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Hybrid Fractional Laser Therapy on Female Stress Urinary Incontinence

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Abbrivations: SUI: Stress Urinary Incontinence; PFMT: Pelvic Floor Muscle Training; MUS: Mid-Urethral Sling; ICIQ: International Consultation on Incontinence; SD: Standard Deviations; Er:YAG: Erbium Yttrium Aluminum Granite

Introduction

Stress urinary incontinence (SUI) is the involuntary loss of urine that occurs under increased intra-abdominal pressure during physical activity or other activities such as coughing or laughing [1]. SUI may develop following injury or age-related changes to the collagen structures supporting the pelvic floor [2,3]. It is a common condition with a prevalence of 45.9% among women in the general population [4] and can cause social embarrassment and psychological distress. It is also associated with increased risk of developing depression and anxiety [5] and can lead to painful dermatitis in the perineal area if left untreated [6].

Current guidelines for the management of SUI recommend first line treatment with conservative therapy, such pelvic floor muscle training (PFMT), vaginal estrogen, or pessary use [7-9]. However, in many cases, first line treatment fails and surgical intervention is required. The most commonly performed surgical treatment for SUI is mid-urethral sling (MUS) implantation [10]. Complications associated with MUS are not uncommon. An extensive review of the literature concluded that at least 15% of women experience a negative outcome following MUS implantation [11]. A recent Cochrane Review reported that 23% of women with MUS develop voiding difficulties in the long-term [12] and a large observational study published earlier this year showed that reoperation occurs at a rate of 6.7% [13].

Vaginal laser therapy has been recently introduced as a non-invasive alternative to surgical treatment for SUI. A meta-analysis of 16 studies published between 2015 and 2020 evaluated the efficacy of laser therapy for treating mild to severe SUI [14]. The laser treatments resulted in a significant improvement of self-reported SUI symptoms in the short-term (12 months after treatment) with few adverse effects, most of which resolved without medical intervention. A recent study comparing laser therapy with MUS implantation also showed that short-term improvement in self-reported SUI symptoms was comparable following the two types of interventions [15].

Over the past ten years, most laser therapy for SUI has been done with fractional non-ablative lasers, which cause minimal thermal injury to the vaginal mucosa and allow for rapid recovery [14]. Unlike full-field lasers, where the beam is applied over the entire treatment area, fractional lasers are broken into columns and applied to small dots of tissue, leaving a large amount of the treatment area intact to support wound healing. Low heat applied by the laser (60-70 °C) causes a thermal injury that triggers the unravelling and contraction of collagen fibers deep within the tissue (up to 500μm) [16]. This process, known as tissue coagulation, stimulates new collagen synthesis and contributes to the remodeling of collagen structures in the anterior vaginal mucosa supporting the urethra [17].

More recently, the hybrid fractional laser has been introduced as a new modality for treating SUI. The hybrid fractional laser delivers sequential ablative (2,940nm) and non-ablative (1,470nm) wavelengths in a single treatment, by the same hand

device and at the same time. This device is tunable to very low densities (percentages of treatment area subject to thermal injury) for providing optimal treatment outcomes while further minimizing thermal injury. A preliminary study showed that the hybrid fractional laser can produce a high rate of symptom improvement (94.7%) in the first three months after a single treatment session [18]. However, this study was limited since most laser treatment protocols follow a course of two or three treatment sessions with a follow-up duration of one to three years [14]. The objective of the following study, therefore, was to evaluate the short-regular-term effectiveness of multi-session (three) hybrid fractional laser therapy for treating mild to severe SUI at follow-up durations greater than three months.

Materials and Methods

Adult women were recruited between January 2019 and December 2020 at a private urogynecological practice (Clinica Ginestetica) in Santiago, Chile. The diagnosis of SUI was based on clinical criteria such as stress related involuntary loss of urine. The concomitance of urinary urgency, mixed urinary incontinence, was not considered as an exclusion to offer this treatment but it was made clear that the objective of the laser was to treat the leakage due to stress. Eligible participants were identified based on the following inclusion criteria: female gender, age ≥ 18 years old, and clinical confirmed diagnosis of SUI by anamnesis & physical examination. Exclusion criteria included isolated urge incontinence, severe pelvic organ prolapse, pregnancy at the time of treatment, prior surgery for SUI, neurological disorders, abnormal vaginal bleeding, hematuria, photosensitivity, or use of photosensitizing drugs. The patients voluntarily accepted the performance of this treatment, all were offered the alternatives of Pelvis Floor Therapy and/or surgery. Consent from participants was obtained prior to laser treatment.

Laser treatment was performed using a hybrid fractional laser with sequential delivery of 2,940 nm and 1,470 nm wavelengths (diVa, Sciton Inc, Palo Alto, CA). Treatment settings were selected according to the manufacturer's instructions for pre- and post-menopausal women and are shown in Table 1. All participants received 3 treatment sessions spaced over 1 month intervals. Each treatment session consisted of two passes applied to the vaginal canal. The procedure is carried out in an automated-robotic way of the hand device, so after programming the protocol for each patient, it is inserted into the vagina inside the single use strengthened quartz dilator and only the ignition pedal is pressed. The device makes the passes without the intervention of the performer but only keep it in the correct position this avoids any human error and variation between different performers. The first pass was delivered to the entire circumference (360°) and the second pass was delivered to the anterior half (180°). On each pass, deep tissue ablation was first performed with the 2,940nm wavelength and coagulation was subsequently induced with the 1,470 nm wavelength.

Table 1: Laser parameters applied in each treatment session according to manufacturer's instructions for pre- and post-menopausal women.

	No. of Passes	2,940 nm (ablation)		1,470 nm (coagulation)	
		Depth µm	Density (%)	Depth (µm)	Density (%)
Pre-menopausal	2	500	6	300	7
Post-menopausal	2	400	4	200	7

The primary outcome for this study was the International Consultation on Incontinence (ICIQ) Score, which is a self-reported measure of symptom severity. The ICIQ Score was calculated from the first three of four-items on the ICIQ for UI Short Form (ICIQ-UI SF) [19], which has been validated for people with SUI [20]. The first item, *How often do you leak urine?*, was rated on a 6-point ordinal scale from 0 to 5, where 0 = never and 5 = all of the time. The second item, How much urine do you usually leak (whether you wear protection or not)?, was rated on a 4-point ordinal scale that increases in increments of two from 0 to 6, where 0 = none and 6 = a large amount. The third item, Overall, how does leaking urine interfere with your everyday life, was rated on a visual analog scale from 0 to 10, where 0 = not at all and 10 = a great deal. The ratings for each item were summed into a total score (ICIQ Score) with a maximum possible value of 21, where higher scores indicated greater severity of symptoms. Severity of SUI was determined from ICIQ Scores as follows: none (0) mild (1-5), moderate (6-12), severe (13-18), and very severe [19-21][21]. The ICIQ-UI SF was administered upon consent during the pre-treatment consultation (Baseline) and once again post-treatment (Follow-up).

The secondary outcome was satisfaction with the treatment, which was evaluated using a non-validated 7-item questionnaire (Appendix A). Each item assessed a different aspect of treatment satisfaction on a qualitative rating scale. The first item

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asked the participant to rate their degree of satisfaction with treatment of UI symptoms (Very Satisfied, Satisfied, Moderately Satisfied, Indifferent, Moderately Dissatisfied, Dissatisfied, Very Dissatisfied). The next two items asked whether the participant would repeat the treatment (Yes, No, Don't Know) and recommend the treatment to a friend (Yes, No or Don't Know). Another two items were dedicated to sexual activity and asked whether the participant was sexually active (Yes, No) and saw improvement in sexual pleasure (Yes, No). This is due to the fact that in patients with sexual activity an improvement in their vaginal sensation has been reported through the use of laser [15]. The sensation of a wide vagina is a concept that is currently very widespread and that was reported by Pardo et al in 2006 although in that report its correction was through a colpoperineoplasty [16]. The participants were also asked to provide their opinion on cost (OK, Expensive, Cheap) and rate overall satisfaction with the treatment (Satisfied, Very Satisfied, Unsatisfied). The satisfaction questionnaire was administered only at Follow-up.

All analyses were performed in Microsoft Excel (Microsoft Corporation, 2021, Version 16.48: https://office.microsoft.com/excel). All Baseline and Follow-up quantitative data were calculated as means and standard deviations (SD). Quantitative data were analyzed with bivariate Pearson correlations and paired t-tests. Qualitative data were presented as proportions of participant responses on a given rating scale.

The authors of this study have been performing intravaginal lasers for the treatment of SUI for many years. It is a practice allowed by local health authorities. The only requirement is the signing of an informed consent and as it was not an experimental study it was not submitted to an ethics committee because we do not consider it necessary in any way.

Result

Table 2: Descriptive data.

Descriptive Variable Value		Baseline		Follow-Up	
		N	Value	N	
Age, mean (SD)		49.02 (7.78)	45	--	--
% Menopausal		35.50%	45	--	--
Parity	Mean (SD)	2.47 (1.24)	45	--	--
	0%	11.1	5	--	--
	1%	0	0	--	--
	2%	44.4	20	--	--
	3%	24.4	11	--	--
	4%	15.6	7	--	--
	5%	4.4	2	--	--
% At least 1 vaginal delivery		64.4	29	--	--
Maximum birthweight (g), mean (SD)		3,558.00 (416.86)	40	--	--
% Urgency		15.6	7		
% Vaginal Dryness		26.7	12	0	0
% Sensation of vaginal laxity		68.9	31	16.1	5
SUI Severity	% None (ICIQ Score = 0)	0	0	48.9	22
	% Mild (ICIQ Score = 1-5)	8.9	4	6.7	3
	% Moderate (ICIQ Score = 6-12)	62.2	28	33.3	15
	% Severe (ICIQ Score = 13-18)	26.7	12	8,9	4
	% Very Severe (ICIQ Score = 19-21)	2.2	1	2.2	1
ICIQ Score, mean (SD)	Total Sample	10.58 (3.76)	45	4.98 (5.76)	45
	Pre-menopausal	11.71 (3.48)	29	5.82 (6.09)	29
	Post-menopausal	8.37 (3.32)	16	3.81 (5.08)	16

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A total of 45 women diagnosed with SUI consented to participate in this study. Baseline and Follow-up descriptive data for our sample are shown in Table 2. The mean (SD) age of our sample was 49.02 (7.78) years and 35.5% (16/45) of participants were menopausal. The majority of participants had given birth to at least one child (40/45, 88.4 %) and mean (SD) maximum birth weight was 3,558 grams (+/- 416.86). Almost two thirds of participants (29/45, 64.4 %) experienced at least one vaginal delivery, and more than two thirds (31/45, 68.9%) recounted feeling a sensation of vaginal laxity. A small number of participants also reported urinary urgency (7/45, 15.6 %) and vaginal dryness before receiving treatment (12/45, 26.7 %). Based on ICIQ scores, Baseline SUI ranged from mild to very severe with moderate SUI presenting most frequently in our sample (26/43, 60.5 %). Mean (SD) Baseline ICIQ Score across the entire sample was 10.58 (3.76). At Baseline all participants reported having at least some SUI symptoms (ICIQ Score ≥ 1) but at Follow-up, 22% of participants reported complete resolution of SUI symptoms (ICIQ Score = 0). No adverse events, pain, or discomfort were reported by any participants.

Due to the nature of this study being carried out under real-world conditions where patient follow-up is more variable than it would be under controlled conditions, follow-up times were not consistent across all patients and ranged from 4 to 30 months after the final treatment session. Therefore, before comparing Baseline and Follow-up ICIQ Scores, we first determined whether there was any correlation between Follow-up ICIQ Score and length of follow-up time after completing treatment. A bivariate analysis revealed a significant moderate negative correlation between Follow-up ICIQ Score and length of follow-up time ($r = -0.32$, $p = 0.030$). To reduce the variance in mean Follow-up ICIQ Scores, participants were divided into four groups based on the length of their follow-up time: 4 – 6 months, 7 – 12 months, 13 – 18 months and > 18 months. Mean Baseline and Follow-up ICIQ Scores for each of the four groups are shown in Figure 1. Treatment led to a reduction in mean ICIQ Score compared to Baseline in all four groups. This change was significant in all but the 4 – 6 month Follow-up group (paired t-test, Table 3). Since treatment caused a reduction in ICIQ Scores in all four groups, we pooled the four groups together and performed a subgroup analysis to compare Baseline and Follow-up ICIQ Scores in pre- and post-menopausal women. At Follow-up, mean (SD) ICIQ Scores were significantly reduced from 11.71 (3.48) at Baseline to 5.82 (6.09) in pre-menopausal women (paired t-test, $p < 0.001$) and from 8.37 (3.32) at Baseline to 3.81 (5.08) in post-menopausal women (paired t-test, $p < 0.001$).

Table 3: Results of paired t-tests comparing Baseline and Follow-up ICIQ Scores. Participants were divided into groups by follow-up duration in 6-month intervals from the last treatment session.

Follow-up Duration (Months)	n	Baseline ICIQ Score mean (SD)	Follow-up ICIQ Score mean (SD)	P Value
6-Apr	6	11.00 (2.00)	7.77 (5.01)	0.205
12-Jul	24	11.45 (1.31)	5.95 (3.30)	0.015
13-18	9	10.54 (5.31)	6.20 (6.53)	0.039
> 18	6	6.67 (2.88)	0.00 (0.00)	0.004

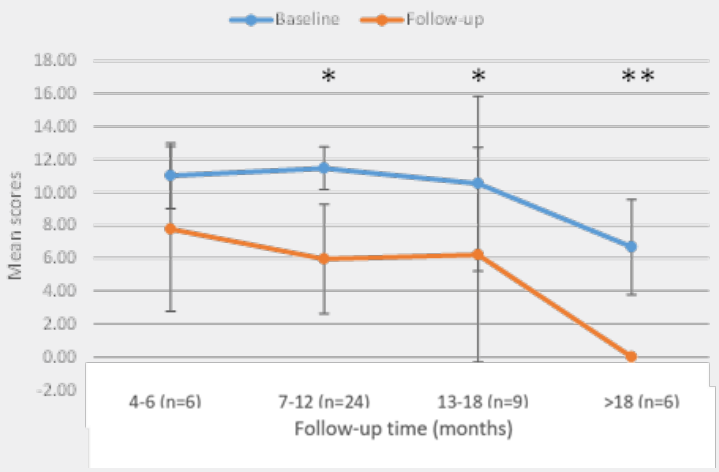

Figure 1: Mean Baseline and Follow-up ICIQ Scores grouped by length of follow-up time. Error bars represent standard deviation, * indicates difference in Baseline and Follow-up values with $p < 0.05$ (paired t-test), ** indicates difference in Baseline and Follow-up values with $p < 0.01$ (paired t-test).

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In addition to decreasing ICIQ Scores, treatment with hybrid fractional laser resulted in a high level of satisfaction in our sample. At Follow-up, most of participants (84%) showed at least some degree of satisfaction (moderately satisfied, satisfied, or very satisfied) with the laser as a treatment for SUI. The majority of participants also said they would repeat the treatment (80%) and recommend it to a friend (89%). In terms of sexual activity, 71% of participants reported sexual improvement and 89% were sexually active. 68% subjects felt that cost of treatment was ok or not expensive. All things considered, 80% of participants were either satisfied or very satisfied overall. Although this was not the objective of this study, we want to emphasize that all patients who presented symptoms of vaginal atrophy showed improvement of this condition after the treatment.

Discussion

In this study short-term effectiveness of hybrid fractional laser therapy for treating SUI using a course of three treatment sessions, each spaced one month apart, was evaluated. The treatment resulted in improvement of self-reported SUI symptoms, with ICIQ Scores remaining below baseline values for up to 30 months following treatment. Longer follow-up times were also associated with lower ICIQ Scores, suggesting that improvement may continue for one to three years following treatment. Most participants were satisfied with the treatment. Several participants indicated that they would repeat the treatment and many reported that the treatment improved their sexual function. In addition, none of the participants reported any adverse events or discomfort resulting from the treatment [22,23].

The findings from this study expand on a preliminary investigation that reported improvement of ICIQ Scores with no adverse events three months after a single treatment session with hybrid fractional laser [20]. In the current study, three treatment sessions were provided with a longer follow-up duration. No other studies have evaluated hybrid fractional laser for treating SUI. The choice of three treatment sessions was informed by evidence from studies on fractional non-ablative laser therapy, where optimal results were achieved after a course of three sessions [18]. The present results are also consistent with findings from studies on fractional non-ablative laser therapy for SUI, where ICIQ Scores remained below baseline values for up to 12 months after treatment [18]. Studies showing improvement in symptoms beyond 12 months are limited and the existing evidence is controversial in terms of its effectiveness on women in different menopausal states. One study using non-ablative CO_2 lasers on post-menopausal women showed significant reduction in ICIQ Scores up to 36 months following treatment [24]. Another study using non-ablative Erbium Yttrium Aluminum Granite (Er:YAG) therapy on post-menopausal women showed a reversal of ICIQ Scores toward baseline values between 18 and 24 months after treatment [25]. Another study evaluating non-ablative Er:YAG therapy in both pre- and post-menopausal women showed that improvement of SUI symptoms can last up to 19 months, but mostly in pre-menopausal women [26]. In contrast with non-ablative laser therapies, hybrid fractional laser appeared to elicit a treatment response in both pre- and post-menopausal women.

While the present study suggests that hybrid fractional laser therapy may produce short-term symptom relief for SUI, there were several limitations in our study design. First, each participant was followed-up for a different length of time. Second, participants completed the ICIQ-UI SF only once during follow-up so we could not evaluate how ICIQ Scores truly change over time following treatment. Finally, while the current study used a larger sample size than the preliminary study [20], a power analysis was not performed and the sample size was still quite small, thus making it difficult to draw conclusions from subgroup analyses.

Conclusion

This report shows that hybrid fractional laser has potential to improve self-reported SUI symptoms up to 30 months following treatment. Despite limitations in the current study, hybrid fractional laser resulted in a significant decrease in ICIQ Scores from Baseline with greater symptom improvement after longer follow-up times. In addition, most participants were satisfied with the treatment and no adverse events were reported. These findings demonstrate the potential of hybrid fractional laser therapy as a safe and effective treatment for SUI in both pre- and post-menopausal women. However, randomized controlled trials with larger sample sizes and consistent follow-up durations are required to further validate our findings. The results of future studies on non-invasive laser therapy could have important clinical implications for reducing the risk of complications from treatment of SUI, especially at low-volume surgical facilities where there is a 37 to 62% greater risk of complications from MUS implantations compared to high volume facilities where the procedure is practiced more often [15,27] (Appendix).

Compliance with Ethical Standards

The corresponding author is an international speaker of Sciton Inc. Company. Which is the manufacturer of the laser that was used to conduct this study. Despite this, he did not receive any kind of financial compensation for this study. The equipment was purchased and paid by the author without any financing from the aforementioned company.

This is not a experimental trial. It is a treatment that I have been doing with different devices for more than 8 years. Patients consult me for stress incontinence and especially seek my laser treatment. Due to this there is no ethical conflict when conducting this study. That is why it was not submitted to an ethics committee. As mentioned in the manuscript, all the patients signed an informed consent made with the laser and that includes the possibility of being admitted to an eventual study.

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Appendix

Patient Satisfaction Questionnaire completed by participants at Follow-up.

1) Please indicate degree of satisfaction in relation to the treatment of urinary incontinence you received with hybrid fractional laser:

- ☐ Very satisfied
- ☐ Satisfied
- ☐ Moderately satisfied
- ☐ Indifferent
- ☐ Don't know
- ☐ Dissatisfied
- ☐ Very dissatisfied

1) Would you repeat the treatment of urinary incontinence with hybrid fractional laser?

- ☐ Yes
- ☐ No
- ☐ Don't know

2) Would you recommend the treatment of urinary incontinence with hybrid fractional laser to a friend?

- ☐ Yes
- ☐ No
- ☐ Don't know

3) Are you currently sexually active?

- ☐ Yes
- ☐ No

4) Have you experience improvement in sexual function following treatment of urinary incontinence with hybrid fractional laser?

- ☐ Yes
- ☐ No

5) In your opinion, how did you feel about the cost of hybrid fractional laser for treating urinary incontinence?

- ☐ OK
- ☐ Expensive
- ☐ Cheap

6) What was your overall satisfaction with the treatment of urinary incontinence with hybrid fractional laser?

- ☐ Very Satisfied
- ☐ Satisfied
- ☐ Unsatisfied

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