Implantable Devices

Evidence for use in Lower Urinary Tract Dysfunction

Dr Ian P Tucker

Urogynaecologist

Continence Foundation of Australia

Implantable Devices

- The control of Lower urinary tract function is an enigma.
- Dr Richard Turner-Warwick once likened the bladder to a 'bumble bee'.

  - " The bumble bee is curious. It is fat, round, has no aerodynamics and should not be able to fly. But the bumble bee doesn't know about aerodynamics so it flies anyway!"

Implantable Devices

- Origins of OAD remain a mystery.
- Many learned gentlemen and ladies have spent much time pondering over this!
- So it is little wonder that we still have a long way to go!

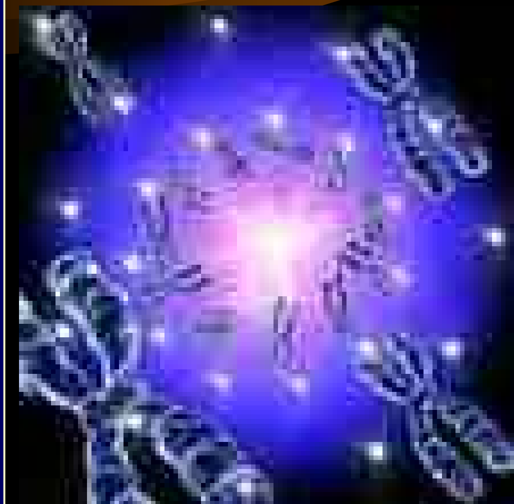
Implantable Devices

- Neurogenic origins may be obvious e.g. known MS.
- Or suspected by sudden onset of symptoms - especially if urodynamic abnormality severe.
- e.g.. Brain tumour

Implantable Devices

Idiopathic causes:

- Strong genetic basis.
- Genes found on [4th] 8th 12th 13th & 22nd chromosomes.
- Wide genetic variance may explain why no single treatment is universally effective.



Continence Foundation of Australia

MEDICATIONS
& the Lower Urinary Tract

- Major medications for OAD are not subsidised on the PBS.
- Many patients cannot afford these preparations.
- They may need to go straight to SNS because of side effects of 'inferior' products.

Continence Foundation of Australia

Implantable Devices

Neuromodulation:

- Recognised as the 'gold standard' for refractory lower urinary tract dysfunction for over a decade.
- Currently approved for Medicare funding for refractory Detrusor overactivity and voiding dysfunction.
- SNS - not approved for CPP syndromes.
- Peripheral nerve stimulation is approved for CPP and SNS is peripheral nerve stimulation!

Implantable Devices

Who should have SNS?:

- Patients with frequency, urgency, nocturia etc.,
  - Refractory ‘idiopathic’ OAD.
  - Neurogenic causes - indication for SNS even stronger [P van Kerrebroeck 2010]
  - Voiding dysfunction
  - chronic pelvic pain syndromes

Implantable Devices

Unilateral SNS:

- OAD now approx 20 yrs experience.
- Results are almost identical from every centre.
- All results are in patients who have failed conservative treatment.
- Groen J, Blok BF, Bosch JL: 5-year results of a longitudinal study in 60 women: J Urol. 2011 Sep;186(3):954-9. Epub 2011 Jul 24.

  Success: 52 patients (87%) at 1 month

  to 37 (62%) at 5 years.

Implantable Devices

Staged procedure or 'straight in'?

- Nikolavsky D, Killinger K, Boura J, Peters K: Int Urol Nephrol. 2011 Mar 10.

  Comparison of patients undergoing a two stage sacral nerve stimulating procedure'

- Majority would benefit from a single-stage procedure (90.3%).
- This would reduce: operative and anesthesia risks,
  time lost from work,
  burden on patients and providers
  probably less infection risk.

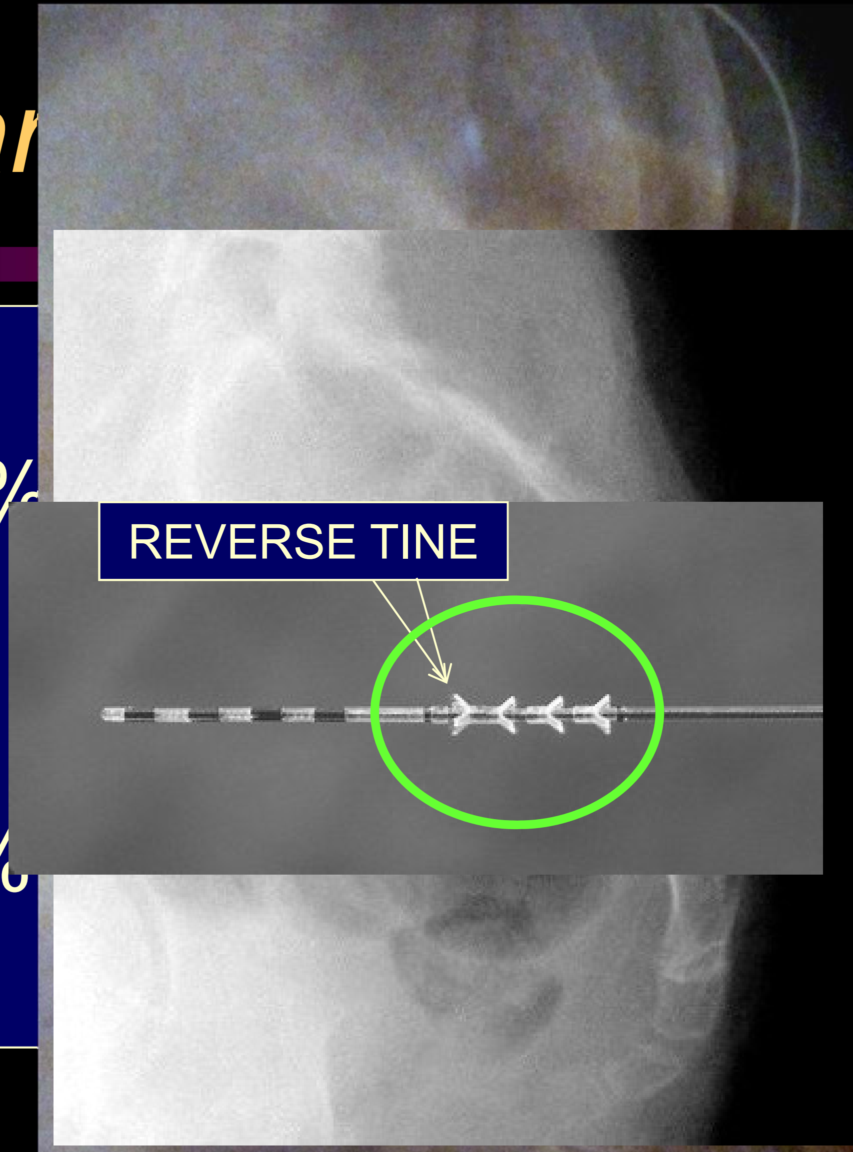
Implantable Devices

- Unilateral V's Bilateral:
- van Kerrebroeck EV, Scheepens WA, de Bie RA, Weil EH.
- In some individuals only bilateral stimulation relieved symptoms.
- If a unilateral percutaneous nerve evaluation test fails, a bilateral test should be considered.
- Of the bilateral placements I have inserted, all have been successful so far.

Implan

Complications:

- Lead Migration – 25%
- Infection - 3%
- Lead fracture – 1%
- Pain at IPG site – 5%



Implantable Devices

Programming:

- SNS doesn’t stop with the procedure.
- Repeated reprogramming may be required for some months.
- Electronics are antiquated – need to be urgently updated.

Implantable Devices

- Satisfaction:
- Leong RK, Marcelissen TA, Nieman FH, De Bie RA, Van Kerrebroeck PE, De Wachter SG: J Urol. 2011 Feb;185(2):588-92. Epub 2010 Dec 18: **Satisfaction and patient experience with sacral neuromodulation: results of a single centre sample survey.**
- High satisfaction rate in patients with sacral neuromodulation.

Neuromodulation:

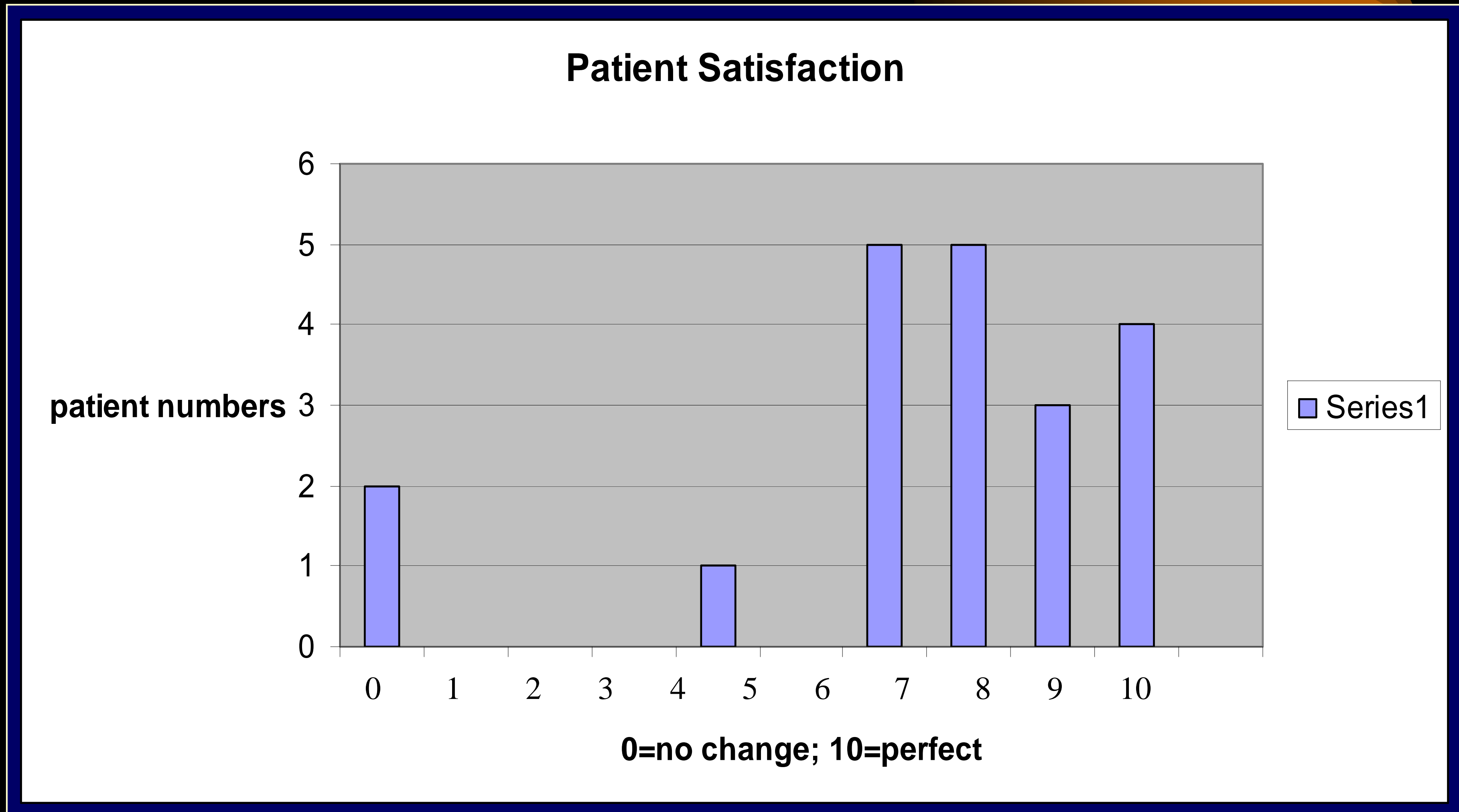
Results – success and would do it again

patient numbers, success, & would do it again.

	patient numbers
1	21
2	19
3	16
4	17.5
5	20

1=test no.; 2=implant no.; 3=success [urine]; 4=success [bowel]; 5=would do it again

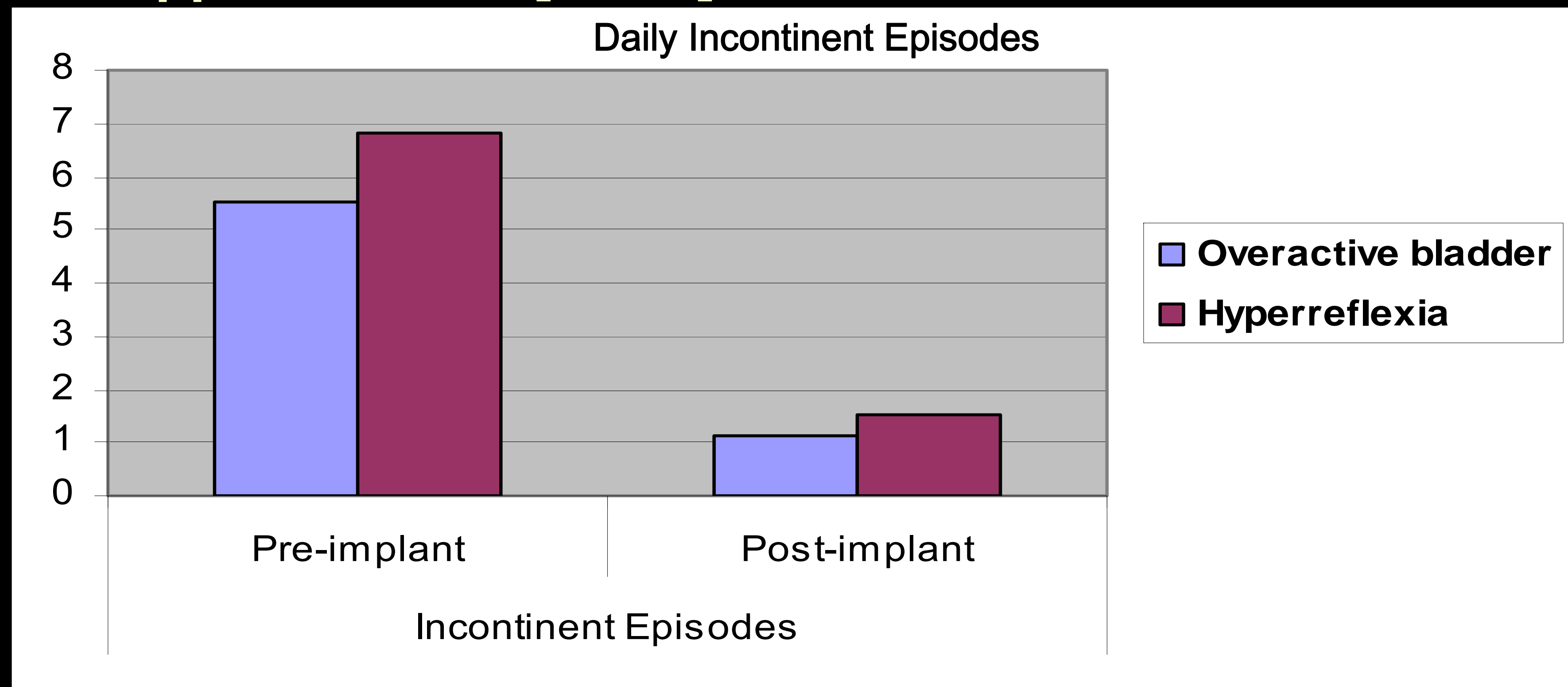
Neuromodulation
Results – patient satisfaction [VAS]



SACRAL NERVE STIMULATION

QUALITY OF LIFE DATA:

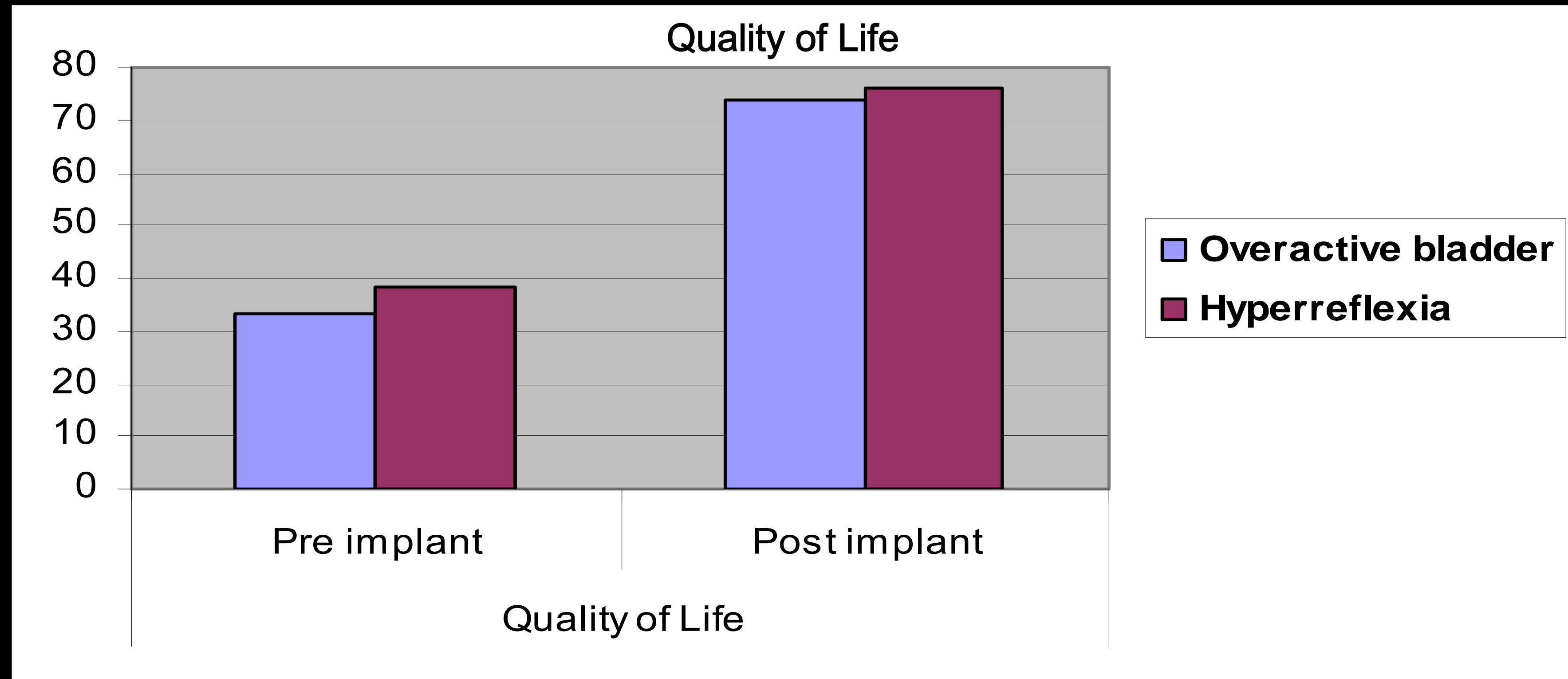
Cappellano et al [Milan]



SACRAL NERVE STIMULATION

QUALITY OF LIFE DATA:

Cappellano et al [Milan].



Implantable Devices

Voiding Dysfunction:

- Jonas U, Fowler CJ et al: Urol. 2001 Jan;165(1):15-9.
- Successful results achieved in 83% of the implant group with retention compared to 9% of the control group at 6 months.
- Temporary inactivation of sacral nerve stimulation therapy resulted in a significant increase in residual volumes (p <0.0001)
- Effectiveness of sacral nerve stimulation was sustained through 18 months after implant.

Implantable Devices

Voiding dysfunction ctd:

- White WM, et al. : Urology. 2008 Jan;71(1):71-4:
- At a mean follow-up of 40 months, 85.7% of patients with refractory, non-obstructive urinary retention demonstrated greater than 50% improvement in symptoms with SNS.

Implantable Devices

Who should perform SNS for LUTS?:

- Urogynaecologists, Urologists. Some non-subspecialists but with special training.
- Need adequate training.
- Should have understanding of basic electronics.
- Must be fully conversant with programming.
- THIS IS NOT for the 'entrepreneurs'!!!

Neuromodulation: Technique

Easy as
a Walk
in the Park!

Implantable Devices

Pudendal Nerve Stimulation:

- Peters KM, et al: Eur Urol. 2011 Sep;60(3):596: **Chronic pudendal neuromodulation: expanding available treatment options for refractory urologic symptoms.**
- 78.6% female; age 51.8 ± 16.9 years of 84 patients had interstitial cystitis/painful bladder syndrome, or overactive bladder.
- 93.2% responded to pudendal stimulation.
- CPNS is a reasonable alternative in complex patients refractory to other therapies.

Implantable Devices

BOTOX:

The Pelvic Floor Disorders Network :

- placebo-controlled trial of cystoscopic detrusor injection of 200 U of Botox versus placebo, randomized in a 2:1 ratio, for women with incontinence caused by refractory idiopathic detrusor overactivity.
- Halted after 43 women received injections (28 with Botox, 15 with placebo).
- Higher-than-expected rate of urinary retention - 12 of 28 (43%).

Implantable Devices

REFRACTORY OAD

Watch upper tracts closely

Neurogenic

Idiopathic

SNS test phase

SNS test phase

success

failure

SNS

SNS

failure

failure

? Bilateral test

? Bilateral test

Add A'Cholinergics

BOTOX

Bilateral SNS STIMULATION

BOTOX

Implantable Devices

Summary:

- The use of Implantable Devices to stimulate the 3rd Sacral nerve unilaterally or Bilaterally is a
  - safe ,
  - effective &
  - cost effective means of treating refractory Lower Urinary Tract Dysfunction.
  - Consider bilateral if unilateral unsuccessful.
  - Further improvements needed!
- Patient satisfaction is very high.

Implantable Devices

FURTHER READING:

- **The neural control of micturition.**

Clare J. Fowler, Derek Griffiths, and William C. de Groat

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2897743/?tool=pubmed.

- **How does neuromodulation work?**

Amend B, Matzel KE, Abrams P, de Groat WC, Sievert KD.

Neurourol Urodyn. 2011 Jun;30(5):762-5. doi: 10.1002/nau.21096