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# Neuromodulation for the Treatment of Urinary Retention

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### Disclosures

- Consultant for Medtronic Inc.
- Consultant for Allergan
- Consultant for StimGuard, Inc.







# Urinary Retention: Neurogenic Causes

- Obstruction
  - Detrusor sphincter dyssyngeria
    - Suprasacral spinal cord injury, Myelitis, Multiple Sclerosis
  - Parkinson's disease
- Decreased Bladder Contractility
  - Lower motor neuron lesion
    - Cauda equina injury, Pevic plexis injury, peripheral neuropathy (DM)
  - Multiple Sclerosis







# Urinary Retention: Neurogenic Bladder

- Sacral Injuries
  - Injury of sacral spinal cord (below vertebral T12-L1) cause loss of parasympathetic innervation
  - Results in areflexia and urinary retention
- Multiple Sclerosis
  - Most common complaint is overactive bladder
  - Urinary retention can occur in up to 40%





# Urinary Retention: Non-Neurogenic Causes

#### • Obstruction

- Primary bladder outlet obstruction
- Inflammatory process (stricture, meatal stenosis, Skene's gland cyst)
- Pelvic prolapse
- Neoplasm (urethral carcinoma)
- latrogenic (anti-incontinence procedures, dilations)
- Gynecologic-(retroverted uterus, vaginal or cervical CA)
- Dysfunctional voiding (High tone pelvic floor)
- External sphincter spasticity





# Urinary Retention: Non-Neurogenic Causes

- Decreased Bladder Contractility
  - Hypotonia (chronic obstruction, radiation cystitis, TB)
  - Detrusor hyperactivity with impaired contractility (DHIC)
  - Psychogenic retention
- Idiopathic Causes
  - Fowler's syndrome







# **Urinary Retention: Fowler's Syndrome**

- Historically, women with idiopathic retention were labeled with psychological problems
- In 1986, Fowler and colleagues identified women with retention who had distinct EMG findings demonstrating impaired urethral relaxation
- Seen more often in women with polycystic ovaries suggesting progesterone role





# Urinary Retention: Idiopathic

- Diffuse pelvic floor dysfunction and spasm has been shown to be associated with retention and fecal incontinence
- Clinical presentation
  - Mean age 27.7 (10-50)
  - 35% spontaneous
  - 43% after surgery (usually gynecologic)
  - 15% after child birth
  - 50% PCOD





# Urinary Retention: Idiopathic Treatment

- Biofeedback, pelvic floor physical therapy
- Sacral Neuromodulation
  - Most successful treatment
  - 68% overall respond and spontaneously void
- Botulinum A Toxin
  - Injection of 80-100 units in sphincter
  - Mixed results reported in the literature





#### **Sacral Neuromodulation**

- Dedicated research started in 1970's
- Dr. Terry Hambrecht named head of National Institute of Neurological Disorders
- Drs. Tanagho and Schmidt at UCSF credited with moving this technology forward
- In 1997 sacral neuromodulation was FDA approved

Schmidt RA. The Winding Path to Sacral Foramen Neural Modulation: a historic chronology. Int. Urogynecol. 2010

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### **Sacral Neuromodulation**

 Sacral neuromodulation is approved for urinary urgency, frequency, urge incontinence, fecal incontinence and nonobstructive urinary retention in patients who have not been helped or could not tolerate more conventional treatments, including pharmacotherapy.







### **Sacral Neuromodulation**

 Utilizes mild electrical pulses to the nerves associated with voiding function. Over 200,000 implants have been performed worldwide.







# Insight Into Mechanism of Action of Sacral Nerve Stimulation

Fowler's syndrome (retention, decreased sensation) blue = deactivated



Normal

red = activated



Courtesy of Clare Fowler, MD

Dasgupta R, Critchley HD, et al. J. Urol, 2005. 174, 2268

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#### Neuromodulation Activates Micturition Centers in the Brain



Courtesy of Clare Fowler, MD

- Deactivations present with an empty bladder and no SNM
  - With full bladder or after SNM
    - more activation
    - less deactivation
  - More nearly normal

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Dasgupta R, Critchley HD, et al. J. Urol, 2005. 174, 2268



#### **Patient Selection for Neuromodulation**

- Idiopathic non-obstructive retention
- High-tone pelvic floor retention
- Fowler's syndrome
- Selective neurologic conditions such as MS, DSD may benefit \*\*NOT FDA APPROVED\*\*
- Not effective in patients with:
  - atonic bladders from chronic obstruction/retention
  - Aged bladder with muscle atrophy





#### **Development of a staged approach**





- Placement of a sacral electrode was initially a complex surgery requiring large incisions and hospitalization
- Advances in technology have made this a minimally-invasive procedure

Peters KM. Atlas Urol Clin. 2004;12:275-291.





### **Completed First-Stage Sacral Nerve Implant**



Peters KM. Atlas Urol Clin. 2004;12:275-291.





#### Implantation of Pulse Generator









#### **Clinical Results Urinary Control: 12 month Efficacy**

79%

80 64% 70 60 50 40 30 20 10 0 Urgency Retention<sup>1</sup> Urge Incontinence<sup>1,2</sup> Frequency<sup>1,3</sup> n = 38n = 38n = 33

1. Medtronic Sponsored Research InterStim Therapy Clinical Summary Insert 2006

- 2. Schmidt RA, Jonas U, et al. J Urol. 1999 Aug;162(2):352-7.
- 3. Hassouna MM, Siegel SW, et al. J Urol. 2000 Jun;163(6):1849-54.

#### **Urge Incontinence**<sup>1,2</sup>

45% completely dry 34% experienced  $\ge 50\%$ reduction in leaking episodes

#### **Urgency Frequency**<sup>1,3</sup>

31% returned to normal voids (4 to 7 voids/day) 33% experienced ≥ 50% reduction in voids

#### **Rentention**<sup>1</sup>

61% eliminated use of catheters 16% experienced ≥ 50% amount of urine emptied from catheter usage

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77%

### **5-Year Clinical Efficacy**

#### **Urinary Retention – 60 month post-implant results**



Patients %

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#### **Alternative: Pudendal Neuromodulation**

- Stimulation of the 3rd sacral nerve has been shown to be effective in treating voiding dysfunction
- The pudendal nerve is a distal branch of S2, S3, and S4
- The potential benefit of pudendal nerve stimulation is increased afferent stimulation through the sacral nerve roots



Peters KM et al. Neurourol Urodyn. 2005;24:643-647.

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#### **Locating the Pudendal Nerve**



Peters KM et al. Neurourol Urodyn. 2005;24:643-647.

Spinelli M, et al. Neurourol Urodyn. 2005;24(4):305-9.





#### **Monitor C-MAP**



Peters KM et al. Neurourol Urodyn. 2005:24:643-647.





#### Advance Quadripolar Lead While Stimulating "Zero" Electrode



Peters KM et al. Neurourol Urodyn. 2005:24:643-647.







Peters KM et al. Neurourol Urodyn. 2005:24:643-647.





### Outcomes

- Approximately 90% of subjects not responding to SNM respond to stimulating the pudendal nerve
- Majority of data has been on the management of refractory urgency, frequency, pelvic pain and pudendal neuropathy
- Personal experience is that pudendal stimulation resolves retention better than SNM
- May be due to increase brain activation





# **Pudendal Nerve Stimulation**

- Alternative to sacral
- Stimulates S2, S3, and S4
- More desired than sacral
- Salvages >90% of sacral failures

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• No multicenter pivotal trial



### **New Technologies**

















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# Wireless Neuromodulation: The Future?

- Limitations of technology 30 years ago
- Advances in technology



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### **Coils are NOT the Answer-Physics**

- Magnetic induction coupling poor
- Surface penetration shallow (2 cm max)
- Fundamentally wrong concept - can never achieve both a small implant and a small easy to wear transmitter











# Why Wireless Now?

- Size injectable- utilizing state of the art concepts to power injectable devices
- Fixation and anchoring- achievable
- Power- wireless wearable technology
- Customizable therapy-upgrades- remote monitoring
- Eliminate adverse events associated connections and batteries



- Create affordable healthcare technology
  - Clinician and patients can influence future rather then the same basic products with minor adjustments in frequencywireless enables a **NEW** healthcare paradigm





# **Benefits of Wireless Technology**

- Percutaneous NM and Anchors Will Save Procedure Time
- Wireless Power Transfer and Recharging Will Save Hassle
- Wireless Programming will Reduce Clinician Support
- Eliminating Implantable Batteries will Save Healthcare Money for Revision Surgeries
- Wireless "Monitoring" will Reduce Number of Ongoing Office Visits





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# **Wireless Technologies**

#### Low-Frequency, Inductive (coil based)

- •200 KHz to 1 MHz
- •Penetration depths less than 2 cm
- •Must ALIGN External Coil Directly on Top of Implant Receiver

#### High-Frequency, Microwave

- 860 MHz to 5 GHz
- Penetration depths up to 12 cm
- Power in line of sight from 3 feet with External Antenna











### Application Specific Integrated Circuit







# Integrated Circuit Allows Miniaturization



- Size- fits within anchor or lead body
  - No internal battery
  - Easily upgradeable
  - Electronic "complexity" outside of body
- Safe- limits infection sources
- Compliant- compact discreet external device with Bluetooth utilizes breakthrough engineering for energy and information transmission

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#### **Wearable Antennas**









### **Transmitting Mattress Pad**



Screencast=O-Matic.com





#### "Band-Aid" Antenna for Tibial Nerve Stimulation







# **Tibial Nerve Target**



- 9 month follow-up demonstrates 80% improvement in symptoms
- Improved quality of life
- ? Help with retention

Courtesy of StimGuard, Inc

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### Conclusions

- SNM is the only FDA approved treatment for nonobstructive urinary retention
- Patient selection is important for success
- Works best for idiopathic urinary retention
- High-tone pelvic floor
- Fowler's syndrome
- Not effective an atonic bladder due to chronic obstruction or atrophy due to aging
- Alternative nerve targets and new technologies are being developed





### **Thank You**





