

Baricitinib Effectiveness and Patient Impressions in Routine Clinical Practice: 12-Month Results From a Prospective Observational Real-World Study



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OBJECTIVE

- To examine the effectiveness of baricitinib therapy on hair regrowth, quality of life, and satisfaction for patients in routine clinical practice

CONCLUSIONS

- Baricitinib demonstrated effectiveness for scalp hair, eyebrow, and eyelash regrowth in a prospective real-world study of participants with scalp hair loss ranging from moderate to complete hair loss due to alopecia areata (AA)
- Clinically meaningful regrowth was observed as early as 3 months in 21% to 59% of participants depending on baseline severity, increasing to 45% to 77% by 12 months
- Over half of participants at Month 3 and two-thirds at Month 12 felt:
 - Much or very much improved
 - Mostly or completely satisfied
- This real-world study of patients with AA from routine clinical practice supports the efficacy findings from clinical trials and provides additional patient perspectives on impressions of change and satisfaction

Fall Clinical Dermatology Conference (Fall CDC)
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BACKGROUND

- Baricitinib, a selective JAK inhibitor, has demonstrated efficacy and a consistent safety profile in patients with severe AA treated for up to 4 years in Phase 3 clinical trials
- Although clinical trials provide essential evidence on the safety and efficacy of treatments for AA under controlled conditions, they often exclude diverse patient populations and real-life variables that may influence overall effectiveness, impacting on quality of life and patient satisfaction

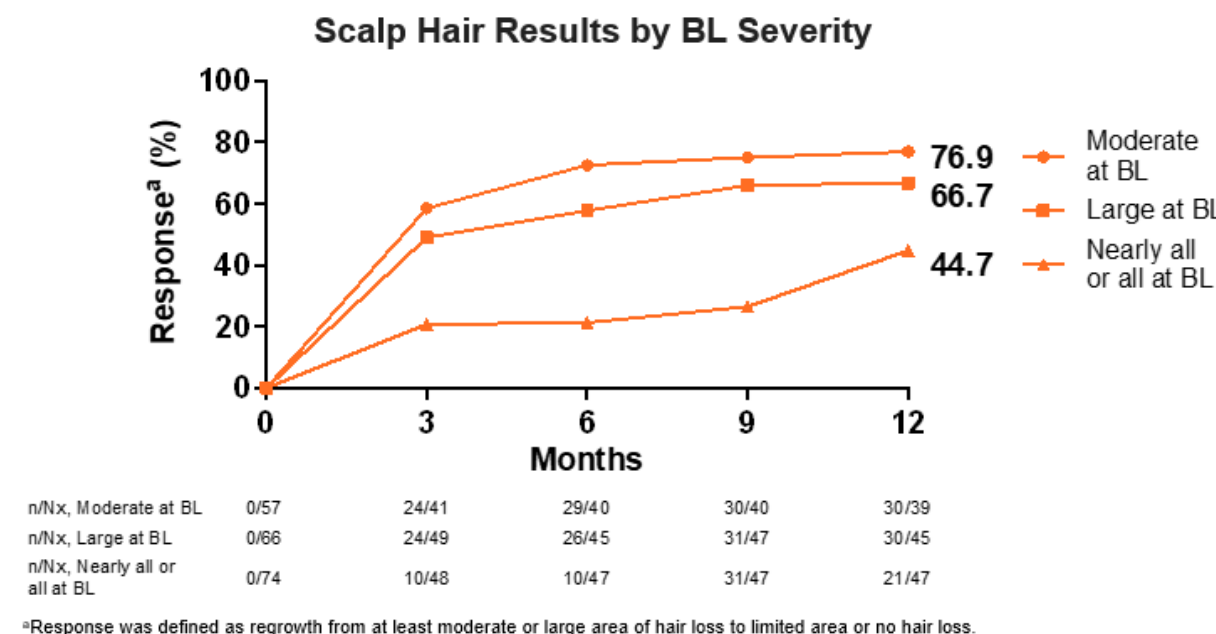
METHODS

Study Population

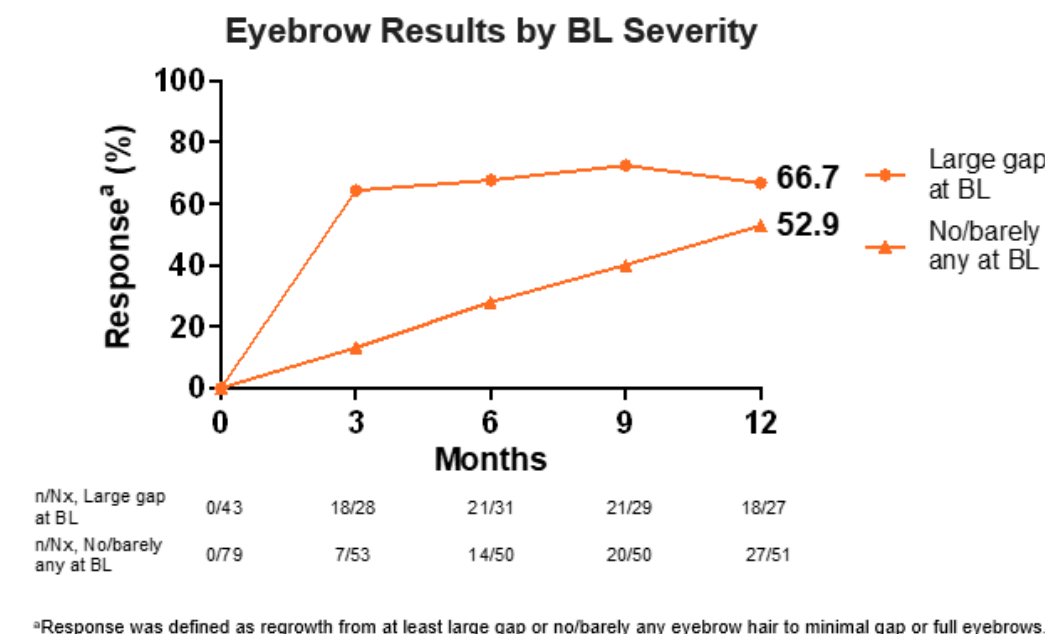
- Adult patients who were participating in the US Baricitinib Patient Support Program for the treatment of severe AA, who had agreed to be contacted for future research studies, were asked to participate in this prospective, observational study
- Participants were surveyed approximately every 3 months after initiation of therapy with baricitinib as the first JAK inhibitor in the previous 60 days

KEY RESULTS

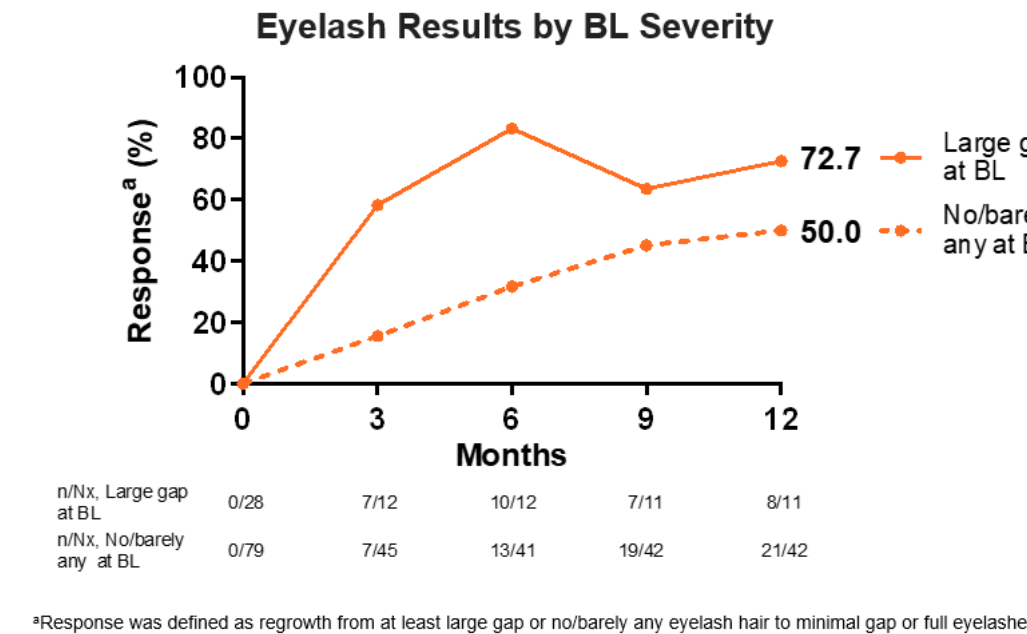
Among Participants With Moderate, Large, or Nearly All or All Scalp Hair Loss at BL, 45% to 77% Achieved Limited/No Scalp Hair Loss by Month 12



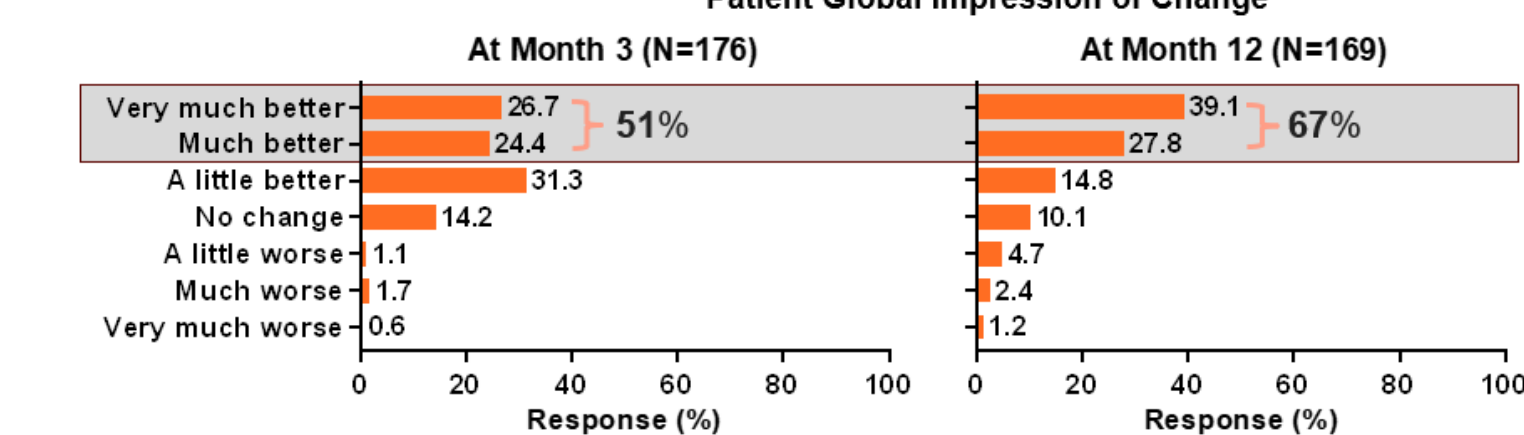
Among Participants With Large Gaps or No/Barely Any Eyebrow Hair at BL, 67% or 53%, Respectively, Achieved Full or Minimal Gaps in Eyebrows by Month 12



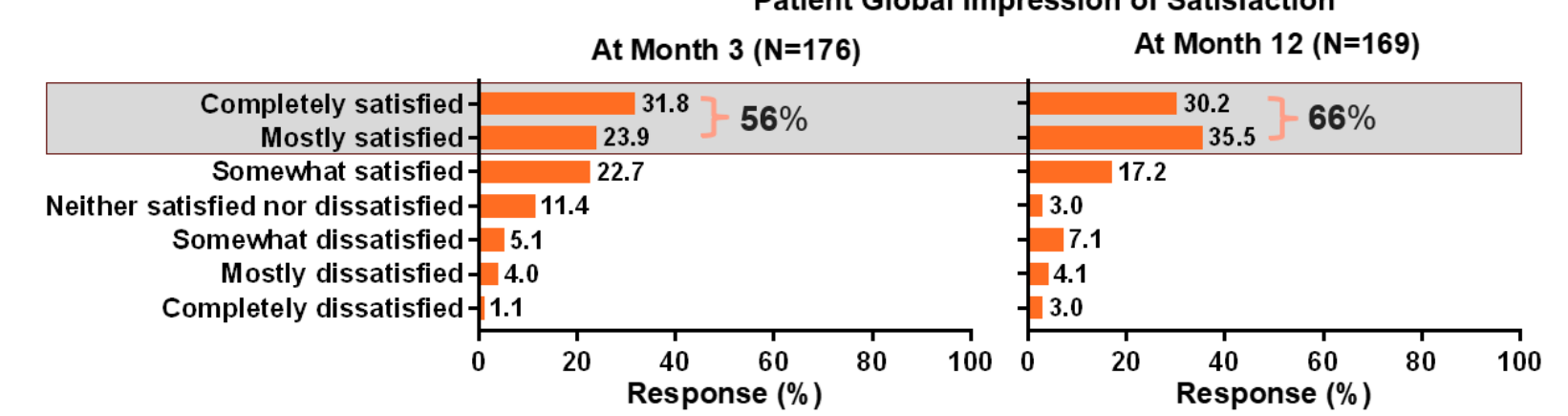
Among Participants With Large Gaps or No/Barely Any Eyelash Hair at BL, 73% or 50%, Respectively, Achieved Full or Minimum Gaps in Eyelashes by Month 12



Over Half of Participants at Month 3 and Two-Thirds at Month 12 Felt Much/Very Much Improved



Over Half of Participants at Month 3 and Two-Thirds at Month 12 Felt Mostly or Completely Satisfied



PRO Measures

Questionnaire	Definition
Scalp Hair Assessment PRO™,1a	Captures scalp hair loss on a 5-point scale: 0: No missing hair (0% missing hair) 1: A limited area (1-20% missing hair) 2: A moderate area (21-49% missing hair) 3: A large area (50-94% missing hair) 4: Nearly all or all (95-100% missing hair)
PRO Measure for Eyebrows/Eyelashes™,2,3a	Captures hair loss on a 4-point scale: 0: Full eyebrows/eyelashes 1: Minimal gaps 2: Large gaps 3: Barely any or no hair

Questionnaire	Definition
Patient Global Impression of Change (PGIC)	Single-item 7-point Likert scale: 1: Very much better 2: Much better 3: A little better 4: No change 5: A little worse 6: Much worse 7: Very much worse

Questionnaire	Definition
Patient Global Impression of Satisfaction (PGIS)	Single-item 7-point Likert scale: 1: Completely satisfied 2: Mostly satisfied 3: Somewhat satisfied 4: Neither satisfied nor dissatisfied 5: Somewhat dissatisfied 6: Mostly dissatisfied 7: Completely dissatisfied

- The AA Symptom Impact Scale (AASIS)⁴: 13-item PRO that measures severity of AA symptoms (from "not present" to "as bad as you can imagine") and their impact on functioning (from "did not interfere" to "interfered" completely) on a scale of 0 to 10
- The Work Productivity and Activity Impairment (WPAI-AA) questionnaire⁴: 6-item PRO that includes 6 questions and yields 4 scale scores: Absenteeism (work time missed), presenteeism (impairment at work), work productivity loss (overall), and activity impairment (non-work)^b
 - Scales are scored from 0% to 100%, with higher scores indicating greater work productivity lost and activity impairment

Statistical Analysis

- Data were analyzed descriptively without imputation

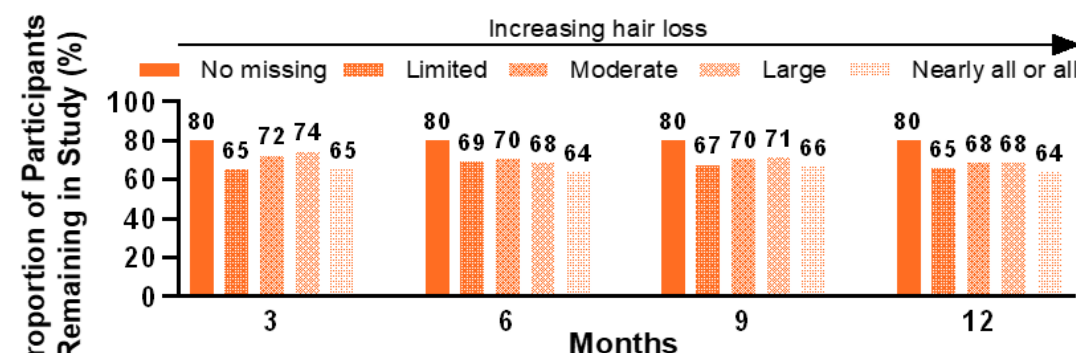
^aScalp Hair Assessment PRO™, PRO Measure for Eyebrows™, and PRO Measure for Eyelashes™ were developed by Eli Lilly and Company. Validation with clinical scale has been demonstrated¹⁻³. ^bQuestions related to absenteeism, presenteeism, and overall work productivity impairment were completed by employed participants, whereas questions concerning non-work activities were answered by all participants.

RESULTS

Baseline Demographics and Clinical Characteristics

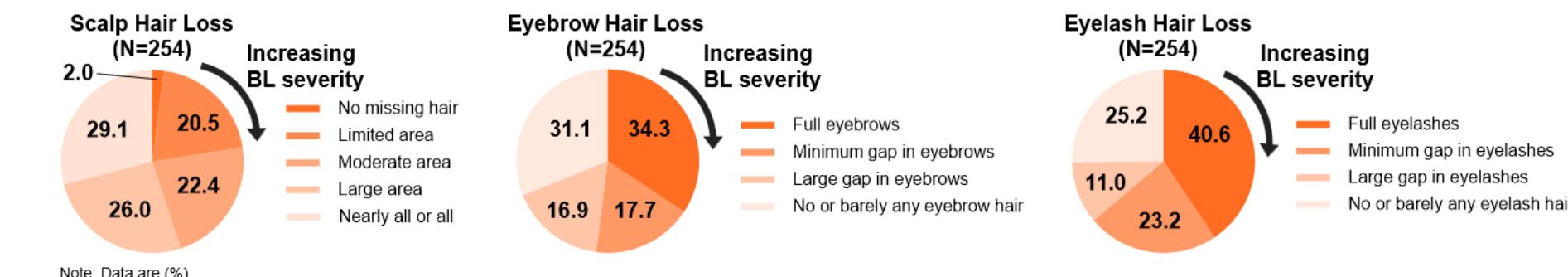
Characteristic	BARI (N=254)
Age, mean (SD), years	40 (14)
Female	184 (72.4)
Race	
White	160 (63.0)
Black or African American	35 (13.8)
Asian	19 (7.5)
Age at AA diagnosis, mean (SD), years	31.4 (16.8)
Current AA episode duration	
<6 months	31 (12.2)
6 months to <1 year	44 (17.3)
1 to <2 years	35 (13.8)
2 to ≤4 years	44 (17.3)
>4 years	100 (39.4)
Hair loss pattern	
AA with single spot/patch	5 (2.0)
AA with multiple spots/patches	119 (46.9)
Ophiasis: Hair loss from behind the ears across the back of the head	17 (6.7)
AT: Complete or nearly complete hair loss on scalp	51 (20.1)
AU: Complete or nearly complete hair loss of all body hair	62 (24.4)
AASIS-global, mean (SD)	3.3 (1.9)
AASIS-symptoms subscale score	3.2 (1.7)
WPAI-Work productivity loss, mean (SD)	15.9 (22.7)
WPAI-Absenteeism, mean (SD)	6.0 (17.0)
WPAI-Presenteeism, mean (SD)	17.9 (25.7)
WPAI-Activity impairment, mean (SD)	26.5 (28.6)

Participation by BL Severity of Scalp Hair Loss

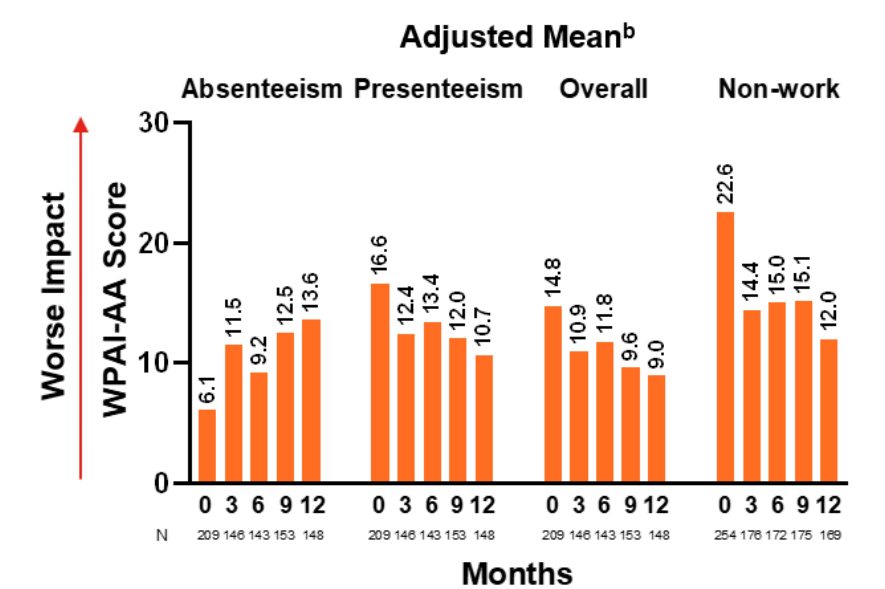


- Most participants who dropped out did so in the first 3 months
- Retention was similar across BL severity throughout the study

BL Scalp, Eyebrow, and Eyelash Hair Loss

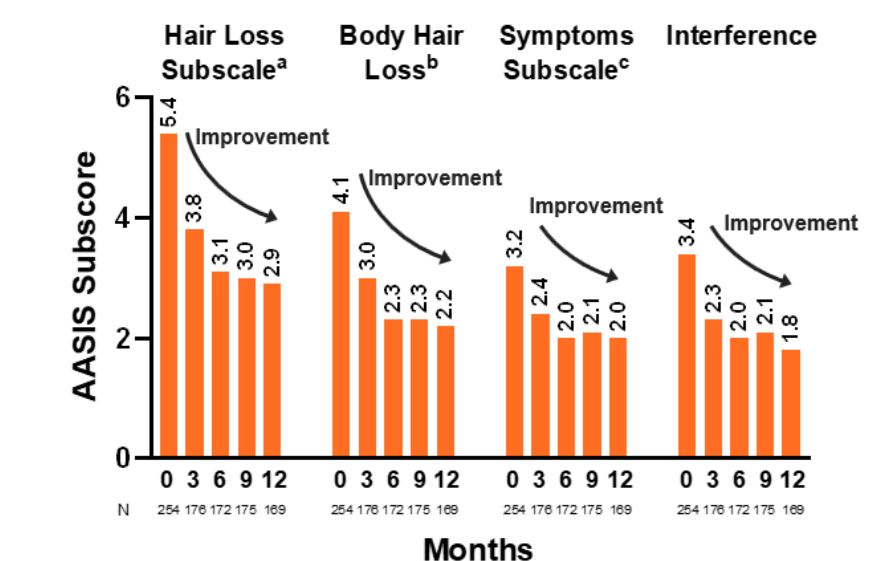


WPAI Total and Subscale Scores by Time^a



^aWork, enjoyment of life, interaction with others, daily activities, sexual relationships, and quality of life; ^bAdjusted for covariates of interest (baseline score, age, sex, education, race/ethnicity). Notes: Questions related to absenteeism, presenteeism, and overall work productivity impairment were completed by employed participants, whereas questions concerning non-work activities were answered by all participants.

Severity of AA Symptoms and Impact on Functioning Improved at 12 Months Relative to Baricitinib Initiation



^aThe hair loss subscale is a composite score of scalp hair loss and body hair loss; ^bBody hair loss include eyelash hair loss; ^cScalp hair loss, itchy or painful skin, irritated skin, feeling anxious or worried, and feeling sad.

References
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Abbreviations
 AA=alopecia areata; AASIS=AA Symptom Impact Scale; AT=alopecia totalis; AU=alopecia universalis; BARI=baricitinib; BL=baseline; JAK=Janus kinase; n=number of participants who responded to treatment; n/Nx=number of participants with non-missing values; PGIC=Patient Global Impression of Change; PGIS=Patient Global Impression of Satisfaction; PRO=patient-reported outcome; SD=standard deviation; WPAI=Work Productivity and Activity Impairment

Disclosures
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SUPPLEMENTAL MATERIALS
Scan the QR code to access Supplemental Materials

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BACKGROUND AND OBJECTIVE

Background

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AA=alopecia areata; PRO=Patient-Reported Outcome

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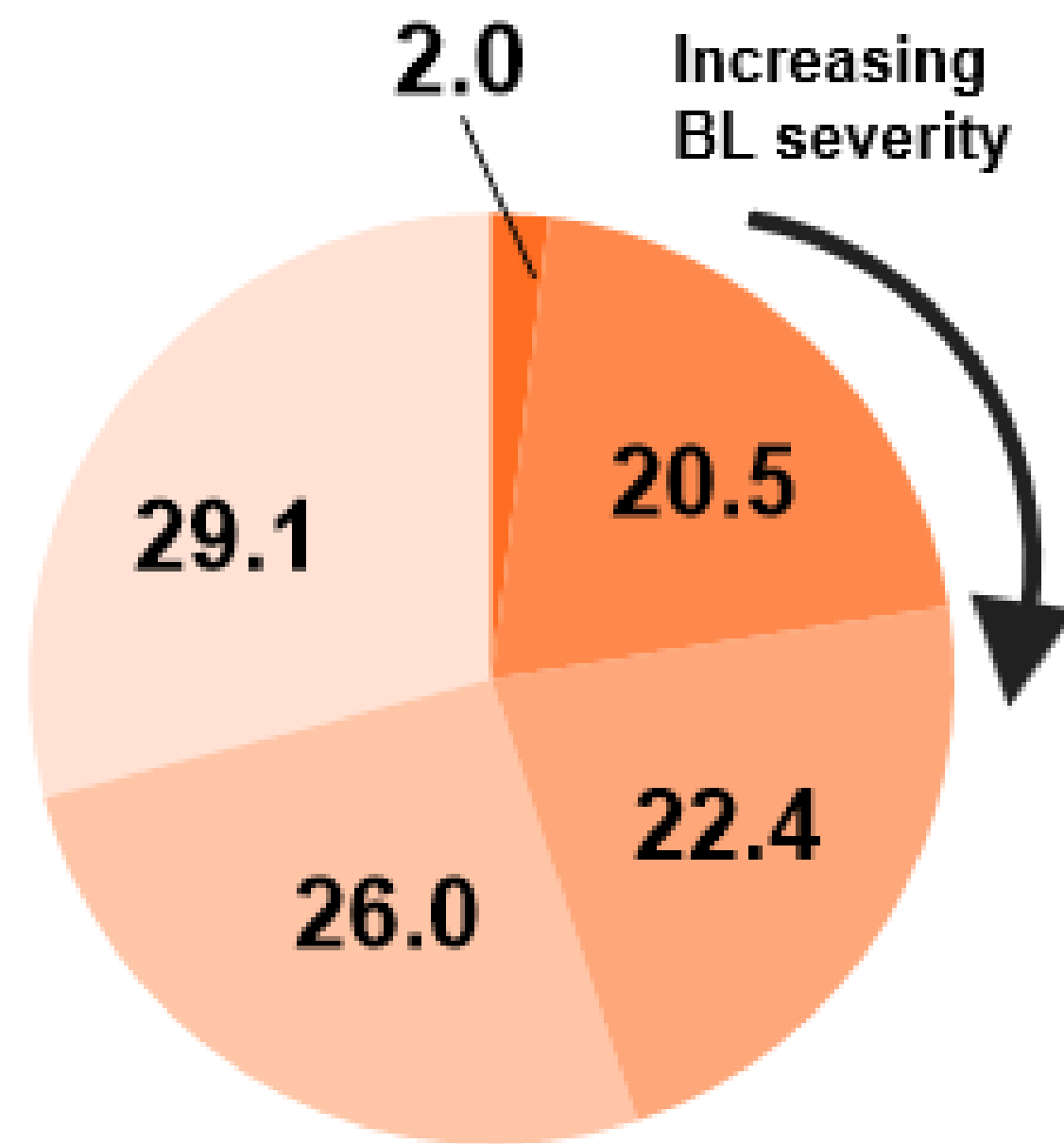
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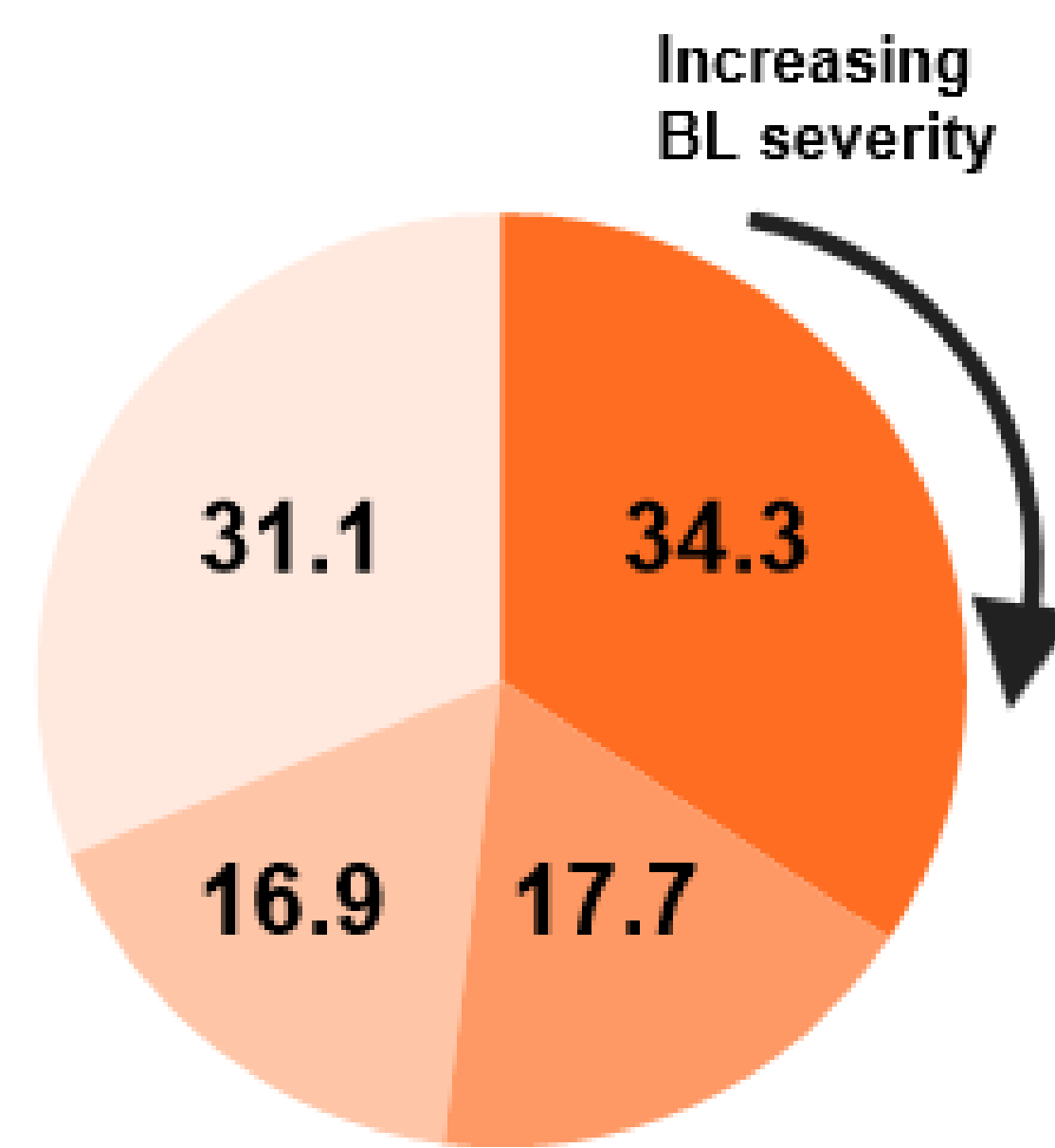
BL Scalp, Eyebrow, and Eyelash Hair Loss

Scalp Hair Loss (N=254)



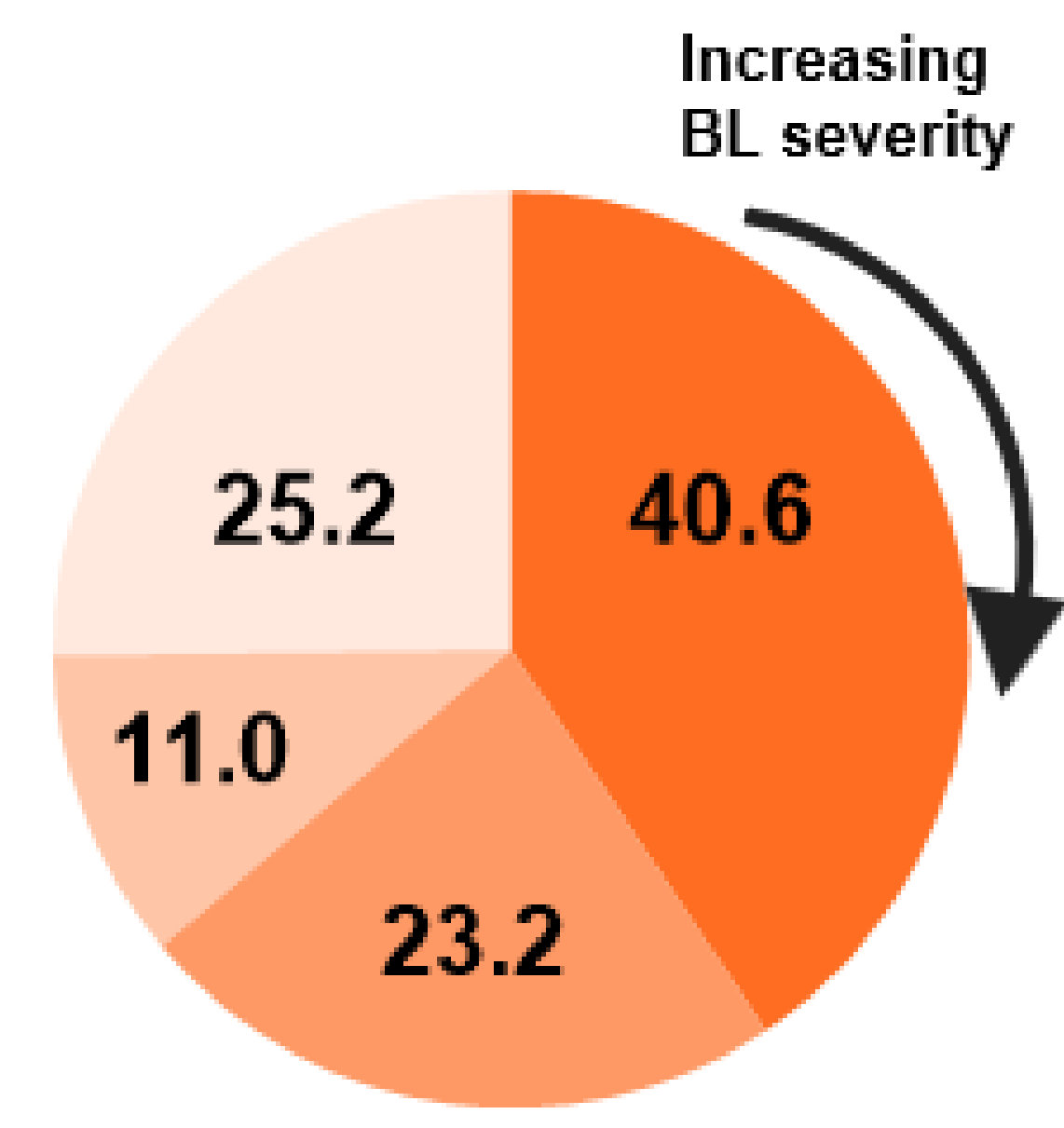
- No missing hair
- Limited area
- Moderate area
- Large area
- Nearly all or all

Eyebrow Hair Loss (N=254)



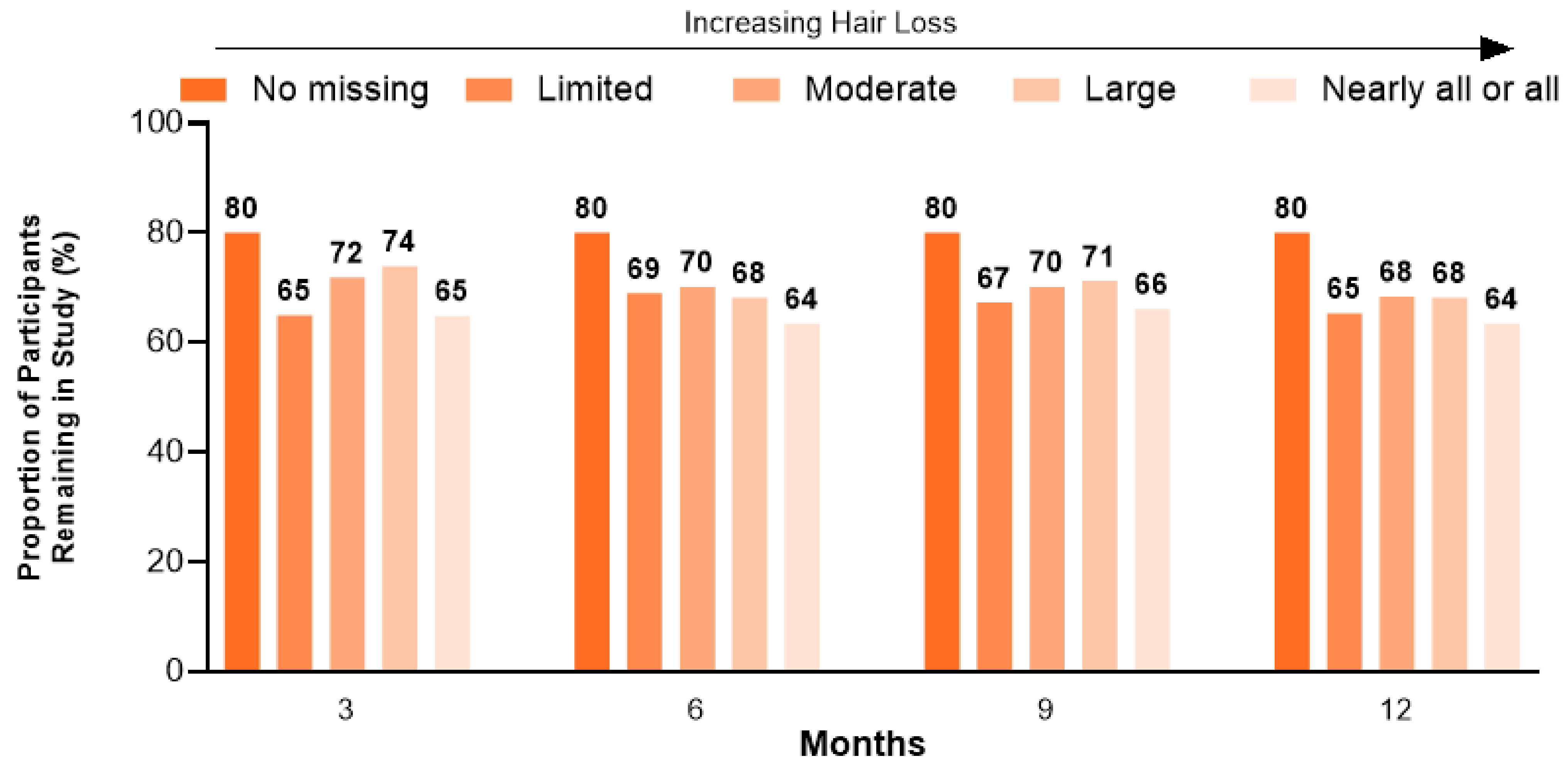
- Full eyebrows
- Minimum gap in eyebrows
- Large gap in eyebrows
- No or barely any eyebrow hair

Eyelash Hair Loss (N=254)



- Full eyelashes
- Minimum gap in eyelashes
- Large gap in eyelashes
- No or barely any eyelash hair

Participation by BL Severity of Scalp Hair Loss

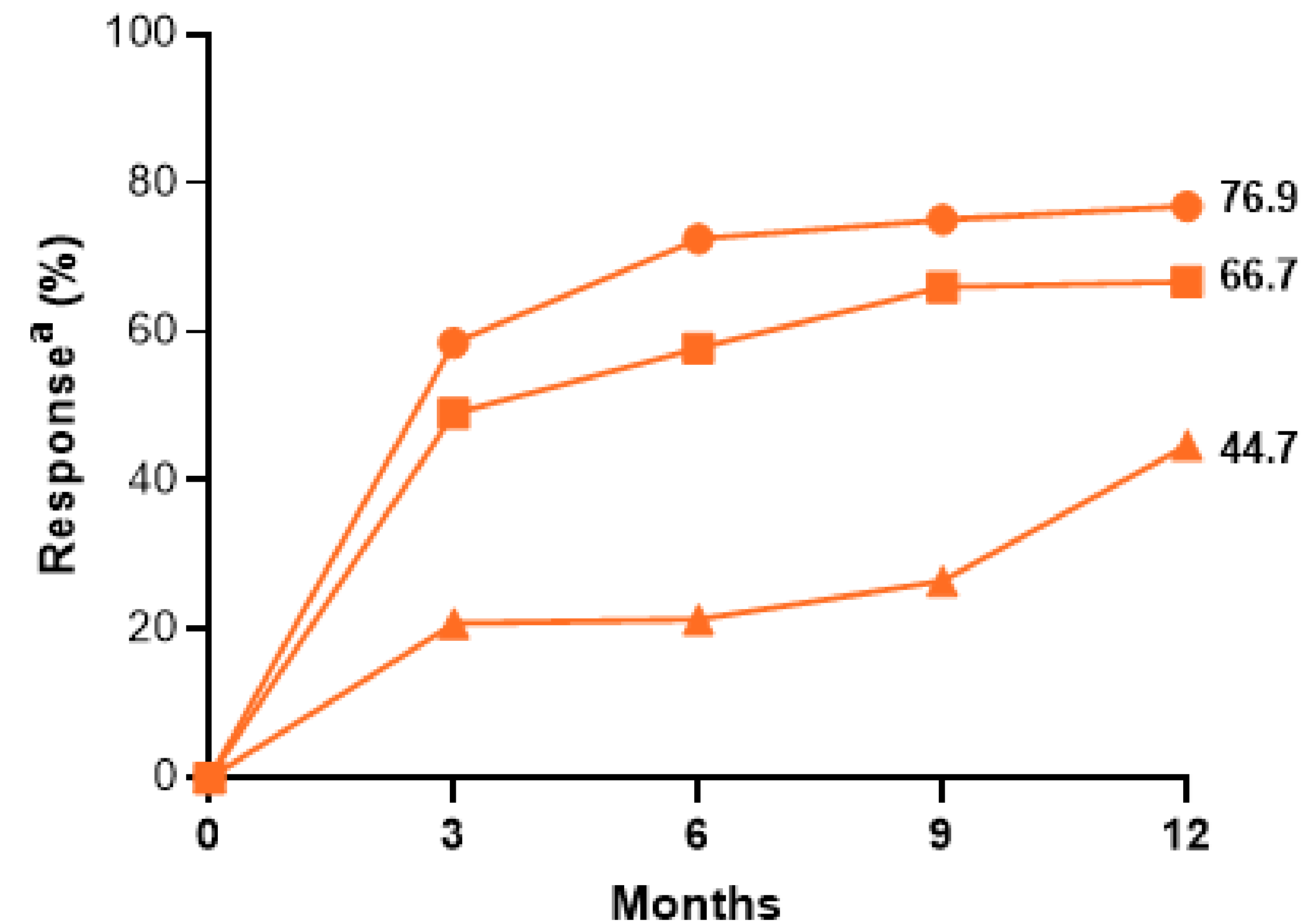


- Most participants who dropped out did so in the first 3 months
- Retention was similar across BL severity throughout the study

Among Participants With Moderate, Large, or Nearly All or All Scalp Hair Loss at Baseline, 45% to 77% Achieved Limited/No Scalp Hair Loss by Month 12

Scalp Hair Results by BL Severity

● Moderate at BL ■ Large at BL ▲ Nearly all or all at BL



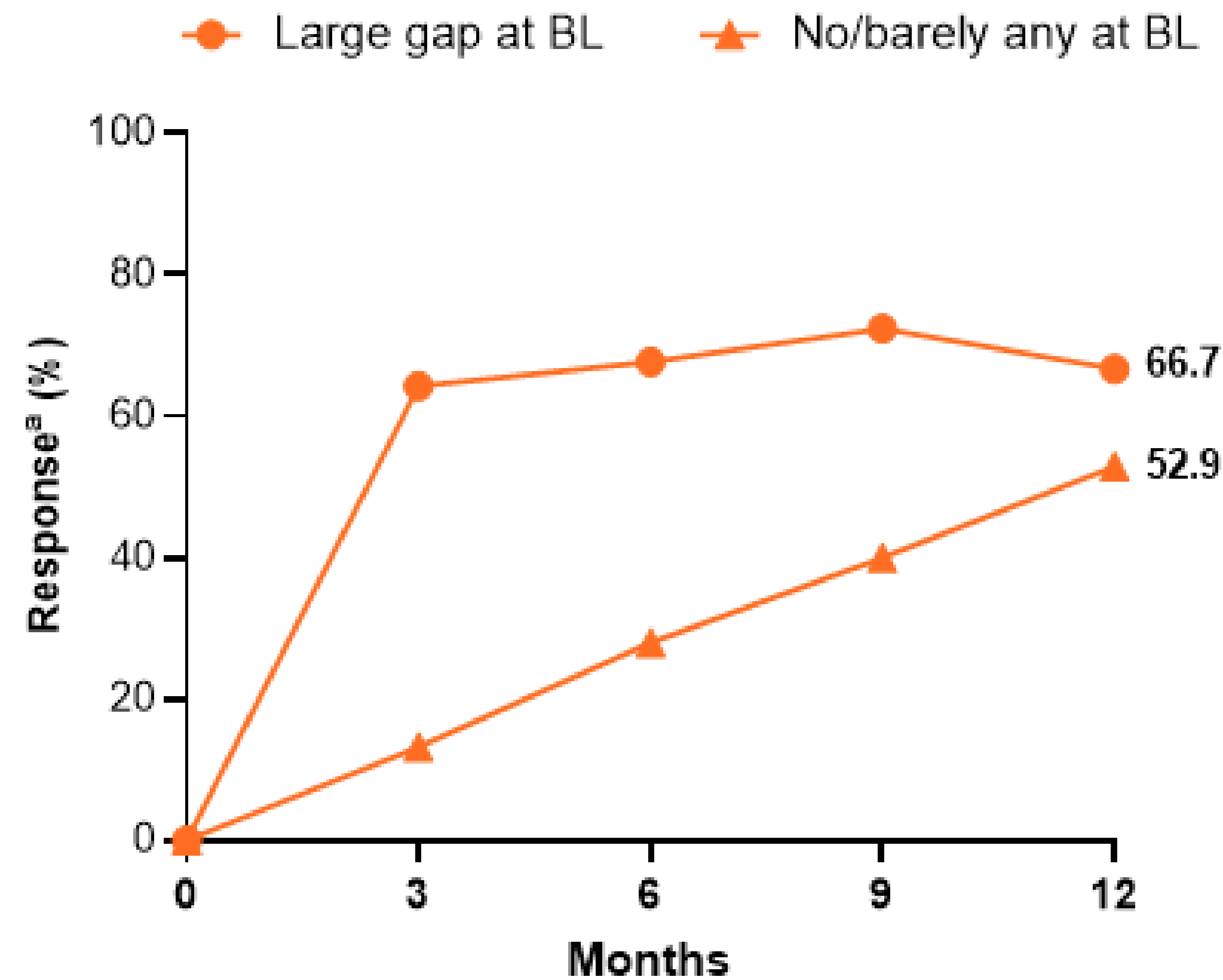
	0	3	6	9	12
n/Nx, Moderate at BL	0/57	24/41	29/40	30/40	30/39
n/Nx, Large at BL	0/88	24/49	28/45	31/47	30/45
n/Nx, Nearly all or all at BL	0/74	10/48	10/47	13/49	21/47

^aResponse was defined as regrowth from at least moderate or large area of hair loss to limited area or no hair loss.

AA=alopecia areata; BL=baseline; n=number of participants who responded to treatment; Nx=number of participants with non-missing values

Among Participants With Large Gaps or No/Barely Any Eyebrow Hair at Baseline, 67% or 53%, Respectively, Achieved Full or Minimal Gaps in Eyebrows by Month 12

Eyebrow Results by BL Severity



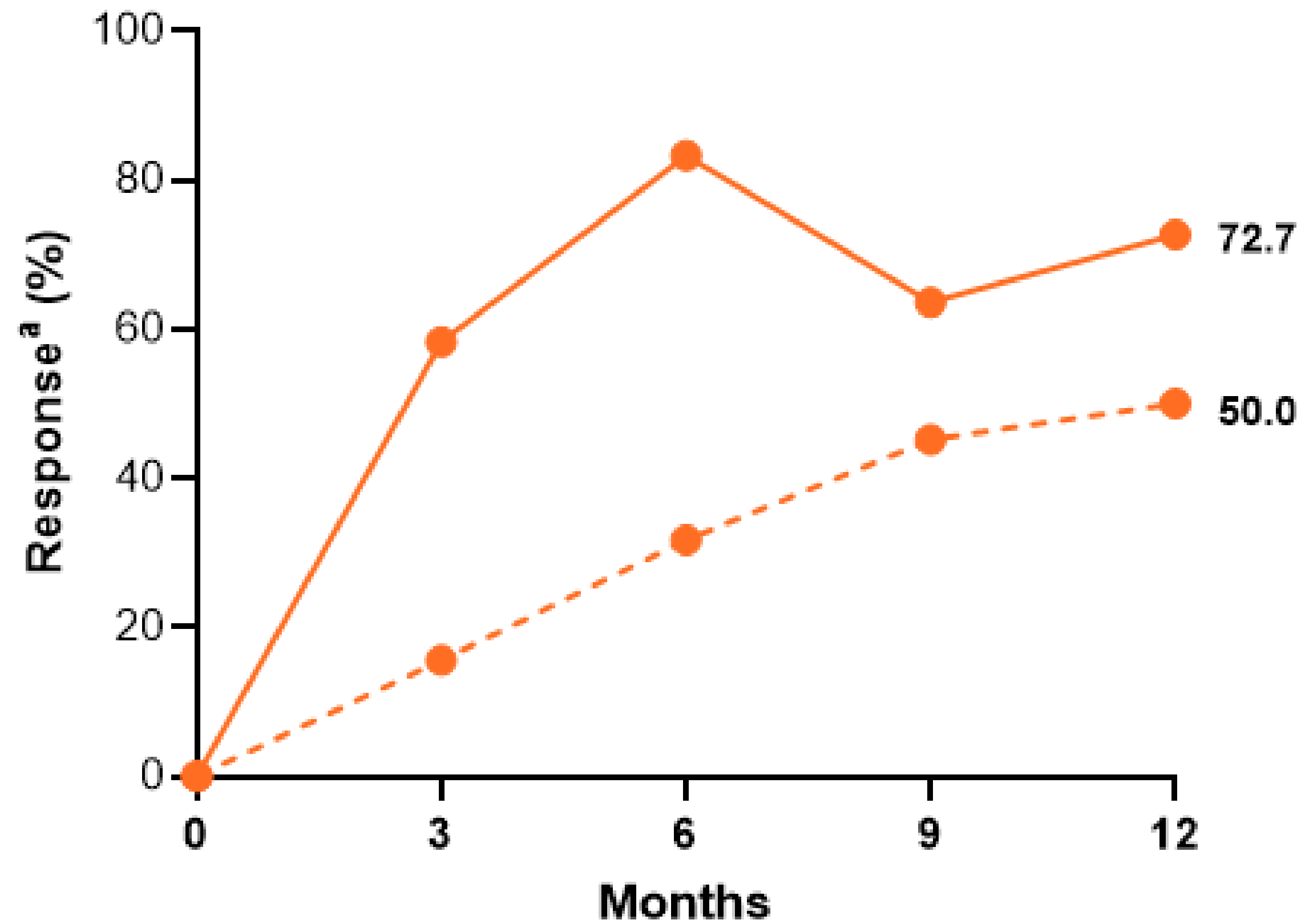
n/Nx, Large gap at BL	0/43	18/28	21/31	21/29	18/27
n/Nx, No/barely any at BL	0/79	7/53	14/50	20/50	27/51

^aResponse was defined as regrowth from at least large gap or No/barely any eyebrow hair to minimal gap or full eyebrows.
BL=baseline; n=number of participants who responded to treatment; Nx=number of participants with non-missing values

Among Participants With Large Gaps or No/Barely Any Eyelash Hair at Baseline, 73% or 50%, Respectively, Achieved Full or Minimum Gaps in Eyelashes by Month 12

Eyelash Results by BL Severity

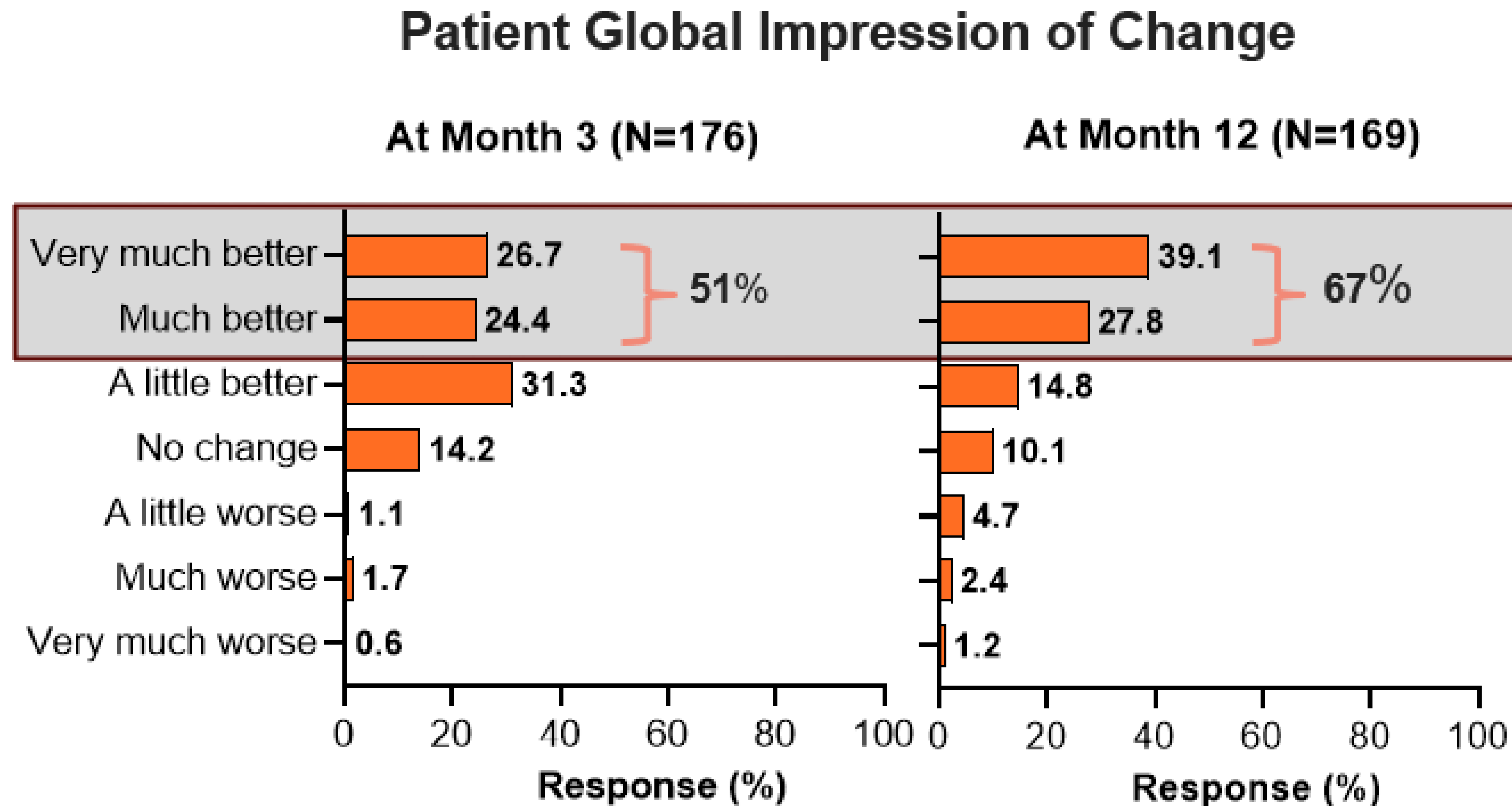
● Large gap at BL ● No/barely any at BL



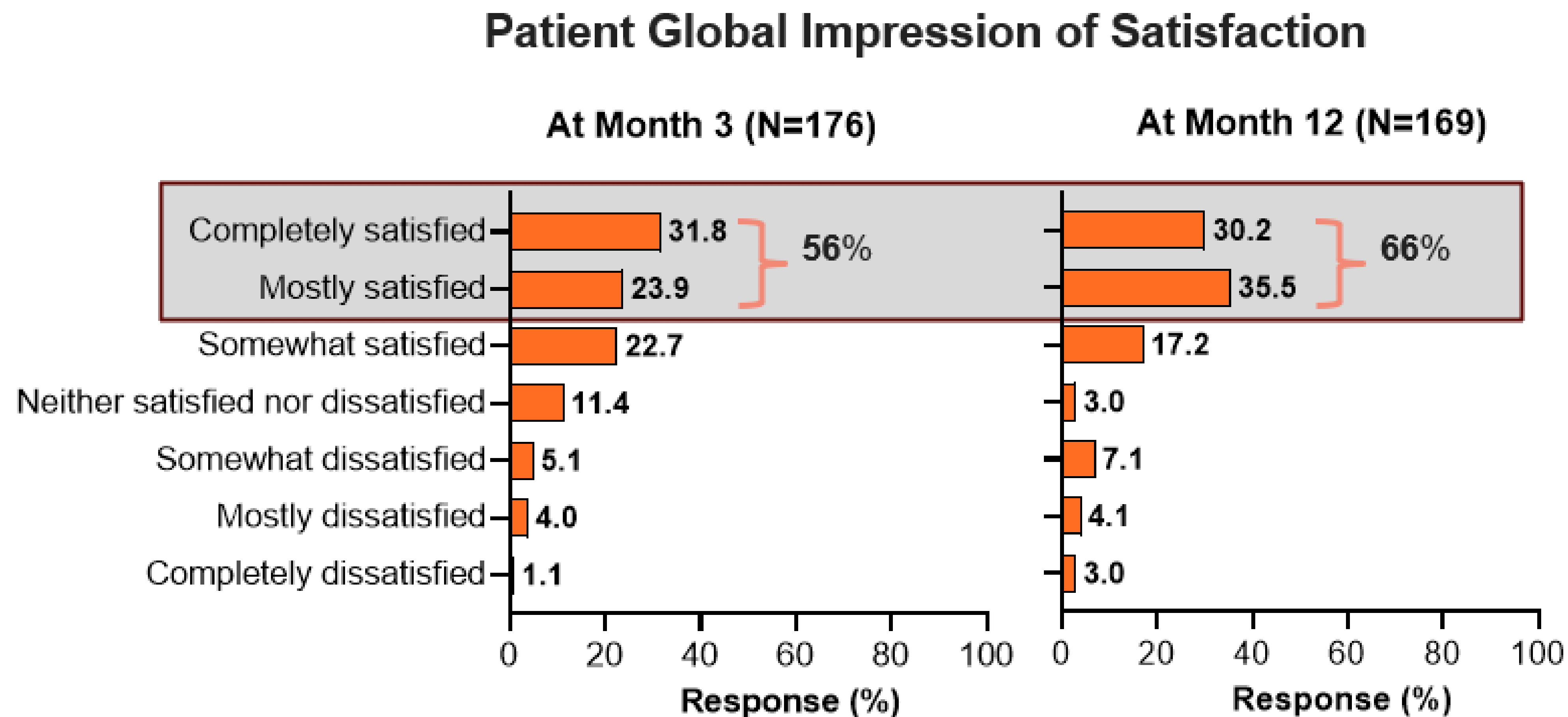
n/Nx, Large gap at BL	0/28	7/12	10/12	7/11	8/11
n/Nx, No/barely any at BL	0/79	7/45	13/41	19/42	21/42

^aResponse was defined as regrowth from at least large gap or No/barely any eyelash hair to minimal gap or full eyelashes.
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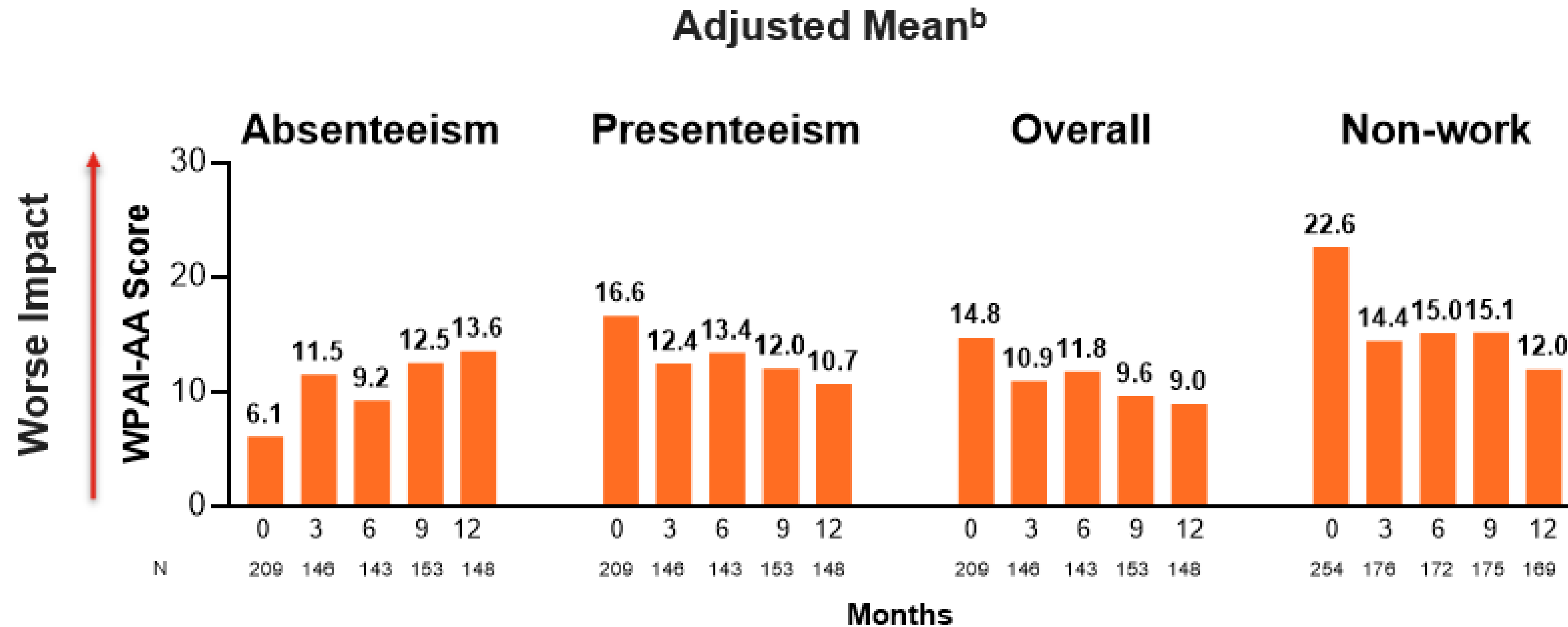
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WPAI Total and Subscale Scores by Time^a

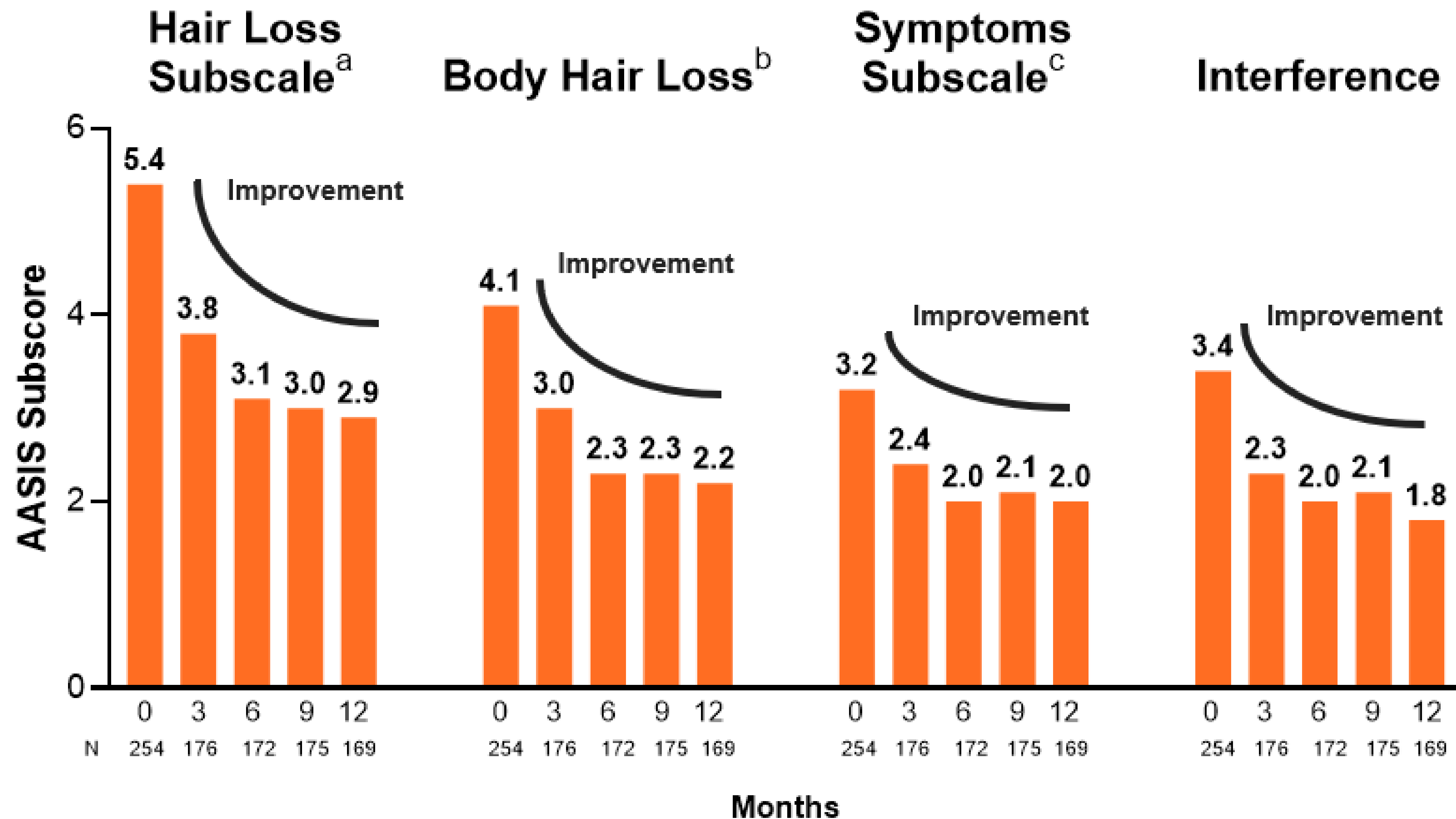


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AASIS Impairment Subscores



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CONCLUSIONS

- Baricitinib demonstrated effectiveness for scalp hair, eyebrow, and eyelash regrowth in a prospective real-world study of participants with scalp hair loss ranging from moderate to complete hair loss due to AA
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PRO MEASURES^a

Scalp Hair Assessment PRO^{TM,1}

0	No missing hair (0% of my scalp is missing hair; I have a full head of hair)
1	A limited area (1-20% of my scalp is missing hair)
2	A moderate area (21-49% of my scalp is missing hair)
3	A large area (50-94% of my scalp is missing hair)
4	Nearly all or all (95-100% of my scalp is missing hair)

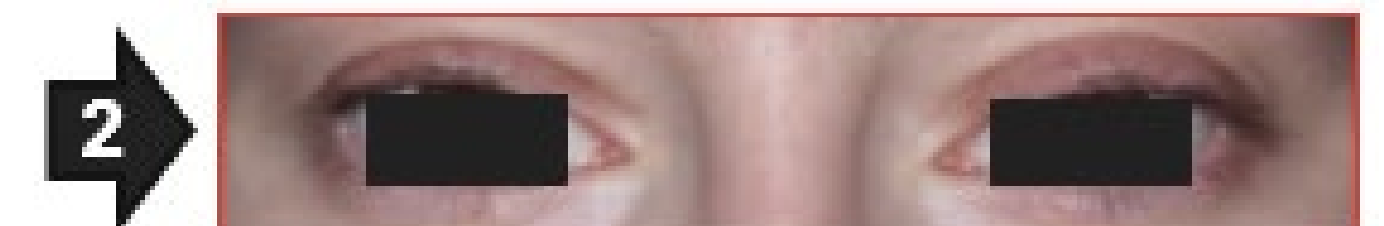
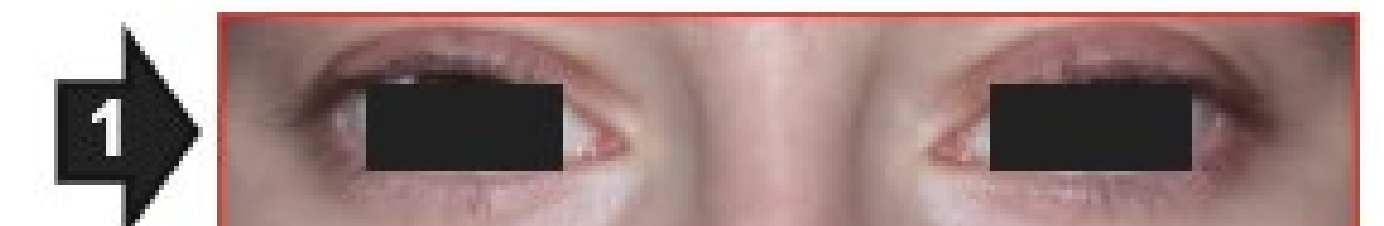
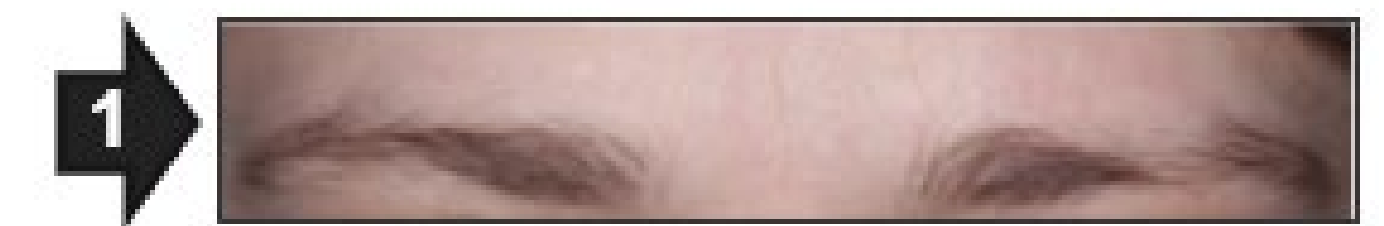
PRO Measure for Eyebrows^{TM,2}

0	I have full eyebrows on each eye
1	I have a minimal gap(s) or a minimal amount of thinning in at least 1 of my eyebrows
2	I have a large gap(s) or a large amount of thinning in at least 1 of my eyebrows
3	I have no or barely any eyebrow hairs

PRO Measure for Eyelashes^{TM,2}

0	I have full eyelashes on each eyelid
1	I have a minimal gap or minimal gaps along the eyelids
2	I have a large gap or large gaps along the eyelids
3	I have no or barely any eyelash hair

Example Photo Guides

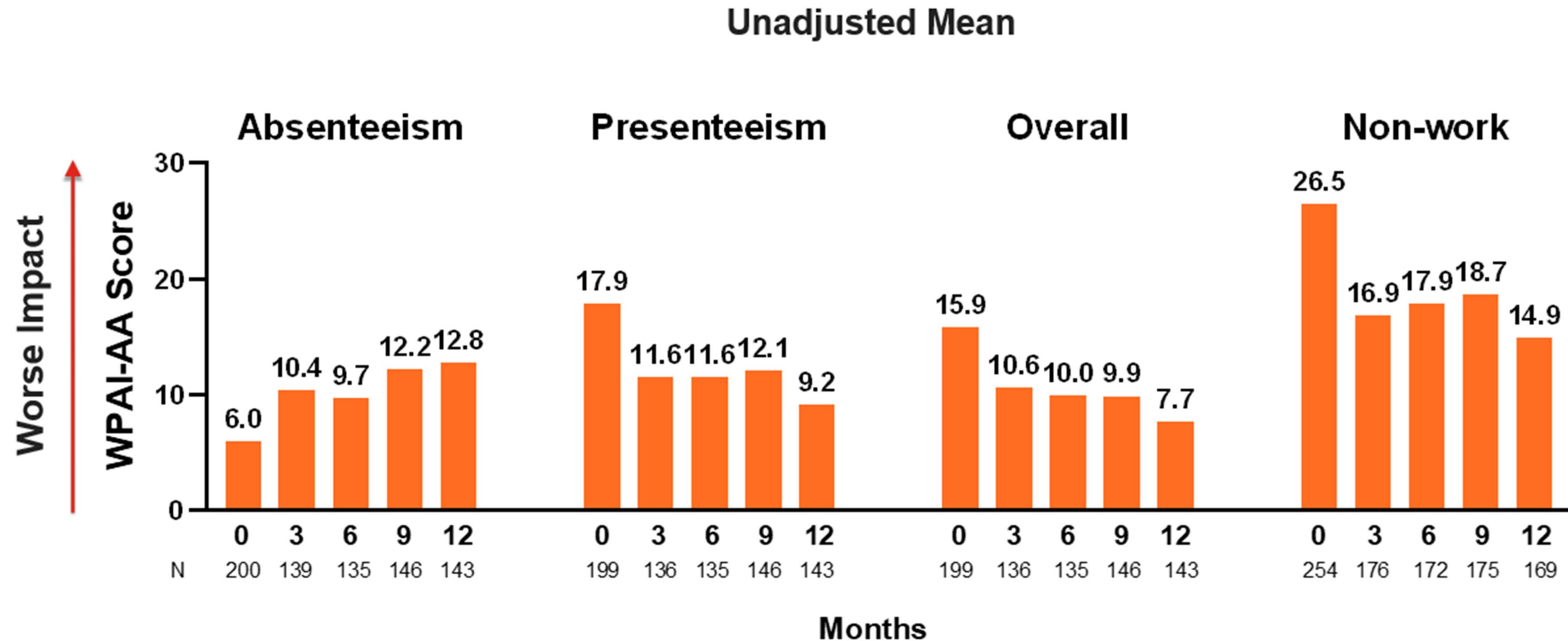


^aScalp Hair Assessment PROTM, PRO Measure for EyebrowsTM, and PRO Measure for EyelashesTM were developed by Eli Lilly and Company. The PRO Measure for EyebrowsTM, PRO Measure for EyelashesTM, and accompanying photo guides are subject to copyright owned by Eli Lilly and Company. Permission to use is granted under Creative Commons Attribution-No Derivatives 4.0 International License (<https://creativecommons.org/licenses/by-nc/4.0/>).

1. Wyrwich KW, et al. *Br J Dermatol.* 2020;183:1065-1072. 2. Wyrwich KW, et al. *Am J Clin Dermatol.* 2020;21:725-732.

PRO=patient-reported outcome.

WPAI Total and Subscale Scores by Time^a



^aWork, enjoyment of life, interaction with others, daily activities, sexual relationships, and quality of life.

Notes: Questions related to absenteeism, presenteeism, and overall work productivity impairment were completed by employed participants, whereas questions concerning non-work activities were answered by all participants.

AA=alopecia areata; WPAI=Work Productivity and Activity Impairment.