

## Unintended Behavior of Artificial Discs Will Cause Problems

In the *Curve/Countercurve* article "Controversies in Surgical Treatment for LBP: Fusion or Disc Replacement?" (*SpineLine*, March/April 2004), my name and article (with co-authors) are often mentioned and quoted, to which I would like to respond.

The percentage of problems following disc arthroplasty seen in the Netherlands is very difficult to deduce because all the operations were done in a neighbouring hospital from 1989 on, or in a private clinic in Germany from 2000 on. Probably 800 to 1000 Dutch patients have been operated with a Charité disc, a truly huge human experiment on its own. The group of

problematic patients we have seen has grown quite rapidly to 55 by now, of which one patient was operated on in Belgium. Patients with complications are also seen by other spine surgeons elsewhere in the Netherlands. Our personal series is indeed around five percent of the total operated group, but taking into account the complications seen elsewhere (and the painful patients not being seen anywhere), the total percentage will be 10% at least. This percentage will certainly grow with longer follow-up. These patients represent the most disabled group of patients that I personally have seen in 24 years of spine practice. VAS scores are almost always 8 and higher and all activities are severely impaired. Sleep is severely disturbed, sitting and standing is almost impossible and walking is mostly limited to around 30 minutes or less.

Dr. McAfee states that osteolysis and inflammatory reactions have not been described with the Charité disc replacement. This is not correct. In my article in the *Journal of Spinal Disorders* (2003;16:369-383), I describe a patient with osteolysis (intraosseous cystic phenomena), massive sclerosis around the prosthesis and flattening of the polyethylene (PE) core. In his response to the arguments of Dr. Yu, Dr. McAfee denies that these changes point to PE wear and calls it a degenerative cyst. In a motion segment with a flattened prosthesis, a degenerative cyst to my mind can only arise as a consequence of PE wear. Because the patient, although in great pain, refuses a reoperation up to now, definite proof in this case is lacking.

However, in two recent retrievals of a

Charité disc after nine and seven years respectively, definite PE wear is seen. In the nine-year follow-up, a well-placed prosthesis at L5-S1 with an adequate size is severely worn out and the surrounding fibrous tissue is filled with many inflammatory cells and giant cells, and loaded with polyethylene particles. In the seven-year follow-up patient, the severely subsided prosthesis in L4-5 was surrounded by very sclerotic bone and some fibrous tissue with much less giant cells and PE particles. This prosthesis showed obvious yellowish discoloration and, on one side, flattening of the peripheral ring with internal cracks. I showed both retrievals in the recent NASS precourse meeting on the "Critical Evaluation of Emerging Technologies," headed by Drs. Mathews and Bertagnoli.

So now, convincing evidence exists that PE wear is an important issue to consider and is more or less equivalent to the changes in total hip and knee joints. I have one patient awaiting revision surgery with massive osteolysis and breakage or fragmentation of the prosthesis, operated on in 1999. Whether different ways of packaging and sterilization of the Charité prosthesis really makes a lot of difference remains to be seen. This change of packaging and sterilization was instituted in 1997, as was said in a reaction by Dr. McAfee.

Another issue is facet joint degeneration. We saw this in all our posterior reoperations (13 in a group of 55 Charité problem patients). Probably this is because of overload of these joints as a consequence of removal of the anterior longitudinal ligament and annulus fibrosis, and placement

of a totally unconstrained prosthesis, especially in axial rotation. Thus an axial rotational instability is created and consequently the facet joints will be the only restrictor of this movement and will wear out with time.

It can be argued that acceleration of adjacent degeneration is instituted by replacing a degenerated disc with an artificial disc that gives unphysiological motion and influences the adjacent levels in a negative way. In any case, the claim of preventing adjacent degeneration in artificial disc surgery is far from substantiated. The randomized clinical trials in the United States should give an answer in that respect in the near future.

The ongoing debate on this topic is very important regarding the problems that will be seen with longer follow-up and are, in fact, seen now in the Netherlands and probably other European countries. Seeing them and reporting them, however, are two different matters. In my opinion, we will see an epidemic of new back pain problems caused by unintended behavior of artificial discs in the near future. We will have to revise and retrieve many worn-out or otherwise malfunctioning artificial discs, which will expose these patients and their surgeons to great risks. Time will tell whether this negative opinion and the negative experience will be shared by others in the upcoming years and whether refinements and usage of new materials will make short- and long-term results better.

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