

825 – FRACTIONAL CARBON-DIOXIDE LASER VERSUS PELVIC FLOOR MUSCLE TRAINING FOR WOMEN WITH STRESS URINARY INCONTINENCE: ONE-YEAR FOLLOW-UP OF A RANDOMIZED CLINICAL TRIAL

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Hypothesis / aims of study

Stress urinary incontinence (SUI) is one of the most common pelvic floor disorders among women.

Aim of study: To evaluate the effect of pelvic floor muscle training (PFMT) and CO₂ laser on improving symptoms in women with stress urinary incontinence (SUI) by reducing the total score of the International Continence Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) after 12 months of follow-up.

Study design, materials and methods

A non-inferiority randomized clinical trial was conducted between January 2020 and March 2023.

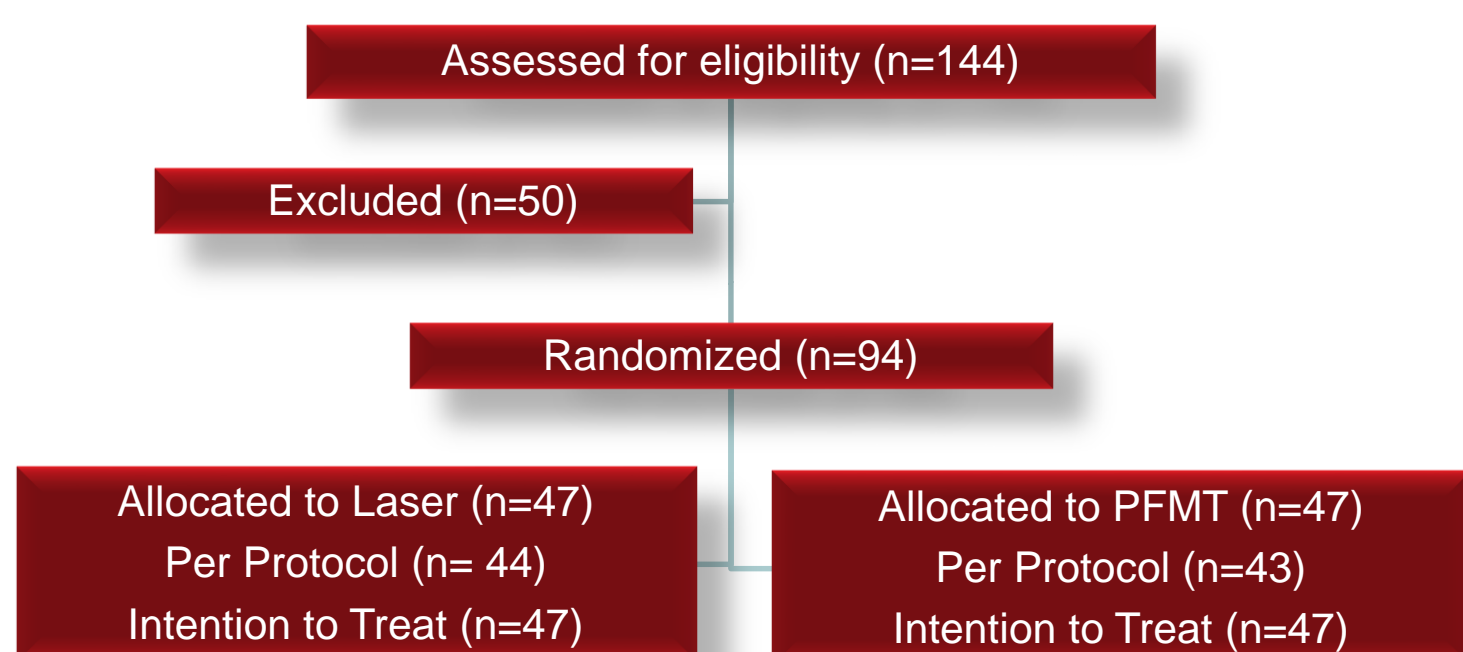
- Inclusion: Women aged ≥ 18 years with complaints of SUI.
- Exclusion: Women with other urinary symptoms, active urinary or vaginal infection, pelvic surgeries, symptomatic genital prolapse, or a history of other pelvic conditions.
- Primary outcome was the mean difference between the total scores of the ICIQ-UI-SF between the groups.
- Secondary outcomes were the evaluation of pelvic floor symptoms (PFIQ-7), sexual function (FSFI), and subjective improvement post-intervention (PGI-I).

Mean difference analysis with a 95% confidence interval was used to identify the non-inferiority margin. Per-protocol and intention-to-treat analyses were considered at a significance level of 5%.

Results

One hundred and forty-four women were recruited. Of these, 94 were randomized into two groups (Laser n=47 and PFMT n=47 (Figure 1).

Figure 1 – Flowchart of the Included Studies



Significant differences were found in the total scores of the ICIQ-UI-SF in both groups (CO₂ laser p<0.001, PFMT group p=0.001) after 12 months of follow-up (Figure 2). There was no difference between the groups in sexual function after 12 months of follow-up (Figure 3).

Figure 2 - ICIQ-Short Form by Group and Assessment Period

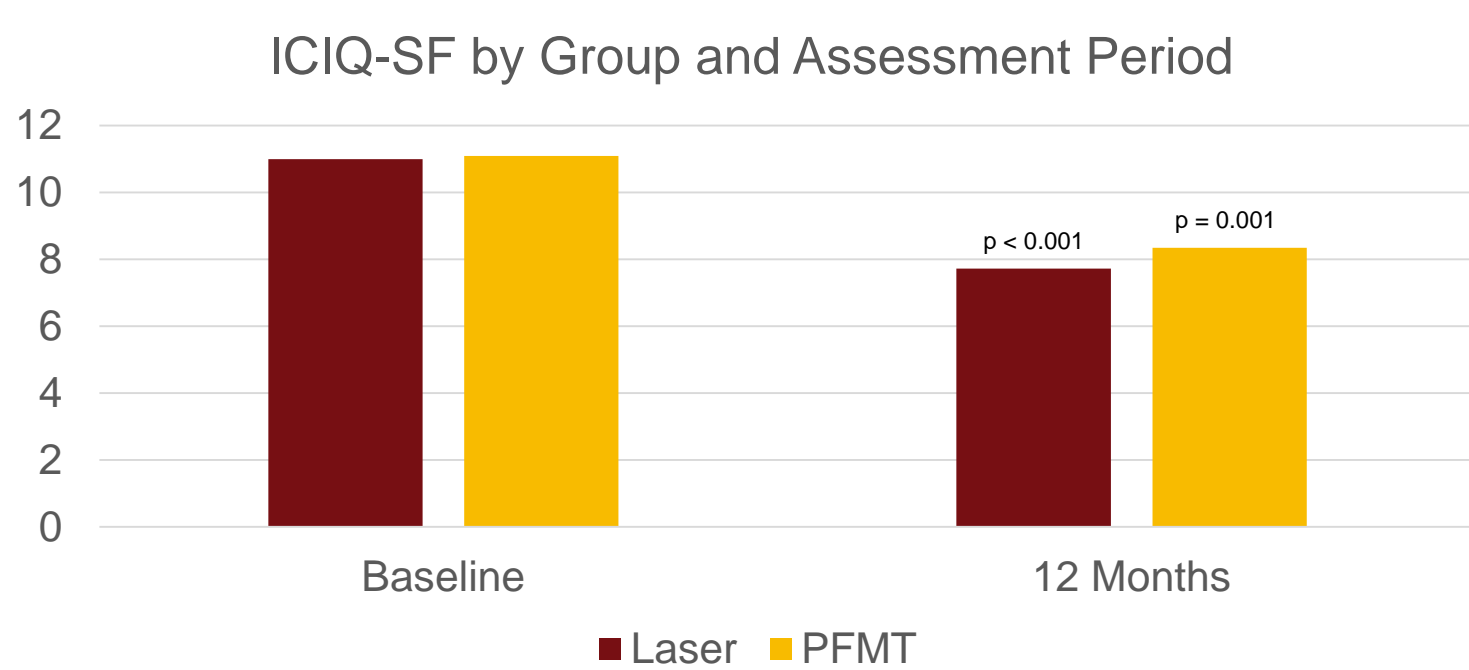
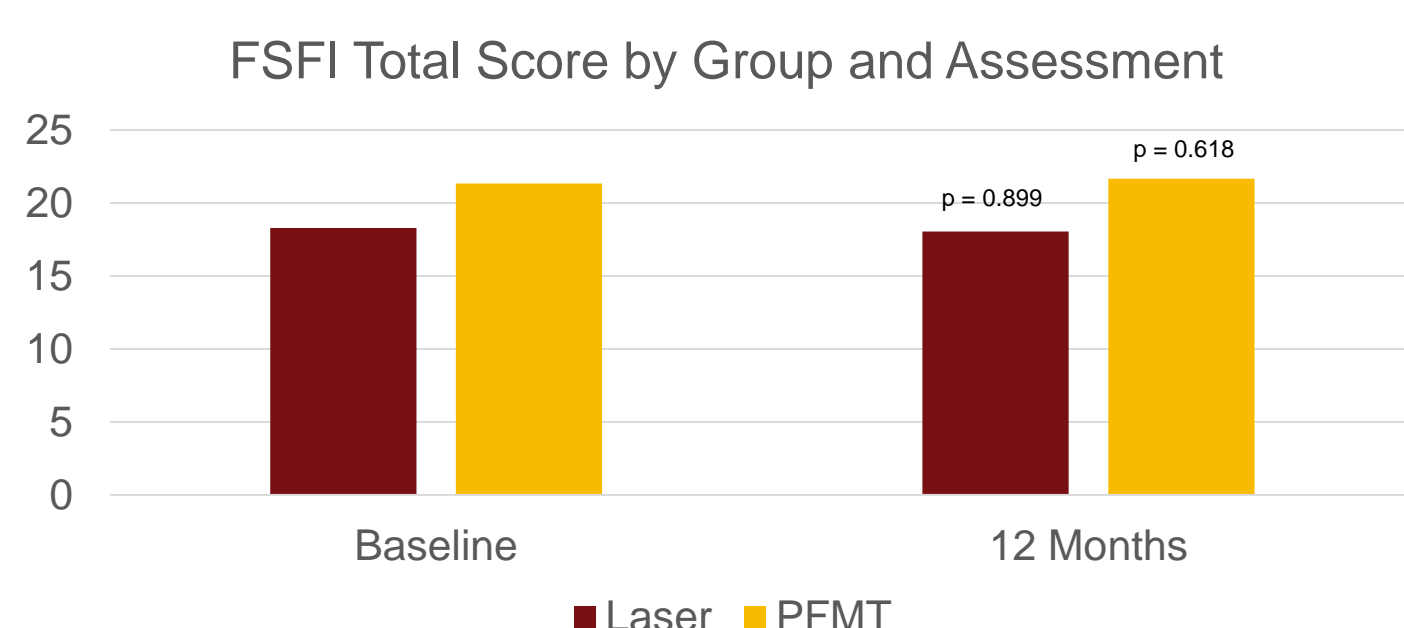


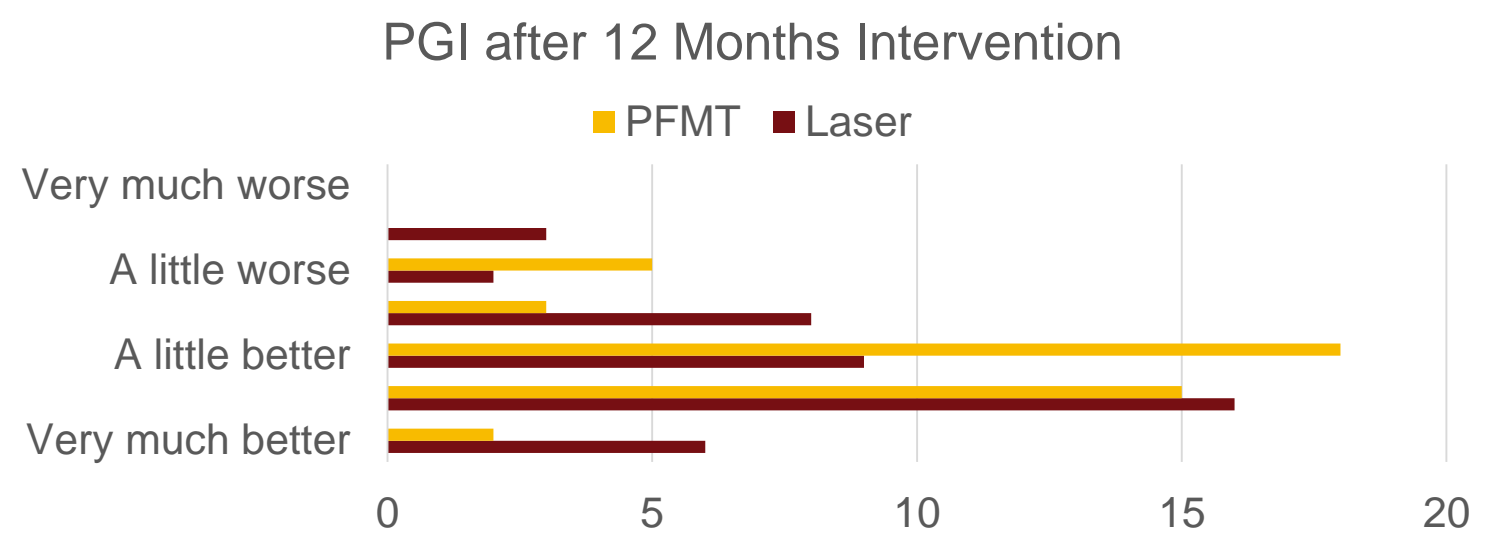
Figure 3 - FSFI by Group and Assessment Period



Wilcoxon test; p-Value: The p value refers to comparisons between baseline and 12 months; PFMT: Pelvic Floor Muscle Training; ; ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form; FSFI: Female Sexual Function Index.

A significant reduction in PFIQ-7 was found only in the PFMT group (from 41.73±46.83 to 31.71±43.04; p<0.001). A higher frequency of "slightly worse" and "slightly better" responses was found in the PFMT group, and "much worse," "much better," and "very better" responses were found in the CO₂ laser group (Figure 4).

Figure 4 - PGI-I by Group and Assessment Period



Fisher test; No values attributed to "Very much worse"; PGI-I: Patient Global Impression of Improvement; PFMT: Pelvic Floor Muscle Training; *p-Value: The p-value refers to comparisons between PFMT group and Laser group; p=0.42

Considering a non-inferiority margin of -4, the CO₂ laser was non-inferior to PFMT in improving the total score of the ICIQ-UI-SF after 12 months of follow-up (per protocol (0.52[-1.95-3.00]; p=0.675) and intention-to-treat (-0.79 [-3.10-1.53]; p=0.501) (Table 1).

Table 1. Non-inferiority analysis of participants' ICIQ-SF scores twelve months after treatment with laser compared with pelvic floor muscle training using a non-inferiority limit of -4:

Outcome	Mean± SD [95% CI]		Mean Difference [95% CI]	p Value
ICIQ-SF Total Score (PP)	Laser (n=44)	PFMT (n=43)		
	8.02±5.61 [6.28-9.77]	7.5±5.93[5.70-9.30]	0.52 [-1.95-3.00]	0.675
ICIQ-SF Total Score (ITT)	Laser (n=47)	PFMT (n=47)		
	8.34±5.38 [6.76-9.92]	7.72±5.80 [6.02-9.43]	-0.79 [-3.10-1.53]	0.501

PP: per protocol; ITT: intention-to-treat; PFMT: Pelvic Floor Muscle Training; SD: Standard Deviation; CI: Confidence Interval; ICIQ-SF: International Consultation on Incontinence Questionnaire- Short Form

Interpretation

- Intravaginal fractional CO₂ laser was non-inferior to PFMT after twelve months of treatment.
- A reduction in the ICIQ-SF scores was seen in both groups and follow-up period.
- It seems that fractional vaginal laser does not lose its efficacy after 12 months.
- Both methods (Laser and PFMT) could be considered for SUI women, especially patients who are not interested to undergo surgical treatment.
- Sexual function did not improve after 12 months of treatment in both groups with no difference between them.
- To date, this study is a pioneer in comparing carbon dioxide laser versus PFMT in women with SUI using validated questionnaires (ICIQ-UI SF, PFIQ-7, PGI-I, and FSFI) after 12 months of intervention.

Conclusions

CO₂ laser and PFMT significantly improved the total scores of the ICIQ-UI-SF after 12 months of follow-up. No significant differences were observed in participants' sexual function. CO₂ laser was non-inferior to PFMT in improving the ICIQ-UI-SF score after 12 months of follow-up.

References

- [1] Rocha-Rangel SC, Pereira GMV, Juliato CRT, Brito LGO. Laser and Pelvic Floor Muscle Training for Urinary Incontinence: A Randomized Clinical Trial. Urogynecology (Phila). 2024 Apr 25. Epub ahead of print.
- [2] Moroni RM, Magnani PS, Haddad JM, Castro RA, Brito LG. Conservative treatment of stress urinary incontinence: a systematic review with meta-analysis of randomized controlled trials. Rev Bras Ginecol Obstet 2016;38:97-111.