

Assessment of the Diagnostic Accuracy of Micro-Ultrasound for the Detection of Clinically Significant Prostate Cancer: Results from a Single-Institutional Preliminary Experience

INTRODUCTION

mpMRI has gained importance in its role as a diagnostic tool for detection of prostate cancer (PCa), however it is limited by cost ineffectiveness, procedural complexity, learning curve and indeterminate results.

High resolution micro-ultrasound is a new, promising alternative for real time guidance of targeted prostate biopsies. Micro-ultrasound operates at 29 MHz, resulting in resolution down to 70 microns, allowing for better diagnostic capabilities in addition to its affordability and ease of use.

OBJECTIVE

This study reports the first three months after introducing high resolution micro-ultrasound into our prostate biopsy clinic.

METHODS:

- 78 patients with suspicion of PCa (abnormal DRE or elevated PSA) were imaged using **ExactVu™** micro-ultrasound system (**ExactVu™**, Exact Imaging)
- **PRI-MUS™** (prostate risk identification using micro-ultrasound) protocol¹ was used to locate targets (**PRI-MUS ≥ 3**)
- The overall presence of clinically significant PCa (csPCa; **GS ≥ 7**) was assessed

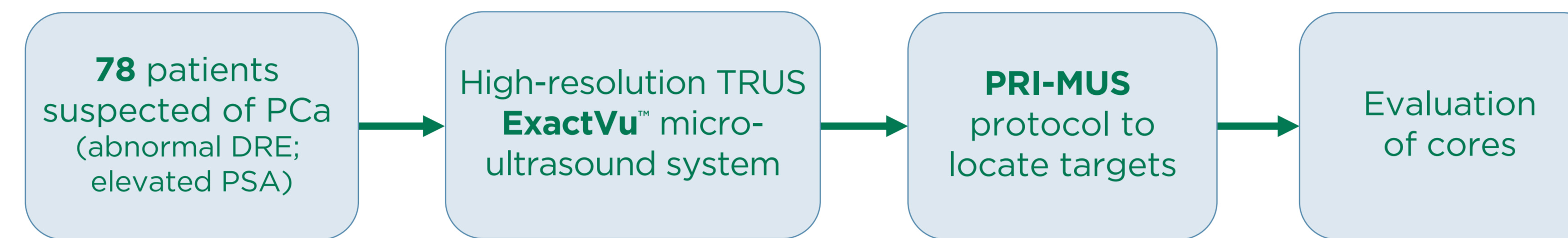


Figure 1: Micro-ultrasound study procedure

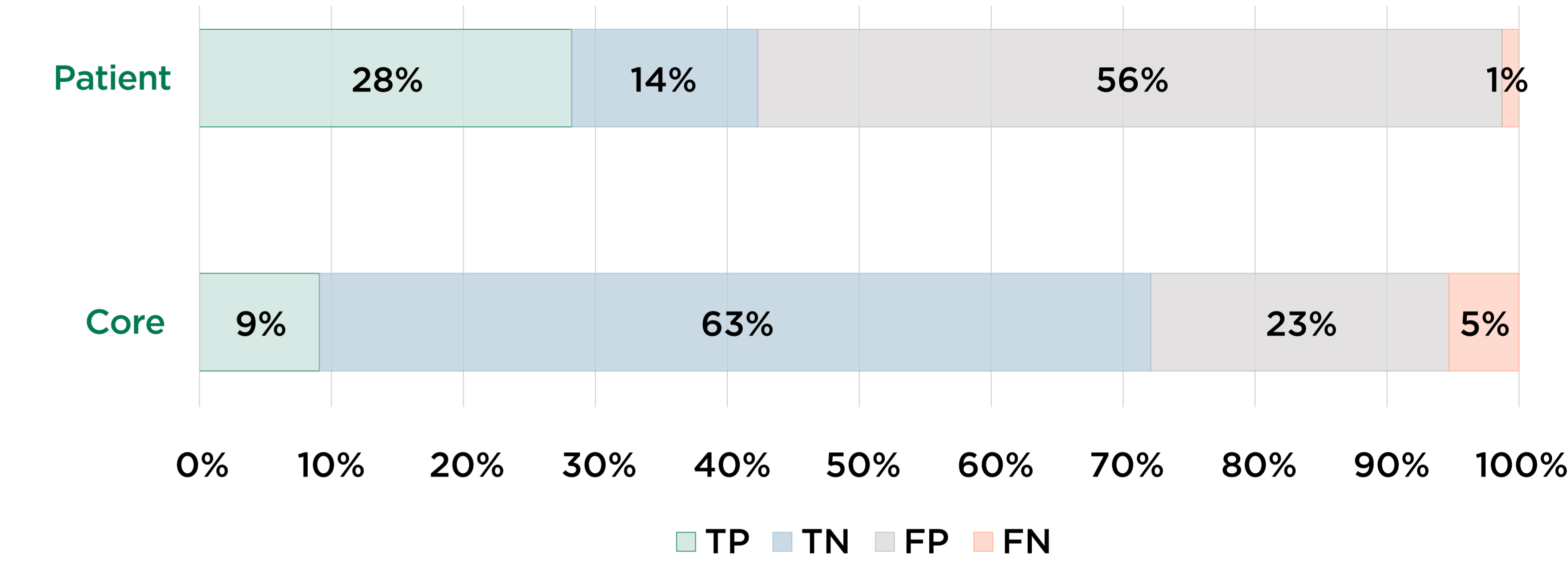


Figure 4: Per-patient and per-core true positive (TP), true negative (TN), false positive (FP), and false negative (FN) results. A TP patient has at least 1 true positive target. TN patients have only TN cores. A FP patient has at least 1 FP core, and no TP, while a FN patient has at least 1 FN core, and no TP or FP.

RESULTS:

- Total of 792 biopsy samples taken for 78 patients
- The micro-ultrasound detected lesions in 66 patients (**PRI-MUS 3, 4, 5** in respectively 9, 31, and 26 patients) (88%)
 - ▶ Biopsy identified 22/23 patients with **Gleason Sum ≥ 7** with at least 1 positive target, contributing to a sensitivity of 96% (Table 1, Figure 4)
- Biopsy also revealed 11/12 patients without micro-ultrasound targets were benign
 - ▶ Retrospectively, the 1 false negative patient revealed a **PRI-MUS 4** lesion missed on initial exam

	Sensitivity	PPV	Specificity	NPV
Micro-Ultrasound	96%	33%	20%	92%

Table 1: Patient results with micro-ultrasound results showing high sensitivity and NPV

CONCLUSIONS:

- Micro-ultrasound sensitivity and NPV in detecting csPCa was **96%** and **92%** respectively, while specificity was **20%** (possibility attributed to learning curve)
- **Micro-ultrasound appears to be a valuable tool to identify and target csPCa in patients with suspected PCa**
- **Micro-ultrasound also appears to be capable of reliably excluding the presence of csPCa in the great majority of patients**

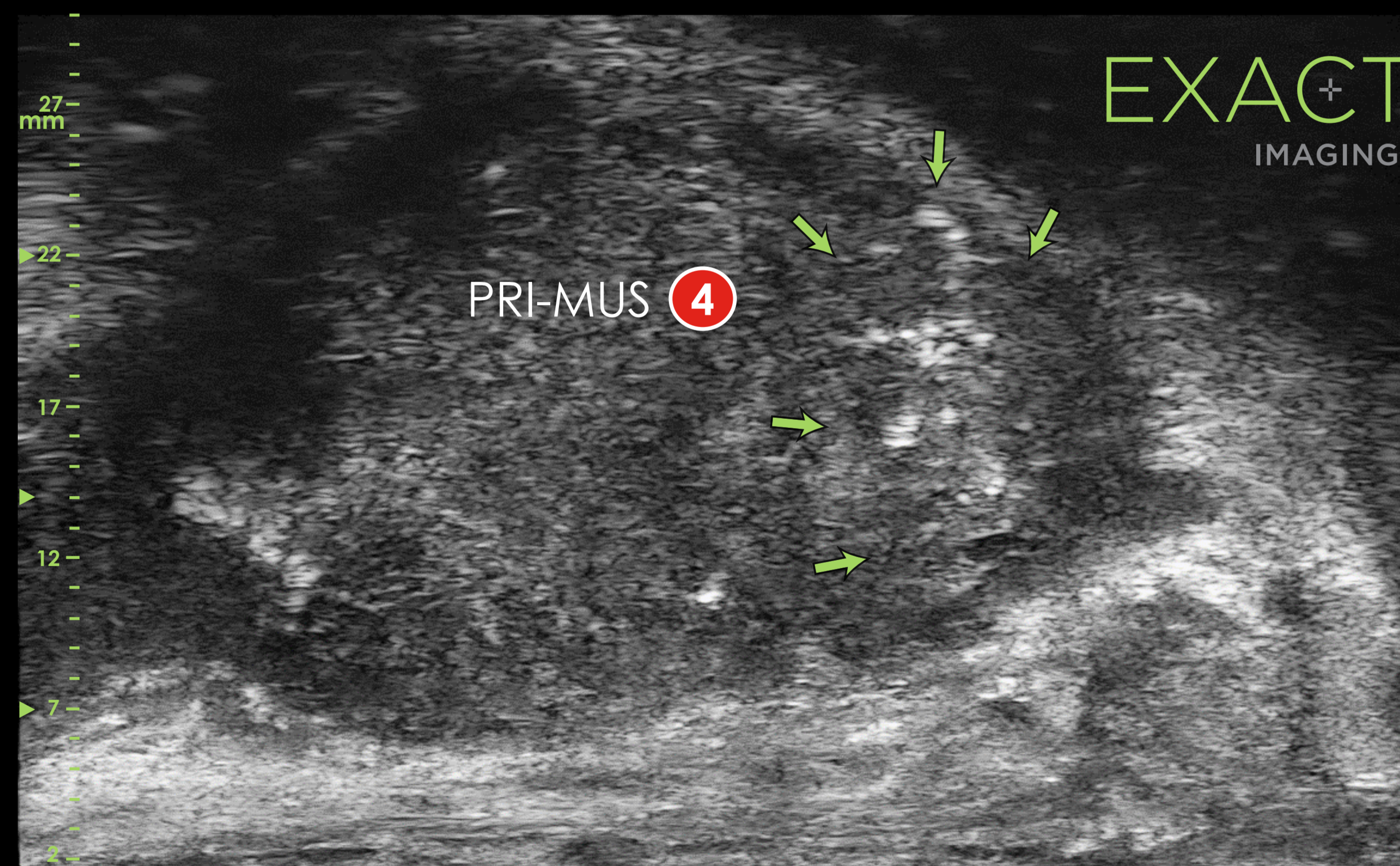


Figure 2: This is a micro-ultrasound image of a **PRI-MUS 4** lesion (suspicious target with "Starry Sky" appearance). This core was positive on Pathology (**GS 7**).

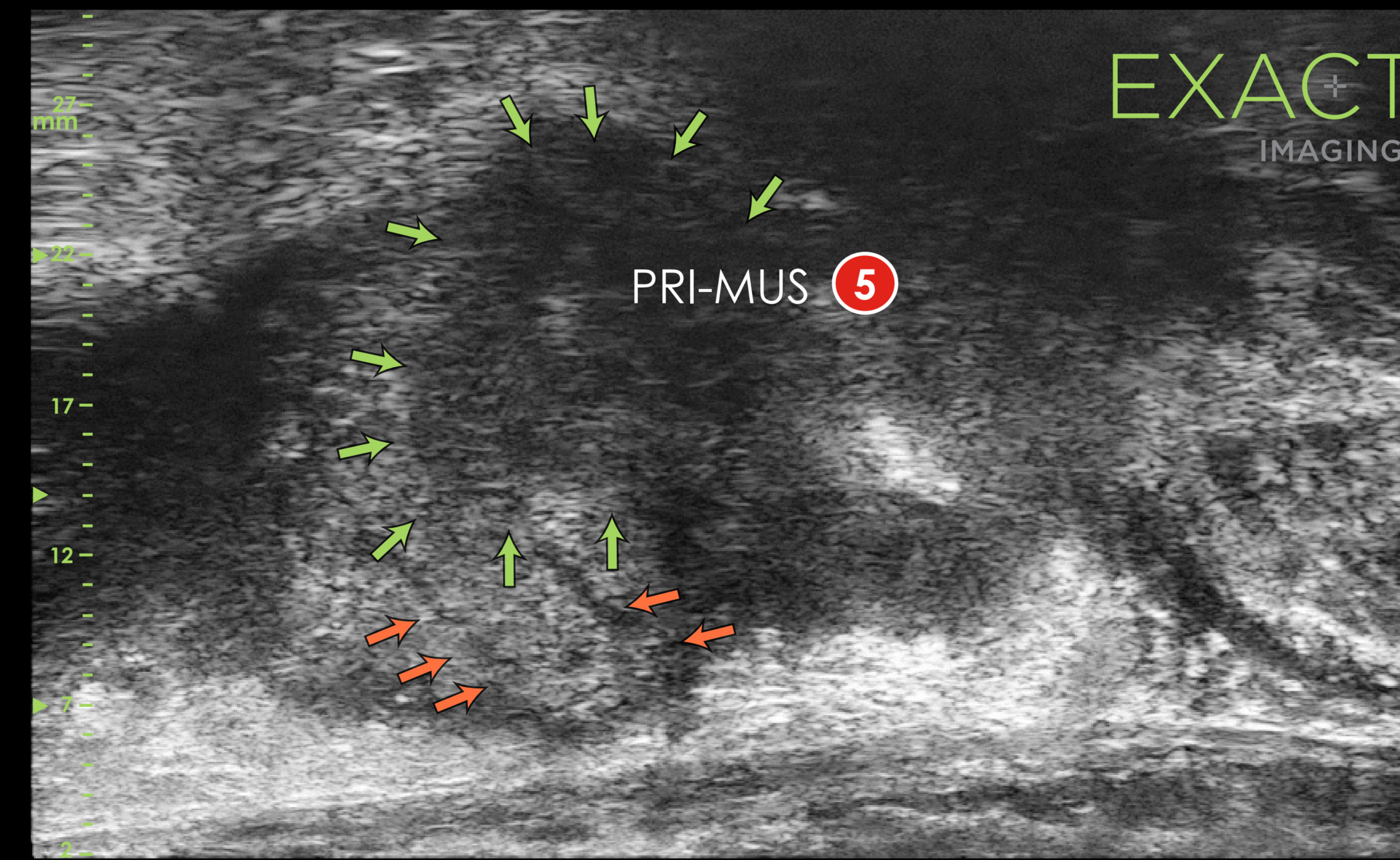


Figure 3: Micro-Ultrasound image of **PRI-MUS 5** (suspicious mixed echo lesion). This core was positive on Pathology (**GS 7**). The lesion is denoted by green arrows, while orange arrows identify 2 prior biopsy needle tracks from 6 months previously. With micro-ultrasound we can see that one of these tracks hit the edge of the lesion, likely resulting in previous GS6 diagnosis.

REFERENCES

1. Ghai S, Eure G, Fradet V, et al: Assessing Cancer Risk on Novel 29 MHz Micro-Ultrasound Images of the Prostate: Creation of the Micro-Ultrasound Protocol for Prostate Risk Identification. J. Urol. 2016; 196: 562-569.