

Focused Tomography

Reducing Radiation in CT

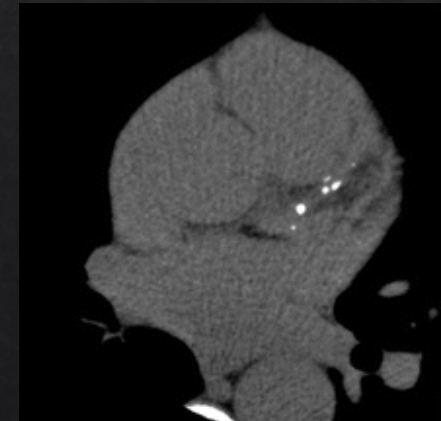
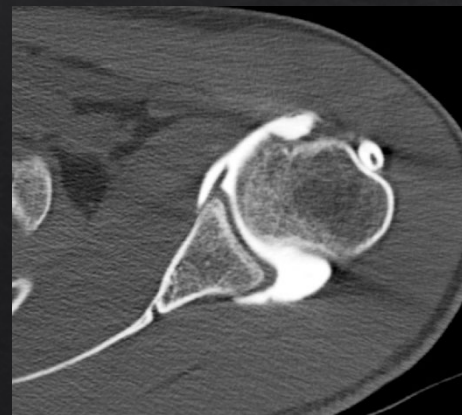
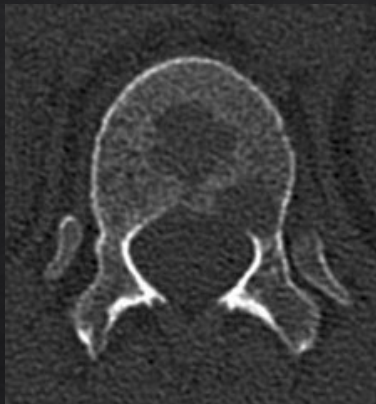
Patent Number 11,801,017 by The University of Florida

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Background and Introduction

Our Differentiating Product

- ◆ Focused Tomography is a technology that permits a dose reduction of up to 90% for CT imaging of an anatomic region of interest (ROI)
- ◆ Current CT technology requires that the entire axial plane of the body be exposed to a relatively uniform dose of radiation
 - ◆ But why expose the entire body to the full dose if a smaller section would suffice?
 - ◆ The Radiologist often doesn't see the full slice of the body, even though its irradiated equally



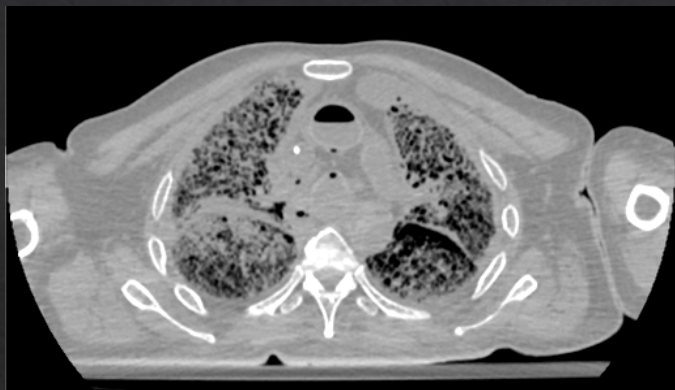


Figure 1: A CT image taken at 17 mGy

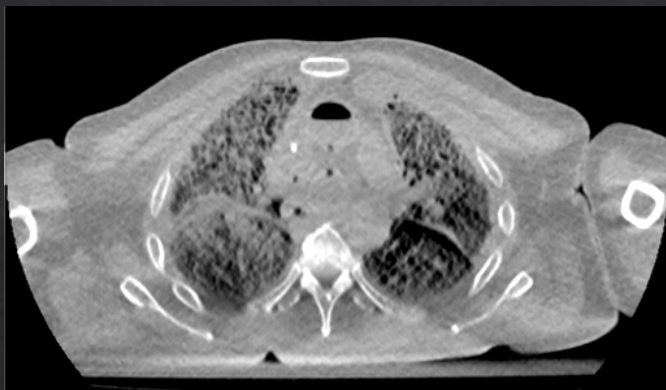


Figure 2: The same image taken at 1.7 mGy

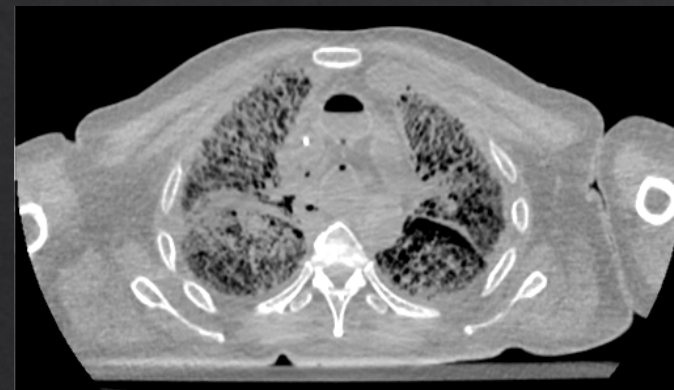


Figure 3: The data from the images in Figs. 1 and 2 were combined using the Focused Tomography method, with an ROI over the spine at 17 mGy, and 1.7 elsewhere.

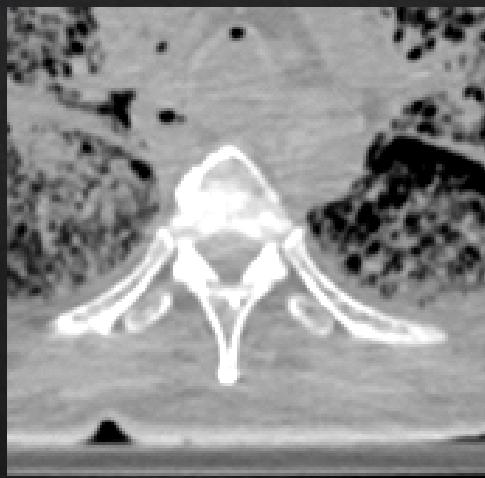


Figure 4: Magnified view of the spine from Fig. 1

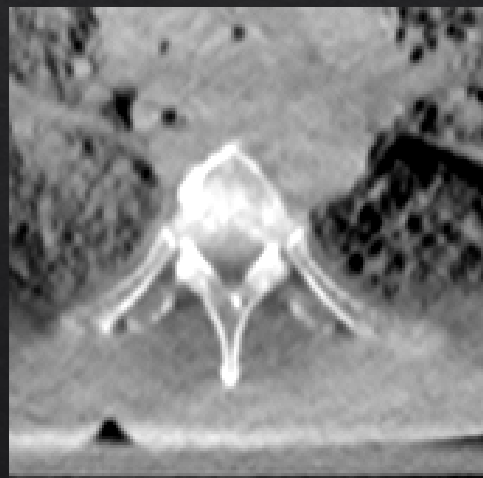


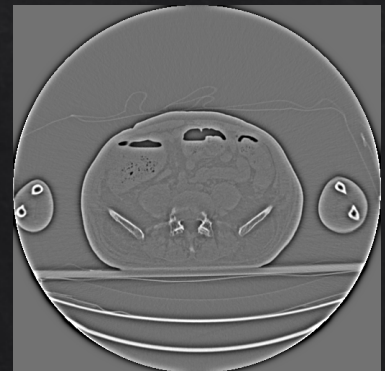
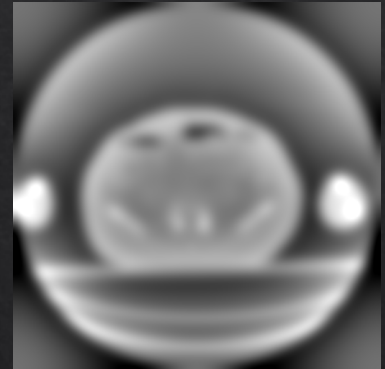
Figure 5: Magnified view of the spine from Fig. 2. Note there is much less definition on the spine.



Figure 6: Magnified view of the spine from Fig. 3.

The Algorithm

- ◇ All images are composed of both high-frequency and low-frequency data
 - ◇ High-frequency data provides fine detail in the image
 - ◇ Low-frequency data provides the overall structure of the image
- ◇ Radiation dose primarily affects the amount of noise in an image, with lower doses resulting in more noise
- ◇ Dr. Olson's insight was that:
 - ◇ The high-frequency data must be acquired with low noise (higher dose), but only within the ROI
 - ◇ The low-frequency data must be acquired over the entire image to permit accurate reconstruction, but higher noise (lower dose) is acceptable



Significant New Points

- ◆ We can accomplish the reconstructions directly from images altered by the adaptive collimator, which doesn't require access to the sinogram data
 - ◆ This makes retrofitting existing machines much easier
 - ◆ This is included under a Continuation in Part (CIP) of the original Focused Tomography patent
 - ◆ Retrofit can be done with a plug and play collimator and minor software alterations
- ◆ We alter the received data, and have proved and demonstrated that images can be obtained at two different dosages with accurate reconstructions and 90% dosage reduction
 - ◆ We utilized the simplest of algorithms to demonstrate this, Filtered Backprojection
 - ◆ Advanced algorithms such as Iterative Reconstruction and AI algorithms will just augment these savings
- ◆ We have theoretically calculated not only the transmitted dosages through the collimator, but have also experimentally verified significant dose reduction in the CTDI phantom

The Market

- ◆ The CT Market is estimated to be 7-8 Billion dollars per year
- ◆ Most of the Majors, i.e. Siemens, GE, and Canon have seen this product and like it but want to wait two years to implement it on their new Photon Counting Machines.
- ◆ We believe that the larger market is for retrofit of the 20-30 thousand CT machines in use
- ◆ CT machines must be continually checked, with their X-ray tubes only lasting a finite amount of time (5-7 years), and they must be continually refocused (6 months)
- ◆ The only Photon Counting Machine on the market currently is priced at ~\$2M. Standard machines are approximately \$750 K
- ◆ While we are looking forward to our altered and patented collimators to go on the new machines, we believe that the used market is much larger
- ◆ We can be at production level for only \$1M, with yearly profits of greater than \$10M
- ◆ We believe that we should consider up to \$2M in financing, to expedite our market entry

The Unit Upgrade Price

- ◆ We believe that we can produce the altered collimators for \$50 K, with \$20 K profit
- ◆ This depends upon the amount that the majors are going to demand for allowing us on their list of acceptable upgrades, etc.
- ◆ We believe that a \$50 K upgrade on a \$500 K piece of used equipment which reduces 90 % of the radiation will sell well
- ◆ Canon alone has approximately 7500 machines worldwide
- ◆ If we upgrade 500 per year, from one manufacturer, that is \$10M in profit.
- ◆ We believe that once one manufacturer agrees, they will all have to follow due to our patent

Focused Tomography Team

- ◆ Dr. Timothy Olson, Patent Co-Author, President, Swamp View Technologies
- ◆ Dr. Stephanie Leon, Patent Co-Author, Department of Radiology, University of Florida
- ◆ Dr. Philip Templeton, formerly Professor of Radiology: Massachusetts General, John Hopkins, Department Head, Radiology, University of Maryland
- ◆ Dr. Chris Lightcap, Founding Owner, KCL Robotics
- ◆ Mr. David Hickman, MBA, Software and Hardware Expert
- ◆ Dr. Richard Albanese, MD, Former Air Force Supervisor, Worldwide Radiation Expert

Academic Primaries' Background

- ◆ Dr. Timothy Olson (mathematician)
 - ◆ Began work in CT in 1988 and developed the mathematical basis of focused tomography in the early 90's
 - ◆ After his publication in 1993, 100+ related papers followed citing his work
 - ◆ However, they all relied upon 0-1 sampling, i.e. sample or don't sample
 - ◆ Not possible in CT, since you cannot turn the x-ray tube on and off so quickly
 - ◆ Interest by the radiology community in dose reduction was limited at the time
- ◆ Dr. Stephanie Leon (medical physicist)
 - ◆ Board-certified in diagnostic medical physics with 17 years of clinical and research experience
 - ◆ Suggested a collimator design that could satisfy the mathematical assumptions of the method in a feasible way, permitting the revival of the project
 - ◆ Dose reduction is now a major concern in Radiology, so the time is right
- ◆ Dr. Philip Templeton (Advisor)
 - ◆ Former Professor Mass General and Johns Hopkins, Former Professor and Chairman of Radiology, University of Maryland, and teleradiology entrepreneur, now founder of DocPanel

The Algorithm and Results

The Algorithm

- ◆ Advantages:
 - ◆ Permits substantial reduction of total patient radiation dose
 - ◆ Fully preserves standard clinical image quality where the radiologist needs it
 - ◆ Can permit adequate visualization of structures outside the clinical area of interest, which may be important for anatomic localization and the detection of incidental findings
 - ◆ Very important if the incidental findings demonstrate metastasis
 - ◆ Very important to avoid critical organs from incidental radiation due to orthopedic CT scans
- ◆ Dr. Olson has developed solutions that work with and without access to the raw (sinogram) data

First Steps

- ◈ Before building the collimator, first steps involved testing the algorithm on realistic clinical images
- ◈ Using a clinical CT scanner, we acquired CT scans of a cadaver at 17 mGy and 1.7 mGy
- ◈ Scans were combined to simulate imaging at full dose inside an ROI and low dose outside the ROI
- ◈ Sinograms were created from the combined images, then re-reconstructed with the Focused Tomography methodology



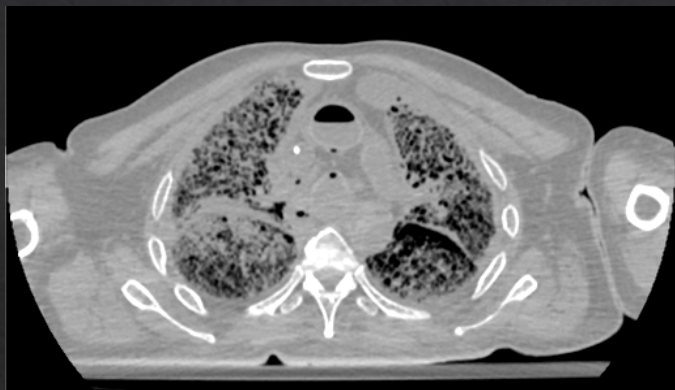


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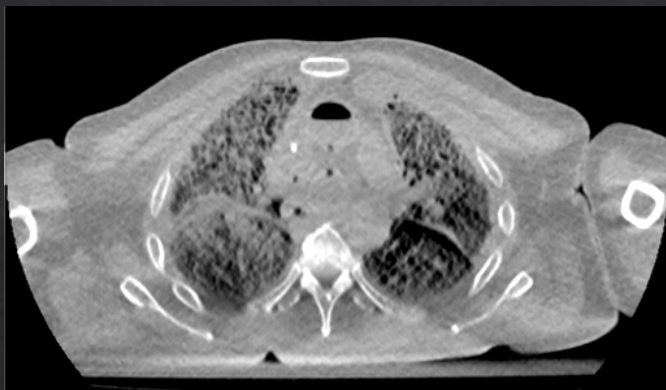


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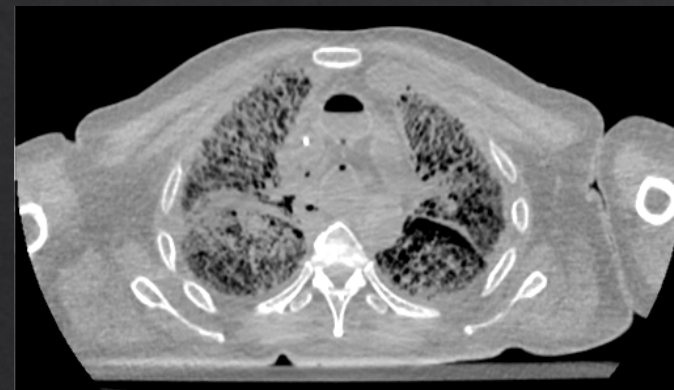


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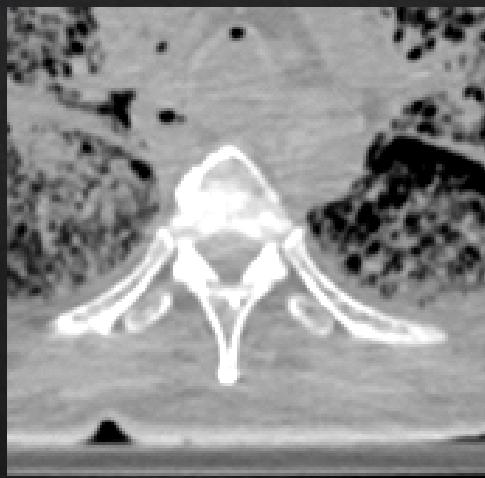


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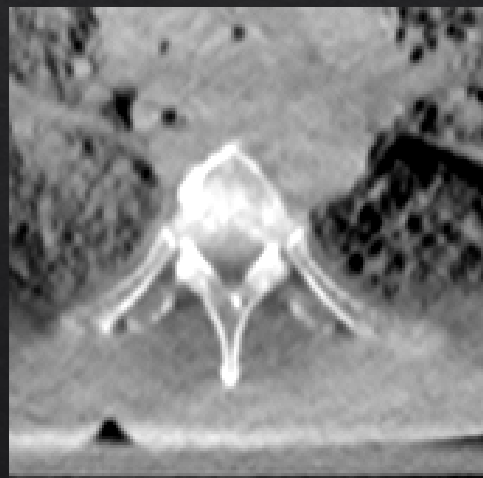


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Accuracy of the Reconstruction

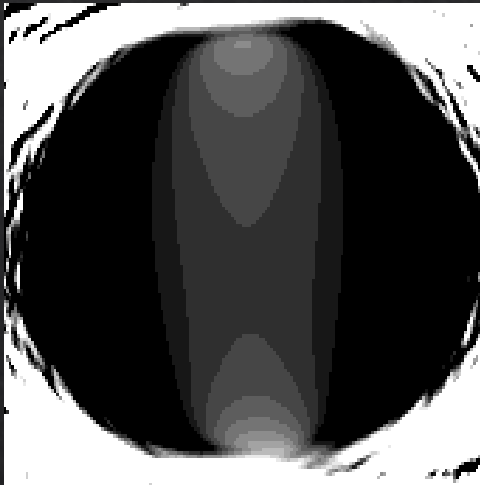
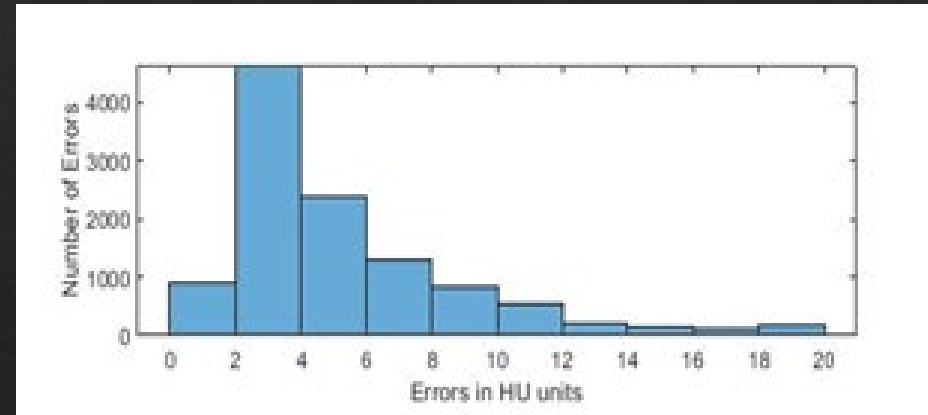


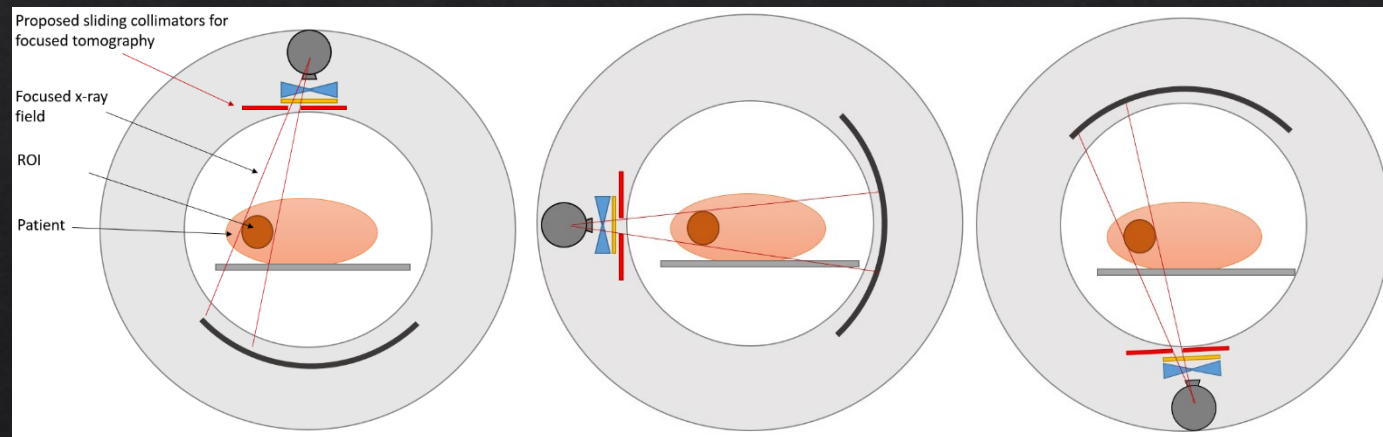
Image showing the difference between the full-dose image and the Focused Tomography image within the ROI, displayed at a window width of 10 HU and level of 0.



Histogram of HU errors between the full-dose and Focused Tomography images. The clinical impact of such small shifts is negligible.

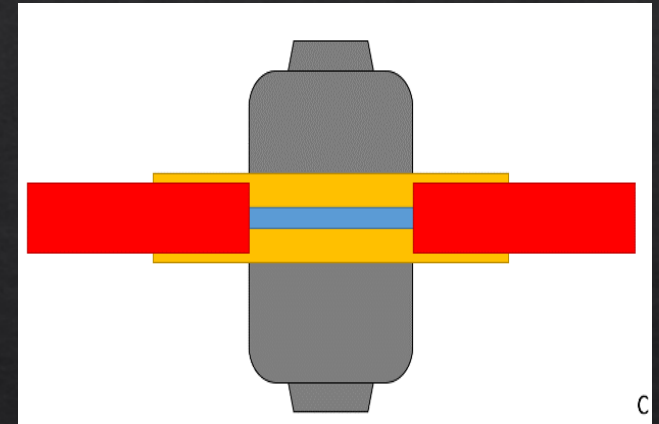
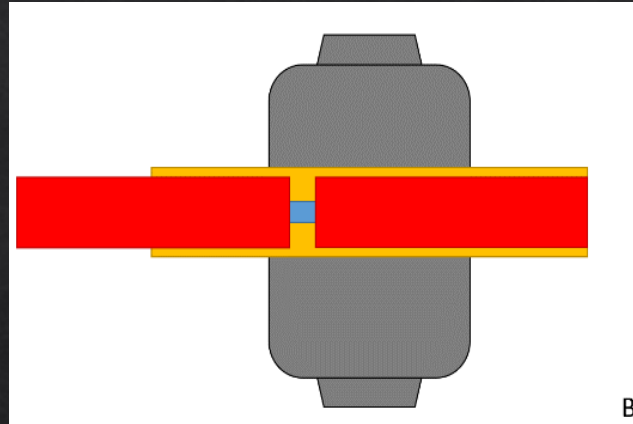
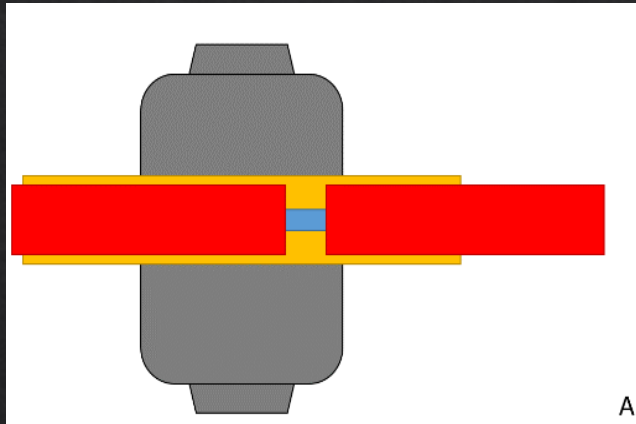
Collimator Design and Construction

- ◇ Having shown that the algorithm works, the next step was to design and build the collimator
 - ◇ Semi-radiolucent sliding blades that transmit $\sim 10\%$ of x-rays
 - ◇ Size and position of opening is adjustable in real-time during gantry rotation
 - ◇ Collimator is installed in addition to existing filters and collimators



“Snapshots” of the x-ray tube and associated components at three different positions during each rotation. The sliding collimators (red) adjust position during the rotation to keep the ROI in focus.

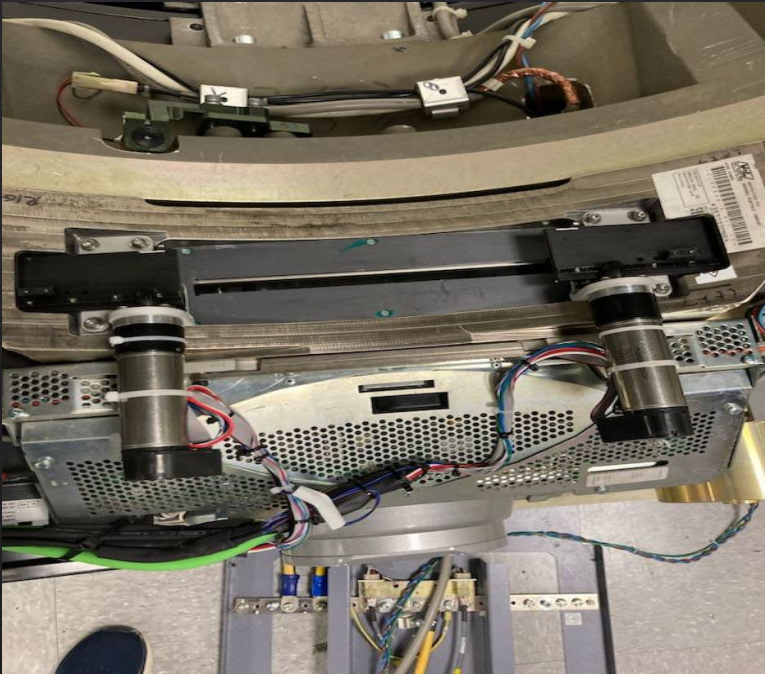
Collimator Design and Construction



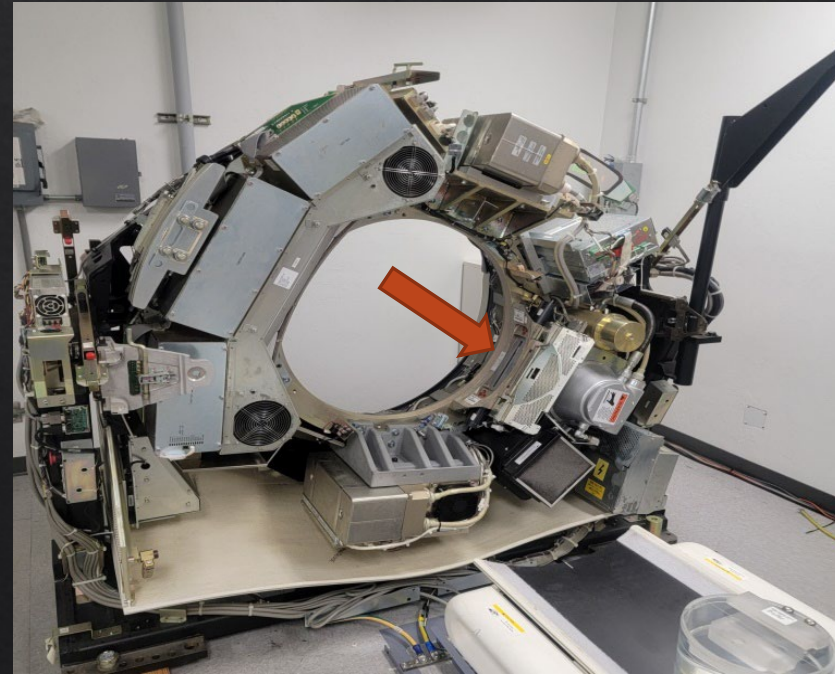
A bottom-up view of the sliding collimator (red), pre-patient collimator (yellow), filters (blue), and x-ray tube (gray). A) and B) show two different positions allowing ROIs of different sizes and locations. C) shows the sliding collimators fully open, permitting a standard CT exam.

Collimator Design and Construction

- ◆ We have installed and tested our collimator on a GE BrightSpeed CT scanner



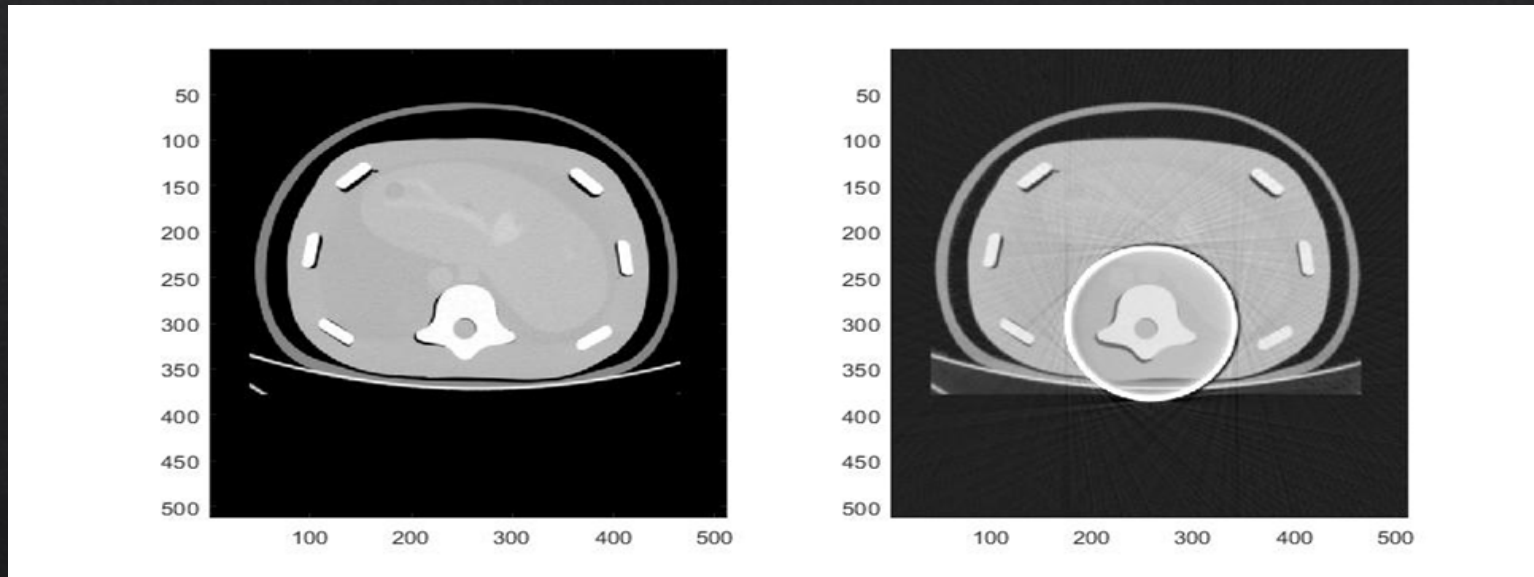
The Focused Tomography collimator



Position of the Focused Tomography collimator within the CT gantry

Preliminary Experimental Images

- ❖ Axial images were acquired of a phantom at 120 kV and 120 mAs, with collimator in place, and reconstructed successfully with the Focused Tomography algorithm.
- ❖ Note the presence of the Gibb's ringing surrounding the ROI. The Gibb's ringing is a results of the sharp edge on the collimator blades and can be eliminated by beveling the blades' edges



Left: full-dose image of the phantom, Right: image of the same slice of the phantom with the collimator focused on the spine

Future Steps and Conclusion

Completing the Equation

- ◆ Focused Tomography can result in sizeable dose reduction with traditional detector technologies and reconstruction algorithms, providing a relatively inexpensive upgrade to traditional in-place CT systems and for the used CT equipment marketplace
- ◆ However, Focused Tomography could also work synergistically to “complete the equation” in dose reduction by being paired with AI reconstruction and processing algorithms, as well as with photon-counting CT (PCT)
 - ◆ AI and PCT can permit excellent image quality with global dose reduction, but don’t change the fact that many organs and tissues do not really need to be irradiated at all
 - ◆ Only Focused Tomography provides “internal shielding” to protect organs that don’t need to be exposed in the first place
 - ◆ Together, these technologies create a **comprehensive dose reduction solution** to allow optimal patient imaging with the lowest possible risk
- ◆ Provides a relatively inexpensive retrofit upgrade to traditional/used CT systems

Applications

- ◇ Especially for situations where repeated monitoring is necessary for:
 - ◇ Monitoring and alteration of cancer therapy
 - ◇ Tracking tumor growth and metastasis
 - ◇ Multiple follow-up studies such as pancreatitis/complications
 - ◇ Recovery from surgical procedures
- ◇ Many different anatomical regions
 - ◇ Spine
 - ◇ Shoulder
 - ◇ Elbow
 - ◇ Hip
 - ◇ Cardiac
- ◇ Pediatric exams to achieve lowest doses possible

Challenges: Device Independence

- ◆ There are many CT machines. We need to be able to implement our solution seamlessly on the most popular of them. There are a number of steps in this process.
 - ◆ Imaging without the original sinograms. The sinograms, or projection data, are not easily available and seem to be hidden within the operating system. We have invented a method which solves this problem, which is detailed in our Continuation in Part of the Patent.
 - ◆ Location of the Gantry: We will have independent verification of the Gantry location.. This is not hard, and will allow us to be further independent of the individual machines.
 - ◆ Placing our Alterations via the Collimator on the Accepted upgrade list of the Majors. GE has an accepted list alterations. This should not be hard once demonstrated.
 - ◆ The collimator blades must be adjusted to avoid Gibbs ringing. This is easy.
 - ◆ Integration of the choice of the Region of Interest (ROI), into the operators controls. This is not hard, but will be much easier with the cooperation of the majors.

Patent and Exclusive Rights

- ◆ University of Florida Research Foundation filed a U. S. Utility Patent Application Serial No.16/986,014, filed August 5, 2020 entitled FOCUSED TOMOGRAPHY.
- ◆ University of Florida Research Foundation has been granted a United States Patent for FOCUSED TOMOGRAPHY, Patent No. 11,801,017. The patent was issued on October 31, 2023.
- ◆ University of Florida Research Foundation has filed a Continuation in Part extension for the United States Patent for FOCUSED TOMOGRAPHY, Patent No. 11,801,017. This covers the algorithm to reconstruct directly from images rather than raw sinogram data.
- ◆ Swamp View Technologies has the exclusive, worldwide license to United States Patent No. 11,801,017 from the University of Florida Research Foundation. We are Swamp View Technologies!

United States Letters Patent No. 11,801,017 for " FOCUSED TOMOGRAPHY." This patent was issued on October 31, 2023, and will expire on August 5, 2040, United States Patent United States Letters Patent No. 11,801,017 for " FOCUSED TOMOGRAPHY." This patent was issued on October 31, 2023, and will expire on August 5, 2040,

Our Financing Needs

- ◆ We have a basic prototype
- ◆ We are seeking a minimum of \$1M in financing to make it to production
- ◆ We believe that \$2M will allow us to adapt to more of the major manufacturers needs at the same time
- ◆ We are looking for a financing company who is willing to join us on this journey

Summary

- ◆ For CT scans focused on an anatomical region of interest, the combination of the Focused Tomography collimator and algorithm permits:
 - ◆ A radiation dose reduction of up to 90%
 - ◆ Preservation of clinical image quality and HU accuracy within the ROI
 - ◆ Visualization of structures outside the ROI
- ◆ The algorithm has been successfully employed on cadaver images on a University of Florida clinical CT scanner, as well as on phantom images employing our collimator
- ◆ The first prototype version of the collimator has been successfully installed and tested on a GE BrightSpeed CT scanner, requiring only minor tweaks
- ◆ University of Florida Research Foundation has been issued a U.S. Patent for Focused Tomography, Patent No. 11,801,017.
- ◆ Swamp View Technologies, LLC has a fully executed license for the exclusive worldwide rights to U.S. Patent for FOCUSED TOMOGRAPHY, Patent No. 11,801,107.