



AARS **HOT TOPICS** MEMBER NEWSLETTER

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TABLE OF CONTENTS

AARS Press Release

[American Acne and Rosacea Society \(AARS\) uncovers real impact of acne](#) 2

Industry News

[Pivotal phase 3 trials of trifarotene in patients](#) 3

[New NRS study shows positive impact of clear skin in rosacea patients](#) 4

New Medical Research

[Photodynamic therapy for severe facial acne vulgaris](#) 4

[Efficacy of stem cell-conditioned medium vs platelet-rich plasma](#) 5

[Comparison of quality of life, depression, anxiety, suicide, social anxiety](#) 5

[Objective analysis of volume restoration in atrophic acne scars and skin pores](#) 6

[Amniotic fluid-derived mesenchymal stem cell products](#) 6

[Active compound chrysophanol of Cassia tora seeds](#) 7

[Efficacy and safety of a novel topical minocycline foam](#) 7

[Patient-reported outcomes in acne patients with skin of color](#) 8

[Pharmacokinetic profile, safety, and tolerability of clascoterone](#) 8

[A phase 2b, randomized, double-blind vehicle controlled, dose escalation study](#) 9

[Safety and effectiveness of microfocused ultrasound](#) 10

[Pathogenetic peculiarities of neuroendocrine and metabolic disorders](#) 10

[A randomized phase 3b/4 study to evaluate concomitant use of topical ivermectin](#) 11

[Efficacy of metformin in the treatment of acne in women](#) 11

Clinical Reviews

[Diode laser and fractional laser innovations](#) 12

[Inflammatory skin is associated with changes in the skin microbiota composition](#) 12

[Hidradenitis suppurativa: comprehensive review](#) 12

[Periodic worsening, or flare, in hidradenitis suppurativa](#) 12

[Depression and anxiety in adults with hidradenitis suppurativa](#) 13

[Rosacea fulminans: two case reports and review of the literature](#) 14

[Update on the treatment of scars](#) 14

[Liposome based combination therapy for acne treatment](#) 14

[Metformin use in women with polycystic ovary syndrome](#) 15

[The use of oral antibiotics in the management of rosacea](#) 15

[Treatment of acne scars with PRP and laser therapy](#) 15

[Assessing the psychological burden of patients with hidradenitis suppurativa](#) 16

[Cortexolone 17 \$\alpha\$ -propionate \(clascoterone\) is a novel androgen receptor](#) 16



AARS Acne Awareness Month News

AMERICAN ACNE AND ROSACEA SOCIETY (AARS) UNCOVERS REAL IMPACT OF ACNE ON YOUNG PROFESSIONALS DURING ACNE AWARENESS MONTH

- Results from a recently conducted survey focuses on the impact of acne on the everyday lives, relationships and careers of adults in their 20s.
- AARS seeks to provide an educational forum and improve the care of people living with acne, hidradenitis suppurativa and rosacea.

MONTCLAIR, NJ, June 15, 2019 — The American Acne and Rosacea Society (AARS) announced today the results of a recent survey conducted among young professionals to highlight the significant health burden and everyday impact of acne during National Acne Awareness Month.

According to the survey of 1,004 men and women between the ages of 22 and 30 conducted by The Harris Poll, many people whose acne persists beyond teenage years into their early professional lives struggle substantially because of it. Nearly 3 in 4 of those surveyed believe most people their age no longer have acne, driving feelings of embarrassment to still have the condition at their age in more than 80% of this group.

“Acne has a very real impact on patients’ lives that often goes under-recognized, particularly in adults who feel ashamed to still be dealing with a ‘teenager’s problem.’ The consequences of acne, including scarring and hyperpigmentation, or discolored patches of skin, can affect people for years after the skin clears,” explains Julie Harper, MD, FAAD, AARS Immediate Past President and dermatologist in Birmingham, Alabama. “Because of this, the psychosocial impact of acne can have far-reaching effects on people’s quality of life and daily activities, driving low self-esteem and shifting how they interact in social and workplace environments.”

Survey respondents say their acne has had a negative impact on their job and career ambitions due to challenges in the workplace. From being judged or treated differently because of their acne to having fewer career opportunities or experiencing slow professional advancement, 42% of young professionals report that they believe their acne holds them back. More than half of employees in their 20s with acne say that having clear skin is important to doing well in their career, and many feel that their coworkers with clear skin will advance more quickly in their careers or that their acne has prevented them from getting a promotion.

Findings show that acne also takes a toll outside of the office. Almost half of survey respondents say they have avoided seeing friends or making plans due to an acne breakout, and while the 20s are known as prime dating years, 46% of respondents (both men and women) report feeling so unattractive or self-conscious that they have given up on dating completely until they have clear skin. Half of unmarried singles with acne even go so far as to say they believe that their friends with clear skin will get married before them. Those in romantic relationships are not immune to this mindset, as one in three individuals report that their partner has made negative comments about their skin.

When it comes to solutions for their acne, nearly 70% feel they are doing everything they can to manage their acne, and more than three quarters of those surveyed remain at a loss on what else can be done. “We urge those still struggling with acne at any age to advocate for themselves and find a dermatologist who understands the true impact of the condition. There are so many new treatment options available, and treatment should be individualized for each person, because each person’s acne is unique. There is no one-size-fits-all solution, and your dermatologist can help

you determine what approach is best for you and your acne," Dr. Harper concludes.

AARS President Mark Jackson, MD, FAAD, urges those of any age with acne and rosacea to seek a professional diagnosis from a healthcare professional and to explore the best treatment plan for that individual. "If interested, patients may also go on to the AARS website to view available clinical trials in their area and gain access to the newest research."

The mission of the AARS is to promote, support, develop and provide an educational forum for the exchange of information, to promote clinical research and mentoring opportunities for dermatology healthcare professionals, and to improve the care of patients who suffer from acne, hidradenitis suppurativa, otherwise known as "acne inversa," and rosacea.

For more information on the American Acne and Rosacea Society (AARS), please visit acneandrosacea.org/.

Industry News

Pivotal phase 3 trials of trifarotene in patients with moderate facial and truncal acne meet all efficacy endpoints. June 10, 2019. DermWire. Practical Dermatology. <https://practicaldermatology.com/news/pivotal-phase-3-trials-of-trifarotene-in-patients-with-moderate-facial-and-truncal-acne-meet-all-efficacy-endpoints-2?c4src=topic:acne:feed>

Results from the pivotal Phase 3 PERFECT 1 and PERFECT 2 clinical trials of once daily trifarotene 50 µg/g cream in patients with moderate acne on the face and trunk, published in the June issue of Journal of the American Academy of Dermatology, met all primary and secondary efficacy endpoints. Trifarotene, an investigational drug, is a new molecule and a unique retinoid receptor agonist that selectively targets retinoic acid receptor gamma (RAR-γ). The two randomized, double-blind, vehicle-controlled studies evaluated the efficacy and safety of once-daily trifarotene 50 µg/g cream compared with vehicle cream over 12 weeks. Patients aged nine years or older with moderate acne vulgaris on the face and trunk (mean age: 19 years) were randomized to once daily trifarotene 50 µg/g cream or vehicle cream at bedtime. A total of 200 sites in the United States, Canada, Europe and Russia enrolled 2,420 patients. The three co-primary efficacy endpoints were IGA success rate on the face (clear/almost clear and at least a 2-grade improvement from baseline) at week 12, and absolute change from baseline in facial inflammatory and non-inflammatory lesion counts from baseline to week 12. The three secondary efficacy endpoints were Physician Global Assessment (PGA) success rate on the trunk (clear/almost clear and at least a 2 grade improvement from baseline) at week 12, and absolute change in truncal inflammatory and non-inflammatory lesion counts from baseline to week 12.3 Safety was assessed through recording of adverse events, local tolerability, vital signs and routine laboratory testing. The two trials met all primary and secondary efficacy endpoints, including IGA/facial acne, changes in inflammatory and non-inflammatory lesion counts, and PGA/truncal acne. The majority of adverse events were local cutaneous irritation mainly during the first weeks of treatment, which improved thereafter. Data from the two trials were included in a New Drug Application (NDA) submitted to the FDA for trifarotene for the treatment of facial and truncal acne. "Acne frequently affects both the face and trunk and can cause permanent scarring. Many patients with facial and truncal acne feel self-conscious and are often reluctant to engage with other people," said Howard Marsh, MD, Vice President of Medical Affairs at Galderma, USA. "Despite the negative outcomes experienced, truncal acne has been insufficiently studied." "PERFECT 1 and PERFECT 2 are the first and only large-scale randomized trials to evaluate a topical retinoid for the treatment of both facial and truncal acne," said Thibaud Portal, Vice President of

Prescription, Strategy and Innovation Group at Galderma. "This underscores Galderma's commitment to innovation, the dermatology community and patients, and we are excited about the potential of trifarotene and its novel features. We hope to bring this next-generation topical retinoid to patients suffering from acne as soon as possible."

New NRS study shows positive impact of clear skin in rosacea patients. June 3, 2019. DermWire. Practical Dermatology. <https://practicaldermatology.com/news/new-nrs-study-shows-positive-impact-of-clear-skin-in-rosacea-patients?c4src=news-landing:feed>

When the signs and symptoms of rosacea are virtually eliminated, the improvement in patients' lives is often dramatic. Treating rosacea can have a major positive impact on patients' lives, according to a new survey by the National Rosacea Society. In the survey of 1,044 rosacea patients, around 76 percent of all respondents saw at least some improvement in their skin after receiving treatment. Among those patients, 40 percent said that treatment had improved their psychological well-being, 35 percent said their social well-being had improved, and 31 percent saw improvement in their occupational well-being. When the signs and symptoms of rosacea are virtually eliminated, however, the improvement in patients' lives was often dramatic, the survey found. Eighty-one percent of those who had achieved clear or almost clear skin said their psychological well-being had improved. Seventy-one percent said it had also improved their social lives, and 62 percent reported improvement in their occupational well-being. In contrast, among patients whose rosacea was only slightly or moderately improved, only 24 percent reported improved psychological well-being, only 21 percent felt their social lives had improved, and just 19 percent were better off at work. "Recent studies of the burden of disease in rosacea have found that it can deeply impact a patient's quality of life due to its effects on facial appearance and confidence," says Dr. Hilary Baldwin, associate professor of dermatology at Rutgers Robert Wood Johnson Medical School, in a news release. "The results of this survey suggest that, on the flip side, achieving clear skin through new advances in medical therapy has the potential to greatly improve a rosacea patient's personal well-being in many ways." According to the recently updated standard classification of rosacea, the presence of persistent facial redness or, less commonly, phymatous changes where the facial skin thickens is considered diagnostic of the disorder. Additional major signs include papules and pustules, flushing, telangiectasia and certain ocular manifestations. The presence of two or more major features independent of the diagnostic signs is also considered diagnostic of rosacea, and secondary signs and symptoms include burning or stinging, swelling and dry appearance. In around half of rosacea patients, the eyes are also affected, including visible blood vessels on the eyelid margin and a bloodshot appearance, as well as inflammation and growth of fibrous tissue. Burning, stinging, light sensitivity and the sensation of a foreign object may also occur, as well as conjunctivitis, blepharitis and crusty accumulations at the base of the eyelashes. Severe cases of ocular rosacea can result in loss of visual acuity. In some patients, especially in men, the nose may become enlarged from the development of excess tissue. This is the condition that gave comedian W.C. Fields his trademark red, bulbous nose. In the NRS survey, 95 percent of respondents reported having facial redness, 80 percent had bumps and pimples, 74 percent reported flushing, 59 percent experienced burning or stinging sensations, and 54 percent suffered from eye irritation.

New Medical Research

Photodynamic therapy for severe facial acne vulgaris with 5% 5-aminolevulinic acid vs 10% 5-aminolevulinic acid: a split-face randomized controlled study. Zhang J, Zhang X, He Y, et al. J Cosmet Dermatol. 2019 Jun 12. doi: 10.1111/jocd.13038. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31187937>

Background: Photodynamic therapy (PDT) with 5-aminolevulinic acid (ALA) has been described as an effective treatment for severe acne. However, very little evidence exists on the optimal concentration of ALA used in PDT for severe acne. **Objectives:** To compare the efficacy and safety of PDT with 5% ALA vs 10% ALA in severe acne. **Methods:** Twenty-three patients with severe facial acne were randomly assigned to receive PDT with 5% ALA or 10% ALA on the left or right side of the face. Four PDT sessions were conducted with a light dose of 96 J/cm². The reduction rates of lesion counts between the two groups were compared at the week-4 and week-12 follow-up visits. Effective rate at the week-12 visit was the primary clinical outcome. Pain and other side effects were evaluated at each visit. **Results:** The decrease in inflammatory lesions in the 10% ALA group was greater than that in the 5% ALA group at both week-4 (79.2% vs 62.5%, $P = 0.009$) and week-12 follow-up visits (88.5% vs 78.3%, $P = 0.018$), while the decrease in noninflammatory lesion counts between the two groups was not statistically significant at each follow-up visit. The effective rate in the 10% ALA group was significantly higher than that in the 5% ALA group (95.7% vs 69.6%, $P = 0.02$). No significant difference was observed in pain scores between the two groups except in the first treatment session. **Conclusions:** Photodynamic therapy using 10% ALA was more effective for severe acne than PDT using 5% ALA.

Efficacy of stem cell-conditioned medium vs platelet-rich plasma as an adjuvant to post-ablative fractional CO₂ laser resurfacing for atrophic post-acne scars: a split-face clinical trial. Abdel-Maguid EM, Awad SM, Hassan YS, et al. *J Dermatolog Treat.* 2019 Jun 10:1-24. doi: 10.1080/09546634.2019.1630701. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31180258>

Objectives: To explore the impact of using topical stem cell-conditioned medium (SC-CM) after fractional carbon dioxide laser (FCL) vs combined FCL and platelet-rich plasma (PRP) or FCL alone in treatment of atrophic acne scars. **Methods:** Thirty-three patients were randomly divided into two split-face groups. Group I ($n = 17$) received FCL plus topical SC-CM on one side or FCL plus saline on the other. Group II ($n = 16$) received FCL plus topical PRP or SC-CM. All patients had 3 monthly sessions. Clinical assessment was done at each visit, with a final assessment after 3 months. Skin biopsies were obtained for histological and quantitative molecular analysis after treatment. **Results:** No significant difference in clinical improvement of acne scars was observed between the FCL/SC-CM and FCL only sides ($P = 0.63$), while better and faster improvement was detected on FCL/PRP side compared to FCL/SC-CM side ($P = 0.006$). There was no significant difference in downtime or adverse effects between the treated sides in either group. Dermal collagen was increased and procollagen type I gene was upregulated in both FCL/PRP and FCL/SC-CM sides compared to FCL only sides ($P = 0.001$ and $P = 0.041$ respectively). **Conclusion:** Topical SC-CM could potentially enhance the efficacy of FCL. However, PRP seems to be a better alternative.

Comparison of quality of life, depression, anxiety, suicide, social anxiety and obsessive-compulsive symptoms between adolescents with acne receiving isotretinoin and antibiotics: a prospective, non-randomised, open-label study. Erdoğan Y, Erturan İ, Aktepe E, Akyıldız A. *Paediatr Drugs.* 2019 Jun 8. doi: 10.1007/s40272-019-00340-y. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31175639>

Background: The effects of isotretinoin on suicide, social anxiety and obsessive-compulsive symptoms in adolescents with acne have not been sufficiently investigated. **Objective:** This study aimed to evaluate the quality of life, depression, anxiety, suicide, social anxiety, and obsessive-compulsive symptoms of adolescents receiving systemic isotretinoin and antibiotic treatments at baseline and at 3 months. **Methods:** The study included a total of 102 adolescents using isotretinoin ($n = 60$) and antibiotics ($n = 42$). The Acne Quality of Life Scale (AQLS), Hospital Anxiety and Depression Scale (HADS), Suicide Probability Scale (SPS), Liebowitz Social Anxiety Scale (LSAS), and

Maudsley Obsessive-Compulsive Question List (MOCQL) were administered to both groups at baseline and at 3 months. In order to exclude patients with comorbid psychiatric disorders, the patients were evaluated at the beginning of the study with the Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL). Results: There were no significant differences in the mean age, gender distribution, educational level, and family history of mental illness between the two groups. There were significant decreases in the Global Acne Grading System scores, visual analogue scale scores, AQLS scores, total and subscale scores of LSAS, and total and subscale scores of MOCQL at 3 months compared with baseline in both groups. However, there were no significant changes in the total and subscale scores of HADS and total and subscale scores of SPS at 3 months compared with baseline in both groups. Conclusion: We found that neither isotretinoin nor antibiotic treatment affected the levels of depression, anxiety, and suicide in acne patients. Moreover, both isotretinoin and antibiotic treatment were shown to improve the quality of life, social anxiety, and obsessive-compulsive symptoms in acne patients. However, clinicians should be careful about psychiatric side effects in patients using isotretinoin. Further studies with a larger number of cases and with a longer follow-up period are needed to investigate the complex effects of isotretinoin on the central nervous system.

Objective analysis of volume restoration in atrophic acne scars and skin pores: a split study using human stem cell-conditioned media. Park CS, Park JH, Kim CR, Lee JH. *J Dermatolog Treat.* 2019 Jun 7:1-16. doi: 10.1080/09546634.2019.1628915. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31172821>

In this study, we investigated the effects of human stem cell-conditioned media (HSCM) as a post-procedural agent after fractional CO₂ laser procedure in patients with atrophic acne scars and skin pores. Both cheeks of 15 subjects were treated with a fractional CO₂ laser. HSCM was randomly applied to one of the resurfacing sites (T) and normal saline was applied to the other site as a control (C). During the next six days, a solution containing 80% HSCM and hyaluronic acid (HA) was applied on the treated side (T) and HA alone was applied to the control side (C). Scar volume and erythema were objectively evaluated using an Antera 3D® CS. After two months, the scar volume was reduced by 23.5% (T) versus 15.0% (C) ($p = 0.143$) and the volume of the skin pores was reduced by 37.6% (T) versus 15.9% (C) ($p = 0.006$), while the erythema was increased by 2.8% (T) versus 3.1% (C) ($p = 0.934$). Atrophic scar and the skin pores in the HSCM-applied area improved by at least 15.0% after a single treatment session, suggesting better results compared with the control side. In conclusion, HSCM may augment the regenerative effects of fractional CO₂ laser.

Amniotic fluid-derived mesenchymal stem cell products combined with microneedling for acne scars: a split-face clinical, histological, and histometric study. El-Domyati M, Moftah NH, Nasif GA, et al. *J Cosmet Dermatol.* 2019 Jun 7. doi: 10.1111/jocd.13039. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31173459>

Background: Postacne scars are still a challenge in its management. Microneedling is a popular minimally invasive technique in treatment of such scars. However, the addition of topical stem cell products after microneedling is considered a new treatment regimen for these scars. Objective: To compare efficacy of amniotic fluid-derived mesenchymal stem cell-conditioned media (AF-MSC-CM) and microneedling vs microneedling alone in management of atrophic acne scars. Methods: Ten cases with atrophic postacne scars received five sessions of microneedling, with 2-week interval on both sides of the face. Then, AF-MSC-CM was topically applied to right side of the face after microneedling. Clinical examination with histopathological and computerized histometric analysis was done 1 month after the sessions. Results: There was significant increase in the improvement percentage of acne scars on right side (dermaroller and AF-MSC-CM) vs left side of face (dermaroller; $P < 0.001$). Histologically, improvement of character

of collagen and elastic fibers was noticed, especially on right side. Meanwhile, significant increase in epidermal thickness on both sides of face was detected. Conclusion: Amniotic fluid-derived mesenchymal stem cell-conditioned media combined with microneedling is more effective in management of atrophic postacne scars than microneedling alone.

Active compound chrysophanol of *Cassia tora* seeds suppresses heat-induced lipogenesis via inactivation of JNK/p38 MAPK signaling in human sebocytes. Kwon HC, Kim TY, Lee CM, et al. *Lipids Health Dis.* 2019 Jun 7;18(1):135. doi: 10.1186/s12944-019-1072-x. <https://www.ncbi.nlm.nih.gov/pubmed/31174532>

Background: Heat induced by infrared (IR) radiation from sun exposure increases skin temperature and can lead to thermal and photo-aging. However, little is known about the relationship between heat induced by IR radiation and lipid biosynthesis in human sebocytes. This study investigated the expression of factors involved in lipid biosynthesis in human sebocytes exposed to heat. The effect of *Cassia tora* extract and chrysophanol, which is widely used as anti-inflammatory agent, on the heat shock effect in sebocytes was then examined. Methods: For the treatment, cells were maintained in culture medium without FBS (i.e., serum starved) for 6 h and then moved for 30 min to incubators at 37 °C (control), 41 °C, or 44 °C (heat shock). Culture media were replaced with fresh media without FBS. To investigate expression of gene and signaling pathway, we performed western blotting. Lipid levels were assessed by Nile red staining. The cytokine levels were measured by cytokine array and ELISA kit. Results: We found that peroxisome proliferator-activated receptor (PPAR) γ and fatty acid synthase (FAS) were upregulated and the c-Jun N-terminal kinase (JNK)/p38 signaling pathways were activated in human sebocytes following heat exposure. Treatment with *Cassia tora* seed extract and chrysophanol suppressed this up-regulation of PPAR γ and FAS and also suppressed the increase in IL-1 β levels. Conclusion: These findings provide evidence that IR radiation can stimulate sebum production; *Cassia tora* seed extract and chrysophanol can reverse lipid stimulated inflammatory mediation and may therefore be useful for treating skin disorders such as acne vulgaris.

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Efficacy and safety of a novel topical minocycline foam for the treatment of moderate-to-severe acne vulgaris: a phase 3 study. Raouf TJ, Hooper D, Moore A, et al. *J Am Acad Dermatol.* 2019 Jun 1. pii: S0190-9622(19)30882-5. doi: 10.1016/j.jaad.2019.05.078. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/?term=31163231>

Background: FMX101 4% topical minocycline foam, has been demonstrated as an effective and safe treatment for acne vulgaris. Objective: Further evaluate the efficacy and safety of FMX101 4% in treating moderate-to-severe AV. Methods: A 12-week, multicenter, randomized (1:1), double-blind, vehicle-controlled study was conducted. Co-primary end points were the absolute change in inflammatory lesion count from baseline and the rate of treatment success (IGA score: 0 or 1 with a ≥ 2 -grade improvement). Results: 1488 subjects were in the intent-to-treat population. FMX101 4% group had significantly greater reductions in the number of inflammatory lesions from baseline ($P < .0001$) and a greater rate of IGA treatment success ($P < .0001$) vs foam vehicle group at week 12. FMX101 4% was generally safe and well-tolerated. Limitations: Efficacy and safety of FMX101 4% was not characterized in subjects with mild AV. Conclusion: FMX101 4% topical minocycline foam was effective and safe for the treatment of moderate-to-severe AV.

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Patient-reported outcomes in acne patients with skin of color using adapalene 0.3%-benzoyl peroxide 2.5%: a prospective real-world study. DuBois J, Chung Wei Ong G, Petkar G, et al. *J Drugs Dermatol.* 2019;18(6):514-520. <https://jddonline.com/articles/dermatology/S1545961619P0514X/0/>

Background: Patients with skin of color (SOC) and Fitzpatrick skin types (FST) IV–VI frequently develop acne. Objective: Evaluate subject-reported outcomes after treatment with adapalene 0.3%/ benzoyl peroxide 2.5% gel (0.3% A/BPO) in subjects with SOC and moderate to severe acne vulgaris. Methods: This was an open-label interventional study conducted in 3 countries (Mauritius, Singapore, and USA) in subjects of Asian, Latin-American, or black/African-American ethnicity, with an Investigator’s Global Assessment (IGA) of moderate or severe facial acne (enrollment 2:1), and FST IV to VI. For 16 weeks, subjects applied 0.3% A/BPO (once daily) and utilized a skin care regimen (oil control foam wash and oil control moisturizer SPF30). Assessments included quality of life (QoL) and subject questionnaires, IGA, Investigator’s Global Assessment of Improvement (GAI), postinflammatory hyperpigmentation (PIH; if present at baseline), and safety. Results: Fifty subjects were enrolled: 20 Asians, 17 black/African Americans, and 13 Latin-Americans. Most had FST IV (74%) or V (22%), with moderate (70%; IGA 3) or severe (30%; IGA 4) acne. At week 16, 77% of subjects were satisfied or very satisfied with treatment, 56% of subjects had an IGA of 0 or 1 (clear/almost clear), and 87% had a good to excellent improvement in GAI. QoL improved throughout the study for all subjects; subject selection of “no effect at all” of acne on QoL increased from 16% of subjects at baseline to 55% at week 16. Of those with baseline PIH (60%), all were rated very mild to moderate. By week 16, the majority (75%) had no or very mild PIH, and the mean decrease in PIH was 27%. There were no adverse events leading to study discontinuation. Conclusion: Patients with SOC and moderate or severe facial acne reported high satisfaction with 0.3% A/BPO treatment and experienced good tolerability, improved QoL, treatment efficacy, and improvement in PIH. Clinicaltrials.gov number: NCT02932267

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Pharmacokinetic profile, safety, and tolerability of clascoterone (cortexolone 17-alpha propionate, cb-03-01) topical cream, 1% in subjects with acne vulgaris: an open-label phase 2a study. Mazzetti A, Moro L, Gerloni M, Cartwright M. *J Drugs Dermatol.* 2019;18(6):563-568.

<https://jddonline.com/articles/dermatology/S1545961619P0563X/1/>

Clascoterone (cortexolone 17 α -propionate, CB-03-01) 1% cream, a topical, androgen receptor (AR) inhibitor under investigation for the treatment of acne vulgaris, is rapidly metabolized to cortexolone in human plasma. The primary objectives of this study were to determine the pharmacokinetic (PK) properties and adrenal suppression potential of clascoterone topical cream, 1% in subjects with acne vulgaris. Study Design: This study was an open-label, multicenter study in 42 subjects \geq 12 years of age with moderate-to-severe acne (Grade 3-4 on the Investigator’s Global Assessment [IGA]), on the face, chest and/or back. Cohort 1 (>18 years of age) and Cohort 2 (12-18 years of age) applied clascoterone topical cream, 1% twice daily (BID) for 14 days. Primary safety endpoints included hypothalamic-pituitary-adrenal (HPA) axis response to cosyntropin via a Cosyntropin Stimulation Test (CST) upon screening (day 1) and at day 14 (HPA axis suppression was defined as a post-stimulation serum cortisol level <18 μ g/dL at day 14); and PK evaluation including concentration-time profiles of clascoterone and cortexolone in plasma—PK parameters were determined using “non-compartmental” analysis. Secondary safety endpoints included clinical laboratory testing, local and systemic adverse events (AEs), physical examination/vital signs, and electrocardiogram (ECG). Results: 42 subjects (Cohort 1=20, Cohort 2= 22) enrolled. Cohort 1 was comprised of 15 females (15/20, 75%) and 5 males (5/20, 25%), non-Hispanic/Latino (20/20, 100%), mean age is 24.4 years. Cohort 2 was comprised of 12 females (12/22, 54.5%) and 10 males (10/22, 45.5%), non-Hispanic/Latino (21/22, 95.5%), and mean age is

15.6 years. Three subjects (3/42,7%), 1 adult and 2 adolescents, demonstrated an abnormal HPA axis response with post-stimulation serum cortisol levels ranging from 14.9 to 17.7 µg/dL at day 14. All returned to normal HPA axis function, four weeks after day 14. None showed clinical evidence of adrenal suppression. Clascoterone plasma concentrations achieved PK steady-state by day 5. Clascoterone systemic exposure was similar between both cohorts. At steady-state, plasma concentrations increased ~1.8 to 2.1 fold versus first dose with mean (coefficient of variation [CV] %) maximum plasma concentrations of 4.4 ng/mL (67%) and 4.6 ng/mL (103%) in Cohort 1 and Cohort 2, respectively. Cortisolone plasma concentrations trended below the lower limit of quantitation (0.5 ng/mL) in both cohorts. Local skin reactions (LSRs) were mostly mild, with only one moderate case of pruritus. There were nine AEs categorized as follows: definitely related (N=2), probably related (N=4), unlikely/not related (N=3), to clascoterone. Conclusion: This study demonstrates the safety and tolerability of clascoterone topical cream, 1% in adolescents and adults with acne vulgaris treated BID for 14 consecutive days.

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A phase 2b, randomized, double-blind vehicle controlled, dose escalation study evaluating clascoterone 0.1%, 0.5%, and 1% topical cream in subjects with facial acne. Mazzetti A, Moro L, Gerloni M, Cartwright M. J Drugs Dermatol. 2019;18(6):570-575. <https://jddonline.com/articles/dermatology/S1545961619P0570X/1/>

Androgens play a key role in acne pathogenesis in both males and females. Clascoterone (CB-03-01, Cortisolone 17α propionate) cream is a topical anti-androgen under investigation for the treatment of acne. The results from a phase 2b dose escalating study are discussed. Methods: Primary objective: to compare the safety and efficacy of topical creams containing clascoterone 0.1% (twice daily [BID]), 0.5% (BID), or 1% (daily [QD] or BID) versus vehicle (QD or BID) in male and female subjects ≥12 years with facial acne vulgaris. Efficacy was assessed by: Investigator's Global Assessment (IGA)--the overall severity of acne using a five-point scale (from 0=clear to 4=severe); inflammatory and non-inflammatory acne lesion counts (ALC); and subject satisfaction with treatment—subjects assessed overall treatment satisfaction using a 4-point scale. Safety assessments: local and systemic adverse events (AEs), physical examination/vital signs, laboratory tests, local skin reactions (LSRs), and electrocardiograms (ECGs). Treatment success required a score of “clear” or “almost clear” (IGA score of 0 or 1) and a two or more-grade improvement from baseline. Results: 363 subjects (N=72, 0.1% BID; N=76, 0.5% BID; N=70, 1% QD; N=70, 1% BID; and N=75, vehicle QD or BID) enrolled. 304 subjects (83.7%) completed the study. Intention to Treat (ITT) population: 196/363 (54.0%) females; 167/363 46.0%) males; (257/363 (70.2%) were white; average age=19.7 years. Demographic and baseline characteristics were similar across all groups. Treatment success at week 12 were highest for the 1% BID (6/70, 8.6%) and 0.1% BID (6/72, 8.3%) groups versus vehicle (2/75, 2.7%). Absolute change in inflammatory (P=0.0431) and non-inflammatory (P=0.0303) lesions was statistically significant among the treatment groups. The median change from baseline at week 12 in inflammatory and non-inflammatory lesions was greatest in the 1% BID group -13.5 and -17.5, respectively. Similar results were observed for the secondary efficacy endpoints whereby the highest success rate and greatest reduction in lesion counts from baseline to week 12 occurred with 1% BID. 93/363 subjects (25.6%) reported ≥1 AEs; total number of AEs=123 with 2 probably/possibly related to treatment (N=1, 1% QD group). Subjects with ≥1AEs: 0.1% BID=25.0%, 0.5% BID=38.2%, 1% QD=22.9%, 1% BID=18.6%, and vehicle=22.7%. AEs were mostly mild in severity and similar across all groups. Most AEs (93/121 76.8%) resolved by the end of the study. Erythema was the most prevalent LSR; 36.8% had at least minimal erythema at some point during the study. Conclusions: All clascoterone cream concentrations were well tolerated with no clinically relevant safety issues noted. Clascoterone 1% BID treatment had the most favorable results and was selected as the best

candidate for further clinical study and development. Two Phase 3 investigations of clascoterone topical cream, 1% for the treatment of moderate-to-severe acne vulgaris in individuals ≥ 9 years recently concluded.

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Safety and effectiveness of microfocused ultrasound for treating erythematotelangiectatic rosacea.

Schlessinger J, Lupin M, McDaniel D, George, R. J Drugs Dermatol. 2019;18(6):522-531.
<https://jddonline.com/articles/dermatology/S1545961619P0522X/1/>

Background: Anecdotal reports indicate the use of microfocused ultrasound with visualization (MFU-V) improves facial redness. Objective: The purpose of this pilot study was to assess the safety and effectiveness of MFU-V for improving the signs and symptoms of erythematotelangiectatic rosacea. Methods & materials: Healthy adults with a clinical diagnosis of erythematotelangiectatic rosacea were enrolled (N=91). Eligible subjects had baseline Clinician Erythema Assessment (CEA) scores ≥ 3 and Patient Self-Assessment (PSA) of erythema scores ≥ 2 . Subjects were randomized to receive one or two low-density MFU-V treatments or one or two high-density MFU-V treatments. Subjects were evaluated at 90, 180, and 365 days after treatment. The primary effectiveness endpoint was treatment success, defined as a 1-point change in CEA scores at 90 days post-treatment. Results: Across groups, 75 to 91.3% of subjects achieved treatment success at 90 days post-treatment. Notable adverse events include bruising (44%), tenderness/soreness (43%), and redness (35%). Treatment results were sustained, lasting up to 1 year. Subject satisfaction was high based on self-assessment questionnaires. Conclusion: The results of this study demonstrated that a single, high-density MFU-V treatment may be effective for treating erythematotelangiectatic rosacea. Based on these results, a large, randomized controlled study of single, high-density MFU-V treatment for erythematotelangiectatic rosacea is warranted.

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Pathogenetic peculiarities of neuroendocrine and metabolic disorders in patients with acne associated with chronic stress.

Dashko MO, Syzon OO, Chaplyk-Chyzho IO, Turkevych SA. Wiad Lek. 2019;72(5 cz 2):997-1001.
<https://www.ncbi.nlm.nih.gov/pubmed/31175732>

Introduction: Acne is a chronic relapsing skin condition with multifactorial nature associated with disorders of sebaceous glands activity, psycho-emotional disorders and slow response to treatment. The aim: To study a pathogenic role of chronic stress and certain metabolic and neuroendocrine disorders in the development of acne in women depending on the duration of the disease. Materials and methods: A total of 119 women with acne were examined. Index insulin resistance (index HOMA), serum cortisol and prolactin, level of Reactivity-Personal Anxiety and Dermatology Life Quality Index (DLQI) was determined. Results: Possible changes in serum cortisol level depending on duration of the disease (increased in women with duration of the disease less than 1 year and decreased in women with duration of the disease 1-5 years), increased index of serum prolactin and HOMA, with more significant changes in women with duration of the disease 1-5 years. The DLQI was determined in all examined patients. An increased level of anxiety, characterized by higher levels of personal anxiety, was also observed, especially in a group of women with duration of the disease 1-5 years. Conclusion: The changes in certain neuroendocrine and metabolic indices, which are the markers of chronic stress, worsening of life quality and significant levels of reactivity and personal anxiety, were observed in women with acne. A strong and moderate correlational relationship between the nature of changes in the abovementioned indices and duration of the disease was detected.

A randomized phase 3b/4 study to evaluate concomitant use of topical ivermectin 1% cream and doxycycline 40 mg modified-release capsules versus topical ivermectin 1% cream and placebo in the treatment of severe rosacea. Schaller M, Kemeny L, Havlickova B, et al. *J Am Acad Dermatol.* 2019 May 28. pii: S0190-9622(19)30867-9. doi: 10.1016/j.jaad.2019.05.063. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31150711>

Background: Randomized controlled studies of combination therapies in rosacea are limited. Objective: Evaluate efficacy and safety of combining ivermectin 1% cream (IVM) and doxycycline 40 mg modified-release capsules* (DMR) versus IVM and placebo (PBO) for treatment of severe rosacea. Methods: This 12-week, multicenter, randomized, investigator-blinded, parallel-group comparative study randomized adult subjects with severe rosacea (Investigator's Global Assessment [IGA]=4) to either IVM and DMR (combination arm) or IVM and PBO (monotherapy). Results: A total of 273 subjects participated. IVM and DMR displayed superior efficacy in reduction of inflammatory lesions (-80.3% vs. -73.6% for monotherapy, $p=0.032$) and IGA score ($p=0.032$). Combination therapy had a faster onset of action as of week 4; it significantly increased the number of subjects achieving IGA 0 (11.9% vs. 5.1%, $p=0.043$)† and 100% lesion reduction (17.8% vs. 7.2%, $p=0.006$) at week 12. Both treatments reduced the Clinician's Erythema Assessment score, stinging/burning, flushing episodes, Dermatology Life Quality Index and ocular signs/symptoms, and were well-tolerated. Limitations: The duration of study prevented evaluation of potential recurrences or further improvements. Conclusion: Combining IVM and DMR can produce faster responses, improve response rates, and increase patient satisfaction in severe rosacea.

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Efficacy of metformin in the treatment of acne in women with polycystic ovarian syndrome: a newer approach to acne therapy. Sharma S, Mathur DK, Paliwal V, Bhargava P. *J Clin Aesthet Dermatol.* 2019;12(5):34–38 <http://jcadonline.com/metformin-acne-may-2019/#>

Introduction: Acne vulgaris is a chronic inflammatory disorder of the pilosebaceous units and has been associated with hyperandrogenism, which, in women, is most commonly caused by polycystic ovary syndrome (PCOS). Metformin treatment can correct ovarian and functional adrenal hyperandrogenism in adolescents with PCOS. Objective: We evaluated the efficacy of metformin therapy in women with acne and PCOS in terms of acne load. Methods: This was a hospital-based, interventional, longitudinal study that included 40 female patients with acne and PCOS diagnosed using the Rotterdam criteria. Hormonal assay, including serum levels of testosterone, dehydroepiandrosterone sulphate, luteinizing hormone, follicle-stimulating hormone, prolactin, and blood sugar, was conducted on the third or fourth day of the menstrual cycle in a fasted state. An abdominal ultrasound was performed on the ninth day of menstrual cycle to diagnose PCOS. Baseline acne severity was assessed as per the Definition Severity Index. Metformin 500mg was given to all selected patients three times a day for eight weeks. Patient follow-up and acne severity reassessment was conducted at Weeks 3 and 6. At Week 8, all work-ups were repeated. Intention-to-treat analysis was done. Wilcoxin signed-rank sum test was used to identify significance in acne severity. Results: Metformin treatment significantly reduced acne severity in patients with PCOS ($p<0.001$). Conclusion: Metformin reduces ovarian hyperandrogenism, leading to clinical improvement of acne in women with PCOS.

Clinical Reviews

Diode laser and fractional laser innovations. Archer KA, Carniol P. *Facial Plast Surg.* 2019 Jun;35(3):248-255. doi: 10.1055/s-0039-1688846. Epub 2019 Jun 12. <https://www.ncbi.nlm.nih.gov/pubmed/31189197>

Laser technology continues to increase in popularity and expand treatment options for patients with common but challenging skin conditions including facial telangiectasias, facial aging, striae distensae, and acne scars. Facial telangiectasias have been estimated to occur in tens of millions of people worldwide. The 585-nm laser was the first to follow the principle of selective photothermolysis for the treatment of cutaneous vascular lesions, but it caused significant postoperative purpura. Newer diode lasers target superficial and deep telangiectasias without the side effects of the 585-nm laser. Ablative resurfacing was introduced in the 1990s with the carbon dioxide laser to address facial rhytids and photoaging. While effective, the risks and downtime were significant. The newest fractionated nonablative lasers are demonstrating impressive results, with decreased risks and downtime. This new generation of lasers is being used extensively and in unique combinations for facial aging, striae, and acne scars.

Inflammatory skin is associated with changes in the skin microbiota composition on the back of severe acne patients. Dagnelie MA, Montassier E, Khammari A, et al. *Exp Dermatol.* 2019 Jun 7. doi: 10.1111/exd.13988. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31173650>

Acne is the most common inflammatory skin disease, affecting up to 85% of the 11-30 years old world population. Skin microbiota appears as a key player involved in several skin dermatoses physiopathology. Here, we show that inflammatory skin is associated with changes in the skin microbiota composition on the back of severe acne patients but also on the face of patients where acne was scored as mild to moderate, comparing with healthy controls. Changes were observed particularly on skin commensals *Propionibacteriaceae*, *Staphylococcaceae* and *Enterococcaceae* families, suggesting the importance of the balance between skin commensals to maintain skin homeostasis and control skin inflammatory process.

Hidradenitis suppurativa: comprehensive review of predisposing genetic mutations and changes. Jfri AH, O'Brien EA, Litvinov IV, et al. *J Cutan Med Surg.* 2019 Jun 6:1203475419852049. doi: 10.1177/1203475419852049. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31167568>

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disorder. A genetic component in the pathogenesis is highly likely considering that ~30% to 40% of patients with HS report a family history of the disease. The genetic mutations related to HS that have been reported to date suggest HS can be inherited as a monogenic trait because of a defect in either the Notch signaling pathway or inflammasome function, or as a polygenic disorder resulting from defects in genes regulating epidermal proliferation, ceramide production, or in immune system function. This review provides a summary of genetic mutations reported in patients diagnosed with HS and discusses the mechanisms by which these genes are involved in its pathogenesis.

Periodic worsening, or flare, in hidradenitis suppurativa: the perspective of people with hidradenitis. Sarfo A, Butt M, Kirby JS. *Br J Dermatol.* 2019 Jun 6. doi: 10.1111/bjd.18210. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31168883>

Hidradenitis suppurativa (HS) is an inflammatory skin disease that described as chronic and recurrent, with intermittent periods of worsening, also described as "flares".(1-3) The core domain set for HS trials is being developed and calls for the assessment of flare frequency and duration.(4) Yet, a recent literature review demonstrated that there are few precise definitions of HS flare.(5) Notably, it is the person with HS who experiences flare and there is little data pertaining to the lived experience of people with HS to inform flare definition. The aim of this study was to explore the patient perspective for HS flare.

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Depression and anxiety in adults with hidradenitis suppurativa: a systematic review and meta-analysis.

Machado MO, Stergiopoulos V, Maes M, et al. JAMA Dermatol. 2019 Jun 5. doi: 10.1001/jamadermatol.2019.0759. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31166590>

Importance: Previous studies suggest that depression and anxiety are common in patients with hidradenitis suppurativa (HS), more so than other dermatological conditions. Yet, to the authors' knowledge, no previous systematic review or meta-analysis has estimated the prevalence or odds ratio (OR) for those psychiatric comorbidities in this population. Objective: To assess the prevalence and odds for depression and anxiety in patients with HS. Data sources: From July 25 to September 30, 2018, observational studies investigating the prevalence and odds for depression and anxiety in adults with HS were systematically searched without language restriction from the inception of each database to July 25, 2018, in PubMed/MEDLINE, Embase, and PsycINFO databases. Searches used various configurations of the terms hidradenitis suppurativa; acne inversa; depressive disorder; depression; anxiety; anxiety disorders; phobia, social; suicide; and suicide, attempted. In addition, the reference lists of included references were screened manually. Study selection: Two investigators independently screened references that measured prevalence rates and odds for depressive and anxiety symptoms in patients with HS. Of 136 unique references, 10 ultimately met inclusion criteria. Data extraction and synthesis: Relevant data were extracted from eligible references. Authors were contacted to provide further information when necessary. Methodological quality of included studies was assessed through a modified version of the Newcastle-Ottawa Scale. Random-effects models were used to synthesize available evidence. Main outcomes and measures: Prevalence rates and ORs for depression and anxiety in adults with HS were the primary outcome measures. Heterogeneity across studies was assessed with the I² statistic. Sources of heterogeneity were explored through subgroup and meta-regression analyses. Results: Ten studies comprising 40 307 participants with HS met inclusion criteria. The overall prevalence of depression was 16.9% (95% CI, 9.9%-27.2%). Heterogeneity was large. In the subgroup of studies that considered a clinical criteria-based diagnosis of depression, the prevalence of depression was 11.9% (95% CI, 4.9%-26.2%), compared with 26.8% (95% CI, 20.4%-34.5%) in studies that used a screening instrument. The methodological quality of included studies moderated those findings. The OR for depression in individuals with HS compared with individuals without HS was 1.84 (95% CI, 1.57-2.15). The prevalence of anxiety was 4.9% (95% CI, 1.7%-13.2%); there were insufficient data to determine an odds ratio for anxiety in persons with HS because 2 studies included a comparison group. Conclusions and relevance: This systematic review and meta-analysis indicates that depression and anxiety are common comorbid conditions in patients with HS. Results suggest that the development of strategies to recognize and treat those psychiatric comorbidities in patients with HS is warranted.

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Rosacea fulminans: two case reports and review of the literature. Angileri L, Veraldi S, Barbareschi M. *J Dermatolog Treat.* 2019 Jun 6:1-11. doi: 10.1080/09546634.2019.1628175. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31169436>

Rosacea Fulminans is a rare and severe inflammatory dermatosis which affects predominantly childbearing women. It is characterized by sudden onset and it usually localizes exclusively on the centrofacial areas, presenting with numerous fluctuant inflammatory nodules and papules which may coalesce. Treatment with isotretinoin in combination with topical and systemic corticosteroids is successful. Clearance of lesions may be obtained under systemic treatment with no or minimal scarring outcomes. Due to rare incidence its pathophysiological mechanisms, diagnosis and management remain controversial. We report two cases of Rosacea Fulminans arised in otherwise healthy people and completely healed after treatment. Our aim is to share our experience about this disease in order to increase knowledge about its diagnosis, management and its treatment. We also make a review of the literature of this peculiar dermatosis.

Update on the treatment of scars. Gonzalez N, Goldberg DJ. *J Drugs Dermatol.* 2019;18(6):550-555. <https://jddonline.com/articles/dermatology/S1545961619P0550X/1/>

Background: Treatment of scars continues to be a persisting challenge. Scar classification is paramount in determining an appropriate treatment strategy. They can be classified into hypertrophic, keloid, or atrophic scars. With the increasing demand for less invasive procedures that result in equal or greater outcomes, there has been an increase in the variety of procedures for the management of scarring. Methods: A Pubmed search was performed for the most recent papers on scar treatments. Findings and applications are discussed in this review. Results: Studies evaluating the efficacy and safety of microneedling, filler agents, toxins, silicone gels, and laser devices such as ablative, non-ablative, fractional, SRT, and radiofrequency are discussed. Conclusion: Review of the literature revealed a myriad of options for the treatment of different scar types. Although there is not vast evidence in the literature in regard to combination treatments, these are becoming more popular, and it is the author's opinion that combination treatments yield better overall results.

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Liposome based combination therapy for acne treatment. Eroğlu İ, Aslan M, Yaman Ü, et al. *J Liposome Res.* 2019 Jun 11:1-31. doi: 10.1080/08982104.2019.1630646. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31185768>

Acne vulgaris is one of the most common chronic diseases worldwide with the high prevalence ratio of about 80-85% in patients who are in puberty period. For the treatment options, many conventional dosage forms are available; however, existing limitations of systemic administration of drugs (oral antibiotics), such as adverse events and resistance, led for seek of new formulation options. In this study, liposomes containing tetracycline HCl and tretinoin were prepared by the film formation method. In vitro characterization studies revealed that liposomes (111.10 ± 8.02 nm; P.D.I.= 0.198 ± 0.03; Z.P.=25.83 ± 0.40mV) with an encapsulation efficiency more than 80% for both APIs were formulated. In order to maintain a suitable viscosity for topical application, optimized liposomal formulations were dispersed in carbopol-based gel. In vitro release of APIs was sustained for 24 hours with released amounts of 56.44% and 58.44% for tetracycline HCl and tretinoin, respectively. Stability evaluation of both liposomes and liposomes in hydrogels were investigated for 6 months at 4 °C and 25 °C; and no statistically significant change was observed in terms of particle size, zeta potential, encapsulation efficiency, appearance, pH and viscosity.

Cytotoxicity tests confirmed the non-toxic structure of liposomal gel formulations on mice fibroblast cells. In addition, antibacterial efficacy has been proven with *Staphylococcus aureus* and *Streptococcus epidermidis* strains as well as the effect on biofilm formation and eradication. As a result, we hereby presented a new combination drug product, which consists of dual active ingredients having comedolytic and bacteriostatic effects in a single, safe and stable liposome formulation.

Metformin use in women with polycystic ovary syndrome. Johnson NP. *Ann Transl Med.* 2014 Jun;2(6):56. doi: 10.3978/j.issn.2305-5839.2014.04.15. <https://www.ncbi.nlm.nih.gov/pubmed/25333031>

Polycystic ovary syndrome (PCOS) is an endocrinopathy characterized by increased resistance to insulin. Metformin is one of the longest established oral insulin sensitizing agents. For decades its use was restricted to management of type 2 diabetes. However, in the past two decades, its properties as an insulin sensitizing agent have been explored in relation to its applicability for women with PCOS. Metformin is an effective ovulation induction agent for non-obese women with PCOS and offers some advantages over other first line treatments for anovulatory infertility such as clomiphene. For clomiphene-resistant women, metformin alone or in combination with clomiphene is an effective next step. Women with PCOS undergoing in vitro fertilization should be offered metformin to reduce their risk of ovarian hyperstimulation syndrome. Limited evidence suggests that metformin may be a suitable alternative to the oral contraceptive pill (OCP) for treating hyperandrogenic symptoms of PCOS including hirsutism and acne. More research is required to define whether metformin has a role in improving long term health outcomes for women with PCOS, including the prevention of diabetes, cardiovascular disease and endometrial cancer.

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The use of oral antibiotics in the management of rosacea. Nagler AR, Del Rosso J. *J Drugs Dermatol.* 2019;18(6):506-513. <https://jddonline.com/articles/dermatology/S1545961619P0506X/1/>

Rosacea is common inflammatory facial dermatosis. Rosacea has variable manifestations including facial flushing, central facial erythema, telangiectasias, and papulopustular lesions. Treatment of rosacea is challenging given the varied manifestations and incompletely understood etiology, but the treatment of papulopustular presentations often relies on oral antibiotics. Tetracyclines, specifically doxycycline, are the most commonly prescribed antibiotics for rosacea. Other antibiotics that can be used include macrolides, commonly azithromycin, and rarely, metronidazole. This paper will review the evidence for the use of antibiotics in the treatment of rosacea.

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Treatment of acne scars with PRP and laser therapy: an up-to-date appraisal. Schoenberg E, Wang JV, Zachary CB, Saedi N. *Arch Dermatol Res.* 2019 May 29. doi: 10.1007/s00403-019-01936-7. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31144021>

Clinically significant scarring is a common complication of acne vulgaris. Recent treatments have included the use of platelet-rich plasma (PRP), especially in combination with laser therapy. Here, we offer backgrounds on PRP and laser therapy and review combination treatment for acne scars. It is important to note that current data are limited to small studies and that there is no standard protocol for PRP administration. Larger studies are needed to better evaluate combination treatment and determine the best modality.

Assessing the psychological burden of patients with hidradenitis suppurativa. Frings VG, Bauer B, Glöditzsch M, et al. Eur J Dermatol. 2019 May 29. doi: 10.1684/ejd.2019.3552. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31145081>

Hidradenitis suppurativa (HS) is accompanied by a significantly compromised quality of life. Assessment of the psychological burden of HS is crucial for evidence-based allocation of resources. We examined methods to easily assess the psychological burden in HS patients. A total of 110 consecutively enrolled HS patients were assessed with respect to sociodemographic data, Hurley scale, and modified Sartorius score. Patients were asked to provide information on time of first diagnosis, previous therapies, surgical intervention, and pre-existing conditions. Distributed questionnaires were the Dermatology Life Quality Index (DLQI) and the Skindex-29, the Visual Analogue Scale (VAS) for pain, and the German version of the Hospital Anxiety and Depression Scale (HADS-D) for evaluation of anxiety (HADS-D/A) and depression (HADS-D/D). Of the 110 patients with HS (mean age: 38 ± 12 ; range: 18 to 75 years), 61 were female and 49 were male. We found a statistically significant correlation between HADS-D/A, VAS ($p = 0.009$), between Skindex-29 and Sartorius score (symptoms: $p = 0.024$; emotions: $p = 0.019$; functional status: $p = 0.002$), as well as between Skindex-29 and VAS (symptoms: $p = 0.000$; emotions: $p = 0.001$; functional status: $p = 0.000$). Additionally, VAS correlated significantly with DLQI ($p = 0.000$) and body mass index with Sartorius score ($p = 0.038$). Our study provides evidence that HS patients experience a high level of psychological distress. Interestingly, a clear correlation between psychological burden and HS patients was inferred by the VAS for pain. We underline that HS patients require active management for their physical as well as psychological health.

Cortexolone 17 α -propionate (clascoterone) is a novel androgen receptor antagonist that inhibits production of lipids and inflammatory cytokines from sebocytes in vitro. Rosette C, Agan FJ, Mazzetti A, et al. J Drugs Dermatol. 2019 May 1;18(5):412-418. <https://www.ncbi.nlm.nih.gov/pubmed/31141847>

Cortexolone 17 α -propionate (clascoterone) is a novel topical androgen antagonist that is being analyzed for its ability to treat acne. The pathogenesis of acne is attributed to multiple factors, including altered sebum production, inflammatory processes, dysregulation of the hormone microenvironment, and the proliferation of the skin commensal bacteria, *Propionibacterium acnes* (*P. acnes*). Androgens induce the proliferation and differentiation of sebocytes, (cells that comprise the sebaceous gland), help regulate the synthesis of the lipids that are incorporated into sebum and stimulate the production of cytokines that are found in inflammatory acne lesions. Several studies have established that clascoterone is a potent antiandrogen that is well tolerated and has selective topical activity. Its potency as an acne therapeutic is currently being analyzed in a large phase 3 clinical trial. The study described herein elucidates for the first time the mechanism of action of clascoterone. Clascoterone was found to bind the androgen receptor (AR) with high affinity in vitro, inhibit AR-regulated transcription in a reporter cell line, and antagonize androgen-regulated lipid and inflammatory cytokine production in a dose-dependent manner in human primary sebocytes. In particular, when compared to another AR antagonist, spironolactone, clascoterone was significantly better at inhibiting inflammatory cytokine synthesis from sebocytes. Therefore, clascoterone may be an excellent candidate to be the first topical antiandrogen to treat acne.

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