ISSN 1855-9913

Journal of the Laser and Health Academy
Vol. 2021, No.1; www.laserandhealth.com

G-Runner Robotic Vaginal Probe for IncontiLase® and IntimaLase® Treatment – a Pilot Study

Jorge E. Gaviria P[1], Maša Bucik[2]
[1] *Korpo Laser, Caracas, Venezuela*
[2] *Laser and Health Academy, Ljubljana, Slovenia*

ABSTRACT

Introduction: The objective of our study was to evaluate the safety and efficacy of a new robotic vaginal probe (G-Runner) for stress urinary incontinence and vaginal tightening.

Methods: 23 patients participated in our study. The patients were treated with either IntimaLase® treatment for vaginal laxity or IncontiLase® treatment for stress urinary incontinence, depending on their symptoms. 16 patients (Group 1) received IntimaLase® treatment and 7 patients (Group 2) received IncontiLase® treatment. The treatments were performed using the G-Runner robotic probe with Er:YAG laser / Fotona SMOOTH® mode, in the period between October and December, 2015. All patients received three sessions with a one-month interval between sessions. ICIQ-SF questionnaire was used to measure improvement of stress urinary incontinence (SUI) symptoms. A patient-reported VAS scale (range 0-10) was used to evaluate sexual gratification, lubrication and SUI symptom improvement following treatment. Patient satisfaction after the IntimaLase® procedure was evaluated through telephone interviews one month after the final (3rd treatment) and after the 6 month follow-up. They were asked to rate the improvement of their vaginal firmness.

Results: All patients completed a three-treatment therapy. SUI symptoms improved after both the first and the second treatment. Significant improvement was seen both between baseline and the third treatment ($p=0.0018$), and between the second and third treatments ($p=0.0045$). Sexual gratification and lubrication improved already after the first treatment, while additional treatments did not result in significantly better improvement. For patients who received the IntimaLase® treatment for vaginal tightening, there was no significant impact on the results when preforming one or two passes using the G-Runner. Patients reported improvement of sexual gratification and lubrication 1 month after the 1st treatment (before the second treatment) and one month after the second treatment (before the third treatment). There were also no significant differences between the 1- and 2- pass treated groups using the IntimaLase® protocol at the 1 and 6-month telephone follow-ups. There were no reported side effects after any of the treatments.

Conclusions: The G-Runner probe is a safe, effective and easy-to-use-option for performing IncontiLase® and IntimaLase® procedures.

Key words: G-Runner probe, stress urinary incontinence (SUI), vaginal laxity (VL), Er:YAG, sexual gratification, lubrication.

Article: J. LA&HA, Vol. 2021, No.1; onlineFirst.
Received: Jun 22, 2021; Accepted: Dec 3, 2021

I. INTRODUCTION

Stress urinary incontinence (SUI) is the complaint of involuntary loss of urine during an effort. It is a medical problem affecting many women worldwide, which is more prevalent in middle-aged women following vaginal birth [1,2]. Symptoms of SUI present as unwanted urine leakage with increased abdominal pressure, such as jumping, sneezing or coughing. Many women with SUI also suffer from urinary urgency. Risk factors for urinary incontinence include aging, pregnancy, vaginal childbirth, menopause, obesity and smoking [3]. Traditional treatments involve pelvic floor muscle therapy and surgery [4]. In the last decade, a vaginal laser treatment using non-ablative Fotona SMOOTH® Er:YAG laser (IncontiLase®) has become a new non-invasive option for SUI treatment [5–10].

Vaginal Laxity (VL) is a condition that can detrimentally affect women's quality of life. It is one of the symptoms of pelvic floor dysfunction, where a woman complains about the loss of physical sensation and decreased sensation during sexual intercourse [11–13]. It is associated with age and vaginal childbirth [14]. VL and sexual gratification can be improved with surgical techniques that aim to remove excess tissue and reduce the size of the vagina, such as vaginoplasty and /or perineoplasty [15]. The risks of these procedures

include bleeding, loss of sensation, infection or just dissatisfaction with the results [16]. The Fotona SMOOTH® Er:YAG treatment for VL, known as IntimaLase®, has proven to be safe and effective in managing VL symptoms [9,14,17,18].

The acute need for non-invasive treatment methods for SUI and VL has resulted in a high interest in this laser treatment among patients.

The IntimaLase® and IncontiLase® procedures work by inducing collagen shrinkage and stimulating new collagen production [19,20] while at the same inducing remodeling of the vaginal epithelium; this results in strengthening of the pelvic floor support and functional improvement of the symptoms of pelvic floor dysfunction, such as VL or SUI.

The treatments were initially performed using the manual G-set. Recently, a robotic handpiece – the G-Runner was also introduced. Both modes of treatment – manual and automatic – deposit an equal amount of energy on the tissue, with the only difference being the spatial sequence of energy deposition. With the G-set procedure, the energy is deposited in a linear fashion, from the distal to proximal position, while with the G-Runner, deposition of energy is performed in a circular mode along the vaginal canal. The advantages of using the G-Runner include automated and precise deposition of energy with minimal inter-operator variability.

Figure 1: G-Runner Robotic Vaginal probe.

The purpose of this study was to assess the safety and efficacy of the G-Runner robotic handpiece in treatments of SUI and VL.

II. MATERIALS AND METHODS

Sixteen (16) patients suffering from VL and seven (7) patients suffering from SUI were submitted to IntimaLase® and IncontiLase® treatment with an Er:YAG laser (SP Dynamis, Fotona, Slovenia).

All treatments were executed at a single location, the Aldana Laser Center in Caracas, Venezuela in the period between October and December 2015.

The inclusion criteria were: clinical diagnosis of VL or SUI, normal PAP smear, negative urine culture, and a vagina free of injures (including the introitus and vestibulum).

The exclusion criteria were: pregnancy, intake of photosensitive drugs, injury or/and active infection in the treatment area, undiagnosed vaginal bleeding and active menstruation.

The study has been performed in accordance with the Declaration of Helsinki, and all patients signed a specific informed consent prior to each laser session.

Two protocols were performed, IntimaLase® and IncontiLase®. All patients received a 3-session laser treatment with a one-month interval between the sessions.

Patients were allocated to Group 1 (IntimaLase® protocol) or Group 2 (IncontiLase® protocol) according to their medical condition. Patients in Group 1 were randomly assigned to one or two passes laser treatment.

a) IntimaLase® protocol

The IntimaLase® treatment was performed in two steps with 2940 nm Er:YAG laser (SP Dynamis®, Fotona, Slovenia) using the vaginal G-Runner probe. 16 patients were treated using the IntimaLase® protocol (Group 1). 10 patients from Group 1 were treated with a single pass, while 6 patients received two passes in the first step of the protocol. 9 patients were treated using the large glass speculum (L; GClear30) and 7 using the small glass speculum (S; GClear25), depending on the degree of vaginal laxity.

The first step was performed using the green insert ContFull adapter / GRA-FG (7 mm, 3.5 J/cm^2 (S) or 4.5 J/cm^2 (L), 4 SMOOTH pulses, 3.3 Hz) with a full beam, which was used to treat the whole vaginal canal. The G-Runner automatically deposits the energy in a circular motion along the entire vaginal canal. One to two passes were performed in the first step.

In the second step, external treatment of the introitus and vestibulum was performed using the red insert (patterned beam) – Direct Pixel adapter/ GRD-PR (7 mm, 10 J/ cm^2, 2 pulses, 1.6 Hz, 10% overlapping) with a straight adapter, 2 passes around the vestibulum and introitus.

b) IncontiLase® protocol

The IncontiLase® treatment was performed in three steps with Er:YAG (SP Dynamis®, Fotona, Slovenia) using the vaginal G-Runner probe. 7 patients were treated using the IncontiLase® protocol (Group 2).

The first step was performed using the yellow insert – TopPixel adapter/GRA-PY (7 mm, 10 J/cm^2 (S) or 11 J/cm^2 (L), 2.0 Hz). 5 complete circles were performed in

the first step. The second step was performed with the ContFull / GRA-FG adapter (7 mm, 3.5 J/cm² (S) or 4.5 J/cm² (L), 3.3 Hz). Two complete passes were done. The third step was performed with a Direct Pixel adapter / GRD-PR (7 mm, 10 J/ cm², 2 pulses, 1.6 Hz, 10% overlapping); 2 passes over the vestibulum and introitus were performed.

No anesthesia was used in any of the treatments. No special post-treatment was needed. Patients were only advised to avoid sexual activities for a period of 72 hours after each of the treatment sessions.

c) Aguilera tonometry

In our study we used a "Vaginal Tonometer", which can be compared with a Perineometer, an instrument that enables objective pressure measurements of vaginal basal tone and contraction of the vaginal muscles. It is assembled with a tubular silicone balloon, which is connected to an instrument that measures pressure (in mmHg) over a range from 0–100. Measurements were done during vaginal contraction before and after each treatment. Tonometry was done for both tested groups.

d) Evaluation methodology

All patients received three monthly treatments. Measurements of symptom improvement were performed one month after the initial treatment (at the time of the 2nd treatment) and two months after the initial treatment (at the time of the 3rd treatment). All patients who received the IncontiLase® treatment were asked to evaluate symptom severity at baseline, after one month and after the second month using ICIQ-SF questionnaire. The ICIQ-SF results were grouped by the magnitude of symptom reduction: no change (no change in ICIQ-SF score), improvement (1-5 point decrease) and strong improvement (>5 points decrease in ICIQ-SF score). As indicators of patient satisfaction, improvement in sexual gratification and lubrication following laser treatment was evaluated by patients using a 0-10 VAS scale.

Measurements of improvement in vaginal tone during pelvic floor muscle contraction were performed before and after each treatment. Results are given as an average of all measurements at each time point.

Follow-ups were performed via telephone interview. Patients were asked to describe improvement through a questionnaire by choosing: worse, same or better at the 1-month and 6-month follow up.

Friedman's test (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp) and non-parametric paired-samples t-test (GraphPad Prism version 9.1.2 for Windows, GraphPad Software, San Diego, California, USA) were used to assess statistical significance between treatments.

III. RESULTS

A total of 23 patients suffering from SUI or VL were included in this study16 patients (69.6 per cent) were complaining about symptoms of VL and were treated with IntimaLase® (Group 1); while 7 patients (30.4%) with SUI were treated with IncontiLase® (Group 2). The impact of the treatments on the symptoms and quality of life was evaluated using several patient-reported measures.

The average patient age was 48 years (range from 22 to 63 years). In Group 2 (IncontiLase®) all seven patients responded to the ICIQ-SF at baseline (before the first treatment), one month after the 1st treatment and after the second month at the 3rd treatment, respectively. A significant reduction in patient-reported SUI symptoms between baseline and the third treatment, and between the second and third treatment ($p= 0.00018$; $p=0.0045$; respectively; Figure 2) was evident. The average ICIQ-SF score was 10.6 at baseline, 9.1 at one month after the 1st treatment, and 5.0 at 2 months after the 1st treatment.

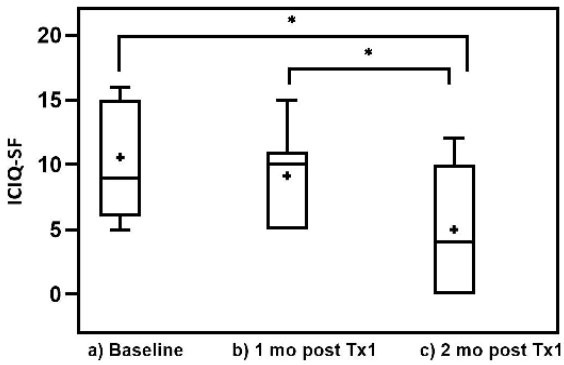

Figure 2: ICIQ–SF scores (IncontiLase® group) (range 0–21) at: a– baseline (before 1st treatment), b–one month after first treatment (before 2nd treatment), c–2 months after first treatment (before 3rd treatment). Data is presented as box and whisker plots, presenting min to max, where the line represents median value, + represents mean value, * denotes statistically significant differences between baseline (before 1st treatment) and at two months (before 3rd treatment) and before the 2nd and 3rd treatments (nonparametric paired-samples t-test; p=0.00018, p=0.0045).

Sexual gratification and lubrication improvement in the IncontiLase® group were rated high by patients on a 0–10 VAS scale. The average VAS score for sexual gratification was 7.0 at 1 month and 8.4 at 2 months after the 1st treatment. The average VAS score for lubrication was 7.0 at 1 month and 8.0 at 2 months after the 1st treatment, respectively.

There was no significant difference in improvement of sexual gratification or lubrication between one month after the 1st session and two months after the 1st session (paired t-test, p=0.284). Improvement in SUI symptoms as measured on a 0-10 scale was rated highly by patients (Figure 3).

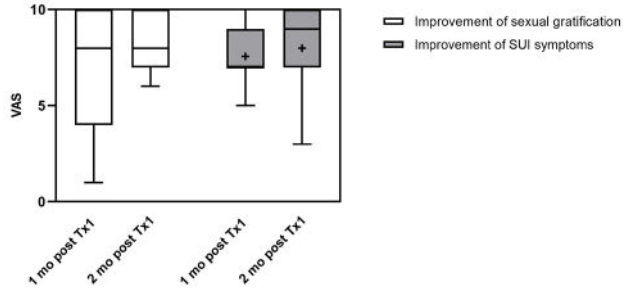

Figure 3: Patient satisfaction on a VAS scale (IncontiLase® group) (range 0–10) 1 month after 1st treatment (before 2nd treatment) and two months after 1st treatment (before 3rd treatment) with respect to improvement of sexual gratification and improvement of SUI symptoms. Data is presented as box and whisker plots presenting min to max, where the thickened line represents the median value and + represents the mean value.

Sexual gratification and lubrication improvement in the IntimaLase® group were also rated high by patients on a 0–10 VAS scale. The average VAS score with the single-pass treated protocol for sexual gratification was 7.0 at 1 month and 8.9 at 2 months after the 1st treatment. The average VAS score for lubrication was 7.9 at 1 month and 8.9 at 2 months after the 1st treatment. With the two-pass treatment protocol, the average VAS score for sexual gratification was 8.0 at 1 month and 7.0 at 2 months after the 1st treatment. For lubrication the score was 7.0 at 1 month and 8.50 at 2 months after the 1st treatment (Figure 4).

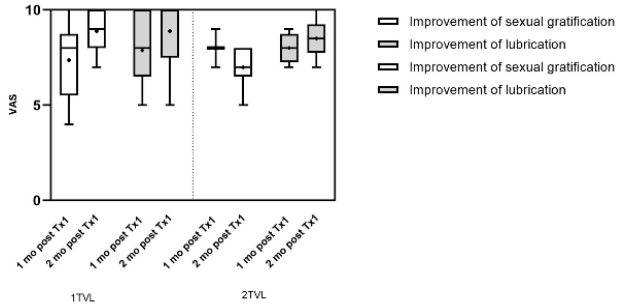

Figure 4: Patient satisfaction on a VAS scale (range 0–10) 1 month after 1st treatment (before 2nd treatment) and two months after 1st treatment (before 3rd treatment) in improvement of sexual gratification and lubrication. Data is presented as box and whisker plots presenting min to max, where the thickened line represents the median value and + represents the mean value. The left part of picture represents the single-pass group and the right part represents the two-pass group.

It should be mentioned that for all of the 16 patients in Group 1 (IntimaLase®) there was no significant difference in the between the 2nd and 3rd sessions with respect to improvement of sexual gratification and lubrication, nor between the single- or double-pass protocol (paired t-test; p=0.064 for sexual gratification (1 pass), p=0.208 for lubrication (1 pass), p=0.058 for lubrication (2 passes), respectively).

Patients also informed about improvement of vaginal laxity symptoms at the one- and six-month follow ups via telephone interview, only for the IntimaLase® group (Group 1) (Table 1 and Table 2).

Table 1: Results of 1- and 6-month follow-ups via telephone interviews, single pass IntimaLase (n=10)

Group	Follow up time	Number of participants	Worse	Same	Better
Single-pass treatment	1 month	10	10%	40%	50%
Single-pass treatment	6 months	9	11%	44.5%	44.5%

Table 2: Results of 1 and 6 months follow-ups via telephone interviews two pass IntimaLase (n=6)

Group	Follow up time	Number of participants	Worse	Same	Better
Two-pass treatment	1 month	6	33.3%	33.3%	33.3%
Two-pass treatment	6 months	6	33.4%	66.6%	/

Tonometry measurements were performed in all 23 patients during vaginal contraction. After laser treatment, the maximum pressure measured during vaginal contraction was greater than before treatment, but with no significant difference between the measurements (Friedman's test; p= 0.223) (Table 3).

There were no adverse effects reported after any of the treatments.

Table 3: Average of vaginal tonometry measurement (mmHg) during vaginal contractions (n=23)

Vaginal Tonometry	
Time	**mmHg (average)**
Before 1st treatment	36.57
Immediately after 1st treatment	37.6
Before 2nd treatment	35.43
Immediately after 2nd treatment	37.86
Before 3rd treatment	33.42
Immediately after 3rd treatment	35.29

IV. DISCUSSION

In our study we wanted to evaluate the effectiveness and safety of the G-Runner robotic handpiece in performing the IntimaLase® and IncontiLase® procedures. The G- Runner uses equivalent parameters to the manual G-set, while being simpler to use and achieving high uniformity of tissue coverage. Our evaluation was based on patient–reported outcomes. The IncontiLase® treatment improved SUI symptoms after the first and second treatment and also improved sexual gratification and lubrication. ICIQ-SF score showed a significant decrease after the 2nd treatment, while at 1 month after the 1st treatment the decrease was evident, but not significant. The improvement in lubrication and improvement of SUI symptoms as measured by VAS scale were already evident at 1 month after the 1st treatment. The average ICIQ-SF score was 10.6 at baseline, 9.1 at 1 month after the 1st treatment and 5.0 at 2 months after the 1st treatment.

The IntimaLase® protocol has also shown high improvement in sexual gratification and lubrication after the 1st treatment, with additional improvement after the 2nd treatment. The average VAS score for improvement of sexual gratification was 7.0 at 1 month and 8.4 at 2 months after the 1st treatment. The average VAS score for lubrication was 7.0 at 1 month and 8.0 at 2 months after the 1st treatment.

Our study has shown similar results to previously published studies that used the manual G-set for performing the IncontiLase® and IntimaLase® procedures. Recently, several studies reported long-term results in treatments in SUI and VRS [14]. Pardo et al. [21] reported patient-reported improvement of vaginal laxity with a mean satisfaction of 7.5 on a 0-10 VAS scale after IntimaLase® treatment. Midori et al. [11] showed 92.7% improvement in sexual gratification after the IntimaLase® protocol for vaginal laxity. Barber et al. [9] reported 70% of patients with vaginal laxity experiencing improvement in their sex lives, and 20% reporting an increase in sexual desire. Our results show that the treatment with the G-Runner probe improved sexual gratification and lubrication. It was performed without reported adverse effects, with good results and even better patient satisfaction.

Fistonić et al. [22] used Er:YAG for early stages of SUI and have reported results with perineometry measurements, PISQ-12 questionnaire and Q-tip test. The maximum pressure increased after treatment. Before the treatment the mean pressure was 7.1 mmHg, after one month 10.7 mmHg, and after 6 months 12.2 mmHg. Our measurements were done with Vaginal tonometer after each treatment, as described in Aguilera et al. [23]. There was no significant difference in average values observed between treatments [23]. Barber et al. [9] also presented an improvement of SUI, with urinary incontinence symptoms improving in 75% of patients. Improvement in SUI symptoms was also rated highly by patients in our study.

Limitations of this study include small patient groups, short follow-up and a small number of patients included in the follow up; however, as the aim was not to assess the treatments as such, but to assess the results using the G-Runner probe, we believe that this pilot study managed to show that the initial results were similar to those reported in other published studies using the G-set, showing that the G-Runner is an effective and safe alternative to the manual G-set protocol.

V. CONCLUSIONS

According to our results, the new G-Runner robotic handpiece for performing vaginal Fotona SMOOTH® treatments seems to be a safe and effective, user-friendly method. Further prospective, controlled and randomized studies, with longer follow-ups and larger number of patients are needed for further assessment.

REFERENCES

1. Vizintin Z, Rivera M, Fistonić I, Saraçoğlu F, Guimares P, Gaviria J, et al. Novel Minimally Invasive VSP Er:YAG Laser Treatments in Gynecology. J Laser Heal Acad. 2012;2012(1):46–58.
2. MacLennan AH, Taylor AW, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. Vol. 107, British Journal of Obstetrics and Gynaecology. 2000. p. 1460–70.
3. Persson J, Wølner-hanssen P, Rydhstroem H. Obstetric Risk Factors for Stress Urinary Incontinence. Obstet Gynecol. 2000;96(3):440–5.
4. Rovner ES, Wein AJ. Treatment options for stress urinary incontinence. Rev Urol. 2004;6 Suppl 3(Table 1):S29-47.
5. Fistonic I. Laser treatment for early stages of stress urinary incontinence and pelvic muscle relaxation syndrome. J Laser Heal Acad. 2013;2013(1):9913.
6. Sencar S, Bizjak-ogrinc U. *Laser Treatment of Stress Urinary Incontinence (SUI). J Laser Heal Acad. 2013;2013(1):9913.
7. Lukanovic A, Blaganje M, Scepanovic D, Zgur L. Laser thermotherapy in pelvic floor dysfunction, randomised placebo controled study. Neurourol Urodyn. 2014;33(6):920.
8. Koch J. IncontiLase / IntimaLase – our Findings. J Laser Heal Acad. 2013;2013(1):S23.
9. Barber MA, Eguiluz I, Baren C, Leon F De, Palmas L. Patient Satisfaction with Vaginal Erbium Laser Treatment of Stress Urinary Incontinence , Vaginal Relaxation Syndrome and Genito-urinary Syndrome of Menopause. J Laser Heal Acad. 2016;2016(1):18–23.
10. Fistonić I, Fistonić N. Prediction of Er:YAG Laser Treat ment's Short-term Efficacy on Stress Urinary Incontinence in Women; a Croatian Prospective Cohort Study. J Laser Heal Acad. 2016;2016(1):9913.
11. Mitsuyuki M, Štok U, Hreljac I, Yoda K, Vižintin Z. Treating Vaginal Laxity Using Nonablative Er:YAG Laser: A Retrospective Case Series of Patients From 2.5 Years of Clinical Practice. Sex Med. 2020;8(2):265–73.
12. Campbell P, Krychman M, Gray T, Vickers H, Money-Taylor J, Li W, et al. Self-Reported Vaginal Laxity—Prevalence, Impact, and

Associated Symptoms in Women Attending a Urogynecology Clinic. J Sex Med. 2018;15(11):1515–7.
13. Dietz HP, Stankiewicz M, Atan IK, Ferreira CW, Socha M. Vaginal laxity: what does this symptom mean? Int Urogynecol J. 2018;29(5):723–8.
14. Gaviria JE, Lanz JA. Laser Vaginal Tightening (LVT) – evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome. J Laser Heal Acad Artic J LAHA. 2012;2012(20121):59–66.
15. Goodman MP, Placik OJ, Benson RH, Miklos JR, Moore RD, Jason RA, et al. A large multicenter outcome study of female genital plastic surgery. J Sex Med. 2010;7(4 PART 1):1565–77.
16. Shaw D, Lefebvre G, Bouchard C, Shapiro J, Blake J, Allen L, et al. Female Genital Cosmetic Surgery. J Obstet Gynaecol Canada. 2013;35(12):1108–12.
17. Gaviria J, Korosec B, Vizintin Z. Up To 3-year Follow Up Of Patients With Vaginal Relaxation Syndrome Participating In Laser Vaginal Tightening: #186. Lasers Surg Med. 2016;48(1):63–4.
18. Pardo J, Dalenz V. Laser Vaginal Tightening with Non-ablative Er : YAG for Vaginal Relaxation Syndrome . Evaluation of Patient Satisfaction . 2016;2016(1):12–7.
19. Lukac M, Gaspar A, Bajd F. Dual Tissue Regeneration : Non-Ablative Resurfacing of Soft Tissues with FotonaSmooth ® Mode Er : YAG Laser. J Laser Heal Acad. 2018;2018(1):1–15.
20. Lukač M, Lozar A, Perhavec T, Bajd F. Variable heat shock response model for medical laser procedures. Vol. 34, Lasers in Medical Science. 2019. p. 1147–58.
21. Pardo J, Dalenez V. Laser Vaginal Tightening with Non-ablative Er : YAG for Vaginal Relaxation Syndrome . Evaluation of Patient Satisfaction . 2016;2016(1):12–7.
22. Fistonic Ivan, Findri-Gustek Stefica FN. Minimally invasive laser procedure for early stages of stress urinary incontinence (SUI). J Laser Heal Acad. 2012;1(1):67–74.
23. Aguilera O, Ii MP, Iii MP, Vallejos C. Evaluación tono vaginal en reposo y en contracción voluntaria de músculos elevadores del ano en mujeres sexualmente activas , utilizando Tonómetro Vaginal . Introducción. 2013;