SPINE Volume 31, Number 8, pp 948–953

Computed Tomography Assessment of the Accuracy of *In Vivo* Placement of Artificial Discs in the Lumbar Spine Including Radiographic and Clinical Consequences

Vikas V. Patel, MA, MD,*† Carol Andrews, MD,‡ Ben B. Pradhan, MS, MD,* Hyun W. Bae, MD,* Linda E. A. Kanim, MA,* Michael A. Kropf, MD,* and Rick B. Delamarter, MD*

Study Design. Prospective cohort study of 52 patients who had undergone artificial lumbar disc replacement.

Objectives. To evaluate the implantation accuracy of prosthesis positioning, subsequent facet joint changes and prosthesis migration, and the clinical consequences of implant position.

Summary of Background Data. Accuracy of spinal prosthesis implantation has not been evaluated rigorously, especially with a mini-incision approach. It is unknown if the inexact placement of a mobile device in the spine has any biomechanical, radiographic, or clinical repercussions.

Methods. A total of 52 consecutive patients were treated using standard methods of disc implantation with an intervertebral prosthesis. Computed tomography scans were performed within 3 days and again at 6 to 24 months. An independent radiologist analyzed the images for prosthesis position, rotation, migration, and facet changes. Results were compared with clinical outcome, measured by the Visual Analog Scale and Oswestry Disability Index.

Results. Deviation of the prosthesis from the center position was under 1.2 mm, and rotation off of midline was under 12°. Follow-up CT scans showed no migration or facet changes. Regression analysis showed no correlation of prosthesis position with clinical outcome.

Conclusions. Current prosthetic disc implantation methods, with minimally invasive access techniques, are relatively accurate. Although there can be deviation of the prosthesis from ideal placement, no repercussions were attributable.

Key words: artificial disc replacement, center of rotation, spinal biomechanics, outcomes, position, computed tomography. **Spine 2006;31:948–953**

Spinal disc replacement surgery has been used clinically since the early 1950s with limited success.[1] Hundreds of designs have been introduced in theoretical or clinical form over the subsequent 50 years,[2] and currently a few are being employed and studied in clinical trials in the United States. Initial European and U.S. results have shown a high degree of success with the latest versions of these prostheses and disc arthroplasty has become a feasible alternative to fusion for degenerative disc disease.[3–7] The first prosthesis became commercially available in the United States after FDA approval in October 2004 and the second was recently approved in January 2006. An increase in usage is expected as more surgeons are trained in implantation techniques.

Intervertebral prostheses have been tested with biomechanical studies, short-term clinical studies,[3,6–8] and retrospective evaluations of complications.[9] The implantation techniques, however, have not been critically evaluated for their association with positional and alignment accuracy. It is also not known what the clinical consequences may be of deviations from the manufacturer's recommended "perfect" positioning of the prostheses. These deviations may result in poor function or pain relief, increased facet loads with subsequent arthrosis, and prosthesis migration or subsidence.

The purpose of this study was to radiographically evaluate the positioning accuracy of artificial disc prostheses implanted in the clinical setting and assess its clinical relevance. Additionally, implant position changes and facet joint changes were characterized relative to prosthesis position for diseased and adjacent levels.

Methods

Design. This study includes a consecutive subset of patients from one site of a multicenter prospective FDA IDE clinical trial. CT scans were obtained immediately after and at 6 months after surgery. CT scans were analyzed by an independent radiologist. The association among parameters of device position determined from CT scans and clinical outcomes were evaluated.

These radiographic parameters/results were compared to patients' outcomes available from the clinical trial.

Device Description. The PRODISC device (ProDisc II, Synthes Spine Solutions, West Chester, PA) is composed of three components: an inferior CoCrMo plate with a large central keel, an ultra-high molecular weight polyethylene (UHMWPE) insert, and a superior CoCrMo plate also with a central keel for anchorage into the vertebral body. Both of the plates, including the keel, have a porous coating for bony ingrowth. The UHMWPE insert snap-locks into the inferior plate and provides an inferior convex bearing surface (Figure 1).

From the *Spine Institute at St. John's Hospital, Santa Monica, CA; †Spine Center at the University of Colorado Health Sciences, Denver CO; and ‡Mink Radiologic Imaging, Beverly Hills, CA.
Acknowledgment date: March 9, 2005. First revision date: May 8, 2005. Acceptance date: May 9, 2005.
The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.
Other funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.
Address correspondence and reprint requests to Vikas V. Patel, MA, MD, Chief, Orthopaedic Spine Surgery, University of Colorado Health Sciences, Anschutz Outpatient Pavilion Suite 4200, 1635 Ursula St., Mail Stop F722, PO Box 6510, Aurora CO 80045-0510. E-mail: vikas.patel@uchsc.edu

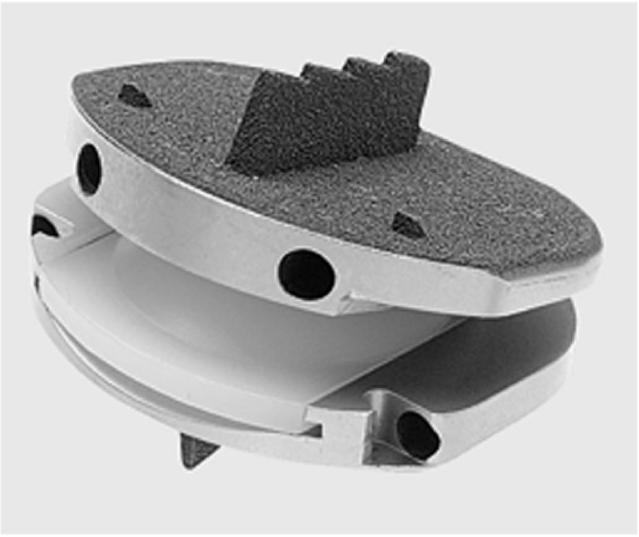

Figure 1. Prosthesis. The Prodisc II disc replacement consisting of three components. Metallic superior endplate (chromium cobalt), ultra high molecular weight polyethylene insert, and metallic inferior endplate (chromium cobalt). Endplates are coated with a plasma spray finish for bony ongrowth.

Surgical Procedure. The PRODISC prosthesis was implanted using a standard left sided, anterior, retroperitoneal approach and straight anterior insertion was performed. After surgical exposure, implantation of the prosthesis begins with the marking of the anterior spinal midline. Both fluoroscopy and direct visualization are used to find the anterior midline based on the pedicle and spinous process relationships to the vertebral body (Figure 2). The midline is typically marked with electrocautery, and lateral fluoroscope views are used for the rest of the implantation procedure (Figure 3). Complete discectomy is performed through a straight anterior, approximately 2.5 cm wide window in the anulus fibrosis. Care is taken not to disrupt the anulus laterally; however, the posterior anulus may require release for proper decompression of the spinal canal or for proper distraction of the disc space. Once discectomy is completed, the disc space is measured under lateral fluoroscopy using trial sizers of appropriate thickness and lordotic angulation. Using the inserted trial and the electrocautery marks from the beginning of the procedure as guides, osteotome bone cuts are made simultaneously in the superior and inferior endplates and vertebral bodies. These cuts determine the position and angulation of the implant keels. Finally, the prosthesis endplates are positioned at the osteotomies and tapped into place before insertion of the modular, UHMWPE insert. The prosthesis is final-checked on anteroposterior (AP) and lateral fluoroscope views and the wounds are closed.

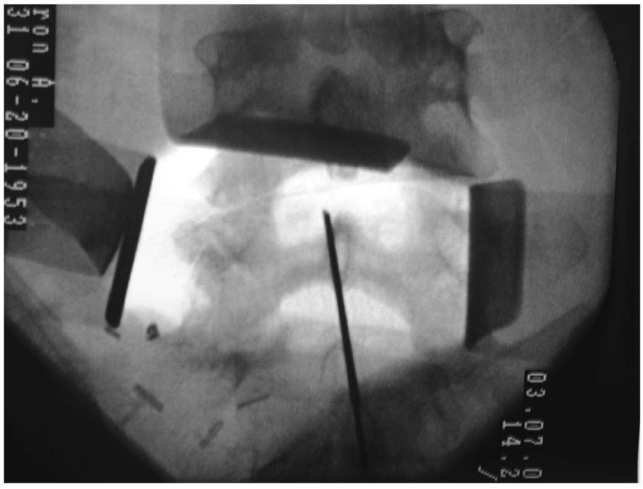

Figure 2. Intraoperative fluoroscopic view. Intraoperative fluoroscopic radiograph of the needle localization of disc space midline. Note in this view that the needle is still slightly to the left of midline.

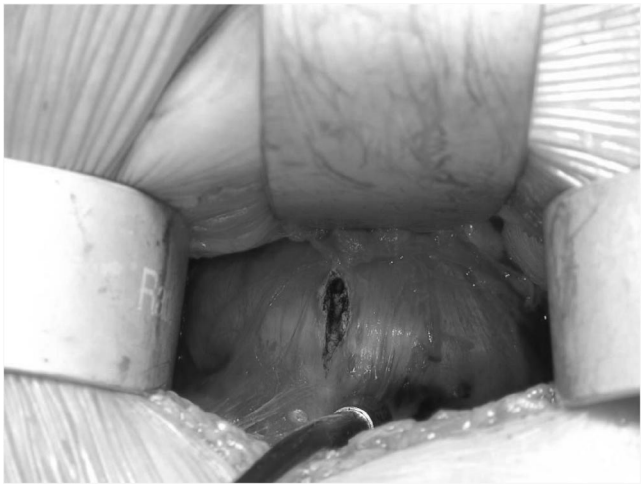

Figure 3. Intraoperative exposure. Intraoperative view of spine exposure and anterior midline marked based on fluoroscopic view.

CT Scans. All scans were performed on a Siemens Somatom Plus spiral scanner (Siemens AG, Munich, Germany). The early postoperative CT scan was performed during the first 3 days after surgery. A second CT scan was performed at least 6 months after surgery. Images were reconstructed with a slice thickness of 1 mm. The CT data were transferred to a workstation for three-dimensional evaluation by an independent radiologist.

The CT images in transverse and sagittal reconstruction sections were evaluated using SIENET MagicView 300 software (Siemens AG Medical Solutions, Erlangen Germany). The central keels of the device present in the vertebral bodies facilitated measurement of orientation and characterization of the device association to the vertebral body on imaging studies.

Measurements were recorded for AP, medial-lateral (ML), and angular position of the artificial disc prosthesis. The center of the vertebral body with the prosthesis fin perpendicular to the posterior vertebral wall was deemed the ideal position. Deviation from ideal AP position was defined as one half the difference between the anterior vertebral edge to the keel distance (AVD) and the posterior vertebral body edge to the keel distance (PVD) (Figure 4). For example, if the AVD was 4 mm and the PVD was 2 mm, then the AP deviation was half $(4 - 2)/2 = 1$ mm anterior. ML deviation was defined as one half the difference between the left side vertebral edge to the keel distance and the right side vertebral body edge to the keel distance (Figure 5). Rotational measurements were defined as fin position relative to the posterior vertebral body edge. This

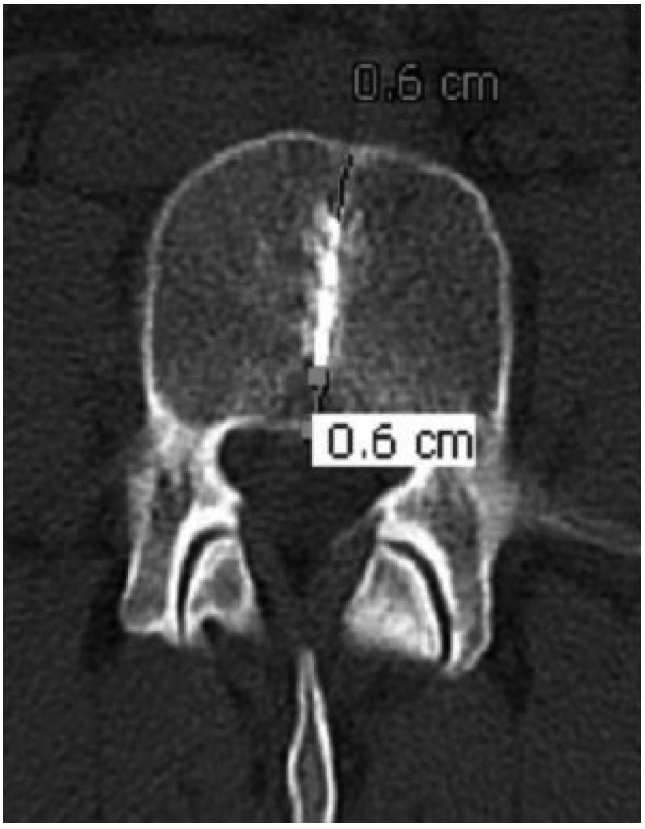

Figure 4. Transverse CT image of AP measurement. CT image showing measurements of anterior and posterior fin to vertebral body distances. The deviation from center is defined as half the difference of these measurements.

edge was verified by concordance with a line drawn between the bases of the pedicles (Figure 6).

The presence of any lucency between the bone and prosthesis or subsidence into the endplate was determined from the sagittal and coronal CT reconstructions (Figure 7). All measurements were repeated for the superior and inferior endplates of the prostheses.

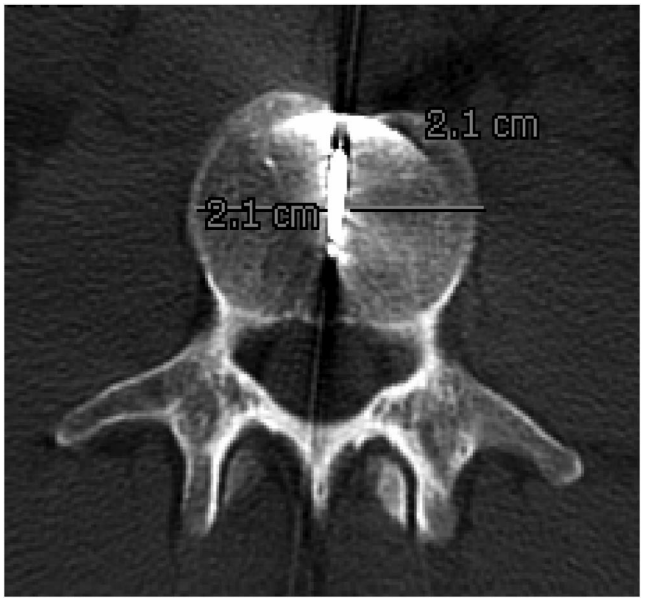

Figure 5. Transverse CT image of ML measurement. CT image showing measurements of left and right fin to vertebral body distances. The deviation from center is defined as half the difference of these measurements.

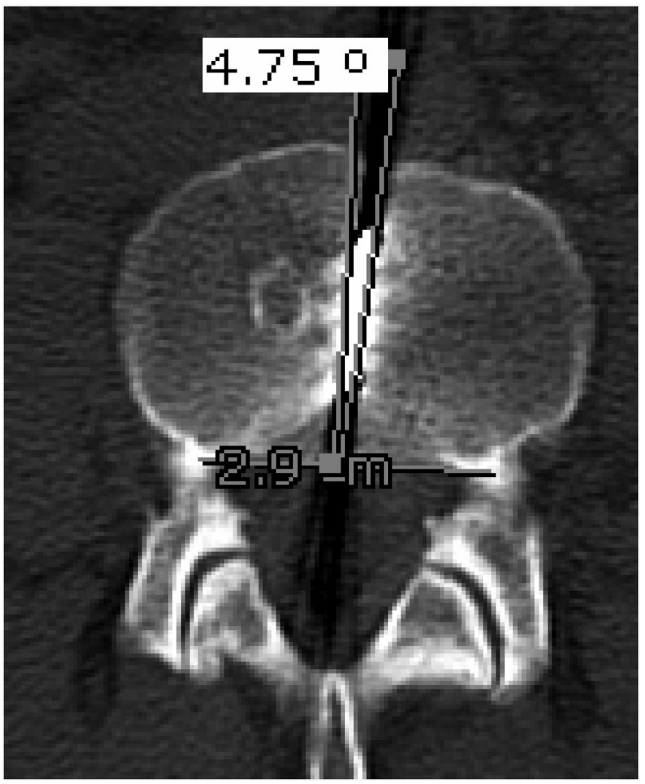

Figure 6. Transverse CT image of angular position measurement. CT image showing measurements of prosthesis fin rotation relative the posterior vertebral edge and pedicles.

Facet joints were graded on a 4-point scale, with 0 indicating no arthrosis, 1 indicating mild arthrosis, 2 indicating moderate arthrosis, and 3 indicating severe arthrosis at the implanted and adjacent levels. Mild arthrosis was defined as minimal osteophyte formation and no significant articular surface changes or joint space narrowing. Moderate was defined as early bony surface changes and some joint space narrowing. Severe was defined as loss of joint space, with significant bony sclerosis and osteophyte formation.

The same measurements were made on follow-up CT scans. Comparisons were made for change in prosthesis position, change in facet joint arthrosis, and change in the bone prosthesis interface, including subsidence of the prosthesis.

Oswestry and Visual Analog Scale inventories were collected before surgery, and at 6, 12, 24 weeks, and 1 and 2 years after surgery.

Statistical Analysis. Means and standard deviations for numerical data and frequencies for categorical data were calculated. Difference between 6-month and early postoperative CT findings yielded a value of change. Vertebral levels including segments L3–L4, L4–L5, and L5–S1 were analyzed separately and in aggregate. The association between measures on clinical outcome and CT parameters was analyzed using correlation and multivariate regression techniques (SAS, Correlation, GLM procedures, Cary, NC). Statistical analysis was performed for correlation with values of average deviation from the "ideal" center midline position.

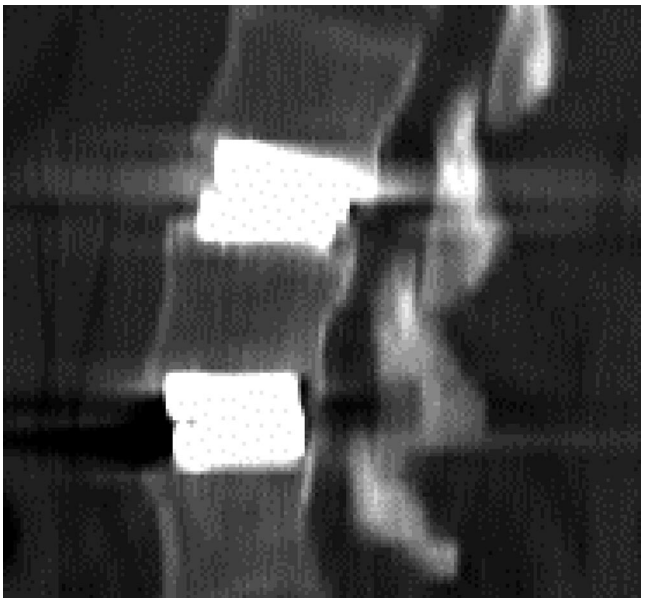

Figure 7. Reconstructed CT image. Midsagittal reconstruction showing bone prosthesis interface at the level of the prosthesis fin and no sign of subsidence.

■ Results

Fifty-two patients treated with artificial disc replacement had immediate postoperative and minimum 6-month CT scans available for evaluation between January 2002 and October 2004. Mean follow-up time to final CT scan was 41.5 weeks (range, 26–69 weeks). Patient average age at time of implantation was 41.6 years.

Rotational deviation from the midline ranged from 8.9° left to 9.0° right for the superior endplate implants and from 11.9° left to 9.0° right for the inferior endplate implants. Initial ML deviation from central position ranged from 1.2 mm left to 1.1 mm right for superior endplate implants and from 1.1 mm left to 0.6 mm right for inferior endplate implants (Table 1). AP deviation from central position ranged from 0.7 mm anterior to 0.4 mm posterior for the superior endplate and from 0.5 mm anterior to 0.6 mm posterior for the inferior endplate.

Follow-up CT evaluation of the superior and inferior endplate implants revealed no significant subsidence, migration, or rotational change (Table 2). Facet joints also showed no significant change at implanted or adjacent levels, nor did they show any signs of fracture or increased degeneration.

Clinical outcome scores for Visual Analog Scale and Oswestry improved from a mean of 7.44 and 31.26 to 4.38 and 15.07, respectively (Table 3). Multivariate regression analysis of positional deviation from center or midline and change at follow-up relative to clinical outcomes showed no correlation.

■ Discussion

Spine arthroplasty has been available in theoretical and clinical form for a long time. Many designs from the Fernstrom balls to the design by Hou have been discontinued,[1,5,10–12] and others such as the Link-Charite and the ProDisc have undergone multiple iterations to reach their current status.[3,13,14] Although the early designs were not ideal, initial promising results led to design changes such that current designs yield excellent results.

While biomechanical and animal studies can validate some of the design features of the prostheses, only well-designed clinical trials will evaluate efficacy of current artificial disc replacement designs.

This study evaluates our ability to place the prosthesis in the "ideal" central position within the intervertebral space. Future biomechanical and other clinical studies may show that the "ideal" position is actually other than center–center with no angulation; however, for this study, it was the implantation goal. The results show that there is some variation from the central position up to 1.2 mm ML and 0.7 mm AP in this series. The angular variation was also somewhat greater than expected with rotational deviation up to 11.9°. This may be explained by a number of factors. First, it is difficult to accurately assess the exact angulation of the vertebral body based on the AP fluoroscopic view. Minor deviations in this initial visualization may be accentuated by the fact that only the midline is marked on the anterior vertebral body. If there is initial rotation that is not accounted for during implantation, the angle may be off even though the entry point is accurate. Finally, the position of the surgeon relative to the patient (at our institution the surgeon stands on the left side) and the typically left-sided retroperitoneal approach may increase the tendency to deviate to the left side.

Table 1. Initial Postoperative CT Measurements, Deviation From "Ideal" Center Position

CT Parameter	Average	Range	
Superior endplate rotation	1.29° left	8.9° left	9° right
Inferior endplate rotation	2.23° left	11.9° left	9° right
Superior endplate anterior-posterior deviation	0.09 mm anterior	0.7 mm anterior	0.4 mm posterior
Inferior endplate anterior-posterior deviation	0.14 mm posterior	0.5 mm anterior	0.6 mm posterior
Superior endplate medial-lateral deviation	0.05 mm right	1.1 mm right	1.2 mm left
Inferior endplate medial-lateral deviation	0.01 mm right	0.6 mm right	1.1 mm left

Deviation from ideal AP position was defined as one half the difference between the anterior vertebral edge to the keel distance (AVD) and the posterior vertebral body edge to the keel distance (PVD). ML deviation was defined as one half the difference between the left side vertebral edge to the keel distance (LVD) and the right side vertebral body edge to the keel distance (RVD). Rotational measurements were defined as fin position relative to the posterior vertebral body edge.

Table 2. Follow-Up CT Measurements, Change in Position and Angulation From Immediate Postoperation to at Least 6-Month Postoperative Images

CT Parameter	Average Change	Range of Change	
Superior endplate rotation	0.1° left	0.5° left	0.5° right
Inferior endplate rotation	0.1° left	0.0° left	0.5° left
Superior endplate anterior-posterior deviation	0.09 mm anterior	0.1 mm anterior	0.1 mm posterior
Inferior endplate anterior-posterior deviation	0.03 mm anterior	0.0 mm anterior	0.1 mm posterior
Superior endplate medial-lateral deviation	0.05 mm left	0.1 mm right	0.1 mm left
Inferior endplate medial-lateral deviation	0.02 mm right	0.1 mm right	0.0 mm left

Contrary to a recent study that implied positioning inaccuracies in initial *versus* late implants by surgeons in an FDA trial,[15,16] the notable positional and angular deviations from ideal position in this group of patients show no clinical correlation. This may be related to a number of variables. The fin and plasma coat surface minimize the risk of migration, whereas the more constrained single axis center of rotation may decrease the risk of abnormal intervertebral motion. The spherical design of the bearing surface of the prosthesis may also allow relatively large angular deviations without compromising biomechanics.

It is notable that there was no prosthesis migration or subsidence. It has been postulated that prosthesis designs with greater constraint may result in increased migration or subsidence due to higher forces on the bone–metal interface.[17] Although the ProDisc II has no significant axial rotational constraint, it is constrained in the AP and ML planes. Since there was no significant change in position in this group of patients, however, it does not appear that migration is a significant risk. This is likely the result of a combination of the high friction plasma coat surface and the keel of the implant.

The limitations of this study include the time of the follow-up examinations. Although only long-term studies will show the overall efficacy of disc replacement surgery, the highest risk for subsidence or migration would be during the first few weeks after implantation, before the bone ingrowth has taken place. Once the bone ingrowth is complete, the likelihood of such migration diminishes significantly. The fact that the bone–prosthesis interfaces were flush and without lucency implies that bone ingrowth had taken place. Computed tomography is certainly not the ideal method of evaluating bone ingrowth; however, histologic or microradiographic studies were not possible in this *in vivo* study.

Another consideration may be use of roentgen-stereophotogrammetry for analysis of motion and change in prosthesis position. Such imaging would be an excellent method of validating the CT imaging methods as roentgen-stereophotogrammetry has similar accuracy of up to 0.3 mm and the in-plane resolution of the CT images was 0.13 mm. Unfortunately, such imaging techniques were not available in this study.

Table 3. Means for the Oswestry and Visual Analogue Scale (VAS): Values From Preoperative, Immediate Postoperative, and Multiple Follow-Up Visits

	Assessment Interval			
Outcome Measure	Preoperative (mean)	6 Weeks (mean)	3 Months (mean)	6 Months (mean)
VAS (10-cm scale)	7.44	2.89*	3.65†	4.38
Oswestry (50-point scale)	31.26	20.65	17.93‡	15.07

VAS = Visual Analogue Scale.
*Preoperative vs. 6 Weeks ($F = 11.05$, $P < 0.002$), significant interaction for type of treatment by time after surgery.
†Preoperative vs. 3 Months ($F = 10.80$, $P < 0.0002$), significant interaction for type of treatment by time. Preoperative vs. 6 Months, $F = 11.05$, $P < 0.005$), significant main effect for time after surgery. Oswestry: Preoperative vs. 6 Weeks ($F = 19.77$, $P < 0.001$), main effect of follow-up after surgery (time).
‡Preoperative vs. 3 Months ($F = 4.67$, $P < 0.05$), interaction between type of treatment by time. Preoperative vs. 6 Months ($F = 44.78$, $P < 0.0001$), main effect of follow-up after surgery.

■ Conclusion

Prosthesis implantation under fluoroscopic guidance is relatively accurate. These current techniques appear adequate as there was no association between positional and angular deviation and adverse clinical outcome. Subsidence or migration of this particular prosthesis also does not appear to be of significant risk. Further biomechanical studies are needed to verify that the ideal position is the center/midline position.

■ Key Points

- Spine disc replacement techniques are relatively accurate.
- Intervertebral prosthesis designs are robust enough to tolerate small deviations in implant positioning.
- No prosthesis migration is observed over the first 6 months after implantation.

References

1. Cinotti G, David T, Postacchini F. Results of disc prosthesis after a minimum follow-up period of 2 years. *Spine* 1996;21:995–1000.
2. Link HD. History, design and biomechanics of the LINK SB Charite artificial disc. *Eur Spine J* 2002;11(suppl 2):98–105.
3. Delamarter RB, Fribourg DM, Kanim LE, et al. ProDisc artificial total lumbar disc replacement: introduction and early results from the United States clinical trial. *Spine* 2003;28(suppl):167–75.
4. Fassio B, Ginestie JF. Discal prosthesis made of silicone: experimental study and 1st clinical cases [in French]. *Nouv Presse Med* 1978;7:207.

5. Fernstrom U. Arthroplasty with intracorporeal endoprosthesis in herniated disc and in painful disc. *Acta Chir Scand Suppl* 1966;357:154–9.
6. McAfee PC, Cunningham BW, Orbegoso CM, et al. Analysis of porous ingrowth in intervertebral disc prostheses: a nonhuman primate model. *Spine* 2003;28:332–40.
7. Regan J, McAfee PC, Guyer R, et al. Charité artificial disc replacement evaluation of the learning curve and complications in a multicenter prospective randomized controlled FDA IDE trial. *Spine J* 2004;4(suppl):75.
8. Szpalski M, Gunzburg R, Mayer M. Spine arthroplasty: a historical review. *Eur Spine J* 2002;11(suppl 2):65–84.
9. McAfee P, Cunningham B, Geisler F, et al. The importance of surgical volume as a predictor of outcomes with spinal surgery: a prospective randomized multicenter trial of 276 patients undergoing lumbar disk replacement [Paper No. 19]. In: *11th International Meeting on Advanced Spinal Techniques*. Southhampton, Bermuda, 2004.
10. Guyer RD, McAfee PC, Hochschuler SH, et al. Prospective randomized study of the Charite artificial disc: data from two investigational centers. *Spine J* 2004;4(suppl):252–9.
11. McAfee PC, Fedder IL, Saiedy S, et al. SB Charite disc replacement: report of 60 prospective randomized cases in a US center. *J Spinal Disord Tech* 2003; 16:424–33.
12. Zigler JE. Clinical results with ProDisc: European experience and U.S. investigation device exemption study. *Spine* 2003;28(suppl):163–6.
13. Zigler JE, Burd TA, Vialle EN, et al. Lumbar spine arthroplasty. Early results using the ProDisc II: a prospective randomized trial of arthroplasty versus fusion. *J Spinal Disord Tech* 2003;16:352–61.
14. Cunningham BW, Gordon JD, Dmitriev AE, et al. Biomechanical evaluation of total disc replacement arthroplasty: an in vitro human cadaveric model. *Spine* 2003;28(suppl):110–7.
15. van Ooij A, Oner FC, Verbout AJ. Complications of artificial disc replacement: a report of 27 patients with the SB Charite disc. *J Spinal Disord Tech* 2003;16:369–83.
16. Hou TS, Tu KY, Xu YK, et al. Lumbar intervertebral disc prosthesis: an experimental study. *Chin Med J* (*Engl*) 1991;104:381–6.
17. Reitz H, Joubert MJ. Intractable headache and cervico-brachialgia treated by complete replacement of cervical intervertebral discs with a metal prosthesis. *S Afr Med J* 1964;38:881–4.