Prospective Evaluation of a 3-Blade Speculum Cannula for Minimally Invasive Lumbar Microdiscectomy

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Abstract: Minimally invasive spine technology is still in an evolutionary stage. This prospective study reports the technical feasibility, benefits, and limitations of using a 3-blade speculum cannula for minimally invasive lumbar microdiscectomies. We studied 52 consecutive patients, 24 males and 28 females, with a mean age of 36.1 years (range 20 to 68 years) and body mass index of 29.6 who underwent a microdiscectomy using this access device that opened to create a cylindrical working channel. We prospectively documented the length of the incision, estimated blood loss, length of surgery, outcomes using the visual analog scale for leg pain, and complications. The average incision length was 20.9 mm (range 13 to 30 mm). Average blood loss was less than 50 mL. Ninty-six percent of the patients had complete resolution of their radicular leg pain with improved mean visual analog scale scores from 8 to 0.3 postoperatively ($P < 0.5$). Mean surgical time decreased with experience from 135 minutes for the first 15 patients, 103 minutes for the next 22, and 75.2 minutes for the last 15, to an overall mean of 108 minutes (range 51 to 188 minutes) and a 56% decrease for the last 38 patients. Body mass index did not affect surgical time or incision length. Seventy-five percent of the patients were discharged on the day of surgery and the remainder within 23 hours. Two symptomatic hematomas required reoperation using the retractor at 3 days and 4 weeks postoperatively. This new speculum minimal access device was effective for lumbar microdiscectomy in limiting the size of the incision without the need for sequential dilation, providing excellent visualization with the aid of a microscope, allowing same-day discharge after surgery, and demonstrating improved outcomes even in obese patients. This device may provide insights for the improvement of design considerations for other minimally invasive access devices.

Key Words: minimally invasive, microdiscectomy, cannula, percutaneous, spine, endoscopic, access

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Historically, many minimally invasive approaches to the treatment of lumbar herniated discs have evolved that include chemonucleolysis, percutaneous manual nucleotomy, automated percutaneous lumbar discectomy, laser discectomy, microendoscopic or arthroscopic discectomy, transforaminal speculum microdiscectomy, and intradiscal electrothermy.[1–9] However, in recent years, there has been a growing commercial interest in minimal access devices to aid minimally invasive spine surgery (MISS) procedures. As a result, there is a rapid technological evolution in the methods and access devices used for MISS. These devices and techniques have the benefits of minimizing soft tissue dissection and injury, improving visualization with optical aids and light sources, reducing perioperative blood loss, shortening recovery time, hospitalizations, and health care costs compared to traditional open discectomies. However, MISS technology is still in an evolutionary stage, and there is minimal reported clinical outcome data and experience with these newer devices to guide surgeons in making a choice between access devices and methods. The purpose of this prospective study is to report the technical feasibility and limitations of using this speculum cannula for minimally invasive lumbar microdiscectomies and to determine if there are associated benefits. The authors hypothesized that this MISS device will decrease the duration of surgery and length of incision with progressive experience and that obese patients, typically difficult to do open microdiscectomies on, will not have longer operation time and incision lengths compared to thinner patients.

METHODS

A series of 52 consecutive patients, 24 males and 28 females, with a mean age of 36.1 years (range 20 to 68 years) were prospectively followed up after excision of a symptomatic lumbar disc herniation by a single surgeon (KRC). A 3-blade speculum minimal access device that opened to create a cylindrical cannulated working channel was used to provide visualization and direct access to the herniated disc. The device was manufactured and distributed by SYNTHES Spine (SYNTHES Spine, West Chester, PA). The patients were selected on the basis of the diagnosis of a herniated disc on magnetic resonance imaging and concordant sciatica that did not improve with nonoperative therapy for a minimum of 4 months. The lumbar disc levels involved were L5-S1 in 32 patients, L4-5 in 17, L3-4 in 2, and L2-3 in 1. There were

3 extraforminal herniated discs and 2 patients with 2 symptomatic disc levels at L4-5 and L5-S1. These patients had two separate incisions. All were primary procedures except in one patient referred from an outside facility for a revision operation, done with this technique 13 months after the primary procedure.

Patient demographic information, including height and weight, were documented at the initial visit and their body mass index (BMI) was calculated. Postoperative parameters such as the duration of surgery, estimated blood loss, length of incision, and complications were also documented in each patient's chart. Comparative analysis was done to assess the effects of BMI and progressive experience with the device on the duration of surgery. The data were analyzed using Microsoft Excel 2002 (Microsoft Inc., Redmond, WA). Statistical comparisions were made using Student t test, with statistical significance defined as $P < 0.05$.

Surgical Technique

Patients underwent general anesthesia and were then positioned prone on an Andrews table (Orthopaedic Systems, Union City, CA) with all bony prominences well padded. The lumbar spine was prepped and draped in sterile fashion. Then, using a 22-G spinal needle and fluoroscopy, the affected disc space level was localized. The skin and soft tissues were infiltrated with 20 mL of 1% lidocaine and 1:200,000 epinephrine. Next an incision, approximating the width of the surgeon's index finger, was made approximately 1 cm lateral to the midline of the spine on the side toward the herniated disc at the appropriate level. Using a Cobb elevator, the subcutaneous layers were elevated off the lumbodorsal fascia, obviating the need for sequential dilation for access. In morbidly obese patients, the lumbodorsal fascia may not be seen clearly under direct vision and the Cobb elevator was used to provide tactile feedback to the depth of the fascia and the location of the spinous process. In other patients, the fascia can be clearly seen while using the Cobb elevator to retract the subcutaneous tissues. Then an incision, 0.5 mm lateral of the spinous process, and in line with the skin incision was created through the lumbodorsal fascia. Again with the Cobb elevator, the erector spinae muscles were elevated off the associated laminae and spinous processes. The speculum retractor system was then placed in the wound using the leading edge of the beveled side of the speculum and moving in a back-and-forth clockwise and counterclockwise rotation while advancing through the soft tissues. Once docked against the facet and lamina, using the assistance of a microscope and a pituitary rongeur, the intervening soft tissues inside the cannula were removed until the interlaminar space was identified. A lateral fluoroscopic view was then taken with the speculum in place to confirm the location relative to the desired disc space (Fig. 1). If necessary, a laminotomy allowed access to the disc space, except at L5-S1 where bone resection was rarely needed because of the larger interlaminar space. Extraforaminal discs were excised from outside the spine, also without resecting bone. The dura and nerve roots were exposed and retracted away from the herniated disc. A probe was used to locate the annular defect and a pituitary ronguer was used to remove only loose disc fragments. The canal space beneath the nerve root and the dura were explored for loose disc fragments and the foramen was probed to ensure adequate space for the nerve root. Forced irrigation was placed into the disc space through the annular defect to remove any missed loose disc fragment. The wound was copiously irrigated and hemostasis was achieved. The lumbodorsal fascia was closed in layers to achieve a watertight closure. The length of the incision (in mm) was determined at the completion of wound closure using a sterile ruler. In our series, the duration of surgery was from the time of incision to the time of dressing application. The first 3 patients had drains placed postoperatively that were removed before discharge on the morning of the first postoperative day. This practice was subsequently abandoned because patients started going home within 2 h of surgery. Each patient was scheduled for admission after surgery but was given the option to leave on the day of surgery without any involvement in the decision by the surgical team. The patients were allowed to walk immediately postoperatively. Light activity with no heavy lifting was recommended for the first 2 weeks postoperatively until follow-up in the clinic, at which time, unrestricted activity was permitted.

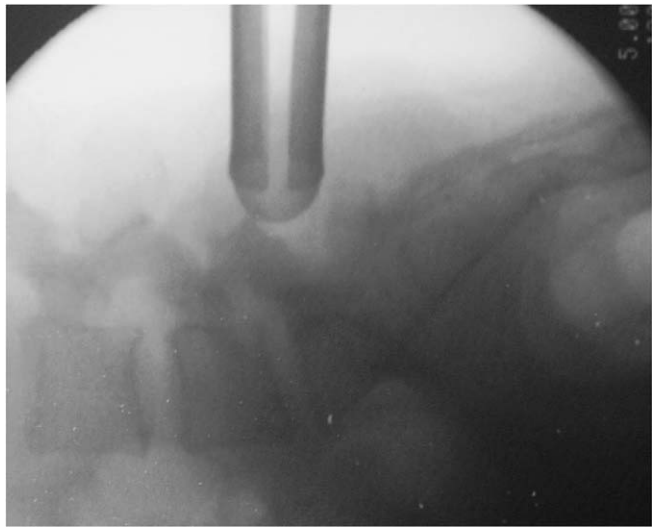

FIGURE 1. Fluoroscopic confirmation of the placement of the cannula.

The custom-made retractor system looks similar to the traditional gynocological speculum used for routine pelvic examinations. There is an addition of a third blade that prevents soft tissue from obstructing the visualization of the lumbar disc space. The blades are inserted into the lumbar soft tissue and the handle is squeezed to open the blades. There is a tightening bolt on the handle that

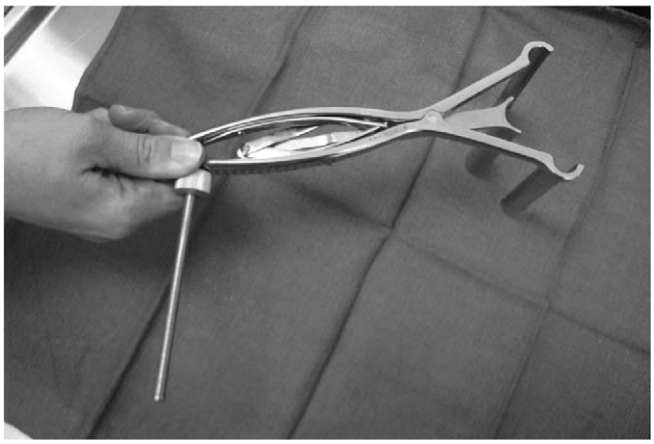

FIGURE 2. The cannula fully opened.

locks the blade in place, once optimal positioning has been achieved. The opening to the top of the cannula measured 13 mm when fully closed and opened maximally to 69 mm cephalocaudad and 31 mm mediolateral. The length measured 83 mm from the base to the longer side of the beveled tip and 73 mm from the base to the shorter side of the tip. It was made of stainless steel (Fig. 2).

RESULTS

Patients were followed up for an average of 12 months (range 3 to 22 months). Seventy-five percent (39/52) of the patients chose to be discharged the same day of surgery and 13 were discharged within 23 h of admission. The average blood loss was less than 50 mL. Ninty-six percent of the patients stated they had resolution of their leg symptoms by initial follow-up. There was a significant improvement in the mean visual analog scale scores for leg pain from 8 preoperatively to an average of 0.3 postoperatively ($P < 0.5$).

The average length of the incision for all patients was 20.9 mm (range 13 to 30 mm). The average incision length decreased with progressive experience (Table 1). Obese patients with BMI > 30 had an average incision length of 21.1 mm (range 18 to 30 mm) compared to 20.8 (range 13 to 30 mm) for those with BMI < 30.

The average length of surgery was 108 minutes (range 51 to 188 minutes) for all patients. The mean duration of surgery decreased with progressive experience from 135 minutes (range 88 to 188 minutes) for the first 15 patients, to 103 minutes (range 55 to 180 minutes) for the 16th to 37th patient, to 75.2 minutes (range 51 to 108 minutes) for the 38th to 52nd patient ($P < 0.5$) (Table 1). This represented a 56% decrease in the duration of surgery for the last 38 patients. Obese patients with BMI > 30 had an average duration of surgery of 108 minutes (range 51 to 188 minutes) compared to 107 (range 55 to 180 minutes) for those with BMI < 30. Patients with incision lengths less than 20 mm had an average duration of surgery of 88 minutes (range 51 to 139 minutes) compared to 116 minutes (range 56 to 188 minutes) for patients with incision lengths ≥ 20 mm.

TABLE 1. Results With Progressive Experience

Patients	Average Length (mm)	Average Surgical Time (minutes)	Average BMI	Average Age (years)
1–15	24.5	135	31.6	37.4
16–37	20.0	103	27.01	33.8
38–52	19.6	75.2	29.5	38.1

The average BMI of the patients was 29.6 (range 18.1 to 37.1). There did not seem to be a relationship between surgical time or incision length and the patient's BMI. The 3 highest BMIs were 36.5, 36.9, and 37.1. Their surgical time and incision lengths were 108, 19; 51, 18; and 98, 21, respectively.

Complications after the procedure were limited and none of the operations had to be converted to an open procedure. There was one small dural tear that occurred without the need for suture closure. One patient had delayed wound healing and a symptomatic hematoma/seroma; however, she was a very obese woman (BMI 34.5) with noninsulin-dependent diabetes. Three patients had seromas that developed postoperatively, one could be aspirated in the office and 2 had reoperations for irrigation and debridement and exploration 3 days and 4 weeks after the primary procedure. Only these latter 2 patients had leg pain.

DISCUSSION

Minimally invasive access to the lumbar disc for the treatment of lumbar herniated disc or for insertion of interbody devices is an area of increasing interest both for the commercial industry and the surgeons. Historically, MISS techniques included percutaneous methods, such as chemonucleolysis, manual and automated percutaneous nucleotomy, laser diskectomy, and intradiscal electrothermal therapy. The goal of these operations was to remove the central portion of the central nucleus pulposus with the hope that the herniated disc fragment and annulus retract to their normal confines and thus indirectly relieve the pressure on the offended nerve root. The overall success rate of these procedures ranges between 50% and 89%.[1,3,6] Complications of these procedures have been high and include neurovascular injury (nerve root injury, cauda equina syndrome), discitis, and cerebrospinal fluid leak, similar to complications of open discectomy procedures.[7,8]

The development of fiberoptic visualization allowed surgeons the ability to use rigid or flexible discoscopes and endoscopes to gain access to the posterior spinal elements with improved visualization. Arthroscopic techniques developed with the use of uni- or biportal techniques through a variety of approaches:

posterolateral, posterior interlaminar, or foraminal approaches. These visualization aids have allowed the offending disc material to be removed under direct guidance with minimal trauma to the surrounding soft tissue. Arthroscopic techniques can be performed under conscious sedation with local anesthesia, and patients are positioned either prone or in the lateral decubitus position. Successful outcomes with arthroscopic techniques, as defined by patient satisfaction with the operation, has been reported between 85% and 92%, with less than 2% reoperation rate.[5,7] Complications due to these procedures that have been described include discitis, instrument breakage, and psoas hematoma.[5,7]

Unlike percutaneous discectomy, lumbar microdiscectomy allows access to all types of disc herniation including those that are sequestered after extruding through the annulus and lie dorsal to the posterior longitudinal ligament. Herniations that are intra-annular, subligamentous, or extraligamentous can be accessed by arthroscopic means but migrated fragments outside the triangular working zone cannot be addressed. Although many former MISS techniques demonstrate high success rates, none have been shown to yield superior results to lumbar microdiscectomy.[9] The fact that lumbar microdiscectomy can be done in a minimally invasive manner and achieve excellent results makes it the gold standard of MISS for the treatment of herniated intervertebral discs with associated radiculopathy.

The new speculum minimal access cannula device described in this article was effective for lumbar microdiscectomy in limiting the size of the incision on average approximately 2 cm and providing excellent visualization with the aid of a microscope. Utilization of a microscope with a light source provided a stereoscopic view and allowed for enhanced magnification and illumination at the targeted operative field for direct visualization and removal of the herniated disc, which was especially advantageous in obese patients where the disc was deep below the skin surface. The ability of the cannula to expand was advantageous in obviating the need for sequential dilation to the appropriate cannula size. The beveled tip made it fairly easy to insert deep into the spine without interference from the tissues. A small amount of tissue creep occurred between the blades when the cannula was opened but this was easily removed with a pituitary rongeur and subsequently did not obscure visualization. Thus, the technical attributes of this device are advantageous for microdiscectomy and appear to minimize the expectation that surgical time and incision length would be increased with larger BMI.

As with most new devices or procedures, there was a learning curve with the use of our device. The results in this series showed that with increasing experience with the device, there were decreases in the average length of the incision, and average surgical time. Also, all these procedures were performed at a teaching institution with prolongation of surgical time to allow residents and a spine fellow the opportunity to work under the microscope. Familiarity with the use of the microscope also added to the learning curve. Ten of the first 15 patients were operated with an older microscope with a much shorter focal length and intense light source and this added substantial difficulty to these early cases. In some cases, the light reflected off the cannula, forcing us to use a more focused beam that required more maneuvering of the camera to provide proper illumination. The fixed length of the cannula was a disadvantage for thin patients because the cannula projected further above the skin surface and was more unstable (Fig. 3) and thus required an assistant to manipulate the cannula for visualization. At times, this necessitated the surgeon to reposition the cannula many times during the procedure, given the lack of a stabilizing arm. In more obese patients, deeper retraction was more difficult to maneuver or hold in a fixed position by the assistant because there was less of the cannula protruding above the skin surface. A Cobb elevator was needed to blindly create a path for the retractor before the insertion, which is more difficult in obese patients. This also resulted in soft tissues being caught within the cannula. This was often easily remedied by removing the soft tissues under direct vision using the microscope. These disadvantages are being addressed by the manufacturer and the newer device will have multiple lengths and widths, a black finish to minimize light reflection, tissue dilators, and an arm to hold the device in a fixed position without the aid of an assistant.

FIGURE 3. The cannula was stabilized with the surgeon's abdomen.

Despite these disadvantages, 75% of the patients chose to leave the same day as the operation, and there was no reoperation for a retained disc, showing that this device and technical procedure provided excellent visualization and caused minimal iatrogenic morbidity to the patient. The limitations of this device can be overcome with experience, and they provide insights for improving design considerations for other minimally invasive access devices.

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