

THE FIRST 3 YEARS CLINICAL EXPERIENCE WITH THE SINUX NUCLEUS  
REPLACEMENT DEVICE – AN INJECTABLE TREATMENT FOR LUMBAR  
DISC HERNIATION IN DEGENERATIVE DISC DISEASE

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Herniation of the nucleus pulposus is a key, primary event in degenerative disc disease (DDD). Nucleotomy is currently the gold standard treatment. However, whilst this may relieve pain, the subsequent loss of disc height and increased segmental mobility that can occur over time may lead to further degeneration in adjacent spinal segments and post-nucleotomy syndrome. Nucleus replacement offers the opportunity for earlier intervention in such patients and provides an alternative to spine arthroplasty or fusion. This technology may slow or even stop the degenerative cascade by maintaining disc height, segmental stability and normal range of motion.

The injectable SINUX nucleus replacement device is made from a cold-curing, permanently-elastic polymer consisting of a modified polydimethylsiloxane and a platinum catalyst. It replaces the nucleus material that is removed during nucleotomy and conforms to the shape of the void created within the annulus fibrosus. Injection of the SINUX nucleus replacement can be achieved via normal surgical approaches to the lumbar intervertebral discs. The position of the patient during surgery is not critical and established surgical techniques for standard discectomy or microdiscectomy do not need to be modified. SINUX nucleus replacement is used as an adjunct to primary nucleotomy procedures and is intended to reduce the incidence of post-nucleotomy syndrome and improve long-term outcomes compared with patients treated by nucleotomy alone.

During the last 3 years a total of 28 patients have been treated with SINUX at our Clinic for Neurosurgery and Spinal Surgery, Schwerin, Germany and our experience is described herein.

Patients with symptomatic DDD at one level between L1 and S1 were eligible for SINUX nucleus replacement at the Clinic. Pain severity was assessed using Oswestry, Prolo and Visual Analogue Scale (VAS) scores. Post-operative checks included physical examination, X-ray and magnetic resonance imaging (MRI) scans. Following the encouraging results with the first group of patients (n=13), all subsequent, eligible patients (n=15) were recruited to a prospective, non-randomised, clinical trial. In this study clinical response was defined as an improvement in Oswestry low back pain intensity of  $\geq 25\%$  after 6 months. Post-operative scores were measured at each follow-up visit (6 weeks, 3, 6, 12 and 24 months). Other assessment criteria remained the same.

All 28 patients who received SINUX nucleus replacement following nucleotomy have shown considerable improvement in Oswestry, Prolo and VAS pain scores. All the patients, several of whom were manual labourers, have returned to their former vocations. MRI scans showed that implant position and disc height has been maintained post-operatively (for  $\geq 2$  years in 10 patients).

All 15 patients enrolled in the clinical trial are eligible for analysis. There were 8 males and 7 females aged 23-47 years (mean: 37.5 years). Their mean pre-operative Oswestry score was 36.5 (range: 19-58). The post-operative scores reported varied from 3 months (2 patients) to 18 months (1 patient). The mean post-operative Oswestry score was 16.7 (range: 10-38) resulting in a mean overall improvement of 54.2%.

There have been no serious complications to date. Of the 28 patients, 3 have required further surgery. One of the first patients to be treated required a second operation to reduce the amount of SINUX polymer that had been injected. The optimum amount of SINUX to inject has since been determined and the operating technique is well established with no recurrence of this complication. Another patient received an additional SINUX nucleus replacement at the next level after reporting with a prolapsed nucleus pulposus. The third patient, a 54-year-old female, required a repeat

nucleotomy at the same level after 8 months due to a recurrent prolapse. The SINUX nucleus replacement (which was still *in situ*) was easily removed, but reimplantation was not possible because of a large, unrelated, annular defect. The patient subsequently underwent fusion.

These results suggest that SINUX nucleus replacement is a safe and effective adjunct to nucleotomy procedures. This device is now CE marked. To further investigate the ability of SINUX nucleus replacement to slow the degenerative cascade, a larger, multicentre, post-marketing study is due to begin shortly.

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