Concordance of AI-Derived Quantitative Measures and IGA Scores Demonstrates Superior Efficacy with Faster Onset for an Investigational Extended-Release Oral Minoxidil Tablet (VDPHL01) Versus Immediate-Release Oral Minoxidil for Androgenetic Alopecia (AGA)

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Background

Advances in AI have enabled quantitative assessment of AGA outcomes via image analysis. AI analysis was conducted comparing AGA outcomes in a Phase 2 trial evaluating an investigational oral minoxidil extended-release tablet (VDPHL01) for 20 male subjects completing 4 months of VDPHL01 8.5mg BID with a published dataset of 33 males receiving IR oral minoxidil 5mg QD for 6 months. Results were compared to previously-generated blinded IGA scores. Dermatologists (n=3) evaluated the appropriateness of the AI analysis outputs.

Methods

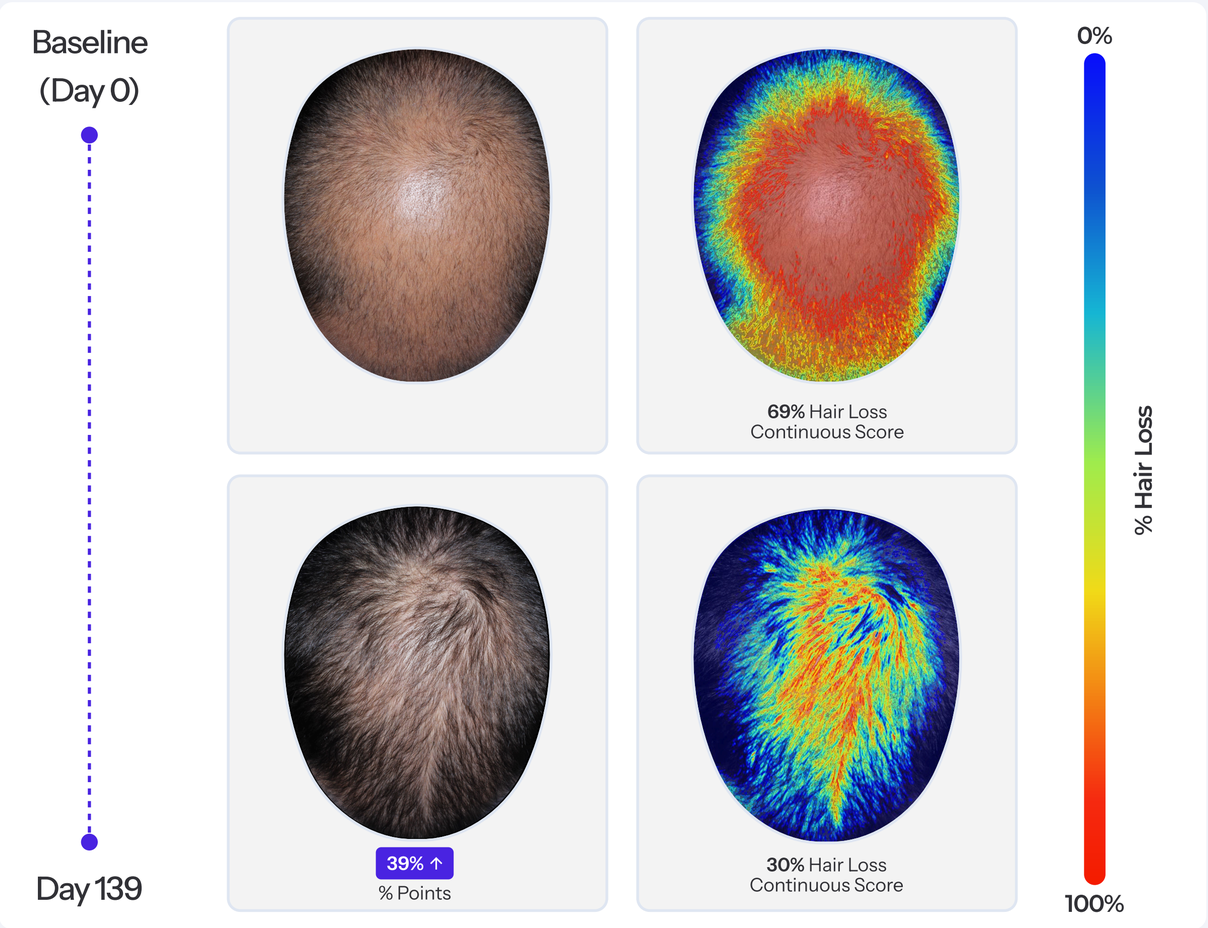
Global HairMap™ (SOCAi), an AI-based platform, was used to retrospectively generate hair loss percentages (HL%) on images from the vertex scalp for both groups before and after treatment. Results were assessed for correlation to per-subject average blinded IGA scores Dermatologists assessed the appropriateness of the AI HL% outputs.

Objectives

- To compare the magnitude and onset of treatment response between extended-release (VDPHL01) and immediate-release oral minoxidil using AI-derived HL%.
- To assess concordance between AI-derived hair loss percentage (HL%) and blinded Investigator Global Assessment (IGA) scores in male androgenetic alopecia.
- To evaluate dermatologist agreement on the clinical appropriateness of AI-derived HL% outputs for assessing treatment response.

Results

Mean baseline HL% was similar between groups (p=0.7323). Improvement in HL% was 2.6x greater for VDPHL01 versus IR oral minoxidil (12.53% vs. 4.79%, respectively; p=0.0003). AI-based HL% improvements were concordant with IGA scores (Spearman correlation=0.665, p<0.0001). AI outputs were rated appropriate in 93.4% of cases, with strong statistical agreement between raters.



Conclusion

VDPHL01 at 4 months produced statistically-significant superior improvement in AI-based HL% versus IR oral minoxidil, at 6 months, demonstrating that VDPHL01 is faster-acting and potentially superior in treating AGA. These results are concordant with those generated from blinded IGA scoring, and AI outputs were considered appropriate in determining HL%. Limitations include the retrospective review methodology.