Since the October FDA approval of the Charite' artificial disc, thousands of patients with severe back pain are evaluating artificial disc replacement. I sifted through some of the tricky questions the patient community have (Nov-Dec 04) and posed them to the top ADR (artificial disc replacement) doctors at from the Texas Back Institute. Below, you can read the replies to the patients' questions from M.D.(s) Stephen H. Hochschuler, Scott L. Blumenthal and Richard D. Guyer.

1. **Patient community**: "What are the major criteria that U.S. doctors use to assess and qualify the selection of a patient for ADR? In addition, how does a patient know when and if they are a good candidate for ADR?"

   Dr. Hochschuler: An ideal candidate is one who has had low back pain with minimal leg pain for longer than 6 months, which has not resolved with all appropriate conservative therapies. A patient needs to be evaluated thereafter by a qualified spine surgeon.

   Dr. Blumenthal: Chronic incapacitating low back pain from Degenerative Disc Disease is the main criteria that United States' doctors use to assess and qualify the selection of a patient for ADR. After careful consulting with a qualified surgeon, and after a patient has tried extensive non-operative methods, a patient can begin to explore the possibility of being a candidate for an ADR procedure.

   Dr. Guyer: In general, patients have to have had debilitating back pain for at least 6 months, which has been unresponsive to extensive conservative therapy; which includes anti-inflammatories, active core stabilization physical therapy, chiropractic, and injections. They should have back pain that equals or is greater than leg pain and should have no evidence of instability or osteoporosis.

2. **Patient community**: "There seems to be an increasing variety of arthroplasty options available for treating patient today. Some patients have genuine concerns about the biomechanical differences between several different artificial disc designs (e.g. constrained vs. unconstrained) To what degree should a patient inform themselves about the technological differences between devices?"

   Dr. Hochschuler: It is always worthwhile to be educated in all options. A great website for patient education is www.spine-health.com. However, the only FDA approved lumbar artificial disc as of this writing is the Charite.

   Dr. Blumenthal: At this point, the differences between constrained and unconstrained designs are purely theoretical. Until there are extensive comparative studies done, no clinical differences between the two can be addressed.

   Dr. Guyer: All the present discs are first generation discs. While there are variations among them, they are not significant and are more theoretical. There are situations where Grade 1 spondylolisthesis, an instability pattern of a mild degree, may be better treated with a more motion limiting ADR. The Charite is an unconstrained device and is not suitable for instability patterns. For that matter, none of the others has been proven safe either, but may be on a theoretical basis.

Richard Longland, ADRSupport.org: The patients from the ADRSupport discussion board come from a wide variety of geographies, backgrounds and health conditions. Unfortunately, one common issue is that patients get "stuck" in a prolonged and complicated diagnostic stage where there seem to be more questions than answers. Here are a few tricky questions that several people are dealing with presently:

3. **Patient community**: "With a badly degenerate disc (i.e. marked loss of height and/or desiccation) how questionable is a negative pain response to discography particularly when discogenic pain remains following ADR surgery to adjacent levels? Despite a negative pain response with discography, how diagnostically significant is a positive dye distribution (dye not held by the disc but leaks immediately into surrounding tissue)?"

   Dr. Hochschuler: The only worthwhile discographic finding for an operative indication is a positive concordant pain response on discography. We all have degenerative discs, which often times are not painful, and therefore not candidates for surgery.

   Dr. Blumenthal: Discography remains a controversial test but it is still the most specific indicator of pain. Studies continue to be done on the different responses to discography. In the FDA study, discography was used to determine which discs receive the Charite.

   Dr. Guyer: These are tough questions and must be dealt with on an individual basis. Because we are dealing with a diagnosis that is sometimes difficult to make, we must rely on as many of these tests to identify the "pain generator." If a discogram is negative, it may be due to inadequate pressurization, or procedural technicalities. If one operates in the face of a painless abnormal disc, the results will be less predictable than if it reproduces the pain. In the Charite study in which we used discography, 88% of the patients were happy with the surgery though they were not pain free. On the average, they had 50% reduction of their pain.

4. **Patient community**: "How risky is a subsequent anterior spinal surgery to implant additional artificial discs at adjacent levels?"

   Dr. Hochschuler: To operate at an adjacent level is far easier than at the same level, nevertheless this should primarily be tackled by a very experienced approach surgeon who has done hundreds of previous approaches. Such a vascular approach surgeon is often associated with a busy spine practice like the Texas Back Institute.

   Dr. Blumenthal: The risk attached to subsequent anterior spinal surgery really depends on the extent of previous surgery. I have already implanted a Charite at an additional level in a patient who had previously undergone ADR. With the aid of an experienced access surgeon, procedures like this can be done with few risks attached.

   Dr. Guyer: If the surgery is performed by experienced access surgeons, either general or vascular surgeons, the surgery is safe. Our access surgeons have each done more than 3000 of these approaches so our complication rates are extremely low. The most serious complications are vascular injuries.

5. **Patient community**: "Are there any indications to date that ADR will not protect against next level degeneration if more than one level has been implanted? Are there any studies that go beyond the two year mark that shows the prevalence of next level degeneration in patients with single or multiple fusions?"

   Dr. Hochschuler: The analysis is adjacent level degenerative changes after a total anterior disc replacement has not yet been thoroughly evaluated.

   Dr. Blumenthal: There are European studies that do go beyond the 2-year mark that show no indications for degeneration adjacent to an implanted disc. With fusion, you have a 15-35 percent increase in degeneration in adjacent discs.

Dr. Guyer: We are just now beginning to see 10 and 11-year follow-up of the Charite from Europe. There is also a small group of ProDisc. It appears that there is about a 10% reoperation rate most of which were for continued pain by either to carrying out a posterior fusion or in some cases of disc replacement exchange. There is very little data showing a significant level of degeneration at the next level. It will take years of follow-up to determine if the theoretical advantages are a reality. Clearly, however, there are many biomechanical studies showing the increased stress with fusion on the next level and the lack of such with disc replacement. There is a great debate among spine surgeons arguing that next level degeneration is natural history versus increased stresses. I believe it is due to increased stress as I see many of patients 5-15 years out from fusions who had normal discs at the unfused level only to degenerate them years later.

Richard Longland, ADRSupport.org: Thank you, doctors, for taking the time to answer these questions. We look forward to speaking with you again in the future.

The Texas Back Institute can be reached at 800-247-2225 or through their web site at: http://www.texasback.com/.

Disclaimers

The content contained within this document and on this web site is intended solely for the information of the reader. It should not be used for treatment purposes, but rather for discussion with the patient's own physician(s).

No guarantee is given regarding the accuracy, reliability, or completeness of the information provided here or by following links from this or any other page within this site, and under no circumstances will the author or service provider be liable for any loss including but not limited to direct or indirect damages caused by using the information.