Reflexonic
Innovative Urological Solutions

Certifications:
FDA, CE, ISO 13485:2003, CMDCAS, Health Canada

FDA Indications:
Class II medical device for home and clinic use to provoke penile erection in men with erectile dysfunction, and to provoke ejaculation in men with spinal cord injury (prescription use).

CE Indications:
Penile vibratory stimulation device for the treatment of erectile and ejaculatory disorders (prescription use).

Penile vibratory stimulation is an easy and non-invasive nerve stimulation method, similar to sexual intercourse or manual stimulation that helps to activate nerve receptors (nerve antennas) that are located on the skin surface of the penis. These nerves communicate with sexual centers of the brain and spinal cord. Activation and initiation of sexual reflexes (pudendocavernosus & bulbocavernosus) by the Viberect device helps to initiate penile erection, rigidity, orgasm and ejaculation. This device is designed by urologists specializing in sexual dysfunction to help men benefit from this modality with ease in the comfort of their home.

Clinical Studies on benefits of Penile Vibratory Stimulation with Viberect®

An Objective Evaluation of Viberect® Vibratory Device in Comparison to Intracavernosal Vasoactive Injection for Penile Duplex Doppler Ultrasound Blood Flow Analysis

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Accepted Abstract: International Congress of Andrology, Melbourne, Australia . February 23-26, 2013

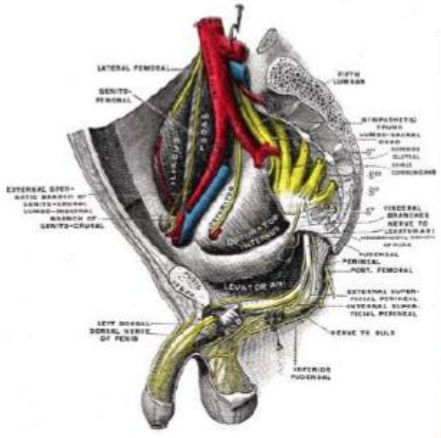
***Background*:** Viberect® is a new FDA-cleared medical vibrator for inducing penile erection, a neurovascular event involving genital afferents.

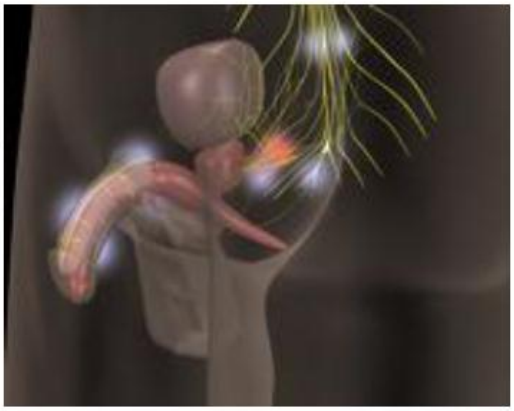
Objective: We compare penile blood flow induced by Viberect® versus intracavernosal injection (ICI) using color duplex Doppler ultrasound (CDDU) technology.

***Methods*:** Forty patients with erectile dysfunction consented to receive instructions and correctly use the vibrator prior to undergoing penile CDDU in our sexual dysfunction clinic. Viberect® stimulation was performed by the patient at 70-100 Hz for 6-10 minutes and CDDU performed as per standard protocol. After the penis was fully flaccid, an ICI (7-15 mcg prostaglandin-E1, PGE1) was administered and CDDU repeated.

Findings: Eighteen men (called "positive-responders" to Viberect®) showed similar systolic velocity measurements with 90% tumescence+70% rigidity erection response (2-tailed paired t-test value of 0.06). Ten patients showed "borderline" systolic velocity and 80% tumescence+30-40% rigidity with Viberect® compared to PGE1 (2-tailed paired t-test value of 0.002). Only four patients (called "non-responders") showed no erection response with Viberect®, but good velocity and 90% tumescence + 60% rigidity with PGE1 (t-test value of 0.006). Eight patients did not complete Viberect® stimulation due to impending ejaculation. Thus, Viberect® induced blood flow response and erection similar to ICI in majority of patients undergoing CDDU evaluation. No complaints or adverse events were reported with Viberect®.

***Conclusions*:** This study suggests that Viberect® that stimulate bulbocavernosus reflex, is a safe, convenient, well-tolerated modality for CDDU. Randomized prospective multicenter trials will be needed to further validate these results and the concept of stimulating bulbocavernosus reflex with Viberect® for ED diagnosis and treatment.





VIBERECT® DEVICE USE BY MEN WITH ERECTILE DYSFUNCTION: SAFETY, EASE OF USE, TOLERABILITY, AND SATISFACTION SURVEY

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Podium Poster, November 2011 SMSNA 2011, Las Vegas, Nevada

Introduction: Penile erection is a nerve generated vascular and mechanical event. Genital afferents activate spinal nuclei and higher centers responsible for sexual and urinary function. Viberect® is a new FDA−cleared medical device indicated to provoke erection and to treat anejaculation in spinal cord injured men. We report a preliminary survey of Viberect® use by men with erectile dysfunction (ED).

Patients and Methods: A representative sample of urology patients with ED (N = 10) were recruited (Table 1). Men were instructed by a unique repetitive reflex teaching program for optimal Viberect® experience. Viberect® stimulation was performed at home for 5−10 minutes at 70−110 Hz at least 3 times a week for one month. Treatment satisfaction was assessed by Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) and Treatment Satisfaction Scale (TSS).

Results: All men completed the surveys. No complaints or adverse events were reported. Viberect® was easy to use, painless, and acceptable. 90% were satisfied with the Viberect® treatment (EDITS Index >50); mean EDITS index score was 77. Mean TSS score was increased significantly from baseline (41.8) to active (66.8) ($p < 0.01$). 90% would continue Viberect® treatment and recommend its use to their friends.

Conclusion: This preliminary survey suggests Viberect® use by men with ED is a safe, convenient, well−tolerated, and highly satisfying modality for treatment of ED. Randomized prospective trials are necessary to authenticate these important findings.

	Age	Diagnosis	Baseline IIEF-ED*	Time of Prostatectomy to beginning Survey	EDITS Score (Patient)	TSS Baseline	TSS Active
1	69	ED, PCA	21	2 months	75	26	59
2	55	ED, PCA	26	10 days	84	38	63
3	61	ED, PCA	19	8 months	89	33	62
4	60	ED, PCA	24	8 months	89	50	78
5	60	ED, PCA	16	4 months	61	41	58
6	80	ED	2	N/A	63	25	60
7	32	ED, Depression	20	N/A	97	68	92
8	49	ED	25	N/A	92	70	95
9	55	ED	16	N/A	47	34	33
10	73	ED	18	N/A	75	33	64

PCA: prostate cancer
*: IIEF-ED prior to radical prostatectomy if applicable

Abstract

Objective Assessment of the Efficacy of the Viberect Device to Provoke Penile Erection in Men with no ED

Johns Hopkins University Preliminary study

Introduction & Objectives

Current strategies employed to treat erectile dysfunction (ED) all target the vascular component of erections to achieve improved tumescence and rigidity for sexual intercourse. A new, FDA-approved treatment for ED, which exploits vibratory stimulation of genital afferent nerves as means of provoking erections, the Viberect® device, has not been rigorously assessed in clinical studies. The objective of this study was to objectively assess the efficacy of the Viberect® device to provoke erections in healthy men with no ED.

Methods

Six healthy subjects with normal erectile function as measured by responses to the IIEF-EF questionnaire were studied. The Erection Hardness Score (EHS) was used for subjective assessment of maximally rigid erection. Subjects were instructed on a penile stretching exercise meant to stimulate the bulbocavernosus reflex to achieve reflex erection. The Rigiscan device, set to the provocative ambulatory mode, was applied to the penis, and the Viberect® treatment initiated without any external visual sexual stimulation (VSS). Rigiscan measures of rigidity were recorded, as were adverse effects.

Results

Subjective assessments of erectile rigidity using the EHS for both the BCR stretching exercise as well as the Viberect® treatment did demonstrate a notable erectile response. 5/6 patients scored their maximal erection with the Viberect® device at 4/4 without the use of any visual sexual stimulation. Objective assessment with the Rigiscan did demonstrate the ability of the Viberect® to stimulate an erectile response, with a mean increase in penile basal girth of 2.3 cm, mean tumescence percentage above baseline of 24.5% and an average time of the tumescence episode beyond 55% total rigidity of 15%. There were no reported adverse effects, and all subjects felt that the Viberect® would be a reasonable, practical treatment for ED.

Conclusion

The results of this study provide evidence of an erectile stimulatory effect of penile vibratory stimulation utilizing the Viberect® device in healthy men without ED in the absence of VSS. These results provide proof that penile vibratory stimulation can be employed to provoke erections, and support further study of this modality in men with ED.

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THE MIAMI PROJECT TO CURE PARALYSIS

EFFICACY OF A NEW DEVICE FOR INDUCING EJACULATION IN MEN WITH SPINAL CORD INJURY (SCI)

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OBJECTIVE

- Most men with spinal cord injury are anejaculatory and require medically assisted ejaculation procedures to retrieve semen for insemination or for investigation.
- Penile vibratory stimulation (PVS) is recommended as the first line of treatment for this problem.

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J Urol 2010;183(6):2304-8

OBJECTIVE

- A new device for PVS of men with SCI has become available (Viberect®; Reflexonic, USA), however, its success rate in treating SCI-related anejaculation has not been reported.
- Our goal was to test the efficacy of the Viberect device for ejaculation of men with SCI.

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METHODS

- Patients were selected based on historical data with the Ferti Care device.
- At least three previous trials.
- Consistent pattern of response on all trials.

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METHODS

- Patients received trials with the Viberect device.
- A retail version of the Viberect was used which delivered an amplitude of 3 mm.
- PVS applied for 2 minutes. If no ejaculation, PVS repeated after 2 minute break.

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Testing with Retail Viberect

Pt	Level of Injury	Completeness of Injury	Previous ejaculation with FertiCare?	Ejaculation with Viberect Prototype?	Ejaculation with Retail Viberect?
1	C4	C	Yes	No*	-
2	C5	C	Yes	No*	Yes
3	C5	C	Yes	Yes	Yes
4	C7	I	Yes	No*	-
5	T3	I	Yes	No*	Yes
6	T4	C	Yes	Yes	Yes
7	T4	C	Yes	Yes	Yes
8	T7	C	Yes	No*	
9	T10	C	Yes	No*	No*
10	C7	C	No	No	-
11	T5	C	No	No	-
12	C4	I	Yes	-	Yes
13	C5	I	Yes	-	No*
14	C6	C	Yes	-	Yes
15	C6	C	Yes	-	Yes
16	C8	C	Yes	-	Yes
17	T2	I	Yes	-	Yes
18	T3	C	Yes	-	Yes

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C = Complete, I = Incomplete, *Subsequent ejaculation with Ferti Care

Conclusions

- This is the first study to report the efficacy of the Viberect device for ejaculation of men with SCI.
- Although this is a preliminary study in a small group of patients, the results indicate that the Viberect can be used to safely induce ejaculation in patients with SCI.
- Larger studies are required to assess candidates for the Viberect versus other devices for PVS of men with SCI.

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Urology. 2007 Mar;69(3):552-5; discussion 555-6.

Assessment of penile vibratory stimulation as a management strategy in men with secondary retarded orgasm.

Nelson CJ, Ahmed A, Valenzuela R, Parker M, Mulhall JP.

Source

Department of Psychiatry and Behavioral Sciences, Memorial Sloan-Kettering Cancer Center, New York, New York 10022, USA. nelsonc@mskcc.org

Abstract

OBJECTIVES:

To evaluate the effectiveness of penile vibratory stimulation for the management of retarded orgasm. Retarded orgasm, a condition characterized by difficulty achieving orgasm and ejaculation, is one of the most recalcitrant of the male sexual dysfunctions. Currently, no evidence-based treatments have been proven to ameliorate this condition.

METHODS:

Men who had a complete inability to achieve an orgasm during sexual relations in the previous 3 months were instructed in the use of penile vibratory stimulation. The men's responses were measured by self-report of orgasm function and using the orgasm and satisfaction domains of the International Index of Erectile Function. The responses were assessed at baseline (admission into the study) and at 3 and 6 months.

RESULTS:

A total of 36 men met the inclusion criteria, and 72% reported the restoration of orgasm. These responders reported that orgasm during sexual relations occurred 62% of the time. A statistically and clinically significant increase occurred in the orgasm and satisfaction domains of the International Index of Erectile Function between the baseline visit and the 3-month follow-up visit. These gains were sustained at 6 months.

CONCLUSIONS:

Penile vibratory stimulation is an effective treatment for retarded orgasm. Penile vibratory stimulation should be integrated into current cognitive-behavioral sex therapy techniques to achieve maximal effectiveness and satisfaction.

Int J Impot Res. 1996 Dec;8(4):221-5.

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

Chun SS, Fenemore J, Heaton JP, Johnston B, Morales A.

Source

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

Abstract

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.

J Sex Med. 2009 Jul;6(7):1867-74. Epub 2009 Apr 24.

Prevalence and characteristics of vibrator use by men in the United States.

Reece M, Herbenick D, Sanders SA, Dodge B, Ghassemi A, Fortenberry JD.

Source

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Abstract

INTRODUCTION:

While vibrating products have been recommended by clinicians for the treatment of male sexual dysfunctions, knowledge is lacking with regard to the prevalence of vibrator use among men in the United States, the characteristics of men who use vibrators, and whether there are relations between vibrator use and sexual function among men.

AIMS:

To establish lifetime and recent prevalence rates for vibrator use by men in the United States, to document the characteristics of men who use vibrators and their reasons for using vibrators, and to explore relations between men's vibrator use and sexual function.

METHODS:

During April 2008, data were collected from a population-based cross-sectional survey of 1,047 men aged 18-60 years in the United States. Analyses were conducted using post-stratification data weights.

MAIN OUTCOME MEASURE:

Measures included sociodemographics, health status and health-related behaviors, sexual behaviors, vibrator use, and sexual function.

RESULTS:

For both solo and partnered sexual activities, the prevalence of men who had incorporated a vibrator into sexual activities during their lives was 44.8%, with 10.0% having done so in the past month, 14.2% in the past year, and 20.5% over 1 year ago. Men who had used vibrators, particularly those with more recent use, were more likely to report participation in sexual health promoting behaviors, such as testicular self-exam. Men who had used vibrators recently also scored higher on four of the five domains of the International Index of Erectile Function (erectile function, intercourse satisfaction, orgasmic function, and sexual desire).

CONCLUSIONS:

Among men in the United States, vibrator use during solo and partnered sexual interactions is common and is associated with a wide array of positive sexual health characteristics. Future research should continue to explore ways in which men incorporate vibrators into solo sexual acts, partnered sexual play, and sexual intercourse.

J Sex Med. 2011 May;8(5):1299-312. doi: 10.1111/j.1743-6109.2011.02211.x. Epub 2011 Feb 16.

The role of genital nerve afferents in the physiology of the sexual response and pelvic floor function.

Tajkarimi K, Burnett AL.

Abstract

INTRODUCTION:

Our understanding of genital and pelvic floor physiology is rapidly expanding. Penile erection is a neurovascular event controlled by spinal autonomic centers, the activity of which is dependent on input from supraspinal centers and the genitalia. Genital afferent stimulation excites spinal autonomic nuclei and supraspinal sexual centers of both genders.

AIM:

To present a detailed understanding of the functional importance of genital afferent neuroanatomy and neurophysiology.

METHODS:

English-written articles of diverse disciplines from 1980 to 2010 that contained information on genital anatomy, pudendal/dorsal/perineal/cavernous nerves, vibratory stimulation, reflexogenic erection, peripheral/central nervous system-mediated erectile and micturition pathways, and sexual arousal in animals and humans were reviewed.

MAIN OUTCOME MEASURES:

Analysis of supporting evidence for the role of genital afferents in the physiology of erectile response and pelvic floor function.

RESULTS:

Basic science and clinical studies support the concept that pudendal nerve circuitry serves an essential purpose for sexual behavior, erectile function, penile rigidity, ejaculation, and micturition. Males and females share a comparable pattern of genital afferent neuroanatomy and neurophysiology, and sexual and micturition reflexes are similar in both genders. Pudendal nerve branches communicate with the cavernous nerves and are nitric oxide synthase positive. Genital afferents activate multiple spinal reflexes that modulate erection and micturition. Genital sensory information is transmitted to supraspinal centers important for sexual function.

CONCLUSIONS:

There is expanding support for the critical role of genital afferent neurophysiology in the mechanisms of erectile function and micturition. Genital afferent stimulation is a safe and natural modality that can be harnessed to amplify autonomic and somatic activity within the penis, female genitalia, spinal cord, and higher centers via established neurological principles. Such physiological adaptive processes may be beneficial in improving sexual response, erectile function, and micturition in many disease states, including in men after radical pelvic surgery. Well-designed and -executed studies in each specific population are needed to authenticate such prospects.