

Conemaugh Valley Memorial Medical Center
Department of Pathology and Laboratory Medicine
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**Utility of Telepathology in Diagnosis of Pigmented
Lesions by Conventional (H+E) and
Immunohistochemical (IHC) Techniques**

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Study Summary

- This study will evaluate the practicability of remote diagnosis of pigmented lesions.
- Evaluation of cases involving dysplastic nevi (DN) and early melanomas will be performed on both conventional slides (H&E) and immunohistochemical (IHC)-stained slides.
- Conducted in the Conemaugh Valley Memorial Medical Center (MMC) Pathology Department, the server site, and the University of Pittsburgh Medical Center (UPMC) Dermatopathology Unit, the remote site.

Study Summary

- Involve two phases.
- Slides will be retrieved from UPMC Dermatopathology files.
- None of the cases will have been previously evaluated by the evaluators.

Pre- Study

- Case selection, diagnosis confirmation, record de-identification, and time required compiling and shipping cases will be conducted by a non-evaluating pathologist at the remote site (UPMC).
- 80 cases from UPMC will be randomly selected from early melanomas and dysplastic nevi diagnoses.
- 20 cases each dysplastic nevi type (mild, moderate and severe cytologic atypia) and 20 early melanoma cases will be selected.

Pre-Study

- Ten cases of each case type must have 3-5 IHC stains available (including S100, HMB45, Melan-A/Mart-1, Tyrosinase and Ki67) while the other half must have 3-5 additional levels (H&E).
- A de-identified summary of each case history minimally necessary for diagnosis will be provided during scoring.
- The scoring sheet data (including values for scoring and classify dysplastic nevi (DN) and melanomas (MM) will be completed by the non-evaluating pathologist and used as the standard.
- Each type of case will be divided into two sets (SET G = glass and SET D = digital).

H&E slides evaluation form

H&E LEVEL EVALUATION

Study Participant ID:		Date:
Case #:		
Number of Slides Viewed:		
Stain:		
Evaluation Start Time:		
CHARACTERISTIC	DESCRIPTION	POWER REQUIRED FOR EVALUATION
Lateral Circumscription	<input type="checkbox"/> PRESENT	
	<input type="checkbox"/> ABSENT	
Symmetry	<input type="checkbox"/> PRESENT	
	<input type="checkbox"/> ABSENT	
Junctional Extension	<input type="checkbox"/> UNILATERAL	
	<input type="checkbox"/> BILATERAL	
	<input type="checkbox"/> ABSENT	
Rete Ridge Distortion	<input type="checkbox"/> OCCASIONAL	
	<input type="checkbox"/> USUAL	
	<input type="checkbox"/> ALWAYS	
Fibrosis	<input type="checkbox"/> EOSINOPHILIC	
	<input type="checkbox"/> LAMELLAR	
	<input type="checkbox"/> BOTH	
Melanocyte Distribution	<input type="checkbox"/> ABSENT	
	<input type="checkbox"/> NEST	
	<input type="checkbox"/> SINGLE-CELLS	
	<input type="checkbox"/> BOTH	

Upward Migration	<input type="checkbox"/> CENTER	
	<input type="checkbox"/> LATERAL	
	<input type="checkbox"/> BOTH	
	<input type="checkbox"/> ABSENT	
Suprapapillary Plates	<input type="checkbox"/> SPARED	
	<input type="checkbox"/> INVOLVED	
Nuclear Size	<input type="checkbox"/> SMALL	
	<input type="checkbox"/> MEDIUM	
	<input type="checkbox"/> LARGE	
Nucleoli	<input type="checkbox"/> SMALL	
	<input type="checkbox"/> MEDIUM	
	<input type="checkbox"/> LARGE	
Chromatin	<input type="checkbox"/> UNIFORM	
	<input type="checkbox"/> CONDENSED	
	<input type="checkbox"/> COARSE	
Mitoses/ Dermal	ABSOLUTE NUMBER: _____	
Evaluation End Time:		
Slide Features:		
Case Evaluation/Diagnosis/Comments:		

IHC evaluation form

APPENDIX B: SCORING CRITERIA

IHC EVALUATION FORM

Study Participant ID:	Date:
Case #:	
Number of Slides Viewed:	
Stain(s):	
Evaluation Start Time:	

CHARACTERISTIC	DESCRIPTION	POWER REQUIRED FOR EVALUATION	STAIN THAT ILLUSTRATES FEATURE BEST
Lateral Circumscription	<input type="checkbox"/> PRESENT <input type="checkbox"/> ABSENT		
Symmetry	<input type="checkbox"/> PRESENT <input type="checkbox"/> ABSENT		
Junctional Extension	<input type="checkbox"/> UNILATERAL <input type="checkbox"/> BILATERAL <input type="checkbox"/> ABSENT		
Rete Ridge Distortion	<input type="checkbox"/> OCCASIONAL <input type="checkbox"/> USUAL <input type="checkbox"/> ALWAYS		
Diminished Staining w/ Dermal Descent	<input type="checkbox"/> NO DERMAL STAINING <input type="checkbox"/> STAINED TO MID DERMIS <input type="checkbox"/> STAINED THROUGHOUT		
Melanocyte Distribution	<input type="checkbox"/> NEST <input type="checkbox"/> SINGLE-CELLS <input type="checkbox"/> BOTH		
Upward Migration	<input type="checkbox"/> CENTER <input type="checkbox"/> LATERAL <input type="checkbox"/> BOTH <input type="checkbox"/> ABSENT		
Suprapapillary Plates	<input type="checkbox"/> SPARED <input type="checkbox"/> INVOLVED		
KI67 Positivity	ABSOLUTE NUMBER: _____		

Evaluation End Time:
Slide Features:
Case Evaluation/Diagnosis/Comments:

Phase I

- Two pathologists at the server site and two pathologists and a fellow at the remote site will evaluate cases.
- The pathologists at both sites will evaluate 2 H&E levels from each SET G case using a light microscope and 2 H&E levels from SET D case through provided software.
- Time to transmit, open and view/evaluate H&E cases will be documented in a survey completed by all reviewing pathologists at both sites.
- Magnification requirements for the evaluation of DN and MM features and it's characteristics will be indicated for each of them, (as in the Pre-Study).
- Participant feedback will be recorded to evaluate software and remote consultation.

Phase II

- Following a 1 month washout period, the pathologists at both sites will evaluate 3-5 H&E levels from SET G1 (half of the SET G representing 5 of each case type) and 3-5 IHC slides from SET G2 (the remaining half of the SET G cases) using a light microscope.
- Same division and procedure will apply to cases from SET D.
- Time to transmit, open and view/evaluate H&E cases will be documented in a survey completed by all reviewing pathologists at both sites.
- Magnification requirements for the evaluation of DN and MM features and it's characteristics will be indicated for each of them, (as in Phase I).
- Participant feedback will be recorded to evaluate software and remote consultation.

Post-Study

- Summaries will be generated and distributed (via publications/presentations) to the medical community, with evaluation of:
 - 1-Remote telepathology costs
 - 2-Time and logistics
 - 3-Diagnostic concordance (agreement) of real time static telepathology and light microscope in regards to stringent criteria for DN and MM diagnosis
 - 4-DN scoring criteria
 - 5- Impressions and data from remote IHC consultation
 - 6- Impressions from software utility.

APPENDIX A: STUDY SCHEMA

PRE-STUDY

SELECT 80 RANDOM DN and MELANOMA CASES and ARBITRARILY (but evenly) DIVIDE INTO SETS G and D (non-evaluating pathologist):

10 Mild Atypia	10 Moderate Atypia	10 Severe Atypia	10 Early Melanoma
10 Mild Atypia	10 Moderate Atypia	10 Severe Atypia	10 Early Melanoma

Prepare Patient History

(Organize patient information into discrete sets.)

Confirm Case Diagnosis

(For later comparison of microscope vs. digital concordance)

Prepare Patient History

(Organize patient information into discrete sets.)

PHASE 1

MMC (SERVER SITE)

EVALUATE 2 (H&E) LEVELS:

SET D TELE-EVALUATION	SET G LIGHT MICROSCOPE
10 Mild Atypia	10 Mild Atypia
10 Moderate Atypia	10 Moderate Atypia
10 Severe Atypia	10 Severe Atypia
10 Early Melanoma	10 Early Melanoma

SHIP SLIDES

UPMC

EVALUATE 2 (H&E) LEVELS:

SET G LIGHT MICROSCOPE	SET D TELE-EVALUATION
10 Mild Atypia	10 Mild Atypia
10 Moderate Atypia	10 Moderate Atypia
10 Severe Atypia	10 Severe Atypia
10 Early Melanoma	10 Early Melanoma

WASH-OUT PERIOD

PHASE 2

TELE-EVALUATION		LIGHT MICROSCOPE		LIGHT MICROSCOPE		TELE-EVALUATION	
EVALUATE 3-5 (H&E) LEVELS:	EVALUATE 3-5 IHC SLIDES:	EVALUATE 3-5 (H&E) LEVELS:	EVALUATE 3-5 IHC SLIDES:	EVALUATE 3-5 (H&E) LEVELS:	EVALUATE 3-5 IHC SLIDES:	EVALUATE 3-5 (H&E) LEVELS:	EVALUATE 3-5 IHC SLIDES:
SET D1	SET D2	SET G1	SET G2	SET G1	SET G2	SET D1	SET D2
5 Mild Atypia	5 Mild Atypia	5 Mild Atypia	5 Mild Atypia	5 Mild Atypia	5 Mild Atypia	5 Mild Atypia	5 Mild Atypia
5 Moderate Atypia	5 Moderate Atypia	5 Moderate Atypia	5 Moderate Atypia	5 Moderate Atypia	5 Moderate Atypia	5 Moderate Atypia	5 Moderate Atypia
5 Severe Atypia	5 Severe Atypia	5 Severe Atypia	5 Severe Atypia	5 Severe Atypia	5 Severe Atypia	5 Severe Atypia	5 Severe Atypia
5 Early Melanoma	5 Early Melanoma	5 Early Melanoma	5 Early Melanoma	5 Early Melanoma	5 Early Melanoma	5 Early Melanoma	5 Early Melanoma

Complete Surveys

(Determine strength of DN criteria, usability of software and ease of real time static telepathology evaluation by comparing diagnostic concordance and evaluator opinions.)

POST STUDY

FINAL ANALYSIS: Cost, Time to Diagnose (digital vs. microscope), Time to Prepare Digital Cases, Time for Consultation (remote v. direct w/ shipping), Diagnostic Accuracy, Software Usability, IHC (digital v. microscope), Concordance (digital v. microscope), Dysplastic Nevus Assessment Metrics

Study Benefits

- Provides an opportunity to familiarize with telepathology and implement it early in my future pathology career.
- Telepathology methods in my residency training program would allow other members in my program to start utilizing telepathology early in our careers.
- After completion of this study I hope to start with my own research program in telepathology, and develop educational modules for residents in MMC and UPMC.

Study Benefits

- Knowledge and experience gained through this study will provide an opportunity for my pathology residency program to be more competitive and more attractive to future residents and staff.
- CAP conducts numerous proficiency testing programs. It is our believe the results of this study could provide CAP with validation results to eventually implement digital PT processes via telepathology (static, dynamic, or virtual slide-based).

Thank You!