Quality of Life with an Aging Prostate:
The Sperling Prostate Center Protocol

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As men age, physiological changes affect QOL

- Testosterone levels ↓ (low T)
- Prostate gland volume ↑ (benign prostatic hyperplasia)
- Prostate cancer risk ↑ (PCa)
- Objective: How Sperling Prostate Center protocols address these
Today’s objective

How the Sperling Prostate Center addresses men’s health aging-related issues and improves QOL
Testosterone deficiency or low-T

- Generally defined as < 300 ng/dL
- Affects estimated 2% of men in midlife
- Numbers increase with aging (50% of men age 80)
- More common with other health risks (e.g. diabetes, obesity)
Low-T impacts men’s QOL

• Erectile dysfunction (ED)
• Energy loss/fatigue
• Reduction in lean muscle mass and strength
• Mood changes (depression, irritability)
Benign prostatic hyperplasia (BPH)

- Affects about 50% of men between ages 51-60
- 70% at age 60
- 90% at age 70
BPH reduces men’s QOL

- More frequent need to urinate
- Sense of urgency
- Nocturia
- Difficulty urinating
- Weak stream/inadequate bladder emptying
- Increased risk of UTIs
- Medications may not help or have unpleasant side effects
Increased risk of prostate cancer (PCa)

• About 2/3 of cases are diagnosed at age 65+
• Generally, the greater age at Dx, the less aggressive the disease
Prostate cancer treatment can impair QOL

Radical prostatectomy risks
- Incontinence
- ED

Radiation risks
- late onset dysfunction (bladder, sexual, bowel)
- secondary cancers

Androgen deprivation therapy (ADT; chemical castration) – breast tenderness, mood shifts, loss of bone density, loss of libido, ED, hot flashes, etc.
Improvements in Clinical Practice
Protect & Preserve QOL as Men Age

• Testosterone Replacement Therapy
• Minimally invasive BPH treatments
• Focal therapies for PCa
Improvement: Testosterone replacement therapy (TRT)

- Level 1 evidence supports safety and improved QOL
- Improves sexual function/desire
- Improves body composition
- Improves bone density

TRT – generally safe

Possible risks include:

• Biochemical changes can include change in cholesterol & lipid levels
• Lower sperm count
• Rise in PSA
• Increased red blood cell count
• Higher risk of blood clots
• May increase risk of heart attack and stroke
Controversy: TRT and PCa

• 1940s to 1990s – belief that high total T levels fuel PCa growth
• Based on observing effect of ADT/chemical castration on PSA and T levels
• Assumption that testosterone “fuels” PCa
• Conclusion – PCa contraindicates TRT
• Starting in 2004, new research challenged that 60-year old belief
Morgentaler’s published work – paradigm shift

Harvard expert Abraham Morgentaler

• 2004 – Men with high T levels had no greater PCa risk

• 2008 – Limited ability of androgens to stimulate PCa growth once androgen receptors in prostate tissue are saturated\(^2\)

• This “saturation model” began changing old beliefs

• Now a growing body of evidence supports TRT safety for PCa patients with low-T\(^3\)


Ongoing studies

• Some controversy and questions remain
• Paradoxically, recent findings correlate low blood levels of free T and overall T with PCa progression
• Gat-Goren hypothesis (free T saturation in prostate due to vascular problem) offers possible explanation\(^4\)

\(^4\)San Francisco IF, Rojas PA, DeWolf WC, Morgentaler A. Low free testosterone levels predict disease reclassification in men with prostate cancer undergoing active surveillance. *BJU Int.*, 2014
What’s the Bottom Line?

Need excellence in monitoring
➢ TRT risks in general
➢ TRT for PCa patients
Improvement: Minimally invasive BPH therapies

Medications may be ineffective or have unpleasant side effects

Conventional surgical interventions to relieve symptoms are transurethral

- Transurethral resection of the prostate (TURP)
- Transurethral needle ablation (TUNA)
- Laser vaporization (e.g. GreenLight Laser)
- Urolift system
- Rezum
What’s the bottom line?

• Transurethral procedures: recovery, efficacy, and risks vary
• Need intervention alternative to transurethral procedures
Improvement: Focal therapy for PCa is now recognized

- Mid-1990s ushered in PSA screening (early detection)
- Prevailing belief then: PCa = multifocal disease
- Standard of care was 2 choices: radical tx or WW
- Early 2000s pathology evidence → 1/3 of cases are unifocal
- Around 2010, shift in belief begins regarding insignificant vs. significant PCa
- Groundswell in patient awareness about over-tx and under-tx
- Radical treatments (surgery, radiation, cryotherapy) put QOL at risk
- Watchful waiting/Active Surveillance risks missing tx window
What’s the bottom line?

- Need better PCa-specific early detection
- Need more accurate diagnosis to enable best treatment match
- Need a middle-ground alternative to radical tx
- Minimum risk of side effects that lower QOL
- Maximum cancer control
- Leave future tx options open
- Rational alternative to WW/AS
The prostate health game changer:

3 Tesla
Multiparametric MRI
Multiparametric MRI (mpMRI)

- Imaging revolutionizes prostate detection, diagnosis, and treatment.
- Powerful 3 Tesla magnets produce very high resolution 3-D images.
- Specific scanning sequences (parameters) characterize healthy vs. diseased tissue:
  - Anatomy
  - Motion of water molecules
  - Blood flow
  - PCa aggressiveness
- mpMRI achieves baseline and prostate monitoring.
- mpMRI enables image-guided biopsy (dx) and Focal Laser Ablation (tx).
Benefits of mpMRI

• Excellent functional soft-tissue contrast contrary to TRUS and CT
• Identify and localize diseased tissue (inflammation, BPH, PCa, etc.)
• Guide probes into targeted tissue for biopsy or treatment
• Monitor and control interventions in real-time
• No exposure to ionizing radiation as with CT scans or X-rays
mpMRI: Portrait of a Prostate

In conjunction with ever-improving biomarkers (e.g. testosterone blood levels, PSA/variants, genomic analysis), mpMRI information has a direct bearing on QOL as men face age-related health changes:

• TRT - baseline before starting, then periodic monitoring
• BPH - image-based prostate profiling
• Suspected PCa - identification of suspicious area and in-bore targeted biopsy
• Diagnosed PCa - qualifying patients for AS vs. tx
• Diagnosed BPH or PCa, qualifying patients for best tx choice including focal tx
What’s the bottom line?

A picture is worth a thousand words. mpMRI has permanently changed the prostate health landscape and empowers men and their doctors to make the most informed decisions and treatment matching.
Focal Prostate Therapy

Targeted ablation

Hemiablation

Zonal ablation
MRI-guided Focal Laser Ablation (FLA)

The Sperling Prostate Center is the leading pioneer and practice in MRI-guided FLA for focal PCa tx.

• Focal Laser Ablation was originally developed to treat brain tumors
• MRI-guided, precision placement (transrectally) of a slender optical fiber that carries the laser light beam
• When the tip of the fiber is positioned in the targeted tissue, the beam is activated
• When the laser contacts tissue it generates a sphere-shaped zone of heat intense enough to coagulate (but not vaporize) tissue
The FLA treatment process

- Outpatient
- No general anesthesia
- Each ablation lasts 2-4 minutes and includes an additional ablation “safety margin”
- Temperature monitoring assures precise zone of destruction and correct temperature
- Multiple ablations are possible during the same treatment by repositioning the fiber
- After ablation, mpMRI confirms no viable tumor tissue
- Procedure duration typically 1.5 hours
Confirming FLA ablation zone

MRI-guided FLA creates ablation with no evidence of viable cells in treated regions.

mpMRI images following FLA using contrast enhancement are more reliable than damage-estimation maps.
Patient selection and FLA advantages

• mpMRI to detect suspicious area(s)
• In-bore MRI-guided targeted biopsy into suspicious areas = most accurate sampling
• Confirmation of tumor focality and significant/insignificant PCa on biopsy
• Patient QOL and preferences (take whole person into account)
Advantages for qualified patients

- Zero-to-minimal risk of urinary and sexual side effects
- Outpatient procedure
- Very rapid recovery and return to normal activities
- Very high QOL
- Cancer control comparable to whole-gland procedures
- Repeatable if necessary
- Leaves all future treatment options open if necessary
### Table 2 – Early functional and oncologic outcomes (n = 25)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>After ablation (3 mo)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUASS, median (IQR)</td>
<td>5.5 (3–13.5)</td>
<td>5 (2–10.75)</td>
<td>0.112 a</td>
</tr>
<tr>
<td>SHIM score, median (IQR)</td>
<td>20.5 (12.75–24)</td>
<td>21 (16–24)</td>
<td>0.205 a</td>
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<tr>
<td>Incontinence (%)</td>
<td>0</td>
<td>0</td>
<td></td>
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<tr>
<td>Mean PSA (ng/ml)</td>
<td>5.3</td>
<td>2.9</td>
<td>0.0003 b</td>
</tr>
<tr>
<td>Residual cancer in FA (%)</td>
<td>4</td>
<td></td>
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</tbody>
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AUASS = American Urological Association Symptom Score; SHIM = Sexual Health in Men; IQR = interquartile range; PSA = prostate-specific antigen; FA = focal abnormality.

a Wilcoxon signed-rank comparison between baseline and 3 mo.
b t-Test comparison between baseline and 3–6 mo.
FLA for BPH

• Focal Laser Ablation for BPH is an alternative to transurethral procedures
• The outpatient treatment is similar to FLA for PCa (transrectal) so there is no urethral entry or tissue damage
• The ablated area gradually shrinks as harmless scar tissue forms and then is reabsorbed
• Pressure/constriction of the urethra is relieved as prostate volume reduces
• This alternative to transurethral treatments
• Zero-to-minimal temporary side effects
• Very rapid recovery/return to normal activities
• Durable
The Sperling Prostate Center Protocol

*Excellence in Protecting and Maintaining Prostate Health*

- Testosterone Replacement Therapy
- BPH
- Prostate Cancer Detection, Diagnosis, and Image-Guided Treatment
The Sperling Prostate Center Protocol for TRT

- Baseline mpMRI prior to TRT
- Monitor changes in prostate at regular intervals as prescribed using mpMRI
- Monitor PCa patients on TRT during AS
- Preserves and protects QOL
The Sperling Prostate Center Protocol for BPH

- Baseline mpMRI
- Evaluate sources of anatomic compression or blockage of urethra
- Ongoing monitoring using mpMRI for patients simply watching and waiting
- Ongoing monitoring using mpMRI for patients on medications
- Treatment planning and symptom relief using MRI-guided FLA
- Restores QOL
The Sperling Prostate Center Protocol for PCa

- Baseline mpMRI
- PCa detection using mpMRI
- PCa diagnosis using real-time MRI-guided biopsy in conjunction with other clinical factors
- Tx planning enhances effectiveness of any whole-gland or focal tx option
- MRI-guided FLA for qualified patients
- Monitoring patients on AS
- Annual post-treatment mpMRI after any tx, in conjunction with PSA/biomarkers
- Protects and maintains QOL before, during and after PCa treatment
To review:

• Age-related changes in testosterone and prostate health can lower QOL
• A man’s well-being and self-image are intimately connected with his pelvic health
• Our protocol offers mpMRI and minimalist treatments that preserve quality of life and get men back on the road of life.