

---

---

# A Novel Minimal Invasive Percutaneous Device for Treatment of Lumbar Spinal Stenosis. Preliminary Results.

M.BALSANO, S.CASERTA, C.DORIA, PV.NARDI

---

## INTRODUCTION:

Lumbar Spinal Stenosis (LSS) is a pathological condition that causes a compression of the contents of the canal, particularly the neural structures. Subjects with such degenerative changes induce a borderline canal diameter, but without complaints, and have abnormal patterns of motion in sagittal extension recalling those in stenotic patients. Many surgical procedures have been proposed to increase the sizes of the narrowed foramina. The purpose of this study was to investigate the effect of a new minimal invasive percutaneous device in the treatment of LSS. The PercuDyn™ system (Interventional Spine, Inc., Irvine, CA) is one such system that has been developed and previously studied to effectively prevent extension motion. Unlike interspinous process spacers that rely on the relatively weak spinous process, the device is inserted at the base of the much stronger inferior facets to prevent extension motion. However, during the surgical technique, a countersinking step is used to remove a small radius of bone from the inferior facet and some of the pars/lamina.

## METHODS:

This is a prospective, non-randomised study to investigate safety and efficacy of a new percutaneous device, PercuDyn, for patients presenting LSS who did not respond to conservative treatment. The mechanism of symptom relief is by preserving disc and foraminal height. Using percutaneous over-the-wire techniques and a 15mm incision, the Teleport® dilator establishes a posterior working port at the base of the inferior facet. Each device has a titanium Anchor and a PCU/titanium Stabilizer that are serially introduced and mechanically connected *in vivo* via a secure locking mechanism. Once the Anchor is driven through the pars into the pedicle, the Stabilizer is ratcheted over the serrated shaft and wedged between the inferior facet and the pars/lamina. One size accommodates all patients with working lengths of 28-35mm. Devices are placed bilaterally at each treatment level. No additional rods or connecting hardware are required. The procedure is reversible with minimal anatomic impact on the spine.

## OUTCOME MEASURES:

Length of stay in hospital (LOS), Oswestry Disability Index (ODI) and Visual Analogue Score (VAS) for subjective pain at 3, 6, and 12 months. Adverse events register.

## TECHNIQUE:

Local anaesthesia (LA) and sedation or general anaesthesia using over the wire insertion method with sequential dilator port. The device has a titanium core consisting of a pedicular anchor screw and polycarbonate-urethane (PCU) stabilising head that augments the facet.

## RESULTS:

A clinical series of 12 patients with 36 implants have been included in the study. All of them showed segmental stabilisation in flexion and extension with increased foraminal area and reduced disc pressures. Surgical operative time ranged between 5-20 minutes per device implanted. Length of stay ranged from 4 to 24 hours. Median preoperative ODI was 64 to baseline, improving to 13 at 6 months and 9 at 1 year. VAS improved from 8.5 preoperatively to 1.9 at 6 months and 0.7 at 1 year.

## CONCLUSIONS:

Initial results from the use of this device in the treatment of LSS are favourable with the advantage of a minimally invasive approach. This is a simple and novel technique that may avoid more invasive surgery in some patients but a formal prospective randomised control trial and further user experience are welcomed to establish its benefits in this respect.