

# BEYOND DRUGS AND PUMPS:

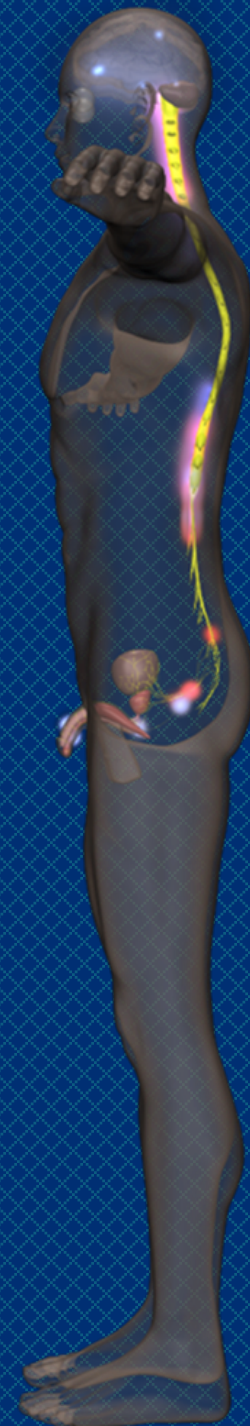
## A NEW APPROACH TO THE MANAGEMENT OF ERECTILE DYSFUNCTION

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# Disclosures:

- ▶ Reflexonic, Innovative Urological Solutions
- ▶ Life Technologies

# Study

## An Objective Evaluation of Viberect® Male Medical Vibrator in Inducing Functional Erection in Comparison to Intracavernosal Vasoactive Injection using Penile Duplex Ultrasound Blood Flow Analysis

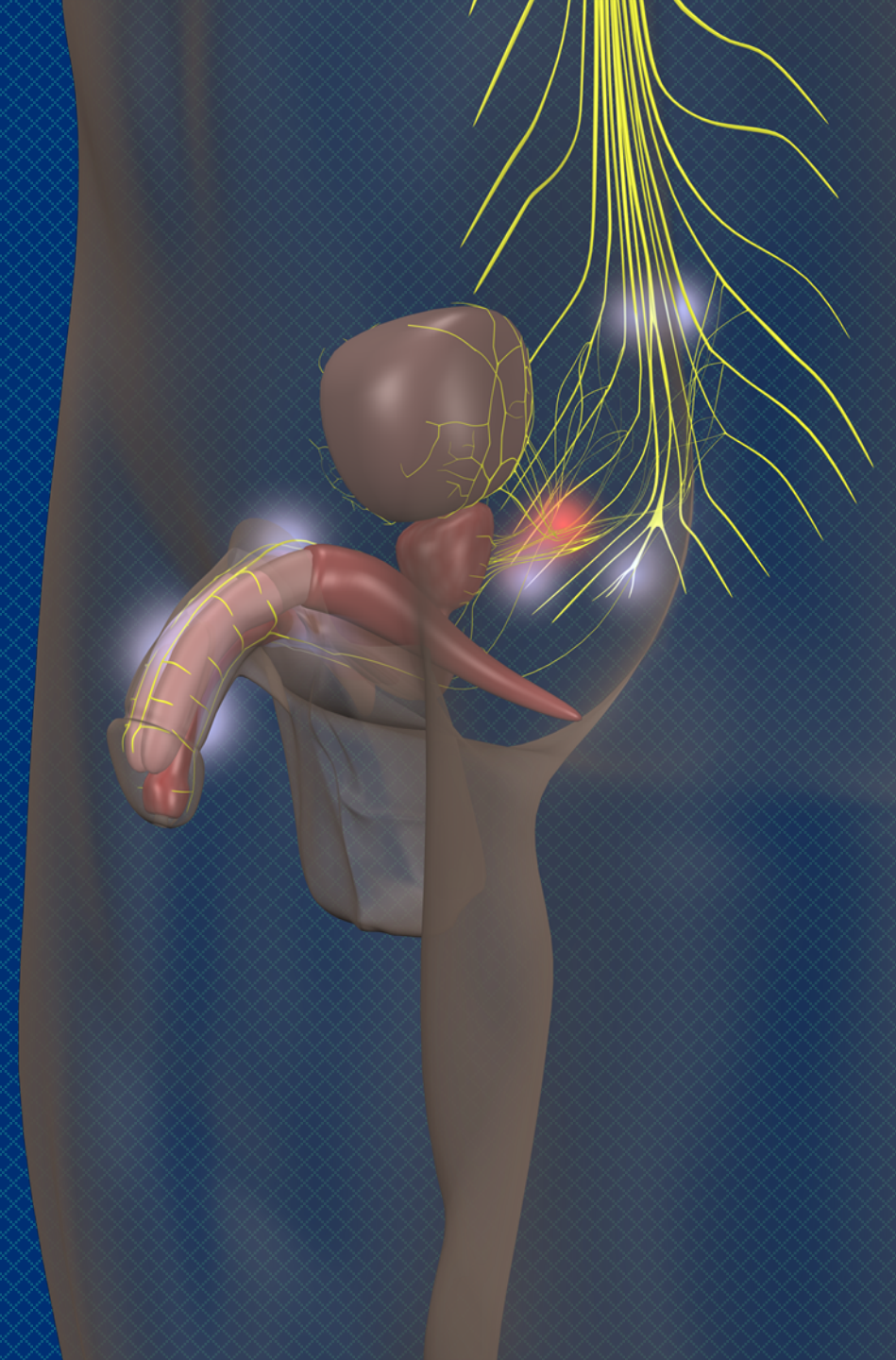
SURESH C. SIKKA<sup>1</sup>, KAMBIZ TAJKARIMI<sup>2</sup>, ARTHUR BURNETT<sup>3</sup>, AND  
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# BACKGROUND

Our understanding of  
erectile neurophysiology  
is rapidly expanding.



- ▶ Recent Interest in modalities with restorative potential, and promotion of erectile health
- ▶ Neuromodulatory therapy (neuroprotective agents, electrical stimulation, biochemical compounds (statins, EPO))



# RADICAL PROSTATECTOMY AND ED

- Surgery offers excellent long-term rates of cancer control
- ED remains a major complication of surgery
- Cavernous nerve-sparing techniques have reduced ED rates
- Nerve injury remains main cause (neuropraxia)

Bill-Axelsson A et al. N. Eng J Med 352:1977, 2005  
Burnett AL. JAMA 293:2648, 2005.

ERECTION = NERVES + BLOOD FLOW +  
PELVIC FLOOR MUSCLE STRENGTH



# ED TREATMENT OPTIONS

## Education

Sexual education / Counseling

## Oral agents

PDE5 inhibitors

## Devices

Vacuum constriction devices

## Vasodilation Medications

Intracavernosal injections (alprostadil)

Intraurethral medications (alprostadil)

## Surgical Options

Penile Implants

Vascular Surgery

# NONCOMPLIANCE. NO DURABLE SOLUTION FOR ED AFTER RRP

- Patients have high non-compliance rate with these treatments at 1 year. Little data on 5 year outcome.
- With men with durable 10-15 year sexual longevity, it is apparent that we do not have a durable and permanent solution for treating ED after RRP.
- Progressive hypoxia related cavernosal fibrosis has been shown to produce veno-occlusive dysfunction

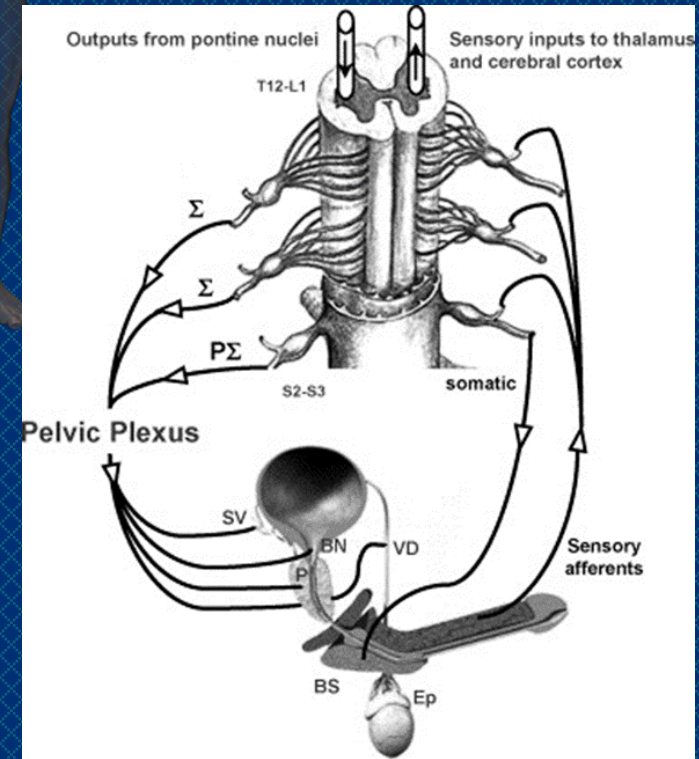
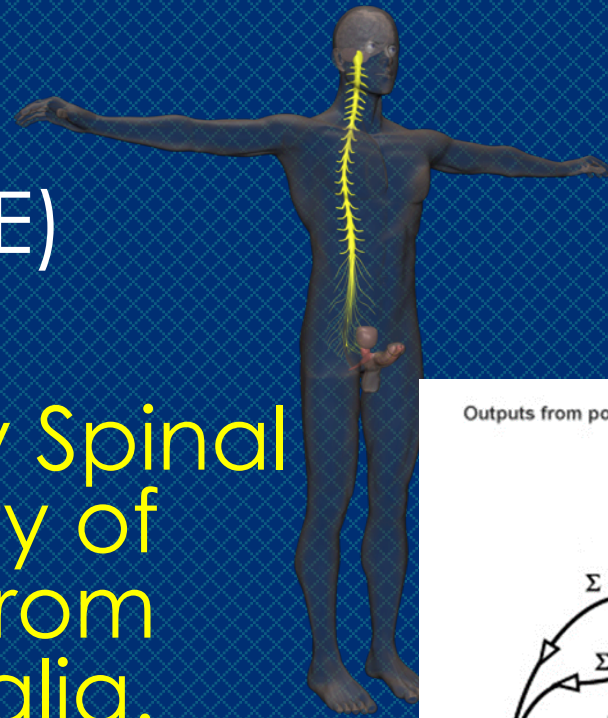
Mulhall, et. Al. J Urol. 166:  
1371-1375. Mar 2002

# ERECTION RECOVERY IS A “DYNAMIC PROCESS”

requiring motivation, spousal support, and willingness to take advantage of natural pro-erectile pathways already established in our bodies, including nerves, muscles, and vessels.

# PENILE ERECTION (TUMESCENCE)

- Penile Erection is controlled by Spinal autonomic centers, the activity of which is dependent on input from supraspinal centers and genitalia.
- Culmination of multiple successful nerve reflexes that initiate a vascular event
- ICP reaches Systolic BP

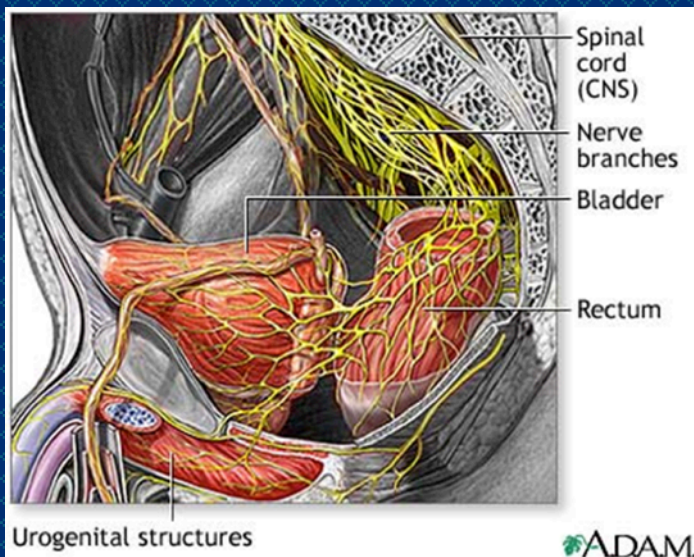
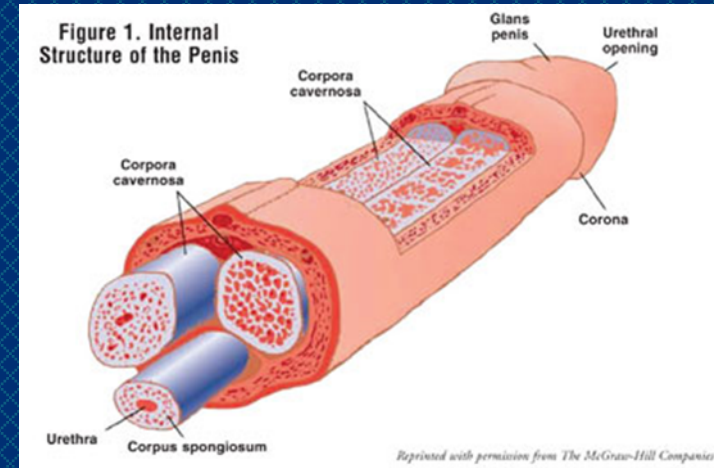


Allard, Edmunds. Neuroscience 2008; 155:283-90

Yang, CC et al. J. Sex Med 2009;6:221-8

# MAINTENANCE OF ERECTION AND RIGIDITY

Combination of neurovascular cavernosal reactivity, venous occlusion, and Rhythmic perineal muscle contraction

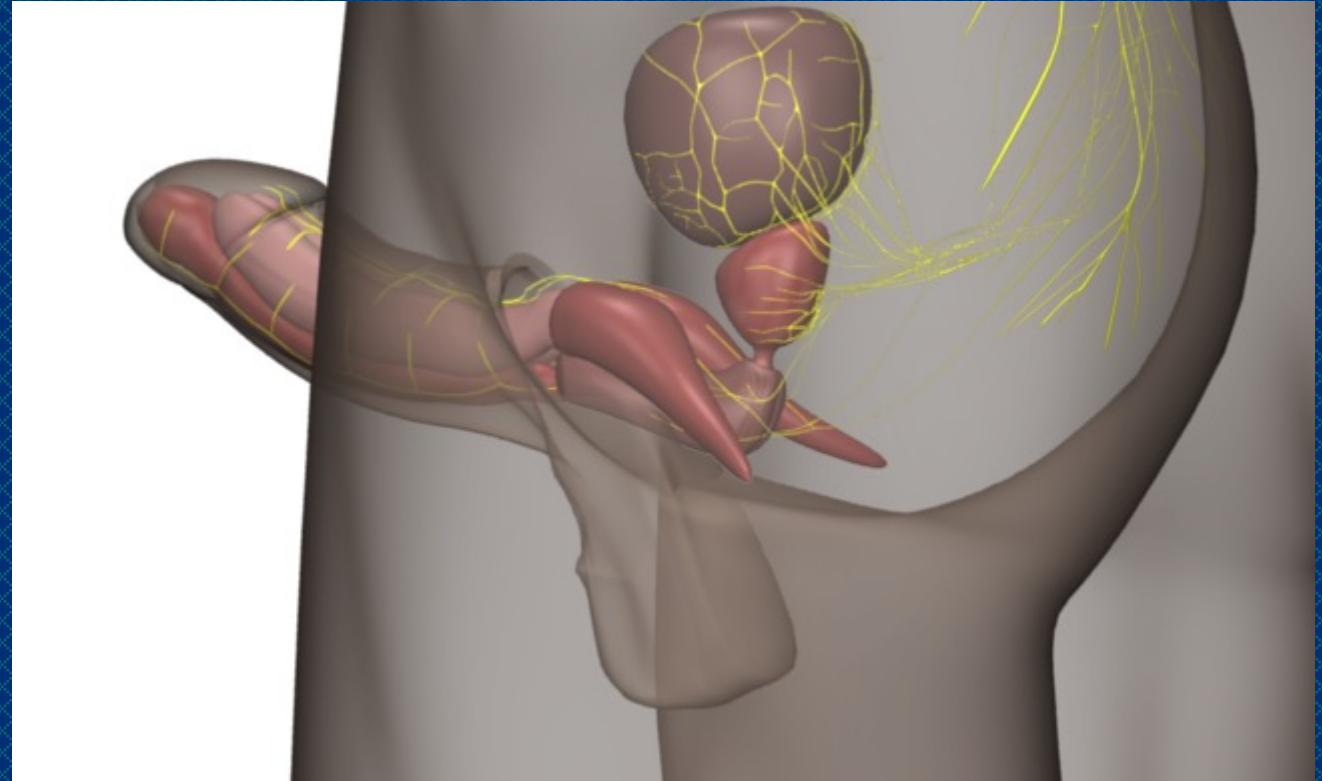


Lue TF. Physiology of penile erection and pathophysiology of erectile dysfunction. Campbell-Walsh urology. 2007:750–87.

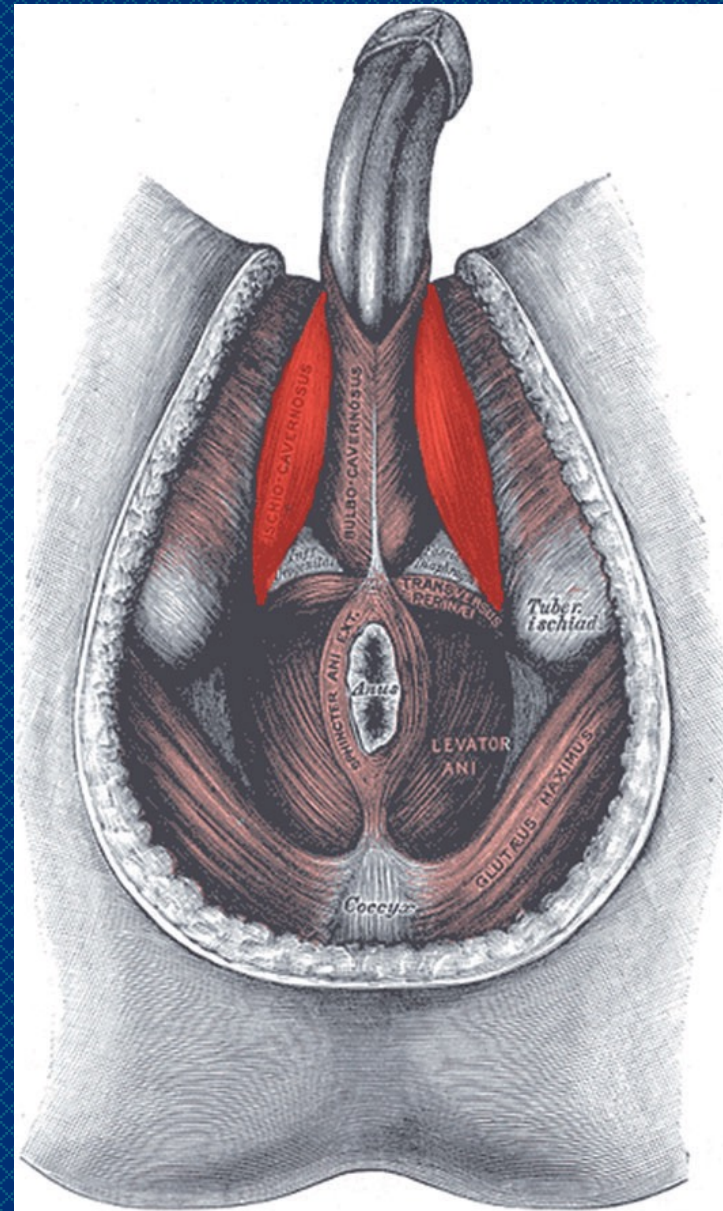
Gratzke C, et al. JSM 2010;7:445-75

# RIGID ERECTION = INTRACORPORAL HYPERTENSION

- **suprasystolic pressures of >230 mm Hg.**
- This is not achieved by nitric oxide blood flow alone.
- Rhythmic contraction of pudendal nerve innervated perineal muscles (ischiocavernosus muscles) achieve such pressures.
- This ability is gradually lost by age, neuropathy, surgery.



Lue TF, et al. Hemodynamics of erection in the monkey. J Urol 1983;130:1237-41



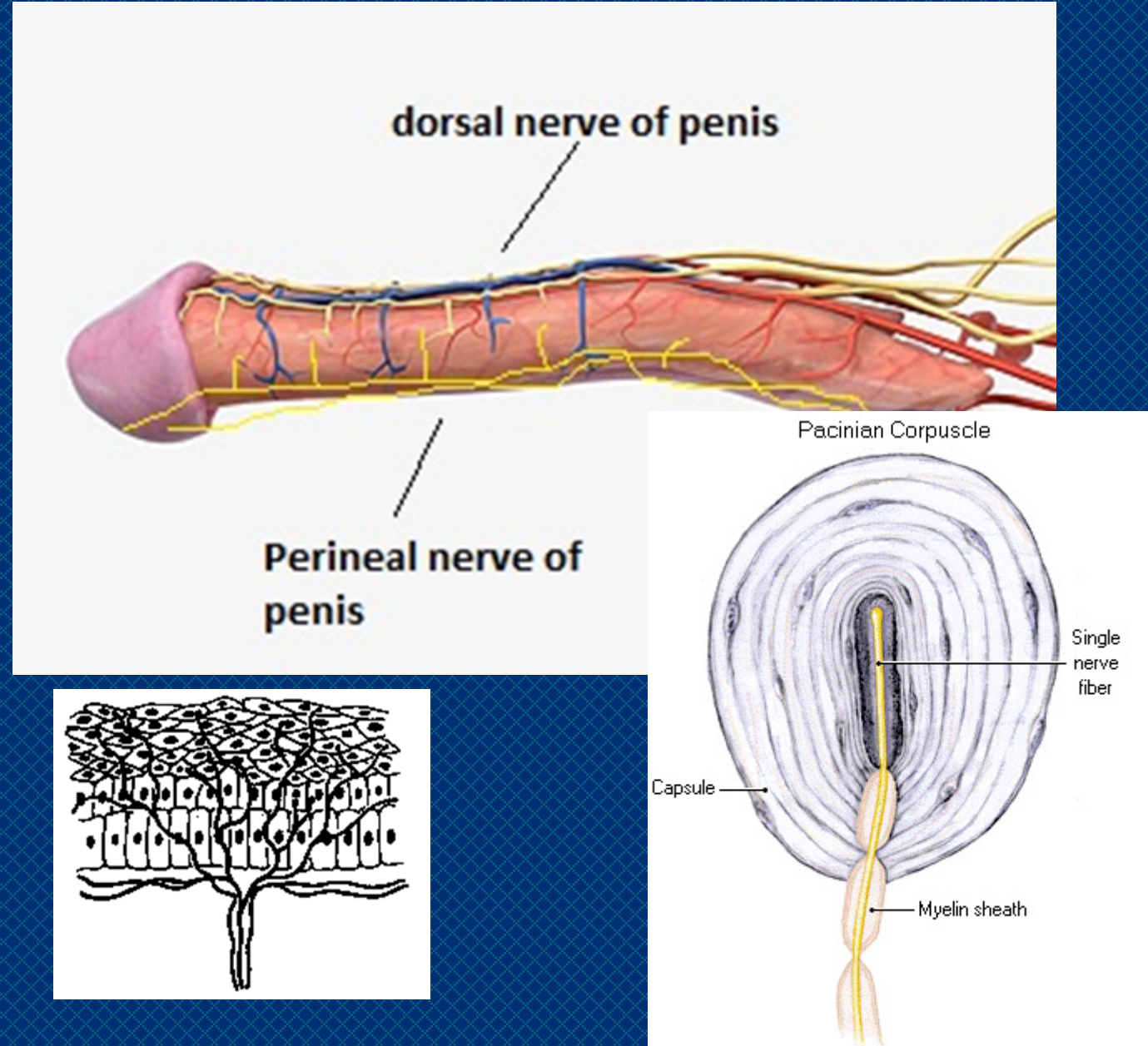
Gray's Anatomy

# PENILE GLANS

(&CLITORIS)

- Millions of sensory nerve termination
- Thin Myelinated A<sub>δ</sub> and unmyelinated C fibers
- Convergence as dorsal nerve and perineal nerve, then pudendal nerve
- Desensitization of the glans of rats, cats, severely impairs erectile ability and successful penile intromission.
- FNE exhibit “Polymodality and dissociated sensitivity”

Munger, et al. Brain res.  
371, 205 1986





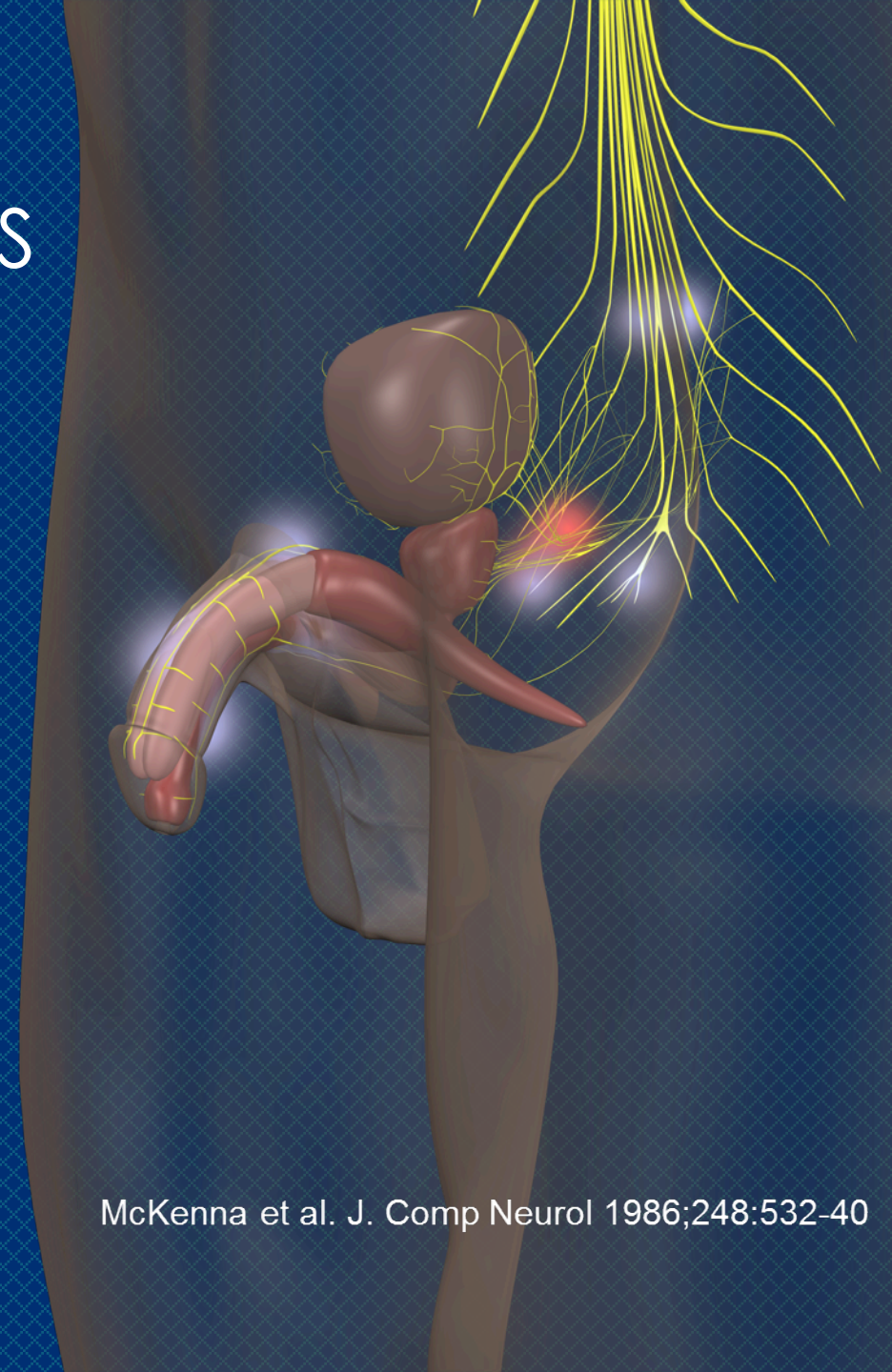
# PUDENDAL NERVE IS KING OF PELVIS

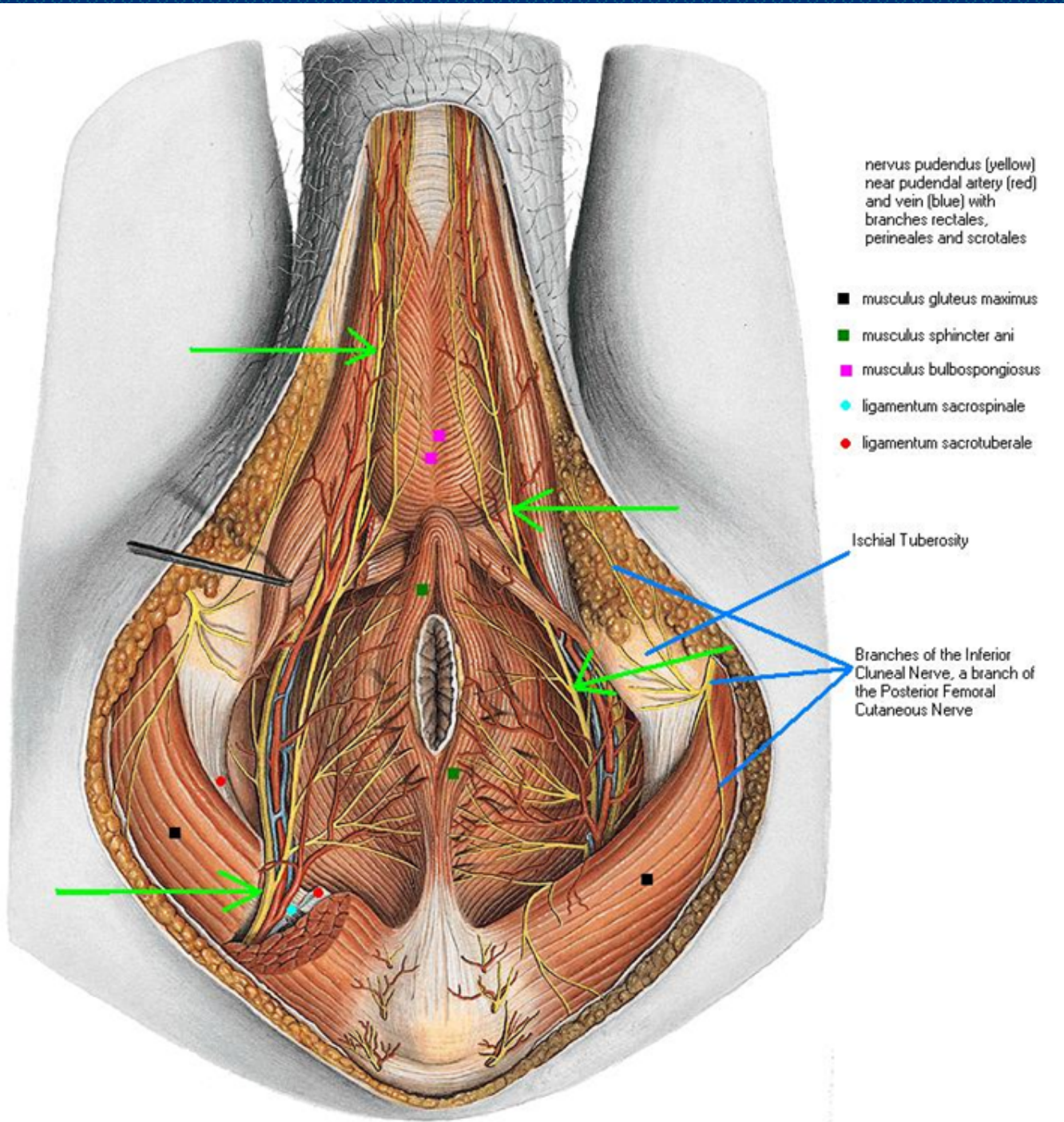
Somatic sensory: Entire Pelvis

Motor: All sphincters, pelvic floor, rigidity muscles

Autonomic (nitric oxide synthase +), possible direct role for glans erection independent of cavernous nerves.

Activates sexual reflexes, numerous centers in the brain to modulate erection, pleasure, orgasm, ejaculation, and state of well-being, mood (oxytocin release).





nervus pudendus (yellow)  
near pudendal artery (red)  
and vein (blue) with  
branches rectales,  
perineales and scrotales

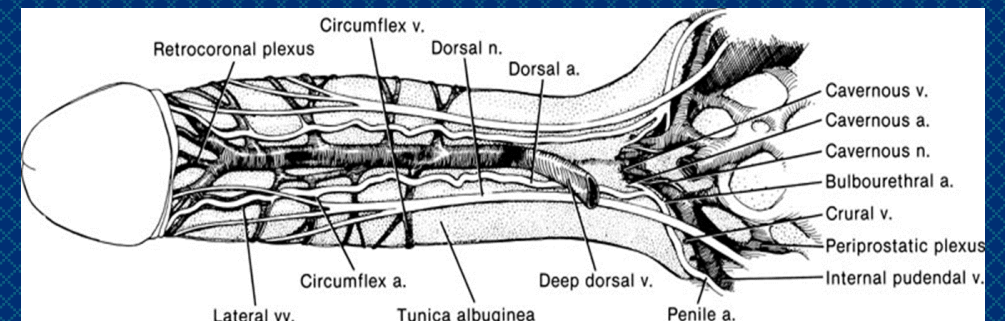
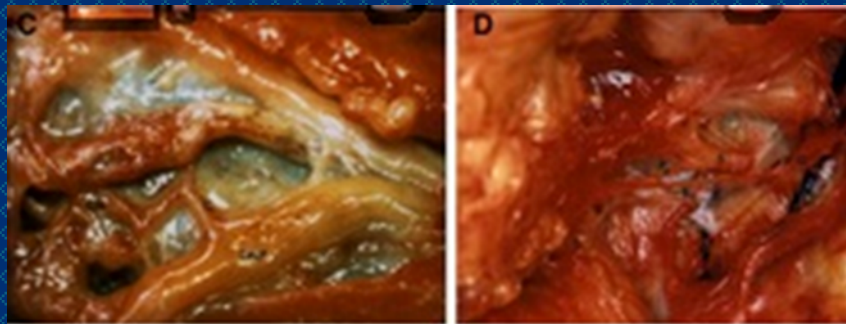
- musculus gluteus maximus
- musculus sphincter ani
- musculus bulbospongiosus
- ligamentum sacrospinale
- ligamentum sacrotuberale

Ischial Tuberosity

Branches of the Inferior  
Cluneal Nerve, a branch of  
the Posterior Femoral  
Cutaneous Nerve

# PUDENDAL NERVE AND PROSTATE CANCER SURGERY

- After radical prostatectomy, cavernous nerve neuropraxia develops for 18 months to 2 years
- Pudendal nerve becomes the only reliable form of communication between penis & CNS
- Pudendal nerve and Cavernous nerves are interconnected



## PELVIC FLOOR MUSCLES



- Critical role in creating and maintaining rigidity of erection
- They are weak, and get weaker with age
- Pelvic floor therapy has shown to improve erection recovery after prostatectomy

(Geraerts, et al. Int. J. of Impotence Res (2015) 28, 9-13

Prota C. J Imp Res. Sep;24(5):174-8, 2012

MAMMAL EVOLUTION:  
PUDENDAL NERVE IS DIRECTLY CONNECTED TO  
MANY KEY LOCATIONS IN THE BRAIN NECESSARY  
FOR SURVIVAL, WELL BEING, PROCREATION

Thalamus (Wind-up)

Hypothalamus (4 F's: Fear, Fight, Feeding, Frustration)

Paraventricular nucleus

Medial Amygdala (PTSD depression, suicide)

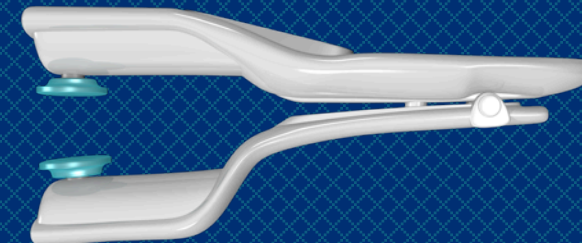
Medial reticular formation

Cerebral cortex



# PENILE VIBRATION OF MEN WITH SPINAL CORD INJURY FOR EJACULATORY DYSFUNCTION EXPOSED MANY PROFOUND AND UNANTICIPATED ADDITIONAL BENEFITS

- Penile erection
- Relief of lower extremity contractions
- Increased bladder capacity
- Reduced detrusor contractions
- Increased urinary sphincter control
- Increased fecal control

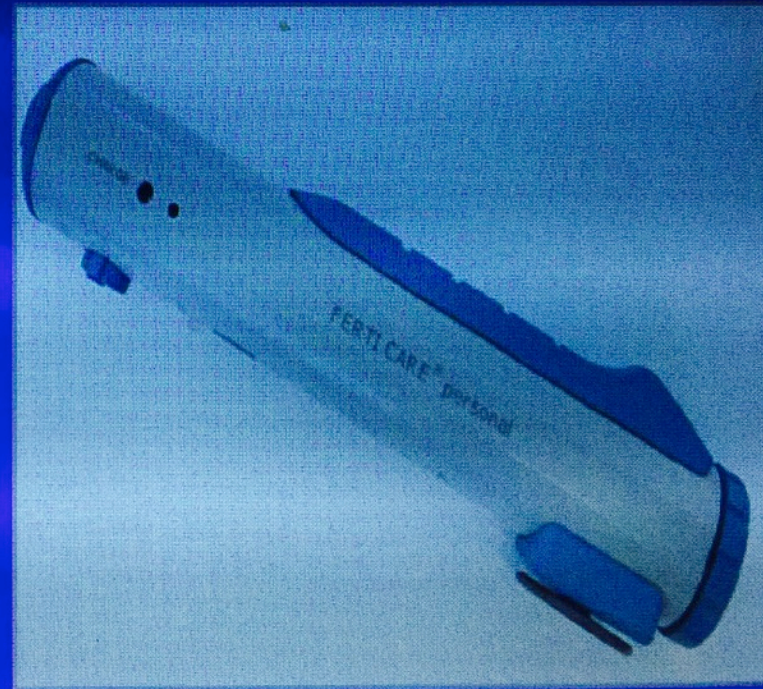


# Penile vibratory stimulation in the recovery of urinary continence and erectile function after nerve-sparing radical prostatectomy: a randomized, controlled trial

Mikkel Fode\*, Michael Borre†, Dana A. Ohl‡, Jonas Lichtbach§ and Jens Sønksen\*

\*Department of Urology, Herlev University Hospital, Herlev, †Department of Urology, Aarhus University Hospital, Aarhus, Denmark, ‡Department of Urology, University of Michigan, Ann Arbor, MI, USA, and §Department of Physiotherapy, Herlev University Hospital, Herlev, Denmark

- Randomized prospective trial involving 30 patients receiving penile vibratory stimulation (PVS) and 38 patients receiving monitoring only
- PVS using FERTI CARE vibrator once daily, beginning 1 week before surgery and continuing 6 weeks afterwards
- At 12 months, 16/30 (53%) of patients in the PVS group and 12/38 (32%) of patients in the control group achieved an IIEF score  $\geq 18$  ( $p=0.07$ )







# Enhancement of erectile responses to vasoactive drugs by a variable amplitude oscillation device

SS Chun, J Fenemore, JPW Heaton, B Johnston and A Morales

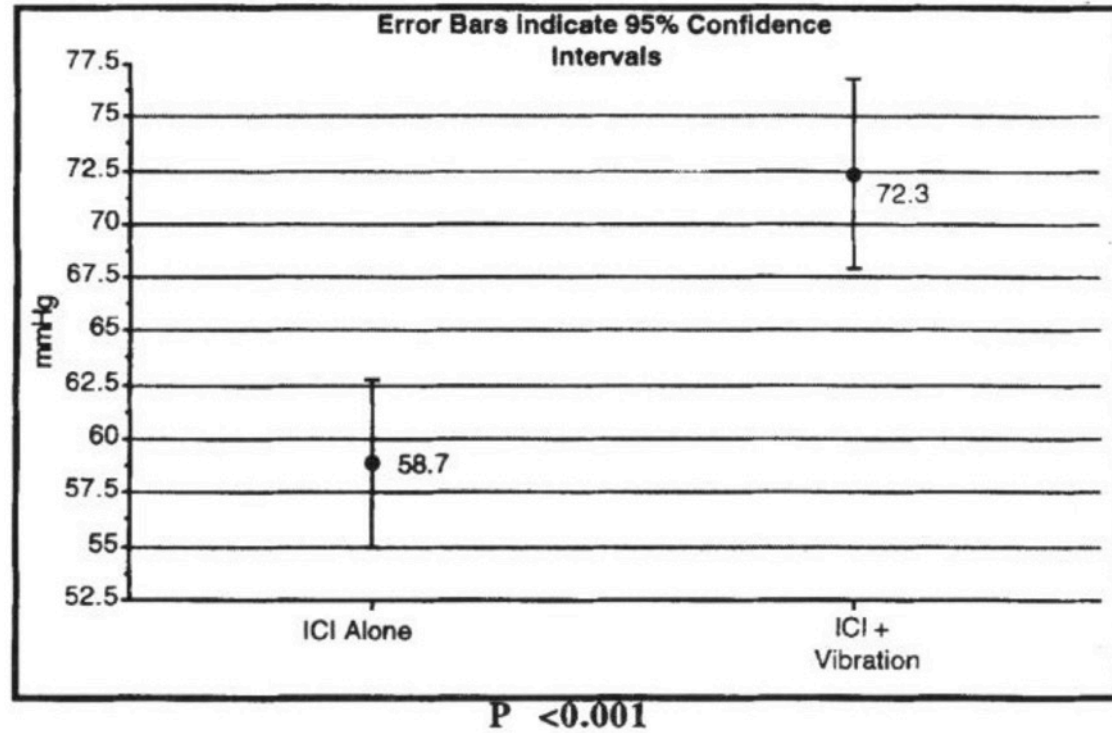
*Department of Urology, Queen's University, Kingston, Ontario, Canada*

**The limitations of intracavernosal injection (ICI) of vaso-active drugs as a diagnostic tool in the evaluation of erectile dysfunction are well recognized and, prominently, include the artifacts induced by the unfamiliar environment on the patient. We report on the benefits of adding a vibratory stimulus to ICI to improve the sensitivity of this test in a population of 170 patients with erectile dysfunction who were evaluated using a standard protocol. Intracavernosal pressure was measured following ICI alone and ICI with vibratory stimulation of the penis.**

**A statistically significant improvement in intracavernosal pressure (ICP) with the addition of vibration was observed in 87% of the subjects as compared to ICI. In 52% the improvement in ICP was greater than 20% over that achieved by ICI. This study showed that the addition of vibration to intracavernosal administration of vaso-active drugs significantly increases the erectile response in a controlled and reproducible manner. Vibratory stimulation provides a better reflection of erectile potential than the pharmacological challenge alone.**

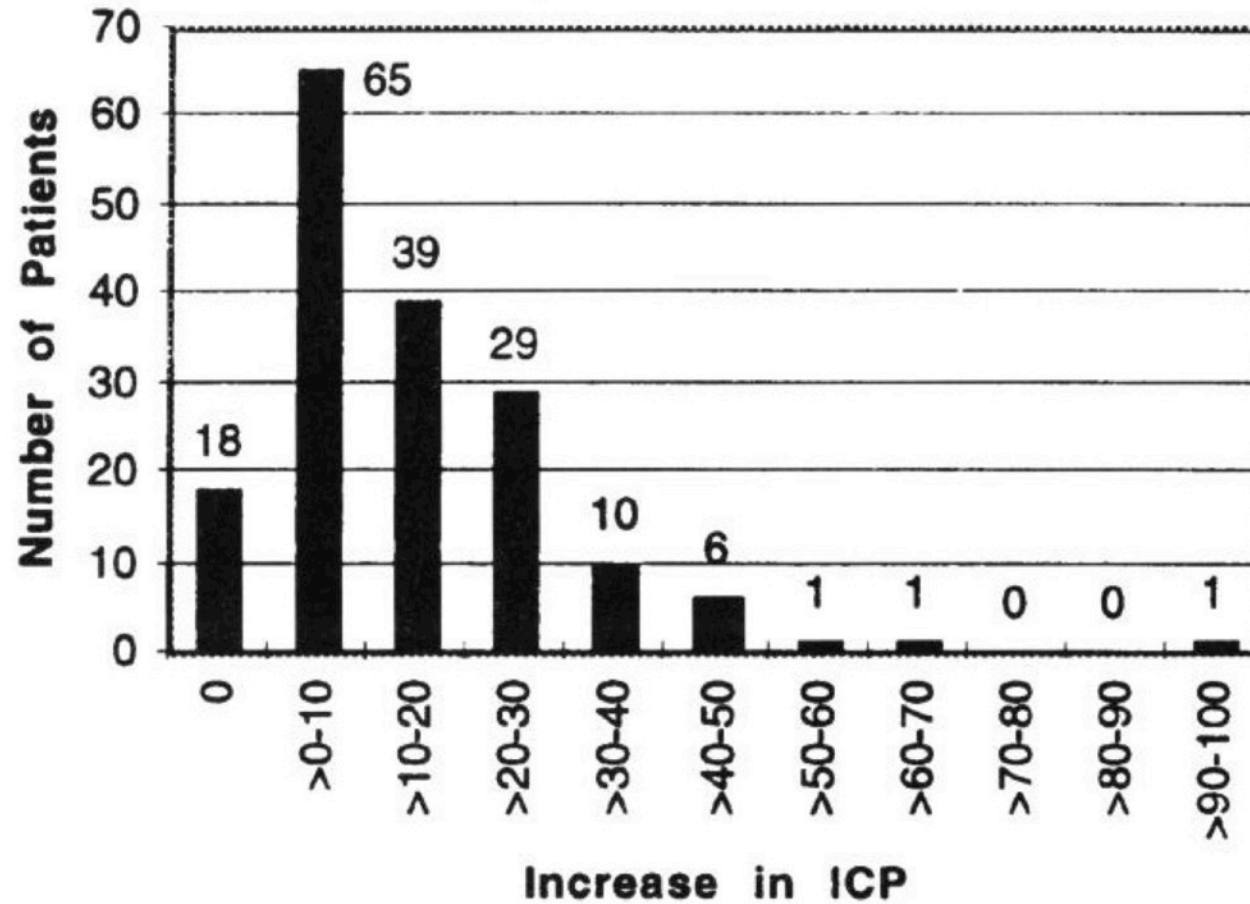
**Keywords:** Pharmacological erections; vibratory stimulation

Comparison of Mean Intracavernosal Pressure  
ICI vs. ICI and Vibration



**Figure 2** This figure illustrates the differences in intracavernosal pressures recorded in the same patients following the administration of vasoactive agents alone or with the addition of a vibratory stimulus.

## Absolute Improvement (mmHg)



**Figure 4** Absolute improvement (mmHg) recorded after the addition of vibratory stimulation to the use of intracavernosal vasoactive compounds.

# VIBERECT

FDA Statement: Viberec is a hand held medical device to provoke penile erection in men who experience erectile dysfunction

Frequency 70-110 Hz

Amplitude: 2-3 mm

Approved for OTC use (October 2014)

Simultaneous stimulation of both branches of the pudendal nerve

Certifications: US FDA, CE, Health Canada, ARTG (Australia)

Made in USA



# *Viberecct penile vibratory stimulation system: evaluation of its erectogenic efficacy*

Robert L. Segal, MD,<sup>1</sup> Kambiz Tajkarimi, MD,<sup>2</sup> Arthur L. Burnett, MD<sup>1</sup>

<sup>1</sup>The James Buchanan Brady Urological Institute, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA

<sup>2</sup>Frederick Urology Specialists, Frederick, Maryland, USA

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SEGAL RL, TAJKARIMI K, BURNETT AL. Viberecct penile vibratory stimulation system: evaluation of its erectogenic efficacy. *Can J Urol* 2013;20(4):0000-0000.

**Introduction:** Current non-surgical strategies employed to treat erectile dysfunction (ED) target the vascular component of erection physiology. The Viberecct handheld device (Reflexonic, LLC, Chambersburg, PA, USA) is a new FDA-cleared ED treatment, which exploits vibratory stimulation of genital afferent nerves for provoking erections. The aim of this study was to evaluate the clinical feasibility of the Viberecct device for the achievement of penile erection and rigidity.

**Materials and methods:** Subjects for this study were five healthy men (mean age 26.4 years) with normal erectile function as measured by responses to the IIEF-EF. The Viberecct treatment at 75 Hz with ventral stimulation was initiated without any external visual sexual stimulation. Both objective Rigiscan measurements of rigidity and subjective Erection Hardness Score (EHS) responses were recorded and correlated. Tolerantion and safety were monitored.

**Results:** Rigiscan demonstrated that 4/5 patients achieved tumescence episodes beyond 60% total rigidity (considered the minimum required to achieve a non-buckling erection capable of vaginal intromission). According to EHS, the Viberecct treatment yielded scores of 4/4 (penis is completely hard and fully rigid) in 2 patients, 3/4 (penis hard enough for penetration but not completely hard) in 2 and 2/4 (penis is hard but not enough for penetration) in 1. There were no complications, and all subjects felt that Viberecct would be a reasonable, practical ED treatment.

**Conclusion:** This study provides evidence that Viberecct produces a non-invasive, well-tolerated erectogenic effect. These results indicate that penile vibratory stimulation provokes erections via neurostimulatory principles and support further study of this modality in treating men with ED.

**Key Words:** erection, bulbocavernosus, reflex, Rigiscan

## CASE REPORT

# Safety and efficacy of a new device for inducing ejaculation in men with spinal cord injuries

SM Castle, LC Jenkins, E Ibrahim, TC Aballa, CM Lynne and NL Brackett

**Study design:** Prospective case series.

**Objectives:** Male infertility is a common sequela of spinal cord injury (SCI). Fatherhood is a goal in this group of young patients; however, most are anejaculatory. Penile vibratory stimulation is recommended as the first line of treatment for this condition. Our study evaluated the safety and efficacy of a new device designed to induce ejaculation in these patients.

**Setting:** The Miami Project to Cure Paralysis, Miami, FL, USA.

**Methods:** The Viberec-X3 (Reflexonic, Frederick, MD, USA) was applied to 30 consecutive anejaculatory men with SCI whose level of injury was T10 and rostral.

**Results:** The ejaculatory success was 77% (23/30). No adverse events occurred, and there were no malfunctions of the device.

**Conclusion:** In this first report on the efficacy of the Viberec-X3 for treatment of anejaculation in men with SCI, we conclude that the device is safe and effective for inducing ejaculation in men with SCI. Recommendation of the Viberec-X3 versus other devices intended for this purpose should not be made until randomized controlled trials are performed.

*Spinal Cord* (2014) **52**, S27–S29; doi:10.1038/sc.2014.110

# An Objective Evaluation of Viberec® (Male Vibrator Device) in Inducing Functional Erection in Comparison to Intracavernosal Vasoactive injection for Penile Duplex Doppler Ultrasound Blood Flow Analysis

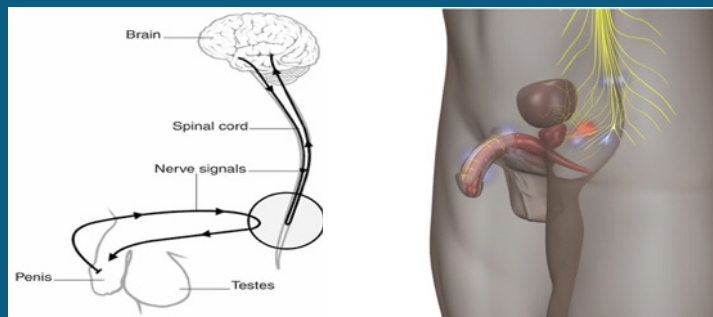
Suresh C. Sikka<sup>1</sup>, Kambiz Tajkarimi<sup>2</sup>, Arthur L. Burnett<sup>3</sup>, and Wayne JG Hellstrom<sup>1</sup>

<sup>1</sup>Department of Urology, Tulane University School of Medicine, New Orleans, LA, USA; <sup>2</sup>Frederick Urology Specialists, Frederick, MD, USA;

<sup>3</sup>Department of Urology, Johns Hopkins Medical Institutions, Baltimore, MD, USA

## Introduction

Penile erection is a neurovascular event. Genital afferents activate spinal nuclei and higher centers responsible for sexual function. Intracavernosal injection (ICI) of vasoactive agent(s) to induce erection is a useful modality for diagnostic and therapeutic purposes but requires a needle. Viberec® (a non-invasive tool) is a new FDA-cleared medical device for inducing penile erection and treating anejaculation in spinal cord injured men. We report a comparative evaluation of penile blood flow parameters and erection response induced by Viberec® versus well-established ICI using color duplex Doppler ultrasound (CDDU) technology.



Afferent to Efferent Vibratory Therapy

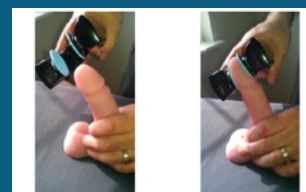
## Methods

105 patients with ED+/-PD 2011-2013 consented as IRB Protocol to use Viberec prior to undergoing penile CDDU. Viberec® stimulation was then performed by the patient at 70-100 Hz for 6-10 minutes prior to performing CDDU as per our standard protocol (Sikka *et al*, *J Sex Med*, 2013). Following this, the patient rested until the penis was fully flaccid. An ICI of PGE1 at a dose of 7-15 mcg was then administered and CDDU repeated. Settings and visual sexual stimulation were similar for both CDDU evaluations.

Right: Viberec Penile Vibratory Therapy System: Hand held medical device to provoke penile erection in men with ED, and to provoke ejaculation in men with spinal cord injury



Right: Viberec Demonstration



## Aims and Objectives

- To compare blood flow velocity parameters induced by the Viberec® (a “male-vibrator”) versus the intracavernosal injection (ICI) of PGE-1 using color duplex Doppler ultrasound (CDDU) technology.

## Conclusions

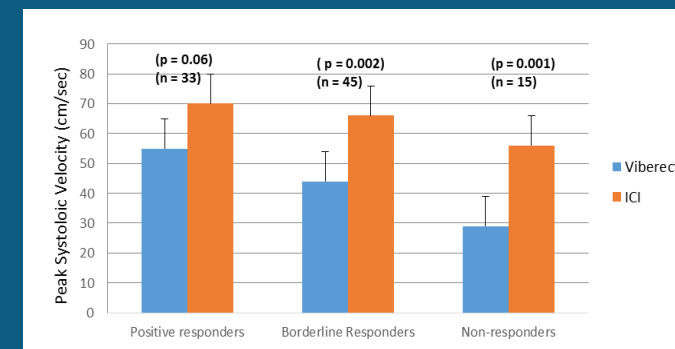
This study suggests that Viberec that stimulates the bulbocavernosus reflex is very safe, convenient, well-tolerated modality for inducing erection certain non-anxious men. In addition, such stimulation prior to ICI may improve erection response to vasoactive agent (priming effect) that may reduce the effective dose and thus the cost and possible side effects. Randomized prospective multicenter trials will be needed to further validate these results and the concept of stimulating bulbocavernosus reflex with Viberec® for ED diagnosis and treatment.

## Results

	(+ ) Responders (33)		Borderline (45)*		(-) Non-Responders (15)	
	Viberec	ICI	Viberec	ICI	Viberec	ICI
Average	55	70	44	66	29	56
SD	15.4	19.7	11.9	16.3	5.1	12.2
T test	-1.91		-3.80		-5.87	
95% CI	(-17.6) – (0.53)		(-45.6) – (-12.6)		(-47.4) – (-14.8)	
P Value	0.06		0.002		0.001	
Erection Response	90% Tumescence (T) >60% rigidity (R) for both		80% T + 30-40% R with Viberec, while 90% T + 60% R with PGE1		No erection response with Viberec, but 90% T + 60% R with PGE1	
[Note:	12 patients did not complete the study due to ejaculatory issues]					

Comparative Doppler Data (Peak Systolic Flow) using Viberec and ICI (in same patient)

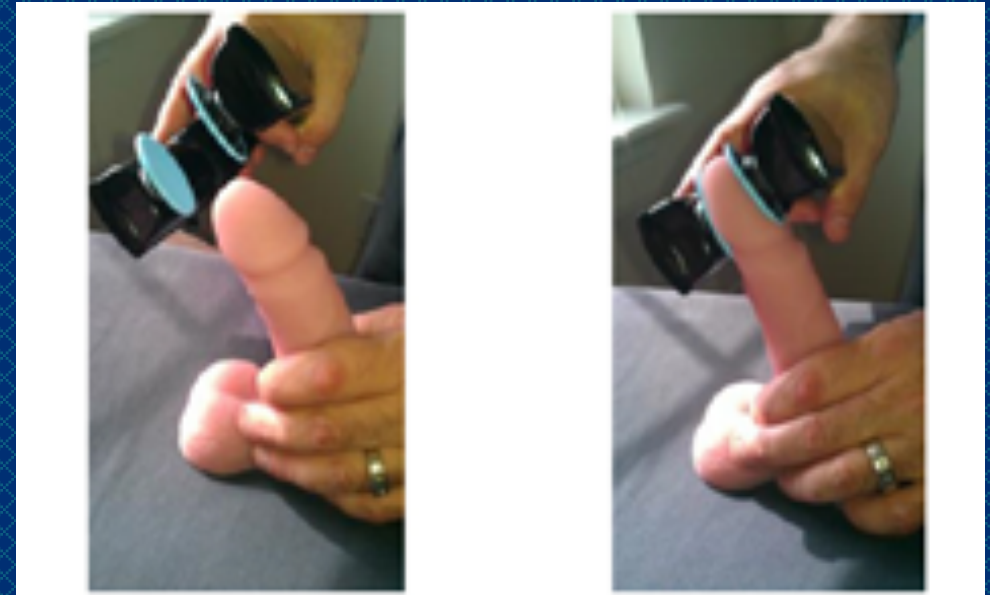
\* = High anxiety and other environmental issues using the device in clinical setting



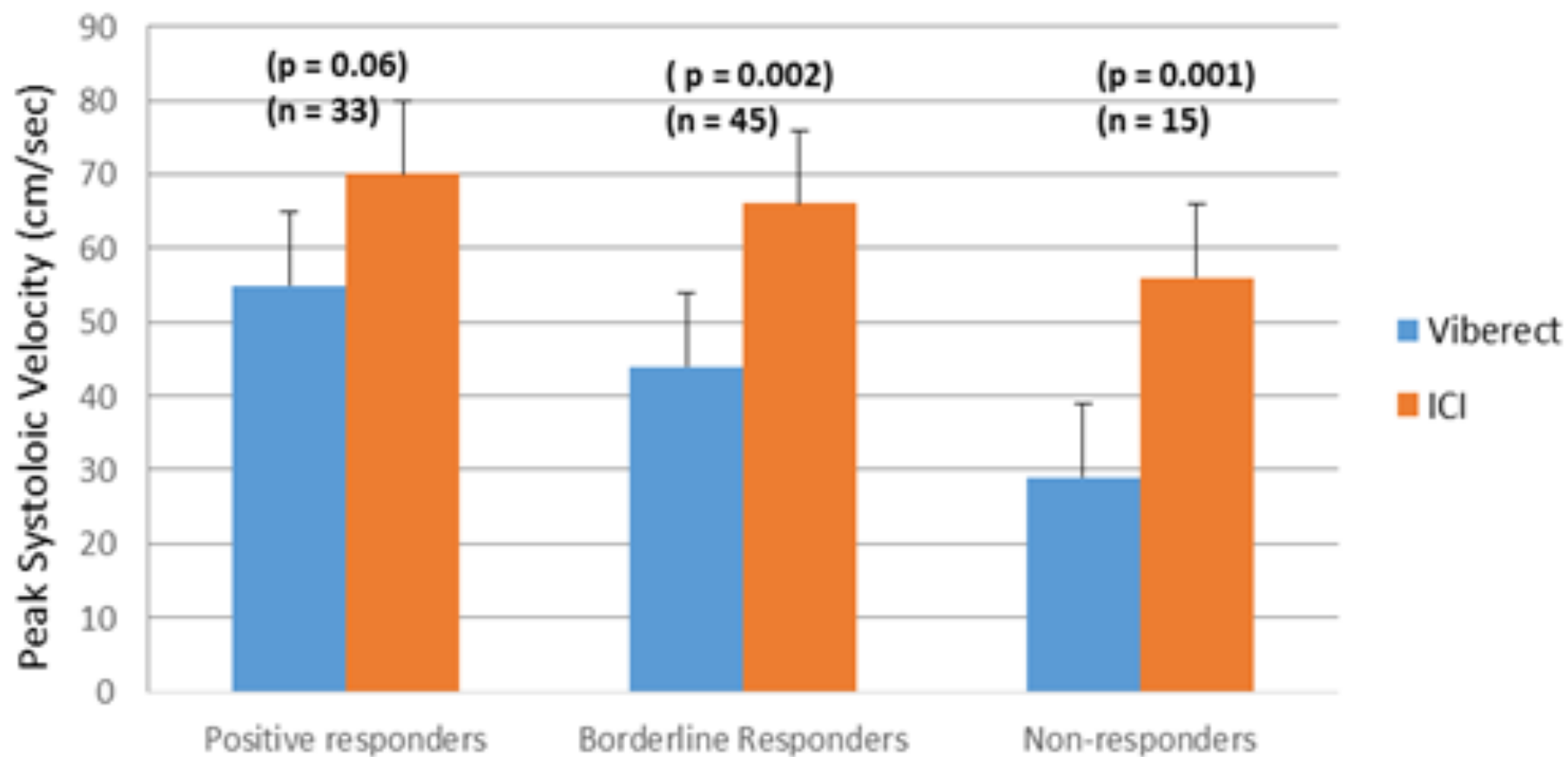
Peak Systolic Velocity (Mean +/- SEM) using Viberec and ICI

## METHODS

- ▶ 105 patients with ED+/-PD 2011-2013 consented as IRB Protocol to use Viberec prior to undergoing penile CDDU. Viberec® stimulation was then performed by the patient at 70-100 Hz for 6-10 minutes prior to performing CDDU as per our standard protocol (*Sikka et al, J Sex Med, 2013*). Following this, the patient rested until the penis was fully flaccid. An ICI of PGE1 at a dose of 7-15 mcg was then administered and CDDU repeated. Settings and visual sexual stimulation were similar for both CDDU evaluations.







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### Drawbacks:

1. Clinic is not ideal setting for PVS
2. Randomization is necessary
3. PVS benefits are not immediate and should be measured over a period of 3-6 months.

# PENILE VIBRATORY STIMULATION AND PELVIC FLOOR THERAPY

## Clinical Applications

1. First line therapy for mild to moderate ED?
  - Head to head studies with PDE5 lacking.
2. Penile rehabilitation after prostate cancer treatment
3. Combine with injection therapy to reduce effective dose & pain
4. Treat retarded orgasm and ejaculation disorders

PRIVATE GYM AND VIBERECT  
ERECTION RECOVERY PROGRAM



# Erection Recovery is a Dynamic Process

## To Improve, Restore, and Maintain Erectile Function

- ▶ Maintain Cardiovascular health
- ▶ Weight Control & Exercise
- ▶ Avoid smoking and excess alcohol
- ▶ Avoid triggers of anxiety and depression
- ▶ Optimize Nerves, blood flow and pelvic floor muscle strength









# PTSD AND NEUROMODULATION

Vagal nerve stimulation

Deep brain stimulation

Trigeminal nerve stimulation

Acupuncture

“Memory consolidation”

“Fear extinction”

Penile Vibratory Stimulation to treat  
PTSD and Psychogenic ED?



THANK YOU