doi:10.36849/JDD.9761

 ORIGINAL ARTICLE

Efficacy and Safety of Clascoterone Cream 1% and Adapalene Gel 0.3% in Patients With Acne

Leon Kircik MD,[a–d] Angela J. Lamb MD,[a] Aram Kircik,[e] Nicholas Squittieri MD,[f] Kizito Kyerematen PharmD[f]

[a]Icahn School of Medicine at Mount Sinai, New York, NY
[b]Indiana University School of Medicine, Indianapolis, IN
[c]Physicians Skin Care, PLLC, Louisville, KY
[d]DermResearch, PLLC, Louisville, KY
[e]SUNY Buffalo, Buffalo, NY
[f]Sun Pharmaceutical Industries, Inc., Princeton, NJ

ABSTRACT

Background: Clascoterone cream 1% is a topical androgen receptor inhibitor approved for the treatment of acne vulgaris in patients ≥12 years of age. The American Academy of Dermatology recommends topical combination therapy using medications that target different mechanisms of acne pathogenesis. This 20-week, open-label, pilot study (NCT06336603) evaluated the efficacy and safety of clascoterone cream 1% combined with adapalene gel 0.3% in patients with acne.

Methods: Patients aged ≥12 years with moderate-to-severe acne applied clascoterone cream 1% twice daily and adapalene gel 0.3% once daily for 16 weeks. Efficacy assessments included Investigator's Global Assessment (IGA) score; inflammatory, noninflammatory, and total lesion counts; and Dermatology Life Quality Index (DLQI) through week 16. Tolerability and safety were assessed from local skin reactions and adverse events through week 20.

Results: Twenty patients were enrolled; 17 completed the study (female, 53%; mean [standard deviation (SD)] age, 22 [10] years). At week 16, 65% of patients achieved an IGA score of clear (0) or almost clear (1). From baseline to week 16, there were significant reductions in lesion counts (mean [SD] percent reduction: inflammatory, 90.5 [10.1]; noninflammatory, 84.8 [13.5]; total, 87.3 [11.4]; all $P<0.001$) and DLQI score (mean [SD] reduction, 3.7 [6.2]; $P=0.02$). Treatment was well tolerated, with most local skin reactions reported as absent or trace, and no adverse events reported.

Conclusions: This open-label pilot study shows promising results for combination treatment with clascoterone cream 1% and adapalene gel 0.3% for the treatment of patients with acne.

J Drugs Dermatol. 2026;25(6):545-550. doi:10.36849/JDD.9761

INTRODUCTION

Acne vulgaris is among the most common dermatologic conditions worldwide.[1,2] Acne typically begins during adolescence and may persist into adulthood, particularly in women.[3-5] Acne vulgaris is characterized by hyperseborrhea, noninflammatory lesions (open and closed comedones), and inflammatory lesions (papules-pustules, nodules, and cysts), most often affecting the face and trunk.[3,5,6] The pathophysiology of acne is multifactorial, involving excess sebum production, follicular hyperkeratinization, *Cutibacterium acnes* colonization, and inflammation.[7-13] Sebum production is largely regulated by androgens such as testosterone and 5α-dihydrotestosterone, which bind to androgen receptors in sebocytes and activate gene expression that drives lipogenesis and sebocyte differentiation.[14] The resulting excess sebum triggers downstream pathways that culminate in lesion formation.[15]

Clascoterone cream 1% is a first-in-class topical androgen receptor inhibitor approved for the treatment of acne vulgaris in patients 12 years of age and older.[16] In two Phase 3 trials (NCT02608450 and NCT02608476), clascoterone cream 1% monotherapy demonstrated superior efficacy vs vehicle, significantly reducing acne severity and lesion counts, and showed a favorable safety profile, which was maintained during up to 9 months of treatment in an extension safety study.[17,18] Although no studies have fully characterized the mechanism of action of clascoterone cream 1%,[16] evidence from in vitro studies suggests that it competes with dihydrotestosterone to bind to androgen receptors and inhibits downstream androgen-regulated sebum production and associated inflammatory pathways.[19,20] Consistent with this, treatment with clascoterone cream 1% for 12 weeks significantly reduced casual facial sebum levels in patients with mild-to-moderate acne.[21]

Given its efficacy and safety, clascoterone cream 1% is included among the topical therapies (topical retinoids, benzoyl peroxide, topical antibiotics, salicylic acid, and azelaic acid) recommended by the American Academy of Dermatology (AAD) for the treatment of acne of any severity. Notably, it remains the only topical antiandrogen approved to treat acne.[22] The AAD recommends multimodal therapy combining topical agents with mechanisms of action that target different aspects of acne pathogenesis.[22] As the only topical treatment that targets androgen-induced sebum production, clascoterone cream 1% is potentially a key component of combination treatment regimens.[21] Therefore, combining clascoterone cream 1% with adapalene gel 0.3%, a topical retinoid, represents a rational therapeutic strategy to directly reduce androgen-driven sebum production while also addressing follicular hyperkeratinization and inflammation.[19,20,23,24]

In a pilot study, clascoterone cream 1% was stable when combined with other topical acne medications in vitro, including adapalene gel 0.3%. However, no clinical studies have evaluated the efficacy and safety of clascoterone cream 1% in combination with adapalene gel 0.3% in patients with acne.[25] The objective of this study was to evaluate the efficacy and safety of clascoterone cream 1% in combination with adapalene gel 0.3% for the treatment of patients with moderate-to-severe acne.

MATERIALS AND METHODS

Study Design

This was a 20-week, open-label, pilot study (NCT06336603) conducted from February 13, 2024, to October 29, 2024. The protocol was approved by a central Institutional Review Board prior to study initiation. The study was conducted in accordance with the principles of the Declaration of Helsinki, Good Clinical Practice guidelines, and all local and regulatory regulations. All patients and/or parents or guardians provided informed consent prior to study initiation.

Patients

The study enrolled male and nonpregnant female patients ≥12 years of age of any race with moderate-to-severe facial acne (Investigator's Global Assessment [IGA] score of 3 [moderate] or 4 [severe]). Patients were excluded if they had an allergy or hypersensitivity to any component of the study medications, skin disease/disorder that might interfere with the diagnosis or evaluation of acne, recent alcohol or drug abuse, or were using any of the following prohibited medications: over the counter acne medications or bleaching agents within 1 week of Visit 1; topical retinoids, topical antibiotics, benzoyl peroxide, dapsone, cryotherapy, chemical peels, or microdermabrasion within 2 weeks of Visit 1; oral antibiotics for acne or investigational drugs within 4 weeks of Visit 1; or oral retinoids or laser resurfacing and dermabrasion within 24 weeks of Visit 1.

Treatments and Assessments

All patients applied a thin layer of clascoterone cream 1% (approximately 1 g) to affected areas twice daily (morning and evening), and a thin layer of adapalene gel 0.3% to the face and other affected areas of the skin once daily in the evening. Efficacy assessments included IGA, using a 6-point scale from 0 (clear) to 5 (very severe); inflammatory lesion count (ILC); and noninflammatory lesion count (NILC). The impact of acne on patients' quality of life was evaluated using the Dermatology Life Quality Index (DLQI), with scores ranging from 0 (no effect) to 30 (maximum effect).[26] All assessments were administered at baseline and every 4 weeks through week 16.

The primary efficacy endpoint was the percentage of patients achieving an IGA score of clear (0) or almost clear (1; IGA 0/1) at week 16. Secondary efficacy endpoints included percent reductions in ILC, NILC, and total lesion count (TLC) from baseline to week 16. Improvement in skin-related quality of life was evaluated based on the reduction in DLQI score from baseline to week 16. Safety and tolerability assessments included the frequency and severity of adverse events (AEs) assessed at week 4 and every 4 weeks thereafter through week 16, and the current severity of local skin reactions (erythema, scaling, dryness, oiliness, burning/stinging, and pruritus), graded at screening, baseline, and every 4 weeks through week 16. Investigators graded the severity of erythema, dryness, peeling, and oiliness on a 5-point scale from 0 (absent) to 4 (severe) and interviewed patients to determine the severity of pruritus and burning/stinging, which was graded on a 6-point scale from 0 (absent) to 5 (severe).

Statistical Analysis

As this is a pilot study, no formal sample size calculation was performed. The intention-to-treat population included all enrolled patients and was used for all analyses. Continuous variables were reported using means and standard deviations (SDs), and categorical variables using frequencies. Statistical significance was determined using 2-sided Wilcoxon rank sum tests (lesion counts) and Wilcoxon signed rank tests (DLQI). *P* values <0.05 were considered statistically significant.

RESULTS

Demographics and Baseline Clinical Characteristics

The study enrolled 20 patients; 1 patient withdrew consent after 4 study visits, and 2 were lost to follow-up; the remaining 17 patients completed the study and were included in this analysis. The majority of patients were female (52.9%), and the mean ± SD age was 22 ± 10 years (range, 13–44 years; Table 1). At baseline, the majority of patients had moderate acne (IGA score, 3; 70.6%), and the mean ± SD DLQI score was 5.6 ± 6.1 (Table 1).

Efficacy

IGA score

The percentage of patients with IGA 0/1 increased over the 16-week study period following combination treatment with clascoterone cream 1% and adapalene gel 0.3% (Figure 1). At week 4, only 1 (5%) patient (95% confidence interval [CI], 0%–31%) had an IGA score of 0/1 (Figure 1); 10 (59%) patients had mild acne, and 6 (35%) patients had moderate acne. The percentage of patients with IGA 0/1 increased to 59% (95% CI, 33%–81%) at week 8; 5 (29%) patients had mild acne, and 2 (12%) patients had moderate acne. At week 16, 11 (65%) patients (95% CI, 39%–85%) achieved an IGA score of 0 (5 [29%] patients) or 1 (6 [35%] patients; Figure 1); 6 (35%) patients had mild acne, and no patient had moderate acne. By week 16, all 17 patients achieved a ≥1-point improvement from baseline in IGA score.

Lesion Counts

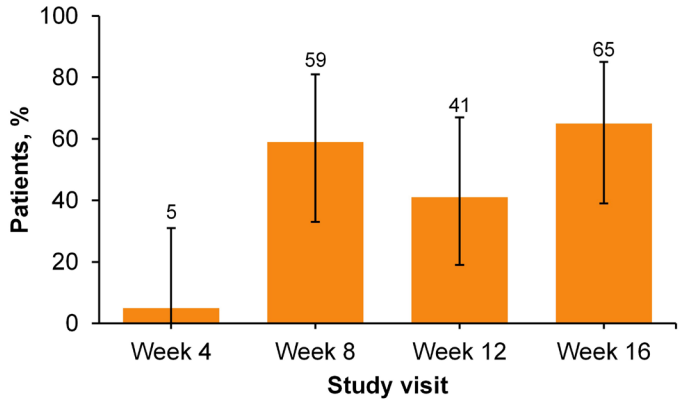
Combination treatment with clascoterone cream 1% and adapalene gel 0.3% resulted in significant reductions in lesion

TABLE 1.

Demographics and Baseline Clinical Characteristics	
Demographics	**Patients (N = 17)**
Mean ± SD	22 ± 10
Range (min–max)	13–44
Sex, n (%)	
Female	9 (52.9)
Male	8 (47.1)
Race/ethnicity, n (%)	
Asian	4 (23.5)
Black	4 (23.5)
Hispanic	5 (29.4)
White	4 (23.5)
Clinical Characteristics	**Patients (N = 17)**
IGA, n (%)	
Moderate	12 (70.6)
Severe	5 (29.4)
Lesion counts, mean ± SD	
ILC	22.9 ± 11.8
NILC	32.1 ± 18.6
TLC	54.9 ± 26.6
DLQI score, mean ± SD	5.6 ± 6.1

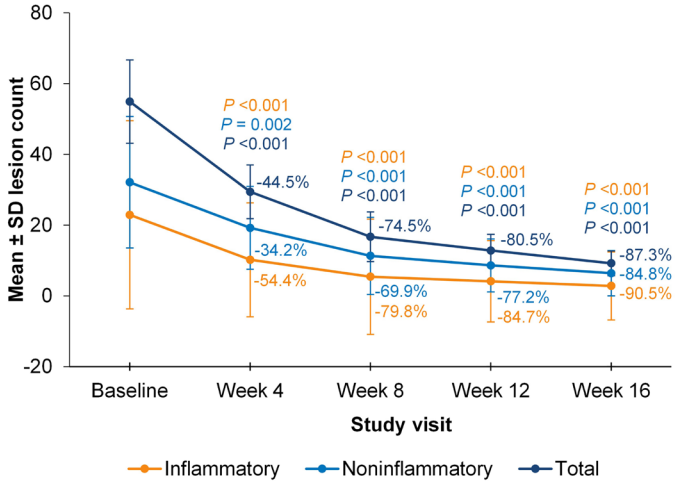
DLQI, Dermatology Life Quality Index; IGA, Investigator's Global Assessment; ILC, inflammatory lesion count; max, maximum; min, minimum; NILC, noninflammatory lesion count; SD, standard deviation; TLC, total lesion count.

FIGURE 1. Proportion of patients with an IGA score of clear or almost clear through week 16.



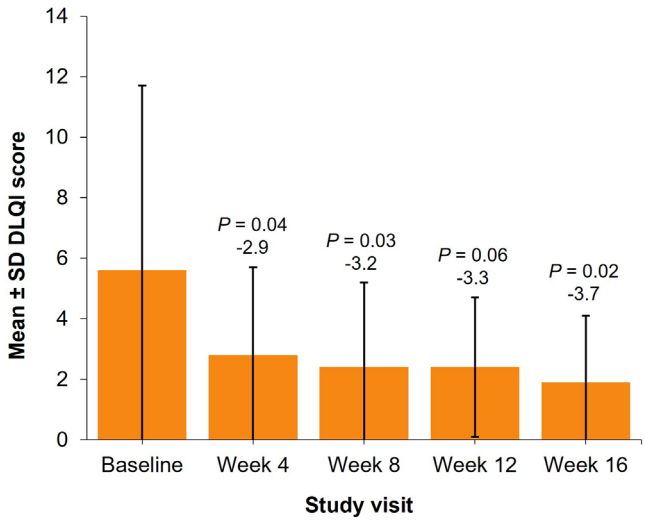
Error bars show the 95% confidence intervals.
IGA, Investigator's Global Assessment.

FIGURE 2. Reduction in lesion counts (ILC, NILC, and TLC) through week 16.



Data labels show the mean percent reductions from baseline. *P*-values signify differences from baseline.
ILC, inflammatory lesion count; NILC, noninflammatory lesion count; SD, standard deviation; TLC, total lesion count.

FIGURE 3. Improvement in DLQI score through week 16.



The DLQI score ranges from 0 (no impact) to 30 (greatest impact); higher scores indicate greater impairment in QoL.
Data labels show the mean reductions from baseline. *P*-values signify differences from baseline.
DLQI, Dermatology Life Quality Index; QoL, quality of life; SD, standard deviation.

TABLE 2.

Frequency and Severity of Local Skin Reactions Through Week 20						
Measure	**Baseline**	**Week 4**	**Week 8**	**Week 12**	**Week 16**	**Week 20**
Erythema						
Absent/trace	13 (76%)	15 (88%)	17 (100%)	17 (100%)	16 (94%)	17 (100%)
Mild	4 (24%)	2 (12%)	0	0	1 (6%)	0
Moderate	0	0	0	0	0	0
Dryness						
Absent/trace	17 (100%)	17 (100%)	17 (100%)	17 (100%)	17 (100%)	17 (100%)
Mild	0	0	0	0	0	0
Moderate	0	0	0	0	0	0
Peeling						
Absent/trace	17 (100%)	17 (100%)	17 (100%)	17 (100%)	17 (100%)	17 (100%)
Mild	0	0	0	0	0	0
Moderate	0	0	0	0	0	0
Oiliness						
Absent/trace	13 (76%)	14 (82%)	16 (94%)	16 (94%)	16 (94%)	16 (94%)
Mild	3 (18%)	3 (18%)	1 (6%)	1 (6%)	1 (6%)	1 (6%)
Moderate	1 (6%)	0	0	0	0	0
Burning						
Absent/trace	17 (100%)	17 (100%)	16 (94%)	16 (94%)	17 (100%)	17 (100%)
Mild	0	0	1 (6%)	1 (6%)	0	0
Moderate	0	0	0	0	0	0
Pruritus						
Absent/trace	16 (94%)	15 (88%)	15 (88%)	16 (94%)	16 (94%)	17 (100%)
Mild	1 (6%)	2 (12%)	1 (6%)	1 (6%)	1 (6%)	0
Moderate	0	0	1 (6%)	0	0	0

Data are shown as n (%).
Investigators graded the severity of erythema, dryness, peeling, and oiliness on a 5-point scale from 0 (absent) to 4 (severe) and interviewed patients to determine the severity of pruritus and burning/stinging, which was graded on a 6-point scale from 0 (absent) to 5 (severe).

counts after 16 weeks (Figure 2). At week 4, ILC, NILC, and TLC decreased by 54.4%, 34.2%, and 44.5%, respectively, compared with baseline; these improvements continued through week 16, with reductions of 90.5%, 84.8%, and 87.3%, respectively, from baseline. Reductions in ILC, NILC, and TLC were statistically significant at all assessed time points (all $P \leq 0.002$; Figure 2).

Quality of Life

Patients experienced significant reductions in DLQI scores at most time points through week 16 of combination treatment (Figure 3). The mean ± SD DLQI score decreased from 5.6 ± 6.1 at baseline to 2.8 ± 2.9 at week 4 (change from baseline, –2.9 ± 5.4; $P=0.04$), 2.4 ± 2.8 at week 8 (change from baseline, –3.2 ± 6.4; $P=0.03$), 2.4 ± 2.3 at week 12 (change from baseline, –3.3 ± 6.7; $P=0.06$), and 1.9 ± 2.2 at week 16 (change from baseline, –3.7 ± 6.2; $P=0.02$; Figure 3).

Safety and Tolerability

Most local skin reactions were reported as absent or trace throughout the study. Mild erythema was reported in 4 (24%) patients at baseline, decreasing to 1 (6%) patient at week 16, and was absent by week 20. Mild oiliness occurred in 3 (18%) patients at baseline and 1 (6%) patient from weeks 8 through 20. Mild pruritus was reported at all visits up to week 16, affecting 1 (6%) patient at weeks 8, 12, and 16, and 2 (12%) patients at week 4. One patient reported moderate pruritus at week 8. Mild burning was reported in 1 (6%) patient at weeks 8 and 12. Except 1 case of mild oiliness, all other local skin reactions were reported as absent or trace by week 20 (Table 2). No AEs were reported.

DISCUSSION

The results of this 20-week pilot study are promising and support the efficacy and safety of clascoterone cream 1% combined with adapalene gel 0.3% in patients with moderate-to-severe acne. The primary and secondary endpoints were met, with nearly two-thirds of patients achieving clear or almost-clear skin by week 16, along with significant reductions in lesion counts and improvements in quality of life. Treatment was well tolerated, with the majority of local skin reactions graded as absent or trace, and no AEs were reported. These findings suggest that dual targeting of androgen-driven sebum production and follicular hyperkeratinization with clascoterone cream 1% and adapalene gel 0.3%, respectively, is a feasible and effective approach for managing acne, consistent with the AAD guidelines.[22]

No studies to date have directly compared the efficacy and safety of combination treatment with clascoterone cream 1% and adapalene gel 0.3% vs either agent as monotherapy. In the pivotal Phase 3 trials, 16.1% and 23.3% of patients treated with clascoterone cream 1% and adapalene gel 0.3% monotherapy, respectively, achieved IGA 0/1 at week 12.[17,27] By comparison, a higher proportion of patients in the current study (41%) achieved IGA 0/1 at week 12 following combination treatment with clascoterone cream 1% and adapalene gel 0.3%. Additionally, clascoterone cream 1% monotherapy resulted in reductions from baseline in the ILC, NILC, and TLC up to 46.9%, 30.6%, and 37.3%, respectively, at week 12 across the Phase 3 trials; the corresponding reductions for patients treated with adapalene gel 0.3% were 62.5%, 52.1%, and 55.6%, respectively.[17,27] In contrast, the combination treatment in our study resulted in mean percent reductions at week 12 in ILC, NILC, and TLC of 84.7%, 77.2%, and 80.5%, respectively, which were numerically greater than those reported with monotherapy. Together, these findings suggest that combining clascoterone cream 1% and adapalene gel 0.3% may provide additive therapeutic benefits, resulting in more robust disease control than either agent alone.

A limited number of studies have reported the efficacy and safety of clascoterone cream 1% in combination with other topical agents. In an 8-week, open-label trial, clascoterone 1% cream plus clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% gel resulted in an approximate 60% reduction in ILC by week 8, with improvements as early as week 1 and a favorable tolerability profile.[28] Two Canadian case series similarly showed that adding clascoterone cream 1% to existing regimens, including clindamycin 1%/benzoyl peroxide 5% gel, topical retinoids, spironolactone, or isotretinoin, significantly improved acne severity, with fewer AEs, and greater patient satisfaction.[29,30] Collectively, these studies highlight the benefit of incorporating a topical antiandrogen into combination regimens for acne management.

This study has limitations, including a small sample size, an open-label design, and the absence of comparator arms (clascoterone cream 1% or adapalene monotherapy, or vehicle), which restricts generalizability and prevents assessment of the individual contributions of clascoterone cream 1% and adapalene gel 0.3%. The short treatment duration also precludes assessment of long-term safety or durability of response. Nonetheless, the findings from this study are promising and warrant further investigation of the concomitant use of clascoterone cream 1% and adapalene gel 0.3% for the treatment of acne in larger studies.

CONCLUSION

In this open-label pilot study, combination treatment with clascoterone cream 1% and adapalene gel 0.3% significantly reduced acne severity from moderate at baseline to clear or almost clear at week 16, accompanied by a significant reduction in lesion counts and improvements in quality of life. The 20-week regimen was well tolerated, with no AEs reported. These findings indicate that combining clascoterone cream 1% with

adapalene gel 0.3% is a safe and effective treatment strategy for patients with acne, consistent with the AAD's recommendation to use multimodal therapy targeting multiple aspects of acne pathogenesis.

DISCLOSURES

LK has served as an investigator, speaker, advisory board member, or consultant for 3M, Abbott, Aclaris Therapeutics, Allergan, Amgen, Anacor Pharmaceuticals, Assos Pharmaceuticals, Astellas Pharma, Asubio Pharma, Bayer, Berlex Laboratories (Bayer), Biogen, BioLife, Biopelle, Blue Willow Biologics, Boehringer Ingelheim, Breckenridge Pharmaceutical, Celgene Corporation, Centocor, ColBar LifeScience, CollaGenex Pharmaceuticals, CombiMatrix Molecular Diagnostics, Connetics Corporation, Coria Laboratories, Dermik Laboratories, Dermira, Dow Pharmaceutical Sciences, DUSA Pharmaceuticals, Eli Lilly, Embil Pharmaceutical, EOS Pharmaceutical, Ferndale Pharma Group, Galderma, Genentech, GSK, Healthpoint, Idera Pharmaceuticals, Innocutis Medical, Innovail, Johnson & Johnson, Laboratory Skin Care, LEO Pharma, L'Oréal, Maruho, Medical International Technologies, Medicis Pharmaceutical, Merck, Merz Pharma, Novartis, Noven Pharmaceuticals, Nucryst Pharmaceuticals, Obagi Medical Products, Ortho Neutrogena, Pediapharma, Pfizer, Pharmaderm, Promius Pharma, PuraCap Pharmaceutical, QLT, Quatrix, Quinnova Pharmaceuticals, Serono (Merck-Serono International), SkinMedica, Stiefel Laboratories, Sun Pharma, Taro Pharmaceutical Industries, TolerRx, Triax Pharmaceuticals, UCB, Valeant Pharmaceuticals, Warner Chilcott, XenoPort, and ZAGE. AJL has served as an advisor or consultant for AbbVie, Galderma, and Pfizer. NS and KK are employees of Sun Pharmaceutical Industries, Inc. AK has no conflicts of interest to disclose.

Funding: The study was funded by Sun Pharma. Statistical analyses were provided by Doug Lorenz, PhD, and funded by Sun Pharma. Medical writing and editorial support were provided by Nitish Chaudhari, PhD, of Red Nucleus, and funded by Sun Pharma.

ACKNOWLEDGMENT

The authors thank Doug Lorenz, PhD, for statistical analysis support and Nitish Chaudhari, PhD, of Red Nucleus, for medical writing and editorial assistance. Both the statistical analyses and medical writing and editorial assistance were funded by Sun Pharma.

REFERENCES

1. Saurat JH, Halioua B, Baissac C, et al. Epidemiology of acne and rosacea: a worldwide global study. *J Am Acad Dermatol.* 2024;90(5):1016-1018.
2. Tan JK, Bhate K. A global perspective on the epidemiology of acne. *Br J Dermatol.* 2015;172(suppl 1):3-12.
3. Dréno B, Thiboutot D, Layton AM, et al. Large-scale international study enhances understanding of an emerging acne population: adult females. *J Eur Acad Dermatol Venereol.* 2015;29(6):1096-1106.
4. Perkins AC, Maglione J, Hillebrand GG, et al. Acne vulgaris in women: prevalence across the life span. *J Womens Health (Larchmt).* 2012;21(2):223-230.
5. Skroza N, Tolino E, Mambrin A, et al. Adult acne versus adolescent acne: a retrospective study of 1,167 patients. *J Clin Aesthet Dermatol.* 2018;11(1):21-25.
6. Capitanio B, Sinagra JL, Bordignon V, et al. Underestimated clinical features of postadolescent acne. *J Am Acad Dermatol.* 2010;63(5):782-788.
7. Pappas A, Johnsen S, Liu JC, et al. Sebum analysis of individuals with and without acne. *Dermatoendocrinol.* 2009;1(3):157-161.
8. Guy R, Kealey T. Modelling the infundibulum in acne. *Dermatology.* 1998;196(1):32-7.
9. Jeremy AH, Holland DB, Roberts SG, et al. Inflammatory events are involved in acne lesion initiation. *J Invest Dermatol.* 2003;121(1):20-27.
10. Ganceviciene R, Fimmel S, Glass E, et al. Psoriasin and follicular hyperkeratinization in acne comedones. *Dermatology.* 2006;213(3):270-272.
11. Josse G, Mias C, Le Digabel J, et al. High bacterial colonization and lipase activity in microcomedones. *Exp Dermatol.* 2020;29(2):168-176.
12. Li ZJ, Choi DK, Sohn KC, et al. Propionibacterium acnes activates the NLRP3 inflammasome in human sebocytes. *J Invest Dermatol.* 2014;134(11):2747-2756.
13. Spittaels KJ, van Uytfanghe K, Zouboulis CC, et al. Porphyrins produced by acneic Cutibacterium acnes strains activate the inflammasome by inducing K(+) leakage. *iScience.* 2021;24(6):102575.
14. Barrault C, Garnier J, Pedretti N, et al. Androgens induce sebaceous differentiation in sebocyte cells expressing a stable functional androgen receptor. *J Steroid Biochem Mol Biol.* 2015;152:34-44.
15. Del Rosso JQ, Kircik L. The primary role of sebum in the pathophysiology of acne vulgaris and its therapeutic relevance in acne management. *J Dermatolog Treat.* 2024;35(1):2296855.
16. WINLEVI® (clascoterone cream 1%) [full prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2025.
17. Hebert A, Thiboutot D, Stein Gold L, et al. Efficacy and safety of topical clascoterone cream, 1%, for treatment in patients with facial acne: two phase 3 randomized clinical trials. *JAMA Dermatol.* 2020;156(6):621-630.
18. Eichenfield L, Hebert A, Gold LS, et al. Open-label, long-term extension study to evaluate the safety of clascoterone (CB-03-01) cream, 1% twice daily, in patients with acne vulgaris. *J Am Acad Dermatol.* 2020;83(2):477-485.
19. Rosette C, Agan FJ, Mazzetti A, et al. Cortexolone 17alpha-propionate (clascoterone) is a novel androgen receptor antagonist that inhibits production of lipids and inflammatory cytokines from sebocytes in vitro. *J Drugs Dermatol.* 2019;18(5):412-418.
20. Rosette C, Rosette N, Mazzetti A, et al. Cortexolone 17alpha-propionate (clascoterone) is an androgen receptor antagonist in dermal papilla cells in vitro. *J Drugs Dermatol.* 2019;18(2):197-201.
21. Draelos ZD, Kyerematen K, Squittieri N. Reduction in facial sebum production following treatment with clascoterone cream 1% in patients with acne vulgaris: 12-week interim analysis. *Dermatol Ther (Heidelb).* 2025;15(9):2657-2666.
22. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol.* 2024;90(5):1006.e1-1006.e30.
23. Shroot B, Michel S. Pharmacology and chemistry of adapalene. *J Am Acad Dermatol.* 1997;36(6 Pt 2):S96-103.
24. Michel S, Jomard A, Démarchez M. Pharmacology of adapalene. *Br J Dermatol.* 1998;139(suppl 52):3-7.
25. Draelos ZD, Draelos MM, Kyerematen K, et al. Clascoterone stability when combined with topical acne medications in vitro. *Dermatol Ther (Heidelb).* 2025;15(12):3605-3613.
26. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)—a simple practical measure for routine clinical use. *Clin Exp Dermatol.* 1994;19(3):210-216.
27. Thiboutot D, Pariser DM, Egan N, et al. Adapalene gel 0.3% for the treatment of acne vulgaris: a multicenter, randomized, double-blind, controlled, phase III trial. *J Am Acad Dermatol.* 2006;54(2):242-250.
28. Yu Z, Swenson K, Graber E. Prospective pilot evaluation of the safety, tolerability, and efficacy of clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% gel plus clascoterone 1% cream in adult patients with acne. *J Clin Aesthet Dermatol.* 2025;18(1):20-23.
29. Tay E, Loo WJ. Real-world experience of clascoterone cream 1% in acne management: case series and Canadian experience. *Clin Cosmet Investig Dermatol.* 2025;18:161-167.
30. Lynde C, Abdulla S, Andriessen A, et al. Real-world cases of clascoterone topical treatment for acne and related disorders. *J Drugs Dermatol.* 2025;24(1):73361s3-73361s14.

AUTHOR CORRESPONDENCE

Leon Kircik MD
E-mail:..... wedoderm@yahoo.com