

173

**Comparative Clinico-Radiological Study of Interlaminar Decompression in Lumbar Canal Stenosis with and without Coflex™ Interspinous Spacer; Prospective Observational Study***N. Kumar<sup>1</sup>, Y.H. Ng<sup>1</sup>, B.W.L. Tan<sup>1</sup>*<sup>1</sup>National University Health System, Orthopaedic Surgery, Singapore, Singapore

**Purpose:** To determine whether additional implantation of Coflex™ following decompression provides better clinical outcomes compared to decompression alone. To study whether clinical outcomes were related to any of the radiological parameters studied.

**Materials and methods:** A prospective observational study comparing outcomes of patients undergoing decompressive surgery for symptomatic lumbar canal stenosis & back pain with or without additional implantation of Coflex™ interspinous spacer (ISP). 46 patients were treated for 1 or 2-level symptomatic lumbar canal stenosis & back pain. Patients opting for Coflex™ implantation formed the Coflex™ group (22 patients) while those opting for decompression alone formed the Control group (24 patients). Pre- and postoperative disability and pain scores were measured using the Oswestry Disability index (ODI), the Visual Analogue Scale (VAS) for back and leg pain, and Short Form-36 (SF-36). Pre- and postoperative radiological parameters (disc heights, intervertebral foraminal heights, sagittal angles) of the operated segment were assessed. Patients underwent postoperative assessments at 3, 6, 12 and 24 months and were followed up for at least 2 years.

**Results:** Coflex™ patients experienced statistically greater improvements ( $p < 0.0005$ ) in all 3 clinical outcome indicators (ODI, VAS for back and leg pain, SF-36) at 6 months, 1 year and 2 years. The radiological parameters also showed significantly greater improvement ( $p < 0.0005$ ) in the Coflex™ group but we were unable to establish any correlation with clinical outcomes.

**Conclusions:** The Coflex™ device provides an effective additional treatment in decompressive surgery for lumbar canal stenosis and associated back pain, with better clinical outcomes sustained at 2 years.