Evaluation of a novel Laser Navigation System (LNS) for CT guided interventions

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The clinical study was performed at the Institute for Microtherapy without financial compensation.

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Amedo sponsored the clinical study by providing the LNS prototype.

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Introduction

Velocity and precision of CT guided needle placements are heavily dependent on the experience of the medical team. Varying treatment times impede a smooth clinical workflow.

Although available aids for CT guided punctures increase the precision and reduce X-ray exposure they suffer from low acceptance because their operation is cumbersome and time-consuming.

LNS

A first prototype of a new assistance system for CT-guided punctures was build. This Laser Navigation System (LNS) directly transfers the monitor drawn needle trajectory on the patient. LNS automatically aligns a laser pointer according to the planned needle path.

The physician sees a laser spot on the skin of the patient. At this point the needle is inserted. Then the needle is aligned with the laser beam and advanced to the target.

The purpose of this prospective, randomized, controlled clinical trial was the first evaluation of the novel Laser Navigation System (LNS) in CT guided interventions.

Study target parameters

- Procedure time
- Precision of needle placement
- Number of control scans
- Clinical usability

Approval has been obtained from the local ethical review board.
The investigation was conducted in 3 steps

**STEP 1: Preclinical Phantom Study** (30 freehand punctures and 30 LNS guided punctures)
CT-guided lumbar perineural steroid injections were simulated using a spine phantom. On one side of the spine the treatment was performed freehand and on the other side an identical procedure was conducted with LNS guidance.

**STEP 2: Epidural and Perineural Injection Study** (31 freehand punctures and 31 LNS guided punctures)
Epidural and perineural steroid injections were performed in patients with chronic lumbar radicular symptoms. In the study patients attended for 2 visits. At one visit the therapy was performed freehand and at the other visit with LNS assistance.

**STEP 3: Clinical Routine Usability Test** (patients underwent various LNS guided drug deliveries)
Different physicians used LNS for everyday drug instillations. There was no provision in terms of indications to be treated. The day’s program and the willingness of patients to participation in the study determined the treatments performed with LNS.

**Data assessment**
In STEP 1 and STEP 2 a well trained interventionalist (> 15,000 CT guided interventions) performed conventional freehand punctures and LNS guided punctures. The target parameters were time, precision and number of scans. Time was extracted from the DICOM headers of the first and the last CT-image of a treatment. Precision measurements were conducted with the Software JiveX by an overlay of the planned needle trajectory on the image of the final needle position. The length of the misplacement vector was calculated in x, y and z (slice misplacement) direction.

In the clinical routine usability test the possibilities and limitations of LNS were explored in everyday use. In STEP 3 the target parameter were usability, problems and benefits.

**Data analysis**
Differences in procedure time, precision parameters and number of control CT images were statistically evaluated. Significance was tested with paired t-test (Shapiro-Wilk > 0.1) or Wilcoxon signed-rank test (in cases of non Gaussian distributions).
**Patient Preparation**
Written informed consent was obtained by all treated subjects. Interventions were performed without premedication in prone position.

**Freehand method for CT guided drug delivery**
- Tape thin wire to skin (marker)
- Acquire CT image
- Draw one line from skin entry point to target structure
- Draw one line from skin entry point to marker
- Mark therapy slice on patient with felt tip pen using CT gantry laser line
- Determinate skin entry point by ruler measurement. Mark entry point with felt tip pen.
- Antiseptic skin preparation and draping
- Advance needle outside CT gantry with estimation of needle angulation
- Perform control scans till needle reaches satisfactory position
- Perform test injection – Acquire CT image - Instill drug

**LNS method for CT guided drug delivery**
- Acquire CT image
- Draw one line from skin entry point to target structure
- Antiseptic skin preparation and draping
- Insert needle at laser dot
- Align needle to laser beam
- Advance needle to target point
- Perform test injection – Acquire CT image - Instill drug
Results of STEP 1: Preclinical Phantom Study
(Comparison of freehand puncture with LNS, N=30)

**Time for needle placement (mm:ss)**

<table>
<thead>
<tr>
<th>Method</th>
<th>N</th>
<th>Mean</th>
<th>SDA</th>
<th>Min</th>
<th>25 % -Perz.</th>
<th>Median</th>
<th>75 % -Perz.</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freehand</td>
<td>30</td>
<td>09:18</td>
<td>03:50</td>
<td>03:48</td>
<td>06:42</td>
<td>09:03</td>
<td>10:57</td>
<td>18:49</td>
</tr>
<tr>
<td>LNS</td>
<td>30</td>
<td>05:04</td>
<td>03:15</td>
<td>01:03</td>
<td>03:05</td>
<td>03:58</td>
<td>06:21</td>
<td>15:10</td>
</tr>
</tbody>
</table>

Normal distribution (Shapiro-Wilk test > 0.1). Significance entry point: t-Test: p-value < 0.0001.

LNS reduced the median needle placement time from 9 min 3 sec to 3 min 58 sec.

**Needle entry point deviation**

<table>
<thead>
<tr>
<th>Method</th>
<th>N</th>
<th>Mean</th>
<th>SDA</th>
<th>Min</th>
<th>25 % -Perz.</th>
<th>Median</th>
<th>75 % -Perz.</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freehand</td>
<td>30</td>
<td>3.14</td>
<td>2.03</td>
<td>0.00</td>
<td>1.78</td>
<td>2.93</td>
<td>4.50</td>
<td>7.20</td>
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<tr>
<td>LNS</td>
<td>30</td>
<td>0.52</td>
<td>0.67</td>
<td>0.00</td>
<td>0.00</td>
<td>0.45</td>
<td>0.90</td>
<td>2.67</td>
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</tbody>
</table>

Normal distribution (Shapiro-Wilk test > 0.1). Significance entry point: t-Test: p-value < 0.0001. Significance target point: t-Test: p-value < 0.0014.

LNS reduced the median needle entry point deviation from 2.93 mm to 0.45 mm. LNS reduced the median target point deviation from 3.74 mm to 1.86 mm.

**Number of control CT images**

<table>
<thead>
<tr>
<th>Method</th>
<th>N</th>
<th>Mean</th>
<th>SDA</th>
<th>Min</th>
<th>25 % -Perz.</th>
<th>Median</th>
<th>75 % -Perz.</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freehand</td>
<td>30</td>
<td>2.7</td>
<td>1.3</td>
<td>1.0</td>
<td>2.0</td>
<td>3.0</td>
<td>4.0</td>
<td>5.0</td>
</tr>
<tr>
<td>LNS</td>
<td>30</td>
<td>1.4</td>
<td>0.7</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
<td>2.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Non-normal distribution. (Shapiro-Wilk test ≤ 0.1). Wilcoxon signed-rank test: p-value < 0.0001.

LNS reduced the median number of control scans from 3 to 1.
Results of STEP 2: Epidural and Perineural Injection Study

(Comparison of freehand puncture with LNS, N=31)

Freehand and with LNS 100% of the treatments were technically successful. Technical success was defined as proof of contrast agent test injectant inside epidural space respectively at nerve root.

**Time for needle placement (mm:ss)**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>SDA</th>
<th>Min</th>
<th>25 %-Perz.</th>
<th>Median</th>
<th>75 %-Perz.</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freehand</td>
<td>31</td>
<td>09:04</td>
<td>03:33</td>
<td>05:22</td>
<td>06:06</td>
<td>08:33</td>
<td>10:13</td>
<td>21:24</td>
</tr>
<tr>
<td>LNS</td>
<td>31</td>
<td>07:05</td>
<td>01:39</td>
<td>04:42</td>
<td>05:58</td>
<td>07:03</td>
<td>07:44</td>
<td>12:25</td>
</tr>
</tbody>
</table>

Normal distribution (Shapiro-Wilk test > 0.1). Significant difference: t-Test; p-value < 0.006

LNS reduced the median needle placement time from 8 min 33 sec to 7 min 3 sec.

**Deviation between planned and punctured ENTRY POINT (mm)**

Normal distribution (Shapiro-Wilk test > 0.1), Significant difference: t-Test; p-value < 0.0001

LNS reduced the median needle entry point deviation from 3.6 mm to 0.9 mm.

**Deviation between planned and punctured NEEDLE ANGLE (°)**

LNS reduced the median needle angle deviation from 2.1° to 0.2°.

**Number of control CT images**

Non-normal distribution. (Shapiro-Wilk test ≤ 0.1). Wilcoxon signed-rank test; p-value < 0.0004.

LNS reduced the mean number of control scans from 1.9 to 1.1.

In 49% of the freehand cases and in 91% of the LNS cases the needle reached the target at first attempt.
Results of STEP 3: Clinical Routine Usability Study

(Punctures were performed with LNS under everyday clinical conditions to explore possibilities and limitations.)

- 67 patients underwent LNS guided drug deliveries in 81 visits.
- Treatments were performed by 4 physicians. 1 radiological assistant operated the CT.
- Therapies: Epidural and perineural steroid injections in cervical, thoracic and lumbar spine. Drug deliveries in facet joints, sacroiliac joints and hips.
- LNS guidance was fast and precise and feasible for all examined indications.
- 1 to 6 needles were positioned

<table>
<thead>
<tr>
<th>No. of needles</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>in no. of treatments</td>
<td>25</td>
<td>23</td>
<td>21</td>
<td>11</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

A total of 184 needles were placed. 181/184 needles were positioned with LNS. 3 needles were placed freehand because of severe patient movements. 184/184 needle placements were technically successful. Technical success was defined as proof of contrast agent test injectant at target structure.

- 123/184 needles reached the target at first attempt. Patient movements occurred mainly from puncture pain reactions and reduced the precision in multi-needle-procedures. At the end of the study this problem was overcome by marking of all needle entry points prior to the first needle insertion. In combination with LNS these markings effectively served as a motion control and allowed to reposition slightly misplaced patients.

<table>
<thead>
<tr>
<th>Needle entry point deviation [mm]</th>
<th>N</th>
<th>Mean</th>
<th>SDA</th>
<th>Min</th>
<th>25 %-Perz.</th>
<th>Median</th>
<th>75 %-Perz.</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNS</td>
<td>184</td>
<td>2.573</td>
<td>1.645</td>
<td>0.00</td>
<td>1.42</td>
<td>2.29</td>
<td>3.6</td>
<td>9.94</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Needle target point deviation [mm]</th>
<th>N</th>
<th>Mean</th>
<th>SDA</th>
<th>Min</th>
<th>25 %-Perz.</th>
<th>Median</th>
<th>75 %-Perz.</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNS</td>
<td>184</td>
<td>4.11</td>
<td>2.58</td>
<td>0.00</td>
<td>2.25</td>
<td>3.67</td>
<td>5.85</td>
<td>11.9</td>
</tr>
</tbody>
</table>

- The reduced number of needle corrections and fewer control scans shortened procedure times.

<table>
<thead>
<tr>
<th>Needle placement time in 1 needle treatments [mm:ss]</th>
<th>N</th>
<th>Mean</th>
<th>SDA</th>
<th>Min</th>
<th>25 %-Perz.</th>
<th>Median</th>
<th>75 %-Perz.</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNS</td>
<td>25</td>
<td>08:30</td>
<td>02:07</td>
<td>05:50</td>
<td>06:39</td>
<td>07:40</td>
<td>09:36</td>
<td>13:42</td>
</tr>
</tbody>
</table>

- Patient benefit: reduced pain and X-ray exposure due to less needle corrections and reduced table time.
Conclusions

- LNS is a promising assistance system for CT-guided needle interventions because it simplifies procedures, saves time, reduces needle deviations and minimizes X-ray exposure.

- Even a highly experienced interventional team was able to reduce procedure time, increase accuracy and decrease X-ray exposure and possible adverse events associated with the procedure.

- With LNS guidance the reduced table time minimizes the patient discomfort and increases the throughput of CT-guided puncture procedures.

- LNS is easy and intuitive to use and it optimizes the clinical workflow.

- Further acceleration of LNS guided therapy should be possible if antiseptic skin preparation and draping is performed prior to the first CT scan.

- It is expected that less experienced physicians and radiologists will benefit even more from this innovation.
Parallel to the clinical evaluation of the first LNS prototype a CE marked LNS has been developed.

At the University Hospital of Frankfurt the new CE marked Laser Navigation System shows promising results for thoracic and abdominal punctures.