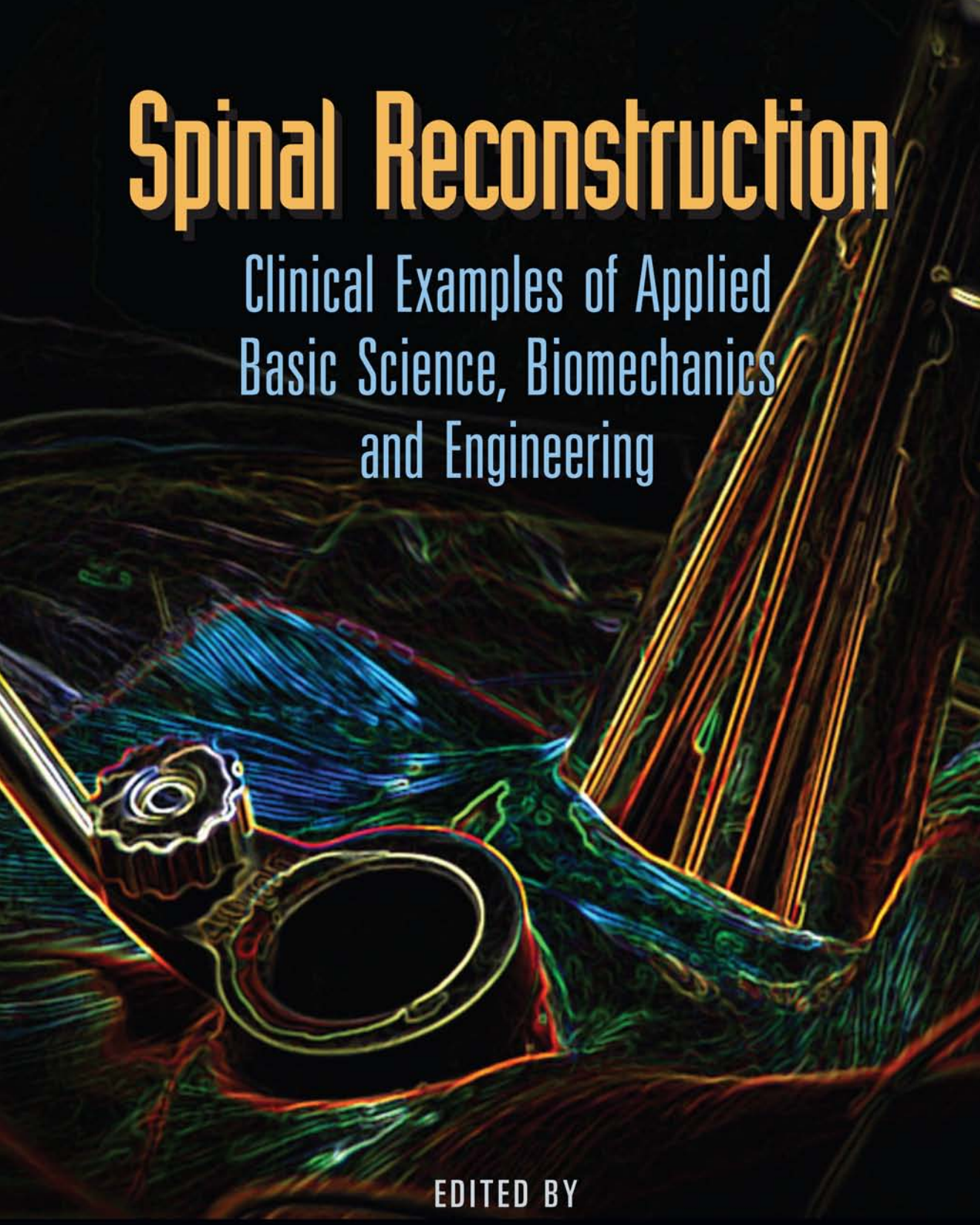
Spinal Reconstruction

Clinical Examples of Applied Basic Science, Biomechanics and Engineering



EDITED BY

Kai-Uwe Lewandrowski • Michael J. Yaszemski • Iain H. Kalfas

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edited by

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Preface

Spinal fusion remains at the center of many reconstructive procedures of the spine. However, several new concepts have recently emerged, which led many spine surgeons to rethink traditional approaches to common clinical problems. Examples of these new trends include use of artificial disc replacements for reconstruction of degenerated spinal segments instead of interbody fusion devices, percutaneous pedicle screw fixation systems instead of open screw placement, and minimal invasive decompressions through small percutaneously placed tubes instead of open, wide laminectomy procedures through large incisions. Minimally invasive techniques are now aided by computerized navigation systems; substitute, and expander materials are increasingly employed as adjuncts to autologous bone grafts; and growth factors, such as BMP-2, are now strongly considered as a replacement material for iliac crest bone grafts.

With the ongoing expansion and aggressive marketing of novel spinal device and implant systems, judging many of the newer developments presents a growing challenge to clinicians as it is not clear whether all of these innovative concepts represent true improvements over established clinical standards of care. Extensive work is currently underway to study the healing success and decrease in morbidity with less rigid implant systems, more bioactive and mechanically sound bone graft substitutes, and growth factor applications to establish clinical outcomes and rates of failure.

The illustrative description of the development of a new generation of materials and devices capable of specific biological interactions to improve reconstruction of the spine and to enhance reconstitution of diseased spinal segments are at the heart of this new reference text: *Spinal Reconstruction: Clinical Examples of Applied Basic Science, Biomechanics and Engineering*. Improvement of these materials and devices is in a constant state of activity, with the challenge of replacing older technologies with those that allow better exploitation of advances in a number of technologies; for example, motion preservation; navigation; less rigid, biologically active, and/or biodegradable implants that exert less stress to adjacent levels; drug delivery; recombinant DNA techniques; bioreactors; stem cell isolation and transfection; cell encapsulation and immobilization; and 3D scaffolds for cells. The chapters within this text deal with issues in the selection of proper technologies that address biocompatibility, biostability, and structure/function relationships with respect to specific clinical problem scenarios. Other chapters also focus on the use of specific biomaterials based on their physiochemical and mechanical characterizations. Integral to these chapters are discussions of standards in analytical methodology and quality control.

The readers of *Spinal Reconstruction: Clinical Examples of Applied Basic Science, Biomechanics and Engineering* will find it derived from a broad base of backgrounds ranging from the basic sciences (e.g., polymer chemistry and biochemistry) to more applied disciplines (e.g., mechanical/chemical engineering, orthopedics, and pharmaceutics). To meet varied needs, each chapter provides clear and fully detailed discussions. This in-depth but practical coverage should also assist recent inductees to the circle of spinal surgery and biomaterials. The editors trust that this reference textbook conveys the intensity of this fast-moving field in an enthusiastic presentation.

Kai-Uwe Lewandrowski

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1 The Role of Minimally Invasive Surgery in Instrumented Lumbar Fusion

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Over the years, we have seen the new and innovative techniques that have allowed the surgeon to minimize exposure to potentially maximize the patient's outcome. Minimally invasive surgical approaches and treatment have become the standard in many surgical specialties. When we look at this evolution, we are drawn to the use in the surgical procedure for a cholecystectomy (1). The minimally invasive approach via laparoscopy has now replaced the traditional open approach, and the results have shown less morbidity and movement of this procedure to an ambulatory outpatient procedure. In orthopedics, this has been seen with the advent of the arthroscope, where an open procedure was the standard and the only option. Now, one can treat many joints, especially the knee and shoulder, with a minimally invasive approach through the arthroscope.

This concept of minimally invasive surgery has now become evident in all aspects of orthopedics—especially, most recently, with total hip and total knee replacement surgery with the main driving force for minimally invasive surgery being sooner and quicker recovery. The results from this approach to the hip and knee have shown promise. Spine surgery has also had its evolution from the classic open laminectomy and discectomy to microdiscectomy, which has evolved into, and in many centers, is now an ambulatory outpatient procedure. The reason for this transition and the success has been based on the premise of less bone disruption, less bleeding, less paraspinal muscle damage than that which was seen with the classic approach (2–4). Concerns have existed with any procedure in the lumbar spine, open or via microdiscectomy, as to the degree of soft-tissue dissection and stripping of the paraspinal muscles and damage during muscle retraction. Problems have been identified from these, which include elevated creatinine phosphokinase MM (5), a high incidence of low back pain (6), and an increased incidence in the development of failed back syndrome (7).

As a result, any approach that minimizes these problems and can improve surgical outcomes and rehabilitation time would be met with support from the spinal community.

In the advent of the progression to a minimally invasive approach to the spine for decompression and discectomy, we have seen the evolution from the open approach, where good clinical results have been seen to the micro-approach, which has also evolved into a small incision ambulatory procedure with good surgical and clinical outcomes (8).

If we believe our concerns about muscle damage and their effects, and a new approach, such as minimally invasive or minimal access were developed, then it should provide access channels to the spinal anatomy and bony structures with minimal muscle stripping and damage. The first system to address this was METRx™ (Medtronic Sofamor Danek) (Fig. 1), which involved a tubular retraction system that allowed direct visualization, minimal muscle stripping and damage, and the ability to perform a decompression and discectomy. Foley (9) and Hilton (10) have reported their results, showing a reduction in hospital stay, improved clinical outcomes, and quicker return to work with the METRx system.

Additional systems have now been developed to provide access to the spine and provide results similar to that reported. Such systems include the DePuy Pipeline™ (which provides access through a retractor system that allows it to be expanded to the size and length needed), NuVasive MaXcess™ (which is similar to the others with distracters that provide access to any length of the spinal exposure needed) (Fig. 2), Endius (which is different from the others in that it utilizes an arthroscopic camera system to visualize the operative field

FIGURE 1 Medtronic METRx™ minimally invasive system with next generation X-tube modification for screw and rod insertion. *Source*: Courtesy of Medtronic Sofamor Danek, Memphis, Tennessee.

and visualize the spine), and EBI VuePass Tubular (which uses a radiolucent tubular system that provides ease with accessing radiographs for placement of the retractors and identifying the levels, and moreover is free of metal interference on X-rays) (Fig. 3). In addition, with the ability to perform a decompression and discectomy through this approach, these systems allow the surgeon to perform an interbody fusion as well.

With proper positioning and placement of the initial guide wires, and paying attention to the angle for the type of procedure desired, followed by proper placement of the retractors, one can approach the interspace and perform a posterior lumbar interbody fusion (PLIF) or transforaminal interbody fusion (TLIF).

The technique begins by identifying the proper landmarks for the skin incision (Fig. 8) and then under C-arm visualization guide wires at the specific levels. Proper positioning involves the placement of the guide wires 3 to 5 cm from the midline (Fig. 4) and at the specific level and angle based on the approach. If performing a PLIF, then a more direct approach is used (Fig. 5), and for a TLIF, a more angled position is utilized for the insertion point (Fig. 6). The radiographs shown in Figure 7 can be used to ascertain proper position and placement. Subsequently, through dilators and a small fascial incision (Fig. 8), the muscle fibers are split and separated along the muscle plane, so as to prevent muscle damage and injury. Permanent retractors are then inserted for the specific system used, and the standard procedure that would be done open can be performed. A decompression, facetectomy, discectomy can be easily performed and an interbody fusion can be completed (Fig. 9).

Preliminary studies have shown that in this approach and technique, fewer complications have been reported; no graft or implant failure have been seen; decreased blood loss;

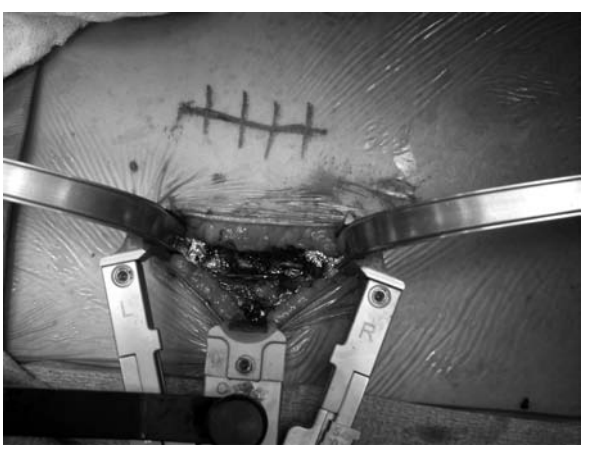

FIGURE 2 The NuVasive MaXcess™ system (Nuvasive, San Diego, California) for insertion of pedicular screws and rods with direct view of facets and landmarks for screw placement and decompression for interbody fusion.

FIGURE 3 EBI VuePass™ (EBI, L.P., Parsippany, New Jersey) minimally invasive system showing ability to perform bilateral access to the spine for instrumented fusion with ease of graft insertion in posterolateral gutter.

shorter hospital stays; and good clinical outcomes are reported (11,12). However, with this technology, we were unable to stabilize the spine posteriorly with instrumentation, and could only provide anterior column support via interbody fusion after a decompression in the initial systems that were developed. As technology has continued to evolve and strove to identify a process to instrument the spine posteriorly, a percutaneous system, through a minimally invasive approach, would be ideal (13,14). This minimally invasive concept has now given rise to a truly percutaneous system, the Sextant System.

The Sextant System™ (Medtronic Sofamor Danek) allows one to insert pedicle screws percutaneously with the aid of radiographic C-arm. The technique involves the insertion of percutaneous guide wires first, followed by dilators over the guide wires. The pedicles are then prepared and screws inserted. With the screws inserted, extenders are attached to the screw heads and aligned and interlocked.

This allows the screw heads to be aligned appropriately and the arc-shaped rod awl is driven through to engage each screw head, and then the arc-rod insertor is utilized to pass the rod into the screws, and locking nuts are applied. This system lends itself well as a supplement for an anterior approach, but can also be applied to posterior decompression with or without interbody fusion, using a Wiltse approach, with insertion of the screws through this incision and percutaneous screw insertion on the opposite side. The Sextant System allows one to perform a single-level instrumented fusion in its initial design, and currently, multiple-level instrumented fusions with the next-generation Sextant System. This system does have its limitations in its use, especially with severe deformities of the spine, patients with increased lumbar lordosis, and if considering instrumentation at the L5-S1 level or if a posterolateral fusion is to be performed. As with any

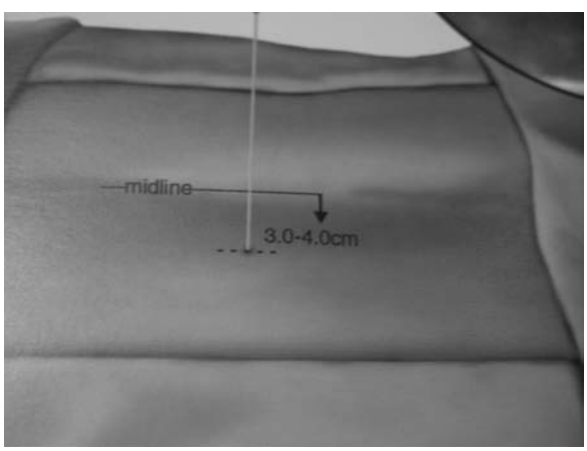

FIGURE 4 Initial placement of skin marking and guide pin insertion point. *Source*: Courtesy of Medtronic Sofamor Danek, Memphis, Tennessee.

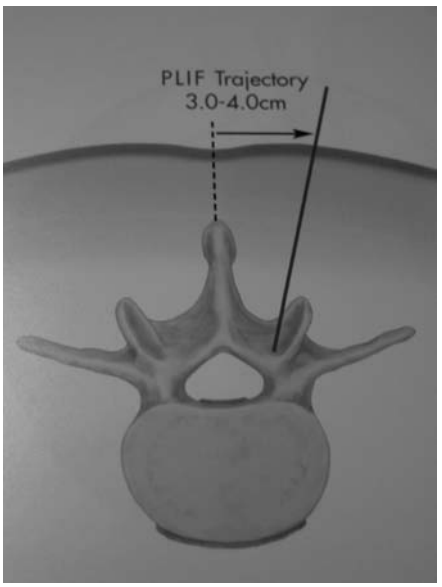

FIGURE 5 Guide pin angle for insertion for a minimally invasive approach for performing a posterior lumbar interbody fusion. *Source*: Courtesy of Medtronic Sofamor Danek, Memphis, Tennessee.

evolving technology, modification and refinement will occur and move to a still minimally invasive access approach with more visualization of the spine and greater flexibility in the performance of additional procedures, such as an instrumented fusion with posterolateral fusion, which is limited in the percutaneous system.

Systems that have evolved and which allow the insertion of pedicular screws through a minimally invasive approach and incision, coupled with the ability to perform a posterolateral fusion, include the Medtronic X-Tube™ (Fig. 1), Spinal Concepts Pathfinder, DePuy Aperture, DePuy Viper, NuVasive SpherRx™ and SpherRxDBR™, and Endius.

These systems utilize a Wiltse approach (15) to provide an intramuscular plane to the spine, between the multifdus and longisimus. Guide wires are placed, and taps and screws are inserted. Rods are then inserted through both direct visualization and placement or with the aid of slotted connectors that align the screw heads for placement of the rods, and then locking screws are guided into place (Fig. 11). Advantages include less blood loss, less

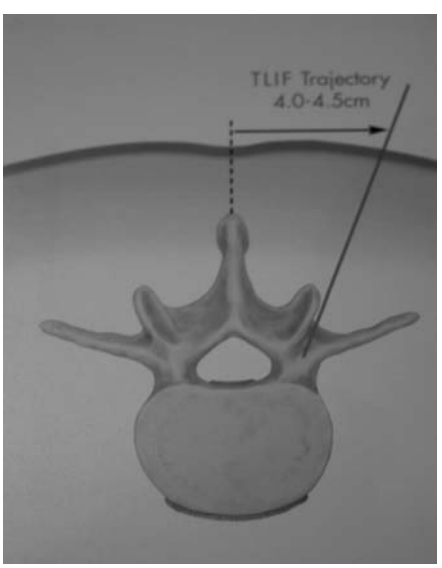

FIGURE 6 Placement and angle for direction of system for a transforaminal interbody fusion approach. *Source*: Courtesy of Medtronic Sofamor Danek, Memphis, Tennessee.

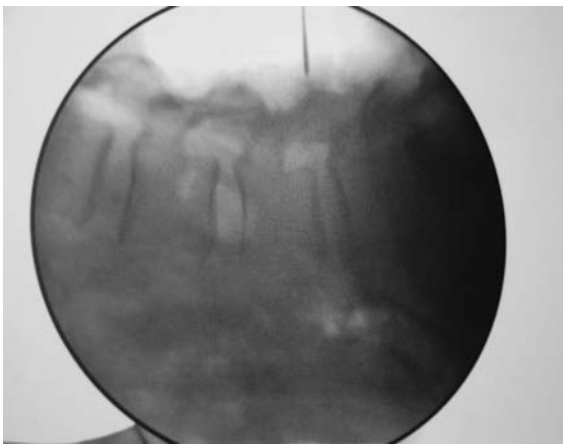

FIGURE 7 Radiographic image of proper placement and angle on lateral radiograph for the appropriate level.

muscle damage, the ability for reduction of a spondylolisthesis, compression and distraction across a spinal segment, and use in multilevel instrumented fusions. Disadvantages include limitations in the ability to decompress the spine, visualization of the neural structures for discectomy, and the ability to perform an interbody fusion.

The ability to perform all aspects of a fusion through a minimally invasive approach have taken all that was previously developed and evolved it, so as to include decompression, interbody fusion, and instrumentation through a single simple approach. Systems that have been developed include the Medtronic Quadrant System (Fig. 10), NuVasive MaXcess (Fig. 2), Endius ATAVI, and the EBI VuePass System (Fig. 3). These systems allow one to have direct visualization of the spine, potentially less muscle damage, limited dissection of the soft tissues and preservation of the tissues, the ability to perform a decompression, perform a PLIF or TLIF, and insert pedicular screws and instrumentation. These systems are all applicable for either single- or multi-level fusions. Advantages are similar in all these systems, with the exception of the EBI VuePass System that allows one to utilize C-arm easily as the retractor system is radiolucent, and allows the surgeon to perform the surgery his way with little change in his technique.

The advantages of the EBI VuePass System include the ability to span a multi-level segment for instrumented fusion; the ability to insert bilateral tubes for simultaneous work on both sides of the spinal column; the ability to use any spinal instrumentation system or interbody fusion device that one desires; and ease to perform a posterolateral fusion with minimal movement of the retractor system (Figs. 3 and 11). This system encompasses all these and has been shown to have reproducibility, and as a result offers distinct advantages over any of the current available systems.

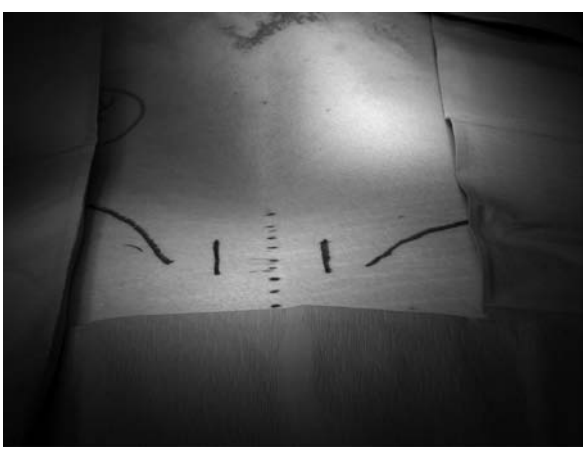

FIGURE 8 Landmarks and placement of skin incision for minimal access and minimally invasive approach to the lumbar spine.

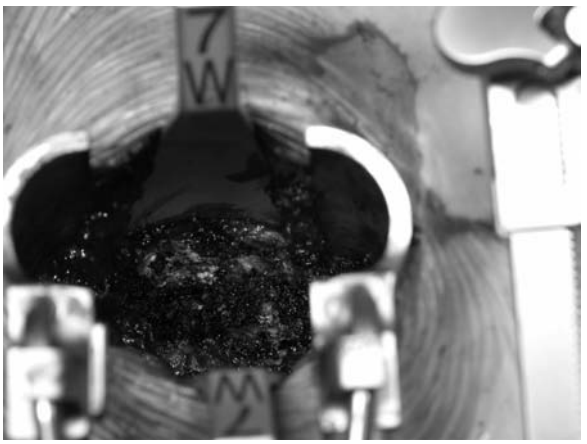

FIGURE 9 Direct visualization of anatomic structures of the lumbar spine through the Medtronic Quadrant System with visualization of facets and landmarks for screw insertion and decompression.

Nevertheless, the influx of all these systems and the interest in minimally invasive spine surgery, the premise at the advent of these technologies, was to decrease surgical morbidity, decrease hospitalization days, decrease pain, cause less muscle damage, offer a quicker return to functional activity, and most importantly offer reproducibility.

We have seen that through minimally invasive surgery, we can decrease our overall blood loss; decrease the surgical morbidity associated with these procedures; and offer less pain with less muscle damage, as seen with many microdiscectomy procedures, now being performed as an outpatient.

To see the overall effect of minimally invasive fusion surgery in terms of hospital stay, complications, operative time, and rehabilitation, the authors undertook a study comparing a matched group of 12 patients in each group, with one receiving minimally invasive fusion versus a standard open approach in the other. The results revealed that the overall operative time was only lengthened by 20 minutes (105 minutes in the open vs. 125 minutes in the minimally invasive); blood loss was reduced by 50% in the minimally invasive group (75 cc) compared with the open group (150 cc); hospitalization was reduced by 1.25 days (1.75 days in the minimally invasive group with two patients discharged in 23 hours compared with three days in the open group), and no additional complications were reported.

With reference to rehabilitation potential, the results were dramatic with those patients in the minimally invasive group into physical therapy (PT) one day sooner, 50% ahead in terms of

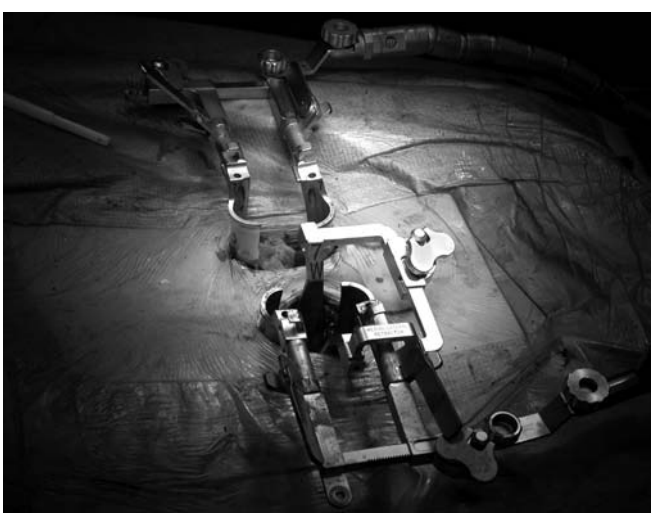

FIGURE 10 Medtronic Quadrant™ System for minimally invasive surgery with bilateral simultaneous access retractor placement.

FIGURE 11 Direct visualization via EBI VuePass™ (EBI, L.P., Parsippany, New Jersey) of landmarks and anatomy for screw insertion and decompression.

aerobic activities as well as strengthening and conditioning when compared with those in the open group at one month. At two months, over again, the minimally invasive group was 60% ahead of the open group in terms of overall strength and endurance, and 80% were ready to return to work compared with 45% in the open group.

At three months, 95% of the patients in the minimally invasive group returned to work compared with 65% in the open group, and all patients were accessed via Functional Capacity Evaluations, and matched to job requirements, before these patients returned to work. This study concludes that minimally invasive spine surgery and fusion does offer distinct advantages in terms of overall ability to improve rehabilitation, improve strength and endurance, and return patients to functional activities and work at a sooner time frame than with the standard open fusion.

Interest in minimally invasive surgery and fusion continues to expand as it has a potential to deliver benefits to the patient, surgeon, and the hospital. As the technology is enhanced, and our understanding of the indications continues to grow, and with proper patient selection and proper system selection, greater patient satisfaction can be potentially achieved.

Preliminary study has shown the efficacy of this technology, and most importantly that with the right system, the surgeon does not have to alter his technique and can perform the surgery his way and not be governed by the system or the technology. This technology has the potential to continue to decrease surgical morbidity and offer quicker recovery time and return to functional activities, including work, than with the standard open approaches.

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2 Minimally Invasive Transforaminal Lumbar Interbody Fusion

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INTRODUCTION

An increasingly popular method for lumbar arthrodesis is transforaminal lumbar interbody fusion (TLIF) (1–5). In a manner similar to posterior lumbar interbody fusion (PLIF) (6,7), TLIF provides for a 360° spinal fusion. Traditional posterolateral onlay techniques have been reported to have lower arthrodesis rates than interbody lumbar fusion techniques (8–12).

Transforaminal lumbar interbody fusion and PLIF offer a number of potential benefits over conventional posterolateral intertransverse arthrodesis, including increased fusion surface area; copious fusion blood supply via cancellous vertebral body bone; complete access for medial and lateral decompression; and restoration of intervertebral body height (8). Unfortunately, with PLIF, retraction and manipulation of the neural elements are required for disc space access. This has linked PLIF with a significant rate of neurologic injury (13–17).

As a more lateral approach, TLIF provides access to the disc space without the need for significant retraction of the nerve roots or thecal sac. Transforaminal lumbar interbody fusion is a unilateral procedure, and therefore avoids the need for bilateral dissection within the epidural space. It also makes revision surgeries less challenging, as there is less need to mobilize the nerve roots away from scar tissue. Finally, important midline supporting bony and ligamentous structures are preserved with TLIF.

Conventional posterior lumbar surgery, regardless of the fusion technique, is associated with significant soft-tissue morbidity that can adversely affect patient outcomes (18–23). Reduction in the iatrogenic soft tissue injury that occurs with muscle stripping and retraction during routine spinal exposure is the rationale of minimally invasive posterior lumbar fusion techniques (24–26). In this Chapter, we will outline the indications, surgical technique, results, and complications of performing the TLIF procedure using a minimally invasive approach.

Iatrogenic soft tissue and muscle injury that occurs during routine surgical exposure accounts for most of the significant morbidity of open instrumented lumbar fusion procedures. The deleterious effects of extensive muscle stripping and retraction have been well documented in the medical literature (18–23,27). These negative effects of lumbar surgery occur so commonly that the term fusion disease has been used to describe their occurrence. The effects of retractor blade pressure on the paraspinous muscles during surgery have been evaluated by Kawaguchi et al. (18,19) and Styf et al. (23). They found that elevated serum level of creatine phosphokinase MM isoenzyme, a direct marker of muscle injury, is related to the retraction duration and pressure. The beneficial effects of surgery can be negated by the long-term problems of this iatrogenic muscle injury. Rantanen et al. (21) concluded that patients who had poor outcomes after lumbar surgery were more likely to have persistent pathologic changes in their paraspinous muscles. It has been shown that patients who had undergone fusion procedures had significantly weaker trunk muscle strength than discectomy patients (20).

Minimally invasive spinal surgery with a less traumatic approach aims to achieve the same objectives as open surgery. However, reducing the approach-related morbidity must be accomplished without reducing procedure efficacy.

Surgical Technique

Following the induction of general endotracheal anesthesia, the patients were positioned prone on a Jackson (OSI) table. The patients were prepped and draped in the usual sterile manner. Lateral and anteroposterior (AP) C-arm fluoroscopic images were obtained. With the use of fluoroscopic guidance and an 18-gauge spinal needle, a 2.5-cm incision was centered on the interspace of interest approximately 5.0-cm lateral to the midline. The TLIF approach was carried out on the side ipsilateral to the worst radiculopathy. Contralateral Pathfinder (Abbott Spine, Austin, Texas, U.S.A.) pedicle screws and rod were placed through a separate 2.5-cm, mirror-image incision centered over the interspace. Through this incision, one can distract the interspace using the Pathfinder distracter, and then provisionally tighten the screw–rod connections in the distracted position. On the TLIF side, electrocautery was used to incise the fascia, after which serial dilators were used to create a muscle-sparing surgical corridor, as originally described for the microendoscopic discectomy (MED) procedure (28–31). An appropriate-length 22 diameter METRx (Medtronic Sofamor Danek, Memphis, Tennessee, U.S.A.) tubular retractor was docked on the facet joint complex (Fig. 1). The remainder of the procedure can be performed with the operative microscope or with loupe magnification, depending on surgeon preference. A total facetectomy was carried out using a high-speed drill. The removed bone was denuded of all soft tissue, morselized, and then later used for interbody graft material. The lateral margin of the ligamentum flavum was resected to expose the ipsilateral exiting and traversing nerve roots. Typically, only the most lateral margin of the traversing root was exposed so that it could be identified, protected, and decompressed as necessary. If needed, though, the tubular retractor could be wanded (angled) medially so that a more extensive decompression could be carried out (including decompression of central canal stenosis) (Fig. 2).

A discectomy was next performed through the ipsilateral tubular retractor. Epidural veins were controlled with bipolar cautery and thrombin-soaked Gelfoam was used for additional hemostasis, as necessary. At this point, distraction was performed, which allowed better access to the interspace, improved visualization of the annulus, and further, protected the nerve roots. Intervertebral distraction was performed in a bilateral and simultaneous manner by using the interbody paddles inserted into the disc space through the ipsilateral METRx tube, and applying the Pathfinder distracter to the contralateral pedicle screws (Fig. 3). This distraction was maintained via provisional tightening of the contralateral Pathfinder construct. However, if anterolisthesis was present and reduction was warranted, it could be accomplished using the Pathfinder reduction instruments (Fig. 4). The distracted position allowed improved access to the contralateral side of the interspace to complete the discectomy and prepare the endplates for fusion. Typically, cartilaginous materials were removed from the endplates, but their cortical portions were retained. Structural allograft bone, cages, bone morphogenetic protein (BMP), various bone graft expanders, and/or local autologous bone graft can be placed into the interspace, depending on surgeon preference. The local autograft

FIGURE 1 Dilation up to 22 mm using serial dilators, approximately 4 to 5 cm from midline with oblique orientation.

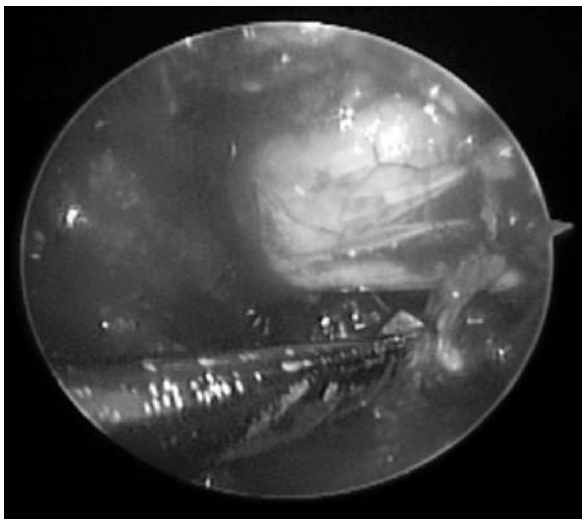


FIGURE 2 View through tubular retractor. The port has been wanded to allow a more extensive decompression of the thecal sac.

(combined with a BMP-soaked collagen sponge or other bone graft expander) was placed anteriorly and contralateral to the annulotomy within the interbody space (Fig. 5).

Additional autograft bone was placed into the interspace after insertion of the structural graft, if space allowed. Once the interbody fusion had been carried out, the contralateral pedicle screw construct was compressed using the Pathfinder Compressor. The tubular retractor was removed and an ipsilateral Pathfinder pedicle screw–rod construct was

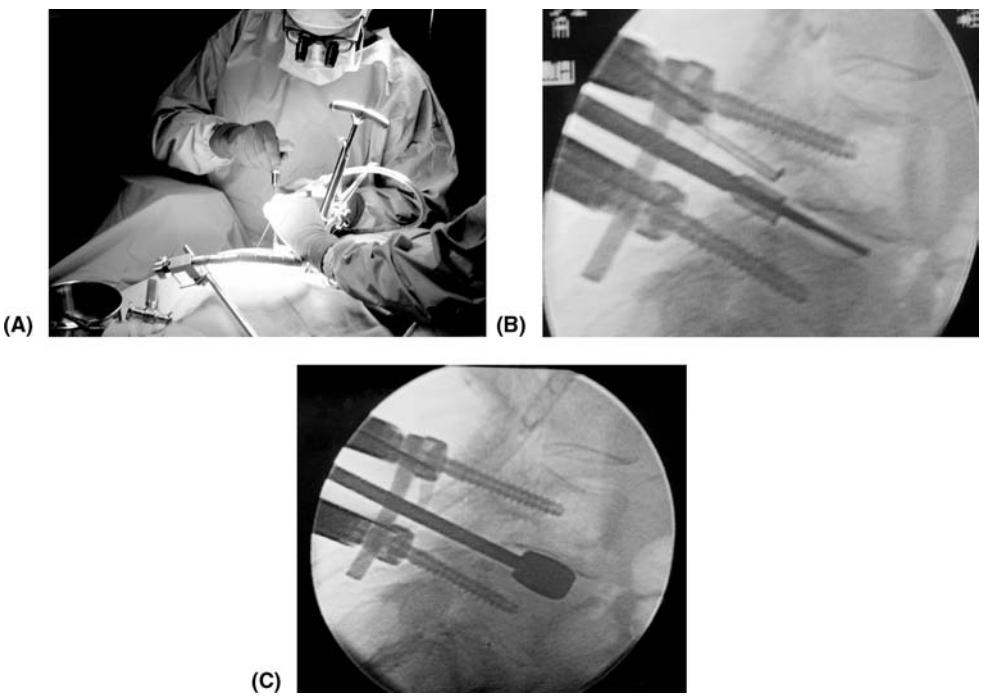


FIGURE 3 (**A**) Distraction using intervertebral paddle distracter (in hand) and Pathfinder distracter applied to contralateral pedicle screws. (**B**) Lateral fluoroscopic view of paddle distracter inserted into disc space and Pathfinder distracter placed on contralateral pedicle screws: predistraction. (**C**) Lateral fluoroscopic view following simultaneous application of Pathfinder distracter and rotation of intradiscal paddle distracter. Note the significant change in disc space height.

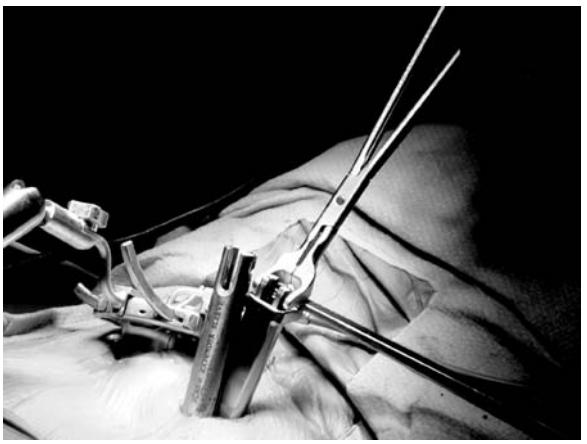
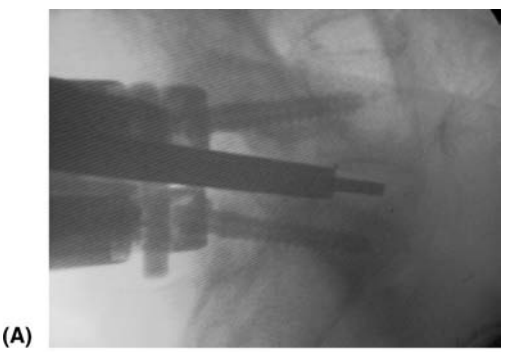
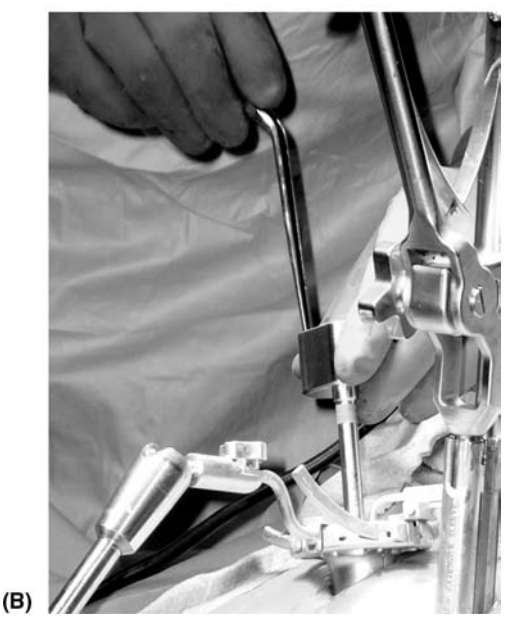


FIGURE 4 Spondylolisthesis reduction instrumentation.



(A)



(B)

FIGURE 5 (**A**) Lateral fluoroscopic image showing placement of implant spacer within the disc space. (**B**) Placement of morselized autograft into disc space via funnel.

placed through the same incision. Bilateral compression was applied to the construct prior to final tightening, providing compression of the bone graft within the middle column and recreating lordosis.

Clinical Study

A nonrandomized, prospective study was carried out on patients treated with a uniform surgical technique by a single surgeon. The patient group consisted of 31 patients with mean age of 54.2 years. All patients were taking narcotic medications prior to surgery. Slightly over half of the patients were working preoperatively.

All interbody procedures were performed via unilateral TLIF procedure. The TLIF component was performed through a 22-mm tubular retractor. Exposure of the disc space through the foramen followed facetectomy. Subtotal discectomy allowed for the interbody cage and bone graft to be placed in an oblique fashion. Bilateral percutaneous pedicle-screw instrumentation was then completed. Percutaneous pedicle-screw instrumentation was accomplished under electromyogram (EMG) and fluoroscopic control. Patients were assessed radiographically and clinically preoperatively and at 3, 6, 12, and 24 months.

All surgeries were for one-level disease, primarily spondylolisthesis. All of the devices were implanted via unilateral TLIF. The average surgical data: EBL-estimated blood loss: 125 cc, 211- minute surgical time, hospital stay of 2.2 days. There were five complications: one CSF-cerebral spinal fluid leak (unrelated to pedicle-screw insertion), one ileus, one right leg numbness (resolved), one superficial wound infection and one interbody graft retropulsion (required re-operation). Mean Oswestry scores were preoperation, 31.2; 12 months, 19.9; and 24 months, 18.1. Mean back pain scores were preoperation, 8.8; 12 months, 3.2; and 24 months, 2.8. Two-thirds of the patients were working at two years postoperation. Six of the 31 patients retired at two years postoperation, and four were on disability at two years. Nearly, 96.8% patients demonstrate rigid fusion on flexion–extension films at two years post-operation. The reoperation rate was 3%. At 24 months, 19% of patients were taking narcotic medications. Ninety-seven percent of patients were satisfied with the outcome of the surgery.

DISCUSSION

In this chapter, we have discussed the minimally invasive TLIF (MITLIF) procedure. Specialized instruments, such as a tubular retractor system and the Pathfinder system have made the TLIF procedure feasible. Serial dilation of the paraspinous operative corridor allows the surgeon to dissect through the muscle and fascia with minimal tissue trauma. Percutaneous pedicle screws can be placed through the same incisions.

The creation of a working channel between the muscle fibers permits access to the bony anatomy without the need for muscle stripping, unlike the open TLIF procedure. As a result, the estimated blood loss in our experience averaged only 125 mL, including pedicle-screw placement. Blood loss during conventional lumbar fusion surgery can be quite significant; in fact, patients commonly donate autologous blood preoperatively or a cell saver is used during the surgery. None of our patients required a blood transfusion. Compared with similar open procedures, patients had less postoperative pain following the MITLIF. Narcotic use was significantly reduced postoperatively. In addition, the hospital stay was at a relatively short average of 2.2 days.

We have outlined the many potential benefits of the MITLIF procedure. Minimally invasive transforaminal lumbar interbody fusion does have its drawbacks and limitations. A learning curve that must be surmounted before technical proficiency can be achieved is not insignificant. Standard landmarks that are visualized during open procedures may be unexposed during minimally invasive procedures, and lead to anatomic disorientation. Minimally invasive transforaminal lumbar interbody fusion is more technically demanding than open TLIF. This is attributed to a number of factors, including working in a smaller area and the need for longer and bayoneted surgical instruments. Additionally, placement of percutaneous pedicle screws requires the surgeon to be able to accurately interpret AP and lateral fluoroscopic images to safely insert these devices. Screw misplacement can be minimized by attention

to anatomic detail. Use of intraoperative electromyography is also helpful in avoiding this potential complication. Image guidance systems would possibly further reduce screw placement error.

When severe neural compression is present on the side contralateral to the TLIF approach, consideration should be given to direct decompression of the neural structures on that side. This can be accomplished by inserting a tubular retractor through the contralateral incision, prior to contralateral percutaneous pedicle-screw placement.

SUMMARY

To summarize, this chapter has briefed on the rationale, suggested benefits, and techniques of MITLIF. Although the efficacy and outcomes of open spinal decompression and fusion procedures have been validated in numerous longitudinal studies, these surgeries typically involve significant soft-tissue dissection and muscle retraction. The MITLIF techniques aim to minimize iatrogenic damage to the soft tissues around the lumbar spine, while allowing the surgeon to perform effective decompression and fusion. As with all new surgical techniques, MITLIF has a learning curve in addition to its associated disadvantages.

CONCLUSION

Minimally invasive transforaminal lumbar interbody fusion offers a number of potential advantages over traditional open lumbar fusion techniques. It is a technically demanding procedure. It is a feasible option for many patients, and can be performed with a relatively low complication rate.

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3 Nonendoscopic Percutaneous Disc Decompression as Treatment of Discogenic Radiculopathy

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INTRODUCTION

Lumbar pain and sciatica are responsible for a significant portion of health care expenditure afflicting approximately 10 million individuals at an estimated cost of several billion dollars in diagnosis, treatment, and lost wages (1,2). A variety of spinal structures can serve as the source of incapacitating lumbar pain. However, the lumbar intervertebral disc has been demonstrated to be the most common cause of chronic low back pain (3). Lower limb pain in the presence of lumbar pain may be somatically referred from deep spinal structures (4) or may be the manifestation of nerve root insult (5). Intervertebral disc herniation has long been recognized as a common source of neural injury (6,7), and can present as lower limb pain with or without motor or sensory deficits (8). Radicular signs and symptoms are addressed in a therapeutically different fashion than axial discogenic symptomatology. These treatment measures have been molded by the prevailing theory of spinal pathophysiology.

Cervical spine disorders have been estimated to affect 9% to 12% of the general population, and rival their lumbar counterpart as a common presenting complaint to the health care practitioner (9). Cervical intervertebral disc herniation was first discovered in the 1920s after presenting as myelopathy, and was believed to be because of spinal cord tumors (10,11). In 1936, Hanflig first ascribed upper limb radicular pain to cervical arthritis-induced cervical nerve root inflammation (12). Shortly thereafter, Semmes and Murphey (13), followed by Spurling and Scoville (14), and Michelson and Mixter (15), correlated cervical nerve root irritation with cervical intervertebral disc herniation in the absence of cord compression. Succeeding studies established the relationship between cervical radiculopathy and radicular pain, and cervical intervertebral disc protrusions (16–18). Subsequent clinical studies established the most common etiologies of cervical radiculopathy as cervical intervertebral disc herniation (19) followed by cervical spondylosis (20).

The implicit premise founded by these early works (6,13) has been that biomechanical compression of neural elements was the sole etiologic factor leading to the manifestation of signs and symptoms. However, there is evidence that mechanical influence is not the sole etiologic factor (21–30). There is little correlation between the severity of radiculopathy and the size of disc herniation (22,25,26,31). Resolution of symptoms after conservative treatment has been observed without a concurrent reduction in disc herniation volume (25,26). Mixter and Ayers, a year after Mixter and Barr's hallmark paper, demonstrated that radicular pain could occur without significant disc herniation (27). However, it was not conclusive if this "radicular pain" was nerve root-mediated or somatically referred from another spinal structure. It is probable that, in most instances, biomechanical injury is not the singular cause for the expression of lumbar radicular symptoms related to lumbar intervertebral disc herniation.

Early observations by Haberman and later Lindahl (29) in 1949 established the presence of pathologic changes including inflammatory cells in nerve roots of patients suffering

from sciatica. Subsequent animal studies have demonstrated autoimmune and inflammatory reactions to autogenous nucleus pulposus (32,33). The human intervertebral disc has been shown to be a potent source of phospholipase A_2 (PLA_2) (28), a regulator of the inflammatory cascade which causes perineural inflammation, conduction block, axonal injury (34), and dorsal root demyelination and mechanically induced ectopic discharges in the rat animal model (35). Herniated cervical (36,37) and lumbar (37,38) intervertebral discs have been observed to spontaneously produce increased amounts of other potentially neurotoxic inflammatory mediators (37,39). A rapid transport route may exist bridging the epidural space and intraneural capillaries, providing quick access for this nuclear material to spinal nerve axons (40).

In stark contrast to the peripheral nerve, the nerve root lacks a perineurium, which provides tensile strength and a diffusion barrier (41,42). Consequently, the nerve root possesses less resilience to tension forces and chemical irritants (42). Furthermore, the epineurium, which provides mechanical cushion to resist compression, is less abundant or developed, in the nerve root (42). Within the nerve root itself the fasciculi do not branch to form a plexiform pattern; instead, they run in parallel loosely held together by connective tissue (41,42). Hence, the nerve root is not as well suited to withstand either mechanical or chemical insult as compared with a peripheral nerve. Furthermore, once the inflammatory cascade is initiated, the nerve root lymphatic system is poorly equipped to adequately clear the inflammatory mediators (42). An inflamed nerve root is thus predisposed to a chronic inflammatory reaction with invasion by fibroblast with eventual development of intraneural fibrosis (42).

Cadaveric studies have discovered a functional tethering of the nerve root to the intervertebral foramen (42,43). When an intervertebral disc herniates in a posterior or posteriolateral fashion, the exiting nerve root is placed under tension and not always compressed (42). The ensuing inflammatory response sensitizes the involved nerve root, decreasing its resilience to biomechanical influences. An inflamed nerve will fire repetitively with just minor perturbations; whereas, a nonirritated nerve will tolerate more vigorous manipulation without prolonged firing patterns (41,44). The length to which a nerve root must be stretched for it to incur neurophysiologic dysfunction is believed to be 10% to 15% of resting length (45,46). Clinically, nerve root irritability can be appreciated by elevating the involved lower limb with the knee extended, straight leg raising (SLR). Goddard et al. (43) demonstrated stretch without displacement of the nerve root upon raising the affected limb 20–30 to 70°. As no nerve root motion is occurring, the radicular pain elicited by this maneuver is a consequence of nerve root tension (43). In asymptomatic patients, this movement is nonpainful despite the same amount of tension placed on the neural elements. Provocative SLR has been demonstrated to be indicative of elevated prostaglandin E2 levels at the disc herniation–nerve root interface (47). Hence, dural tension signs are markers of nerve root inflammation and do not necessarily imply nerve root compression.

The natural history of radiculopathy because of a herniated intervertebral disc treated conservatively including spinal injections is marked by gradual improvement over a period of a few weeks to three to five months (48–55). Over this time period, 50% to 60% of these herniations will resolve to a variable degree (25,26,52,56). Asymptomatic disc herniations have been documented to occur in both the cervical (57–59), and lumbar (21,23,24,60) spines. Thus, the extension of nuclear material through a rent in the annular fibers presumably represents a reversible anatomical abnormality responsible for limb pain owing to nerve root insult. Such an injury results in both biochemical and biomechanical harassment of the spinal nerve root. Over a period of time, both or either of the biomechanical and biochemical insults will abate allowing for resolution of signs and symptoms of nerve root injury. In this sense, a component of the disc herniation pathophysiology will effectively reverse. Whether or not the associated nerve root injury reverses depends on the level of nerve injury (neurapraxia versus axontmesis) (61). If symptoms persist despite physical therapy, oral anti-inflammatory medications, and a tincture of time, fluoroscopically guided transforaminal epidural corticosteroid (TFESIs) or selective nerve root injections (SNRIs) are the appropriate successive steps in the treatment algorithm (49,50,52,53). The majority of the patients' symptoms will improve with one to four injections (55,62–68) as the inflammatory response of the herniation is rendered inert. The remaining one-fourth to one-third of patients who do not respond to conservative care and do not appreciate a steroid benefit from TFESIs and/or SNRIs may require

mechanical decompression of the offended nerve root(s) in order to alleviate the neural compression and the source of inflammation (50–53).

Open surgical discectomy has traditionally been the standard of care for persistent radicular limb pain owing to a herniated intervertebral disc (6). Although surgical results have been quite successful (69,70), open surgery is not without risks (71–73). Prospective trials have observed a major complication rate of 1.6% to 13% (71,72) ranging from major neurologic injury (71) and nerve injury (72), discitis (72), to intraoperative death (71,72). Advent of the microdiscectomy technique has not decreased surgical complication rate. Pappas et al. observed a rate of complication of 10.8% including two vascular injuries, one fatal, and a major injury in 654 cases (73). Reoperation rates for recurrent disc herniation range from 5% to 21% (74–78). Primary protrusions without an anular defect are more likely to require revision surgery than extruded or sequestered disc fragments (74,78). Despite the favorable natural history of discogenic radiculopathy (50–52), a protracted conservative regimen addressing severe radicular symptoms should be avoided to maximize odds for a successful outcome (79). Treatment for a contained herniation-induced radiculopathy unresponsive to physical therapy, oral anti-inflammatory medications, and spinal injections might best be achieved by one of a variety of percutaneous disc decompressive techniques (80–124). Disc decompression via the percutaneous approach was pursued as a means by which to decompress a reversible anatomical defect alleviating neural injury with less morbidity and mortality than the open surgical approach.

The predominant indication for decompression remains limb pain owing to a reversible anatomic source (80–83,88,89,98,106,108,110,119–124). Some studies fail to differentiate these two symptomatically distinct groups (90,94,97,104,109,117,118); in these studies, meaningful conclusions regarding treatment efficacy are difficult to formulate. Consequently, the use of percutaneous disc decompressive procedures to treat solely axial pain remains speculative with less structured support than similar treatment of discogenic radiculopathy. Because of such difficulties, this Chapter will *not* attempt to discuss the efficacy of nonendoscopic percutaneous decompressive techniques for axial pain, but will focus primarily on efficacy and safety for limb pain.

DISCOGENIC BEHAVIOR AND PATHOPHYSIOLOGY

In a healthy adult intervertebral disc, the nucleus pulposus behaves as a semi-fluid mucoid mass. Under loads, the nucleus will deform owing to an applied pressure while maintaining an incompressible volume. Consequently, once the nucleus incurs pressure from any angle it will attempt to deform and effectively transmit the applied pressure in multiple directions (7). The nucleus is comprised of 70% to 90% of water largely contained within the chemical domains of large molecular proteoglycans (125). This immense volume of hydration provides the nucleus with its fluidity. Type II collagen fibrils (126), small elastic fibers, and other noncollagenous proteins (127) are interspersed throughout the proteoglycan network. These proteinaceous nuclear components provide a viscous stiffness facilitating transmission of pressure (7). Chondrocytes are embedded in the proteoglycan meshwork located near the vertebral endplate where they manufacture the proteoglycan and collagen constituents of the nucleus (128).

Surrounding the nucleus circumferentially is the annulus fibrosus composed of proteoglycans imbibing water (128), and both type I and II collagen fibers, with type I predominating (129), intermixed with elastic fibers (130). The collagen fibers are concentrically arranged into parallel sheets of lamellae (131). Fibers within each lamellar sheet run at an angle of 65° to 70° vertically and alternately in direction from one lamellae to the next (132). A binding proteoglycan gel helps maintain a linear cohesion between adjacent lamellae (128). Although the lamellae circumscribe the nucleus, the posterior portion of the annulus fibrosus is relatively thinner than its anterior and lateral counterparts (133), and the lamellae in the posterolateral region of the disc are structurally incomplete (134).

The construction of tightly packed lamellae endows the annulus fibrosus with an element of stiffness to withstand axial compressive loads transmitting weight from one vertebra to the next (135,136). However, without a nucleus the annulus will deform under a constant load causing buckling of the collagenous lamellae (7), and may be less resilient to translatory and

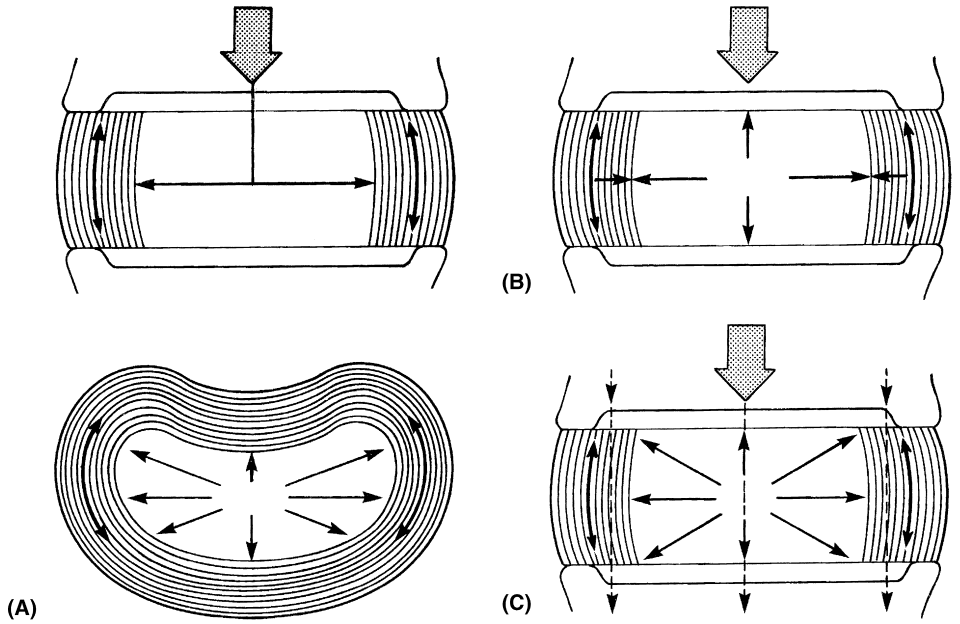

FIGURE 1 The mechanism of weight transmission in an intervertebral disc. (**A**) Compression raises the pressure in the nucleus pulposus. This is exerted radially onto the anulus fibrosus and the tension in the anulus rises. (**B**) The tension in the anulus is exerted on the nucleus preventing it from expanding radially. Nuclear pressure is then exerted on the vertical end-plates. (**C**) Weight is borne, in part, by the anulus fibrosus and by the nucleus pulposus. The radial pressure in the nucleus braces the anulus, and the pressure on the end-plates transmits the load from one vertebra to the next.

torsional strains. When presented with a vertical load, the nucleus will deform but not compress. As the nuclear height is reduced under a load, the nucleus exerts counterpressure both outward against the annulus and vertically against adjacent endplates (7). An equilibrium is established whereby radial nuclear expansion is balanced by annular resistance owing to the tensile strength of the annular fibers. Consequently, load is transmitted from one vertebra to the next as pressure is transferred by the nucleus to the verterbral endplates lessening the load placed on the annulus. Yet, the pressure imposed on the annulus by the nucleus effectively prevents annular buckling augmenting the annular capacity to bear weight (Fig. 1) (7). Conceptualizing the nucleus of the intervertebral disc as a contained semi-fluid, incompressible tissue will allow one to then realize how a breach in containment of the nuclear contents triggers a progressive degenerative cascade that can eventually lead to herniation of nuclear material.

Relative to the intervertebral disc, both intrinsic and extrinsic factors interact accomplishing the herniation of nuclear material. Internal derangement or internal disc disruption has been vastly studied to better delineate the sequence of events culminating in disc injury (137–151). The vertebral endplate can be damaged under sustained (139) or repetitive loads (138), which can be related to forceful muscle contraction (140). A damaged vertebral endplate deforms more when placed under a load (139) allowing for either more space for the nuclear contents to occupy or passage of the nucleus through the endplate resulting in a drop in intradiscal pressure (141). Consequently, this relatively decompressed nucleus is less resilient to withstand an applied axial load placing greater forces on the adjacent annular fibers (142). Delamination of the annular lamellae ensues as high stress gradients disrupting the proteoglycan glue and forcing the inner annulus inward and outer annulus outward (142,143). Reduction in the nuclear intradiscal pressure inhibits nuclear chondrocytes from producing more proteoglycans (144,152) interfering with water retention and ultimately restoration of nuclear volume effectively promoting a catabolic state in the disc (7,142). Elevated annular peak stresses impair disc cell metabolism and interfere with reparative efforts of the collagen network (142,144). Endplate injury might additionally interfere with metabolite transport into the nucleus from

the vertebral body vasculature (145,148), or by instigating an inflammatory (146,147) or autoimmune reaction (7) in the intervertebral disc. Circumstantial evidence exists suggesting an integral role of endplate damage in disc herniation as Schmorl's nodes have been associated with lower lumbar disc herniation on magnetic resonance imaging (MRI) (149). Other factors have been deemed to be associated with degenerative disc changes and structural changes themselves should not be viewed as simply markers of the aging disc (142,153,154). Cigarette smoking increases the incidence of disc degeneration (150), and a genetic predisposition may also exist contributing to disc degeneration (151,155,156).

A critical degree of disc degeneration may not be a prerequisite to herniation of nuclear tissue. The incidence of disc herniation in the adolescent population has been observed to be consistently less than 15% (157) and perhaps less than 5% (158,159). Seventy-three percent of 63 adolescent disc herniation cases retrospectively reviewed had sustained a single precipitating traumatic event. None of these cases revealed evidence of vertebral endplate fracture intraoperatively (156). Although inconclusive, the cumulative findings from these studies would suggest that congenially weakened annular fibers were integral in herniation of nuclear material. The fact that 27% of these adolescent herniations were not traumatically induced and no structural endplate abnormality was observed supports the notion that intervertebral disc herniation in the adolescent may be related to a congenially weakened annular fiber.

Extrinsic variables also play a contributory role in disc injury, one of which, cigarette smoking, was previously mentioned (51). Additionally, various spinal movements will expose the intervertebral disc to injurious forces. Flexion and extension in the sagittal plane and torsion in the axial plane impose different stresses on the disc. As the spine flexes, the anterior annulus is compressed and will tend to buckle (137) as the nucleus is deformed posteriorly and is not able to fortify the annular fibers (7). As the long extensor musculature of the spine contracts to control flexion, intradiscal pressure increases owing to this applied load by the muscle contraction (7). Consequently, an increased pressure is exerted on an already stretched posterior annulus as the vertebral bodies separate. Concurrently, a flexed spine will incur greater anterior shear force owing to a relative decrease in posterior shear force generation by the spinal long extensor musculature (160). Rotation in the axial plane with a center of rotation within the geometric center of the vertebral body prestresses annular fibers. As further rotation occurs, the axis of rotation shifts posteriorly to the zygapophyseal joints subjecting the disc to additional lateral shear forces (Fig. 2) (7). Combined flexion and rotation greatly increases the risk of injury as annular fibers are maximally prestressed in flexion when additional rotation strains the involved annular fibers beyond their normal strain limit (161). The combination of lateral shear and torsion strain results in circumferential tears in the outer annulus (162) typically located in the posterolateral annular region (163) where annular strain is high (164). These circumferential tears can coalesce to form radial extensions providing a channel through which nuclear contents may extrude. The posterior annular fiber's capability to withstand both tension and pressure is inherently compromised owing its structural attenuation (134) in this region of the disc. Furthermore, any previous injury or degeneration will have weakened the lamellae in that area of the intervertebral disc increasing the responsibility of the remaining intact lamellae in supporting the applied load (7). Consequently, the pressure exerted by the nucleus may herniate nuclear content through a newly developed rent in the annular fibers.

Repetitive movements in the sagittal plane with or without superimposed axial rotation will repetitively tax the intact intervertebral discs which may lead to nuclear degeneration and annular disruption. Damage to the vertebral endplate reduces intranuclear pressure in adjacent discs by up to 57%, and doubles the amount of compressive stress in the posterolateral annular fibers (140). Similar effects occur consequent to other structural changes such as radial fissures and posterior herniation that create more space available for the nucleus (154). Consequently, greater force is transmitted to the annulus. Bogduk has previously described this scenario (7). If one-third of a disc's annular fibers are injured and rendered dysfunctional, the remaining fibers would have to contend with the same load and thus increase their individual stress by 43%. Disruption of two-thirds of the annular fibers would increase the stress on the remaining one-third by three times their normal strain. These structural alterations may manifest

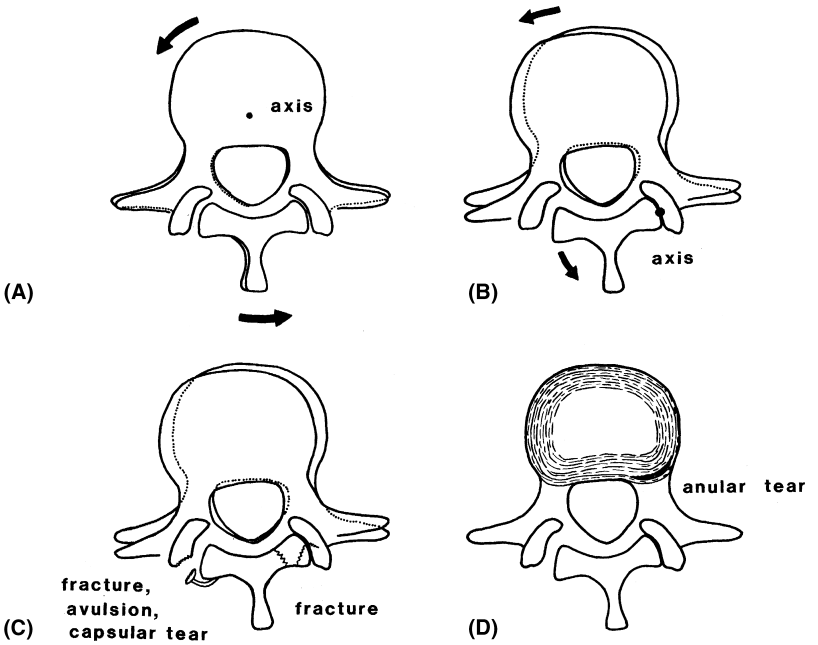

FIGURE 2 Torsion injuries to a lumbar intervertebral joint. (**A**) Rotation initially occurs about an axis through the posterior third of the intervertebral disc, but is limited by impaction of a zygapophysical joint. (**B**) Further rotation occurs about a new axis through the impacted joint. The opposite joint rotates backwards while the disc undergoes lateral shear. (**C**) The impacted joint may suffer fractures of its articular processes, its subchondral bone or the parts interarticularis. The opposite joint may suffer capsular injuries. (**D**) Subjected to torsion and lateral shear, the annulus fibrosus suffers circumferential tears.

clinically as intermittent or fluctuant axial lumbar pain that may progress to constant symptomatology or acutely progress to nuclear herniation resulting in radiculopathy. Such a patient may report explosive onset of lower limb pain with concurrent reduction in the midline axial lumbar pain. The new lower limb syptomatology is related to insult of a nerve root from frank herniation of nuclear material instigating an inflammatory reaction and increasing nerve root tension and perhaps compression. In this instance, both biochemical and biomechanical alterations are responsible for radicular signs and symptoms. Successful outcome may be achieved without significantly addressing the mechanical effects of the herniation. However, in the minority of patients, the mechanical influence will prevail after initial therapeutic interventions warranting more aggressive treatment.

EFFICACY OF NONENDOSCOPIC PERCUTANEOUS DISC DECOMPRESSION BY TECHNOLOGY

Enzymatic Degradation—Chymopapain

Chymopapain is a protease derived from the latex of the papaya tree and was first isolated by Jansen and Balls 65 years ago (165). The enzyme acts exclusively on the nuclear noncollagen ground substance producing loss of glycosaminoglycans and water resulting in volume reduction (166). The efficacy of intradiscal chymopapain in treating lumbar radiculopathy because of herniated intervertebral discs was first reported by Lyman Smith in 1964 who coined the term chemonucleolysis (167). Since this initial investigation, intranuclear injection of chymopapain has become the most extensively evaluated and regulated minimally invasive intervention for radicular pain recalcitrant to conservative treatment (168). More recently, collagenase has been investigated and compared with chymopapain (169,170). Despite 42 years of clinical and basic science research, chemonucleolysis remains a controversial treatment for discogenic radiculopathy (168).

Smith observed in an uncontrolled study, improvement of sciatica in 10 patients treated with intradiscal chymopapain. Each patient was suffering from intractable symptomatology despite other treatments, demonstrated signs of nerve root injury, and had been deemed "operative cases." Seven patients experienced complete relief of their lower limb symptoms, and three had gradual improvement. One patient eventually experienced recurrent contralateral lower limb symptoms necessitating open surgical discectomy. Nine patients had two discs injected after the performance of discography indicating an "abnormal" disc. Follow-up correspondence was short, however, occurring at or within two months (167).

The first prospective, randomized, controlled trial was orchestrated by Schwetschenau et al. and published in 1976 (171). Sixty-eight of 130 appropriate patients were randomized to 1 ml of 20 mg chymopapain/5 ml of saline or 1 ml of 20 mg sodium iothalamate/5 ml of saline placebo solution. Each patient demonstrated one or more signs of lumbosacral radiculopathy corroborated by myelographic evidence of a correlative disc abnormality that did not respond to three weeks of conservative care. Each subject was evaluated by history and physical examination at six weeks, three months, six months, and one year. Outcome was categorized as completely asymptomatic, greatly improved, and moderately improved. Two of the initial 68 patients were lost to follow-up. Of the 66 enrolled patients, 35 had been randomized to receive placebo and 31 received chymopapain. No statistically significant difference was observed between the groups. However, mutiple methodologic flaws preclude the formulation of any conclusion. Among the concerns are that the investigators used a potentially therapeutic, active placebo agent; chose a therapeutically inadequate chymopapain dose; were admittedly inexperienced leading to improper needle placement; and committed improper timing of code break (80,81).

Javid et al. engineered a much more sound study in which 55 patients were randomized to receive 3 ml of chymopapain (3000 units/1.5 ml) while 53 patients were randomized to 3 ml of pyrogen-free saline (80). Each patient had persistent lumbosacral radicular pain despite six weeks of conservative care with reproduction of this pain with SLR, and either myotomal weakness, dermatomal sensory abnormality, or a diminished muscle stretch reflex. Myelography revealed a correlative, single-level disc abnormality, and discography confirmed internal injury of this disc. Outcomes were measure primarily at six weeks and six months by assessing improvement in radicular signs and symptoms, and subjective improvement as deemed by the patient and physician. Three patients were lost to follow-up. Eighty-two percent of the chymopapain patients had a successful clinical course with 91% of the successful cases attributable to the chymopapain intervention. In contrast, just 41% of the placebo arm achieved successful outcome attributable to the placebo intervention. The remaining 59% crossed over to the chymopapain arm and 91% of these cases were then successfully treated. Although six months is a short follow-up interval, this investigation proved that chemonucleolysis is clearly superior to placebo in treating patients with lumbosacral radiculopathy because of disc herniation, and is a safe procedure when performed by orthopedic specialists (80).

Fraser published two-year data after randomizing 30 patients to receive 2 ml (8 mg) of intradiscal chymopapain and 30 patients to receive 2 ml of intradiscal saline (82). Each patient had not responded to 6 to 24 weeks of conservative care including physical therapy. Myelography demonstrated a corroborative posterolateral disc herniation affecting the clinically suspected nerve root. All patients reported radicular pain on SLR to 50° or less. Outcomes were measured by pain rating and the patient's subjective report of the treatment assessed at six months and again at two years while maintaining blinding of both the investigator and the patients. All 60 initial patients were evaluated at both follow-up intervals. Seventy-three percent of the chymopapain group versus 47% of the control group felt the treatment was successful at two years. Fifty-three percent of the treatment group was pain-free at two years compared with 23% in the saline group. At the time of follow-up, 40% of the saline group and just 20% of the chymopapain group had required laminectomy. Fraser's work provided the first prospective, controlled long-term follow-up data demonstrating a sustained therapeutic benefit of chymopapain to treat lumbosacral radiculopathy because of disc herniation.

Three years later, Dabezies et al. published the largest prospective, randomized, controlled trial of 173 patients suffering from lower limb radicular pain recalcitrant to at least

two weeks of conservative care (81). Myelography and/or computed axial tomography revealed a soft disc herniation offending the involved nerve root, and each patient's physical examination included an associated diminished muscle stretch reflex, sensory abnormality, myotomal weakness, or dural tension signs. Eighty-seven patients received 2 ml (8 mg) of chymopapain, and 86 received an equivalent volume of cysteine-edetate-iothalamate in a randomized fashion. Patients were assessed at six weeks, three months, and six months after intervention and improvement was defined by subjective improvement in pain, normalization of neurologic findings, and a return to previous level of occupation. This study contained an inordinately large number of code breaks as patients requested to become unblinded in order to pursue chymopapain treatment once the sponsor announced it would afford all patients in the placebo arm the opportunity to travel out of the country for treatment. Including the results after the code breaks revealed successful outcome in 71% in the treatment arm compared with 45% in the control group at six months. These numbers changed to 67% and 44%, respectively when the code-break patients were excluded from data analysis. These findings are commensurate with previously published studies (80,82).

Gogan and Fraser published 10-year data of their 60 patients initially studied at six months and two years (83). Their protocol has previously been described. All the patients had remained blinded to identity of their intervention and were assessed by an independent observer who was unaware of the original therapy. Each patient answered the question of whether or not their treatment was successful. Each patient was then evaluated by the investigator and determined to be pain-free, moderately improved, unimproved, or worse. Eighty percent of the chymopapain patients compared with 34% of the saline group found their treatment successful. Of the chymopapain group, 53 percent were completely pain-free at 10 years in contrast to 23% of the saline group at 10 years. Six of the 30 chymopapain patients eventually underwent open surgical discectomy at the treated level but none of these cases occurred two years after treatment. In short, 77% of the chymopapain patients and 38% of the saline patients achieved a good result at 10 years.

This study provided definitive evidence that chymopapain treatment of discogenic lumbosacral radiculopathy can achieve therapeutic benefit in properly selected patients not responding to conservative care. There is a distinct increase in the number of patients relieved of limb pain and a faster rate of improvement in patients treated with chymopapain compared with saline. The laminectomy rate did not reach statistical significance at two years but did by 10 years (83).

Cervical chemonucleolysis has not been studied as intently as in the lumbar region. Gomez-Castresana published an initial series of 40 patients treated for 44 cervical herniated intervertebral discs (172). Eighty-five percent were successfully treated at a mean follow-up of 21.4 months (172). These results have been stable and expanded to a successful treatment of 90% of 147 patients treated for 171 cervical intervertebral disc herniations (173). All patients were available at a mean follow-up of 101 months (2–103 months), and 72% of repeat MRIs demonstrated a reduction in the size of the disc herniation (172).

Efficacy of chemonucleolysis compares well with that of open surgical discectomy (84,85). Outcomes at one year were not significantly different between patients treated with chemonucleolysis versus open surgical discectomy in a randomized, prospective, controlled trial (85). However, this trial did show a statistically significant difference at six weeks and three months in favor of the surgical group (85). In Nordby's experience, good to excellent results occurred at six weeks in 80% of 100 patients treated with chemonucleolysis. Eighty-five percent of their 100 surgical counterparts experienced good to excellent results at six weeks. Although open surgical discectomy was statistically superior ($P = 0.13$) than chemonucleolysis at six weeks, no statistical difference was measured at six months or one year (168). In a retrospective review 10 years after treatment, Tregonning et al. observed minimal difference in efficacy between 145 patients treated with chymopapain and 91 patients treated surgically (86). Overall, mean success rates of chemonucleolysis in trials comparing it with open surgical discectomy have been calculated to be 66% compared with 77% for open surgery (84).Taking into account similar efficacy between chemonucleolysis and open surgical discectomy, the former may be more cost-effective than the latter in treating discogenic lumbosacral radiculopathy because of the lower associated costs (87).

Enzyme Degradation—Collagenase

The potential risk of allergic reactions and other complications such as central nervous system damage have led to the development of colllagenase as an alternate enzyme to effect intervertebral disc herniation (170). In a double blind study, collagenase produced successful outcomes in 80% of the treated patients compared with 30% in the placebo group (169). However, collagenase may not be as effective as chymopapain. Wittenberg et al. observed good and excellent results in 72% of the patients treated with chymopapain compared with 52% of the patients treated with collagenase (170). Eight-eight percent of the chymopapain group and 80% of the collagenase group were available at follow-up at five years. However, the collagenase group experienced an increased rate of neurologic injury which is discussed later in the Chapter.

Mechanical Decompression—Automated Percutaneous Discectomy

Although chemonucleolysis has been well studied providing strong evidence attesting to its efficacy, its use has fallen out of favor because of concerns over catastrophic complications. By 1994, most centers in the United States had discarded chemonucleolysis as a means to decompress a herniated intervertebral disc because it was perceived as less effective than standard open discectomy, and the associated complication rates were higher than could be accepted on the basis of this efficacy (174). Consequently, in late 1999, Boots Pharmaceuticals (Lincolnshire, IL, U.S.A) halted the manufacturing and distribution of its chymopapain product (93). Alternative means to achieve mechanical decompression of the herniated disc percutaneously were pursued. Pioneering investigations of mechanical percutaneous disc decompression initiated in the mid-1970s (91) incorporated large canulas with an associated risk of nerve injury, and required the involvement of modified pituitary forceps which proved to be cumbersome and time-consuming (91,92). In 1984, Onik first introduced an automated percutaneous device by which to mechanically remove herniated nuclear material in order to decompress the affected nerve root (90). Using this technique, a 2-mm, 8-inch long blunted closed-tip probe containing a side port with a reciprocating blade is placed within the nucleus. Suction is applied through the inner cannula pulling nuclear material into the port. The sharpened end of the inner cannula is pneumatically driven across the port severing the aspirated nuclear material from the parent source. The removed nuclear material is then aspirated into a collection container (90).

Following Onik's initial case report of immediate resolution of lower limb radicular pain in a 33-year-old male after automated percutaneous lumbar discectomy (APLD) was performed on a L4-5 intervertebral disc protrusion (90), Maroon and Onik published their initial results of the first 20 patients treated with APLD (175). Eighty percent of the treated patients experienced good to excellent improvement at a six-month follow-up interval. Four patients did not improve and eventually required microsurgical excision of sequestered disc fragments. Findings of a multicenter prospective trial by these investigators and others revealed a reported 75% success rate at follow-up at least one year after the procedure in 327 patients treated by APLD. Patients who experienced persistent lower limb greater than axial lumbar pain, provocative SLR, and two out of four signs of radiculopathy despite at least six weeks (mean duration of 11.6 months) of conservative care (94) were enrolled. However, objective data such as visual analog scale (VAS) scores and disability assessment were not reported, findings prior to one year were not revealed, and 18% of the discectomies involved two levels which clouds statistical assessment of the intervention's efficacy.

A subsequent prospective study of 518 patients by Davis and Onik (95) with similar inclusion criteria demonstrated a success rate of 85% at a minimum follow-up of one year after removing a mean of 2.1 g of nuclear material. Patients were evaluated at three-month intervals up to two years after the procedure. However, data from evaluations prior to one year were not presented in the article; yet, the authors did comment that 70% of successfully treated patients returned to work within two weeks (95). Davis and Onik confirmed the absence of intervertebral disc extrusion but did not clarify the size of the herniation volume. The absence of the postprocedure data at three-month intervals prevents an assessment of the rate of improvement which might allow commentary regarding the efficacy of the

intervention relative to the natural history of the condition. A regression toward the mean analysis might have proven helpful to demonstrate a plateau of the patients' signs and symptoms prior to treatment because no control group was available for comparison. Fiume et al. found similar results in 64% of the 84 treated patients with small to medium disc protrusions at a mean follow-up of 22 months. The investigators removed a mean of 2.3 g of nuclear material, and reported pain relief and return to work at 24 and 21 days, respectively (96).

In a large prospective study of 1525 patients, Teng et al. found a success rate of 83%, 56% of patients became pain-free, and 26% of patients greatly improved, at a mean follow up of 18.3 months with 51 patients lost to follow-up (176). Using a device with a revolving blade rotating 400 cycles per minute, the authors treated 1289 patients who presented with sciatica and 185 patients presenting with complaints of primarily low back pain. These diagnostic categories were not separated prior to data analysis. Patients had persistent symptoms after a minimum of two months of conservative care and demonstrated a corroborative disc herniation on MRI or computed tomography (CT).

In a prospective assessment of over 1350 patients treated with APLD, Bonaldi observed successful outcomes in 67.5% patients at six months. He found favorable results in certain subgroups (97). Almost 80% of 83 elderly patients who are 70 years or older, experienced good or excellent results, and 78% of 108 postsurgical patients suffering a recurrent disc herniation at the previously treated level appreciated good or excellent results (97). His technique included the injection of 80 mg of methylprednisolone and 1 ml of 0.5% bupivicaine into the nucleus upon completion of the discectomy. In patients with radicular complaints, he injected 40 mg of methylprednisolone and 1 ml of bupivicaine around the offended nerve root. All patients demonstrated a corroborative protruded disc on MRI or CT or postdiscography CT (97). Bonaldi's data suggests that the addition of corticosteroid and anesthetic does not significantly alter the effect of APLD on clinical outcome. However, his patient cohort was not pure and contained patients with both purely axial and radicular pain, thus preventing the assessment of the effect of corticosteroid on clinical signs and symptoms. Yet, his work is the largest investigation of postsurgical patients with recurrent disc herniation. Seventy-eight percent success rate in this subgroup approaches findings in earlier work (95). However, a 9.6% rate of loss to follow-up, short follow-up interval, and outcomes measured largely by postal questionnaires were flaws of the study.

In a prospective audit of 30 patients presenting with radicular signs and symptoms owing to a contained disc herniation, Ramberg and Sahlstrand recorded immediate improvement in radicular pain and improved SLR at one week after APLD in 20 patients (98). A mean of 0.9 g of nuclear material was aspirated from the herniated discs (range 0–2.1). Four patients were lost to follow-up but were included in the initial assessments. Ten patients eventually required open surgical intervention. The remaining 16 patients demonstrated gradual improvement over the ensuing five weeks with gradually less improvement between six weeks and final follow-up at two to five years (98). Disability as measured by the Oswestry Disability Scale improved most dramatically from six weeks to follow-up at two to five years.

In a prospective, randomized trial, Revel et al. compared APLD with chemonucleolysis in 141 patients with lumbosacral radiculopathy unresponsive to 30 days of conservative medical treatment (99). Each patient had a corroborative disc herniation at a single level as detected by MRI, CT, or myelography. Seventy-two patients underwent chemonucleolysis in which 2 ml (4000 U) of chymopapain was administered intradiscally into each treated disc. Sixty-nine patients underwent APLD but the volume of the nuclear tissue removed was not reported. Thirty-two patients did not complete the study and were treated as failures. At six months follow-up, 61% of the chemonucleolysis group and 44% of the APLD group considered the treatment outcome to be successful. The patient had to consider his or her improvement better than "moderate" to be categorized as a treatment success. In contrast, the investigators judged 77% of the chemonucleolysis group and 83% of the APLD group as successfully treated. At one year, 83% of the chemonucleolysis patients felt their outcome was successful while 61% of their APLD counterparts held the same conviction. The authors did not attribute the low rate of success for APLD to a particularly low rate of loss to follow up (3%).

Chatterjee et al. randomized 31 patients to APLD and 40 patients to microdiscectomy as treatment for lumbosacral radiculopathy owing to a small disc protrusion unresponsive to six

weeks of conservative care (100). At six months, 29% of the APLD group, after removal of a mean of 2.1 g of nuclear content, and 80% of the microdiscectomy group experienced good or excellent results. Twenty of the 22 failed APLD cases elected to undergo microdiscectomy and 13 (65%) achieved good or excellent results, which is less than the 80% success rate of the microdiscectomy group. This calculation may underestimate the failure of microdiscectomy in this subgroup of patients if all 22 had undergone surgery with just 13 successful outcomes leading to a 59% success rate. Furthermore, the 80% success rate observed in the surgical group is less than the 93% success rate in initial microdiscectomy cases encountered in an independent trial pursued by the investigators (93).

Grevitt et al. enrolled 137 patients into a prospective study utilizing VAS, Oswestry Back Disability form, and Short Form 36 as outcome measurement tools to assess improvement in radicular signs and symptoms after APLD (177). Each patient did not improve despite conservative care of physical therapy and epidural steroid injections, and the mean duration of preprocedure symptoms was 16 months (3–26 months). Twenty-two patients were lost to follow-up, and 17 patients eventually required surgical intervention. At a mean follow-up period of 55 months, 52% of patients were successfully treated with APLD. If the 22 patients lost to follow-up had been successfully treated, successful outcome may have been achieved in 64% of the patients. Two of the surgical cases had persistent radicular pain because of sequestered disc material at the index level. The majority of patients eventually undergoing late surgery were being treated for persistent and progressive axial lumbar pain. The authors did not report any results of further diagnostic evaluation, such as provocative discography or diagnostic facet joint blocks, to verify the source of persistent lumbar pain.

Few data have been collected regarding the role of automated percutaneous cervical discectomy. Bonaldi reported his experience in treating 84 patients over a 13-year time period. Sixty percent of cervical radicular patients experienced complete regression of pain and 20% appreciated a satisfactory, partial regression of pain (178). These data were communicated as an oral presentation, and the investigator did not report the duration of preprocedure symptoms, length of conservative care, or follow-up interval.

Thermal Decompression—Laser

The poor performance of APLD compared with conventional open discectomy interfered with its momentum as a minimally invasive percutaneous decompressive technology. In 1986, Choy and Ascher employed thermal technology to remove nuclear contents effectively decompressing the intervertebral disc (179). The term *laser* is an acronym for light amplification by stimulated emission of radiation (180). The laser–tissue interaction in biological tissues is determined by the physical properties of the laser (wavelength, pulse-length, energy density), and the optical, biomechanical, and biochemical properties (absorption, heat conduction, scattering, reflection) of the targeted tissue. The absorption spectrum of the nucleus pulposus is comparable with other water-containing tissues (180). Therefore, ablating nuclear tissue by energy absorption will best be achieved by utilizing a laser with wavelength matched to the known absorption bands of water—the visible and infrared regions (115). Choy and Ascher reported their experimental findings of reducing intradiscal pressure in human cadavericlumbar discs using the laser wavelengths emitted by neodymium embedded in an Yttrium-Aluminum-Garnet crystal, Nd:YAG (103). The Nd:YAG laser is the most widely used medical laser system and produces a distribution of the applied energy within the nuclear tissue (180).

Choy communicated his initial clinical experience with percutaneous laser disc decompression (PLDD) in 12 patients suffering from "symptomatic lumbar disc herniation." Each patient was treated using a Nd:YAG laser via a 400-μm optical fiber. Nine of these 12 patients experienced improvement during the two-minute procedure after not improving with conservative care of an undisclosed period of time. Five of these initial nine patients subsequently underwent repeat surgery for recurrent symptoms, while four out of the initial 12 remained symptom-free at 7–16-month follow-up (179). However, despite all 12 patients demonstrating a symptomatic disc herniation, the report did not reveal if all 12 patients complained of radicular or axial lumbar pain. The period of preprocedure conservative care may not have been long enough to allow natural improvement in a certain number of cases. Technical details

consequent to the novelty of the new procedure may have interfered with adequate nuclear absorption, hence decompression.

Choy later reported his findings after treating 333 patients who had persistent radicular symptoms despite three months of conservative care because of a contained lumbosacral disc herniation by MRI or CT (103). Patients demonstrating spondylolisthesis, central or lateral canal stenosis, or advanced disc degeneration were excluded. At a mean follow-up of 26 months, 78.4% of 333 patients were assessed as having good to fair results as defined by the Macnab criteria. Sixty-four percent of 261 good to fair patients experienced relief during the procedure, 21% experienced gradual and progressive relief starting three to four days after the procedure, and 24% reported partial recurrence on postprocedure day one with gradual improvement over the ensuing two to three weeks. Each patient was treated using the Nd:YAG laser connected to a 400-μm optical fiber for three to four minutes. The authors did not differentiate the proportions of fair or good responses which might represent two different clinical outcomes despite being grouped together in the same category. Although the Macnab criteria for a fair result includes no signs of radiculopathy, patients in this group may be functionally nonproductive and might still require certain medications because of intermittent episodes of mild lumbar or radicular pain. Choy has published his subsequent experiences (104,105) with inhomogenous patient populations complaining of either radicular or axial pain, undergoing treatment of multiple levels, again relying on loosely defined outcome criteria at long-term follow-up.

McMillan et al. found the short-term improvement of PLDD beneficial, primarily in patients suffering from lumbosacral radicular symptoms rather than axial lumbar pain (106). Each patient underwent PLDD with the Nd:YAG laser in a similar fashion to Choy's description. Of 30 patients with primarily radicular pain at baseline, 24 (80%) demonstrated improvement as measured by the American Academy of Orthopedic Surgeons Pain Assessment Questionnaire, and the mean scores improved by 68% between baseline and follow-up. Assessment was completed at follow-up evaluations at three months, and each patient underwent treatment of one segmental level after MRI evidence of a corroborative disc herniation with less than 50% reduction in disc height (106). Although flawed by a short follow-up period, McMillan utilized an objective measurement tool to document improvement in an endpoint.

Relying on the modified Macnab criteria for assessment, Casper et al. treated 222 patients who presented with signs and symptoms of lumbosacral radiculopathy (107). Each patient did not respond to six weeks of conservative care including physical therapy, anti-inflammatory medications, selective nerve root blocks, and epidural steroid injections (107). Patients who were deemed to be symptomatic because of central or lateral canal stenosis or disc herniation sequestration were excluded. Each patient underwent PLDD using Holmium:YAG (Ho:YAG) laser with a Sidefire fiber containing a 550-μm optical fiber (107). Good and excellent results were deemed successful while fair or poor were unsuccessful. Eighty-four percent of treated patients were successfully treated at a follow-up of one year. Of these, 62.5% experienced excellent results and 37.4% experienced good results. Only one patient was lost to follow-up because of nonprocedure-related death. Of the 35 failures, 10 underwent open surgery for sequestered disc fragment, lateral stenosis, or suspected discitis, 12 underwent a second PLDD at the index level, and 13 experienced fair or poor outcomes. Although the modified Macnab criteria more stringently evaluate postprocedure outcomes that were impressive, the absence of a control group precludes conclusion that PLDD was solely responsible for the measured improvement. However, the mean duration of preprocedural symptoms was 24.8 months, which presumably would have allowed for natural regression toward the mean.

In a prospective study of 50 patients, Nerubay et al. performed PLDD using carbon dioxide laser (108). The range of preprocedure symptom duration was four months to 10 years with a mean of 33 months. Each patient had complaints of axial and radicular pain accompanying advanced imaging evidence of a corroborative disc herniation despite three months of conservative care. Patients whose imaging revealed spinal stenosis, spondylolisthesis, or large disc herniation were excluded. Sixty percent of patients had excellent results using Macnab's criteria, 14% had good results, and no improvement or worsening symptoms were observed in 26%. Follow-up was carried out up to two to five years with a mean of 2.8 years. This was a small study of 50 patients but with adequate preprocedure conservative care.

Percutaneous laser disc decompression has been applied to the cervical spine with success (109,110). In a prospective study of 105 patients with cervical and/or upper limb radicular pain, Knight et al. observed a good or excellent outcome in 51%. Eight patients were lost to follow-up and the mean follow-up was 43 months. Another 25% of the patients experienced functional improvement. Each patient failed to improve with at least six months of conservative care and demonstrated a corroborative disc abnormality on MRI. Provocative discography was performed to verify the painful level in patients with multilevel involvement. Eighty milligrams of depo-medrol was injected intradiscally in addition to laser treatment. The study cohort enrolled in Knight's work was not homogenous as patients had either axial or radicular pain.

In a more pure patient population, Choy evaluated 93 patients after treating cervical radicular symptoms due to MRI-documented disc herniations unresponsive to three months of conservative care (110). Just 58 patients were available at an undisclosed follow-up evaluation conducted by a telephone interview. Ninety percent of these patients were reportedly improved by the Macnab criteria. However, if the remaining 35 patients were considered failures in addition to the other six (10% of 58), the success rate would decrease to 56% at an undisclosed follow-up interval.

Twenty-eight out of 31 prospectively studied patients treated with Ho:YAG laser using a 400-nm-wide probe tip demonstrated objective and subjective improvement in their cervical radicular complaints at six weeks follow-up (111). In this study, Siebert enrolled patients after an undisclosed duration of conservative care and symptoms. Yet, the follow-up interval was short and the outcome measures were not stringent. In a smaller study, Harada prospectively evaluated seven patients with cervical radiculopathy and corroborative MRI findings of disc herniation at one week and then again at three to six months (112). Each patient had not improved with six weeks of conservative care while the length of symptoms preprocedure was not reported. The authors treated the herniated cervical discs using the Nd:YAG laser and reported a good result defined by Macnab criteria in all patients and improvement in the Japan Orthopedic Association (JOA) score for cervical radiculopathy. The number of treated patients was low and the authors did not perform statistical analysis on the change in the mean JOA scores from baseline to each time point.

Nonthermal Decompression—Nucleoplasty

Radiofrequency ablation (RFA) of tissue is the process of applying directed radiofrequency energy to targeted tissue to destroy or modify that tissue. RFA has been applied to various tissues including tonsillar and pharyngeal tissues (181), cardiac muscle and nervous tissue (182), and peripheral nerves (183). Radiofrequency ablation was pursued in the orthopedic arena to shape and remove articular tissue (184). Anecdotal evidence has been generated attesting to more rapid healing of cartilaginous soft tissue with less scarring with RFA as compared with lasers and electrocautery (185). In contrast to its laster counterpart, RF heating causes less tissue destruction without a similar amount of inadvertent thermal damage to adjacent tissue. Application of RFA to the intervertebral disc was a logical extension of this new technology.

Nucleoplasty is the percutaneous decompression of an intervertebral disc by the application of patented Coblation^{TM} (Arthrocare, Sunnyvale, California, U.S.A.) technology in which RF energy is applied to a conductive medium causing a focused plasma field to form around the energized electrodes. This plasma field contains highly ionized particles of sufficient energy to cleave organic molecular bonds within the tissue forming a channel (186). The by-products of this nonheat-driven process are the elementary molecules and low molecular weight inert gases which escape via the introducer needle (186,187). As the RF probe is withdrawn, the newly created channel is thermally treated producing a zone of thermal coagulation. Thus, nucleoplasty combines coagulation and tissue ablation to form channels within the nucleus and decompress an intervertebral disc herniation (188).

Initial data regarding the efficacy of nucleoplasty were presented in 2001. Singh reported improvement in both axial and radicular pain in a small cohort of patients evaluated postprocedurally at three months (188). However, patients with complaints of either axial lumbar pain or radicular pain were enrolled in the study. A year later, Sharps and Isaac published their

findings again in a cohort of patients with mixed complaints of axial lumbar and radicular lower limb pain (117). The authors initially enrolled 49 patients and reported a 79% success rate at three months in 41 patients. A successful outcome was defined as a greater than 2-point reduction in visual analogue scale (VAS) score, patient satisfaction, absence of narcotic use, and return to work. The authors additionally reported a decrease in the mean VAS score of 3.3 points among the 13 patients who were assessed at 12 months after the procedure. The authors, however, did not report the narcotic utilization, return to work, or patient satisfaction data (117). Later in 2002, Singh et al. prospectively studied 80 patients with either lumbar or radicular pain (118). Sixty-nine patients were available for follow-up evaluation at 12 months by either telephone interview or clinical encounter. Seventy-five percent of these 69 patients reported a reduction in their pain scores which were statistically significant with 54% of patients reporting relief of 50% or more. Compared with baseline, nearly half of the patients reported statistically significant improvement in their sitting, standing, and walking capabilities (118). However, this was an uncontrolled study and assessment of improvement can only be suggested to be attributable to the intervention, and different diagnostic categories, axial versus radicular, were evaluated similarly.

In the largest clinical trial investigating nucleoplasty in the lumbar spine, Alexandre et al. studied 1390 patients presenting with either axial or radicular pain because of a contained disc herniation demonstrated by advanced imaging studies (119). The symptoms had been ongoing for a minimum of three months despite appropriate conservative care. At 12 months, 55.8% of the treated patients achieved excellent (total resolution of symptoms, full return of function) results and 24.9% good (fairly total symptom resolution, good quality of life) results. However, the authors did not confirm how many subjects were available at follow-up. No prospective, controlled trials investigating nucleoplasty's utility in treating specifically lumbosacral radiculopathy have been published. A multicenter trial is underway assessing nucleoplasty's efficacy versus therapeutic selective nerve root injections for lumbar radicular pain because of contained disc herniations.

Application of nucleoplasty in the cervical spine has been studied (120–122). Slipman and DePalma reported successful outcome in 91% of 21 patients at six months in an uncontrolled study (120). The investigators employed a two-pronged approach by injecting corticosteroid and anesthetic around the affected nerve root directly after completion of the nucleoplasty procedure (120). Each patient demonstrated a corroborative disc herniation of $\leq$5 mm. Also, in each instance, there had to be an objective correlating finding indicative of root involvement: myotomal deficit, or positive electrodiagnostic evaluation, or positive diagnostic selective nerve root block. The average VAS score decreased from a preoperative level of 6.9 to 1.3 at six months, and eight patients were without pain at six months. Their findings were sustained at 12 months in that 19 of 21 patients experienced successful outcome (121). The average VAS rating at 12 months was 1.4. The average duration of preprocedure symptoms was 10 months, and each patient had been deemed an appropriate operative candidate by a fellowship-trained spine surgeon (121). Nardi et al. prospectively evaluated 50 consecutive patients with cervical radiculopathy because of a contained disc herniation (122). The authors incorporated a randomized control group of 20 patients and demonstrated a complete resolution of symptoms in 80% of the treatment arm at a follow-up of 60 days (122). No patients in the control group reported complete relief at 60 days, and approximately 75% reported no change in their symptoms. Nardi, however treated patients with a contained herniation $\leq$3 mm, and enrolled patients with axial or radicular pain (122).

Mechanical Decompression—Dekompressor Probe™

In January 2001, the Food and Drug Administration (FDA) approved the clinical use of a new 1.5-mm percutaneous lumbar discectomy probe, the Dekompressor Probe™ (Stryker, Kalamazoo, Michigan, U.S.A.), for the treatment of contained intervertebral disc protrusions (123). This device is a disposable hand-held instrument driven by a battery-powered subminiature DC motor connected to an implant grade precision ground titanium probe with a helical auger as its distal tip (189). A 17-gauge outer cannula provides access to the disc via an extrapedicular approach. When activated, the auger tip rotates at 12,000 rotations per minute creating

localized suction removing nuclear material and aspirating it through the cannula into a collection chamber using an Archimedes pump principle (123,124,189). The thixotropic nature of the nucleus in which nuclear material becomes less viscous when in motion provides an ideal application for the Archimedes pump mechanism employed by the Dekompressor Probe (189). The helical auger tip is relatively inactive when engaged in the more fibrous annular tissue (189).

The first human application was reported in 2003 in an open forum describing the successful treatment of a 36-year-old male suffering from contained 4.5-mm herniation at L4-5 and 9.5-mm herniation at L5-S1. Alo et al. then pursued a prospective study of 50 consecutive patients with stringent inclusion and exclusion criteria (123). Each patient presented with lumbosacral radicular signs and symptoms of at least six-month duration because of a corroborative contained disc herniation $\leq$6 mm in size. Conservative care including physical therapy, oral analgesic and anti-inflammatory medications, and transforaminal epidural corticosteroid and anesthetic injection did not provide lasting relief. Subsequent to these failed therapeutic injections each patient underwent confirmatory diagnostic selective nerve root blocks with 0.5–1.5 cc of anesthetic with a positive response defined as >80% reduction in the preblock radicular pain level for the duration of the pharmacologic effect of the anesthetic. Twelve patients underwent percutaneous decompression at two levels, and outcomes were assessed at six months regarding VAS rating, analgesic usage, patient satisfaction, and functional improvement. Patient satisfaction and functional improvement were assessed subjectively by asking each patient if these parameters had improved. During decompression, 0.75 to 2.0 cc of nuclear material was removed. At follow-up, 74% of the patients had reduced their analgesic intake, 90% reported improvement in their functional status, 80% reported an overall satisfaction with their treatment, and the reduction in the mean VAS rating was 60.25%, which was significant ($P < 0.001$). Six patients experienced zero radicular pain at six months. No remark was made regarding surgical intervention of any of the treatment failures, and objective, validated outcome measurement tools for patient satisfaction and function were not utilized, and the follow-up interval was short.

In a subsequent study reported by Amoretti et al., 10 patients were retrospectively reviewed at a range of 6 to 10 months after percutaneous disc decompression using the Dekompressor Probe (124). Each patient had a history of recalcitrant "sciatica" related to a corroborative contained intervertebral disc herniation on MRI that did not improve despite CT-guided periradicular "infiltration," and any medical therapy. The authors did not reveal the volume of tissue removed, and assessed outcome by VAS ratings and analgesic usage. At a mean follow-up of 8.6 months (6–10), eight patients (80%) were satisfactorily treated with a decrease in VAS rating of more than 70% and complete elimination of medical therapy. The two failed cases initially experienced improvement with one undergoing open discectomy for an extrusion that may have been misinterpreted on initial MRI evaluation, and the second responded to medical treatment. This was a small retrospective study without validated outcome measures other than VAS ratings that suggests improvements may be stable beyond six months. Although no other clinical trials have been published, our experience using Dekompressor to treat lumbar radiculopathy because of contained disc herniations after no prolonged benefit from transforaminal epidural steroid injections or therapeutic selective nerve root injections mirrors the results of Alo (123) and Amoretti (124).

SAFETY OF NONENDOSCOPIC PERCUTANEOUS DISC DECOMPRESSION BY TECHNOLOGY

Enzymatic Degradation

The overall complication rate of chemonucleolysis has been calculated as 3.7% with a rate of severe complications of 0.45% (190). However, this calculation may be an overestimate. Data reported to the FDA revealed 121 adverse reactions in approximately 135,000 patients (191). Of the 121 adverse events reported to the FDA (191), seven cases were of fatal anaphylaxis, 24 cases of infection, 32 cases of hemorrhage, 32 cases of neurologic deficits (such as paraplegia, paraparesis, hemiparesis, and foot drop), and 15 miscellanous cases of cardiac and respiratory

complications. The overall mortality rate was 0.019% (191). The most common side effect is backache and stiffness ranging from 15% (80) to 100% (167). Lumbar muscle spasm or guarding has been observed in 36% to 41% of patients treated with chymopapain (80). Discitis (82,83), lower limb deep venous thrombosis (83), anaphylactic shock and death (90), acute transverse myelitis (90) [a causal relationship between chymopapain and central nervous system (CNS) could not be substantiated (192)], and cerebral hemorrhage (193) have been rarely reported. Anaphylaxis was recognized in one of 87 patients receiving chymopapain in Dabezies' 1987 study (81). However, since then the incidence of anaphylactic reactions has decreased to 0.25% because of sensitivity testing and antihistamine administration preinjection (168). Males have lower incidence of an anaphylactic reaction than do females, 0.3% versus 0.9%, respectively. African-American women, however, are at an increased risk with a reported incidence of 2% (84). No epidural or intraneural fibrosis has been observed (81). Although the incidence of anaphylaxis may be less with collagenase, neurologic deficit may be increased (170).

Loss of disc height does occur after chymopapain administration (82,167,194,195). Fraser demonstrated no difference in disc height loss between discs treated with chymopapain and saline but did not assess for a change relative to baseline in each group (82). Liesveth et al. observed an average disc height loss of 15.8% at 31 to 124 months after treating intervertebral discs with chymopapain (194). However, reconstitution of disc height was achieved over this same time period in discs treated with a lower dose of chymopapain (194). Maintenance of disc height loss in the discs treated with higher dose of chymopapain had an impact on the success of the intervention (194) and will be discussed under mechanism of action. However, these investigations used serial plain radiography which requires accurate placement of the central ray of the X-ray beam which can be difficult (195). Using digital lateral radiographs and CT, Mall et al. documented an invariable loss of disc height in 16 out of 17 patients treated with chemonucleolysis (only 16 were evaluated by digital radiography). However, the authors did not differentiate change in disc height relative to successful versus nonsuccessful cases (195).

Chemonucleolysis has been compared with open surgical discectomy regarding complication rates. A meta-analysis performed by Bouillet revealed an overall complication rate of 3.7% and rate of serious complications of 0.45% in 43,662 chemonucleolysis patients compared with 26% and 4.2%, respectively in 2051 surgery patients (190). No mortalities were reported in the chemonucleolysis group compared with three deaths reported in the surgical group (190). In a separate meta-analysis, Nordby and Wright found 15 times more infections, six times more neurological and vascular problems, and an overall mortality three times greater in laminectomy patients than chemonucleolysis patients (191). Brown performed a third literature analysis and concluded that chemonucleolysis is 3 to 20 times safer than surgery for the treatment of lumbosacral radiculopathy as a result of disc herniation (196).

Automated Percutaneous Discectomy

After treatment with APLD, most patients will experience mild paravertebral lumbar muscle spasm or guarding lasting a few days. Rarely, these spasms are severe (94), and appear to require analgesic medications less frequently than after chemonucleolysis (42% vs. 10%) (99). Discitis occurs with similar frequency as in provocative discography with an observed incidence of 0.06% to 0.2% (94,97,176). Rare cases of psoas muscle hematoma have been reported (94,97). The overall complication rate as observed in large trials has fallen between 0.06% (176) and 0.95% (97). Permanent injury to neural elements, dura, urinary tract, gastrointestinal system, or major blood vessels is extremely rare and has not been encountered in large trials (94,95,97,176). However, two isolated cases of cauda equina injury have been documented as a result of probe misplacement (159,197). Disc height loss of greater than 50% occurred less frequently in levels treated by APLD compared with chemonucleolysis (99).

Laser

The most common side effect of PLDD is postprocedure paraspinal muscle spasm or guarding which occurs in 10% of the cases (113). These symptoms can vary from mild stiffness to

disabling pain with the patient listing toward the side of tightness (113). Typically, the lumbar pain dissipates over three to four days and can be addressed with oral muscle relaxers (113). Although not reported in most trials (102–108), Choy and Knight have remarked in personal communications about postprocedure sacroilitis occurring in 2% of lumbar cases and speculate that this may be because of an unlocking of the sacroiliac joint leading to overused "friction" related sacroilitis (113). Infectious and aseptic discitis each occur with an incidence of 0.3% per treated disc (105), and in Choy's experience infectious discitis has not occurred since the implementation of routine preprocedure intravenous antibiotics (105). In Choy's initial experience with 47 treated cervical intervertebral discs, one retroesophageal abscess had been encountered for a complication rate of 2% (105). However, this rate has decreased to 0.6% after treating 178 total discs in 93 patients (113), and is in accordance with Casper's findings of a 0.4% incidence of aseptic discitis per disc level treated (107). Thermal injury of nervous tissue has been observed with an incidence varying from 0% to 0.8% (105–107), or as high as 8% in one study (108) and is likely related to incorrect fiber placement (113). Most cases are transient and resolve over one to five months (107,108) but permanent injury can occur (108). Isolated cases of intestinal injury, sympathetic chain irritation (114), introducer needle heating (113), and dislodgement of needle tips have been reported (113). Thermal endplate necrosis has been reported (98) but has not been encountered by experienced physicians (103–107). Its occurrence appears to be operator-related and due to rotation of the side-firing probe in a cephalad and/or caudad direction thus directing the laser beam toward an endplate (113). Data regarding changes in disc height have not been tabulated.

Nucleoplasty

The most common side effect of lumbar nucleoplasty is localized soreness at the procedure site which was observed at 24 hours in 48% of the 150 patients treated at The Penn Spine Center (Philadelphia, PA, U.S.A.) (198). Axial lumbar pain can be a complaint in 5% of patients for up to 10 to 14 days (198). Less commonly at 24 hours, 9% of patients reported new areas of inconsequential leg pain and 8% new areas of lumbar pain. No permanent neurologic, vascular, or orthopedic injury has been observed (117–122). Intradiscal temperatures have been measured exceeding 60°C within 3 to 4 mm of the nucleoplasty probe tip (199). However, histologic studies have not found gross or microanatomical evidence of extreme tissue damage (200,201). Within the nucleus, a small 1.0-mm channel is created surrounded by intact fibrocartilage cells and collagen matrix. No alteration of the proteoglycan or collagen structure, or endplate damage has been observed to occur (200,201). Furthermore, no damage of the neural elements has been documented (117–122,200,201). If the applicator is maintained at a distance of 3 to 4 mm from any critical structure, unintentional thermal damage may be avoided (120).

Dekompressor Probe™

Of the 60 published Dekompressor cases, no complications have been reported (123,124). Complications were not specifically reported by Alo et al. (123), but Amoretti (124) remarked that no complications were encountered at any point in the postprocedure period. Nuclear tissue removed in Alo's study reportedly did not reveal evidence of tissue injury in any of the samples (123). Direct and intentional operation of the device against annular fibers did not visually affect or remove annular tissue in lamb cadavers (189). In our experience, a minority of patients will report localized soreness at the insertion site that eventually resolves over five to seven days. Equally common, patients may experience mild, transient paresthesias in the distribution of the previously affected nerve root around seven days after the procedure that eventually resolve over the ensuing seven to ten days. The first author has encountered one case in which a patient developed severe radicular pain 24 to 28 hours after the decompressive procedure that was subsequently abolished within 24 hours of the completion of a transforaminal epidural steroid injection at the index level. Of all the cases we published and performed, we are not aware of any infections, vascular injury, viscous injury, or injury of neural elements. Presumably, risk of infection would be similar as with discography.