Trans-rectally Delivered, MRI-Guided Laser Focal Therapy of Prostate Cancer: How We Do It

The Prostate Cancer Support Association of New Mexico
Albuquerque, NM
September 19, 2015

Bernadette Greenwood, BSRS, RT (R) (MR)
Ms. Greenwood has nothing to disclose
STATE of WISCONSIN

OFFICE of the GOVERNOR

Proclamation

WHEREAS on Thursday, June 4, 2015, Milwaukee Area Technical College is hosting a "Wake up and Smell the Coffee – Prostate Cancer Update 2015" session from 11 a.m. – 2 p.m., that is open to the public; and

WHEREAS in the United States alone, new prostate cancer cases for 2014 were estimated at 235,000 and deaths at more than 29,000; and

WHEREAS screening can help diagnose the disease in its early stages, increasing the chances of survival; and

WHEREAS there are no noticeable symptoms of prostate cancer while it is still in the early stages, making screening critical; and

WHEREAS ongoing research promises further improvements in prostate cancer prevention, early detection, and treatments; and

WHEREAS educating everyone about prostate cancer and early detection strategies is crucial to saving lives, and preserving and protecting families;

NOW, THEREFORE, I, Scott Walker, Governor of the State of Wisconsin, do hereby proclaim Thursday, June 4, 2015, as

PROSTATE CANCER AWARENESS DAY

throughout the State of Wisconsin, and I commend this observance to all of our citizens.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Wisconsin to be affixed. Done at the Capitol in the City of Madison this 2nd day of June 2015.

[Signature]
SCOTT WALKER
GOVERNOR

By the Governor:

[Signature]
DOUGLAS A. FOLLETTE
Secretary of State
1. History of Trial #NCT 02243033
2. Literature review
3. Procedure overview
4. Results and conclusions
BREAST MRI

• Complements Mammo / US

• Breast intervention (do a targeted biopsy under MR) per ACR practice guidelines

• Mastectomy vs. lumpectomy and focal treatment

PROSTATE MRI

• Complements PSA / DRE / TRUS

• Prostate intervention (targeted biopsy under MR-guidance)

• MR/US fusion biopsy

• Focal therapy vs. whole-gland, radical treatment (prostatectomy, XRT, ADT)
Breast vs. Prostate Cancer Research

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
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<td>Total NCI</td>
<td>$4,792.6</td>
<td>$4,827.6</td>
<td>$4,966.9</td>
<td>$5,098.1</td>
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<td>AIDS</td>
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<td>Brain &amp; Central Nervous System</td>
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<td>273.7</td>
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<td>76.1</td>
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<td>18.2</td>
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<td>246.7</td>
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<td>Pancreatic Cancer</td>
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<td>89.6</td>
<td>97.1</td>
<td>99.5</td>
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<td>Prostate Cancer</td>
<td>296.1</td>
<td>285.4</td>
<td>285.1</td>
<td>300.5</td>
<td><strong>288.3</strong></td>
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<td>Stomach Cancer</td>
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<td>12.4</td>
<td>15.4</td>
<td>14.5</td>
<td>13.4</td>
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<td>Uterine Cancer</td>
<td>16.6</td>
<td>17.1</td>
<td>18.0</td>
<td>14.2</td>
<td>15.9</td>
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</tbody>
</table>

How did I get here?

**PSA**
- Sensitivity: 34.9%
- Specificity: 63.1%

**DRE**
- Sensitivity: 27.1%
- Specificity: 49.0%

http://www.jyi.org/research/re.php?id=931

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**Current practice**

biopsy negative, but high PSA persists — another systematic ultrasound-guided biopsy at urologist

- **Screening**
- **Diagnosis**
- **Staging**

- **DRE / PSA** +
- **Systematic Biopsy** +
- **Gleason score, % involvement, if high risk, bone scan** + persists

- **PSA**
  - 12 months
Targeted, Focal or Precision Treatment
<table>
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<th>Era</th>
<th>Event</th>
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<td>1920's</td>
<td>Barringer: Transperineal needle biopsy</td>
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<tr>
<td></td>
<td>Young: Open perineal biopsy</td>
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<tr>
<td>1930's</td>
<td>Ferguson: First perineal needle aspiration biopsy</td>
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<tr>
<td></td>
<td>Astraldi: First transrectal biopsy</td>
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<tr>
<td>1940's</td>
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<td>1950's</td>
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<tr>
<td>1960's</td>
<td>Takahashi and Ouchi: TRUS to evaluate prostate</td>
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<td></td>
<td>Watanabe et al.: First clinically useful TRUS images</td>
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<td></td>
<td>McNeal: proposes three distinct glandular zones</td>
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<tr>
<td>1970's</td>
<td>Mid-1980's - improvements in transducer technology and biopsy capability</td>
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<tr>
<td>1980's</td>
<td>PSA test introduced for prostate cancer screening</td>
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<tr>
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<td>McNeal: modern era of systematic prostate biopsy begins</td>
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<td>1990's</td>
<td>Stamey: modified sextant technique to include laterally directed</td>
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<tr>
<td></td>
<td>Nash et al.: peri-prostatic nerve blockade used for biopsy pain management</td>
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<td></td>
<td>Eskew et al.: systematic extended biopsy technique</td>
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<td>2000's</td>
<td>Beyersdorff et al.: MRI-guided prostate biopsy at 1.5T</td>
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<td>2010's</td>
<td>Greenwood et al.: Transrectal MRI-guided laser interstitial thermal therapy of PCA</td>
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<td>Pinto et al.: MRI/US fusion prostate biopsy</td>
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<td></td>
<td>NCCN Guidelines include Multiparametric MRI</td>
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<tr>
<td></td>
<td>Greenwood et al.: transperineal MRI-guided rectal laser ablation</td>
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Adapted from Applewhite, Cancer Control 141, March/April 2001, Vol. 8 No.2
Prostate Biopsy in the 1920’s

Prostate Biopsy in the 1930’s

Prostate Biopsy in the 1960’s

1963 – Takahashi and Ouichi: TRUS to evaluate prostate

1968 – Watanabe et al.: First clinically useful TRUS images

1968 – McNeal: proposes three distinct glandular zones

Prostate Biopsy in the 1980’s

1980’s  
Mid-1980’s – improvements in transducer technology and biopsy capability

1986 – PSA test introduced for prostate cancer screening

1989 – Hodge et al.: modern era of systematic prostate biopsy begins

Prostate Biopsy in the 1990’s

1995 – Stamey: modified sextant technique to include laterally directed

1996 – Nash et al.: peri-prostatic nerve blockade used for biopsy pain management

1997 – Eskew et al.: systematic extended biopsy technique
Figure 1 A 36-core saturation biopsy scheme, as used by Delongchamps et al.


Andriole GL (2009) The lottery of conventional prostate biopsy
Nat Rev Urol doi:10.1038/nrurol.2009.46
Figure 2 Prostate as seen on transrectal ultrasonography during saturation biopsy


Andriole GL (2009) The lottery of conventional prostate biopsy
Nat Rev Urol doi:10.1038/nrurol.2009.46
Saturation Biopsy

Photography courtesy of Thomas Polascik. M.D., Duke University
Saturation Biopsy
Saturation Biopsy
Saturation Biopsy
Prostate Biopsy in the 2000’s

Ultrasound vs. MRI

Figure 7: Ultrasound scan of the prostate gland
“Fast is fine, but accuracy is everything.”

Wyatt Earp
Why MRI for the Prostate Today?

- Easy access to patient for biopsy

Gleason 4 + 3 = 7
What is it? Why does it matter?

Gleason Grades Determine Gleason Score

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Gleason Grades Determine Gleason Score

Original Gleason System Versus 2005 ISUP Modified Gleason System: The Importance of Indicating Which System Is Used in the Patient's Pathology and Clinical Reports

By: Rodolfo Montironi, Liang Cheng, Antonio Lopez-Beltran, Marina Scarpelli, Roberta Mazzucchelli, Gregor Mikuz, Ziya Kirkali and Francesco Montorsi

European Urology, Volume 58 Issue 3, September 2010, Pages 369–373
Published online: 01 September 2010

What is it? Why does it matter?

Genomic testing results
Prostate Intervention in the 2010’s

2010’s  2011 – Greenwood et al.: Transrectal MRI-guided laser interstitial thermal therapy of PCa
        2011 – Pinto et al.: MRI/US fusion prostate biopsy
        2012 – NCCN Guidelines include Multiparametric MRI

Prostate Cancer Early Detection

Repeat Biopsy Technique
Patients with prior negative biopsies, yet persistently rising PSA values should undergo repeat biopsy. Important factors in predicting chance of cancer on repeat biopsy include PSAV and the adequacy of initial biopsy (number of cores, prostate size). Cancer detection rates are higher in men with prior negative sextant biopsies compared to those with prior negative extended biopsies. Yields are highest in the laterally directed cores and the apical cores. Particular attention should be given to apical sampling including the anterior apical horn, which is comprised of peripheral zone. Transition zone biopsies can be considered in repeat biopsy patients. In patients with two negative extended biopsies, yet persistently rising PSA values, a saturation biopsy may be considered. Recent evidence showed that multiparametric MRI (T2 weighting plus functional techniques such as diffusion weighting) can aid in cancer detection in patients with persistent PSA elevation but negative TRUS-guided biopsy (reviewed by Pinto et al.). Additional MRI imaging can be considered in select cases.
Adoption of Prostate MRI

• MRI Volumes Reached 34.9M in 2014
  • The two highest volume categories of MRI imaging were Spine (23%) and Brain (22%) procedures.

• Prostate
  • From 2013 to 2014, the biggest percentage increase in MR procedure volume is for prostate procedures which more than doubled from 0.2 to 0.5 million
  • Though the volume of prostate procedures is only 1% of 2014 MR procedures, growth of 150% shows application adoption

• Other Growth Areas
  • Pelvis & abdomen procedures grew 28% from 2.5 to 3.2 million
  • Chest procedures grew ~ 25% from 0.8 to 1.0 million procedures.

IMV: MRI 2014 Outlook Report
Leading International Scientists Announce New Guidelines for Improved Prostate Cancer Diagnosis

Scientific Cooperation Aims to Accelerate Transfer of High Quality Prostate MRI from Laboratories to Clinics

- The Joint Steering Committee of the American College of Radiology (ACR), AdMeTech Foundation and the European Society of Urogenital Radiology (ESUR) today released new clinical imaging guidelines to assist early detection and treatment of prostate cancer. The new guidelines were announced at the meeting of AdMeTech’s International Prostate MRI Working Group (AdMeTech's Group) held in conjunction with the Annual Meeting of the Radiologic Society of North America (RSNA).

The Joint Steering Committee developed Prostate Imaging Reporting and Data System Version-2, (PI-RADSv2) as global guidelines for high quality multi-parametric prostate MRI service. This work has built on the initial PI-RADS standardization, which was recommended by AdMeTech's Group in 2010 and created by ESUR in 2011. PI-RADSv2 has defined minimum technical requirements for creating images and in coordination with RSNA's Radiologic Lexicon Committee, set standards for communicating the risk and location of aggressive prostate cancer. These clinical guidelines were established in order to expedite wide-scale transfer of the high quality clinical service from the few leading research centers to the international medical community.

* American College of Radiology, www.acr.org
National Guidelines - 2009

NCCN® Practice Guidelines in Oncology – v.2.2009

Prostate Cancer

INITIAL MANAGEMENT OR PATHOLOGY

SURVEILLANCE

- PSA as often as every 3 mo but at least every 6 mo
- DRE as often as every 6 mo but at least every 12 mo
- Repeat prostate biopsy as often as annually

RECURRENCE

PSA, DRE, prostate biopsy may be done less frequently

Active surveillance

Life expectancy ≥ 10 y

Life expectancy < 10 y
Repeat Biopsy Technique
Patients with prior negative biopsies, yet persistently rising PSA values should undergo repeat biopsy. Important factors in predicting chance of cancer on repeat biopsy include PSAV and the adequacy of initial biopsy (number of cores, prostate size). Cancer detection rates are higher in men with prior negative sextant biopsies compared to those with prior negative extended biopsies. Yields are highest in the laterally directed cores and the apical cores.\textsuperscript{90} Particular attention should be given to apical sampling including the anterior apical horn, which is comprised of peripheral zone.\textsuperscript{91} Transition zone biopsies can be considered in repeat biopsy patients. In patients with two negative extended biopsies, yet persistently rising PSA values, a saturation biopsy may be considered.\textsuperscript{92} Recent evidence showed that multiparametric MRI (T2 weighting plus functional techniques such as diffusion weighting) can aid in cancer detection in patients with persistent PSA elevation but negative TRUS-guided biopsy (reviewed by Pinto et al.\textsuperscript{93}). Additional MRI imaging can be considered in select cases.
ESUR prostate MR guidelines 2012

Jelle O. Barentsz · Jonathan Richenberg · Richard Clements · Peter Choyke · Sadhna Verma · Geert Villeirs · Olivier Rouviere · Vibeke Logager · Jurgen J. Fütterer
TRIM Compared to 2nd or 3rd TRUS Bx

*Based on 71 patients

J Urology 2010; 183: 520-528
Ultrasound vs. MRI

ACR Appropriateness Criteria
ACR PI-RADS V2, published 2014

Prostate Cancer — Pretreatment Detection

https://acsearch.acr.org/docs/69371/Narrative/
TRUS biopsy

Needle penetrates next to the tumor or does not reach it

Less aggressive tumor is biopsied

Less aggressive part of the tumor is biopsied

The patient can end up on active surveillance while harboring clinically significant disease

Courtesy Jelle Barentsz, M.D., PhD, Univ. Medical Center, Nijmegen, The Netherlands
Prostate Intervention in the 2010’s

2011 – Pinto et al.: MRI/US fusion prostate biopsy

2012 – NCCN Guidelines include Multiparametric MRI
Rationale for Prostate MRI

- Ability to biopsy tumor suspicious regions in the prostate

- MRI guidance for biopsy planning to target tumor-suspicious regions (TSRs)
Transrectal Interventional MR Guidance Device

Interventional Device

Interventional Instruments

18 G MR compatible
TRUS-Biopsy & MR-Biopsy vs. Prostatectomy

Hambrock 2010  SCBTMR “Lauterbur Award”
MR-guided Laser Focal Therapy

1. Water-cooled disposable laser probe
   980 nm diode laser
   1.65 mm in diameter

2. Endorectal needle guide

3. 14 G titanium coax needle

Heat-diffusing tip
Laser Workstation

- 15 Watt laser (Fiberoptic)
- Standard power plug
- Integrated to MR (Ethernet)
- Software: real-time prediction model; MR thermometry; safety control features
- FDA 510(k) clearance
  Sept 10, 2008
FDA cleared with broad, general indications

“for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy. . . in neurosurgery, general surgery, urology. . .” and multiple additional named specialties.

Technology is FDA cleared for commercialization in the US:

- Laser Applicator K053087 (March 2006)
- Laser System K060304 (March 2006)
- Workstation Software K063505 (December 2006)
- Visualase Thermal Therapy System K071328 (August 2007) K081656 (September 2008)
- 30 W Laser System K092197 (November 2009)
Thermometry interface
MR Thermometry and Image Generation

https://www.bing.com/images/search?q=baking+a+cake&view=detailv2&&id=E0619BA4C321DB343BDA407A101E9D9E45BB0B6C&selectedIndex=4&ccid=v6Af2VQj&simid=607992663429939575&thid=JN.t2FcJIB1rEYOUlBkmIhvLoIajxhist=0
MR Thermometry and Image Generation

Proper parameter selection allows for exploitation of tissue properties:

- Tissue contrast
- Flow quantification
- Perfusion
- Diffusion
- Phase shifts

- Echo Time
- Repetition Time
- Flip Angle
- Bandwidth
- Signal Averages
- Matrix
Contouring and Safety Controls
Real Time MR Thermometry

Test Dose
4W (27%)
~100 degrees F

Treatment Dose
12W (80%)
90 sec
Irreversible Damage Estimate
Laser interstitial thermal therapy margins

Precision and Control

Sharp transition zone between dead and viable tissue

Transition zone in HIFU can be 5-10 mm
Transition zone in RF and Cryo can be 5-10 mm
Visualase transition zone is less than 1 mm

Source
http://jcp.bmjjournals.com/content/53/5/391/F1.expansion

* Photos at different scales

US-guided HIFU lesion
Necrotized tissue
Technical aspects of trans-rectally delivered, MRI-guided laser therapy of prostate cancer

Poster No.: C-1045
Congress: ECR 2011
Type: Scientific Paper
Authors: B. M. Greenwood¹, J. F. Feller², R. McNichols³; ¹Pewaukee, WI/US, ²Indian Wells, CA/US, ³Houston, TX/US
Keywords: Genital / Reproductive system male, Oncology, Pelvis, MR, CAD, Image manipulation / Reconstruction, Ablation procedures, Laser, Computer Applications-General, Tissue characterisation
DOI: 10.1594/ecr2011/C-1045
Results: NCT 02243033, as of Sept. 2015

• 45 patients
• 4 salvage patients for BCR
• 62 cancer foci treatments
• Age range: 50-81 years
• Initial PSA
  Range = 0.9 - 28
  Mean = 7.12
• MRI tumor volume
  Range = 0.1 – 4.1 cc
  Mean = 0.88 cc
Results: Treatment Naïve

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<th>Gleason Score*</th>
<th>Patients</th>
<th>Cancer Foci</th>
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<td>3+3</td>
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<td>3+4</td>
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<td>4+3</td>
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<td>TZ</td>
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<td>CZ</td>
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* Four patients had GS6 and GS7 lesions, one had both 3+4 and 4+3
† Seven patients were treated for multifocal cancer
Results: Salvage

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<td>Proton beam</td>
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<td>Cryotherapy</td>
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<table>
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<th>Gleason Score</th>
<th>Cancer Foci</th>
<th>Patients</th>
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<tbody>
<tr>
<td>3+3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3+4</td>
<td>1</td>
<td>1</td>
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<tr>
<td>4+3</td>
<td>3</td>
<td>2</td>
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<tr>
<td>4+4</td>
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<tr>
<td>4+5</td>
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<td>1</td>
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</table>
Results: Treatment Naïve

• Total procedure time = 1.5-4.0 hours
  Goal of eliminating T2W / ADC map attained initially in 80%
  MRI vol. of coagulation necrosis 1.2-11.8 cc
• No serious adverse events, no morbidity!
  2 cases of asymptomatic periprostatic necrosis
  3 cases of retention cyst
  13 patients with positive biopsy at treatment site
    consistent with residual/recurrent cancer
• Positive margin rate = 26%
• Incidence cancer rate = 6%
• 10 patients retreated with laser focal therapy
Results - PSA

47% decrease of mean PSA 1 year after laser focal therapy
Results - IPSS

\[ y = 8.4191 \times 10^{-04} \]
\[ R^2 = 0.0002 \]
Results - SHIM

\[ y = 15.821x^{0.0149} \]
\[ R^2 = 0.012 \]
Results: Patient Withdrawal

• 1 patient expired from metastatic melanoma
• 1 patient withdrew for personal reasons
• 1 patient withdrew after negative 6 month bx (GS 3+3) because of travel
• 5 patients went on to whole gland therapy (11%)
  • 4 incidence cancer patients (2 GS 4+4, 1 GS 4+3 multifocal, 1 3+4) elected RP*
  Importantantly, no additional technical difficulty reported with RP
  • 1 GS 3+3 elected PBT before 6 month Bx

*One 4+4 was downgraded to 4+3 at surgery
Small Series Conclusions

1. Outpatient MR guided transrectal laser focal therapy of prostate cancer is feasible and safe
2. Positive margin rate = 26%
3. Whole gland therapy rate = 10%
4. Incidence cancer rate = 6%
5. Patients are still re-treatment viable (focal or whole gland therapy)
6. Continuity of imaging modality:

   Multiparametric MRI >> MR Guided Bx >> MR Guided Focal Therapy
Take Home Message

Establishing an MRI based prostate laser focal therapy program is a multi-disciplinary team sport!
MRI Program for Detection and Treatment of Prostate Cancer

I. Multi-parametric MRI of the prostate
II. MR guided biopsy
III. MR guided focal laser ablation of prostate cancer (Investigational)

MRI is the GPS for detecting and localizing prostate cancer!
Acknowledgements

DMI RESEARCH TEAM
• John Feller, MD
• Stuart May, MD
• Bernadette M. Greenwood, BSc
• Roger McNichols, PhD (Visualase Inc.)
• Axel Winkel (Invivo-Germany)
• Wes Jones

• Andrew Farrall, PhD
• Elda Railey, Co-founder Focus on Research
Thank you for your attention!

bernadette.greenwood@desertmedicalimaging.com