

AC5 IN THE MANAGEMENT OF MILD ANDROGENETIC ALOPECIA : RESULTS FROM A LARGE INTERNATIONAL OBSERVATIONAL STUDY

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INTRODUCTION

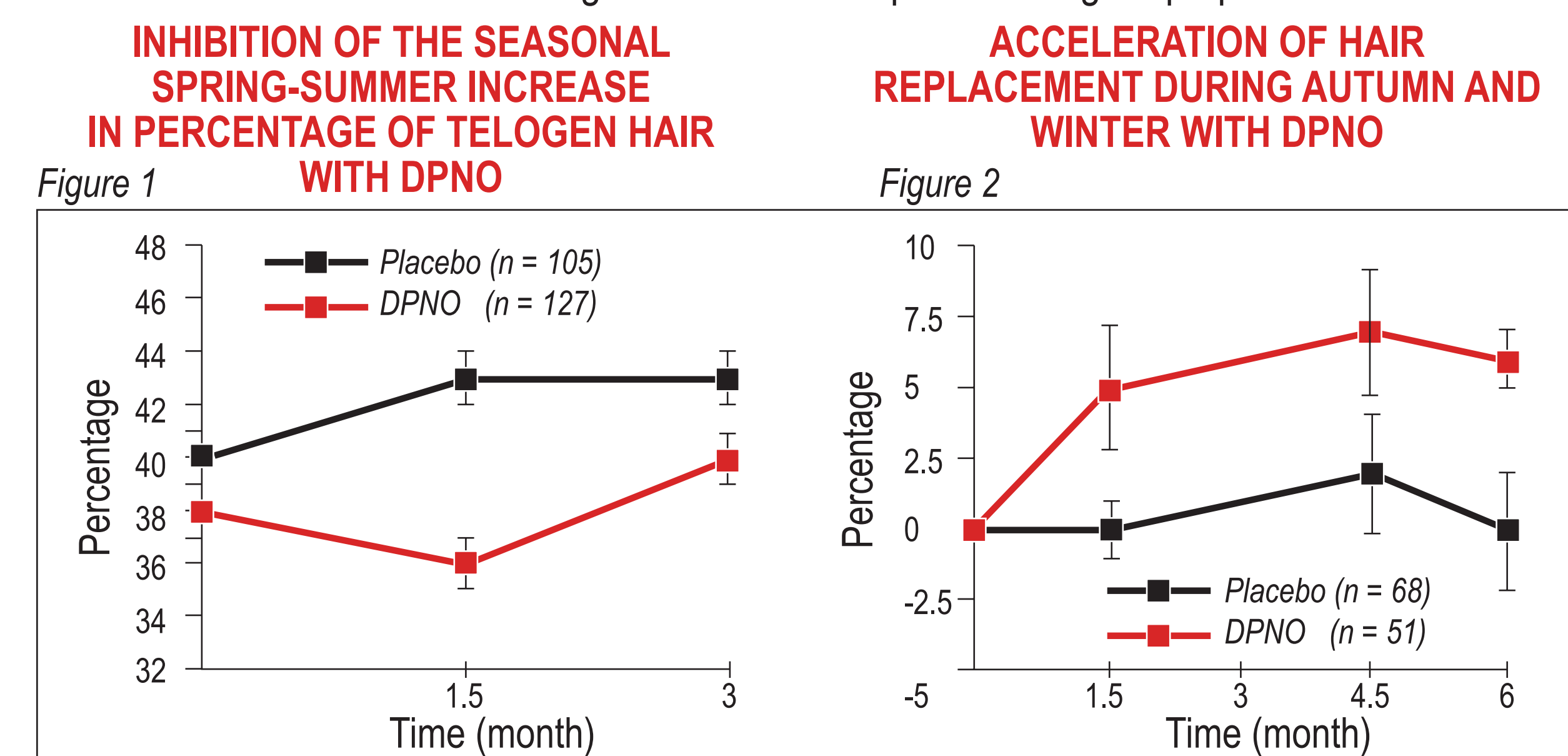
Androgenetic alopecia (AGA) is a chronic scalp condition, representing the primary cause of hair loss in both women and men.¹

AGA manifests in different clinical patterns among women and men. In women, AGA or female pattern of hair loss (FPHL) results in a decreased hair density and thickness predominantly in the frontal area with a sparse pattern.¹⁻³ Male pattern of hair loss (MPHL) presents predominantly in the temporal areas and the vertex more regularly than FPHL.⁴

Alopecia causes emotional distress, impact the individual's quality of life and can also be the first symptom of an underlying systemic disease.^{5,6}

AC5 contains 2,4-Diamino-Pyrimidine-N-Oxyde (DPNO, Aminexil), Arginine, 6-O glucose linoleate (SP94), Piroctone olamine and Vichy volcanic mineralizing water (VVMW) as active ingredients; which have proven their benefits in hair loss or inflammation shown the benefit in hair loss or skin inflammation.⁷⁻¹⁰ Figure 1 and Figure 2 show the benefit of DPNO alone on hair growth as published by Loussouarn.⁹

Table 1 summarizes AC5 active ingredients and their pharmacological properties.



DPNO: 2,4-Diamino-Pyrimidine-N-Oxyde

Table 1 ACTIVE INGREDIENTS OF AC5 AND THEIR PHARMACOLOGICAL PROPERTIES

Ingredient	Pharmacological properties
2,4-Diamino-Pyrimidine-N-Oxyde (DPNO, Aminexil)	Inhibits lysyl hydroxylase, and thereby collagen reticulation and fibronectin network densification
Arginine	Key substrate of cellular mechanisms. Stimulates microcirculation, promotes the intake of nutrients essential for hair bulb growth, and sustains the synthesis of polyamines to maintain hair growth
6-O glucose linoleate (SP94)	Provides both energy and lipid precursor to hair with glucose and vitamin F
Piroctone olamine	Has anti-microbial properties and soothing effect of the scalp
Vichy volcanic mineralizing water	Strengthens the skin barrier components and reduces skin inflammation

AIM

The aim of this study was to assess hair loss improvement and hair quality with AC5 in subjects with mild AGA in real life settings.

METHODS

This cosmetic, observational, international real-life study was conducted in Lebanon, Poland, Czech Republic, Russian Federation, Mexico and Belgium.

The study was planned for the inclusion of at least 400 female and male subjects aged between 18 and 45 years with mild AGA defined for women as a score of 0 or 1 on the Ludwig scale and for men as a score between I and IV on the Hamilton-Norwood scale. AC5 was to be applied alone or as an adjunct once daily on the scalp for 3 months using a specifically developed applicator device stimulating the scalp and helping for a precise product application.

At study end, the investigators evaluated treatment compliance and the impact of AC5 on the subjects' hair loss on a 4-point scale ("worse", "stable", "slightly improved", "clearly improved"), asked the subject to rate local tolerance of AC5 from "yes, very well" to "no, not at all" and rated their satisfaction on a scale ranging from "not at all satisfactory" to "highly satisfactory".

Subjects assessed their perception of hair growth and hair quality on an 8-point questionnaire and their overall satisfaction on a visual analog scale (VAS) from 0 (not at all) to 10 (completely satisfied).

RESULTS

Overall, questionnaires from 527 subjects were collected. Data from 421 subjects were evaluable for the statistical analysis of clinical efficacy.

Detailed demographic and baseline data are provided in Table 2.

At the time of inclusion, 85.2% of subjects started to applied AC5 as a monotherapy while the remaining 14.8% used it in combination with other prescription treatments (14.3% (60/419) topical and/or 1.7% (7/419) oral treatments).

Subjects applied AC5 in average during 82.9±17.5 days; 94.8% (398/420) applied AC5 once daily. Subjects applied AC5 in average during 82.9±17.5 days. Overall compliance was 95.9±6.6%, with no notable difference between women and men.

Figure 3 provides a summary of clinically benefit (slightly/clearly improved) of AC5 used in combination or in monotherapy rated by the dermatologists. Overall, clinical benefit was very high, exceeded 80% in all subjects and in those who used AC5 in monotherapy.

Table 2 DEMOGRAPHIC AND BASELINE DATA

Parameter	Female (n = 247)	Male (n = 174)	Total (n = 421)
Gender (n, %); n = 421	247 (58.7%)	174 (41.3%)	
Age (years); n = 378*			
Mean±SD	34.3±9.5	33.8±8.5	34.1±9.1
Median	34.0	33.0	33.0
Min;Max	18.0;69.0	18.0;59.0	18.0;69.0
Duration of alopecia (years); n = 395*			
Mean±SD	1.25±1.80	2.25±2.57	1.65±2.20
Median	0.58	1.00	0.83
Min;Max	0.08;12.00	0.08;12.00	0.8;12.00
Age at onset (years); n = 356*			
Mean±SD	32.9±9.4	31.2±8.6	32.2±9.1
Median	32.5	30.0	31.0
Min;Max	16.0;67.5	16.7;58.4	16.0;67.5
Onset (n, %); n = 355*			
Acute	81 (37.3%)	23 (16.7%)	104 (29.3%)
Progressive	136 (62.7%)	115 (83.3%)	251 (70.7%)
Alopecia care at inclusion; n = 419*			
Medicated products	32 (13.0%)	30 (17.3%)	62 (14.8%)
Topical medication	32 (13.0%)	28 (16.2%)	60 (14.3%)
Oral medication	2 (0.8%)	5 (2.9%)	7 (1.7%)
Alopecia Severity; n = 421	Ludwig scale	Hamilton-Norwood scale	
	L0: 71 (28.7%)	N0: 6 (3.4%)	
	L1: 176 (71.3%)	N1: 19 (10.9%)	
		N2: 71 (40.8%)	
		N3A: 27 (15.5%)	
		N3V: 33 (19.0%)	
		N4: 18 (10.3%)	

* number of subjects for whom data were available

Figure 4 provides an overview of investigator satisfaction (satisfied/very satisfied) in the global population as well as for subjects who applied AC5 in monotherapy. Overall, investigator satisfaction was very high.

A total of 98.4% (60/61) would recommend AC5 for further use.

AC5 met the subjects' expectations in 88.8% (371/418, CI95% [85.7;91.8]); results were similar in women (90.2%, 221/245, CI95% [86.5;93.9]) and men (86.7%, 150/173, CI95% [81.6;91.8]). In subjects applying AC5 alone with no other product, AC5 met the subject's expectation at the same proportions (89.0%; 315/354, CI95% [85.7;92.2] with slightly more women (91.0% (193/212, CI95% [87.2;94.9]) than men (85.9%; 122/142; CI95% [80.2;91.6]). Detailed results for subject rating are provided in Figure 5.

The mean subject satisfaction score on the VAS scale was 7.9±1.7; the difference to the average value (5 on the scale from 0 to 10) was significant (p<0.0001). Mean satisfaction was slightly higher in women (8.0±1.7, p<0.0001) than in men (7.8±1.7, p<0.0001).

Tolerability was rated good to very good by 98.6% (502/509, CI95% [97.6;99.6]) of all subjects.

Figure 3 INVESTIGATOR-RATED HAIR LOSS REDUCTION EFFECTIVENESS IN THE GLOBAL POPULATION AND IN SUBJECTS HAVING RECEIVED AC5 IN MONOTHERAPY

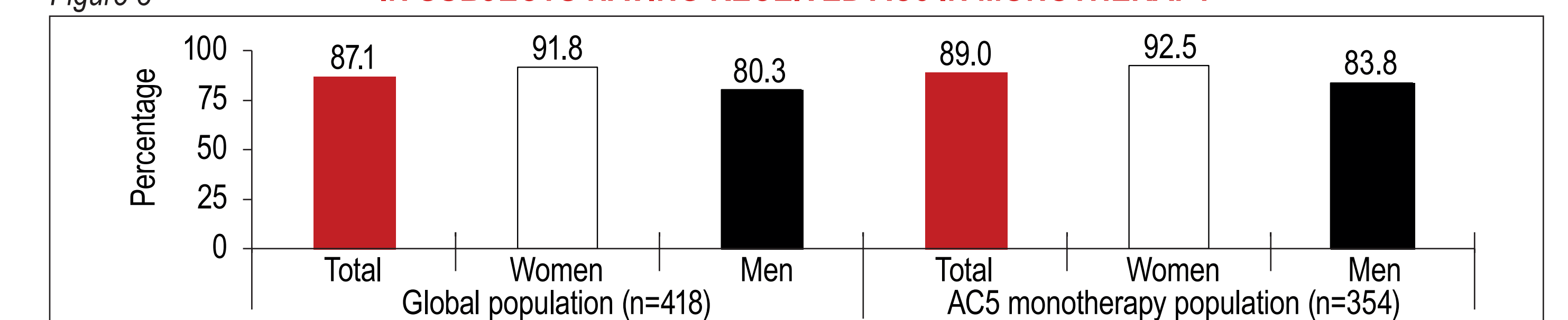


Figure 4 INVESTIGATOR SATISFACTION IN THE GLOBAL AND AC5 MONOTHERAPY POPULATION

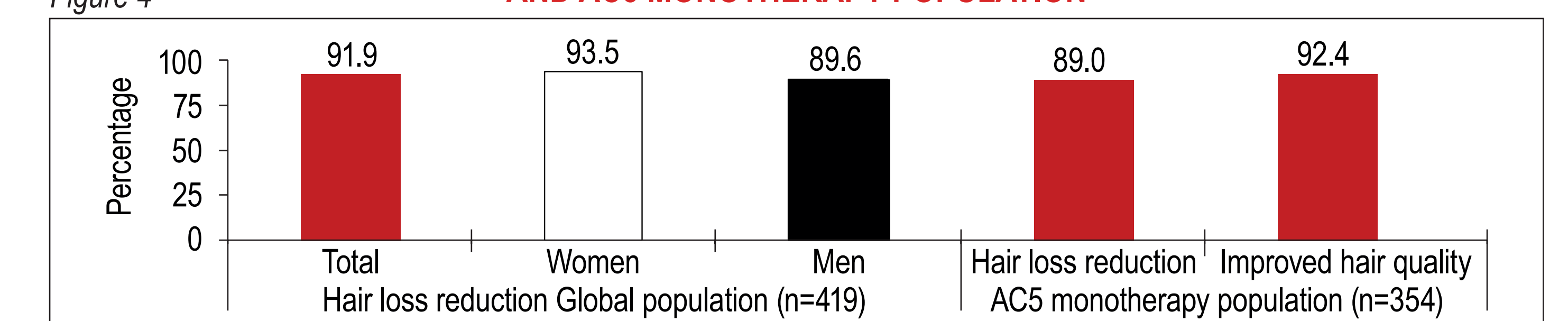
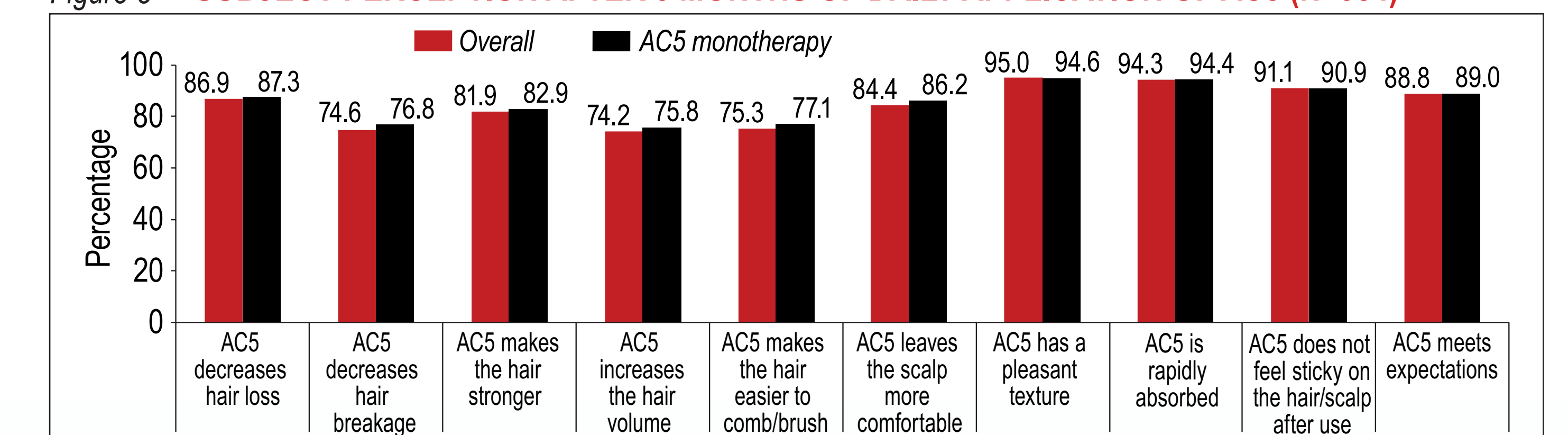


Figure 5 SUBJECT PERCEPTION AFTER 3 MONTHS OF DAILY APPLICATION OF AC5 (N=354)



CONCLUSIONS

AC5 improves hair loss and hair quality in subjects with mild AGA with an excellent tolerability, a pleasant texture and a high satisfaction rate

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Conflict of interest: Pascal Reygagne, Victor Desmond Mandel and Sergio Vano-Galvan are consultants of Laboratoires Vichy International. Florence Pouradier, Jean-Francois Michelet are employees of l'Oréal France. Delphine Kerob is an employee of Laboratoires Vichy International France. The other authors have no conflict of interest to disclose.

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