

# **Total Disc Replacement**

## **What is it?**

The replacement of a lumbar intervertebral disc with a mechanical device made of metal or metal and plastic which allows for motion of the segment to continue after complete removal of the disc.

## **History**

About twenty years ago European surgical specialists, who had been the original inventors of total hip and total knee joint replacements, began to experiment with total replacements of the lumbar discs. The problem with spinal fusion, as a treatment for disabling back pain, is that it robs the lumbar spine of some movement and leads to progressive early wear and tear of nearby discs. Instead of stiffening the spine, the total disc replacement intends to preserve motion. The disc replacement operation is done through an abdominal approach because the disc cannot be completely removed through the back as the spinal nerves are in the way. The abdominal organs and the main blood vessels lying on the front of the spine are moved aside allowing the disc to be removed and the artificial disc to be implanted.

Early results led to some serious complications as the artificial disc sometimes slipped forward, compressing and damaging the aorta and vena cava carrying blood to and from the legs. Consequently, in the first four or five years significant changes were made before a more satisfactory prosthesis was developed.

It is about 20 years since the first satisfactory disc replacement operations were performed and so we now have some information about the life expectancy of the metal and plastic device. Just as total knees and hips wear out, some of the total discs have worn out, initially as a result of failure of the plastic component. This has led to new designs with metal on metal total disc replacements which don't have any plastic at all.

## **American Experience**

Following the publication of a fourteen-year follow up from France in 2000 the Food and Drug Administration was asked by the European manufacturers to allow a multi-center trial to be carried out in the United States. At the end of two years this has been completed and FDA approval has now been granted for more widespread use of these devices. Only one, the French Charite', has been approved at the moment and surgeons who want to implant these artificial discs are required to attend workshops and labs to learn how to do the operation on cadavers before they are allowed to operate on patients.

## **Who is it for?**

The best candidates to receive a disc replacement are those patients who have pain coming from a disc without the development of severe arthritic changes. The replacement of the painful disc then leaves the joints and ligaments free to move without pain. If there are very severe arthritic changes of the whole segment and pain is coming from the facet joints as well

as the disc, clearly the operation will not work, as the pain will still continue to be disabling. Patients for whom abdominal surgery would be dangerous are also not candidates. Patients with many painful discs do not qualify as the FDA has only approved this procedure for one or two level implantation.

## **What is the European Experience?**

A review article is published in the European Spine Journal for the end of 2003 in which 9 case series involving 411 patients were reviewed. This means that on average there were less than 50 reports in each paper. Good and excellent results were reported in 50-81% of the patients, but anything from 3 to 50% had complications. That means that from 20-50% of the patients did not do very well and a number of the patients who failed had to be converted to a fusion. None of these were controlled trials and it seems most likely that patient selection was very patchy. In one of the studies a quarter of the patients went on to spontaneous fusion even after having a total joint placed in the disc space.

Can a spinal fusion be taken apart and converted to a disc replacement? No, but the surgeons in Europe have reported the use of total disc replacement next to spinal fusion segments. This might mean that a combined procedure using fusion for profound degenerative change with total disc replacement for less destructive change could be performed alongside each other.

## **Where does this leave us?**

None of that represents very good news. Almost all of these reports are based upon the oldest of the total disc replacement designs, which is the only one that has been approved for use in the United States. The only device available in America, the Charite' disc, is based upon 1980's technology using a metal and plastic interface. The plastic is a thin wafer between two metal plates and failure of the plastic insert has been responsible for a lot of the problems. The good news is that there are three newer designs with fewer problems, which have yet to be approved for use in the USA. Some are metal on metal and are designed to prevent dislocation or misplacement of the components. They are not likely to be released for use in the USA for 1-2 years.

While the American reports of experience with the Charite' design have relatively few complications, the total number implanted is only a few hundred and the follow up is only 2 years. Matched patients who have had spinal fusions carried out, at the end of 2 years, have almost identical satisfaction with their operation and we know that it will be 10-15 years before they begin to develop complications at the next segment. It may be much less than 10-15 years before complications develop with the current brand of total disc replacement that is available. It is strongly recommended that progress in TDR technology should be watched, but wait for the approval of newer designs.

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