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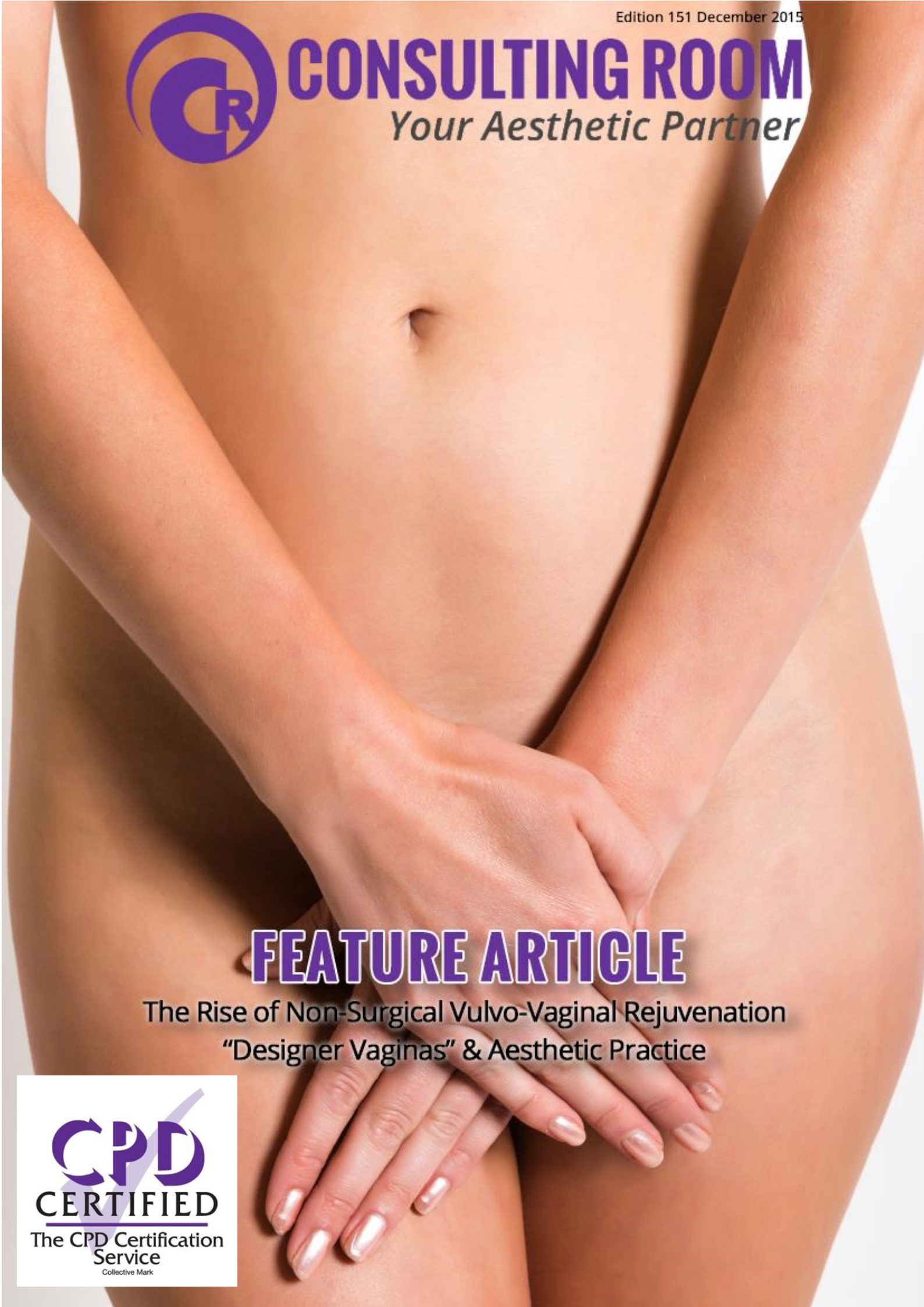

FEATURE ARTICLE

The Rise of Non-Surgical Vulvo-Vaginal Rejuvenation "Designer Vaginas" & Aesthetic Practice

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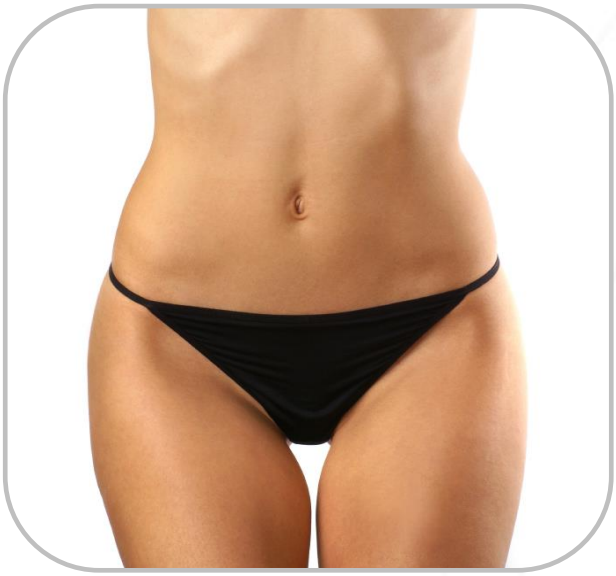
Feature Article

The Rise of Non-Surgical Vulvo-Vaginal Rejuvenation
"Designer Vaginas" & Aesthetic Practice



The female genitalia or vagina is considered by many, (and rightfully so, speaking as a woman!), to be a special, sacred and sacrosanct region of a woman's body – of course when it comes to the human desire to improve on what God or nature gave us, the word sacrosanct goes out of the window and female genital cosmetic surgery (FGCS) or genitoplasty is born. Nothing it seems is too important, or too valuable, or too special to us to be interfered with and 'made cosmetically better' or 'work a bit better' – welcome to the era of the 'Designer Vagina'.

Cosmetic and medical, surgical procedures now available, and quite commonplace, via private healthcare providers include vaginoplasty (in the form of vaginal tightening), labiaplasty (reshaping of the labia majora and minora), hymenoplasty (recreation of the hymen, often referred to as 'revirgination', common for religious reasons before marriage) and hoodectomy (reduction or reshaping of the clitoral hood), as well as fat transfer to the labia or for contouring the mons pubis. And that's just the surgical options!

According to the American Society for Aesthetic Plastic Surgery (ASAPS), over 7,500 labiaplasty procedures were performed by its members in the USA in 2014, that's a 48.6% increase on the number of procedures performed in the previous year. In fact, the increase in the numbers for this procedure has been quite staggering, and rapid, with 2013 figures also showing a 44% increase on 2012. Thus it appears that year on year the American marketplace for this surgical vaginal procedure is growing in number by half again each year.

One theory proposed to explain this growth in demand, came from a panel discussion at the 2013 annual ASAPS meeting, in which it was noted that since the advent and popularity of Brazilian hair waxing techniques, women have become more conscious of their vaginal area, which has led to concerns over the size, shape and 'dangle' of their labia.

Of course, not all labiaplasty (or other FGCS) are performed for cosmetic reasons, there are valid medical reasons for surgical intervention such as pain and discomfort due to the size and shape of the labia such as hypertrophy or asymmetry, complications post pregnancy and childbirth including prolapse and urinary incontinence or defects due to trauma, disease or congenital abnormalities, as well as the effects of ageing on the region.

According to the NHS Choices website the number of labiaplasties performed on the NHS (not for cosmetic reasons) has risen five-fold since 2001, with 2,000 operations carried out in 2010. Of course, as we know, in the UK most operations of this kind for cosmetic reasons are carried out in the private sector, where rises in demand have also be reported. In September 2012, The Hospital Group noted a 56% rise in enquiries for their cosmetic gynaecology services (labiaplasty, vaginal tightening and pelvic floor surgery) over the previous year.

But that really isn't the whole story…

Not every woman wants surgical procedures, despite their concerns about their genitalia, and like many other sectors within our industry, less invasive options start to appear to be a reality and demand follows.

Vulvo-vaginal rejuvenation and the non-surgical treatment options available have expanded rapidly in recent years to target both improvements in aesthetic appearance of the female genitalia as well as function; both practical (urinary) and sexual. This has led to innovations in heat based technologies such as laser and radiofrequency for tissue tightening and collagen stimulation, as well as dermal fillers for volumisation and hydration, alongside more natural, healing and stimulatory treatments such as Platelet Rich Plasma (PRP) therapy. Even skincare ranges are coming to market now directly aimed at use in the vulvo-vaginal area.

Getting an exact idea of just how many surgical and non-surgical vaginal procedures are being performed is really tricky, but it is safe to say that both observed demand and provision are rapidly growing, with many aesthetic practitioners diversifying into offering ‘off-face’ cosmetic treatments to their female patients who may have mentioned their ‘other’ bodily concerns in passing.

If you have been to any aesthetic industry trade shows in the last twelve to eighteen months you will no doubt have seen both presentations on conference agendas and exhibitors on the floor promoting a variety of different solutions to vulvo-vaginal indications.

In this article, I aim to explore the many minimally invasive vulvo-vaginal treatment options now available, the issues surrounding treating this area of the female anatomy, as well as confronting the big elephant in the room – is this really an appropriate specialism for aesthetic medical practitioners?

Designer Vagina Controversies

Any procedure, whether for medical, cosmetic or religious reasons that involve the female genitalia have often courted controversy in the eyes of society, the media and in some cases the law.

Female Genital Mutilation (FGM)

It is true that there has been concern in recent years that, in the eyes of the law, cosmetic, surgical procedures such as labiaplasty or hymenoplasty could all get lumped in with the more sinister practice of female genital mutilation (FGM), which often involves the unconsented removal of clitoral tissue in young girls for religious or cultural reasons. FGM is illegal in the UK.

The law in place (Female Genital Mutilation Act 2003) does not make specific reference to exempting FGCS as performed by plastic surgeons, which has led to both caution and confusion within the medical sector. There are calls for an amendment to the twelve year old law to adequately clarify and exempt FGCS, so as to avoid any potential for future prosecutions as warned by **Teresa May** a year ago. Caution is thus still required in terms of the psychological evaluation and vulnerability status of women seeking surgical cosmetic enhancement of their genitalia. Treating patients under the age of 18 is a particularly difficult area and ill-advised unless within the NHS. It is unlikely that non-surgical treatments would risk association with this law, but it’s simply not been tested yet so could be argued that the same cautions should apply.

Pornography Driving Demand

Many feminist groups believe that pressure for women to conform to idealised values of beauty is made even worse if that pressure is in relation to the appearance of their most private parts. There are those who feel that the concept of cosmetic alteration of the female genitals is pandering to a ‘designer vagina’ look often associated with top-shelf pornographic magazines and videos which portray unrealistic imagery and pressure women, young and old, into ideas of vaginal beauty. This is then backed up by heavy promotion of cosmetic vaginal solutions by the private healthcare sector.

Yet, one Australian research project disputed this. A Facebook survey of 1,083 women, 85% of whom were from Australia, by Bethany Jones from the Australian National University (ANU) in Canberra and her colleague, Camille Nurka, found the majority of women surveyed were content with the appearance of their vagina.

Having noted that many media outlets reported the rise in popularity of labiaplasty as attributable to women's exposure to pornography, particularly due to Internet porn, they set out to investigate whether exposure to porn, typically involving images of "tucked in" vulvas with no protruding labia, led women to become dissatisfied with the appearance of their genitals. While the study found some correlation between exposure to pornography and a willingness to consider a labiaplasty, it also found there was no meaningful connection between porn consumption and whether a woman was satisfied or dissatisfied with her vagina.

The authors concluded that the results indicated that pornography consumption alone could not explain women's satisfaction or dissatisfaction with their genitals. The pursuit of cosmetic surgery is a complex behaviour which includes different psychological characteristics and mental health indicators such as depression, anxiety and body dysmorphia, so it's not unreasonable to assume that they might also play a role in decisions to have labiaplasty.

No Need to Treat

Some medics have even spoken out about such treatments and procedures being performed unnecessarily, and to the detriment of the patient long term. Many feeling that the rise in provision of cosmetic solutions to treat the

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vagina is not healthy. This coincides with the concept of body dysmorphia in which a person is unhappy with the appearance of part of their body, to the point of fixation, and often no amount of cosmetic intervention will satisfy and solve the underlying mental health concern.

Speaking in a **statement** in 2007, the American College of Obstetricians and Gynecologists (ACOG) stated;

"*So-called "vaginal rejuvenation," "designer vaginoplasty," "revirgination," and "G-spot amplification" procedures are not medically indicated, nor is there documentation of their safety and effectiveness. Moreover, it is deceptive to give the impression that any of these procedures are accepted and routine surgical practices.*"

ACOG recommends that women considering cosmetic vaginal procedures should be informed about the lack of data supporting the effectiveness of these procedures as well as their potential complications, including infection, altered sensation, dyspareunia (pain), adhesions, and scarring.

They also noted that many women do not realise that the appearance of their genitals varies significantly from woman to woman, that an honest discussion needed to be had about the wide variation in the appearance of normal genitalia which could reassure women who are insecure about the way that theirs looks before they seek cosmetic improvement.

Similarly the Royal Australian College of General Practitioners (RACGP) are the first in the world to issue **guidelines to GPs** on how to respond to women who visit them asking about FGCS and to help them to understand and discuss the concerns that a woman might have about the appearance of her genitals.

Who should be doing vulvo-vaginal treatments?

If you ask the person in the street, their first reaction would probably be a gynaecologist, and to be honest there is part of me that thinks they are probably right – it is their specialism after all. I wouldn't go to a cosmetic practitioner for a heart condition, but as ever the aesthetic industry, which incorporates many medical professionals from differing backgrounds and specialist interests is branching out into treating this region, just as many have into managing vascular complaints – which carries its own detractors.

The Consulting Room ran an industry sentiment survey to find out just how concerned we are as a marketplace about the rise in this sector.

When asked if aesthetic medical practitioners should be getting involved in delivering non-surgical vulvo-vaginal treatments, almost 60% felt that they should (providing that have undertaken specific anatomical and product training), over 30% deemed it the arena of obstetricians and gynaecologists and just under 10% felt that they shouldn't be, but agreed that there was nothing to stop them.

Some of the primary concerns raised included, a lack of adequate practitioner training, including a poor understanding of the anatomy and physiology, as well as an understanding of the diseases of the vulvo-vaginal region, a lack of broader experience in female health and hormone therapy prescribing, an inability to recognise abnormal pathology in the region, and knowing when to refer for a specialist opinion.

One Doctor pointed out that he wasn't concerned with aesthetic practitioners getting involved in this area as long as their training and qualifications allow them to do so and "*not just because we can use fillers, and therefore it's fair game*". Another practitioner that I spoke to did say, when asked about the growth in this sector within the aesthetic industry, that "*from a female perspective I found the enthusiasm of the men in the industry quite distasteful*".

Others were concerned that practitioners were simply jumping on the bandwagon, and perhaps engaging in gimmicky treatments (such as G-spot enhancement), without adequate research and evidence being available regarding the safety and efficacy of some of the marketed treatments.

Equally there was concern that this could become yet another area where non-medics start practicing with very little training or qualifications to back them up.

Something which did also get discussed, and was more of a concern for the medical practitioners themselves than whether or not they are suitable to practice, was the potential for complaints, with many survey respondents discussing a need for privacy and perhaps extra chaperones when a practitioner is treating a patient in this area. It was suggested that practitioners should be making sure that full assessments for body dysmorphia signals should be carried out adequately prior to this procedure – especially given the controversies raised with FGM.

What are we trying to treat?

Most practitioners involved in treating female genitalia, whether surgically or non-surgically will suggest that they are not just trying to make it 'look pretty', but are aiming to solve a medical or pseudo-medical concern caused by cosmetic abnormalities or ageing.

The procedures now being practiced, discussed and written about within the aesthetic arena demonstrate a distinct blurring of the line between cosmetic and medically indicated procedures, with many now being performed for both purposes, as well as often having a psychological benefit of increasing confidence and self-esteem for the individual:

- Stress urinary incontinence
- Painful sex
- Desire for increased sexual gratification
- Hypertrophy of labia majora and minora (enlargement in the outer and inner vaginal lips)
- Labial laxity or deflation (requiring tissue tightening and volume improvement)
- Perineal loosening after episiotomy during childbirth or surgery
- Vaginal laxity following childbirth or menopause – Vaginal Relaxation Syndrome
- Vaginal atrophy
- Vaginal dryness (lack of hydration)
- Dysesthetic vulvodynia (burning pain in vulva)
- Lichen sclerosus (patchy areas of pale, thin skin in the vulva, common in menopausal women)

In fact, most of the cosmetic techniques now employed for these treatments have a foundation in treating actual gynaecological concerns. A variety of different treatments are now being employed which already have a foundation in the aesthetic industry too.

Cosmetic Fillers

In recent years hyaluronic acid (HA) based fillers, most commonly used as a volumising and hydrating agent for the face and backs of hands, have been trialled for different indications including the balls of the feet and for genital enhancement in both males and females. This has led to innovations in techniques and indication-specific products becoming available.

Some practitioners have used HA as a way of augmenting the G-spot, with a procedure marketed as the "G-shot". The female G-spot is found up inside the female vagina on the front wall; the hope with injecting HA into this area is that the increased prominence or amplification leads to more sexual stimulation and increased sexual enjoyment (via more orgasms or better ones) for the recipient.

Some practitioners have labelled this procedure, (which is neither permanent nor long lasting) as gimmicky. With a serious lack of credible scientific study for this application, including its safety and efficacy, as well as just exactly where to inject to hit the illusive G-spot, the detractors are many. Yet, those who practice this procedure are adamant that it works and claim to have plenty of patients to testify to it.

More recently, woman have become more vocal in complaining about laxity and volume loss in their labial and vaginal region, as well as problems with vaginal dryness due to inadequate labial structure in the region. Such complaints are clearly not all about having a 'designer vagina', but more about alleviating pain, discomfort or a lack of sensation in the region. HA fillers can thus be used to plump up where volume is lacking, to enhance the look, increase any discomfort caused by the volume loss and aid the maintenance of vaginal hydration.

It is not however without its own controversies and detractors.

Dr. Neeta Nirdosh, who was quoted in the national press when her practice was overwhelmed with requests, noted that using HA injections in the genitals is not without risk, and even went as far as to say that there are more risks associated with use in this region than with their use in the face and hands. This she noted was due to the vast amount of nerves and blood vessels that exist in the area around the clitoris, labia and the urethral opening. She said that this opens it up to risks such as nerve paralysis, bleeding, swelling and a loss of sensation during sex. Attempting to use HA fillers in the vulvo-vaginal region thus requires specialist training.

This is backed up by a **clinical paper** from 2010 which reported a case in Korea of a pulmonary embolism in a woman as a result of the illegally administered, cosmetic, hyaluronic acid injections performed by a non-medic.

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Desirial™

Introduced to the UK in early2014, **Desirial** is manufactured and distributed by the French company, Laboratoires VIVACY. This is the same company behind the Stylage range of dermal fillers used for facial rejuvenation and volumisation. It is distributed in the UK by **Rosmetics**.

Desirial is a non-animal, cross-linked hyaluronic acid dermal filler, with added mannitol, which is used to reduce the side effects of injecting hyaluronic acid, namely, redness and swelling. Desirial has been developed and marketed specifically for treating female vulvo-vaginal conditions. Offered as a non-surgical labiaplasty it is used to add volume to the labia majora and has been promoted by some clinics under the name 'labial puff'.

The HA in Desirial is made using IPN-like® Technology (Interpenetrated Network), Vivacy has created something which has two structures—the monophasic A and B structure, and the IPN-like structure. The two are mechanically independent, so Desirial is easy to inject and the increased density of its cross-linking nodes make it long-lasting. This method requires less BDDE which the company claims is more effective and results in a safer, longer lasting product.

Desirial can be used to rejuvenate the labia majora, conceal the labia minora for a more symmetrical and proportional appearance and improve dryness. Generally treatment is performed in conjunction with application of a topical local anaesthetic cream to avoid discomfort. The results are said to typically last 1 to 2 years.

There are two different formulations for Desirial – Desirial (19mg/ml) targeted at restoring hydration and Desirial Plus (21mg/ml) targeted at treating vulval imperfections, vaginal atrophy and hypotrophy of the labia majora.

Platelet Rich Plasma (PRP) Therapy

Platelet Rich Plasma (PRP) has seen a dramatic rise in use in recent years, to the point where a significant number of U.K. Aesthetic practitioners now offer this, more natural option, as a treatment for facial rejuvenation or for improving the décolletage and backs of the hands.

A PRP procedure uses the platelets and growth factors gathered from centrifuging a sample of the patient's own blood to separate it out, discarding the red blood cells and then reinjecting the plasma back into the individual. The aim being to stimulate collagen synthesis and the growth of newer, healthy tissue.

Studies are few and far between, but data is starting to show that PRP may have a place in treating some of the nuances associated with urinary incontinence problems, as noted in this **2013 study**. Platelet Rich Fibrin matrices have also been successfully studied for vaginal prolapse repair as in this **2012 study**. It's true that as always more data is needed as most results are empirical and anecdotal.

The O-Shot®

The **O-Shot®** or Orgasm Shot® originally hails from the USA, where Charles Runels M.D. is heralded as the pioneer. The aim of this treatment, which has PRP at its foundation, is to rejuvenate the vagina, to assist with urinary incontinence and sexual satisfaction problems such as difficulty reaching orgasm or painful sex.

Having gathered the PRP growth factor solution, and applied a topical anaesthetic, a very thin needle is used to inject into the clitoris and into the upper vagina into an area most associated with sexual response, the G-spot. Results are expected to be noticeable after 3 or 4 weeks.

Anecdotal patient reports include improvements in arousal from clitoral stimulation, sexual desire, the tightness of the vaginal opening and natural lubrication, as well as the ability to have a vaginal orgasm, have stronger or more frequent orgasms, and a decrease in urinary incontinence or pain associated with intercourse.

The technique is being pioneered in the UK by Dr. Sherif Wakil, who has trained many other practitioners this year.

Rejuvula

Rejuvula is a joint-creation from PRP pioneer Dr. Daniel Sister. The Frenchman, who practices in the UK, is well known for his Dracula Therapy™ concept and kit. He has trained and presented extensively on the use of PRP in

aesthetic medicine. Teaming up with Irish cosmetic nurse, Claudia McGloin, he has introduced and marketed a treatment which uses PRP for vaginal rejuvenation, together they have called it Rejuvula.

The treatment aims to help to rejuvenate vaginal tissue, enhance sexual response and help with urinary incontinence. Having performed the procedure a number of times now, the creators note that results often take a few weeks to be fully achieved, but they have been proven to last up to 18 months based on their experience to date.

"*I decide where specifically I am going to inject the PRP after consultation with the patient, as people are looking to treat different areas such as for urinary incontinence or vaginal dryness etc. I have 3 main injection points but target it to what the patient needs at that time*"; notes Claudia.

Radiofrequency

Radiofrequency or RF energy is proven to cause tissue contraction, or tightening of the collagen fibres, when an optimum temperature (heat) is achieved on penetration of the RF into the targeted tissue. Thus, much like it is applied on other areas of the body, such as the face or thighs, abdomen etc. to target skin laxity and body contouring, it can also be used on the external and internal areas of the vulvo-vaginal region to target labial skin laxity and increase the tightness of the vaginal opening. Various devices are now available and being promoted in the UK, as well as a device from America called **ThermiVa** which has yet to reach our shores but was shown at IMCAS earlier this year.

BTL Protégé Intima

The BTL Protégé Intima is part of a range of RF based devices offered by **BTL Aesthetics**, which is marketed for non-invasive labial remodelling.

According to **trial results** from the manufacturers, 80% of tested subjects noted an improvement in appearance of the area as moderate or excellent; the remaining 20% noted only a mild or no improvement. 60% reported an improvement in sexual satisfaction of moderate or excellent and the remaining 40% mild improvement.

A water-based gel is first applied to the skin of the outer labia and the RF energy is delivered in pulses as the hand-piece is moved across the area. Treatment time is short and some improvement is noted immediately post treatment, with additional tightening over time as the collagen remodels; a treatment programme of four sessions are usually recommended at a cost of around £1,000 to the patient.

Treatment is promoted as pain-free with patients just feeling a warming sensation during treatment.

Viveve®

Viveve is manufactured by an American women's sexual health company based in California. It is not yet available for sale in the United States due to a current lack of FDA approval, but is approval for sale in Canada, Europe and various countries in Asia. It is distributed in the UK by **CoachHouse Medical Ltd** who have been pioneering its use in the UK since this summer with Dr. Sherif Wakil, who has the first device in the UK.

It's targeted at treating vaginal laxity (especially post childbirth), which can cause a decrease in sexual satisfaction and physical sensations during intercourse, through the use of patented radiofrequency (RF) energy to produce vaginal tightening.

The device itself consists of a table-top unit with a specially designed hand-piece featuring a single-use treatment tip.

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During a 30-minute procedure this tip is inserted just inside the vaginal opening and the RF energy is delivered, in conjunction with cooling, as the tip is moved in a clockwise or anticlockwise rotation around the circumferential vaginal opening. The pulsed delivery of RF causes collagen contracted in the underlying tissues, leading to the stimulation of new collagen formation over the following 30 to 90 days and continued improvement at 6 and 12 months. The overlying tissue is not damaged so there is said to be little to no downtime or pain and no local anaesthesia is required during the procedure. Typical complications noted include redness, swelling, slight abdominal discomfort, white vaginal discharge, tingling or altered sensation after treatment – all are said to be mild and temporary, resolving quickly. Rarely infections can occur. The manufacturers do also note that although it has never been reported and did not happen in trials, there is a potential risk of damage to the urethra or rectum.

To date the treatment has been tested in two prospective clinical trials in the USA and Japan which assessed the safety and efficacy of the treatment. The results from both studies showed that at 12 months after treatment vaginal tightness improved significantly (for 88% of women in the study), often to pre-childbirth levels, with a 68% mean increase in vaginal laxity scores, with no serious adverse effects reported in either study. No data after 12 months has been gathered, so the long-term effects and their longevity are currently unknown.

CO_2 Laser

CO_2 lasers are the ultimate in ablative lasers, attracted to the chromophore of water, more so than your average frog, their resurfacing power is immense. Over the last decade, we have seen this power tamed and harnessed into more controllable fractional forms which create only micro-spots of ablated tissue. This technology is now being used for vulvo-vaginal treatments too, yet some feel that despite apparent good results from it, comprehensive data is still lacking.

Hot off the press this December, Dr. S. Stefano et al published a **review study** in which they looked at the literature regarding the safety and efficacy of the use of a pulsed CO_2 laser for the treatment of vulvo-vaginal atrophy. They concluded that "*increasing evidence with histological and clinical data supports the use of pulsed CO_2 lasers in the treatment of vulvo-vaginal atrophy; however, no randomised control trial (sham versus treatment) has yet been produced and no data on the duration of therapy are currently available.*"

FemiLift® by Alma Lasers

FemiLift, which is marketed to achieve vaginal tightening to relieve stress urinary incontinence, is manufactured by Alma Lasers and distributed in the UK by ABC Lasers.

FemiLift uses a fractional CO_2 or carbon dioxide laser which creates tiny, white, ablated dots on the mucosal tissue inside the vaginal canal. As with other fractional laser techniques used in aesthetics, the principle is that this stimulates the healing response in the non-ablated tissue surrounding each micro-dot, and thus collagen synthesis results and the thickness of the vaginal lining is improved. The probe used to deliver the CO_2 energy has a 360° rotation and is used with a single use, hygienic sleeve.

The device has a history in gynaecological applications where CO_2 lasers have been used by medical practitioners for several decades to remove genital warts and some cancers.

According to a manufacturer backed study from 2013 by Dr. Gabriel Femopase and Dr. Ignacio Lares in Argentina, which looked at 72 FemiLift patients, using the Female Sexual Function Index before, and 60 days post treatment - the results showed that 87% of patients experienced an increase in the overall score of tightening, level of improvement, satisfaction and vaginal lubrication, 10% of which was a mild improvement. Only 3% didn't report any changes at all.

A course of up to 5 treatment sessions in recommended, spaced two to four weeks apart.

MonaLisa Touch® by DEKA/Cynosure

The MonaLisa Touch® is a CE marked fractional CO_2 laser treatment manufactured by the Italian company **DEKA** (and distributed by Cynosure) which is marketed to treat vaginal atrophy.

The treatment is based on their SmartXide^2 system (which was introduced in Europe in 2008) with their HiScanV^{2}LR scanning system which they claim guarantees optimal reliability and performance due to their exclusive CO_2 laser which has PSD® (Pulse Shape Design) technology, a special pulse designed for this treatment application.

Developed for facial aesthetic applications, the HiScanV^{2}LR scanning system is used to make sure that the correct and precise delivery of the ablated micro-spots occurs – this can be done in single dots, lines or square formation with spacing from 0 to 2000µm. It comes with a wide range of different probes for treating the inside of the vagina and for treating the external, vulvar side. These include a probe that emits the laser energy in a 360° fashion, there is a graduated scale, together with a vulvar ring, which allows complete control on the treatment uniformity, and three single-angle probes are available for treating vaginal atrophy, urinary stress incontinence and vulvar treatments.

A variety of published papers are now available which evaluate the use of the MonaLisa Touch. Dr. S Salvatore et al published a **paper** in April 2015 which looked to investigate the effects of its use on sexual function and overall satisfaction with their sexual life in postmenopausal women with vaginal atrophy. The prospective study looked at 77 patients and concluded that the MonaLisa Touch treatment was associated with a significant improvement in sexual function and sex life satisfaction in the targeted group.

Er:Yag Laser

When it comes to the use of lasers in vulvo-vaginal procedures, the use of an Er:YAG (2940nm) is considered to be less invasive than using CO_2 laser, with faster healing times. This is backed up by some published studies. Like carbon dioxide lasers, the chromophore for erbium YAG lasers is water, which is in abundance in the mucosal tissues of the vagina. With adjustable pulse lengths, the Er:YAG is considered to be gentler with less risk of tissue necrosis or carbonisation, as can happen with over-zealous use of a CO_2 laser. The use of the erbium YAG laser is targeted at treating stress urinary incontinence, vaginal atrophy and a condition known as vaginal relaxation syndrome or vaginal laxity which is associated with the overstretching of the vaginal canal during childbirth, but can also be a natural problem caused by ageing and menopause. Pubmed reveals quite a significant amount of clinical data for the use of Er:YAG lasers for these indications.

ACTION II Petit Lady by Lutronic

The **ACTION II Petit Lady™** from Korean manufacturer **Lutronic** received a European CE Mark for the treatment of vaginal relaxation syndrome and stress urinary incontinence in June 2014. This is an expansion to the existing applications for the ACTION II device which is already used for aesthetic treatments. Prior to its European launch, the ACTION II Petit Lady was clinically proven in Asia and the Middle East, showing a statistically significant improvement in vaginal relaxation without pain, safety issues, or side effects.

The device is marketed with two specially designed hand-pieces for cosmetic gynaecology the Petit Lady 360° hand-piece which delivers micro-pulses of 2940nm Er:YAG laser to all the vaginal mucosa and tightens the vaginal canal through collagen remodelling, and the Petit Lady 90° hand-piece which is intended for treating stress urinary incontinence by producing an enhanced thermal effect which caused shrinkage in the endopelvic fascia, ligaments and mucosal tissue in the anterior vaginal canal. A fractional hand-piece is also available.

The ACTION II has three independent operating modes which can be combined for maximum clinical efficacy - including the multiple micro-pulsed mode for precise epithelium ablation and the long-pulsed mode up to 1000ms for a non-ablative thermal effect which can be combined into a unique dual mode which allows a deeper secondary thermal effect and controlled heating of the delicate target tissues of the vaginal wall to stimulate collagen synthesis.

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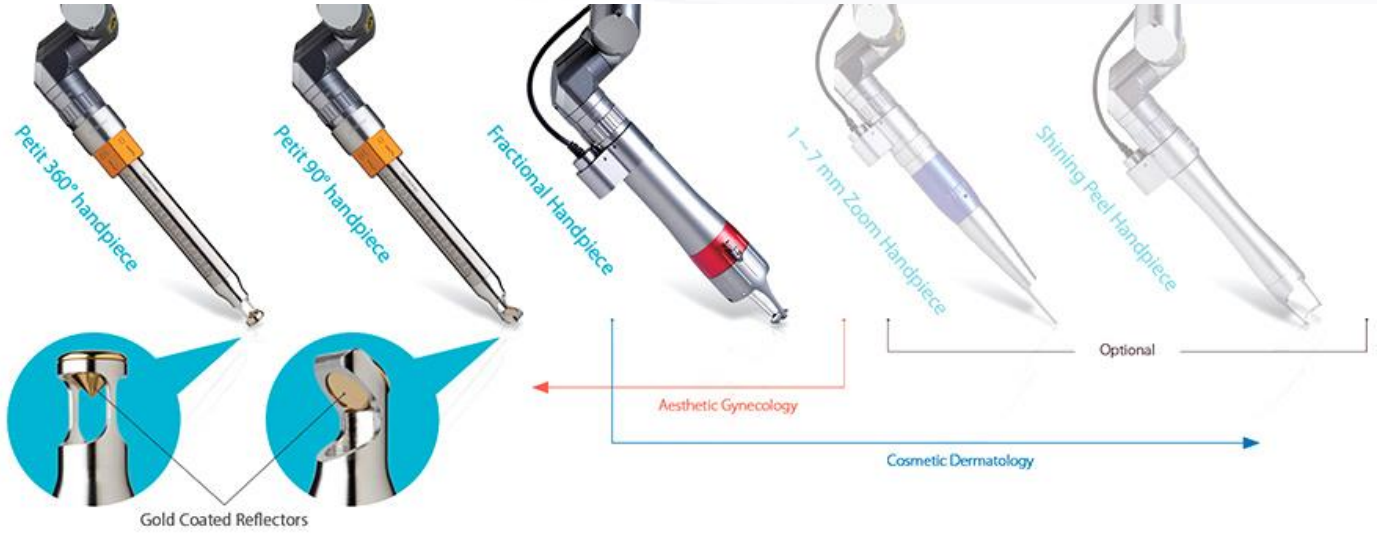

A course of treatments is usually recommended consisting of 3 sessions at two week intervals.

A **study** from 2014 which evaluated the clinical efficacy of the ACTION II Petit Lady for vaginal relaxation syndrome looked at 30 women. The participants were split into two groups and different protocols were delivered using the 360° and 90° hand-pieces. All completed the study with no adverse effects. Both groups, with their differing protocols, produced significant improvement in vaginal relaxation.

IntimaLase®, IncontiLase® and RenovaLase® by Fotona

Slovenian-based Fotona manufacture a variety of European CE approved laser products and market two of their systems for aesthetic gynaecological applications. Their multi-application laser platform FotonaSmooth SP which includes an Er:YAG, Nd:YAG and QCW (Quasi Continuous Wave) Nd:YAG lasers and their FotonaSmooth XS stand-along Er:YAG laser are both used for the IntimaLase®, IncontiLase®, and RenovaLase® treatments. The company is credited as the first manufacturer to introduce Er:YAG laser wavelengths into gynaecological applications.

They include adjustable ablative technology so that gentle ablation and non-ablative thermal injury can be used to maximum effects, and better precision, for this type of treatment. A wide variety of hand-pieces are available for use with the FotonaSmooth platforms including gynaecologically shaped solutions - such as one which comes with a 4mm spot size and a detachable and sterilisable tube and another with variable spot sizes from 2 to 7mm which is designed for use with specialised gynaecological adapters for performing minimally invasive procedures.

The IntimaLase® is marketed for tightening the vaginal canal through photothermolysis with the 2940nm Er:YAG laser to treat vaginal relaxation syndrome.

The application of the laser stimulates collagen remodelling and new collagen synthesis in the vaginal mucosa tissue and the collagen-rich endopelvic fascia, this then results in a tightening of the vaginal canal, improved quality of life and greater sexual satisfaction for patients. Two treatment sessions are recommended for optimal results.

Clinical trials have shown this treatment to be a safe, fast and easy procedure to perform with high levels of patient satisfaction. The company note that the average shrinkage of the vaginal canal after IntimaLase treatment was 17% in studies.

The IncontiLase® treatment also uses the 2940nm Er:YAG laser for treating mild to moderate stress urinary incontinence. The process is essentially the same as the IntimaLase, with application in the region of the vestibule and urethral orifice, as well as the anterior vaginal wall; the result being that with increased tightening of the vaginal mucosa tissue there is greater support provided for the bladder and normal continence should be restored.

Several multi-centre studies which were evaluated have shown both the IntimaLase and the IncontiLase to be promising treatments for vaginal relaxation syndrome and stress urinary incontinence.

The RenovaLase® treatment again utilises the 2940nm Er:YAG laser, this time for treating the symptoms of vaginal atrophy. The principle of the treatment is very much the same as the others with the final result being increased epithelial thickness and vascularisation of the lamina propia, to reduce symptoms such as dryness, irritation or itching and painful sexual intercourse. The manufacturers point out that studies have shown that it also eliminates the need for long-term oestrogen treatment.

A 2013 **study** published by Dr. Gaspar in Argentina compared the RenovaLase treatment using the 2940nm Er:YAG laser to his previous device of choice, a 10600nm CO_2 laser for treating vaginal atrophy. He used 70 patients in his study, split into two groups of 35, one group were treated with the Er:YAG and the other with the CO_2. The results and his conclusions were that the RenovaLase is gentler and less invasive than the ablative CO_2 procedure. In addition, he noted that the RenovaLase could provide better results, avoiding undesirable complications that are present in more invasive laser treatment alternatives. He sounded a word of caution that; "*Although our findings suggest that treatment based on the principle of selective photothermolysis can increase tissue metabolic activity and thereby improve the conditions caused by vaginal atrophy, more research is needed to better address the use of lasers for this purpose.*"

Training is provided by the affiliated not-for-profit **Laser & Health Academy** which holds regular workshops in the use of Fotona lasers across Europe. Fotona lasers are distributed in the UK by **ABMEtech Ltd**.

Juliet by Asclepion

The Juliet treatment is the newest Er:YAG laser application to hit the UK for vulvo-vaginal treatments. Dr Harryono Judodihardjo is the first clinician, at his clinic in Cardiff, to have the device and will be the key opinion leader and training centre for it.

Manufactured by German company, Asclepion, who are credited with manufacturing the first erbium laser for dermatology and aesthetic applications, the Juliet treatment is based on the Asclepion MCL31 Dermablate device which is a 2940nm Er:YAG laser. Juliet is marketed as the feminine laser. Like other devices on the market it is indicated for treating vaginal relaxation syndrome, vaginal atrophy and stress urinary incontinence.

The Juliet treatment uses a specially designed V-Spot hand-piece which consists of a stainless steel tube with a quartz window and a gold mirror inside it. The optic is inserted into the tube (which can be autoclaved after use) and is secured with a special screw cap. The laser beam exuded from the device heats the gold mirror and is reflected at an angle of 90° through the window onto the vaginal tissue.

The V-Spot hand-piece also features a specially designed MicroSpot optic with a squared spot of 9mm x 9mm, consisting of 169 MicroSpots. This allows for fractional delivery. A 360° hand-piece is also available with a reflecting gold-coated cone.

Findings from a **prospective study** by Dr. Evgenii Leshunov, who some of you may have seen presenting on this subject at last summer's FACE conference, confirmed high efficacy and an acceptable safety profile for the Juliet treatment for urinary stress incontinence.

Asclepion lasers are distributed in the UK by **Carleton Medical Ltd**.

Other Treatments

The above is not an exhaustive list of non-surgical treatment options that are being used in vulvo-vaginal procedures. There are many other solutions and aesthetic techniques that are being tried and tested by practitioners. Similarly traditional medicine includes the prescribing of hormonal solutions, depending on the age and menopausal status of a woman.

It have been noted that PDO or polydioxanone threads are now being used in the labia majora for tissue tightening and collagen stimulation. This enhancement is said to be preferable for some patients, in place of the use of fillers, where such augmentation would increase visibility and prominence through tight clothing (causing the camel toe

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effect). The use of surgical sutures is of course nothing new in this area, being commonplace firstly in the practice of perineoplasty where the perineum is repaired with the placement of dissolving suture threads.

Another treatment is carboxytherapy, the application of carbon dioxide gas through small injection points causes the body to react to oxygenate the area with oxygen rich blood, thus activating the healing processes and new cell proliferation in the area. Several treatment sessions are usually recommended. No published studies could be found to support the use of carboxytherapy in the vulvo-vaginal region however.

Summary

One thing that we can always be sure of in this industry is that when someone introduces a new concept or treatment type there will be those who get excited, those who sit back and shake their heads, and those who decide to wait and see before nailing their colours to the post. The aesthetic industry is nothing if not controversial, so just like vitamin drips and fat reducing injections, the notion of non-surgical vulvo-vaginal treatments as part of aesthetic medicine is ripe for debate and fist-fights!

One doctor told me that he felt that, "*there are far too many amateurs teaching these "techniques" and making some very wild and completely unsubstantiated claims*".

Yet, there are many well-known UK aesthetic professionals embracing this sector and claiming to see great results and feedback from their patients. But all seem to offer a word of caution to their industry colleagues – training and understanding is key, as is patient expectation and psychological vulnerability.

Dr. Kathryn Taylor-Barnes who has pioneered the use of Desirial in the UK pointed this out to me; "*The practitioner needs to really tap into their client's psyche with this particular treatment as it's such a sensitive area to volumise. A degree of hand-holding post-procedure is vital to ensure an optimal outcome.*"

It's clear to see, particularly when evaluating the products and devices which are being actively marketed to the aesthetic industry, that there is a blurring between the concepts of cosmetic treatment (make it look nice, less old, rejuvenate it etc.) and medical concerns (sex is painful, childbirth or the menopause has made me slightly incontinent etc.). Historically, gynaecologists would treat the medical, but with a cash strapped NHS, even this started to move into the private sector, so perhaps it's a natural move that whilst a medical condition is addressed, a cosmetic one comes along for the ride and the private clinics involved in treatments expand to include those already involved in cosmetic treatments.

As I was researching this article it became apparent to me that the anatomical learning required presents a pretty big curve for anyone with currently limited experience in this area, and cosmetic medical practitioners really need to think carefully about their skills to date, and their desire to immerse themselves in the gynaecological journey.

Although, not always practiced, (no doubt always advised by the gynaecologists), some practitioners are recommending PAP smears and pregnancy tests (in peri-menopausal women) prior to embarking on any of the energy based treatments. Having the time and resource to do this may not be something that aesthetic practitioners wish to do or indeed feel the need to do – could that be problematic, who knows. Makes you think though doesn't it!

Any practitioner thinking about getting involved in this sector really needs to think about their motivations, their skills and knowledge and how this all fits in (or doesn't) with their existing cosmetic practice. This is such a growth area that long-term we will be dedicating a whole section of The Consulting Room's treatment information pages to this, as more and more aesthetic clinics are now offering solutions for vulvo-vaginal concerns. Are you one them?

Lorna Jackson

Lorna has been Editor of The Consulting Room™, the UK's largest aesthetic information website, for over a decade, since 2003. She has become an industry commentator on a number of different areas related to the aesthetic industry, collating and evaluating statistics, plus researching, investigating and writing feature articles, blogs, newsletters and reports for The Consulting Room™ and various consumer and trade publications, including *Cosmetic News, Journal of Aesthetic Nursing, Body Language*, *PMFA News*, *Aesthetic Medicine* and *Aesthetic Dentistry Today.* Lorna has also been asked to present at various industry events, including Smart Ideas, BACN and Merz Aesthetics Business Workshops, the FACE Conference and the Clinical, Cosmetic & Reconstructive (CCR) Expo. She was awarded *Journalist of the Year* at the MyFaceMyBody Awards 2014.

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