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Performance evaluation study of a novel digital microscopy system for the quantitative analysis of bone marrow aspirates

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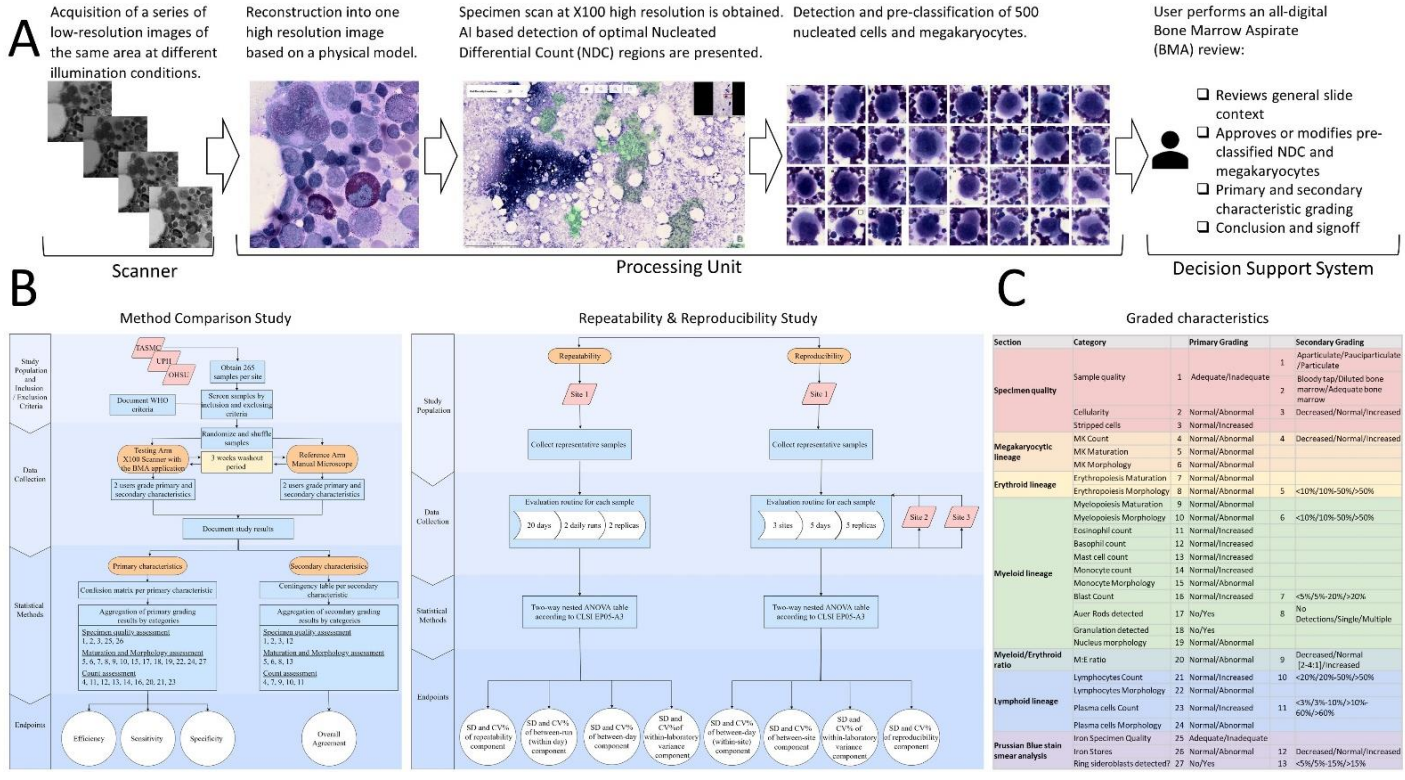
Introduction: Current methods for the analysis and reporting of bone marrow aspirate (BMA) specimens are based on analog microscopy. The lack of uniformity between experts in the field, originating from a subjective manual review, can lead to inconsistencies in disease diagnosis and classification, and thereby affect treatment and clinical outcomes. Considering the complexity of the manual BMA analysis, even more so in routine laboratory settings with competitive turnaround times, a digital transformation can sustain the desired standardization, increased sensitivity and efficiency in routine workflow. **Methods:** This multisite study is taking place at: Hospital of the University of Pennsylvania (HUP), Oregon Health and Science University (OHSU), and Tel Aviv Sourasky Medical Center (TASMC). The collected BMA 265 samples hold a distribution of 55.61% males, with 2.02%, 9.46%, 16.39%, 54.73% and 17.40% of ages 13-21, 22-39, 40-55, 56-75 and >75 respectively. All samples were diagnosed by WHO criteria, and include AML, ALL, MPN, MDS, PCN, lymphoid neoplasms, aplastic anemia, ITP and normal morphology marrow and hemodiluted samples. BMA analysis is performed with a manual microscope as the reference arm and in Scopio Labs X100 Full Field BMA application (A) as the test arm (B). The report presents 27 primary and 13 secondary characteristics for the morphological assessment of BMA (C). These include evaluation of specimen quality, evaluation of count, maturation and morphology of trilineage hematopoietic elements, as well as lymphocytes and plasma cells. Repeatability and reproducibility will also be tested (B).



Section	Category		Primary Grading		Secondary Grading
Specimen quality	Sample quality	1	Adequate/Inadequate	1	Aparticulate/Pauciparticulate /Particulate
				2	Bloody tap/Diluted bone marrow/Adequate bone marrow
	Cellularity	2	Normal/Abnormal	3	Decreased/Normal/Increased
	Stripped cells	3	Normal/Increased		
Megakaryocytic lineage	MK Count	4	Normal/Abnormal	4	Decreased/Normal/Increased
	MK Maturation	5	Normal/Abnormal		
	MK Morphology	6	Normal/Abnormal		
Erythroid lineage	Erythropoiesis Maturation	7	Normal/Abnormal		
	Erythropoiesis Morphology	8	Normal/Abnormal	5	<10%/10%-50%/>50%
Myeloid lineage	Myelopoiesis Maturation	9	Normal/Abnormal		
	Myelopoiesis Morphology	10	Normal/Abnormal	6	<10%/10%-50%/>50%
	Eosinophil count	11	Normal/Increased		
	Basophil count	12	Normal/Increased		
	Mast cell count	13	Normal/Increased		
	Monocyte count	14	Normal/Increased		
	Monocyte Morphology	15	Normal/Abnormal		
	Blast Count	16	Normal/Increased	7	<5%/5%-20%/>20%
	Auer Rods detected	17	No/Yes	8	No Detections/Single/Multiple
	Granulation detected	18	No/Yes		
	Nucleus morphology	19	Normal/Abnormal		
Myeloid/Erythroid ratio	M:E ratio	20	Normal/Abnormal	9	Decreased/Normal [2-4:1]/Increased
Lymphoid lineage	Lymphocytes Count	21	Normal/Increased	10	<20%/20%-50%/>50%
	Lymphocytes Morphology	22	Normal/Abnormal		
	Plasma cells Count	23	Normal/Increased	11	<3%/3%-10%/>10%-60%/>60%
	Plasma cells Morphology	24	Normal/Abnormal		
Prussian Blue stain smear analysis	Iron Specimen Quality	25	Adequate/Inadequate		
	Iron Stores	26	Normal/Abnormal	12	Decreased/Normal/Increased
	Ring sideroblasts detected?	27	No/Yes	13	<5%/5%-15%/>15%

Expected outcome: The introduction of Scopio's full field morphological evaluation of BMA smears, promotes an accurate diagnosis haematological disorders including haematological malignancies, and enables a remote evaluation of BMA smears. By reviewing the entire BMA smear, and by counting a very large number of cells, this novel approach provides a new and highly accurate tool for early detection of pathological conditions, including residual disease following therapy.