

INSTRUCTIONAL LECTURES & PANEL PRESENTATIONS

PROBLEMS AND COMPLICATIONS RECORDED WITH CLINICAL TRIAL OF 40 PATIENTS IMPLANTED WITH PROSTHETIC DISC NUCLEUS

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Significance: In the study a total 37 patients who failed to be adequately helped by non-surgical treatment for pain caused by degenerative disc disease (DDD), have been implanted with the PDN Prosthetic Disc Nucleus. Clinical experience for 17 of these patients in the feasibility portion of the study who have been followed for 2 years will be presented.

Materials/Methods: Since January, 1998, 17 patients in the feasibility portion of the study were implanted with the PDN prosthesis after unilateral discectomy. Study inclusion criteria were lumbar DDD restricted to a single level, reduced disc height with at least 5mm disc height remaining intact facets chronic with low back pain unresolved by conservative treatment. The PDN prosthesis, which are implanted in pairs, are available in various sizes and shapes to accommodate patient anatomy.

Findings: Two years follow up for 10 of the 34 patients show improvement of low back pain and increased range of motion as evidenced by 90% improvement of the Oswestry score and 87% improvement in the visual analog score. The recorded complications are as follow:

retrobulge,

migration

Anterior migration

Posterior migration

Disc end plate changes

Diskitis

Conclusion: There are problems and complications within acceptable range and still there is room for improvement regarding the device and the technique and in our experience PDN has shown to be promising treatment for mild and moderate degenerative disc disease.