

## MEDICAL INNOVATION: CERVICAL DISC (MEDICAL DEVICE: THERAPEUTIC)

**Physician: Dr. Vincent Traynelis**  
**Industry: Medtronic**

### Situation

#### *Few options for treating crippling disc disease*

Degenerative cervical disc disease (cervical DDD) is a natural occurrence of growing older. As people age, the critical discs between the vertebrae of their neck that allow for movement of the bones lose their flexibility, elasticity and shock-absorbing characteristics. The ligaments that surround the discs, in turn, become brittle and are torn more easily. At the same time, the soft gel-like center of the disc begins to dry out and shrink.

Patients with cervical DDD complain of neck pain and stiffness, especially toward the end of the day. Other symptoms include pain that radiates down to the back of the shoulder blades or into the arms, numbness and tingling, difficulties with hand dexterity or walking, and muscle weakness. Approximately three out of five people over the age of 40 suffer from a form of cervical DDD, and many suffer so much pain and weakness that surgery is the only option.

Until recently, the main form of surgery for cervical disc disease was a procedure known as discectomy with a spine fusion, in which some of the disc material between affected vertebrae in the neck is removed to relieve pressure, and then the bones are fused together using a bone graft to prevent painful movement. Unfortunately, this treatment – used in some 200,000 patients a year, restricts movement of the vertebrae that are fused together, and often results in a limited range of motion for the arms and neck following surgery.

### Physician-Industry Collaboration

#### *A neurosurgeon has a different idea*

A distinguished neurosurgeon at the University of Iowa named Vincent Traynelis had a different idea. He imagined developing a device that could be implanted in the neck to replace a deteriorated disc while still allowing for normal movement between the vertebrae. This would preserve the ability of patients with cervical DDD to participate in activities that involved an almost full range of motion that they enjoyed previously.

As promising as his idea was, Dr. Traynelis had little engineering experience to transform it into a reality that could actually work in the human body. Fortunately, he got in touch with Greg Marik, a product development engineer at the medical device company Medtronic. Marik had years of experience working on surgical products involving the human spine.

Working over several years, Traynelis and Marik were able to design, produce and field a “ball-and-trough” artificial cervical disc design made of metal, screws and plastic that aimed to preserve the ability of the joined vertebrae to move naturally and safely between themselves in place of diseased disc material that was removed surgically. In 2007, Medtronic received permission from the FDA to market the product, known as Prestige®, as the first commercially available artificial disc in the U.S.

### Innovation Benefits

## ***Superior overall and neurological success compared to spinal fusion***

The Prestige disc as an alternative to spinal fusion was evaluated in a clinical study that involved 541 patients – the largest clinical study of its kind ever conducted and completed for the cervical spine. At 24 months, patients in the study showed superior overall success and superior neurological success in the area of sensory, motor, and reflex functions.

The study also demonstrated that the group of patients receiving the cervical disc had a median return-to-work that was 26.2% earlier than the median in the spinal fusion treatment group. In addition, patients with the disc experienced no device failures (breakages), and fewer patients with the disc required revision surgical procedures than those who were treated with spinal fusion.

## **Patient Benefits**

### ***A long distance swimmer overcomes the odds to realize his dream***

Medtronic tells the powerful [story](#) of a patient whose once-active life was restored through cervical disc technology: A 53-year-old investment banker from outside of Chicago, Doug McConnell was once a decorated collegiate swimmer at the University of Illinois, where he was ranked in the top 25 in the world several times. Since college, Doug maintained his interest in swimming, particularly in long open-water swims.

When his father passed away in 2008 after a 14-year battle with the neurological disease known as ALS, or Lou Gehrig's disease, Doug had a dream of putting his long-distance swimming skills to use in raising awareness of the disease -- and money for finding a cure -- by attempting something that fewer than 50 people his age had ever accomplished: completing the "Everest of open-water swimming," the 21-mile crossing of the English Channel.

Well on his way to training for the event, Doug was dealt a crippling setback in late 2009 when he developed a severely herniated disc in his neck, resulting in the loss of all use of his left arm. After trying physical therapy and other unsuccessful treatments, Doug considered spinal fusion surgery, but that procedure would make it virtually impossible to continue his love of swimming, as it would drastically restrict the range of motion in his arms.

Fortunately, he was given another option, and underwent a cervical disc replacement procedure with the Prestige disc system, designed to maintain motion at the treated vertebral segment. In a small procedure in his neck, the disc was successfully implanted, and Doug was back in the pool six weeks later. Within several months, Doug slowly built back his endurance, and regained strength in his arm and the ability to move his neck to breathe while swimming.

Less than two years later, in August 2011, Doug became the 48th person over the age of 50 to complete the swim of the English channel, making the crossing in 63-degree waters in an impressive 14 hours, 18 minutes. Realizing his dream, he drew international attention to the need for a cure for ALS, and raised more than \$130,000 for research into the disease.

"I'm a little sore, a little beaten down, but pretty good overall," Doug said. "I never would have been able to complete this challenge were it not for the advances of medical technology."