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RCOG SCIENTIFIC IMPACT PAPER SUMMARY

Laser treatment for genitourinary syndrome of menopause

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Plain language summary

Genitourinary syndrome of menopause (GSM) is the term used to describe the group of symptoms including vaginal pain, vaginal dryness, itching, pain during sexual intercourse and fragile vaginal tissues as well as urinary symptoms including urinary frequency, urgency, incontinence, blood in the urine (haematuria) and recurrent urinary tract infections that occur due to a lack of the hormone estrogen.

These symptoms can have a significant negative impact on psychosexual issues, sexual function and quality of life in postmenopausal women. Traditionally women have been treated with vaginal lubricants, vaginal moisturisers or low-dose vaginal estrogens.

Lasers have been used in the cosmetic industry for collagen remodelling and repair of the skin. Therefore, it has been suggested that laser therapy may be used on the vagina as an alternative treatment for GSM. A review of all the published studies assessing the safety and efficacy of laser therapy for GSM have shown promising beneficial results. The majority of studies to date have been small, short-term, observational studies. However, there are randomised controlled trials underway. Laser treatment may be beneficial for the symptoms of GSM but until more robust evidence is available it should not be adopted into widespread practice, and should be used as part of a research study only.

1 | INTRODUCTION

There has been growing enthusiasm for the use of energy-based devices (EBDs) in treating vaginal atrophy (thinning, dryness and inflammation of vaginal tissues due to a reduction in estrogens) and other gynaecological conditions. EBDs include lasers as well as radiofrequency devices that use electromagnetic waves to cause tissue remodelling. However, there is limited evidence to support the adoption of such devices. In 2018, the United States Food and Drug Administration (FDA)[1] issued a warning against the use of EBDs, including laser, to perform 'vaginal rejuvenation' or vaginal cosmetic procedures, and caution has been advised, calling for greater evidence on the efficacy and safety of vaginal lasers.[2,3]

The scope of this Scientific Impact Paper is confined to outlining the level of evidence available for the use of laser in the treatment of genitourinary syndrome of menopause (GSM), as well as to highlight areas of uncertainty and debate.

Within this document we use the terms woman and women's health. However, it is important to acknowledge that it is not only women for whom it is necessary to access women's health and reproductive services in order to maintain their gynaecological health and reproductive wellbeing. Gynaecological and obstetric services and delivery of care must therefore be appropriate, inclusive and sensitive to the needs of those individuals whose gender identity does not align with the sex they were assigned at birth.

2 | GENITOURINARY SYNDROME OF MENOPAUSE

GSM is a condition which encompasses the vulvovaginal symptoms including vaginal pain, dyspareunia, vaginal dryness, itching, tissue friability and sexual dysfunction, as well as urological symptoms including urinary frequency, urgency, incontinence, haematuria and recurrent urinary tract infections.[4] Signs of GSM include atrophic changes of the external and internal female genitalia with regression and thinning of the labia minora, retraction of the introitus and prominence of the urethral meatus.[5] Tissue changes also occur at a histological level, with thinning of the stratified squamous epithelium, decreased glycogen stores in the epithelial cells and loss of the vascularity and dermal papillae.[6] Symptoms of GSM can have a significant negative impact on sexual function and quality of life in postmenopausal women. Traditionally they have been treated with either non-hormonal or hormonal therapies. Non-hormonal therapies include water- or silicone-based vaginal lubricants, vaginal moisturisers or herbal remedies.[7] Hormonal treatments: low-dose vaginal estrogens are considered the gold standard treatment and are safe and well tolerated. Possible alternatives include vaginal dehydroepiandrosterone and an oral selective oestrogen receptor modulator (ospemifene).[7]

3 | LASER MODALITIES AND MODE OF ACTION ON TISSUES

Owing to its known thermal effects on the dermis of skin, laser therapy has been postulated to have similar effects on the vaginal epithelium and lamina propria in order to improve symptoms and signs of GSM and may potentially be an attractive alternative non-hormonal treatment option for women with GSM. Laser has potential for three groups of women:

1. those for whom vaginal estrogens have failed,
2. those for whom vaginal estrogens, vaginal dehydroepiandrosterone and ospemifene are contraindicated or less desirable compared with a non-hormonal therapy, such as those undergoing active treatment for breast cancer,[8,9]
3. those who decline vaginal estrogens or other options.

This paper is limited to discussion of the treatment of vulvovaginal atrophy symptoms, however there are published papers with evidence for laser therapy for the urinary symptoms of GSM as well as stress urinary incontinence and other gynaecological conditions in pre- and postmenopausal women.[10,11]

Lasers have traditionally been used in gynaecology for surgery, excision and ablation of tissues.[1] Laser therapy works by stimulating mechanisms to repair, grow and heal the tissues resulting in an increase in capillary density and connective tissue remodelling.[12,13] For tissue remodelling, there are two main categories of laser used in gynaecology, depending on the medium used to generate the laser energy source: the CO_2 laser and erbium YAG (Er:YAG) laser. Lasers aim to achieve collagen remodelling of the subepithelial connective tissue, however, the mechanism of action is different depending on whether the effects of the laser are ablative or non-ablative. Both the CO_2 and the Er:YAG lasers can have an ablative effect on tissues.[12,13]

Ablative lasers create short pulse, high-peak power and rapidly deliver focused microablation to the epithelium and subepithelial tissue by creating microscopic columns of thermal injury into the deeper tissues, without destruction of superficial tissue, which subsequently stimulates fibroblast activation and collagen production without fibrosis. Different lasers, independent of the medium used to generate the energy, will have different tissue penetration and can cause different collateral thermal injury and tissue fibrosis.[12,13]

The CO_2 laser MonaLisa Touch (DEKA, Italy) has a patented design able to generate specific pulse modes to selectively target mucosa or skin. The dedicated D-Pulse has an enhanced effect on the vaginal epithelium and lamina propria by an initial high-peak portion (to vaporise the epithelium) and a low-peak long tail to diffuse laser energy in the connective tissue. Repetitive pulses can improve these effects to be adapted to any vaginal tissue. These technological features stimulate vaginal tissue regeneration without fibrosis.[6]

The Er:YAG laser has a wavelength of 2940 nm, which has 10–15 times the affinity for water absorption compared with the CO_2 laser, with a wavelength of 10 600 nm.[12] The Er:YAG laser SMOOTH (Fotona, Slovenia) is a patented 'smooth mode' that exerts a non-ablative effect on tissues and creates a gradual thermal effect, resulting in a controlled heating of the subepithelial connective tissue, which is rich in water and promotes breakage of the collagen cross linkages and shortening of the collagen fibres. After shortening of the collagen fibrils, subsequent thermomechanical interaction with the deeper tissues causes tissue shrinkage, tissue retraction and then, over a period of time, new collagen fibre formation.[12] Both modalities have been shown histologically to bring about connective tissue remodelling.[14,15]

There is no established standardisation for laser therapy. In addition to the difference in types of laser and their modes of action, different clinical trials have adopted a variety of energy settings, treatment parameters, number of treatment sessions and intervals between treatments. Laser treatments are usually performed in the outpatient setting with or without the need for pretreatment with topical analgesia. Treatment sessions usually last up to 15–20 min, and are spaced 4–6 weeks apart, with three to five treatments required in total.

4 | LASER TREATMENT FOR GENITOURINARY SYNDROME OF THE MENOPAUSE

There have been numerous publications assessing the efficacy of both CO_2 and Erbium YAG lasers in the management of GSM; the majority of which use either the MonaLisa Touch (CO_2) or the SMOOTH laser, with only one short-term follow-up case series using the ablative Er:YAG laser.[16–34] If participants from all studies are amalgamated, in total, 1780 women have been treated. The populations

studied have been heterogeneous, with some exclusively treating breast cancer survivors for whom hormonal therapies were contraindicated, while others included women of varying age with GSM symptoms. The majority of studies have been prospective, observational studies or case series. Duration of follow-up was often short, ranging between 3 and 6 months, with seven studies following up between 12 and 24 months.[20,21,24,26–29]

Vaginal health can be measured in women with GSM using a variety of validated assessment tools. These include symptom scores such as the visual analogue scale (VAS) which scores vaginal dryness, dyspareunia, irritation and leucorrhoea. Objective investigations include vaginal cytology or histology, vaginal pH as well as tools such as the Vaginal Health Index Score (VHIS) which determines a score on a scale of 1 (poorest) to 5 (best) for each of five parameters: vaginal moisture, vaginal fluid volume, vaginal elasticity, vaginal pH and vaginal epithelial integrity.[35] There is now a validated tool for the assessment of GSM called the DIVA (Day-to-Day Impact of Vaginal Aging) questionnaire, a multidimensional self-reported measure developed to measure the impact of moderate to severe vaginal symptoms such as dryness, soreness, irritation, itching, or pain with sexual intercourse on the women's functioning and wellbeing.[36]

Tools chosen for objective assessment of vaginal health in the laser studies varied between studies. The main primary outcome measures in the majority were VAS and/or VHIS. Six studies also evaluated sexual function using the validated female sexual function index (FSFI) score.[37] Two papers[14,15] examined histological changes in the vaginal epithelium in women treated with laser for GSM. All the observational studies reported an improvement in symptom scores (VAS) and improved VHIS with an apparent persistent effect up to 12 months, with some studies showing improvement continuing up to 18 months. After 18 months there is a gradual decline in VAS and VHIS scores back to baseline by 24 months. Only one study has examined the effect of repeated treatments and suggested four/five treatments were more efficacious than three, however, this was a small prospective study and further evaluation is required.[30] Four randomised controlled trials (RCTs) have assessed laser for GSM.[22,31–33] Three papers assessed the ablative vaginal CO_2 MonaLisa laser versus vaginal oestriol and one compared vaginal CO_2 laser to prometriene cream or vaginal lubricant.[31–33] Follow-up period in the RCTs varied from 14 weeks to 6 months post treatment. All showed significant improvement in VAS and VHIS, with the laser showing benefit that was comparable with topical estrogens.

There are three trials of laser versus sham treatment for GSM. The first trial was small and underpowered (n = 14 and 16 patients in sham and CO_2 laser groups respectively) with 6-month follow-up and showed no difference between groups.[38] The second was a larger study (n = 30 and 28 respectively) with a 4-month follow-up period that showed significant improvement in GSM symptoms in the CO_2 laser group.[39] The final sham-controlled trial was larger and had 12-month follow up (n = 42 and 43 respectively) and showed no difference in GSM symptoms between the sham and CO_2 laser group.[40] It is difficult to interpret the results of the three trials as the treatment regimes were different and follow-up intervals varied significantly. All studies acknowledged significant limitations in their methodology, which further emphasises the need for further large multicentre randomised trials in the future.

At the time of writing there are three registered ongoing RCTs to assess various lasers for GSM. These include an RCT to assess Er:YAG versus hyaluronic acid for GSM in breast cancer survivors,[41] another to assess Er:YAG versus sham in GSM[42] and lastly to assess hybrid laser versus sham in GSM.[43] A further study will compare Er:YAG laser and CO_2 laser in GSM.[44]

In summary, the evidence suggests laser therapy may be beneficial in treating GSM, however, the studies to date (including RCTs) are too small and often underpowered. In addition, the optimum treatment regimen or interval and the role of vaginal estrogens either before or in addition to laser treatment are unknown. The effects of treatment appear to subside after 18 months and the effects of repeated treatments are unknown.

5 | ADVERSE EFFECTS AND COMPLICATIONS

The effects of outpatient laser therapy appear well-tolerated, with most studies quoting low pain scores on VAS and high levels of patient satisfaction. As described by the manufacturers, after effects appear to be minimal and transient. They include mild discomfort during the procedure (which is usually very well tolerated in the outpatient setting), transient urgency, mild tissue oedema and swelling, which usually lasts a few days, and a transient increase in vaginal discharge.[12,16] Adverse effects also appear to be mild and transient. The most common adverse effects are: vaginal discharge (4%); oedema (3.4%); pain – during treatment only (1.4%); and pinpoint bleeding (1.2%).[12,15,26,45] Symptoms are not long lasting and subside after 2 weeks. Analysis of the MAUDE (Manufacturer and User Facility Device Experience) database and a published case series identifies the potential risks of laser use, such as subsequent long-term pain, dyspareunia and vaginal fibrosis. Cases of significant harm have usually been attributed to operator error or inappropriate use of the laser.[46,47]

6 | OPINION

- Vaginal estrogens are still considered the gold standard for treating symptoms of GSM. Patients should be appropriately investigated and counselled about the high level of safety and efficacy of vaginal estrogens and also counselled regarding non-hormonal treatments before considering vaginal laser as a treatment for GSM.

- Although limited, the evidence to date suggests that laser therapy may be beneficial as a non-hormonal treatment for the management of GSM and appears to have similar efficacy in treating symptoms to vaginal oestrogen.
- There are uncertainties about the long-term efficacy and safety of laser treatment for GSM. Studies to date have largely been small in size, either prospective/retrospective observational in design, with short-term follow-up and have utilised heterogeneous tools for the evaluation of efficacy. Further research and RCTs are necessary to evaluate and establish the long-term efficacy and safety of this technology before it can be recommended for the management of GSM.
- The evidence suggests that duration of the effect of laser therapy reduces with time, and by 18 months symptom scores return to baseline levels. As yet the effect of repeated doses cannot be determined.
- In aesthetics and gynaecology, lasers currently have US FDA approval for 'incision, excision, ablation, vaporisation and coagulation of body soft tissues' only. Treatment of GSM in the US has still to be approved. The Er:YAG laser was approved by the Canadian FDA in August 2019 for use in 'GSM and stress urinary incontinence'.
- Clinicians should be cautious in adopting new technologies without robust evidence to support their use. Clinicians should counsel and consent women about the limited evidence for lasers in clinical practice.
- International consensus group recommendations and National Institute for Health and Care Excellence (NICE) guidelines suggest laser therapy should be restricted to research settings until robust data are available.[48,49]
- Indiscriminate treatment with laser therapy with little evaluation, assessment and counselling will lead to poor satisfaction outcomes and morbidity. It is too early to encourage the widespread adoption of laser therapy in gynaecology outside a research trial until the results of larger, multicentre sham-controlled studies are available.
- When using energy-based devices, clinicians must ensure they have appropriate training both in the use of lasers but also the conditions they are treating (e.g. GSM, SUI etc.). The use of lasers for gynaecological conditions by laser therapists other than gynaecologists should be discouraged unless they can demonstrate appropriate training and governance. There also needs appropriate regulation on the use of lasers, which is currently lacking especially in the aesthetic industry.[50]
- Treatment regimens must be recorded, including energy settings, number of passes, treatment parameters, intervals between procedures, as well as the indication, assessment and follow-up outcomes including complications. Clinicians should record their data preferably on a database with mandatory reporting of adverse events.
- Clinicians should be aware of the differences between different types of lasers, as well as the research evidence for the safety and efficacy of each particular laser, including the specific clinical indication, target tissue (e.g. skin, animal model, epithelium) and energy level/treatment parameters. Most published research examines the CO_2 MonaLisa Touch (eight papers) and Er:Yag SMOOTH (six papers). Lessons learnt from the mesh debate[51] indicate that companies should not claim their product is as effective as another, without providing specific evidence for the efficacy and safety of their own product. As such, clinicians should quote the appropriate literature.

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CONFLICT OF INTEREST

Completed disclosure of interests form available to view online as supporting information.

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