Prostate Biopsy and Targeted Therapy

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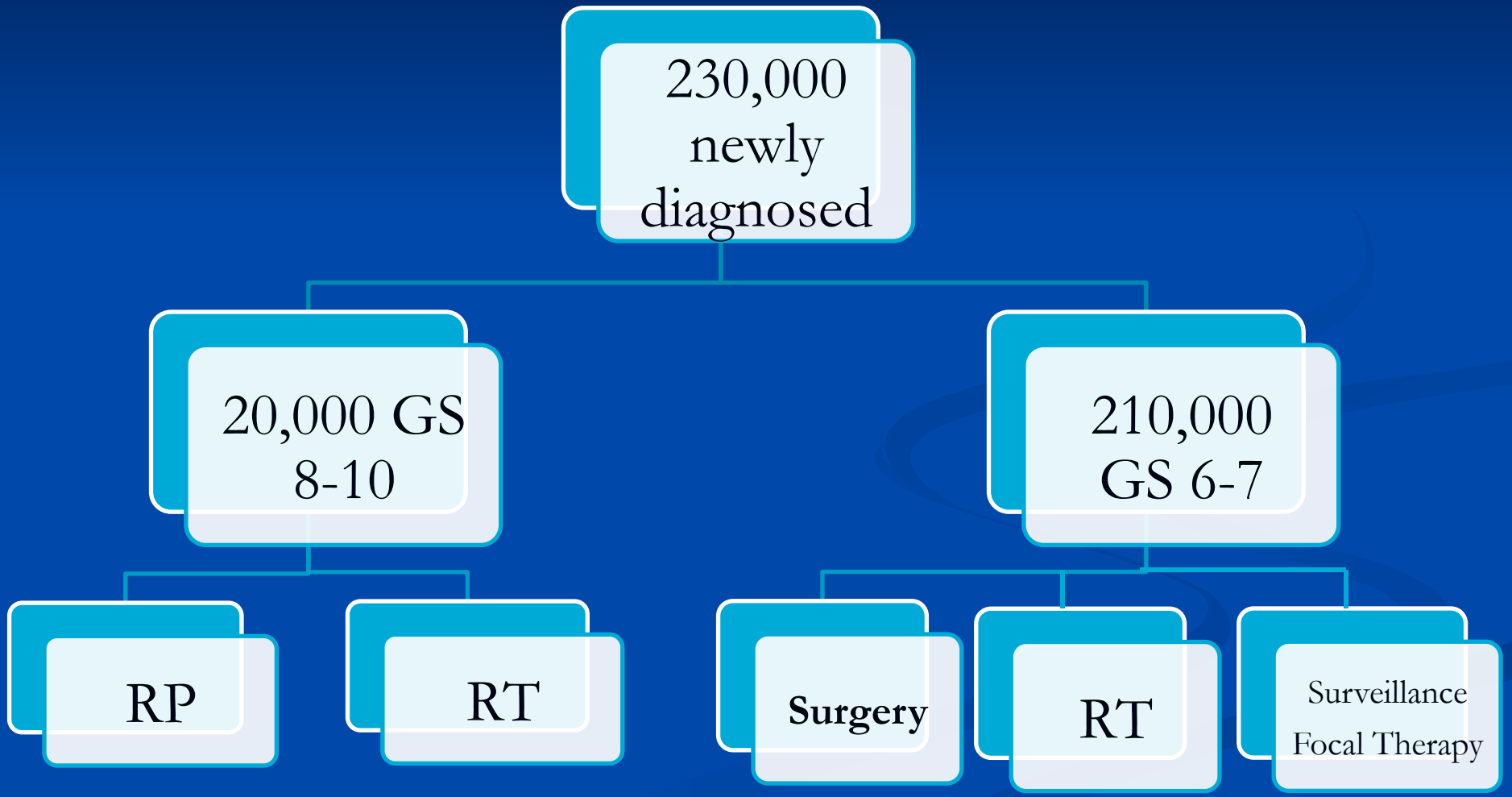
Disclosure

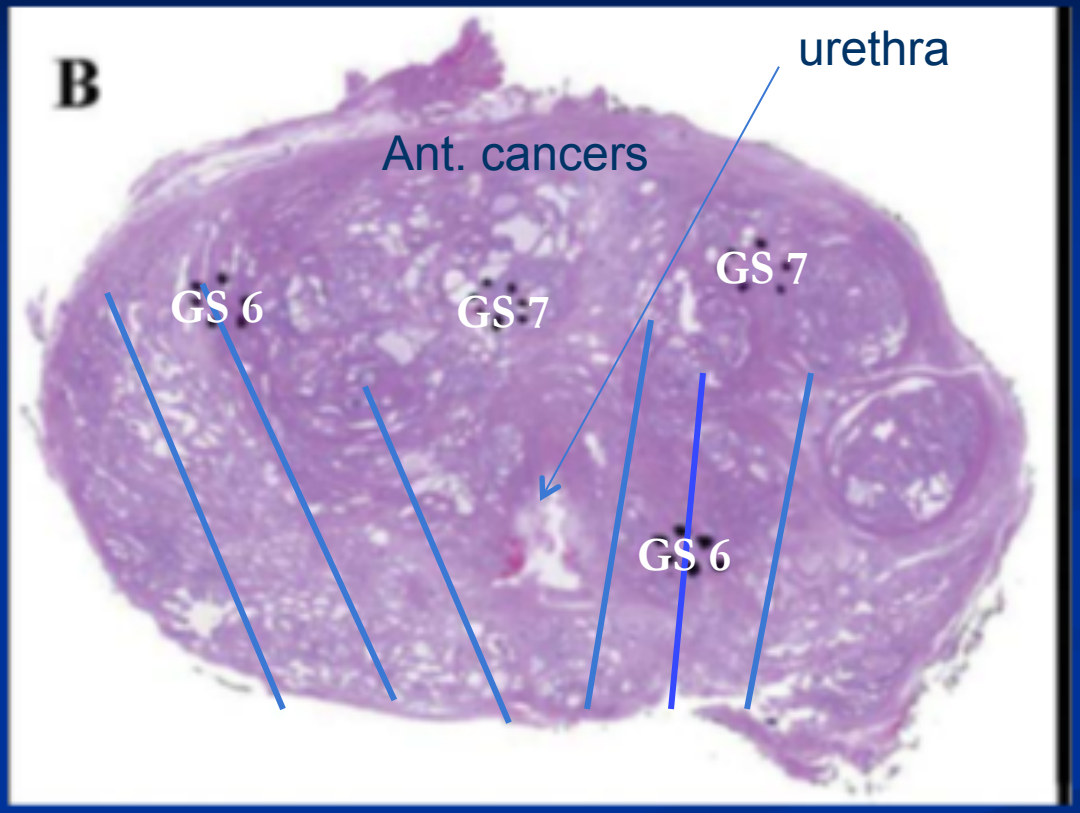
- President and CEO 3DBiopsy LLC

Biopsy Techniques 2016

- 12-core standard transrectal (TRUS)
  - 1.2 million/year
  - 3.3 million world-wide
- mpMRI guided transrectal
- Transperineal
  - template guided ± mpMRI
  - 3D-mapping guided

Current Biopsy/Treatment Algorithm





ANTICANCER RESEARCH 29: 5155-5162 (2009)

Pathologic Findings in Radical Prostatectomy Specimens From Patients Eligible for Active Surveillance With Highly Selective Criteria: A Multicenter Study

Jean-Baptiste Beauval, Guillaume Ploussard, Michel Soulié, Christian Pfister, Simon Van Agt, Sébastien Vincendeau, Sébastien Larue, Jérome Rigaud, Nicolas Gaschignard, Morgan Rouprêt, Sarah Drouin, Mickael Peyromaure, Jean Alexandre Long, Francois Iborra, Guy Vallancien, Francois Rozet, Laurent Salomon, and Members of Committee of Cancerology of the French Association of Urology (CCAFU)

- Retrospective analysis of 10,785 consecutive radical prostatectomy performed in 10 university hospitals
- 919 patients fulfilled the following criteria:
  - T1c
  - PSA <10 ng/mL
  - 1 positive biopsy, tumor length <3 mm and Gleason score <7.
- Gleason score was upgraded in 34% of patients, including 1.2% Gleason score 8-9. Pathologic stages were pT2 in 87.3%, pT3 in 11.1%, and pT4 in 1.4% of cases. Extraprostatic extension was found in 12.5%.
- **Only 26% of patients had "insignificant" tumors.**

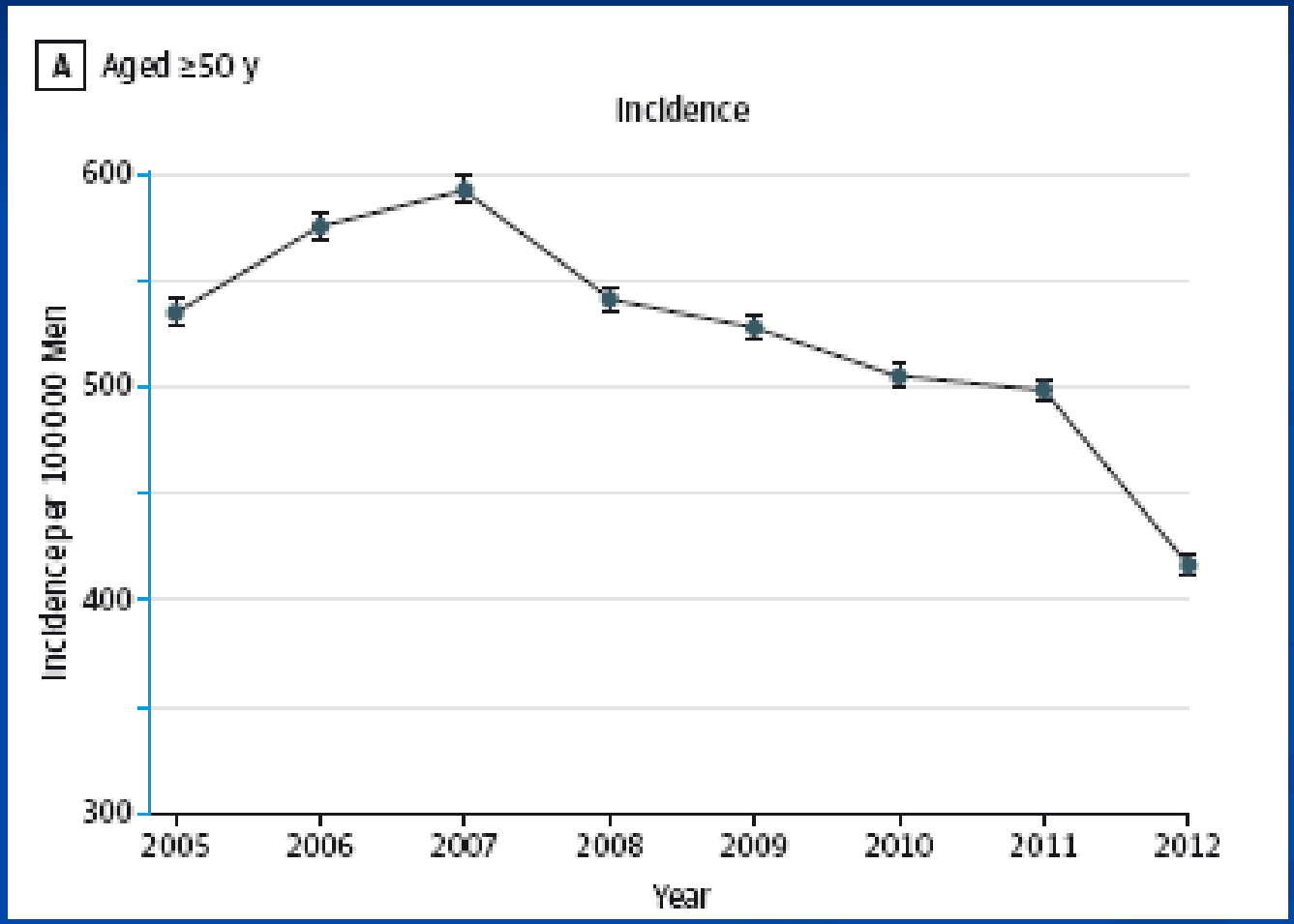
UROLOGY 80: 656–660, 2012.

The Playing Field Has Changed

- When TRUS biopsy introduced cancers were larger and detectable by both DRE and TRUS
- Today lesions are very small or located in regions that are not discoverable by DRE or TRUS
- This has resulted in the 12-core biopsy being a "semi-blind" procedure.
- Re-biopsy using the same technology does not yield better results

Prostate Cancer Incidence and PSA Testing Patterns in Relation to USPSTF Screening Recommendations

Ahmedin Jemal, DVM, PhD; Stacey A. Fedewa, MPH; Jiemin Ma, PhD; Rebecca Siegel, MPH; Chun Chieh Lin, PhD; Otis Brawley, MD; Elizabeth M. Ward, PhD



Screening rates ↓
10% 2005-2008
18% 2010-2013

JAMA. 2015;314(19):2054-2061. doi:10.1001/jama.2015.14905

The Centers for Medicare & Medicaid Services (CMS) seeks stakeholder comments on the following clinical quality measure under development:

Title: Non-Recommended PSA-Based Screening

Description: The percentage of adult men who were screened unnecessarily for prostate cancer using a prostate-specific antigen (PSA)-based screening test

Prostate Testing Should Be Up to the Patient

Wednesday, December 2, 2015

That the U.S. Preventive Services Task Force states that PSA causes "more harm than good" is an unfortunate byproduct of the success of PSA. However, the problem isn't PSA but the biopsy technique used to diagnosis prostate cancer. The solution to this problem is to improve the biopsy test. Investigators are having

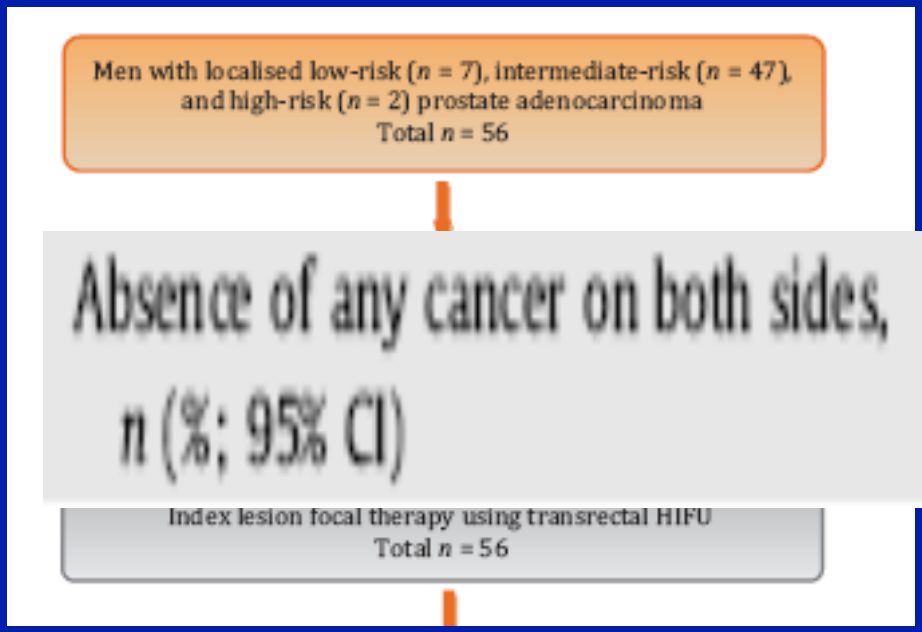
NELSON N. STONE, M.D.
New York

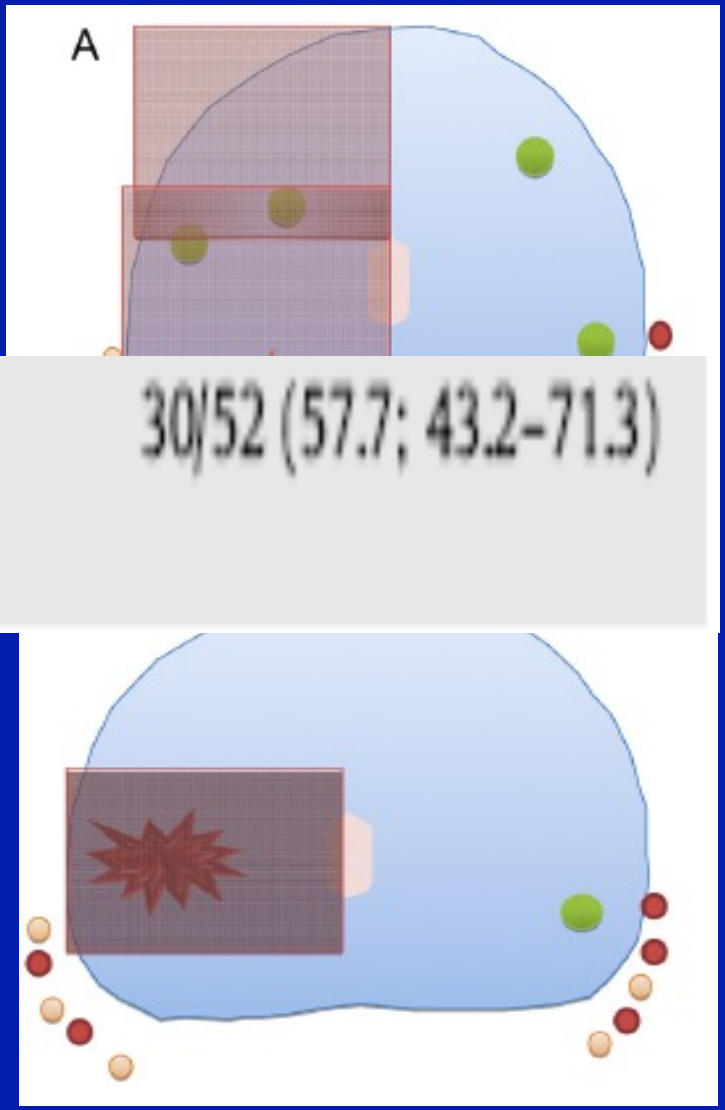
Biopsy Approaches

- mpMRI
  - Only identify index lesion and hemi-ablate
- TPMB
  - Ablate individual lesions-targeted focal therapy

Focal Ablation Targeted to the Index Lesion in Multifocal Localised Prostate Cancer: a Prospective Development Study

Hashim U. Ahmed [a,b,†,], Louise Dickinson [a,b,†], Susan Charman [c,d], Shraddha Weir [b], Neil McCartan [b], Richard G. Hindley [e], Alex Freeman [f], Alex P. Kirkham [g], Mahua Sahu [b], Rebecca Scott [a], Clare Allen [g], Jan Van der Meulen [c,d], Mark Emberton [a,b]*

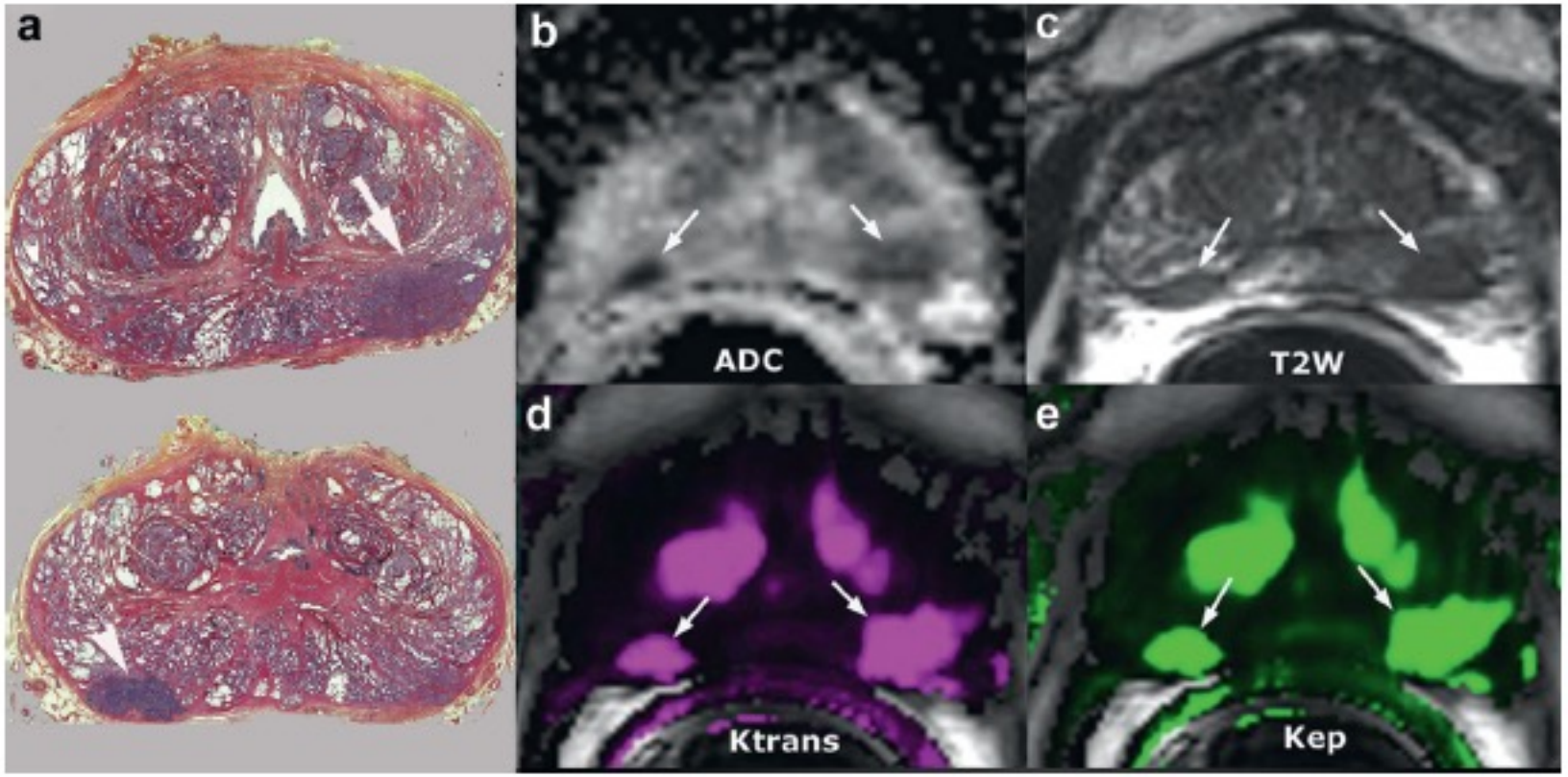




EUROPEAN UROLOGY 68 (2015) 927–936

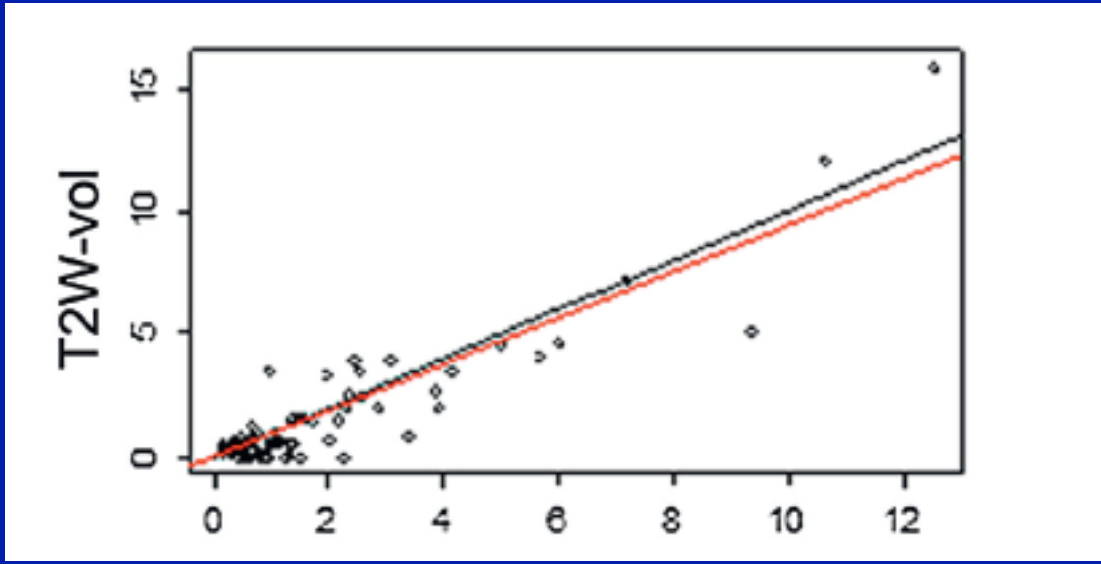
Tumor Target Volume for Focal Therapy of Prostate Cancer—Does Multiparametric Magnetic Resonance Imaging Allow for a Reliable Estimation?

F. Cornud,* Gaby Khoury, Naim Bouazza, Frederic Beuvon, Michael Peyromaure, Thierry Flam, Marc Zerbib, Paul Legmann and Nicolas B. Delongchamps



THE JOURNAL OF UROLOGY®

Vol. 191, 1272-1279, May 2014



	slope [IC95]	p-value	correlation coefficient	r^2
T2W volume	0.94 [0.87-1.01]	0.12	0.88	0.84
DW volume	1.05 [0.98-1.13]	0.16	0.90	0.85
DCE volume	0.65 [0.55-0.76]	$<10^{-4}$	0.62	0.48

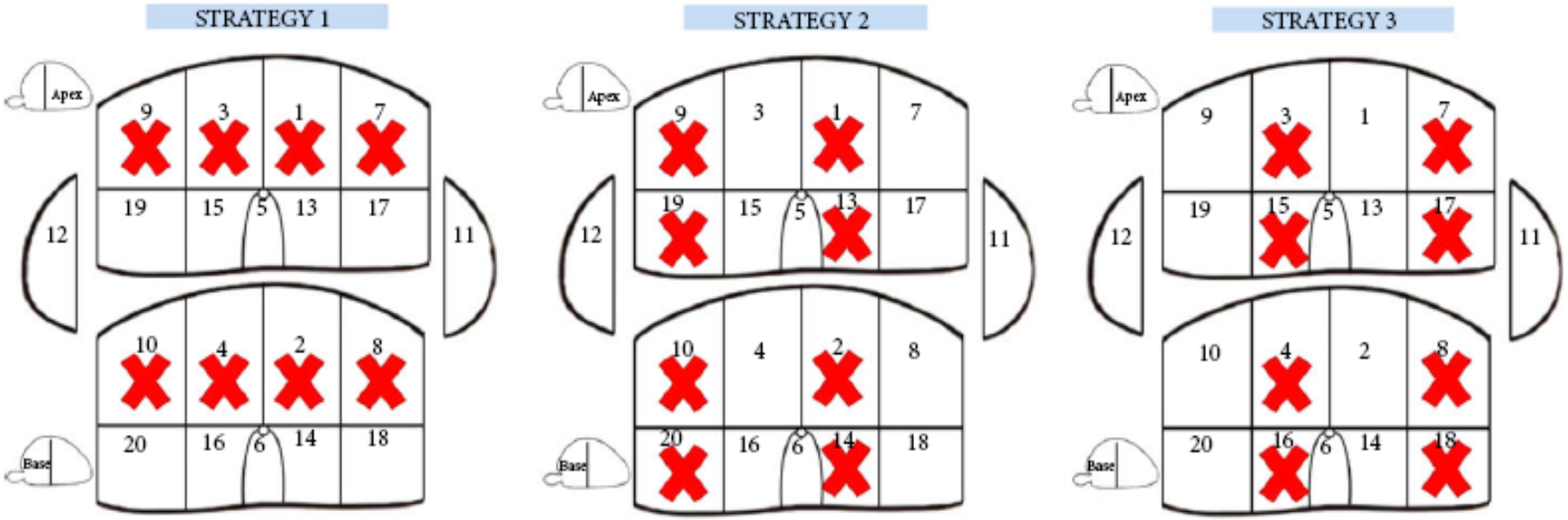
Underestimation in 43/87 (49%) by mean of 0.56 cc (0.005-2.84)

Transperineal Template-Guided Prostate Biopsy and TFT

Transperineal template prostate-mapping biopsies: an evaluation of different protocols in the detection of clinically significant prostate cancer

Massimo Valerio*†‡, Chukwuemeka Anele*†, Susan C. Charman§, Jan van der Meulen§, Alex Freeman¶, Charles Jameson¶, Paras B. Singh**, Mark Emberton*† and Hashim U. Ahmed*†

Fig. 2 Visual representation of the three strategies simulating reported variations of 5-mm TTPM.



N=391

Average number cores 46

	Strategy 1	Strategy 2	Strategy 3
Sensitivity (95% CI), %	78 (73–84)	85 (80–90)	84 (79–89)
NPV (95% CI), %	73 (67–80)	80 (74–86)	79 (72–84)

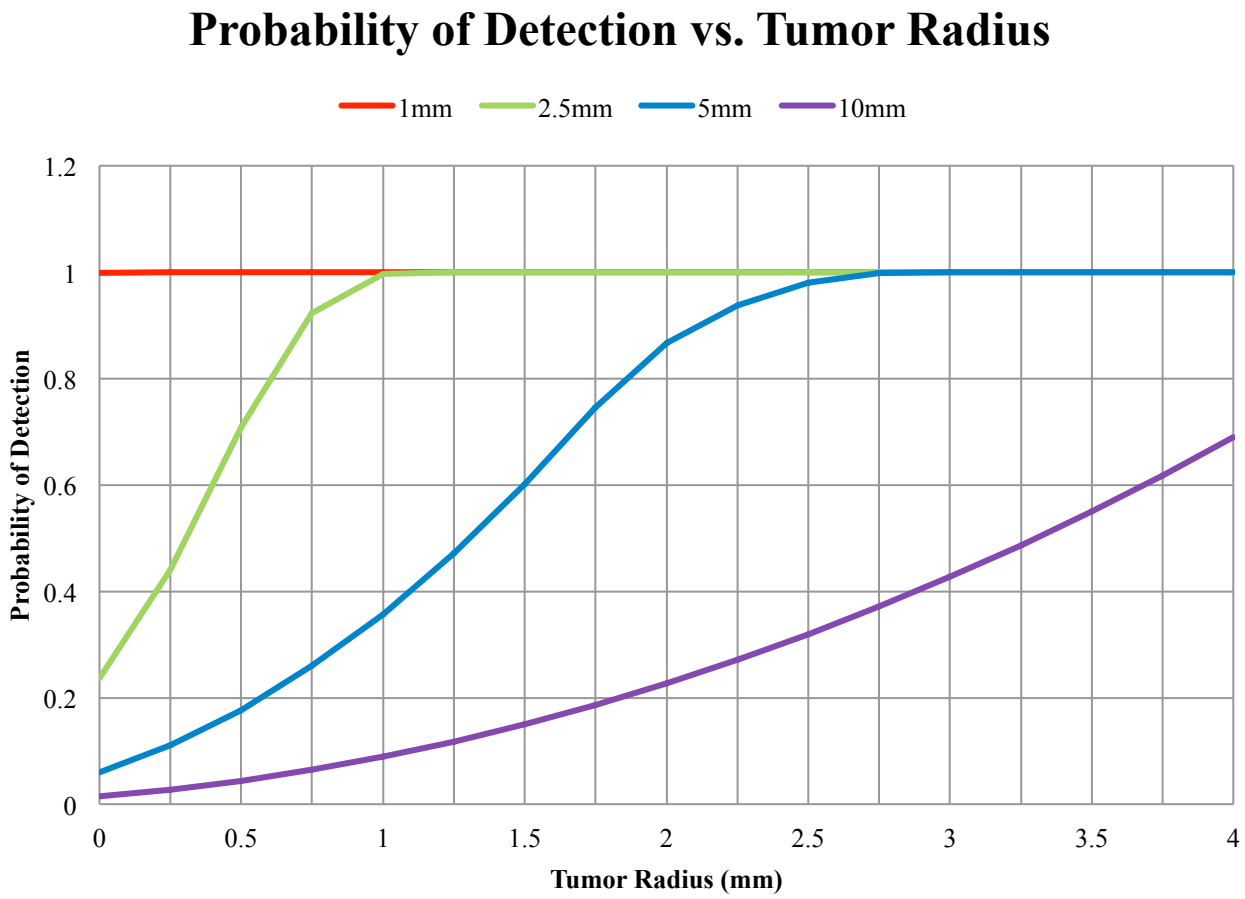
How important is it to *know* all the pathology in the prostate?

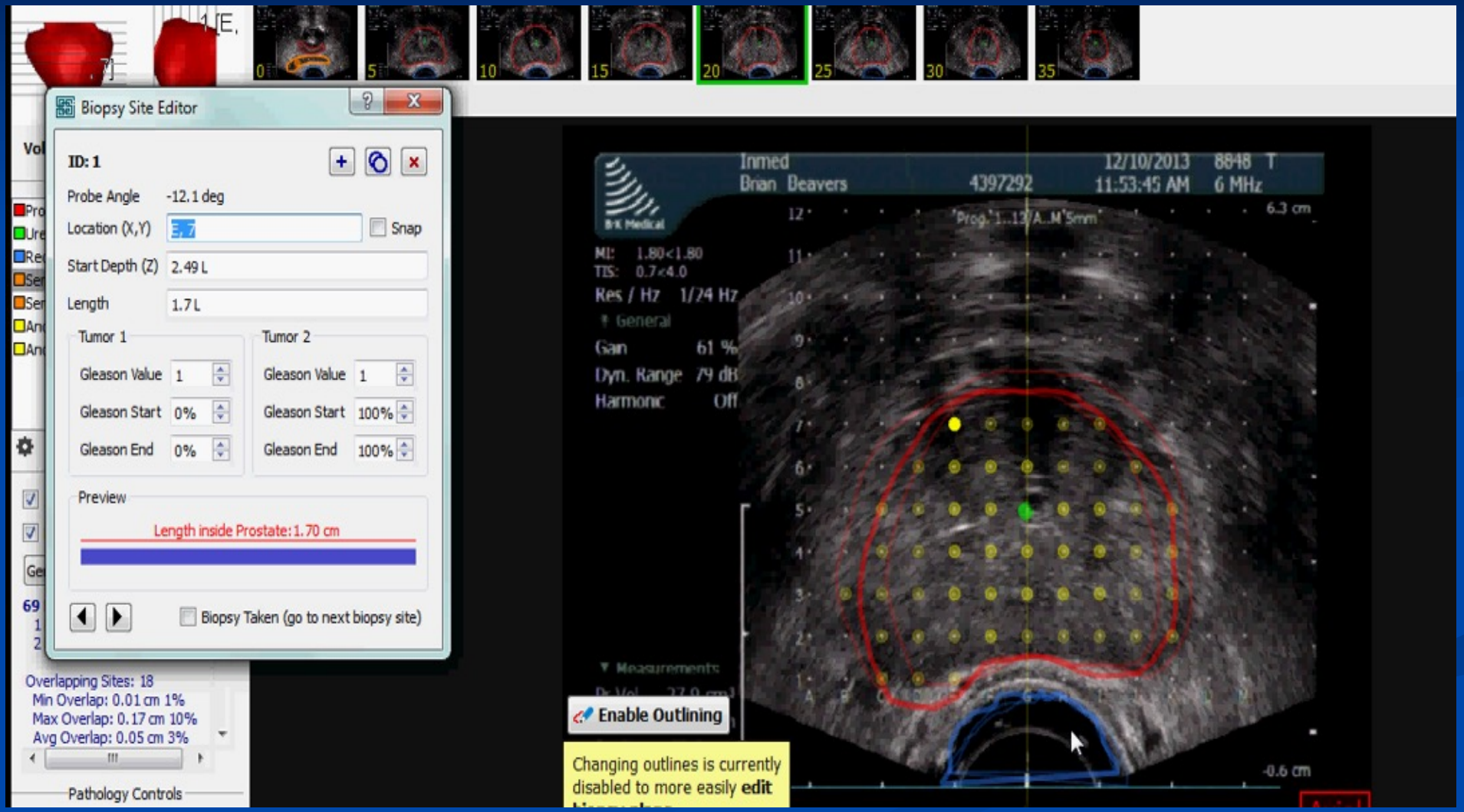
- Crawford et at AUA 2016
  - RP stage was pT2a/b in 4 (16%), pT2c in 13 (52%) and pT3 in 8 (32%). The 2 patients with low volume disease on RP each had 1 core GS 6 with TPMB.
  - TPMB correctly identified 100% of the RP patients.
- Skouteris et al
  - Urinary tract infections are 5x more common in TRUS biopsy compared to TPMB
  - Urinary retention occurred in 7.4% of TPMB and was associated with older age and increased prostate size.

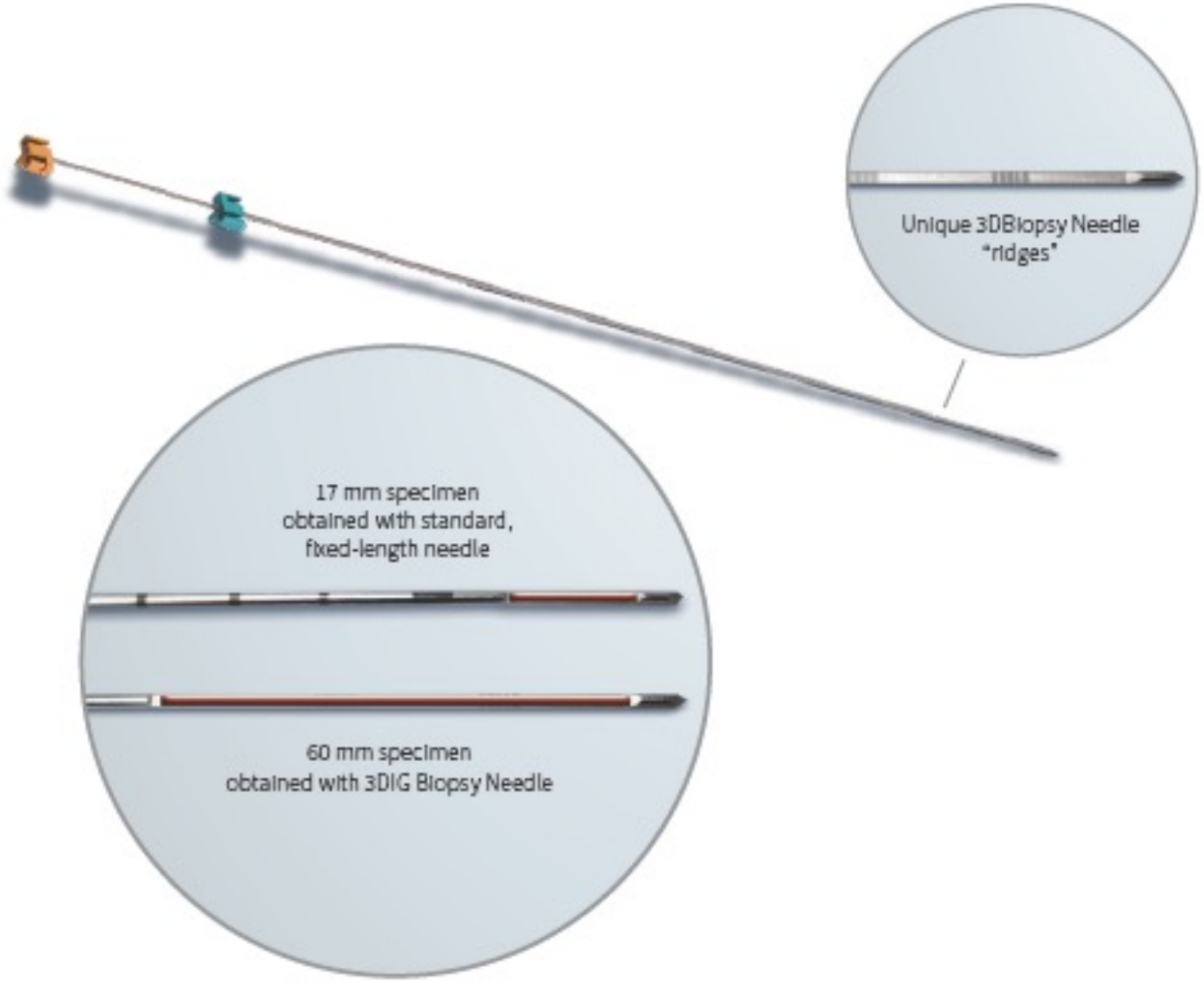
Inadequacy of Current Technology

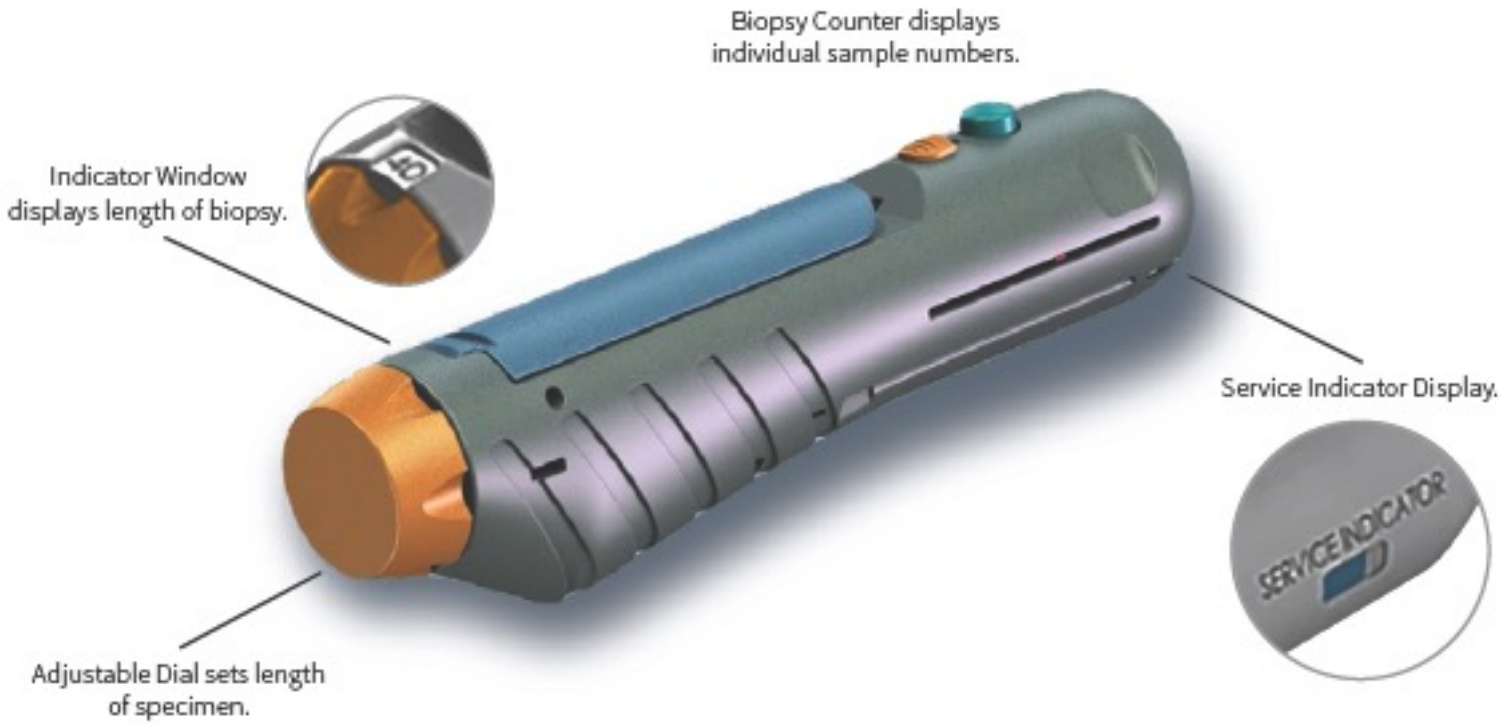
- Biopsy needles designed >30 years ago with limited core size and length
- No software that provides real-time tracking, representation and recall
- Procurement and registry of pathology is time consuming and error prone

Probability of Detection vs. Tumor Radius
(Grid sizes (mm) = 1, 2.5, 5, 10 – 15 gauge needle)

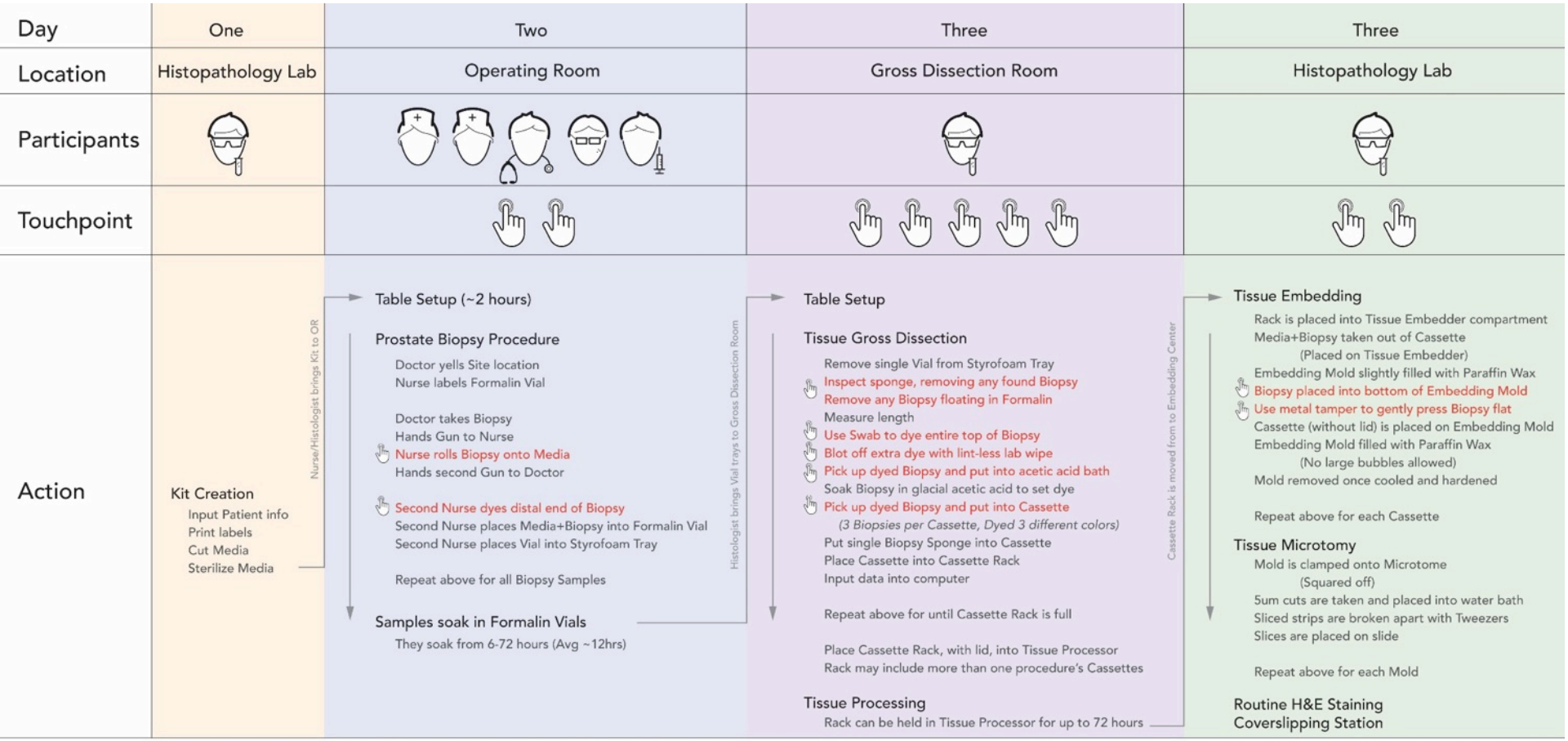



Biopsy Site Editor
ID: 1
Probe Angle -12.1 deg
Location (X,Y)
Snap
Start Depth (Z) 2.49 L
Length 1.7 L
Tumor 1
Gleason Value 1
Gleason Start 0%
Gleason End 0%
Tumor 2
Gleason Value 1
Gleason Start 100%
Gleason End 100%
Preview
Length inside Prostate: 1.70 cm
Biopsy Taken (go to next biopsy site)
Overlapping Sites: 18
Min Overlap: 0.01 cm 1%
Max Overlap: 0.17 cm 10%
Avg Overlap: 0.05 cm 3%
Pathology Controls
Inmed
Brian Beavers
4397292
12/10/2013 11:53:45 AM
8848 T
6 MHz
MI: 1.80<1.80
TIS: 0.7<4.0
Res / Hz 1/24 Hz
General
Gain 61 %
Dyn. Range 79 dB
Harmonic Off
Enable Outlining
Changing outlines is currently disabled to more easily edit


Unique 3DBiopsy Needle
"ridges"
17 mm specimen
obtained with standard,
fixed-length needle
60 mm specimen
obtained with 3DIG Biopsy Needle


Biopsy Counter displays individual sample numbers.
Indicator Window displays length of biopsy.
Service Indicator Display.
SERVICE INDICATOR
Adjustable Dial sets length of specimen.

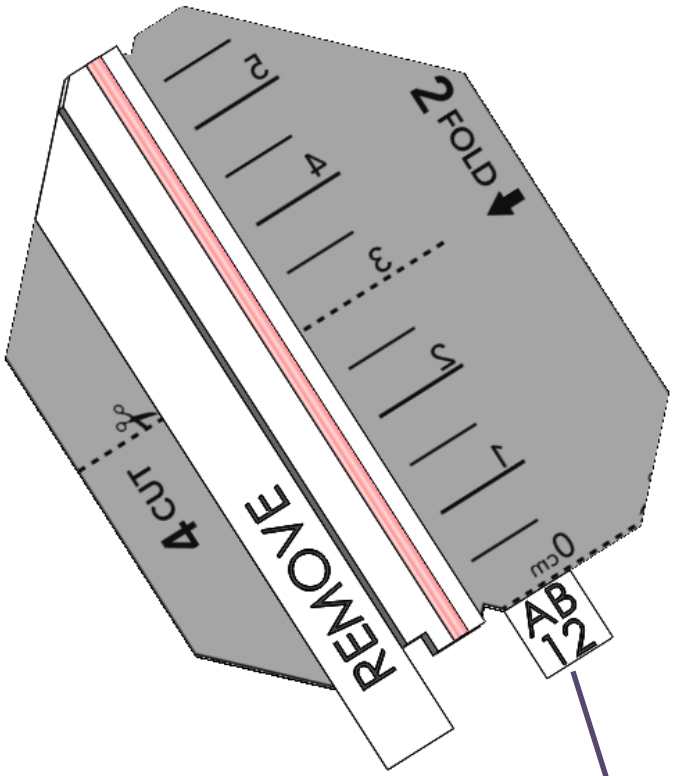
Previous Workflow



The Biopsy Carrier Concept

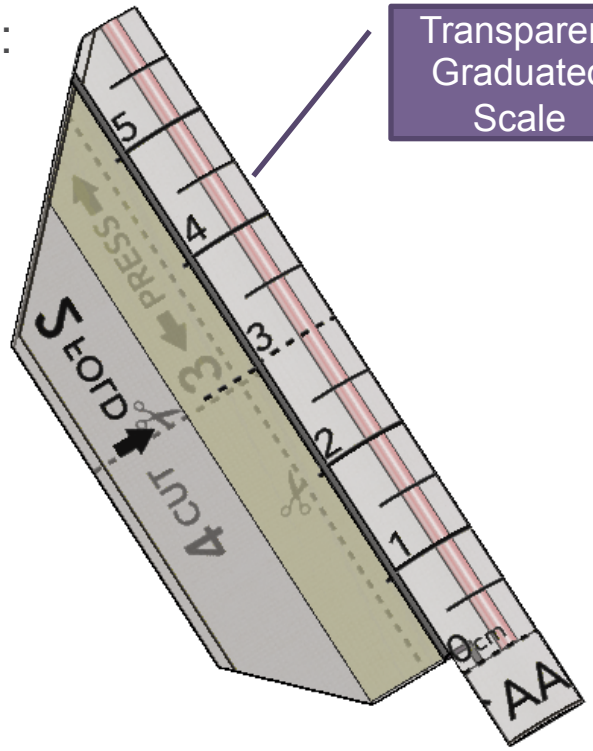
A Biopsy Carrier that stays with tissue sample from the OR to the pathology slide.

Open:



Unique Identifier

Closed:



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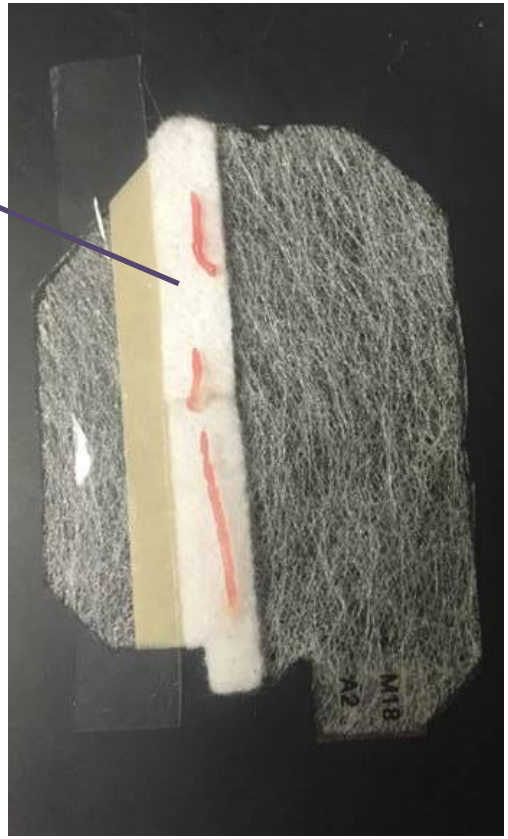
A Biopsy Carrier Prototype

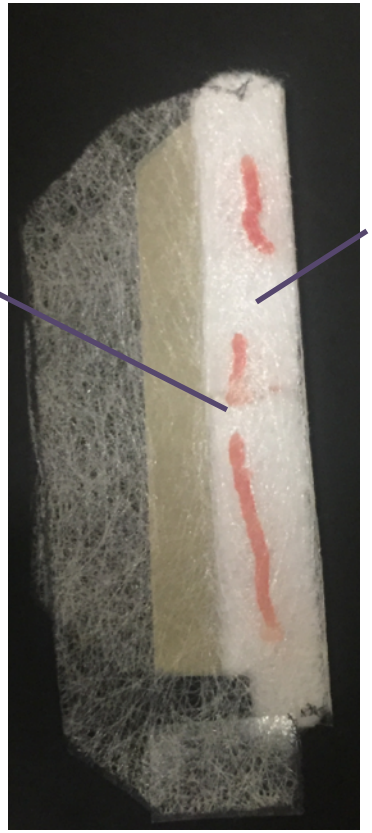
Open:



Non-woven material grabs tissue

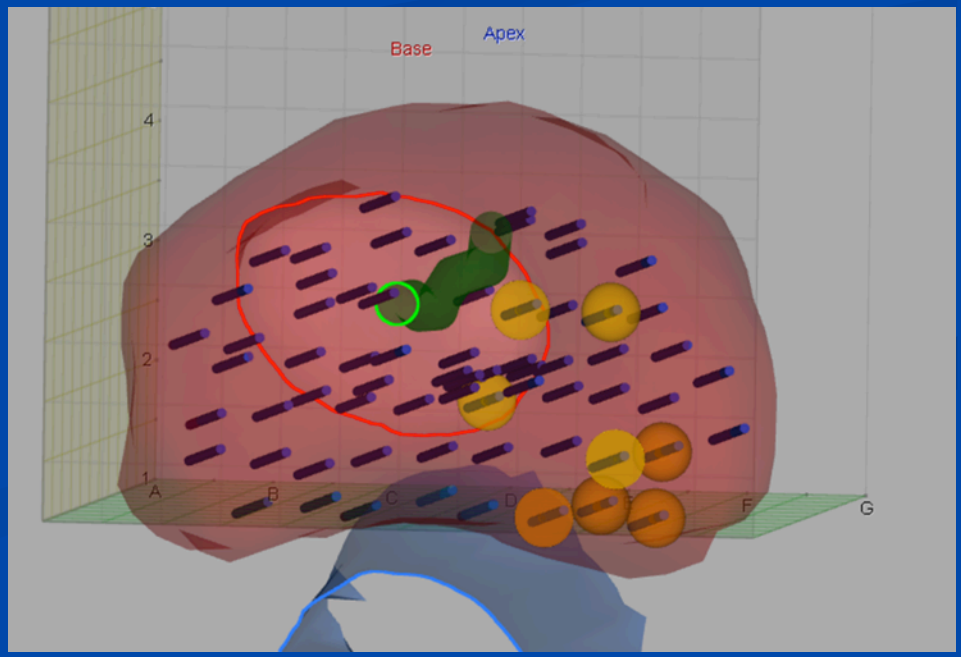
The carrier is able to be processed, embeddable and sliced on microtome

Closed:



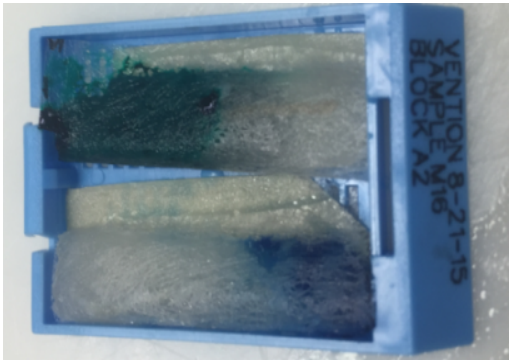
Backer material is transparent and retains sample


9
8
7
6
5
4
3
2
1
A


Base
Apex
4
3
2
1
A
B
C
D
F
G

In the Histology Lab

10. Dye tissue with tissue marking ink. This indicates distal and proximal ends

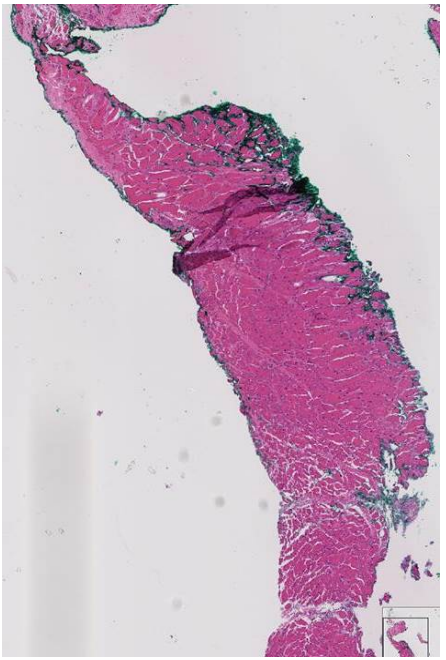


11. Run cassettes through standard tissue processing

In the Histology Lab

14. Run slides through standard H&E staining and cover slip

15. Slide is ready to analyze!



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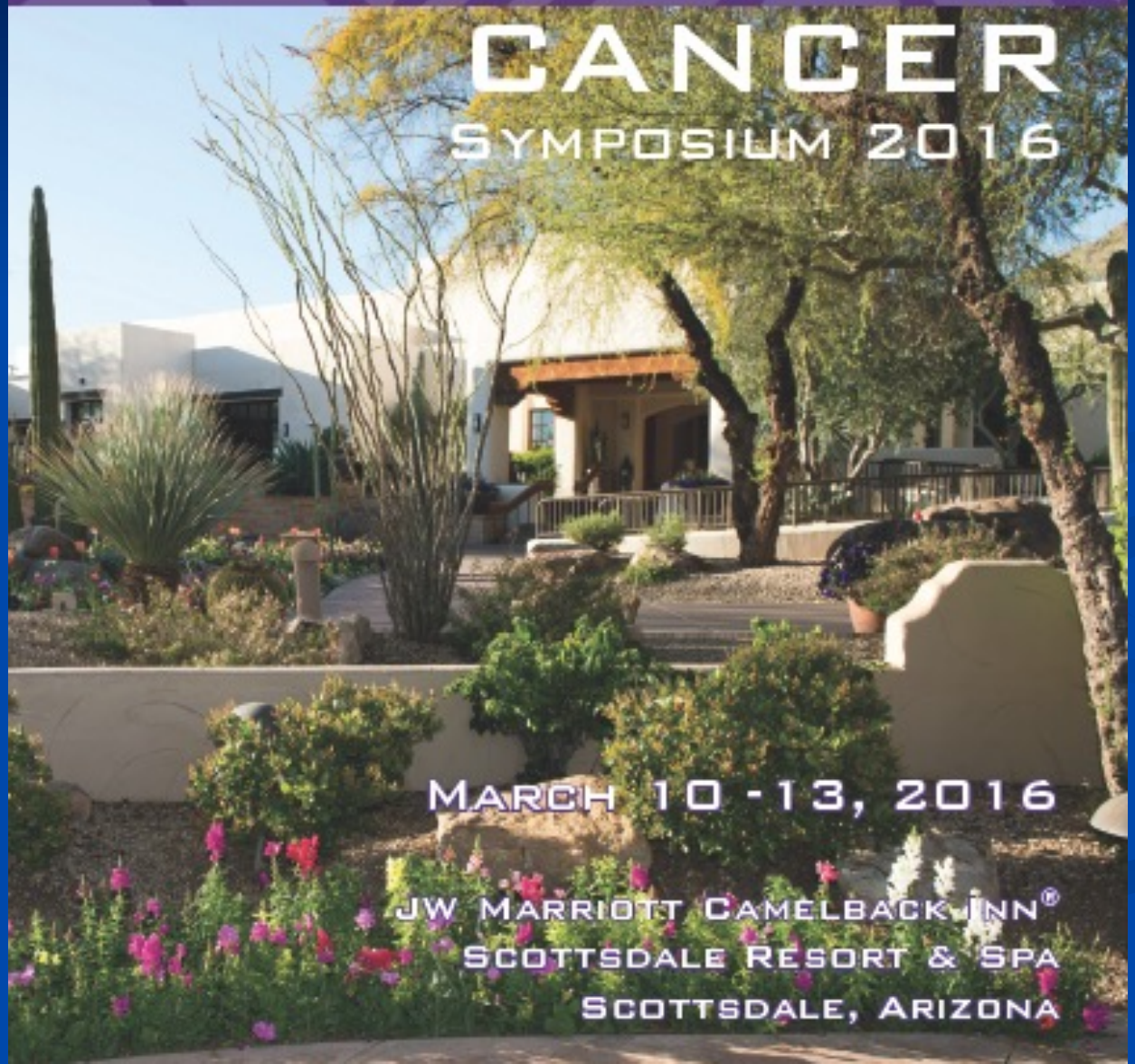
Conclusions

- Selection of surveillance candidates can be improved with mpMRI targeted biopsies or TPMB
- Targeted focal therapy (TFT) requires precise location of ALL significant lesions and THEN a roadmap for treatment planning
- The jury is out as the whether some or all lesions need treatment
- Proof of success (lesion eradication) remains elusive.

21ST ANNUAL SCOTTSDALE

PROSTATE CANCER SYMPOSIUM 2016



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