Lasers in the era of evidence-based medicine

Climacteric Volume 23, 2020 - Issue sup1: Vaginal lasers in gynecology: the peer-reviewed Proceedings of the 5th VELA Meeting

T. C. Hillard
Tim Hillard, Consultant Gynaecologist
University Hospitals Dorset, Poole, UK
Published online: 30 Oct 2020

- https://doi.org/10.1080/13697137.2020.1774536

Hillard's publication reviews indications for transvaginal laser therapies, particularly genitourinary syndrome of the menopause and stress urinary incontinence. The article reviews the current data pertaining to the place of these devices in current clinical practice.

"The evidence suggests that vaginal laser therapy with either the erbium-doped yttrium aluminum garnet laser (FotonaSmooth®) or the CO_2 laser (MonaLisa Touch®) is an effective intervention for the relief of symptoms of vulvovaginal atrophy in symptomatic women. The benefits of three laser treatments appear to last for at least 12 months and the procedure is generally well tolerated, with transient minor discomfort being the most common adverse event. Whilst there has been a rapid increase in the number of publications over the last few years, many of the studies are of small numbers, short duration, and poor quality and are device-sponsored."

He states that "the vaginal laser certainly has the potential to be an alternative treatment to vaginal estrogens for those groups of women, such as breast cancer patients, who cannot take them, there are still many unanswered questions".

Some of the questions pertain to some less clear indications for this treatment (for example, see the following review on lasers for symptomatic genital prolapse), and Hillard encourages further research.

The author of this website, Dr Burrows, agrees that more research and data examining these so called 'minor', (but in reality often distressing symptoms for many women) is to be welcomed. I will continue to keep the website updated as further evidence is published.

Pelvic Organ Prolapse and Lasers

When you make your initial consultation you will be assessed by a gynaecologist. Most patients who suffer the symptoms of pelvic organ prolapse are initially referred to a qualified pelvic floor physiotherapist, and offered topical oestrogen treatment (if suitable). In addition, significant prolapse that requires surgical repair may be referred to a subspecialist called a Urogynaecologist, who performs and advises of the risks and benefits of surgical correction.

The following well designed study from the urogynaecology department in Athens is a randomized, assessor-blinded controlled trial of the Erbium YAG smooth laser in postmenopausal women with symptomatic stage 2 or 3 vaginal prolapse who had opted to undergo surgery. Please note that this is NOT the Monalisa Touch, although the science is relevant to both devices.

> Athanasiou S, Pitrrantouni E, Cardozo L et al. Can pelvic organ prolapse in postmenopausal women be treated with laser therapy? Climacteric 2020. https://pubmed.ncbi.nlm.nih.gov/32720552/

All 30 women in the study had extensive assessment of their symptoms by various appropriately validated questionnaires and by physical assessment using the POP-Q scoring system (Pelvic Organ Prolapse Quantification System). The primary endpoint, defined as the 'objective cure rate,' was the proportion of patients with POP-Q stage 0 or 1. Secondary endpoints included measurements of all POP-Q points and subjective cure rates assessed by the Pelvic Floor Distress Inventory Questionnaire short-form [PFDI-20], Pelvic Floor Impact Questionnaire short- form [PFIQ-7] and the Patients Global Impression of Improvement [PGI-I]). The women were randomised to receive either Laser therapy (n=15) or a watchful-waiting group (n=15) who were not offered any additional therapy such as pelvic floor muscle training or a pessary. Laser therapy was performed using the Er:YAG laser (Intimalase Fotona SMOOTHTM), and all women in the laser group received one treatment at monthly intervals for three consecutive months. The treatments were all performed by an experienced independent physician blinded to the study objective. Outcomes in both groups were assessed at baseline and 4 months post-baseline. The POP-Q assessment was carried out by another independent physician who was blinded to participant allocation. Patient-reported outcome questionnaires, as above, were completed at baseline and 4 months.

The study found that after three Er:YAG laser treatments, there was no improvement in the pelvic anatomy as judged by the POP-Q assessment, and none of the participants in this study were objectively or subjectively cured following laser therapies. There were no changes in the patient-reported outcomes, and the laser therapy results were no different from those of the watchful-waiting group.

No adverse events were reported by any of the participants.

The authors conclude that their study results do not support the use of intravaginal Er:YAG laser as a therapeutic option in postmenopausal patients with symptomatic pelvic organ prolapse, defined in the study as '***the problem as pelvic floor prolapse for women who felt that there symtoms were so significant that they would undergo surgical correction'*.**

IMS Live (International Menopause Society) comments on the Australasian Menopause Society publication, December 2020:

"***Whether or not the laser could have a potential role in women with mild asymptomatic POP and perhaps prevent progression or deterioration of its severity is speculative and would need further analysis in appropriately conducted trials. Any such trials should include assessing laser therapy alongside and in combination with other standard conservative therapies (i.e. pelvic floor muscle training)".***

After topical oestrogen therapies, pessaries and pelvic floor training from a physiotherapist, some women feel that they need to consider surgical intervention. The trial participants were at that stage. Surgery for POP (pelvic organ prolapse) does, of course, have its risks (Baessler K, Christmann-Schmid C, Maher C et al. Surgery for women with pelvic organ prolapse with or without stress urinary incontinence. Cochrane Database Syst Rev 2018;8:CD013108. https://pubmed.ncbi.nlm.nih.gov/30121956/) so anything along the clinical pathway that may prevent deterioration is worthy of further study.

This results of this publication are not surprising, as the relatively superficial mode of laser action (around only 0.5 mm depth of CO2 laser in the case of MonaLisa Touch) may improve the connective tissue overlying any prolapse but would be unlikely to have any effect on the deeper structural defects. It is damage to the deeper fascial supports (muscles and ligaments) that are an integral part of the pathophysiology of an established prolapse. Common mechanisms include damage during childbirth, chronic constipation or increased states of ongoing elevated intra-abdominal pressures.

Is there enough evidence to justify the use of laser and other thermal therapies in female lower urinary tract dysfunction? Report from the ICI-RS 2019

Robinson D et al, Neurourol Urodyn. 2020 Jul;39 Suppl 3:S140-S147.

https://pubmed.ncbi.nlm.nih.gov/32040871/

The evidence for SUI (Stress Urinary Incontinence) is reviewed in the latest edition of Climacteric.

They concluded that **"**The current available evidence, though of low or very low quality, appears promising for the use of laser therapy in the management of genitourinary syndrome of the menopause, there are some data to suggest a possible role in SUI although very little evidence for urogenital prolapse."

The last statement is in concordance with the Pelvic Organ Prolase study above (Athanasiou), but does lend support to the current use of lasers for urinary stress incontinence. Again, I would stress that in our practice we take a careful assessment (for example urgency and stress incontinence can exist separately or as a mixed picture). Often exclusion of other pathology such as prolapse or urine and vaginal infections is necessary.

We will always adopt a wholistic approach which will often involve others such as qualified pelvic floor physios, expert in management of bladder disorders and training, as well as all options for prolapse management (both surgical and non-surgical), along with management of secondary issues resulting from disease (vaginismus,pain,psychosexual issues).