

Current Issues in Male Health

Friday, June 17, 2011
Madrid I ~ 2:10pm - 2:55pm

Shea Samara, MD
3433 NW 56th St, Ste 920
Oklahoma City, OK 73112
Tel: 405-943-1137
Fax: 405-947-0731
Email: dcarter@ssook.org

Objectives

- Provide an overview of BPH, ED and treatment for male incontinence

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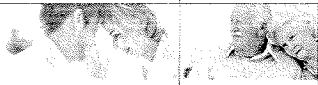
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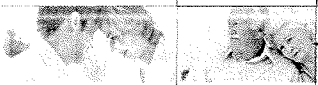
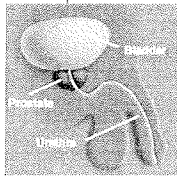
Corporate Organizations

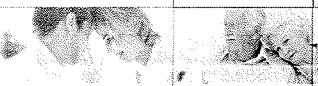
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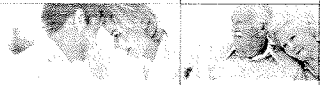
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<p>E.N. Shea Samara, M.D. June 17, 2011</p>	
<h3>Men's Health Update</h3> <p><i>BPH, Erectile Dysfunction and Male Incontinence</i></p>	

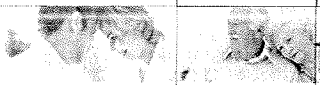
	
<h4>Overview of the Prostate</h4> <ul style="list-style-type: none">• Walnut-sized gland at base of the male bladder• Surrounds the urethra• Produces fluid that transports sperm during ejaculation• Makes PSA	
	

	
<h4>Aging & the Prostate</h4> <ul style="list-style-type: none">• By age 60, half of all men have an enlarged prostate¹• Affects most men by age 85¹• Stress and diet are contributing to an increased presence of enlarged prostate in younger men.	



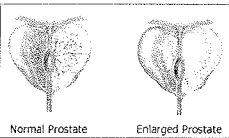
What is BPH?

- Benign Prostatic Hyperplasia
 - Commonly known as enlarged prostate
- Non-cancerous enlargement of the prostate gland
 - BPH is not an indicator or predictor of cancer
 - PSA level is not an indicator of BPH
- Prostate grows to normal size as a teenager, then begins to grow again around the age of 50

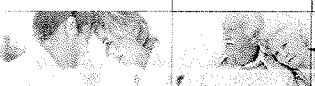


The Effects of BPH

- As the prostate enlarges, it can put pressure on the urethra
- This causes urinary problems
- Not usually life threatening, but can be bothersome
- Symptoms are treatable!




Normal Prostate Enlarged Prostate




Recognizing the Symptoms

- Frequent urination
- Nocturia
- Sudden urge to urinate
- Difficult or painful urination
- Weak or slow flow
- Incomplete elimination
- Hematuria



Work-Up

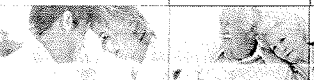
- H&P
- UA
- Urine Culture
- PSA
- Renal Imaging and Cystoscopy if hematuria present
 - Urine cytology



Treatment Options


- Watchful waiting
- Medication
- Surgery
 - Heat treatments (TherMatrix)
 - Laser therapy (GreenLight or Revolix laser)
 - TURP
 - Open prostatectomy

Different treatments are appropriate for different patients.




Watchful Waiting

Advantages	Disadvantages
No surgery	No improvement in symptoms
No drugs	Risk that symptoms will worsen
No side effects	




Treatment Option: Medication

Advantages	Disadvantages
No surgery Potential for symptom relief	Ongoing medication therapy Potential side effects (low-gred sexual drive, erection problems, congestion and dizziness) ¹ Insufficient treatment efficacy ² High out-of-pocket cost Many men don't like taking medications



Treatment Option: Surgery (TURP)


Advantages	Disadvantages
Proven approach	Invasive procedure Hospitalization required ¹ General anesthesia necessary Significant side effects possible ¹



Beyond Medication & Surgery

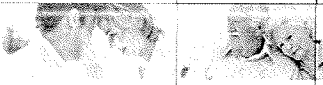
- Heat treatment
 - TherMatrix Office Thermo Therapy
- Laser treatment
 - GreenLight Laser Therapy

*Both therapies are covered by Medicare and most private insurance companies.
Can be effective, economic alternatives to the ongoing cost of medications.*



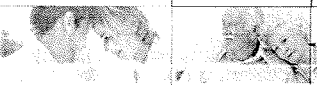
TherMatrix Office Thermo Therapy

- A safe and advanced BPH treatment
- Provides long-lasting symptom relief ^{3,4}
- A single, non-surgical treatment ^{3,4}
- Done in the office ^{3,4}
- Alternative to the ongoing cost, side effects and inconvenience of other therapies



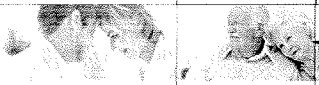
TherMatrix: How it Works

- Uses gentle application of heat to the prostate ^{3,4}
- Heat delivered through a small, flexible catheter inserted into the urethra
- Catheter contains a tiny microwave antenna that provides exactly the right amount of heat to a precise area of the prostate



TherMatrix: Minimal Side Effects

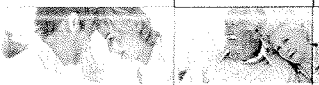
- Less than 1% reported sexual side effects⁵
- Low incidence of incontinence or retrograde ejaculation
- Minor, short-term side effects only^{4,6}
 - Urgency, hematuria
 - Generally go away quickly on their own
- Does not affect your ability to take erectile dysfunction medications



GreenLight or Revolix Laser Therapy

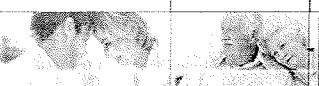
- A safe and advanced BPH treatment
- Provides long-lasting symptom relief ^{7,8}
- A single, definitive treatment⁸
- Done in an outpatient setting ^{7,8}
- Alternative to ongoing cost, side effects and inconvenience of other therapies⁷

Per the American Urological Association (AUA) guidelines, laser therapy provides equivalent symptom relief compared to TURP.



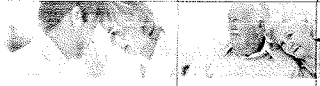
Laser Photovaporization: How it Works

- Uses laser energy to remove excess prostate tissue¹
- Laser energy is delivered through a small, flexible fiber inserted in the urethra
- Procedure is performed through a cystoscope



Minimal Side Effects

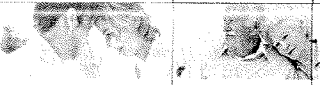
- Less than 1% of sexual side effects reported in clinical trial⁹
- Minor, short-term side effects
 - Generally go away quickly on their own



The Connection Between BPH & ED

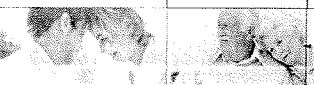
If you have enlarged prostate symptoms, you may be experiencing erectile dysfunction as well.

"40% of men with LUTS and enlarged prostates have significant ED." ¹⁰




What is ED?

The inability to maintain an erection firm enough to have sexual intercourse



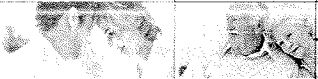
How Common is ED?

- 1 in 10 men in the U.S. ¹¹
- 90% physical, 10% psychological
- 40% of men with LUTS and enlarged prostate¹²




Physical Causes of ED

- Diabetes
- Heart disease
- Surgery (prostate, colon, bladder, rectal)
- Medications
- Spinal injury
- Hormone imbalance



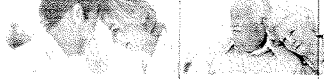
Treatment Options

- Oral Medications (Viagra, Levitra, Cialis)
- Vacuum erection devices
- Injection therapy
- Urethral suppositories
- Penile implants




Oral Medications

- Not effective in approximately 30% of cases³
- Work only in response to sexual stimulation^{4,5}
- Must take at least ½ hour to one hour before anticipated sexual activity^{4,5}
- Viagra can remain effective for up to 4 hours⁴, Cialis can be effective up to 36 hours⁵
- High fat meals can affect absorption of Viagra⁴
- Estimated cost per pill: \$15-\$18



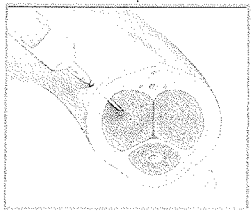
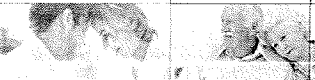
Oral Medications

- Few and mild side effects^{2,5}
 - Headache, Facial Flushing, Runny Nose, Upset Stomach
- What to watch out for^{2,3,...}
 - Cannot take with NITRATES (nitroglycerin, isosorbide, etc.)
 - Precautions with medications for prostate enlargement (Flomax, Cardura, Hytrin, etc.)
 - Serious liver or kidney problems




Vacuum Erection Devices

Advantages	Disadvantages
On-demand use	• Cumbersome
No systemic side effects	• Unnatural erection
Cost	• Possible side effects may include <ul style="list-style-type: none">• Bruising burst blood vessels• Penile pain• Ejaculatory blockage• Numbness




Injection Therapy

- Advantages
 - Effective
 - No partner side effects
 - No need for sexual stimulation
- Disadvantages
 - Needles
 - Pain
 - Scarring
 - Cumbersome
 - Risk of priapism

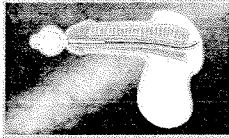


Urethral Suppositories

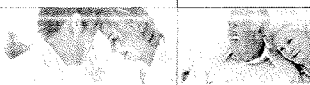
MUSE®
Small medicated pellet placed in the tip of the



- **Advantages**
 - Relatively easy
 - Fast
- **Disadvantages**
 - Side effects include pain
 - Must be refrigerated

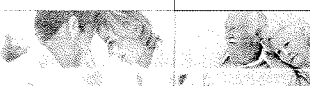


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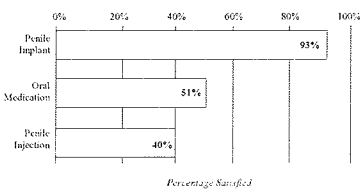
Some Are More Satisfying Than Others

- Oral Medications
 - Not effective in 30% of cases
- Vacuum Erection Devices
 - Cumbersome, unromantic
- Injection Therapy
 - Needles, expensive, may cause burning sensation, scarring
- Urethral Suppositories
 - Expensive, may cause burning sensation



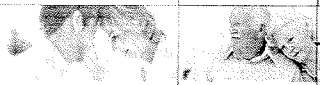
Penile Implants vs. Other Treatment Options

Overall Patient Satisfaction with ED Treatments¹



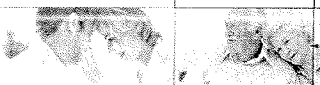
Treatment Option	Percentage Satisfied
Penile Implant	93%
Oral Medication	51%
Penile Injection	40%

Percentage Satisfied



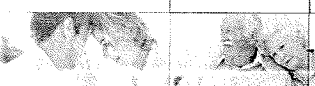
Penile Implants

- Ideal for men who have tried other treatments without success
- On the market for over 30 years
- Over 300,000 implants to date
- High patient and partner satisfaction



Proven Benefits

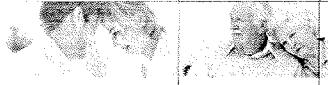
- Achieve an erection easily and maintain it
- Erection hard enough for penetration and allows you to complete sexual intercourse
- Doesn't interfere with ejaculation
- Easy to use




Information to Consider

There are some aspects that concern patients about implants:

- Requires surgery
- Risk of surgical complications which may include infection
- Cost may be prohibitive
- Possible discomfort or pain from use
- Non-reversible
- In rare cases, there may be mechanical failures which may require revision



The 3-Piece Inflatable Implant




- Simple to use
- More Spontaneous than drugs
- Fast and simple 'one-step' deflation
- Totally concealed in body
- Natural flaccidity compared to non-inflatable implants
- Expands the girth of the penis
- Feels softer and more flaccid when deflated

Three-Piece Inflatable Penile Implant

Advantages

- Totally concealed in body
- Looks & feels like a natural erection
- Device is inflated to provide rigidity and deflated for concealment
- Expands in girth (all AMS 700[®] cylinders) and length (AMS 700 LGX[®] cylinders)
- AMS 700 with InhibiZone[®] is the only inflatable penile prosthesis with clinical evidence showing a significant reduction in the rate of revision due to infection




Disadvantages

- Requires some manual dexterity
- Possibility of leakage or malfunction



13 F. Morras et al. AMS Three-piece inflatable implants for Erectile Dysfunction: A Long-Term Multicenter Study in 200 Consecutive Patients. Eur Urol 2002; 41: 500-5

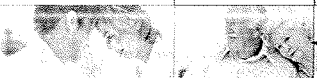
High Mechanical Reliability

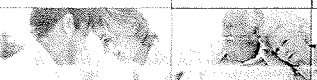
- Designed for long-term dependability
- Over 90% of patients report satisfactory prosthetic erections at almost two years with inflatable prosthesis¹²



12. Fagundes A, et al. Comparison of satisfaction rates and erectile function in patients treated with inflatable penile prostheses using aggressive and conservative implant surgery techniques. J Urol 1997; 158: 2023

	
The 3-Piece Inflatable Implant	
<ul style="list-style-type: none">• Disadvantages• Requires some manual dexterity• Possibility of leakage or malfunction• Possibility of unintentional erections	

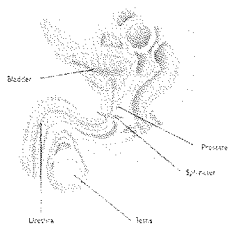
Risks	
Other Considerations	
<ul style="list-style-type: none">• Will make latent natural or spontaneous erections as well as other interventional treatment options impossible• If an infection occurs, the prosthesis may have to be removed• May cause the penis to become shorter, curved or scarred• May cause lasting pain• There may be mechanical failures of the prosthesis	

Summary	
<ul style="list-style-type: none">• ED is a common problem• Nearly every man can be successfully treated for ED• Penile implants offer a dependable, long-term solution	

What is Incontinence?

Male urinary incontinence is usually caused by a damaged sphincter.

When damaged, often the unavoidable result of prostate cancer surgery, the muscle cannot close off the urethra. This causes urine to leak.



The diagram shows a cross-section of the male pelvic region. Labels include: Bladder (top left), Prostate (middle right), Sphincter (bottom right), Urethra (bottom left), and Testis (bottom center).

Types of Incontinence

- **Stress Urinary Incontinence (SUI)**
Leakage during a physical activity like lifting, exercising, sneezing, and coughing, most common following prostate cancer surgery.
- **Urge Incontinence**
Leakage associated with an overwhelming need to urinate... *Gotta go, gotta go!* Often called "overactive bladder."
- **Overflow Incontinence**
Leakage when your bladder never completely empties

What Causes Incontinence?

- Prostate Surgery
(Radical Prostatectomy or TURP)
- Conditions such as diabetes, multiple sclerosis, Parkinson's disease or stroke
- Pelvic Trauma
- Birth Defects

Male Urinary Incontinence is not fun

150 men reported the practical inconveniences associated with incontinence¹⁴:

- 52% Extra laundry
- 37% Smell
- 17% Extra expense
- 12% Skin irritation
- 11% Disturbed sleep

14. Hurdair S. Sexes in one hundred and fifty men with urinary incontinence. Scand J Prim Health Care 1993; 11: 101-106

Treatment Options

- Absorbent Products
- Internal Collection Devices
- External Devices
- Collagen Injections
- Surgical Options



Medication

- No FDA approved medication for stress incontinence in men.

Absorbent Products: Pads, Diapers

Are these the best solution?

- How often are you changing them?
Cost can be a factor...
 - Changing a pad twice a day: \$625/year
 - Changing a pad four times a day: \$1,250/year
 - Changing a pad seven times a day: \$2,200/year
- Skin irritation and rashes
- Inconvenience



Devices: Clamps


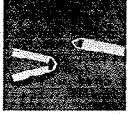
Cunningham Clamp, C3-clamp

Advantages:

- Non-medical, non-surgical
- Easy to use
- Functional
- Inexpensive

Disadvantages:

- Bulky
- Scarring
- Pain



15. <http://www.prostatecancer.com/using-urethral-clamp-to-control-urine-flow>
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Devices: Catheters

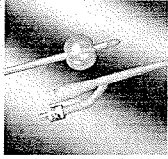

External vs. Internal

Advantages

- Functional

Disadvantages

- Attached to a bag
- Increased risk of infection



Urethral Injections

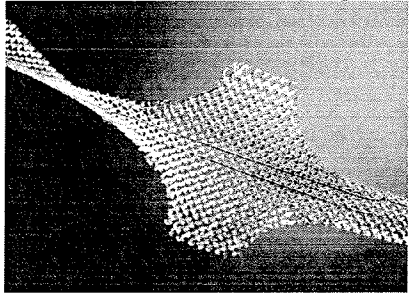
- Collagen, carbon beads, autologous fat
- Usually not a permanent fix requiring multiple injections
- Success rates for collagen ~ 17% after prostatectomy¹⁶

© Springer 16 Clin Oncol (Lond) 2006; 19: 52-64
Curr Opin Urol 2006; 16: 52-64

Surgical Options

- AdVance Male Sling
- Artificial Urinary Sphincter

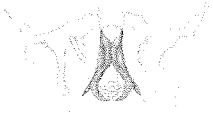
AdVance Male Mesh Sling



AdVance Male Sling: Benefits

For mild to moderate incontinence

- Outpatient surgery
- May be performed under spinal or general anesthesia
- Recovery is often rapid – results may vary
- Often no catheter necessary upon discharge
- No device activation required
- Immediate improvement
- Restored dignity and quality of life



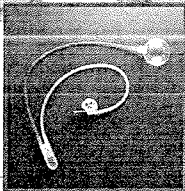
AdVance Male Sling

AdVance is not for people with:

- Urinary tract infections
- Blood coagulation disorders
- Compromised immune systems or any other condition that would compromise healing
- Renal insufficiency and urinary tract obstruction
- Not as effective if urethra or bladder neck has had surgery or injection procedures

Artificial Urinary Sphincter

The Gold Standard for treatment of moderate to severe incontinence

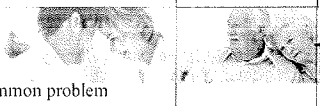


- The cuff wraps around the urethra and is inflated/closed at rest
- Pump in the scrotum deflates/opens sphincter and allows urination

The next slide will illustrate how this system works

Summary

- Incontinence is a common problem
- Some treatments are more effective than others
- Surgical treatment options offer proven, long-term solutions



1. Hoescher-Vogel PM, Anilina P, Van Appels S, Dijkstra F, Groen W. KLF laser versus transurethral microwave coagulation treatment of prostatic enlargement. *Urology* 2009; 74: 105-10.
2. Verheijen FMJ, Bogaard JP, Heerink GJ, Bosch RP, de Jongh PHJ, van der Meulen WJM. Treatment of benign prostatic hyperplasia with the Ho:YAG laser: a comparison of the Ho:YAG laser and the Nd:YAG laser. *Urology* 2004; 64: 1028-1034.
3. Macfarlane G. A series of robotically performed transurethral prostatectomies (TURP) using the Ho:YAG laser. *Urology* 2004; 64: 1028-1034. (abstract 41)
4. Albers DM, Palmier RL, Turk ME, Kabanis F, Andrich C, Davis NS, Kim GS, Kishida T, Luyten JJ, Niazanelli J, Soudam C. Office-based transurethral prostatectomy using the Ho:YAG laser. *Urology* 2009; 74: 1028-1034.
5. Albers DM, Andrich C, Kim GS, Kishida T, Luyten JJ, Niazanelli J, Soudam C. Long-term experience of Ho:YAG laser (Ho:YAG) using the Ho:YAG laser (Ho:YAG) in the treatment of benign prostatic hyperplasia. *Urology* 2009; 74: 1028-1034. (abstract 41)
6. Madsen RS, Bannert PM, Kuznetsov BS. High-power potassium-titanyl-phosphate laser vaporization prostatectomy. *Urology* 1998; 51: 852-854.
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