

Added Value of mpMRI and High-Resolution 29 MHz Micro-Ultrasound Targeting during Prostate Biopsy on Suspicion of Prostate Cancer

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INTRODUCTION:

The low negative predictive value of conventional ultrasound leads to systematic biopsies, and a high rate of under-diagnosis. New recommendations include multi-parametric MRI (mpMRI) targeted biopsies. Here we compare the added diagnostic potential of mpMRI with new **29 MHz micro-ultrasound** (micro-US), a novel technique enabling real-time targeting without the complexities, costs and challenges of performing MRI.

METHODS:

- Prospective database study including 51 subjects presenting with elevated PSA or abnormal DRE undergoing prostate biopsy using **ExactVu™ micro-ultrasound system** (Exact Imaging, Markham, Canada)
- These subjects had also received mpMRI imaging which indicated targets for biopsy
- Each case was analyzed to determine whether mpMRI and/or micro-US targeted samples identified the highest **Grade Group (GG)** detected for the subject by any technique.

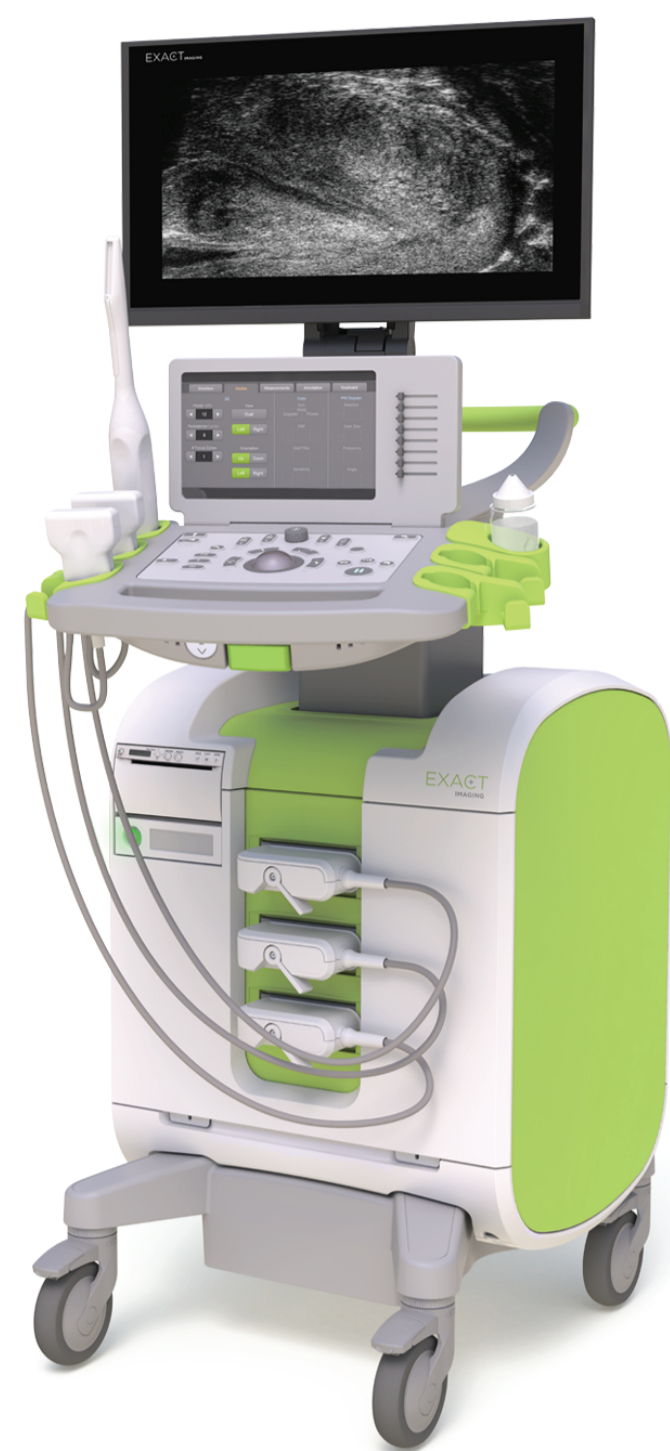


Figure 1: ExactVu™ 29 MHz Micro-Ultrasound System

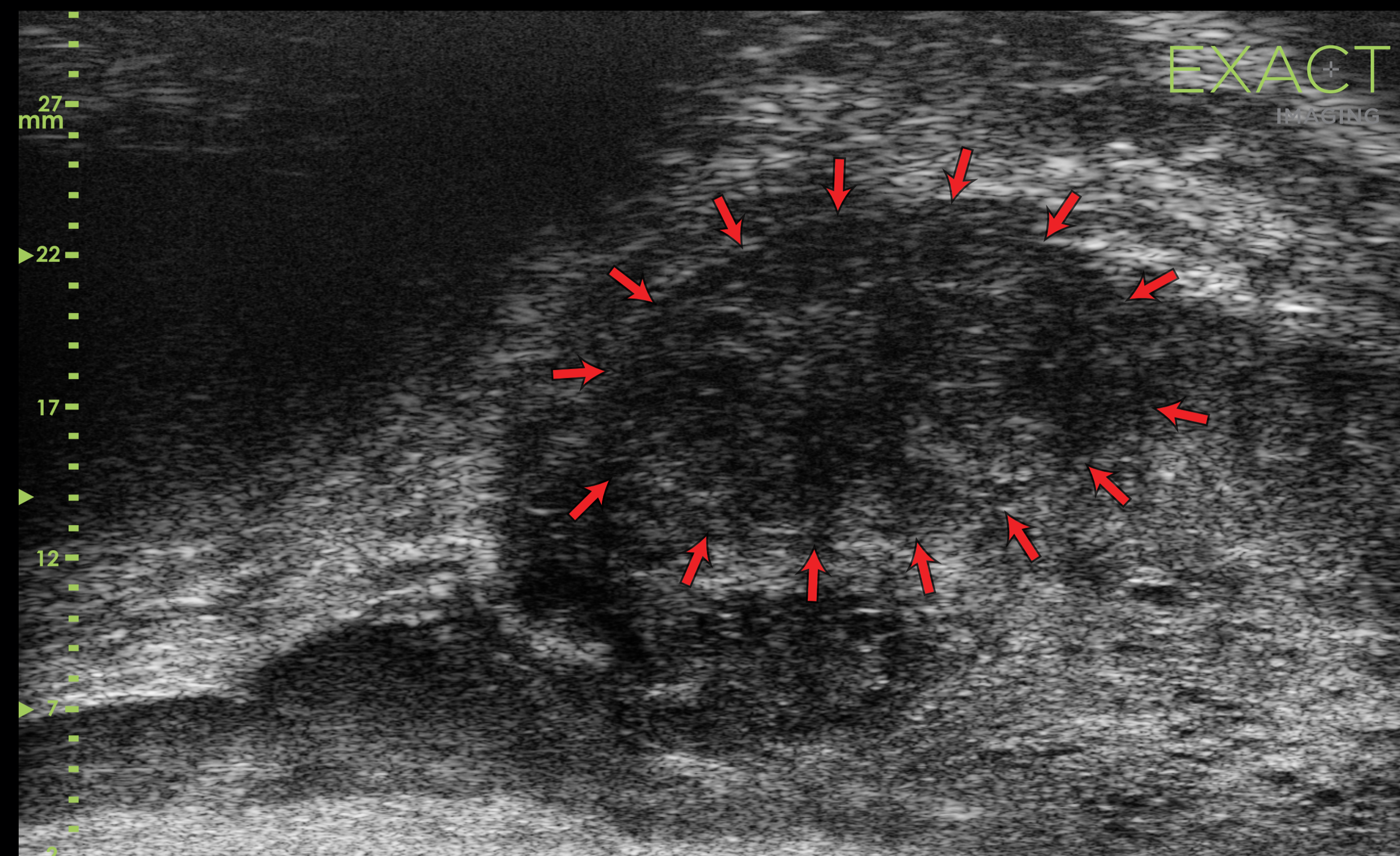


Figure 2: Micro-ultrasound image showing large anterior **GG 3** lesion not visualized on mpMRI. In this case mpMRI suggested a target at the contralateral apex only, which was found to contain a lower grade cancer with **GG 1**.

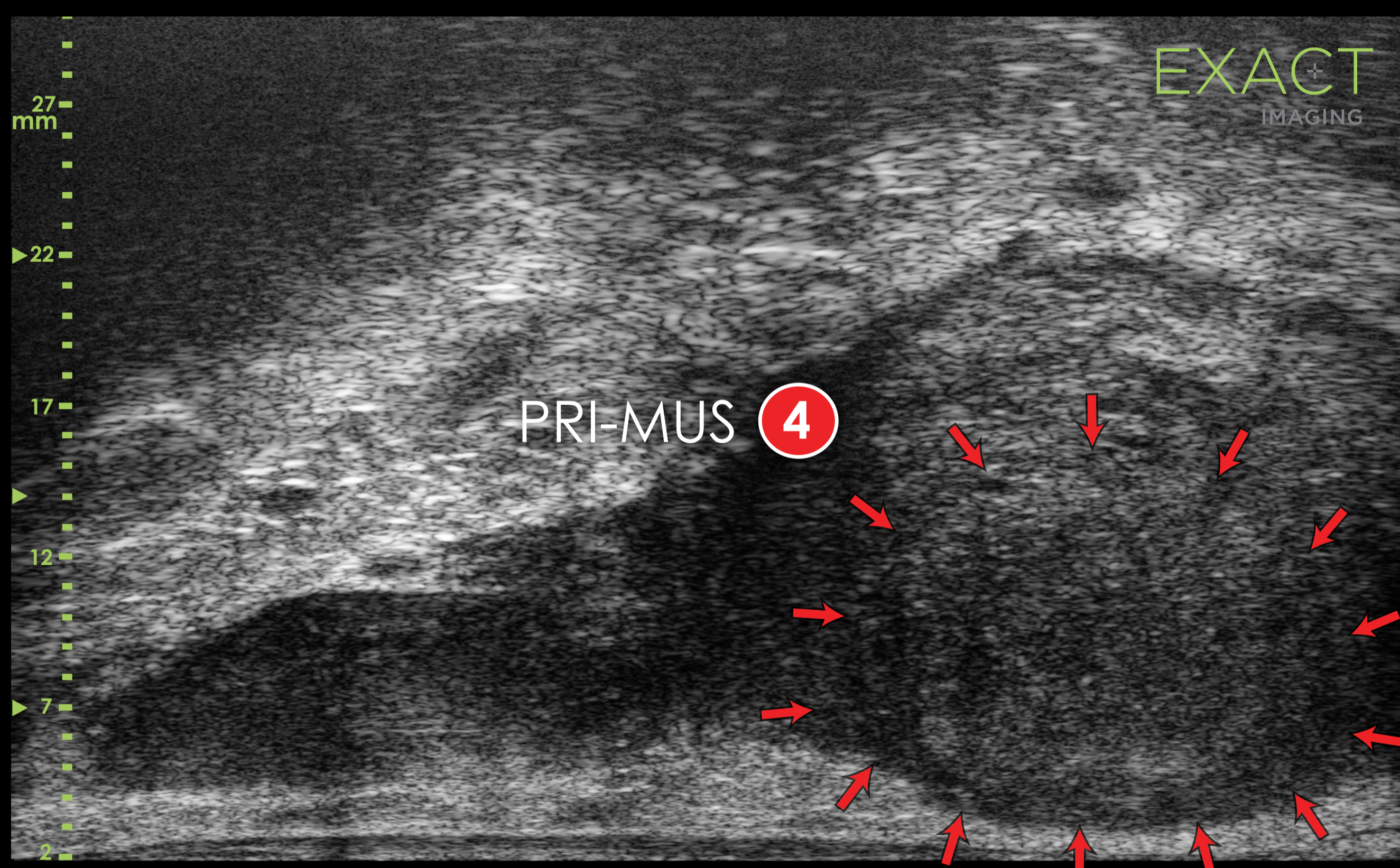


Figure 3: Micro-ultrasound image showing large posterior **GG 4** lesion only partially visualized mpMRI. In this case mpMRI suggested a target at the apex only, which was found to contain a lower grade cancer with **GG 3**, while the more serious **GG 4** lesion was focused at the base.

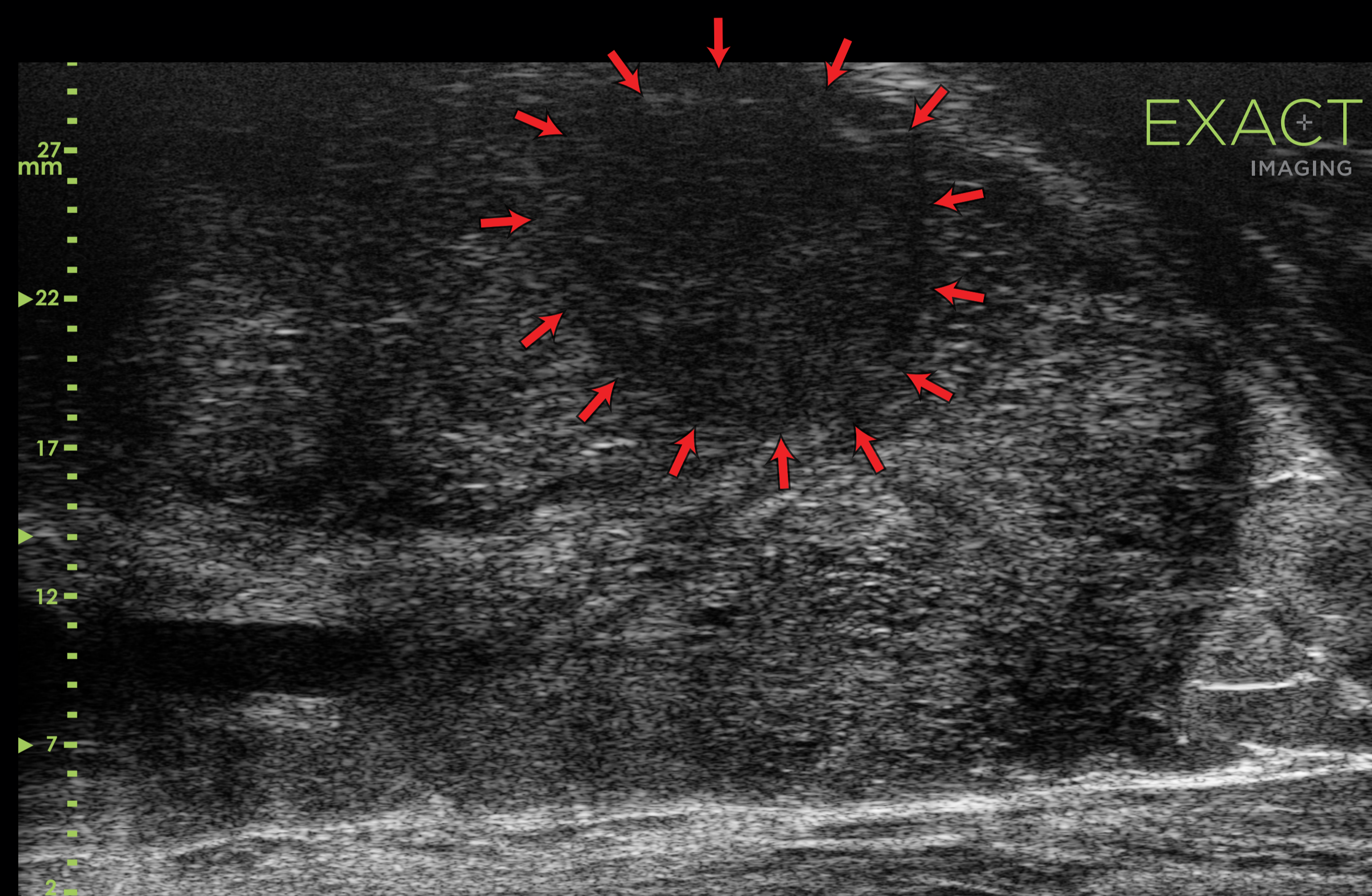


Figure 4: Micro-ultrasound image showing large anterior **GG 4** lesion also visualized on mpMRI. This patient had a negative biopsy in 2016, followed by a negative MRI in 2017. A repeat MRI in 2018 showed a lesion in the left anterior zone. Micro-ultrasound biopsy targeted this anterior lesion, which given a **GG 4** by pathology. Radical prostatectomy confirmed the location of the lesion but downgraded it to **GG 3**.

RESULTS:

- Prostate cancer was identified in 27/51 (53%) subjects, and was clinically significant (GG 2) in 22/51 (43%)
- In 19/27 (70%) of all cancers and 16/22 (73%) GG 2 cancers, both micro-US and mpMRI targets identified the highest GG cancer
- mpMRI alone detected 3/27 (11%, GG1,1,3) cancers which were not identified by micro-US
- Micro-US alone detected 3/27 (11%, GG2,2,4) cancers which were not identified by mpMRI
- Systematic biopsies detected the highest GG in 2/27 (7%) patients, although in each case both mpMRI and micro-US had identified a lower GG region
- In patients without mpMRI, 2 had positive biopsies in areas identified by micro-US

CONCLUSIONS:

- Image-based targeting of prostate biopsies **added significant value** with **high rates** of clinically significant cancer detection
- With strong agreement between MRI and micro-US in most cases, micro-US may be a reasonable alternative to MRI for targeted biopsy

Detection Rate	Overall	Micro-US	mpMRI
All Cancer	27/51 (53%)	24/51 (47%)	24/51 (47%)
csPCa (GG > 1)	22/51 (43%)	21/51 (41%)	19/51 (37%)
Highest GG per patient	N/A	22/27 (81%)	22/27 (81%)
Highest GG per patient (csPCa only)	N/A	19/22 (86%)	17/22 (77%)

Table 1: Detection rate results overall and per modality.

Both modalities showed strong concordance in identifying csPCa at the patient level, however micro-ultrasound targets upgraded 2 cases of clinically significant cancer to a higher Grade Group than MRI targets.

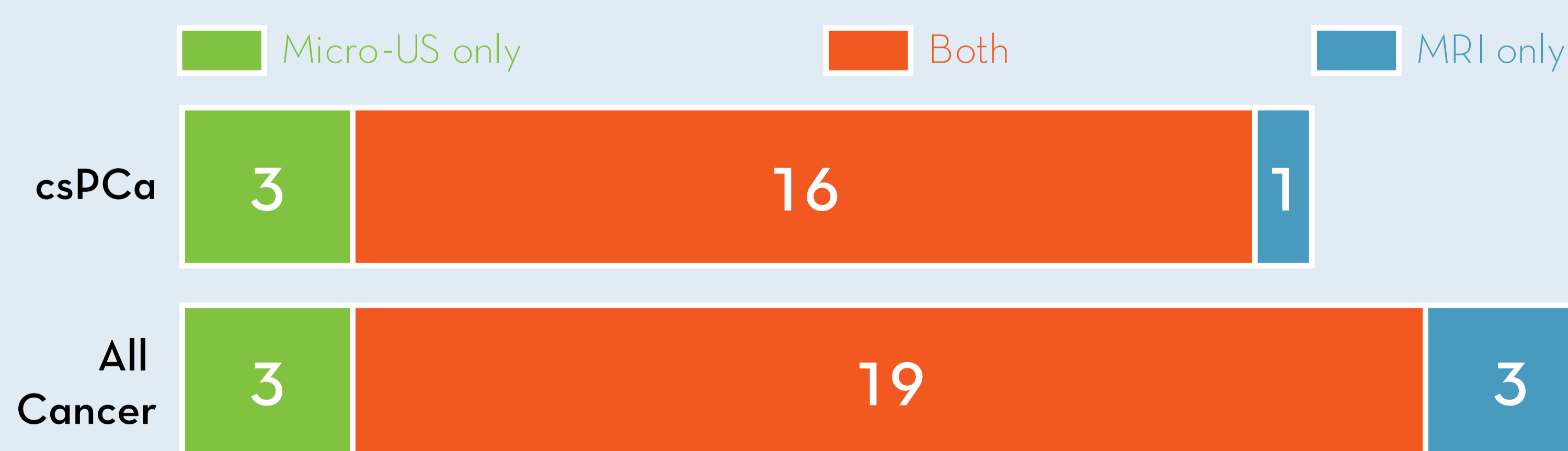


Figure 5: Patient-level detection of All Prostate Cancer and Clinically Significant Prostate Cancer by Modality.

Micro-ultrasound alone detected higher grade group cancer in 3 cases above mpMRI. mpMRI alone detected 1 case above micro-ultrasound. Systematic biopsies detected the highest grade group cancer in 2 cases. Both targeting modalities were highly concordant, detecting the same grade lesions in 16/22 cases of csPCa.