Improving Spine Care with Advances in the Research Laboratory and Operating Room

A Message from Gordon R. Bell, MD
Director, Center for Spine Health

The discipline of spinal surgery is a rapidly evolving field in which new techniques and agents are continually emerging and becoming available to patients with various spine conditions. In this issue of Spinal Column, we highlight some of these newer strategies.

Two articles deal with different aspects of spinal fusion. The first, by Dr. Robert McLain, discusses a new technique to harvest bone marrow cells from the vertebral body in order to augment the bone-healing potential of spinal fusion. Dr. McLain describes the science behind this technique and outlines several advantages.

An article by Dr. Douglas Orr reviews a new intraoperative imaging technique that facilitates the accurate insertion of spinal instrumentation. Known as the O-arm®, this technique involves real-time computed tomography imaging, which is particularly useful in patients with spinal deformity who are undergoing fusion with spinal instrumentation. The O-arm also is helpful for instrumenting the thoracic spine, where accuracy of screw placement is of paramount importance in avoiding cord injury.

A second piece by Dr. McLain examines disc arthroplasty as an alternative to fusion in selected patients with axial back pain. He briefly reviews the history of the artificial disc, the rationale behind its development and indications for its use, as well as summarizing the Cleveland Clinic experience with this new device.

Dr. Andre Machado discusses the salvage strategy of spinal cord stimulation, which can be useful when spine surgery fails to relieve patients’ preoperative pain and further surgery is not indicated. This technique for managing chronic back pain can be an attractive alternative to other treatments such as long-term opiate use.

Finally, Dr. Michael Steinmetz recounts some exciting new pharmacological developments in the field of spinal cord injury. These agents are designed to limit the secondary damage occurring from the inflammatory response that follows the initial mechanical insult of the injury. These and other medications offer the 11,000 patients with these devastating injuries the potential for functional improvement.

We hope that our readers will find these topics enjoyable and stimulating. As always, we welcome your comments and suggestions for future topics in Spinal Column.

FOR MORE INFORMATION
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The Vertebral Body: a Superior Site for Harvesting Marrow Cells

By Robert F. McLain, MD

Successful spinal fusion surgery often depends on creating a solid and substantial bony fusion in the affected area. Autograft bone, the most commonly used fusion material, has traditionally been aspirated from the iliac crest, a rich source of autologous connective tissue progenitor cells (CTPs) – osteogenic stem cell precursors. The iliac crest is considered the gold standard for harvested graft material. However, iliac crest autograft harvesting is associated with considerable morbidity and chronic pain in many patients.

Within the past five years, Cleveland Clinic Center for Spine Health surgeons have pioneered an alternative source of CTPs, the vertebral body cancellous reservoir, and have found it to be an even richer source, with significant advantages over the iliac crest.

Iliac Crest Poses Challenges

Iliac crest harvesting has a number of limitations: This site is not easy to access, it may have been harvested previously and it may have relatively small cancellous volume for marrow aspiration. Moreover, iliac crest bone volume may be inadequate to complete the fusion when patients require long, extensive fusions or revision surgery after a previous graft harvest; have paralytic deformities that require fixation into the pelvic wings; or have undergone pelvic irradiation. Even when autograft material is sufficient, iliac crest harvesting involves stripping the outer cover of connective tissue to get to the bone, which can be painful and debilitating and can predispose patients to serious complications. Consequently, patients are often reluctant to have bone taken from the hip.

Vertebral marrow harvesting is accessible to surgeons only during specific surgical procedures, such as instrumented spinal fusions, that depend on fusion for clinical success. The cells can be harvested from the pedicle screw site, which prevents other tissue from exposure to added trauma. Removal of the marrow progenitor cells does not compromise the mechanical integrity of the vertebral body and can be accomplished without incrementally increasing surgical risk. Because entry into the vertebral pedicle can be achieved without disrupting the facet joint or the articular tissues, it is feasible to use this point of access to harvest marrow cells for uninstrumented fusions as well.

Bone morphogenetic proteins (BMPs) present yet another option. These synthetic autograft materials do not require harvesting and are easy to use but quite costly, with a higher risk than a patient’s own cells of absorption. Vertebral marrow represents an effective compromise: It is less costly than BMPs and less painful and difficult to harvest than the iliac crest.

Studies Support Technique

The Center for Spine Health was first to use a validated technique to apply vertebral bone-aspirated cells in a spinal fusion. In a 2007 study conducted at Cleveland Clinic Department of Orthopaedic Surgery, aspirates from the vertebral body and the iliac crest were compared. Twenty-one adults undergoing posterior lumbar arthrodesis and pedicle screw instrumentation underwent transpedicular aspiration of CTPs. Aspirates were obtained from three depths within the vertebral body and quantified relative to matched, bilateral iliac crest aspirates obtained from the same patient at the same time. Cell count, progenitor cell concentration (cells/cc marrow) and progenitor cell prevalence (cells/million cells) were calculated.

Aspirates of vertebral marrow demonstrated comparable or greater concentrations of progenitor cells than the iliac crest yield. The concentration of osteogenic progenitor cells was, on average, 71 percent higher in the vertebral aspirates compared with the paired iliac crest samples.

In a second study, we determined the concentration of connective tissue osteo progenitor cells available in sequential aspirates taken from the human vertebral body by a transpedicular route. In 13 patients undergoing lumbar surgery for degenerative disc disease or lumbar instability, with pedicle screw instrumentation as part of the procedure, eight discrete 2.0 cc aspirations were harvested from each vertebral level using a coaxial, transpedicular technique. The results showed a viable population of CTPs within the portion of the vertebral body routinely instrumented during pedicle screw placement. Initial aspiration does not deplete the marrow reservoir along the axis of the pedicle and vertebral body traversed during pedicle screw placement. CTP concentrations are at least comparable to iliac crest levels and remain high enough during sequential aspirations to allow at least four aliquots to be harvested before concentrations decrease.

Additional studies at Cleveland Clinic have demonstrated that these cell aspiration techniques do work; when they were applied in spine fusion surgeries, the fusion was reliably obtained and robust. Patients did not have to undergo a formal iliac crest graft to achieve good results.

Standard Procedure

Vertebral body harvesting has become easier with the development of an aspiration tool designed specifically for this purpose, which is safer and easier to use than a biopsy needle. With this tool, we can provide the best care with the least trauma to the patient.

Our research and experience show that autograft bone from the vertebral body works well in stimulating fusion for both routine lumbar surgery and difficult fractures of the long bone. Vertebral marrow harvesting has become standard procedure for augmenting fusion mass for spinal reconstruction at the Center for Spine Health. It takes a single-step routine and uses it for two purposes. We have not harvested the iliac crest for routine care in several years. Patients have been pleased with the results, especially given that graft site pain has been eliminated altogether.

Robert F. McLain, MD, is a spine surgeon in Cleveland Clinic’s Center for Spine Health. His specialty interests include back and neck surgery, minimally invasive disc and fusion surgery, and cervical and lumbar artificial disc replacement. He can be contacted at 216.444.2744 or mclainr@ccf.org.

References


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The O-arm: Seamless Integration in Spinal Surgery
By R. Douglas Orr, MD

In complex spinal surgery and in newer, minimally invasive procedures, surgeons have extensively used intraoperative X-rays and fluoroscopy for guidance. In these cases, we are using anteroposterior (AP) and lateral images of the spine to estimate where structures are. Optimally, surgeons would like to visualize the axial plane as seen on a computed tomography (CT) scan.

Image-guided navigation systems have been in use for 15 years, but are limited by the requirement that the patient have the CT performed before the procedure and that the preoperative CT then be matched with the patient in the operating room. This process leads to two problems: The first is that the orientation of spinal structures may change between the time the preoperative CT is performed and when the surgery is done. In addition, the preoperative CT is performed in a supine position, while the surgery is done in the prone position. The second problem is the time-consuming process needed to “register” the spine with the CT. The ability to seamlessly integrate the CT and the image guidance system in real time in the OR represents a major advance in spinal surgery.

Less Radiation Exposure in Minimally Invasive Procedures

One such advance is the O-arm®, which is essentially a portable CT unit that can be brought into the OR to acquire images at different points during a procedure. The O-arm can then be linked with any of a number of image guidance systems. In this manner, surgeons can obtain accurate scans and link them immediately with the navigation system. If spinal alignment is changed, a new scan can easily be obtained.

Another benefit of the O-arm is that minimally invasive spine procedures can be performed without the use of intraoperative fluoroscopy, thus lessening radiation exposure for both the surgical team and the patient. Radiation exposure to surgeons doing spinal instrumentation is higher than with most other uses of fluoroscopy, and annual safe radiation exposure levels can be reached in as few as 100 surgeries.1 With the O-arm, a scan is acquired with the surgical team out of the field and the procedure is then performed with no further radiation exposure, which eliminates the need for the OR staff to wear lead gowns. Wearing lead throughout a long procedure can increase fatigue and also exacerbates back pain for many people.

Reduced Risk in Complex Procedures

In complex procedures such as spinal osteotomies, the O-arm can be used to assess the progress of surgery at multiple points. Figure 1 shows an intraoperative image of a young man who had myelopathy due to cord compression across a congenital kyphosis. Resection of this type of anomaly carries a relatively high risk of spinal cord injury. Using the O-arm, surgeons were able to safely insert the hardware, and the image navigation system was then used to guide the vertebral resection.

Figure 2 shows a scan of the same patient, obtained to ensure that the vertebra had been completely resected prior to closing of the osteotomy. In this procedure, the ability to seamlessly integrate the CT and the image guidance system in real time in the OR represents a major advance in spinal surgery.

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Reference

Spinal Cord Stimulation for Failed Back Surgery Syndrome

By Andre Machado, MD, PhD

Failed back surgery syndrome (FBSS) is defined as persistent or recurrent pain after spinal surgery. Patients with this condition not only suffer from low back pain and/or leg pain; they also have failed medical and surgical treatment. In the United States, FBSS is one of the most common indications for spinal cord stimulation (SCS), which is FDA-approved for the management of chronic pain syndromes. Recent controlled studies have demonstrated that SCS can be superior to reoperation of the lumbar spine for FBSS in selected patients and that SCS is cost-effective in this patient population. A prospective, randomized, international, multicenter study with 100 FBSS patients found that SCS provided significantly greater improvements in quality of life compared with conventional medical management.

Diagnosis

The differential diagnosis of patients with failed back surgery syndrome is often complex. Patients may still suffer from the original pain syndrome that triggered the medical and surgical interventions that failed to help. In addition, new factors such as complications from previous procedures may have modified the initial pain syndrome.

Further, the more chronic the pain, the harder it is to manage. Complications from long-term narcotic usage and psychological comorbidities usually add complexity to the evaluation of these patients. Secondary gain is also a frequent concern. Formal evaluation by an experienced psychologist can provide helpful insight in the assessment of these patients and can contribute to the decision-making process and patient selection.

Options for Implantation

There are several technical alternatives and device options for spinal cord stimulation. The implantable devices have two major components: the lead(s) and the pulse generator (“pacemaker”). Leads can be divided into two main categories: cylindrical leads that can be implanted with percutaneous technique and paddle leads that are usually implanted via a small laminectomy or laminotomy.

The most important advantage of implantation with percutaneous technique is that it is minimally invasive. The procedure is routinely performed under sedation or local anesthesia, frequently on an outpatient basis. Limitations to percutaneous implants include migration of the leads and inconsistent stimulation. Patients often report that the effects are positional, varying with decubitus, posture and activity.

Implantation with paddle leads tends to provide more consistent stimulation effects, and lead migration is uncommon. The long-term effects of stimulation with paddle leads are likely more consistent than with percutaneous (cylindrical) leads and the efficiency of the electrical stimulation has been shown to be superior. However, implantation is performed via an open – even if minimally invasive – surgical procedure, with inpatient observation. The recovery time is greater than with percutaneous implants and incisional pain requires more management.

Trial Precedes Implantation

Usually, candidates for spinal cord stimulation first undergo a percutaneous externalized trial period of SCS with an external pulse generator for five to 10 days. The lead typically is implanted under conscious sedation with patient feedback. The lead is positioned and stimulation is programmed with the aim of producing paresthesias that match the pain territory. During the trial, patients are asked about the extent of pain relief and satisfaction with the temporary stimulation. Patients who report significant satisfaction and pain reduction to approximately half or less of the baseline pain levels are often considered for implantation with an internalized SCS system.

The decision on implantation with paddle or percutaneous leads depends on the patient’s characteristics and preferences, lifestyle and surgical considerations. Some patients prefer to have a paddle lead implanted, with the goal of achieving more stable results. Patients who undergo implantation with percutaneous leads may also benefit significantly from SCS without need for revisions. Conversion of the SCS system to a paddle lead is often considered if complications or inadequate stimulation are attributed to the limitations of the cylindrical lead design.

Andre Machado, MD, PhD, is Director of Cleveland Clinic’s Center for Neurological Restoration. He specializes in deep brain stimulation for Parkinson’s disease, tremor, dystonia, obsessive-compulsive disorder and emerging applications, as well as in surgical treatment of medically refractory pain and spasticity. He can be contacted at 216.444.4270.

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Back pain affects most of us at some point in life and, for many, it can become a chronic, disabling problem that threatens family, employment and health. For those who need surgery, total disc replacement may offer the best hope of pain relief and functional recovery.

Current Treatment Options

Depending on the cause of low back pain, some treatment strategies offer better results with fewer risks. The key to good outcomes is picking the best treatment for each patient.

Any patient with severe back pain will need to start treatment with conservative therapy, which includes physical therapy, mild medications and activity modifications. Nonoperative care is effective in more than 85 percent of people with back pain, so it is always a good place to start.

Patients who fail to improve with a full conservative therapy program need further evaluation. Many will benefit from pain management programs designed to ease leg pain or back spasm, but some will be persistently impaired by focal, severe back pain, aggravated by activity and physical therapy. When imaging studies (X-ray and MRI) show a single degenerated lumbosacral disc to be the culprit—the “pain generator”—surgical treatment can be considered.

If the disc space has collapsed and the vertebrae no longer move normally in relation to each other, the patient may be said to have “vertical instability” or may demonstrate actual spondylolisthesis—a vertebral slip—between the affected vertebrae. Treatment for lumbar instability (back pain > leg pain) has been tried with needle procedures and laser discectomies, with poor results. The two options with proven effectiveness for these patients are fusion and disc replacement surgery.

While fusion is successful in reducing back pain and improving function in most patients, the altered mechanics caused by stiffening the spine concern surgeons and scientists alike and may result in later wear and tear changes in the adjacent spine, referred to as “transition syndrome.”

Wear and tear at the level above or below a fusion can cause adjacent level disease, which may eventually need to be treated with more surgery. Different investigators have found that, over time, 20 to 35 percent of patients developed significant symptoms, sometimes as early as five years after fusion. For young patients needing surgical treatment for disc disease, this is a particular concern.

The Rationale for Total Disc Replacement

Disc replacement surgery removes the damaged disc and restores the normal alignment of the spine just as a fusion should, but it also:

- Maintains motion and spinal balance at the operated level
- Potentially slows or eliminates adjacent level disease
- Can be converted to fusion if not successful

Cleveland Clinic Center for Spine Health has been a participant in FDA-approved trials of total disc replacement (disc arthroplasty), and has extensive experience with this surgical approach. We can offer selected patients this alternative to fusion when the risks of transition syndrome warrant a motion-preserving strategy.

Device History

The device we use, the FDA-approved ProDisc L, was developed in France and was initially implanted in 53 discs in 41 patients in the early 1990s. Before additional procedures were performed, these patients were followed; seven to 11 years after their surgeries, all implants were still intact, all patients were still mobile and 93 percent were still very satisfied with their outcomes. Small modifications were made in the implant until the current model became standardized in 1999. We now have follow-up of nine years or longer on more than 30,000 patients worldwide.

What the FDA Study Has Found

Surgical implantation of the artificial disc has consistently been quicker than lumbar fusion techniques and has resulted in less blood loss and shorter hospital stays.

Postoperatively, both fusion and disc replacement patients showed significant improvement in pain and increase in function, though the disc replacement patients achieved slightly better results at both two years and five years. More disc replacement patients than fusion patients said they would have the operation again. Over subsequent years, fewer of the disc replacement patients needed any other type of surgery.

What the Cleveland Clinic Experience Has Shown

With either the Charlie® device or the ProDisc device (the two types approved by the FDA for use in the lumbar spine), excellent pain relief and return to function can be obtained in carefully selected and prepared patients (Figures 1 and 2). Moreover, disc replacement options are now available to patients with neck pain and disc degeneration. Two devices (Prestige® and ProDisc-C®) have been approved for use and several more are awaiting FDA approval, offering patients with unremitting neck pain an attractive new option for pain relief and improved function.

The biggest headache current patients face is insurance approval. Disc replacement surgery is still considered experimental by some insurance companies, even though the FDA has declared these devices appropriate for use and no longer investigational. Some companies have a policy that they will not pay for these procedures. Patients interested in disc replacement for back problems need to check with their insurers. If coverage can be obtained, disc replacement surgery offers a new alternative to standard lumbar fusion for back pain treatment.
Immune Response in Spinal Cord Injury: Could Drug Combination Limit Damage?
By Michael Steinmetz, MD

Researchers in Cleveland Clinic Lerner Research Institute’s Department of Neurosciences are teasing apart the complex immune response in spinal cord trauma, with the intent of devising pharmacologic interventions that would limit the secondary damage wrought by the response, preserve neural integrity, speed recovery and enhance restoration of function.

The challenge is substantial, but there is progress. Two pharmacologic agents already have been shown to modulate the response and produce measurable benefits in animal models. It may be fortuitous that both these agents are on the market, one (rolipram) in Europe and the other (clodronate) in the United States.

Initial and Secondary Trauma

Mechanical trauma to the spinal cord, albeit destructive, seldom transects the cord in its entirety. The preservation of relatively few axons can support a partial recovery.

The immune response (i.e., neuroinflammation) is deemed responsible for a significant portion of the damage seen in spinal cord trauma, and is also thought to hinder the pace and limit the extent of recovery. The response is an orchestrated series of events that transpires over the course of two or more weeks.

Initially, the trauma is limited to the zone of injury. Within hours, a region of secondary cell death begins to expand as neurons, microglia and microglial cells perish. The neutrophil population at the site rises, peaks and falls precipitously over a 24-hour span. Macrophages and microglial cells are recruited and become predominant within 48 hours. They may reside at the site and remain active for up to two weeks.

When these cells disappear, they leave a cavity that is surrounded by a glial scar consisting of reactive astrocytes and activated microglial cells. The process, start to finish, is directed by a continually changing stew of cytokines and chemokines.

Therapy Targets Immune Response

With the current, although arguably incomplete, understanding of the initiation and evolution of the immune system’s involvement in secondary damage, a Cleveland Clinic research team selected two agents for investigation in animal models of spinal trauma.

Clodronate is a non-nitrogenous bisphosphonate approved by the Food and Drug Administration to treat osteoporosis and hypercalcemia of malignancy. Among its properties is an ability to induce selective apoptotic cell death in monocytes and phagocytic macrophages. Rolipram is a phosphodiesterase inhibitor approved in Europe as a treatment for depression and other disorders. It has anti-inflammatory effects and can reduce the production of pro-inflammatory cytokines such as TNF and ICAM-1. The latter factor allows the adhesion of neutrophils.

Two-Drug Treatment Shows Promise

The two drugs were studied as single agents and in combination in 66 spinal cord-injured female Sprague Dawley rats randomly assigned to a control group, a group receiving clodronate encapsulated in liposomes, a group receiving rolipram and a group receiving the two agents in combination.

The combination treatment led to greater locomotor recovery compared with the controls and single-agent recipient animals. There was substantial axonal sparing and/or sprouting from brainstem motor nuclei and the hindlimb motor cortex. The amount of axonal sparing in the group receiving the drug combination was three to four times that seen in the other groups. Histological assessment showed a 53 percent reduction in lesion volume and a 45 percent reduction in lesion area at the injury epicenter. The agents also significantly increased the extent of myelinated tissue sparing.

These early findings are a significant step toward clinical trials. Bear in mind that both agents are approved and have established pharmacokinetic and safety profiles. The availability of a new treatment would be of substantial benefit to the 11,000 Americans who incur acute spinal cord injury annually.

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