Pilot Clinical Studies

The efficacy of PEVArx™ was studied in a pilot, placebo controlled study (2011)

Population: 43 men with PE, 24-67 years of age (37.9±1.2)

Study duration: 3 months

Results

Duration of sexual intercourse in the treatment group increased on average from 0.9 minute to 3.5 minutes ($p<0.05$) in 67.8% of patients

The efficacy and safety of PEVArx™ was studied in and open label, multi center study (2013)

Population: Men with reported rapid ejaculation

Sites: 9

Results:

- Increased length of penetration phase on average by 2.5 times
- Improved sexual function as a whole and over all well being

PEVArx™ Clinical Study

The efficacy and safety of PEVArx™ was studied in a multi center, non-interventional (observational) study in men with sexual dysfunction

Population: 665 men with sexual dysfunction (analysis on 630 patients)
Clinical sites: 23 centers
Duration: 2 months
Study design: Observational
Study article: PEVArx™ - two (2) capsules taken twice daily (oral)
Inclusion: Sexual dysfunction (PE ED, anxiety, erosion of orgasm)
Exclusion: Contraindication for study article, acute psychiatric symptoms
Measurement tools:

- Individual registration card (IRK)
- Concomitant therapy information
- Hospital anxiety and depression scale (HADS)
- Modified IIEF to measure ejaculatory function

PEVArx™ Clinical Study Design

- ICF
- Assessment criteria
- IRK
- Record concomitant therapy
- Modified IIEF (measure sexual dysfunction)
- HADS
- Dispense study article

- IRK
- Record concomitant therapy
- Modified IIEF (measure sexual dysfunction)
- HADS

- IRK
- Record concomitant therapy
- Modified IIEF (measure sexual dysfunction)
- HADS

Population: 665 adult men with sexual disorder
Duration: 2 months
Dosage: 2 capsules/ twice daily

PEVArx™ Clinical Study Data Analysis

Data was divided into three groups:

- **Group 1**: PE (rapid ejaculation) Self reported (N=582 / 92.4%)
- **Group 2:** Orgasmic disorder (N=17 / 2.7%)
- **Group 3**: Urologic disease (inflammatory disease of the prostate, ED, BPH etc.) secondary to anxiety (N=31 / 4.9%)

Evaluation of effectiveness on duration of penetration phase of sexual contact time grading scale

- **Pronounced effect:** ≥ 50% increase in duration
- **Good effect** 30-49% increase in duration
- **Satisfactory effect:** 10-29% increase duration
- **An unsatisfactory effect:** absence of positive dynamics of the patient or the patient's degradation

PEVArx™ Effectiveness on Duration

Effectiveness of treatment in patients during penetration phase of sexual contact (duration time)

All groups

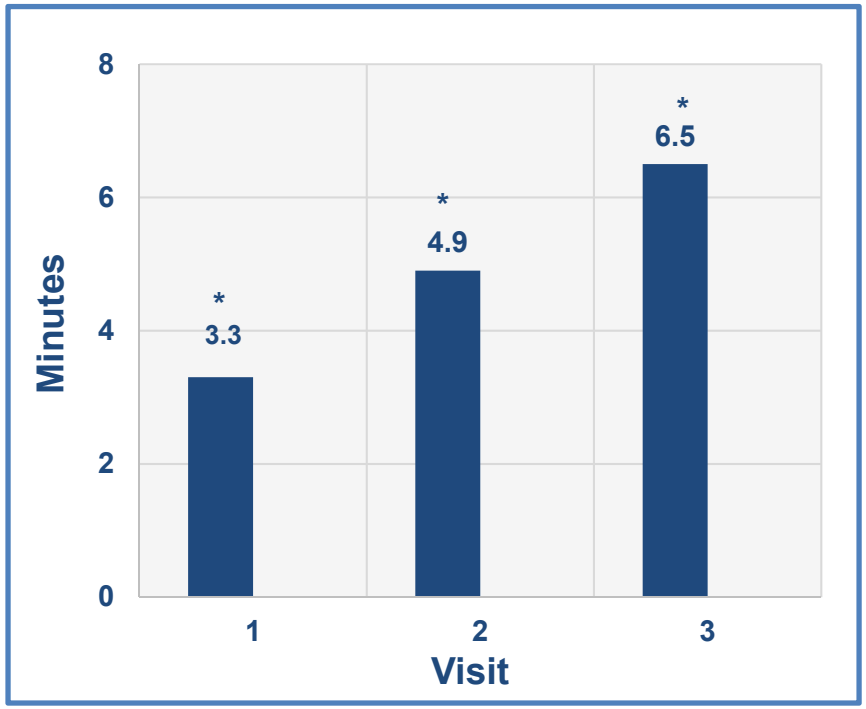
	Visit 2		Visit 3		$(p)_{2-3}$
	(n)	%	(n)	%	
Pronounced	358	60.6	470	81.0	0.00
Good	54	9.1	34	5.9	0.052
Satisfactory	35	5.9	19	3.3	0.014
Unsatisfactory	144	24.4	57	9.8	0.00
Total	591		580		

Group 1: PE patients

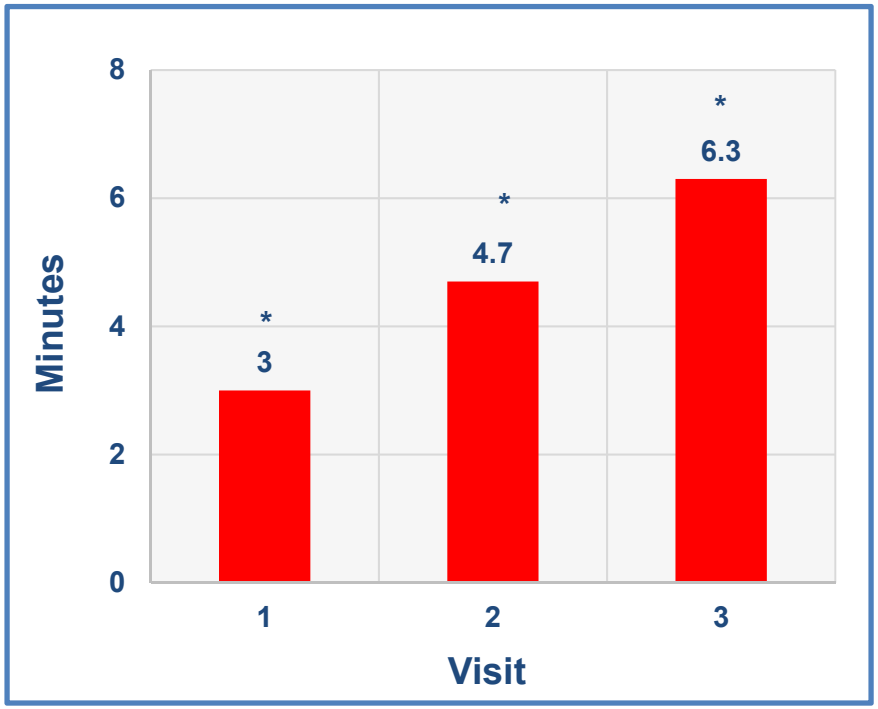
	Visit 2		Visit 3		$(p)_{2-3}$
	(n)	%	(n)	%	
Pronounced	344	61.9	451	82.8	0.00
Good	50	9.0	32	5.9	0.06
Satisfactory	34	6.1	16	2.9	0.017
Unsatisfactory	128	23.0	46	8.4	0.00
Total	556		545		

Mean Duration of Sexual Intercourse

All groups



Group 1: PE patients

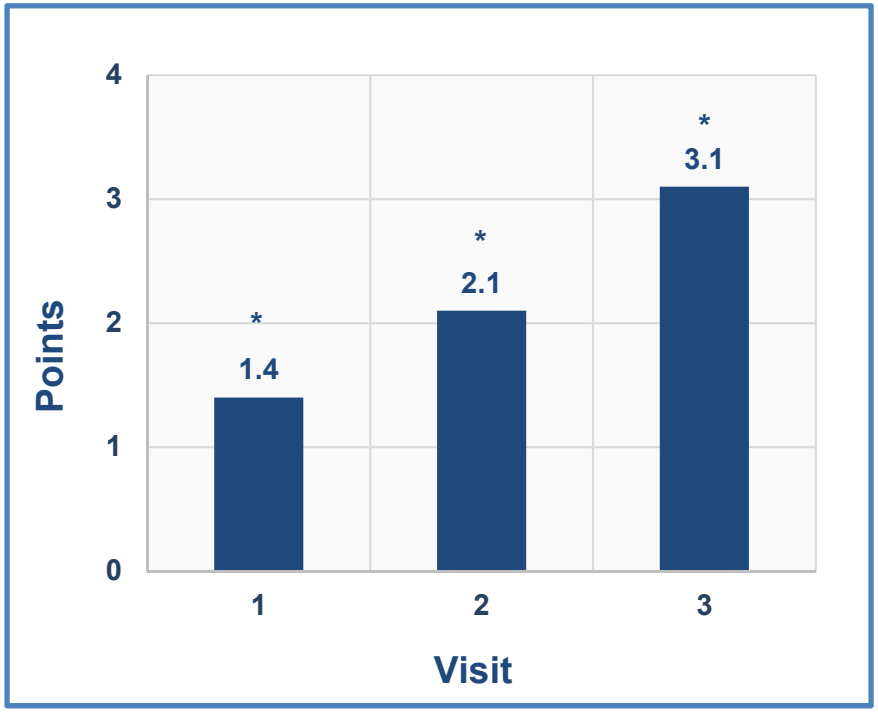


* = P < .001

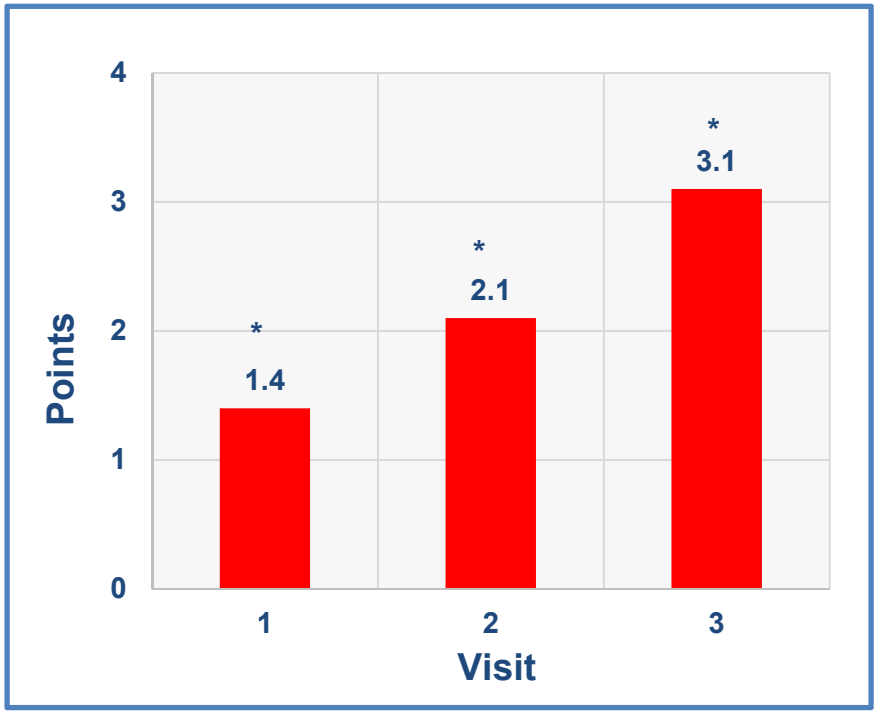
2.5 times increase in penetration duration in PE patients

Mean Satisfaction with Sexual Intercourse

All groups



Group 1: PE patients

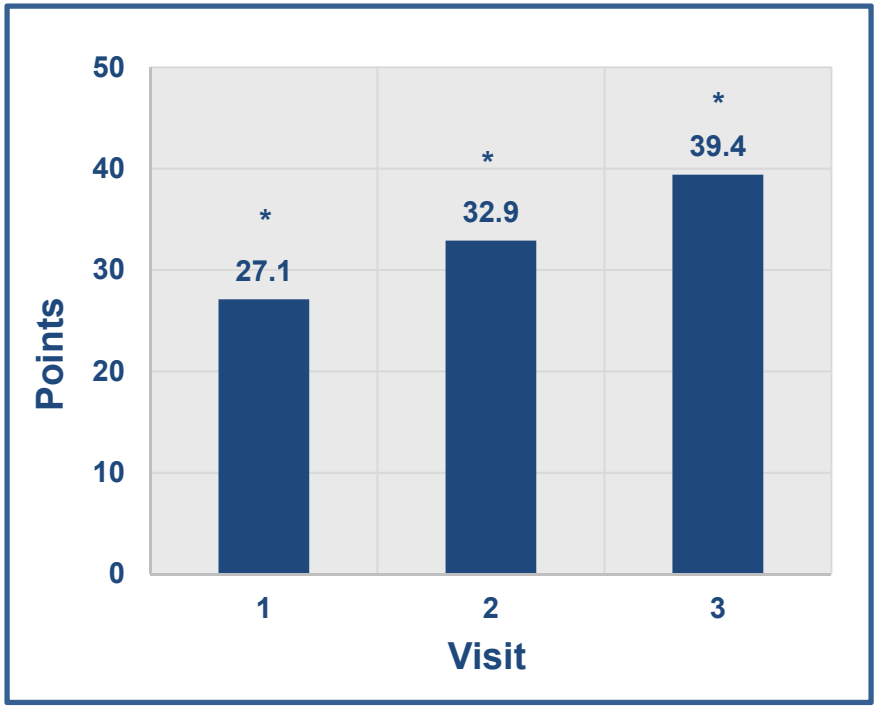


* = P < .001

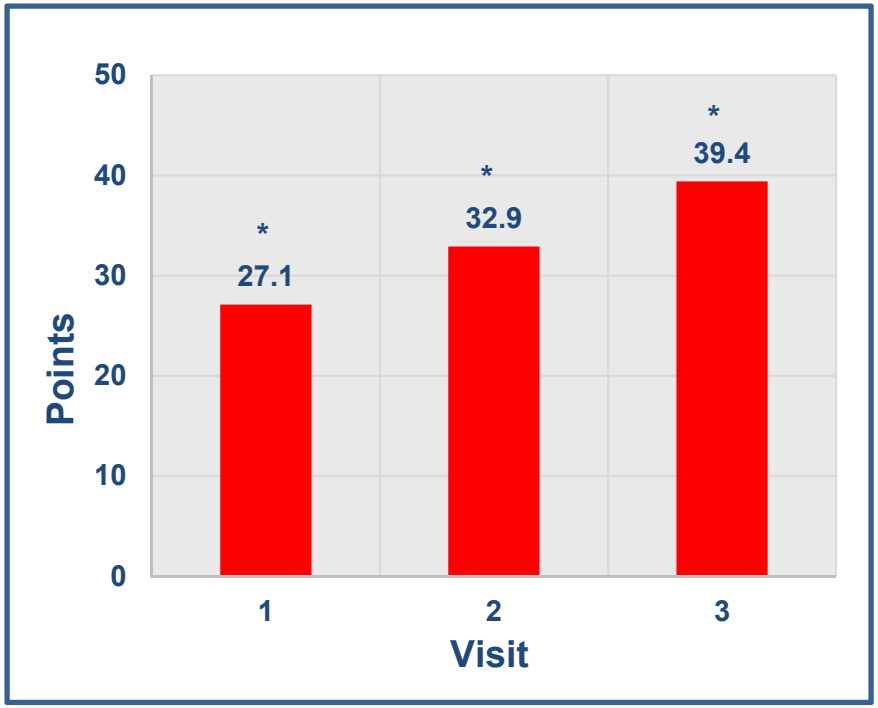
PE patients reported on average a 3 fold increase on total satisfaction

Mean IIEF Sum of Points

All groups



Group 1: PE patients



* = P < .001

Statistically significant improvement on almost all domains

PEVArx™ Adverse Events

Adverse events related to PEVArx™

AE	N	%
Mild allergic reaction	1	0.16
Hyperemia	1	0.16
Drowsiness	3	0.47
Dry cough	1	0.16
Total	**6**	**0.95**

Adverse events possibly related to PEVArx™

AE	N	%
Neuralgia, nausea	4	0.63
Perineal discomfort	2	0.32
Heart rate increases slightly	1	0.16
Total	**7**	**1.1**

PEVArx™ Clinical Study Results

Efficacy

- Penetration duration: 91.6% of patients in Group 1 (PE population) reported an increase on average of 2.5 times at end of study
- Overall patient satisfaction: On average, 3 times increase in all groups
- IIEF domains: Statistically significant improvement of sexual function of patients on virtually all domains
- Anxiety-depressive symptoms: Decrease on symptoms HADS scores in 90% of the patients.
- Concomitant medications: Notable decline in continued use of other medicines and dietary supplements (Group1 decreased from 21.9% to 12.7% by end of study)

Safety

- Well tolerated both alone and in combination with other drugs