FemTouch™ For the treatment of recurrent urinary tract infections in post-menopausal women

Bob Yang - Urology Specialist Registrar
Steve Foley - Urology Consultant
Claire Foley - Aesthetic Nurse Practitioner

Introduction

Recurrent Urinary Tract Infections (UTIs) in women is a prevalent disease worldwide. In the UK, near 50% of all women experience at least one episode of UTI in their lifetimes, with UTI being the most common reason women present to ambulatory care (Al-Badr et al 2013, Foxmann et al 2014). Of these women, 20-30% will experience recurrent UTIs, as defined by "three or more episodes of UTI during a 12 month period or two or more within 6 months" (Albert et al 2004).

The prevalence of UTI increases with age. The underlying pathophysiology behind this lies in the fact that post-menopausal women have lower oestrogen levels, depressing active rejuvenation of the vaginal wall lining as well as the loss of the commensal bacteria Lactobacillus, within the vaginal microenvironment. Lactobacillus is essential in the synthesis of lactic acid, maintaining the normal low pH environment within the vagina that prevents colonisation by uropathogens (Al-Badr et al 2013).

Patients suffering from recurrent UTIs, often require continuous prophylactic antibiotics long term treatment, however, the consequence of antibiotic overuse may result in the rapid emergence of multi-resistant bacteria. Multi-resistant bacteria is such an emerging risk, that the World Health Organisation issued a global action plan to combat antibiotic resistance, declaring this deadly issue as one of the greatest threats to global health in our lifetime (WHO GAP 2015). There is a global urgency to find antibiotic-free therapies, for instance reinforcing natural mechanisms of defence.

Fractional CO_2 lasers, applied to the vaginal lining, induce histological changes, resembling oestrogen therapy (Zerbinati et al 2015, Salvatore et al 2015). Biopsies from treated patients demonstrate the restoration of thick squamous epithelium, intra-cellular glycogen storage and synthesis of new components for the extra-cellular matrix. Fractional CO_2 laser treatment restores the natural lubricated vaginal microenvironment, leading to commensal lactobacillus colonisation, which in turn re-establishes the natural protective acidic pH environment within the vagina.

Here we used the FemTouch delivery system to provide fractional treatments to the vaginal wall. Through the use of the FemTouch probe, laser energy was delivered in a fractional manner, selectively treating less than 100% of the tissue surface to induce vaginal restoration.

We present the first experience in the United Kingdom of using the CO_2 vaginal laser FemTouch™ to treat a preliminary cohort of post-menopausal women with recurrent UTIs over a 1 year period.

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Methods

12 post-menopausal women with recurrent UTIs were identified and recruited. Preceding any intervention, all women received a smear test for histological analysis as well as a vaginal swab for microbiology analysis. This is to exclude any underlying active infection or malignancy, which would affect the suitability of the patient to undergo fractional laser therapy. Each woman then received vaginal FemTouch™ treatment at monthly intervals for a total of 3 courses over a 3-month period. Each woman was then followed up at 6 months and 12 months since treatment 1, resulting in a cumulative follow up of 12 months from beginning of treatment (see figure 1).

Figure 1: Study timeline, each of the 12 post - menopausal women received three treatments at monthly intervals and followed up at 6 and 12 months post treatment 1.

Each woman was assessed (preceding each monthly treatment and at month 6 and 12) for rates of UTI recurrence, as well as assessing vaginal health using the internationally recognised Vaginal Health Index Score (VHIS), which assesses the elasticity, fluid, pH, integrity and moisture of the vagina. A VHI score of less than 15 is considered atrophic. Patients were also asked to complete a subjective visual analogue assessment for vulvovaginal atrophy symptoms.

During treatments and follow-up period, no women received concurrent antibiotic prophylaxis or hormonal treatment.

Results

All 12 women successfully completed the entire treatment course. Immediately after treatment, the women were asked to rate treatment discomfort/ pain based on a visual analogue scale where the extreme left indicates “no pain” and extreme right indicates “intolerable pain”. When converted to a score out of 10 (with 0 being no pain and 10 being intolerable pain). Procedure related discomfort was 1 out of 10 on average, throughout treatment.

Of the 12 women, 11(92%) women remained UTI free for a period of 3 month after the last treatment. Nine (75%) women remained UTI free for a period of 9 month after the last treatment (Figure 2).

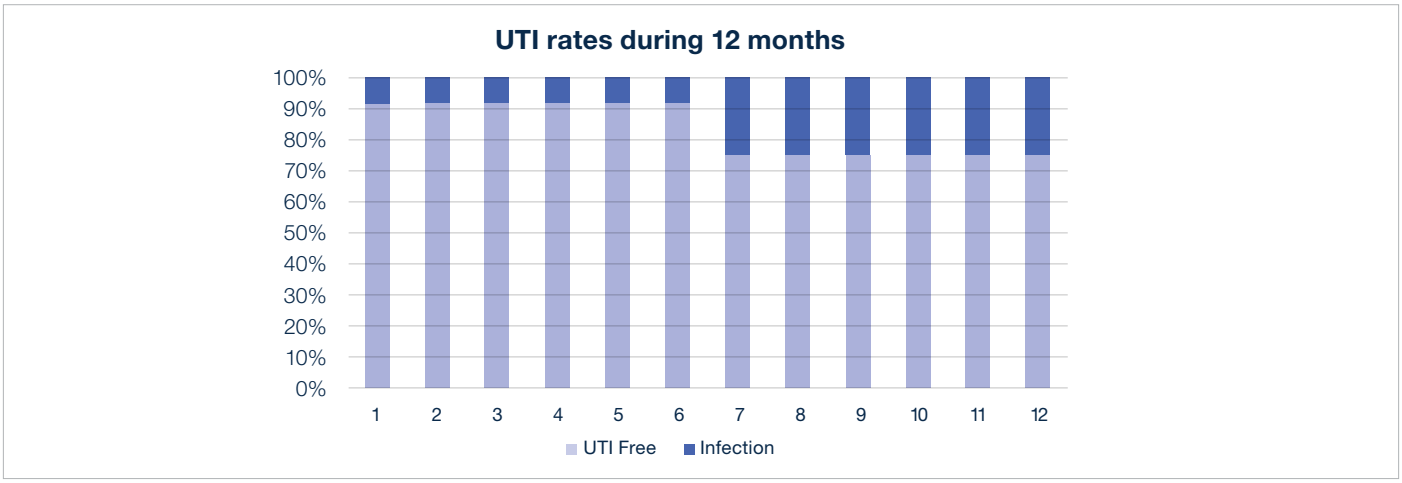

Figure 2: Proportion of women who remained UTI free versus those who developed an infection during the 12 month study period post Femtouch treatment.

The average vaginal pH before and after laser treatment improved dramatically from pH 7.0 to pH 5.4, reflecting the restoration of the acidic micro-environment. Twelve months after the first treatment, vaginal pH increased to pH 6.0 on average (as shown in Table 1 and Figure 3).

	Before 1st treatment (baseline)	Before 2nd treatment	Before 3rd treatment	6 months follow up	12 months follow up
pH	7.0	5.8	5.4	5.4	6.0

Table 1: Average vaginal pH of all patients before and with subsequent laser treatments

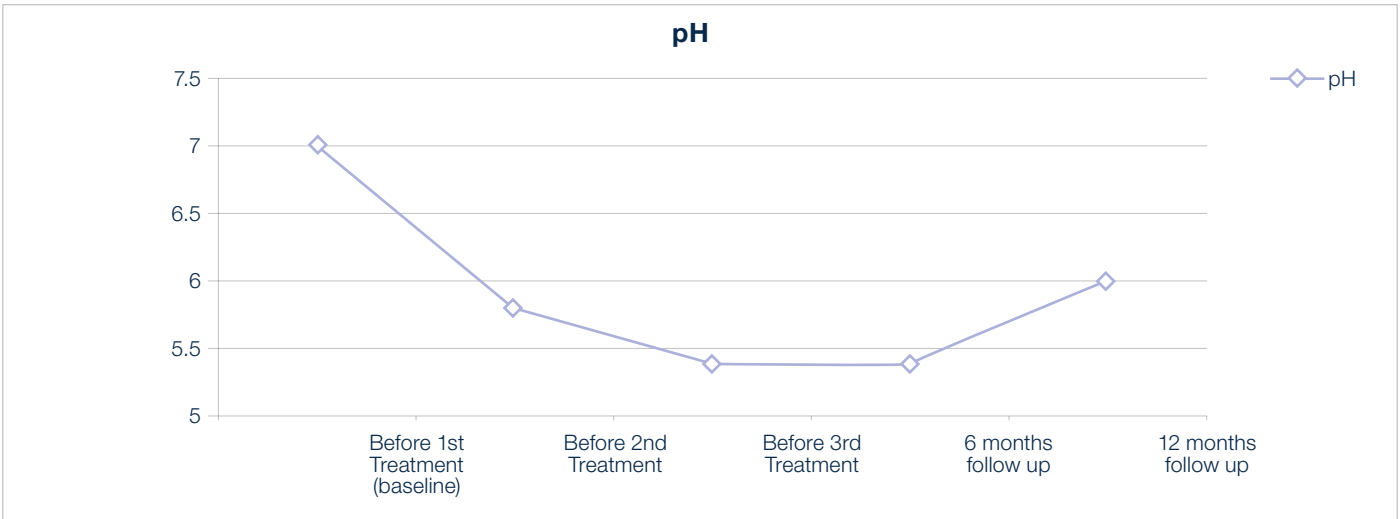

Figure 3: Average vaginal pH before and following laser treatment

In addition to the preventative effects against UTIs, the VHIS score improved dramatically throughout the treatment period when compared to baseline (Table 2, Figure 4). The VHIS score reflects the concurrent restoration of the women's vagina out of an atrophic state. VHIS score at baseline was 11, improving to 16 and 20 immediately before treatment two and three respectively, maintained at 19 during 6 months follow-up visit. Twelve months post treatment VHIS score was 15 still higher than VHIS scores measured at baseline.

Average VHIS (1 = poor, 5 = excellent)					
	Before Treatment 1	Before Treatment 2	Before Treatment 3	6 months follow up	12 months follow up
Elasticity	3	4	4	4	3
Fluid	2	3	4	4	3
pH	1	2	3	3	2
Integrity	3	4	5	4	4
Moisture	2	3	4	4	3
Total	**11**	**16**	**20**	**19**	**15**

Table 2: Average VHIS score before and following laser treatments for all patients

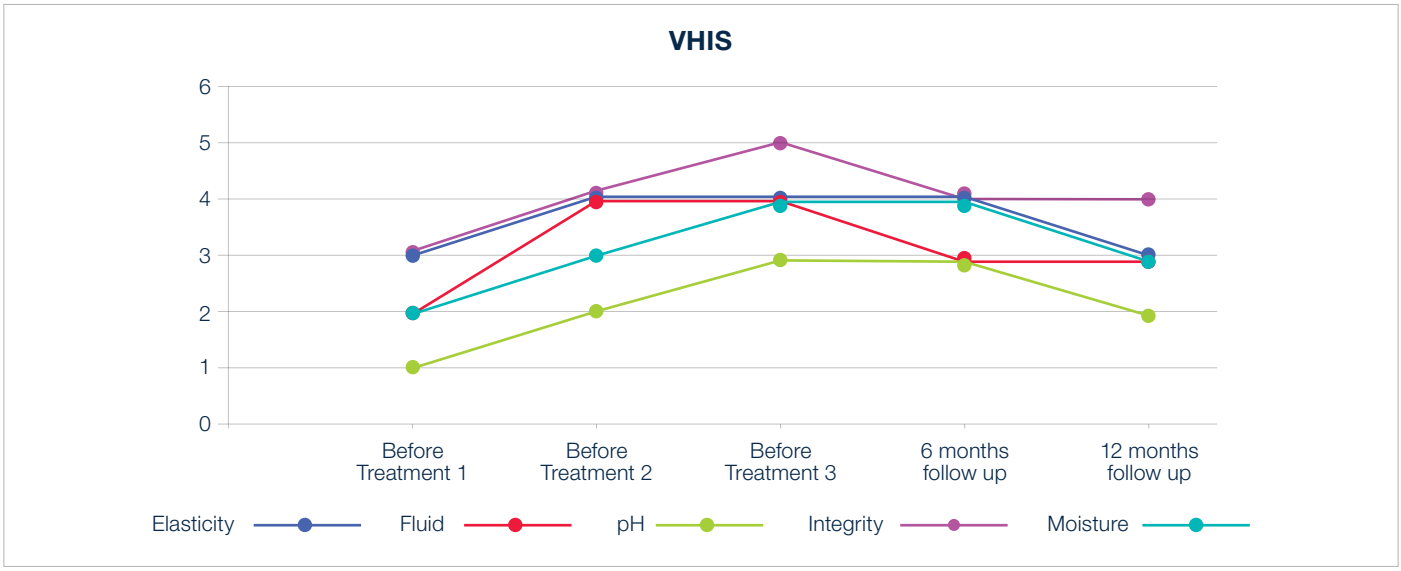

Figure 4: VHIS score before and following laser treatment

Women were asked to complete the Subjective Assessment of Vulvovaginal Atrophy symptoms questionnaire that include vaginal itching, vaginal burning, vaginal dryness, dyspareunia, and dysuria. The severity of each symptom was evaluated by the patient on a 10 cm VAS where extreme left indicated "absence of the symptom" and extreme right indicated "symptom as bad as it could be".

On average each of the symptoms improved in correlation with the clinically assessed VHIS score (Table 3, Figure 5). At 12 months follow-up vulvovaginal atrophy symptoms were still improved when compared to baseline values.

	Before 1st treatment (baseline)	Before 2nd treatment	Before 3rd treatment	6 months follow up	12months follow up
Itching	4	2	1	1	3
Burning	6	3	2	2	4
Dryness	9	5	3	2	5
Pain	9	6	4	3	5
Total	**28**	**16**	**10**	**8**	**17**

Table 3: Subjective Assessment of Vulvovaginal Atrophy symptoms indicated by VAS of vaginal itching, vaginal burning, vaginal dryness and dyspareunia

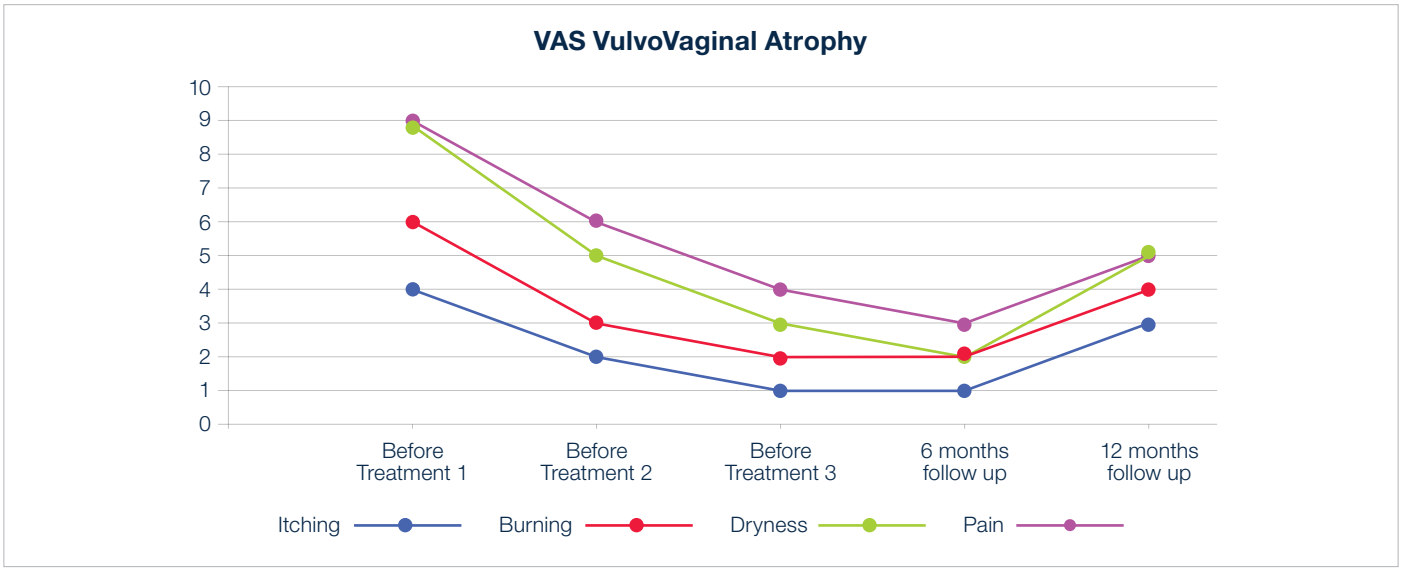

Figure 5: Subjective Assessment of Vulvovaginal Atrophy symptoms indicated by VAS of vaginal itching, vaginal burning, vaginal dryness and dyspareunia

Discussion

Our preliminary results show that FemTouch™ treatments were effective and well tolerated for recurrent UTIs in postmenopausal women. These results may satisfy the WHO Global Action Plan and offer a potential viable alternative to antibiotic prophylaxis. No side effects were reported in this initial cohort of patients.

Furthermore, FemTouch™ treatment concurrently improved the general vaginal health of the patient, restoring their previously atrophic vaginal conditions to a healthy pre-menopausal state on the Vaginal Health Index Score. The successive benefit of this includes patients reporting a subjective decrease in vaginal burning, itchiness, dryness and less pain on having sex.

With 3 months of treatment, the benefits are still present 12 months after the initial treatment, however symptoms by this time are starting to return, suggesting additional treatment cycles might be needed to maintain a long term improvement.

The results above show that there seems to be enough merit in establishing a national multi-centre trial with the aim of evaluating the efficacy of vaginal lasers in larger groups of patients for a longer follow up period. Additional studies on maintenance treatment at different treatment intervals to maintain the long term effect should also be considered.

We at Reading Urology Partnership and Royal Berkshire Hospital are currently looking into establishing such a trial.

As the use of vaginal lasers, including FemTouch™, becomes increasingly more common, their use in providing a novel antibiotic-free preventative treatment for women suffering from recurrent UTIs is a field harbouring both great interest and great potential.

FemTouch™ has received outstanding feedback both regarding outcomes and the application process. Not only are patients relieved to find out no general anaesthetic is required, but as mentioned above, patients who have undergone this therapy describe the “pain” during treatment as only 1 out of 10 on average.

> One delighted patient reports:
>
> *(My) Menopause symptoms and frequent urinary tract infections had got so bad that I didn’t want to have sexual intercourse anymore. I discovered FemTouch™, a 5 minute pain free vaginal procedure. (After undergoing the procedure), I’ve now got my life back.*

> One patient remarked:
>
> *I have tried many treatments over the years for my painful bladder and vaginal discomfort and this is the first time I have had 3 months without any symptoms or discomfort.*

Warnings and risks

CO_2 lasers are intended solely for use by physicians trained in the use of the Carbon Dioxide laser (10.6 µm) wavelength. Incorrect treatment settings or misuse of the technology can present risk of serious injury to patient and operating personnel. Risks that may be associated with any CO_2 laser procedure may include change of pigmentation, infection, erythema, skin induration or scarring. Read and understand the CO_2 systems and accessories operator manuals for a complete list of intended use, contraindications and risks. The use of Lumenis® CO_2 laser is contraindicated where a patient has taken Accutane (Isotretinoin) within the past 6-12 months, has a history of keloid formation and demonstrate excessive or unusually prolonged erythema.

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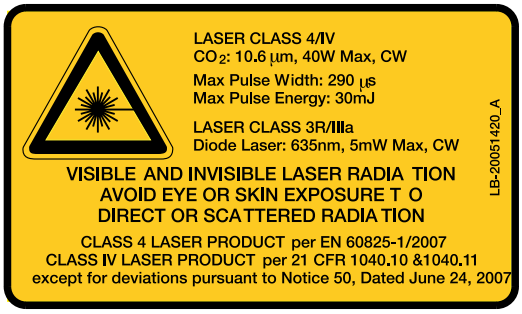

Lumenis Ltd.
Yokneam Industrial Park
6 Hakidma Street P.O.B. 240
Yokneam 2069204, Israel
Tel: +972-4-959-9000

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