

# **OLD GADGET, NEW TRICKS: SCIENCE AND CLINICAL EVIDENCE OF VACUUM THERAPY**

盧致誠  
2016-3-5

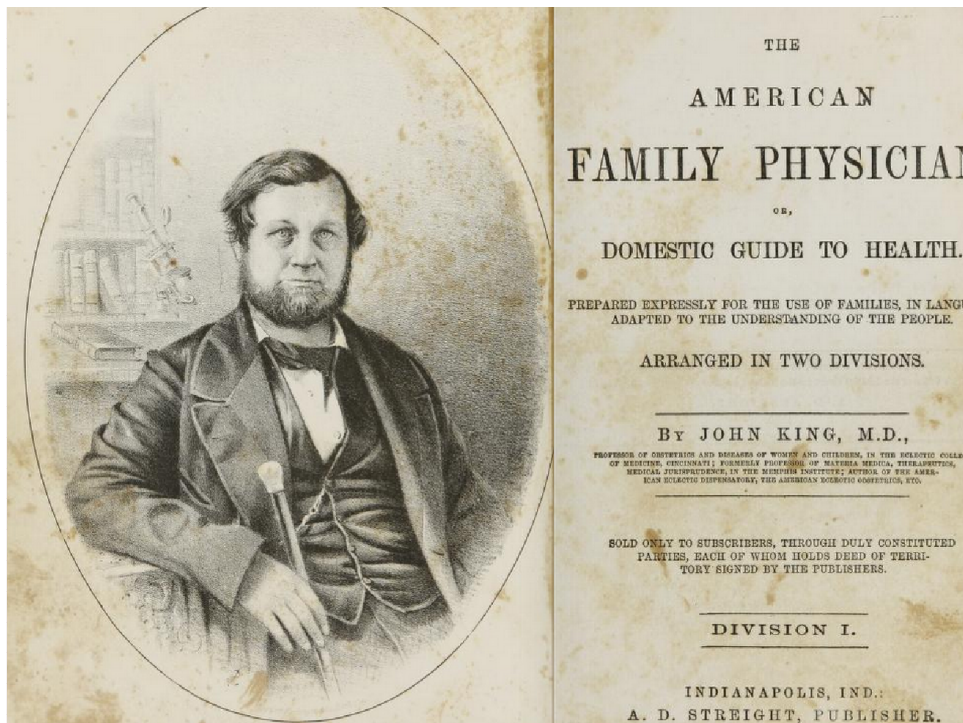
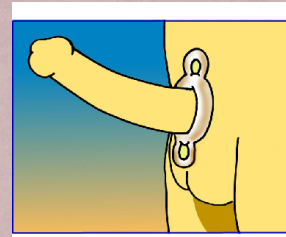
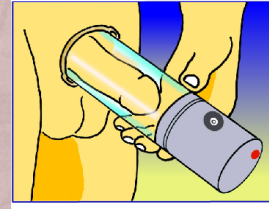
## **OUTLINES**

- **Historical Perspective**
- **Science & Clinical evidence**
  - **mechanism of action (MoA)**
  - **safety and efficacy**

## Historical Perspective

### Defined Terminology

- Vacuum therapy (VT) uses negative pressure to distend the corporal sinusoids and to increase blood inflow to the penis.
- Vacuum Constriction Device (VCD)
- Vacuum Erection Device (VED)



When there is impotency, with a diminution in the size of the male organ, the organ should be shampooed every day, and a liniment applied to it and the neighboring parts, composed of, Oil of Rosemary one fluidounce. Phosphorus twelve grains; mix in a flask, and dissolve it over a lamp, then while warm, add, Oil of Sweet Almonds one fluidounce, Tincture of Musk one fluidounce. In addition to this, the **glass exhauster** should be carefully applied to the part, once every day.\* If necessary the following may be given internally:—take of Musk six grains, Phosphorus one grain, Ether one fluidrachm; mix, and dissolve the Phosphorus. The dose is



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\* The **glass exhauster** is a cylindrical glass tube, about nine inches in length, and two inches in diameter; one end is open, the other is fitted with a nipple for a small exhausting pump to be placed upon, the same as in a cupping glass. The male organ being placed in this glass, the air is exhausted, the blood fills the vessels of the part, and thus excites a new action. Great care must be taken not to exhaust the air too rapidly, or to too great a degree, as injury to the parts would follow.



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## Historical Perspective

### History

**1874**

**John King, MD** (when there is impotency with a diminution of the size of the male organ, the glass exhauster should be applied to the part)



**1917**

**Otto Lederer** (first patent-surgical device to produce erection with vacuum in conjunction with a compression ring)



**1960s**

**Geddins Osbon** (popularizing and perfecting the device with personal use of the device for more than 20 years)



**1982**

**1<sup>st</sup> VCD approved by US FDA**



**1986-1989** (established efficacy and safety profiles)

**Nadig /Witherington, MDs**



**1996**

**AUA** (recommendation in the guidelines as one of the treatment for organic ED)

## Historical Perspective

### Historical milestones in medical community

**1991 : Lue's commentary in the Journal: "I recommend a vacuum constriction device to all of my patients (except those with coagulation disorders and sickle cell disease) as the initial medical option"**

penile prosthesis implantation

#### Recommendations

**Guideline:** In order to optimize efficacy and safety, men interested in trying the vacuum constriction device should be given individual instruction in its use. Only VCDs available by prescription should be used.

The Treatment of  
Organic Erectile  
Dysfunction  
Archives  
For Reference Only

Clinical Practice Guidelines

J Urol 1991; 145: 1112 ; J Urol 1996; 156: 2007-2011

## Science & Clinical evidence

### MoA – Animal Model



European Association of Urology

#### Sexual Medicine

### Molecular Mechanisms of Vacuum Therapy in Penile Rehabilitation: A Novel Animal Study

Jiuhong Yuan<sup>a,b</sup>, Haochen Lin<sup>c,b</sup>, Ping Li<sup>d</sup>, Rongzheng Zhang<sup>e</sup>, Annie Luo<sup>e</sup>,  
Francesco Berardinelli<sup>f</sup>, Yutian Dai<sup>e</sup>, Run Wang<sup>b,g,\*</sup>

**Results and limitations:** EF was improved with VED therapy measured by ICP/MAP ratios and AUC. VED therapy reduced HIF-1 $\alpha$  expression and AI significantly compared with control. Animals exposed to VED therapy had decreased TGF- $\beta$ 1 expression, increased smooth muscle/collagen ratios, and preserved ASMA and eNOS expression.

**Conclusions:** To our knowledge, this is the first scientific study to suggest that VED therapy in the BCNC rat model preserves EF through antihypoxic, antiapoptotic, and antifibrotic mechanisms.

Eur Urol. 2010 Nov;58(5):773-80

## Science & Clinical evidence

### MoA – Human Study

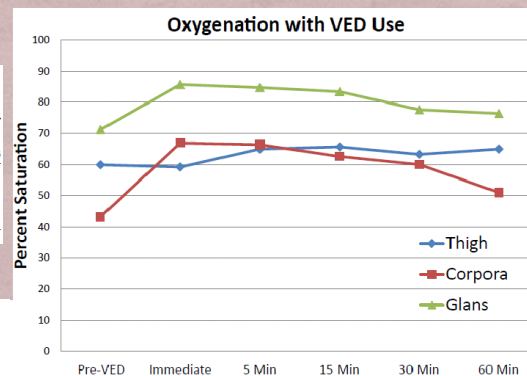
#### A Pilot Study to Determine Penile Oxygen Saturation Before and After Vacuum Therapy in Patients with Erectile Dysfunction After Radical Prostatectomy

R. Charles Welliver Jr, MD,\* Clay Mechlin, MD,<sup>†</sup> Brianne Goodwin, MS, MPH,<sup>‡</sup> Joseph P. Alukal, MD,<sup>§</sup> and Andrew R. McCullough, MD<sup>¶</sup>

**Table 2** Percent change in oxygen saturation at tissue sites (percent change compared with baseline)





	Immediate	5 minutes	15 minutes	30 minutes	60 minutes
Thigh	-1	8	10	6	9
Glans	20	19	17	9	7
Corpora	55	54	45	39	18

**Figure 1** Tissue oxygenation after 2 minutes/10-cycle application of VED. VED = vacuum erection device



J Sex Med. 2014 Apr;11(4):1071-7

## VACUUM AS RECOMMENDED MEDICAL THERAPY AMONG CONTEMPORARY GUIDELINES

	EAU 2015 	AUA 2009 	KSSMA 2011 	JSSM 2006 
First-Line	PDE 5Is <b>VCD</b> Shockwave*	PDE 5Is	PDE 5Is <b>VCD</b>	PDE 5Is <b>VCD</b>
Second-Line	ICI Combination	<b>VCD</b> , Urethral/Local alprostadil, and penile prostheses	ICI	Urethral/Local alprostadil,
Third-Line	Penile prosthesis		Penile prosthesis	Penile prosthesis

\*Current data are still limited and clear recommendations cannot be given.

## TAKE HOME MESSAGE

- Vacuum erection devices provide a safe, cost effective, and noninvasive **alternative** for ED men (**Historical**)
- A resurgence because of the proven science and clinical evidence (**Physical, Animal, Human, Clinical, EBM**)
  - ✓ Recommended among the guidelines and further used in combination for salvage patients
  - ✓ VED therapy for penile rehabilitation is achieved by increasing arterial inflow, anti-apoptotic, anti-fibrotic and anti-hypoxia mechanisms.
  - ✓ Protection of the vasculature through physical oxygenation with non-nerve dependent mechanism
- Requiring appropriate **individual instruction** & training in the use of vacuum device

## OLD GADGET, NEW TRICKS:



衛生福利部食品藥物管理署

Food and Drug Administration, Ministry of Health and Welfare

### 西藥、醫療器材、化粧品許可證查詢

詳細處方成分 | 藥物外觀 | 仿單/外盒資料 | 授權使用 |  
價資料 | 離 開

#### 許可證詳細內容

\*\*\* 衛部醫器輸字第025952號 \*\*\*

註銷狀態		註銷日期	
註銷理由			
有效日期	108/03/03	發證日期	103/03/03
許可證種類	醫 器		
舊證字號		醫療器材級數	第二等級