

High-Intensity Focused Ultrasound (HIFU) Treatment of Vulvar Lichen Sclerosus

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Abstract: Vulvar lichen sclerosus (VLS) is a chronic, recurrent dermatosis predominantly affecting postmenopausal women. It is characterized by atrophic and sclerotic changes in the vulvar skin, often causing severe discomfort and functional impairment. Although potent topical corticosteroids remain the primary treatment, high-intensity focused ultrasound (HIFU) emerges as a promising alternative in recurrence cases. This study reports the case of a 73-year-old woman with VLS treated using HIFU, aiming to assess the safety and efficacy of this novel therapeutic approach. The patient presented with significant discomfort due to VLS and had a history of limited response to previous treatments. HIFU therapy was applied using the System ONE-M device operating at 20 MHz, targeting specific lesions. The dermoscopic evaluation was performed pre- and post-treatment to assess the treatment response. Immediate post-procedural whitening of tissues was observed, followed by gradual healing over five months. The patient experienced significant symptom relief, including reduced pain and itching, with minimal adverse effects. The treated areas displayed nearly normal skin color, texture, and improved function within five months post-treatment. This case illustrates the potential of HIFU as an effective and precise non-invasive treatment for VLS, offering significant symptom relief while sparing healthy tissue. Further research is needed to refine treatment parameters and explore the broader clinical applicability of HIFU for VLS management.

Keywords: high-frequency focused ultrasound, HIFU, vulvar lichen sclerosus

Introduction

Vulvar lichen sclerosus (VLS) is a chronic and recurrent inflammatory dermatosis that predominantly affects postmenopausal women, though it can manifest at any age.¹ This progressive skin disease mainly targets the anogenital areas and is more common in females, with its prevalence estimated between 0.1% to 3% in pre-pubertal and postmenopausal individuals respectively.^{2,3} VLS typically presents with porcelain-white, atrophic plaques that may coalesce into larger patches. The lesions are often symmetrical and most frequently involve the labia minora, labia majora, clitoral hood, and perineum. In more advanced cases, architectural changes may occur, including resorption of the labia minora, narrowing of the introitus, or burial of the clitoris. Common symptoms include intense pruritus, burning, pain, and dyspareunia. In some patients, fissures, petechiae, or purpura may also be present, particularly in areas subject to friction or trauma. Despite uncertainties about its exact incidence, VLS remains a frequent cause for medical consultations related to vulvar discomfort or structural changes.⁴ It is characterized by white, patchy skin that is thinner than normal, leading to significant discomfort and complications such as severe itching, pain, and scarring.⁵ Scarring process may lead to complete loss of the labia minora, sealing of the clitoral hood, and burying of the clitoris. These symptoms can cause difficulties in urination and sexual dysfunction due to narrowing of the vaginal opening and fusion of the labia.⁶

The primary treatment for LS involves the use of potent topical corticosteroids, which help reduce inflammation and itching.⁷ For patients who do not respond to steroids or who experience severe side effects, topical immunomodulators like tacrolimus and pimecrolimus may be used as alternatives.^{8,9} In severe cases where scarring has caused anatomical changes, surgical interventions may be necessary to alleviate symptoms and restore normal function.^{10,11} These could include procedures to release adhesions or to correct severe narrowing of the vaginal opening. Emerging treatments such

as photodynamic therapy and laser therapy are also being explored for their potential to alleviate symptoms and prevent progression of the disease.^{12–14} These treatments utilize precise application of light or laser energy to improve skin condition without the side effects associated with systemic medications.

High-Intensity Focused Ultrasound (HIFU) is a novel approach for the treatment of inflammatory skin conditions.^{15,16} This technique uses focused ultrasound waves to target deep tissue layers, inducing thermal and mechanical effects that can potentially alter the disease's progression.^{16,17} These treatments work by causing lesion destruction through cell necrosis and tissue denaturation. The biological reaction to this treatment involves the removal of the damaged cells and tissues, either externally to a wound crust or internally via the vascular and lymphatic systems, making these techniques either directly or indirectly ablative.¹⁵ HIFU offers a promising alternative for patients who cannot tolerate traditional treatments or for whom such treatments have failed, providing targeted therapy with minimal side effects.¹⁸ This makes HIFU a valuable addition to the range of options available to patients suffering from this challenging and often debilitating condition. The detailed description provided in this case report marks the first instance of using 20 MHz HIFU in lichen sclerosus with dermoscopy analysis, showcasing its potential as a novel therapeutic approach.

Case Report

In May 2023, a 73-year-old female patient presented with lichen sclerosus of the vulva (Figures 1A and 2A). The patient had a history of vulvar skin complaints for approximately five years, initially managed by a dermatologist with various topical ointments, but without lasting improvement. As part of the diagnostic workup, the patient was evaluated for associated autoimmune diseases, including thyroid and connective tissue disorders. No autoimmune comorbidities were identified during this assessment. She presented to the outpatient clinic (OTC) on May 8, 2021, at which time no histopathological confirmation was available. A skin biopsy performed later in May 2021 confirmed lichen sclerosus. As

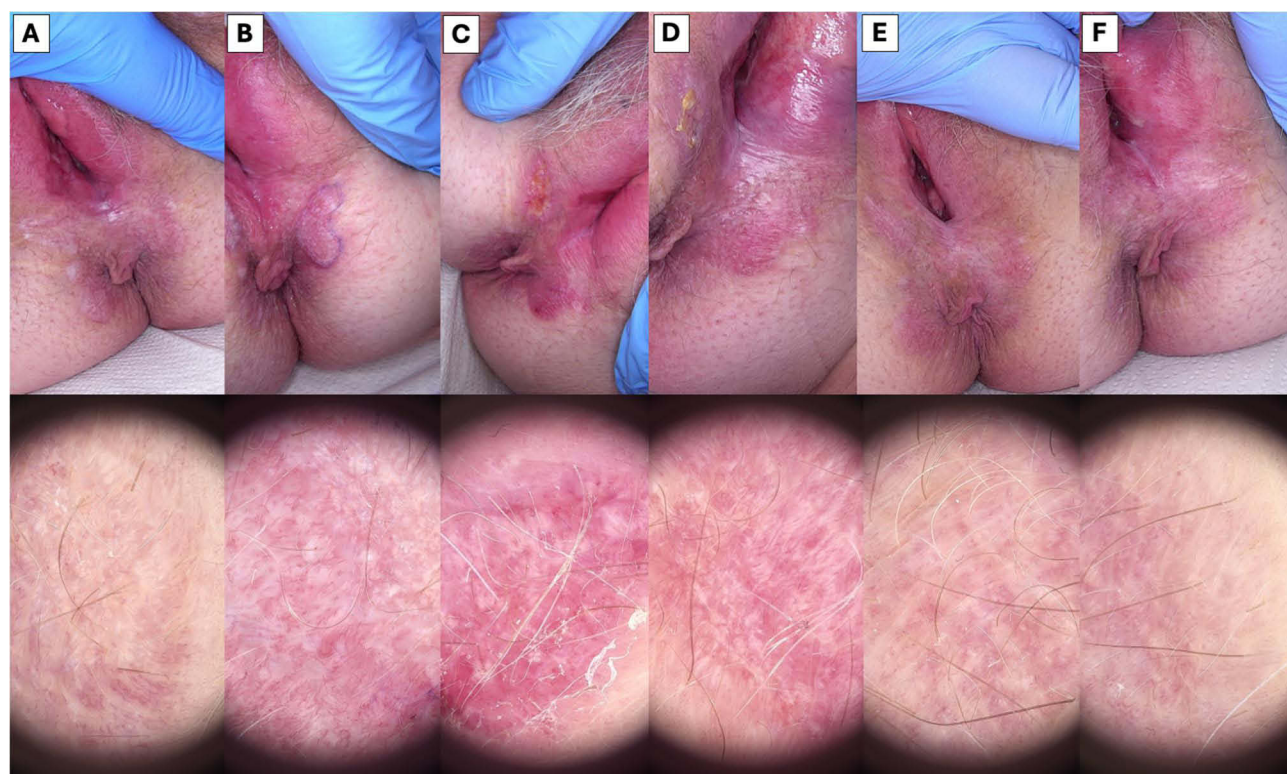


Figure 1 The application of HIFU in treating a 73-year-old female patient with vulvar lichen sclerosus on the left side of the vulva. (A) Initial images show pre-treatment clinical condition with a macroscopic view and characteristic dermoscopic features. (B) Macroscopic and dermoscopy view just after treatment.; (C) Macroscopic and dermoscopy view after one-week post-treatment; (D) Macroscopic and dermoscopy view after one-month post-treatment; (E) Macroscopic and dermoscopy view after two-month post-treatment; (F) Macroscopic and dermoscopy view after five-month post-treatment.

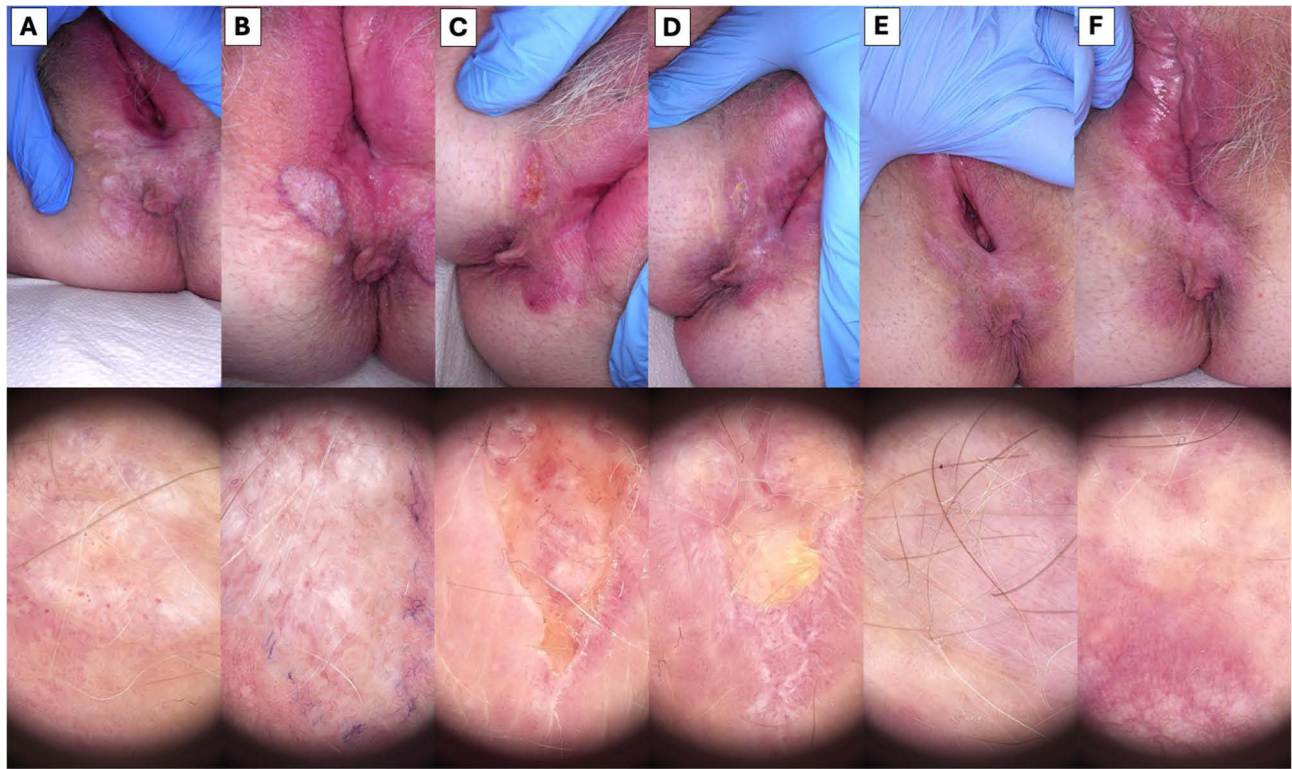


Figure 2 The application of HIFU in treating a 73-year-old female patient with vulvar lichen sclerosus on the right side of the vulva. **(A)** Initial images show pre-treatment clinical condition with a macroscopic view and characteristic dermoscopic features. **(B)** Macroscopic and dermoscopy view just after treatment; **(C)** Macroscopic and dermoscopy view after one-week post-treatment; **(D)** Macroscopic and dermoscopy view after one-month post-treatment; **(E)** Macroscopic and dermoscopy view after two-month post-treatment; **(F)** Macroscopic and dermoscopy view after five-month post-treatment.

a result, photodynamic therapy (PDT) was performed on June 5, 2021. It was noted that her symptoms, characterized by burning and pain, had recently intensified. The patient experienced difficulty walking, urinating, and defecating. Dermoscopic examination revealed white structureless areas, white lines, dotted vessels, and whitish-pink polymorphous areas. Written informed consent was obtained from the patient for the HIFU procedure and the publication of both clinical details and images. According to institutional guidelines formal ethical approval was not required for single case reports.

On January 2nd, a HIFU procedure was performed. (Figures 1B and 2B). No local anesthesia was administered prior to the procedure. Instead, the patient received a single oral dose of Doreta — a prescription analgesic containing tramadol hydrochloride (37.5 mg) and paracetamol (325 mg) — approximately 30 minutes before the HIFU session. This provided adequate pain relief, and no additional analgesia was required during the treatment. HIFU treatments were conducted using the System ONE-M (TOOsonix A/S, Hoersholm, Denmark), which operates at 20 MHz and is specifically designed for dermatological uses. The system was equipped with four handpieces that had nominal focal depths (NFD) ranging from 0.8 to 2.3 mm beneath the skin surface, allowing for attachment to the device. These handpieces featured an integrated high-resolution digital camera functioning as a dermoscope, enabling real-time observation of the treated area on the user screen. The precise control of the ultrasound field's high spatial resolution, along with real-time dermoscopy, facilitated accurate delivery of therapeutic energy directly to the selected LS lesions. Thus the lesions were difficult to distinguish from the surrounding skin due to low contrast, they were marked with a water-resistant pen to enhance visibility. Different HIFU settings were used for the right and left sides due to variations in lesion depth and structure. Prior to treatment, high-frequency ultrasound imaging was performed to assess the tissue architecture and determine the optimal treatment parameters. The energy levels and number of pulses were then individually tailored to match the

anatomical and pathological characteristics of each lesion, ensuring precise and effective ablation while minimizing damage to surrounding healthy tissue.

A 1.3 mm transducer with an energy setting of 0.7 J/cm² and a total of 150 pulses at an exposure time of 150 ms were applied on the right side. Immediate post-procedural whitening of tissues was observed. On the left side, a similar 1.3 mm transducer was used with an exposure time of 150 ms and an energy setting of 0.5 J/cm². A total of 270 pulses were administered, revealing initially a white structureless area with numerous white lines and vessels resembling dots and loops. Post-procedural whitening of the epidermis was evident, with visible well-demarcated structureless areas of fibrosis, collagen fibers, independent of polarization. Surrounding tissue whitening was not polarization-dependent. No additional treatments were administered following the HIFU procedure during the follow-up period.

Approximately one week later, epidermal damage was observed without the formation of crust on the left side (Figure 1C). The treated area exhibited intense erythema with pinkish-white structureless areas and areas of desquamating epidermis. Fibrotic changes were noted around the lesion, albeit less pronounced than in later stages. On the right side a crust developed over the entire treated area, appearing as an orange, raised nodule surrounded by numerous vessels, predominantly linear and dotted (Figure 2C).

After two additional weeks, a reduction in the size of the crust was noted, with continued regression towards the center of the lesion (Figures 1D and 2D). A pinkish structureless area with numerous white lines and vessels was observed within the previously treated region, displaying reduced intensity compared to earlier stages. From a highly erythematous area, the lesion transitioned to a pinkish hue, with prominent white lines and several dots arranged in a square pattern.

In a subsequent evaluation, approximately one month post-treatment, nearly normal skin was observed, exhibiting increased paleness compared to surrounding skin, devoid of white lines associated with healing (Figures 1E and 2E). The skin was slightly lighter than the surrounding tissue, with no visible dyschromia. In later assessments, particularly in April, two months post-treatment, completely normal skin was observed, without visible pigmentation changes (Figures 1F and 2F). A residual pinkish structureless area with scattered dots, loops, and vessels was present, albeit less intense than in previous stages.

The patient rated the pain level during treatment as 3 on a 10-point scale, but a few minutes after the procedure, it was 0, with the level of itching after the treatment also at 0. When asked about previous experiences, the patient described HIFU as causing significantly less discomfort than photodynamic therapy. Overall, she rated the severity of all adverse effects as mild. In this context, “mild” refers to the patient’s personal perception of adverse effects, which she described as minimal and not interfering with her daily activities. A week after the treatment, the patient rated the healing process as highly satisfactory, with pain and itching levels in the treated areas both rated as 0 on a 10-point intensity scale. Regarding the healing process, the patient described the HIFU method as causing significantly less discomfort than photodynamic therapy. After five months, the patient provided a consistent evaluation, describing the healing process as highly satisfactory, with pain and itching levels remaining at 0 on a 10-point intensity scale. She maintained that the HIFU method resulted in significantly less discomfort compared to photodynamic therapy. The patient did not have difficulty walking, urinating, or defecating.

Follow-up assessments included histopathological examination conducted one year after the treatment to evaluate the long-term effects and tissue changes (Figures 3 and 4). Histopathological examination conducted one year post-treatment showed significant changes consistent with the resolution of acute inflammatory processes and the establishment of chronic reparative features. Key findings included reduced inflammatory infiltrate and prominent dermal fibrosis, suggestive of ongoing tissue remodeling and healing. Dilated dermal capillaries and reactive, hyperchromatic nuclei in fibroblasts were observed, which could reflect post-therapeutic effects promoting vascularization and collagen synthesis. These results align with the clinical improvements noted in the patient and suggest that HIFU facilitates a regenerative microenvironment conducive to long-term healing.

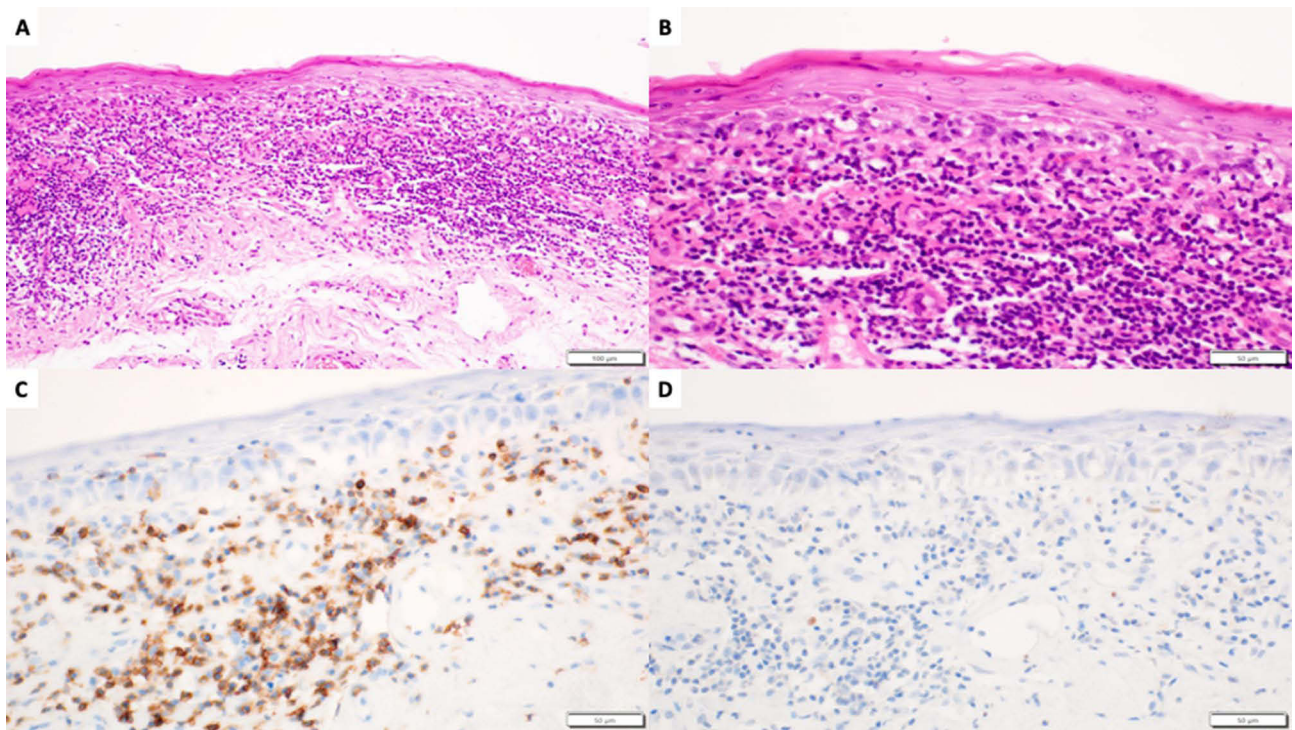


Figure 3 Vulvar lesion before treatment. Lichen sclerosus, inflammatory phase. Massive interface reaction pattern with prominent destruction of basal keratinocytes ((A) HE, 200x; (B) HE, 400x). Immunohistochemistry for LCA (leukocyte common antigen) highlighted prominent inflammation (C) 400x. Lack of melanocytic proliferation in this biopsy (negative staining for SOX10) (D) 400x.

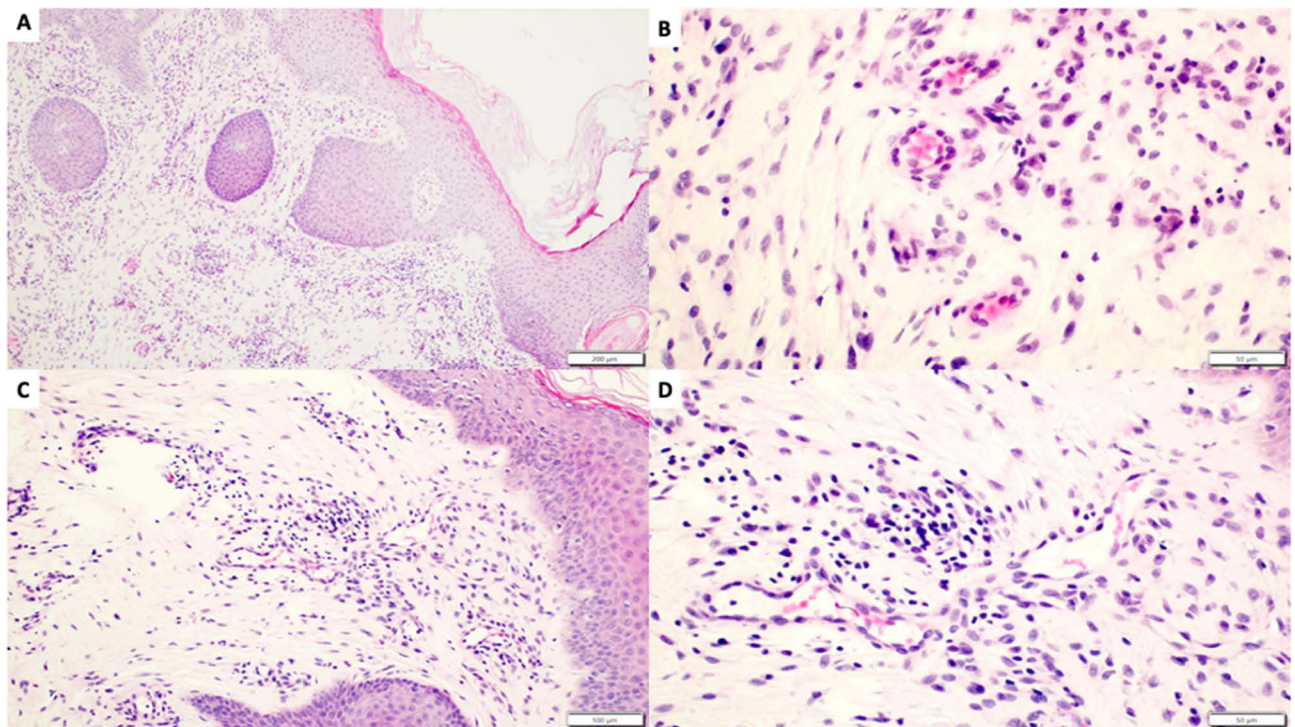


Figure 4 Lesions after treatment. (A and B) perianal location. (C and D) Vulvar location. Chronic inflammation located in the dermis with dermal fibrosis. Dilated dermal capillaries were also observed with reactive, hyperchromatic and mildly enlarged nuclei (probably as a post-therapeutic effect). Chronic inflammation was more advanced in the perianal area ((A) HE, 200x; (B) HE, 400x; (C) HE, 200x; (D) HE, 400x).

Discussion

The utilization of High-Intensity Focused Ultrasound (HIFU) in treating vulvar lichen sclerosus (VLS) represents a significant advancement in dermatological therapies, leveraging its thermal and mechanical effects to target and ablate affected tissues non-invasively. This innovative treatment modality not only minimizes the need for surgical intervention but also promotes tissue repair through mechanisms like revascularization and collagen and elastin fiber synthesis.^{15,19,20} Recent studies, including one involving 36 pediatric and adolescent patients, have underscored the high efficacy of HIFU, with impressive response rates: 91.6% at six months and 86.6% at twelve months post-treatment. Long-term follow-ups indicate a sustained response rate of 75% over five years, with a recurrence rate of 12.5%.²¹ A notable example of HIFU's application is illustrated in another study conducted by Wu et al, where 136 patients with various non-neoplastic epithelial disorders of the vulva were treated.²² This group included 44 patients with VLS, who were treated using HIFU parameters of 3.5W power and 10 MHz frequency over durations ranging from 15–30 minutes. This treatment achieved a 93.38% response rate, highlighting significant improvements in symptoms and the physical appearance of the vulva with minimal severe complications, emphasizing HIFU's potential as a safe and effective treatment option for VLS.

Furthermore, the integration of HIFU into the treatment spectrum for VLS challenges the conventional reliance on potent topical corticosteroids, which, while effective in reducing inflammation and itching, come with potential side effects and limitations, particularly in cases resistant to such therapies.^{23,24} HIFU offers a promising alternative, especially for patients who cannot tolerate traditional treatments or for whom these treatments have failed. Moreover, the detailed case presentation of a 73-year-old female patient treated with HIFU, using the System ONE-M device, demonstrates the precise and controlled application of this technology. The patient's treatment involved specific handpieces adjusted for depth, showcasing HIFU's adaptability to individual patient needs based on lesion characteristics.²⁵ Post-treatment observations revealed immediate tissue responses and subsequent healing stages, evidencing HIFU's capacity to achieve targeted destruction of diseased cells with considerable preservation of surrounding healthy tissues. Notably, while histopathological evaluation still indicated the presence of chronic inflammatory changes and fibrosis associated with the disease, the patient experienced remarkable clinical improvement. This included the resolution of symptoms such as pain and itching, along with the restoration of functional comfort, highlighting the therapeutic potential of HIFU in effectively managing vulvar lichen sclerosus despite persistent microscopic findings. An important aspect of our work is the very low pain experienced during the procedure. In contrast to other methods like photodynamic therapy, where pain is often rated as high, the patient herself found the treatment more comfortable.²⁶

In conclusion, the expanding use of HIFU in dermatology, particularly for challenging conditions like VLS, offers new horizons in patient care. Its ability to effectively manage symptoms, coupled with a favorable safety profile, positions HIFU as a valuable addition to the therapeutic arsenal against VLS. This case highlights the potential of HIFU as a promising, non-invasive treatment approach for vulvar lichen sclerosus. However, further studies—particularly randomized controlled trials—are needed to validate its efficacy and safety on a larger scale. Close and long-term follow-up is necessary to evaluate the durability of the therapeutic response and detect any potential recurrence or delayed adverse effects. A limitation of this report is the absence of a validated patient-reported outcome measure such as the Vulvar Quality of Life Index (VQLI), which could have provided further insight into the patient's subjective improvement.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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