

StrataMGT for the Treatment of Vulvar Lichen Sclerosis

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INTRODUCTION

Lichen Sclerosis (LS) is a chronic vulvovaginal condition that affects women's quality of life by causing:

- Itching
- Pain
- Burning
- Scarring in the anogenital region

Current Treatment

- Ultra-potent corticosteroids are the standard treatment but can cause side effects.
- Many women continue to experience symptoms despite treatment.¹⁻³

StrataMGT

- A gel known for its **hydrating and protective properties**.
- Hall's study demonstrated significant symptom improvement in LS patients, supported by pathological evaluations showing reduced inflammation.⁴

Study Objective

To evaluate **the efficacy and safety of StrataMGT** in treating vulvar lichen sclerosis (VLS).

- The primary endpoint focuses on confirming its **effectiveness in reducing inflammation and scarring**, as determined by biopsy analysis.
- The secondary endpoint will **assess patient-reported outcomes**, including:
 - Symptom Improvement
 - Quality of Life

METHODS

This open-label, exploratory study involves five biopsy-confirmed LS patients, recruited from a single center.

Assessments

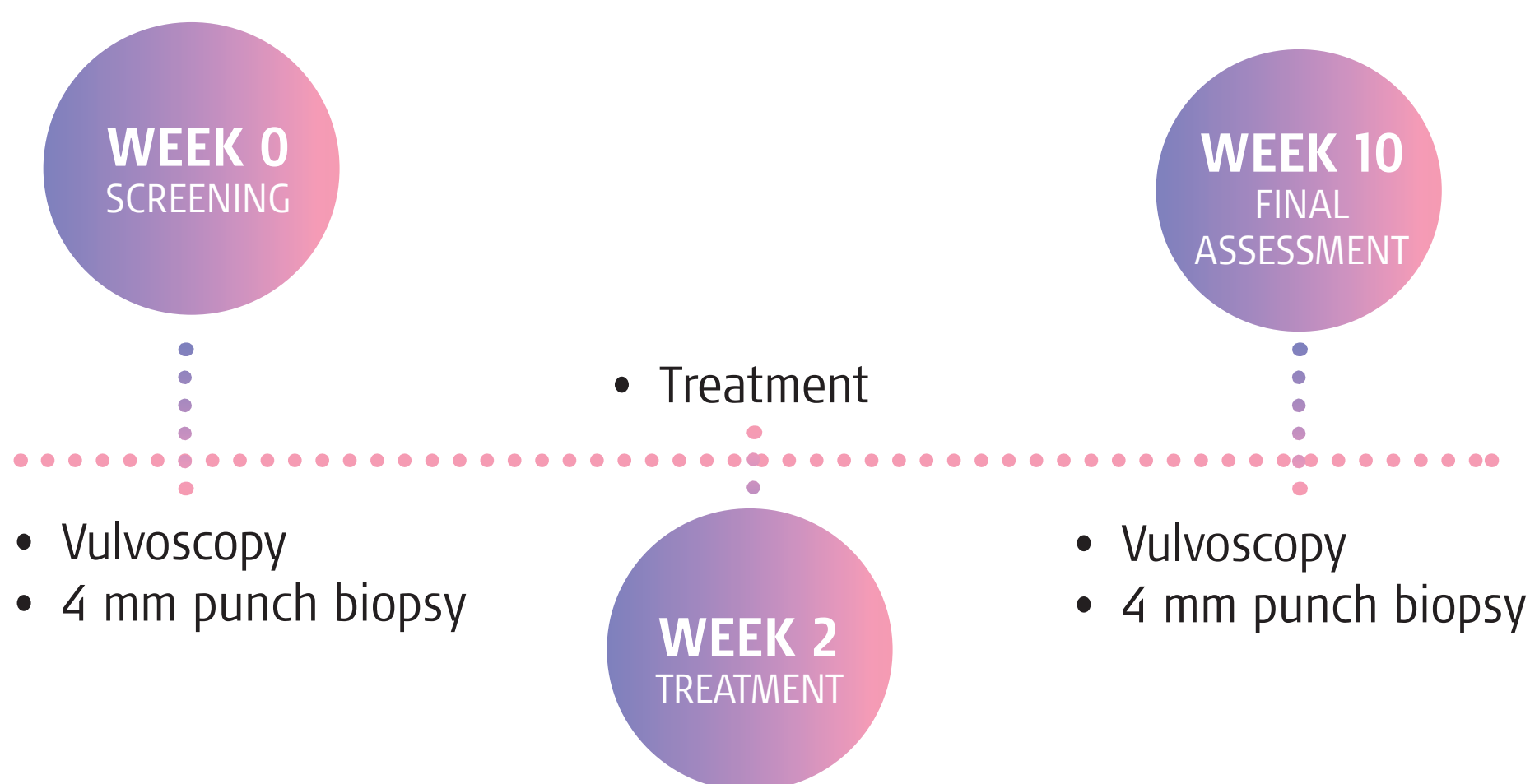


Figure 1: Schematic illustration of the study timeline.

A vulvoscopy is performed at screening visit and after treatment, to rule out vulvar intraepithelial neoplasia (VIN) or carcinoma.

Primary endpoint:

- Evaluation of inflammatory infiltration in biopsy samples on a 0-3 scale, assessed by a dermatopathologist

Secondary endpoints:

- Changes in scores on the Vulvar Quality of Life Index (VQLI)
- Skindex 29
- Clinical Lichen Sclerosis Scoring Scale (CLISSCO).

All adverse events, including serious ones, will be recorded, and a physical examination will be conducted at each visit.

CONCLUSIONS

This study aims to confirm these findings through biopsy analyses, providing objective histological evidence of StrataMGT's impact on inflammation and tissue remodeling in VLS, offering a potential alternative treatment without the side effects of corticosteroids.

INTERIM RESULTS

Preliminary results show a decrease in lichen sclerosis symptoms as measured by the VQLI in 3 of 5 participants. Additionally, there was a decrease in inflammation between pre and post treatment biopsies in 2 of the 4 participants.

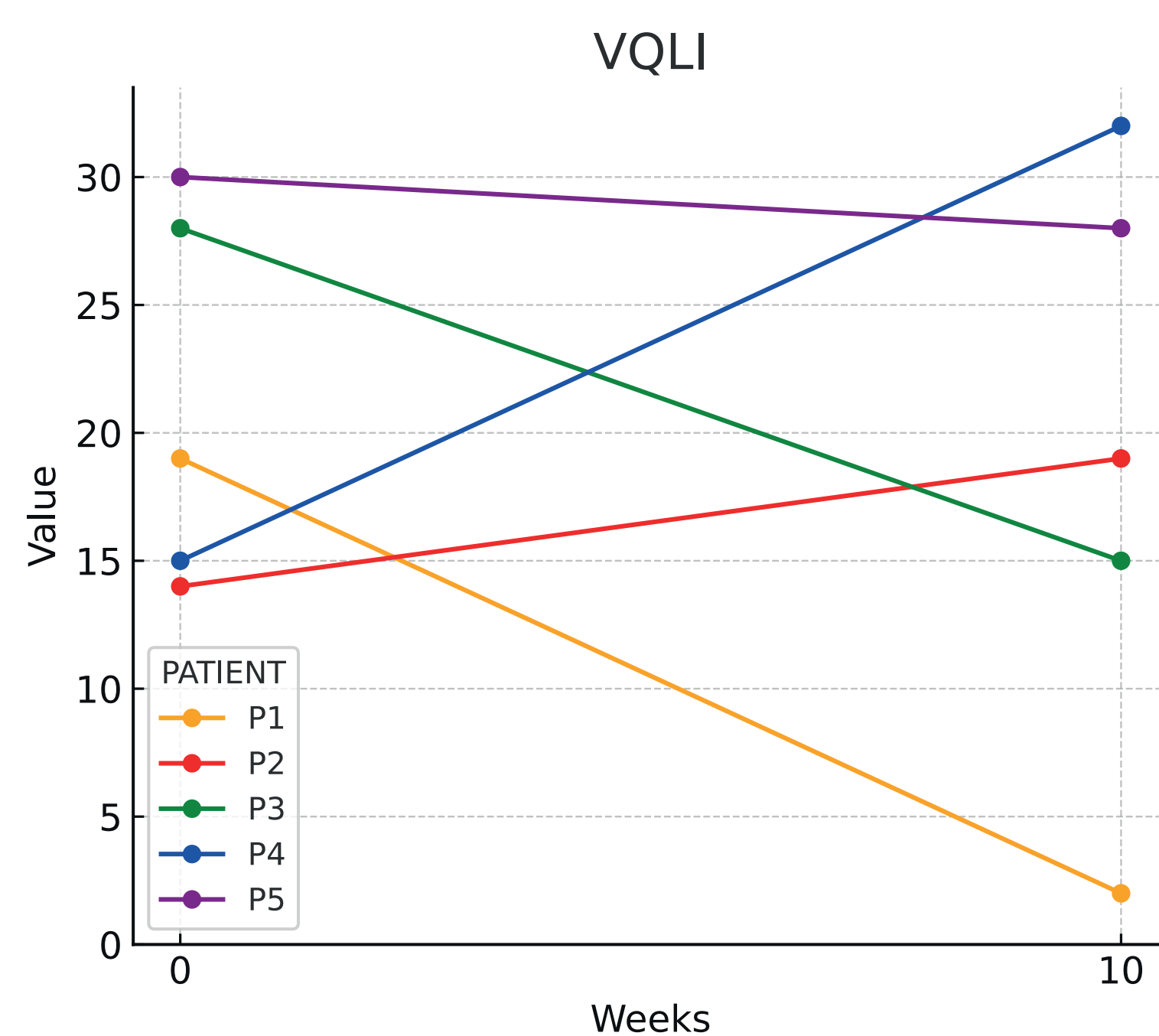


Figure 2: Progression of VQLI scores over the 10-week study period.

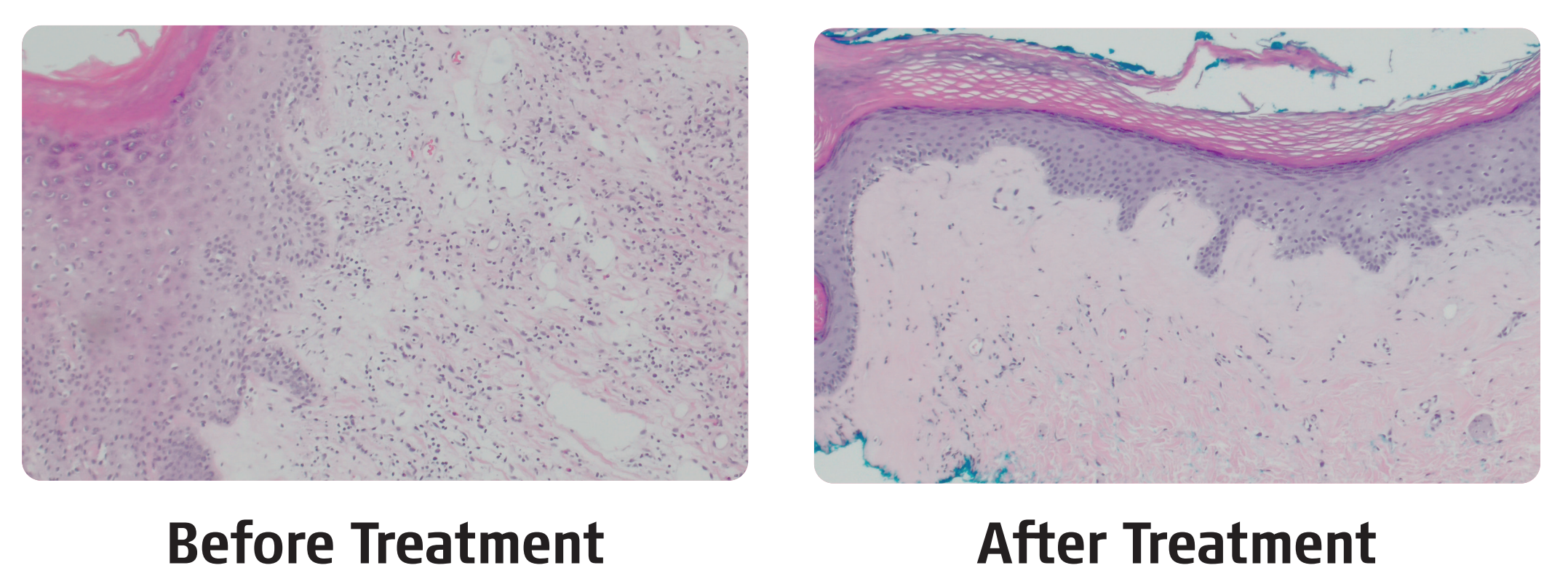


Figure 3: Histopathology demonstrates decreased inflammatory infiltrate between pre and post treatment biopsies.

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 [2] Wijaya M, Lee G, Fischer G. Why do some patients with vulval lichen sclerosis on long-term topical corticosteroid treatment experience ongoing poor quality of life? Australas J Dermatol. 2022 Nov;63(4):463-472. doi: 10.1111/ajd.13926. Epub 2022 Oct 8. PMID: 36208206; PMCID: PMC9828553. [3] Wijaya M, Lee G, Fischer G, Lee A. Quality of Life in Vulvar Lichen Sclerosis Patients Treated With Long-Term Topical Corticosteroids. J Low Genit Tract Dis. 2021 Apr 1;25(2):158-165. doi: 10.1097/LGT.0000000000000599. PMID: 33746196. [4] Hall. P. (2018). A novel topical treatment for common vulvovaginal conditions. 22nd Australian Menopause Society Conference. Brisbane, Australia.