UL / White paper

A practical guide to transperineal ultrasound-guided MRI fusion biopsy of the prostate

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Introduction

Prostate cancer (PCa) was the second most commonly diagnosed cancer in men worldwide in 2022[1]. PCa is a heterogeneous disease, with slow-growing, non-aggressive types (insignificant cancers) and faster-growing, aggressive types (significant cancers). In patients with suspected PCa, urologists are required to establish a correct diagnosis, as only significant cancers require active treatment, while insignificant cancers can be followed up with proactive surveillance.

Prostate biopsy has been the gold standard to diagnose PCa in men with suspicion of cancer. In the past, it was common practice to take several randomly placed samples, also known as systematic biopsies, during a prostate biopsy procedure without prior localization by imaging. This method is relatively blind and involves a risk of missing significant cancers.

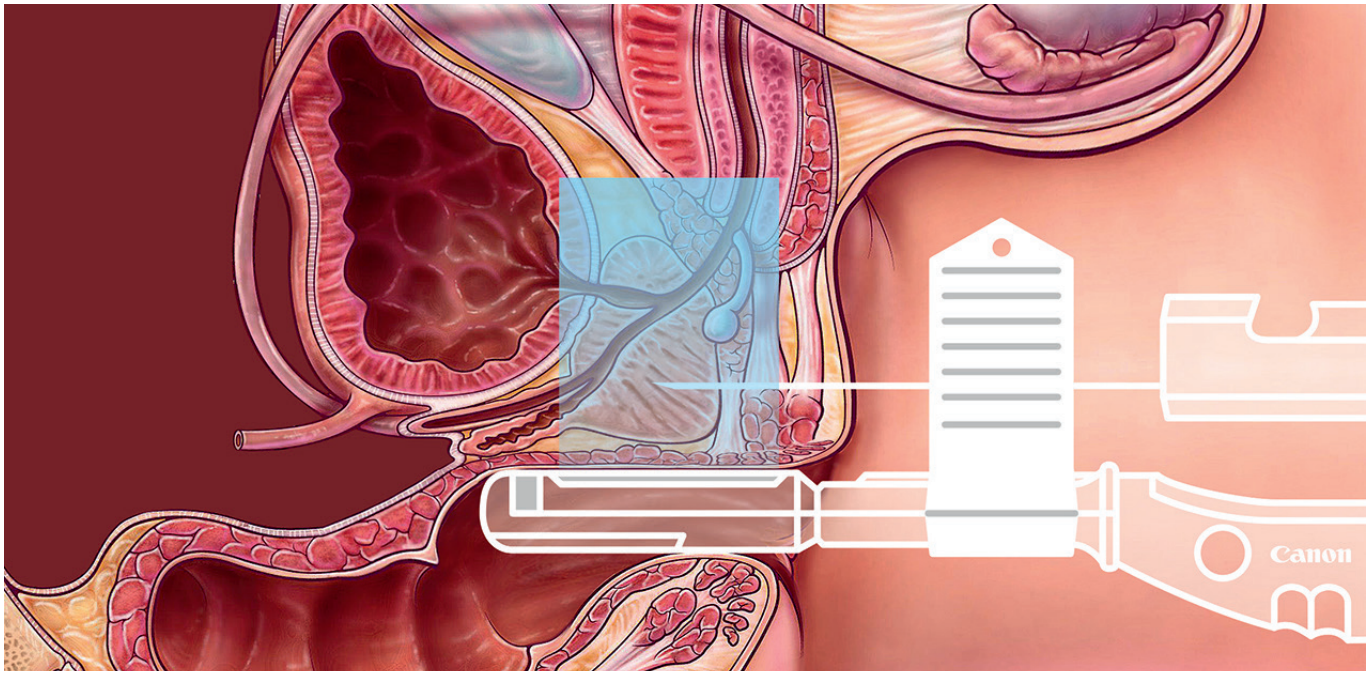

Figure 1 Schematic representation of a targeted prostate biopsy following a transperineal approach.

The introduction of prostate MRI has changed the work-up of PCa as it has a very high negative predictive value (NPV) for excluding significant prostate cancers[2]. Essentially, this means that if the MRI does not show a significant lesion, a prostate biopsy is not required. However, if a suspicious area is found, a biopsy is obligatory. With high-quality software fusion, a targeted biopsy in the suspicious area can be performed very accurately.

The most established method of performing prostate biopsies is via the transrectal way, also known as transrectal biopsy under transrectal ultrasound (TRUS) guidance. In recent years, however, mainly due to its significantly reduced incidence of post-procedural sepsis, prostate biopsy via the transperineal approach has regained attention. In the latest update of the PCa guidelines of the European Association of Urology (EAU)[2] transperineal biopsies are preferred over transrectal biopsies to reduce post-procedural sepsis and performing MRI-targeted biopsy of the prostate is strongly recommended (Fig. 1).

As one of the first centers having extensively evaluated the newly developed integrated automatic real-time MRI-fusion biopsy application package on the Aplio i800 ultrasound scanner from Canon, we started to switch mainly to this technique for all our patients who are sent to our department for fusion biopsy since the beginning of 2021. Having developed a routine protocol for Transperineal MRI-targeted fusion prostate biopsies (TPFBx) in our department, we have now completed over 700 cases on Aplio i800. In 2023 we published the results of our first 203 patients[4].

Preparation of TPFBx procedure

After the MRI scan, which is acquired and reported according to the Prostate Imaging Reporting and Data System (PI-RADS) Version 2.1[3], patients are selected for TPFBx when at least one lesion with PI-RADS ≥3 is present. The MRI data are being loaded either from an external medium (USB, CD/DVD, etc.) or from the hospital picture archiving and communication system (PACS) into the Aplio i800 internal hard drive. The preloaded MRI dataset is first reviewed on the ultrasound system and suspected regions of interest (ROIs) previously described by the radiologist in the prostate MRI protocol are now marked for easier recognition during the biopsy procedure (Fig. 2). Before starting the procedure, informed consent is obtained from the patient. We consider it very important to provide thorough explanation to patients for their comfort and reduce their anxiety. The patient is placed in lithotomy position with the perineum at the lower end of the examination table. The Aplio i800 is placed on the right side of the patient and the electromagnetic transmitter is placed under the patient's right leg (Fig. 3). The required materials for the local anesthesia (LA) and biopsy are prepared in advance by the assisting nurse on a side table (Fig. 4). The ultrasound probe is prepared and covered with a plastic sheath with ultrasound gel inside the sheath. A thin layer of gel between the sheath and the probe is important to achieve optimal image quality during the procedure. The reusable sterilizable needle guide is attached to the probe (Fig.5). The patient's scrotum is lifted and fixed upwards. The perineal skin is thoroughly disinfected with a betadine solution (10%). LA is applied in two steps. First, we inject 10 ml Linisol (Lidocaine hydrochloride) 1% in a wide area in the perineal skin. Next, a deep prostatic nerve block is performed under ultrasound guidance, through the biopsy needle guide attached to the probe, with 20 mL Linisol 1% and 10 mL Ropivacaine (2.5 mg/ml), divided into two injections, one on each side of the neurovascular bundle. The injection sites are approximately 1 cm above the horizontal line of the upper anal border and 1 cm lateral to the midline (Fig. 6). For anterior lesions, part of the anesthetic solution is administered specifically in the region of interest against the prostatic capsule. After LA, the MRI-TRUS fusion procedure is performed.

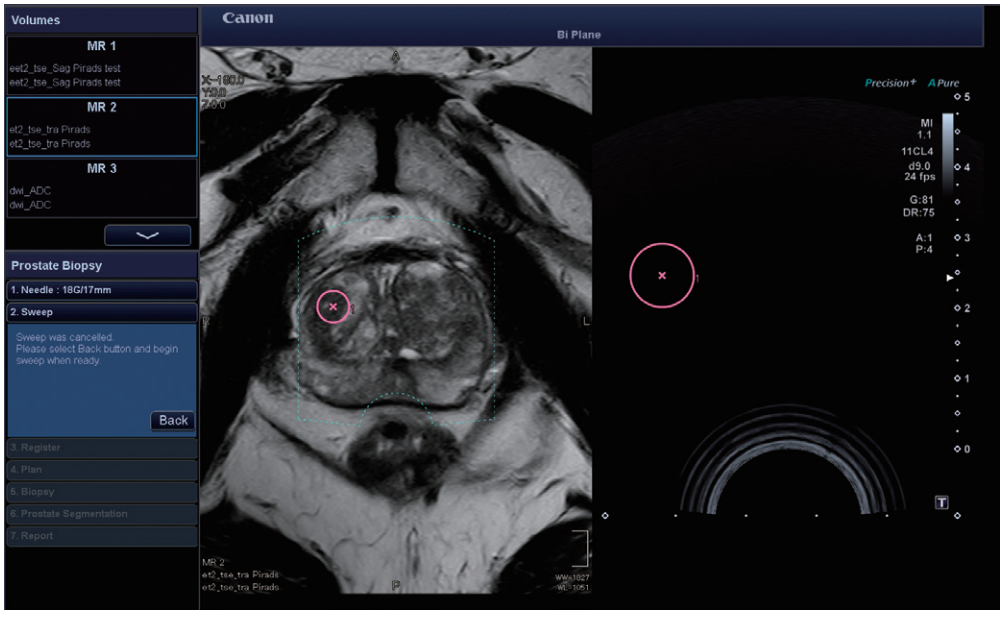

Figure 2 Review of the pre-loaded MRI dataset can be directly done on the ultrasound machine.

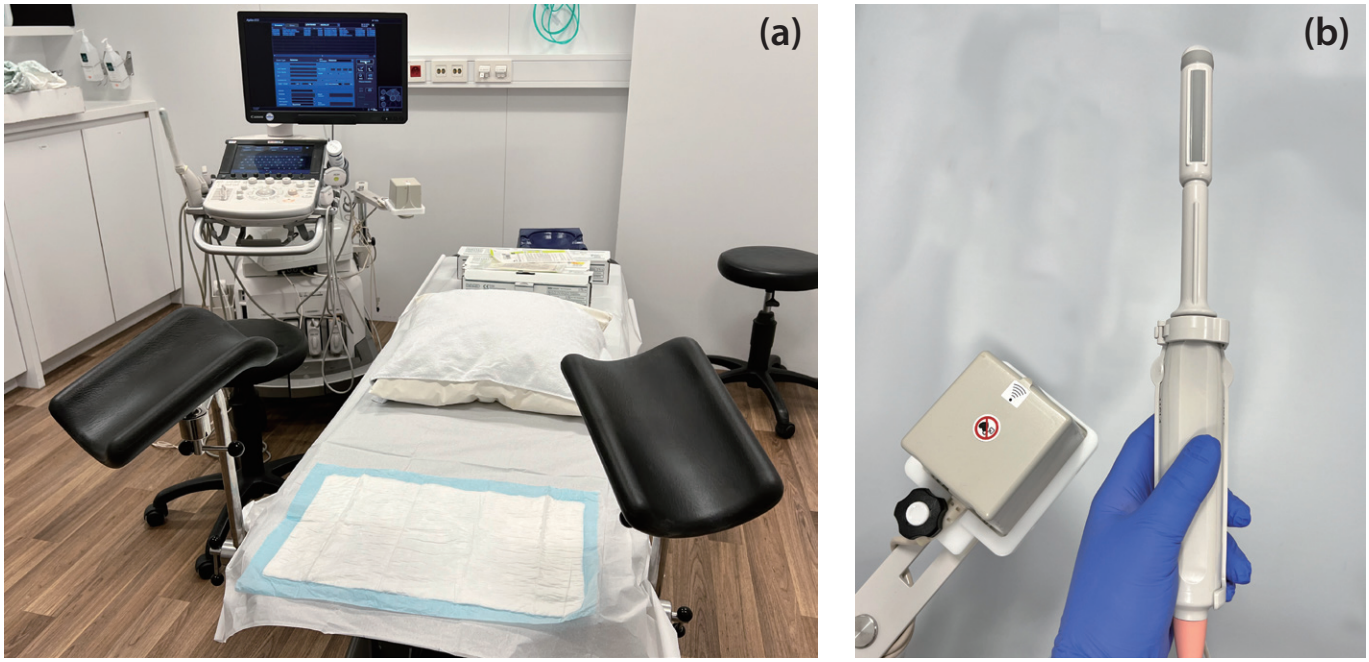

Figure 3 Setup of the transperineal biopsy procedure: (a) the ultrasound system is positioned to the left of the operator next to the patient. (b) the electromagnetic transmitter is placed near the endorectal probe using the articulating arm.

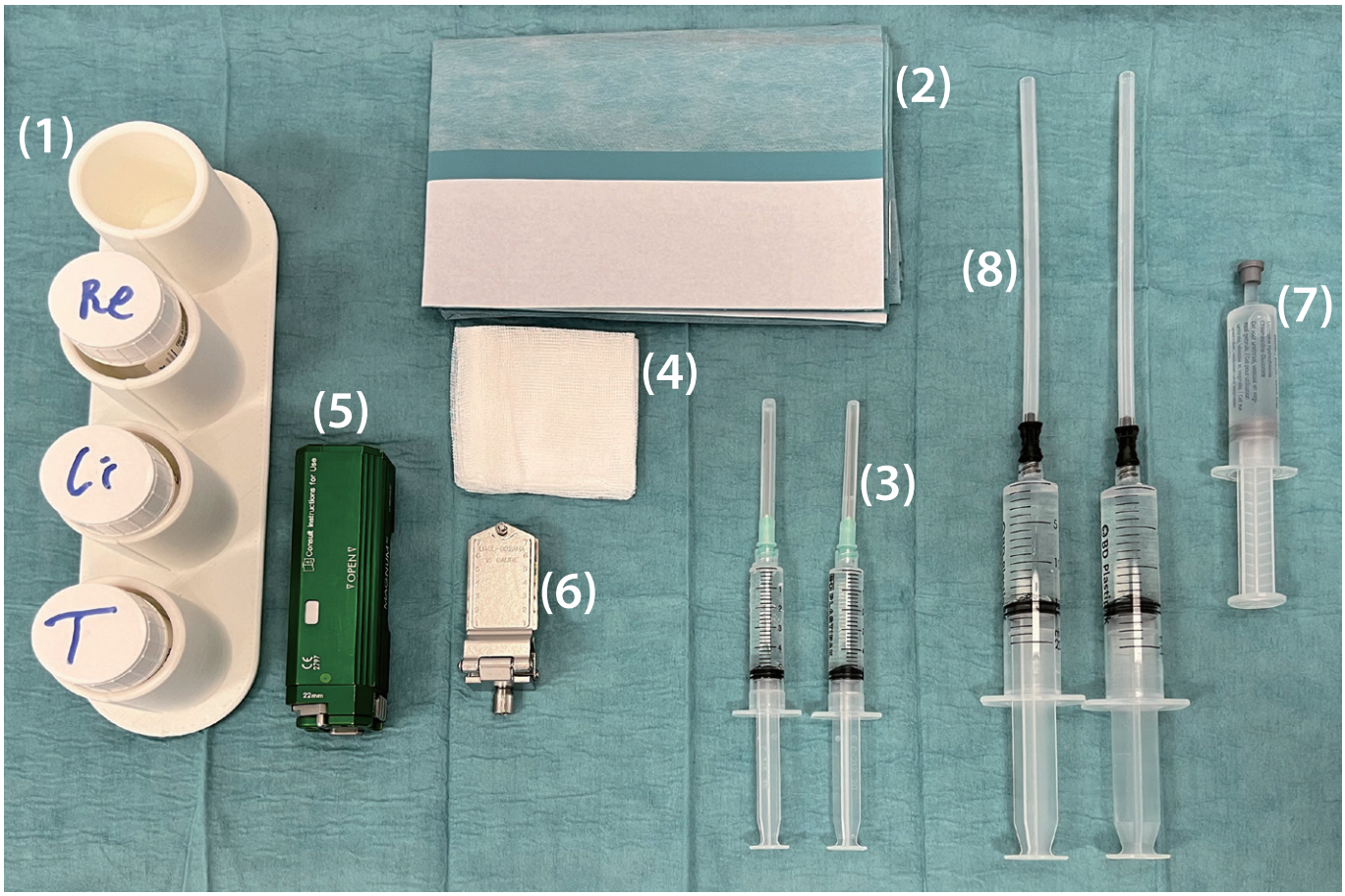

Figure 4 The sterile kit required for anesthesia and biopsy, which was prepared in advance on a side table (1) Three jars with formaldehyde solution to fix the tissue samples for histological examination. Tissue from target biopsy and systematic biopsy are kept separate. (2) Sterile drape to be placed under the patient's bottom over the table edge. (3) Two syringes of 5 mL Linisol 1% solution for superficial skin anesthesia. (4) Sterile compresses. (5) The Magnum reusable core biopsy instrument to combine with a disposable 18 Gauge TruGuide coaxial biopsy needle (not shown). (6) A reusable needle guide that can be attached to the TRUS probe with seven trajectories also shown on the ultrasound image to guide biopsy. (7) Sterile gel to facilitate the rectal insertion of the TRUS probe. (8) Two syringes of 10 mL Linisol 1% combined with 5 mL Ropivacaine (2.5 mg/ml) and a Chiba needle for deep periprosthetic nerve block.

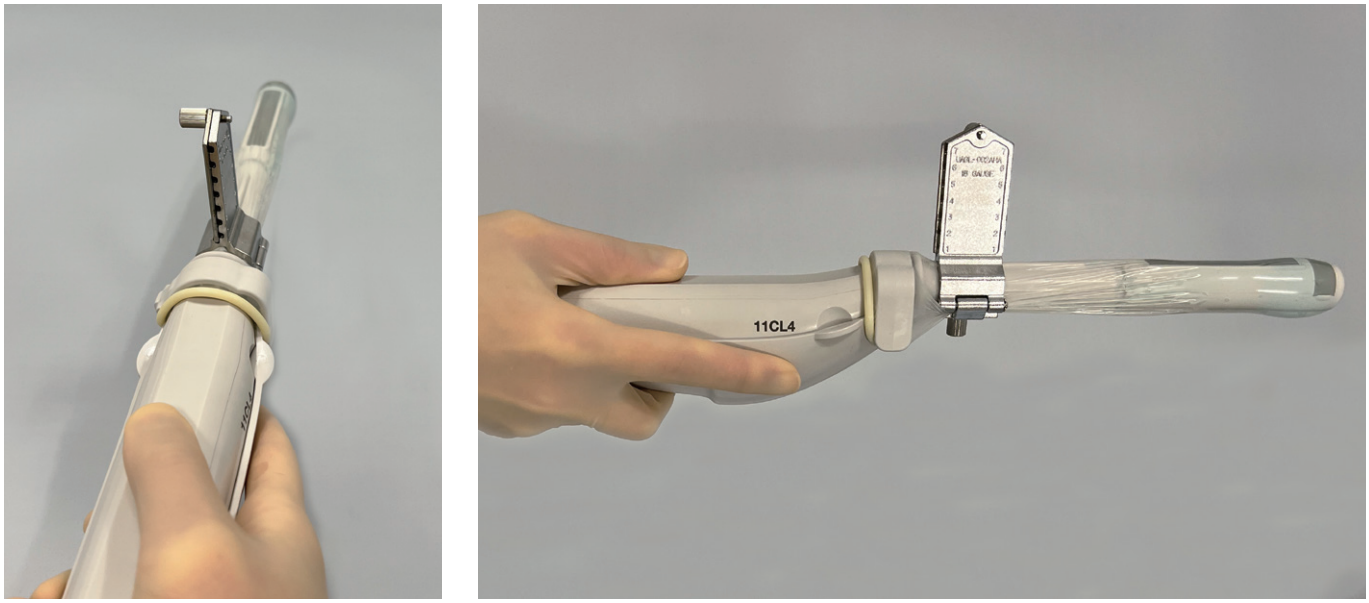

Figure 5 Canon's reusable, sterilizable biopsy guide, shown here attached to the biplane probe, is robust and compact, easy to handle and provides an environmentally friendly and cost-effective solution.

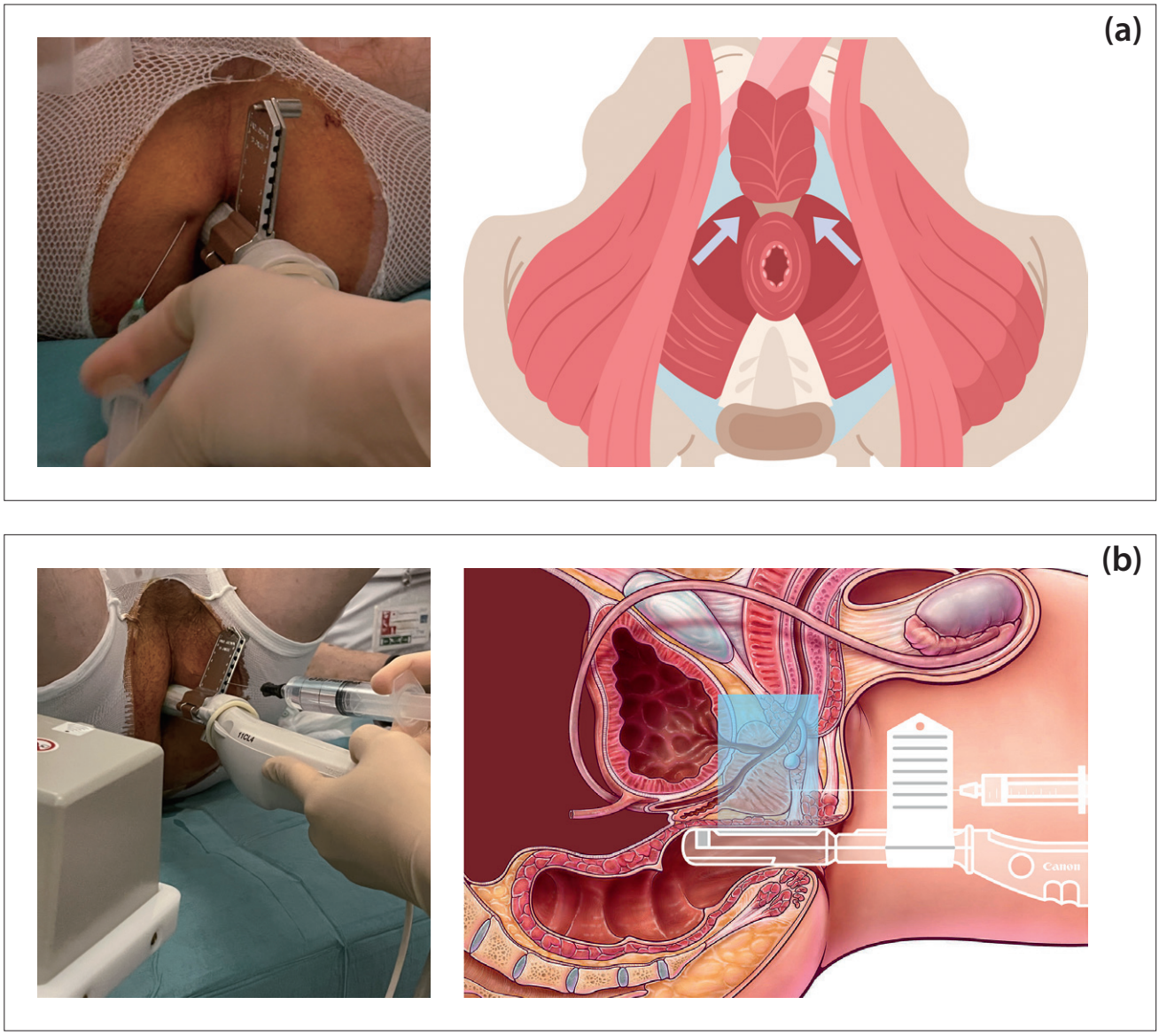

Figure 6 Local anesthesia in two steps: (a) wide-area anesthesia of the perineal skin, (b) deep prostatic nerve block under ultrasound guidance, divided into two injections, one on each side of the neurovascular bundle.

Automatic MRI ultrasound 3D volume fusion

We are using the PVL-715RST bi-plane transrectal probe with a linear and a micro-convex sidefire array and with an electromagnetic sensor attached to the probe (Fig. 7). The quality score for the position accuracy of the electromagnetic sensor attached to the probe in our set-up is during the procedure always above the minimum recommended value of 6 out of 10. First, a 3D ultrasound volume data set is acquired by sliding the transrectal probe in a single steady movement inside the rectum in longitudinal direction over a couple of centimeters from one end of the prostate to the other (Fig. 8). The ultrasound system automatically generates a continuous 3D volume dataset and displays it next to the MRI dataset on the monitor of the Aplio i800.

The automatic co-registration (synchronization) process between the MRI data and the ultrasound data is started after the operator identifies an anatomical landmark on the MRI data and the ultrasound data. Any landmark can be used to link both volumes. Most commonly, we used the urethra at the most apical part of the prostate, an internal cyst in the prostate or a specific part of the boundary of the prostate.

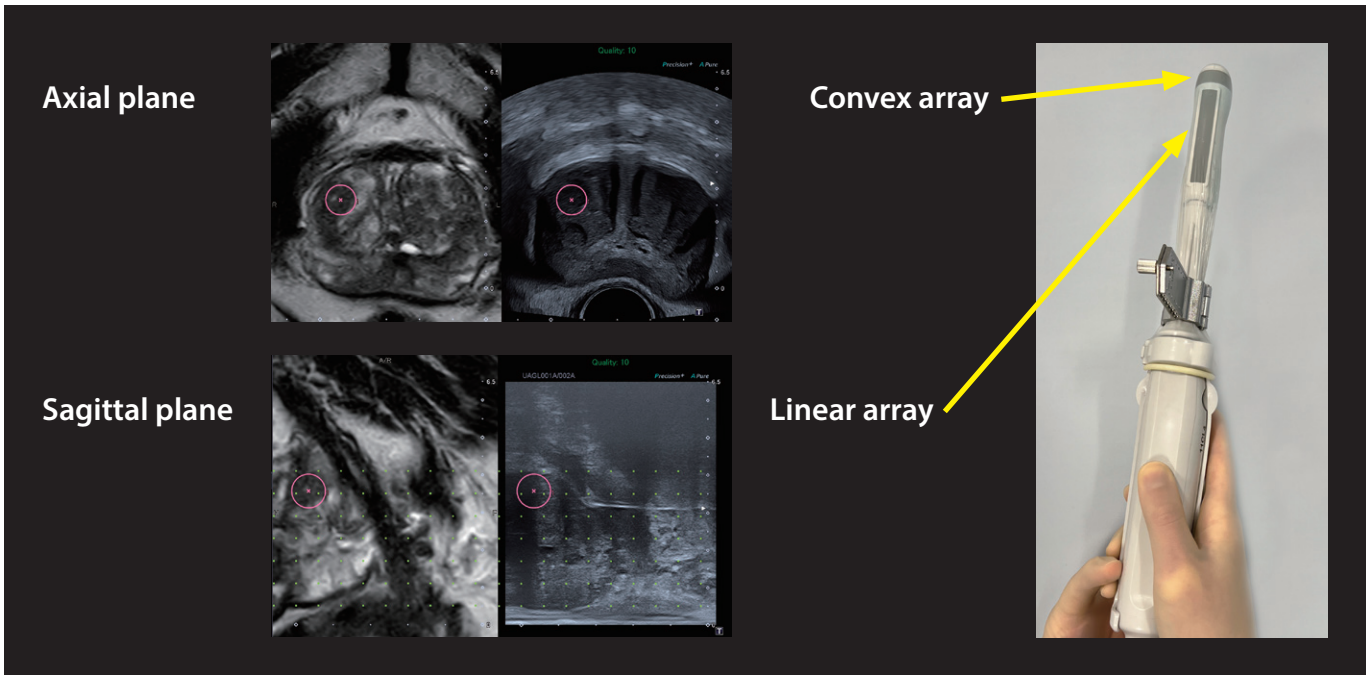

Figure 7 Canon's biplane endorectal transducer PVL-715RST permits imaging in the axial plane with its convex array and in the sagittal plane with its linear array.

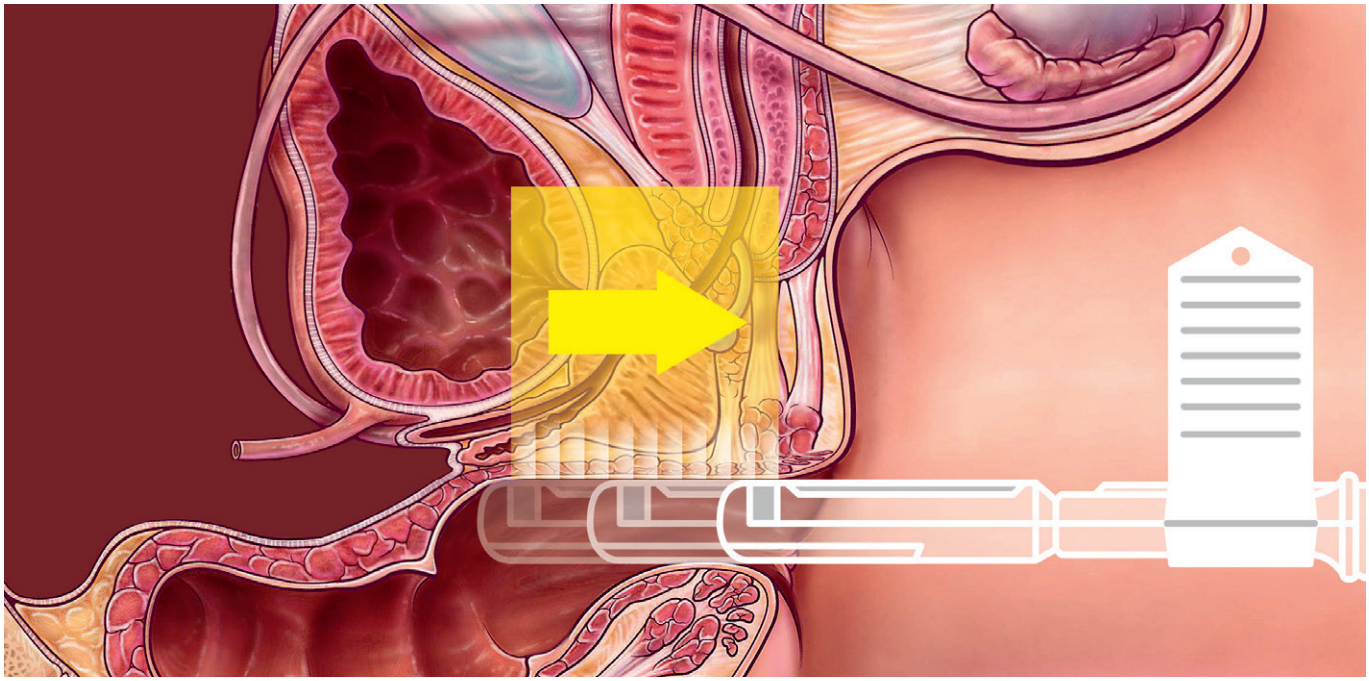

Figure 8 A 3D ultrasound volume is acquired by imaging the prostate in an axial view from the base to the apex by gently pulling the transrectal probe in a longitudinal direction.

After the co-registration process is completed, automatically reconstructed slices of the MRI volume can be viewed side-by-side with the corresponding real-time ultrasound images either from the micro-convex or the linear array on the PVL-715RST (Fig. 9). Should the patient move relative to the magnetic field during the fusion process, the operator can easily readjust the synchronization by re-linking landmarks. Previously marked ROIs on the MRI images are automatically copied to the ultrasound images in the same position.

Biopsies

Once a satisfactory MRI-TRUS correlation is achieved, the target lesion area is located and can be identified by the ROI showing on both real-time TRUS images and MRI images (Fig. 10). The target lesion area (marked as ROI on the MRI and ultrasound images) can be checked in the axial and sagittal planes by switching the probe between the convex and linear array. Small adjustments in volume synchronization can be done in both planes. For carrying out the biopsies, we generally utilize the linear sidefire array as it follows the direction of the biopsy needle. Biopsies are performed with a reusable core biopsy gun (Bard-Magnum™ biopsy instrument) with a disposable needle and a sterilizable needle guide, which is attached and aligned in parallel to the probe and equipped with seven channels for 18-gauge needles that are spaced at 5 mm intervals. Needle markers can be overlayed on the MRI and ultrasound images (Fig. 11). This aids in choosing the right needle insertion height depending on the posterior or anterior location of lesions, whilst maintaining the freedom of freehand biopsies. In our department the standard protocol consists of 5 targeted biopsies of the suspected lesion, followed by conventional systematic biopsies with 5 samples on each side, so that a total of 15 cores are taken. The latter is done in consensus with our Urology Department.

Documentation of sampling cores

After each sampling, the needle tip can be marked on the TRUS image. At the end of the procedure the prostate is segmented and a 3D volume model showing the location of the biopsy cores can be rendered (Fig. 12).

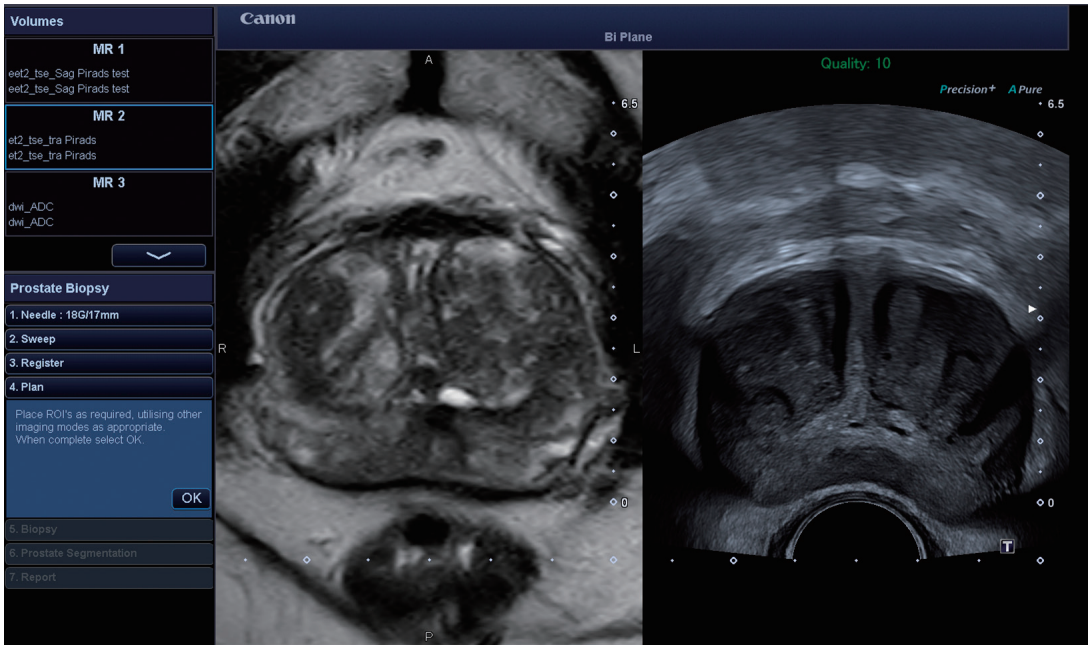

Figure 9 Semi-automatic registration of the ultrasound volume of the prostate with the MRI data set

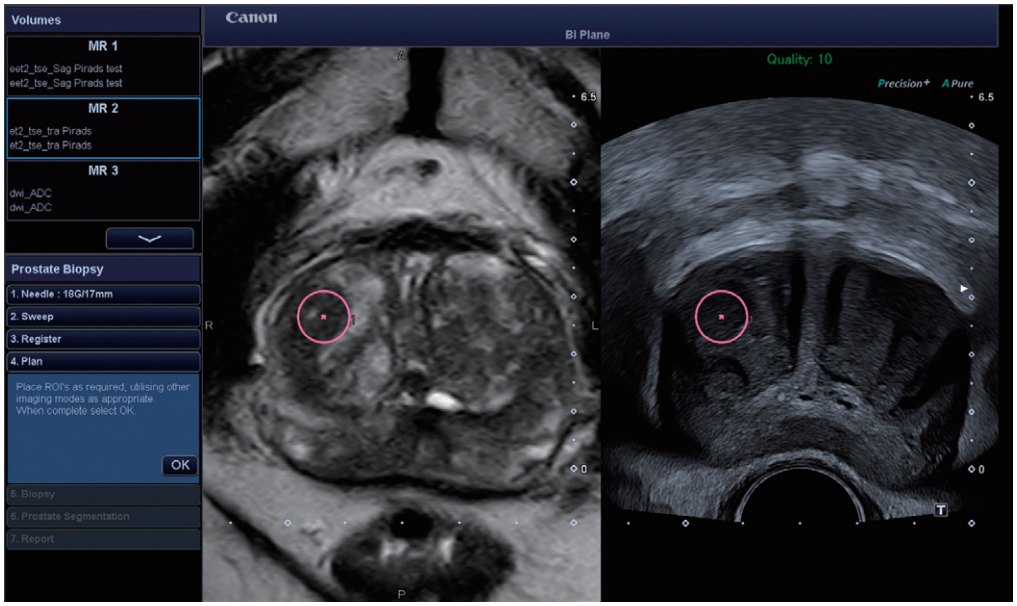

Figure 10 ROIs are showing simultaneously on both the live TRUS and MRI images for user-friendly navigation.

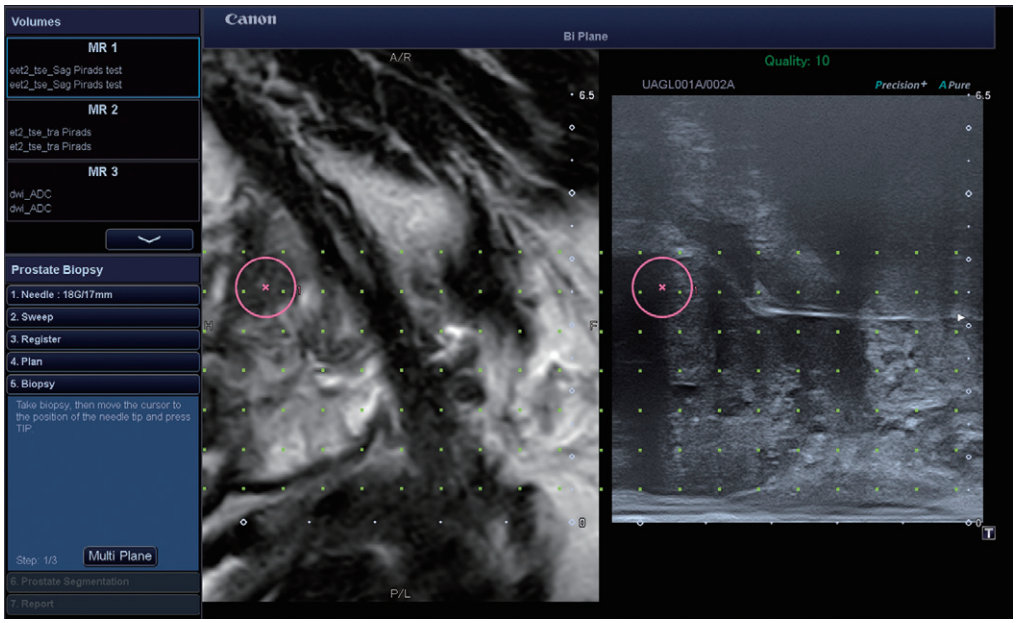

Figure 11 Corresponding with the position of the channels in the needle guide, the green grid can aid in choosing the right insertion height depending on the location of the lesion, whilst maintaining the freedom of freehand biopsies.

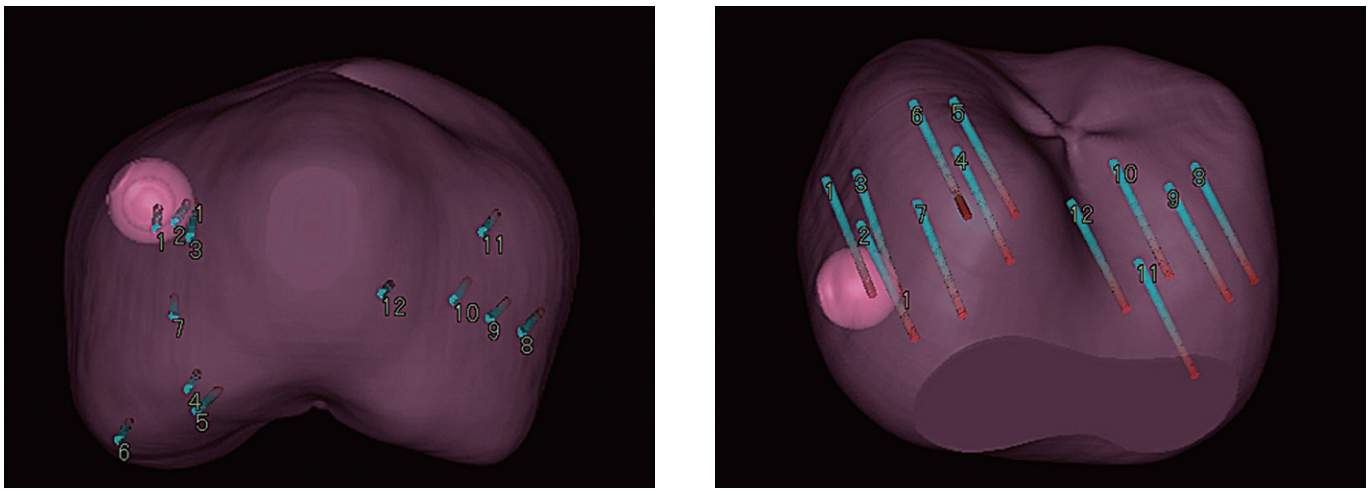

Figure 12 3D-reconstructed model of the prostate indicating the target lesion and biopsy cores taken during targeted and systematic biopsies.

Results and experience

Cancer detection rate

In a previously published study[4] based on the above procedures and protocols on 203 patients we could achieve a very good overall cancer detection rate (CDR) of 73.5% (164 histologically positive biopsies on 223 lesions identified by MRI as suspicious lesions) and high detection rate of clinically significant PCa Detection Rate (csPCaDR) of 60.1% (134/223).

Patient comfort

Patients tolerated the procedure well under LA. They scored the dual injection of the anesthetic solution as the most painful part of the procedure with an average rating of 3.7/10 on a numerical pain rating scale (NPRS) between 0 and 10. After LA, discomfort during prostate sampling was minimal with an average NPRS of 1.6/10.

Time efficiency

Our procedure was time efficient with a mean procedure time of 22.5 min, including image fusion, target biopsy and systematic biopsy. With only target biopsies, it would have taken less than 15 min on average.

Adverse effects

In our first 607 patients, we had an infection rate of 0.6% (one uncomplicated prostatitis, two cases of prostatitis with sepsis and one case of epididymitis). These data are not yet published, but are in line with the recommendations of the EAU guidelines, which stipulate an infection rate of under 1% for transperineal biopsies and therefore recommend the transperineal over transrectal approach. In our group, we only had an acute urinary retention rate of 0.3% (two cases with a very large prostate volume).

Summary

Meanwhile we have performed over 700 transperineal ultrasound-guided MRI fusion biopsies of the prostate with Aplio i800, confirming the results and experiences from our published study[4]. We believe, we are performing a very efficient and effective procedure with very high accuracy and increased safety, conform the European urology guidelines. In our experience, we can confirm its high potential in approving the detection of PCa in Europe and worldwide.

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https://global.medical.canon

Model number: TUS-AI800
MWPUS0028EA 2024-11 CMSC/Produced in Japan

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The clinical results described in this paper are the experience of the author.
Results may vary due to clinical setting, patient presentation and other factors.