Restoring Bladder & Bowel Function by Electrical Stimulation after SCI

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Normal Bladder Function

– Emptying

– Storage
SPINAL INJURY
(conus, cauda)

Parasympathetic & Somatic
SACRAL INNERVATION

- Areflexic
  - usually low SCI lesion

- Reflexic
  - supra-sacral SCI
  - can be stimulated
SPINAL CORD INJURY

ELECTRICAL STIMULATION

S2
S3
S4
Parasympathetic & Somatic
Stimulation

Bladder Pressure

Sphincter pressure

Post-Stimulus Voiding
OUTCOMES OF STIMULATION

- Micturition on demand
- Low residual volumes
- Reduced infection
Residual Volumes

Before: 212 ± 106
After: 22 ± 14

Mean

n=20  p<0.0001
Symptomatic Urinary Tract Infections/year

Before: Median 7
After: Median 1

n=15, p<0.0001
Normal Bladder Function

- Emptying
- Storage
Bladder Function after SCI

- Paralysis
- Hyper-reflexia
BRAIN

SPINAL CORD INJURY

Hyper-reflexia

Dys-synergia
BRAIN

SPINAL CORD INJURY

ELECTRICAL STIMULATION

RHIZOTOMY
OUTCOMES OF RHIZOTOMY (a)

- Abolished detrusor hyper-reflexia
- Increased bladder capacity
Before Rhizotomy
After Rhizotomy
OUTCOMES OF RHIZOTOMY (b)

- Abolished detrusor hyper-reflexia
- Increased bladder capacity
- Preserved upper urinary tracts
- Reduced incontinence
- Fewer urine collection appliances
- Reduced anticholinergic medication
- Reduced autonomic dysreflexia
Urine Collection Appliances

Pre-op 12 months

- Condom
- I.C.
- Foley

n=23
Anticholinergic Medication

Oxybutynin

n=23
Autonomic Dysreflexia

Pre-op

Post-op

n=23
Effects on Bowel

• Bowel
  – Reduced constipation
    • Decreased transit time
    • Increased stool water content
  – Defecation in 50-70% subjects
  – Reduced bowel program time
  – Reduced medication
TIME FOR DEFAECATION

n = 17

Mean

BEFORE

293 ± 232

AFTER

107 ± 104

Cleveland 1998

p < 0.005
Techniques for Bowel Emptying

Days per month

Digital Stimulation  Suppositories

Pre 3m 6m 12m

n=12
SAFETY & RELIABILITY

• Implant infection
  – approximately 1% of patients

• Implant faults
  – average of one fault every 20 patient-years

n=500 patients  1923 patient-years  Brindley 1995
COSTS

• Costs of bladder & bowel care
  – Life-care plan administered to 12 patients implanted with device

• Costs of implanting and using stimulator
  – hospital and distributor
ANNUAL COSTS

- Physician Visits
- Bowel Supplies
- Bladder Supplies
- Medications

Before After

n=12 Cleveland 1998
ECONOMIC SUMMARY

- Average reduction in costs >$6,000 per year
- Break-even point: 5 years
- Thereafter progressive savings to payer
Change in Overall Quality of Life after Implant

The bladder system has improved the quality of my life
K.B.
on the beach
in Jamaica
Cumulative number of Implants

- USA
- Rest of world


Cumulative number of Implants:
- USA
- Rest of world

Graph showing the cumulative number of implants from 1976 to 2000.
Electrical Stimulation ± Rhizotomy

- PRO
  - Restore reservoir function
  - Micturition on demand
  - Low residual volumes
  - Greatly reduced infection
  - Reduced incontinence
  - Elimination of catheters
  - Elimination of anticholinergics
  - Reduced autonomic dysreflexia
Electrical Stimulation ± Rhizotomy

- PRO (continued)
  - Improved bowel function
  - Reduced labor & costs
  - Cosmetically appealing

- CON
  - Side effects of rhizotomy
    - reflex erection
    - reflex ejaculation
Posterior rhizotomy

• Advantages
  – Restore reservoir function of bladder
  – Preserve kidney function
  – Improve continence
  – Abolish autonomic dysreflexia
  – Improve urine flow
    ↓ sphincter spasticity
    ↓ detrusor-sphincter dyssynergia

NB: These are as important as stimulation
Posterior rhizotomy

- Disadvantages
  - Abolish reflex erection
  - Abolish reflex ejaculation
  - Abolish sacral sensation

{ } if present
Alternatives to rhizotomy

1. Bladder hyper-reflexia
NEUROMODULATION (sensory stimulation) to inhibit hyper-reflexia of bladder
Neuromodulation via genital nerve

STIMULATOR
15Hz
0.05ms Pulse
50-70mA

Cystometrogram
Continuous Neuromodulation

Genital nerve stimulation increases bladder volume and compliance

Control CMG

CMG with Electrical Stimulation

Genital nerve stimulation 50μs, 15Hz, 70mA
Increase Bladder Capacity

Neuromodulation

Bar chart showing volume at bladder contraction for different CMG numbers.
Conditional Neuromodulation

![Graph showing blood pressure and detrusor pressure over time with electric stimulation]

Lee & Creasey 2002 ©GHC2000
NEUROMODULATION (sensory stimulation) to inhibit hyper-reflexia of bladder

Sacral nerves

Genital nerve
Neuromodulation by implant

• **Inhibiting** bladder hyper-reflexia by implant increases bladder capacity

(3 paraplegic subjects in London with Brindley implants and no rhizotomy)

Kirkham et al. 2002
**NEUROMODULATION**
(sensory stimulation) *inhibit* hyper-reflexia of bladder

- Sacral nerve
- Pudendal nerve
- Genital nerve

- Genital nerve
- Pudendal nerve
- Sacral nerve

- SPINAL CORD
Alternatives to rhizotomy

1. Bladder hyper-reflexia

2. Sphincter hyper-reflexia
HIGH FREQUENCY BLOCK to prevent hyper-reflexia of sphincter

Pudendal nerves
Testing pudendal block

Bhadra, Bhadra, Kilgore & Gustafson 2012
Testing pudendal block

Bhadra, Bhadra, Kilgore & Gustafson 2012
Sacral stimulation + Pudendal block

Improved Voiding

Cats with acute SCI in Cleveland

No rhizotomy

Improved Pressures

Boger, Bhadra & Gustafson 2008
Sacral stimulation + Pudendal block

Efficient voiding for at least 3 months

Cats in Cleveland with chronic SCI & chronic electrodes

No rhizotomy

Franke, personal communication
Clinical Trial in Humans

Sacral stimulation without rhizotomy

• Neuromodulation
  – Evaluate bladder capacity & continence

• High frequency block
  – Evaluate voiding

Funded by Department of Defense
FDA approval for 4 sites in USA
Recruitment & Screening

- Complete suprasacral SCI
- Male or female
- Age >22
- Urodynamics
  - Evaluate inhibition of bladder with surface electrodes (TENS) on genital nerves
Stage 1

• Implant sacral nerve electrodes & stimulator
  – Evaluate inhibition of bladder with implanted electrodes
    • Capacity
    • Continence
Stage 2

- Apply high frequency stimulation
  - Evaluate block of sphincter contraction
    - Bladder emptying
Next steps

• Opening of new sites
  – Santa Clara Valley Medical Center, CA
  – Metrohealth Medical Center, OH
  – ? Another site

• FDA Supplement
  – High frequency block

• Additional funding from Medicare/CMS
Further Resources

• Protocol
• Investigational Device Exemption
• Draft IRB Application & Consent Form
• Slides & Video
• Manuals
  – Clinicians
  – Patients
SELECTION OF CANDIDATES
INDICATIONS

• Spinal Cord Injury
  – Reflex bladder contraction
  – Clinically complete
  – Bladder complications
BLADDER COMPLICATIONS

• Urine infection
• Stones
• Hydronephrosis
• Urinary incontinence
• Autonomic Dysreflexia
• Catheter problems
BOWEL COMPLICATIONS

Usually an additional reason for implant

- Prolonged bowel program
- Difficulty with defecation
- Fecal incontinence
CONTRA-INDICATIONS

- Absent bladder reflexes
- Active pressure ulcers
- Active sepsis
URINE COLLECTION

• Males
  – able to handle urinal?
  – able to retain condom & legbag?
• Females
  – able to transfer to toilet?
IDEAL CANDIDATE

• Female
• Paraplegic
• UTI
• Reflex incontinence
ORDER OF PRIORITY

• Female paraplegic
• Males (para or tetraplegic)
• Female tetraplegic
TIMETABLE

• Initial screening
  – History & Examination
  – Cystometrogram

• Subsequent assessment
  – KUB X-ray
  – Renal Ultrasound
  – Cystourethrogram/VCUG
  – Spine imaging
CHECK HISTORY

- Voiding
- Continence
- Collection of urine
  - Hand function
  - Transfers
- Condom fixation (quads)
- Back-up method
- Bowel function
OTHER CONDITIONS

- Sphincterotomy
- Reflux or hydronephrosis
- Suprapubic catheter
- Bladder augmentation
- Urethral stricture (males)
- Urethral dilatation (females)
- Pregnancy