Er:YAG TREATMENT OF VAGINAL RELAXATION SYNDROME WITH ACTION II™ USING PETIT 360° AND PETIT 90° SCANNING SCOPES: A PILOT STUDY

Min Seok Lee

Sophie-Marceau Women's Clinic, Daegu, South Korea

Addressee for Correspondence:

Min Seok Lee MD PhD,
706-817 Sophie-Marceau Women's Clinic,
42-2, Beomyeo 3-Dong, Suseong-Gu
Daegu Metropolitan,
South Korea
Tel: 82-53-756-3006, 4006(O)
Fax: 82-53-756-5077
Email: msleesena@hanmail.net

Er:YAG Treatment of Vaginal Relaxation Syndrome with ACTION II™ Using Petit 360° and Petit 90° Scanning Scopes: A Pilot Study

ABSTRACT

Background and Aims: Vaginal relaxation syndrome (VRS) is both a physical and psychological problem for women and often their partners. Tightening of the vaginal canal has been attempted with exercise, medication and the conventional or laser-assisted surgical vaginoplasty approach. Recently the 2940 nm Er:YAG laser has attracted attention for nonsurgical VRS treatment. The current study evaluated the clinical efficacy of this laser procedure with two different treatment protocols for this indication.

Subjects and Methods: Thirty postpartum female patients with VRS or vaginal atrophy participated, ages from 33 – 56 yr (mean 41.7 yr) divided randomly into two groups, Group A and Group B. Both groups were treated for 4 sessions at 1~2-weekly intervals with the 2940 nm Er:YAG ACTION II Petite Lady™ system (Lutronic, Goyang, South Korea). In Group A, the multiple micropulse mode group, the first 2 sessions were performed with the Petit 360° scope and the final 2 with the Petit 90° scope in multiple micropulse mode, 1.7 J/shot, 3 multishots, 3 passes per session. Group B underwent multiple micropulse mode treatment with the Petit 90° scope in all 4 sessions, multiple micropulse mode, 1.7 J delivered per shot, 3 multishots, 3 passes per session; then during the final 2 sessions an additional 2 passes/session were delivered with the Petit 360° scope, long-pulsed mode, 3.7 J delivered per shot. Perineometer assessments were performed at baseline and at 2 months post-treatment for vaginal tightness. Histological specimens were taken at baseline and at 2 months post-procedure. Subjective satisfaction with the result was assessed subjectively together with partner's input on improvement in vaginal tightening, and regarding the patient's assessed improvement in sexual satisfaction. Results were tested for statistical significance with the paired Student's *t*-test.

Results: All subjects successfully completed the study with no adverse events. Significant improvement in vaginal wall relaxation was seen in all subjects at 2 months post-procedure based on the perineometer values, on the partners' input for vaginal tightening (76.6%) and for sexual satisfaction as assessed by the patients themselves (70%). The histological findings suggested better elasticity of the vaginal wall with tightening and firming.

Conclusions: Both regimens of Er:YAG laser treatment for VRS produced significant improvement in vaginal relaxation. With multishots delivered in the multiple micropulse mode, nonsurgical Er:YAG laser treatment with the ACTION II Petite Lady™ was pain-free, safe, easily tolerated, side effect free and effective.

Key words: Multiple micropulse mode; vaginal tightening; 360° scanning scope; 90° scanning scope; perineometer; sexual satisfaction; elastinogenesis; collagenesis; tissue remodeling

Introduction

As women age, relaxing of the vaginal wall can lead to vaginal relaxation syndrome (VRS), which is exacerbated by childbirth, especially multiple pregnancies and deliveries, and the vaginal atrophy associated with menopause-related hormonal changes. VRS can lead to a number of problems, both physical and psychological, a major one of which is lessening of sexual satisfaction for both the female and her partner, often referred to as "loose vagina". Urinary incontinence (UI) is another problem associated with VRS, either of the stress or urge type, and can be mildly irritating or totally debilitating. The quality of life of affected women can decline dramatically as they become afraid to go out socially or even to work because of the humiliation of an unpredictable episode. According to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) in the USA, women experience UI at least twice as often as men. The combination of loss of sexual satisfaction for both partners and the psychological and social problems associated with UI mandate that a real, lasting and consistent solution for VRS is required.

A variety of VRS treatment options exists spanning the spectrum from noninvasive approaches to frankly invasive surgical procedures. For the noninvasive approaches, behavioral training such as Kegel exercises can tighten up relaxed musculature in the pelvic floor and to a lesser extent in the vaginal wall; "tightening creams", hormonal creams, sprays and other pharmacological approaches are also available. However, although these are noninvasive and innocuous, the effectiveness is somewhat limited and the latency period temporary, requiring continuous application in the case of the pharmacotherapies. Surgical procedures, in which vaginal and associated tissues are incised and rearranged,[1] can offer a much better and longer lasting final result. The results of surgical vaginoplasties, however, have to be balanced against the much greater risks involved in any surgery performed on the extremely sensitive vaginal tissues. Downtime for recovery is longer, and there are recognized risks associated with scar formation or nerve damage leading to dysesthesia.[2,3]

The laser has recently been added to the traditional armamentarium associated with surgical approaches for VRS The use of the diode laser has been reported, and because of their precision and the ability to limit damage depth, lasers have been trialled with wavelengths having high water absorption, such as the CO_2 (10600 nm). This approach was called laser-assisted vaginoplasty.

Taking the bulk laser beam and splitting it into multiple microbeams has provided even more control of the depth of the microablative columns (MACs), resulting in better efficacy with less downtime for the subject, and has become popularized as so-called "vaginal tightening". Compared with a vaginoplasty, this approach encompasses non-reconstructive strategies aimed at restoring the muscle tone of the vagina by tightening the

supportive structures of the vulvovaginal complex, in an effort to at least reduce the effects of aging and childbirth. The Petite Lady™ delivery system based on an Er:YAG laser is not a laser-assisted vaginoplasty, but is a nonsurgical approach falling under the concept of vaginal tightening. With special scanning scopes, one allowing 360° beam delivery and the other a 90° side-firing scope, selective and precise ablation with controlled coagulative damage can be delivered to the entire vaginal wall for the treatment of all symptoms of VRS, or to the wall of the anterior vaginal canal for the treatment of UI, or both. The present study was designed to assess the efficacy of the multiple micropulse mode Er:YAG laser fitted with Lutronic's Petite Lady delivery system in the treatment of VRS, and compares two different treatment protocols.

Subjects and Methods

Subjects

The study subjects comprised 30 postpartum females with VRS or vaginal atrophy, ages from 33 - 56 yr (mean 41.7 yr) who were divided randomly into two groups, Group A and Group B. Five subjects had given birth once, 20 twice, and 5 had undergone 3 deliveries. There was no significant difference between the groups as regards mean age (Group A, 42.93 yr; Group B, 40.53 yr), body mass index (BMI) (Group A 22.3; Group B, 22.6) or parous status. Regarding the menstrual status, in Group A, pre-, peri- and postmenopausal females accounted for 9, 1 and 5 subjects, respectively; in group B, 14, 1 and 0. Group A was thus at a more advanced menopausal status than group B. One subject in Group A had undergone a cesarean section, compared with 5 subjects in Group B. The subject demographics and relevant histories are given in Table 1. Regarding the degree of VRS, 3, 9 and 3 subjects were graded mild, moderate and severe, respectively, in Group A, compared with 7, 3 and 5 in Group B (Table 2). Levator ani muscle (LAM) power as assessed with a digital examination was good, moderate, poor and very poor in 5, 2, 7 and 1 subjects, respectively, in Group A, compared with 4, 7, 3 and 1 subjects, respectively, in Group B (Table 2). Table 2 also shows the baseline perineometer readings for the maximum (Pm) pressures and average (Pa) pressures (in mmHg) and the time for which pressure was maintained (Pt, seconds).

Laser system

The laser system used was the ACTION II™ Er:YAG (Lutronic, Goyang, South Korea) delivering a wavelength of 2940 nm. When fitted with the dedicated vaginal scanning scopes (Petite Lady™) the laser can be operated in the multiple micropulse mode, or in the long-pulsed mode.

Table 1: Patient characteristics

Serial No	Age	BMI(%)	Parous status	Delivery type	Menstrual status	Remarks
			Group 1 (n=15)			
P-1	36	21.9	2	NSVD	premen	
P-2	38	23.2	2	C-sec	premen	
P-3	35	22.6	2	NSVD	premen	previous p-repair Hx(+)
P-4	40	20.1	2	NSVD	premen	Previous sexual assault Hx(+)
P-5	41	24.1	3	NSVD	premen	
P-6	53	27.1	2	NSVD	postmen	atrophic vaginitis case
P-7	56	25.0	2	NSVD	postmen	atrophic vaginitis case
P-8	35	19.7	1	NSVD	premen	previous LEEP Hx(+)
P-9	35	19.7	1	NSVD	premen	
P-10	56	24.4	3	NSVD	postmen	
P-11	51	24.3	2	NSVD	perimen	
P-12	52	22.4	3	NSVD	postmen	atrophic vaginitis case
P-13	43	20.4	2	NSVD	premen	
P-14	36	22.0	2	NSVD	premen	
P-15	37	20.6	2	NSVD	premen	
			Group 2 (n=15)			
P-16	49	20.0	3	NSVD	premen	
P-17	42	24.3	1	C-sec	premen	
P-18	42	25.0	2	NSVD	premen	
P-19	33	22.0	2	C-sec	premen	
P-20	38	19.1	2	C-sec	premen	
P-21	40	20.6	1	NSVD	premen	
P-22	34	32.2	2	C-sec	premen	
P-23	42	23.2	2	NSVD	premen	
P-24	44	24.3	2	C-sec	premen	
P-25	41	20.8	1	NSVD	premen	previous TOT op(+)
P-26	33	17.6	3	NSVD	premen	
P-27	33	18.4	2	NSVD	premen	
P-28	52	26.7	2	NSVD	perimen	previous TOT op(+) / HRT(+)
P-29	38	22.8	2	NSVD	premen	
P-30	47	21.4	2	NSVD	premen	

KEY: BMI, body mass index; NSVD, normal spontaneous vaginal delivery; C-sec, cesarean section; Premen, premenstrual; perimen, perimenstrual; postmen, postmenstrual; p-repair, posterior vaginal repair; LEEP, loop electrosurgical excision procedure; TOT, transobturator tension-free surgical tape; HRT, hormone replacement therapy

Table 2: Vaginal wall relaxation status at baseline as assessed by digital examination, at baseline and after treatment tested with a perineometer, postprocedural partner's assessment of vaginal tightening and patient's assessment of postprocedural sexual satisfaction

Pat. No	Degree of VWRS	LAM power (digital exam)	Perineometer test values						Vaginal tightening (Partner)	Sexual satisfaction (Patient)
			B/L			Post-2 months				
			Pm (mmHg)	Pa (mmHg)	Pt (s)	Pm (mmHg)	Pa (mmHg)	Pt (s)		
Group 1										
P-1	mild	good	39	34	10	41	35	17	3	3
P-2	mild	good	48	38	9	61	44	10	2	3
P-3	moderate	poor	13	6	20	17	6	36	0	0
P-4	moderate	good	28	21	6	49	42	8	0	0
P-5	moderate	poor	12	7	6	22	16	19	2	2
P-6	moderate	good	28	19	20	50	40	21	3	3
P-7	mild	poor	7	3	21	13	7	19	3	3
P-8	moderate	good	11	6	23	32	24	23	1	1
P-9	moderate	poor	8	6	7	15	11	25	3	3
P-10	severe	moderate	19	14	2	27	20	14	1	0
P-11	severe	poor	13	8	2	19	9	6	1	1
P-12	moderate	moderate	8	4	10	31	25	16	3	3
P-13	moderate	poor	8	4	16	14	8	26	2	2
P-14	moderate	poor	20	10	49	22	10	53	3	3
P-15	severe	very poor	0	0	0	15	10	8	1	1
Group 2										
P-16	severe	moderate	21	15	21	20	14	23	1	1
P-17	moderate	moderate	8	5	11	10	6	10	1	0
P-18	mild	good	19	9	46	15	8	40	0	0
P-19	mild	moderate	15	5	37	24	16	25	0	0
P-20	mild	good	20	12	8	28	19	8	0	0
P-21	mild	good	37	30	13	38	24	17	1	1
P-22	mild	poor	26	19	14	34	26	15	3	3
P-23	moderate	very poor	0	0	0	20	12	14	3	3
P-24	mild	moderate	17	14	22	22	18	56	2	2
P-25	moderate	good	22	15	36	32	24	17	1	1
P-26	severe	moderate	31	24	5	34	28	5	0	0
P-27	severe	poor	18	12	25	19	12	33	0	0
P-28	severe	moderate	27	21	4	65	54	8	2	2
P-29	mild	poor	10	7	24	14	10	58	1	1
P-30	severe	moderate	22	18	30	15	9	56	2	2

Pat. No, patient reference No; VWRS, vaginal wall relaxation status; LAM, levator ani muscle; BL, baseline values; Post-2 months, values 2 months after the final treatment; Pm, maximum pressure; Pa, average pressure; Pt, time for which pressure was maintained; Vaginal tightening (Partner), assessment by the patient's partner of the degree of improvement in vaginal tightness post-treatment using the following scale: little or no improvement, 0; some improvement, 1; good improvement, 2; excellent improvement, 3. Patient sexual satisfaction was self-rated using the following scale: dissatisfied, 0; somewhat satisfied, 1; satisfied, 2; extremely satisfied, 3.

There were two scopes comprising the dedicated vaginal scanning scope system (Figure 1): one scope delivered a 360° ring-shaped beam with an approximate beam diameter of 2-3 mm (Petit 360°), and the other delivered a round-shaped beam with an approximate beam diameter of 5 mm (Petit 90°), both scopes being supported in the vagina by a specially designed guide (Figure 2). In general, for the Petit 360 or 90° scopes the supporting guide is inserted, then the scope is fully inserted into the guide. The laser parameters are set, including the multiple pulse option, the laser is fired, the Petit 360° scope is withdrawn by 1 gradation marked on the scope body, and the process repeated for the entire length of the vaginal canal. Multiple passes may be made.

For the Petit 90° scope in the treatment of UI, following insertion of the supporting cage the probe is inserted with the active part of the scope at the 12 o'clock position. The laser is fired, and the scope turned to the 2 o'clock position, fired again, then turned to the 10 o'clock position and fired again. The scope is withdrawn by two gradations, returned to the 12 o'clock position, and the process is repeated for several passes.

Figure 1: Petit 360° scanning scope (left) and the Petit 90° scanning scope (right)

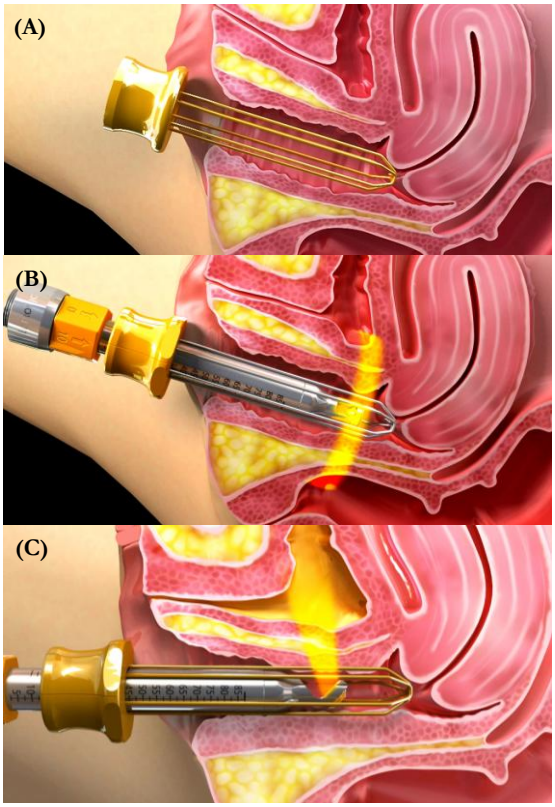

Figure 2: (A) Illustration showing the specially designed guide for the scanning scopes inserted in the vagina; (B) Petit 360° delivered a 360° ring-shaped beam with an approximate beam diameter of 2-3 mm; (C) Petit 90° delivered a round-shaped beam with an approximate beam diameter of 5 mm

Treatment protocol by group (N=15 for both groups)

Group A: The protocol called for four treatment sessions, 1-2 weeks apart. In sessions 1 and 2, treatment was applied with the 360° scope as described above using the multiple micropulse mode. The multishot option was set to 3 multishots and 1.7 J/shot was selected. (It is the manually selected 15 mJ pulse energy on the touch screen display in multiple micropulse mode.) Three passes were delivered along the entire length of the vaginal canal in each treatment session. In sessions 3 and 4, the 90° scope was used at the same parameters as for sessions 1 and 2. However, for each set of shots the active part of the scope was set at the 12 o'clock, then 2 o'clock, 4 o'clock, 6 o'clock, 8 o'clock and 10 o'clock positions.

Group B: Four treatment sessions were delivered, 1-2 weeks apart. Sessions 1-4 called for the 90° scope used as in Group A, multiple micropulse mode, 3 multishot, and 15 mJ pulse energy displayed on the screen. Three passes were delivered for each treatment session. In sessions 3 and 4 an additional 2 passes per session were delivered with the 360° scope in long-pulsed mode, pulse width of 1 s, 3.7 J/shot (It is manually selected 11 J/cm² with a spot size of 6.4 mm on the display screen in long pulsed mode.).

Assessments

Punch biopsies were taken at baseline and at 2 months after the final session, formalin fixed and routinely prepared for light microscopy with hematoxylin and eosin and elastica van Giesen staining. Perineometer readings were repeated at the same time point and compared with the baseline values. Subjective assessments at the same time point included the subject's partner's evaluation of the degree of vaginal tightening, and the patient's own evaluation of the degree of improvement in sexual satisfaction. Subjective scoring was on 4-point scales as follows: Partner's assessment of vaginal tightening: little or no improvement, 0; some improvement, 1; good improvement, 2; excellent improvement, 3. For patient sexual satisfaction: dissatisfied, 0; somewhat satisfied, 1; satisfied, 2; extremely satisfied, 3.

Results

All subjects completed the treatment and the 2-month assessment. All patients were aware of some heating in the vagina during treatment, and a very few patients felt mild vaginal ecchymosis with a mild burning sensation which lasted for 24-48 hr and evolved spontaneously. No subject reported any major or lasting adverse side effects after any of the treatments. Improvement was seen in all perineometer scores, in the majority of subjects (76.6%) for the partner's assessment of vaginal tightening and in the patient's own assessment of improved sexual satisfaction (70%).

Statistical assessments (Table 3)

Overall values in the vaginal wall relaxation status for the total subject population showed a statistically significant improvement between the baseline and findings at 2 months after treatment for the perineometric maximum pressure (p <0.01), and the average pressure (p < 0.05), with marginal significance noted in the time for which the pressure was maintained (p < 0.1). In the comparison of results between groups, Group A had slightly better results than Group B with marginal significance in the maximal pressure (p <0.1) and an increased trend without significant difference seen in the average perineometer pressure or the time for which pressure was maintained. As for vaginal tightening as assessed by the sexual partner, Group A showed an increasing trend without significance compared with Group B, but with a statistically significant difference seen for the increase in sexual satisfaction assessed by the patients themselves (p <0.05).

Histological assessment

The histological findings in general showed evidence of a thicker and more cellular epithelium and a more compact lamina propria with a denser arrangement of connective tissue. Figures 3 (Patient 1) and 4 (Patient 2) show representative specimens at baseline and two months after the final treatment under hematoxylin and eosin and elastica van Giesen staining, respectively. Taken together, the results of the histological analysis suggest tightening and firming of the vaginal wall. Both specimens came from comparatively young patients, but even in these young patients improvements in and rejuvenation of the vaginal structures can be seen 2 months after the final Petite Lady treatment.

Table 3: Statistical analyses of the data comparing the baseline and post-procedure results for the entire patient population, and between Groups A and B

Groups	Pm (mmHg)		S-Sig (*p*)	Pa (mmHg)		S-Sig (*p*)	Pt (s)		S-Sig (*p*)	VT	SS
	BL (SEM)	Post (SEM)		BL (SEM)	Post (SEM)		BL (SEM)	Post (SEM)			
Total	18.50 (2.04)	27.27 (2.60)	***< 0.01 (=0.0052)**	12.87 (1.76)	19.57 (2.3)	***p < 0.05 (=0.013)**	16.57 (2.4)	22.87 (2.9)	**< 0.1 (=0.097)**	-	-
Grp A* vs Grp B**	17.47 (3.4)	28.53 (3.9)	*<0.1 **(= 0.091)**	12.00 (2.92)	20.47 (3.55)	**NS (=0.330)**	13.4 (3.19)	20.07 (3.13)	**NS (=0.539)**	**NS (=0.101)**	***< 0.05 (=0.011)**
	13.73 (2.05)	18.67 (2.09)		13.73 (2.06)	18.67 (3.09)		19.73 (3.49)	25.67 (4.81)			

BL, baseline; Pm, maximum pressure; Pa, average pressure; Pt, time for which pressure was maintained; SEM, standard error of means; Post, 2 months post-treatment; S-Sig, statistical significance; (*p*), P value (paired Student's *t*-test); VT, vaginal tightening (assessed by patient's partner); SS, sexual satisfaction (patients subjective assessment); NS, no significance

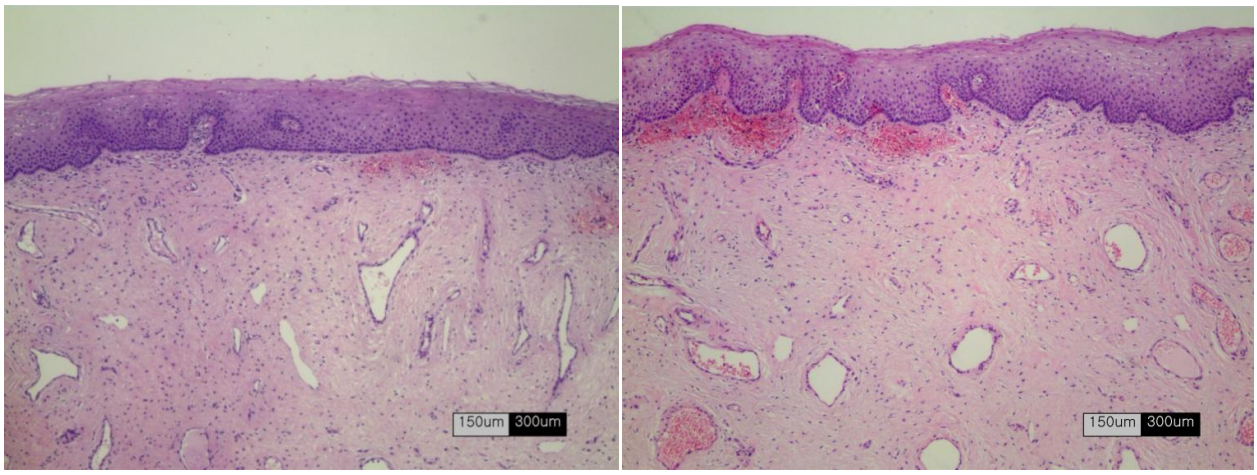

Figure 3: Hematoxylin and eosin stained specimens of the vaginal wall from Patient 1 (Left) at baseline, and (right) 2 months after Petite Lady treatment showing improved mucosal architecture in both the epithelium and lamina propria. Scale units are as shown on the bars.

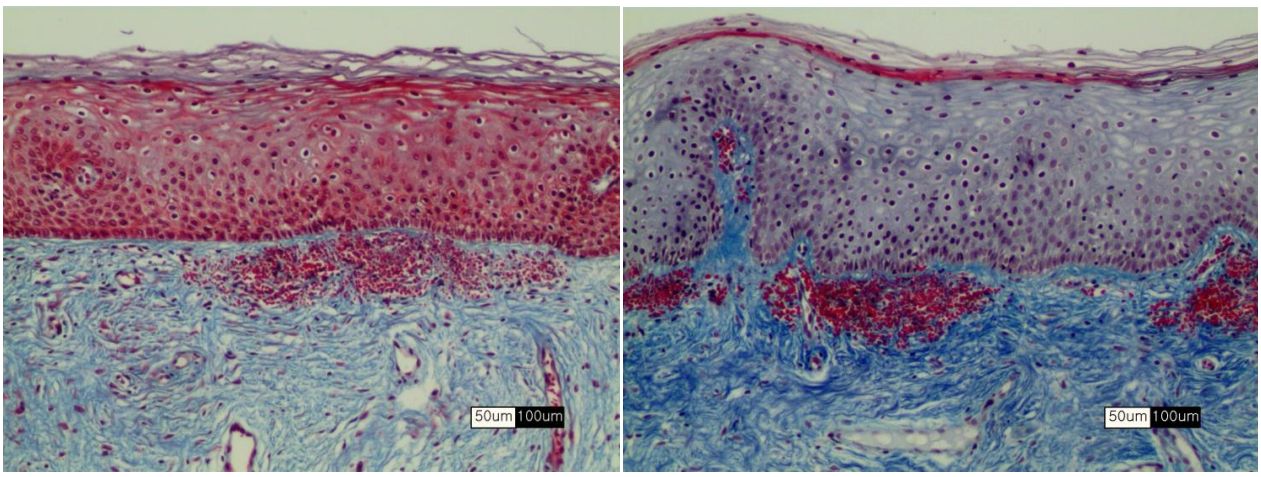

Figure 4: In these elastica van Giesen stained specimens from the vaginal wall of Patient 2, the findings can be seen comparing the baseline (left) with the situation 2 months post-treatment (right) where a thicker epithelium and denser lamina propria are observed. Scale units are as shown on the bars.

Subject assessments

As seen in Table 2, in the case of the subjects' partners, 23 out of 30 (76.6%) noted improvement in vaginal tightening as follows: some improvement, 9; good improvement, 6; and excellent improvement, 7. There was no statistical significance in these results between groups A and B. As for the patient's sexual satisfaction compared with the preoperative condition, 21 out of the 30 patients were satisfied (70.0%), made up as follows: somewhat satisfied, 7; satisfied, 5; and extremely satisfied, 9. Group A subjects were significantly more satisfied than subjects in Group B ($p < 0.05$)

Discussion

The important fact from the present study, based on the results of the nonsurgical multiple micropulse mode Er:YAG treatment for vaginal relaxation syndrome, was that all patients completed the study and improvement was seen in both vaginal tightening and increased sexual satisfaction for the majority of the total patient population. The choice of the Er:YAG with its 2940 nm wavelength for the Petite Lady procedure was predicated on the absorption peak of water at that wavelength. As human tissues, especially mucous membranes, have a very high percentage of water, they are a good target for this wavelength. Because of the extremely high absorption, the incident photon energy is almost totally quenched in the first few micrometers of tissue, producing a very controlled column of ablation with an extremely narrow band of secondary coagulation, known as residual thermal damage (RTD).[4] This meant shorter downtime with quicker healing, and was the cornerstone of the use of the Er:YAG in full-face ablative laser resurfacing compared with the CO_2 laser, which had a much larger RTD zone.[5] For many clinicians practicing laser resurfacing, however, this larger zone of RTD actually made the CO_2 laser superior to the Er:YAG in terms of the latency and degree of the result, although it dramatically increased the downtime or side effects such as scarring and prolonged erythema. In the case of the very delicate vaginal canal, however, the precise depth control associated with the Er:YAG wavelength offers major benefits.

Accumulating Er:YAG laser energy with multiple micropulses further controls the depth of the ablative and thermal damage zones (referred to as microablative columns [MACs]), which allows the deposition of adequate RTD to ensure a healthy and swift wound healing process while leaving undamaged normal tissue between the MACs and thereby speeds up tissue recovery even more because of the participation in the process of the normal tissue. In the delicate tissues of the vaginal canal, it is imperative that the ablative damage depth is controlled, but that enough RTD is created in the MACs to induce actively the wound healing process, plumping up and rejuvenating the squamous epithelial component of the mucosa, while firming up the connective tissue of the lamina propria (Figure 5) and thus causing tightening of the supportive structures of the vulvovaginal complex.

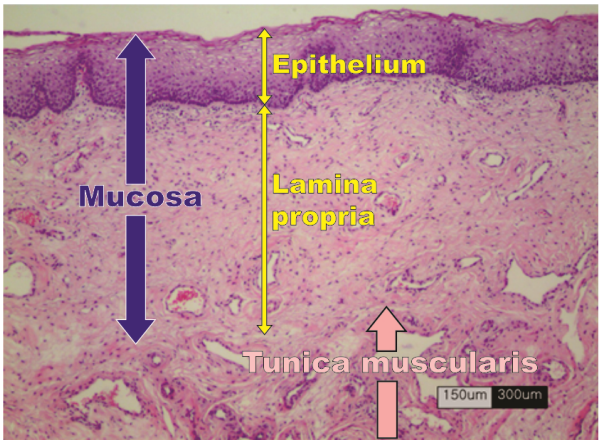

Figure 5: Hematoxylin and eosin-stained section of the vaginal wall (from a patient in the present study), with the various zones labeled.

In the case of Petite Lady approach, there were two scanning scopes to deliver the multiple micropulses: the Petit 360° and the Petit 90° scope. The 360° scope delivered a ring-shaped circular beam with beam diameters of 2-3 mm, whereas the 90° scope delivered a round beam with diameters of approximately 5 mm. For both scopes, the first set of multiple micropulses cleanly created an epidermal window in the vaginal epithelium with minimal RTD, and subsequent micropulses created a pulse-stacking effect with thermal build-up down into the lamina propria, increasing the RTD zone and ensuring a good wound healing response (**Figure 6,** left panel). Therefore, taking the respective beam diameters into consideration, to ensure even coverage of the target tissue the 360° scope was withdrawn by 1 increment marked on the scope body after each set of shots, and the 90° scope was withdrawn by 2 increments for each set of shots.

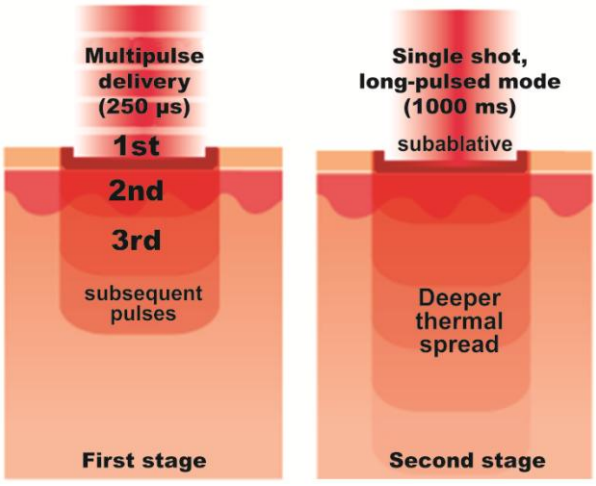

Figure 6: Schematic representation of the dual-mode technique. In the first stage (left panel) the 1st shot of the 250 µs multipulse ablates a window in the epidermal tissue, allowing the thermal effect of subsequent shots to penetrate into the lamina propria. In the second stage, the subablative single shot in the long-pulsed mode delivers thermal damage deep into the lamina propria through the existing epidermal window.

In the present study, to attempt even better tightening of the vaginal canal through induced enhanced tissue remodeling, it was considered that a more "CO_2-like" effect should be delivered to the tissue, *i.e.* more residual thermal damage with controlled precise ablation. It was shown as early as 2001 that the Er:YAG at appropriate parameters could deliver almost as good a coagulative effect as the CO_2 through an ablated epidermal window [6], so for the Petite Lady Group B the 1000 ms long-pulsed mode was added for the last 2 sessions as an adjunct to the 250 μs multiple micropulse mode treatment to deliver more of a thermal effect (Figure 5, right panel).

This protocol actually represents a potential limitation of the present study, because the protocol for group A was not exactly repeated in Group B with the addition of the long-pulsed mode, and this makes it more difficult to compare the effect accurately between the groups with and without the long-pulsed mode. Groups A and B both received 4 sessions, 1-2 weeks apart. However in Group A the first 2 sessions were delivered with the 360° scope, and sessions 3 and 4 with the 90° scope, multiple micropulse mode in all cases. For group B, on the other hand, all 4 sessions were delivered with the 90° scope in multiple micropulse mode, but in the last 2 sessions patients were additionally treated with the 360° scope in the long-pulsed mode.

In the group of 30 patients as a whole, significantly better results were seen in the perineometer readings, vaginal tightening and sexual satisfaction. However, the author expected to see better results in Group B because of the additional long-pulsed mode treatment, but as the data show, it was Group A patients who had the statistically significantly better results, both from the perineometer readings and the patients' own assessment of sexual satisfaction. This was not a little surprising, especially as Group A was at a more advanced menopausal state than Group B, and so might have had more vaginal atrophy. In addition, subjects in Group A had experienced more natural childbirths than in Group B, with 1 C-section in the former compared to 5 C-sections in the latter: A C-section obviously puts much less strain on the birth canal, especially the vulvovaginal complex. In short, a better result was achieved in Group A whose vaginal canal was in potentially worse physiological condition than Group B.

Overall, however, the objective perineometry readings clearly showed high statistical significance between the baseline and the 2-month post-procedural readings for the entire patient population, as did the patient and partner assessments of sexual satisfaction and vaginal tightening, respectively, so both treatment protocols were efficacious and safe. It is an accepted fact that a fluence delivered by a larger spot size penetrates better and deeper than the same fluence with a small spot size. Why was the result superior in Group A when the fluence for the multiple micropulse mode was identical at 15 J/cm²? The answer is uncertain. Perhaps the order of treatment was important, with the 2-3 mm spot size of the 360° scope for the first 2 sessions, followed by the 90° scope with its 5 mm beam diameter in Group A's protocol. Future studies need to be designed to take these considerations into account, with the addition if possible of histological assessment immediately after treatment to help compare the morphology at baseline with changes in the vaginal architecture after Petite Lady treatment, and related with the follow-up results.

Conclusions

Both regimens of Er:YAG laser treatment for VRS and vaginal atrophy with the multiple micropulse mode (Group A) and dual mode (multiple micropulse mode with 2 additional sessions of long-pulse mode, group B) produced significant improvement in vaginal relaxation with tightening in both the objective perineometer readings, from the results of the partners' assessments of improved vaginal tightness (76.6%), and from the subjects' own improvements in perceived sexual satisfaction (70.0%). This nonsurgical treatment involving multiple micropulse and dual Er:YAG modes with the ACTION II Petite Lady™ was safe, easily tolerated, pain- and side effect free and effective.

The advantages of the Petite Lady approach are:

- Ambulatory procedure
- No risk of anesthesia
- Infection and rejection of materials used in traditional techniques
- Short operation time
- No definite contraindication
- Early coitus (1 week postop)
- No antibiotics or painkillers required
- Easily repeated

However, there are also disadvantages, in that it is currently a blind procedure, and objective assessment is rather difficult.

References

1: Goodman MP. Female cosmetic genital surgery. Obstet Gynecol, 2009;113:154-159.
2: Davies MC, Creighton SM, Woodhouse CR. The pitfalls of vaginal construction. BJU Int, 2005;95:1293-1298
3: American College of Obstetricians and Gynecologists (ACOG). Vaginal "Rejuvenation" and Cosmetic Vaginal Procedures (in PDF) (2007)
4: Price CR, Carniol PJ, Glaser DA. Skin resurfacing with the erbium:YAG laser. Facial Plast Surg Clin North Am. 2001; 9: 291-302.
5: Newman JB, Lord JL, Ash K, McDaniel DH. Variable pulse erbium:YAG laser skin resurfacing of perioral rhytides and side-by-side comparison with carbon dioxide laser. Lasers Surg Med, 2000; 26:208-214.
6: Trelles MA, Mordon S, Benítez V, Levy JL.Er:YAG laser resurfacing using combined ablation and coagulation modes. Dermatol Surg, 2001; 27:727-34.