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DEFLECTION ANALYSIS OF DIFFERENT NEEDLE DESIGNS FOR TRANSPERINEAL PROSTATE BIOPSY AND FOCAL THERAPY

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Objective: Precise localization of cancerous regions within the prostate gland require a biopsy needle that sample tissue without deflection. This requirement is critical if the biopsy information is used for planning targeted focal therapy (TFT) and MRI guided biopsies. The biopsy needles currently used were designed for a transrectal biopsy and are known to experience significant deflection from the point of entry into the gland to the needle tip during specimen procurement. If accurate 3-dimensional representation of the biopsy site is going to be utilized for planning TFT, then the entry and resting position of the biopsy needle should be the same.

Methods: Five designs were selected for testing: 18-gauge (G) Bard, 15-G lancet-tip needle with 12° vet-point cannula, and trocar-tip needle with 12°, 15° and 20° vet-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 20 mm. 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 cm^3 vs 0.0011 cm^3. A 6 cm biopsy collected with 15 G needle has a core volume equal to 0.0033 cm^3, six times that of the Bard needle. The needles were bench tested on a spring-loaded platform and fired into gelatin matrix with modulus of elasticity similar to human prostate (gelatin at 4.0% by mass to water resulting in an average elastic modulus of 3.6 psi). High-speed images of entry and deployed positions of the needle were captured and post-processed to determine deflection angle and distance. A total of 71 tests were performed with the variable needles fired at 20 mm, 40 mm and 60 mm core sample lengths. Mean comparisons of the Bard and variable core-length designs were analyzed by paired T-test (2-tailed).

The results of the test firings for the five needle designs are shown in the table. Figure 1 demonstrates significant deflection while Figure 2 has minimal deflection.

Table: Deflection Test Results

Needle	Cannula	No. of Tests	Mean (mm)	Mean (°)	Difference (p value)
Bard	Bard	8	0.9	1.9	Reference
Lancet Point	Vet Point, 12°	9	0.9	0.9	0.671/0.064
Trocar	Vet Point, 12°	18	0.3	0.3	0.033/0.002
Trocar	Vet Point, 15°	17	0.2	0.1	0.013/0.002
Trocar	Vet Point, 20°	18	0.2	0.2	0.000/0.000

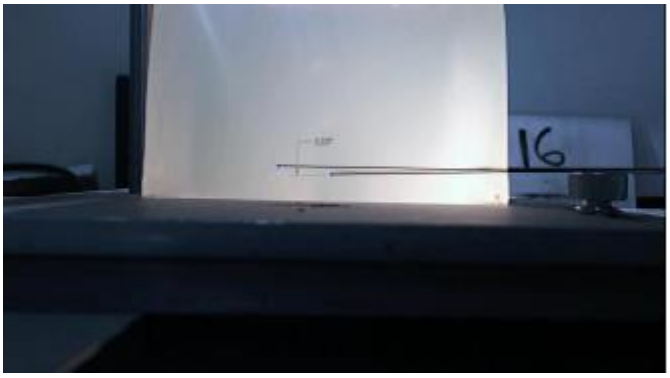

Figure 1

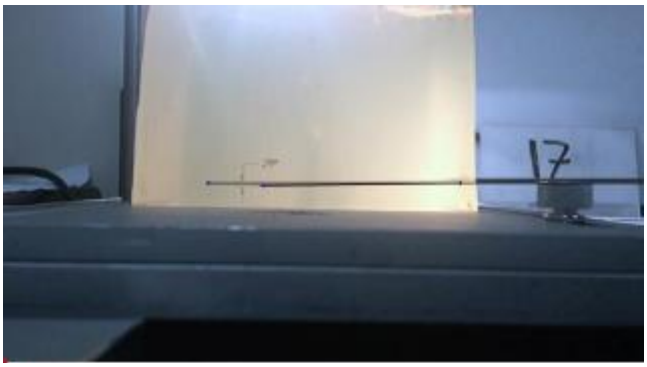

Figure 2

Conclusion: No measurable deflection occurred with the trocar-tip needles with vet-point cannulas at 20 mm and 40 mm core lengths. Despite increasing the size of the biopsy device from 18 G (Bard) to 15 G no statistical reduction of deflection was noted for the larger needle as each possesses a lancet-point tip. However, the Trocar-point needles paired with a 12-20^0 vet-point cannula demonstrated a significant reduction in deflection. A variable length 15-gauge core needle with a trocar-tip combined with a 20^0 vet point cannula provides a straight (no deflection) biopsy when taking a full length core from apex to base. This approach has the potential to improve lesion localization when planning focal therapy.