INTRODUCTION:

The Charite III artificial disc replacement was approved for use in the United States in October of 2004 by the FDA. Another similarly designed lumbar disc replacement called the ProDisc II was also approved by the FDA a year later in January of 2006. The purpose of this study was to retrospectively review 29 patients with either the Charite III or the Prodisc II disc replacement surgery and complications.

METHODS:

This is a retrospective review of 29 patients with either the Charite III or the Prodisc II performed. Specifically, patient outcome data in the form of the Oswestry Disability Index (ODI) and the Short Form – 36 (SF-36) were analyzed. The probable sources of pain were also determined based on diagnostic facet and nerve root injections, SPECT bone scans, CT scans, MRI scans, flexion extension radiographs, bone scans, CT scans, MRI scans, flexion extension radiographs, history, as well as physical examination and direct surgical observations when possible.

RESULTS:

All 29 patients were between the ages of 21 and 54, (mean 42 years). Twenty-six patients received Charite III replacements, two patients Prodisc II, and one patient had an Acroflex implanted in Australia. Fifteen patients had one level replaced, ten of which had L5-S1 and five had L4-L5 replaced, and 14 patients had two levels replaced with all being both L5-S1 and L4-L5, except for one patient who had L3-4 and L4-5 replaced. All patients were two years to seven years from their index surgery, except for one who was 16 months out. All patients were consistently on daily narcotics that ranged from a minimum of 20mg of hydrocodone bitartrate to repeated doses of controlled – release oxycodone.

Complications: Facet Compression, Distraction, Fractures And Subsidence

1. Five out of 29 (17%) failures had facet fractures on CT scan. One of these was after a subsequent laminectomy and was considered a post laminectomy facet fracture. Three out of 29 (10%) had bilateral pars fractures, one of which being present at two levels pre-operatively.
2. All 29 patients had either distraction of the facets or conversely compression of the facets due to posterior concentration of stresses. This determination was made by measuring the joint space of at least one set of normal facets of a normally preserved level and comparing it to that of the involved facets. Over-distraction varied from 50% to 100% of the normal disc space as determined by comparing intervertebral disc space height of normal levels to the involved level.
3. Twenty out of 24 (83%) patients had leg pain in addition to back pain yet had no obvious areas of impingement on CT scan. Eight of these patients were sent for diagnostic facet injections and all had some partial relief of the leg pain, but only for the duration of the local anesthetic. Seven out of 29 (24%) had endplate fractures resulting in subsidence with all but one being less than 4 mm of subsidence. In patient 11 the subsidence fracture was approximately 30% of the vertebral body height causing posterior extrusion of the artificial disc replacement polyethylene component.
4. A common clinical feature of all 29 patients was severe back pain.
5. Twenty-four out of 29 (83%) patients also had leg pain with 11 out of 29 (38%) being bilateral. Ten out of 29 (34%) patients have been surgically revised. Of these, three operative revision patients at this institution were contemplating suicide pre-operatively.

Operative Treatment of Failed Replacements

Ten of the 29 (34%) underwent surgical treatment. Patients 20-29 had relief of pain after injection of the involved facets. Patient 22 also had a positive SPECT scan over the area of the superior plate subsidence as did patient 23. Patient 24 had pain relief after injecting the pedicle screws used for her previous fusion when the disc replacement (Acroflex) had been removed. Therefore, her pedicle screws were removed.

Revision Patients

Oswestry Disability Index (ODI), Short Form 36 Physical Health Compiled scores (SF-36 PCS), and Short Form 36 Mental Health Compiled scores (SF-36 MCS) were compiled for all patients treated with revision surgery both before surgery and at nine months post surgery. All of these patients (n=10) were noted at nine months minimum to have radiographic evidence of a consolidated fusion mass, solid hardware without signs of any bone interface loosening, and lack of motion at the fused level(s). ODI scores averaged 36 before surgery and 17.4 after, for a mean improvement of 18.6 (p = 0.006). SF-36 PCS were 24.18 before and 31.58 after, for a mean improvement of 7.4 (p = 0.2). SF-36 MCS were 29.38 before and 46.4 after, for a mean improvement of 17.02 (p = 0.006).

Non-revision Patients

ODI, SF-36 PCS, and SF-36 MCS were compiled at a minimum of one year post disc replacement on ten of the 19 non-revised patients. The ODI scores averaged 36.7, SF-36 PCS 22.31, and SF-36 MCS 29.4.

Comparison of outcomes for revision vs. non-revision patients

Comparison of mean scores for the non-revision patients were not significantly different from the pre-revision scores of the revision patients (ODI: p = 0.9; SF-36 PCS: p = 0.4; SF 36 MCS: p = 0.99). Conversely, the post-revision scores were significantly different from both the pre-op scores in the revision patients as well as the scores of the patients not revised (p < 0.01) with the exception of the SF-36 PCS Score before and after revision (p = 0.2).

DISCUSSION:

All patients presenting with failed disc replacements had ODI and SF-36 scores exhibiting marked disability both physically and mentally. There was a large improvement in all scores in those patients undergoing revision. This difference was statistically significant for the ODI data and the SF-36 MCS (mental), but did not achieve statistical significance for the SF-36 PCS (physical) though the averages were clearly improved in each category. This suggests that the successful objective outcome achieved in the revision patients by our evaluation for a solid fusion post facet excision and distraction or compression of lumbar segment, correlated to patients’ subjective scores. Careful evaluation for the source of pain in these failed disc replacements via the means discussed herein, followed by deliberate surgical intervention to specifically address these sources of pain, appears to offer consistent and significant improvement in the patients we treated.