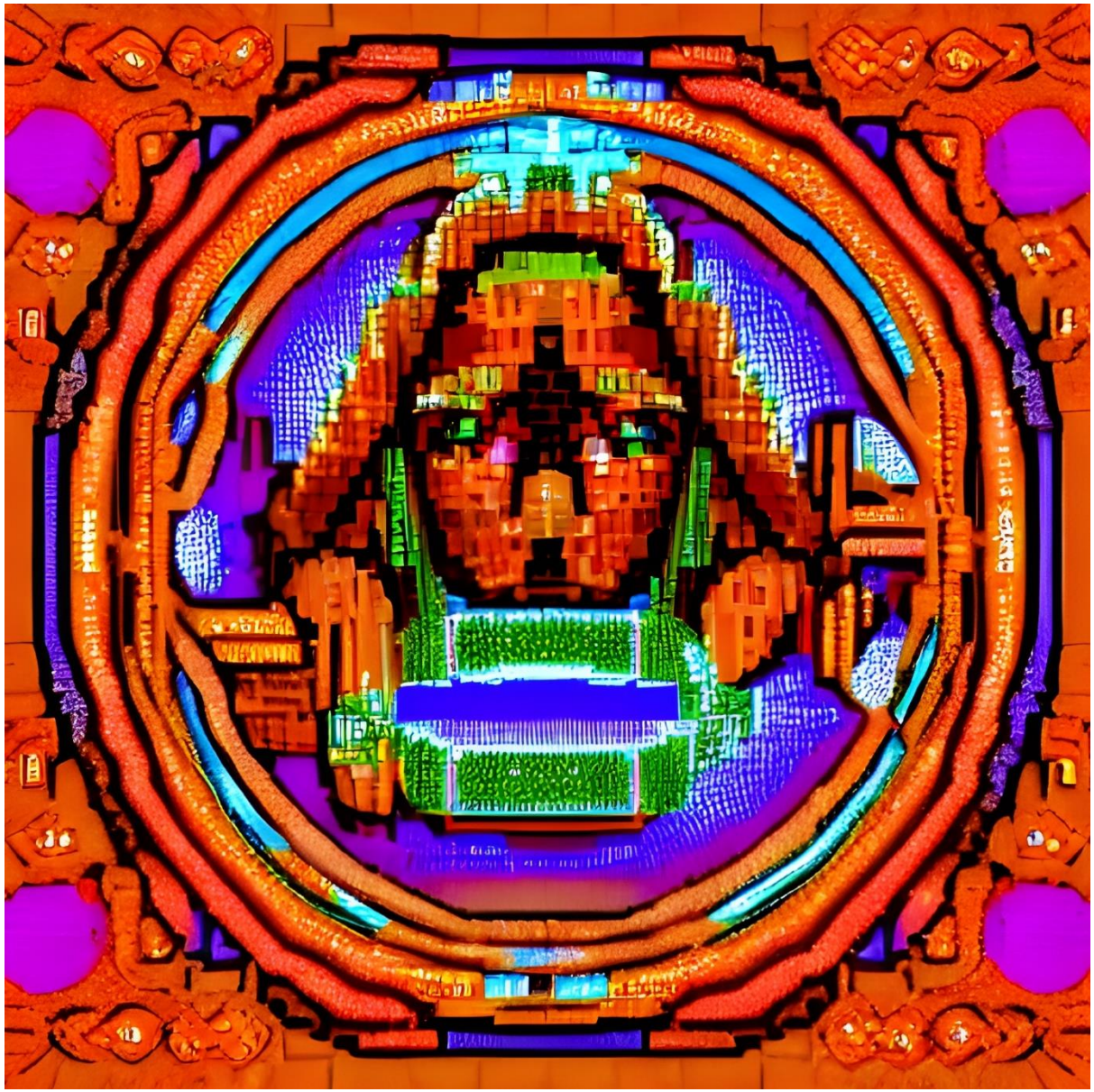


Burning the Vaginas

NICE market-driven research guideline

Mohamed Helmy

MD, PhD

Thursday 18 May, 2023

NICE Terminology

[1] On 26 May 2021, National Institute for Health and Care (NICE) UK published '*Interventional procedures guidance [IPG697]*' titled '*Transvaginal laser therapy for urogenital atrophy*' (NICE atrophy 2021b) and evidence supporting (NICE atrophy 2021a).

[2] 'Atrophy' implies 'wasting away' (Morton 1720). 'Urogenital' implies the urinary organ system which is connected with the genitals. Should the urinary system begin to fail, or become blocked for example through its outlet, the patient needs urgent medical treatment such as dialysis, or surgical relief of a block.

[3] While age-related changes occur in all living beings, 'urogenital atrophy' is not a term applied to men.

[4] On page 2 of (NICE atrophy 2021a) it states: "…The National Institute for Health and Care Excellence (NICE) prepared this **interventional procedure** overview to help members of the **interventional procedures** advisory committee (IPAC) make recommendations about the safety and efficacy of an **interventional procedure**. It is based on a **rapid review** of the medical literature and professional opinion. It should not be regarded as a definitive assessment of **the procedure**…" (emphasis added).

[5] On page 2 of (NICE atrophy 2021b) it states: "…**this procedure should only be used in the context of research**…Further research should be appropriately **powered randomised controlled trials**…NICE encourages further research into transvaginal laser therapy for urogenital atrophy…" (emphasis added).

[6] On this NICE front webpage it states: "…Guideline types…clinical…social care…public health…medicines practice…cancer services…antimicrobial prescribing…".

[7] What is a NICE 'research guidline'?

[8] What is a NICE 'research procedure' to be performed on UK woman?

[9] Are NHS healthcare workers expected to power clinical trials independently and based on (NICE atrophy 2021a; 2021b)?

INPUT: Evidence used to market research procedures on vaginas by NICE

[10] The articles used by NICE to support burning vaginas with laser are summarised in Table 1.

[11] The criteria for assessing the use of laser to burn vaginas were: "…The Vaginal Health Index assesses 5 components on a scale of 1 to 5: elasticity, fluid volume, pH, epithelial integrity and moisture…[and]…The Female Sexual Function Index (FSFI) is a multidimensional measure of female sexual functioning with 19 items that are scored from 0 (or 1) to 5. There are 6 domains: desire, arousal, lubrication, orgasm, satisfaction and pain…" (NICE atrophy 2021a, page 4).

[12] These criteria were measured using something called '*Visual Analogue Scale*'. Frankly I did not know what that was so I had to look it up. I was confused. I wondered how one may measure pH, epithelial integrity, and elasticity visually at all, if desire, arousal, and satisfaction may theoretically be possible to assess by inspection.

[14] The 'Visual Analogue Scale' is a Likert scale. You know the device you find at the exit of WCs in airports and malls with the faces ranging from 'very unhappy' to 'very happy'? That's the one.

[15] One patient may complain of losing buckets of blood after a minor wound. Another patient will silently suffer insidious blood loss for years, and when the patient's haemoglobin is measured, one wonders how the patient is alive at all. There are many reasons why clinical examinations are necessary.

[16] There are also many reasons why desire, arousal, satisfaction, and painful intercourse cannot be assessed with a WC-device thing on paper or otherwise. One reason is these processes involve partners though NICE developers may have their own practices.

[17] In any case, out of the fourteen (14) articles rapidly reviewed by NICE to encourage NHS works to power clinical trials of burning vaginas:

(a) One article measured dryness and it ranged from 1m to 18m ('m' is presumably millimetre on the so-called 'Visual Analogue Scale' though Standard International Units state 'm' is for metre);

(b) One article showed hypercellular changes after burning the vaginas with laser;

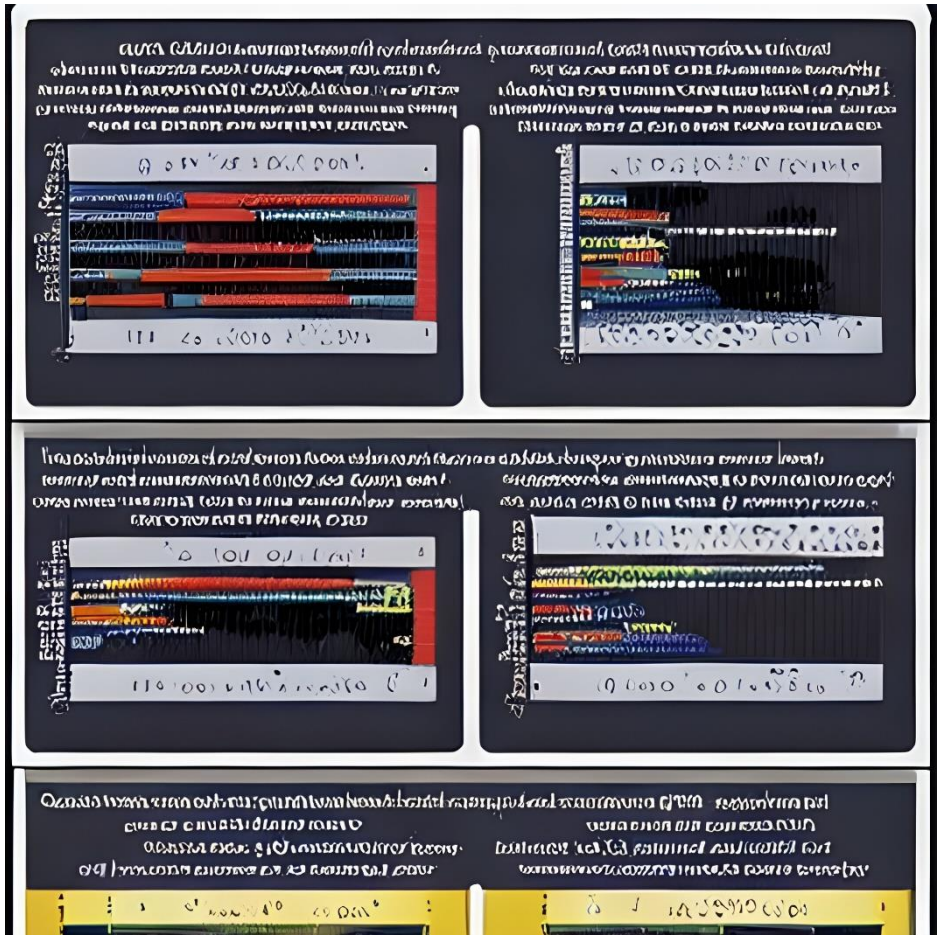
(c) One article showed improved 'Vaginal Health Index' after laser or hormone crème and it ranged from about 9 to 19 unknown units;

(d) One article showed laser has no significant effect on 'Vaginal Health Index'.

(e) One article showed *worsening* of 'Female Sexual Function Index' after burning the vagina with laser;

(f) One article showed that hormone crème is better than laser for any change in 'Female Sexual Function Index'.

[18] So out of 24 putative data slots, we find only 6 data. 3 of which are not in favour of burning vaginas with laser, 1 of which is merely histological, and 2 of which, because of the ranges reported, are meaningless.



PROCESS: Numbers not in support of burning vaginas with lasers

[19] What NICE did in their publications, as usual, is throw a bunch of numbers and say what they were going to say anyways. It is dismal that the numbers (or what numbers are there and do they mean anything) are very much against what they set out to say.

OUTPUT: Burn the vaginas for research

[20] As mentioned in paragraphs [4] and [5] above, the output was 'power clinical trials to use lasers in NHS clinics to burn vaginas for research purposes'.

[21] See also the NICE burning vaginas '*Consultation comments and responses*' and which highlight the absurd and market-driven nature of this 'research' guideline.

[23] Recommendations 1.6. of *NICE Menopause: diagnosis and management* concerns so-called ‘premature ovarian insufficiency’. This confirms the findings in the *woman = premature menopause + hormone replacement therapy* report under The Woman Object.

[24] We had an old Professor of Obstetrics and Gynaecology who appeared to be ill and yet came to classes until the end. She would pause during the lecture and clear her throat quietly when she ran out of breath.

During rounds, if she asked one, ‘Did you check/look for this-and-that symptom/sign?’, and one had not (and unless one is very stupid, one admits straight away), she would never ask, like other Professors, ‘Why not?’. She would say kindly, ‘Why should you look for this-and-that sign in this patient?’

One day during the rounds, an intern made the mistake of saying “…patient so-and-so, complaining of amenorrhea…” without stating if the cessation of menstruation was primary (she had never had a period) or secondary (she had periods and now does not). The Professor spent more than fifteen minutes of the round loudly humiliating the intern, such that the Head Nurse came up from Emergency and begged her to stop. I had wondered why the Professor did that. Now I know.

Table 1. Articles included in (NICE atrophy 2021a)						
#	**Article**	**Vaginal Health Index reported by article?**	**Female Sexual Function Index reported by article?**	**Power reported by article?**	**Satisfaction reported by NICE?**	**Comment**
1	(Pitsouni et al. 2017) Systematic review	Only dryness measured on Visual Analogue Scale in eleven (11) studies included in this review, at least four (4) of which were by the authors themselves. The improvement/decrease ranged from 1m to 18m before/after.	No.	No	No.	The authors called it "…genitourinary syndrome of menopause (GSM)…". They conclude: "…In conclusion, laser-therapy seems a promising and safe non-pharmaceutical therapeutic option for GSM in both clinical and pathophysiological aspect…" and at the same time "…Currently, evidence-based change in clinical practice for the management of GSM with/without UI, cannot be proposed…". Also the 'low or very low' quality of evidence, which is astonishingly largely their own. All but one author are affiliated with National and Kapodistrian University of Athens, Greece. The piece is published in *Mauritius* the Editor-in-chief of which is Irene Lambrinoudaki at National and Kapodistrian University of Athens, Greece. The abstract of the piece can also be found on page 42 of *Asclepion Laser Technologies Studies Book* Juliet (Germany, date unknown).
2	(Jha, Wyld, and Krishnaswamy 2019) Systematic review; breast cancer survivors	Data not shown.	Data not shown.	No	58.9% to 96.1%	The authors state "…To date, no randomised controlled trials comparing topical oestrogen cream with vaginal laser has been undertaken in BC survivors…". Can oestrogen cream be administered to breast cancer survivors?

#	Article	Vaginal Health Index reported by article?	Female Sexual Function Index reported by article?	Power reported by article?	Satisfaction reported by NICE?	Comment
3	(Ruanphoo and Bunyavejchevin 2020) Clinical trial	Data not shown.	Data not shown	40 W, dwell time 1,000 ms, dot spacing 1,000mm, and the smart stack parameter from 1 to 3	8% to 31% in laser and sham	"…we did not study the effect of vaginal laser on sexual function…" "…Vaginal microablative fractional CO2 laser could be an alternative treatment for postmenopausal women with vaginal atrophy…". However, the alternative was sham which is a treatment only in clinical trials and not in reality.
4	(Cruz et al. 2018) Clinical trial	Hypercellular changes with laser.	Worsening with laser.	300 W, dwell time of 1,000 ms, dot spacing of 1,000mm, and smart stack of 2	More pain misreported by NICE: "…No adverse effects of laser treatment or pain during laser application were observed during the study..."	"…[laser] group showed significant worsening of pain domain…"
5	(Paraiso et al. 2020) Clinical trial	No significant difference.	No significant difference.	30 W, dwell time 1,000ms, dot spacing 1,000mm and the smart stack parameter set at 1..3	72%-83% crème being higher.	"…Sixty-nine women were enrolled in this trial before enrollment was closed due to the Federal Drug Administration requiring the sponsor to obtain and maintain an Investigational Device Exemption…". Article available from sponsor.

#	Article	Vaginal Health Index reported by article?	Female Sexual Function Index reported by article?	Power reported by article?	Satisfaction reported by NICE?	Comment
6	(Politano et al. 2019) Clinical trial	From 9.5 to 18.7 for laser. From 9.8 to 10.4 for crème.	Not significant for laser. Significant for crème.	40 W, with a dwelling time of 1.000ms, dot spacing of 1.000mm, and a smart stack of 2	No.	"…The use of fractional CO2 laser therapy to treat genitourinary syndrome resulted in better short-term effects than those of promestriene or lubricant with respect to improving the vaginal health in postmenopausal women…". But what about 'sexual function' where crème was better?
7	(Gambacciani et al. 2018) ?	?	No.	?	No.	?
8	(Gambacciani, Albertin, et al. 2020) ?	No	?	?	?	This 'study' was "…spontaneous…" there was no control group, only laser.
9	(Pieralli et al. 2017) ?	?	?	30 W power and transmitted through an intravaginal probe with a dwell time of 1000 μs, a dot spacing of 1000 μm and a smart stack parameter of 1	0% to 93%	"…We observed a decline in patient's satisfaction between 18 and 24 months after laser therapy…" BUT "…The data from our study confrmed the efectiveness of fractional CO2 laser treatment and the short-term efects of the therapy at T4 which were demonstrated…"!!! More laser?! And "…The clinical improvement reported in these patients had a duration of 15–30 days. This efect is probably due to infammatory response rather than to tissue remodeling after treatment…"

#	Article	Vaginal Health Index reported by article?	Female Sexual Function Index reported by article?	Power reported by article?	Satisfaction reported by NICE?	Comment
10	(Gordon, Gonzales, and Krychman 2019) Case report	No.	No.	No.	No.	"…Four cases are presented, which demonstrate complications after completion of three consecutive laser treatments for GSM…"
11	(Guo et al. 2020) Systematic review	No.	No.	No	No.	"…Identified complications suggest most reported "adverse events" represent lack of treatment effect…"!
12	(Eftekhar et al. 2021) Clinical trial	Laser not significant.	No.	40 w, dwell time of 100 ms, and 1000 mm spacing using a normal scan mode with the Smartstack setting of 1 and 3	No.	Radiofrequency ablation better than laser ablation.

#	Article	Vaginal Health Index reported by article?	Female Sexual Function Index reported by article?	Power reported by article?	Satisfaction reported by NICE?	Comment
13	(Salvatore et al. 2021)	No.	Between within groups?	30 W; dwell time, 1000 ls; spacing, 1000 lm; depth, SmartStak parameter 1–3 depending on treatment status; D-pulse mode; pulse energy, 43.2 mJ, 86.4 mJ, and 129.6 mJ at the first, second, and third session, respectively	No	"…this RCT verifies…a finding that up to this day could only be hypothesized…" and at the same time "…The findings of this study are markedly similar to those previously reported by observational studies…"
14	(Gambacciani, Cervigni, et al. 2020) Survey	No.	No.	No.	No.	?

References

Cruz, Vera L, Marcelo L Steiner, Luciano M Pompei, Rodolfo Strufaldi, Fernando L Afonso Fonseca, Lucila H Simardi Santiago, Tali Wajsfeld, and Cesar E Fernandes. 2018. "Randomized, Double-Blind, Placebo-Controlled Clinical Trial for Evaluating the Efficacy of Fractional CO2 Laser Compared with Topical Estriol in the Treatment of Vaginal Atrophy in Postmenopausal Women." *Menopause* 25 (1): 21–28. https://www.researchgate.net/profile/Marcelo-Steiner/publication/318847662_Randomized_double-blind_placebo-controlled_clinical_trial_for_evaluating_the_efficacy_of_fractional_CO2_laser_compared_with_topical_estriol_in_the_treatment_of_vaginal_atrophy_in_postmenopausal_women/links/5a7c2f2f458515c95de557b5/Randomized-double-blind-placebo-controlled-clinical-trial-for-evaluating-the-efficacy-of-fractional-CO2-laser-compared-with-topical-estriol-in-the-treatment-of-vaginal-atrophy-in-postmenopausal-wome.pdf.

Eftekhar, Tahereh, Leila Ghorbani, Zinat Ghanbari, Jafar Razavi, and Fatemeh Dolatshad. 2021. "Comparison of the Effect of Radiofrequency and Laser Treatment on Mixed Urinary Incontinence and Vulvovaginal Atrophy in Iranian Menopausal Women: A Randomized Controlled Trial." *Int J Womens Health Reprod Sci* 9 (1): 61–68. http://ijwhr.net/pdf/pdf_IJWHR_571.pdf.

Gambacciani, M, E Albertin, MG Torelli, GL Bracco, AC Casagrande, L Martella, G Baiocchi, S Alfieri, N Russo, and M Cervigni. 2020. "Sexual Function after Vaginal Erbium Laser: The Results of a Large, Multicentric, Prospective Study." *Climacteric* 23 (sup1): S24–27. https://www.tandfonline.com/doi/full/10.1080/13697137.2020.1804544.

Gambacciani, M, M Cervigni, A Gaspar, A Novakov Mikić, J Gaviria, N Koron, and Z Vizintin. 2020. "Safety of Vaginal Erbium Laser: A Review of 113,000 Patients Treated in the Past 8 Years." *Climacteric* 23 (sup1): S28–32. https://www.tandfonline.com/doi/pdf/10.1080/13697137.2020.1813098.

Gambacciani, M, M Levancini, E Russo, L Vacca, T Simoncini, and M Cervigni. 2018. "Long-Term Effects of Vaginal Erbium Laser in the Treatment of Genitourinary Syndrome of Menopause." *Climacteric* 21 (2): 148–52. https://www.tandfonline.com/doi/full/10.1080/13697137.2018.1436538.

Gordon, Catherine, Savanah Gonzales, and Michael L Krychman. 2019. "Rethinking the Techno Vagina: A Case Series of Patient Complications Following Vaginal Laser Treatment for Atrophy." *Menopause* 26 (4): 423–27.

Guo, Julia Z, Colby Souders, Lynn McClelland, Jennifer T Anger, Victoria CS Scott, Karyn S Eilber, and A Lenore Ackerman. 2020. "Vaginal Laser Treatment of Genitourinary Syndrome of Menopause: Does the Evidence Support the FDA Safety Communication?" *Menopause* 27 (10): 1177–84.

Jha, Swati, Lynda Wyld, and Priyanka H Krishnaswamy. 2019. "The Impact of Vaginal Laser Treatment for Genitourinary Syndrome of Menopause in Breast Cancer Survivors: A Systematic Review and Meta-Analysis." *Clinical Breast Cancer* 19 (4): e556–62. https://eprints.whiterose.ac.uk/150612/3/final_manuscript_version_as_submitted.pdf.

Morton, Richard. 1720. *Phthisiologia, Or, A Treatise of Consumptions: Wherein the Difference, Nature, Causes, Signs and Cure of All Sorts of Consumptions Are Explained...: Of Original Consumptions from the Whole Habit of the Body, of an Original Consumption of the Lungs, of Symptomatical Consumptions, Or Such as Are the Effects of Some Other Distempers: Illustrated by Particular Cases... with a Compleat Table of the Most Remarkable Things*. W. and J. Innys.

NICE atrophy. 2021a. "[EVIDENCE] Interventional Procedure Overview of Transvaginal Laser Therapy for Urogenital Atrophy, INTERVENTIONAL PROCEDURES PROGRAMME, NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE, IP1817 [IPG697]." https://www.nice.org.uk/guidance/ipg697/evidence/overview-final-pdf-9134043373 https://www.nice.org.uk/guidance/ipg697/evidence.

NICE atrophy. 2021b. "Transvaginal Laser Therapy for Urogenital Atrophy Interventional Procedures Guidance." https://www.nice.org.uk/guidance/ipg697/resources/transvaginal-laser-therapy-for-urogenital-atrophy-pdf-1899874410944965 https://www.nice.org.uk/guidance/ipg697

Paraiso, Marie Fidela R, Cecile A Ferrando, Eric R Sokol, Charles R Rardin, Catherine A Matthews, Mickey M Karram, and Cheryl B Iglesia. 2020. "A Randomized Clinical Trial Comparing Vaginal Laser Therapy to Vaginal Estrogen Therapy in Women with Genitourinary Syndrome of Menopause: The VeLVET Trial." *Menopause* 27 (1): 50–56. https://monalisatouch.ch/wp-content/uploads/V2LR_Paraiso_et_al_Menopause_Sep2019.eng_.pdf.

Pieralli, Annalisa, Claudia Bianchi, Manuela Longinotti, Serena Corioni, Noemi Auzzi, Angelamaria Becorpi, Maria Grazia Fallani, Giuseppe Cariti, and Felice Petraglia. 2017. "Long-Term Reliability of Fractioned CO 2 Laser as a Treatment for Vulvovaginal Atrophy (VVA) Symptoms." *Archives of Gynecology and Obstetrics* 296: 973–78.

Pitsouni, Eleni, Themos Grigoriadis, Matthew E Falagas, Stefano Salvatore, and Stavros Athanasiou. 2017. "Laser Therapy for the Genitourinary Syndrome of Menopause. A Systematic Review and Meta-Analysis." *Maturitas* 103: 78–88. https://www.sciencedirect.com/science/article/abs/pii/S0378512217300804.

Politano, Carlos A, Lucia Costa-Paiva, Luiza B Aguiar, Helymar C Machado, and Luiz F Baccaro. 2019. "Fractional CO2 Laser versus Promestriene and Lubricant in Genitourinary Syndrome of Menopause: A Randomized Clinical Trial." *Menopause* 26 (8): 833–40. https://www.smilemonalisa.ca/wp-content/uploads/sites/2/2020/06/41-Menopause-Politano_et_al_-Aug2019_Fractional-CO2-laser-versus-promestriene-and-lubricant-in-GSM-a-randomized-clinical-trial.pdf.

Ruanphoo, Purim, and Suvit Bunyavejchevin. 2020. "Treatment for Vaginal Atrophy Using Microablative Fractional CO2 Laser: A Randomized Double-Blinded Sham-Controlled Trial." *Menopause* 27 (8): 858–63. https://doi.org/Vaginal microablative fractional CO2 laser could be an alternative treatment for postmenopausal women with vaginal atrophy.

Salvatore, S, E Pitsouni, T Grigoriadis, D Zacharakis, G Pantaleo, M Candiani, and S Athanasiou. 2021. "CO2 Laser and the Genitourinary Syndrome of Menopause: A Randomized Sham-Controlled Trial." *Climacteric* 24 (2): 187–93. https://www.erkenmenopoz.com/wp-content/uploads/2020/12/ekimm11.pdf.