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Industry News

FDA approves of Sol Gel's Twyneo for acne. July 30, 2021. DermWire, Practical Dermatology. <https://practicaldermatology.com/news/fda-approves-of-sol-gels-twyneo-for-acne?c4src=news-landing:feed>

The FDA has approved Sol Ge's first proprietary drug product, TWYNEO (tretinoin/benzoyl peroxide) cream, 0.1%/3%, for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older. TWYNEO uses Sol-Gel's patented technology to entrap tretinoin, a retinoid, and benzoyl peroxide within silica-based microcapsules to stabilize tretinoin from being degraded by benzoyl peroxide and to slowly release each of the active drug ingredients over time to provide a favorable efficacy and safety profile. TWYNEO is patent protected until 2038. Sol-Gel has partnered with Galderma to commercialize TWYNEO in the U.S. Sol-Gel expects to receive a regulatory milestone payment in conjunction with this approval and retains the option to regain U.S. commercialization rights five years following first commercialization in the US. "The FDA approval of TWYNEO underscores our ability to deliver innovative, proprietary drugs to the market," says Dr. Alon Seri-Levy, Co-Founder and Chief Executive Officer of Sol-Gel, in a news release. "Based on the clinical data observed, we believe that TWYNEO has the potential to change the treatment landscape for the tens of millions of patients suffering from acne vulgaris. With market leader, Galderma, handling the product launch of TWYNEO, we are excited that TWYNEO will soon be available to patients in the US. We remain focused on obtaining FDA approval of EPSOLAY® (benzoyl peroxide), our other Galderma-partnered product – the approval of which has been delayed due to FDA's COVID-19-related restrictions. We are also making progress on our innovative earlier stage programs for erlotinib, roflumilast and tapinarof with the intent of advancing them into the clinic." "Galderma was founded forty years ago around a commitment to serve the dermatological needs of healthcare professionals and their patients," says Baldo Scassellati Sforzolini, Global Head of Research & Development at Galderma. "Our heritage in acne dates back to our founding and we are excited to partner with Sol-Gel to bring yet another acne innovation to market for a condition that impacts up to 50 million Americans annually." "TWYNEO combines, for the first time, two of the most commonly used topical agents available for the treatment of acne into a single application. Due to stability issues, these products don't play well together, and we were never able to recommend even consecutive co-application of the two agents. Sol-Gel's technology has solved this problem," explains Hilary Baldwin, MD, Clinical Associate Professor of Dermatology, Rutgers Robert Wood Johnson School of Medicine, Medical Director, The Acne Treatment and Research Center and Past President of the American Acne and Rosacea Society. "The approval of TWYNEO offers patients efficacy with these two products in a single convenient application. I believe physicians will look forward to adding TWYNEO to their acne treatments toolbox." The New Drug Application (NDA) for TWYNEO was approved by the FDA on July 26, 2021. The NDA was supported by positive results from two Phase 3, randomized, double-blind, vehicle-controlled, multi-center studies (NCT03761784, and NCT03761810), in which TWYNEO demonstrated efficacy and a favorable tolerability profile in subjects nine years of age and older with facial acne vulgaris. TWYNEO is the first FDA-approved fixed-dose combination of tretinoin and benzoyl peroxide.

Ortho Dermatologics announces 2021 Aspire Higher scholarship recipients. July 29, 2021. Ortho Dermatologics. https://ortho-dermatologics.com/staging/wp-content/uploads/ORD.0130.USA_21-Trade-News-Release-Ortho-Announces-2021-Aspire-Higher-Recipients_FINAL.pdf

Scholarships awarded to nine students affected by dermatologic conditions. Ortho Dermatologics, one of the largest prescription dermatology health care businesses, today announced the recipients of their 2021 Aspire Higher scholarship program. The program, which began in 2012, will award nine students who have been treated for a dermatologic condition with a scholarship up to \$10,000 to pursue their undergraduate or graduate degrees. "For nine years, Ortho Dermatologics has supported students in achieving their higher education goals through our Aspire

Higher scholarship program. Beyond the demands of their schooling and extracurricular activities, these students have also had to manage the burden of living with a skin condition,” said Scott Hirsch, senior vice president and chief strategy officer, Bausch Health, and president, Ortho Dermatologics. “The stories our 2021 scholarship recipients shared with us are inspiring, and we are honored to provide them with this award to recognize their achievements and help them pursue their academic aspirations.” The 2021 honorees were chosen from nearly 150 applications and were selected in part due to their essays overviewing their educational journeys while living with dermatologic conditions and the role a health care professional played in treating the condition. The applications were judged by an independent panel of dermatologists from across the country. The Aspire Higher scholarship program recognizes students across a wide range of educational pursuits, with scholarships in three categories, including the Undergraduate Scholar Awards, the Graduate Scholar Awards, and the Today’s Woman Scholar Awards for mothers pursuing undergraduate or graduate degrees.

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New Medical Research

Patient perspectives on the lived experience of acne and its treatment among adult women with acne: A qualitative study. Barbieri JS, Fulton R, Neergaard R, et al. JAMA Dermatol. 2021 Jul 28. doi: 10.1001/jamadermatol.2021.2185. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34319378/>

Introduction: Acne often persists into adulthood in women. However, few studies have specifically explored the lived experience of acne in adult populations. Objective: To examine the lived experience of acne and its treatment among a cohort of adult women. Design, setting, and participants: A qualitative analysis was conducted from free listing and open-ended, semistructured interviews of patients at a large academic health care system (University of Pennsylvania Health System) and a private practice (Dermatologists of Southwest Ohio). Fifty women 18 to 40 years of age with moderate to severe acne participated in interviews conducted between August 30, 2019, and December 31, 2020. Main outcomes and measures: Free-listing data from interviews were used to calculate the Smith S, a measure of saliency for each list item. Semistructured interviews were examined to detect themes about patient perspectives regarding their acne and its treatment. Results: Fifty participants (mean [SD] age, 28 [5.38] years; 24 [48%] White) described acne-related concerns about their appearance that affected their social, professional, and personal lives, with many altering their behavior because of their acne. Depression, anxiety, and social isolation were commonly reported. Participants described successful treatment as having completely clear skin over time or a manageable number of blemishes. Many participants described frustration with finding a dermatologist with whom they were comfortable and with identifying effective treatments for their acne. Conclusions and relevance: The results of this qualitative study suggest that women with acne have strong concerns about appearance and experience mental and emotional health consequences and disruption of their personal and professional lives. In addition, many patients describe challenges finding effective treatments and accessing care. Future trials to understand the optimal treatment approaches for women with acne are needed to improve outcomes in this population.

Interleukin19 gene polymorphism and its serum level in acne vulgaris patients. Bazid BASE, Marae A, Tayel N, et al. J Immunoassay Immunochem. 2021 Jul 22. doi: 10.1080/15321819.2021.1952425. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34292139/>

Numerous cytokines are involved in acne vulgaris pathogenesis, though few studies correlate interleukin IL-19 to acne vulgaris. So this study aimed to assess the IL-19 (rs 2243191) gene polymorphism and its serum level in acne vulgaris. This case-control study involved 90 acne vulgaris cases and 90 age- and sex-matched controls. Acne severity was assessed according to Global Acne Grading System (GAGS), and serum IL-19 was assessed by ELISA

and IL-19 (rs 2243191) gene polymorphism was assessed by real time PCR. This study showed that acne cases had significantly higher IL-19 levels than controls. Also, its level was significantly higher in severe cases than moderate and mild cases. Regarding IL-19 gene polymorphism (rs 2243191), TT and CT genotypes were significantly higher in patients than in controls. The incidence of minor allele T was greater in patients than in controls. There were significant differences between IL-19 genotypes and disease severity. Serum IL-19 was significantly higher in genotypes TT and CT acne cases than in those with genotype CC. We concluded that TT genotype of IL-19 might be a hereditary risk factor for acne vulgaris development. It is associated with a high IL-19 serum level, which could be a marker of acne severity.

Efficacy of a combined chemical peel and topical salicylic acid-based gel combination in the treatment of active acne. Calvisi L. J Cosmet Dermatol. 2021 Jul;20 Suppl 2:2-6. doi: 10.1111/jocd.14281. <https://pubmed.ncbi.nlm.nih.gov/34318988/>

Background: Acne vulgaris is a common skin condition affecting the pilosebaceous unit of the skin characterized by the presence of comedones, papules, pustules, nodules, and cysts, which might result in permanent scars. It commonly affects adolescents, but it can occur in any age-group with the second group of incidence in young women in their 30s. Acne vulgaris can highly affect a person's quality of life. Therefore, it is necessary to act against it to prevent emotional impact and long-term complications. Aim: This study aimed to demonstrate the efficacy of a chemical peel in combination with a home care-exfoliating and purifying product in improving mild and moderate acne. Methods: The study included 45 patients with mild-to-moderate acne. Patients were treated with a chemical peel containing a mix of salicylic acid, pyruvic acid, and retinoic acid once every 3 weeks for 4 times, plus a home care treatment after the healing process. Michaelson's acne severity score, Subject Global Aesthetic Improvement Scale, and Face Skin Q questionnaire were used to evaluate patients' skin improvement and patients' satisfaction. Results: All patients have shown improvement in skin lesions after 4 sessions of chemical peel according to Michaelson's acne severity score and Subject Global Aesthetic Improvement Score. Face Skin Q questionnaire demonstrated an improved quality of life in all treated patients. Conclusion: The combination of salicylic acid-based chemical peel plus exfoliating home care treatment appears to be a very good strategy against acne. Therefore, the physician may use this combination as an effective treatment for patients dealing with acne vulgaris.

A clinical study of carbon dioxide lattice laser-assisted or microneedle-assisted 5-aminolevulinic acid-based photodynamic therapy for the treatment of hypertrophic acne scars. Yan D, Zhao H, Li C, et al. Photodermatol Photoimmunol Photomed. 2021 Jul 17. doi: 10.1111/phpp.12716. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34273202/>

Objective: To study the clinical efficacy, recurrence rate and safety of 5-aminolevulinic acid-based photodynamic therapy (ALA-PDT) combined with microneedle or CO₂ lattice laser (CO₂FL), in comparison with intrascar betamethasone injection in the treatment of hypertrophic acne scar. Methods: Fifty-two patients with hypertrophic acne scars at the mandibular angle were enrolled and assigned to different therapy groups. Sixteen patients were treated with microneedle-assisted incorporation of ALA. Twenty-eight patients underwent CO₂FL-assisted incorporation of ALA. Eight patients received standard therapy with intrascar injection of glucocorticoid. Two dermatologists, blinded to the therapy groups, independently evaluated the scars in all patients using the average value of the Vancouver Scar Scale score, which was treated as an integer variable. Results: After three rounds of treatment, there was no significant difference in therapeutic effective rate among the microneedle, laser and topical glucocorticoid groups (93.75% vs 100% vs 100%, P = .855). One out of 16 patients (6.25%) in the microneedle group, no patient (0%) in the laser group and two out of eight patients (25%) in the topical glucocorticoid group had recurrence. The laser group showed a higher rate of adverse effects, which were usually mild and reversible, except

for pigmentation. Adverse reactions could be completely subsided within 3 weeks. Conclusions: Either CO2FL or microneedle combined ALA-PDT for hypertrophic scar, as to topical glucocorticoid therapy, showed equivalent clinical effects but lower recurrence rate within 6 months of follow-up period.

A novel mechanism of carvedilol efficacy for rosacea treatment: Toll-like receptor 2 inhibition in macrophages. Zhang J, Jiang P, Sheng L, et al. *Front Immunol.* 2021 Jul 12;12:609615. doi: 10.3389/fimmu.2021.609615. eCollection 2021. <https://pubmed.ncbi.nlm.nih.gov/34322115/>

Background: Rosacea, a chronic inflammatory skin disorder etiologically associated with immune cells and the antibacterial peptide cathelicidin LL-37, can be effectively treated by oral carvedilol administration. Objective: To investigate the molecular mechanisms underlying carvedilol efficacy in rosacea treatment. Methods: Skin samples of patients with rosacea were subjected to histopathological (hematoxylin and eosin) and immunohistochemical (CD68, Toll-like receptor 2 (TLR2), kallikrein 5, cathelicidin, TNF- α , and IL-1 β) evaluation. An in vivo murine rosacea-like inflammation model was established by LL-37 intradermal injection with or without carvedilol gavage-based pretreatment. Erythema proportion (Image J) and skin redness (L*a*b colorimetry) were quantified. Murine skin samples underwent pathological examination for inflammatory status and immunofluorescence staining. Murine skin and lipopolysaccharide-stimulated RAW 264.7 cells with or without carvedilol pretreatment were evaluated by quantitative reverse transcription-polymerase chain reaction and western blotting. Clinical facial images of patients were obtained using the VISIA skin analysis system before, 4, and 6 months following oral carvedilol administration. Results: Rosacea skin lesions exhibited more pronounced inflammatory cell infiltration than peripheral areas, with profound macrophage infiltration and inflammatory cytokines (TLR2, kallikrein 5, cathelicidin, TNF- α , and IL-1 β). In vivo, carvedilol alleviated inflammation in LL-37 mice, down-regulating TLR2, KLK5, and cathelicidin expression. In vitro, carvedilol decreased TLR2 expression in RAW 264.7 cells, further reducing KLK5 secretion and LL-37 expression and ultimately inhibiting rosacea-like inflammatory reactions. Clinical manifestations and facial redness obviously improved during 6-month follow-up with systemic carvedilol administration. Conclusion: Carvedilol is effective against rosacea, with inhibition of macrophage TLR2 expression as a novel anti-inflammatory mechanism.

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A topical gel of tea tree oil nanoemulsion containing adapalene versus adapalene marketed gel in patients with acne vulgaris: A randomized clinical trial. Najafi-Taher R, Jafarzadeh Kohneeloo A, Eslami Farsani V, et al. *Arch Dermatol Res.* 2021 Jul 12. doi: 10.1007/s00403-021-02267-2. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34251536/>

Adapalene is used for treatment of acne vulgaris, a common dermatological disease. Nano-based carriers have been developed to improve solubility and bioavailability of adapalene and other acne treatment drugs. In our previous report, tea tree oil nanoemulsion containing adapalene gel (TTO NE + ADA Gel) showed appropriate physical and biological properties such as stability, viscosity, pH, size, morphology and biocompatibility in an animal model. The present study was designed to assess efficacy and safety of the TTO NE + ADA Gel in comparison with 0.1% adapalene marketed gel (ADA Marketed Gel). A total of 100 patients were randomized to receive TTO NE + ADA Gel or ADA Marketed Gel, once daily at night, for 12 weeks. Analysis for efficacy was conducted by acne lesion count (total, inflammatory and non-inflammatory) and acne severity index at weeks 4, 8 and 12 using generalized estimating equation along with the safety assessments in each measurement for assessing dryness, erythema, burning sensation and irritation. Significantly better reduction in total, inflammatory, and non-inflammatory acne lesions were reported for TTO NE + ADA Gel as compared to the ADA Marketed Gel overall and on each measurement occasion (p value < 0.001 for all). Mean acne severity index also reduced with TTO NE + ADA Gel significantly in comparison with ADA Marketed Gel (p value < 0.001). Dryness was the most common adverse effect reported in both groups and

it was higher in TTO NE + ADA Gel group. In conclusion, TTO NE + ADA Gel compared to ADA Marketed Gel appears more effective in the treatment of acne vulgaris, with no important change in adverse effects.

A randomized controlled pilot study: Combined 595-nm pulsed dye laser treatment and oxymetazoline hydrochloride topical cream superior to oxymetazoline hydrochloride cream for erythematotelangiectatic rosacea. Sodha P, Suggs A, Munavalli GS, Friedman PM. *Lasers Surg Med.* 2021 Jul 7. doi: 10.1002/lsm.23439. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34233378/>

Background and objectives: We evaluated if oxymetazoline therapy combined with 595-nm pulsed dye laser (PDL) will be more beneficial than topical oxymetazoline alone for the improvement of erythematotelangiectatic rosacea. **Study design/materials and methods:** This was a randomized, controlled, prospective clinical trial approved by an independent Institutional Review Board, which enrolled 34 patients with moderate to severe clinical erythema (CEA) into a two-arm study of PDL with concomitant oxymetazoline cream (Arm 1) and oxymetazoline cream alone (Arm 2). Patients in Arm 1 were treated with 3 monthly laser sessions, which were started after 1 month of topical oxymetazoline cream. Thirty subjects continued with the study, and 25 subjects (Arm 1: 14, Arm 2: 11) completed the 6-month follow-up. With photographic comparison to baseline images, efficacy endpoints were based on clinical on-site grading by both the investigator and the patient, using the grading tools for CEA, Global Aesthetic Improvement (GAI) assessment, vessel size improvement, and subject self-assessment. These scales were assessed at baseline and/or at each clinical follow-up at 1, 2, 3, and 6 months. Subject satisfaction as well as post-treatment immediate response and treatment-associated pain scores were also evaluated. **Results:** Statistically significant improvement in CEA was seen in both arms at the 1-, 2-, and 3-month post-baseline visits ($P < 0.01$). Only Arm 1 presented statistically significant improvement in CEA ($P < 0.001$) at 6 months post baseline with a mean score of 1.6 (almost clear-mild) compared with 3.2 at baseline. Arm 1 showed significantly greater mean vessel size improvement at 3 months ($P < 0.01$) and 6 months ($P < 0.05$) post baseline compared to Arm 2. Significantly greater improvement ($P < 0.05$) in the investigator GAI score was reported at the 2- and 6-month follow-ups compared with Arm 2. Subject GAI scores showed statistically significant greater improvement in Arm 1 compared with Arm 2 at both the 3- and 6-month follow-ups ($P < 0.01$). There were no complications or long-term effects associated with PDL or topical oxymetazoline treatments. **Conclusion:** The prospective trial verifies a safe, enhanced clinical outcome with the combination of PDL therapy and topical oxymetazoline for the treatment of erythematotelangiectatic rosacea patients.

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Transplantation of autologous fat, stromal vascular fraction (SVF) cell and platelet rich plasma (PRP) for cell therapy of atrophic acne scars: Clinical evaluation and biometric assessment. Nilforoushadeh MA, Heidari-Kharaji M, Alavi S, et al. *J Cosmet Dermatol.* 2021 Jul 6. doi: 10.1111/jocd.14333. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34228901/>

Scarring is an unfortunate result of acne because it causes the psychological and cosmetic problems for the patients. Unfortunately, no single treatment is suitable, and using multiple methods may have a better result. The autologous fat and stromal vascular fraction (SVF) cells and their secretory factors can enhance the angiogenesis, collagen synthesis, and migration of fibroblasts, therefore, regenerate hurt tissues. Moreover, other treatments for acne scarring, like platelet rich plasma (PRP), induce the increase of scars. This study aimed to verify the effectiveness of transplantation of autologous fat, SVF cells, and PRP as cell therapy techniques on atrophic acne scars. This study included into 9 adult patients with atrophic acne scars on face. All patients received the transplantation of autologous fat, stromal vascular fraction (SVF) cells, and PRP. The treatment outcome was measured by biometric assessment (Visioface 1000 D, Colorimeter, multi-probe adapter Cutometer Tewameter, Mexameter, and skin ultrasound imaging system), also the satisfaction of patients was evaluated. The patients were followed 6 months after the treatment.

There was a significant improvement in the skin pores, spots, skin lightness and melanin content of skin, skin elasticity and TEWL (trans epidermal water loss) after 6 months of the treatment. Furthermore, denser skin layers were observed both in the epidermis and dermis. Moreover, 66.6 % of patients showed good satisfaction after the treatment. In brief, the transplantation of autologous fat, SVF cells, and PRP is an effective cell therapy for atrophic acne scars.

The effect of intense pulsed light on the skin microbiota and epidermal barrier in patients with mild to moderate acne vulgaris. Liu J, Liu L, Zhou L, et al. *Lasers Surg Med.* 2021 Jul 5. doi: 10.1002/lsm.23426. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34224604/>

Background and objectives: The skin microbiota partly determined by epidermal barrier plays an important role in acne vulgaris and intense pulsed light (IPL) has been verified as a safe and effective therapeutic option for this disease. Nevertheless, the exact role of the IPL treatment on the skin microbiota and epidermal barrier for patients with acne vulgaris remains unclear. This article was designed to solve this problem. Study design/materials and methods: Nineteen healthy controls and 20 patients with mild to moderate acne were enrolled in this study, who received IPL treatment for 12 weeks. The epidermal barrier and skin samples were collected at baseline and after treatment. The microbial diversity was analyzed based on a high-throughput sequencing approach, which targets the V3-V4 region of the bacteria 16S ribosomal RNA genes. Results: After treatment of IPL, the Global Acne Grading System (GAGS) scores, sebum, sclererythrin, and red area of patients were significantly improved by IPL treatment ($P < 0.05$). Although there was no difference in microbiota diversity before and after IPL treatment, the Nonmetric Multidimension Scaling (NMDS) analysis showed that the samples of the acne patients before and after treatment could be divided into two different sets by skin microbiota ($P = 0.011$), which could be verified by heatmap analysis. Moreover, we found that the relative abundance of *Staphylococcus epidermidis* (*S. epidermidis*) significantly increased, but *Cutibacterium acnes* (*C. acnes*) decreased after IPL treatment. The sebum concentration was positively correlated with PH value ($R = 0.525$, $P = 0.017$), and the GAGS was positively associated with both sclererythrin ($R = 0.477$, $P = 0.002$) and red area ($R = -0.503$, $P = 0.001$). Conclusions: IPL could successfully improve the GAGS scores of acne vulgaris, as well as regulate the equilibrium between *C. acnes* and *S. epidermidis* and inhibit the sebum secretion.

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Efficacy and safety of topical spironolactone 5% cream in the treatment of acne: A pilot study. Ayatollahi A, Samadi A, Bahmanjahromi A, et al. *Health Sci Rep.* 2021 Jul 1;4(3):e317. doi: 10.1002/hsr.2.317. eCollection 2021 Sep. <https://pubmed.ncbi.nlm.nih.gov/34250269/>

Background: Spironolactone is an effective treatment for female patients with acne vulgaris. However, topical spironolactone could be a valuable treatment option in both male and female acne patients due to the less possibility of systemic side effects with its topical formulation. Objective: To evaluate the efficacy and safety of 5% spironolactone cream in the treatment of mild to moderate acne vulgaris. Methods: In this pilot clinical trial, topical spironolactone 5% was evaluated to treat patients with mild to moderate acne twice a day for 8 weeks. The rate of improvement as any alterations in the number of open and closed comedones, facial inflammatory papules, and acne global grading scores were assessed. Moreover, skin biometric characteristics including skin hydration, erythema, transepidermal water loss (TEWL), pH, sebum, and *Propionibacterium acnes* bacteria activity were also assessed following the treatment. Results: Fifteen patients participated in our study with a mean age of 25 ± 4.87 years old. A total of 66.6% ($n = 10$) were female and 33.4% ($n = 5$) were male. The number of acne papules, open and closed comedones, and acne global grading score decreased significantly 4 and 8 weeks after the beginning of treatment ($P < .05$). No considerable side effect was reported. Moreover, there was no significant difference between the skin hydration, melanin, erythema, TEWL, pH index, sebum, and *P. acnes* bacteria activity before, 4, and 8 weeks after the treatment with topical

spironolactone cream ($P > .05$). Conclusion: The topical 5% spironolactone cream seems to be an effective and safe treatment of acne vulgaris in both male and female patients.

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Clinical Reviews

The use of lasers and light devices in acne management: An update. Li MK, Liu C, Hsu JTS. *Am J Clin Dermatol*. 2021 Jul 21. doi: 10.1007/s40257-021-00624-5. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34287769/> Acne vulgaris is a disease of the pilosebaceous unit and the most common inflammatory dermatosis worldwide. It is also associated with significant economic burden. Limitations of conventional topical and systemic treatments include long treatment course, intolerable adverse effects, antibiotic resistance, and patient compliance. Therefore, laser and light-based interventions present as alternative options over the past decade and have been used in combination with conventional pharmacological therapies and other physical modalities. An updated overview on the use of lasers and light-based devices in acne management is presented to help clinicians understand the safety and efficacy of these treatment options. The effectiveness of neodymium:yttrium aluminum garnet (Nd:YAG) for treating acne is supported by more high-level studies compared with other laser devices. There is limited evidence to support the use of CO₂ lasers, potassium titanyl phosphate lasers, and 1565-nm non-ablative fractional lasers for treating acne. Among light devices, photodynamic therapy is the most studied, showing higher efficacies than some of the conventional topical and oral acne therapies. Intense-pulsed light and blue light therapies also show favorable outcomes. A limitation is that most studies are non-randomized and lack a control group, and report on a variety of device settings, treatment regimens, and outcome measures, making it challenging to summarize and generalize findings. Although the use of laser and light devices to treat acne is promising, further work with randomized controlled study designs and larger sample sizes will provide improved guidance on the application of these modalities.

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Acid-base combination principles for preparation of anti-acne dissolving microneedles loaded with azelaic acid and matrine. Xing M, Yang G, Zhang S, Gao Y. *Eur J Pharm Sci*. 2021 Jul 17;165:105935. doi: 10.1016/j.ejps.2021.105935. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34284096/> To overcome the poor solubility, skin irritation, and low permeability of azelaic acid (AZA) existed on the marketed formulations, a co-drug principle via matrine (MAT) was adopted to prepare anti-acne dissolving microneedles (DMNs). The formula was optimized according to the solubility and antibacterial activity of novel ionic salt. The results indicated solubilization of AZA could be achieved at a molar ratio between AZA and MAT was 1:1. Meanwhile, synergistic antibacterial and anti-irritative properties were acquired. The matrix materials were composed of sodium carboxymethyl cellulose (CMC), polyvinylpyrrolidone (PVP), and trehalose. And drug loadings of AZA and MAT in DMNs were $201.88 \pm 4.81 \mu\text{g}$ and $259.71 \pm 1.72 \mu\text{g}$, respectively. After insertion into porcine skin for 10 h, the cumulative permeability of AZA and MAT were $68.16\% \pm 3.79\%$ and $57.37 \pm 5.17\%$, respectively, while just $4.13 \pm 0.39\%$ ($p < 0.01$) was detected for commercially available AZA gel. In vitro antibacterial experiment, bacteriostatic rates of DMNs were all above 95% for *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Propionibacterium acnes*. Besides, DMNs exhibited no cytotoxicity and skin irritation. In conclusion, combination between AZA and MAT addressed shortcomings of AZA, and made it easier, safer, and more effective in acne treatment.

Efficacy of short-term intravenous clindamycin prior to oral clindamycin-rifampicin treatment in hidradenitis suppurativa: A retrospective case-series. Nikolakis G, Kristandt A, Hauptmann M, et al. *Br J Dermatol.* 2021 Jul 16. doi: 10.1111/bjd.20645. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34270785/>

Antibiotics represent the first-line hidradenitis suppurativa (HS) treatment, although HS is not an infectious disease. Prolonged antibiotic courses exhibit an anti-inflammatory effect, utilized for treating follicular/inflammatory skin diseases, e.g. acne and rosacea. Clindamycin/rifampicin or tetracyclines are usually administered for 10 to 12 weeks in moderate-to-severe HS treatment, mostly based on retrospective studies using non-validated severity scoring systems.

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Comparison of 2940 nm Er: YAG laser treatment in the microlaser peel, fractional ablative laser, or combined modes for the treatment of concave acne scars. Chen L, Wang Y, Jiang L, et al. *Medicine (Baltimore).* 2021 Jul 16;100(28):e26642. doi: 10.1097/MD.00000000000026642. <https://pubmed.ncbi.nlm.nih.gov/34260562/>

Objective: To compare and analyze the effects of Er:YAG laser treatment in the microlaser peeling, fractional ablative laser, or combined modes for the treatment of concave acne scars. Method: Ninety patients of concavity acne scar were randomly assigned to three different groups: microlaserpeeling mode group (MM group), fractional ablative mode group (FM group) and combined mode group (CM group). MM group received microlaserpeeling mode with depth of 60 µm and a repetition rate of 20%, FM group received fractional ablative mode with depth of 300 µm and a fractional density of 8%, and CM group received a fractional depth of 200 µm, density of 8%, and a peeling depth of 30 µm, repetition rate of 20%. All patients were evaluated for their treatment effects and side effects 30 days after treatment, including the treatment satisfaction, the ECCA grading scale, pain score and pigmentation level. Results: According to the effect satisfaction of patients' self-assessment, the difference among the three groups was statistically significant ($P < .05$), the CM group was better than the other two groups, but there was no significant difference between the FM group and the MM group ($P > .05$). About the ECCA grading scale 30 days after treatment, the statistical result among the three groups was significant ($P < .05$), the CM group is much lower than the FM group which is approximately equal to the MM group. There was statistical difference in pain score among the three groups and every two groups ($P < .05$), the CM group had the highest pain score, while FM group had the lowest. About the pigmentation level, there was statistical difference among the three groups ($P < .05$), FM group had the lightest pigmentation, while the CM group had the heaviest. Conclusions: Three treatment modes are all effective in treating the concavity acne scar. Among the three modes, CM group is best effective, also accompanied with the most severe side effect; FM group achieves the best balance between treatment effect and side effect. The treatment practices indicate that when the Er:YAG laser with a wavelength of 2940 nm is used to treat concavity acne scars, the right treatment mode should be subject to the severity of the scar.

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Antimicrobial and antioxidative activity of newly synthesized peptides absorbed into bacterial cellulose carrier against acne vulgaris. Golonka I, Greber KE, Oleksy-Wawrzyniak M, et al. *Int J Mol Sci.* 2021 Jul 12;22(14):7466. doi: 10.3390/ijms22147466. <https://pubmed.ncbi.nlm.nih.gov/34299085/>

The ongoing search for effective treatment of Acne vulgaris is concentrated, i.a., on natural peptides with antimicrobial properties. The aim of this work was the development of new amino acid derivatives with potential activity on dermal infections against selected microorganisms, including the facultative anaerobe *C. acne*. The peptides P1-P6 were synthesized via Fmoc solid phase peptide synthesis using Rink amide AM resin, analyzed by RP-HPLC-MS, FTIR, DPPH radical scavenging activity, and evaluated against *C. acne* and *S. aureus*, both deposited and non-deposited in BC. Peptides P1-P6 presented a lack of cytotoxicity, antimicrobial activity, or antioxidative properties correlated

with selected structural properties. P2 and P4-P6 sorption in BC resulted in variable data, i.a., confirming the prospective topical application of these peptides in a BC carrier.

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Clascoterone: A new topical anti-androgen for acne management. Santhosh P, George M. Int J Dermatol. 2021 Jul 9. doi: 10.1111/ijd.15752. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34242398/>

Clascoterone is an androgen receptor inhibitor which has been approved by the United States Food and Drug Administration for the topical treatment of acne vulgaris in patients 12 years of age and older. It competes with androgens, especially dihydrotestosterone, for androgen-receptor binding and limits their binding, thus inhibiting downstream signaling of pathways involved in the pathogenesis of acne. It inhibits androgen receptor-regulated gene transcription and antagonizes lipid and inflammatory cytokine production in a dose-dependent manner in human primary sebocytes. Clascoterone is commercially available as 1% (10 mg/g) cream. Adverse effects of topical clascoterone are mild and infrequent and are mostly limited to local skin reactions. Long-term safety studies have shown an absence of systemic antiandrogenic effects like reduced libido or feminization in male participants. Clascoterone seems a promising topical drug with a novel mechanism of action that could be added to the armamentarium of therapies for acne.

A stereoscopic optical system for objective quantification of the change in cumulative acne scar depth following various treatment interventions. Salameh F, Shehadeh W, Sprecher E, et al. J Cosmet Dermatol. 2021 Jul 6. doi: 10.1111/jocd.14334. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34228895/>

Current approaches for assessment of acne scars are subjective. We aimed to evaluate the reliability and feasibility of a new objective stereoscopic optical system for atrophic acne scars cumulative depth and monitoring therapeutic response. This retrospective case study aimed to validate accuracy and present initial data of a new, simple, non-contact, high-resolution 3D stereoscopic optical imaging system (Cherry Imaging, Yokneam, Israel) in the setting of acne scarring. Feasibility of the system was assessed by monitoring the cumulative depth of atrophic acne scars after a single treatment by means of various approaches. investigator's Qualitative Scarring Grading Score (QSGS) and patient's Self-Assessment of Clinical Acne-Related Scars (SCARS) were also calculated before and four weeks after the intervention. Scar depth measured by the imaging system correlated significantly with the actual depth of printed surface depressions. The changes in SCARS and 3D optical imaging assessments correlated significantly ($R=0.68$, $P = 0.012$), but there were no correlations between changes in QSGS and 3D optical assessment measures, or between the QSGS and SCARS results. The new stereoscopic optical system is a reliable and practical objective method for assessing the cumulative depth of atrophic acne scars and monitoring treatment response. It is more sensitive, accurate, and informative than subjective scales.

The impact of isotretinoin on the pituitary-ovarian axis: An interpretative review of the literature. Abdelhamed A, Ezz El-Dawla R, Karadag AS, et al. Reprod Toxicol. 2021 Jul 2;104:85-95. doi: 10.1016/j.reprotox.2021.06.017. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/34224824/>

Isotretinoin (13-cis-retinoic acid), a derivative of vitamin A, is used in the treatment of severe acne resulting in sebum suppression induced by sebocyte apoptosis. Isotretinoin treatment is associated with several adverse effects including teratogenicity, hepatotoxicity, and dyslipidemia. Isotretinoin's effects on endocrine systems and its potential role as an endocrine disruptor are not yet adequately investigated. This review presents clinical, endocrine, and molecular evidence showing that isotretinoin treatment adversely affects the pituitary-ovarian axis and enhances the risk of granulosa cell apoptosis reducing follicular reserve. Isotretinoin is associated with pro-apoptotic signaling in sebaceous glands through upregulated expression of p53, forkhead box O transcription factors (FOXO1, FOXO3),

and tumor necrosis factor-related apoptosis inducing ligand (TRAIL). Two literature searches including clinical and experimental studies respectively support the hypothesis that isotretinoin's toxicological mode of action on the pituitary-ovarian axis might be caused by over-expressed p53/FOXO1 signaling resulting in gonadotropin suppression and granulosa cell apoptosis. The reduction of follicular reserve by isotretinoin treatment should be especially considered when this drug will be administered for the treatment of acne in post-adolescent women, in whom fertility may be adversely affected. In contrast, isotretinoin treatment may exert beneficial effects in states of hyperandrogenism, especially in patients with polycystic ovary syndrome.

Treatment of rhinophyma with fractional CO2 laser resurfacing in a woman of color: Case report and review of the literature. Kassirer SS, Gotkin RH, Sarnoff DS. *J Drugs Dermatol.* 2021 Jul 1;20(7):772-775. doi: 10.36849/JDD.C702. <https://pubmed.ncbi.nlm.nih.gov/34231998/>

Rhinophyma is a disfiguring disorder that is characterized by an erythematous, hypertrophied, and inflamed lower two-thirds of the nose. Widely accepted as the severe form of acne rosacea, rhinophyma can result in functional, aesthetic, and psychosocial concerns that require treatment in a cosmetic fashion. Rosacea should be treated in its earliest manifestations to mitigate the progression towards rhinophyma; therefore, early detection and intervention is a crucial part of treatment. Little has been written on this subject in people of color. We present the first reported case of rhinophyma in a 62-year-old Fitzpatrick V female patient who was successfully treated with one session of fractional CO2 laser resurfacing. This case highlights the successful use of the fractional CO2 laser to treat rhinophyma in darker skin types (Fitzpatrick IV–VI) and underscores the potential for future use among patients of color.

Racial/ethnic variations in acne: Implications for treatment and skin care recommendations for acne patients with skin of color. Alexis AF, Woolery-Lloyd H, Williams K, et al. *J Drugs Dermatol.* 2021 Jul 1;20(7):716-725. doi: 10.36849/JDD.6169. <https://pubmed.ncbi.nlm.nih.gov/34232006/>

Background: Acne vulgaris is among the most common dermatologic diagnoses observed, including skin color (SOC) populations. This project sought to help clarify the existing published data and provide consensus statements on acne presentation, prevention, treatment, and maintenance in SOC populations to help improve patient outcomes. Methods: Six SOC dermatologists convened for a virtual meeting and used a modified Delphi process to address: 1) Are there racial/ethnic differences in the clinical presentation and sequela of acne? 2) Are there racial/ethnic differences in the therapeutic endpoint of acne treatment and patient expectations? 3) Is there a need for specialized approaches to therapeutic options and skincare in acne patients with SOC? The results of a literature review and the outcome of discussions, coupled with the panel's expert opinion and experience, are intended for health care providers caring for acne patients and clinician-researchers. Results: Racial/ethnic differences in the clinical presentation, sequelae, and desired treatment outcomes for acne have been reported. Notwithstanding limitations in the number, size, and methodologies of studies to date, the available data suggest that strategies that improve outcomes in acne patients with SOC include: Early initiation and maintenance of treatment regimens and careful consideration of tolerability of active ingredients, vehicles, and dosing. Using pH-balanced, non-irritating cleansers and non-comedogenic ceramides containing moisturizers help minimize irritation or dryness. Conclusions: There a need for specialized approaches to therapeutic options and skincare in acne patients with SOC. OTC skincare products are recommended before and during prescription therapy and as part of a maintenance regimen.

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