GEOMETRIC SYSTEMATIC PROSTATE BIOPSY
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ABSTRACT
Objective: The distribution of cores in the common sextant prostate biopsy schema is defined pictorially and lacks a 3-dimensional (3D) geometric definition. The objective of the study was to determine the influence of the geometric distribution of the cores on the probability of detection of prostate cancer (PCa), independent of other factors in a well-controlled simulation study. Methods: The detection probability of significant (>0.5cm³) and insignificant (<0.2cm³) tumors were quantified based on a novel three-dimensional (3D) capsule model of the biopsy sample and anatomical constraints of the needle access. The pelvic anatomy of the Visible Human Project (National Library of Medicine) was used. The geometric distribution of the cores was optimized to maximize the probability of detecting significant cancer. Biopsy schemata were calculated for various prostate sizes (20 to 100cm³), number of biopsy cores (6 to 40 cores) and biopsy core lengths (14 to 40mm) for transrectal and transperineal biopsies. Results: The probability of detection of significant cancer can be improved by geometric optimization. With the current extended sextant biopsy, up to 20% of tumors may be missed at biopsy in a 20 cm³ prostate due to the schema. Higher number and longer biopsy cores are required to sample with an equal detection probability in larger prostates. The detection probability of both significant and insignificant tumors are directly correlated to the number of biopsy cores. But a higher number of cores increases predominantly the detection of insignificant tumors. Conclusion: The study demonstrates mathematically that the geometric biopsy schema plays an important clinical role. It also demonstrates that increasing the number of systematic biopsy cores is not necessarily helpful.

Keywords: Prostate cancer, systematic biopsy, biopsy optimization, probability of detection, significant, insignificant tumor.

Introduction
In 2016, an estimated 180,890 new PCa will be diagnosed in the US alone [1]. While studies have shown that significant overtreatment exists [2], PCa will still cause 26,120 mortalities [1]. These underscore the need for more reliable PCa diagnosis and patient stratification [3, 4].

The classic prostate biopsy method is guided by transrectal ultrasound (TRUS). Yet, standard gray-scale ultrasound is unreliable in differentiating PCa from normal gland tissues; therefore needle guidance is cancer blind [3] and systematic sextant biopsy schemata are used to uniformly sample the gland instead of actually targeting the tumors.

To address this problem targeted methods have been developed [5], such as the Fusion biopsy. This uses pre-acquired Magnetic Resonance Imaging (MRI) to depict cancer suspicious regions (CSR) within the prostate, registered (fused) to the TRUS which is used to guide the procedure in real time [6]. Numerous clinical studies have already shown higher PCa detection than traditional untargeted methods [7, 8].
However, the fusion is not normally performed for primary biopsy patients, but in high-risk and active surveillance patients [9], typically for selected repeat biopsies. With over 1 million prostate biopsies performed annually in the United States and Europe [10], the MRI time required for fusion will simply be overwhelming. As such, the large majority of prostate biopsies remain systematic, and will likely continue so in the foreseeable future. With current systematic biopsy methods the sensitivity and specificity of the biopsy test are low [11]. Therefore, if anything could be done to improve systematic biopsies, then it probably should.

Margins of leeway exist in several aspects, for example in regard to the manual execution errors. Biopsy targeting errors are significant even among experienced urologists, in average 9.0 mm, and with significant variation among urologists [12]. For this, new biopsy devices are emerging to assist the physicians [13, 14]. Another source of error is the deflected path of needle insertion that is typical with biopsy needles (commonly have a bevel point) [15].

In this study we focus on the actual biopsy plan, to see if the systematic biopsy schemata could be improved for a higher cancer detection yield. Currently, the most formal definition of the sextant biopsy plan is a grid of points on a 2D coronal view of the prostate [16]. As shown in Figure 1ab, this definition is vague from a geometric standpoint. The sextant divisions and the location of the points within the sextant regions is subjective. In 3D the uncertainty widens, leaving much room for subjective interpretation as shown in Figure 1c.

Computer simulated biopsy studies to determine optimal biopsy plans have been performed based 3D images or whole mount prostates [17-22]. One notable approach was to produce a continuous cancer distribution probability function from histopathology series of prostatectomy specimens. Based on this probability model, the detection rates of different biopsy plans were measured by calculating the number of tumors detected by the simulated biopsy cores and an optimal protocol was determined. The biopsy schemata were defined precisely with coordinate locations and core directions. Among them, results were somewhat different possibly due to different statistical maps of tumor occurrences [17, 18].

Another optimization approach used 2D analyses to determine the probability of significant cancer detection for transperineal biopsy using equally spaced parallel needles [23, 24]. This probability is calculated based on the area sampled by the cores per unit grid on the transversal 2D cross section. The study also showed that false-negative probability could be evaluated.

Our approach builds upon the 2D probability calculation model of [24] by expanding it to 3D and transrectal TRUS-guided biopsy. Specifically, their circle area model was extruded to a
cylindrical volume with semi-spherical ends, which we defined as a capsule model. Biopsy optimizations were implemented based on this model to maximize the probability of significant cancer detection. Preliminary results of this work were reported at the Engineering and Urology Society conference [25].

Material and Methods
To develop the tumor detection probability model, we first assumed that tumors are spherical in shape. This model is the worst-case scenario since the sphere has the lowest surface to volume ratio making it hardest to detect per unit volume [23]. That is, for an identical volume the furthest distance between any two points is smallest on the sphere (Figure 2a), requiring the highest density of biopsy cores to be detected. This also assures that the probability of detection is independent of the biopsy needle orientation [23].

Next, we assumed that the probability of tumor occurrence is uniform throughout the prostate volume. This also represents a worst-case scenario, since only sampling certain regions of the prostate would require less biopsy cores.

Finally, we defined the clinically significant tumor size ≥0.5cm³ (radius 4.924mm) and insignificant tumor size ≤0.2cm³ (radius 3.628mm) [26].

In the capsule model, a tumor was considered sampled if the biopsy core intersected the tumor. The tumor intersects the core if the distance from its center to the axis of the needle is smaller than its radius (d ≤ R), which makes its center fall within the capsule (Figure 2b). From this, a single core’s sampling volume for a spherical tumor of radius R can be quantified as the volume of the capsule with the radius of the sphere (R) and the length of the core (L). We neglect the thickness of the biopsy core since they are very slim and have a small influence to the sampling volume.

![Image](image.png)

Figure 2: (a) Equal volume (0.5 cm3) tumor (blue) and a sphere model (yellow). (b) Capsule model definition and detected (red) and undetected (yellow) tumors

The sampling volume of one core for a tumor of radius R within the prostate is,

\[ V_{s,1}^R = V_p \cap V_c^R \]  
(Eq. 1)

For \( n \) cores, intersection of sampling volumes should be considered. Therefore,

\[ V_{s,n}^R = V_p \cap ( V_{c,1}^R \cup V_{c,2}^R \cdots \cup V_{c,n}^R ) \]  
(Eq. 2)

The probability of detection for multiple cores is:

\[ P_n = \frac{V_{s,n}^R}{V_p} = \frac{V_p \cap ( V_{c,1}^R \cup V_{c,2}^R \cdots \cup V_{c,n}^R )}{V_p} \]  
(Eq. 3)
The significant and insignificant probabilities of detection are:

\[ sP = p^{4.924} \quad \text{and} \quad iP = p^{3.628} \quad \text{(Eq. 4)} \]

The probability of a false-negative result is then \( (100 - sP) \).

The \( P \) is a function of the position and orientation of the biopsy cores. Core orientation may be parameterized by the biopsy needle entry point location and the core center position. Therefore, a biopsy plan for \( n \) cores may be defined as a state matrix \( \Pi(n \times 6) \) as:

\[
\Pi = \begin{bmatrix}
e_{11} & e_{12} & e_{13} & c_{11} & c_{12} & c_{13} \\
& \vdots & \vdots & \vdots & \vdots & \vdots \\
e_{n1} & e_{n2} & e_{n3} & c_{n1} & c_{n2} & c_{n3}
\end{bmatrix}
\quad \text{(Eq. 5)}
\]

where, \( E_{ij}(e_{i1}, e_{i2}, e_{i3}) \) and \( C_{ij}(c_{i1}, c_{i2}, c_{i3}) \) are the needle entry point respectively the core center positions of core \( i \).

Then, the \( P(\Pi) \) for any given biopsy plan \( \Pi \) is defined as:

\[
p^R = \frac{N(\Omega)}{N(\Gamma)}
\quad \text{(Eq. 6)}
\]

where, \( N(\Omega) \) and \( N(\Gamma) \) is the number of voxels within the prostate and voxels of the capsule that overlap with the prostate respectively.

Core positions and entry points are subject to the following anatomical constraints:

1. Core positions should avoid the urethra (green in Figure 3) to prevent hematuria and urinary retention. This is achieved by manually setting a bounding box of the urethra.
2. The entry point constraints of each biopsy path reduces the rank of the state matrix, (Eq.5) enabling the parameterization of a simplified state matrix \( \Psi \) as follows.
   - Transrectal biopsy: The needle is passed alongside the TRUS probe, which is pivoted about the anal sphincter. The entry points are constrained to the probe circumference (Figure 3a, yellow circle) and are determined by the probe rotation \( \theta_i \). Accordingly, the state matrix \( \Psi(n \times 4) \) becomes:
     \[
     \Psi = \begin{bmatrix}
\theta_1 & c_{11} & c_{12} & c_{13} \\
& \vdots & \vdots & \vdots \\
\theta_n & c_{n1} & c_{n2} & c_{n3}
\end{bmatrix}
\quad \text{(Eq. 7)}
\]
   - Template transperineal biopsy: The needle directions are parallel to each other. The entry points are constrained to the discrete grid hole locations \( X_{ij}(x_{i1}, x_{i2}) \) of the template (Figure 3b). The core positions are restricted along the direction of the needle at depth \( d_i \). Accordingly, the state matrix \( \Psi(n \times 3) \) becomes:
     \[
     \Psi = \begin{bmatrix}
x_{11} & x_{12} & d_1 \\
& \vdots & \vdots \\
x_{n1} & x_{n2} & d_n
\end{bmatrix}
\quad \text{(Eq. 8)}
\]
   - Angled transperineal biopsy: The entry points are constrained to the perineum and may be parameterized to points \( X_{ij}(x_{i1}, x_{i2}) \) in a constrained region on the perineum plane (Figure 3c, yellow circle). Accordingly, the state matrix \( \Psi(n \times 5) \) becomes:
     \[
     \Psi = \begin{bmatrix}
x_{11} & x_{12} & c_{11} & c_{12} & c_{13} \\
& \vdots & \vdots & \vdots & \vdots \\
x_{n1} & x_{n2} & c_{n1} & c_{n2} & c_{n3}
\end{bmatrix}
\quad \text{(Eq. 9)}
\]
The optimization problem is to find the biopsy plan $\Psi$ that maximizes the probability of detection of significant tumors.

$$\Psi_{\text{optimal}} = \arg\max (P(\Psi)) \quad \text{(Eq. 10)}$$

Intuitively, the algorithm searches for a solution $\Psi$ that maximizes the sampling of the prostate by capsules by minimizing overlapping between capsules and avoiding extending out of the prostate. The maximization may be implemented with iterative methods such as a gradient descent or pattern search optimization method [27]. Here we show the implementation of the pattern search, which is a heuristic algorithm [27].

The optimization starts with an initial biopsy plan $\Psi^0$ that follows the sextant plan (Figure 4).

At each step $k$, an exploratory move $\Delta^k$ is applied to each element $\psi_{ij}^{k-1}$ of the current state $\Psi^{k-1}$, where

$$\Delta^k = [\delta_1 \delta_2 \ldots \delta_m], \text{where } \delta_j > 0 \text{ for } j = 1 \ldots m \quad \text{(Eq. 11)}$$

An exploratory move $\delta_j$ is applied to each state matrix element while maintaining the other elements:

$$\psi_{ij}^{\text{expl}} = \begin{cases} \psi_{qr}^{k-1} \pm \delta_j, & q = i \text{ and } r = j \\ \psi_{qr}^{k-1}, & \text{otherwise} \end{cases}, \text{for } i = 1 \ldots n \text{ and } j = 1 \ldots m \quad \text{(Eq. 12)}$$

The probability of detection $P(\psi_{ij}^{\text{expl}})$ is calculated for all $2nm$ exploratory moves. If any of these provides a positive gain relative to the previous state, the move $\Psi^{\text{expl}}$ that provided the maximum gain is retained to update the state matrix of the next iteration:
\[
\Psi^k = \begin{cases} 
\Psi^{expl} \mid \text{Max}(sP(\Psi_i^{expl})) & \text{if } sP(\Psi_i^{expl}) - sP(\Psi^{k-1}) > 0 \\
\Psi^{k-1} & \text{otherwise}
\end{cases}
\] (Eq. 13)

If there is no positive gain, the exploratory move \(\Delta^k\) is reduced:

\[\Delta^k = \lambda \Delta^{k-1}\] with reduction parameter \(0 < \lambda < 1\) (Eq. 14)

When this reaches a small cutoff value, it is then reset to the initial value \(\Delta^0\) and the above steps are repeated to check convergence to a better optimal solution, until there is no improvement.

In our case \(\Delta^0 = \{5.0 \text{ mm}, (c_{ij}, x_{ij}, d_i), 10^\circ, (\theta_i)\}, \lambda = 0.5\) and cutoff value of 0.1mm was chosen.

For biopsy simulation we reconstructed the male pelvic anatomy of the Visible Human Project (VHP) [28]. Manual segmentations of the prostate, urethra, rectum, and pubic bone with the perineal wall were done by an experienced urologist using the Amira Visualization platform (FEI Company, Burlington, MA). In the actual case, only the prostate segmentation is required, which is commonly done with semi-automatic segmentation algorithms [29].

The biopsy plan optimization was implemented with custom developed C++ modules for the Amira using an Intel Core I7 CPU. The size of the prostate, 21.4 cm\(^3\), was also measured using the Amira. To simulate the effect of prostate volumes on detection probability, the VHP’s prostate was uniformly scaled about the center of its bounding box to 5 sizes: 20 cm\(^3\) to 100 cm\(^3\) in 20 cm\(^3\) increment.

First, to determine convergence of the optimization method, the 12-core transrectal biopsy optimization using the typical 18 mm core length was performed for the 20 cm\(^3\) prostate. The initial condition was based on the classic systematic biopsy (Figure 1), where the position and orientation of the biopsy plane were manually selected to simulate the variation in biopsy planning. A total of 100 optimization trials with different initial conditions were performed.

Then, we investigated the relationship between the number of cores and the size of the prostate while maintaining the standard 18 mm core length. For this, the \(sP\) were evaluated for 18 biopsy plans of 6 to 40 cores (increment of 2, added symmetrically on the left and right lobes) for each of the 5 prostate sizes.

Next, we investigated the relationship between the core lengths and the size of the prostate for the 12-core biopsy. For this, the \(sP\) were evaluated for 14 core lengths between 14 mm and 40 mm (2 mm increment) for each of the 5 prostate sizes.

In all cases, the optimal biopsy plan \(\Psi\) was determined by maximizing the significant tumor probability of detection \(\text{Max} \left( sP(\Psi) \right)\) for all three biopsy paths. The probability of inadvertently detecting insignificant tumors with the optimal plan \(sP(\Psi)\) was then evaluated, as well as the ratios of the \(sP\) to \(iP\).
Results

The convergence of this nontrivial optimization problem was verified with multiple experiments. Figure 5a shows an example of randomly selected 10 optimization trial results on a 20 cm³ prostate. The dotted lines denote the $^s\text{P}$ of 10 different trials, and the red solid line denotes the average of all trials. The optimized plan has a higher $^s\text{P}$ than the systematic biopsy plan. The average $^s\text{P}$ of the initial systematic and the optimized biopsy plan are 61.1% and 81.8% respectively, with standard deviation of 3.6% and 0.7% respectively. Although the coordinates of the optimized cores were different, the $^s\text{P}$ converged with small variance. The average computation time of each iteration and total computation was 0.29s(s) and 34.7(s).

Figure 5. (a) Iterative improvement in the probability of detection during the optimization process (20 cm³ prostate size) and (b) a typical example of systematic (left) and optimized (right) biopsy plans shown with capsules (top) and cores (bottom)

An example of a transrectal biopsy plan optimization that starts from the systematic biopsy plan is presented in Figure 5b (12-cores, 18 mm core length, 40 cm³ prostate). The $^s\text{P}$ increased from 42.5% to 54.4% after optimization.

The results correlating the dependency of the $^s\text{P}$, $^i\text{P}$, and their ratio on the number of the biopsy cores for a constant 18mm biopsy core length are represented in Figure 6abc.
The $P_s$ increased with more cores and thus, larger prostates required more cores to achieve a certain $P_s$ level (Figure 6a). The $P_s$ and $P_i$ are similar for different biopsy paths, with slightly higher $P_s$ values in the order of transrectal, angled transperineal, and template transperineal biopsy. Concurrently, when more cores were used the $P_i$ also increased (Figure 6b). The $P_s$ to $P_i$ ratio decreased with the number of cores for all 3 biopsy paths (Figure 6c). For a 12-core transrectal biopsy (18 mm) on a 40 cm$^3$ prostate, the $P_s$ and $P_i$ were 54.1% and 28.0% respectively, and the $P_s$ to $P_i$ ratio was 1.9.

For prostate sizes larger than 60 cm$^3$, 99% $P_s$ couldn’t be reached even with 40 cores. Before the $P_s$ curves plateaued, these were approximately linear, so that the number of cores required to achieve the same $P_s$ level is proportional to the prostate volume.

Figure 6def depicts the dependency of the probability of cancer detection on the length of the biopsy cores for the common 12-core extended biopsy. The $P_s$ increases with the length of the core (Figure 6d). This saturates at a length that is close to the depth of the prostate in the direction of biopsy (90% @ 25mm for a 20 cm$^3$ prostate). The increase in the core length is also followed by increased $P_i$ (Figure 6e). Before saturation, $P_s$ and $P_i$ were approximately linear to the core length. The ratio of $P_s$ to $P_i$ decreased with the core length for all 3 biopsy paths (Figure 6f).
Discussion

A novel capsule model is defined to evaluate the probability of prostate cancer detection that a biopsy schema may yield. This also enables to optimize the schema to maximize the detection of PCa. Currently, biopsy plans are not typically individualized for patients. It was suggested that biopsy core numbers should be adjusted [30, 31] based on the prostate volume, yet it remains unclear if and how it should be done [30, 32]. Our results confirm that more and longer cores are needed for larger prostates up to a certain saturation limit, being in agreement with previous studies [18, 30].

The capsule model also enables to estimate the probability of a false-negative result [24] together with the risk of over diagnosis, that is the risk of detecting insignificant cancer (<0.2 cm³). We believe that this study is first to quantitatively report the probability of detecting insignificant cancer.

Results shows that the risk of detecting insignificant cancer ($iP$) is a tradeoff of sampling more biopsy cores for higher $nP$. Moreover, $iP$ increases faster than $nP$ with the number of cores, especially for smaller prostates. Thus, careful consideration for over detection should be given when increasing the number of cores. This agrees with clinical findings in this respect [33]. The ultimate goal would be to determine the biopsy plan that would detect all significant tumors utilizing the lowest number of biopsy cores, and minimize $nP$ [34].

Besides its theoretical role, the method could be used practically within limitations. The method demands the use of 3D imaging for the 3D reconstruction of the prostate, and defining anatomical constraints for needle access. For this, the method applies directly to modern biopsy devices such as mechanically [13] and magnetically tracked [35] TRUS probes, image fusion systems [6], TRUS robots [14, 36], and MR Safe robots [37]. These devices will also substantially improve the biopsy execution accuracy. The method does not apply to standard 2D TRUS-guided biopsy.

The proposed method is a purely geometrical analysis with several assumptions. First, tumors are considered to be spherical shape rather than irregular, curvilinear, or fusiform [23]. Second, our model assumes that tumors are evenly distributed within the gland while the majority of tumors occur in the peripheral zone [38]. Finally, scaling the prostate model is a limitation as the prostate shape would change as it enlarges. Some of these limitations are worst case scenarios with respect to cancer detection rates. As such, the method establishes the lowest expectation level on potential improvements that could be made to the “blind” systematic biopsy.

For example, current clinical values on the probability of significant cancer detection with conventional 12-core freehand TRUS biopsy averages 43% [12] in a small prostate. Could this be improved without the fusion? Our study demonstrates that if a urologist (device) would perfectly execute the 12-core sextant schema the rate would be no less than 61% (20 cm³ prostate); with the optimized schema this could be at least 82%.

As such, we demonstrate mathematically that substantial leeway exists to improve sextant biopsy methods, and define the expectation levels of PCa detection for several parameters. There is no question that targeted biopsy methods such as the fusion are superior, having the potential to achieve 100% detection with 1-core. However, systematic methods are here to stay for primary biopsies, and these could be markedly improved.
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