

Development and Validation of a Clinical Grading Scale to Assess the Vulvar Region: The Vulvar Architecture Severity Scale

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Abstract

Background: The vulva is composed of aesthetic units that can be affected differently by vulvar conditions. A reliable, comprehensive, and quick-to-use clinical scoring system is required to assess the disease extent in the vulvar area.

Objectives: The aim of this study was to develop and validate a grading scale based on the aesthetic unit principle to evaluate the extent of vulvar lichen sclerosus (VLS).

Methods: After reviewing photographs of 100 patients affected by VLS, the authors targeted the aesthetic units most frequently affected. The disease signs were recorded and graded in 4 levels of severity (none, mild, moderate, severe) taking into account the vulvar architecture and skin involvement. To validate the scale, 14 observers were asked to apply it to photographs of 25 VLS patients on 2 different occasions. Intra- and inter-observer reliabilities were determined employing Pearson's and intraclass correlation coefficients.

Results: A 6-region, 4-point grading system was designed and identified as the Vulvar Architecture Severity Scale (VASS). In all 6 areas, the Pearson's r was greater than 0.9 (mean, 0.994; 95% confidence interval [CI] = 0.992), indicating that the intra-observer reliability of the VASS was consistent over time ($P < 0.001$). Intraclass correlation at time 1 was 0.928 (95% CI = 0.910, 0.943) and at time 2 was 0.944 (95% CI = 0.931, 0.996), indicating a high reliability level among different observers.

Conclusions: The VASS is a reliable scale to assess the severity of VLS, and it might be considered as an outcome measure in future VLS trials.

Level of Evidence: 4

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Vulvar Architecture and the Regional Aesthetic Units Principle

The vulvar region is composed of convex and concave surfaces that define multiple anatomical elements differing in surface structure, skin thickness and pigmentation, and composition of subcutaneous tissue. Similar to other areas of the body, such as the face, these factors contribute to greater variability of landmarks, formation of lines, and discontinuity region, which have been defined as aesthetic units.^{1,6} Normal vulvar architecture is composed of the following aesthetic units: labia majora, labia minora, clitoral area, posterior fourchette, perineum, and anal area (Figure 1). Different vulvar conditions can affect 1 or more aesthetic units, causing the loss of normal vulvar architecture.

Lichen Sclerosus and Loss of Vulvar Architecture

Vulvar lichen sclerosis (VLS) is a chronic inflammatory condition that may present heterogeneous features; in mild cases, only hypopigmentation and tissue atrophy are present, whereas hyperkeratosis and lichenification are present in other cases.⁷⁻¹⁰

The typical skin lesions are circumscribed porcelain-white papules and plaques with areas of atrophy or hyperkeratosis; these lesions are often associated with ecchymosis from repeated scratching in addition to postinflammatory hyperpigmentation. Crinkled skin texture change is a general pathognomonic, although a shiny, smooth texture can be distinguished.¹¹ Fissures and tears can develop, and the scarring process may cause architectural changes, including flattening of the labia majora, adhesion and fusion of the labia minora, and clitoral phimosis.¹² Typical histopathology findings are hyperkeratosis, epidermal thinning and basal cell degeneration, hyalinization of the upper dermal collagen, and a mid-dermal lymphocytic inflammatory infiltrate.⁸

Symptoms include itching, burning, and pain; genital vaginal mucosa is not involved, although mucocutaneous junctions might be affected, resulting in fissuring and scarring in the posterior fourchette with consequent introital narrowing.^{13,14} The presence of erosions, fissures, scarring, or introital narrowing can lead to significant and debilitating dyspareunia and resulting sexual dysfunction.¹⁵

A definitive cure for VLS does not exist. Standard treatment includes topical super-potent steroids to control symptoms and to prevent both anatomical changes and malignant transformation.⁸ However, randomized controlled trials to ascertain the effectiveness of 1 ultrapotent steroid over another or to define the length of treatment are lacking, and treatment needs to be individualized. Other first-line treatments include calcineurin inhibitors,

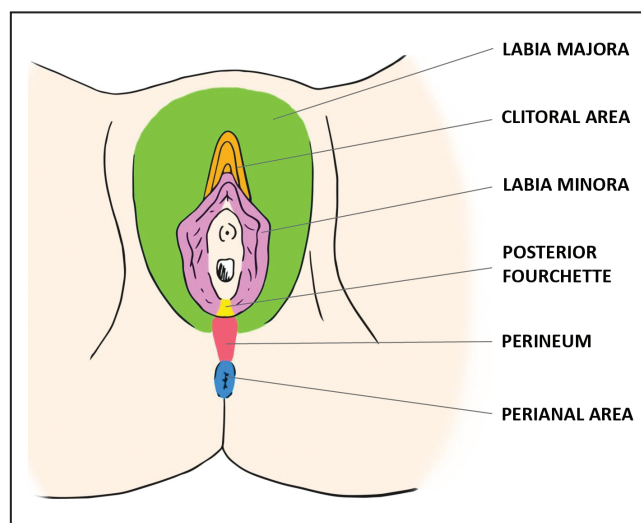


Figure 1. The vulvar aesthetic units. The diagram illustrates the main 6 aesthetic units composing the vulvar region: labia majora (green), labia minora (pink), clitoris (orange), posterior fourchette (yellow), perineum (red), and perianal area (blue).

followed by systemic immunomodulatory agents such as plaquenil, methotrexate, and acitretin.¹ Although skin lesions can be treated topically in an effective manner, the anatomical modifications and functional defects are not reversible with topical treatment and require surgical reconstruction.^{16,17} To date, there is no consensus on the role of surgery in VLS: although the interventions to excise the scar tissue are associated with a 50% recurrence rate even with full thickness skin grafts,¹⁸ there is a clear benefit of surgical intervention in the postinflammatory sequelae of the disease to correct the architectural changes¹²; surgical interventions are indicated for functional defects and to restore the loss of the vulvar architecture. Surgical reconstruction to restore the vulvar architecture includes dissection of clitoral adhesions, dissection of fused labia, and labia minora reconstruction. Vulvoperineoplasty (modified Fenton's procedure) is also indicated to correct introital stenosis due to scarring in perineum and posterior fourchette. The goal of these techniques is to regain access to the vagina and urethra, restore sexual function, ameliorate symptoms, and improve patients' quality of life.¹⁹ In addition, the utilization of regenerative surgery has recently been proposed in VLS to improve dermal fibrosis and increase subcutaneous tissue bulk. Autologous lipotransfer, adipose-derived stem cells, and platelet-rich plasma are different strategies that aim to replace volume loss and regenerate the vulvar skin by reversing fibrosis, ameliorating skin elasticity, and preventing anatomical modification. Improvements in sexual function and quality of fibrotic skin have been reported following lipotransfer and platelet-rich plasma.²⁰⁻²² However, evidence is limited, and a clear

role for regenerative strategies in VLS is still a matter of debate.²³

Although efforts to identify the optimal management for VLS are ongoing,^{13,24} an accurate grading scale to describe the amplitude of alterations that can occur at the same time in the different vulvar aesthetic units is presently lacking.²⁵ The scales proposed so far have attempted to describe only the main signs of the disease as individual items (ie, hyperkeratosis, atrophy, purpuric lesions, pallor, erosions, fissuring, sclerosis). The main limitation of these scores is that they consider only the overall presence of the skin lesions without taking into account the involvement of the aesthetic units.²⁵⁻²⁷ Without indicating which aesthetic unit is affected, they are inadequate for the accurate reporting of disease severity. In fact, significant differences in disease severity may occur between the various anatomical areas: lichen sclerosus is a progressive condition that may worsen with time, not only in terms of disease severity but also affecting different parts of the vulvar region to a lesser or greater extent. An aesthetic unit approach is ideal to systematically assess the disease severity and will improve clinical practice by facilitating communication among healthcare professionals treating the same patient, and by assisting with adequate pre- and postoperative surgical evaluation.

Objectives

We aimed to develop and validate a clear and easy-to-use clinical scale to grade levels of severity of vulvar lichen sclerosis utilizing the aesthetic unit principle.

METHODS

Scale Development

One hundred photographs of patients affected by VLS were reviewed. The inclusion criteria were as follows: clear photographs showing the entire vulvar region; representing VLS disease only; any age older than 18 years; and any ethnicity. Exclusion criteria: images only partially representing the vulvar area; the presence of overlapping skin disease; and age younger than 18 years. The images were obtained from the website www.vulvovaginaldisorders.org after private credentials (username and password) were provided from the website administrators, along with the permission to utilize the material for the research purpose.

The scale was developed in 2 stages between January 2017 and December 2018. In the first stage, for each photograph, the aesthetic units affected by the disease were targeted and the anatomical modification recorded. All the clinical features were also identified and recorded. In a second stage, at the end of the analysis, a map of the most

frequently affected vulvar regions was delineated along with the main associated clinical features. A scale was then developed to grade independently each aesthetic unit with a disease severity of 4 levels (none, mild, moderate, severe), taking into account the vulvar architecture and the presence of skin lesions.

Scale Validation

Once the scales were created, 25 different photographs representative of VLS were selected from the same database across a spectrum of disease severity. The images were selected by a multidisciplinary team composed of plastic surgeons (A.A. and P.B.), gynecologists (N.Z., D.B., and W.R.), a dermatologist (V.S.), and a vulval specialist nurse; all the team members were familiar with vulvar disease. The images selected were administered to 14 clinicians along with the Vulvar Architecture Severity Scale (VASS), and for each photograph the participants were asked to grade all the aesthetic units on 2 distinct occasions (Time 1 and Time 2).

Statistical Analysis

To validate the scale, intra-observer and inter-observer reliabilities were evaluated. The intra-observer reliability was assessed with the Pearson's correlation coefficient (Pearson's r),²⁸ which was computed for the mean ratings at Time 1 vs the mean ratings at Time 2 for each aesthetic unit, with 95% confidence intervals (CIs) based on the Fisher r -to- z transformation.

Inter-observer reliability was calculated utilizing the intraclass correlation coefficient (ICC), which is currently the most popular method employed to test for the inter-reliability of medical instruments.²⁹ Analysis was performed with the software SPSS, Statistical Package for the Social Sciences (SPSS Statistics for Macintosh, Version 23.0, IBM, New York, NY).

RESULTS

Development of the VASS

The photograph analysis revealed that all the vulvar aesthetic units can be affected by VLS to a lesser or greater extent. The clinical signs of the disease were characterized by a combination of architectural changes (partial or total loss of the aesthetic unit) and the presence of skin lesions, with a wide variety of clinical scenarios.

The aesthetic units affected by the architectural modifications were labia majora (partial or total volume loss), clitoral area (scarring of the prepuce of the clitoris, adhesions and fusion of clitoral hood, clitoral phimosis, sealing

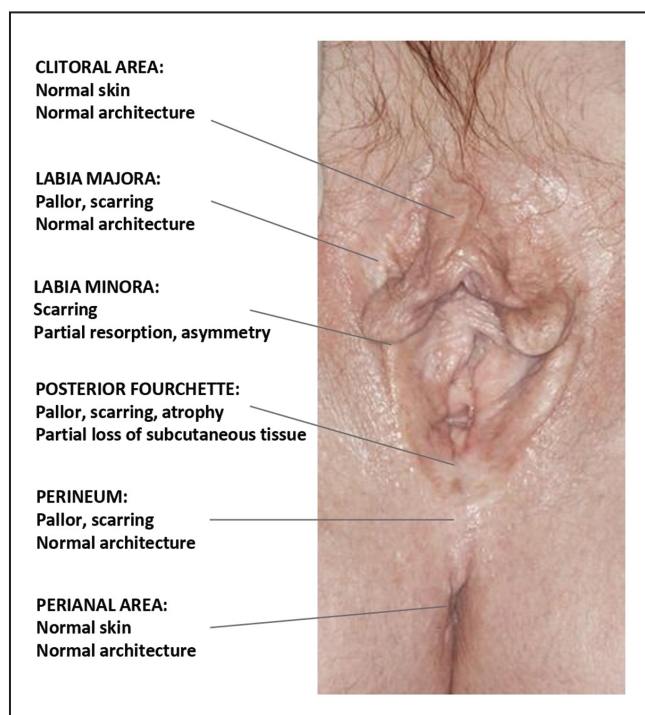


Figure 2. This photograph of a 62-year-old woman represents a typical patient affected by VLS. Note the partial resorption of the labia minora at the bases, with asymmetry between the 2 sides (partial loss of architecture). Scarring is present in the labia majora (interlabial sulci), labia minora, and posterior fourchette; pallor is present in the labia majora (interlabial sulci), posterior fourchette, and perineum is evident.

of the clitoral hood resulting in burying of the clitoris, total loss of clitoris), labia minora (flattening of the labia minora at the bases, labia minora asymmetry, agglutination to the interlabial sulcus, formation of synechiae anteriorly and/or posteriorly, labial agglutination, partial labial resorption, total labial loss), posterior fourchette (skin atrophy, fissuring and splitting and consequent scarring with formation of fibrotic band and introital narrowing, loss of tissue bulk), and perineal and perianal area (skin atrophy or fibrosis, fissuring and splitting and consequent scarring, loss of tissue bulk).

The most common skin lesions were pallor (in the labia majora, labia minora, clitoris, perineum, and anal area); atrophy (mainly in the posterior fourchette but also in the labia majora, minora, and clitoris); hyperkeratosis (in the labia majora, labia minora, clitoris, perineum, and perianal area); lichenification (in the labia majora, labia minora, clitoris, perineum, and perianal area); ecchymosis, purpura, or telangiectasia (in the labia majora, labia minora, clitoris, perineum, and anal area); erosions, fissuring, or ulceration (in the labia majora, labia minora, clitoris, fourchette, perineum, and perianal area); and skin fibrosis and scarring (in the labia majora, labia minora, clitoris, fourchette, perineum, and perianal area). Figures 2 and 3 illustrate representative VLS cases.

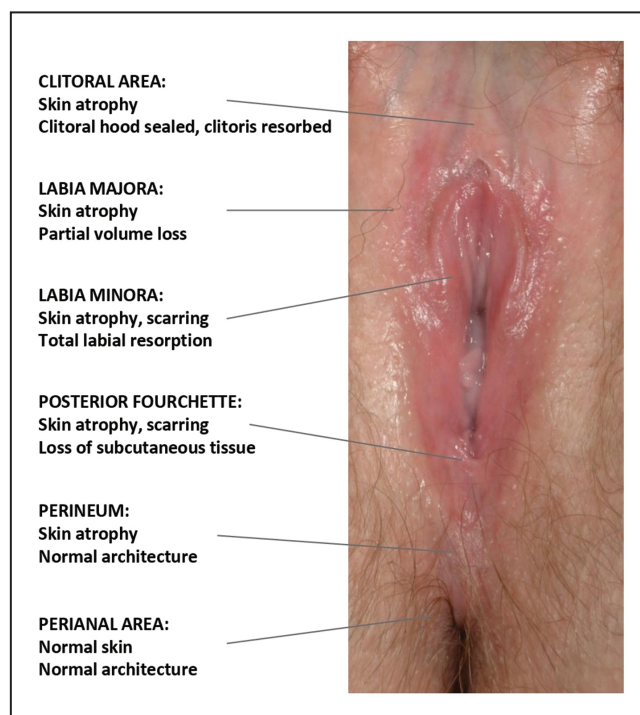


Figure 3. This photograph of a 35-year-old woman represents a typical vulvar lichen sclerosus patient presenting total loss of the labia minora and fusion of the clitoral hood with total resorption of the clitoris (total loss of architecture in both the subunits). Note the skin atrophy in labia majora, posterior fourchette, and perineum.

Once the affected areas had been identified and targeted, the information collected was then assigned to 1 of 4 levels of disease severity (none, mild, moderate, and severe) to create a 6-region, 4-grade severity scale (Appendix A). The scale was named VASS-Lichen Sclerosus. In the VASS, each aesthetic unit is assessed independently taking into account the vulvar architecture and skin involvement as follows: none: normal architecture, normal skin; mild: normal architecture, presence of skin lesions; moderate: partial loss of the architecture, with or without the presence of skin lesions; severe: total loss of the architecture, with or without the presence of skin lesions. An additional section was added to better describe which type of skin lesion is present by ticking the appropriate box. The full assessment should be completed in less than 3 minutes, and the domain of each aesthetic unit is reported separately at the end. Appendices B and C represent example of grading with the VASS referring to the VLS cases illustrated in Figures 2 and 3.

Validation of the VASS

The number of days between the first and second rating ranged from 7 to 14 days, with a mean of 7.5 days. The

Table 1. Intra-Observer Reliability of the VASS (Pearson’s *r*)

Aesthetic unit	Pearson’s <i>r</i>	95% CI	<i>P</i>
Labia majora	0.995	0.986, 0.998	<0.001
Labia minora	0.998	0.995, 0.999	<0.001
Clitoral area	0.994	0.986, 0.997	<0.001
Posterior fourchette	0.994	0.986, 0.997	<0.001
Perineum	0.994	0.986, 0.997	<0.001
Perianal area	0.994	0.983, 0.998	<0.001
Overall	0.994	0.992, 0.996	<0.001

The table presents the Pearson’s *r* coefficients to estimate test-retest reliability between Time 1 and Time 2 based on the mean scores of the 14 raters for each of the 6 areas observed in the photos. CI, confidence interval; VASS, Vulvar Architecture Severity Scale.

Pearson’s *r* coefficients computed for the mean ratings at Time 1 vs the mean ratings at Time 2 for each photograph, with 95% CIs, indicated that the test-retest reliability of the scale was consistent over time (Pearson’s *r* = 0.994 to 0.998) (Table 1). Figure 4 shows a scatterplot with linear trend line illustrating the mean ratings at Time 1 vs the mean ratings at Time 2 for all 14 raters. The straight line reflects the excellent overall level of test-retest reliability of the grading scale (Pearson’s *r* = 0.994, *P* < 0.001; 95% CI = 0.992, 0.996).

The values of the ICC computed utilizing the data collected from the same 14 raters at Time 1 and Time 2 are represented in Table 2. Excellent inter-observer reliability for the mean measures of the scale was computed for the 6 areas observed in the photographs by the 14 raters at Time 1 (ICC = 0.928, 95% CI = 0.910, 0.943) and Time 2 (ICC = 0.944, 95% CI = 0.931, 0.996) (Table 2). The average measures of the ICC were also consistent when computed for each of the 6 specific areas observed in the photographs at Time 1 (ICC = 0.886-0.959) and Time 2 (ICC = 0.936-0.965).

DISCUSSION

Clinical grading scales are valuable tools in clinical practice, research, or audit for the systematic assessment of disease extent, the description of deformities in a manner that is easily translatable from physician to physician, and in assisting with adequate pre- and postoperative surgical evaluation.^{30,31}

The scale proposed in this study is based on the clinician’s pattern recognition of disease findings and was

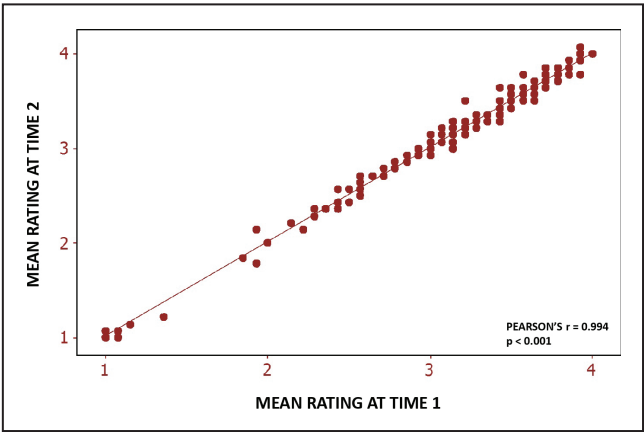


Figure 4. Intra-observer reliability. The Pearson’s *r* reflected the consistency of the test-retest data by determining how closely the paired observations follow a straight line. The scatterplot represents the mean ratings at Time 1 vs the mean ratings at Time 2 for all 14 raters. The straight line reflects the excellent overall level of test-retest reliability of the Vulvar Architecture Severity Scale.

created by a multidisciplinary team familiar with vulvar disease. The novelty of the scale consists in its approach based on the aesthetic unit principle, which allows a systematic assessment of the vulvar architecture to be made in a few minutes. The approach to standardization of the vulvar exam and its scoring presents several advantages, including (1) accurate evaluation of disease progression over time, (2) accurate evaluation of response to treatment, (3) assistance with treatment and surgical planning, (4) ease of communication among different healthcare professionals treating the same patient (medical physicians, surgeons, specialist nurses), and (5) standardization of outcome measures to enable studies and trials to be compared in meta-analysis.

The creation of a grading scale is challenging, because the ideal scale should be effective, sensible, as well as succinct and easy to use: if it is too complicated and time-consuming, it is unlikely to be employed in clinical practice because healthcare providers do not often have a lot of time during consultation. This study attempts to address an important gap in the clinical and research literature regarding the female genital area by proposing a new physician-based scoring system with an aesthetic unit approach.

This scale is innovative compared with the ones proposed previously, because it aims to assess the vulval region systematically, taking into consideration the different aesthetic units at the same time rather than focusing on the presence of 1 sign.

Until now, the majority of studies (including randomized clinical trials) have included nonvalidated composite scores of severity for VLS, where each item (skin lesions)

Table 2. Inter-Observer Reliability of the VASS (ICC)

Aesthetic unit	ICC T1	95% CI T1	ICC T2	95% CI T2
Labia majora	0.903	0.835, 0.951	0.936	0.892, 0.967
Labia minora	0.886	0.803, 0.943	0.958	0.930, 0.979
Clitoral area	0.959	0.931, 0.979	0.965	0.941, 0.982
Posterior fourchette	0.938	0.895, 0.968	0.954	0.921, 0.976
Perineum	0.947	0.907, 0.974	0.941	0.899, 0.971
Perianal area	0.954	0.912, 0.981	0.944	0.895, 0.976
Overall	0.928	0.910, 0.943	0.944	0.931, 0.956

The table represents the ICC to estimate the inter-observer reliability at T1 and T2 based on the mean scores of the 14 raters for each of the 6 areas observed in the pictures. Excellent inter-observer reliability for the mean measures of the scale was computed for the 6 areas observed in the pictures by the 14 raters. The average measures of the ICC were also consistent when computed for each of the 6 specific areas observed in the pictures at Time 1 (ICC = 0.886-0.959) and at Time 2 (ICC = 0.936-0.965). CI, confidence interval; ICC, intraclass correlation coefficient; T1, Time 1; T2, Time 2; VASS, Vulvar Architecture Severity Scale.

is scored individually. The individual scores are then summed together to obtain a final score.²⁵ Only 1 study proposed a validated composite score, which consists in physician-based scales for 6 clinical features: erosions, hyperkeratosis, fissures, agglutination, stenosis, and atrophy. Each item is graded on a 3-point Likert scale ranging from 0 to 2, with 0 representing normal findings, 1 moderate changes, and 2 severe changes, obtaining in total 0 at minimum and 12 at maximum.³² Other nonvalidated composite scores included different clinical features: Cattaneo et al assessed hyperkeratosis, atrophy, and sclerosis³³; Virgili et al evaluated erythema, pallor, hyperkeratosis, and purpuric lesions/itching-related excoriations³⁴; Goldstein et al included lichenification and ulceration/fissuring³⁵; Terras et al looked at hypopigmentation, sclerosis, atrophy, hyperkeratosis, erosions, edema, and erythema³⁶; Tamburino et al assessed erosion, hyperkeratosis, fissures, agglutination, stenosis, and atrophy³⁷; and Patsatsi et al combined the clinical features instead of utilizing a composite score. They graded disease severity as follows: no disease: no inflammatory signs; mild disease: mild erythema, infiltration, lichenification, excoriation; moderate disease: moderate erythema, infiltration, lichenification, excoriation; and severe disease: severe erythema, infiltration, lichenification, excoriation.³⁸ The main limitation of these scores is that they attempt to quantify the disease extent taking into account only the overall presence of the skin lesions; without considering the involved aesthetic units, they fail in giving a general snapshot of the vulva. In fact, the presence of a skin feature alone does not necessarily correspond to a lower or higher disease severity and neither does the general description of “architectural change,” which is too generic and not accurate in describing the vulvar involvement.

Only 2 studies considered the description of the involvement of aesthetic units in VLS, albeit not in a systematic way. Funaro et al assessed clinical signs (white papules,

atrophy, erosion, erythematous patches, lichenification) in 5 specific regions: perianal, perineal, labia majora, labia minora, and clitoris. The clinical evaluation consisted in a score of 0 to 3 (none; mild; moderate; severe).³⁹ Lee et al considered the anatomical distribution of the clinical features but only in a generic descriptive way: figure of 8, localized on an area of the vulva, clitoris, or perineum, or symmetrical involvement of the vulva, labial fusion, and clitoral hood fusion.²⁷ The main limitation of these studies is that, despite their effort, they included the vulvar architecture only with a generic description that is not adequate for illustrating the disease extent a systematic way.

A systematic approach comprising all the aesthetic units assessed independently is advisable because it allows a more precise description of the vulva in its entirety. A recent 3-stage Delphi consensus exercise regarding the VLS assessment confirmed the importance of the architectural changes to properly assess the severity of VLS; the participants included were members of the International Society for the Study on Vulvovaginal Disease and were therefore all familiar with vulvar disease. Among them, 87% considered the architectural changes important for an adequate disease assessment.⁴⁰

Essential requirements of clinical scales are validity, feasibility, and reliability. Validity represents the capacity to accurately measure what it is supposed to measure⁴¹; feasibility means that the practical utilization of the scale is suitable in clinical practice; and reliability represents the extent to which the scale measurements could be replicated across the readers or the same reader at 2 different time points. In this study, statistical analysis showed that the VASS has excellent intra- and inter-observer reliabilities. A high level of intra-observer reliability indicates that no significant change in the ratings of the individual raters occurs over time. The Pearson's *r* ranged from 0.994 to 0.988. Intra-observer reliabilities that fall within the generally acceptable range needed for clinical assessment

usually exceed Pearson's $r = 0.7^{29,42}$; therefore, in this study, the intra-observer agreement can be considered high. A high level of inter-observer reliability indicates that there is no significant change in the ratings among 2 or more raters of a specified item.⁴³ In this study, the ICC was 0.928 at time 1 and 0.944 at Time 2; according to Lee et al, an ICC value greater than 0.75 indicates good consistency between multiple raters.⁴⁴ According to McGraw and Wong, the ICC values can be classified as follows: excellent (≥ 0.81), good (0.61-0.80), moderate (0.41-0.60), and poor (≤ 0.40).⁴⁵; therefore, in this study, the inter-observer agreement can be considered as excellent.

Strengths and Limitations

Despite its strengths, this study has limitations. Firstly, it is based only on visual grading from photos without the advantage of physical examination of the vulvar tissues. A preliminary validation based on photographs was considered advantageous in the study design to increase the study power above the absolute minimum required without incurring additional costs. Indeed, a larger number of raters and photographs produced narrower CIs around the reliability estimates than a smaller number of raters and photographs.⁴⁶ In reality, no consensus exists on the minimum number of patients needed for principal-component analysis; according to Cohen,⁴⁷ the minimum total sample size needed to achieve an acceptable power of 80% at the conventional $P = 0.05$ significance level is 28 if the expected effect size is large ($r^2 = 0.50$ corresponding to $r = 0.71$). In this study, there were 14 raters with an actual total sample size of 150, given by the product of the number of raters per number of photographs of each area observed by each rater. The total actual sample size was over 5 times (150/28) the absolute minimum total sample size. Although a photograph-based validation was convenient for the scale validation, further confirmation of reliability involving clinical examination is required.

Another limitation could be that the sensitivity to change with the VASS was not assessed; this could not be performed because the study was based on photograph evaluation and not on the direct examination of patients. Future studies are required to confirm this aspect.

Lastly, in this study we considered only the physician pattern of recognition of the disease without correlating it to patient-reported outcome measures for symptoms, sexual function, and overall quality of life; it was not possible to make such a correlation due to the nature of the study, which only involved photographs. In future works, we plan to correlate the VASS with patient-reported outcome measures to test convergent and discriminant validity and confirm if the subjective clinician rating on macroscopic inspection correlates with patient-reported perceived disease severity and distress.

CONCLUSIONS

This study proposes a new succinct and reliable clinical grading system to assess the extent of VLS. The VASS can be useful in providing physicians and vulvar nurses with a scoring system that addresses the amplitude and variation of alterations that can occur at the same time in the different vulvar aesthetic units. The scale could be considered as an outcome measure in future VLS trials.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com

Disclosures

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