

# SAFETY AND EFFICACY OF CO<sub>2</sub> FRACTIONAL LASER THERAPY IN WOMEN WITH VESTIBULODYNIA

Sue W. Goldstein CSE, CCRC, IF, Susan Kellogg  
Spadt PhD, CRNP, IF, CST, Filippo Murina, MD,  
Noel Kim PhD, IF and Irwin Goldstein MD, IF



# DISCLOSURES

- Consultant/Advisory Board: AMAG Pharmaceuticals, Strategic Science & Technologies
- Research: AbbVie, AMAG Pharmaceuticals, BTL Industries, Ipsen, Lipocine, TGI
- Speakers bureau: AMAG Pharmaceuticals, Clarus



# INTRODUCTION

- Investigator-initiated with 3 sites
  - San Diego – Goldstein
  - Milan – Murino
  - Philadelphia – Kellogg-Spadt
- Double-blind, sham-controlled CO<sub>2</sub> fractional laser (MonaLisa Touch) to treat vestibular pain



# METHODS

- Inclusion:
  - Vestibular pain
  - Age 21-80, BMI <37 kg/m<sup>2</sup>
  - Willing to attempt sexual activity between visits
- Exclusion:
  - Significant findings on physical exam
  - Medical condition or psychologic disorder
  - Unwilling to maintain systemic E<sub>2</sub> or SERM
  - Unwilling to wash out of topical medication
  - Vulvar lesions or vulvar/vaginal infections





# METHODS

- Screening
- Randomized 2:1 active:sham (*special software w/ sham*)
  - 3 Treatments (4 weeks between)
- Follow-up 4 weeks later, unblinded
- After unblinding sham subjects start active treatments
  - 3 Treatments (4 weeks between)
- Follow-ups at 4 and 8 weeks after last active treatment
- 2-way repeated measures ANOVA



# METHODS

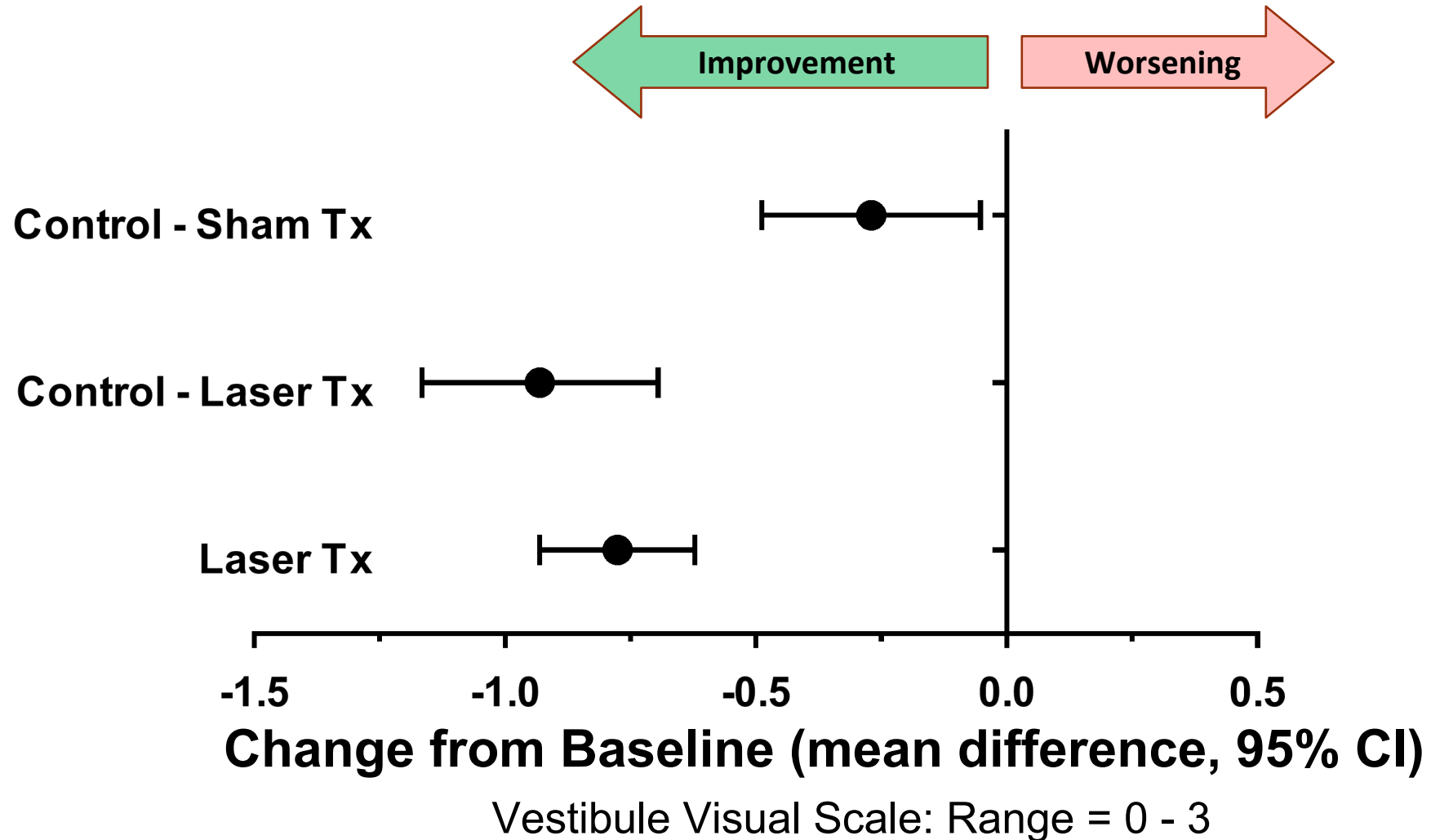
- Endpoints: changes from baseline to follow up
  - VGTA based on photographs (*blinded assessment*)
  - Cotton-tipped swab test 1,3,5,6,7,9,11 o'clock
  - Questionnaires:
    - FSFI pain domain
    - FSFI total score
    - FSDS-R
    - ICSI/ICPI (IC Symptoms/IC Problems)



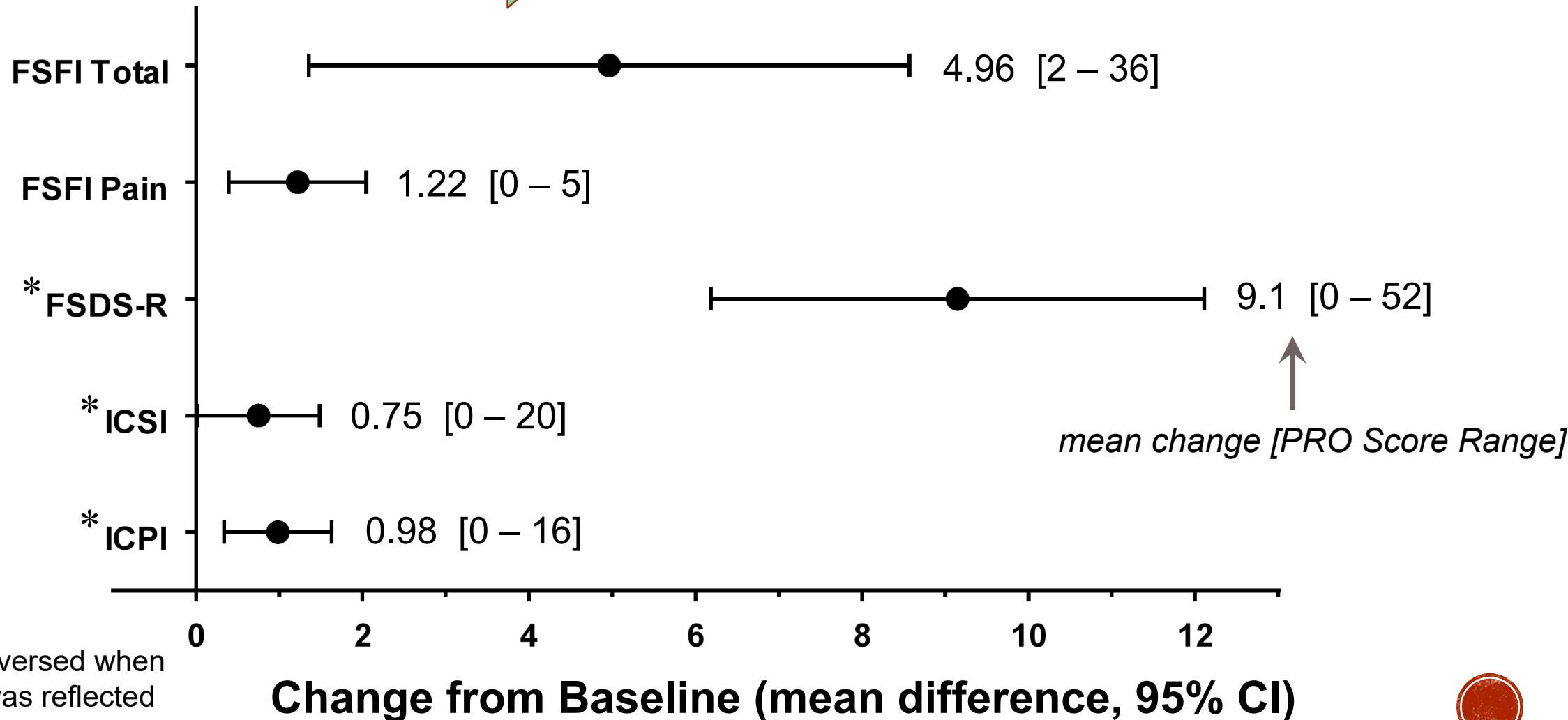
# Vulvoscopic Genitourinary Tissue Appearance (VGTA) Scale

	0	1	2	3
Labia majora resorption	Normal	Mild loss	Moderate loss	Severe loss / disappeared
Labia minora resorption	Normal	Mild loss	Moderate loss	Severe loss / disappeared
Clitoral atrophy	Normal	Mild decrease	Moderate decrease	Severe decrease / phimosis
Urethral meatal prolapse	Normal	Mild prominence	Moderate prominence	Severe prominence
Introital stenosis	Normal	Mild decrease / stenosis	Moderate decrease or stenosis	Severe decrease or stenosis
Pallor	Normal	Mild decrease	Moderate decrease	Severe decrease
Erythema	Normal	Mild	Moderate	Severe
Mucosa inflammation	Normal	Mild	None / mucosa not inflamed	None / mucosa inflamed
Vaginal rugation	Normal	Mild loss	Moderate loss	Severe loss
Anterior vaginal wall atrophy	Normal	Mild loss	Moderate loss	Severe loss

# EFFECTS OF FRACTIONAL CO<sub>2</sub> LASER THERAPY ON VESTIBULE VISUAL SCALE



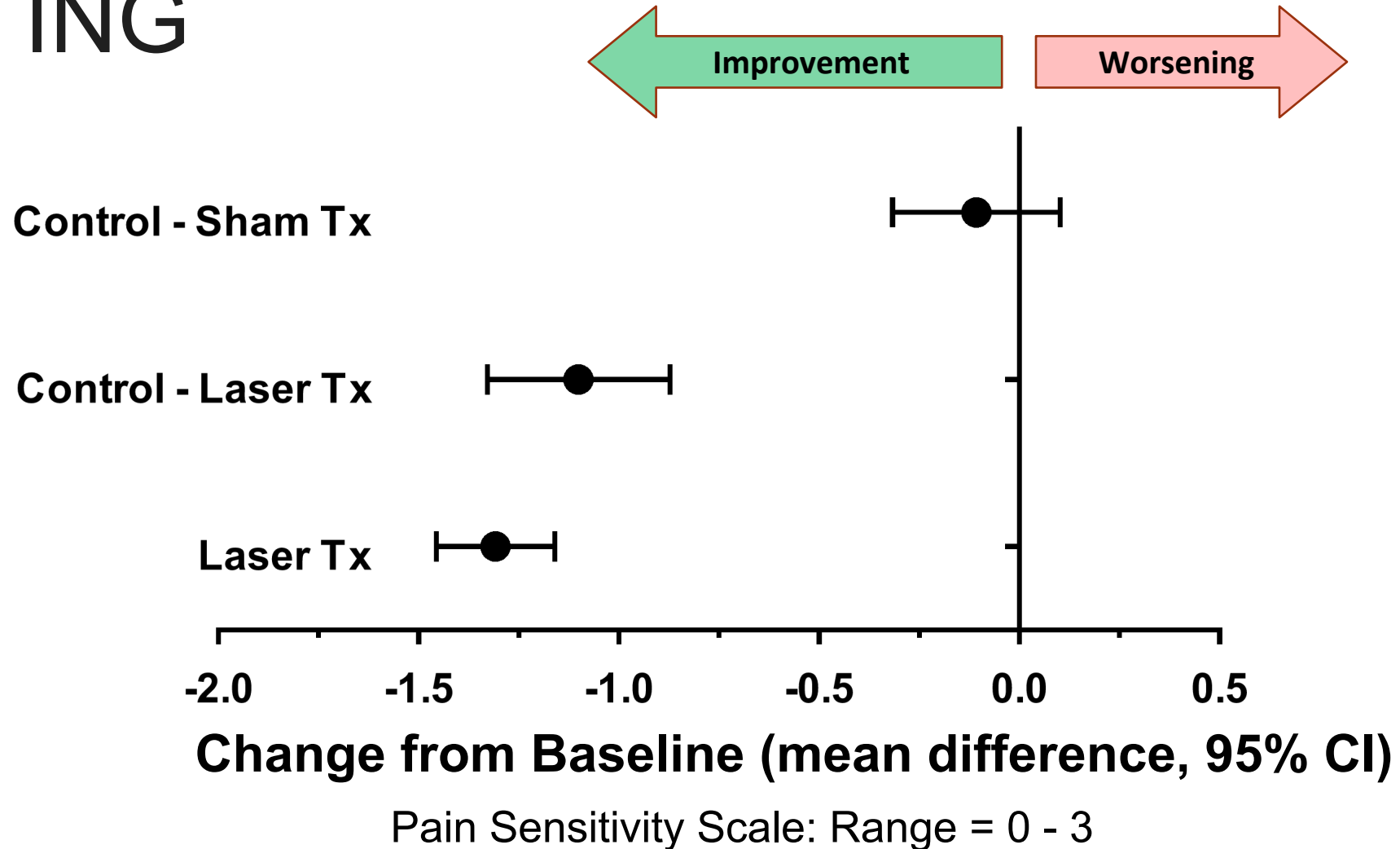
# EFFECTS OF FRACTIONAL CO<sub>2</sub> LASER THERAPY ON SEXUAL FUNCTION & BLADDER SYMPTOMS



\*Signs were reversed when improvement was reflected by decreasing scores



# EFFECTS OF FRACTIONAL CO<sub>2</sub> LASER THERAPY ON COTTON SWAB TESTING



# RESULTS – ADVERSE EVENTS (N=57)

- No serious adverse events occurred.
- Mild and moderate adverse events related to the procedure included
  - burning (n=4) lasting 2 to 3 days
  - itching (n=1) lasting 2 to 3 days
  - a fissure and increased vestibular pain (n=1) possibly related to procedure



104 NVS – screen Aug 15, 2017  
Baseline



104 NVS – Visit 6 FU 2 Dec 19, 2017  
Last FU after Active Treatment





107 MGW – screen Nov 1, 2017  
Baseline



107 MGW – Visit 6 FU 2 Mar 2, 2018  
Last FU after Active Treatment



313 – Visit 1  
Baseline



313 – Visit 6  
Last FU after Active Treatment





301 – Visit 1  
Baseline



301 – Visit 6  
Last FU after Active Treatment



323 – Visit 1  
Baseline



323 – Visit 6  
Last FU after Active Treatment





02 GMM – Visit 1  
Baseline

02 GMM – Visit 5  
1<sup>st</sup> FU after Sham Rx

02 GMM – Visit 6  
Last FU after Active Rx



315 – Visit 1  
Baseline



315 – Visit 5  
1<sup>st</sup> FU after Sham Rx



315 – Visit 6  
Last FU after Active Rx





319 – Visit 1  
Baseline



319 – Visit 5  
1<sup>st</sup> FU after Sham Rx



319 – Visit 6  
Last FU after Active Rx



# CONCLUSION

- CO<sub>2</sub> fractional laser (MLT) treatment shows functional improvement in women complaining of vestibular pain
- CO<sub>2</sub> improvement in visual parameters of the VGTA
- CO<sub>2</sub> fractional laser treatment showed improvement:
  - Sexual pain (FSFI pain domain, cotton-tipped swab test, pain diary)
  - Overall sexual function (FSFI)
  - Sexual distress (FSDS-R)
  - Voiding difficulties (ICSI) and associated pain (ICPI)
- Improvement was not correlated to Free T values

