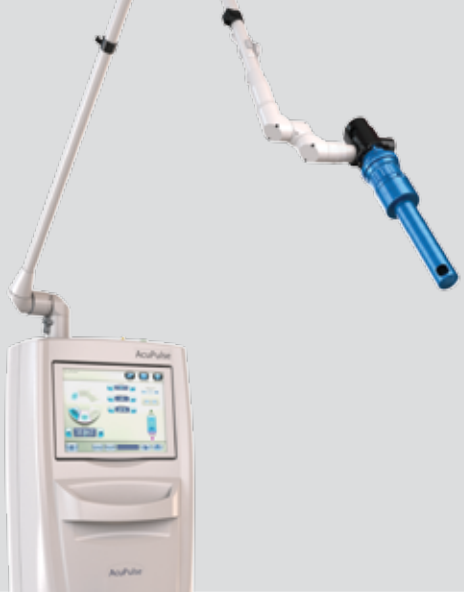
Initial experience of using FemTouch™ for the treatment of recurrent urinary tract infections in post-menopausal women

Steve Foley consultant urologist
Bob Yang urology trainee
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 of 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 proliferation 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 resulted 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). As a result, there is a global imperative and urgency to finding alternative therapies that avoid the use of antibiotics, such as by reinforcing the natural mechanisms of defence.

Fractional CO_2 lasers, when applied to the vaginal lining, have been histologically proven to induce changes to the vaginal lining, similar to oestrogen therapy (Zerbinati et al 2015, Salvatore et al 2015). This is seen by the restoration of the thick squamous epithelium, intra-cellular glycogen storage and synthesis of new components for the extra-cellular matrix. The consequence of this not only restores the natural lubricated vaginal microenvironment, but also restores the commensal lactobacillus colonisation, allowing for the re-establishment of 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.

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.

Methods

10 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 3 months post final treatment, resulting in a cumulative follow up of 6 months from beginning treatment (see figure 1).

Figure 1: Study timeline, each of the 10 post –menopausal women received 3 treatments at monthly intervals and followed up at 3 months post final treatment.

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

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

Results

All 10 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 described by all woman was 1 out of 10 on average, throughout treatment.

Women were evaluated for experience recurrent UTIs, as defined by three of more episodes of UTI during a 12-month period or 2 or more within 6 months. Of the 10 women, 9 women (90%) remained UTI free throughout the treatment and follow-up period.

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 as shown in Table 1 and Figure 2.

Before Treatment	After Treatment 1	After Treatment 2	After Treatment 3
pH. 7.0	pH. 5.8	pH. 5.4	pH. 5.4

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

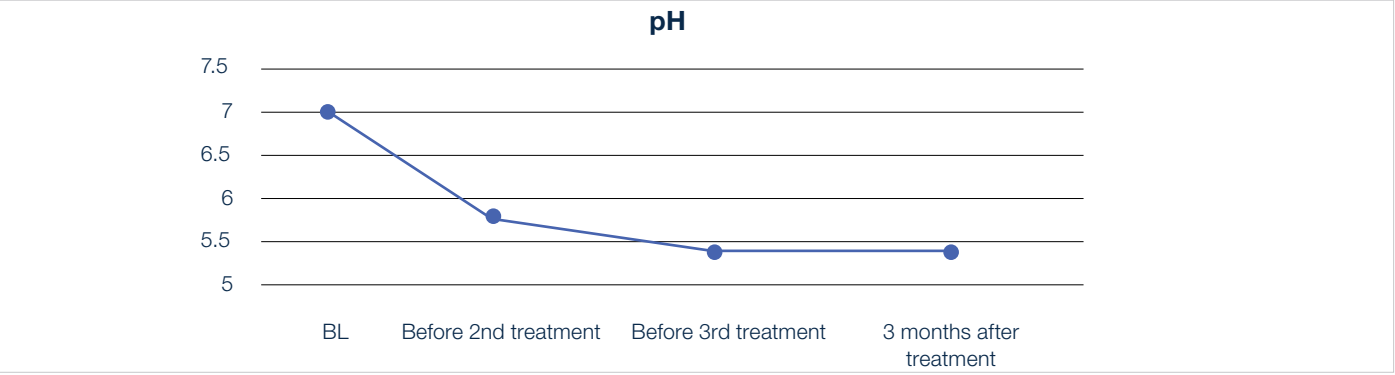


Figure 2: Average vaginal pH before and following laser treatment

In addition to the preventative effects against UTIs, the VHIS score improved dramatically throughout the treatment period when compared to baseline (Table 2, Figure 3). An average VHIS score of all patients was measured at 11 before treatment, improving to 20 immediately before treatment 3, maintaining at 19 at 3-month follow-up post third treatment. The VHIS score reflects the concurrent restoration of the women's vagina out of an atrophic state.

Average VHIS (1=poor | 5= excellent)				
	Before Treatment 1	Before Treatment 2	Before Treatment 3	3 Month After Treatment
Elasticity	3	4	4	4
Fluid	2	3	4	4
pH	1	2	3	3
Integrity	3	4	5	4
Moisture	2	3	4	4
Total	**11**	**16**	**20**	**19**

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

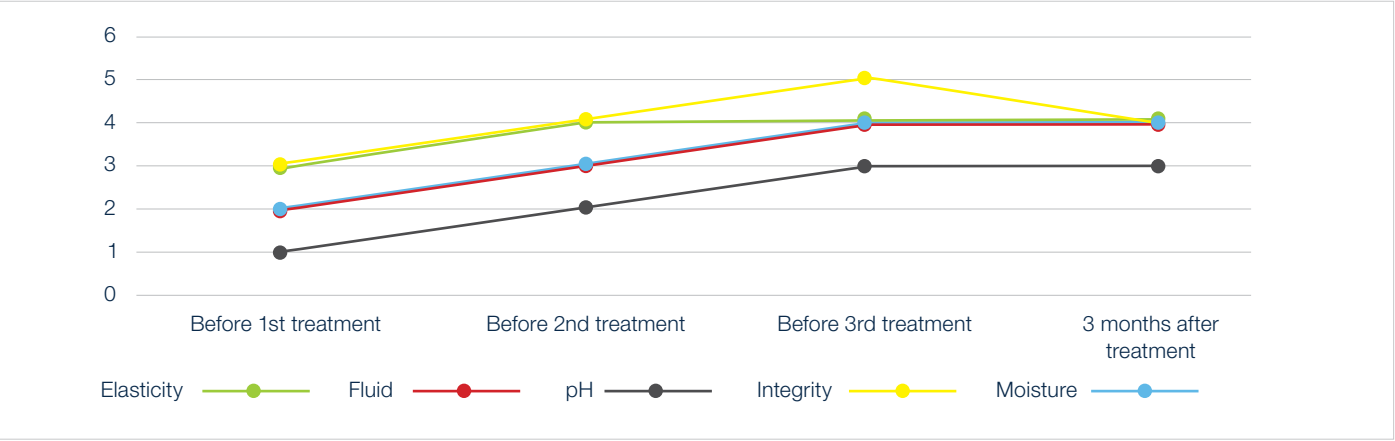


Figure 3: VHIS score before and following laser treatment

Women were asked to complete the Subjective Assessment of Vulvovaginal Atrophy symptoms 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 as correlated by the clinically assessed VHIS score Table 3, Figure 4.

	Before 1st Treatment (Baseline	Before 2nd Treatment	Before 3rd Treatment	3 Month After Treatment
Itching	4	2	1	1
Burning	6	3	2	2
Dryness	9	5	3	2
Pain	9	6	4	3

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

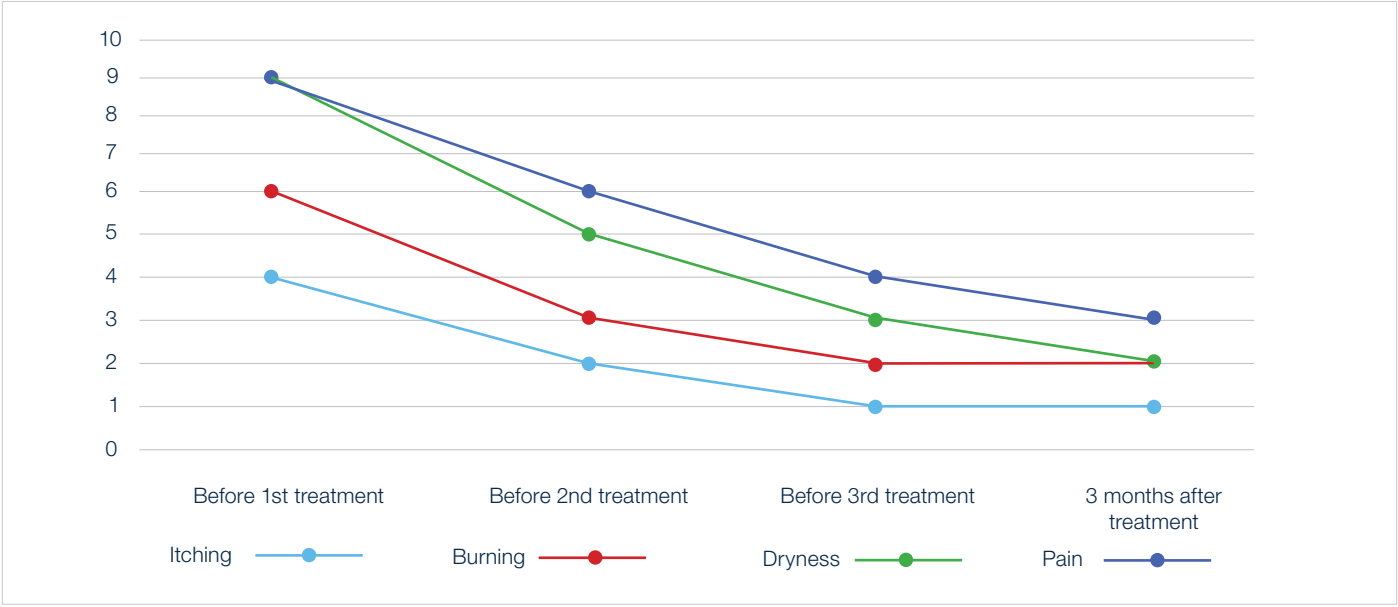


Table 4: Subjective Assessment of Vulvovaginal Atrophy symptoms indicated by VAS of vaginal itching, vaginal burning, vaginal dryness and dyspareunia

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.

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.

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

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 described the “pain” of the procedure 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.

References

Al-Badr A, Al-Shaikh G. Recurrent Urinary Tract Infections Management in Women: A review. Sultan Qaboos University medical journal. 2013 Aug;13(3):359-67. PubMed PMID: 23984019. Pubmed Central PMCID: 3749018.

Albert X, Huertas I, Pereiro, II, Sanfelix J, Gosalbes V, Perrota C. Antibiotics for preventing recurrent urinary tract infection in non-pregnant women. The Cochrane database of systematic reviews. 2004 (3):CD001209. PubMed PMID: 15266443.

Foxman B. Urinary tract infection syndromes: occurrence, recurrence, bacteriology, risk factors, and disease burden. Infectious disease clinics of North America. 2014 Mar;28(1):1-13. PubMed PMID: 24484571.

"GLOBAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE 2015". World Health Organisation Western Pacific Region Site. N.p., 2017. Web. 17 May 2017.

Salvatore S, Leone Roberti Maggiore U, Athanasiou S, Origoni M, Candiani M, Calligaro A, et al. Histological study on the effects of microablative fractional CO_2 laser on atrophic vaginal tissue: an ex vivo study. Menopause. 2015 Aug;22(8):845-9. PubMed PMID: 25608269.

Zerbinati N, Serati M, Origoni M, Candiani M, Iannitti T, Salvatore S, et al. Microscopic and ultrastructural modifications of postmenopausal atrophic vaginal mucosa after fractional carbon dioxide laser treatment. Lasers in medical science. 2015 Jan;30(1):429-36. PubMed PMID: 25410301.