The Potential Biomechanical Etiology for Lumbar Disc Replacement Failures: Review of 24 Patients and the Rationale for Revision
C Rosen, D Kiester, T Lee

Abstract
The Charite III artificial disc replacement was approved for use in the United States in October of 2004 by the FDA when Depuy Spine, the manufacturer, received their letter of conditional approval. Like all current models of lumbar disc replacements, the Charite may have been based on a faulty design that concluded the center of rotation of lumbar segmental motion was anterior to the spinal canal. As a result, numerous failures began quickly appearing and accumulating as time passed. The authors began seeing increasing numbers of patients who had both the Charite III, as well as the Prodisc II, implanted with poor results and complications. These included not only various fractures and dislocations, but, most disturbingly, patients in severe pain without any seemingly obvious radiographic abnormalities. These events had been either written off as surgeon error, “learning curve,” or an unexplained event not related to device failure. This lack of a logical solution may have been re-enforced with a financial disincentive to find one, given that the design had been accepted, applied, and marketed at great expense to both industry and investors. This manuscript addresses the failures of lumbar disc replacements presenting to the UCI Spine Center in terms of their cause and treatment. The authors discuss the possible reasons and its lack of correction before FDA approval of disc replacements in the U.S. Specifically, the complications presenting to the University of California (UCI) Spine Center were compiled and analyzed. Attempts to determine the probable sources of pain from some of the disc replacements were made by diagnostic testing as well as direct surgical intervention. Ultimately, the concept of lumbar segmental motion was revisited so that the complications were explained. All previous biomechanical models that lead to the current concepts of spinal motion used mathematical assumptions that were well known to be unreliable and erroneous for the small degrees of angular measurement of segmental spinal motion. Additionally, some of the previous findings that are contrary to current assumptions were not considered. As a result, current disc replacements may be inherently flawed in their intended function.

INTRODUCTION
Lumbar disc replacements have evolved from early designs such as the Fernstrom ball over decades in Europe to the current design as represented in the Charite III and the Prodisc II. Their overall goal has been to treat painful degenerated lumbar discs, and has been offered as an alternative to fusion. The Charite was approved for single level implantation for degenerative lumbar disc disease in the U.S. after FDA approval in October of 2004. Since then, thousands have been implanted. A second lumbar disc replacement made by Synthes and called the Prodisc II was later approved in August of 2006 for use in the U.S. Dozens of companies now have either plans or aspirations to market their own disc replacement in order to tap into the lucrative and growing market for spinal care. Low back pain from degenerative discs is a leading cause of pain and disability for adults in this country with over $34 billion in annual health costs. The Charite III and Prodisc II are representative of the general design of all current lumbar disc replacements in terms of center of rotation, which is assumed to be located within the disc space, namely anterior to the spinal canal. The purpose of this design is to preserve motion in the lumbar segment and therefore impart presumed benefits that outweigh presumed disadvantages of fusion. However, numerous types of complications have been documented with lumbar disc replacements. These include facet joint degeneration, unexplained radiculopathy and/or back pain, extrusion of the implant, and fractures. Many of these failures have been described as surgical errors in either...
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placement or sizing, surgical approach errors, inexperience, inappropriate indications, and patient non-compliance. These complications of disc replacement however, cannot be attributed solely to the reasons noted above, but maybe are the result of an inherent design flaw. This critical flaw originates from the assumption that the center of rotation of the normal human lumbar segment is in the disc space. It has been shown as early as 1967, that the correct location of the center or rotation of segmental lumbar motion is posterior to the spinal canal. The objective of this study was to evaluate the authors’ experience with patients presenting with disc replacement failures at the UCI Spine Center and to review the pertinent literature.

MATERIALS AND METHODS
At the UCI Spine Center, twenty four patients presenting with severe pain after disc replacements received at other medical care facilities were retrospectively reviewed.

All patients had radiographs and CT scans obtained after disc replacements. These patient's data were collected by reviewing the charts for radiographic abnormalities on CT scans and x-rays; pain patterns, age; location and number of replaced levels; physical examination when possible; diagnostic injections, revision procedures, results and follow up. Institutional Review Board approval for the study was obtained at the University of California for the retrospective review of these patients. Specifically, complications due to facet compression, distraction, fractures and subsidence are carefully analyzed. Thereafter, non-operative and operative treatment of failed replacements is described.

RESULTS
All twenty – four (24) patients were between the ages of 21 and 54, with a mean of 42, and of these 11 were males and 13 were females. (Table 1) Some patients did not present in person, but only sent in x-rays, computerized tomography (CT) scans, and histories. This is indicated where a physical exam was not performed. Of the twenty–four (24) patients presenting, twenty–one (21) were Charite III replacements, two (2) were Prodisc II, and one (1) was an Acroflex implanted in Australia. Eleven (11) of the twenty–four (24) patients had one level replaced with six (6) of these L5-S1, and five (5) being L4-L5. Thirteen (13) patients had two levels replaced with all being L5-S1 and L4-L5, with the exception of one patient who had L3-4 and L4-5 replaced. All patients were consistently on daily narcotics that ranged from a minimum of 20mg of hydrocodone bitartrate to repeated doses of controlled-release oxycodone.

Table 1

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Level Replaced</th>
<th>Facet Fracture</th>
<th>Distraction</th>
<th>Compression</th>
<th>Subsidence</th>
<th>Radiculopathy</th>
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<tr>
<td>1</td>
<td>30</td>
<td>L4-L5</td>
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<td>Yes</td>
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<td>No</td>
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<tr>
<td>2</td>
<td>35</td>
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<td>40</td>
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</tr>
</tbody>
</table>

COMPLICATIONS

FACET COMPRESSION, DISTRACTION, FRACTURES AND SUBSIDENCE
Five out of twenty four (5/24) failures had facet fractures on CT scan as in Figure 1. One of these was after a subsequent laminectomy and was considered a post laminectomy facet fracture (19). Three out of twenty four (3/24) had bilateral pars fractures with one of these being present at 2 levels pre-operatively. All twenty four patients had either distraction of the facets (figure 2) or conversely compression of the facets (figure 3) due to posterior concentration of stresses. Over-distraction varied from 50% to 100% of normal disc space. Fifteen out of twenty four (15/25) patients had leg pain in addition to back pain yet had no obvious areas of impingement on CT scan. Three 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. Six out of twenty four (6/24) had endplate fractures resulting in subsidence with all but one being less than 4mm of subsidence. In patient 11, pictured in Figure 4, the subsidence fracture was approximately 30% of the vertebral body height causing posterior extrusion of the polyethylene component.
A common clinical feature of all twenty four patients was severe back pain. Nineteen out of twenty four (19/24) patients also had leg pain with ten out of twenty four (10/24) being bilateral and nine out of twenty four (9/24) being unilateral. Five out of twenty four (5/24) patients have been surgically revised. Of these, three operative revision patients at this institution were contemplating suicide pre-operatively due to the pain.

NON-OPERATIVE TREATMENT OF FAILED REPLACEMENTS

In all patients presenting to UCI, a minimum of 6 weeks of physical therapy along with NSAIDS had been already tried prior to presentation at our institution. As noted in Table 1, some patients already had epidural steroid injections (ESI), facet blocks, and in a few cases, facet rhizotomies with only patient #5 noting temporary relief. Four (4) patients underwent diagnostic facet blocks under our care which were successful in temporarily relieving pain. Three (3) of these underwent revision at our institution, and one is currently scheduled for this. All patients remained on daily narcotics for pain control.

OPERATIVE TREATMENT OF FAILED REPLACEMENTS

Our rationale for the surgical treatment was based on three concepts. Firstly, it was postulated that there was a posterior transfer of load that caused compression of the facets and subsequent severe local back pain. Even when the replacements seemed in good position, the lack of any shock absorption as in normal disc motion was thought to add to
this posterior transfer of load. Secondly, in cases where the facets were distracted and the patients had leg pain, the capsular stretch along with traction on the nerve root and dorsal ramus was suspected to be the source of pain. Clinical evidence that support these concepts was the relief of back and leg pain temporarily with a diagnostic facet injection in some patients as indicated in Table 1. Thirdly, the transfer of load posteriorly was thought to be the reason for the “subsidence” of the superior part of the disc replacement into the superior vertebral body. This was considered, as discussed below, to realistically be a fracture of a portion of the endplate. As such, it was thought to be a source of pain, as any fracture would. The observation that it almost always occurred in the posterior third of the vertebral body is consistent with the idea of posterior transfer of load.

The surgical treatment would, therefore, be to address the above concepts. It was felt that the compressed facets, which were often fractured and not healed - namely a non-union - needed to be excised or at least unloaded. The distracted facets required the release of the tension on the capsule, nerve root, and dorsal ramus by either excision of the facet or at least some reduction of the distraction by compression. It was reasoned that the endplate fractures needed to be unloaded to allow healing, or least relief of pain. These actions would be accomplished during an instrumented posterior fusion. If the premises for the sources of pain were correct, and these were addressed in the fashion described, then removal of the prosthesis would not be necessary.

Figure 5 is an example of a patient with a facet fracture after disc replacement. Treatment, shown in Figure 6, was with excision of the facet followed by a posterior fusion. This resulted in excellent relief of the low back and thigh pain. Bone morphogenetic protein in a compression resistant matrix was used as the graft material in the lateral gutters for the postero–lateral fusion. Instrumentation in all of the cases was in the form of pedicle screw fixation. Figure 7 shows an example of distracted facets. The normal facets above are pictured in Figure 8 for comparison. This was patient #23 who had bilateral leg pain that was relieved after facet excision, instrumentation with slight compression, and then fusion. Although one would think this is only minimally appearing distraction, it was nevertheless unstable at the time of surgery. Grasping the posterior spinous process at this level revealed surprising gross instability of the sort one would expect in an unstable spondylolisthesis. Yet, it was only the distraction of the facets joints to this degree that was abnormal. However, it should be remembered that this was imaged with the patient in the supine position.
Figure 8
Figure 7: Distracted facets in patient #23.

Figure 9
Figure 8: Normal facets of patient #23.

DISCUSSION
The FDA approval letter in October 2004 approved the sale and marketing of the Charite disc replacement in the US based on an IDE study, despite the fact that a full 64% of the Charite patients in the study at 2 years were still on daily narcotics.\textsuperscript{2,7} Specific conditions for follow up were described in the letter. This was preceded by an FDA panel discussion which included presentations by various interested parties. A transcript of this committee meeting is available online.\textsuperscript{12} In this transcript, a number of disturbing items are noted. The panel discussion leading to a vote for approval conditional upon follow up, was mixed with conflict about the both the methodology of the study, as well as the mechanics and testing of the device itself. Financial conflict as well was present among some voting members of the panel, but public disclosure of the nature of these was withheld under FDA rules. The FDA statistician assigned to evaluate the study expressed outright concerns of bias in handling of the data, as well as the design of the study. He testified that the positive outcome for the Charite might not have occurred had the data been evaluated in a more unbiased fashion. The FDA biomechanical engineer voiced concerns over the adequacy of the testing to support the long term survival of the device when implanted in patients.

Surprisingly, it appears that flexion and extension range of motion of the implanted Charite itself was not considered a primary endpoint of success, nor was it even published to our knowledge, despite this seeming to be its purported function. Prior studies suggest greater than 90% of clinically successful replacements ultimately ankylose or autofuse, accounting for their longevity.\textsuperscript{8}

There were additional concerns with the methodology of the study in 2004 by Geisler et al.\textsuperscript{3} that was used by the FDA for approval. Firstly, the initial 26% of the experimental patients (Charite) were eliminated from the final results. They were categorized as “training” patients. No study in the last 5 years published in the Spine Journal, has been found by these authors to have such a large number of “outliers” deliberately eliminated. Additionally, this would seem to erroneously suggest that final results will not reflect the reality of complications that occur when the procedure is released for use in the general population.

Secondly, the control group for the study was that of a procedure known to be a failure, namely, the stand-alone BAK fusion cage. Although it was an accepted procedure at the time the study was designed, it was considered a failed procedure by the majority of spine surgeons in this country at the time the study was executed. Nevertheless, the study was not re-designed. The failure rate for this control group has been documented to be 60%.\textsuperscript{13}

There are various assumptions made about lumbar mechanics that are questionable in authors' opinion. For example, there is no discussion of note of the normal disc's
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function as a shock absorber. The shock absorption capability of the Charite disc replacement is essentially nil.\textsuperscript{14} In addition, the principle of MacNab’s Triad is that disc degeneration is accompanied by facet degeneration.\textsuperscript{15} Therefore, the question arises as to whether there even exists any degenerated lumbar segment that is isolated to the disc and not the facets. This leads to a question of how a disc replacement would not make these inherently degenerated facets worse by artificially increasing their range of motion, and possibly even in the wrong range. Another issue is that there is no evidence clinically to support the theoretical notion that disc replacements prevent adjacent segment degeneration. In fact, there is strong evidence that refutes the notion of adjacent segment degeneration next to a fusion.\textsuperscript{16,17} There is no difference in adjacent level degeneration based on an adjacent level being decompressed, fused, or not having any operation at all. Wai et al. in 2006 followed patients for 20 years and documented no correlation whatsoever of segment degeneration and its proximity to a fused level.\textsuperscript{17}

And finally, probably most importantly, there is no evidence to these authors knowledge, which correlates the radiographic range of motion conferred by disc replacements and the patients’ clinical improvement. Such information was lacking even in the FDA study.\textsuperscript{7} Of worrisome note, is that the FDA ordered post market approval follow–up in regards to this correlation. As well, wear analysis of all retrieval specimens was ordered as part of post market approval follow-up, and this too appears to have been disregarded to these authors' knowledge. No FDA enforcement action or penalty for this is evident either.

POTENTIAL ETIOLOGY
THE CENTER OF ROTATION OF SEGMENTAL MOTION

After seeing these patients and trying to piece together the causes of pain, a number of parameters became apparent as primary etiologic factors based on observation and the literature.

The center of rotation (COR) of the normal lumbar segment is the center of a circle formed by the facets as seen in Figure 9.\textsuperscript{11} As the disc compresses under a load, the vertebral body goes down as seen in Figures 10 and 11. Since all motions in the spine are well known to be coupled, the flexion and extension is accompanied by rotation as Figures 10 and 11 accurately depict. The COR for this combined motion is the COR of the facets in Figure 9. Because there are no collateral ligaments, there is no restriction to this side-to-side rotational motion. (The anterior and posterior longitudinal ligaments restrict motion in flexion and extension only, not side-to-side.) This combined motion is viewed from above in Figures 12 and 13. Essentially, Figures 10-13 show the motion dictated by the facet anatomy. Although coupled motion is beyond the scope of this article, one key concept should be mentioned. Coupling the motion decreases the amount of compression shown, but does not change the side to side motion of the vertebral bodies dictated by the facet anatomy.

Figure 10
Figure 9: Center of rotation (COR) of a lumbar segment.
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**Figure 11**
Figure 10: Segment in neutral.

**Figure 12**
Figure 11: Segment in coupled flexion and rotation.

**Figure 13**
Figure 12: Segment in neutral (top view).

**Figure 14**
Figure 13: Segment in coupled flexion and Rotation.

**THE FUNCTION OF THE ANTERIOR LONGITUDINAL LIGAMENT**

The presence of anterior and posterior longitudinal
ligaments, and the absence of collateral ligaments, facilitates the side to side motion shown above. The authors considered the anterior longitudinal ligament as a checkrein to excessive extension in the disc space. In performing a disc replacement, this ligament is incised. It is felt that this allows for a significant increase in extension beyond normal. Extrusion of the disc replacement as a result of this and the ligaments absence as containment may subsequently occur as in Figure 14. It is also thought that abnormally high loads occur posteriorly while concurrently being decreased anteriorly adding to this occurrence. The polyethylene core may be expelled either with or without the metal endplates. Catastrophic results may ensue due to vascular injury.

**Figure 15**

Figure 14: Extrusion.

Motion preservation appears to be accomplished largely by removing the anterior longitudinal ligament. The resultant increase in extension is discussed frequently by advocates of disc replacement, but there is a notable paucity of discussion about the lack of increase in flexion and rotation. These latter motions are a greater part of daily activities than isolated extension.

**DISC REPLACEMENT CENTER OF ROTATION**

The disc replacement design, in contrast to the normal human disc, assumes that all centers of rotation are anterior to the spinal canal in the disc space. With the replacement in place, there are now two centers that sum to disallow motion at all unless something "gives." What "gives" depends on which center of rotation "wins" out over the other. If the disc replacement's center of rotation that is anterior dominates, then the facets which are posterior are damaged by abnormal movements. If the normal posterior center about the facets dominates, then the disc replacement, which is anterior, moves abnormally and subluxes or dislocates. In Figure 15, the false center of rotation artificially placed anteriorly by the disc replacement overcomes the normal posterior center. Subsequently, the facets undergo abnormal motion and loading which can lead to a fracture or rapid degeneration as in Figures 16 and 17. Here, the degree of facet degeneration that one would expect to occur over a period of years instead occurred over a period of 8 months after disc replacement. Local anaesthetic injection relieved all back and thigh pain temporarily in this patient. Subsequently, she underwent surgical treatment with facet excision and fusion that resulted in excellent pain relief.

**Figure 17**

Figure 16: Normal facets one month prior to disc replacement in patient #22.

**Figure 18**

Figure 17: Same facets as in figure 15 but 8 months after disc replacement. Note joint space loss and subchondral cysts.
LEG PAIN IN DISC REPLACEMENTS

In the patients in this study, in cases of severe distraction of the facets, there was often accompanying leg pain that lacked any radiographic evidence of impingement. This suggested that traction on the underlying nerve root may be a reasonable etiology. This could be either directly or via the dorsal ramus. The cases of pain relief after facet block in this situation appear to support this proposed etiology of the pain. As a result of this, the rationale for excision or compression of the facets surgically was formed. As discussed above, this was done to relieve the tension on the capsule, nerve root, and dorsal ramus. Leg pain relief was excellent when this was done (Table 1).

SUBSIDENCE

The complication described as “subsidence” of the metal endplate of the disc replacement into the vertebral body is more accurately described as a fracture of the vertebral endplate, in the authors’ opinion as discussed above in the rationale for surgical revision. After all, one cannot imagine how the metal plate migrates into the body of the vertebrae unless the structural integrity of the bone is compromised - namely fractured. The artificial disc does not have any of the natural shock absorption that the healthy human disc does, and this is thought by the authors’ to contribute to a posterior transfer of load.14 This affect is engendered by the excision of the anterior longitudinal ligament which leads to an increase in extension. Yet, the posterior longitudinal ligament remains intact. Thus, the vertebral body has the anterior loads decrease and the posterior loads increase. Add to this the increased forces of distraction of the disc space by a large disc replacement, and the groundwork for a subsidence fracture in this area is laid. All the cases of endplate fractures in this study occurred in the area of the posterior third of the vertebral body.

CALCULATION OF COR

All previous biomechanical models of spinal motion used mathematical assumptions that were well known to be unreliable and erroneous for the small degrees of angular measurement of segmental spinal motion. As a result, all current disc replacements that are based on these models may be inherently flawed in their intended function. Instantaneous center of rotation is defined as a point on the plane having zero velocity at the instant considered.18 Since Reuleaux,19 first published a graphical solution to find the center of rotation, as the point of intersection of perpendicular bisectors of the two lines joining the initial and final positions of two points on the plane. Instantaneous center of rotation and center of rotation have been used interchangeably based on the assumptions that the difference in the actual location of the center of rotation and instantaneous center of rotation of a joint are small and the differences decrease with the number of intervals into which the total range of motion is divided.20 Due to its simplicity Reuleaux method is still one of the most commonly used techniques to locate the center of rotation. However, several studies have demonstrated not only its inaccuracy to locate the center of rotation for a small amount of angular displacement but also its high dependency on the marker conditions, which might not be able to optimize during the experimental testing.21-23 Several guidelines were also suggested to maximize its accuracy to locate the center of rotation of planar joint motion which has fewer constraints on locating the markers, resulting in more accurate determination than with the Reuleaux method. Among all of the currently-existing methods, however, there is a strong agreement that there is no technique to accurately locate the center of rotation for a small amount of angular displacement, such as in thoracolumbar spinal joints.

CONCLUSION

The authors feel that there may be a flaw in the current design of disc replacements because of an erroneous assumption of the location of the center of rotation being in the disc space. This is felt to be the reason for the failures and why all such designs based on this should be abandoned. Also, the actions of the FDA need to be strongly condemned, as well, for allowing such poor and biased study designs to be implemented. Deliberate exclusion of initial data, use of failed controls, non-enforcement of follow-up data collection, and allowance of biased study designs, are not in the best interests of the American public and its physicians. The regulatory function of the FDA to provide for the safety and efficacy of devices has been breached in this case. The authors believe this may be due to the inappropriate influence of industry on both the researchers and the approval process.

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