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## PROSTHETIC DISC NUCLEUS RESTORES THE FLEXIBILITY AND DISC HEIGHT OF A DISC AFTER NUCLEOTOMY

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### Introduction:

The intended use of the RayMedica Prosthetic Disc Nucleus (PDN<sup>®</sup>) device is to reduce low back pain, maintain or increase disc height at the operated level and to maintain or improve range of motion. The specific aim of this study is to investigate whether the original mobility of the L4-L5 disc is restored after implanting a PDN<sup>™</sup> following a nucleotomy.

### Material and Methods:

A PDN<sup>™</sup> implant is composed of a polymeric hydrogel, which is encased in a woven polyethylene fabric jacket. The hydrogel component is a block co-polymer of polyacrylamide-polyacrylonitrile. The water content after hydration ranges from 65–85%. The polyethylene material is a strong, high modulus and low stretch material. The device consists of two individual implants, which are not hydrated when implanted. The device is oriented transversely within the nucleus cavity (Fig. 1). Re hydration and expansion of the device occurs after implantation.

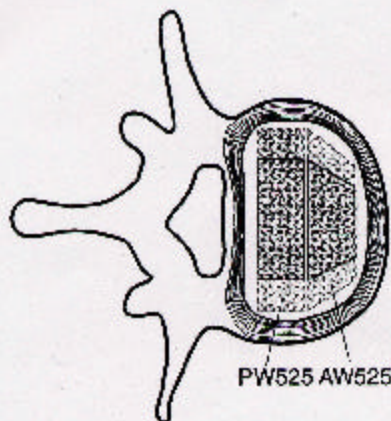


Fig. 1: Top view of the orientation of the PDN device

Six human L4-5 specimen spines were mounted in a spine tester and loaded with pure moments of  $\pm 7.5$  Nm in flexion/extension, left and right lateral bending, right and left axial torsion. The following different states were investigated. 1) intact spines, 2) after removal of the nucleus 3) after inserting the dehydrated PDN (PW525 and AW525) (Fig. 1). These *in vitro* tests were performed with and without an axial preload of 200N. ROM and NZ were determined from the third

### Results:

Nucleotomy increased the median values of the range of motion (ROM) normalized to the intact state in flexion/extension to 118 %, in lateral bending to 112 % and axial rotation to 121 % (Fig.2). PDN implantation reduced it to 102 %, 88 %, 90 %. These differences were even more distinct comparing the neutral zone (NZ) with 210 %, 173 %, 107 % after nucleotomy and 146 %, 149 %, 43 % after PDN implantation.

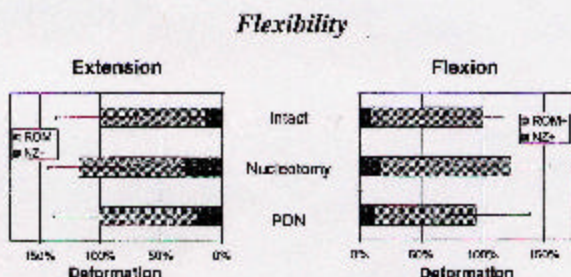


Fig. 2: ROM and NZ (medians and ranges) in flexion/extension (normalized to the ROM in the intact state)

In the intact state, with a preload of 200N, disc height was reduced by about 1 mm. After nucleotomy, without preload, we found only a slight decrease in disc height. However, applying a preload, reduced the disc height by about 2mm. Implantation of the PDN device restored the disc height, showing the same change in height as the intact specimens with a 200N preload.

### Discussion:

PDN implantation can restore ROM and NZ increase after nucleotomy to normal values. Disc height loss after nucleotomy can also be restored by implantation of the PDN device. Further tests should be performed to fully characterize the biomechanical characteristics of this therapy with the PDN device.

### Acknowledgement:

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