

SPINAL IMPLANTS

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INTRODUCTION

Spinal implants constitute the fastest growing segment of the orthopedic medical device industry. The area has until

the last 5 to 10 years been vastly under-studied for the proportion of patients who are afflicted with diseases and injuries to the spine. Consequently, new spine medical devices and medical device companies are emerging every day with new and better treatment strategies for prevalent spine disorders. This article will explore the physiological conditions and disease states that require treatment and then demonstrate some treatment strategies that are being used today. The devices in this text are not comprehensive (we would need a much larger space to do that) but do allow an understanding of the state-of-the art in medical treatment of spinal disorders.

Human Spine

The human spine is a mechanical structure as it performs three fundamental biomechanical functions simultaneously (1). First, it transfers the weights (and resultant bending moments) of the head, trunk, and any weights being lifted to the pelvis. Second, it allows the sufficient physiological motion among the head, trunk, and pelvis. Third, and most important, it protects the delicate spinal cord from the potential damaging forces (and moments) resulting from the physiological motions and trauma (1).

Figure 1 show a schematic of the human spine, which is divided into three main regions: the upper region with 7 vertebrae (cervical spine), the middle region with 12 vertebrae (thoracic spine), and the lowermost with 5 vertebrae (lumbar spine). At the distal end of the spine, there is a basin-shaped structure, the pelvis, that supports the spinal column and is made of sacrum and coccyx with fused vertebrae. The human spine is not a straight structure, but it has specific curvature. The spine in the cervical and in the lumbar region is slightly convex anteriorly, whereas in the thoracic and sacral region, it is slightly convex posteriorly. The specific shape allows the increased flexibility while maintaining the overall spinal stability. It also facilitates increased shock-absorbing capacity along with adequate stiffness (1).

Each vertebra is made up of several parts. Figure 2 shows schematic of the vertebrae in a vertebral column. The body of the vertebra is the primary weight-bearing area. Between the vertebrae lie the intervertebral disks, which separate the adjacent vertebrae and act as cushions between them while allowing the movement of one vertebra relative to another. There is a large hole in the center part (spinal canal) that is covered by the lamina. The spinal cord runs through this spinal canal. There is a protruded bone in the central posterior region, called the spinous process. There are pairs of transverse processes that are orthogonal to the spinous process and provide attachment sites for the back muscles. Four facet joints are also associated with each vertebra. Four facet joints in two pairs (superior and inferior) interlock with adjacent vertebrae and provide the stability to the spine (1). An intervertebral disk is situated in between adjacent vertebrae. The disks are labeled with respect to the vertebrae levels, between which they are located. Thus, the T12/L1 disk is located between the twelfth thoracic and first lumbar vertebrae, whereas the L3/L4 disk is located between the third and fourth lumbar vertebrae.

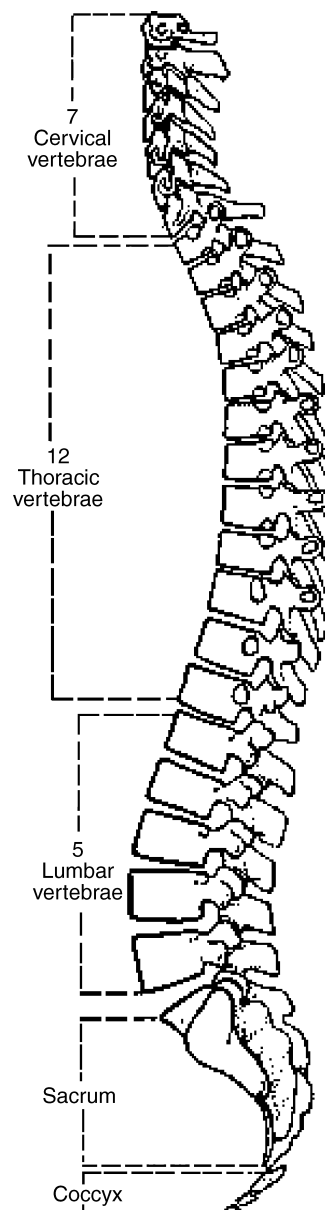


Figure 1. Schematic of human spine (2).

The intervertebral disk is basically a composite structure made up of three different tissues; the central core is called the nucleus pulposus (Fig. 3), which is attached radially to the multilayered fibers of the annulus fibrosus and attached superiorly and inferiorly to cartilaginous end plates (1). The nucleus is predominantly water in a matrix of proteoglycan, collagen, and other matrix proteins. The water content of the nucleus is very high at birth (approximating 90%) and then decreases through the aging cycle down to 70% or less. The annulus surrounds the nucleus with successive layers of tissue with collagen fibers oriented in alternating directions. The annulus is under tension when the nucleus absorbs water and swells. The cartilaginous end plates have multiple perforations that allow exchange of water and nutrients into the disk (4–6).

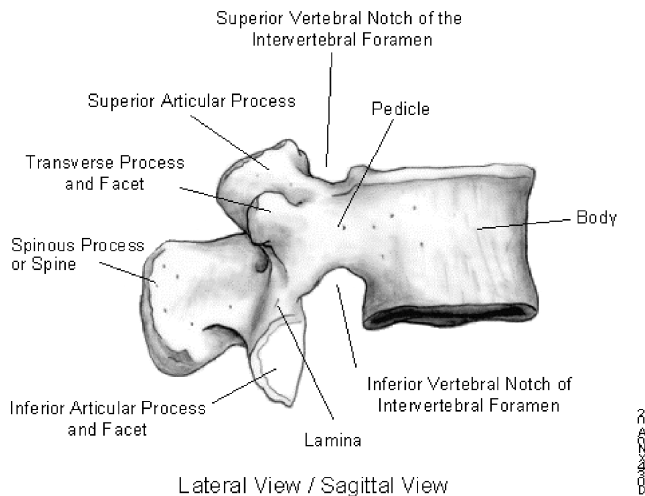


Figure 2. Spinal vertebrae (3).

SPINAL DISORDERS

Various spinal disorders are observed in humans; some manifest in pediatric patients, whereas others affect middle-aged and older patients. The most common spinal disorders can be generally described by three different categories: developmental bone deformities (scoliosis and kyphosis), bone degeneration (vertebral compression fractures), and degenerative disk disease (herniation, rupture and spinal cord stenosis).

Developmental Bone Deformities

The spine is a complex biomechanical structure and performs complex functions. This puts spine under greater strains, and bone deformities may develop during the course of time while performing the demanding functions such as supporting the cranium and trunk, or absorb stresses generated during daily physiological activities. Most common spinal disorders under this category include scoliosis and kyphosis.

Scoliosis. Scoliosis is a lateral curvature of the spine. The symptoms of the scoliosis include uneven waist,

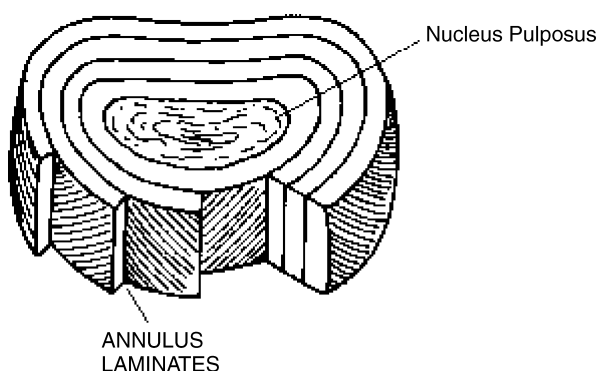


Figure 3. Schematic of an intervertebral disk (1).

different height shoulders, raised/prominent hip, and leaning of body to one side (7). Some causes of scoliosis include congenital deformity, cerebral palsy, atrophy, and neuromuscular problems.

Scoliosis can either be structural or functional. Structural scoliosis is referred in case of adjacent vertebrae rotation upon each other. This is generally followed by deformation of rib cage. In case of functional scoliosis, there is no fixed vertebral rotation or fixed deformity in the thoracic region. The rate of curve progression is not constant; however, the lumbar curves progresses more rapidly than thoracic curves. The scoliosis is generally classified as adolescent idiopathic scoliosis (AIS), adult scoliosis (with or without degenerative changes), and *de novo* scoliosis (which develops secondary to degenerative changes of the lumbar spine, especially in older age) (7).

The most common tools used for diagnosis of scoliosis include plane radiograph, computed tomography (CT) scans, and magnetic resonance imaging (MRI). Treatment options depend on the various factors, including the age, curvature angle, progress rate, location, flexibility, and spinal maturity. Conservative management (no treatment) is commonly incorporated when the curvature is mild (less than 20°).

Orthopedic braces are recommended in case of curvature angle of 25–40°, to prevent further spinal deformity, especially in children. The bracing, however, merely prevents the worsening of the existing curvature and does not restore normal alignment (8). Many types of braces are commercially available in the market. The brace, depending on the type and application, may extend from neck to pelvis (Milwaukee Brace) with plastic pelvic girdle, neck ring, and pressure pads (Fig. 4) (9), or it may just cover below the breast to the initial pelvic region only (Boston Brace). The use of braces has been generally effective in case of children, to prevent the further worsening of the scoliosis, but there is still a lack of consensus about the indications for the brace, type, and wearing time over the body.

Surgical options are used only in case of severe scoliosis (curvature angle greater than 45°) or for the curves that do not respond to nonsurgical treatments. The goals of the

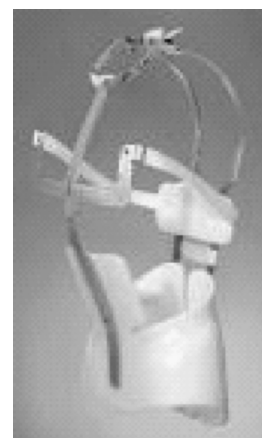


Figure 4. Milwaukee Brace (9).

surgical treatment are to prevent the progression of the curve and correct the deformity using instrumentation (7). The most common method to treat severe scoliosis is spinal fusion (anterior or posterior) and bone grafting/substitute. Bone graft can either be autologous iliac crest, from rib or allograft. In general, the facetectomy is followed by placement of bone graft and fixation. Various instrumentation options are available to surgeons for fixation. Basically, fixation is achieved by use of single/dual rods, posteriorly or anteriorly, along with screws and wires to the fixation point(s). The structures of the vertebral body, such as pedicles, sublaminar region, facets, and processes, may serve as fixation points for fusion (7). Anterior structural support is generally provided by mesh cages or ring allografts. Single thoracic curves are generally treated posteriorly using posterior instrumentation (hooks) and fusion.

Kyphosis. When viewed from the side, the normal spinal column is not completely straight. There are several gentle curves due to the shape and alignment of the vertebrae. Kyphosis is an exaggerated curvature of the spine or a rounded, "hunched" back. Most causes (metabolic, neuromuscular conditions, osteogenesis, spina bifida, among others) of the kyphosis are due to shortening of the anterior column, a weakening or lengthening of the posterior column, or both (7). The symptoms of kyphosis include difference in shoulder heights, forward bend of head compared with the rest of body, and tight hamstring (back thigh) muscles.

As in scoliosis, plane radiographs are also useful in diagnosing kyphosis. These help in defining the nature of sagittal deformities. Cobb (angle) measurements on these radiographs are performed to quantify the deformity in the sagittal and coronal plane. The angle is measured using the adjacent vertebral endplates (plane) as the basis of calculation. CT scans and MRI also find a place as useful diagnostic tools for better assessment of the spinal deformity.

The use of braces is recommended when the curve angle is between 40° and 60° on X ray. Surgical treatment is recommended when the curvature deformity is progressive, and the deformity may lead to neurological compromise. Again, spinal fusion (anterior or posterior) is referred for cases of severe deformity. In the case of young patients, posterior fusion might be considered, which would allow continuous anterior growth to partially correct the deformity (anterior release with posterior instrumentation).

Bone Degeneration

Compression fractures are generated in vertebrae when the bone tissue becomes weak due to degenerative changes. In most cases, the cause of the compression fracture is reduction in bone mineral density leading to weakening of bone (osteoporosis) (1,7). Osteoporosis causes both inorganic and organic phase bone loss. Loss of bone crystal weakens the bone to compressive loading, whereas loss of the organic matrix of bone makes the tissue more brittle, making the bony construct more susceptible to fracture. Other manifestations of osteoporosis include hyperkyphosis with chronic spinal pain and osteoporotic burst

fractures. However, the most common manifestation of the bone loss is a vertebral compression fracture (VCF).

To diagnose vertebral compression fractures, plane radiographs are used. To follow the progression of bone density loss throughout the osteoporotic disease process, dual photon absorptiometry (DPA) (which measures axial skeletal bone mass density) and dual energy X-ray absorptiometry (DEXA) (which measures baseline bone density with precision) are used. Quantitative CT can also be used in diagnosis of compression fractures.

Surgical treatment available for reduction of compression fractures is vertebral body augmentation: either kyphoplasty or vertebroplasty (7). Vertebroplasty is a procedure performed to relieve the pain and strengthen the weak vertebrae. During the procedure, an image-guided (X-ray) bone needle may be passed through the patient's back to have precise control over its location. Bone cement (polymethylmethacrylate or PMMA) is pushed through the needle to stabilize the fractured location of the vertebra. After curing, the PMMA biomaterial serves to stabilize the vertebra and to minimize the pain associated with the fracture.

Kyphoplasty is another method of vertebral augmentation, which uses bipedicular approach and balloon tamps to create voids in the bone. The instrumentation (cannula) used in kyphoplasty differs that from used in vertebroplasty. The void created by balloon is filled with PMMA. Other materials, such as calcium phosphate, hydroxyapatite, polymeric hydrogels, and combinations thereof, are being investigated as an alternative solutions to PMMA.

Degenerative Disk Disease

Lower back pain is one of the most prevalent socioeconomic diseases and one of the most important health-care issues today. Over five million Americans suffer from lower back pain, making it the leading cause of lost work days next only to upper respiratory tract illness (10–14). On an average, 50–90% of the adult population suffers from lower back pain (15), and lifetime prevalence of lower back pain is 65–80% (16). It is estimated that 28% experience disabling lower back pain sometime during their lives, 14% experience episodes lasting at least 2 weeks, whereas 8% of the entire working population will be disabled in any given year (16). The total cost of the lower back disabilities is in the range of \$50 billion per year in the United States (17) and £12 billion per year in the United Kingdom alone (18). The causes of lower back pain often remain unclear and may vary from patient to patient. It is estimated that 75% of such cases are associated with lumbar degenerative disk disease (DDD).

Many conservative treatment options exist for lower back pain. These generally aim at reducing the pain arising out of nerve root impingement and inflammatory response because of the migrated nucleus. The most commonly used surgical treatments include discectomy and spinal fusion and are sought when conservative treatments fail.

Progression of Degenerative Disk Disease. As the human life progresses, significant changes occur in the tissues of the intervertebral disk. DDD can be simply defined as the

loss of normal disk architecture accompanied by progressive fibrosis. At birth, the water content of the annulus fibrosus is about 80% and that of nucleus pulposus is about 90%. Through the degenerative process, this water content decreases to as low as 70% for the nucleus (19). Microscopic changes such as fragmentation of fibers, mucinous degeneration of fibers leading to cyst formation, and focal aggregation of the collagen to form round aggregates of amorphous material are observed in early stage of degeneration (20). The salient features of the DDD can be denoted as the loss of gelatinous nucleus pulposus, gradual disappearance of the originally well-defined border between the nucleus and the annulus, coarsening of the annulus lamellae, progressive fibrosis, and later fissuring of the annulus fibrosus with the deposition of the aging pigment (21–24).

The load transfer mechanism is clearly altered in the case of a dry nucleus. As a result, the end plates are subjected to reduced pressure at center and more pressure around the periphery. The stress distribution in the annulus is also altered significantly. Essentially, the nucleus does not perform its function of load transfer and the load transfer occurs through end plate—annulus—end plate route (1). The annulus is subjected to abnormal stresses and is more prone to injuries, and cracks/fissures first develop into the annulus.

With continued degeneration, the central nucleus may migrate through the crack developed in the annulus toward the periphery. The migration of the nucleus material is referred to as “disk herniation” (17). Approximately 90% of the disk herniation would occur at the L4-L5 and L5-S1 levels. The migrated material may impinge on the nerve root. The contact of the migrated nucleus with the nerve root irradiates debilitating back pain. Also, the herniated material elicits an inflammatory response because of the avascular nature of the nucleus. It is difficult to distinguish between the effects of aging from that of degeneration on the biomechanical behavior of the lumbar disk. The biomechanical behavior of the disk is dependent on its state of degeneration, which in turn depends on the age.

In case of the normal disk, any load acting on the disk is transferred to the annulus by means of swelling pressure (intradiscal pressure) generated by the nucleus (1). The water binding capability of the nucleus is a function of chemical composition of the nucleus. However, with aging and/or degeneration, changes occur to the proteoglycans as proteases and MMPs attack the molecules. The result is a decrease in the proteoglycan/collagen ratio, which leads to the lower water binding capability of the nucleus (25,26).

The load transfer mechanism in case of such a dehydrated disk is significantly altered (Fig. 5). The nucleus cannot generate sufficient intradiscal pressure to maintain disk height and normal mechanical function (25,27,28). Although it is not well understood, the consequence of the structural and mechanical changes to the disk may be a cause of lower back pain.

Stenosis. The reduction in the disk volume leads to instability, resulting in the growth of bone, end plates, and ligaments to compensate for this volume loss (stenosis). Stenosis is narrowing of the spinal canal (29). It occurs as a

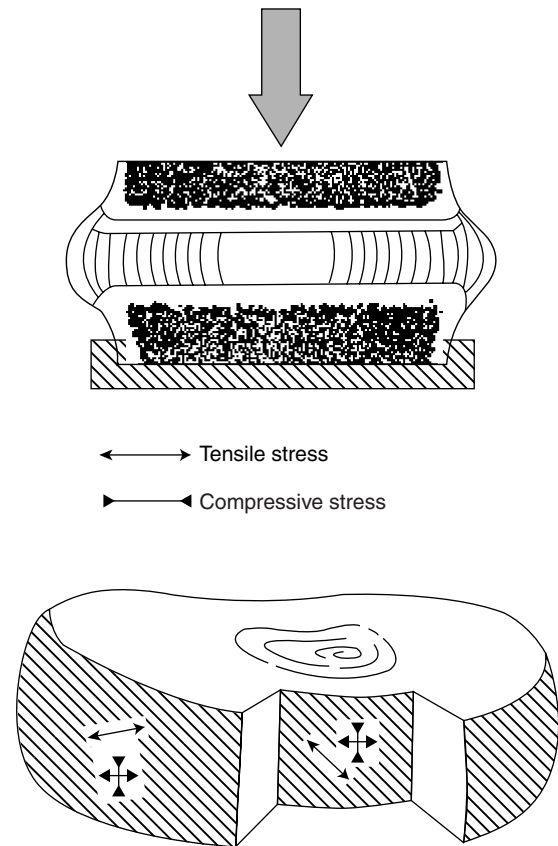


Figure 5. Degenerated disk (1).

result of aging and/or degenerative disk disease. The water content of the nucleus decreases, causing an abnormal load transfer mechanism within the disk. The disk height is reduced, and this dry/hardened disk may bulge into the spinal canal space. Additionally, the facet joints may become thick, thus narrowing the spinal canal further. Spinal stenosis in the lumbar spine may result in cauda equina syndrome and loss of bowel and bladder function. In general, the symptoms are not observed with stenosis. However, when present, the symptoms may include low back stiffness, leg weakness, numbness in the back/legs, and cramping.

Most common methods to diagnose and analyze the stenosis are plane X ray, MRI, and CT scan (7). These treatments, alone or in combination, provide valuable information about the patient's spine structure, location, and the extent of the disease. In particular, the following information can be revealed:

- Disk space narrowing
- Endplate osteophytes and sclerosis
- Facet enlargement and osteophytes formation
- Loss of lumbar lordosis

If conservative treatments such as medication, physical therapy, and spinal injections fail, a surgical approach may be recommended in the cases with persistent back pain

and/or progressive leg weakness. The indications for surgical treatment include radicular pain or neurogenic claudication with MRI or CT. In general, the goals of surgery are pain relief, increased mobility, and improvement in the patient's quality of life. Most common surgical treatments are laminectomy (in case of simple stenosis) and spinal fusion. Fusion is recommended when there is a stenosis in conjunction with

- Degenerative scoliosis or kyphosis
- Degenerative spondylolisthesis

The goal of the laminectomy or, lumbar decompression surgery, is to widen the spinal canal (30) to allow more space for spinal nerves. The treatment would ideally relieve the leg pain and, to a certain extent, back pain. When there is a vertebrae slippage relative to each other (spondylolisthesis), an abnormal motion would occur, which might require spinal fusion along with decompression.

Spondylolisthesis. Spondylolisthesis is defined as displacement or slippage of one vertebra on another (7). Osteoarthritis of the facet joints (degenerative arthritis that breaks the cartilage between the facet joints) can lead to instability of the vertebral segments. The L4-L5 motion segment has most flexion-extension movement and is more prone to such slippage, as a result of weakened facet joints.

The most common symptoms are pain irradiating in lower extremities and cauda equina compression along with incontinence of bowel or bladder. Like most other spinal disorders, surgical treatment is recommended only when the nonsurgical treatments such as activity modification and physical therapy show no significant improvement in the patient's quality of life. The goals of the surgical treatment are pain reduction, prevention of further slip, and stabilization of spine (7). Surgical treatments include spinal fusion (with or without decompression), slip reduction or instrumentation, and interbody fusion.

Recommended operative treatments of degenerative spondylolisthesis are decompressive laminectomy (removal of lamina and medial joints), decompression with postero-lateral fusion (complete laminectomy and partial facetectomy along with fusion of the transverse process), and decompression with instrumental fusion.

TREATMENT OPTIONS AND MEDICAL DEVICES

Most spinal medical devices involve permanently fusing vertebral bone to correct a deformity or to limit a motion segment to stabilize the joint segment and relieve pain. Spine medical devices have their origin in plates, screws, and rods made from stainless steel and titanium, and today, these components comprise the majority of the implantable devices today.

Implants for Developmental Spine Deformities

Implants for developmental bone deformities such as scoliosis and kyphosis, generally use metal rods, screws,

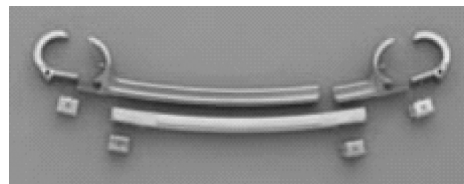


Figure 6. VEPTR for the treatment of pediatric scoliosis from Synthes Spine (41).

plates, and rib cages. For example, CD Horizon from Medtronic (Fig. 10) can be used for treatment of such deformities. Recently, the Food and Drug Administration (FDA) approved the Vertical Expandable Prosthetic Titanium Rib (VEPTR) from Synthes Spine (41,43), which is a surgically implanted device used to treat thoracic insufficiency syndrome (TIS) in pediatric patients. TIS is a congenital condition where severe deformities of the chest, spine, and ribs prevent normal breathing and lung growth and development.

The VEPTR device (Fig. 6) is a curved metal rod that is attached to ribs near the spine using hooks located at both ends of the device. The VEPTR device helps straighten the spine and separate ribs so that the lungs can grow and fill with enough air to breathe. The length of the device can be adjusted as the patient grows. It is hoped that the device will accomplish more normal growth pattern without spinal growth limitations, decreased chest, spine, and rib deformity and increased lung volume (43).

Implants for Degenerative Bone Disease

In case of kyphosis caused by osteoporosis (decrease in bone mass density with increased bone brittleness), minimally invasive methods such as vertebroplasty or (balloon kyphoplasty) are being used (7). Vertebroplasty involves the percutaneous injection of (PMMA) into a fractured vertebral body. Balloon kyphoplasty is another surgical approach to treat the kyphosis or deformity of the spine. In this procedure, an inflatable balloon is inserted between the vertebrae space to increase the disk height. Increase in disk height helps to reduce the deformity. The extra space created by balloon is filled with bone cement (PMMA), which when cured, binds the fracture. The hardened cement thus provides the strength to fractured/weak vertebrae and stability to the spine along with reducing the pain.

Implants for Degenerative Disk Disease

The treatment options for the patient would vary based on the age, pain history, and severity. When conservative treatments (such as rest, medications, physical therapy, etc.) fail, the patient is advised to undergo surgery. The goal of the surgery is to alleviate the pain. Most popular surgeries include lumbar microdiscectomy, lumbar laminectomy, microendoscopic surgery, and arthroscopic lumbar discectomy (30,31).

Lumbar microdiscectomy (or lumbar decompression) is a proven technique to reduce the back pain associated with herniated disks. In this treatment, a small portion of the

bone over the nerve root is removed to get relief from pain. A microscope is used to aid in visualizing the pinched nerve and subsequent microsurgical procedure to remove the excess portion of the herniated disk. Similarly, an open decompression (lumbar laminectomy) is another type of surgery that is performed to reduce the pain caused by neural impingement, which is particularly effective as a treatment for spinal stenosis. It is typically done with a posterior approach. The spine is approached by cutting the left and right back muscles off the lamina and removing the lamina itself. The facet joints are then trimmed to allow more space to nerve roots (30).

Even with these surgical treatments, pain may not be relieved for disks that are more severely degenerated. In these cases, fusion is required to restrict the motion of the segment and thus attempt to relieve pain. A discussion of fusion technologies and the associated implants follows. More recent advances in non-fusion technologies are aimed at preserving the motion segment while relieving pain. Such non-fusion technologies include total disk replacement, nucleus replacement, and annulus repair. Numerous new companies and new medical implant strategies are being explored currently and will hopefully prove to be clinically relevant pain relief and function restoring solutions to DDD.

Fusion Solutions. Spinal fusion is recommended when the discectomy approach may not be clinically relevant, and the goal is to relieve pain by stopping the motion of a spine segment. Spinal fusion instrumentation is essentially of three main types: pedicle screws, anterior interbody cages, and posterior lumbar cages. The bone generally fuses more effectively when its motion is minimized; hence, these devices are used to limit the motion of the fused segment. Similarly, the spinal fusion is based on the assumption that if the joint does not move, it will not create pain.

Pedicle screws (Fig. 7) are the means of providing anchor to the spine. They are used in combination with the short rod to grip the spine and are made from biocompatible metals such as medical-grade stainless steel or titanium. After a sufficient time, these screws can be removed by doing a surgery; however, most surgeons recommend keeping the screws unless it causes discomfort to patient.

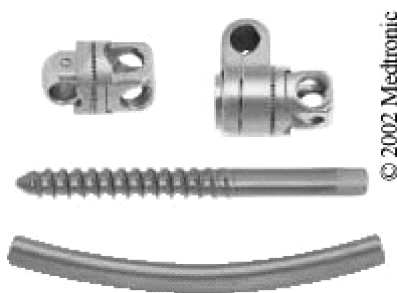


Figure 7. Pedicle screws and instrumentation from Medtronic (32).



Figure 8. Jaguar Interbody Cage from Depuy Spine (33).

Anterior interbody cages (Fig. 8) have been recently approved by the FDA to use in the disk space. The cages are made from titanium and are porous, which allows the bone graft to grow. Cages are also made of novel composite materials (e.g., Jaguar from Depuy) such as carbon fiber-reinforced polymeric materials. The bone graft grows through the cage from one vertebra to another.

These cages are placed in front (anterior) of the lumbar spine and, hence, the name. The cages can be inserted using either mini-laparotomy or endoscopy, however, the former is preferred. In general, a 3 to 5 in. (7.6 to 12.7 cm) incision on the left side of the abdomen is made to approach the damaged disk.

Anterior lumbar interbody fusion (ALIF) surgery is often combined with posterior lumbar interbody fusion (PLIF) surgery to provide more rigid fixation. When the cages are placed from back of the spine, it is called posterior fusion. Coda (Fig. 9) is a titanium alloy device for PLIF with pedicle screws from Abbott Spine and features intraoperative adjustment for lordosis.

There is another form of the fusion surgery: transforaminal lumbar interbody fusion (TLIF), which is considered as an extended form of PLIF. In TLIF, an entire facet joint is removed to get a better access to disk space as compared with PLIF. This facilitates better visualization and more removal of the disk material and placement of larger bone graft/implant. The success rate of the cages almost entirely depends on the vertebrae condition. The surgery is not recommended in the case of osteoporosis because the vertebral body would not sustain the cage, leading to eventual failure of the end plates. In that sense, the pedicle screws are better than anterior cages as a



Figure 9. Coda PLIF device with pedicle screws from Abbott Spine (34).



Figure 10. CD Horizon Legacy from Medtronic (32).

fixation device. The anterior/posterior fusion is performed in the case of severe spinal instability or in revision surgery. The advantage of the anterior/posterior fusion is that it provides more surface area for the bone fusion to occur.

The gold standard in the case of fusion is considered to be postero-lateral gutter fusion surgery (30). A bone graft is placed in the postero-lateral portion of the spine. The transverse process of the vertebral body serves as an attachment site to the bone graft, which eventually grows to complete the fusion at the site.

The recent trend is to offer the spinal systems that can be used for multiple spinal treatments. For example, the CD Horizon Legacy Spinal System (Fig. 10) can be used as a posterior, noncervical, nonpedicle screw fixation system for treatment of DDD, spinal stenosis, spondylolisthesis, spinal deformities like scoliosis, and kyphosis. When used as a pedicle screw fixation system of the noncervical posterior spine, it may be indicated for degenerative spondylosis, kyphosis, and scoliosis.

Novel concepts for spine care (e.g., Dynesys from Zimmer Spine and Wallis from Abbott Spine) are recently introduced in the market. Dynesys (Fig. 11) is a posterior

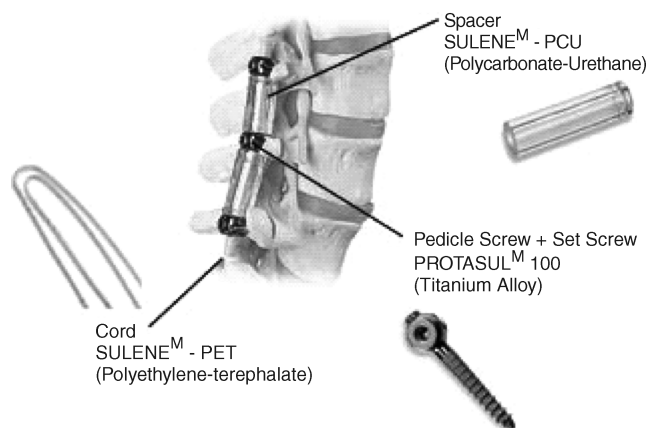


Figure 11. Dynesys from Zimmer Spine (35).



Figure 12. Wallis from Abbott Spine (34).

dynamics stabilization system, which is designed to bring the lumbar vertebrae back into more anatomical position while stabilizing the affected segments. The system used flexible materials threaded through pedicle screws, achieving dynamics stabilization.

The Wallis device (Fig. 12) from Abbott Spine is also another non-fusion spinal stabilization device that is under clinical trials in United States. The system is designed to treat the pain caused by initial stage DDD and aims to stabilize the lumbar spine without fusion, with a minimally invasive procedure.

The bone grafts used for the fusion can be either taken from patient's iliac crest (autograft) or from a human cadaver (allograft), such as Puros (Fig. 13) from Zimmer Spine (34). Autografts have the obvious advantage of compatibility with the patient's body. It helps in osteoconduction (bone growth) by means of providing calcium scaffold along with osteoblasts (bone growing cells) and morphogenic proteins (bone growing proteins). The allografts, in comparison, do not have osteoblasts and morphogenic proteins and merely provide the calcium scaffold for the fusion to occur. However, autografts lead to higher and longer postoperative pain as the bone graft is taken from the patient's own body.

Recently, synthetic bone grafts are introduced (e.g., Infuse), which represents an rhBMP-2 (recombinant human bone morphogenetic protein- 2) formulation combined with a bovine-derived absorbable collagen sponge (ACS) carrier. The INFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device, from Stryker Spine (36) (Fig. 14) is indicated for spinal fusion procedures in skeletally mature patients with DDD at one level from L4-S1, who may also have up to grade I spondylolisthesis at the involved level.

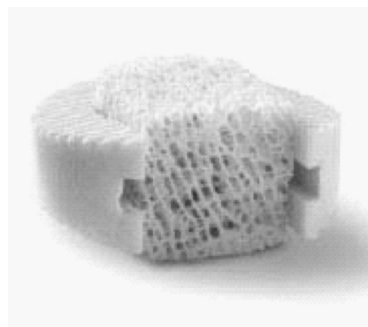


Figure 13. Puros allograft from Zimmer Spine (35).

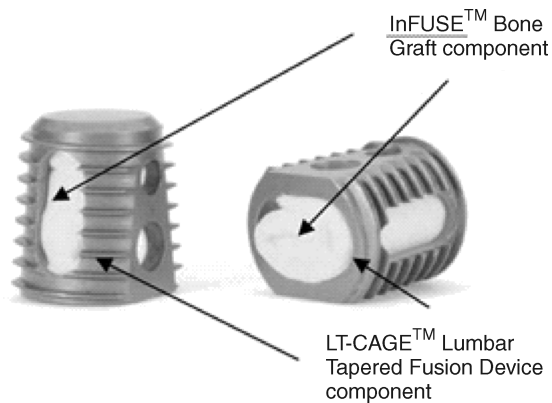


Figure 14. Infuse synthetic bone graft from Stryker Spine (36).

Bone stimulators offer another approach that potentially aid in spinal fusion. These externally applied devices emit low electrical current (30). This is aimed at facilitating stimulation of bone growth and increasing the chance of achieving spinal fusion. These are used in the case of patients who have a potentially very slow rate of obtaining solid fusion or in the case of the revision surgery.

The fusion and discectomy relieve pain but do not restore the normal spinal motion (37,38). The motivation behind exploration of the new and better solutions for the treatment of lower back pain is the failure of current treatments (conservative and surgical) in terms of restoring the motion and normal disk biomechanics. This is further aggravated by the complications that may occur after the surgical treatments, such as discectomy and/or spinal fusion.

Non-Fusion Solutions. Total disk replacement, where an entire diseased disk is removed and replaced by a synthetic implant, and nucleus pulposus arthroplasty, where only the nucleus of the disk is replaced either by a synthetic implant or recreated using tissue engineering approach, are the emerging approaches as alternatives to current surgical procedures for the treatment of the lower back pain (39). Annulus repair techniques, where defects in the annulus are either modified or repaired, also finds a place in emerging techniques and can be potentially used either alone or in combination with nucleus pulposus arthroplasty procedures, depending on the degenerative state of the intervertebral disk.

Total Disk Replacement. Total disk replacement targets later stages of disk degeneration (Galante grade IV), where the annulus is severely degenerated and is beyond repair (40). The diseased disk is entirely removed and replaced by a medical device that provides motion to the joint segment. Disk replacement may serve to eliminate the back pain and restore the physiological motion. A similar approach for total knee and hip replacement is highly successful. Total disk prostheses may be better options to spinal fusion and/or discectomy as it allows the physiological motion between the adjacent vertebrae. Another advantage would be that the effectiveness of the surgery will not be dependent on

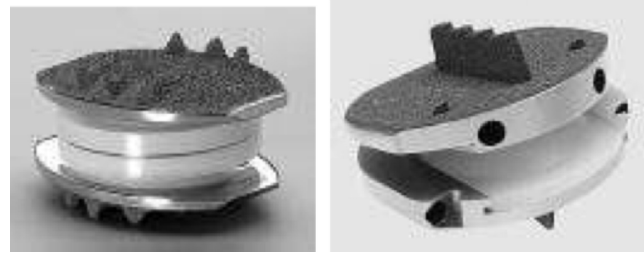


Figure 15. Charite from Depuy Spine (33) and ProDisc from Synthes Spine (41).

the integrity of the annulus or degeneration state. To simulate the natural structure and function of the spinal unit, total disk prostheses also provide adequate fixation to the vertebrae.

There are a variety of total disk replacement design strategies, but two of the concepts that are furthest along are the Charite and the ProDisc, which are each based on metallic end plates that are porous coated and allow fixation to the superior and inferior end plates as well as an ultra-high molecular end plate polyethylene core, which provides a low friction articulation of the adjacent vertebrae. The use of artificial disks (Fig. 15) as a replacement to the damaged disk is currently in various phases of development and clinical trials. The Charite received FDA approval in 2004, and ProDisc, Maverick, and Flexicore are under clinical evaluation at the time of this writing (30).

Nucleus Replacement. The nucleus pulposus is a major component of the intervertebral disk and is actively involved in the disk function and load transfer mechanism. It is also involved with the pathologic changes of the disk. Researchers began to consider replacement of the nucleus alone because this tissue seems to degenerate before the annulus fibrosus. If this tissue alone can be replaced, preserving the annulus fibrosus, this may prolong the life of the disk and postpone or prevent the need for a more aggressive procedure such as fusion or total disk replacement. Nucleus replacement, as in case of total disk replacement, aims for restoration of the normal disk mechanics and functions, in contrast with the current surgical procedures of the discectomy and the spinal fusion.

There are several nucleus implants in the various phases of development and clinical trials. Some are already implanted in humans in Europe (e.g., RayMedica PDN, Disc Dynamic's DASCOR), whereas most other nucleus implants are undergoing bench-top testing and/or investigational device exemption (IDE) submissions. The Raymedica prosthetic nucleus device (Fig. 16) has the longest history of all nucleus implants on the market. The clinical results of the PDN have been promising for pain relief and disk height restoration (41), but they are troubled by expulsion of the device from the annulus. Alternative implant designs and surgical procedures have limited this complication, but it remains a major challenge for these types of devices.

To perform surgical intervention on the intervertebral disk (e.g., in the case of nucleus replacement), outer

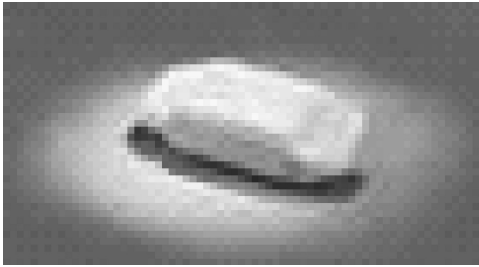


Figure 16. Single prosthetic nucleus device by Raymedica (42).

annulus fibrosus needs to be compromised. If the artificial incision in the annulus is not repaired, there is very high risk of nucleus implant expulsion, even under mild physiological loading. The main idea is to seal the annulus incision and/or prevent the expulsion of the nucleus implant from the created window. A barrier can be placed in between the nucleus and the annulus to prevent expulsion. These technologies are currently being explored in early clinical trials and in preclinical evaluations.

APPENDIX 1

Spinal Disorder	Treatment Options	Device/Implant
Stenosis	-Laminectomy -Spinal fusion	-Fusion Instrumentation • Cages • Pedicle screws • Metal rod • Autograft/Allograft
Spondylolisthesis	-Laminectomy -Spinal fusion	Fusion instrumentation • Cages • Pedicle screws • Metal rod • Autograft/Allograft
Scoliosis	-Bracing -Spinal fusion	-Braces -Fusion instrumentation • Cages • Pedicle screws • Metal rod • Autograft/Allograft
Kyphosis	-Balloon kyphoplasty	-Bone cement
Vertebral compression Fracture	-Vertebroplasty -Kyphoplasty	-Bone cement-Emerging materials
Disk degeneration and herniation	-Discectomy -Spinal fusion -Total disk prosthesis -Nucleus replacement	-Fusion instrumentation • Cages • Pedicle screws • Metal rod • Autograft/Allograft -Facet replacement -Nucleus implant device -Total disk arthroplasty

CONCLUSIONS

This is perhaps the most exciting time in the development of medical devices for spinal applications. Never before have so many academic researchers, clinicians, and corporations so aggressively pursued solutions to spinal conditions that have a potential to be solved with medical devices. Along with this tremendous interest is the interest in better understanding of the anatomical structure, biochemistry, and function of the spinal structures. As more information becomes available, further refinements in treatments through medical devices will be improved offering more tools to the surgeon and a better chance of relieving pain while preserving the function of the spine.

APPENDIX 2. TERMINOLOGY

Allograft The transplant of an organ or tissue from one person to another.

Autograft The transplant of an organ or tissue from one body site to another body site of the same person.

Compression Fracture Collapse of the bone of the vertebral body, mostly due to osteoporosis and trauma.

Disk Degeneration The loss of normal disk architecture accompanied by progressive fibrosis. This is seen as loss of hydration of the disk material and loss of disk height. This complex process alters the normal biomechanics of the spine and may cause back pain.

Disk Herniation Migration of the central nucleus pulposus of the disk toward disk periphery through cracks or fissures in outer annulus.

Discectomy A procedure in which in an excess portion of the disk impinging on the nerve root is cut off.

Kyphosis An exaggerated curvature of the back bones (vertebrae) in the upper back area or a rounded, "hunched" back.

Kyphoplasty A procedure that combines the vertebroplasty technique with balloon catheter technology to treat the osteoporotic vertebral compression fractures.

Laminectomy A procedure in which the lamina (roof) of the vertebra is trimmed to create more space for the spinal nerves.

Nucleus Implant An artificial material, which can be used as a replacement to the degenerated nucleus of the intervertebral disk to relieve back pain and preserve the normal motion.

Osteoporosis A disease in which bones become fragile and brittle, making it prone to break easily.

Scoliosis A curvature of the spine.

Spinal Fusion A procedure in which an intervertebral disk between the adjacent vertebrae is replaced by bone graft. The procedure is performed to relieve the back pain and stabilize the spinal segment by fusing the vertebrae together, with or without spinal instrumentation.

Spondylolisthesis Slippage of one vertebra on another.

Stenosis Narrowing of the spinal canal.

Total Disk Prosthesis An artificial device, which can be used as a feasible replacement of the degenerated disk to relieve back pain and preserve the motion.

Vertebroplasty A procedure that stabilizes the collapsed vertebra with the injection of the medical-grade bone cement into the spine.

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See also HUMAN SPINE, BIOMECHANICS OF; SCOLIOSIS, BIOMECHANICS OF.