Preliminary application study on LABIELLE (Labial EndoliftX Laser Enhancement) vulvar treatment for labia minora and majora tightening

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ABSTRACT

This scientific article provides a comprehensive overview of Labielle, a minimally invasive vulvovaginal treatment designed to enhance the aesthetic and functional aspects of both labia majora and labia minora. The article discusses the anatomy of the female genitalia, the indications for Labielle, the treatment procedure, potential benefits, safety considerations, and future directions in this emerging field of gynecological aesthetics aimed at respecting the female anatomy with a non-surgical minimally invasive treatment, that respects the functionality and the natural appearance as well as the personal diversity of each patient.

Key words: labiaplasty, laser, tightening, endolift, labia majora, labia minora.

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Introduction

The female genitalia, like any other part of the body, can undergo changes due to various factors such as aging, childbirth, hormonal fluctuations, or genetic predisposition. These changes may lead to discomfort, decreased self-esteem, or diminished sexual satisfaction. To address these concerns, aesthetic gynecology has evolved, offering non-surgical and minimally invasive treatments, one of which is Labielle. This innovative procedure has gained popularity due to its effectiveness in addressing a range of aesthetic and functional concerns associated with both labia majora and labia minora. ²

To comprehensively understand the rationale behind the use of this therapeutical option, it is imperative to delve into the intricate anatomy and functionality of the female genitalia. The female external genitalia, known as the vulva, comprises several components, with the labia majora and labia minora being key structures.³

The labia majora are the outermost folds of skin that encase the vulva. These are prominent and often referred to colloquially as the "outer lips." Beyond their aesthetic role, the labia majora serve crucial functions in protecting the internal structures of the vulva.4 They act as a barrier against friction, trauma, and pathogens, helping to maintain the overall health and integrity of the genital area. Additionally, the labia majora contain adipose (fatty) tissue, which serves as insulation and cushioning, enhancing comfort during activities such as walking and sitting. Moreover, the labia majora have a role in temperature regulation, helping to maintain the optimal conditions for the functioning of the reproductive and urinary systems.⁵ Situated within the labia majora are the labia minora, also known as the "inner lips." The labia minora are thinner and more delicate than the labia majora and serve multiple functions. They play a pivotal role in protecting the clitoris, urethral opening, and vaginal entrance from friction and potential irritants.⁶ Moreover, the labia minora contain a dense network of blood vessels, which contribute to sexual arousal and sensitivity. During sexual activity, they can become engorged with blood, enhancing pleasure.7 The labia minora also helps maintain the moisture and pH balance of the vaginal area, contributing to overall vaginal health.8

Understanding the dynamic interplay between the labia majora and labia minora is crucial in the context of aesthetic gynecology. The labia majora provide a protective and supportive framework for the labia minora, and changes in the labia majora can affect the overall appearance and function of the vulva. The labia minora, on the other hand, have a direct impact on sexual sensitivity and comfort.⁹

Materials and Methods

Reduction of the labia majora

Excess labial skin (analogous to the hypertrophy and sagging of the scrotal skin in men), the labia majora hang down as empty skinfolds. If there is fat atrophy, volume replacement with autologous fat is indicated. If there is excess labial skin, the labia majora require tightening.¹

Reduction of the labia minora

Although it is often measured differently, the labia minora length is the maximum distance from the origin of the labia at the start of the interlabial fold until its insertion into the perineum. The labia minora height, on the other hand, is the maximum distance from the base of the interlabial fold to the free edge of the labium minus. This distance is best measured with the patient standing. 10 At what point do we refer to hypertrophy of the labia minora? There is no internationally recognized definition. If the labia minora height exceeds 2 cm from the base at the interlabial fold, the inner vaginal lips generally start to be visible outside the shelter of the labia majora and are then associated with more detrimental physical and psychological effects. If they measure more than 2 cm in height, therefore, the labia minora can be described as hypertrophic.11

In this study, we included patients with Labia majora flaccidity and Labia minora with mild hypertrophy grade 1 (up to 2 cm from the margin of the labia majora) normo-hypertrophic in thickness (3-4 mm – more 4 mm) to correct hypertrophy of the labia minora, but the technique can be applied in patients with moderate hypertrophy with volume reduction beyond not correcting the hypertrophy, understanding the limitation of the technique.

This study was conducted according to the guidelines of the Helsinki Declaration,² and resolution 196/96 of the National Health Council on Research Involving Human Subjects.

After receiving permission from Ethical committee, a detailed explanation of the study protocol was provided to the participants that signed the written informed consent.

Study protocol

All patients have been treated with a non-ablative SSVL (LASEmaR 1500TM - EUFOTON - Trieste Italy) with a wavelength of 1470 nm using a power (in Watt) of 5-8 Watt in continuous or pulsed mode.

It is a medical device approved by a CE-certified (Figure 1).



Figure 1. Device used in the study: Lasemar 1500.



Figure 2. Optical fiber used in the study, with graphic identification of the beam profile and different calibers.

The probe used is either a radial fiber with different caliber with different core calibers, namely 300, 400, and 600 microns naked (Figure 2).

The overall energy used on average was 100 Joules for labia minora (each) and 300 Joules for labia majora (each). The treatment was performed in an outpatient setting. According to the protocol, the procedure involves Informed consent and pre-procedure assessments, application of anesthetic cream 15 minutes prior to the procedure in the area to be treated (Lidocaine 23% Tetracaine 7%), vulvoperineal asepsis and antisepsis, marking of the area, tumescent anesthesia at each entry point, initial anterograde infiltration, and then retrograde volume 8mL in both labia majora and 3mL in each labia minora.

After Labielle technique for both labia majora and labia minora was employed, the following follow-up and post-operative care was recommended: avoid sexual relations for 72 hours, keep the treated area clean; maintain personal hygiene; avoid putting gels or creams on the treated area; analgesia according to pain, mandatory medical checks after 21 days.

Data collection and analysis

A total of 15 women were informed about the study; Of these, 12 fit the inclusion criteria and completed the 180-week follow-up and therefore were included in the study for a total of 48 areas treated (left and right internal and external labia) (Table 1).

Results

A standardized gynecologic clinical assessment¹² for the evaluation of the results was performed measuring both at baseline an at follow up at 180 days to assess the fol-

Table 1. Demographic.

Participants n° (%)	12 (100%)
Age at enrolement (mean)	28
Hormonal condition Premenopause Postmenopause	10 2
BMI (kg/m², mean, ±SD) Normal Overweight Obesity	21 8 4 0

lowing: i) the reduction of the labia minora size (measured in mm); ii) assessment of the tightening for labia majora (Range: 1 to 5; higher scores indicate better trophism); iii) tolerance to treatment (vulvar or vaginal pain) using the Visual Analog Scale (0–10) with scale ranging from 0 (no pain/no hurt) to 10 (worst pain possible); iv) report on vaginitis, burning, itching sensation, hurting, irritation were assessed as existing or non-existing; v) the overall result level of satisfaction was assessed using a Likert scale at follow up, after 180 days, with scores ranging from "Not at all Satisfied" (1), "Partly Satisfied" (2), "Satisfied" (3), "More than Satisfied" (4), "Very Satisfied" (5).

In Table 2 of this section, the outcomes of the Labielle procedure are presented. This includes changes in labial appearance, patient-reported outcomes, and any relevant statistical data.

No significant difference has been noted between premenopause and postmenopause patients.

Discussion

Labielle addresses these concerns by providing a comprehensive solution for both labia majora and labia minora. This treatment not only improves the appearance of the genitalia but respect its diversity and the natural aspect, contrary to a surgical approach where for the labia minora the tissue is uniformly cut to achieve a vulva with symmetrical labia minora, approaching a hegemonic vulva as a result. ¹³ As we delve into the details of the Labielle procedure, its potential benefits, and safety considerations, it becomes evident that this approach represents a significant advancement in gynecological aesthetics, offering a holistic

solution for a wide range of concerns that individuals may seek to address. 14

The benefits of Labielle are the following: i) outpatient procedure: Labielle is typically performed on an outpatient basis, allowing patients to return home on the same day. This minimizes the need for hospitalization and ensures a more convenient experience for individuals seeking labial tightening; ii) local anesthesia: The use of local anesthesia enhances patient comfort during the procedure. This localized approach minimizes pain and discomfort, contributing to a smoother and more tolerable experience; iii) respect for anatomy: Labielle is designed to respect the natural anatomy of the female genitalia. It aims to enhance the appearance and functionality of the labia while preserving the integrity of the anatomical structures; iv) maintenance of vascularization: The procedure is designed to maintain vascularization in the treated area. This ensures adequate blood flow to the labia, promoting tissue health and minimizing the risk of complications; v) preservation of sensitivity: Labielle is conducted with precision to minimize the risk of sensitivity impairment. Patients can expect to maintain their natural sensations, contributing to a positive post-procedure experience; vi) simplicity and single anatomical area: Labielle is a focused procedure performed in a single anatomical area. Its simplicity and specificity contribute to a straightforward and efficient treatment process; vii) short and reproducible learning curve: medical professionals can quickly acquire the skills required to perform Labielle effectively. This short and reproducible learning curve ensures that more practitioners can offer this treatment to meet the growing demand; viii) no visible scarring: Labielle is a minimally invasive procedure that leaves no visible scarring. Patients can enjoy the aesthetic benefits without worrying about unsightly

Table 2. Results.

Total areas n° (%) 48 (100%)	Baseline (pre-procedure assessment)	180 days follow up (post-procedure assessment)
Labia Minora areas observed n° (%) 24 (50%) Length mean in cm	1,5	1
Labia Majora areas observed n° (%) 24 (50%)		
Tightening	2	4
Tolerance VAS (mean)	2	0
Vaginitis n°	4 (0%)	0
Burning n°	1	0
Itching n°	8	2
Hurting n°	8	1
Irritation n°	10	0
Likert scale n°		4

marks; ix) low risk of dehiscence: the risk of dehiscence (wound separation) is minimal with Labielle due to its minimally invasive nature and the preservation of tissue integrity; x) quick resumption of sexual relations: patients often experience a rapid recovery period, allowing for a quick resumption of sexual relations. This not only enhances patient satisfaction but also contributes to a positive overall experience.

Further when compared to Ablative resurfacing the following points, relative to ablative methodology, should be taken in consideration: significant downtime during the recovery period; during the first week, significant erythema and edema, and wound care is necessary; reactivation of recurrent herpes disease; increased risk of infection; risk of post-inflammatory hyperpigmentation; anomalous healing.

Conclusions

Labielle, as a comprehensive treatment that targets both labia majora and labia minora, is strategically designed to rejuvenate these structures by effectively addressing a spectrum of concerns, including laxity, asymmetry, and discomfort. It represents a minimally invasive option, offering a nuanced approach to labial tightening that

Before



Figure 3. Clincal case: age 32, effect: length reduction of labia minora 0,6 mm. Tightening improvement of Labia majora +2.

strives to attain optimal outcomes while ensuring patient satisfaction across both aesthetic and functional dimensions (Figure 3).

However, it's vital to acknowledge that Labielle, while highly effective in addressing a wide range of labial concerns, has specific limitations. This treatment is most suitable for cases characterized by mild hypertrophy of the labia minora, but the technique can be applied in patients with moderate hypertrophy with volume reduction beyond not correcting the hypertrophy, understanding the limitation of the technique.

Conversely, severe hypertrophy or deflation of the labia majora falls outside the recommended scope for Labielle. In cases of severe hypertrophy, alternative treatment modalities should be considered to be used as a coadjuvant to address the extensive tissue excess effectively.

In summary, Labielle represents a sophisticated and minimally invasive approach to labial rejuvenation, where both aesthetic refinement and functional enhancement are essential considerations.

Conflict of interest: the authors declare no potential conflict of interest, and all authors confirm accuracy.

Ethics approval: the Ethics Committee from "Comité Central de Ética en Investigación" of Buenos Aires and the study is conformed with the Helsinki Declaration of 1964, as revised in 2013, concerning human and animal rights.

Informed consent: all patients participating in this study signed a written informed consent form for participating in this study.

Patient consent for publication: written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

Availability of data and materials: all data generated or analyzed during this study are included in this published article.

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