Purpose
Evaluate safety and performance of the PDN® Prosthetic Disc Nucleus in 28 patients with disc herniation and degenerative disc disease. Patients underwent surgery between May 1997 and June 2000 and were implanted utilizing improved surgical techniques, tools, devices and rehabilitation plan.

- 14 enrolled in feasibility study
- Study indications: disc herniation cases with chronic low back pain (LBP), with or without leg pain.
- Majority suffered from LBP from 2+ to 10 years.
- Referred to clinic as fusion candidates.

Materials/Methods
- Implanted in pairs, PDN device is comprised of polymeric hydrogel encased in inelastic polypropylene jacket. Upon implantation, devices absorb body fluid, expanding approximately 2 mm in height to act as spacer, maintaining or restoring disc height and segmental stability (Fig. 1).
- Patients implanted with PDN device after unilateral discectomy. As much nucleus material removed as possible. Two PDN devices inserted and positioned transversely in disc space.
- In second series of 14 patients, 2 PDN devices were sutured together.

Findings
At 2 years follow-up there was a 70% (4 patients) improvement in the Oswestry score and a 70% (4 patients) improvement in the Visual Analog Scale.

Complications
Within the first series of 14 patients, implanted May 1997 to May 1998, 7 patients (50%) had device displacements due to either protrusion or extrusion of device (5 patients) or migration (2 patients), which occurred with device design no longer being manufactured. Others are believed to have been due to an operative technique learning curve and insufficient removal of nucleus material. All displacements occurred within first 2 postoperative months. In the second series of 14 patients, implanted June 1999 to June 2000, 2 patients experienced complications. One patient: device protrusion leading to readjustment and fixation of the device; 1 patient developed infection leading to removal of both PDN devices.

Conclusions
Early experience with the PDN device showed a high extrusion rate, which while unacceptable, can be explained by the changes made to the shape of the device and typical learning curve in a product development cycle. The Raymedica PDN implant is a very promising product that is definitely preferable to fusion for this patient population. This product also allows the option of conversion to a fusion if needed. Patient selection is critical and early experience has shown it to be suitable for mild to moderate DDD while not suitable for severely degenerated discs.