Robotic Navigation and Guidance for Percutaneous CTguided Interventions

<u>Yilun Koethe, Sheng Xu, Gnanasekar Velusamy,</u> Bradford J. Wood, Aradhana M. Venkatesan

NIH Medical Research Scholars Program Fellow, NIH Center for Interventional Oncology, Bethesda, MD Duke University School of Medicine, Durham, NC

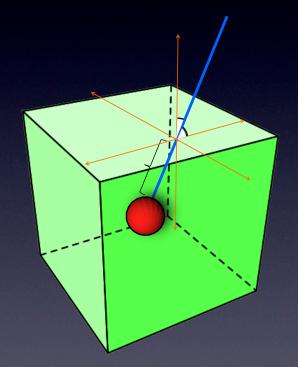
Disclosures

The study was supported by the NIH Center for Interventional Oncology and the NIH Intramural Research Program. NIH and Perfint Healthcare have a Cooperative Research And Development Agreement (CRADA). The device was supplied through a materials transfer agreement by Perfint Healthcare.

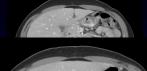
The year-long research fellowship for <u>Y.K.</u> was made possible through the National Institutes of Health (NIH) Medical Research Scholars Program, a publicprivate partnership supported jointly by the NIH and generous contributions to the Foundation for the NIH from Pfizer Inc, The Leona M. and Harry B. Helmsley Charitable Trust, and the Howard Hughes Medical Institute, as well as other private donors. For a complete list, please visit the Foundation website at <u>http://www.fnih.org/work/programs-development/medical-research-scholars-program</u>). The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. Accurate CT-guided needle placement is highly dependent upon physician experience, entailing a series of mental estimations of:

Surface-to-target distance

Needle angulations



Conventional freehand technique involves multiple steps, each with the potential for errors.





3-D visualization of target and environment from 2-D images



Plan trajectory

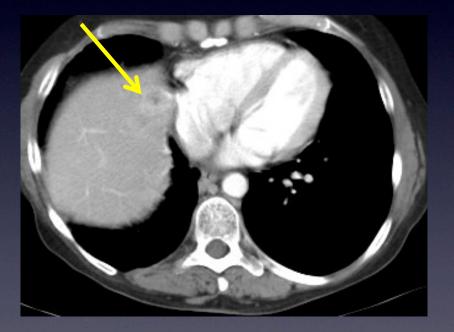
Execute plan

Areas of vulnerable anatomy have low tolerance for needle placement errors. Thus challenging targets frequently mandate:

Frequent needle adjustments

Serial Imaging

Prolong procedural duration Increase patient risk Increase radiation exposure



A variety of different approaches have been designed to improve the accuracy of CT-guided needle placement

Medical Global Positioning System Technologies: Electromagnetic Tracking Optical Tracking



AccuPlace® Drace Stereotaxic Needle Guide SeeStar® Mechanical needle guidance: Laser pointers Needle stabilization - bubble levelers, adhesive arcs, robotic devices

Decrease physician radiation exposure

Early robotic navigation and guidance systems have demonstrated improved accuracy and reduced procedure time compared to conventional freehand technique



Preclinical phantom: ¹ 1.7 +/- 0.8 mm (n=25)

<u>Clinical Study</u>:² 14 patients, RF ablations of liver tumors Randomized to robot-assisted probe placement or conventional CT guided manual placement

	Robotic				Manual			
	Mean	Std. Dev.	Max	Min	Mean	Std. Dev.	Max	Min
time to successful targeting (min)	3.57	1.13	4	2	8.57	1.99	12	6
overall procedure time(min)	44.57	6.68	53	36	67.57	8.28	57	78
number of probe passes	1		1	1	3.71	1.25	6	2
patient radiation exposure (mrem)	469.71	177.09	836	279	7075.71	3181.65	2923	12522
physician radiation exposure (mrem)	0				577.57	250.56	327	1097

¹Solomon SB et al. "Robotically Driven Interventions: A Method of Using CT Fluoroscopy without Radiation Exposure to Physician" *Radiology.* 2002

²Patriciu A et al. "Robotic Assisted Radio-Frequency Ablation of Liver Tumors –Randomized Patient Study" *Med Image Comput Comput Assist Interv.* 2005; 8(Pt 2):526-533



INNOMOTION (Innomedic, Herxheim & FZK Karlsruhe Germany & TH Gelsenkir)
MR and CT compatible
In a phantom study, INNOMOTION had minimal needle placement error with an euclidean distance of 1.69 +/- 0.772 mm, and normal distance of 1.42 +/- 0.78 mm



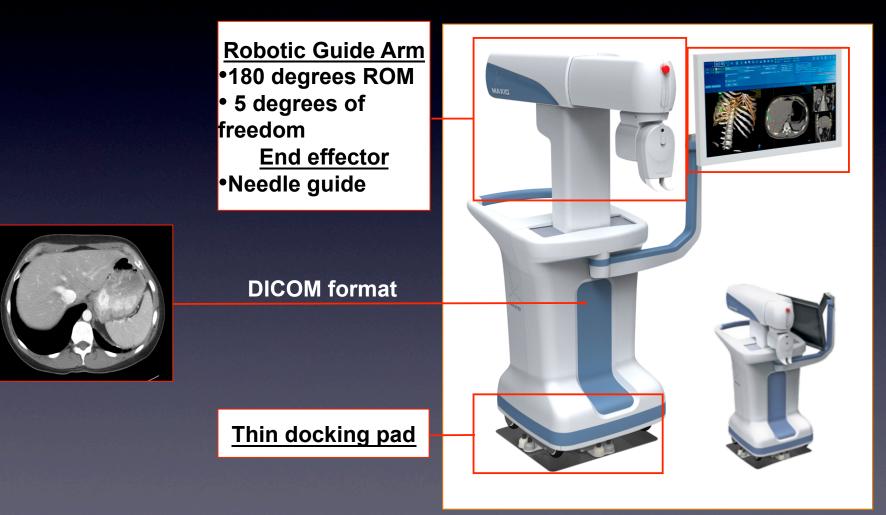
<u>B-Rob II (ARC Seiberdorf Research)</u> •In a phantom study, B-RobII placed biopsy needle with high accuracy (0.66+/- 0.27 mm)²

¹Stoffner et al. "Accuracy and Feasibility of Frameless Stereotactic and Robot-Assisted CT-based Puncture in Interventional Radiology: a comparative Phantom Study" *Fortschr Rontgenstr* 2009; 181(9): 851-858.

²Cleary et al. "Interventional robotic systems: Applications and technology state-of-theart". *Minimally Invasive Therapy*. 2006; 15:2; 101-113

HYPOTHESIS

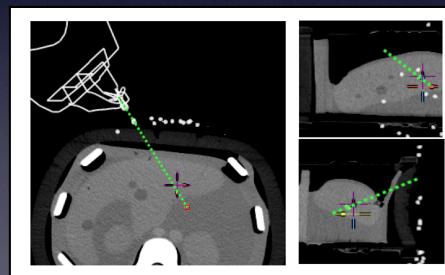
Improved needle placement accuracy compared to conventional techniques may be achieved via a novel interventional radiologist assistance platform

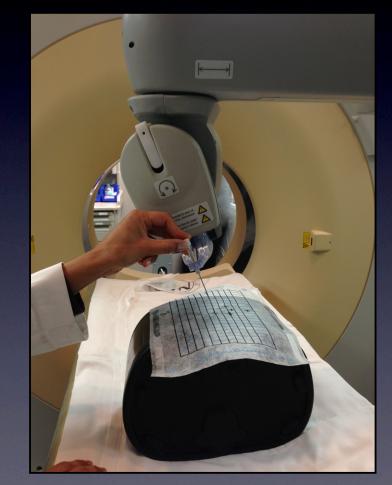


METHODS

17 Multi-angle trajectories were selected with mean entry-totarget distance of 10.9 ± 0.4 cm and angles greater than 30 (avg 65) degrees on research software (NIH).

Single-pass needle insertions
18 G, 15 cm needle
CIRS 57 abdominal phantom
No intra-procedural scans
No needle adjustments
Freehand vs. IR assistance platform



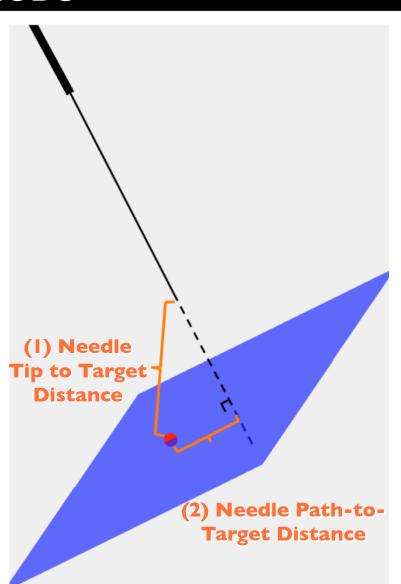


METHODS

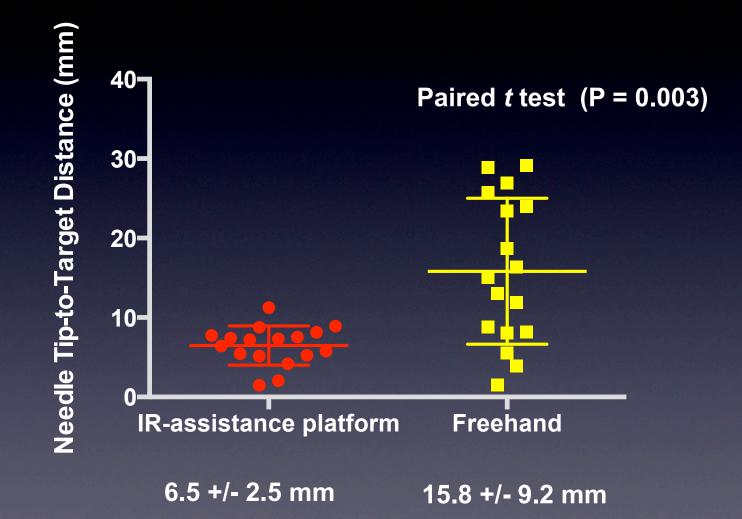
Post-procedural CT scans were analyzed for two errors using research software (NIH):

(1) Needle tip-to-target distance and

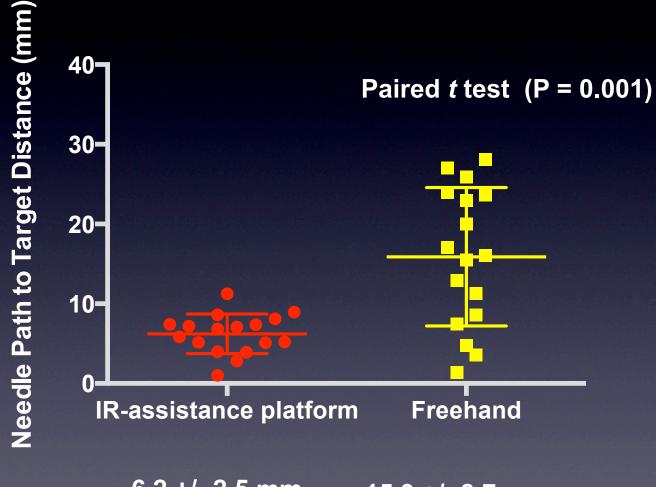
(2) Needle path-totarget distance



RESULTS Needle Tip-to-Target Distance



RESULTS **Needle Path to Target Distance**



6.2 +/- 2.5 mm

15.9 +/- 8.7 mm

RESULTS

System Capabilities:

- Successful import of DICOM images
- Accurately display CT table position
- Allow trajectory planning
- Accurate execution of needle trajectory plan

DISCUSSION

Sources of error:

Elastic recoil of needle after release

Device Limitations:

- Physical docking limits craniocaudal range of targets
 - 60 degrees of craniocaudal angulations permitted
- Complex calibration during installation
- Occasional software instability of this pilot release

Study Limitations:

- Assessment of single pass needle insertion is not realistic
- Phantom is a non-perfect model

CONCLUSIONS

- Percutaneous needle placement is feasible
- Readily integrated into standard workflow without registration with each use
- Can improve accuracy, precision, and reproducibility of first-pass needle placement

Future clinical trials:

- Clinical impact
- Risk
- Procedure time
- Safety
- Outcome
- Additional system capabilities (e.g. tumor ablation planning)

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