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Painful Disc Degeneration

Patient Information



Treatment Options for Lumbar Degenerative Disc Disease

What types of treatment are available for DDD?

If your medical practitioner makes the diagnosis of DDD, there are a number of treatment options available. Initial treatments may consist of anti-inflammatory medications, physical therapy, and pain management techniques. If these treatments fail to provide meaningful and long-lasting relief of the DDD symptoms, then fusion surgery may be an option. There are a number of surgical procedures available for the treatment of DDD. You will need to discuss your treatment options as well as the risks and benefits of surgical procedures with a qualified spinal surgeon.

The goal of the Axle® minimally invasive procedure is to help prevent painful motion and serve to alleviate pressure off the damaged discs and affected nerves. The decision to undergo surgery is not an easy one. Even with the latest techniques, the risks and benefits need to be carefully evaluated between you and your spine surgeon.

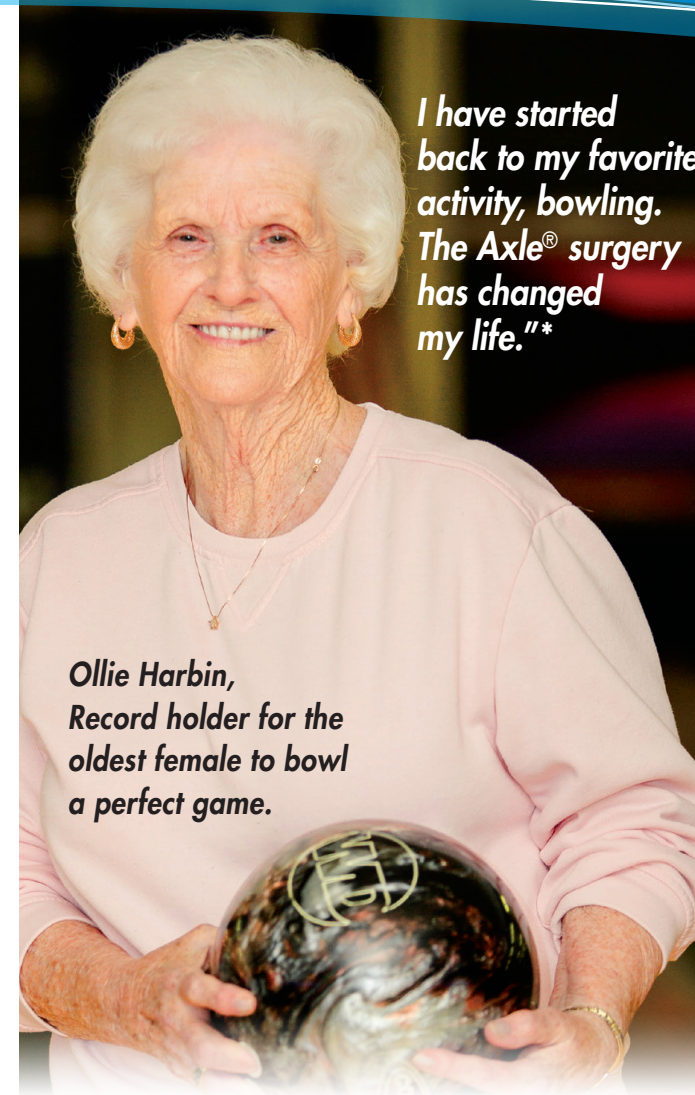
** Ollie Harbin suffered severe pain in her right leg for nearly 2 years. She underwent treatments and was prescribed medications, however, the pain continued to intensify. Ollie became dependent on a cane and walker, which prevented her from participating in her all-time favorite activity – bowling. Ollie Harbin holds the record for the oldest female to bowl a perfect 300 game. One month after surgery, Ollie is pain free and ready to bowl again!*



WARNING: In the USA, this product has labeling limitations. See package insert for complete information.
CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

X-spineSM, the X-spine logoSM, the AXLE logoTM, and AXLE® mark are all trademarks or service marks of X-spine Systems, Inc. This product is covered by U.S. Patent No. 8,262,697. Other U.S. and foreign patents are pending. All products are not currently available in all markets. © 2015 X-spine Systems, Inc., All rights reserved.

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*I have started back to my favorite activity, bowling. The Axle® surgery has changed my life.***

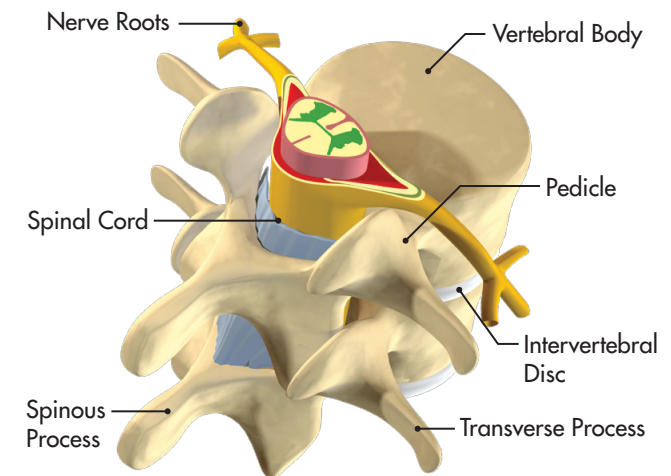
**Ollie Harbin,
Record holder for the
oldest female to bowl
a perfect game.**



Spine and Lumbar Degenerative Disc Disease Overview

There are a total of 24 bones, also known as vertebrae, in your spine. Your spine comprises of three major sections: the cervical, the thoracic and the lumbar spine. In between each set of vertebrae lies a disc, serving as the shock absorber when the spine is in motion.

Degenerative Disc Disease (DDD) is a form of arthritis or joint inflammation which affects the lower back. This condition can cause degeneration of the lumbar discs, obstruction of the lumbar vertebrae and can produce chronic, often debilitating pain.



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Is the Axle® Implant right for you?

If you can answer yes to the following questions, you're ready to take the next step.

- I have been diagnosed and suffer from DDD or Spondylolithesis.
- My back and leg pain is relieved when I sit down or lean forward.

Your next step involves talking to a healthcare professional. To find a spine specialist in your area, visit www.DDDcare.com

Please note, the Axle® Implant procedure is covered by Medicare and select private health plans. Private health plans typically require you or your doctor to submit paperwork for pre-authorization of an elective surgery.

Causes of Lumbar Degenerative Disc Disease

What causes DDD?

In a healthy spine, lumbar discs function as shock absorbers to the several movements and activities in our daily lives. Throughout our lifetimes, our discs are subject to millions of forces. Over the years, some discs will wear out or degenerate. Mild disc degeneration occurs in nearly everyone by a certain age, and may not cause a significant problem for some. However, this process may become more aggressive and painful for others.

There are a number of factors which can contribute to the development of DDD. These include obesity, smoking, repetitive back strain, advancing age, spinal deformities (such as scoliosis or flat-back), and genetic factors. In many cases, no specific "cause" for DDD can be identified.

Symptoms of Lumbar Degenerative Disc Disease

How do I know if I have DDD?

It is important to distinguish between true DDD and other causes of back pain. The diagnosis of DDD can only be made by a qualified medical practitioner who will evaluate your pain history, physical examination, response to treatments and an MRI scan.

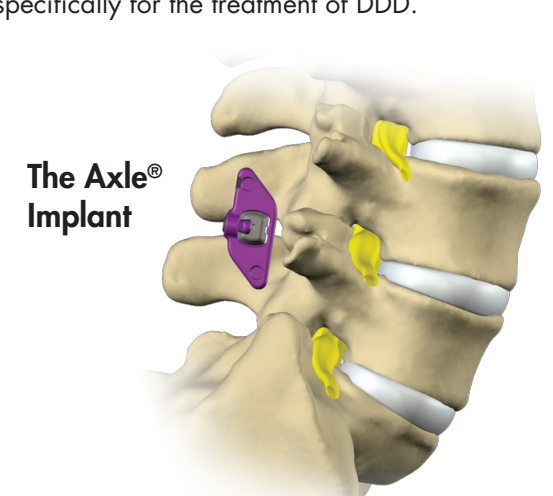
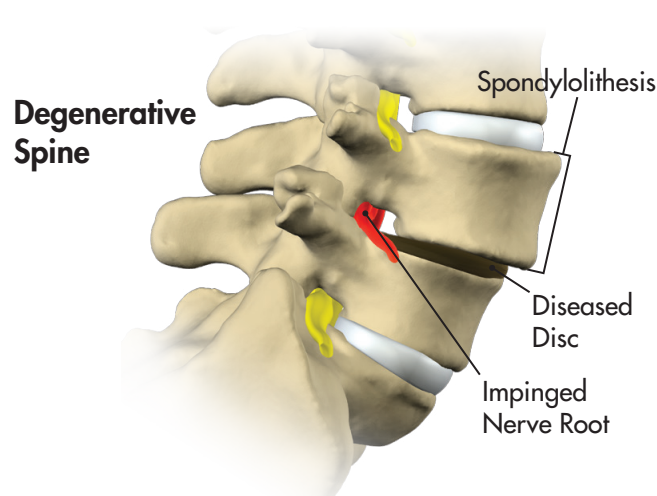
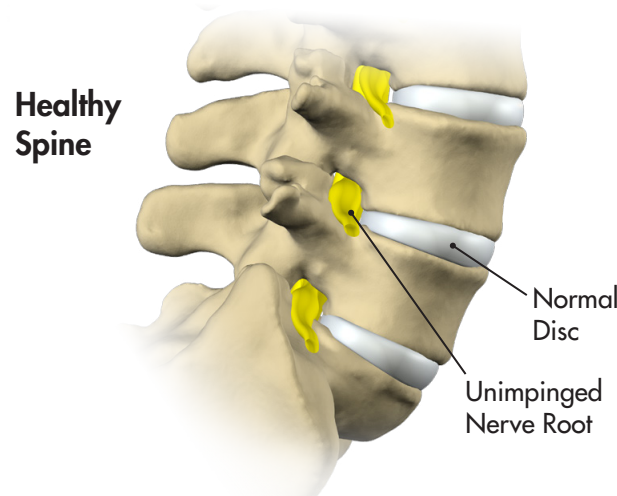
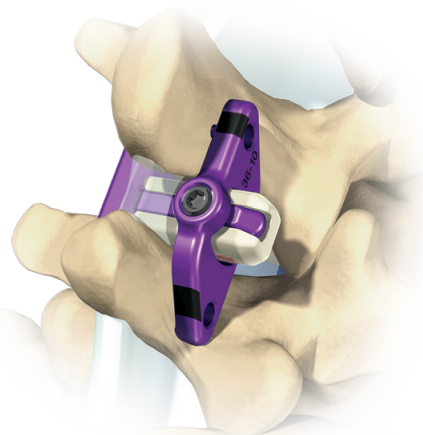
In a typical case of DDD, a patient will often have lower back pain which may radiate to the legs or buttocks. This pain is often aggravated by prolonged sitting, bending, lifting or twisting activities. An MRI scan, which identifies the presence of water in the tissues, will demonstrate dehydration of the disc and may also exhibit inflammation of the bone next to the disc.

About the Surgery

What is DDD surgery using the Axle® system?

As fusion surgery continues to undergo rapid technological evolution, less invasive procedures have become more favorable. Most recently, the main option for doing fusion surgery consisted of the placement of stabilizing screws and rods into the vertebrae of the spine in combination with bone graft. Screw and rod fusion requires placement of four screws into the bone of the vertebrae above and below the degenerated disc.

An alternative to a traditional screw procedure is the Axle® implant, which stabilizes the spine by clamping onto the cortical interspinous surface of vertebrae above and below the degenerated disc, and the procedure does not require drilling. This makes the Axle® implant less invasive than other procedures. The Axle® device has been cleared by the USFDA specifically for the treatment of DDD.



DISCLAIMER: Information in this brochure is intended to be general and does not represent medical advice or recommendations. The evaluation and examination of the patient by a physician is necessary. Care was taken to ensure the information contained herein is accurate; however, X-spine does not assume any liability for the accuracy and/or completeness of the information, and X-spine is not liable for any losses of any kind that may be caused by the use of or reliance thereon.