A prospective, Randomized, Controlled Clinical Trial for the Evaluation of a Laser Navigation System (LNS) Used in Computed Tomography Guided Lumbar Spinal Interventions

C. Moser1, J. Becker1, D.W. Groenemeyer1
1Groenemeyer Institute for Microtherapy, University Witten/ Herdecke, Bochum, Germany

Background: For successful spinal intervention procedures detailed anatomical information and precise placement and guidance of the needles are pivotal. A novel Laser Navigation System (LNS) was developed to provide an exact needle route planning tool. In a preliminary interventional spine phantom study and consecutive clinical trial the LNS now was employed during computed tomography-guided perineural steroid injections in patients with chronic lumbar radiculopathies.

Methods: In a prospective, randomized, controlled trial 30 patients with chronic lumbar radiculopathy were treated with CT-guided perineural steroid injections. Each patient received two treatments. At a first appointment the patients were treated with a conventional freehand CT-guided injection (method A), whereas at a second treatment date patients received a LNS-assisted CT-guided injection (method B) or vice versa. Needle position adjustments and number of CT scans were exclusively conducted in accordance to individual medical needs. During method A, the intervention was planned at the CT workstation monitor plotting the path of the probe and marker distance. The needle entry point on the skin of the patient was determined via CT gantry laser and distance measurement. The exact entrance angle of the probe relies on the physician’s degree of experience and stepwise approach to the target area was assured by consecutive scans. Using method B, the needle path was also planned and plotted on the CT monitor. The LNS transferred the planned entrance route and needle angle via a visible laser beam on the patients’ skin and the physician now aligned and inserted the probe according to the beam. The results of both methods were analyzed using the DICOM-image viewing software JiveX (Visus, Bochum).

Results: Using the new LNS prototype, intervention precision could be improved (each p<0.0001 comparing planned and actual penetration point as well as planned and actual needle angle in both groups). In 9 out of 10 cases the needle at was positioned using the LNS at first go, therefore reducing risks of unintended punctures, pain and radiation exposure (p<0.0004 comparing number of control scans necessary until final needle position).

LNS also accelerated the workflow by increased speed and improved predictability of the therapeutic process (p<0.006 for the comparison of the time difference between planning screen and image with placed needle).

Conclusion: LNS is a promising and intuitive new technology for CT-guided percutaneous interventions. An experienced medical team could work significantly faster, safer, and patient-friendly with LNS. It is likely that particularly less experienced specialists and MTRA will benefit from this innovation. Ongoing evaluations will examine the suitability of any axial interventions.