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CONTRACTING ORGANIZATION: University of Illinois at Chicago

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14. ABSTRACT

Our initial findings illustrate the potential of the stretched exponential model parameters to better characterize high-grade prostate cancer.Additional work is underway to establish the correspondence between the DDC and a-maps with histological sections of the entire prostate gland. Given the technical difficulty with comparison of radical prostatectomy histology with imaging, we have also introduced a method to evaluate the accuracy of our novel diffusion imaging with biopsy histology. Development of a non-invasive quantitative imaging biomarker for high grade PCa will be useful for improving biopsy yield and grade accuracy, accurately identifying men

15. SUBJECT TERMS
FROC, Prostate Cancer, MRI, Diffusion

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INTRODUCTION:

Accurate detection of aggressive prostate cancer (PCa) using existing clinical prediction tools is a challenge. Prostate MRI is promising technology for PCa detection and characterization. However, its accuracy has been sub-optimal especially in the setting of benign prostate inflammation or hyperplasia. We have developed a more sophisticated computational model of diffusion weighted MRI (FROC-DWI) that produces quantitative information regarding tissue architecture in-vivo. We also acknowledge additional models of water DWI and compute those as comparisons. We hypothesize that the use of FROC-DWI in men with clinical suspicion for PCa will differentiate high grade PCa from indolent PCa and benign prostate pathology and therefore improve biopsy detection of aggressive PCa as compared to existing models and clinical standards..

KEYWORDS:

FROC, Prostate Cancer, MRI, Diffusion

ACCOMPLISHMENTS:

What were the major goals of the project?

The major goal of the project is to generate a quantitative MRI signature that differentiates high grade prostate cancer (PCa) from low grade PCa and benign prostate tissues. The quantitative parameters of the signature will be compared with histologic tissue architecture (Gleason score) using RP specimens from our biorepository archive as well as prostate core needle biopsies. The diffusion parameters will be correlated with stromal and epithelial architecture of areas of benign and malignant prostate tissue and a predictive model will be created to differentiate Gleason pattern 4 or higher PCa from other tissue types.

Aim 1: Generate a quantitative diffusion weighted MRI signature that differentiates high grade PCa from low grade PCa and benign prostate tissues

Aim 2: Determine the feasibility of using co-registered histology from surgical RP as well as MRI directed core needle biopsy to measure the accuracy of in-vivo MRI imaging for prostate cancer

Aim 3: Validate the MRI signature in a patient cohort undergoing MRI guided prostate needle biopsy and determine what utility it adds to current clinical standard of care MRI image interpretation

What was accomplished under these goals?

Aim 1 accomplishments to date:

The development of a quantitative DWI signature for prostate cancer has been accomplished using two patient datasets after gaining the approval of the University of Illinois at Chicago IRB and Cancer Center Protocol Committee. Several models have been developed and tested via custom MATLAB programming including a kurtosis model, stretched exponential model, traditional mono-exponential apparent diffusion coefficient model. Finally, the fractional order calculus (FROC) model has been implemented as well as shown in the tables and figures below.

The first (development) cohort was 6 men undergoing RP for localized prostate cancer. The distance from the prostatic apex for both the histology and MRI were used to matchimage pairs for analysis. Two hundred and twelve (212) target quadrant regions were identified as benign or high-grade PCa from six patients. For all quadrant regions, the mean, median, minimum, maximum and range values of ADC, α, DK, K, Df , β , and μ were calculated and examined with histograms. The median values were used for all statistical analyses. The mean of each parameter from the benign and high-grade PCa quadrant were compared with box-plots and paired-sample t-tests. Receiver operating characteristic (ROC) regression was used to combine the stretched-exponential model parameters (ADC, and α), the kurtosis model parameters (DK, and K)) and the FROC model parameters (Df ,β , and μ). The sensitivity, specificity, and diagnostic accuracy of each parameter was calculated at the Youden's index points of the corresponding ROC. We used patient number as a covariate in multivariate logistic regression due to the non-independence of quadrants taken from a given patient. All statistical analyses were carried out using MATLAB (MathWorks, R2016a, Natick, MA), with a statistical significance level at p-value < 0.05.

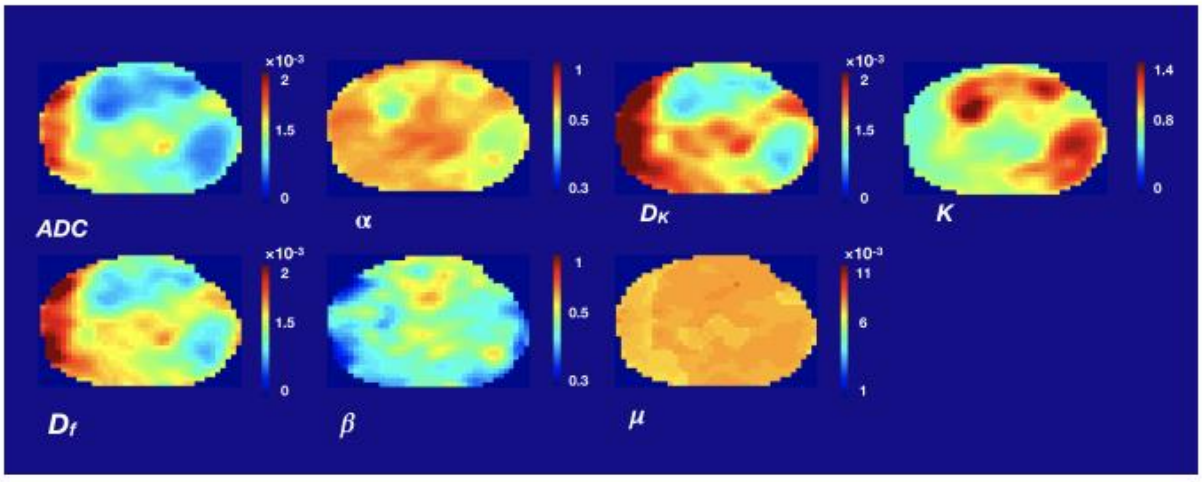

Figure 1: Representative processed images from an MRI prostate slice

	Sensitivity	Specificity	Accuracy	AUC	95% CI of AUC
$ADC\ (mm^2/s)$	0.75	0.75	0.75	0.80	[0.74 ,0.86]
ADC, α	0.82	0.71	0.76	0.80	[0.74, 0.86]
D_K, K	0.77	0.76	0.76	0.81	[0.75, 0.87]
D_f, β	0.77	0.76	0.76	0.81	[0.75, 0.87]
D_f, μ	0.82	0.71	0.76	0.82	[0.76, 0.87]
β, μ	0.82	0.57	0.69	0.72	[0.65, 0.78]
D_f, β, μ	0.74	0.77	0.76	0.82	[0.76, 0.88]

Figure 2: Diagnostic accuracy of the quantitative models

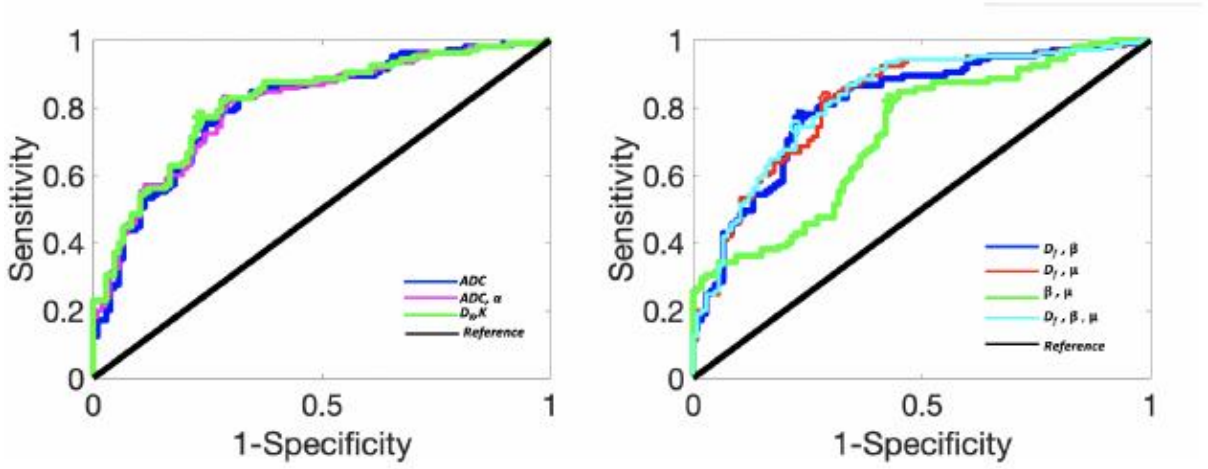

Figure 3: ROC of the SEM and Kurtosis models (left), and FROC model (right)

As shown, the FROC model had the best performance with an AUC of 0.82 for prostate cancer. To further investigate these promising results, and second cohort of 31 patients with MRI prior to prostate biopsy was examined. Evaluated subjects underwent clinical 3T prostate MRI for either surveillance of known PCa or suspected PCa between July 2015 and November 2016. Those selected had at least one region of interest (ROI) with a PI-RADS score ≥3 and had MRI guided needle biopsies using realtime fusion of the MRI with TRUS. Thirty-one patients with 39 ROI met the criteria. The median age of men was 62 years (51-73 years), and the median serum PSA was 7.5 ng/mL (4.40-26.20 ng/mL).

All MR/US fusion biopsies were performed on the GE logiq E9 Ultrasound platform (GEHealthcare, Chicago, IL) under TRUS guidance after fusion with T2WI in the mid-sagittal plane by the PI. The patients had two to four 18- gauge core biopsies performed

for each MRI ROI. The biopsies were embedded and stained with hematoxylin and eosin and evaluated for presence of PCa by a board-certified genitourinary pathologist. PCa grade was categorized based on the International Society for Urologic Pathology Gleason Score (GS). The accuracy of the aforementioned models were computed, and compared to the PI-RADS score, which relies only on non-processed and non-quantitative MRI images. The results are shown below:

	Cutoff	Sensitivity	Specificity	Accuracy	AUC	95% CI of AUC
$PI-RADS$	3	N/A	0.42	0.61	0.74	[0.58, 0.90]
$ADC\ (mm^2/s)$	9.58×10^{-4}	0.84	0.76	0.79	0.84	[0.69, 0.98]
α	0.80	0.69	0.73	0.71	0.70	[0.52, 0.89]
$D_K\ (mm^2/s)$	1.4×10^{-3}	0.92	0.80	0.84	0.81	[0.66, 0.97]
K	0.86	0.73	0.76	0.74	0.75	[0.60, 0.91]
$D_f\ (mm^2/s)$	1.2×10^{-3}	0.92	0.80	0.84	0.83	[0.68, 0.98]
β	0.64	0.73	0.61	0.69	0.63	[0.45, 0.82]
μ	7.7×10^{-3}	0.69	0.76	0.71	0.69	[0.52, 0.86]

Figure 4: Accuracy of quantitative MRI parameters compared to PI-RADS in an MRI guided biopsy cohort

	Cutoff	Sensitivity	Specificity	Accuracy	AUC	95% CI of AUC
ADC, α	0.60	0.85	0.88	0.87	0.86	[0.71, 0.99]
D_K, K	0.61	0.92	0.80	0.84	0.81	[0.65, 0.97]
D_f, β	0.65	0.92	0.80	0.84	0.83	[0.68, 0.98]
D_f, μ	0.66	0.92	0.76	0.82	0.82	[0.67, 0.98]
β, μ	0.67	0.76	0.53	0.61	0.65	[0.46, 0.85]
D_f, β, μ	0.64	0.84	0.80	0.82	0.82	[0.67, 0.98]

Figure 5: Accuracy of the quantitative models in the MRI guided biopsy cohort

As shown, the SEM, Kurtosis, and FROC models significantly outperformed the clinical standard PI-RADS score. Notably, while the SEM showed the best accuracy with an AUC of 0.86, the accuracy of the FROC model in this cohort was consistent with that of the first cohort of RP quadrants. The ROC depicting these data are shown below:

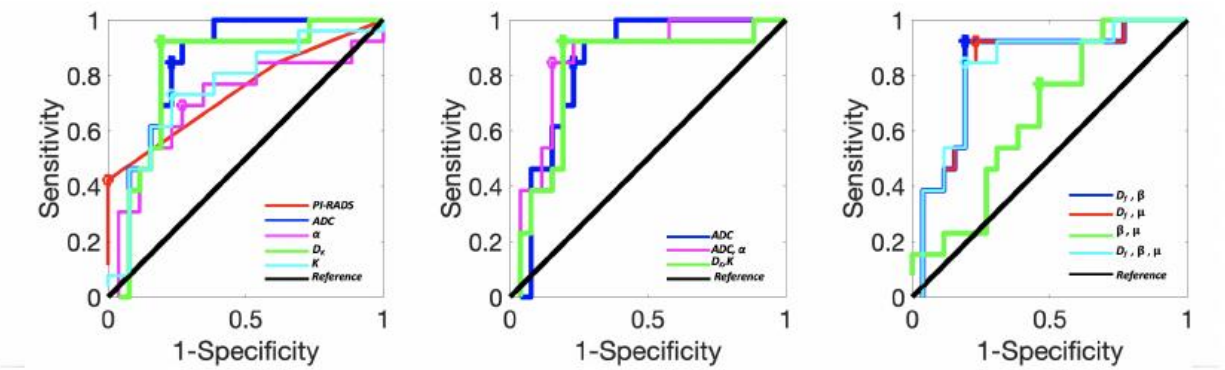

Figure 6: ROC of the PI-RADS and SEM parameters (left), the SEM and Kurtosis models (center), and the FROC model (right)

Next steps are to publish these data (in-process), to encourage external validation of our promising results indicating that quantitative DWI models can outperform the clinical standard PI-RADS score.

Aim 2 accomplishments to date:

Year 1:

- IRB approval has been acquired for this aim
- The histology samples have been requested from the UIC biorepository for and digitized
- All MR images have been collected and prepared for image processing and analysis
- MR images have been de-identified and prepared in MatLab for quantitative analysis by the bioengineering co-investigators
- The histology specimens have all been retrieved and digitized so the grades of cancers can be outlined by the pathology co-investigators
- The UIC IRB has approved the continuing review of the protocol on 3/29/16
- 3 cases have had digital pathology annotation and MR image computation.
- Quality control testing of the MR imaging files has been completed.
- An abstract was presented to the IMPaCT conference for August 4-5 2016
- An abstract was presented to the ISMRM Workshop for September 11-16 2016

Year 2:

- The MatLab code for the production of alpha and DDC MRI maps was de-bugged, corrected, and finalized

- The MatLab code for co-registration of digital radical prostatectomy histology to T2 weighted MRI images of alpha and DDC maps to T2 weighted MRI was completed and tested
- 8 retrospective cases were analysed
- A new cohort of retrospective cases were added to the study to improve the sample size for model development : 30 patients that had pre-biopsy mpMRI and MRI targeted biopsies. This was approved in an IRB amendment.
- All MRI images for the added cohort have been collected and re-analysed
- Currently added cohort images are undergoing alpha and DDC map processing
- All biopsy pathologic data have been collected for the added cohort
- 2 abstracts were submitted to ISMRM 2018 conference – 1 for the initial results of the DDC/alpha map comparison to prostatectomy histology and 1 for the image co-registration methodology
- 1 abstract was submitted to the AUA 2018 conference with prelimary diagnostic accuracy thresholds for DDC and alpha parameters

Year 3:

- The method for the co-registration of digital radical prostatectomy histology to T2 weighted MRI images of alpha and DDC maps to T2 weighted MRI was completed
- A new cohort of retrospective cases were added to the study to improve the sample size for model development : 30 patients that had pre-biopsy mpMRI and MRI targeted biopsies.
- The analysis of the biopsy cohort was completed. The findings have been submitted as an abstract for the SUO 2018 conference.
- 2 abstracts were presented at ISMRM 2018 conference – 1 for the initial results of the DDC/alpha map comparison to prostatectomy histology and 1 for the image co-registration methodology
- 1 abstract was presented at the EUS section of the AUA 2018 conference testing the association between image co-registration accuracy using standard diffusion weighted MRI parameters. This work has been submitted to the Journal of Magnetic Resonance Imaging (pending).

Aim 2 accomplishments:

We have developed and tested three methods for comparing the processed MRI images (quantitative models) to the gold standard histopathology to date: MRI guided biopsy result, whole embedded RP slice quadrants, and whole embedded RP completely co-registered to the MRI. The latter method provides the ability for a pixel-wise comparison of the entire prostate gland. Each method may have value depending on the clinical

scenario. Below, we show the data supporting our adoption of an 8 control-point method of non-linear registration:

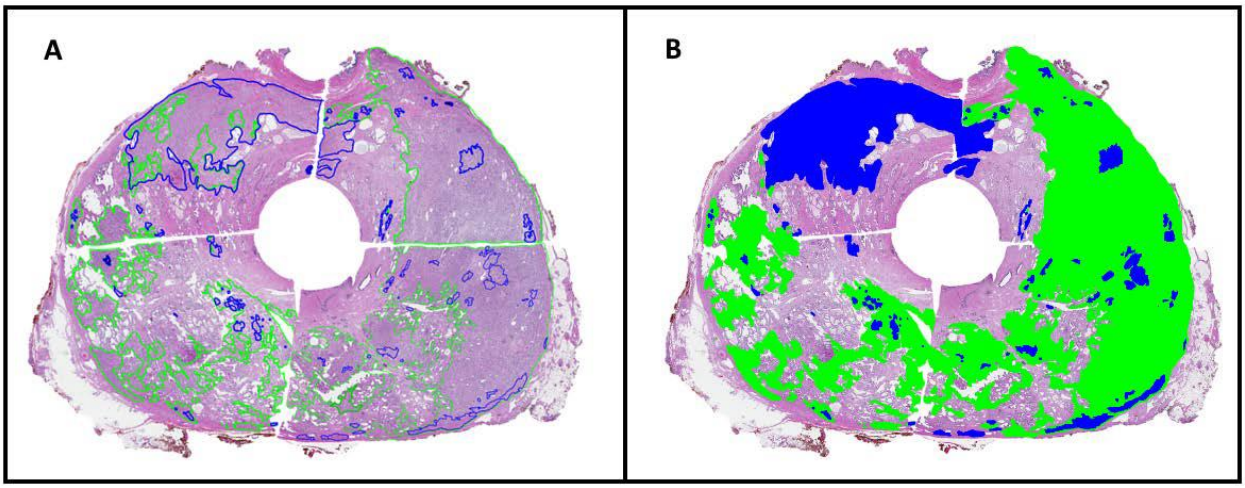

Figure 7: Preparation of the reconstructed annotated axial pseudo whole mount slice A. before annotation filling and B. after annotation filling. Gleason score 3 colored green, 4 colored blue, 5 colored red (not shown).

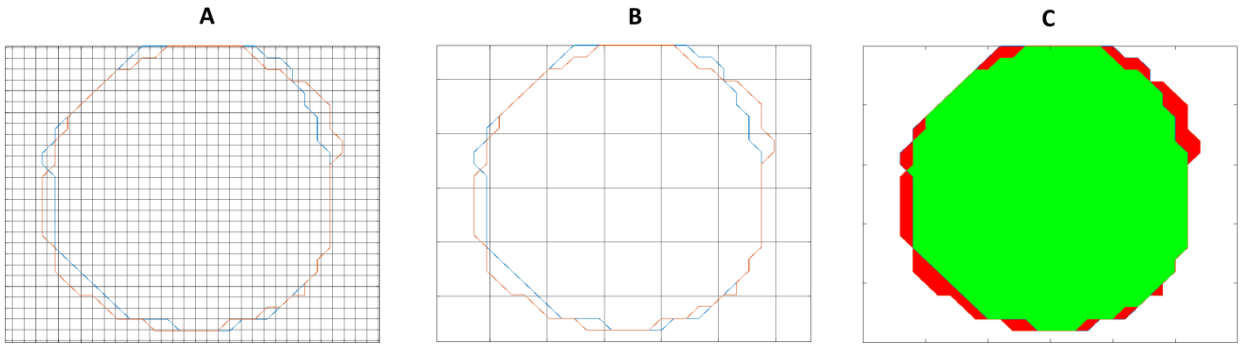

Figure 8: Quantitative registration accuracy methods. Contour overlap at A. 1 mm and B. 5 mm threshold resolution. C. Basis for spatial overlap index, the Dice similarity coefficient (DSC). Green indicates area overlap; red indicates non-overlapping areas.

Table 1
Control Point Optimization

Number of Control Points	Mean (SD) 1mm Contour Overlap	Mean (SD) DSC
4 control pts	0.83 (0.03)	0.95 (0.01)
8 control pts	**0.92 (0.03)**	**0.95 (0.008)**
12 control pts	0.91 (0.03)	0.95 (0.007)
16 control pts	0.89 (0.08)	0.94 (0.02)

DSC, Dice similarity coefficient

Table 2
Registration Accuracy of the control point method compared to traditional methods of DSC and contour overlap:

Patient Number	Number of Slices	Mean 1 mm Contour Overlap	Mean 5 mm Contour Overlap	Mean DSC
1	9	0.88	1.00	0.9498
2	10	0.69	1.00	0.9415
3	10	0.79	1.00	0.9440
4	9	0.73	1.00	0.9471
5	10	0.79	1.00	0.9454
6	8	0.82	1.00	0.9456
Total	56	0.78	1.00	0.9455

DSC, Dice similarity coefficient

We then computed the mono-exponential as well as SEM, and Kurtosis models using the pixel-wise registered data as a method to compare to the other two methods:

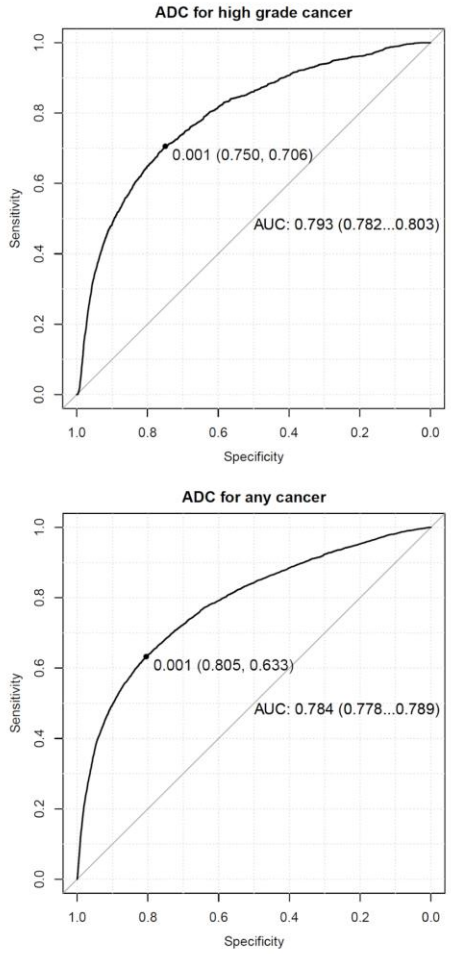

Figure 9: ROC of the mono-exponential DWI model using pixelwise registration

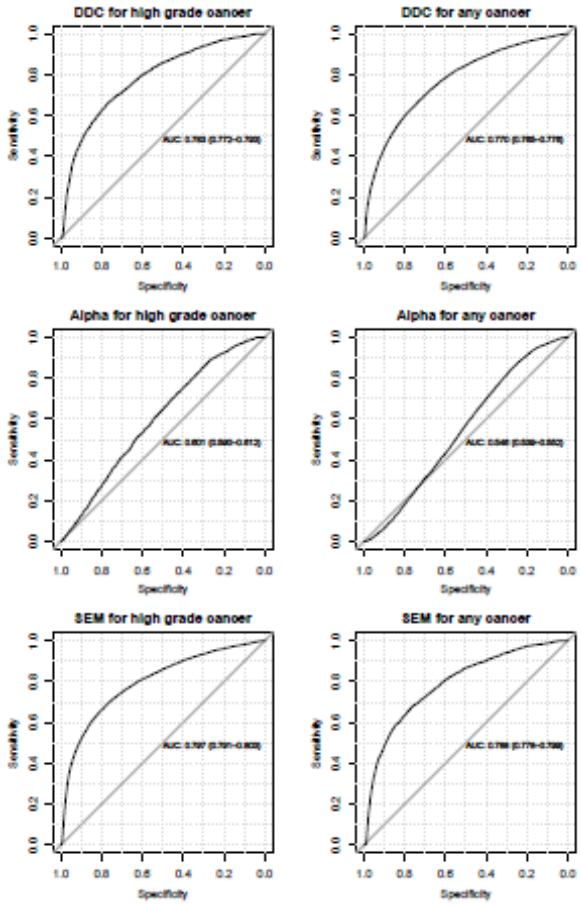

Figure 10: Stretched exponential model using the pixelwise registration

These data demonstrate similar accuracy of the SEM and mono-exponential models, which validate that the pixel-wise registration method and quadrant registration methods may each be useful to compare in-vivo MRI imaging to RP histology. The next step is to combine these two methods of analysis into the previously submitted manuscript to boost its impact and make it suitable for publication.

Aim 3 accomplishments:

Based on the data from the prior 2 aims, we have designed a prospective study to test a novel MRI acquisition protocol that will facilitate our quantitative prostate cancer signature in 50 men prior to prostate needle biopsy. The schema of the study is shown below:

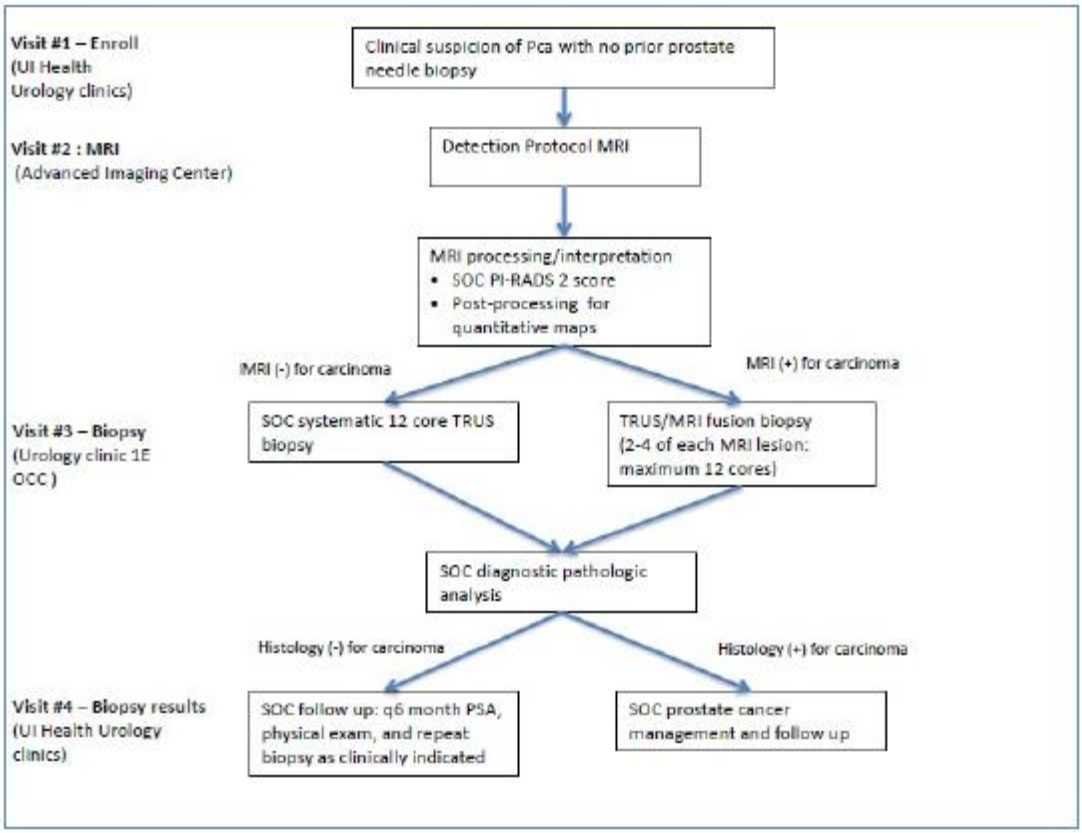

Figure 11: Prospective cohort study schema

To date, regulatory approval has been gained. Volunteer MRI of the new protocol at the UIC 3T Center for MRI research have been conducted, and the protocol optimized. The clinical research coordinators have begun enrollment to the study starting 10/8/2019. The goal is to accrue 50 patients that require prostate needle biopsy. We will be able to prospectively validate our quantitative models, and also determine the clinical utility of those maps and the utility of extending the DWI spectrum to higher b values. The goal in this final reporting period is to completely accrue this cohort, and use the results to design a multi-center clinical trial.

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

Dr. Abern, the PI, proposed a training plan as part of this grant. He has completed several of the objectives.

- Dr. Abern was awarded the UIC School of Public Health Clinical Research Methods certificate.
- Dr. Abern completed HPA 472 (Clinical Research Methods 1), HPA 473 (Clinical Research Methods 2), HPA 479 (Evaluation of Clinical Interventions), with a grade of A. He completed BHIS 509 (Informatics for the Clinical Investigator) with a grade of B. He completed HPA 464 (Sociocultural Dimensions of Health Disparities) with a grade of A.
- Dr. Gann has been teaching his course, Molecular Epidemiology and Biomarker Development (EPID512) , in a one-on-one fashion during weekly meetings
- He has attended the biweekly Works-in-Progress Seminar that includes participation from the Mentor's lab (Dr. Gann) as well as several other senior faculty members (including Dr. Gail Prins, Dr. Larissa Nonn) focusing on PCa.
- He attended the 2016 DOD IMPACT conference, which allowed for discussions and collaboration with several other DOD funded investigators.
- He attended the Prostate Cancer Foundation annual conference October 27-29, 2016.
- He was accepted for the EAU/AUA Exchange program for 2018 during which preliminary results from the studies supported by this grant were presented at 3 European academic medical centers.

- **Dr. Abern was selected as the study section chair of the Prevention, Treatment, and Epidemiology (PTE) session of the DOD PCRP for November 2019.**
- **Dr. Abern was promoted to Associate Professor of Urology with indefinite tenure by the University of Illinois College of Medicine in part due to the work resulting from this grant.**
- **Dr. Abern was named head of the University of Ilinois at Chicago Cancer Center Genitourinary Cancer Integrated Practice Unit.**

Dr. Meltem Uyanik successfully completed her PhD in Bioengineering at The University of Illinois at Chicago and defended her thesis which was primarily based on the work from this grant.

How were the results disseminated to communities of interest?

For this reporting period two abstracts were presented. One abstract was presented at the International Society of Magnetic Resonance Medicine (ISMRM) Congress in Montreal Quebec in May 2019 by Dr. Uyanik. Another abstract was presented at the American Urological Association Congress in Chicago, Illinois in May 2019 by Dr. Vigneswaran.

What do you plan to do during the next reporting period to accomplish the goals?

The following were proposed in the 2018 annual report. Please find the status of the proposed goals to date, followed by a detailed explanation:

- 2018 goal: Publication of the co-registration/ radical prostatectomy model development manuscript (revise based on feedback from the Journal of Magnetic Resonance Imaging review process) – status: IN PROCESS
    - **Plan for completion**: The data analyzing the quantitative imaging models using sectors of the prostate have been added to the rejected manuscript in order to strengthen it. This will allow for comparison of pixel-wise registration to anatomic sector based registration to demonstrate the non-inferiority of the simpler sector method. The manuscript will be submitted for re-consideration during this final reporting period.
- 2018 goal: Publication of the biopsy cohort validation dataset (target is Journal of Magnetic Resonance Imaging) – status: IN PROCESS (SUBMITTED)
    - **Plan for completion:** This manuscript has been submitted to the Journal of Magnetic Resonance Imaging. This was delayed to add the

FROC and clinical standard PI-RADS methodology to improve the impact.

- 2018 goal: Accrual of prospective biopsy cohort. – IN PROCESS
    - **Plan for completion:** Regulatory approval was gained for the prospective biopsy cohort by the University of Illinois at Chicago IRB and UIC Cancer Center Protocol Review Committee. The scan protocol was implemented on the research MRI scanner. Patient accrual has begun. The clinical research coordinators will screen patient care clinics biweekly to enroll the targeted 50 men in an estimated 6 months. This data will be analysed for publication, and the target journal is to be determined pending results.

IMPACT:

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

The preliminary data from this project has been used to develop a prostate cancer detection specific MRI protocol thereby improving the accuracy of prostate biopsy. We feel that if our findings and approaches are validated externally in a multi-center clinical trial they have the potential to change clinical practice in the diagnosis of prostate cancer while reducing biopsy related morbidity.

What was the impact on other disciplines?

The development of a whole mount prostatectomy grossing protocol will be beneficial for the Research Histology and Tissue Imaging Core at UIC.

The development of a methodology of digital prostate cancer annotation and mapping will provide a valuable resource for future projects.

The development of a new imaging co-registration method will be of interest to the scientific imaging community at large

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:

Changes in approach and reasons for change

Due in part to staff turnover during the prior reporting period, completion of the data for publications and accrual of the prospective patient cohort have been delayed. Therefore, we submitted for a 1 year no cost extension to complete these tasks. Dr. Meltem Uyanik has transitioned to a new role as a full time post-doctoral fellow (50% supported by this grant) to ensure timely completion.

Actual or anticipated problems or delays and actions or plans to resolve them

No additional delays or problems are anticipated.

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals.

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

PRODUCTS:

Publications, conference papers, and presentations

Journal publications.

Nothing to report.

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers, and presentations.

1. Michael Abern MD, Brandon Caldwell BS, Virgilia Macias MD, Winnie Mar MD, Karen Xie MD, Andre Kajdacsy-Balla PhD/MD, Richard Magin PhD, Joe Zhou PhD, Peter Gann ScD/MD; *High Grade Prostate Cancer Characterization Using Fractional Order Calculus Diffusion Weighted MRI*; 2016; Abstract and poster for PCRP IMPaCT Conference; Presented 10/2016; Yes (federally supported)
2. Meltem Uyanik MS, Michael Abern MD, Brandon Caldwell BS, Muge Karaman PhD, Winnie Mar MD, Joe Zhou PhD, Richard L. Magin PhD; *Prostate Cancer Classification Using a Stretched Exponential Model of Diffusion*; 2016; Abstract and poster for ISMRM Workshop; Presented 9/2016; No
3. Brandon Caldwell BS , Meltem Uyanik MS, Michael Abern MD, Virgilia Macias MD, Cristian Luciano PhD, Richard L. Magin PhD; *A methodology for Registering Prostate Histology and Radiologic Imaging to Validate*

Prostate Cancer Detection in 2D; 2017; Abstract for ISMRM Congress; Presented 6/2018; No

4. Brandon Caldwell BS , Meltem Uyanik MS, Virgilia Macias MD, Winnie Mar MD, Richard L. Magin PhD, Michael Abern MD; *Fractional order calculus model of magnetic resonance diffusion weighted imaging for high grade prostate cancer detection*; 2017; Abstract for AUA Congress; Presented 5/2018; No
5. Meltem Uyanik MS, Michael Abern MD, Brandon Caldwell BS, Muge Karaman PhD, Winnie Mar MD, Virgilia Macias MD, Xiaohong Joe Zhou PhD, Richard L. Magin PhD; *Prostate Cancer Classification Using Stretched Exponential Model Parameters of Diffusion Signal Decay*; 2017; Abstract for ISMRM Congress; Presented 6/2018; No
6. Rolf Reiter MD, Meltem Uyanik MS, Hari Vigneswaran MD, Brandon Caldwell MS, Winnie Mar MD, Karen Xie DO, Bernd Hamm MD, Dieter Klatt PhD, Richard L. Magin PhD, Michael Abern MD. DIAGNOSTIC PERFORMANCE OF PROSTATE CANCER ASSESSMENT USING THE STRETCHED-EXPONENTIAL MODEL DIFFUSION-WEIGHTED MR IMAGING; 2018; Abstract for SUO Conference; Submitted; No
7. Hari Vigneswaran MD, Meltem Uyanik PhD, Rolf Reiter MD, Virgilia Macias MD, Winnie Mar MD, Karen Xie DO, Richard L. Magin PhD, Michael Abern MD. Improved Accuracy of MRI/US Fusion Prostate Biopsy Using a Stretched Exponential Diffusion Parameter; 2019; Abstract for AUA Congress; Presented 5/2019; No
8. Meltem Uyanik PhD, Rolf Rieter MD, Michael Abern MD , Winnie Mar MD, Virgilia Macias MD, Hari T. Vigneswaran MD ,and Richard L. Magin PhD. Prostate Cancer Classification by Using Mono Exponential, Stretched Exponential and Kurtosis Model Parameters of Diffusion Signal Decay; 2019; Abstract for ISMRM Congress; Presented 5/2019; No

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Michael Abern, MD
Project Role: PI
Researcher Identifier: mabern
Nearest person month worked: 12 x 0.4 = 4.8
Contribution to Project: Dr. Abern has acted as the project lead

Name: Peter Gann, MD
Project Role: Co-mentor
Researcher Identifier: pgann
Nearest person month worked: 12 x 0.1 = 1.2
Contribution to Project: Dr. Gann has contributed as mentor for the histologic analytic aspects of the project, and has conducted bi-weekly meetings with the PI

Name: Andre Balla, MD/PhD
Project Role: Pathology consultant
Researcher Identifier: aballa
Nearest person month worked: 12 x 0.05 = 0.6
Contribution to Project: Dr. Balla has consulted regarding the tissue preparation of the prostatectomy specimens for Aim 2

Name: Virgilia Macias, MD
Project Role: Pathology consultant
Researcher Identifier: vmacias
Nearest person month worked: 12 x 0.05 = 0.6
Contribution to Project: Dr. Macias has assisted in screening the retrospective pathology samples for adequacy for analysis

Name: Xiaohong “Joe” Zhou, PhD
Project Role: Co-mentor
Researcher Identifier: xjzhou
Nearest person month worked: 12 x 0.05 = 0.6
Contribution to Project: Dr. Zhou has contributed by holding bi-weekly meetings with the PI and consulting regarding the MR processing for aim 1, and for the scan protocol for aim 2

Name: Brandon Caldwell
Project Role: Study Coordinator
Nearest person month worked: 9 x 0.50 = 4.5

Contribution to Project: Mr. Caldwell has contributed to the study via IRB management and submissions, Cancer Center compliance and research design.

Name: Richard Magin, PhD
Project Role: Mathematical image analysis team
Researcher Identifier: rmagin
Nearest person month worked: 12 x 0.05 = 0.6
Contribution to Project: Dr. Magin has contributed as the designer of the FROC model and supervisor of the MR image processing

Name: Meltem Uyanik, MS
Project Role: Mathematical image analysis team
Nearest person month worked: 3 x 0.5 = 1.5
Contribution to Project: Ms. Uyanik has performed the MR image processing

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?

Nothing to report.

SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

Nothing to report.

QUAD CHARTS:

Nothing to report.

APPENDICES:

Please see the attached submitted meeting abstracts.