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Female intimate surgery: review of methods and trends

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Plastic surgery and cosmetology. 2014 (2)161-320

Abstract (as provided in the Russian publication)

The work presents the review of the present literary data on the history, methods and tendencies of development of female intimate surgery. The methods of performance of the procedures are described considering the reports of surgeries made in the clinic of Prof. Yutskovskaia.
1. INTRODUCTION

Procedures aimed at correcting appearance and restoring functions that are carried out in the female urogenital area are customarily referred to as intimate plastic surgery (IPS). This surgery includes traditional methods of correcting vaginal prolapse and looseness of the vaginal vestibule, and also aesthetic correction of the vulva. The boundary between medical and aesthetic indications for the performance of procedures is blurred, and nowadays many operations are carried out with both objectives in mind.

A major contribution to the development of this sphere in the world is provided by cooperation between gynaecologists, urogynaecologists and reconstructive surgeons. Unfortunately in Russia we see a complete lack of mutual understanding between specialists engaging in “sexual medicine”, so that it is not possible to talk of the quality of the results of intimate plastic surgery or of sexual wellbeing as a whole. At the first interview with a prospective patient, a gynaecologist or surgeon should be able to provide a patient, who is looking to have intimate plastic surgery with a full and informed explanation concerning all the options and the potential for correction in the urogenital area. The patient should, in addition, be examined by a psychologist to check for dysmorphophobia. It is important to be sure that the woman is taking the decision independently, without any coercion or pressure from her sexual partner.

Historical information

The previous history of female intimate surgery is associated with genital surgery – ritual manipulations that date back deep into antiquity and have distinct ethnic characteristics. Some approaches and methods used in modern-day sexual surgery have, however, been assimilated specifically from these rituals. One particular aspect of this surgery is that operative intervention is, in a number of cases, carried out not because of medical indications, but in connection with the patient’s dissatisfaction with her sex life.

Female genital mutilation is an operation that consists in the removal or resectioning of parts of the female genitalia, up to and including removal of the tip and part of the body of the clitoris (clitoridectomy) and the labia minora, performed without medical indications. As things stood in 2008, between 100 and 140 million women had undergone this operation, mainly in Africa (in Egypt, Sudan and Ethiopia, more than 80% of women have this operation), and also in Saudi Arabia and Indonesia. With time, it was female ritual circumcision that served as a prototype for female intimate cosmetic surgery.

To begin with, female intimate cosmetic operations were common among commercial sex workers, nude models, bathing suit models, actresses who appeared naked and certain categories of women suffering from such diseases as urinary incontinence, congenital sex organ development defects or birth-related injuries.

Articles about female intimate plastic surgery first began to appear in North American journals in 1978, and the first article describing a method of correction of the female urogenital area appeared in 1984 [1,2]. When Gary Alter presented the results of his own labiaplasty, vaginoplasty and G-spot enlargement work in 1998, there was a sea change in world opinion concerning intimate surgery. Although operations to tighten the vagina had been carried out earlier, the difference in the new method was that they incorporated aspects of plastic surgery, and concentrated on the appearance of the vulva [3].

Intimate filling as a method appeared at the end of the 1990s, and did not begin to be actively used until after 2000. When the method first began to be practised, various fillers were widely used to augment the tissues of the anogenital area, and on occasion some of these did not meet safety requirements. In the USA, for example, numerous complications were seen that were linked to the use of implants based on bovine collagen and liquid silicone. For a long time a leading role in intimate plastic surgery was taken by lipofilling, often in combination with liposuction of the pubic region and the inside surfaces of the thighs. The first experience of lipofilling of the anogenital area was described by E. Hernandez-Prez in 1996 [4]. Following the commencement of use by cosmetologists of hyaluronic acid based products, doctors performing intimate zone correction also began to take a closer look at these. The first publications concerning the safe and effective use of products containing hyaluronic acid in sexual surgery appeared in 2003 [5]. In 2006, the Italian plastic surgeon A. Alessandrinia was the first to familiarise a Russian audience, at a congress in Moscow, with intimate filling methods [6]. Since 2006, Professor Ya.A. Yutskovskaia and her colleagues have been engaged in the development and introduction of intimate filling methods for correction work in the anogenital area.

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6 This 3-word phrase is given in parentheses, in English, in the Russian text; but the Russian word translated as ‘mutilation’ – обрезание – literally means ‘circumcision’, and contains none of the overtone of ‘mutilation’, so where it occurs subsequently I have translated it as ‘circumcision’ – Translator.
In discussing sexual medicine generally, mention must be made of the role played by professional medical societies. The International Society of Cosmetogynecology (ISCG) is the first, and the world’s largest, association of specialists in aesthetic gynaecology and intimate surgery. It was founded in 2004 by Marco A. Pelosi II and Marco A. Pelosi III, and takes in over 700 members and more than 30 countries. The society was set up with the aim of consolidating academic knowledge in the sphere of female intimate aesthetics and of making changes to gynaecological practice. Moreover the organisers appreciated that doctors working on sex-related problems enter into unique relations with patients, which provides an opportunity for fuller aesthetic control. It is important to make the point that as medical activities become increasingly commercialised, the market for services on offer in the sphere of sexual medicine will grow, while the lack of a legal field in this area enables these services to be licensed in the certification register for a variety of types of medical activity. So perhaps specialists engaged in sexual medicine, be they urologists, gynaecologists or cosmetologists, will not run up against ethical/legal problems, but by the same token patients can anticipate strictly medical problems of quality control for the provision of medical services.

2. INTIMATE SURGERY

Women’s views

Women go to a doctor both for aesthetic correction and because of functional disorders, including pain during the sex act or while engaging in sport, frequent irritation, vulvalintertrigo and discomfort while wearing underwear or clothing.

Women aged 18-44 prefer to undergo epilation in the bikini zone, which makes for better visualisation of the vulva [7]. In 2008, D. Herbenick and colleagues carried out a study in which 2 500 women took part. The extent of the practice of pubic hair removal was investigated, and the ways in which it was done, and the influence of pubic pilosis on the quality of one’s sex life. The study results gave rise to the conclusion that a complete absence of pubic hair is linked to a higher FSFI (sexual function index) level [8].

Konig and colleagues discovered that 78% of 482 women questioned had learned about labiaplasty through the media, while 14% thought that their own labia minora looked abnormal [9]. A feeling of awkwardness, “changing-room syndrome” and problems with sex life are also commonly adduced as reasons for wanting intimate correction. Bearing in mind the possibility of congenital deformations of the vulva, psychological problems may occur during the early adolescent period [10].

Possible dysmorphophobia should be borne in mind: one way or another it is the media who are to blame for this, by giving coverage to it in women’s magazines, alongside fashion and the accessibility of pornography on the Internet. Meanwhile the rise in the popularity of the procedures has spawned TV reality shows, where the subject of the ideal appearance of female external sex organs has been actively pursued. Michala and colleagues described a study of 16 girls (average age 14.5) who went to a clinic to have their labia minora (LMin) reduced in size [11]. Six girls were worried about LMin asymmetry, while 10 complained of protrusion of the labia minora, regardless of their normal size.

The concept of ideal external sex organs among women in Western countries differs from that among women in other countries. In Rwanda and Mozambique, for example, extended labia minora are considered attractive [12], whereas in Japan the most attractive vulva is considered to be one shaped like a butterfly (fig. 1) [13].

Fig. 1. Vulva that looks like a butterfly.
Doctors’ views

Traditionally, it has been gynaecologists who engaged in surgical correction of the vagina and vulva. Since growing numbers of urologists and plastic surgeons are carrying out labiaplasty, intimate filling and cosmetic vaginal operations, the need for correction of complications following interventions is steadily increasing. Most surgeons perform intimate plastic surgery without having had any training in aesthetic vaginal surgery. This gives rise to complications such as non-aesthetic appearance, functional incompetence of the vulva and sexual dissatisfaction. Increasing numbers of patients come to us for correction of such complications as asymmetry, excessive tissue removal, loss of sensitivity and pain in the vulvar area. Around 10% of interventions in the urogenital area that are performed at our centre arise out of unsuccessful operations.

In general, cosmetic surgery on the vulva does not require medical indications. According to the results of the consensus adopted in 2007 by the American College of Obstetricians and Gynecologists, the medical indications for intimate surgery are:

- the need to reconstruct the vulva following circumcision;
- asymmetry and hypertrophy of the labia minora;
- sclero-atrophic processes in the vulva;
- hypertrophy of the clitoris as a result of an excess of androgens.

Most surgeons, however, perform intimate plastic surgery with aesthetic objectives or to improve the quality of sex life of the woman and her partner. In a multi-centre, retrospective study, 76% of 258 women had an operation for functional reasons; 53% underwent an operation for cosmetic reasons and 33% to improve self-esteem. Fifty four percent of women who underwent vaginoplasty/perineoplasty and 24% of those who had the combined procedure, including vagino-/perineoplasty, labiaplasty and plastic surgery on the hood of the clitoris, did this to increase their partner’s sexual satisfaction [14].

3. METHODS

Vaginoplasty

Vaginoplasty is an intravaginal operation. Vaginoplasty is not intended to eliminate defects in the pelvic floor, but this reconstructive procedure is a modification of traditional colporrhaphy and is often carried out in conjunction with reconstruction of a pelvic floor prolapse.

Classically, the vaginoplasty procedure involves anterior or super-posterior colporrhaphy, modified by the use of plastic surgery methods, excision of the lateral wall of the vaginal mucosa, and also a combination of these methods. Practical experience has shown that, in contrast to other methods, lateral colporrhaphy is less often complicated by a scar process. Ablation or excision of strips of the mucosa from the lateral walls of the vagina enables the diameter of the vagina to be perceptibly narrowed, looseness of the vestibule to be eliminated and the quality of the sex life of the woman and her partner to be improved, but may not be used with prolapse of the pelvic floor (fig. 2) [15,16]. This operation is currently used to treat “vaginal relaxation” syndrome. To achieve a better result, the procedure may be combined with perineoplasty and labiaplasty. We have improved on the classical vaginoplasty method, so we can carry out some of the procedures under local anaesthesia. Thus instead of a scalpel we make use of a latest-generation Surgitronradio-frequency apparatus (Ellman International, USA) which enables us to make incisions with exceptional precision and the minimum of trauma. The procedure takes about 60 minutes, and the rehabilitation period 10-15 days.

Complications following an operation to tighten the vagina include dyspareunia, a defect in the mucosa which takes a long time to heal and stress urinary incontinence [17]. In Goodman and colleagues’ study, 16.6% of women reported complications, including poor healing of wounds, dyspareunia, post-operative haemorrhaging, pain, excessive constriction of the vestibule and injury to the intestine or bladder with the creation of fistulas [14].

Fig. 2. Diagram of performance of a lateral colporrhaphy.

The dotted line shows the zones of excision of vaginal tissues.
In the past, patients with a high risk of haemorrhage and low regenerative capacity used to undergo vaginoplasty using neodymium, diode or CO\textsubscript{2} lasers [18]. Nowadays CO\textsubscript{2} and erbium lasers are universally used. The action of the laser is aimed at the submucosal layer, where a thermal impact is used to begin remodelling of the extracellular matrix, which in turn has the effect of increasing the elasticity of the vaginal wall and tightening of the vagina. A. Gaspar and colleagues assessed the impact of two fractional laser systems – CO\textsubscript{2} and erbium lasers – in conjunction with the topical use of platelet-enriched plasma and pelvic floor exercises. An improvement in the condition of the vaginal wall and a tightening of the vagina were observed in both groups, but more complications were recorded in the patient group on which a CO\textsubscript{2} laser had been used. Complications following the use of a CO\textsubscript{2} and an erbium laser include a burning sensation and excessive tightening of the vagina [19].

At our clinic we use a sixth-generation erbium laser made by Asclepion (Asclepion Laser Technologies GmbH, Germany). The MCL-31 laser system was first used for a gynaecological operation in December 2013 (fig. 3). A provisional analysis of the results of the first 15 procedures supports our view that the level of efficacy and safety of this laser system is high. The rehabilitation period takes 3-5 days, depending on the individual characteristics of the woman. Protocols are currently being drawn up for procedures with a variety of changes to the vagina.

![Fig. 3. The Asclepion MCL31 erbium laser (a); Asclepion handpieces for treatment of vaginal relaxation syndrome and stress urinary incontinence (b).](image-url)

There are separate reports concerning the use of lipofilling and hyaluronic acid gels with the aim of tightening the vagina [20]. In our view, fillers are not suitable for use in this procedure, and we would like to warn that this procedure is still in the experimental stage.

Despite a lack of studies meeting the requirements of evidence-based medicine, following aesthetic vaginoplasty patient satisfaction is high as regards both medical and functional results and also psychological results. It is not clear
whether some kind of ablative or non-ablative laser technology will be developed, or an ultrasound or radio-frequency system, which could be used to address the problems of pelvic floor muscle prolapse. The existence of undesirable events means that lengthy monitoring is needed to analyse long-term efficacy and safety.

Perineoplasty

The visible area between the vagina and the rectum is known as the perineum. This is an area where tearing and distension often occur, and kraurosis, and where episiotomies and perineotomies are performed during natural childbirth. Plastic surgery on the perineum (or perineoplasty) is carried out to restore the normal structure of this area through excision of surplus skin, plastic surgery on scar lesions following an episiotomy and insertion of sutures on the muscles of the perineum to eliminate looseness of the vestibule and tighten the entry to the vagina. Most plastic surgeons who carry out vaginoplasty actually perform a perineoplasty as a simpler method of correcting the anterior part of the vagina. Perineoplasty is often combined with labiaplasty and super-posterior colporrhaphy [21].

The following indications for a perineoplasty may be listed:

- existence of scarring to the perineum;
- looseness of the vaginal vestibule;
- low position of the perineum;
- kraurosis.

The performance method comprises excision of a rhomboid area on the perineum above the anus and within the confines of the vaginal vestibule. The lateral boundaries are the remnants of the hymen. The bulbocavernous and superficial transverse muscle of the perineum are identified, and these are subsequently sutured to create the effect of a tightening of the vaginal vestibule, raising the edges of the vestibule and restoring the structural integrity of the perineum (fig. 4).

This procedure is carried out under local anaesthetic with excision of scar tissue using radio-frequency or laser technologies. Use of an erbium laser enables the removal of rough edges and surplus skin, resection of skin neoplasms, enhancement of skin elasticity and elimination of skin hyperpigmentation (fig. 5).

Fig. 4. Diagram of how a perineoplasty is performed in conjunction with an anterior colporrhaphy
Fig. 5. Patient, aged 39, before and after perineoplasty and laser vaginal rejuvenescence (photography from archives at Professor Yutskovskaia’s clinic).

Labiaplasty

The dimensions of the LMin are individual for each woman and change during the course of her life. In the anterior part, the widest part when spread, the breadth of the LMin is on average from 2 to 4 cm. During the course of life, under the influence of endogenous (hormones) and/or exogenous (injury or wearing of underwear) factors, there is a change in shape and loss of function in the LMin, and such changes are known as involution [22].

Hypertrophy of the labia minora comes as an increase in the size of the LMin, leading to a decrease in the erectility and sexual hypo-aesthesia both of the LMin themselves and of the tip of the clitoris.

Elongation of the labia minora is a lengthening of the LMin by more than 5 cm in their peak state of extension. Most women think that the ideal length of the LMin should be within 1 cm in a non-extended state.

Protrusion of the labia minora is when the LMin protrude from the sexual cleft, whereas they should be fully concealed by the labia majora (LMaj).

Besides elongation and hypertrophy of the LMin, a distinct, to a greater or lesser extent, asymmetry in them is a common enough observation, linked to anatomical idiosyncrasies and constituting a version of normal development of the external sex organs. Asymmetrical labia usually give women greater discomfort than labia that are evenly enlarged.
Labiaplasty is a procedure that entails a diminution in or alteration of the shape of the LMin. Labiaplasty not only enables the shape of the LMin to be altered, but may also be used to eliminate pigmented areas and excess wrinkles. Labiaplasty is usually carried out when there is lengthening (elongation) or asymmetry of the LMin. Any non-malignant formations (e.g. papillomas and condylomas) of the LMin may also serve as a reason for surgical intervention. When labiaplasty was being developed, its objective was to reduce the size of the LMin and to remove pigmentation and excess wrinkles, so the main method was considered to be marginal (linear) resection. But this method has serious deficiencies associated with loss of sensitivity and of the natural appearance of the vulva. At many clinics, however, this method is used because it is simple to perform (fig. 6) [23].

The de-epithelisation method entails the creation of an elliptical de-epidermised area on the surface of the LMin while maintaining the integrity of the underlying tissues. This is the least destructive method, but still has a number of drawbacks, the most fundamental of which is the lack of potential to use the method with hypertrophy of the LMin to over 4 cm, since in this case their thickness is significantly increased. At the current stage of development of labiaplasty, a combination method is most commonly used, which means outline resection with elements of the de-epithelisation method (fig. 8) [25].

Outline resection is carried out according to the canons of plastic surgery, using W-Y- and Z-plasty elements. There is virtually no risk of complications when this is done. When the intervention is carried out, it is best that intradermic sutures are used. One drawback of the method is a lack of efficacy with very distinct pigmentation of the urogenital area (fig. 7) [24].

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**Fig. 6.** Diagram of performance of marginal (amputational) labiaplasty.

**Fig. 7.** Diagram of performance of outline resection.
There are dozens of ways and methods of performing this operation, but they all have their own advantages and drawbacks. We have come up with a unique algorithm for selection of a method individually for each patient.

The advantages of the “laser scalpel” over the surgical one come down to a more accurate incision line, absolute sterility and a lack of sutures and scars. The operation time and rehabilitation period are significantly curtailed. LMin correction using a surgical laser is basically carried out using a CO₂ and Nd:YAG-laser. We also make use of a radio-frequency method to perform labiaplasty.

**Fig. 8. Diagram of performance of de-epithelisation labiaplasty.**

Following a resection, an intradermic cosmetic suture is usually applied. At the end of the operation, a long-lasting local anaesthetic is introduced into each LMin, which enables the patient to return home with no problem on the day of the operation. Since the area of the genitalia features a good blood supply, the mucosa heals quite quickly and no perceptible scars are left behind.

Following the operation, the recommendation is to apply antiseptic agents to treat the wound margins (5-6 times a day) for 7 days. For 2-3 weeks it is best not to go to gyms, swimming-pools or saunas. Sexual contacts are ruled out up to 3 weeks. The patient will not have any social life for just 1-2 days. Complications are encountered extremely rarely when a labiaplasty is performed, and they are mainly linked to individual idiosyncrasies of the body. The commonest complications are haemorrhaging lasting more than 3 hours and the formation of haematomas, which sort themselves out within no more than 4 days [26].

We conducted a retrospective analysis of 130 patient outpatient cards following surgical labiaplasty. Complications were encountered in 12% (15 patients), and these included pain in the area of the post-operative wound that lasted more than 3 days for 20% (3 patients), and LMin hypaesthesia in 46% (7 patients). There was also hyperpigmentation in the post-operative suture zone in 34% of cases (5 patients). Through a prospective assessment of the patients’ sexual function before and after the operation, conducted using the Female Sexual Function Index (FSFI) questionnaire, we established that the procedure undergone had had a positive impact on the women’s sexual health.

Plastic surgery on the hood (extreme tip or mantle) of the clitoris. An enlargement of the LMin in the upper third is commonly accompanied by an enlargement of the hood of the clitoris, which leads to an aesthetically unsatisfactory appearance, sexual hypaesthesia and a diminution in sexual satisfaction. Genetics, hormonal changes and the nature of the woman’s sex life may introduce substantial changes into the way the clitoral area looks. A poorly performed labiaplasty, not taking into account surplus skin in the clitoral area, may give rise to a disruption of the structure of this area.

At our clinic we carry out surgical correction of folds of skin to the side of the clitoris. At the same time as this procedure, correction of the frenulum of the clitoris is carried out to fix the head of the clitoris in a sexually advantageous position. The clitoris and its nerves are not directly involved in this. The procedure of surgical correction of the hood of the clitoris takes place under outpatient conditions, under local anaesthesia. The procedure takes 30 minutes and the rehabilitation period is 7-10 days (*fig. 9*).
Correction of the hood and frenulum of the clitoris using hyaluronic acid products. With congenital developmental anomalies or aggressive surgical intervention in the LMin area, it is possible for a situation to arise where the head of the clitoris is not covered by the hood, as it should normally be. This leads to constant difficulty when wearing tight underwear, discomfort and a fall in the number and quality of clitoral orgasms. In this situation the performance of a surgical operation is not possible because of the complexity of the reconstructive techniques and the need for a lengthy rehabilitation period. To correct an existing defect we use high-viscosity gels based on hyaluronic acid which have been specially developed for intimate filling. The procedure takes place under local application anaesthesia and rehabilitation takes 3 days.

**Correction of involution lesions of the labia majora**

An enlargement of the LMaj may be associated with loss of elasticity and surplus skin, and also with local fatty deposits. Such an enlargement of the LMaj may, when the woman is wearing trousers, bathing costumes and tight-fitting underwear, look like an unaesthetic convexity, and may also cause discomfort associated with enhanced perspiration in the external sex organs. The LMaj may be enlarged from birth, and they may also change after childbirth or with age. In many women quite large and wrinkled labia are observed following major weight loss, and especially following bariatric surgery. To achieve the optimum aesthetic result, a half-moon-shaped flap of skin is excised on the inside of the labia, and the margins are sutured using a cosmetic suture which is concealed between the labia minora and majora. LMaj plastic surgery is carried out at our clinic under local anaesthesia, and the procedure takes 60 minutes.

Another important problem is deformation of the inferior commissure of the LMaj, which in turn gives rise to looseness of the vaginal vestibule and the entry of intestinal microflora into the vagina – the main cause of recurrent infections of the vagina, urethra and bladder.

To correct the volume of the LMaj, a subcutaneous injection of various fillers is carried out. This is known as intimate filling. Earlier the “gold standard” for LMaj augmentation was lipofilling. This method entails preliminary liposuction and subsequent introduction of aspirated fatty tissue into the area where correction is intended. Purified fat is gathered from areas of local fatty deposits such as the knees, stomach and thighs, and is then treated by passing it through a system of filters. Syringes with a volume of 10-20 ml with a Luer-Lock type lock and blunt-ended 14G cannulas are used for the injections. For stabilisation of it and improvement of its regenerative properties, the collected fat is mixed with autologous platelet-enriched plasma (PRP) at a ratio of 4:1. Experience in the use of lipofilling in other areas of aesthetic medicine has revealed the negative properties of this method, such as low plasticity, lack of predictability of its effect, and frequent instances of the formation of lipogranulomas and filler migration. The mean frequency of complications when this method
is used is 6.6%. In the available literature there is information on the use of liquid silicone, bovine collagen and a polyurethane biopolymer for LMaj augmentation. The authors themselves, however, mention the high risk of complications, associated primarily with the high level of toxicity of the materials and their capacity to migrate and cause aseptic inflammation [27].

To achieve the desired aesthetic result and to lower the risk of complications developing, a search was made for a bio-compatible filler with optimal physical and chemical properties. A visco-elastic hyaluronic-acid-based gel that is well known to doctors working in aesthetic medicine turned out to be a suitable candidate. There are numerous products now on the cosmetology market which could be used for plastic surgery to shape face and body. As creators of an original method for intimate filling, we recommend the use of the only filler that is currently legitimate – Bellcontour® GVISC (HyalIntertrade S.A. Swiss), which we have been actively using since 2005. The lack of immunogenic properties and migration, lengthy biodegradation and unique rheological properties make this the optimal product for intimate filling. All procedures are carried out under local application anaesthesia, and the procedure time is 20 minutes.

At Professor Yutskovskaia’s Clinic we were the first in Russia to make use of the Pelleve radio-frequency apparatus (Ellman International, USA) for intimate plastic surgery. This procedure may primarily be of assistance to patients suffering from unsightly enlarged LMaj which have lost their tone. Patients who previously used to suffer from the so-called “camel toe” (swelling of the LMaj when wearing skintight clothing) may now avoid plastic surgery on the LMaj by undergoing a 30-minute non-invasive procedure (fig. 10).

*Fig. 10. Patient aged 45: before (a) and after performance of laser epilation and the Pelleve procedure in the labia majora area (b) (photography from archives at Professor Yutskovskaia’s clinic).*

One question that is under discussion is the use of thread lifting to correct involution lesions to the vulva. We use various Aptos thread systems for this purpose. To correct a loose vestibule and perineum height, the Thread 2G system is used, and the NanoVitis and Excellence Elegance systems (Aptos, Russia) for modelling of the labia minora and majora. Work is currently under way to create a protocol for the performance of this procedure.
Laser rejuvenescence of the vagina

Lasers have been in use for over 20 years for the correction of age-related changes in the vaginal area. Examples include venereal warts and colpectasia and scars from episiotomies and perineotomies. They are also used to treat pre-cancerous diseases of the vulva, kraurosis (sclero-atrophic lichen) and afflictions of the neck of the womb. We and our patients often notice changes to the appearance of the vulva that happen following laser treatment: elimination of hyperpigmentation, and a taut and aesthetically pleasing appearance.

At Professor Yutskovskaia’s Clinic we use laser rejuvenescence of the vagina to treat vulvar kraurosis. The intervention protocol includes treatment with an ablative erbium laser and the use of autoplasma (PRP) and non-stabilised hyaluronic acid.

Use of a fractional erbium laser supports collagen regeneration and enables the skin to be smoothed out and scars to be reduced in size, with no injury to surrounding tissues. Laser vaginal and vulvar rejuvenescence are performed under local anaesthesia. The procedure lasts between 15 and 30 minutes, and the rehabilitation period is 5-7 days.

G-spot enlargement

The G-spot (lip of the urethra, G point, “12 o’clock zone”, G zone, Gräfenberg spot (zone), internal trigger) is the point of projection of the female prostate onto the anterior wall of the vagina, pressure on which may be a way to achieve erogenous stimulation. G-Shot® (enlargement of the G-spot) is a trademark registered in 2001 by David Matlock. This is a low-invasive method of tissue augmentation in the anatomical area to increase sexual excitation during coitus [28]. For quite some time, the legitimacy of this procedure was questioned in scientific reports. When on 18 October 2008 the Federal International Committee on Anatomical Terminology (FICAT), based on studies conducted by M. Zaviacic, included the term “female prostate gland” in its Glossary of Terms, all doubts were resolved [29].

Hyaluronic acid gel is introduced into the submucosal layer in the G-spot area and the gap between the anterior vaginal wall and the urethra, using a drop, linear-retrograde or “fan” technique. The volume of product introduced is 0.5-3.0 ml. A 25-27G needle is used. This leads not only to an enlargement of the G-spot projection zone, but also to a certain diminution in the volume of the vagina, which is particularly marked during sexual contact at the time of formation of what is known as the “orgasmic cuff”. As a result of the intervention, the G-spot projection zone becomes the most protruding part of the anterior vaginal wall, and more accessible to tactile impact, which increases its sensitivity and thus improves the quality of sexual relations [30].

The introduction of other fillers, such as autologous fatty tissue, collagen or Radiesse (MerzPharma GmbH & Co, Germany) may lead to unpredictable results and culminate in complications such as descent of the vaginal wall, stress urinary incontinence, bleeding and infection.

4. CONCLUSION

The objective of intimate surgery is to alleviate psychological and/or physical suffering caused by aesthetic or functional deficiencies of the genitalia. Although the number of surgeons engaged in intimate plastic surgery is rising, the increase in patient numbers is being promoted by media activity. Some gynaecologists are unable to comprehend the attitude taken by a woman to her own vulva/vagina. It is becoming clear that modern women have a psycho-biological need to obtain sexual satisfaction as a support for their self-esteem and self-respect. Modern girls and adult women who perform bikini zone epilation have a clear picture of the perineum, its proportions and beauty standards for it. Intimate images that are actively dispersed via the Internet and other media are helping to consolidate an ideal “image” in women’s awareness – a narrow vestibule and delicate labia minora.

Surgeons performing intimate plastic surgery and having a conflict of interests may unintentionally discredit intimate surgery with modern scientific society and potential patients. It is not worth performing procedures on girls who are subsequently planning to become pregnant and who have not yet achieved sexual maturity. Women wishing to have intimate plastic surgery performed should be made aware of all the possible options for correction of the vulva and vagina and examined to see whether they have any pelvic disorders for which proven treatment methods are available. The ethical duties of surgeons in respect of a patient include professional honesty, prevention of any conflict of interests and carrying out the wishes of the patient.
REFERENCES


GENITOURINARY SYNDROME

& VAGINAL LAXITY
Application of laser technologies for treatment of urinary stress incontinence in women of reproductive age


Abstract

Urinary incontinence is a significant health problem with considerable social impact. Prospective study was carried out to assess the efficacy and safety of erbium laser (Er:Yag 2940 nm) for treatment urinary stress incontinence in women of reproductive age and its influence on quality of life in the area of sexuality. 37 women (mean age 36.2 years) with mild and moderate urinary stress incontinence were enrolled in the study. The control group consisted of 20 women of similar age. Treatment was delivered in outpatient settings without anesthesia and sedation. Laser system Dermablate MCL 31 (Asclepion Laser Technologies, Germany) with a set of vaginal heads V-Asclepion was employed. All patients underwent examination including Q-tip test and Valsalva maneuver and completed ICIQ-SF H FSFI forms. Within 1 month postoperatively all 37 patients noted significant reduction of urinary stress incontinence symptoms and favorable changes in quality of sexual life. Positive trend was found in urethrovesical junction angle changes. No postoperative complications were registered. The findings from this prospective study confirmed high efficacy and an acceptable safety profile of the new treatment of urinary stress incontinence.
Introduction

**Quality of life** (eng. - quality of life, abbr. - QOL; Germ. - Lebensqualitat, abbr. LQ) - the category which characterises the vital circumstances of life. This determines the degree of self-worthiness and freedom of being for each individual [1]. There are many factors that determine the quality of life of a woman in her reproductive age. According to the demographic, from the age of 15 through to 49 a woman is considered to be in her reproductive age.

During this time she is able to carry and give birth to a child. Although Pregnancy and childbirth are both physiological processes, they also have a significant impact both on the functions of individual organs, as well as on a woman’s organism on the whole. These often contribute to the emergence of symptoms that significantly lower the quality of life. One such symptom is the manifestation of urinary incontinence (UI) during pregnancy and after birth.

Many studies have shown that an overwhelming number of women suffering from UI had a previous history of pregnancy and childbirth [2,3,4]. The frequency of UI in pregnant women, maintained by several authors, varies from 12 to 74% [5,6]. The frequency of UI after the first birth is between 24 and 29% [7].

A study conducted in 2008 shows that the manifestation of the symptoms of urinary incontinence during pregnancy and in the first year after giving birth affects 21.7% of women. Such cases are most frequently observed in the presence of aggravated gynaecological, obstetric and somatic anamnesis. [8]

Furthermore, the frequency of urinary incontinence is directly related to the number of pregnancies of a woman, the presence of recurrent inflammatory diseases of the genital tract, obstetric injuries and dissections of the perineum during childbirth, and the clinical manifestations of the syndrome of undifferentiated connective tissue dysplasia in blood relatives.

It is noted that some women’s control of urination is restored spontaneously within a few weeks or months after birth; however, according to a study EPINCONT (2003), 42% of women in this group develop persistent stress incontinence over a period of five years. Moreover, amongst women suffering from rare and sporadic episodes of incontinence, persistent postpartum, stress incontinence develops within five years in 92% of cases [9].

According to Russian statistics in 2006, about 30 million Russian women, two thirds of whom are of working age suffer from this severe, chronic relapsing disease: this problem affects one in five women of reproductive age [10]. Overall, 30% to 70% of women in Russia suffer from various types of UI [11].

The effect of UI on the quality of life varies from significant to severe [12]. Without being life-threatening, the pathological loss of urine is considered a “quietly crippling force” - a social disease. Its significance is comparable with depression and diabetes, and the economic costs of diagnosis and treatment in developed countries exceed those of cardio renal bypass surgery and kidney dialysis put together [13, 14]. It affects professional life and employment, and it complicates family and social behaviour.[15].

The majority of patients prefer minimally invasive procedures to surgical treatment [16]. Thus, the search for new treatments for stress urinary incontinence in women is of great relevance. It is necessary to develop more effective minimally invasive methods - treatment that would reduce the incidence of intraoperative and postoperative complications and maximise the rehabilitation of patients.

Laser medicine in urogynecology originated in the last decades of the twentieth century, and at this day and age it is difficult to imagine progress without laser technology, which has opened up new possibilities for resolving numerous health problems. The development of laser medicine in urogynecology is divided into three main categories: laser surgery (using high-energy medical lasers), laser therapy (the use of lasers with low-intensity radiation) and laser diagnostics.

**Asclepion Technology**

It is known that the causes of stress urinary incontinence is the relaxation of the anatomical structure that supports the periurethral tissue, and the weakening of the urethral sphincter. Damage to the innervation of the pelvic floor muscles during vaginal delivery may lead to loss of strength and neurohumoral regulation of tone of the pelvic muscles, which in turn can cause incontinence and damage to the pelvic floor support. Studies have shown that the ligaments and pubocervical fascia in women with stress urinary incontinence have reduced collagen content, or are characterised by a significant change in collagen. Changes in the metabolism of connective tissue leads to a lack of support for the urinary tract.

The method of local hyperthermia has a significant place in modern medical technology - when the primary effect which is either directly related to the denaturation of collagen, or achieved by heating the selected tissue area to a temperature corresponding or slightly above the beginning of denaturation. Local heating of the tissue in medical practice is carried out using either an infrared laser or radiofrequency radiation, or using an electric current.

The erbium (Er: YAG) laser has a wavelength of 2.94 micron radiation (medium IR range). Its working regime is impulsive. The depth of penetration into the tissue with the erbium laser radiation does not exceed 0.05 mm (50 microns).
The main mechanism of function of the Asclepion V-Spot Technology is the achievement of selective stimulation of the synthesis of sub-mucosal collagen. The immediate reaction is a reduction of collagen fibres and the acceleration of neocollagenesis, which lead to hardening of the tissue and an increase in flexibility. The treated area is gradually reduced and tightened, improving support of the bladder, thereby reducing the symptoms of stress urinary incontinence.

**Objective:** To prospectively evaluate the clinical efficiency and safety of a minimally invasive treatment of stress urinary incontinence using Asclepion V-Spot Technology in women of reproductive age.

**Materials and methods:**
A total of 37 women aged between 28 and 43 years took part in this study (the average age was 36.2). A control group to assess the impact of anti-stress treatments on the quality of sexual life were 20 patients of a similar age, who do not suffer from symptoms of stress urinary incontinence. The study was conducted in accordance with the rules stipulated in the protocol and GCP and does not contradict the Declaration of Helsinki.

All participants in the study were examined by a physical therapist, a urologist and a gynaecologist.

The following criteria for inclusion in the study were used: previous natural childbirth, normal cytology (pap smear), a negative urine culture, the absence of acute medical illness, a verified diagnosis of stress urinary incontinence in mild to moderate severity.

The following criteria for exclusion were used: pregnancy, lactation, taking photosensitive drugs, injury and / or active infection in the treatment stage, diagnosed vaginal bleeding, and active menstruation.

Laser treatment of stress urinary incontinence is based on the use of a 6th generation erbium laser, Asclepion MCL 31 Er: YAG, 2940 nm with a set of vaginal nozzles (Fig. 1).

![Fig. 1 Er: YAG 2940 nm. laser system with a set of 31 MCL vaginal nozzles Asclepion V (Asclepion Laser Technologist).](image)

The procedure was performed in an ambulatory environment, without anaesthesia or sedation. In the first stage, the vaginal canal is processed in the ablation method along the entire length of the vesico-urethral angle to introitusa, the second stage
is non-ablative (thermal mode). The combination of ablative and non-ablative methods allows the achievement of high efficiency treatment with maximum security, eliminating the excessive damage to the vaginal mucosa.

After the procedure, the vagina was treated with a water-based solution of chlorhexidine, for the evacuation of tissue detritus. The period without sexual activity was 72 hours. Topical antiseptics were used for the prevention of infectious complications. In the case of a history of episodes of genital herpes, valacyclovir was administered for prophylaxis at the standard dose for three days before and after the procedure. The patients were able to return to their normal activities on the same day.

Results

All patients involved in the study have undergone laser treatment for stress urinary incontinence using Asclepion V-Spot Technology. The procedure was carried out without complications in the intra - and postoperative period. During the procedure, the patients did not notice any pain or discomfort.

To evaluate the clinical efficiency, three fixation points were identified: before treatment, after 1 month and 6 months after the procedure.

During each visit, the following procedures were carried out: a vaginal examination, a PAP-test, a Q-tip test, a Valsalva manoeuvre, a cough test, filling out FSFI questionnaires, the ICIQ-UI SF, QOL SF-36.

During the vaginal examination prior to the procedure, at 1 and 6 months after the procedure, no pathological changes were found. The PAP test has also shown no change in the condition of the cervix before and after the procedure.

A vital part of this stage of patient’s examination is the indication of involuntary urine loss. In other words, complaints of stress urinary incontinence need to be confirmed by a demonstration of involuntary loss of urine at the time of physical stress. A cough test is carried out with the women in the gynaecological chair in the lithotomy position. The patient is asked to produce cough shock in a series of 3, i.e. by coughing 3-4 times with intervals between series of aftershocks on a full breath.

Prior to the laser treatment for urinary incontinence in 37 (100%) patients, who participated in the study, a positive cough test was carried out. After 1 month only 6 (16%) patients reacted positively. 6 months after the procedure, the sample was negative in all patients involved in this study.

In international practice, to evaluate the degree of omission of the bladder neck and upper third of the urethra, the so-called Q-tip test is widely used. The test is theoretical, popular and deepens the analytical capabilities of the mechanisms leading to incontinence. The results are shown in Fig. 2 as follows: before the procedure, during the Valsalva manoeuvre, the angle averaged to 45.2± 4.79°. 1 month after the procedure, it was - 40.4± 1.23 °. After 6 months, it was - 36.2± 2.42°.

The Valsalva manoeuvre, or a test under pressure, is necessary to simulate the true state of the urethra at the time of pressure.

![Q-tip test](image)

Fig. 2 The dynamics of changes in the urethrovesical angle within 6 months of the study.

Despite its extensive routine use in urogynecological practice, the significance of the test is relatively small. Not all patients suffering from stress incontinence demonstrate a positive Q-tip test result, and not all patients demonstrating a positive test result suffer from stress incontinence.
ICIQ-UI SF is an international profile to determine the severity of stress urinary incontinence. By using the ICIQ-UI SF, stress incontinence can be divided into the following four degrees of severity: mild (1-5), medium (6-12), severe (13-18) and very severe (19-21). The results of the study of the dynamics of SUI symptoms are presented in Fig. 3. Prior to the procedure, the average value was 8.3 ± 2.79 points. 1 month after the procedure, the average value was 3.1 ± 1.03 points. 6 months after the procedure, the average value was 0.6 ± 0.54 points (p < 0.05).

Fig. 3 The change in the severity of symptoms of stress urinary incontinence according to the questionnaire ICIQ-UI SF. To properly assess the quality of life before and after treatment, a modified questionnaire was used: “SF-36 Health Status Survey” (SF-36). The purpose of the above questionnaire for women with urinary incontinence was to assess not only the effectiveness of medical treatments, but also changes in the patient’s quality of life (physical activity, mental state, social role, sexual function, subjective assessment of their health) before and after treatment.

The heading “before treatment” was taken into account the patient’s feelings from the onset of the illness until the treatment. The heading “after treatment” included the second stage: 1 and 6 months after treatment. The results of the evaluation presented in Table 1 have enabled an improvement of therapies used.

<table>
<thead>
<tr>
<th></th>
<th>Before the procedure</th>
<th>After 1 month</th>
<th>After 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>PF</td>
<td>54.4±12.0</td>
<td>65.2±11.6</td>
<td>84.7±14.7**</td>
</tr>
<tr>
<td>RP</td>
<td>39.1±18.8</td>
<td>53.3±15.4*</td>
<td>79.3±15.5**</td>
</tr>
<tr>
<td>BP</td>
<td>52.3±12.1</td>
<td>70.1±11.6*</td>
<td>81.0±15.1**</td>
</tr>
<tr>
<td>GH</td>
<td>54.8±9.6</td>
<td>73.0±9.3*</td>
<td>84.8±14.2**</td>
</tr>
<tr>
<td>VT</td>
<td>41.6±11.6</td>
<td>62.4±10.6</td>
<td>75.3±12.2**</td>
</tr>
<tr>
<td>SF</td>
<td>65.5±9.8</td>
<td>66.7±10.1</td>
<td>74.7±10.1*</td>
</tr>
<tr>
<td>RE</td>
<td>40.2±18.1</td>
<td>62.7±11.8</td>
<td>87.9±15.8**</td>
</tr>
<tr>
<td>MH</td>
<td>43.6±9.8</td>
<td>58.5±9.4*</td>
<td>78.8±10.7**</td>
</tr>
</tbody>
</table>

Table 1 The dynamics of changes in quality of life according to the SF-36 questionnaire. Please note: * - p<0.05, ** - p<0.01 (in comparison to before the procedure)

As evident in the results shown in Table. 1, after 1 month there was a significant positive trend following the indicators on the SF-36 scale: RP, BP, GH, MH. Distinct positive dynamics after 6 months including a high level of confidence (p <0.01) was observed in all parameters of the SF-36 scale, except SF. Furthermore, after 6 months, according to all QoL indicators, adaptive and testifying levels showing a high quality of life are observed.

The questionnaire to calculate the index of sexual function in women (Female Sexual Function Index (FSFI)) is required for a prospective evaluation of the quality of sexual life in women before and after anti-stress treatments. The comprehensive
The format of the questionnaire provides a wide range of applicability of this questionnaire in clinical practice, as well as being very accessible to the respondents themselves.

The results of the investigation on the sexual function of women before the procedure are shown in Table 2.

<table>
<thead>
<tr>
<th>Headings of the FSFI questionnaire</th>
<th>Indicators (M ± SD) Norm</th>
<th>Indicators (M ± SD) SUI</th>
<th>FSFI changes in comparison to the norm in (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attraction</td>
<td>5.12 ± 0.37</td>
<td>4.14 ± 1.57</td>
<td>-14.58%</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Arousal</td>
<td>4.67 ± 0.74</td>
<td>4.21 ± 1.47</td>
<td>-16.20%</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Lubrication</td>
<td>4.8 ± 0.56</td>
<td>4.36 ± 1.36</td>
<td>-9.17%</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Orgasm</td>
<td>5.5 ± 0.87</td>
<td>4.21 ± 1.33</td>
<td>-13.79%</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>5.2 ± 0.61</td>
<td>4.34 ± 1.44</td>
<td>-14.98%</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Pain</td>
<td>5.68 ± 0.43</td>
<td>4.62 ± 1.51</td>
<td>-18.34%</td>
<td>&lt;.0001*</td>
</tr>
</tbody>
</table>

Table no. 2 The comparison of a healthy population with patients suffering from stress urinary incontinence. Note: M - average, SD - standard deviation. p ≤ 0.05 - a statistically significant result.

As shown in the results table of the FSFI questionnaire comparing healthy women with women suffering from stress urinary incontinence, it was found that all sections of the questionnaire results are reduced in the group of women with SUI. Moreover, comparing groups of all sections of the questionnaire revealed a strong statistical link - <.0001, which indicated that women with SUI have a clearly decreased sexual function in comparison with a healthy population. The research showed a decreased sexual function (performance in the FSFI questionnaire <27) is present in 18% of women who were not complaining about any sexual dysfunction.

<table>
<thead>
<tr>
<th></th>
<th>Improvement</th>
<th>No changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attraction</td>
<td>28 (75%)</td>
<td>9 (24%)</td>
</tr>
<tr>
<td>Arousal</td>
<td>31 (73%)</td>
<td>6 (16%)</td>
</tr>
<tr>
<td>Lubrication</td>
<td>29 (78%)</td>
<td>8 (21%)</td>
</tr>
<tr>
<td>Orgasm</td>
<td>21 (57%)</td>
<td>16 (43%)</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>32 (77%)</td>
<td>5 (13%)</td>
</tr>
<tr>
<td>Pain</td>
<td>16 (43%)</td>
<td>21 (57%)</td>
</tr>
<tr>
<td>Total</td>
<td>31 (84%)</td>
<td>6 (16%)</td>
</tr>
</tbody>
</table>

Table 3 The change in the FSFI questionnaire indicators in all sections in percentages (%).

The data shown in Table 3 shows that in the total population, female sexual function has improved in 84% of patients, and has not changed in 16%. This proves the high efficiency of this type of treatment, and a positive effect of laser correction of stress urinary incontinence in women, thus restoring their sexual function.

Analysis of the safety profile: the presence of vaginal discharge of a bloody consistency was 20 (55%), low-grade fever 6 (16%), cystalgia 2 (6%). Any side effects did not require an appointment for special treatment and were resolved on their own in up to 3 days.

Discussion
The particular feature of treating women of reproductive age with stress urinary incontinence, is their inability to perform most common operational procedures. This is due to the fact that subsequent births can nullify the result of any surgical intervention. Conservative treatment methods recommended to women of such reproductive age result in a temporary effect, yet they do not allow patients to return to active life. In this regard, the development of minimally invasive treatments that do not require a rehabilitation period and anaesthetics is a priority in medical science.

Using modern laser technology enables us to convert loose and untoned connective tissue into densely formed connective tissue. This is done through remodelling of the extracellular matrix. Qualitative changes in the connective tissue at the expense of the synthesis of collagen and elastin proteins restore the lost function of the carcass.

The use of 6th generation MCL31 erbium laser (Asclepion Laser Tech.) allows for a large variability of the duration and intensity of the pulse, and furthermore enables us to perform the individual selection of treatment for each individual case. Data analysis of the study shows the high efficiency of the Asclepion V-Spot Technology on the symptoms of stress urinary incontinence in women of reproductive age.

Objective criteria for the adequacy of the treatment are as follows: lack of clinical incontinence, lack of sexual dysfunction, restoration of normal MP and urethral syntopy MP and the urethra and also the improvement in the quality of life of the patient.

The observed changes in the results of the Q tip test confirm periurethral connective tissue remodelling and improvement of maintenance functions, which in turn leads to changes in the urethrovesical angle and restores the continence function. This data is equally supported by the reduction of episodes of urinary incontinence.

Within the 6 months of monitoring, improvement in sexual function of women was observed, which is important in terms of prevalence of female sexual dysfunction in women with stress urinary incontinence. Changes in intra-coital sensitivity are also associated with a change in the innervation and blood supply of the anterior wall of the vagina.

The objectification of sensations of the patient by means of assessing the level of quality of life provides an opportunity to adequately analyse the results of the treatment. In this study, positive dynamics in changes in the quality of life of patients with stress urinary incontinence were reported, improving both mental and physical aspects.

No post-operative complications were reported. This proves the safety of the method in the absence of inflammatory changes and reactions, which is an advantage over previously well-known methods.

Laser correction of stress urinary incontinence using the Asclepion V-Spot Technology is a modern, minimally invasive method of treatment, with a high level of efficiency and a high safety profile.
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Vaginal erbium laser: the second-generation thermotherapy for the genitourinary syndrome of menopause

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Abstract

Aim To evaluate the effects of the vaginal erbium laser (VEL) in the treatment of postmenopausal women suffering from genitourinary syndrome of menopause (GSM).

Method GSM was assessed in postmenopausal women before and after VEL (one treatment every 30 days, for 3 months; n = 45); the results were compared with the effects of a standard treatment for GSM (1 g of vaginal gel containing 50 μg of estriol, twice weekly for 3 months; n = 25). GSM was evaluated with subjective (visual analog scale, VAS) and objective (Vaginal Health Index Score, VHIS) measures. In addition, in 19 of these postmenopausal women suffering from stress urinary incontinence (SUI), the degree of incontinence was evaluated with the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) before and after VEL treatments.

Results VEL treatment induced a significant decrease of VAS of both vaginal dryness and dyspareunia (p < 0.01), with a significant (p < 0.01) increase of VHIS. In postmenopausal women suffering from mild to moderate SUI, VEL treatment was associated with a significant (p < 0.01) improvement of ICIQ-SF scores. The effects were rapid and long lasting, up to the 24th week of the observation period. VEL was well tolerated with less than 3% of patients discontinuing treatment due to adverse events.

Conclusion This pilot study demonstrates that VEL induces a significant improvement of GSM, including vaginal dryness, dyspareunia and mild to moderate SUI. Further studies are needed to explore the role of laser treatments in the management of GSM.
Genitourinary syndrome of menopause and the use of laser therapy

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Abstract

Genitourinary syndrome of menopause is a common condition that left untreated can progress and negatively affect quality of life and sexual function. Laser therapy has a therapeutic role for several gynecologic conditions and most recently has gained interest as a non-hormonal treatment for genitourinary syndrome of menopause (GSM). The laser is well tolerated and may increase thickness of the squamous epithelium and improve vascularity of the vagina. These morphological changes presumably alleviate symptoms of dryness, dyspareunia, and irritation. However, the duration of therapeutic effects and safety of repeated applications at this point is not clear. Further research is needed in the form of controlled studies of the laser and other non-hormonal GSM therapies. The objective of this paper is to review the existing literature describing laser therapy for GSM.
Rationale and design for the Vaginal Erbium Laser Academy Study (VELAS): an international multicenter observational study on genitourinary syndrome of menopause and stress urinary incontinence

M. Gambacciani, M. G. Torelli *, L. Martella †, G. L. Bracco ‡, A. G. Casagrande **, E. Albertin † †, S. Tabanelli ‡ ‡, M. Viglietta ** *, G. D’Ambrogio † † †, G. Garone ‡ ‡ ‡ and M. Cervigni ***

Abstract

The genitourinary syndrome of menopause (GSM) and stress urinary incontinence (SUI) are common clinical challenges for women’s health and quality of life. The laser treatment and particularly the vaginal erbium laser (VEL) may provide a new non-invasive treatment for both GSM and SUI. However, the estimation of the ultimate results of different laser treatments may be altered by different issues, such as patient selection, concomitant treatments, and long-term effect of vaginal laser thermotherapy. In the present paper, we present the protocol for a large multicenter study on the evaluation of the efficacy and safety of VEL for the treatment of GSM and SUI, the Vaginal Erbium Laser Academy Study (VELAS). This study will evaluate the effects of three laser applications in 1500 postmenopausal women. Subjective and objective symptoms will be evaluated prior to the first laser treatment with follow-up visits after 4 weeks from the last laser application, and subsequently after every 3 months for 1 year. Findings from the VELAS have the potential to affect clinical care practice and health decisions for millions of women world-wide for a non-hormonal treatment for GSM and a non-invasive treatment of SUI.
Laser Vaginal Tightening (LVT) – evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome

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Aldana Laser Center, Caracas, Venezuela

Abstract

The objective of this study was to evaluate the safety and efficacy of a novel laser treatment for vaginal relaxation syndrome.

Method: A pilot study was conducted on 21 patients who received the novel laser treatment for vaginal tightening with a 2940 nm Er:YAG laser between June 2011 and January 2012. All patients received two treatment sessions with an interval between sessions of 15 to 30 days. In a non-ablative, thermal-only mode, laser energies of approx. 90 J per treated area in the vaginal canal and of approx. 10 J per treated area at the vestibule and introitus were delivered to the patient’s vaginal mucosa. A special Laser Vaginal Tightening (LVT) questionnaire was designed for assessing the improvement of vaginal tightness via patient self evaluation and by their sexual partner’s assessment. POP-Q measurements were also performed prior to both treatment sessions in an attempt to objectively assess the change in vaginal tissue structure. Additionally, a PISQ-12 questionnaire was also used as a standard assessment tool for pelvic organ prolapse, urinary incontinence and sexual gratification. Patients were also asked about treatment discomfort, potential adverse effects, and their general satisfaction with the treatment.

Results: Twenty of twenty one patients (95%) reported significant (moderate and strong) improvement of their vaginal tightness, and also all of their partners confirmed an improvement of vaginal tightness during sexual intercourse (85% reported significant improvement and 15% reported mild improvement). All patients but one (95%) reported better sex after the treatment. Five patients had prolapses (of stages 1-3) before receiving the treatment, which improved in all of these patients, leaving just two of them with prolapses (one with stage 1 and one with stage 2). Three patients suffering from SUI before the treatment reported significant improvement (2) and complete healing (1). There were no adverse effects and patient discomfort was assessed as minimal.

Conclusions: The novel laser vaginal tightening therapy is an effective and safe method for the treatment of vaginal relaxation syndrome.

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Abstract

Objectives This is the first assessment of efficacy and safety of the Er:YAG laser in the treatment of stress urinary incontinence. The aim of this study was to assess the short-term outcome of a non-invasive laser treatment for mild-to-severe stages of this condition and to check its applicability in different body mass index and age groups.

Methods A prospective cohort, single-center study at the Ob/Gyn Clinic, Zagreb, Croatia recruited a consecutive sample of 73 female patients suffering from stress urinary incontinence. The procedure was performed with a 2940-nm Er:YAG laser (XS Dynamis, Fotona, Slovenia) designed to achieve heating up of vaginal mucosa to around 60 °C, 500 – 700 μm in depth.

Results The score in the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form was reduced to a median of 46% (95% confidence interval 33 – 67%; \( p < 0.001 \)). The reduction was significantly higher in women with normal body mass index (67%) than in overweight women (25%), as well as in women younger than 39 years (100%) compared with those older than 60 years (8%) ( \( p < 0.001 \)). No serious adverse events were noticed.

Conclusion This study of Er:YAG laser therapy in women has demonstrated a clinically relevant, short-term improvement of stress urinary incontinence, with minimal adverse events of a transient nature.
Minimally invasive laser procedure for early stages of stress urinary incontinence (SUI)

Fistonić Ivan, F̦ndrište Şefika, Fistonić Nikola

Abstract

The objective of this labeled, prospective, single-center pilot study was to assess the efficacy and safety of a novel minimally invasive, non-ablative laser treatment in the early stages of SUI.

A total of 39 patients suffering from mild to moderate stress urinary incontinence underwent treatment with an Er:YAG (2940 nm) laser in non-ablative fractional mode. Assessment tools included the ICIQ-UI SF questionnaire for assessing the degree of incontinence and its impact on the quality of life, the Q-tip test for evaluating the mobility of the urethra and bladder neck, PISQ-12 for assessing quality of life in the area of sexuality, and perineometry for the measurement of muscle strength. Follow-ups were scheduled after 1 month for 39 patients, after 3 months for 22 patients and after 6 months for 6 patients.

Preliminary results of post-treatment evaluation showed significant improvement (p< 0.05) in all the domains tested: ICIQ-UI scores decreased by more than 3 points at all follow-ups. A mean duration of muscle contraction measured with perineometry at 1 month increased by 4.7 s, at 3 months by 11.8 s and at 6 months by 22.8 s. Q-tip angle decreased by 14.7˚ at 1 month follow-up, by 15.9˚ at 3 months and by 22.5˚ at 6 months. PISQ-12 scores increased after 1 month by 5.4 points, after 3 months by 5.9 points and after 6 months by 6.6 points.

The preliminary results confirm that a minimally invasive, non-ablative fractional laser treatment (IncontiLaseTM) is an effective, safe and comfortable treatment option for symptom relief in patients with mild and moderate SUI.
Treatment of Vaginal Relaxation Syndrome with an Erbium:YAG Laser Using 90° and 360° Scanning Scopes: A Pilot Study & Short-term Results

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Abstract

Background and Aims: Vaginal relaxation syndrome (VRS) is both a physical and psychological problem for women and often their partners. Recently the 2940 nm Er:YAG laser has attracted attention for VRS treatment. The current study evaluated the clinical efficacy of this nonsurgical laser procedure.

Subjects and Methods: Thirty postpartum females with VRS or vaginal atrophy, ages from 33 – 56 yr (mean 41.7 yr) were divided randomly into two groups, Group A and Group B. Both groups were treated for 4 sessions at 1~2-weekly intervals with a 2940 nm Er:YAG via 90° and 360° scanning scopes. In Group A the first 2 sessions were performed with the 360° scope and the final 2 with the 90° scope in multiple micropulse mode, 1.7 J delivered per shot, 3 multishots, 3 passes per session. Group B underwent multiple micropulse mode treatment with the 90° scope in all 4 sessions (same parameters as Group A) then during the final 2 sessions an additional 2 passes/session were delivered with the 360° scope, long-pulsed mode, 3.7 J delivered per shot. Perineometer assessments were performed at baseline and at 2 months post-treatment for vaginal tightness. Histological specimens were taken at baseline and at 2 months post-procedure. Subjective satisfaction with vaginal tightening was assessed together with improvement in sexual satisfaction. Results were tested for statistical significance with the paired Student’s t-test.

Results: All subjects successfully completed the study with no adverse events. Significant improvement in vaginal wall relaxation was seen in all subjects at 2 months post-procedure based on the perineometer values, on the partners’ input for vaginal tightening (76.6%) and for sexual satisfaction as assessed by the subjects themselves (70.0%). The histological findings suggested better elasticity of the vaginal wall with tightening and firming.

Conclusions: Both regimens of Er:YAG laser treatment for VRS produced significant improvement in vaginal relaxation. With multishots delivered in the multiple micropulse mode via scanning scopes, nonsurgical Er:YAG laser treatment was pain-free, safe, side effect free, easily tolerated and effective.
Novel Minimally Invasive VSP Er:YAG Laser Treatments in Gynecology

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Abstract

Some of the most common health problems among women that are caused by a deteriorating laxity, elasticity and tightness of mucous membranes are vaginal relaxation (and the associated loss of sexual gratification) and stress urinary incontinence. Recently, two novel minimally invasive, non-ablative Er:YAG laser techniques have been introduced, a vaginal tightening therapy IntimaLase™ and a stress urinary incontinence therapy IncontiLaseTM, which show the potential to become an optimal solution for many women suffering from these problems. Both treatment techniques exploit the photothermal effect of a laser beam on mucosa tissue in order to cause its shrinkage without any removal of tissue. The overall impact and burden on the patient’s organism is thus minimal, as opposed to more invasive classical or laser surgical procedures.

In this paper, a special Er:YAG Pixel Screen technology used in these novel gynecological treatments, and its ablative characteristics, are first analyzed with the aim to establish a range of laser parameters for safe, single-pulse or SMOOTH mode, non-ablative treatment of mucosa tissue. The initial results of multi-center clinical studies of the IntimaLaseTM and IncontiLaseTM treatments are then presented. All five centers involved in the studies of the IntimaLaseTM treatment reported positive results, i.e an improvement in vaginal tightness for a large majority of treated patients, with practically no adverse effects. Similarly, all four studies of the IncontiLaseTM treatment showed improvement in stress urinary incontinence (SUI) for a large majority of treated patients. Many patients with mild SUI reported to become free of the symptoms of incontinence following the treatment. There were no adverse effects of this treatment reported in any of the studies.
Erbium laser in gynecology

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Abstract

The aim of this paper is to present a novel laser technology utilizing the erbium YAG laser for various minimally invasive, non-surgical procedures in gynecology. Non-ablative, thermal-only SMOOTH-mode erbium pulses are used to produce vaginal collagen hyperthermia, followed by collagen remodeling and the synthesis of new collagen fibers, resulting in improved vaginal tissue tightness and elasticity. This erbium laser technology is used for treatments of vaginal laxity, stress urinary incontinence, pelvic organ prolapse and vaginal atrophy. In the period from 2010 to 2014, several clinical studies covering all four indications were conducted with the aim to prove the efficacy and safety of this novel technology. An overview is presented of the results of these studies where several objective as well as subjective assessment tools were used. The results have shown that SMOOTH-mode erbium laser seems to be an effective and safe method for treating vaginal laxity, stress urinary incontinence, pelvic organ prolapses and vaginal atrophy.
LICHEN SCLEROSIS
A minimally invasive treatment method for lichen sclerosis

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Abstract

Described below is a contemporary, minimally invasive treatment method for lichen sclerosis using an erbium laser and PRP. A prospective study was conducted on the efficacy and safety of the proposed method. The clinical case is discussed below.
Introduction
According to the WHO, it is expected that 46% of all women will be over 45 years old by 2015. There has been a noticeable growth in the number of patients with dystrophic diseases of the vulva, including in children and women of reproductive age, as a result of a change in the population of contemporary society in recent years.

Atrophic changes to the tissues of the external sex organs often have severe clinical manifestations and are accompanied by neuropsychiatric disorders, which significantly decrease the woman's quality of life. Atrophic lichen sclerosis, or kraurosis, was first described at the end of the 19th century, and interest in the disease has increased during the past several decades. An increase in the number of patients with dystrophic diseases of the vulva has been noted all over the world. In the past this pathology was mainly found in women of climacteric and postmenopausal age, whereas at present atrophic lichen sclerosis is also diagnosed in children and women of reproductive age. Little attention is paid to this problem in the literature at the present time. Studies of the aetiology and pathogenesis of atrophic lichen sclerosis, which still remain largely unknown, are few and far between.

Lichen sclerosis and leukoplakia have a persistent and progressive clinical course and are accompanied by a painful and, at times, unbearable itch, which troubles patients almost constantly, is exacerbated by the smallest contact with clothing and is poorly alleviated by medications. In the end, the itch causes emotional disorders and disrupts social relationships. According to M.I. Shtemberg, every second patient experiences psychoemotional disorders even in the early stages of disease. This undoubtedly affects their quality of life.

In this context, it would be expedient to assess the efficacy of medical intervention not only according to clinical data, but also taking into account changes in the indices of these patients' quality of life. In our country, however, no study of the quality of life of patients with dystrophic diseases of the vulva has been conducted. Naturally, there are no methods available for assessing such data.

The problem of treating lichen sclerosis and leukoplakia remains topical due to the low efficacy of existing treatment methods, the duration of the disease, the severity of its course and the likelihood of malignancy.

Despite the wide spectrum of standard treatment used for this pathology, efficacy remains relatively low. The existing standard methods reduce the painful symptoms of the itch of the external sex organs, but do not ensure complete elimination of localised morphological manifestations of the disease or provide prolonged remission, and require ongoing treatment. In addition, the long-term standard therapy for lichen sclerosis and leukoplakia of the vulva does not prevent the development of cancer. And so, according to data collected by Ya.V. Bokhman et al., 30% of patients with cancer of the vulva were observed and received the standard treatment for leukoplakia.

In comparison with the traditional standard treatment of lichen sclerosis and leukoplakia of the vulva, laser therapy is significantly more efficacious but does not guarantee permanent results. The recurrence of the process prescribes the need for repeated courses of therapy and the use of more radical treatment methods. At present, laser surgery occupies a key position among the most radical surgical methods for treating gynaecological patients. Laser treatment offers high accuracy, minimal damage to healthy tissue, exsanguinity, a painless operation and does not result in the formation of coarse scars and stenosis.

Past research demonstrates the efficacy of using CO₂ lasers in the treatment of patients with lichen sclerosis. However, the likelihood of a relapse, the long rehabilitation period and the possibility of complications mean that it is not possible to use this procedure on everyone. Data analysis of existing literature on this subject suggests that the limitations of CO₂ lasers are primarily connected to the properties of the laser itself, its depth of penetration (200 µm) and its pronounced thermal effect. At Professor Yutskovskaya's Clinic we use the latest generation Er:YAG laser. The erbium (Er:YAG) laser has an emission wavelength of 2.94 µm (average IR range). It uses a pulse operation mode. The depth of penetration by the erbium laser emission into the biological tissue does not exceed 0.05 mm (50 µm).

CO₂ and erbium lasers differ significantly. They share a single operating principle based on the phenomenon of selective photothermalysis. The main difference between Er:YAG and CO₂ lasers lies in the power of the laser generator. The peak power of the short pulsed solid-state Er:YAG laser reaches 20 kilowatts, whereas the peak power of the pulse of a CO₂ laser reaches 50 watts. As a result, the CO₂ laser requires either increased pulse duration or repeated pulses on the same area to achieve the necessary ablative depth. The Er:YAG laser causes a significant rise in the temperature of the tissue. As a
consequence an ablation zone forms, surrounded by a zone of irreversible thermal necrosis and a wider zone of coagulation damage due to heat transfer in the tissues.

The depth of penetration of the energy from a CO$_2$ laser always exceeds the depth of formation of the basal lamina and it is always accompanied by an additional zone (from 10 to 50-60 mcm) of coagulation damage that is lower than the level of ablation. The high depth of penetration and significant thermal damage limit the number of procedure pathways to two.

Patient supervision after laser treatment is a pressing problem given that in 30% of patients the vulval itch and pain during sex remains following use of the CO$_2$ laser and the rehabilitation period lasts at least 9 days.

One particularly promising achievement in general and regenerative medicine is the use of growth factors for accelerating regenerative processes at the wound site. Thrombocytes are the most convenient source from which to obtain autogenous growth factors.$^{[10]}$ These factors are all contained in the alpha granules of thrombocytes. This includes platelet-derived growth factor (PDGF), two types of transforming growth factor beta (TGF-beta 1, 2), insulin-like growth factor (IGF), epidermal growth factor (EGF), fibroblast growth factor (FGF), endothelial growth factor, anti-heparin factor and platelet-activating factor.$^{[11]}$

The autogenous platelet-derived mass promotes the formation of collagen, accelerates regeneration of the skin and mucus, stimulates vessel growth and the rapid and essential formation of connective tissue, ensures haemostasis, alleviates pain, decreases the risk of infectious complications, helps attain the best result of the surgical procedure and prevents postoperative complications.

A new method was tested to optimise the therapy of patients with lichen sclerosis using an Er:YAG laser in conjunction with PRP.

**Materials and methods**

38 women aged between 18 and 63 years (average age: 56.2) participated in the study. The study complied with all the rules of the GCP Protocol and did not contravene the Declaration of Helsinki.

Each patient included in the study was examined by a GP and gynaecologist.

The inclusion criteria for the study was a histologically verified diagnosis of lichen sclerosis, normal cytology (Pap smear), a negative urine culture, the absence of acute somatic diseases and the verified diagnosis of mild and moderate stress incontinence.

The exclusion criteria was pregnancy, lactation, taking photosensitive drugs, injury and/or active infection at the treatment site, diagnosed vaginal haemorrhages and active menstruation.

The laser treatment for lichen sclerosis used the 6th generation Asclepion MCL 31 Er:YAG 2,940 nm erbium laser.

The procedure was carried out under outpatient conditions using the infiltration anaesthesia Ubistesin. During the first stage the area of the vulva affected by lichen sclerosis was treated with ablation, and during the second stage an intradermal injection was given prior to the prepared PRP.

After the procedure, the vulva was treated with an aqueous chlorhexidine solution for the expulsion of the tissue detritus.

Abstinence from sex was set at 72 hours. Topical antiseptics were used to prevent infectious complications. In the case of a medical history of genital herpes, a standard dose of valaciclovir was given as a prophylactic three days before and after the procedure. Patients were able to return to normal activity on the same day.

**Results**

The patients included in the study received two laser treatment procedures for lichen sclerosis in conjunction with PRP with a 1 month interval. The procedure was concluded without complications during the pre and postoperative periods. Patients did not experience pain or discomfort during the procedure.

Three fixed intervals were determined to assess clinical efficacy: before the procedure, 1 month after and 6 months after the procedure.

In the initial check-up 1 month after the procedure, 32 patients (85%) had been completely cured of all symptoms of lichen sclerosis and insignificant morphological manifestations remained in 6 patients (15%).
After 6 months, 30 patients (78%) exhibited no manifestations of lichen sclerosis and 8 patients (22%) exhibited weak symptoms, which they considered insignificant.

A modified questionnaire SF-36 Health Status Survey (SF-36) was used to assess quality of life before and after treatment.

The aim of the questionnaire on the quality of life for women with lichen sclerosis was to assess not only the medical efficacy of the treatment, but also the change in the patient’s quality of life (their physical activity, mental state, social, sexual and other role functions, and a subjective health assessment) before and after the treatment.

The heading ‘Before treatment’ refers to the patient’s feelings from the onset of the disease until treatment. The heading ‘After treatment’ included two stages: 1 and 6 months after the treatment. The results of the assessment shown in Table 1 facilitated the optimisation of the treatment method used.

<table>
<thead>
<tr>
<th>SF36</th>
<th>Before the procedure</th>
<th>After 1 month</th>
<th>After 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>PF</td>
<td>54.4±12.0</td>
<td>65.2±11.6</td>
<td>84.7±14.7**</td>
</tr>
<tr>
<td>RP</td>
<td>39.1±18.8</td>
<td>53.3±15.4*</td>
<td>79.3±15.5**</td>
</tr>
<tr>
<td>BP</td>
<td>52.3±12.1</td>
<td>70.1±11.6*</td>
<td>81.0±15.1**</td>
</tr>
<tr>
<td>GH</td>
<td>54.8±9.6</td>
<td>73.0±9.3*</td>
<td>84.8±14.2**</td>
</tr>
<tr>
<td>VT</td>
<td>41.6±11.6</td>
<td>62.4±10.6</td>
<td>75.3±12.2**</td>
</tr>
<tr>
<td>SF</td>
<td>65.5±9.8</td>
<td>66.7±10.1</td>
<td>74.7±10.1*</td>
</tr>
<tr>
<td>RE</td>
<td>40.2±18.1</td>
<td>62.7±11.8</td>
<td>87.9±15.8**</td>
</tr>
<tr>
<td>MH</td>
<td>43.6±9.8</td>
<td>58.5±9.4*</td>
<td>78.8±10.7**</td>
</tr>
</tbody>
</table>

Table 1. The changes in the parameters of quality of life according to questionnaire SF-36. Note: * - p<0.05, ** - p<0.01 (compared with ‘Before the procedure’)

As can be seen from the results shown in Table 1, a reliable positive trend was recorded after 1 month according to the following indices of the SF-36 scale: RP, BP, GH, and MH. A distinct positive trend after 6 months with a high level of validity (p<0.01) is noted across all indices of the SF-36 scale, with the exception of SF. After 6 months, levels are indicative of a reasonably high quality of life observed across all the quality of life indices.

Objectifying the patient’s feelings via the quality of life assessment enables a complete analysis of the results of the treatment given. This study demonstrates positive changes in the quality of life of patients with lichen sclerosis and an improvement in both the mental and physical elements.

No complications were noted during the postoperative period. The safety of this method is demonstrated by the absence of inflammatory changes and reactions, which represents an advantage over the other known methods.

Treatment of lichen sclerosis using an erbium laser in conjunction with PRP is a contemporary, minimally invasive treatment method with a high efficacy and safety profile.

**Clinical case**

The patient was 31 years old. She came to Professor Yutskovskaya’s LLC Clinic complaining of itching of the vulva, changes to the exterior appearance of the vulva and pain during sexual intercourse. She had never before broached this issue with her gynaecologist, who had administered treatment without success. She was examined at the clinic by specialists in gynaecology, urology and dermatovenerology. Taking into account the medical history of disease and the clinical presentation, advanced lichen sclerosis was diagnosed (Fig. 1).
Fig. 1. Lichen sclerosis. The labia minora are diffusely altered.

A biopsy of the vulva was taken which confirmed the diagnosis. Some thickening of the horny and Malpighian layers of the epidermis was noted in addition to areas of parakeratosis. Inflammatory and atrophic changes in the derma were noted in the elastin, which was observed only in small fragments and twisted fibres, and the collagen, which was shown to be sclerosal.

We decided to conduct treatment using an erbium laser in conjunction with PRP. The method of laser treatment using cold ablation (a pulse duration of 100 ms and a pulse density of 3 J/cm²) enables careful removal of the dysfunctional layer without causing a build-up of heat in the underlying structures (Fig. 2A).

Fig. 2A. View of the vulva immediately after laser destruction. B. View of the vulva after injection with PRP
Plasmolifting tubes were used to prepare the PRP. The PRP injections were administered using a mesotherapeutic technique with a 30G needle immediately after the use of the laser (Fig. 2B).

1 week after the initial procedure the patient noticed changes. The intensity of the itching of the vulva was considerably reduced. Touch sensitivity in the labia minora developed. Discharge from the scab and areas of epithelisation (clear mucus) were visible upon examination (Fig. 3).

We decided to continue treatment. Cold fractional laser grinding was administered (with a pulse duration of 100 ms and a pulse density of 15 J/sm²) in conjunction with PRP injections (Fig. 4A,B).

Fig 3. Condition 1 week after the initial procedure.

Fig. 4A. Condition after fractional laser destruction. B. Condition after PRP injections.
Complete clinical remission was achieved 1 month after the initial procedure. The patient received two laser treatments in conjunction with PRP. The interval between procedures was 1 month. There were no complications during the pre and postoperative period.

The patient did not have any further complaints after 6 months. Mucus was bright pink in colour without changes or sites of hyperkeratosis upon examination (Fig. 5).

Both doctor and patient consider the results of these procedures to be outstanding. The results demonstrate the high efficacy of laser treatment for lichen sclerosis in conjunction with PRP injection.

The participants in the study have no material incentive and are in no way affiliated with the manufacturer.

Ye.V. Leshunov acted as external consultant to the company Asclepion due to his experience of working with the MCL 31 laser apparatus.

Fig. 5. 6 months after the initial procedure. Note the complete ablation of the mucus. Mucus is bright pink in colour and there are no signs of inflammation.
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