Lilly’s Loop; a Controlled Study on Minimizing Lead Migration in Percutaneous Spinal Cord Stimulator Trials
Esra B. Riber, MD, sc99fan@aol.com; Abbas Tavakoli, Ph.D., Amy J. Clark, DNP, APRN, FNP-BC
One of the challenges with spinal cord stimulation trials is lead migration. There is no technique that will consistently minimize or eliminate it. In this dual lead study, a “Lilly’s Loop” was introduced in one lead, and as compared with the control lead, migration was commonly minimal or absent during a 3 day trial. Twenty-two consecutive patients deemed good candidates for spinal cord stimulation trials were randomly selected. Trial leads were all Boston Scientific 50 or 70mm. All leads were externally secured by the same physician with Steri-Strips™ (3M) and Tegaderm™ (3M) after mastisol was applied to the skin. Baseline radiographs documenting lead locations were taken immediately after the dressing was applied, before the patient was moved from the fluoroscopy table. Radiographs were taken again at the completion of the 3 day trial, and migration of both leads, if any, was recorded. Pre and post-trial lead position was confirmed by 2 different non-physician observers. Success was defined as migration of 8 mm or less (2 contact lengths) with coverage maintained over affected areas. 78% of Lilly’s Loop leads were successful as compared with 27% of controls. The average lead migration in the control group was 12 mm (3 contact lengths) more than with the Lilly’s Loop group, which showed limited inferior migration of trial leads. Reference: Osborne MD, Ghazi SM, Palmer SC, et al. Spinal Cord Stimulator-Trial Lead Migration Study: Pain Medicine 2011;12 (2): 204-08.

An Ex Vivo Study On Radiofrequency Tissue Ablation Using a Novel Multitined Expandable Electrode
Robert E. Wright, MD, RWright@denverpainmanagement.com, Scott A. Brandt, MD
Radiofrequency (RF) ablation has been effectively used to interrupt nociception arising from various spinal pain generators. Anatomic variation in the targeted neural pathways and suboptimal electrode placement may result in technical failure and poor patient outcomes. Intuitively, larger lesions mean a larger tolerance for both errors in electrode placement as well as the inevitable variation in the anatomic position of target nerves. A novel multitined expandable RF electrode was developed. Objective: Investigate the evolution and topography of a thermal lesion produced by a novel RF electrode. Methods: Sections of raw muscle tissue were allowed to equilibrate to 37°C in a distilled water bath. RF electrode with tines deployed was positioned to contact tissue surface in 10 trials, and was inserted into tissue in 10 trials. A Radionics RFG 3C RF generator energy source was set at 75°C for 80 seconds. Propagation of tissue coagulation was documented with video and a calibrated Flir T-400 thermal camera. Tissue samples were sectioned and coagulation zones measured. Results: Infrared observation demonstrated symmetric and homogenous lesion progression without hot spots or focal over-impeding. Calculated volume averaged 467 +/- 71 mm³/lesion. Topography was elongate spheroid offset from the central axis toward tines. Conclusion: A novel RF electrode prototype using dual deployable tines for electrical field diffusion reliably produces a lesion potentially useful in spinal applications. References: 1. Dreyfuss P, Halbrook B, Pauza K, Joshi A, McLarty J, Bogduk N. Efficacy And Validity Of Radiofrequency Neurotomy For Chronic Lumbar Zygapophysial Joint Pain. Spine 2000;25:1270–7. 2. Lord S, McDonald G, Bogduk N. Percutaneous Radiofrequency Neurotomy of the Cervical Medial Branches: A Validated Treatment for Cervical Zygapophysial Joint Pain. Neurosurgery Quarterly 1998; 8(4): 288–308.

Long-Term Outcomes from a Prospective, Multicenter Investigational Device Exemption (IDE) Pilot Study of Intradiscal Fibrin Sealant for the Treatment of Discogenic Pain
Yin W, zyin@bellinghampine.com, Bellingham Spine Pain Specialists, PS; 2075 Barkley Blvd., #118, Bellingham, WA 98226; Panza K., Olm W., Doerzbacher J.
Irradiscal Fibrin Sealant may reduce inflammation and promote tissue repair.1 Prospective, multicenter IDE human study suggested intradiscal injection of BIOSTAT BIOLOGX® Fibrin Sealant may safely relieve chronic axial discogenic back pain for 6 months.2 Objectives: Assess 12 and 24 month safety and efficacy outcomes for subjects enrolled in the FDA-regulated IDE Biostat pilot study. Methods: Fifteen subjects with single or two level chronic discogenic lumbar pain were enrolled at 3 sites. Adverse event reports, neurological exams and imaging studies were utilized to assess safety. Efficacy measures included VAS, and RMDQ. Fifteen (100%), 13 (87%) and 11 (73%) of subjects completed assessments after 6, 12 and 24 months. Results: No new procedure-related adverse safety events were reported. Mean (95%CI) reductions in low back pain (VAS) compared to baseline [percent reduction (95% CI)] were 40.7 mm (25.4 mm–56.0 mm) [55.6% (36.5%–74.6%)], 37.3 mm (18.9 mm–55.6 mm) [51.2% (27.9%–74.5%)], and 38.5 mm (17.3 mm–59.6 mm) [49.9% (22.8%–77.0%)]; mean (95%CI) physical function improvements (RMDQ) were 6.3 (2.9–9.6) [41.9% (21.6%–62.2%)], 9.0 (5.6–12.4) [58.7% (40.5%–76.8%)], and 9.5 (5.6–13.5) [60.6% (37.7%–83.5%)] points at 6, 12 and 24 months, respec-