Spine Surgery & Market Overview

Anatomy and Pathology of the Spine

The spine is a complex system of bones and soft tissue that provides support, enables motion, and protects the spinal cord and other elements of the neural system. The bones in the spine are called vertebral bodies and are separated by discs that provide flexibility and cushioning for movements and body loads. The discs and bones in a healthy spine allow bending from side to side and front to back and turning left to right.

Most people will suffer from some back or neck pain at some point in their life, and in many patients older than 40, these symptoms are related to a condition called degenerative disc disease (DDD). Changes in the discs may result in degradation in the spine that can cause pain, numbness, or tingling. When a disc degenerates it can lose height and effectiveness, like a car tire that has lost air. Discs can also bulge (herniate) leading to loss of feeling, weakness, pain, or tingling down the arms or legs.

Treatment options

Before artificial discs were available, patients would often receive an Anterior Cervical Discectomy and Fusion (ACDF) or a Lumbar Interbody Fusion (LIF) procedure to alleviate the pain from a herniated or degenerated disc. In a fusion surgery, the disc is removed, and an interbody device is placed in the disc space to restore disc height and remove pressure on the pinched nerves or spinal cord. A metal plate and screws can be placed on the front of the spine to hold the implant in place or a device with integrated screws can be used. The result of this procedure will be a spinal segment that no longer moves or is "fused". The potential downside of a fusion procedure, in addition to the loss of motion, is that it can create additional stress on the spinal levels above and below it. This can cause degeneration at those levels and potentially create a cascade of effects often leading to future surgery.

An artificial disc like pro**disc**® is an option instead of a fusion that will also be placed inside the disc space to restore height and remove pressure on the pinched nerves. As opposed to fusion devices, pro**disc** is designed to allow the spine to maintain normal motion and potentially prevent the adjacent levels from degenerating, possibly preventing future surgeries.

The U.S. spine market: (source: Medtech 360 – Spinal Implants Market Insights 2021, DRG published August 2020)

- Over 700,000 US spinal procedures are conducted annually, driven by the expanding aging population and the uptake of technologies such as the use of non-fusion procedures.
- Most spinal procedures are fusions, representing over 95% of US spine procedures.
- It is estimated that 17,500 of the 214,000 cervical procedures and 1,300 of the 444,000 lumbar procedures in 2021 were artificial disc procedures.

- Cervical artificial discs are estimated to be one of the fastest growing segment of spine, at 25.6% annual growth, with lumbar artificial discs growing at 22.3%.

Growth in disc usage in the next 5 years will be due to multiple factors:

- A large and growing library of clinical evidence demonstrating the long-term safety and efficacy of disc replacement
- Non-fusions are used to treat patients who would otherwise undergo conservative treatment
- Non-fusions enable patients to have the option to undergo surgery that does not hinder mobility in their spine, allowing them to maintain a less restricted lifestyle.
- The number of FDA approved devices will continue to grow
- Expanding approved indications to include two-level lumbar disc replacement (2 Level IDE study completed for pro**disc** L)
- Improved outcomes of TDR over fusion including, but not limited to, reduced re-operation rate, adjacent segment degenerations rate & surgeries, reduced narcotic use, and shorter return to work
- Expanded private insurance coverage for lumbar total disc replacement