WHITE PAPER

SmartXide² V²LR

MonaLisa Touch® Dual Probe Therapy for the Treatment of Lichen Sclerosus and Vaginal Atrophy

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MonaLisa Touch® Dual Probe Therapy for the Treatment of Lichen Sclerosus and Vaginal Atrophy

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Introduction

Lichen Sclerosus (LS) is a chronic, inflammatory, mucocutaneous disorder which affects both females and males. This disease can cause itching, burning, pain, dysuria, dyspareunia, and sexual dysfunction, and can ultimately lead to destruction of normal anatomic structures. In rare cases, progression to squamous cell carcinoma is possible, especially in anogenital LS. While LS was initially described in 1887, its etiology remains unclear, but increasing evidence and general consensus suggest that an autoimmune mechanism is primarily involved in the pathogenesis. Women are affected more often than men, typical of other autoimmune disease processes. The prevalence of LS is uncertain as patients present to a variety of different clinical specialties with a range of clinical presentations and complaints. Estimates in dermatology and gynecology practices have ranges from 0.1-0.3% to 1.7% respectively, but these reports likely underestimate the true prevalence[1,2]. While LS may occur in children and prepubertal girls as well as pre and post-menopausal women, we report our clinical experience on 15 patients with LS and postmenopausal vaginal atrophy treated with MonaLisa Touch® dual probe therapy simultaneously to address both conditions.

Materials and Methods

The study included 15 patients with symptoms of Vulvovaginal atrophy (VVA), known as Genitourinary Syndrome of Menopause (GSM), and also had a history of LS. All patients presented at our Institute for laser treatment of their symptoms with MonaLisa Touch® (performed using the SmartXide², by DEKA – Italy). Given the accompanying diagnosis of LS, patients were offered dual probe therapy to simultaneously address the GSM as well as the LS. The treatment protocol was initially 3 treatments in the office setting at 6-week intervals (40-50 days). At each treatment session, patients underwent treatment of the vagina with the 360° (pyramid) probe followed immediately at the same session with the external (vulvar) probe for affected vulvar tissue. A topical EMLA cream was applied to vulvar tissue for 12-15 minutes prior to treatment. No oral or injectable therapy for pain or anxiety was utilized or necessary. Laser settings used on vaginal probe treatments are shown in Table 1. First treatment with vaginal probe was administrated with Stack 1 and both 2nd and 3rd vaginal probe treatments were done on the Stack 3 setting. Vulvar probe external treatments settings are shown in Table 2. All vulvar treatments, regardless of the number of treatments, were done on Stack 1 settings.

Power (W)	Dwell time (µs)	Spacing (µm)	SmartStack	Emission Mode	Density (%)	Fluence (J/cm²)	Pulse Energy (mJ)
30	1000	1000	1	D-pulse	6.4	2.20	43.2

Table 1: Laser settings for the vaginal treatment performed with the 360° probe.

Power (W)	Dwell time (µs)	Spacing (µm)	SmartStack	Emission Mode	Density (%)	Fluence (J/cm²)	Pulse Energy (mJ)
26	800	800	1	Smart-pulse	8.7	1.93	27.7

Table 2: Laser settings for the vulvar treatment performed with the external vulvar probe.

Results

No complications were detected in patients during the treatment sessions other than mild discomfort or burning during or shortly after the treatment session. Other than Vaseline and topical lidocaine cream or gel, no other post treatment measures were used or needed. All 15 patients completed all 3 dual probe therapy sessions. The results revealed that the 15 patients (100%) reported improvement in their vulvar symptoms with 1 patient reporting only minimal improvement (10%) in vulvar symptoms after 3 treatments. Patients were asked to report their overall symptoms improvement following the 3 dual probe therapy treatments on a scale of 0% to 100% improvements. The mean improvement was 65% with a range from 10% to 100%. In 14 out of 15 patients were satisfied or very satisfied with treatment response (Table 3 and Figure 1 refer to the just mentioned improvements).

Patient ID	Age	Patients Rating Satisfaction (%)
1	62	75
2	66	30
3	66	80
4	73	90
5	68	50
6	63	95
7	62	60
8	79	90
9	53	10
10	70	100
11	83	50
12	74	25
13	92	70
14	67	80
15	77	75
Average	**70,33**	**65,33**

Table 3: Patient overall rating of vaginal & vulvar symptoms improvement after 3 MonaLisa Touch® sessions.

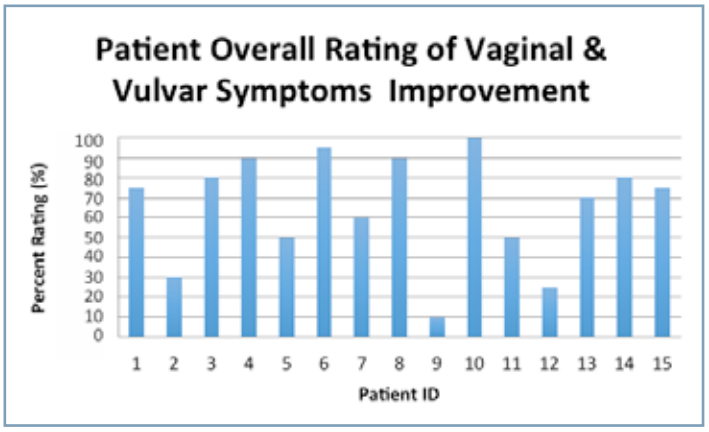

Figure 1: The graph shows vaginal & vulvar symptoms improvement (%) for each patient after 3 MonaLisa Touch® sessions.

Based on evolving treatment protocols and clinical experience with our Italian colleagues, it is felt that some patients may benefit from more extensive or prolonged vulvar therapy. Therefore, upon completion of 3 dual probe therapy treatments, and based on clinical improvement reported by the patients, all of them were offered the opportunity to extend their external probe treatments for LS for 2 additional treatment sessions at 6 week intervals (40-50 days) for a total of 5 vulvar treatments. The 15 patients (100%) desired to continue their treatment for 2 additional sessions. Additional improvement gained by extension of vulvar treatments to a total of 5 will be reported subsequently.

Photos of selected patients were taken prior to initiation for treatment, during the treatment sessions and after completion of the treatment sessions (Figures 2 and 3).

Discussion

In a recent review article, Fistarol and Itin comprehensively discuss the current understanding regarding the diagnosis and treatment of LS[3]. Table 4 summarizes the treatment options from their review. Topical treatment of vulvar tissue with high potency steroid creams has been the mainstay of therapy in recent years. A case series of 12 patients with LS was published by Hillemanns et al. in 1999. Patients were treated with 5-ALA PDT (5-aminolevulinic acid and argon dye laser). In 10 out of 12 patients reported good clinical improvement lasting up to 6 months following treatment. Little else is known about the role of laser therapy for LS. Our case series suggests that fractional CO_2 laser therapy delivered with a dual probe approach with MonaLisa Touch® may offer a valuable addition to the treatment armamentarium of LS. It is easily performed

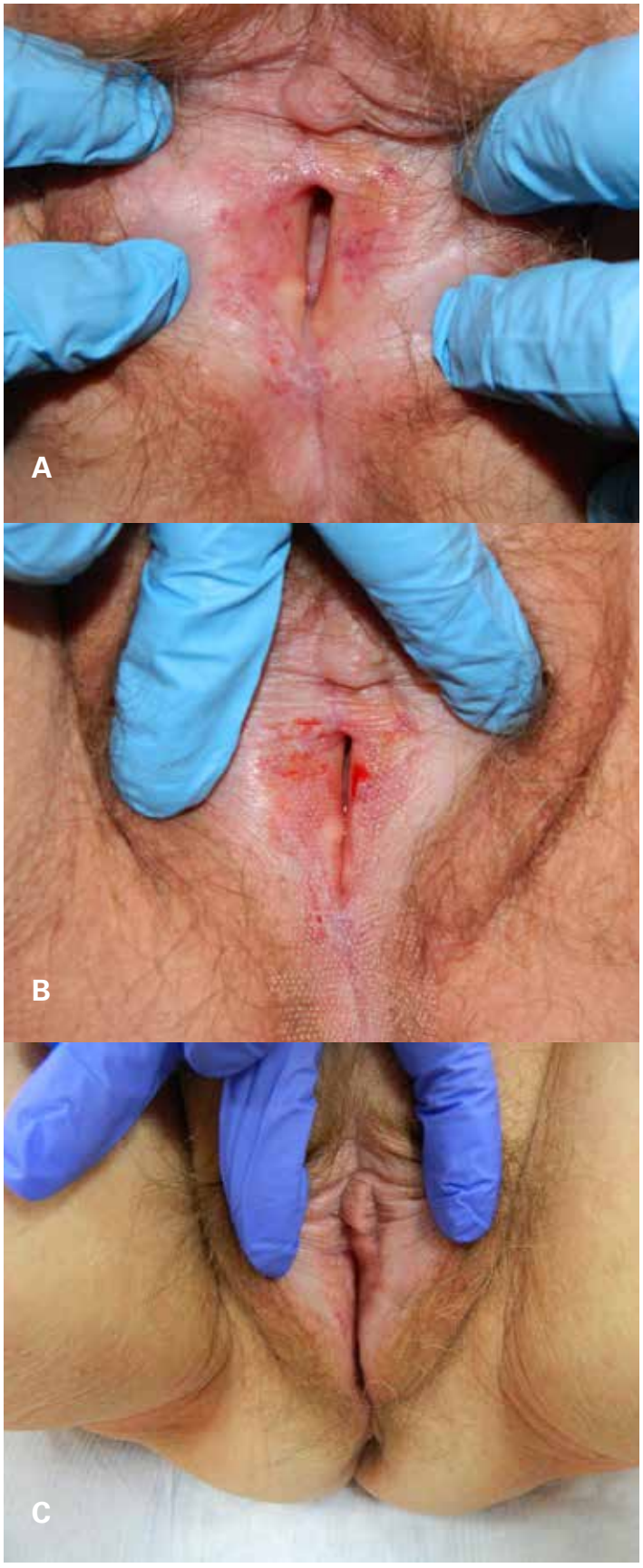

Figure 2: Exhibit I. Patient underwent MonaLisa Touch procedure for GMS and LS. Photographic documentation: (**A**) before treatment; (**B**) immediately after 1st session; (**C**) 6 weeks after 3rd session.

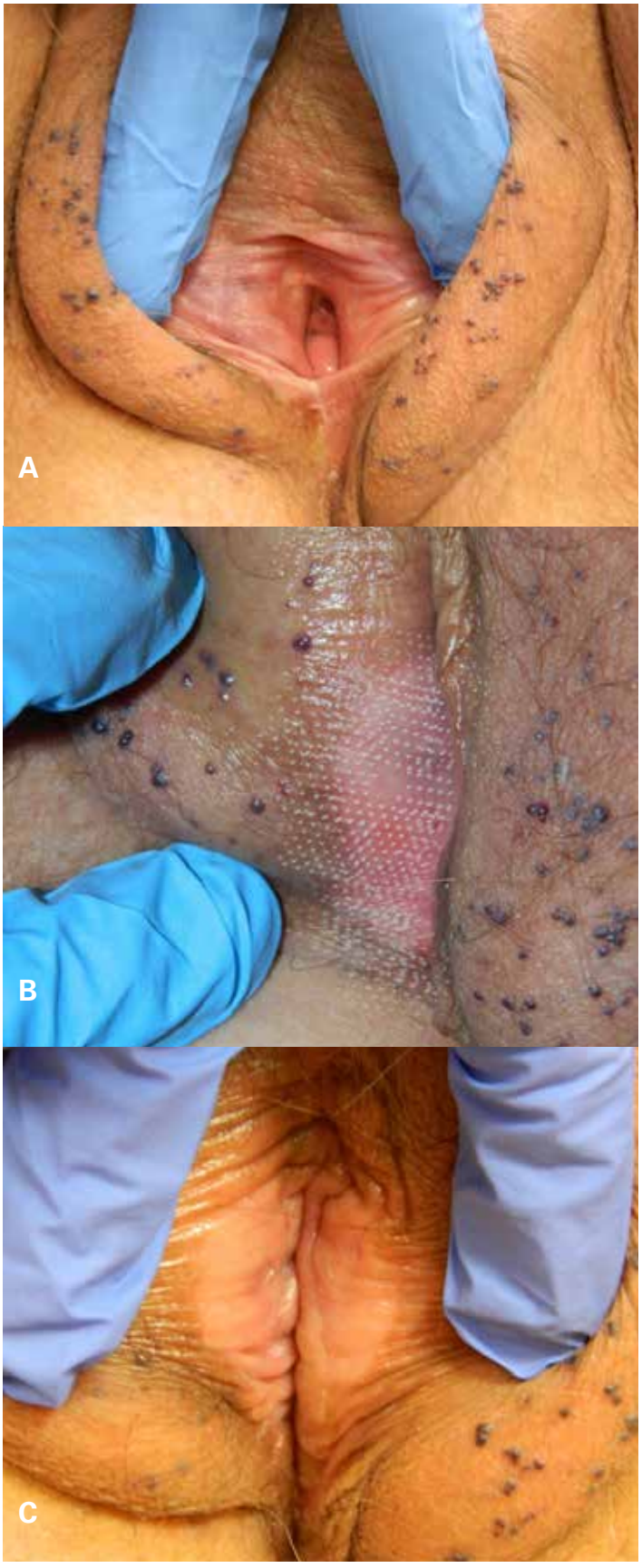

Figure 3: Exhibit II. Patient underwent MonaLisa Touch procedure for GMS and LS. Photographic documentation: (**A**) before treatment; (**B**) immediately after 1st session; (**C**) 6 weeks after 3rd session.

Minimize irritants, soap substitution, avoidance of urinary contact.
Moisturization with emollients.
Treatment of infections.
Ultrapotent or potent topical corticosteroid use daily at night for 4 weeks, then on alternate nights for 4 weeks, and then twice weekly for a further 4 weeks. Continued suppressive therapy according to the ongoing inflammatory activity.
In corticosteroid-resistant cases, consider circumcision in men, application of topical calcineurin inhibitors, topical retinoids in hyperkeratotic lesions, systemic retinoids, or photodynamic therapy.
Surgery for intraepithelial neoplasia or carcinoma.
Long-term surveillance.

Table 4: Treatment of anogenital lichen sclerosus.

in the office setting with only topical anesthetic cream and can be easily repeated at appropriate intervals to maintain symptom control. More formal studies with a range of clinical measures and validated questionnaires will be needed to fully assess the value and role of fractional CO_2 laser therapy in the treatment of LS. Nevertheless, our clinical results in this case series are encouraging.

References

1. Wallace HJ. Lichen sclerosus et atrophicus. Trans St Johns Hosp Dermatol Soc. 1971; 57:9-30.
2. Goldstein AT, Marinoff SC, Christopher K. Srodon, M. Prevalence of vulvar lichen sclerosus in a general gynecology practice. J Reprod Med. 2005 Jul; (50)7:477-80.
3. Fistarol SK, Itin PH. Diagnosis and Treatment of Lichen Sclerosus. An Update. Am J Clin Dermatol. 2013 Feb: 14(1)27-47.

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