

Comparative Efficacy of an Investigational Oral Minoxidil Extended-Release Tablet (VDPHL01) Versus Existing Minoxidil Formulations in Androgenetic Alopecia: A Blinded Retrospective IGA Analysis

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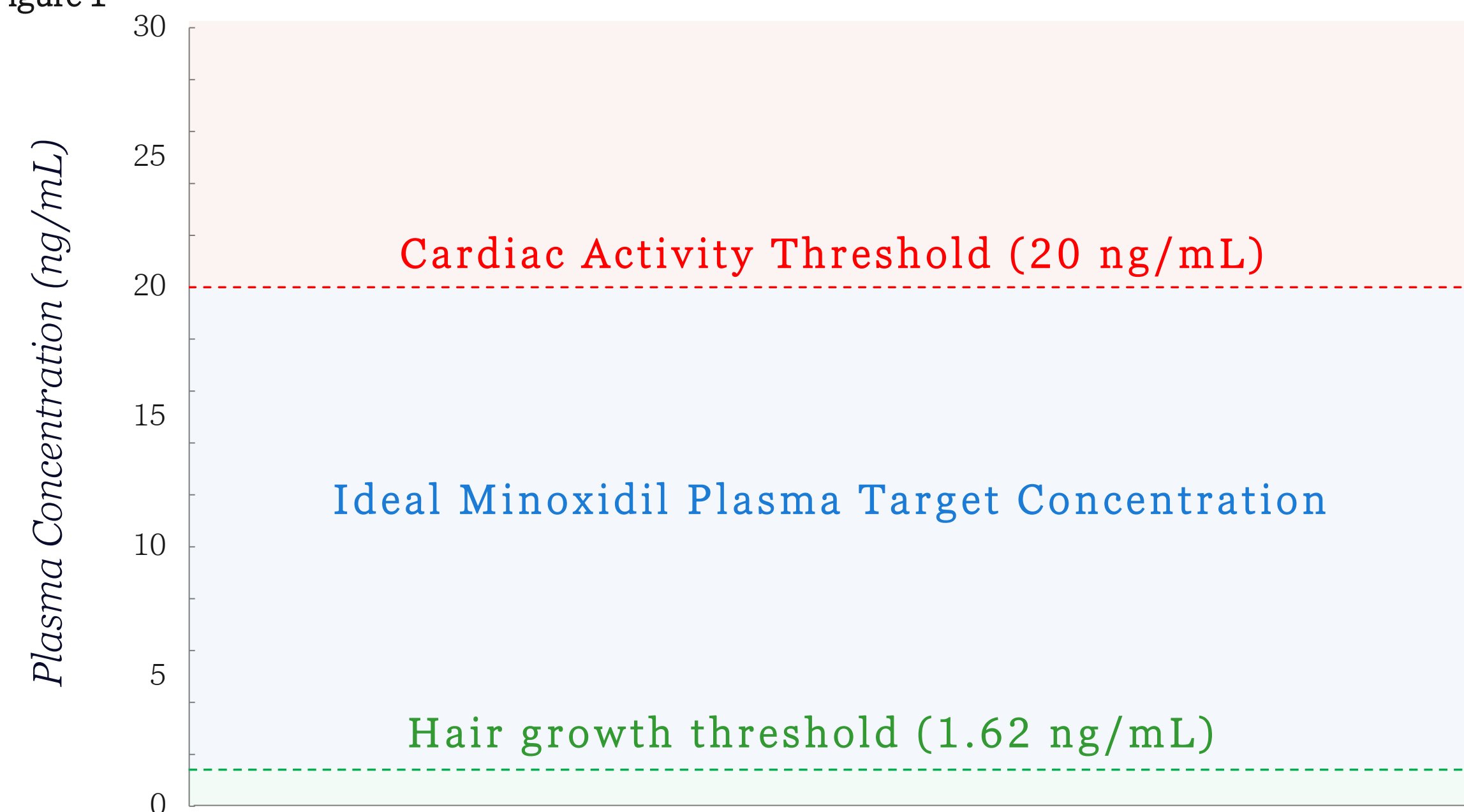
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Introduction

VDPHL01 is an Investigational Extended-Release Tablet that Aims to Optimize Oral Minoxidil for Hair Growth and Cardiac Safety^{1,2}

- Immediate release oral minoxidil peaks quickly risking cardiac activity and only sustains therapeutic hair growth levels for ~4 hours
- There is a 10x difference between minoxidil hair growth threshold and minoxidil cardiac activity threshold³ (Figure 1)
- VDPHL01 is designed to maximize hair growth potential by increasing time and concentration of minoxidil above the hair growth while keeping peak concentrations below the cardiac safety threshold

Figure 1



Methods

Study Design: Retrospective Blinded IGA (Investigator Global Assessment) Study to Compare Efficacy of VDPHL01 at 2 Months⁴ and at 4 months⁵ Versus Oral Minoxidil and Topical Minoxidil at 6 Months⁶

- Before and after image pairs of the vertex and superior scalp for each subject were randomized in order
- Graders selected which image in the photo pair they thought was baseline and then assigned an IGA score based on the presumed baseline photo

Study Endpoints:

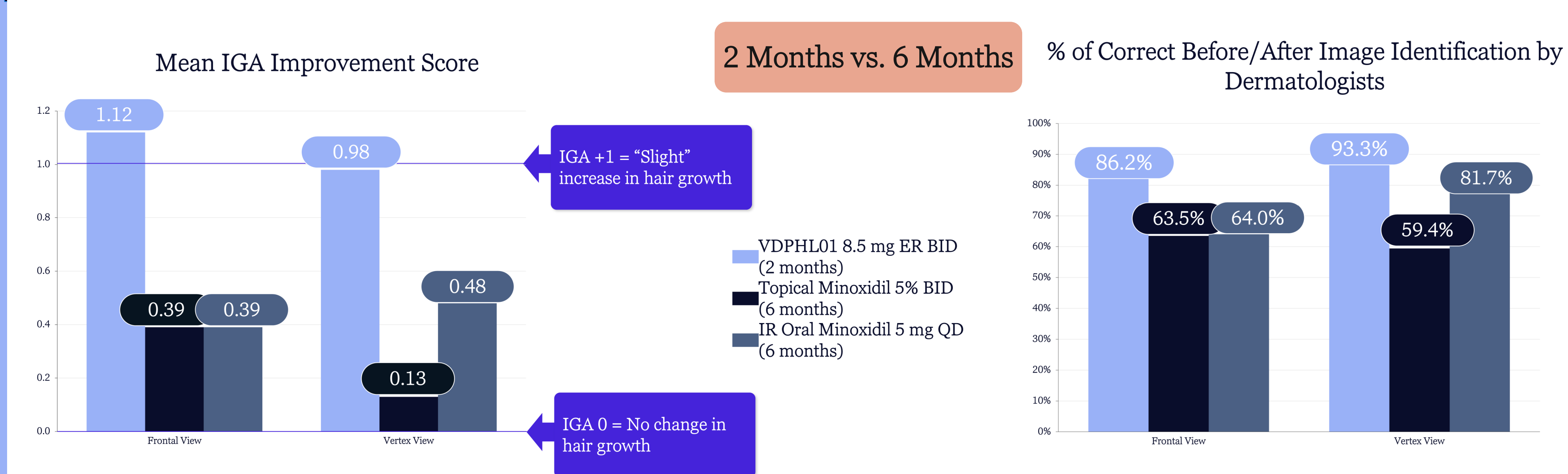
- % Correct baseline identification and Mean blinded IGA score (Figure 2)

Figure 2

Primary Objectives	Study Endpoints
<ul style="list-style-type: none"> Provide a comparison of perceived efficacy outcomes between VDPHL01, IR oral minoxidil 5 mg, and topical minoxidil 5% 	<ul style="list-style-type: none"> % correct baseline identification Mean blinded Investigator's Global Assessment (IGA) score % achieving IGA ≥ 2 (i.e. 'moderately or greatly improved')
<ul style="list-style-type: none"> VDPHL01 2x/Day 8.5mg x 2 months and 4 months From VDPHL01 Phase 2 Study 	
<ul style="list-style-type: none"> IR Oral Minoxidil 1x/Day 5 mg IR x 6 months From Head-to-Head Study (JAMA) 	
<ul style="list-style-type: none"> Topical Minoxidil 2x/Day 5% Solution x 6 months From Head-to-Head Study (JAMA) 	

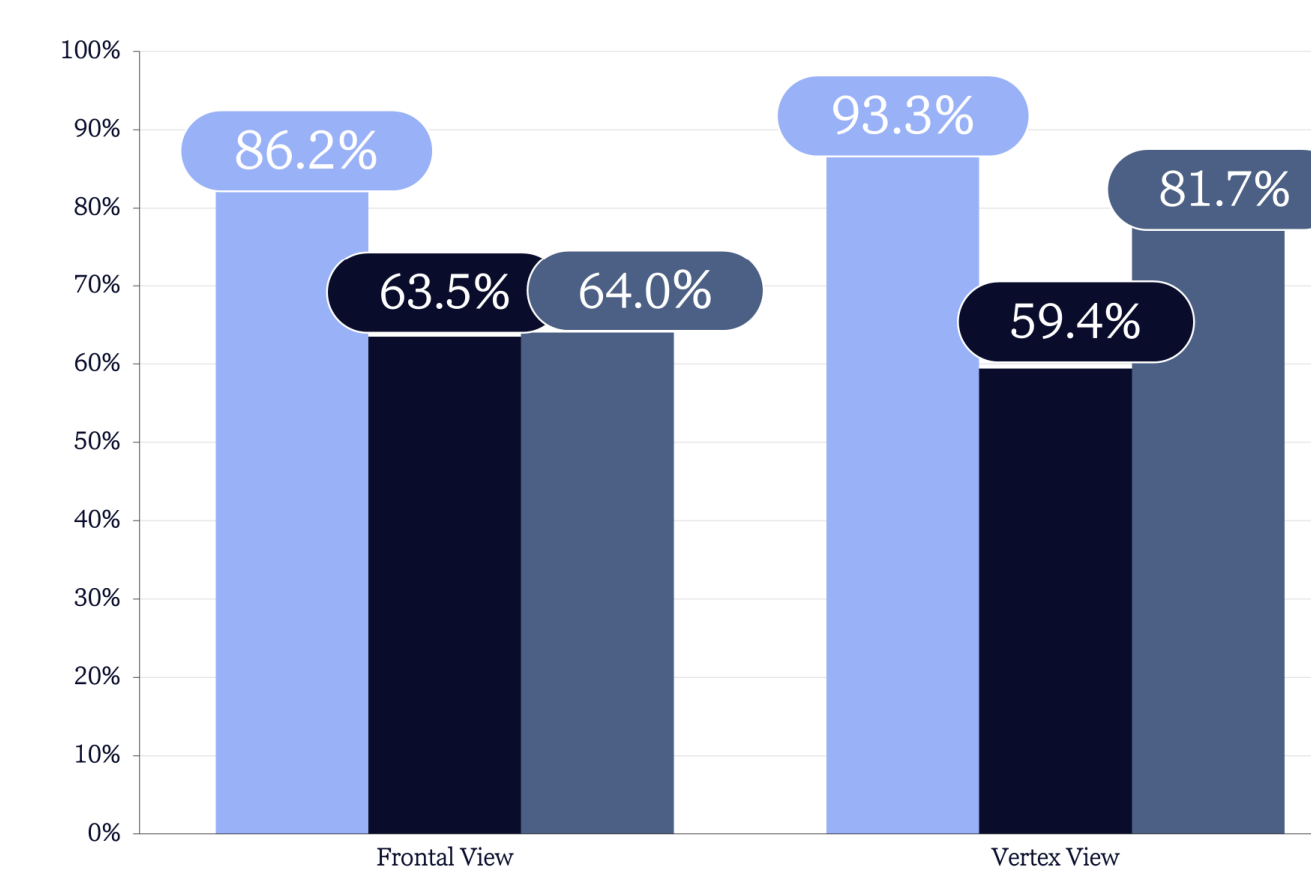
Blinded graders were 9 U.S. hair loss expert dermatologists (6 graders in the 2-month study and 3 graders in the 4-month study)

Results

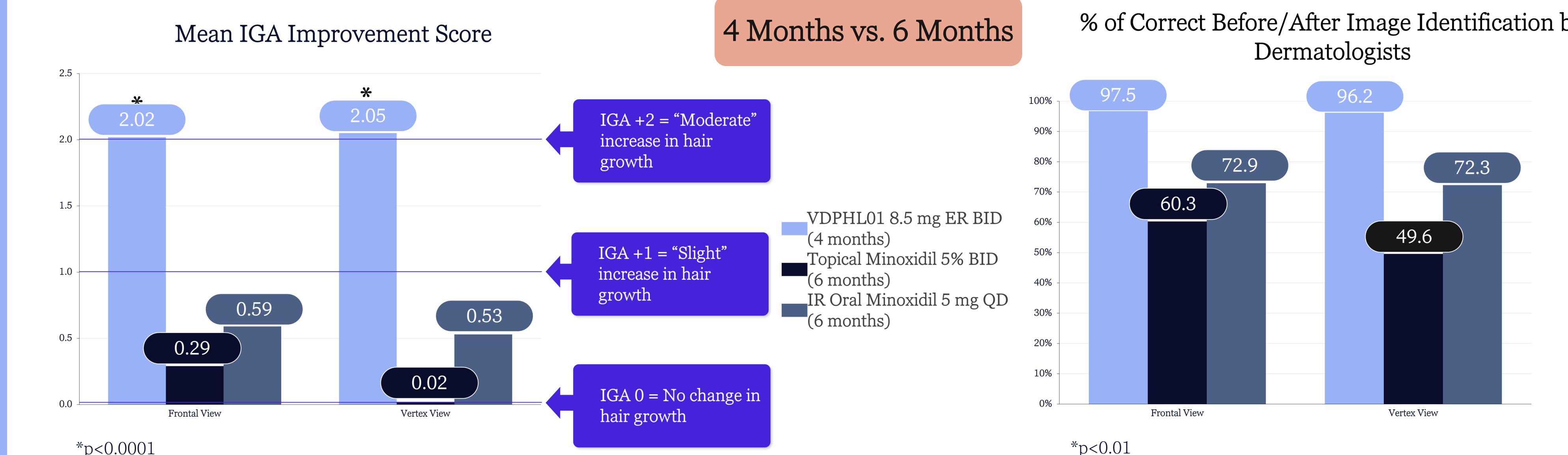


VDPHL01 demonstrated the average subject achieved +1 change

% of Correct Before/After Image Identification by Dermatologists

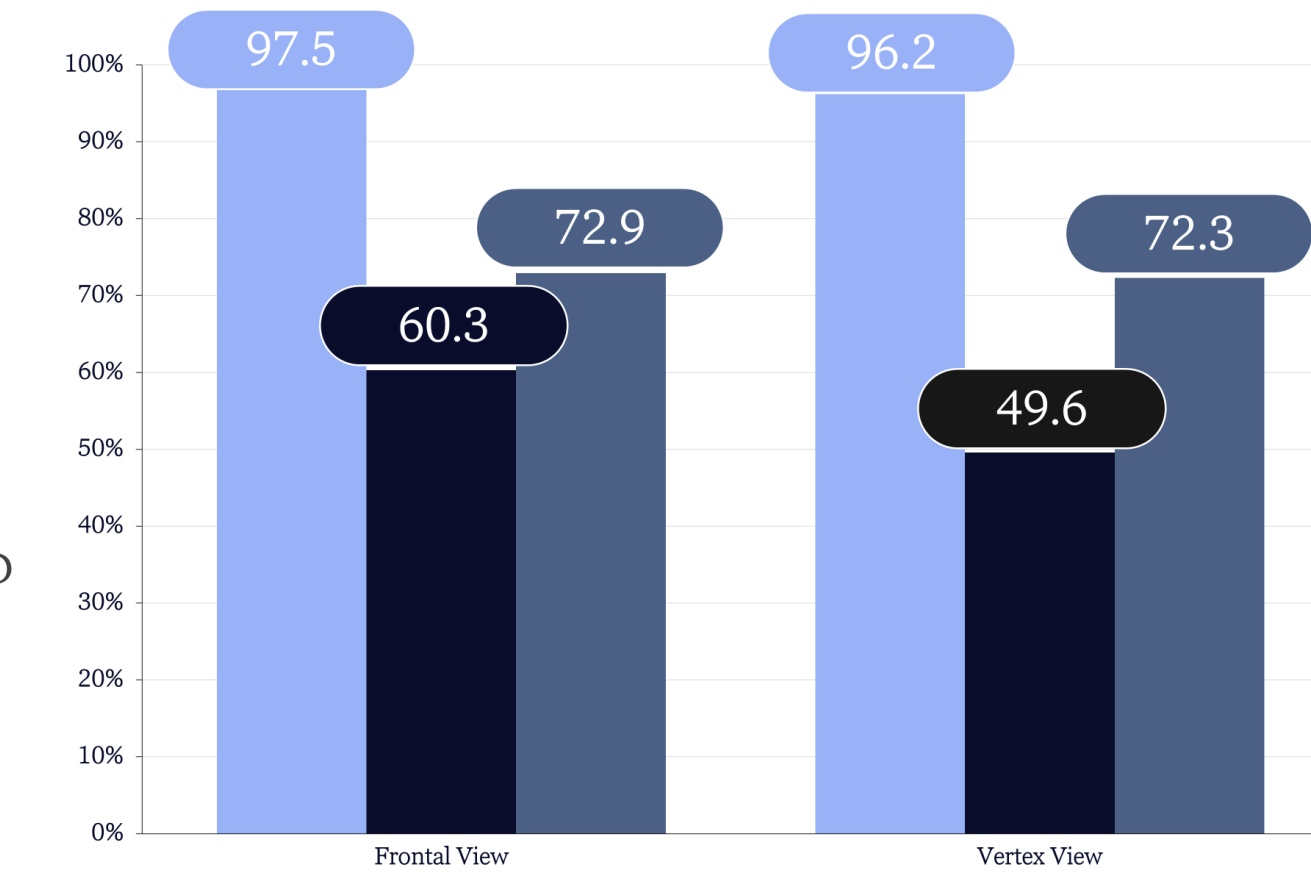


VDPHL01 achieved >85% baseline identification accuracy indicating ability to identify visible change

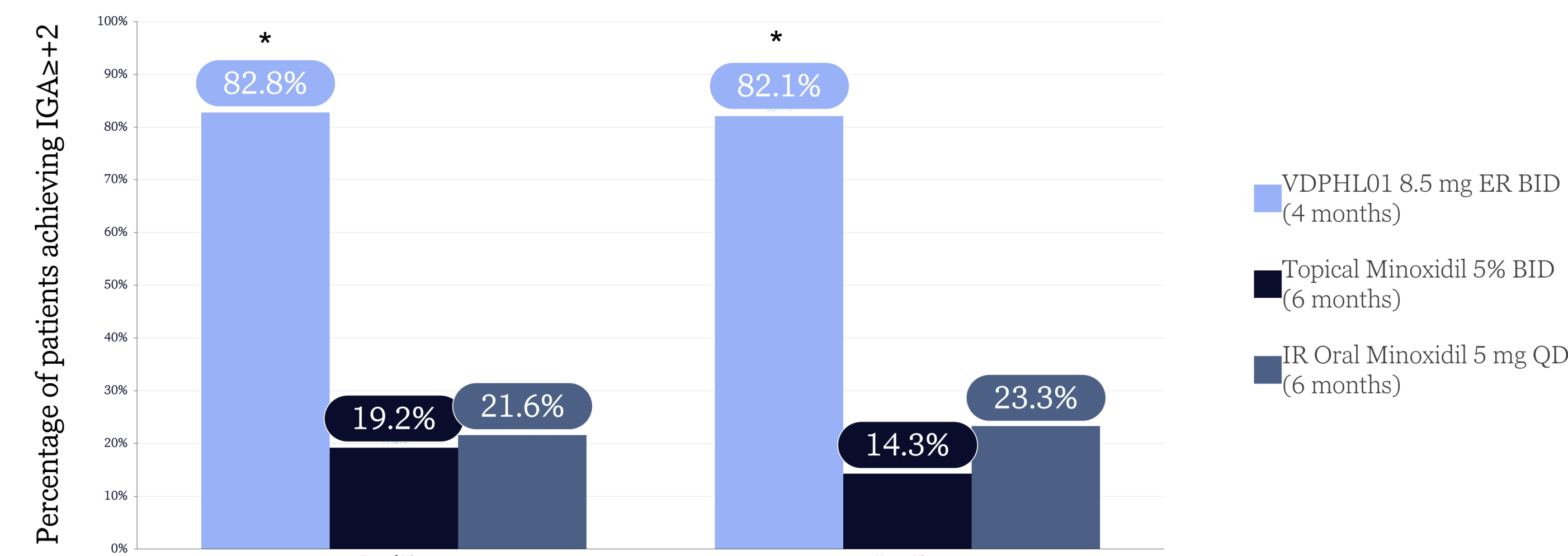


VDPHL01 demonstrated the average subject achieved +2 change

% of Correct Before/After Image Identification by Dermatologists



VDPHL01 achieved >96% baseline identification accuracy indicating ability to identify visible change



*P<0.0001 versus both topical and IR oral minoxidil.

At 4 Months, VDPHL01 was >3X More Likely to Result in Moderately or Greatly Improved Hair Coverage Than Comparators at 6 Months

QD = once daily
 BID = twice daily
 IR = immediate release
 ER = extended release
 IGA = Investigator's Global Assessment: a 7-point scale, -3 (greatly decreased) to +3 (greatly increased), rating hair growth compared to baseline

Conclusions

Superior Efficacy at Shorter Duration

- VDPHL01 achieved IGA ≥ 1 at 2 months and IGA ≥ 2 at 4 months indicating visible improvement
- Average subject experiences less than 'slight' regrowth per IGA for both topical and IR oral minoxidil (6 months)

Obvious Clinical Improvement

- >85% at 2 months and >96% at 4 months correct baseline identification with VDPHL01
- Average subject achieves more than 'slight' improvement after 2 months and more than 'moderate' improvement after 4 months of treatment with VDPHL01

Consistent Superiority

- Better outcomes across all metrics
- Equal efficacy in frontal and vertex regions
- No difference found when comparing topical and IR oral formulations to each other

Study Limitations

- Inherent limitations of retrospective study design methodology
- Use of cross-trial comparison

References

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