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TITLE: Development and Evaluation of a Solid State Head CT

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The goal of this work is to develop a stationary head CT system that would enable head imaging at Forward Operating Bases or similar areas. Without the need for moving parts, such a system could address the clinical need of cross-sectional imaging of the brain, but in a more robust imaging system. Our design relies on linear x-ray source arrays enabled by the novel carbon nanotube x-ray source. The goals in this project extends from prototype design and development, development of reconstruction approaches and an eventual clinical trial in medically stable head trauma patients.

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None listed.

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TABLE OF CONTENTS

	Page
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	9
5. Changes/Problems	9
6. Products	9
7. Participants & Other Collaborating Organizations	10
8. Special Reporting Requirements	11
9. Appendices	None

INTRODUCTION:

The goal of this work is to develop a stationary head CT system that would enable head imaging at Forward Operating Bases or similar areas. Without the need for moving parts, such a system could address the clinical need of cross-sectional imaging of the brain, but in a more robust imaging system. Our design relies on linear x-ray source arrays enabled by the novel carbon nanotube x-ray source. The goals in this project extends from prototype design and development, development of reconstruction approaches and an eventual clinical trial in medically stable head trauma patients.

KEYWORDS:

Traumatic Brain Imaging, Computed Tomography, Trauma, Brain, Imaging, Forward Deployment.

ACCOMPLISHMENTS:

What was accomplished under these goals?

In Phase III, the primary goal of the project has been to convert the system from a benchtop device to a clinical system and perform the clinical evaluation of the system.

For reference, prior Phase Aims and Milestones are listed.

Specific Aim 1a: Head Phantom Simulations

Subtask 1: Conventional CT Geometry Simulation to evaluate dose reduction with conventional CT geometry.

Subtask 2: System geometry evaluation for effects of polygonal shape, projection planes, x-ray source array spacing, detector pixel size on imaging resolution, UQI, and artifact formation.

Specific Aim 1b: System Mockup Using Single Source/Detector Pair

Subtask 1: Linear Array Tube Acquisition and setup
Subtask 2: Detector Acquisition and setup
Subtask 3: System Structure design and construction
Subtask 4: Control software coding
Subtask 5: System Integration

Specific Aim 2a: Construct a prototype s-HCT with the system design from Aim 1.

Subtask 1: Acquire remainder of the hardware necessary for system construction
Subtask 2: Integrate the x-ray control and detector control system.
Subtask 3: Image quality evaluation: the quality of the reconstructed CT images.

Specific Aim 2b: Characterize the s-HCT system:

Subtask 1. Acquire CT images of the anthropomorphic head phantom using a clinical CT scanner. These images will be used as the benchmark for comparison with image generated by the s-HCT prototype. - completed

Specific Aim 2c: Implement the GPU based iterative reconstruction specific to the s-HCT system.

Subtask 1: Implement reconstruction code for GPU to accelerate reconstruction.
Subtask 2: Optimize acquisition code for clinical use.

Specific Aim 3a: Prepare system for clinical trial

Subtask 1: Complete IRB submission
Subtask 2: Submit IRB-approved protocol to HRPO
Subtask 3: Register for FITBIR account. – registered, but FITBIR submission is not required.
Subtask 4: Technologist training

Milestone: Proof of minimal risk determination from IRB, or submission of IDE application to the FDA, within 60 days of Phase III initiation.

Milestone: IRB and HRPO approval obtained.

The remaining relevant Phase III Aims and subtasks are summarized below:

Major Task 2: Recruit and Image Patients

- Subtask 3.2.1: Coordinate recruitment of patients – ongoing
- Subtask 3.2.2: Image patients – ongoing

Major Task 3: Perform Reader study

- Perform Reader Study – ongoing

Milestones: Completed patient recruitment and Reader study.

Phase III Aims and Milestones:

The primary focus of the effort in the last year has been focused on the clinical evaluation of the system in patients with prior head trauma. In the prior reporting period, our focus was on converting the benchtop system to a system capable of imaging patients. Since our system requires the physical translation of patients through the bore of the system, much of the effort was focused on imaging bed integration with the x-ray source and detectors.

Stationary Head CT Hardware

The completed stationary head CT system is seen in Figure 1. A stainless-steel cover surrounds the x-ray tube and detector system. The imaging bed is a refurbished medical imaging table that provides patient motion through the imaging system. Utilizing a commercially available bed saved development costs and reduced concerns about patient safety. The head holder is from a clinical CT scanner integrated into the imaging bed. Most of the x-ray power supplies sit within the black cabinet underneath the imaging system while the black tall cabinet houses most of the control hardware including our control computers. A step stool has been included to assist subjects getting on the platform. The subject in the picture (the trainee responsible for integration) is modeling the position of the patient near the end of imaging. He is approximately 6 feet tall to give a sense of scale.

Figure 1. Stationary head CT components in the former clinical CT space at the UNC Hospital's Ambulatory Care Center. The x-ray tubes and detector assembly are contained within the stainless steel shell. The subject is positioned near the end-scan phase of the imaging. A step stool is provided to assist subjects.

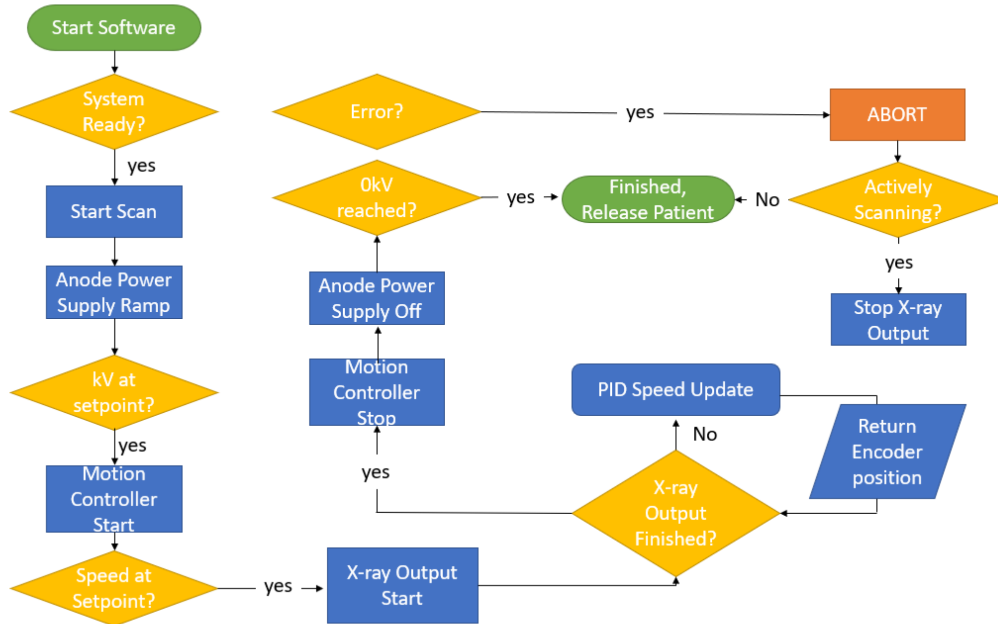
During the last year, after our initial set of patient imaging, we determined that our imaging dose was too conservative to obtain high quality brain imaging. Our existing dose, approximately 10% of a clinical CT, was similar to that of cone beam CT imaging for ENT or dental clinics. These modalities are all focused on osseous imaging, and perhaps not unexpectedly, our osseous images are near diagnostic quality in contrast to the brain images. As a reference, a typical dental cone beam CT is performed with a dose of 5 to 10% that of a clinical head CT.

Based on these initial clinical results, we have sought to find methods to increase the imaging dose of the system. The current x-ray tubes are utilized at near their design limits of 15mA and 2 msec x-ray pulses, and thus attempts to push the dose higher through higher current or longer pulses risks damaging the tubes. Though the underlying technology is capable of higher flux, a redesign of the x-ray tubes would be required for higher power studies. Our primary first option was to reduce the filtering of the x-ray source. This is generally performed to reduce low energy x-rays that only contribute to dose without improving image quality, but typically results in loss of useful imaging flux also. Thus, we replaced our two-layer tin filter with a single layer. This increased the dose to approximately 20% of a clinical head CT. Early evaluation suggests that this remains insufficient for brain imaging, and thus we will need to seek out additional methods to increase dose per slice. Our remaining options are to slow

the acquisition speed and increase pulse width, with our primary goal to identify the likely imaging dose that is necessary to obtain diagnostic brain imaging.

Image Acquisition Software:

The clinical imaging software is fully integrated and functional at this point in time. A flowchart of the involved workflow is in the next figure.



Reconstruction Software:

We have implemented small improvements and rewrites of our primary reconstruction code to assist with artifact reduction sticking with the ASD-POCS reconstruction approach. However, based on the image quality from actual clinical data, as opposed to simulation data, we feel that we have likely maximized the image quality that one can achieve with the reconstruction approach. We are further exploring sinogram inpainting using some published code to attempt to further increase image quality, and are in discussions with other research groups to use more advanced machine learning based approaches. The use of ML is beyond our scope of work, but will likely be necessary to achieve higher quality images.

Clinical Study:

We originally recruited approximately 13 subjects with the original dose protocol and have subsequently recruited 4 patients on the slightly higher dose protocol. Dr. Sindelar an active duty neurosurgeon posted in our Department of Neurosurgery as a military civilian partnership, has continued to serve as the lead PI for the clinical study.

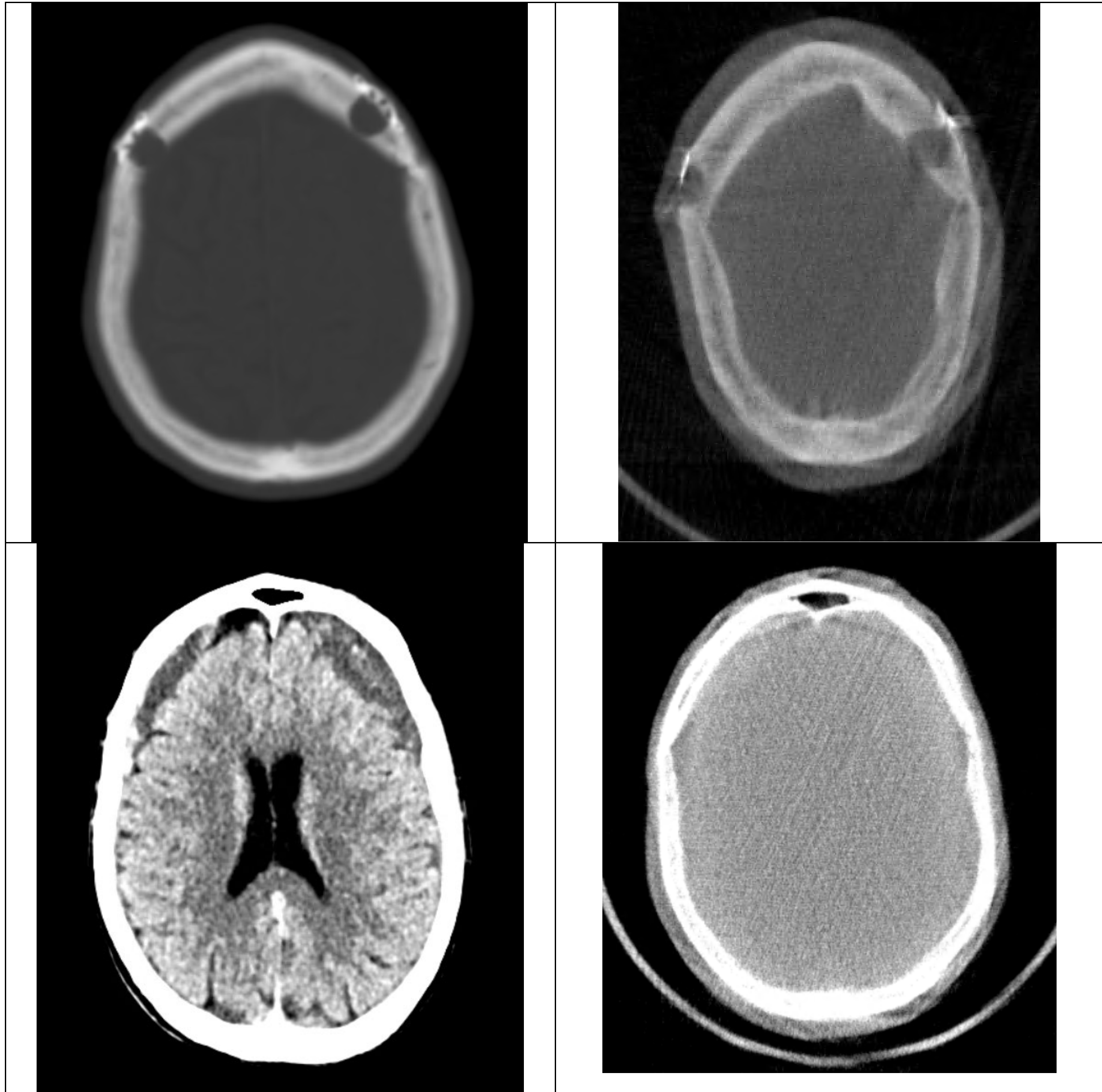


Figure 2. Bone and brain reformats (top / bottom) of a conventional CT and the sHCT (left / right). Osseous structures are relatively clearly defined in the bone reformats, but imaging of the brain parenchyma remains limited.

What opportunities for training and professional development has the project provided?

Our remaining graduate student from the Joint Department of Biomedical Engineering (UNC Chapel Hill/NCSU) has been responsible for hardware/software integration into the clinical system recently successfully defended his PhD and is due to graduate at the end of this calendar year. A medical

student with an engineering background has been exploring the inpainting studies as a part of her summer research project.

Mentorship by the three faculty, Zhou, Lu and Lee continues from both direct and group interactions.

How were the results disseminated to communities of interest?

An additional abstract was presented to SPIE Medical Imaging, 2023. A paper on the development of the benchtop system is currently under revision at a medical physics imaging journal.

W*hat do you plan to do during the next reporting period to accomplish the goals?*

We will work to further improve image quality of the system, through opportunities to further increase or optimize imaging dose. This may require further updates to our IRB, or we may work to increase the dose per slice and reduce our imaging volume to maintain the same total dose to the subject. As

IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

The medical imaging field continues to be interested in stationary or near stationary head CT imaging systems. However, the vast majority of the groups continue to propose systems with a small fraction of the number of x-ray sources of our system. As our team has been public with our approach, it is our hpe that this will encourage the development of these systems.

What was the impact on other disciplines?

We have explored the potential application of this geometry to gated imaging which could improve lung or cardiac imaging.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

CHANGES/PROBLEMS:

We have requested a third NCE for year 5 to focus on continued image quality improvement and patient recruitment. Patient recruitment has been steady, primarily limited due to the availability of technical personnel to run the system as our student is near graduation.

From an image quality perspective, we continue to explore machine learning reconstruction approaches for the system, to further reduce image artifacts. Beyond the sinogram infilling, we are exploring other machine learning approaches that are beyond our scope of work.

PRODUCTS:

A conference proceedings were presented at SPIE Medical Imaging 2023, covering the system conversion to a clinical CT.

1. Billingsley A, Inscoe CR, Xu S, Spronk D, Luo Y, Zhou O, et al. Clinical Developments of a Stationary Head CT Using CNT X-Ray Source Arrays. Presented at the Medical Imaging 2023: Physics of Medical Imaging.

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Yueh Lee
Project Role: Principal Investigator
Research Identifier: ORCID 0000-0003-1846-7680
Nearest person month worked: 3
Contribution to Project: Dr. Lee is leading the project as PI.

Name: Otto Zhou
Project Role: Co-Investigator
Nearest person month worked: 1
Research Identifier: 0000-0003-1476-5517
Contribution to Project: Dr. Zhou is assisting Dr. Lee in supervising graduate students in both system construction and design.

Name: Jianping Lu
Project Role: Co-Investigator
Nearest person month worked: 1
Research Identifier: ORCID 0000-0001-9963-9741
Contribution to Project: Dr. Lu is assisting with the develop of reconstruction algorithms for the system.

Name: Brian Sindelar
Project Role: Co-Investigator
Nearest person month worked: 1
Research Identifier: N/A
Contribution to Project: Dr. Brian Sindelar (neurosurgeon) is the PI of the clinical study. He has been managing IRB protocol development, approval, and helping to review images.

Name: Christina Inscoe
Research Identifier: 0000-0001-8681-9030
Project Role: Co-Investigator / Laboratory Manager
Nearest person month worked: 3
Contribution to Project: Dr. Inscoe is assisting in system development and construction, and will coordinate radiation and electrical safety testing of the system.

Name: Alex Billingsley
Research Identifier: 0000-0001-7630-2134
Project Role: Research Graduate Assistant
Nearest person month worked: 12

Contribution to Project: Mr. Billingsley has performed the clinical hardware integration (microcontroller programming) and system calibration.

Name: Maya Rinehart
Research Identifier: n/a
Project Role: Research Assistant (volunteer)
Nearest person month worked: 3

Contribution to Project: Ms. Rinehart is a medical student at the University of North Carolina at Chapel Hill. As a part of her summer research project, she sought to integrate the inpainting algorithm with our imaging geometry to assist in improving reconstruction.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report.

What other organizations were involved as partners?

Provide the following information for each partnership:

SPECIAL REPORTING REQUIREMENTS

Quad chart will be enclosed as an attachment.