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Commentary

Evaluation of whole slide imaging for routine surgical pathology: Looking through a broader scope

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SUMMARY

In recent years whole slide imaging (WSI) has reached the point of technical quality and acceptance that its use is increasingly contemplated for clinical diagnostic purposes. For instance, recently Redondo *et al*., suggested equivalence on a technical imaging level.[1] Multiple studies have now been published that have demonstrated very good to excellent concordance between WSI and light microscopy for pathological diagnosis.[2,3] As emphasized in a recent comprehensive review,[2] however, many such concordance studies, have been of relatively narrow scope, such as including a relatively limited number of cases, focusing on a single or few subspecialties, and/or selecting cases based on some criterion such as consultation cases or neoplastic diagnoses. Additionally, workflow and operational issues that affect implementation of WSI for routine diagnostic use are usually minimally or not mentioned in studies, and there is an increasing realization that such factors may pose significant challenges to wide scale adoption of WSI for clinical use.[4-7] A recent study by Campbell *et al*.[8] at the University of Nebraska took a broader approach and addressed some of the issues outlined above.

The study by Campbell *et al*., examined the use of WSI for routine diagnosis in a general surgical pathology setting. Two pathologists each reviewed 212 consecutive (after exclusions), previously diagnosed surgical pathology cases by WSI (scanned at 20×). A third pathologist determined concordance between WSI diagnosis and original light microscopic diagnosis, and a jury of additional pathologists reviewed all cases in which discordance was deemed clinically significant. The study included a wide range of cases, with 12 organ systems represented and approximately 25% neoplastic and 75% nonneoplastic diagnoses. The overall concordance rate between WSI and light microscopy diagnosis was 96.5%, comparing well with previous WSI–light microscopy correlation studies. Five cases were determined to be discordant. The authors concluded that none of the discordant cases were a result of WSI image fidelity but resulted from differences in diagnostic criteria or pathologist error.

This study is of particular interest because it reports findings and experience that go beyond just diagnostic concordance and addresses the types of limitations frequently seen in WSI validation literature. First, the study includes cases from a broad range of subspecialties, and cases were taken consecutively rather than selected, such as for consultation material or neoplastic diagnoses. These two aspects of study design enhance its applicability to routine surgical pathology practice. Second, the authors specify two situations in which scanning at 20× may provide less than optimal resolution for diagnostic purposes, although neither was associated with a discrepancy in the study methodology. One was the differentiation of atypical small acinar proliferation

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(ASAP) from adenocarcinoma on prostate biopsy, and the other was resolving the presence of *Helicobacter pylori* on immunohistochemical staining of gastric biopsies. Such cases are common in routine practice, and the time needed to scan such cases at 40× would not be a trivial consideration.

Open questions remain generally as to what constitutes appropriate validation of WSI for use in primary diagnosis in pathology. The Food and Drug Administration (FDA) has recently indicated that it considers WSI systems class 3 medical devices that require premarket approval process for use in primary surgical pathology diagnosis;[9] however, Centers for Medicare and Medicaid Services (CMS) (and not the FDA) has direct regulatory oversight of pathology laboratories through CLIA (Clinical Laboratory Improvement Amendments) and may have greater influence ultimately on laboratories' use (and validation) of WSI for diagnostic purposes. The College of American Pathologists (CAP) has convened a work group that is in the final stages of developing guidance for laboratories in the validation of WSI for clinical use in pathology.[10] As described above, the well-designed study by Campbell *et al.*, addresses limitations often seen in WSI validation studies. One major question in validation studies, though, is whether it is more appropriate to compare WSI diagnosis to a consensus or expert diagnosis for each case or to determine intraobserver discrepancies, that is, would the same pathologist make the same diagnosis by WSI and light microscopy on a given slide? Many argue[2,3,10] that the latter approach is the more important aspect to address as it is not subject to differences in diagnostic expertise, criteria, or experience among pathologists. While the study by Campbell *et al.*, demonstrated excellent concordance between WSI and light microscopy, there was some interobserver variation, including lack of consensus by jury panel in a few of the cases. The authors concluded that "…discrepancy of diagnostic impressions *between* pathologists (italics added) in both WSI and [light microscopy] suggests that cognitive and interpretive differences play a more significant role than the diagnostic modality".

One of the most important conclusions from the study is that production and operational issues were found to be the greatest obstacle to use of WSI in general surgical pathology. There is a growing realization that use and acceptance of WSI for diagnostic purposes require that workflow and operational challenges are addressed.[4-7] In addition, personnel time to scan slides, quality control of the process, and re-scanning of slides all represent significant hidden costs. Two key findings reported in the study by Campbell *et al.* related to operational challenges of implementing WSI in pathology practice – scanning times and re-scan rates. The authors reported that the time to prepare and scan a slide ranged from 5 to 15 minutes with an average of 10 minutes, not counting additional time for slide cleaning or field selection. Slides were scanned in batches of 80-120 and required 12-24 hours of scanning per batch. The slide scanning failure rate was 13.1%, and 6.6% of slides required two or more scans. Three slides failed for four or more attempts and were excluded. The authors reported their impression that problems with the scanning process were much greater than anticipated.

As the use of WSI in surgical pathology is gaining greater acceptance, laboratories must look at how best to implement it in their environments. By "looking through a broad scope" at validation design and operational details, the study by Campbell *et al.*, provides interesting data and insight on the evaluation of WSI for routine diagnosis in pathology.

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