

Preliminary Efficacy of Sildenafil Cream, 3.6% During Female Sexual Arousal

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Disclosures

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Individual Author Disclosures Presented Below:

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Consultant/Advisory Board: Strategic Science & Technologies, Ipsen;
Research: BTL Industries, Ipsen, Strategic Science & Technologies

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Introduction

- ▶ **Sildenafil Cream, 3.6%**, is a novel topical formulation in Phase 2 clinical development for the treatment of Female Sexual Arousal Disorder (FSAD).
- ▶ **Female Sexual Arousal Disorder (FSAD)** is characterized by decreased clitoral and labial sensation, reduced genital engorgement and diminished vaginal lubrication.
- ▶ **Research to date** has provided substantial evidence supporting the role of the NO-cGMP smooth muscle mediated vasodilatory pathway in the female sexual arousal response, advocating for the continued investigation of Sildenafil Cream, 3.6%, as a first-in-class therapy for FSAD.

Study Objectives

Primary Objective:

- To evaluate the feasibility of using thermography to assess the pharmacodynamics of Sildenafil Cream, 3.6% in normal healthy women

Secondary Objectives:

- To evaluate the preliminary efficacy of 2 grams of Sildenafil Cream, 3.6% on vulvar blood flow, as assessed by thermography in normal healthy women
- To estimate the time to onset of 2 grams of Sildenafil Cream, 3.6% on vulvar blood flow, as assessed by thermography in normal healthy women
- To evaluate the preliminary efficacy of 2 grams of 5% Sildenafil Citrate on self-reported physiological genital response, as assessed by the Sexual Arousal Questionnaire
- To further evaluate the safety of a single-dose of Sildenafil Cream, 3.6% in normal healthy women

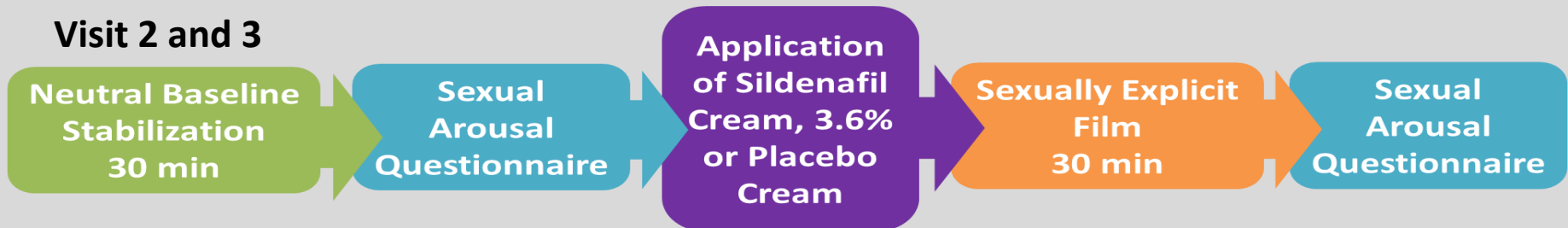
Methods

- **Product:** Sildenafil Cream, 3.6%
- **Sample:** six women (25-55 years) without sexual dysfunction
- **Design:** double-blind, placebo-controlled, 2-way crossover study
- **Treatment:** Visit 1 (no cream); Visits 2-3 (Sildenafil Cream, 3.6% or Placebo Cream)
- **Measurements:** temperature in the vestibule and clitoris (by thermography) and self reported arousal (by sexual arousal questionnaire)

Visit 1



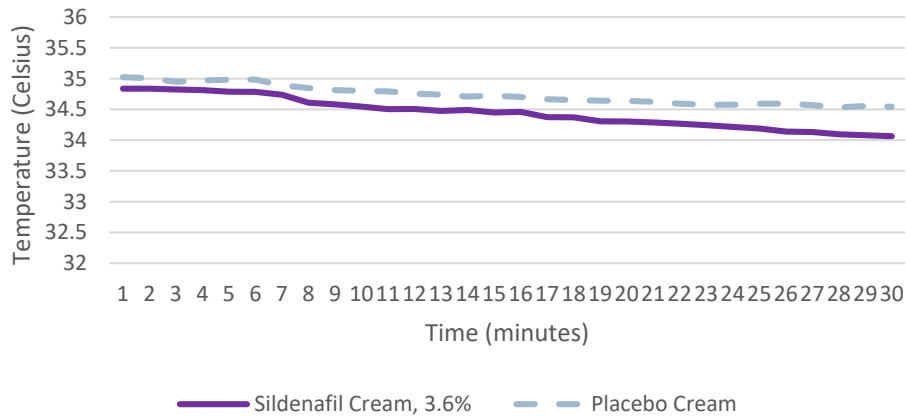
Visit 2 and 3



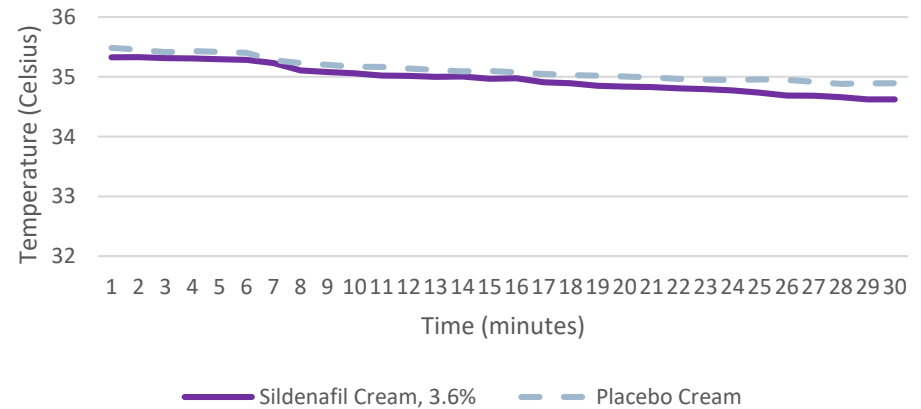
Results: Genital Temperature

Baseline Genital Temperature

Clitoral Temperature: Pre-Dose
Neutral Film



Vestibular Temperature: Pre-Dose
Neutral Film

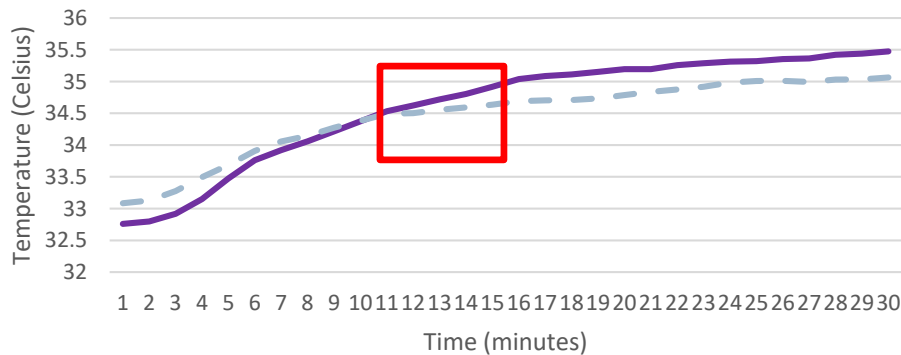


***No Significant Differences in Baseline Genital Temperature
(Sildenafil Cream, 3.6% vs. Placebo Cream)***

Results: Genital Temperature

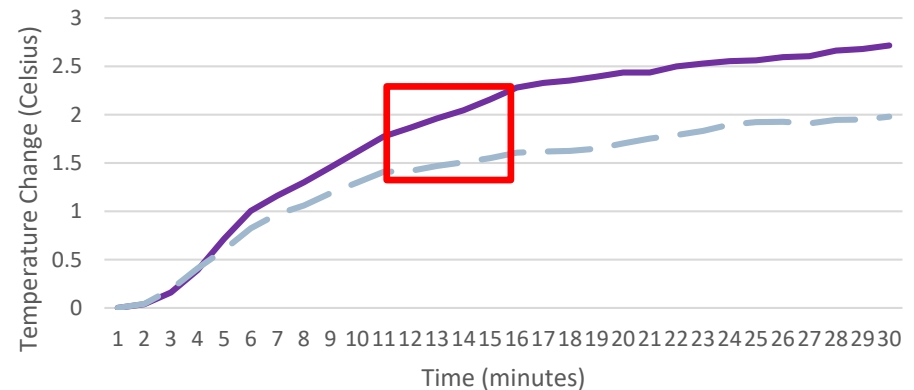
Clitoral Temperature and Change During Sexually Explicit Film

Clitoral Temperature: Sexually Explicit Film



— Sildenafil Cream, 3.6% - - - Placebo Cream

Clitoral Temperature Change: Sexually Explicit Film

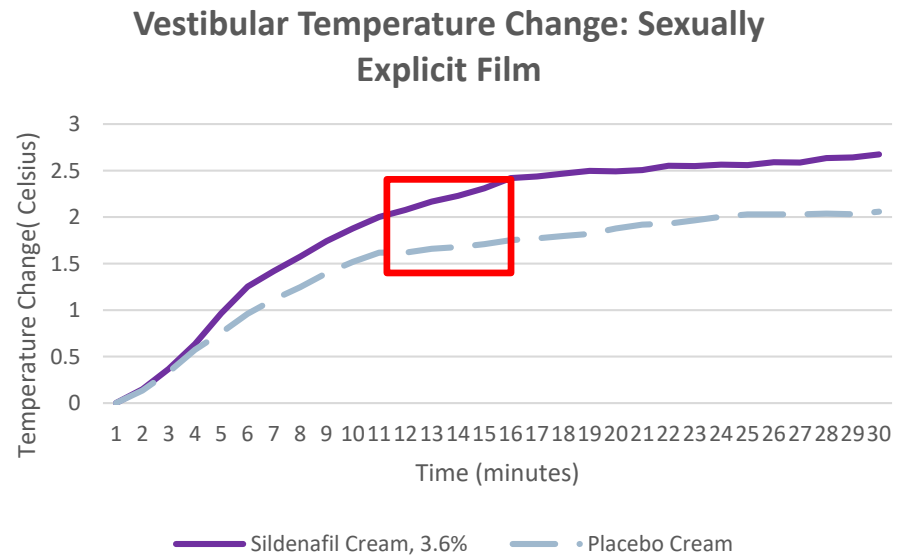
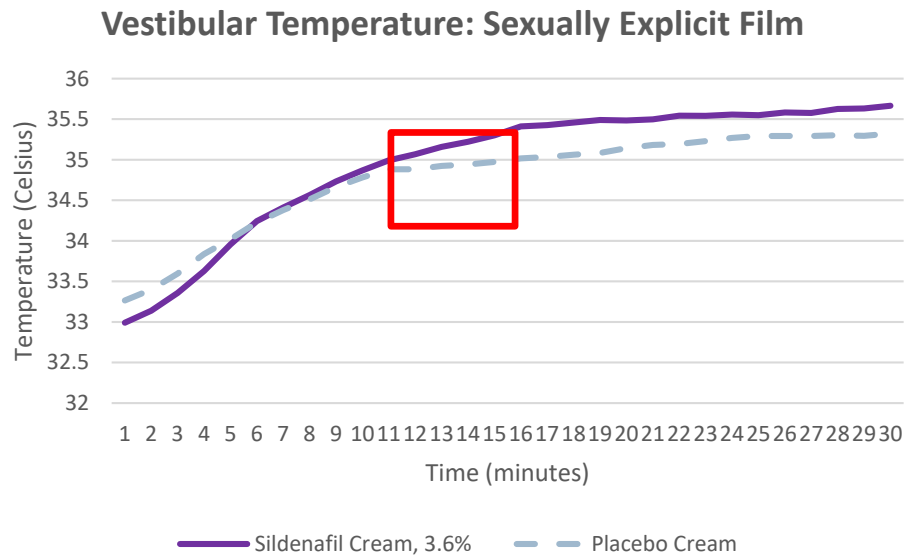


— Sildenafil Cream, 3.6% - - - Placebo Cream

***Significant Differences in Genital Temperature Over Time
(Sildenafil Cream, 3.6% vs. Placebo Cream) $p=.05$***

Results: Genital Temperature

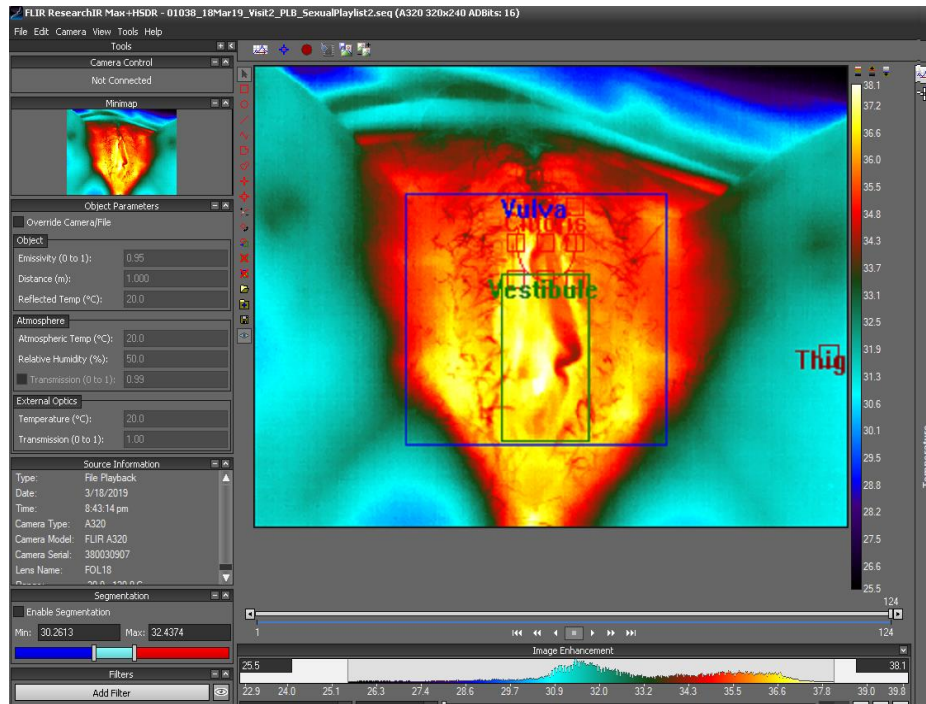
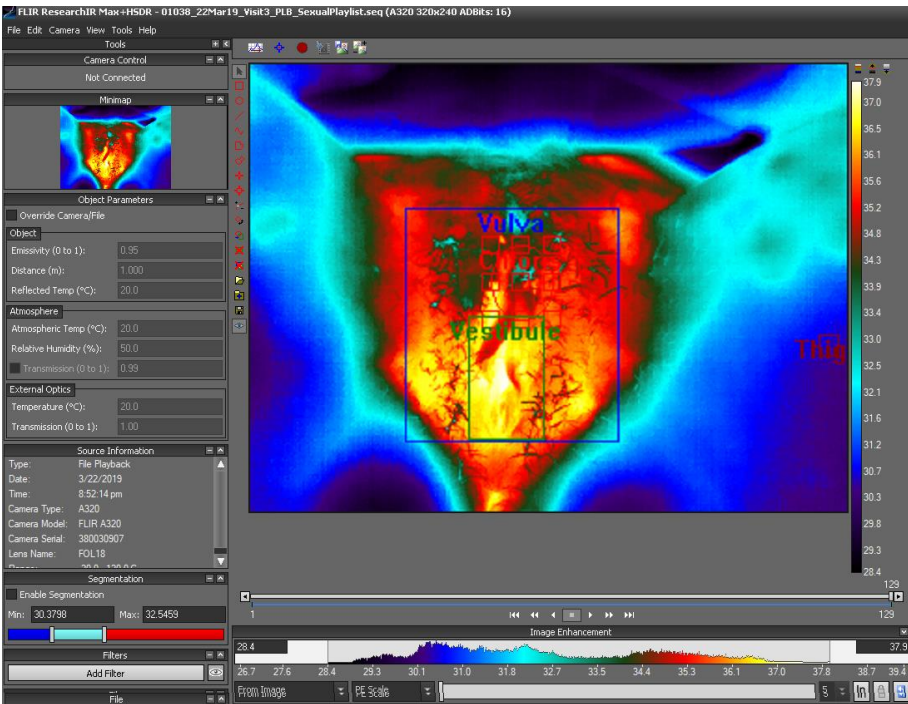
Vestibular Temperature and Change During Sexually Explicit Film



***Significant Differences in Genital Temperature Over Time
(Sildenafil Cream, 3.6% vs. Placebo Cream) $p=.03$***

Results: Genital Temperature

Genital Response From One Patient at 30 Minutes



Placebo Cream

Vestibule: +1.58 °C

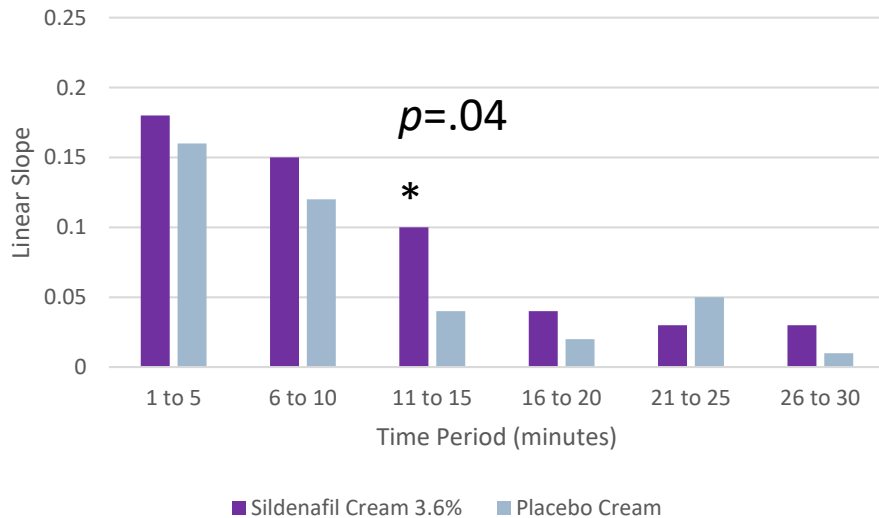
Sildenafil Cream

Vestibule: +2.87 °C

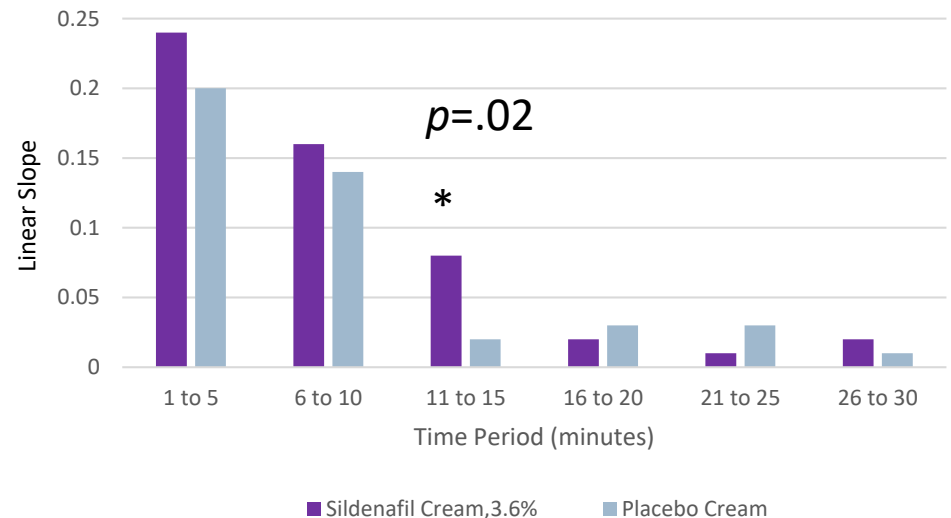
Results: Genital Temperature

Linear Slope Analysis During Sexually Explicit Film

Clitoris: Linear Slope During Sexually Explicit Film



Vestibule: Linear Slope During Sexually Explicit Film

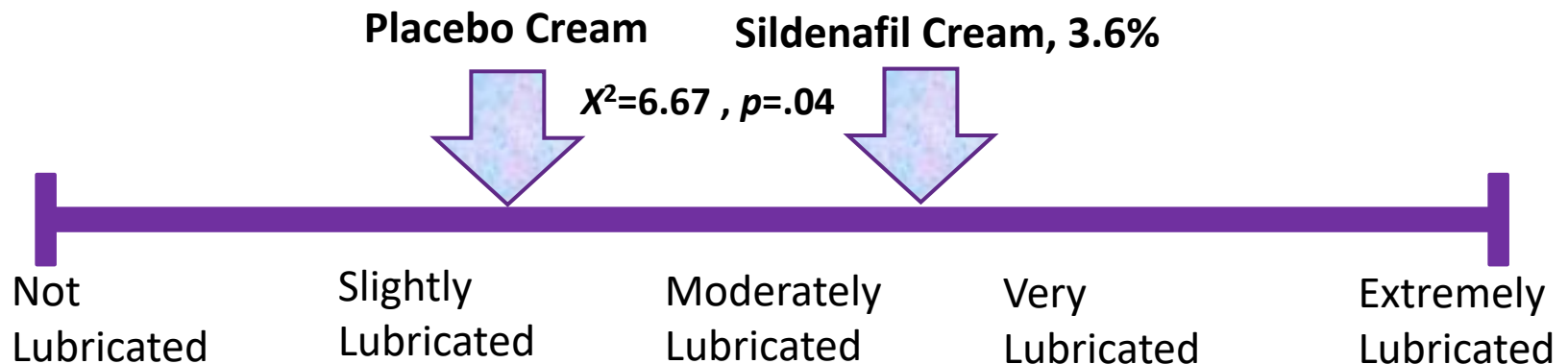


***Significant difference in linear slope for minutes 11-15
(Sildenafil Cream, 3.6% vs. Placebo Cream)***

Results: Self-Reported Arousal

Sexual Arousal Rating	Sildenafil Cream, 3.6%	Placebo Cream	P value
Overall Sexual Arousal	8.17 (1.17)	7.50 (.55)	.24
Peak Sexual Arousal	8.50 (.84)	7.50 (.55)	.03
Mental Sexual Arousal	8.33 (1.21)	7.00 (1.10)	.07
Feel like having sex with partner	9.17 (.75)	7.50 (1.20)	.02
Feel like masturbating	8.50 (1.38)	7.17 (1.33)	.12
Physical Sexual Arousal	8.33 (1.21)	7.50 (1.05)	.23

Perception of Genital Lubrication



Discussion and Conclusions

- Sildenafil Cream, 3.6%, when administered to healthy subjects without sexual dysfunction, induced statistically and clinically significant increases in genital and self-reported measures of arousal compared to placebo cream, exhibiting pharmacodynamic activity 11-15 minutes post-dose.
- These data support the continued development of Sildenafil Cream, 3.6% to be a promising, on-demand treatment for FSAD patients.
- Phase 2b multi-center at-home clinical study planned to be initiated.

