct observation.

Material and Methods: 56 patients were candidates for traditional procedures ranging from laminotomy/microdiscectomy to spinal decompression and/or fusion. ED™ was performed in all patients. Under conscious sedation, every disc, facet, and nerve that required surgical exploration was accessed by the Yeung endoscopic spine system (YESS technique) through the posterolateral portal. Extruded disc fragments were targeted by guiding the endoscope and specially configured operative cannulas to the herniation. Foraminal and lateral recess stenosis were addressed by mechanical means, utilizing trephines, micro rasps, and Ho:yag laser for decompression of the inferior surface of the superior articular process. The ligamentum flavum attachment from the medial edge and the facet was also removed in the presence of central stenosis. Nerves were untethered from osteophytes. Most herniations were extracted directly by forceps through the operating cannula. Visualized pathology-- annular tears, interpositional disc tissue, osteophytes, or inflammatory membranes inside or outside the disc-- was addressed by tissue modulation with adjuvant therapy including radiofrequency, laser, topical steroids, or low dose chymopapain.

Results: The surgical outcomes compared favorably to open traditional approaches, but with minimal morbidity. Patient satisfaction was consistently high due to same-day scheduling, conscious sedation, minimal blood loss, Band-Aid surgery, avoidance of general anesthesia, shorter recovery period, and early return to normal activity and work. There were no instances of disc space infection, cerebrospinal fluid leakage, increased neurological deficit, or hemorrhage requiring transfusion.

Conclusion: SED™ has evolved into successful treatment of a wide spectrum of

pathology producing discogenic pain and has proven to be a significant and viable alternative to open spinal surgery. The inclusion of adjuvant complimentary modalities elevates endoscopic microsurgery to the forefront of minimally invasive spinal technique.

Key Words: Selective Endoscopic Discectomy™, Evocative Chromo-discography™, Microdiscectomy, Lumbar Disc Herniation, Discogenic Pain, Annular Tear, Spinal Endoscopy, Thermal Modulation, Foraminoplasty.

INTRODUCTION

Low back pain, a common cause of disability, may arise from any spinal structure - nucleus pulposus, annulus, facets, ligaments, vertebrae, muscle, and nerve.[12] Axial back pain is commonly encountered by the physician and has a variety of potential pain generators. Study of discogenic pain has demonstrated that annulus fibrosus tear and nuclear fragmentation are important pathologic changes.16,22 but the pathogenesis of degenerative disc disease starts from inside the disc outwards with radial annular tears.[2931]

Annular tears are associated with degenerative disc changes[18] and contribute to the development of abnormal annular bulges that progress to protrusion when more severe. Most disc herniations are not acute events but an accumulation of several insults to the back.[18],[39] The annulus fibrosus is torn in bulging as well as herniated disks.[41] The literature is sparce on the diagnosis and evaluation and treatment of annular tears.[33] Annular tears and focal disk protrusions on MRI, with or without contrast enhancement, are frequently found in an asymptomatic adults. A high intensity zone (HIZ) is observed in many patients with low back pain may represent inflammatory annular pathology. Patients with annular tears may experience low back pain with radiation into the lower limb in the absence of nerve root compression, but in the presence of inflammation. In such a conflicting scenario there is a need to visually demonstrate such tears, establish correlation with back pain, and prevent progression of those annular defects associated with intractable radiating symptoms. While most tears are in the posterior annulus, the location may be anterior in upper lumbar degeneration. Endoscopic technique has the potential to diagnose, locate and routinely address painful tears not usually seen with the traditional open posterior approach. In addition, endoscopy can address herniations and nuclear fragmentation.[40]

Previous published data on percutaneous procedures involved nucleotomy for contained herniations and were gathered by fluoroscopic monitoring but were essentially blind.[32] As techniques evolved, targeted fragmentectomy of herniated disc fragments was possible in the hands of an experienced endoscopist.[19],[20],[21],[35],[40] (figs 1a, 1b, 2a, and 2b) It is now even thought to be an alternative to open surgery and compares with traditional open surgery.[19] Few studies have addressed the multiple causes of discogenic pain entirely endoscopically. Utilizing multiple endoscopic techniques and adjuvant therapies makes it a significant diagnostic and therapeutic tool.

MATERIALS AND METHODS

Inclusion Criteria

1. Patients with disc protrusions or annular tears presenting with back and/or leg pain not responding to adequate conservative treatment were considered for endoscopic assessment and treatment. MRI and a preoperative or intraoperative evocative discogram were used to screen each patient before considering endoscopy. Pain was quantified by visual analog scale.
2. Discogenic back pain that did not centralize or was worsened by extension as in MacKenzie's extension technique after 6 weeks of conservative treatment.

Relative Exclusion Criteria

1. Severe central bony spinal stenosis, severe deformity and instability, mental health and psychological problems that would impact treatment. In selected patients, an experienced spinal endoscopist can get good results with endoscopic foraminoplasty without creating additional spinal instability. When psychologic problems are worsened by chronic pain, patients have responded well to endoscopic intervention.

Exclusion Criteria

1. Pregnancy

Evaluation

Clinical outcome was evaluated by two methods. The first was a surgeon retrospective assessment at each follow up period using modified MacNab criteria. Patients were surveyed at one month, three months, six months, and after one year. Follow up ranged from 21-30 months. The patients were asked to estimate their level of improvement as a percentage of overall improvement based on a visual analog scale of 1-10 for their preoperative back pain and leg pain as separate entities compared to their back and leg pain post-operatively. An excellent result required greater than 75% improvement of both back and leg pain. A good result required a 50% improvement of both back and leg pain, and a fair result required at least a 25% improvement. A poor result was determined when there was no relief or worse pain in the back or leg.

The second method was more complicated. The SF-36 questionnaire was used, but it was difficult to tabulate, so six questions were selected from the complex questionnaire to measure the following domains: pain symptoms, function, well-being, disability, inability to perform in a social role, and satisfaction with care. Any negative response, especially dissatisfaction with the procedure resulted in a mandatory poor rating. The surgeon rating took into account the patient's response to the questionnaire for the final overall result.

Patient Population

There were 56 patients in the study, male 35 and 21 female, with ages ranging from 18 to

75. Table 1 lists the disc levels affected. The total number of herniations and protrusions treated were 86 discs in 56 patients. The locations were 30 central herniations, far lateral 6, paracentral 15, and foraminal 5. Patients with concomitant lateral and central stenosis, and evidence of mild instability were not excluded.

Table 1: Disc Levels Operated	
L1-2	3
L2-3	5
L3-4	9
L4-5	34
L5-S1	35
	86

Surgical Technique
Specialized Equipment (YESS system)

A specially designed multi-channel endoscope (YESS Wolf discoscope) (fig 3) with a large working channel provided the consistent quality imaging needed to target spinal pathology. The multi-channel, flow integrated system kept the surgical field clear for even when the endoscope was directed to areas that bled. A pressure and volume controlled pump, coupled with a 4.0 MHZ bipolar triggerflex radiofrequency probe and side firing Ho:yag laser helped control the bleeding that limited the effectiveness of first generation endoscope systems. A refined technique to find the exact trajectory needed through a skin and foraminal window (fig 4) allowed access to targeted Intradiscal and foraminal pathology. A working cavity was created in the posterior 1/4 of the disc for direct access to the posterior annulus and the epidural space. Specialized cannulas added another dimension of safety and efficacy, exposing pathology for surgical intervention while protecting sensitive nerves.

Intra-operative Discography

Evocative discography (ED^{TM}) was performed on every patient. A nonionic agent (Isovue 200 or 300) was mixed 9:1 with indigocarmine dye to stain degenerated disc and annular tissue. Indigo carmine, with an affinity for an acidic 2 environment, selectively stains acidic degenerated disc tissue a light blue. Reproduction of concordant back pain, correlated with an abnormal discogram pattern, confirmed the need for endoscopic assessment of that disc.

An endoscopic classification for the intra operative discograms without post-discogram CT was adopted for this study. The grades I-V is based on the combined work of Adams, Dallas and Osti. The basic pattern is according to Adams: Grade I to V. Grade I and II are considered normal, exhibiting a cotton ball or bilobular pattern. Grade III is fissured, with extention to the inner annulus. Grade IV extends to the outer annulus, with or without circumferential extention. The radial extensions are as described in the Dallas Discogram Description where it is grade III if the extension is up to the inner annulus and Grade IV if up to the outer annulus and grade V if beyond the outer annulus. The extension of circumferential tears is as described by Osti, divided into the quadrants of involvement noted on the PA and lateral C-arm views. The revised discogram classification used for endoscopic classification therefore is:

Grade I	cotton ball nucleus
Grade II	oval or bilobular nucleus with painless extension of fragmentation beyond center
Grade III	radial extension to inner annulus +pain and fissuring, no circumferential extension
Grade IV	radial extension to outer annulus with circumferential component involving 1, 2, 3 or 4 quadrants
Grade V	radial tear past outer annulus with or without circumferential extension 1 to 4 quadrants

Grades 1 and 2 induce no pain. Grade III evokes pain at moderate pressures. Grade IV tears may produce predominant back pain more than leg pain, and its extent is measured by the number of quadrants involved. It can produce pain at relatively low pressures, depending on the extent of the circumferential tear. This type of tear is associated also with central and lateral disc protrusions that may not be apparent on MRI. Grade V tears extend beyond the annular fibers and can produce pain at low pressures. With grade IV and V tears, Inflammatory membrane may be present. (MRI can only detect posterior tears, while lateral tears are usually only detected by discography. These tears are more difficult to treat, as the size and extent of the tear will influence the clinical course and ultimate result. These tears are also associated with extruded herniations, sometimes undetected by MRI, and healing time can be a variable 1-9 months depending on the size of the tear and the number of layers left to heal (fig 5a + 5b).[38]

Selective Endoscopic Discectomy

Folllowing the discogram, a guide wire is then inserted into the lumen of the 18 gauge spinal needle utilized for the discogram, followed by an incision with a #11 scalpel. An obturator dilates the muscle and docks on the annulus of the disc. The off-set hole in the

two-hole obturator is used to anesthetize the tract, including the annulus. If dilute (.5%) lidocaine is used, there will be no motor weakness, even with generous use of xylocaine around the spinal nerves, and the patient can still feel sensation when the nerve is stimulated manually or with laser or radiofrequency. Blunt technique is used to fenestrate the disc annulus, and a cannula is inserted around the obturator as the tubular access to the disc. A beveled or open slotted cannula with a tang is employed to anchor the ventral portion of the cannula onto the annulus of the disc, leaving the dorsal window open towards the epidural space. The disc, posterior annulus, and epidural space are then in the field of vision of the 20 degree wide angle endoscope. (fig 6) The location and position of the cannula is dependent upon the individual pathologies to be addressed. The stained disc material could then be evacuated by special instruments such as the hinged pituitary forceps and flexible irrigated suction shavers, creating a working space within the dorsal disc cavity. Once the degenerated disc is removed, the annular defect and tears are visualized and thermally modulated with a radiofrequency probe and Ho:YAG laser. The epidural space is explored last to confirm the decompression of the traversing nerve. The cannula can be rotated to expose the exiting nerve either at the 4 o'clock or 8 o'clock position depending on a right or the left side approach. Intradiscal use of the scope to explore spinal structures and to better understand the pathology is an evolving process that is dependent on the surgeon understanding the process as well as his endoscopic skills. The patient is only minimally sedated and monitored for pain during the procedure. The procedure is video taped and operative details recorded on the Image Manager^{TM}, a commercially available program incorporating images in the operative report. Adjuvant modalities available when the visualized pathology dictated were chymopapain for extruded and recurrent fragments and methylprednisolone for inflammatory membranes. In every case, an attempt is made to correlate the patient's symptoms with the pathology visualized.

Postoperative Mobilization

Postoperative treatment progressed in stages, beginning with gentle mobilization and return to activities of daily living. Common sense, early return to function,and principles of lumbar stabilization through corrective exercises are advised. As the pain decreases, gradual increase in aerobic and conditioning exercises are added to the regimen. The final phase of rehabilitation focused on rehabilitating weakened spinal musculature by strengthening regimens.

RESULTS

Overall outcomes were excellent 46%, good 32%, Fair 11%, and poor 11%; An inflammatory membrane was seen in 22/56 patients. The presence of an inflammatory membrane correlated with pain "out of proportion" to the imaging abnormality, but pain relief was also dramatic if there were no complications of dysesthesia. Self-limited and temporary dysesthesia was associated with aggressive removal of the inflammatory membrane in 6 patients. Due to the relatively high incidence of post-op dysesthesia (20%) the senior author to changed the thermal probe from unipolar to a higher frequency (4.0MHZ) bipolar radio frequency probe.(Ellman, International, Hewlett, NY), resulting in a reduction, but not elimination of this transient effect.

There were no infections or iatrogenic nerve injury in this prospective study. The thermal probe broke in one case, but was removed and did not result in any complication. There was severe dysesthesia noted in 4 patients, and these patients were all rated poor. All improved, however, with time and treatment. Avoiding extensive removal of the inflammatory membrane decreased the incidence and severity of dysesthesia, but dysesthesia as a complication of thermal modulation is only speculative, as dysesthesia can result as a delayed phenomenon weeks later, and can occur even without thermal modulation of the inflammatory membrane. It's etiology is still not completely understood. (fig 7)

DISCUSSION

The Role of Evocative Discography

Traditional use of X-ray, MR, CT, or CT myelography is insufficient for pain evaluation in many patients. Current imaging studies can identify an anatomic condition in minute detail and at an early stage, but cannot reliably predict the severity of a patient's pain. Annular tears may manifest on MRI as a high-intensity zone (HIZ) of annular enhancement. It may indicate a painful internal disc disruption.[24] Annular tears and focal disk protrusions, even if identified on MR images, are frequently found in asymptomatic patients.[37] Modic changes seen in MR in end plates have not been correlated with discography assessments.[34]

In a cadaveric study[26] it has was found that in many annular tears the disc may communicate with the neural structures. In case of an incompetent annulus the pain may be due to chemical nerve root irritation. In case of an incompetent annulus the pain mechanism is still unsettled and controversial.[8],[9],[10] But in a disc with competent annulus, discography remains a valid test for diagnosing the discogenic source of pain. When multiple levels are affected it is one of the more significant tools of diagnosis.[26] There is an extensive review of discography recommending its use.[17]

Recent literature has backed Discography as a safe, accurate, reproducible, objective diagnostic tool when tested for volume, pressure, fluoroscopic changes, and pain provocation.[1]

This study focuses on the clinical and imaging assessment of annular tears, disc herniation, and its correlation with pain by discography. The most important determinant of successful treatment in all spinal disorders is accurate diagnosis. Careful selection of patients, meticulous analysis of radiographic findings and proper surgical technique yield good results allowing most patients to improve their quality of life. The authors feel that the selection of patients with an accurate diagnosis for the disc related surgery is important. Once a patient is selected on the basis of symptoms, the pathology will dictate the treatment modality.

An imaging diagnosis of internal disc disruption can be made in a significant proportion of patients with chronic low back pain, but no conventional clinical test can discriminate

patients with internal disc disruption from patients with other conditions. When back pain is the major symptom, however, traditional imaging studies are insufficient to differentiate painful from non-painful discs. The clinical assessment by MacKenzie's method only gives a fair idea about the affected painful disc.[14] After ruling out the muscular, ligamentous, facet and sacroiliac causes of backache, the disc becomes the main source of pain in the back and sciatica. Bogduk estimates its contribution to be 39%.[3] Our experience with discography suggests a higher incidence of over 50%. The MacKenzie assessment process is thought to reliably differentiate discogenic from nondiscogenic pain ($P < 0.001$) as well as competent from an incompetent annulus ($P < 0.042$) in symptomatic discs and may be superior to magnetic resonance imaging in distinguishing painful from non-painful discs.[14]

ED^{TM} visualizes and more accurately confirms the discogenic etiology of the patient's pain. Because of inter-observer variability, whether the pain is concordant or discordant, it is recommended that the endoscopic surgeon perform his own discography to better evaluate patients, especially those with psycho-social disorders and medication dependency. Many patients have asymptomatic herniations, but supersensitive diagnostic imaging identifies pathology that biologically may or may not cause pain. The leg pain also may be referred from the disc.31 Clinical evaluation by ED^{TM} has become more important than ever.

Clinical Pathologic Correlation

The difference of the interstriation angles of collagen fibers in the lamellae between the anterior and posterior annulus fibrosus is known. In the 4th decade of life, collagen fibers in the lamellae show loosening, separation, and a cyst- like cavity, which finally develops into an annular tear. These degenerative changes observed predominantly in the posterior annulus fibrosus suggest that the posterior annulus fibrosus has structural and developmental instability against mechanical stress.[29] This is the fundamental problem.

A radial division of the annulus is not sufficient to produce a clinically relevant disc herniation; further prerequisites are fragmentation of the disc material and a separation from the endplates.[7] This change in the nucleus is well appreciated in discography patterns. The endoscopic assessment and treatment of discogenic pain is designed with this in mind.

Evidence for pain of disc origin is an extensive distribution of small nerve fibers and free nerve endings in the superficial annulus of the disc and small fibers and free nerve endings in adjacent longitudinal ligament.[11] Isolated nerve fibers that express substance P deep within diseased intervertebral discs and their association with pain suggests an important role for nerve growth into the intervertebral disc in the pathogenesis of chronic low back pain.[15]

Compression injuries of the disc are initially asymptomatic but may set in a process that, in time, leads to internal disc disruption, which becomes symptomatic as a result of chemical or mechanical irritation of nociceptors in the annulus fibrosus. Disc prolapse is

one possible end stage of internal disc disruption.[4]

Possible mechanisms of sciatica are many. Severe sciatica results when dorsal root ganglia are subjected to moderate pressure. When ganglia are exposed to autologous nucleus pulposus and phospholipase A2, excitation and loss of nerve function occurs.[11] The chemical irritation is postulated to be arising from the leak through the annular tear and thus the sealing of the tear may be important.

Spinal Endoscopy

The YESS system, with its multi-channel ports and specially designed cannulas, produces high resolution quality imaging of spinal structures. The postero lateral area of the disc and the annulus is targeted by this approach. Bleeding from the epidural veins in most cases obscures visualization. This bleeding is controlled by hydrostatic pressure and the use of radiofrequency or laser coagulation of blood vessels. A suction force, controlled flow and monitored hydrostatic pressure limits fluid extravasation into the epidural space.

The use of sequential local anesthesia gives the surgeon the ability to probe spinal structures for pain. Local anesthesia is currently used to indirectly identify and differentiate pain-causing structures in the back, and specifically the disc. Kuslich[23] found that only the outer annulus, facet capsule and inflamed nerve root is painful. Visualization and identification of spinal anatomy in and around the nerve root and foramen during endoscopy is made easier by the indigo carmine staining technique. Specialized instruments and cannulas allow access to the anatomy in and around the foraminal zone bordered by the facet and lamina dorsally, the exiting nerve root and psoas muscle ventrally, and pedicles of the cephalad and caudal vertebra. Flexible instruments allow the removal of extruded disc fragments. Laser, trephines and rasps make it possible to remove osteophytes and the inferior portion of the superior articular process, thus raising the roof of the foramen to free the tethered nerve roots. Resection of the bulging annulus in a collapsed disc decompresses the traversing nerve. Resecting a portion of the superior articular process also provides more dorsal access to the epidural space.

Annular tear is a major cause of intervertebral disc degeneration that results in disabling back pain.[18] Until the development of third generation spine endoscopes, the annular tear eluded the surgeon's attention. The recently introduced Spinecath technique works on similar principles[33] of addressing the annular tear but the range of the anatomical changes and the symptom spectrum treatable by a catheter put inside the disc blindly, are limited.

The most common finding during intradiscal endoscopy was interposed disc tissue or a HNP extending beyond the outer annular fibers and commonly resulting in nonhealing of the annulus. (fig 8) Direct observation of the offending disc material and removal resolved the patient's pain. When annular modulation was combined with selective discectomy, the defect was reduced in size; and the effectiveness of the procedure increased.

Percutaneous Techniques versus Selective Endoscopic Discectomy

In the past, percutaneous methods of treating back pain and sciatica have had limited application and success due to the utilization of a single surgical device with a narrow spectrum of indications.[36] This study differs because of it's incorporation of multiple modalities to address the pathology at hand. A review of the literature revealed success rates for lumbar discectomy ranging from 80-96%. This study accomplished similar results with less morbidity.

Most other percutaneous studies specifically excluded noncontained disc herniations and targeted only what was in the path of the scope.[13] They targeted the center of the nucleus or the accessible portion of the nucleus only[27], putting the efficacy of the procedure to address the spectrum of discogenic causes of pain in question. The present study specifically included extruded, sequestered, and recurrent disc herniations. In addition to the removal of the offending nucleus, weak collagen fibrils were modified by thermal energy to provide a seal and hasten healing. The heat may have temporarily deadened the nerve supply of the sensitive outer annulus, depopulating the type III and IV nociceptors in the annulus, and allowing for more rapid pain relief than with traditional techniques. Instability is also less likely than after traditional open surgery.[38,35]

The Inflammatory Membrane

In cadaveric and operative specimen studies nuclear fragmentation, migration, and extrusion along radiating annular clefts have been seen. Neovascularization of extruded fragments was thought to bear no relationship with duration of sciatic pain symptoms or clinical outcome.[28] In another cadaveric and operative specimen study[39], blood vessels were observed in 57 of 101 cases (56%) of complete prolapse, 12 of 32 cases (38%) of incomplete prolapse, and 53 of 467 cases of protrusion. Another 100 postmortem spines in individual over 40 years of age manifested neovascuylarization in 47% of discs between T10 and L5.