

Evaluating artificial disc replacement surgery

Lumbar artificial disc replacement, also called total disc replacement, is indicated for the treatment of painful lumbar discs. The facet joints, which are paired and in the back of the spine at each disc level, must have little or no arthritic changes in order for the disc to be treated with artificial disc replacement, to minimize the risk of potential postoperative pain due to continued painful facet joint motion.

Current available artificial implants are FDA approved for use in a single painful disc level from L3-S1 (for the Prodisc-L) or from L4-S1 (for the Charite). Multilevel total disc replacement and disc replacement with prior spinal fusion can be done, but these are considered off-label uses (not FDA approved) currently. Patients must have good bone quality (no severe osteoporosis) to be candidates for total disc replacement, and cannot have pre-existing spinal instability in the form of spondylolisthesis (e.g. spondylolisthesis) or abnormal curvature of the spine (e.g. scoliosis).

How is lumbar artificial disc replacement performed?

Currently, artificial disc implants are designed to be placed into the disc space from the front and center position. To get there, the surgical approach is performed anteriorly (from the front), reaching the spine and disc working around the abdominal contents (retroperitoneal) from an incision at or near the front of the abdomen. Working behind the abdominal contents, the spine is reached by moving the major blood vessels that bring blood to and from the legs off to the side. These vessels are normally found directly on the front surface of the spine, and must be moved and protected in order to work safely on the spine. Because of these needs, a vascular or general surgeon commonly acts as co-surgeon with the spine surgeon during anterior spinal procedures such as total disc replacement.

Anterior interbody spinal fusions are commonly performed through this same approach.

What artificial disc implants are currently available, and what are their differences?

The Charite artificial disc (Depuy Spine) was the first implant approved for lumbar disc replacement in the USA. It received approval by the Food and Drug Administration (FDA) for use in October of 2004. The Prodisc-L (Synthes Spine) has just recently received FDA approval (August 2006) and is just now being used clinically outside of the FDA research study. Both implants rely on metal-plastic (polyethylene) bearing surfaces.

- The Charite disc implant consists of three separate implant components, with an un-attached biconvex polyethylene central core between two metal concave implants attached to the bony endplates. The plastic center is free to move between both endplates, and moves in and out as the spine bends forward and back.
- For the Prodisc-L disc implant, the convex polyethylene component is fixed directly to the lower metal endplate component and articulates with the concave upper metal component like a ball-and-socket joint. The Prodisc implant is considered more intrinsically stable (“semi-constrained”) than the Charite design (“non-constrained”).

Two newer implants, not yet available clinically but well into their FDA trials, utilize all-metal constructs with metal-on-metal bearing surfaces and ball-and-socket configurations. These are

the Maverick disc (Medtronic) and Flexicore disc (Stryker Spine). A number of other artificial disc implants are less far along in development and the FDA approval process. The Maverick clinical trials were done at Hughston Orthopedic Hospital and are awaiting FDA approval.

Do artificial disc implants restore normal spinal mobility?

Normal disc motion in flexion and extension is quite complex. While total disc replacement is designed to leave the disc space mobile to some degree, it does not replicate “normal” spinal motion per se. Each implant design produces different motion patterns. It is unclear at this time if one specific motion is more important than another to maintain or simply if it is important to maintain *some* type of motion in order to lessen the stresses seen at the adjacent discs (as happens with fusion surgery). There have been some reports that patients who have had artificial disc replacement surgery have accelerated posterior facet joint degeneration, and this is felt to be due to the abnormal motion provided by the artificial disc. It is too soon in the clinical experience to say whether or not this phenomenon is real and if it will become a clinical problem.

Does artificial disc replacement provide better relief of pain than spinal fusion?

The clinical studies which have provided evidence for the benefit of the Charite and Prodisc lumbar disc implant are called ‘non-inferiority’ studies. That means, as requested by the FDA, the studies were designed to show only that artificial disc replacement is *not less effective* than spinal fusion. This type of study requires fewer patients than trying to prove that artificial disc replacement is in fact *superior* to spinal fusion. The data provided by these studies do support the claim that artificial discs provide results that are not inferior to fusion surgery, but it cannot yet be determined that artificial disc replacement provides a better result.

What are the potential complications of the anterior (front) approach used for artificial disc replacement or anterior spinal fusion?

For artificial disc replacement and anterior spinal fusion, the spine is approached from the front, with an incision near the belly button. Complications associated with this approach to the spine include injury to the major blood vessels that bring blood to and from the legs with significant bleeding, injury to the tubes which move urine from the kidneys to the bladder (ureters), and injury to the small or large intestines.

In males, an additional potential complication called “retrograde ejaculation” exists, occurring in 2 to 5 % of males. With this complication, patients have normal erections and penile sensation and feel normal orgasms, but do not ejaculate. Instead, with orgasm, the semen moves into the bladder and is later urinated out. This makes having children by natural means difficult if not impossible, and males who are possibly interested in having children in the future are encouraged to bank sperm for later use if needed.

These risks are all significantly higher with revision anterior approaches to the spine.

What are the potential complications associated with the artificial disc implants?

Early implant complications include migration of the metal endplates or the central plastic core. This is an uncommon occurrence, and is usually related to problems with initial implant positioning or unrecognized instability of the spine. If this occurs, immediate revision with replacement of the components or conversion to a spinal fusion is the treatment of choice.

Rarely, the implant can fracture the vertebra upon insertion or the vertebra can fracture in the postoperative period. If this occurs, brace immobilization may suffice or revision surgery with possible conversion to a spinal fusion may be needed.

Late complications may include:

- Collapse of the implant into the bone (subsidence), which may limit implant movement.
- Eventually, the implant may wear out, and require revision or conversion to a fusion. Longer-term (10-20 years following surgery) studies from Europe indicate that wearing out of the artificial disc implant is uncommon.
- Late infection is a very rare complication, with only 2 to 3 cases reported in the medical literature. Treatment with antibiotics may suffice, but removal of the implant and conversion to fusion may be needed.

Does artificial disc replacement prevent the development of adjacent segment disease?

The long-term potential benefit of maintaining spinal motion with artificial disc replacement is believed to be less degeneration and problems with the surrounding discs. However, this is only a theoretical benefit, as no good long-term medical studies have been done (these procedures and devices are too newly available). Only after a longer follow-up time and additional medical studies will we know if this believed benefit is real.

Which is better, artificial disc replacement or spinal fusion?

The potential benefits of artificial disc replacement, including retained mobility and limiting stress on the adjacent discs, must be weighed against the potential for wearing out of the implant over time and the unknown future of the mobile facet joints and other possibilities.

Nothing can replace a full and frank discussion of all the surgical and non-operative options with your surgeon, or multiple surgeons, as well as discussing the risks of any spinal fusion or artificial disc procedure recommended.

Consider also the experience of the surgeon with artificial disc replacement and anterior spinal surgery in general when choosing a surgeon. Few surgeons may have vast experience with total disc replacement at this point in time, but the surgeon should be experienced with anterior spinal surgery in general (including an experienced access surgeon as part of the team) before performing artificial disc procedures.

To find out if artificial disc replacement is right for you contact a Hughston Spine Center physician at 1-866-HUGHSTON.