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**PROSTATE BIOPSY CORE LENGTH CONSISTENCY IN A NEEDLE DESIGNED FOR
TRANSPERINEAL BIOPSY AND FOCAL THERAPY**

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Objective: Precise localization of cancerous regions for focal therapy requires a biopsy needle that samples tissue along the entire length of the gland as one specimen. Sagittal prostate length varies depending on oblique location of site to be biopsied and can be as long as 60 mm. When performing transperineal prostate mapping biopsy (TPMB) the standard needle samples only 17-20 mm of prostate, necessitating up to 3 separate biopsies for longer prostate lengths. In addition, these needles take on average 60% of the possible core length. We developed a 15 gauge (G) biopsy needle to overcome these shortcomings and tested it in a porcine kidney model.

Methods: Five designs were selected for testing: 18-G Bard Monopty™, 15-G trocar-tip needle with 12° and 20° vet-point cannula and 12° and 20° Menghini-point cannulas. The 15 G needle was designed to take a variable specimen sample between 20 mm and 60 mm, while the Bard needle specimen bed was fixed at 17 mm. In addition, the core bed of the 15-G needle was designed with ridges to hold the specimen in place. The differences between these needle designs (Bard 18 G vs. 15 G variable needle) were: needle diameter 1.0 mm vs 1.5 mm, notch depth 0.56 mm vs 0.76 mm, and core volume (at 20 mm) 0.00055 cm³ vs 0.0011 cm³. A 6 cm biopsy collected with 15 G needle has a core volume equal to 0.0033 cm³, six times that of the Bard needle. Parameters tested were spring rate, spring preload and cannula tip geometry. Excised porcine kidney was chosen as a model due to its similarity in elastic modulus to human prostate (2.3 psi vs 2.9 psi). Samples were taken from the renal cortex and renal medulla, avoiding the calyces. Samples were bench tested on a spring-loaded platform that allowed for variable core length settings between 20 and 60 cm and various spring configurations. In addition different spring rate (lbs/in) and preload were tested.

Results: 130 test firings were run with the 5 needles (table). The aggregate firings for the 3 different shot lengths (60 tests) comparing the vet-tip to the Meghini-tip cannulas demonstrated 89.4 vs 84.1% length fill (p=0.02, 2-tailed T-test). (Figure)

Conclusions: Specimen length testing demonstrated that the 15-G trocar needle with 12° vet-tip cannula utilizing a spring rate of 2 lbs/in and a preload of 2 lbs had the highest performance with an average of 92% core fill. When performing focal therapy for prostate cancer precise location of the tumor along the core from base to apex is achievable.

Biopsy Needle	Spring rate (lbs/in)	Preload (lbs)	Shot Size (mm)	Number Tests	Average Length (mm)	Average % Fill	Average % all lengths
Bard Monopty	4.8	2.6	17	10	15.9	94	N/A
15-G Vet-tip 12 ⁰	2	2.5	21.2	10	18.7	88	
15-G Vet-tip 12 ⁰	2	2.5	44.3	10	42.6	96	
15-G Vet-tip 12 ⁰	2	2.5	60	10	54.6	90	92
15-G Vet-tip 12 ⁰	3.2	3	23.5	10	19.4	82	
15-G Vet-tip 12 ⁰	3.2	3	41.2	10	37.4	91	
15-G Vet-tip 12 ⁰	3.2	3	60	10	57.1	95	89
15-G Menghini-tip 20 ⁰	2	2.5	18.3	10	15.1	82	
15-G Menghini-tip 20 ⁰	2	2.5	40	10	35.5	86	
15-G Menghini-tip 20 ⁰	2	2.5	56.3	10	46.1	87	86
15-G Menghini-tip 20 ⁰	3.2	3	20.3	10	18.9	93	
15-G Menghini-tip 20 ⁰	3.2	3	40.8	10	32.7	80	
15-G Menghini-tip 20 ⁰	3.2	3	60	10	47.3	79	84



Figure