Lumbar Total Disc Replacement defeats crippling sciatica

Lumbar disc degenerative disease (LDDD) causes collapse of the spine resulting in agonising sciatica (inflammation of the sciatic nerve, causing pain). Current treatments, including fusion and discectomy, have mixed outcomes with patients often reporting pain after surgery. Lumbar Total Disc Replacement (LTDR) is a treatment largely unfamiliar to patients, yet it is highly effective, and Food and Drug Administration-approved for treating LDDD. Dr Stephen Beatty, from the Waterford Institute of Technology, wishes to bring LTDR to the attention of patients and surgeons to improve LDDD treatment.

The lower back is home to the lumbar region of your spine, it consists of five bones (vertebrae) with spinal discs slotted in between. Acting like mini cushions, the discs provide support for the joints of your spine. Each disc is like a jammy dodger, it has a tough outer ring (the annulus) and in the middle is a jelly-like substance (the nucleus pulposus). Your lumbar spine is constantly in motion and carries a lot of weight putting pressure on your discs. In lumbar disc degenerative disease (LDDD), the discs break down causing a huge amount of pain. One way your discs can misbehave is known as disc herniation. This is where the outer tougher ring bulges or cracks allowing the jelly-like centre to herniate or extrude through the outer ring. This can cause sciatica – excruciating pain caused by irritation to the sciatic nerve.

Sciatica as a result of disc herniation can improve with nonsurgical approaches, resulting in good or excellent

outcomes in 85 – 90% of cases; surgery is reserved for patients with neurologic deficit or unbearable pain.

SURGICAL STANDARDS

Two standard surgical approaches are available for people with LDDD, one of these is discectomy. During a discectomy, the leaky part of the disc is removed, aiming to relieve some of the pressure on the sciatic nerve and reduce the pain. Discectomy has shown to be effective in some patients but not in others. Another problem with this treatment is that it doesn't fix the disc, so patients can end up having multiple disc herniations requiring multiple rounds of discectomies.

Fusion or arthrodesis is the other standard treatment for LDDD. This does what it says on the tin – it fuses the vertebrae together. The idea behind this is that it removes the disruptive disc and stabilises the vertebrae. This treatment is highly controversial with some healthcare practitioners advocating for the procedure while others cannot conclude its superiority to a conservative (non-surgical) approach. There is little evidence supporting lumbar fusion for patients with recurrent disc herniation and there is

a general consensus that fusion can cause degeneration to adjacent segments, known as adjacent segment disease.

LUMBAR TOTAL DISC REPLACEMENT

Lumbar Total Disc Replacement (LTDR) relies on the simple fact that discs do not have or need a blood supply to do their job. The diseased disc can be replaced with a lumbar artificial disc (LAD), relieving the patient of sciatica, reducing the risk of adjacent segment disease and allowing the patient to maintain the normal physical movements of the spine. This sounds like a breakthrough, so what's the problem?

The clinical use of LADs in LTDR has been somewhat frustratingly slow and steady. The first LAD, a steel ball, was implanted in the 1960s. Complications after surgery prompted refinements of the technique throughout the 1990s and early 2000s. Encouraging results at the end of the 1990s, emerging from small amounts of evidence, paved the way for LTDR, resulting in the uptake of the procedure by many spinal surgeons and medical device companies. Due to its complexities and technically demanding nature, spinal surgeons continue to adopt LTDR; but slowly.

To date, the most successful LAD is ProDisc-L, based on a ball and socket principle made with cobalt and polyethylene. It has been rigorously tested in clinical trials with astonishing results. In 2007, the US Food and Drug Administration (FDA) compared outcomes following LTDR (161 patients) verses fusion treatment (75 patients) in a randomised,

Due to its complexities and technically demanding nature, spinal surgeons continue to adopt LTDR; but slowly.

controlled trial. The researchers found after two years the LTDR group fared better in terms of pain, patient satisfaction and range of movement when compared to before surgery and when compared to the fusion group. At five years post LTDR, these observations were maintained. Interestingly, this study wasn't designed to show a difference between these two techniques, its intention was to demonstrate that LTDR wasn't worse than the standard fusion treatment (these are called noninferiority trials and are

often conducted on new treatments). Since the publication of this study, alleviation of symptoms has consistently been reported in studies of LTDR with ProDisc-L, including lower risk of adjacent segment disease.

Following this research the International Society for the Advancement of Spine Surgery (ISASS) educated patients, health care providers, insurers and many others on LTDR. In 2015, ISASS released a policy statement saying that LTDR represents

Sciatica as a result of disc herniation can improve with nonsurgical approaches.

Lumbar disc degenerative disease causes the discs to break down and can cause huge amounts of pain.

Lumbar Total Disc Replacement can allow the patient to maintain the normal physical movements of the spine.

a proven technique and a well-tested treatment that must be accepted for the benefit of patients because it should lead to better outcomes and fewer complications than fusion.

IT'S COMPLICATED...

Despite this positive statement from ISASS, uptake of LTDR by surgeons has been slow. This is largely due to LTDR being an incredibly technically challenging procedure. Years of research has shown that optimum placement of the LAD is essential for successful outcomes. For example, the risk of developing facet arthrosis (limited spinal movement) increases in patients where the disc implant has not been positioned correctly. In the case of ProDisc-L, a study of 42 patients three years after surgery revealed that 37% exhibited signs of facet arthrosis verses 63% who did not. It was revealed that misplacement by a five degree margin was the cause of facet arthrosis.

Although LTDR has some complications relating to incorrect positioning, the outcomes of successful LTDR are far superior to fusion for the treatment of LDDD. Chronic pain can cause depression, social isolation and work disability; evidence shows improved physical capability following ProDisc-L implantation. It's unsurprising that successful LTDR has a positive impact and improves a patient's quality of life.

...AND CHALLENGING

LTDR has survived a difficult introduction to the spinal surgical community but it is now, albeit slowly, gaining acceptance. The pace of uptake can be accounted for by the logistical challenges faced by spinal surgeons who wish to introduce LTDR into their clinic.

It's unsurprising that successful LTDR has a positive impact and improves a patient's quality of life.

Imagine you are a spinal surgeon wanting to introduce LTDR as a procedure in your clinic. First, you must train in a centre of excellence for LTDR because it's a new, challenging protocol, and you must ensure a competent colleague does the same (you also have to ensure that someone else is covering your work at the practice in the meantime). Before committing to this training, you should have received a commitment from local health insurance companies that they will support LTDR (without this support, people will likely not choose the surgery as it becomes too expensive, then your training will become redundant). Bearing in mind the FDA has only approved LTDR for the replacement of a single disc, this must also be adhered to unless you persuade the FDA to alter its approval. This a long, difficult and costly process for surgeons and shows just why uptake has been slow.

AWARENESS

If surgeons are struggling to take this procedure on board at their clinics,

where does this leave patients? If a spinal surgeon proposes spinal fusion to a patient with LDDD and fails to discuss other procedures such as LTDR, then that surgeon is not fulfilling his/her duty of care to that patient. Patients who are not told about alternative treatments and are dissatisfied with their fusion treatment are, rightly, upset that they were not informed about LTDR and its proven benefits over fusion. It's important that patients are aware of all treatment options so an informed decision can be made. Surgeons must advocate for their patients, regardless of their opinion of LTDR, and they must therefore discuss the concept of the procedure for patients who may benefit from it.

Spreading the word of LTDR and its superiority over fusion and discectomy to patients and healthcare professionals will lead to a greater awareness, hopefully manifesting in a society where LTDR is routinely offered to patients who will benefit from it.

Behind the Research

Dr Stephen Beatty

E: stephen@ivr.ie T: +00-353-87-9091673 Twitter: [@SbeattyStephen](https://twitter.com/SbeattyStephen)

Research Objectives

Professor Beatty's research interests include cataract and age-related macular degeneration.

References

Beatty, S. (2018). We Need to Talk about Lumbar Total Disc Replacement. *International Journal of Spine Surgery*, 12 (2) 201-240. <https://www.ijssurgery.com/content/12/2/201>.

Detail

Bio

Professor Stephen Beatty suffered unbearable pain following lumbar disc herniation, but subsequent lumbar total disc replacement (LTDR) restored him to good health. Peeved at his original spinal surgeon's failure to disclose the existence of LTDR, Stephen wishes to bring this proven and FDA-approved technology to the attention of patients.

Personal Response

If awareness of LTDR continues to increase, how long do you think it will be before LTDR is a standard treatment?

// Like all innovations, consumer-led demand is key to success. In other words, if patients are aware of LTDR, the spinal surgical community will respond. //