ORIGINAL ARTICLE

Long-term outcome after implantation of prosthetic disc nucleus device (PDN) in lumbar disc disease

Selviaridis P[1], Foroglou N[1], Tsitlakidis A[1], Hatzisotiriou A[2], Magras I[1], Patsalas I[1]

[1] 1st Department of Neurosurgery, AHEPA University General Hospital, Aristotle University of Thessaloniki, Greece
[2] Agios Loukas Clinic, Thessaloniki, Greece

Abstract

Background: The prosthetic disc nucleus (PDN) device offers an adjunct treatment for patients with degenerative disc disease and herniation, who necessitate surgical intervention, avoiding total-disc replacement or fusion. This prospective, clinical study aimed to gauge the long-term effectiveness of microdiscectomy followed by PDN implantation in relieving pain and improving functional status in patients with symptomatic degenerative lumbar disc disease and herniation.

Methods: Ten patients with a) at least 6 months low back pain and/or sciatica resistant to conservative treatment and b) radiologically documented degenerative lumbar disc disease and herniation have been selected. Follow-up at 6 weeks, 3, 12, 48, and 96 months postoperatively included physical examination, radiological investigation (plain and dynamic radiographs and magnetic resonance imaging), and self-completion of outcome scales (visual analogue, Oswestry, and Prolo functional status). Short Form-36 version 2 Health Survey patient profile at 96 months completed the image of health related quality of life.

Results: Patients' mean follow-up was 100.6 months. Significant improvements in Oswestry, Prolo, and VAS scores were documented (p: 0.004 in all scales at 48 months). Generic health status was rated within the average lumbar disease population (46.3±6.8 for physical component summary and 45.2±9.6 for mental component summary). Lumbar spine range of motion (20.2±11.8 at 96 months) was restricted in relation to normal, but maintained considerable mobility. Treated disc height increased postoperatively (p:0.002) and its maintenance could also be documented in all cases. Disc height at the level above did not show any significant modification. All postoperative MRI showed a non-clinically significant high signal of end-plate on T2 sequences. Clinically relevant complications included one case of pulmonary thrombosis and one case of device extrusion, which was subsequently explanted.

Conclusions: After implantation, most patients continue to enjoy significant pain relief, a considerable amount of mobility is conserved and the disease specific functional outcome is excellent and remains for long, although it could not be supported that the generic health related quality of life is that of the general population. Hippokratia 2010; 14 (3): 176-184

Key words: artificial disc, degenerative disc disease, lumbar disc herniation, prosthetic disc nucleus

Corresponding author: Nicolas G. Foroglou, 1st Department of Neurosurgery, AHEPA University Hospital, Stilponos Kyriakidi 1, 54636, Thessaloniki, Greece, Tel: +302310235472, Fax: +302310230516, e-mail: nforog@med.auth.gr

Successful treatment of moderate degenerative disc disease of the lumbar spine has been a longstanding challenge for medical community. When conservative treatment fails to improve patient's symptoms, few surgical options are available. Mechanical stabilization can provide pain relief, but the procedure is extensive and not always successful. Moreover, the possibility of promoting degeneration in adjacent segments still exists, as the latter must compensate for the immobilized section of the spine[12-4]. One alternative is simple microdiscectomy, which typically eliminates leg pain and may also improve low back pain[5]. This procedure, though, carries the disadvantage of further destabilizing the segment[6-11], since nucleus material must be removed to reduce the possibility of reherniation and eliminate the source of physiodiscogenic pain from the anaerobic metabolic by-products of the diseased disc[12]. The optimal solution for treating symptomatic degenerative disc disease would be to replace all or part of the disc in such a way as to mimic its normal function. In this regard, total-disc replacement devices[13-18] offer a more biomechanically-friendly solution by allowing mobility in the affected segment. Nonetheless, the implant procedure is extensive and these devices do not restore the cushioning function of the replaced disc.

For cases of degenerative disc disease with disc herniation where the degree of degeneration is not sufficiently advanced to warrant a total-disc replacement or fusion, but where there is sufficient pain to necessitate surgical intervention, nucleus replacement technology offers a good alternative. The PDN (Raymedica Inc., MN) prosthetic disc nucleus device, introduced by C.D. Ray in 1996[19,20] is the first nucleus-replacement device made available, designed to replace the functions of the disc that were lost through degeneration. First clinical trials

started in 1996[19,21], with promising results, and the device and technique of implantation has been modified over the years in term to minimize the risk of migration. Indications for PDN implantation have been recently summarized by Ray[22]. Briefly, candidates for implantation should not present advanced degeneration, disc height should be more than 5 mm, body mass index (BMI: weight in Kg/height in m^2) less than 30, and body weight less than 90 kg if the L5-S1 space is treated. Anterior-posterior dimension of the space indicates the use of two implants if more than 37 mm or one if smaller.

The present study was conducted in a prospective manner in term to evaluate the long-term results of PDN implantation after lumbar microdiscectomy in a group of patients suffering from degenerative disc disease with associated disc herniation, but without segmental instability. The end points of the study were the patient reported clinical outcomes and the radiologically evident effects in the lumbar spine.

Materials and methods

Patient selection

A total of 10 patients, 8 male and 2 female, took part in the present study. Their age at the time of operation ranged from 26 to 61 years (mean±SD=41.6±10.4). All of them suffered from long-standing low-back pain and sciatic pain from one-level disc degeneration. The Ethical Committee of our Institution approved the study. Ten patients were enrolled after being informed of the product and the procedure, as well as the intended outcomes and all associated risks. Inclusion criteria were a) lumbar and lower extremity pain caused by unilevel lumbar disc herniation, as proved by magnetic resonance imaging (MRI), and b) no response to adequate conservative treatment for a period of at least six months. All patients presented with severe symptoms interfering with daily activity. Exclusion criteria included a) severe degenerative disc disease with collapsed intervertebral space, b) disc space less than 5 mm, c) serious concomitant disease, d)previous surgical treatment in the lumbar spine, e) severe osteoporosis, and f) segmental instability. The study was initiated in August 1999 and enrolment continued until November 2000.

Treatment standards

All operations were performed by the senior author (PS). The disc was approached posteriorly (posterior intralaminar approach) in a manner consistent with unilateral standard microdiscectomy, under the operative microscope, as previously described[23], accompanied by flavectomy and trimming of the edges of the superior and inferior lamina only when necessary to visualize the nerve root. Before the PDN devices imlantation, preoperative disc-height measurements had been confirmed

Table 1: Demographics, symptoms, diagnosis, time between the onset of the symptoms and the operation, working arrest before surgery, i.e. the time duration the patient could not work because of his/her pain before surgery, and re-enrolment postoperatively[a].

	Age (y)	Gender	Symptoms (side)	Diagnosis	Onset of back pain	Onset of leg pain	PreOp Time	PostOp Time
1	41	Male	1,2,3[b] (Left)	L5/S1 M-L extrusion	6 y	4 m	4 m	Unemp
2	61	Male	1,2,3,4 (Right)	L5/S1 M-L extrusion	6 y	6 y	6 y	3 m
3	39	Female	1,2,3,4 (Left)	L5/S1 M-L extrusion	14 m	14 m	1 m	3 m
4	39	Female	1,2,3 (Left)	L5/S1 M-L extrusion	9 m	9 m	5 m	3 m
5	32	Male	1,2 (Left)	L4/L5 M-L protrusion	6 m	6 m	1 m	4 m
6	33	Male	1,2,3,4 (Left)	L4/L5 M-L extrusion	15 m	13 m	1 m	12 m
7	47	Male	1,2 (Right)	L5/S1 M-L extrusion	6 m	5 m	4 m	2 m
8	26	Male	1,2,3 (Left)	L4/L5 M-L extrusion	6 m	2 m	2 m	2 m
9	53	Male	1,2,3 (Left)	L4/L5 M-L extrusion	7 m	7 m	7 m	6 m
10	45	Male	3,4 (Left)	L4/L5 M-L sequestered	7 m	7 m	1 m	8 m

[a] Abbreviations: y = years, m = month(s), M-L = medial-lateral, PreOp Time = Preoperative working arrest, PostOp Time = Postoperative time before return to work

[b] Symptoms: 1 = back pain, 2 = leg pain, 3 = numbness of leg and/or foot, 4 = weakness of leg and/or foot

Table 2: Clinical and radiological outcomes, with the exception of SF-36v2 (mean±SD)[a].

	VAS	Oswestry	Prolo	RoM	Height	Height above
Preoperatively	6.6±1.6	51.4±15.7	4.1±0.9	28.2±25.7	7.9±1.4	10.7±0.8
6 weeks	-	-	-	-	9.6±2.0	10.7±0.8
3 months	1.7±1.6	8.4±5.9	7.7±1.3	-	9.1±1.2	10.7±0.8
12 months	0.2±0.6	1.4±2.7	9.8±0.4	-	9.1±1.2	10.6±0.8
48 months	0.2±0.6	2.2±3.8	9.8±0.4	26.4±9.9	9.1±1.1	10.6±0.9
96 months	1.6±1.5	6.2±10.4	8.4±1.5	20.2±11.8	11.3±2.7	11.2±2.3

[a] Abbreviations: VAS = visual analogue scale, RoM = range of motion.

through the use of sizing instruments that corresponded to the different PDN sizes available. For all patients in this study, two devices were implanted, anteriorly and posteriorly, to the disc space and finally secured together with a knot. The use of fluoroscopy was essential for the identification of the affected disc space, the verification of the completeness of the enucleation with the help of a water soluble contrast agent, and the alignment of the devices. Patients remained in a recumbent position for twenty-four hours following surgery. They were mobilized thereafter and instructed from the physiotherapist to avoid prolonged sitting, extreme flexion and full physical activities during the first 4 weeks. They were discharged the 4th postoperative day and a lumbar brace was used for 6 weeks, in term to avoid excessive flexion.

Outcome measures

The outcomes reported by the patients using self-administration supervised by the survey administrators (NF, AT) were pain, back specific degree of dysfunction, and work disability, assessed with the visual analogue scale (VAS)[24], Oswestry scale[25,26], and Prolo Functional Economic Scale[27] respectively. In addition, generic health status was assessed with SF-36v2[28].

Along with patient reported outcomes, radiologically evident effects were also studied. Total lumbar range of motion (RoM) was measured in flexion-extension dynamic lateral radiographs with the Cobb method as the change in the angle between the upper surfaces of L1 and S1 vertebral bodies. The height of intervertebral space at the treated level and the level above was measured in midsagittal view of T1 lumbar spine MRI.

Preoperative and postoperative evaluation

Preoperative and postoperative evaluation was performed one week before and 6 weeks, 3, 12, 48, and 96 months after the operation. It included physical examination, recording of patient reported outcomes (VAS, Oswestry scale, Prolo scale and SF-36v2), and radiological assessment (plain films of the lumbar region in anterior-posterior and lateral views, flexion and extension lateral views, and magnetic resonance imaging of the lumbar spine). VAS, Oswestry scale, and Prolo scale instruments were administered in all visits except for the follow-up of 6 weeks postoperatively, because not enough time had elapsed from surgery. The SF-36v2 was administered only in the visit of 96 months after the operation. All follow-up visits included physical examination and radiological assessment (plain films, functional films, and MRI). All operation-related complications were recorded.

Statistical analysis

The normality of all the analyzed variables was studied with the Shapiro-Wilk test. Friedman's analysis of variance (ANOVA) providing with exact significance levels was used, in order to assess the change of the median values of VAS, Oswestry scale, Prolo scale, and disc heights of the intervertebral space at the treated level and the level above. If the latter was statistically significant, it was followed by post hoc Wilcoxon signed ranks tests with the appropriate Bonferroni correction applied (the critical level of exact significance was set at. 005 for VAS, Oswestry, and Prolo scales and at. 00333 for operated disc height). Norm-based scoring (NBS) was applied on each of the health domain scales and summary measures of SF-36v2 and the group scores were compared with the average range for the group scores of the 1998 U.S. general population (47 to 53 NBS points)[28], as well as with the respective mean scores of the back-pain/sciatica specific population, taking minimally important difference (MID) into account[28]. Evaluation of the association between the recorded variables in pairs was conducted with Pearson product moment correlation, when both variables followed the normal distribution, or with Spearman correlation in all other cases. All analyses were conducted with SPSS 15.0 (SPSS Inc., 2005)[29].

Results

Ten patients have been included in the study and completed follow up. One patient denied any radiological evaluation at 48 months after the operation and two patients were lost to follow-up at 96 months after the operation. The demographics, with accompanying history and diagnosis of each patient, are summarized in Table 1 and the clinical and radiological outcomes, with the exception of SF-36v2, are summarized in Table 2. The preoperative and postoperative radiological findings of one case with L4-L5 lateral herniation are illustrated in Figure 1.

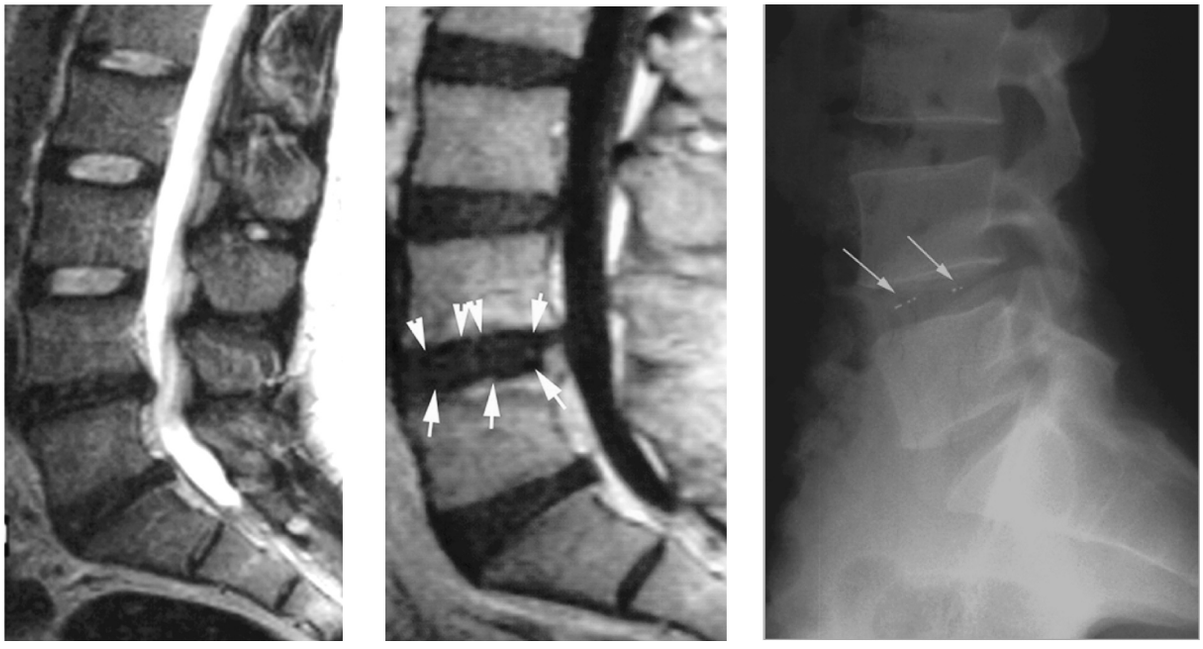

Figure 1: Illustrative case of L4-L5 disc herniation, treated by microdiscectomy and PDN implantation: (A) preoperative MRI, (B) postoperative MRI (small arrows indicate the device contour), and (C) postoperative lateral radiography (large arrows indicate radio-opaque signs of the anterior and posterior device).

Pain, back specific function and work disability

There were statistically significant differences in the score of the visual analogue scale across time (Friedman's ANOVA, p: $1.47x10^{-7}$, df: 4). It appeared that the score of the visual analogue scale was significantly decreased between the preoperative time period and 3 months (Wilcoxon signed ranks test, p: .004), 12 months (p: .002), and 48 months postoperatively (p: .002). No other statistically significant differences were observed, although the score of the visual analogue scale at the 96 months visit still remained lower than the preoperative in all patients (Figure 2A; Table 3).

In addition, there were statistically significant differences in the Oswestry scale across time (Friedman's ANOVA, p: $1.41*10^{-7}$, df: 4). It appeared that the score of the Oswestry scale was significantly decreased between the preoperative time evaluation and 3 months (Wilcoxon signed ranks test, p: .002), 12 months (p: .002), and 48 months postoperatively (p: .002) and between the 3 months and 12 months visit (p: .004). No other statistically significant differences were observed, although the score of the Oswestry scale at the 96 months follow-up still remained lower than the preoperative in all patients (Figure 2B; Table 3).

Furthermore, there were statistically significant differences in the Prolo scale across time (Friedman's ANOVA, p: $1.47*10^{-9}$, df: 4). It appeared that the score of the Prolo scale was significantly increased between the preoperative evaluation and 3 months (Wilcoxon signed ranks test, p: .002), 12 months (p: .002), and 48 months postoperatively (p: .002) and between the 3 months visit and 12 months (p: .004) and 48 months follow-up (p: .004). No other statistically significant differences were observed, although the score of the Prolo scale at the 96 months visit still remained higher than the preoperative in all patients (Figure 2C, Table 3).

Generic health status

From the examination of the SF-36v2 Health Survey Profile at 96 months postoperatively (Figure 3), one could observe that the group scores of PCS (physical component summary, 46.3±6.8 NBS points) and MCS (mental component summary, 45.2±9.6 NBS points) were below the average range for the group score of the 1998 U.S. general population, but there was no clinically important difference from the respective group scores of the back-pain/sciatica specific population.

In particular, the group scores of PF (physical functioning, 50.5±5.1 NBS points), VT (vitality, 49.4±8.1 NBS points), and SF (social functioning, 50.7±6.1 NBS points) were within the average range for the 1998 U.S. general population, while there was a clinically important increase from the respective group scores of the back-pain/sciatica specific population.

On the other hand, the group scores of BP (bodily pain, 42.8±8.2 NBS points) and MH (mental health, 45.4±10.3 NBS points) were also below the average range for the 1998 U.S. general population, but there was no clinically important difference from the respective group scores of the back-pain/sciatica specific population.

Moreover, the group scores of RP (role physical, 42.8±7.1 NBS points), GH (general health, 42.6±4 NBS points), and RE (role emotional, 40.3±8.3 NBS points) were below the average range for the U.S. general popu-

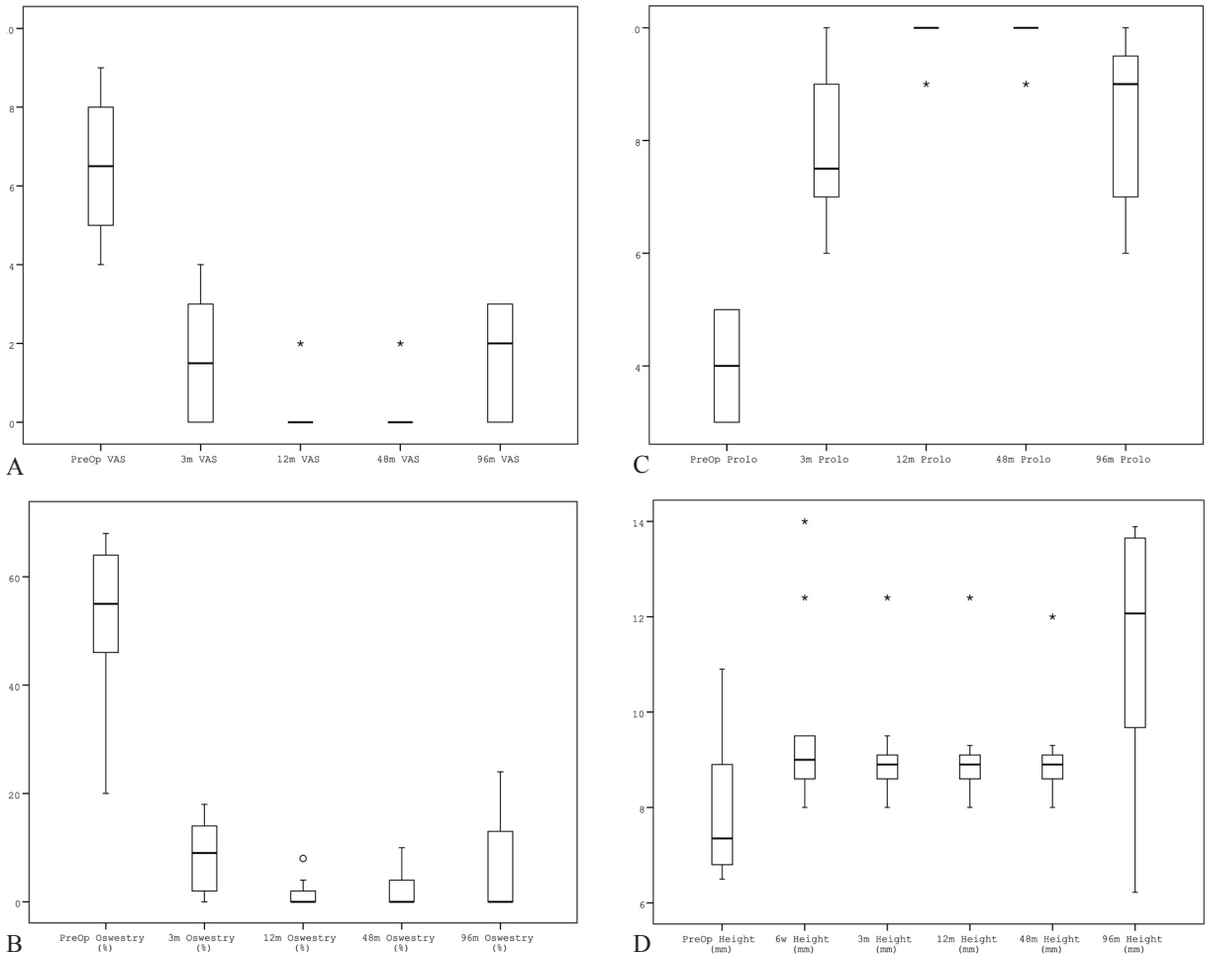

Figure 2: Boxplot of mean values variation of: (A) visual analogue scale, (B) Oswestry scale, (C) Prolo Functional and Economic status, and (D) the disc height of the treated level.

Table 3: Levels of significance (P values) of the differences in the variables between different time periods.

	Height	VAS	Oswestry	Prolo
PreOp[a] – 6w	.002*	-	-	-
PreOp – 3m	.004	.004*	.002*	.002*
PreOp – 12m	.004	.002*	.002*	.002*
PreOp – 48m	.008	.002*	.002*	.002*
PreOp – 96m	.039	.008	.008	.008
6w[b] – 3m	.25	-	-	-
6w – 12m	.125	-	-	-
6w – 48m	.016	-	-	-
6w – 96m	.25	-	-	-
3m[c] – 12m	1.0	.031	.004*	.004*
3m – 48m	.125	.031	.008	.004*
3m – 96m	.109	.938	1.000	.5
12m – 48m	.25	1.000	1.000	1.000
12m – 96m	.109	.063	.25	.031
48m – 96m	.109	.063	.375	.031

* significant differences (P <. 00333 for height and P <. 005 for the rest variables, due to Bonferroni correction)
[a] PreOp: preoperative
[b] w: weeks
[c] m: months

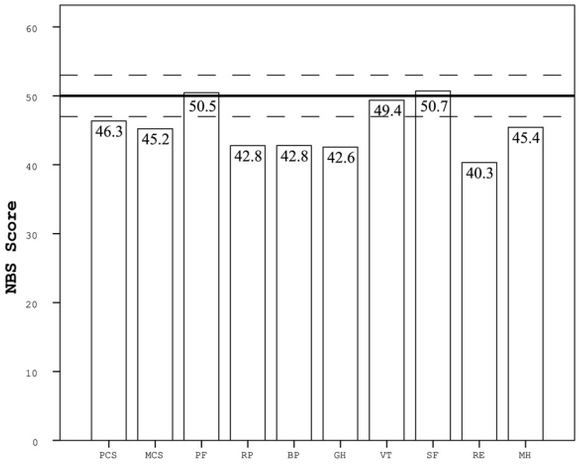

Figure 3: SF-36v2 Health Survey Patient Profile at 96 months postoperatively. The bars correspond to standardized norm-based scores. The thick horizontal line corresponds to the mean in 1998 US gerenal population (the norm), which is 50, and the dashed lines to the values of 53 and 47. A score greater or lesser than these values respectively is considered significantly different than the norm (PCS = Physical Component Summary, MCS = Mental Component Summary, PF = Physical Functioning, RP = Role-Physical, BP = Bodily Pain, GH = General Health, VT = Vitality, SF = Social Functioning, RE = Role-Emotional, MH = Mental Health, all scores in NBS points).

lation, while there was a clinically important decrease from the respective group scores of the back-pain/sciatica specific population.

Relationships between patient reported outcomes

Relationships between patients reported outcome variables were examined preoperatively, at 3 months, 12 months, 48 months, and 96 months follow-up visits.

At 12 months follow-up, significant relationships between the scores of the visual analogue and Oswestry scale (Spearman ρ: .64, p: .045), visual analogue and Prolo scale (Spearman ρ: -.67, p: .04), and Oswestry and Prolo scale (Spearman ρ: -.86, p: .002) were observed.

At the 48 months visit, significant relationships were detected between the scores of the visual analogue and Prolo scale (Spearman ρ: -.67, p: .04) and Oswestry and Prolo scale (Spearman ρ: -.64, p: .045).

At the 96 months visit, significant relationships were detected between the scores of Prolo and SF-36v2 Norm-Based RP Health Domain Scale (Spearman ρ:. 89, p: .003), time between the onset of back pain and the score of SF-36v2 Norm-Based GH Health-Domain Scale (Spearman ρ: -.73, p: .04), and time between the onset of leg pain and the score of SF-36v2 Norm-Based PF Health Domain Scale (Spearman ρ: -.73, p: 0.4).

No other statistically significant relationships between patients reported outcome variables could be traced at any time point.

Complications

Postoperative complications included: (1) pulmonary thrombosis in one patient, which developed one month postoperatively and was successfully treated, resulting in the patient's return to his previous strenuous employment one year after the operation, while retardation of re-enrolment was not relevant to implantation but to the thrombosis, and (2) posterior migration of one device outside the disc space, resulting in nerve-root compression and being subsequently explanted one month postoperatively. In Figure 4, the posterior migration of the device is illustrated in CT scan. The patient remained asymptomatic after the second surgery, and he is still observed closely at regular basis for delayed instability.

Radiological findings

The range of motion at 48 months after the operation was 26.4±9.9 (mean±standard deviation) and at 96 months after the operation 20.2±11.8, which might be regarded as restricted in relation to the normal population according to the literature[30-32], although it should be noted that a considerable amount of mobility was conserved.

There were statistically significant differences in the operated intervertebral disc height across time (Friedman's ANOVA, p: $6.01*10^{-6}$, df: 5). It appeared that the operated intervertebral disc height was significantly increased from the preoperative time period to 6 weeks postoperatively (Wilcoxon signed ranks test, p: 0.002). No other significant changes were observed (Figure 2D; Tables 3 and 4).

There were no statistically significant differences in the intervertebral disc height above the operated one across time (Friedman's ANOVA, p: 0.818, df: 5) (Table 3) and no statistically significant relationships between the height of the operated intervertebral disc and the level above at any time point.

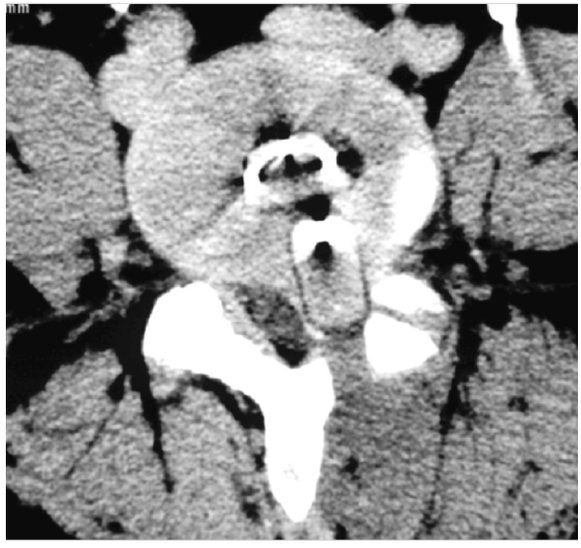

Figure 4: CT scan of posterior migration in the L4-L5 level.

Table 4: Values of disc height at the treated level (left column) and the level above (right column) in mm.

ID	Preoperatively		6 Weeks		3 Months		12 Months		48 Months		96 Months	
1	06.5	11.0	08.0	11.0	08.0	11.0	08.0	11.0	-	-	-	-
2	09.0	10.0	09.5	10.0	09.5	10.0	09.3	10.0	09.3	10.0	-	-
3	08.0	10.1	08.6	10.1	08.6	10.1	08.6	10.1	08.6	10.1	13.5	11.1
4	06.8	10.4	08.9	10.3	08.9	10.4	08.9	10.3	08.7	10.3	13.9	16.5
5	08.9	11.6	14.0	11.6	08.9	11.6	08.9	11.6	08.9	11.6	6.2	10.8
6	10.9	12.3	12.4	12.3	12.4	12.3	12.4	12.3	12.0	12.3	13.0	11.4
7	07.0	10.2	09.2	10.2	09.1	10.2	09.1	10.2	09.1	10.2	9.1	10.8
8	06.8	10.1	08.7	10.1	08.7	10.1	08.7	10.1	08.5	10.1	11.2	10.3
9	07.0	11.1	09.1	11.0	09.0	11.0	09.0	11.0	09.0	11.0	10.3	10.0
10	07.7	10.0	08.0	10.0	08.0	09.8	08.0	09.8	08.0	09.8	13.8	8.5

Except for the case of implant extrusion, where the implant was displaced posteriorly through the posterior ligament opening and compressed the exiting nerve root, there were two more cases of device dislocation, the first presenting an intraspace rotation of 20° and the second presenting a partial subsidence into the inferior vertebral body. Both dislocations were detected in the 12 month postoperative MRI and remained stable till the end of the study without any clinical consequence at any time. It should also be noted that at the 96 months visit, in the patient with posterior migration of one device, asymptomatic recurrence of the remnant lumbar disc herniation was observed.

A stable radiological finding of all patients was the presence of high signal on T2 sequences of the end plates but again without any clinical sign.

Relationships between patient reported outcomes and radiological findings

At 96 months, there was a significant relationship between the operated intervertebral disc height and SF-36v2 Norm-Based GH Health Domain Scale (Pearson r: -.75, p: .03). No other statistically significant relationship could be traced between quality of life, pain or functional status variables, and radiological findings at any time point.

Discussion

Patient reported outcomes

The present study suggests that pain, disease specific functional status, and work disability, in a group of patients with lumbar disc disease treated with PDN implantation, were significantly ameliorated between the preoperative period and the immediately postoperative period and remained stable or better until at least 48 months postoperatively. These findings are in accord with previous clinical studies[19,21,22,33-35]. On the other hand, no significant difference in these outcomes could be detected between the 96 months visit and the preoperative or the other postoperative follow-up, perhaps because of having two patients lost to follow-up, but still all outcomes remained better compared with the preoperative status in all patients.

In specific, it should be noted that PDN implantation resulted in a longer recovery period than simple microdiscectomy, with postoperative lumbar pain graver than that of simple microdiscectomy (as confirmed by the VAS at 3 months), probably due to disc height correction. However, the immediate postoperative lumbar pain was well controlled with usual painkillers, it was shortly decreased, and the long-term outcome justified the use of this technique. Soon lumbar pain and sciatica were satisfactorily controlled and from the 12 months follow-up until the 48 months visit only one patient experienced occasional remnant mild pain, while on the 96 months follow-up mild pain had relapsed in some of the patients and all but two of them had an excellent disease specific functional status and a good or excellent outcome in Prolo scale. Professional activity was allowed after 3 months and most of the patients were able to return to work within the first six months after surgery, while some returned sooner than advised (Table 1).

Regarding the SF-36v2 Health Survey Profile at 96 months postoperatively, the group scores of PCS and MCS indicated that, in general, the patients that comprised the study group did not have the physical and mental performance and capacity of the average population, but that of the lumbar disease population. In specific, the group scores of BP and MH were a sign that the patients' emotional status was characterized more frequently by anxiety and depression than the average general population and that, although they experienced little or no pain for years, they felt limited in their normal activities. Even more, the group scores of RP, GH, and RE suggested that the patients had a pessimistic view for their health in general and also that they had more health-related problems with work or other daily activities than the average population with lumbar disc disease.

On the other hand, the group scores of PF, VT, and SF showed that the patients were characterized by improved subjective well-being and felt they could perform physical and social activities without the health limitations of lumbar disc disease. Perhaps these, largely contradicting, aspects of the patients for their health reflected the avoidance of triggering the pain again and their caution about their health, as they were eight years older than when operated. In consequence, it could be regarded that, though the patient profile was altered as compared with the typical lumbar disc disease population, it still retained many aspects of their disease that should be further investigated.

Radiological findings

The significant increase of disc height of the treated level since the first postoperative control and its stability during the study period could be expected given the hydrophilic nature of the PDN device and its concomitant ability to distract the vertebrae upon hydrating. Additionally, the maintenance of the disc height at the level above in all patients after 8 years may reflect a role of the PDN device in the normalization of lumbar spine function. Both findings have been previously reported[19,21,22,33-35], but for shorter time of follow-up. Furthermore, this study also showed that the range of motion in the long-term had maintained a considerable amount of mobility. It is clear from this study that the restorative role of the PDN device in the lumbar region is stable at least for a period of eight years.

Another interesting radiological finding was the persistence of T2 high signal at the level of treated endplates, but without any clinical consequence, although present even after eight years. It is difficult to interpret this finding, but it has been suggested[21] that it is probably a sign of remodeling due to uneven distribution of loads at the contact areas within the disc space.

Clinical correlations

An important piece of this investigation was the examination of the relationships between the outcomes of interest. For example, it should be noted that the significant correlations between the scores of the visual analogue, Oswestry, and Prolo scale at the 12 months and 48 months visits were probably due to the fact that nearly all patients had excellent scores in these scales at these follow-ups.

Moreover, at the long term visit, significant relationships axist between the scores of various SF-36v2 Norm-Based Health Domain Scales and other patient reported outcomes. In specific, the association between 96 months Prolo and RP could perhaps be explained by the fact that they express similar notions, while the association between the preoperative duration of back pain and the score of GH could probably imply that the patients' estimation of their health in general was related with the time they suffered with back pain. It should also be noted that the correlation between the preoperative duration of leg pain and the score of PF could probably be attributed to an association between physical performance as evaluated by the patients themselves and the time they experienced pain in their lower extremity.

In addition, the only significant correlation of the radiological findings with each other as well as with the other outcomes was an association between the operated intervertebral disc height and SF-36v2 Norm-Based GH Health Domain Scale at 96 months, which remains to be clarified by further research. Interestingly, though, no statistically significant relationship between the height of the operated intervertebral disc and the level above or the treated disc height and pain and the other patient reported outcomes could be traced.

Strengths and limitations

Although amelioration in visual analogue, Oswestry, and Prolo scales was observed, this is not a comparative study that could render these results to PDN implantation or not. Instead, the aim of this study was to evaluate the feasibility and the long-term clinical results of PDN implantation. While most clinical studies have reported short-term results of PDN implantation[19,33], only the Wiesbaden group[21] reported results from a 2-year follow-up and Rosales-Olivares et al[36] from a 4-year follow-up. It seems that this is the first publication reporting results of 8 years of follow-up on a single institution.

The major limitation of this study was its small sample size enhanced by the withdrawal of two patients, which could be rendered responsible for the low power of the statistical tests. The power was not only immediately limited by the sample size, but from the nature of the tests used as well. As most of the variables followed a sparse distribution, the statistics used in their analysis were mostly non-parametric, which are frequently underpowered to detect significant differences and associations. On the other hand, this fact results in adding more confidence to the statistically significant results of the current study.

In patients presenting with low-back pain and sciatic pain due to degenerated disc disease and disc herniation, microdiscectomy associated with artificial disc implantation has the theoretical advantage to eliminate on one hand the risks of long-term disc degeneration, disc collapse, and eventually instability of microdiscectomy alone and on the other hand the risk of adjacent level disease associated with fusion[37]. Currently, the surgical approaches used for PDN implantation are (1) posterior intralaminar, (2) paraspinal transforaminal, and (3) anterior-lateral transpsoatic approach (ALPA)[33,35]. In the present study, the intralaminar approach was preferred as less invasive and more familiar. Classic microdiscectomy represents a refinement of the standard hemilaminotomy with emphasis on magnification, lighting, and hemostasis.

It seems that the most crucial technical point is the minimal necessary opening of the posterior ligament / annulus complex in term to avoid implant extrusion (Figure 4), which may cause some difficulty in disc material removal. In the case of implant extrusion after 2 months postoperatively, immediate removal was easily performed for the posterior extruded device, but the anterior one was removed with difficulty. It should be noted that in this case disc height postoperatively increased significantly comparing to usual. Over-distraction might have been the cause of the extrusion, especially if it was associated with annulus incompetence. Appropriate size selection and limited laminar distraction are crucial for avoiding this complication.

It should also be noted that the two patients that experienced postoperative complications conducted a normal life thereafter at least until the last visit, and that, with the exception of the posterior migration of one device, all other cases of implant dislocation were asymptomatic.

Conclusion

Despite the restrictions of the limited number of the study group, the present study suggests that the clinical outcome of PDN implantation is satisfactory, providing significant pain relief and allowing the majority of the patients to return shortly to work. It is also suggested that the disease specific functional outcome is excellent and remains for long, although it could not be supported that the generic health related quality of life is that of the general population. A considerable amount of mobility is conserved, even though not that much as in the general population. No instability or adjacent level disease has been documented after 8 years of follow-up.

Although results from PDN implantation are very encouraging, further prospective studies comparing simple microdiscectomy with and without implantation are needed in order to establish more trustworthy evidence as regard to this much promising technique.

References

1. Aota Y, Kumano K, Hirabayashi S. Postfusion instability at the adjacent segments after rigid pedicle screw fixation for degenerative lumbar spinal disorders. J Spinal Disord. 1995; 8: 464-473.
2. Lee CK. Accelerated degeneration of the segment adjacent to a lumbar fusion. Spine. 1988; 13: 375-377.
3. Quinnell RC, Stockdale HR. Some experimental observations of the influence of a single lumbar floating fusion on the remaining lumbar spine. Spine. 1981; 6: 263-267.
4. Rahm MD, Hall BB. Adjacent-segment degeneration after lumbar fusion with instrumentation: a retrospective study. J Spinal Disord. 1996; 9: 392-400.
5. Toyone T, Tanaka T, Kato D, Kaneyama R. Low-back pain following surgery for lumbar disc herniation: a prospective study. J Bone Joint Surg Am. 2004; 86-A: 893-896.
6. Kotilainen E, Valtonen S. Clinical instability of the lumbar spine after microdiscectomy. Acta Neurochir (Wien). 1993; 125:120-126.
7. Meakin JR, Redpath TW, Hukins DW. The effect of partial removal of the nucleus pulposus from the intervertebral disc on the response of the human annulus fibrosus to compression. Clin Biomech (Bristol, Avon). 2001; 16: 121-128.
8. Mochida J, Nishimura K, Nomura T, Toh E, Chiba M. The importance of preserving disc structure in surgical approaches to lumbar disc herniation. Spine. 1996; 21: 1556-1564.
9. Padua R, Padua S, Romanini E, Padua L, de Santis E. Ten- to 15-year outcome of surgery for lumbar disc herniation: radiographic instability and clinical findings. Eur Spine J. 1999; 8: 70-74.
10. Schaller B. Failed back surgery syndrome: the role of symptomatic segmental single-level instability after lumbar microdiscectomy. Eur Spine J. 2004; 13: 193-198.
11. Zollner J, Heine J, Eysel P. Effect of enucleation on the biomechanical behavior of the lumbar motion segment. Zentralbl Neurochir. 2000; 61: 138-142.
12. Saal JS, Franson RC, Dobrow R, Saal JA, White AH, Goldthwaite N. High levels of inflammatory phospholipase A2 activity in lumbar disc herniations. Spine. 1990; 15: 674-678.
13. Fraser RD, Ross ER, Lowery GL, Freeman BJ, Dolan M. AcroFlex design and results. Spine J. 2004; 4: S245-S251.
14. Geisler FH. Surgical technique of lumbar artificial disc replacement with the Charite artificial disc. Neurosurgery. 2005; 56: 46-57.
15. Link HD, Buttner-Janz K. LINK SB Charite artificial disc: history, design, and biomechanics. In: Kaech DL, Jinkins JR, eds. Spinal Rehabibilation Procedures. Amsterdam: Elsevier Science; 2002.
16. Mathews HH, Lehuec JC, Friesem T, Zdeblick T, Eisermann L. Design rationale and biomechanics of Maverick Total Disc Arthroplasty with early clinical results. Spine J. 2004; 4: S268-275.
17. Valdevit A, Errico TJ. Design and evaluation of the FlexiCore metal-on-metal intervertebral disc prosthesis. Spine J. 2004; 4: S276-288.
18. Zigler JE. Lumbar spine arthroplasty using the ProDisc II. Spine J. 2004; 4: S260-267.
19. Klara PM, Ray CD. Artificial nucleus replacement. Clinical experience. Spine. 2002; 27: 1374-1377.
20. Ray CD, Schonmayr R, Kavanagh SA, Assell R. Prosthetic Disc Nucleus Implants. Riv Neuroradiol. 1999; 12: 157-162.
21. Schonmayr R, Busch C, Lotz C, Lotz-Metz G. Prosthetic Disc Nucleus implants: the Wiesbaden feasibility study. Riv Neuroradiol. 1999; 12: 163-170.
22. Ray CD. The PDN® prosthetic disc-nucleus device. Eur Spine J. 2002; 11: S137-S142.
23. Hardy RW. Extradural cauda equina and nerve root compression from benign lesions of the lumbar spine. In: Youmans JR, editor. Neurological Surgery. 4th ed. Vol. 3. Philadelphia, PA: WB Saunders; 1996.
24. Carlsson AM. Assessment of chronic pain I. Aspects of the reliability and validity of the visual analogue scale. Pain. 1983; 16: 87-101.
25. Baker D, Pynsent P, Fairbank J. The Oswestry Disability Index revisited. in: Roland M, Jenner J, editors. Back pain: New Approaches to Rehabilitation and Education. Manchester, UK: Manchester University Press; 1989.
26. Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back disability questionnaire. Physiotherapy. 1980; 66: 271-273.
27. Prolo DJ, Oklund SA, Butcher M. Toward uniformity in evaluating results of lumbar spine operations. A paradigm applied to posterior interbody fusions. Spine. 1986; 11: 601-606.
28. Ware JE Jr, Kosinski M, Bjorner JB, Turner-Bowker DM, Gandek B, Maruish ME. User's manual for the SF-36v2© Health Survey. 2nd ed. Lincoln, RI: QualityMetric Inc. 2007.
29. SPSS Version 15.0 [Computer Program]. Chicago, IL: SPSS Inc.; 2005.
30. Greene WB, Heckman JD. The clinical measurement of joint motion. Chicago: American Academy of Orthopedic Surgeons; 1994.
31. Russell P, Pearcy MJ, Unsworth A. Measurement of the range and coupled movements observed in the lumbar spine. Br J Rheumatol. 1993; 32:490-497.
32. Pearcy MJ. Stereo radiography of lumbar spine motion. Acta Orthop Scand Suppl. 1985; 212: 1-45.
33. Bertagnoli R, Schonmayr R. Surgical and clinical results with the PDN prosthetic disc-nucleus device. Eur Spine J. 2002; 11: S143-148.
34. Dadi J, Dongbin Q, Liang Z, Jianting C, Jianming J. Prosthetic Disc Nucleus (PDN) replacement for lumbar disc herniation. Preliminary report with six months follow-up. J Spinal Disord Tech. 2003; 16: 331-337.
35. Shim CS, Lee SH, Park CW, Choi WC, Choi G, Choi WG, et al. Partial disc replacement with the PDN Prosthetic Disc Nucleus device. Early Clinical Results. J Spinal Disord Tech. 2003; 16: 324-330.
36. Rosales-Olivares LM, Perez-Viquez A, Miramontes-Martinez V, Alpizar-Aguirre A, Reyes-Sanchez AA. Experience with prosthetic disc nucleus device in Mexico. Final report of a 4-year follow-up [in Spanish]. Cir Cir. 2007; 75: 31-36.
37. Bao Q-B, Yuan HA. New technologies in spine. Nucleus replacement. Spine. 2002; 27: 1245-1247.

Conflict of Interest Statement

We state that there is no conflict of interest regarding this manuscript and any of its authors, as no funds were received in support of this study.