HIGHER QUALITY, LARGER CORES REDUCE DIAGNOSTIC AMBIGUITY IN PROSTATE BIOPSY

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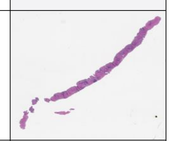
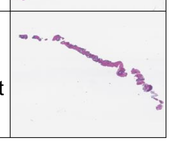
Introduction

The adequacy of prostate core needle biopsies in the era of precision medicine has come into question. There is no standardized method for removing cores from a biopsy needle, leading to poor quality specimens. Fragmentation and tortuosity result in diagnostic ambiguity in some instances. Up to 40% of baseline prostate biopsies are upgraded upon surgical pathology due in large part to insufficient tissue quantity and inferior quality resulting from existing biopsy needle designs and inadequate specimen handling techniques.

Materials and Methods

We conducted a study (NCT05470127) using a proprietary 18ga prostate biopsy needle (Fig. 1) that has been demonstrated to obtain significantly more tissue volume per core by weight than currently used standard of care (SoC) needles in both transrectal ultrasound guided biopsy (TRUS) and MRFUS Trans-Perineal Biopsy (TPUS). Since retrieval of biopsy cores can also impact tissue quality (fragmentation, tortuosity, etc.), tissue transfer from the novel needle utilized a previously described “touch & go” method (Fig. 2) that eliminates tissue handling and preserves core integrity. 28 men undergoing TRUS systematic biopsy were randomized and enrolled in this prospective study. Whole slide images (WSI) from the novel system (Test) and retrieval method were compared with the SoC needle and SoC retrieval (Control). A digital pathology artificial intelligence software was used to measure tissue area for each specimen. Tissue tortuosity (i.e. high quality vs low quality) was measured using a three-tier algorithm which is being incorporated into an open-source software developed under an NIH grant to assess the quality of WSI. Clinical diagnostic parameters were tabulated from standard pathology reports. Biopsies were read by a single blinded pathologist.

	Z. Tort.	XY Tort.	Guidance	Example
Tier I High Quality	Low	Low	Slide passes QC	
Tier 2 Medium High Quality	Low	High	Review CNB pipeline	
Tier 3 Medium Low Quality	High	Low	Recut	
Tier 4 Low Quality	High	High	Review CNB pipeline + recut	

A four tier grading system was employed using the following criteria:

Tier 1:
No skips. 2 or fewer major bends. 6 or fewer minor bends

Tier 2:
No skips. More than 2 major bends OR more than 6 minor bends

Tier 3:
1 or more skips. 2 or fewer major bends. 6 or fewer minor bends

Tier 4:
1 or more skips. More than 2 major bends OR more than 6 minor bends

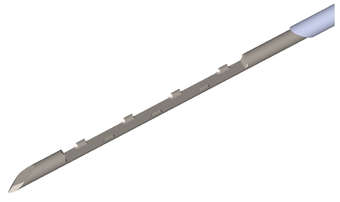


Fig. 1 Novel 18ga coaxially centered needle

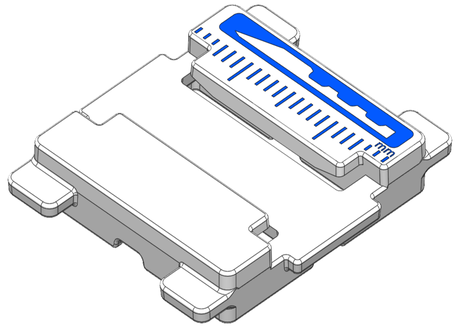


Fig. 2 “Touch and Go” tissue transfer

Results

Compared with Controls (n=168), Test samples (n=167) provide

1. 15% more tissue area than Controls, p<.00001(two-tailed t)
2. Increased high-quality samples, 37% vs 49%, p<.01 (Z test)
3. Reduced low-quality samples, 26% vs 11%, p<.05 (Z test)
4. Reduced Atypical Small Acinar Proliferation (ASAP), 8% vs. 1% p<.05 (Z test)

Conclusions

Specimen retrieval, formalin fixation and transport are crucial steps in the process of diagnostic pathology. Unfortunately, these steps are not standardized and can result in the fragmentation and tortuosity of core biopsies. Tortuosity can lead to artifacts in histology, difficulty in measuring tumor length, and may even result in “missing” tissue on the slide. Fragmentation can make it difficult to determine the number of cores as well as the location of the tumor’s relative position in the prostate. In this head-to-head comparator study the novel needle and specimen retrieval method obtained biopsy specimens that were significantly larger and less tortuous than SoC samples. Reduced tortuosity improves workflow in histology and facilitates interpretation by pathologists. These results suggest that increased size and quality of tissue cores may decrease diagnostic ambiguity as measured by ASAP diagnosis. These promising results are being investigated in a large multicenter study.

Disclosure Statement

The authors of this poster do not have any relevant relationships to disclose.