Clinical and radiological mid-term outcomes of lumbar single-level total disc replacement

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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Abstract

Study Design: Prospective single-center case cohort study.

Objective: Evaluation of clinical and radiographic outcomes of a consecutive 122-patient cohort with discogenic back pain, at 2 - to 10-year follow-up periods, treated by a single surgeon, with CHARITÉ® Artificial Disc (DePuy Spine, Raynham, MA, USA).

Summary of Background Data: Minimum two-year clinical and radiographic Level 1 data for the first lumbar artificial disc, the CHARITÉ® Artificial Disc, has recently been published, demonstrating sustained clinical benefit of the device for the treatment of degenerative disc disease (DDD).

Methods: Patients were assessed preoperatively using clinical outcome measures, including Visual Analogue Score (VAS) back and leg, Oswestry Disability Index (ODI), Short Form - 36 (SF-36), and Roland-Morris Questionnaires (RMDQ), and further assessed postoperatively, 3-months, 6-months, 12-months, and yearly thereafter.

Results: Average follow-up was 44.9±23.3 months (n=122). The median age at surgery was 43.0±9.0 years. Preoperative diagnosis included DDD in 118 (96.7%) and internal disc disruption (IDD) in 4 (3.3%). Surgery was performed at L5-S1 in 96 (77.9%) patients and at L4-5 in 27 (22.1%). Statistically significant clinical improvements from baseline were observed on VAS (back and leg), ODI, SF-36 PCS, SF-36 MCS, and RMDQ from 3 months onwards. Back VAS scores decreased from 78.2±21.3 preoperatively to 21.9±27.8 by final follow-up. ODI scores decreased from 51.1±17.3 to 16.2±17.9 at last follow-up. The RMDQ scores also decreased, from 16.7±4.7 to 4.2±5.8. SF-36 PCS and MCS increased from 25.7±11.0 to 46.4±10.3 for PCS and
from $35.5 \pm 17.4$ to $51.6 \pm 10.8$ for MCS. Patient satisfaction surveys indicated that 90.56% patients rated their satisfaction with the surgery as “excellent” or “good” at 2 years. Range of motion averaged $8.6^\circ \pm 3.5^\circ$ (median: $8.0^\circ$) at the last follow-up time point.

**Conclusions:** Outcomes verify the clinical efficacy of total disc replacement (TDR) for treatment of discogenic back pain with or without radiculopathy. The outcomes instruments demonstrated statistically significant improvements from 3 months onwards.

**Mini Abstract:**
Evaluation of the clinical and radiographic outcomes of a consecutive 122-patient cohort at 2 - to 10-year follow-up periods, treated by a single surgeon, with the CHARITÉ® Artificial Disc. Patients demonstrated sustained clinical benefits, with statistically significant improvements in outcomes from 3 months onwards.

**Keywords:** Prospective, single-centre, total disc replacement, one-level.

**Key Points:**
- Total disc replacement is an important part of the armamentarium for treating discogenic back pain, provided the indications and contraindications are adhered to.
- Significant reductions in pain and improvements in functional outcomes are achievable with TDR.
- The CHARITÉ® Artificial Disc preserves motion at the operative segment in this mid-term data analysis.
The complication incidence and revision incidence is less than most fusion studies at this time point.

Introduction

Chronic low back pain can result from multiple pathologies and is often difficult to diagnose despite increasingly sophisticated diagnostic tools. The majority of patients present with discogenic rather than neurogenic low back pain, originating from either degenerative disc disease (DDD) or internal disc disruption (IDD). Consequently, successful treatment of this patient population relies on accurate diagnosis, to effectively determine the site and nature of the underlying pathology, as well as adequate surgical technique, to achieve complete elimination of the pain source and reconstruction of the spinal column. Historically, spinal fusion performed on the basis of the above principles, and utilizing state-of-the-art technology, has reported high success rates in this challenging group of patients.

Spinal arthroplasty, as an alternative to spinal fusion, in the surgical treatment of DDD/IDD has been studied and reported now for several decades. Lemaire et al., first described 10-year follow-up outcomes in 100 patients. Excellent or good clinical outcomes were observed in 90% of cases. Adjacent level degeneration was observed in 2% cases, while facet joint degeneration occurred in 11% cases. Putzier et al., in a retrospective clinical and radiological study, reported 17-year follow-up data with total disc replacement (TDR). In this study, 60% spontaneous ankylosis was observed, prompting authors to conclude that the long-term efficacy of TDR still needed to be addressed. However, the study had significant limitations, including the use of undersized prototype devices, poor device placement, and inadequate patient selection. David’s subsequent long-term study was published more recently, presenting 10-year data on 106
patients. Only one-level surgeries were performed in this cohort. Excellent or good clinical outcome was obtained in 82.1% patients, with an 89.6% rate of return to work. Preservation of motion with an average flexion/extension of 10.1° was achieved in 90.6% cases. Adjacent level disease was reported in 2.8% cases and facet joint degeneration in 4.6% cases only. The authors thus concluded that disc replacement with the prosthesis was a viable alternative to arthrodesis for the treatment of lumbar DDD. Two additional publications were released from the CHARITÉ® Artificial Disc investigational device exemption (IDE) trial designed to evaluate the safety and efficacy of arthroplasty versus fusion with BAK and autograft. These reports demonstrated statistically significant improvements in disc replacement patients at the 2-year follow-up time point, as compared to preoperative baseline data.

To date, these case series and the 2-year IDE randomized controlled trial represent most of the available data on CHARITÉ® Artificial Disc. This prospective study presents the clinical experience with the CHARITÉ® Artificial Disc in 122 consecutive patients, implanted with the artificial disc at one level from L3 to S1, with a minimum of 2 years and up to 10 years follow-up. This study was designed before the data collection was collated.

The aims of the study were to assess the impact of single level disc replacement for a provisional diagnosis of discogenic back pain. The authors have defined the patient selection criteria through a thorough preoperative workup, and designed the study to have a consecutive database for comparison. The advantages of this type of study allow subjects to be followed over a length of time and to help avoid confounding variables. The disadvantages are that it is expensive, time consuming, and laborious. A criticism of this study is that the lack of a control group. The authors, at the time, were aware of the indications for total disc replacement, and those people who had any contraindications were treated with fusion because of the nature of the
clinical practice. The authors felt it was unethical to apply a technology to a given pathological diagnosis that had already been assessed by other authors as being a contraindication.

Materials and Methods

Patient Demographics

A total of 122 consecutive patients with single level discogenic low back pain were treated with disc replacement by the senior author between 1997 and 2005 at several tertiary care Level-1 institutions, using the same consistent operative technique and surgical implant (CHARITÉ® Artificial Disc).

A provisional diagnosis was established through clinical history, clinical examination, and diagnostic imaging and testing, which included a combination of standing lumbar AP, lateral, flexion and extension radiographs, MRI, provocative discography and a post-discography fine cut CT scan. In patients with radicular symptoms, electrophysiological studies were performed to objectively confirm the presence or absence of true radiculopathy. All patients had exhausted conservative treatment efforts over a period of at least 12 months. The authors have always recommended a proactive approach to discogenic back pain, allowing the patient to travel down all avenues they so choose, but with an emphasis placed on exercise. The exercises encompass core stability, flexibility regimes, and a specific disc replacement rehabilitation programme that has been formulated between the surgeon and the chief physiotherapist. This initially encourages core stability and posture in conjunction with neural glides and stretches.

Contraindications to TDR include segmental instability, severe facet joint arthrosis, osteoporosis (DEXA T-score <-1.5), fusion at the index level, infection and pregnancy. In the absence of contraindications, surgery was indicated only if the history and physical examination
were consistent with the radiographic findings, and provocative discography established concordant pain reproduction. Surgery was not offered in the presence of overt psychological derangement or maladaptive pain behavior. Smoking, obesity, and involvement in workers compensation or other litigation were not regarded as absolute contraindications.

**Surgical Technique**

Surgery was performed with the patient in supine Trendelenberg position. A horizontal or vertical incision, followed by a midline rectus split with a left or right-sided retroperitoneal approach was performed, depending on the patient’s pathology and gender. The disc space was exposed using blunt dissection along anatomical planes. An Omni Tract® retractor system (Omni Tract Surgical, Inc., St Paul, MN) with radiolucent blades was used to retain peritoneal contents to allow for direct, uninterrupted, visualization. Vessels were carefully mobilized and retracted with modular pins.

An H-shaped midline incision was made in the anterior annulus to allow its reflection on stay sutures. Complete discectomy was then performed, followed by removal of the cartilaginous endplate out to the ring apophysis. A balanced resection of the lateral annulus and full release of any contractures within the posterior annulus were attempted as a prerequisite for optimum implant positioning and restoration of posterior disc height in particular. The posterior longitudinal ligament was released or removed as necessary and any protruded or extruded disc material was removed at this stage.

Fluoroscopic guided insertion of the CHARITÉ® Artificial Disc prosthesis was performed according to the recommended surgical technique. Wound closure involved placement of a retroperitoneal or subcutaneous fat graft over the anterior aspect of the prosthesis and the annulus was repaired. A drain was inserted retroperitoneally in 10 patients (7.9%) where
intraoperative blood loss exceeded 250ml. No additional procedures were performed at the time of the index surgery. Following initial postoperative recovery, patients were encouraged to participate in a Pilates programme and increase their aerobic exercise as dictated by their symptoms.

**Clinical and Radiographic Outcomes**

All patients were asked to complete a Visual Analogue Scores (VAS) for back and leg, an Oswestry Disability Index (ODI), the Roland-Morris (RMDQ) and SF-36 questionnaires at the initial consultation, or on admission prior to surgery, and at postoperative follow-ups at 3, 6, 12 months and subsequent yearly intervals.

Patients diagnosed preoperatively with disc herniation were also analysed separately from the rest of the patients for improvements in outcome scores at all time points.

Radiographically, standing AP, lateral, and flexion and extension radiographs were obtained at the same follow-up intervals and assessed by an independent musculoskeletal radiologist for segmental range of motion, heterotopic ossification, and implant placement. For both implant placement and heterotopic ossification, the scale defined by McAfee *et al.*, was used.14

Data analyses were performed by time point. In addition, a last follow-up analysis was conducted, including data from all patients at the last available time point.

**Statistical Analyses**

Categorical variables were analyzed by generating *P* values using the Fisher’s exact test. A *t* test was used to test means.
Results

Patient Demographic and Diagnosis

A total of 122 patients were included in the study. As shown in the patient disposition table (Table 1), 58 patients were female, 64 male, with a median age of 44 (range = 20 – 67 yrs). Of these 122 patients, 6 (4.9%) were involved in military compensation claims and 14 (11.5%) in workers compensation claims.

DDD was diagnosed in 118 (96.7%) cases, and IDD in 4 (3.3%) cases. Additional radicular symptoms associated with disc herniation were present in 30 (24.6%) patients. Eight (6.6%) patients had had prior posterior surgery at the affected levels. Surgery was performed at L5-S1 in 95 (77.9%) patients and at L4-5 in 27 (22.1%) patients. Of the patients who consented to participate in the study, 4 (3.3%) were lost to follow-up.

Complications

There were 4 (3.3%) complications requiring surgical revisions; 3 of these occurred within 12 months of the index procedure. One patient with a core dislocation and another with progressive instability resulting from a prior laminectomy and a partial bilateral facetectomy were successfully converted to an ALIF. A third patient developed an asymptomatic degenerative spondylolisthesis at 12 months postoperatively due to unrecognized preoperative facet arthropathy. The fourth patient previously had a prior posterior spinal fusion at L5-S1 and was assessed to have discogenic pain at L4-5, and was treated with a disc arthroplasty. After 4 years the patient developed facet arthropathy and was treated with an in situ pedicle screw fusion.
Of 6 superficial wound infections, 5 resolved with frequent re-dressing and oral antibiotics, and one required IV antibiotics. One patient developed transient postoperative irritation of the left L5 nerve root. There were no other complications.

**Clinical Outcomes**

**Pain Relief**

Mean VAS scores for back and leg pain and per time points were analysed and are shown in Figure 1. Preoperatively, VAS back scores averaged 78.2±21.3 (median 85.0) and VAS leg scores averaged 55.7±33.2 (median 66.0). At the latest follow-up time point (44.9±23.3 months, median 38.5 months), the average back pain was 21.9±27.8 (median 11.0) and the average leg pain, 16.8±26.4 (median 3.0). The change in VAS score was statistically significant from preoperative to all follow-up time points (p<0.05), including the aggregate VAS score at latest follow-up.

Patients diagnosed preoperatively with disc herniation (the Herniation Group) and those with DDD or IDD (the Disc Group) were compared for changes in leg and back pain at all follow-up time points. Preoperatively, the VAS leg scores averaged 67.1±25.6 (median 73.0) and 50.8±17.1 (median 50.0) for the Herniation and Disc Groups, respectively. At baseline, these two groups were statistically different for leg pain (p=0.0001). At latest follow-up, the VAS leg score averaged 8.7±16.5 (median 0.0) and 19.3±18.9 (median 14.0) for the Herniation and Disc Groups, respectively. These two groups were again statistically different (p=0.007).

Both groups were also analysed in terms of VAS back pain improvements. From preoperative to latest follow-up, the Herniation Group improved from 75.0±22.2 to 9.9±16.6, while the Disc Group improved from 79.3±20.9 to 25.9±29.7. The Herniation and Disc Groups
were not statistically different preoperatively ($p=0.3544$) but were statistically different at last follow-up ($p=0.0059$).

**Disability**

Mean ODI scores per time points were analysed and are shown in Figure 2. Preoperatively, ODI scores averaged $51.1\pm17.3$ (median 52.0). At the latest follow-up time point, the average ODI score was $16.2\pm17.9$ (median 10.0). The changes in ODI scores were statistically significant from the preoperative to the aggregate score at latest postoperative time point. In addition, changes in ODI scores were statistically significant from preoperative to all follow-up time points up to 84 months. For that particular time point, data was only available for 3 patients, and the average ODI score was $20.0\pm14.0$ (median 26.0) from preoperative to 84-months ($p=0.0566$).

As described above, the Herniation and Disc Groups were analysed separately for ODI improvements. From preoperative to latest follow-up, the Herniation Group improved from $52.0\pm18.0$ to $6.7\pm10.1$, while the Disc Group improved from $50.8\pm17.1$ to $19.3\pm18.9$. The Herniation and Disc Groups were not statistically different preoperatively ($p=0.7427$), but were statistically different at last follow-up ($p=0.0007$).

**Roland-Morris Questionnaire**

Mean RMDQ scores per time points were analysed and are shown in Figure 3. Preoperatively, RMDQ scores averaged $16.7\pm4.7$ (median 17.0). At the latest follow-up time point, the average RMDQ score was $4.2\pm5.8$ (median 1.0). The changes in RMDQ scores were statistically significant from the preoperative to the aggregate score at latest postoperative time point and to average scores at all follow-up time points. The Herniation and Disc Groups were
again analysed separately for RMDQ. From preoperative to latest follow-up, the Herniation Group improved from 17.8±4.5 to 0.9±2.7, while the Disc Group improved from 16.3±4.7 to 5.3±6.1. The Herniation and Disc Groups were not statistically different preoperatively (p=0.1288), but were statistically different at last follow-up (p=0.0002).

**Short Form 36 Questionnaire**

Mean SF-36 PCS and MCS scores per time points were analysed and are shown in Figure 4. Preoperatively, SF-36 PCS scores averaged 25.7±11.0 (median 27.0) and SF-36 MCS scores averaged 35.5±17.4 (median 35.0). At the latest follow-up time point, the average SF-36 PCS score was 46.4±10.3 (median 49.0) and the SF-36 MCS score was 51.6±10.8 (median 55.0). The changes in SF-36 PCS scores were significantly different from the preoperative to the aggregate score at latest postoperative time point. In addition, changes in SF-36 PCS scores were statistically different from preoperative to all follow-ups except the 84-month time point. For that particular time point, only 3 patients were available for follow-up and their average SF-36 PCS score was 31.7±7.5 (median 36.0), p value from preoperative to 84-months postoperative=0.2980. The changes in SF-36 MCS scores were statistically significant from the preoperative to the aggregate score at latest postoperative time point and to average scores at all follow-up time points. Herniation and Disc Groups were also analysed separately for SF-36 PCS and SF-36 MCS improvements. For SF-36 PCS and from preoperative to latest follow-up, the Herniation Group improved from 26.4±10.6 to 51.8±7.2, while the Disc Group improved from 25.3±11.3 to 44.5±10.6. The Herniation and Disc Groups were not statistically different preoperatively (p=0.6634) but were statistically different at last follow-up (p=0.0007). For SF-36 MCS and from preoperative to latest follow-up, the Herniation Group improved from 37.2±16.5 to 54.7±8.7, while the Disc Group improved from 34.6±17.9 to 50.5±11.2. The Herniation and
Disc Groups were not statistically different preoperatively (p=0.5142) but showed trends of statistical significance at latest follow-up (p=0.0642).

**Patient Satisfaction and Activity Level**

Patient satisfaction was further tabulated, as shown in Table 2. At all time points, more than 85% patients rated their satisfaction with the surgery as “good” or “excellent”. Activity levels were also recorded for all patients. Preoperatively, 53.7% of patients were unable to participate in any recreational activities. At 24 months 96.2% patients were able to participate in light sport, walking, and even contact sports, with light sport participation increasing from 11.9% to 73.6%, and contact sport increasing from 0 to 5.7%.

**Radiographic Outcomes**

A representative radiograph following TDR at L5-S1 is shown in Figure 5. Heterotopic bone formation was reported in 6 cases (4.9%). Three had Class 1 (2.5%), 2 had Class 2 (1.6%), and one case had Class 3 (0.8%) heterotopic bone formation. Eccentricity of the prosthesis in these cases was noted, with heterotopic bone forming on the more open side of the disc.

Analysis of implant position revealed that 94% of all implants were optimally placed, achieving Grade 1 as defined in Table 2 in both coronal and sagittal planes. The remaining 6% cases were graded as Grade 2, i.e. were placed within 5mm of the ideal placement.

Median average segmental range of motion was $8.6° \pm 3.5°$ (median $8°$) with a range from $2°$ to $22°$. Subsidence over 5mm was detected in 8 cases (6.5%). All eight cases occurred early in the postoperative period, involving the superior L5 endplate, and did not progress beyond the first 3 months. There was no radiographic evidence of adjacent segment degeneration, implant loosening, or wear.
Discussion

In this study, TDR was used to treat patients with intractable chronic low back pain, which was unresponsive to conservative care for at least 12 months. Patients included in this study underwent a thorough preoperative work-up to accurately identify the pain source, and experienced significant and sustained improvements in pain and disability with treatment. The clinical benefits observed in this patient population also translated in high levels of patient satisfaction and increased activity levels.

The VAS, ODI, and SF-36 PCS are all validated clinical outcome tools. Hägg et al., showed that an 18-19mm improvement in VAS back pain and a 10-point improvement in ODI was equivalent to the minimum clinically important difference (MCID) for these particular measurement methods.15 In our study, the average VAS score improvement was 56 mm and the average ODI change, 35 points. Thus, treatment resulted in the pain and disability improvements two to three times beyond the respective MCID values. Polly et al., recently reviewed all published arthrodesis procedures and defined a MCID for SF-36 PCS at 5.42 points.16 In the patient population, the average change in SF-36 PCS reached 20.7 points, or more than three times the SF-36 PCS MCID value. Thus, the clinical improvements were not only statistically significant, but far exceeded the MCID threshold for all measurements.

The current study included patients with radicular symptoms due to nerve root compression. For this particular patient population, statistically significant improvements in the VAS back and leg scores suggest that this technique can achieve excellent relief of nerve compression caused by a herniated disc, while also resolving the underlying problem of discogenic back pain effectively. Patients suffering from DDD typically represent a challenging
patient population, as their pain is difficult to localize and treat. Disc degeneration, a normal component of the ageing process, does not necessarily result in pain and the actual etiology and pathophysiology of discogenic back pain is not completely understood. A complex relationship exists between the mechanical and chemical processes occurring during the degenerative cascade. The pathophysiology of discogenic pain has been discussed by many authors.\textsuperscript{7, 13, 14, 17-21} The biochemical, neural, and biomechanical etiologies of discogenic back pain are addressed by arthroplasty. TDR targets these discogenic pain generators by disrupting the innervation of the disc, removing the chemical cocktail, and providing uniform load transfer. The results shown compare favorably with the existing publications on ALIF and TDR.

The advantages of this study include prospective follow-up, and a drop-out rate of data collection that is extremely low compared to studies by LeMaire, Putzier, and David. Criticisms of these previous studies include, retrospective analysis, and the combination of both single-level and multi-level disease treated with arthroplasty. A further criticism of Putzier’s paper is that they compare outcomes with the Charité I, II, and III.

The prospective nature of this study helped to avoid confounding variables, and provided formalized follow-up with a strong baseline for comparison. An exceedingly low number of patients were lost to follow-up because patients were well-motivated, and tracked by a dedicated research team. In an attempt to gain useful information, part of the primary premise of the study design was to determine how much TDR was able to improve back pain, in what way the functional result was achieved, and the assessment of long-term decay. We believe that this study addresses those issues, resulting in significant reductions in pain, improvements in functional ability, and that the results do not deteriorate in time.

Appropriate patient selection is the key to the successful surgical treatment of chronic low back pain with spinal arthroplasty.

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In this study, patients were subjected to a thorough diagnostic and selection process. Clinical history, physical examination, and adequate imaging, including CT discography, were critical in order to accurately identify the pain source. In addition, meticulous surgical technique, for precise prosthetic placement, in combination with surgical experience, ensured the high clinical success and low complication rate.\textsuperscript{22,23}

The absence of adjacent segment degeneration in this study is consistent with previously published data. In two long-term studies (minimum 10 year follow-up), David and Lemaire reported 2.8\% and 2.0\% adjacent-level degeneration, respectively.\textsuperscript{8,12} These results, as well as our observations, further document the mid-term effectiveness of the procedure in these carefully-selected patients.

The distinction between DDD and IDD is an important one. In 1986, Harry Crock described the concept of internal disc disruption.\textsuperscript{24} By definition, this diagnosis can only be made on discography. He implied that the MRI shows a normal signal, but upon discography the internal architecture of the disc was disrupted with progression of the dye to the periphery and provocation of the pain the patient experienced. The disc was without signs of herniation or any possible nerve root compression. On the other hand, the definition of degenerative disc disease involves a disc that, on MRI, has a combination of loss of signal, loss of height, modic changes, plus or minus herniations (herniated nucleus pulposus).

In this study, carefully selected patients with intractable low back pain due to either DDD or IDD were shown to experience significant and durable clinical improvement through TDR. These improvements allowed patients to increase their activity levels. “Good” to “excellent” results were achieved in more than 85\% of patients at all time points. This study further suggests that TDR represents a viable and effective treatment option for the surgical treatment of low back pain. TDR can also be effectively used for the treatment of DDD with herniation causing
radiculopathy, with these patients having statistically significant improved outcomes in VAS back and leg.

Conclusions

DePalma’s statement, “No operation in any field of surgery leaves in its wake more human wreckage than surgery on the lumbar disc” 25 might have been appropriate nearly 40 years ago. However, quite the opposite is true today, with the help of careful patient selection and surgical application of modern spine technology. This study demonstrates a high satisfaction rate and significantly reduced pain scores and improved functional outcomes in the significant majority of patients. Only long-term follow-up will answer questions of decay, wear, and facet degeneration.

References


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Figure 1: Mean VAS scores by follow-up time points. Significant changes in VAS scores were observed from preoperative to all follow-up time points. The improvements in VAS scores were twice the MCID value for back pain (18-19mm) at all postoperative time points. No statistically significant subsequent changes were observed from 24-months onwards.

Figure 2: Mean ODI scores by follow-up time points. Significant changes in ODI scores were observed from preoperative to all follow-up time points. The improvements in ODI scores were twice the MCID value for ODI improvement (10 points) at all postoperative time points. No statistically significant subsequent changes were observed from 12-months onwards.
Figure 3: Mean RMDQ scores by follow-up time points. As observed with VAS and ODI scores, changes were statistically significant from preoperative to all follow-up time points. No statistically significant subsequent changes were observed from 12-months onwards.

Figure 4: Mean SF-36 PCS and MCS scores by follow-up time points. Improvements from preoperative to postoperative periods exceeded the MCID for SF-36 PCS (5.42 points) at all follow-up time points.
Figure 5: Representative radiographic postoperative films in neutral A/P (a), neutral lateral (b), flexion (c) and extension (d).

Table 1: Patient Demographics

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* Mos denotes months