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ORIGINAL ARTICLE

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Surgical and clinical results with the PDN® prosthetic disc-nucleus device

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Abstract The PDN prosthetic disc-nucleus device has been in use for 6 years, both in clinical trials and through commercial sale. Surgical and clinical data for the device have been collected and analyzed to help determine the strengths and limitations of the implant. The shape of the device has been found to be an important element in predicting surgical success, with wedge and rectangular devices being the most stable. The patient's disc dimensions are also critically important. Data indicate that patients with a disc height of less than 5 mm should be excluded from surgery. Moreover, the anterior-posterior (AP) diameter of the disc endplates must be 37 mm or more in order to properly situate two devices within the disc – patients with a smaller AP diameter should receive only a single device. Body mass and overall patient weight are also good predictors of surgical success. If the patient's body mass index is 30 or greater, then the patient should not receive the implants. Complications related to the PDN implant have included migration of the device and endplate remodeling in some patients. This endplate remodeling has usually been mild, and has occurred in response to the change in load distribution. In a few cases there has been more pronounced remodeling with a loss of disc height. To minimize endplate remodeling, the PDN hydrogel has been reformulated to be softer, absorbing 80% of its weight in water. Subsequent to implementing changes in device design and patient selection, and with the introduction of the ALPA (Anterior-Lateral transPsoatic Approach) technique for implanting the devices, there has been an increase in surgical success with a concomitant reduction in the number of revision surgeries. The current surgical success rate for patients implanted from 1999 through 2001 is 88%. Clinical results are also very encouraging, with marked decreases in Oswestry and visual analog scale pain levels, and disc height also shows improvement and stabilization.

Keywords Degenerative disc disease · Disc arthroplasty · PDN device · Intervertebral disc · on-fusion treatment

Introduction

The PDN prosthetic disc nucleus has been developed for treating moderate forms of degenerative disc disease [7]. The goal of the device is to relieve low-back pain while maintaining disc height and allowing normal flexibility in the affected vertebral segments. The PDN device tries to fill the therapy gap that exists between discectomy and immobilization [6]. Unlike discectomy, the PDN implant restores disc height by increasing anular tension, which is essential for adequate segmental function [5, 8]. In con-

trast to fusion, the PDN device does not affect mobility at the implanted or adjacent vertebral segments [1, 4]. This approach has played a major role in shifting orthopedic research for the treatment of disc degeneration away from immobilization, and focusing it more on maintaining or restoring segmental flexibility. Indeed, the development of many nucleus replacement products such as Newcleus, DPD (Dampening Posterior Device), SINUX, Aquacryl, and Aquarelle can be attributed to the guiding concept of the PDN device.

The PDN device has been in use for the past 6 years, both in clinical trials and through commercial sale. As such, there is a growing pool of data and follow-up information that can be used to gauge the effectiveness of the device. In this paper we examine past and current surgical success rates for the PDN prosthesis, as well as clinical outcomes for low-back pain and disc height. By analyzing our results and reviewing what has been learned over the years, we can continue improving the device and helping our patients regain quality of life.

Surgical results for the PDN device

Clinical trials for the PDN device began on 26 January 1996. Twelve patients were implanted that year, 11 in Germany and one in South Africa. In this initial group, the first three cases were implanted with the devices oriented parallel to the sagittal plane. Thereafter, the surgical technique was modified, and in the remaining patients the devices were placed transversely within the disc. All patients were implanted through an open posterior approach (hemilaminotomy), as is standard in spine decompression surgery. The outcome from this initial group was very encouraging, with marked improvements in Oswestry scores and disc height measurements. Surgical success rates were also good, with only one patient requiring revision surgery in the 1st year of implantation – a laudable result for a new device.

These initial clinical trials were followed by additional implants in Germany, Saudi Arabia, South Africa, Sweden, and the United States between 1997 and 1998. These implant surgeries were performed using the same posterior hemilaminotomy technique as before. This latter patient cohort, however, did not show the same surgical success as the initial group (Fig. 1). Though Oswestry and disc height measurements were satisfactory for those patients with successful implants, overall there was a high rate of device migration (26%), with a concomitant need for revision surgeries.

A multivariate statistical analysis was made of all factors that might be responsible for the high revision rate. This analysis included such variables as device size and shape, aspects of the surgical procedure, and elements of the postoperative patient protocol. The results of the study identified a number of important changes that needed to be implemented to reduce the number of postoperative complications.

The statistical analysis revealed that certain device configurations were less likely to undergo migration. The rectangular and wedge-shaped devices were found to be most stable, as their shapes and sizes could be combined in different ways to best match the angle and shape of the vertebral endplates.

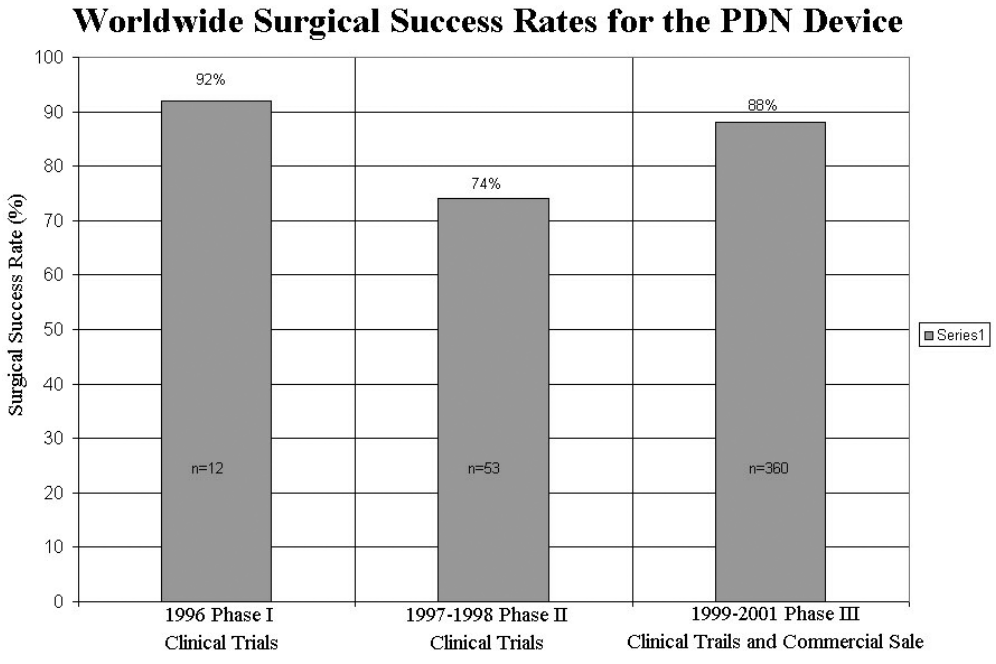

Fig. 1 Worldwide surgical success rates for the PDN device shown in three phases

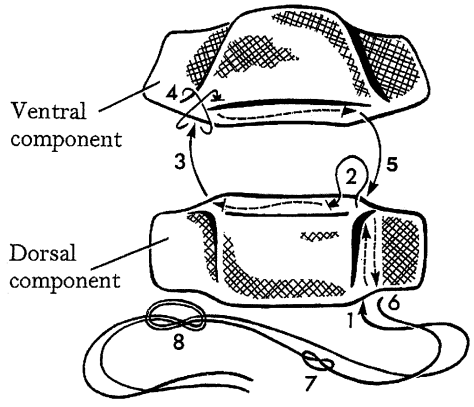

Fig. 2 Anterior (ventral) and posterior (dorsal) PDN devices are tethered together using a #2 polyester suture. Each device is implanted separately into the disc space, but they are pulled together after implantation so that the two devices act as a single system

In order to further stabilize the devices within the disc, a tethering system was developed using a #2 polyester suture. The anterior and posterior PDN devices are now threaded together in such a way that they can be implanted separately, but once within the disc space, they can be secured together (Fig. 2). The resulting implant, though composed of two separate devices, functions as a single system, which is less likely to undergo significant displacement.

Indications/contraindications and patient selection were identified as crucial variables in predicting surgical success. Available data suggested that those patients with disc heights less than 5 mm had a high risk of experiencing device migration. Also important was the patient's anterior-posterior (AP) disc-endplate diameter. When patients with AP disc dimensions of less than 37 mm were implanted with two PDN devices, not only was it difficult to fit both devices into the disc space, but also there was a higher rate of device migration. As such, it is currently recommended that only those patients with AP disc dimensions of 37 mm or greater be implanted with two PDN devices, while patients with smaller discs should be implanted with a single device.

Apart from intervertebral disc size, patient body mass and weight have also been found to be important variables. Those patients with a body mass index of 30 or greater were shown to have significantly higher rates of surgical complications (BMI = weight in kg / height in m^2). For these reasons, careful attention is now given to a patient's body mass before deciding to proceed with PDN implant surgery.

Another significant step towards reducing the number of revision surgeries has been the implementation of the Anterior-Lateral transPsoatic Approach (ALPA), which was introduced in the late 1990s as an alternative method for implanting the PDN device [2, 3]. In contrast to the posterior hemilaminotomy approach, where the disc is accessed from the back, in the ALPA technique the disc is accessed laterally through a minimal invasive approach in a strict lateral plane. After blunt dissection through the lateral abdominal muscles, the retroperitoneal region is accessed and followed laterally to the psoas muscle, where blunt dissection is again used to reach the disc. This approach offers access to the largest possible anatomical area of the disc circumference without impairing important anatomical structures. Once the nucleus material has been removed, the devices are implanted directly into the disc without needing to be turned, as is the case with the posterior surgical approach. Another advantage of ALPA is that the anterior longitudinal ligament and posterior longitudinal ligament (as well as all posterior structures) are kept intact and the anular incision is made on the biomechanically less important lateral aspect. These factors could explain why migration rates are significantly lower with ALPA compared to the posterior approach.

The need for changes to the postoperative patient protocol was also indicated by the analysis. The use of orthosis was found to be beneficial during the first 6 weeks after surgery to keep patients from putting too much strain on their lumbar spine while the PDN devices are conforming to the shape of the endplates.

The aforementioned changes began to be implemented in 1999, and subsequently the number of revision surgeries for the PDN device has decreased significantly. From 1999 through 2001, there have been 462 patients implanted, and of these, 12% have required some type of revision surgery to either reposition or explant the devices – yielding a cumulative rate of 88% successful implantations. This is a remarkable improvement compared to the earlier 1997–1998 implants, where the explant rate had been 26%. It is also important to note that the PDN does not prevent future treatment for those patients who do require some type of surgical revision. Because the devices do not promote fusion of the vertebrae, they can be replaced with other implants such as total disc replacements, or cages and bone grafts (alone or in combination with dorsal instrumentation).

Clinical results for the PDN device

The primary reason for using the PDN device in cases of moderate degenerative disc disease is the great improvement in the low-back pain of our patients. Worldwide clinical results for Oswestry score and pain on a visual analog scale (VAS) have shown marked improvement in pain levels. For 243 patients, the mean preoperative Oswestry score was 52.7. At the 6-month follow-up the average score dropped to 17.4, and at the 24-month follow-up, the mean score had declined further, to 9 (Fig. 3). VAS scores are equally compelling: for 213 patents, the preoperative mean was 7.1. At the 12-month follow-up visit, this pain level had decreased to 2.49, and at the

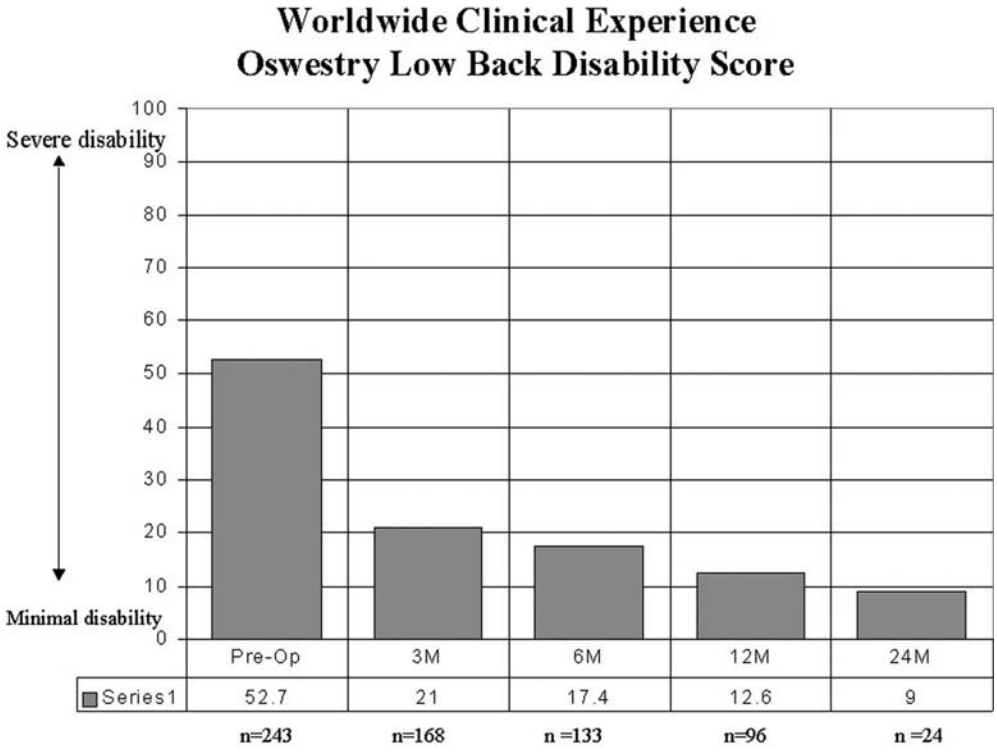

Fig. 3 Oswestry disability scores for the PDN device. Pain levels drop significantly after PDN device implantation

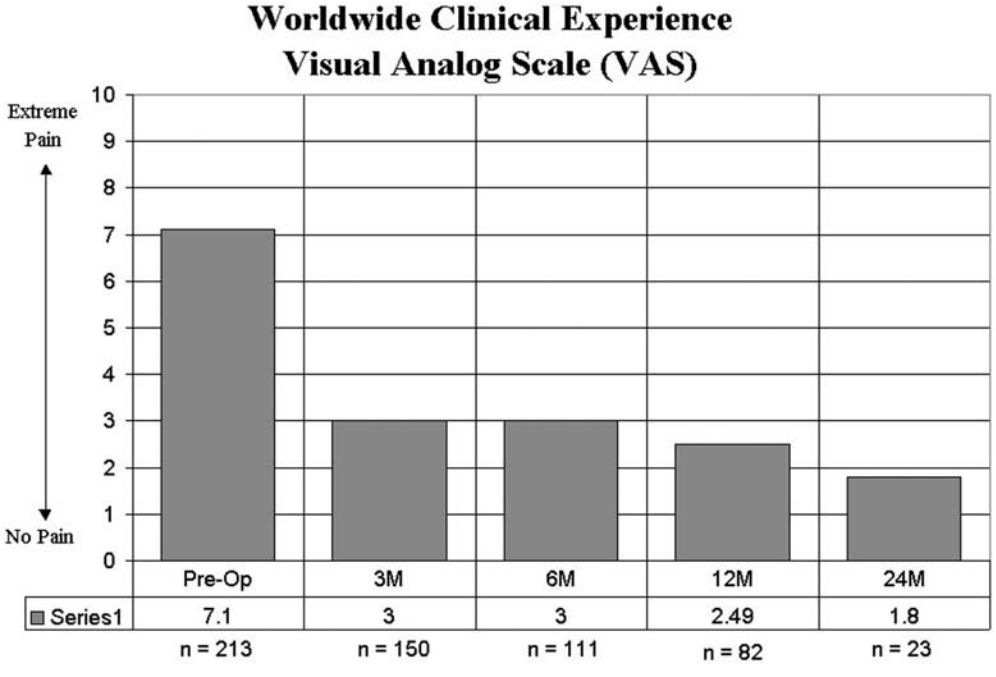

Fig. 4 Visual analog scale (VAS) for patients implanted with PDN devices. Pain levels drop significantly after PDN device implantation

24-month follow-up the level of pain had declined further to 1.8 (Fig. 4). As the number of patients with follow-up information at 24 months is still relatively low, these figures still are of a preliminary character.

This postoperative reduction in low-back pain is accompanied by an increase in disc height, which is a prerequisite for segmental stability to minimize nonphysiologic movements that may cause additional tearing of the anulus. For 218 patients, preoperative disc height averaged 8.1 mm. This measurement increased postoperatively to 9.7 mm at the 12-month follow-up, and 10.2 mm in the cohort measured after 24 months (Fig. 5, Fig. 6).

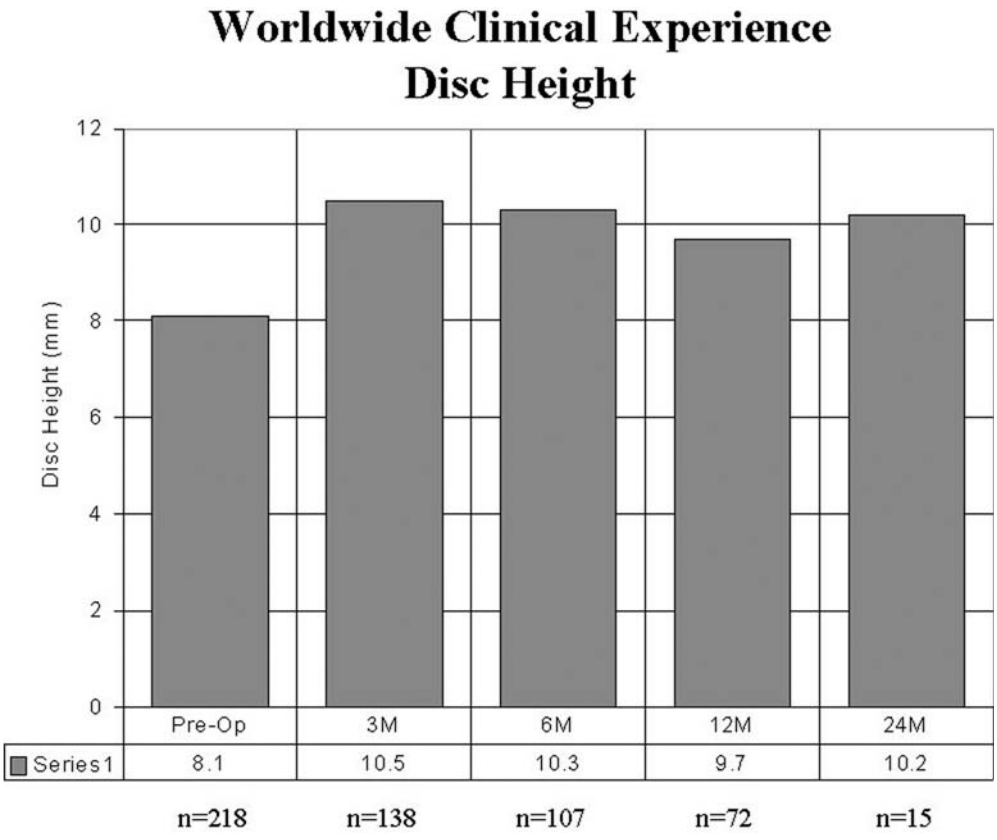

Fig. 5 Disc height measurements before and after PDN device implantation. The device restores/maintains disc height postoperatively

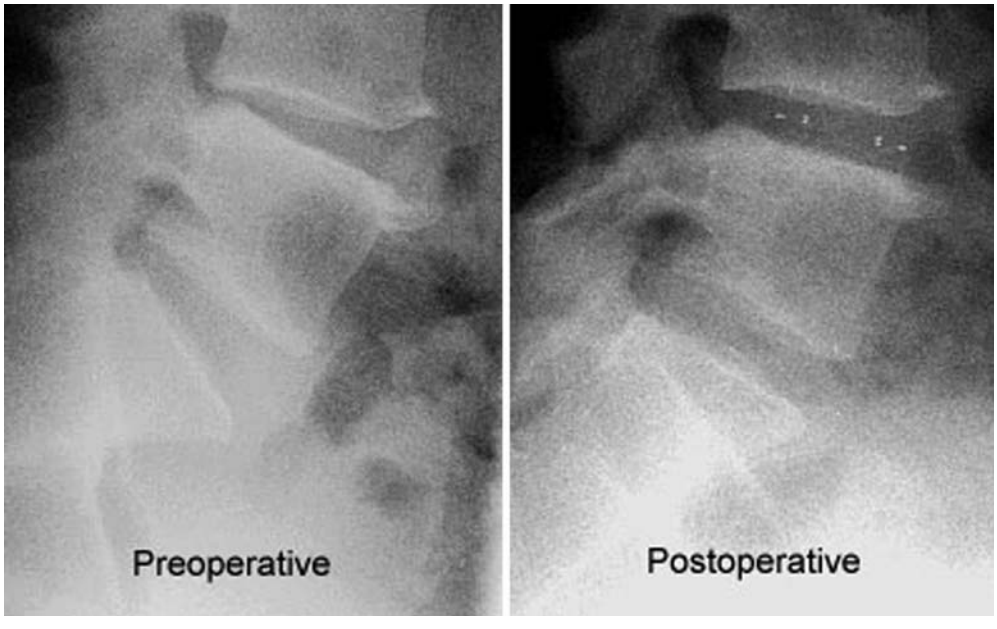

Fig. 6 A 42-year-old man with vertical instability at L4–L5, severe low-back pain, and unsuccessful conservative treatment. PDN devices were implanted via the ALPA (Anterior-Lateral transPsoatic) approach, with subsequent improvements in clinical symptoms and disc height

Discussion

The primary source of complications with the posterior surgical approach for PDN device implantation has been migration. Though not all device migrations have produced clinically relevant symptoms, some have caused discomfort requiring surgical revision or explantation. It is interesting that many patients, having the choice of replacing the PDN implants versus converting to an inter-

body fusion, have decided in favor of replacing the implants, as the concept of preserving segmental function remained attractive.

In some patients implanted with PDN devices, there has been a temporary postoperative increase in low-back pain. Such pain has usually been minor, lasting a relatively short period of time, and probably represents a reaction to segmental distraction caused by the hydrating implants.

Moderate to severe endplate changes have also been noted on some patients implanted with PDN devices. Mild endplate remodeling is probably due to changes in load distribution – the endplates appear to adapt to the contours of the implants. From a biomechanical perspective, endplate remodeling is not unexpected, and when it does occur it tends to be minor and stabilizes fairly quickly, typically within 6 weeks after surgery. It is important, however, to monitor all patients for 12 months to ensure that endplate remodeling has indeed stabilized and that there has not been a significant loss of disc height. Only a few cases of severe remodeling have been reported, strongly suggesting that in these cases there was a mismatch between the strength of the endplates and the stiffness of the implants. To avoid this problem, patients with osteoporosis or osteopathies should be excluded from PDN device surgery.

In response to the possibility of endplate remodeling, the material properties of the PDN hydrogel have been reformulated to be less stiff. The original hydrogel formulation 68, which was used in the first group of patients, has been changed to a formulation 80 – capable of absorbing 80% of its weight in water, with less possibility of having a negative lasting impact on the endplates.

Conclusion

The success of any medical device is measured by its clinical results. No matter how well conceived and engineered the device may be, or how elegant a surgical technique has been developed for implanting the device, the ultimate determination of efficacy is made by patients: Have their lives improved significantly enough to warrant the treatment?

The successful implantations and clinical results of the PDN over the last 2 years certainly seem to indicate that the benefits of implanting a PDN device outweigh the risks. A surgical success rate of 88%, coupled with a marked reduction in back pain and an increase in disc height, suggests that the PDN device is an effective treatment mode for cases of moderate degenerative disc disease that are associated with chronic low-back pain.

As with any new device, there are questions that still remain unanswered and deserve ongoing observation. The long-term reaction of the vertebral endplates to the new load distributions is a focus of our current interest. Radiological findings in a few patients suggest that some adaptation of the endplates to the surface contours of the PDN device is to be expected. Patients should be monitored to guard against significant disc height reductions. In addition, more long-term clinical data are necessary to gauge the efficacy of the PDN device in preventing or retarding progressive segmental degeneration.

It seems that the nucleus replacement concept of the PDN device bears great potential. Six years after the first implantation, we have learned much concerning the surgical technique and indications for the PDN device, and we have learned about the device limitations as well as its benefits. We have also learned that proper indication and patient selection are crucial factors for successful results. There is no doubt that improvements in device design and surgical technique will continue to be made, but already today the clinical results justify the efforts and support the soundness and effectiveness of this concept.

References

1. Aota Y, Kumano K, Hirabayashi S (1995) Postfusion instability at the adjacent segments after rigid pedicle screw fixation for degenerated lumbar spinal disorders. J Spinal Disord 8:464–473
2. Bertagnoli R (2000) Anterior mini-open approach for nucleus prosthesis – a new application technique for PDN. Thirteenth Annual Meeting of the IITS, St. Williamsburg, Virginia, 8–10 June 2000
3. Bertagnoli R, Sachs BL, Ray CD, Pimenta L (2001) Modified surgical technique for implantation of prosthetic disc nucleus devices. Presented at the International Meeting of Advanced Spine Techniques, Paradise Island, Bahamas, July 2001
4. Lee CK (1988) Accelerated degeneration of the segment adjacent to a lumbar fusion. Spine 13:375–377
5. Meakin JR, Redpath TW, Hukins DW (2001) The effect of partial removal of the nucleus pulposus from the intervertebral disc on the response of the human anulus fibrosus to compression. Clin Biomech 16:121–128
6. Ray CD (1992) The artificial disc: introduction, history, and socioeconomics. In: Weinstein JN (ed) Clinical efficacy and outcome in the diagnosis and treatment of low back pain. Raven Press, pp 205–225
7. Yu S, Haughton VM, Ho PS, et al (1988) Progressive and regressive changes in the nucleus pulposus. II. The adult. Radiology 169:93–97
8. Zollner J, Heine J, Eysel P (2000) Effect of enucleation on the biomechanical behavior of the lumbar motion segment. Zentralbl Neurochir 61:138–142