Technology Advances for Prostate Biopsy and Needle Therapies

In 2012 an estimated 241,740 new prostate cancers (PCas) will be diagnosed in the United States alone.\(^1\) A large number of them represent indolent tumors unlikely to limit the life span of the patient due to competing comorbidities. A recent study has shown that it is necessary to treat 48 men to prevent 1 death from PCa, suggesting that significant overtreatment exists.\(^2\) Still, many PCas are aggressive, causing an estimated 28,170 mortalities this year.\(^1\) Therefore, a comprehensive approach is urgently needed to increase the diagnostic accuracy of PCa.\(^3\)

Freehand transrectal ultrasound (TRUS) guided prostate biopsy is the most frequently performed biopsy means for diagnosing PCa with more than 1.2 million procedures performed annually in the United States. However, standard grayscale ultrasound provides minimal PCa specific information, being unreliable in differentiating normal prostate gland from cancer tissue. Accordingly, biopsies do not specifically target cancer suspicious regions of the prostate (CSR). Instead, cancer detection and characterization rely on nontargeted, systematic, sextant biopsy schemata. However, executing the schema with freehand TRUS is a challenging procedure that is beyond typical hand-eye coordination and quality control is subjective. As such, samples are often clustered, miss regions and do not follow the biopsy schema.\(^4,5\) Over diagnosis of clinically insignificant cancer and under diagnosis of potentially lethal cancer exist in the population at risk.\(^3\)

Novel genomic, proteomic and image biomarkers are currently being investigated for the assessment of PCa aggressiveness. However, their gold standard validation relies heavily on pathology results from prostatectomy specimens, which provide single-step stage information in the progression of the disease. Instead, biopsy specimens could provide information with time for longitudinal progression studies but they are typically unreliable due to localization errors.

In short, the common TRUS guided prostate biopsy represents a critical barrier in the field. Clinically, it creates diagnosis and localization uncertainty, which are directly related to the current overtreatment of PCa. Its low repeatability increases the complexity of active surveillance and focal therapies. In research it makes it difficult to monitor the response of biomarkers and chemopreventive agents, and correlate novel PCa imaging modalities with gold standard pathology results from biopsy specimens.

Several novel biopsy devices are currently being investigated or are under development. They apply to biopsy and also to needle ablative therapies, such as brachytherapy and cryoablation. The most common needle paths are transrectal and transperineal. Approaches are gland distributed sextant schemata or targeted biopsies. The most common image guidance modality remains TRUS but registration (image fusion) to pre-acquired PCa images, such as multiparametric magnetic resonance imaging (MRI) and even direct MRI guided systems, are emerging. Biopsy guiding devices are based on 3-dimensional (3D) TRUS, probe position tracking and robotic technologies. Robots can handle the probe and/or a needle guide. Few systems automate needle insertion.

Using 3D TRUS alone for guiding the biopsy is difficult because the unsegmented prostate is difficult to observe and 3D images are not in real time. At the same time, automatic real-time prostate segmentation from TRUS is an active area of research. Several probe tracking (continuously measuring) methods have been developed for 3D as well as 2-dimensional (2D) ultrasound. With special navigation software they show the location of the probe in the image space as it is used freehand by the urologist, so that he or she can apply this feedback to guide the treatment. Several commercial systems are already available with probe tracking accessories, such as the LOGIQ® E9 system.

A TRUS tracking system developed purposely for prostate biopsy is the Artemis (Eigen®). The Artemis system tracks a 3D TRUS with a 4 df encoded passive arm. An important advantage of this mechanical approach is that the arm can be locked in place to support the probe while performing the biopsy.

Another commercial system is TargetScan®. This motorizes the insertion motion of the TRUS probe for ultrasound scanning. Because TargetScan was designed for prostate brachytherapy, it is readily applicable to transperineal biopsy but difficult to use for common transrectal biopsy.

Perhaps one of the most active areas of new technology clinical trials in urology is MRI fused TRUS...
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