

Lumbar Disc Arthroplasty: A Critical Review

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Spinal fusion for the treatment of chronic low back pain due to degenerative disease at one or two levels has been shown to improve outcomes compared with the natural history of patients with such low back pain.^{7,19} Although the general results of fusion are good, not all patients achieve significant pain relief, and some proportion of patients develop pain caused by further degeneration at levels not treated during the initial operation. Biomechanical studies have clearly indicated that stresses are increased within motion segments adjacent to fused (or otherwise stiffened) segments.^{12,18,29} Artificial discs have been developed for implantation after the removal of a degenerated disc. These devices allow some motion to occur at the operated motion segment, and the use of these devices decreases the stress seen at adjacent motion segments.¹⁰ It has been hypothesized that the use of these devices will decrease the incidence of degeneration at adjacent segments caused by fusion, and, therefore, improve patient outcomes.

Artificial discs are extremely attractive to the surgeon and to the “internet informed” patient who desires relief of pain with preservation of motion and with potentially decreased risk of later problems. These devices are extremely attractive to the manufacturers and investors in the manufacturers because they are anticipated to assume a large portion of the of the fusion implant market, representing billions of dollars of revenue. However, these devices are expensive, and because they are new, do not have an established long-term track record for safety. It is the authors’ bias that the widespread application of new technology should be reserved for technologies that provide improved outcomes, enhanced safety, or, alternatively, lowered cost with equivalent safety and outcomes for patients. The purpose of this review is to examine the evidence supporting the efficacy of these implants as a durable treatment for chronic low back pain caused by degenerative disease of the lumbar spine.

ADJACENT SEGMENT DISEASE

Degeneration of the intervertebral disc is an inevitable consequence of staying alive beyond youth. Because degeneration largely occurs in the population beyond childbearing

age, there is no evolutionary pressure for the development of a more durable solution to the phylogenetically unique biomechanical stresses faced by the discs caused by our upright posture and bipedal ambulation. It is widely accepted that disc degeneration is caused, at least in part, by the gradual deterioration of tissues because of these constant physiological stresses. Increasing these stresses would logically be assumed to increase the rate of degeneration.

It has been well established that immobilization of a spinal motion segment increases the motion and stress at adjacent spinal motion segments. For example, Weinhoffer et al.,²⁹ using a cadaver model, demonstrated that intradiscal pressures are increased in flexion when adjacent segments are immobilized. Chow et al.⁶ found that not only was intradiscal pressure increased by adjacent segment immobilization, but also that segmental motion was significantly increased. These changes were further exacerbated by the immobilization of multiple motion segments.⁶ Rao et al.¹⁸ performed a similar study using calf spines and found similar results. Kim et al.¹² used a finite element analysis and determined that decreased motion at the L4–L5 level would be anticipated to lead to degeneration at the L3–L4 level. These studies and others unequivocally support the hypothesis that fusion exacerbates stress and motion of adjacent segments. Furthermore, implantation of an artificial disc seems to ameliorate these biomechanical changes.¹⁰ The next logical question is whether the biomechanical changes associated with fusion lead to clinically relevant degeneration of the adjacent motion segments?

A definitive answer to this question is not currently available in the literature. However, there have been a number of studies performed that provide circumstantial evidence indicating that these changes are probably not clinically relevant. For example, Axelsson et al.¹ performed a study using radiographic stereophotogrammetry in patients treated with lumbar fusion. Stereophotogrammetry is a procedure in which metallic beads are implanted into the vertebral bodies, providing fixed reference points so that precise measurements of movement can be made on dynamic films. The accuracy is significantly better than that achieved with the use of plain films, where the standard error is usually reported in the range of 3 to 5 degrees.¹⁵ The investigators studied the motion of adjacent segments in six patients who had clinically and radiographically solid fusions 1 year after

the index procedure.¹ They found that motion at the adjacent segments was increased in two patients, decreased in two, and unchanged in two. Furthermore, change in motion did not affect clinical outcome.¹ The results of this study seem to indicate that the effects on mobility of a fused motion segment are not as predictable *in vivo* as *in vitro*.

In 1978, Frymoyer et al.⁸ reported their experience in a group of 207 patients followed for at least 10 years (mean, 13 yr) after lumbar disc surgery. One hundred forty-three patients had been treated with fusion, and 64 had not. Overall, there were no significant differences between the groups at long-term follow-up. Because of the retrospective nature of the study and selection bias for fusion, no significant conclusions regarding the efficacy of one procedure over the other can be drawn. However, it was noted that although radiographic signs of adjacent segment degeneration were more common in the fused group, there were no clinically significant consequences. Indeed, fewer (30%) of the fusion patients required further surgery as compared with patients treated without fusion (37%).⁸

Van Horn and Bohnen²⁷ followed 16 patients treated with an anterior lumbar interbody fusion (ALIF) for a minimum of 16 years (range, 16–20 yr). They obtained follow-up x-rays and compared degenerative changes at the adjacent level with those noted in a control group of age- and sex-matched patients who had never been treated with fusion nor been treated for low back pain. They found that there were no significant differences in the radiographic appearances between the groups.²⁷ They interpreted their results as indicating that ALIF did not influence the development of adjacent segment disease and that such radiographic findings were probably clinically insignificant.

Seitsalo et al.²² studied a group of young patients who were treated for isthmic spondylolisthesis (mean age at treatment, 13.8 yr). One hundred forty-five patients were treated with surgical fusion and 82 were followed conservatively. All patients were followed for a mean of 16 years. These authors found that the incidence of radiographic degeneration at the levels adjacent to the listhesis was not influenced by the presence or absence of a fusion. Furthermore, when such changes were noted, there were no correlations between the number of degenerative discs, the severity of degeneration, and the subjective complaints of low back pain.²² Hambly et al.¹¹ studied a cohort of 42 patients who were treated with posterolateral fusion for a variety of indications over a mean follow-up period of nearly 23 years. They assessed the incidence and severity of degenerative changes at the levels immediately adjacent to the fused motion segment and at levels remote from the fused motion segment. They found no differences in the degree of radiographic degeneration between the adjacent and remote segments. Furthermore, when they compared the incidence of such changes in their study population to the incidence of degenerative changes at those

particular spinal levels in a control population who had never been treated with fusion, they found no differences.¹¹ Finally, they could not detect any clinical significance of the degenerative changes when they did occur.

Kumar et al.¹³ studied a group of 28 patients who had been treated with lumbar fusion 30 years previously and compared them with age- and sex-matched controls who had undergone lumbar disc surgery without fusion during the same time period. They found that, although the fusion group had a higher incidence of radiographic changes at adjacent segments, functional outcomes were not affected by such changes when measured by reliable and validated functional outcomes measures, such as the short form 36 (SF-36) or Oswestry Disability Index (ODI).¹³ These studies have failed to demonstrate that the presence of a fusion contributes to clinically relevant adjacent segment degeneration, despite decades of follow-up.

FUSION VERSUS LUMBAR DISC ARTHROPLASTY

When a new technology is developed for the treatment of a particular disease process, it must be compared with the current “gold standard” treatment for that disorder. Although no true gold standard exists for the overall treatment of low back pain caused by degenerative disease, fusion is the surgical gold standard. Several theoretical differences between fusion and disc arthroplasty should be considered. Fusing a motion segment eliminates motion across the segment and, theoretically, should eliminate pain deriving from any of the known pain generators in the lumbar spine, including the disc space, facet joints, and associated structures. Performing a disc arthroplasty does not eliminate motion, and such a procedure would not, in general, be expected to eliminate pain from sources other than the disc space itself. Therefore, patients with pain thought to arise from the facet joints are probably not good candidates for the procedure. Similarly, although fusion of a degenerated segment is, to some extent, simply an acceleration of the degenerative cascade, arthroplasty can potentially reverse loss of motion caused by the degenerative process. Therefore, patients with collapsed disc spaces and without significant segmental motion are probably not candidates for the procedure. Finally, as opposed to fusion, disc arthroplasty is not a stabilizing procedure. Therefore, patients with deformity of the spine, particularly translational deformity, are probably not good candidates for the procedure.^{2,3,30}

Because of these biomechanical issues, patient selection criteria for the use of disc arthroplasty in the randomized trials have been quite strict. For example, in the Charite (Depuy Spine, Raynham, MA) study, patients were excluded if there was evidence of spondylosis or facet arthropathy.³ Patients were also excluded for spondylolisthesis greater than 3 mm, stenosis, or age older than 60 years. Similarly, the

Prodisc (Spine Solutions, New York, NY) study, patients were excluded for age older than 60 years, neurological deficit, stenosis, spondylolisthesis greater than Grade 1, and facet arthropathy.³² After reviewing his results in European studies, Bertagnoli and Kumar² defined the ideal patient for disc arthroplasty as having a single level of disease, greater than 4 mm of retained disc space height, no evidence of osteoarthritis of the facet joints, and intact posterior elements. In short, the ideal patient for disc arthroplasty is young, has an almost normal spine, has no neurological deficits, and has disease defined by magnetic resonance imaging scan and discography at a single level. Several spine surgeons have pointed out that such patients are exceedingly rare. Simmons found that, of 252 patients operated on for disorders of the lumbar spine, 6.3% were potential candidates for disc replacement based on the Charite exclusion criteria and only one patient was thought by the author to be a good candidate for disc replacement.²⁴ In this author's opinion, the population of patients deemed ideal for disc arthroplasty is a population of patients who are often well treated without surgery. In the absence of neurological compression, evidence of instability, disc space collapse, or even significant disc degeneration, results of fusion are likely to be equivocal at best.

Even if we can identify a population of patients who are surgical candidates and who are candidates for disc arthroplasty, is arthroplasty a better alternative than fusion? The Charite study compared disc arthroplasty to stand alone ALIF using BAK (Zimmer Spine, Minneapolis, MN) cages.³ The selection of this fusion technique has been criticized by several authors as being an outdated technology not in current use because of documented high failure rates and better alternatives.^{17,33} To be fair, the BAK cages were the only United States Food and Drug Administration (FDA)-approved interbody device available at the time that the study was designed. Furthermore, the stand-alone ALIF procedure is the procedure most closely related to the disc arthroplasty procedure in terms of approach-related morbidity. However, substantial experience with the use of BAK cages and other devices for stand-alone interbody fusion has been reported, and it is acknowledged that excellent results can be obtained in patients with collapsed disc spaces.^{4,5} Patients with disc space collapse were excluded from the Charite study. Therefore, the results of surgery in the control group would be expected to be mediocre or poor, because this particular procedure is, and was, known to be a suboptimal technique in patients with retained disc space height.

In fact, the results obtained in the fusion group were very poor compared with other contemporary reports of similar fusion techniques. The authors define clinical success as a 25% improvement in the ODI, no device failure, no major surgical complication, and no neurological deterioration. This definition of success is very liberal by modern

standards. The 25% improvement in the ODI is a relatively modest improvement considering the fact that the minimal clinically relevant improvement on the ODI is generally considered to be approximately 20 points and that the mean preoperative ODI score in the series was 50 (thus, a 25% improvement would represent a 12.5 point improvement).³ Using this liberal definition of success, only 46.5% of the control group was thought to have achieved success. This result is abysmal when compared with other series of ALIF in properly selected patients in which success rates in the 85 to 95% range have been reported.^{4,5,21}

The arthroplasty group fared somewhat better than the ALIF group, with a success rate of 57.1%. This success rate, although certainly not inferior to the ALIF group, is really not that impressive given the select patient population and substantial surgical investment. The modest success rate is further tempered by the fact that 72.2% of arthroplasty patients were still using narcotic pain medications at 24 months after surgery, including 64% of those patients judged to have achieved clinical success!³ Return to work rates were relatively poor in both the investigational and the control groups, with absolute return to work rates of 9.2% and 7.4%, respectively (between one-fourth and one-third of patients not working at time of surgery). Although return to work is a multifactorial issue, it is a reliable and important outcome measure in a population that is both healthy and young (the mean age was just younger than 40 in both investigational and control groups).³ In summary, because of the choice of inclusion criteria, control group, and outcomes measures, all that can be definitively stated based on the data presented in the Charite study is that disc arthroplasty results are not inferior to stand-alone ALIF in young, healthy patients who would probably not otherwise be considered for a stand-alone ALIF.

Several other lumbar disc prosthesis are currently under investigation. Results from these studies are currently not available in the peer-reviewed literature. Preliminary publications indicate very similar inclusion and exclusion criteria as used in the Charite study.^{14,26,30-32} A circumferential fusion technique was used as the control, as opposed to a stand-alone ALIF in two of these studies.^{26,30-32} This technique was specifically recommended against in the lumbar fusion guidelines published in 2005 because of higher costs and complications without improved outcomes compared with posterior or posterolateral interbody fusion techniques.²⁰ The results of these studies will hopefully be available for review within the next year. At the present time, it is our opinion that there is no convincing evidence that disc arthroplasty is superior to fusion for the management of low back pain caused by degenerative disc disease. Furthermore, there is no evidence to suggest that the use of lumbar disc arthroplasty has or will have any affect whatsoever on the devel-

opment of clinically relevant adjacent segment disease, the driving force behind the development of the devices.

Earlier in this chapter, the concept that widespread adoption of a new technology should follow the demonstration of improved efficacy, improved safety, or improved costs was presented. At the present time, there is no basis for the claim that these devices provide improved outcomes compared with already available techniques, and these devices are currently much more expensive than fusion alternatives. The manufacturers and proponents of the devices claim that the devices are as safe or even safer than fusion alternatives.⁹ These claims do not make intuitive sense because the dissection and degree of manipulation of the great vessels is necessarily more extensive than in modern ALIF techniques because of the size and geometric constraints of the devices.¹⁷ Furthermore, unique complications occur that have not previously been described in the fusion literature. For example, in the very short time that these devices have been available in even a very restricted fashion, vertical split of the vertebral body, bilateral pedicle fracture, and device migration have all been reported.^{16,23,25} Adjacent segment degeneration has also been observed as a long-term complication of arthroplasty.²⁸ Finally, the future of these devices in vivo with respect to device wear and possible device failure remains unknown at this point in time. We can almost certainly also look forward to new and exciting, unanticipated long-term complications.³³

SUMMARY AND CONCLUSIONS

Lumbar disc arthroplasty may be the most innovative and exciting development in the history of spinal surgery. Manufacturers and proponents cite the ability of these devices to relieve pain while preserving motion at the disc space. The preservation of motion is hypothesized to lower the risk of adjacent segment disease and, thereby, improve long-term outcomes. However, the devices are expensive and their use is associated with the potential for significant complications above and beyond those seen with lumbar fusion. At the present time, there is no evidence to suggest that the use of disc arthroplasty results in better short- or long-term functional outcomes than fusion in properly selected patients. Furthermore, there is little if any evidence to support the hypothesis that adjacent segment degeneration is an important clinical entity. Although the absence of proof is not the same as the proof of absence, greater efficacy must be demonstrated to offset the increased costs and complications associated with these devices. Therefore, these devices require further long-term study in a controlled environment before widespread application.

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