



AARS **HOT TOPICS** MEMBER NEWSLETTER

American Acne and Rosacea Society
201 Claremont Avenue • Montclair, NJ 07042
(888) 744-DERM (3376) • info@aarsmember.org
www.acneandrosacea.org



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Industry News

Novan plans to complete development of SB204 acne candidate via third party funding and execution.

November 08, 2017. DermWire. Practical Dermatology.

<http://practicaldermatology.com/dermwire/2017/11/08/novan-plans-to-complete-development-of-sb204-acne-candidate-via-third-party-funding-and-execution/?c=111&t=>

Novan, Inc., has agreed in principle to a business structure that would enable further development and advancement of SB204 for the treatment of acne vulgaris via third party financing and third party execution of one additional Phase 3 pivotal trial that is required before the filing of a New Drug Application (NDA). The proposed Phase 3 trial would be executed by the third party's dermatology drug development team, which plans to utilize a clinical research organization with extensive dermatology clinical trial experience. Under the proposed transaction, a new entity established by the third party would provide both the necessary capital to fund and the clinical expertise to execute an additional Phase 3 pivotal trial for SB204. The financial return to the new entity would be a pre-determined multiple of the costs incurred to execute the trial, assuming successful completion of the trial and Novan's election to retain all rights to the asset. The new entity would also be entitled to a milestone payment upon NDA approval, as well as potential future sales-based milestone payments tied to the commercial success of SB204 and potential future payments related to certain agreed variations of SB204 that may be subsequently developed. If Novan does not make the election to retain the asset (SB204), the new entity would be granted an exclusive license to SB204 in all geographies apart from Japan, with proceeds from any monetization of the licensed technology being split between the new entity and Novan after returning a multiple of the execution costs to the new entity. In connection with the proposed transaction, the new entity would be granted an option to acquire shares of Novan's common stock (currently anticipated to be approximately 500,000 shares) at an exercise price determined by the trailing 30 day average just prior to the execution of definitive agreements. Having achieved an agreement in principle around the business terms of the transaction, the parties have entered into an exclusive negotiation period and anticipate finalizing binding definitive agreements for the proposed transaction and clinical trial execution following the parties' joint discussion of the Phase 3 pivotal trial protocol with the FDA in the first quarter of 2018. "The advancement of SB204 for the treatment of acne vulgaris is of critical importance to Novan and its shareholders," said G. Kelly Martin, Novan's Chief Executive Officer. "Reaching an agreement in principle to progress SB204 is a 'win/win' for Novan and our third party partner. The deal structure enables Novan to be the beneficiary of the potential successful completion of SB204's development without any direct (to Novan) financial or execution risk relating to the trial." Mr. Martin continued, "Additionally, we believe this creative structure will enable Novan to retain, with the completion of a successful trial and accepted NDA, a significant share of the net present value of SB204, when the value is calculated over the life of the molecule in the marketplace. "Lastly, the combination of the optionality on SB204 with the expansion of the nitric oxide technology into the areas of inflammatory skin diseases and virology allows Novan and its shareholders to have exposure to multiple therapeutic opportunities while distributing inherent drug development risk across a broader platform."

New Medical News

Topical 15% resorcinol for hidradenitis suppurativa: An uncontrolled prospective trial with clinical and ultrasonographic follow-up. Pascual JC, Encabo B, Ruiz de Apodaca RF, et al. *J Am Acad Dermatol.* 2017 Dec;77(6):1175-1178. doi: 10.1016/j.jaad.2017.07.008. <https://www.ncbi.nlm.nih.gov/pubmed/29132852>

To the Editor: Boer and Jemec first described the use of topical 15% resorcinol for hidradenitis suppurativa (HS) in a small retrospective study in 2010,¹ reporting a marked decrease in pain and mean duration of the lesions. In this study we assessed the effects of resorcinol in a prospective open trial in HS by using both clinical measures and ultrasonography. Ultrasound examination in HS provides anatomic information that is clinically unavailable and may be helpful for follow-up.^{2, 3} We recruited participants with Hurley stage I and II HS. Resorcinol was the only prescribed treatment, and participants applied it twice daily for 30 days. We selected a single lesion (≤ 20 mm in size) per participant for study inclusion (fistulous lesions were excluded). Each participant was evaluated at baseline and after 7 days and 30 days of treatment (Fig 1).

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Novel device-based acne treatments: comparison of a 1,450-nm diode laser and micro-needling radiofrequency on mild to moderate acne vulgaris and seborrhea in Korean patients through a 20-week prospective, randomized, split-face study. Kwon HH, Park HY, Choi SC, et al. *J Eur Acad Dermatol Venereol.* 2017 Nov 24. doi: 10.1111/jdv.14714. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29178495>

BACKGROUND: While device-based acne treatments are widely applied for patients not tolerating conventional medications, related controlled studies have been still limited. Recently, non-ablative 1,450-nm diode laser (DL) and fractional micro-needling radiofrequency (FMR) have been effectively used for acne, in addition to well-recognized dermal remodeling effects. **OBJECTIVE:** To compare the clinical course for acne treatment between DL and FMR. **METHODS:** Twenty five Korean patients with mild to moderate facial acne completed treatments with DL and FMR through a 20-week, randomized split-face study. One randomly assigned half side of each patient's face received DL and the other side by FMR. Treatments were scheduled to receive three consecutive sessions at 4-week intervals. Objective assessments including revised Leeds grades, lesion counts, sebum output measurements, and patients' subjective satisfaction were investigated. **RESULTS:** Both DL and FMR demonstrated steady improvement of acne and seborrhea during treatment sessions. While results between two devices were similar during treatment sessions, FMR was superior to DL in the 12-week follow up. Patients' subjective assessments for seborrhea improvement were similar between two devices, while those for acne, skin texture, and acne scars were more satisfactory for FMR. For safety profile, no significant difference was observed between two regimens, while mild post inflammatory hyperpigmentation was observed only in DL side. **CONCLUSION:** Both DL and FMR demonstrated efficacies for acne and seborrhea, with reasonable safety profile. FMR was more effective than DL for the long-term maintenance, and subjective assessments for texture and scar improvements. Therefore, a few sessions of these devices would be a viable option for acne treatments.

Comparative study of buffered 50% glycolic acid (pH 3.0) + 0.5% salicylic acid solution vs Jessner's solution in patients with acne vulgaris. In Jae J, Dong Ju H, Dong Hyun K, Yoon MS, Lee HJ. *J Cosmet Dermatol.* 2017 Nov 21. doi: 10.1111/jocd.12445. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29164826>

BACKGROUND: Superficial chemical peels are frequently used in acne vulgaris treatment. Although glycolic acid (GA) has been widely used in clinical practice, its pH ranges from 0.08-2.75 and thus should be neutralized after application to avoid burns. **OBJECTIVE:** To evaluate treatment efficacy and safety of chemical peeling using buffered 50% GA (pH 3.0) + 0.5% salicylic acid (SA) solution that does not need to be neutralized in the treatment of acne vulgaris compared to the conventional peeling using Jessner's solution. **METHODS:** We performed a prospective, randomized, evaluator-blind, split-face clinical trial. Twenty patients were randomized by assigning one side of each patient's face to receive a 50% GA (pH 3.0) + 0.5% SA peel (GA side) and the other side to receive the Jessner's solution (Jessner's solution side). All patients underwent 2 sessions of treatment spaced 2 weeks apart. Lesion count, acne severity, subjective efficacy assessment, and side effects were evaluated. **RESULTS:** The total lesion count was significantly reduced for the GA and Jessner's solution sides ($P < .001$). However, there was no significant difference in the total lesion count, acne severity, or subjective efficacy assessment between the 2 sides ($P > .05$). The GA side had fewer side effects than the Jessner's solution side. **CONCLUSION:** The results of this study suggest that chemical peeling using the 50% GA (pH 3.0) + 0.5% SA solution can be as effective and convenient as the conventional peeling using Jessner's solution in the treatment of acne vulgaris and may show fewer adverse events than the conventional peeling.

Serum homocysteine levels in acne patients. Jiang H, Li C, Wei B, et al. *J Cosmet Dermatol.* 2017 Nov 21. doi: 10.1111/jocd.12456. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29159884>

OBJECTIVE: This study was designed to investigate serum homocysteine (HCY) levels in acne patients. **METHODS:** Acne patients ($n = 124$) and healthy volunteers ($n = 70$), matched in terms of both age and sex, were enrolled. Serum HCY levels for all subjects were measured by a clinical laboratory. **RESULTS:** Serum HCY levels in male and female patients with severe and moderate acne were significantly higher than in the healthy control group ($P < .05$). The constituent ratio of male and female acne patients with HCY above the normal range (10 mmol/L) was significantly higher than the healthy control group. The severity of acne patients was positively correlated with serum homocysteine concentration, ($P < .01$). **CONCLUSION:** Hyperhomocysteinemia may be an independent risk factor for acne vulgaris. Detection of serum HCY is important for acne patients.

An extension of a multicenter, randomized, split-face clinical trial evaluating the efficacy and safety of chromophore gel-assisted blue light phototherapy for the treatment of acne. Nikolis A, Fauverghe S, Scapagnini G, et al. *Int J Dermatol.* 2017 Nov 20. doi: 10.1111/ijd.13814. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29152718>

A variety of laser/light-based devices have been reported to be effective for the treatment of acne, yet no long-term data on efficacy and safety have been published. A first 12-week clinical trial ("Main trial") recently demonstrated that the KLOX BioPhotonic System, an LED blue light device using photo-converter chromophores, can significantly improve moderate and severe facial acne vulgaris with an excellent safety profile. This Extension trial followed the Main trial, using the same BioPhotonic System, with the same dose and instructions for use, on patients having already completed treatment in the Main trial. Main objectives of this open-label long-term extension 12-week study

were to evaluate the efficacy of the KLOX BioPhotonic System on the untreated hemiface during the Main trial, as well as the duration of response on the hemiface treated during the first 12-week Main trial. Despite their young age (mean age: 21.6 years) and their 12-week participation in the Main trial, 49 (54.4%) of the total number of patients who participated in the Main trial enrolled in this additional 12-week Extension trial. Baseline grading of acne was performed with the Investigator's Global Assessment (IGA) scale. For each patient, the hemiface randomly selected as a control during the Main trial received 6 weeks of treatment (twice weekly) and was then followed up for an additional 6 weeks. The first hemiface treated in the Main trial was consequently observed throughout the Extension trial, allowing for a further 12-week assessment of outcomes (total 24 weeks). In light of an additional 12 weeks of treatment on the contralateral face, the patient compliance rate was excellent, with 91.9% of the total number of patients receiving at least 80% of the treatments. Patients with a baseline IGA grade of 2 (mild) on the treated hemiface demonstrated a success rate of 58.3 and 66.7% at weeks 6 and 12, respectively. At these same time points, subjects with a baseline IGA grade of 3 (moderate) demonstrated a success rate of 81.8 and 90.0%. Patients with a baseline IGA grade of 4 (severe) demonstrated a success rate of 100% at both week 6 and week 12. When evaluating the originally treated hemifaces from the Main trial, the rate of return to baseline at 24 weeks was calculated to be 15.5%. This latter outcome confirmed the long duration of effect following treatment. The patient safety profile was also excellent, with very few related adverse events. The BioPhotonic System, which is comprised of LED blue light phototherapy and photo-converter chromophores, provides long-term efficacy and safety in the treatment of acne vulgaris, with a rate of compliance above what is generally observed in a young population of patients suffering from acne vulgaris, especially in light of sequential enrollment in a study treating one hemiface.

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Clinical behavior of a cohort of adult women with facial acne treated with combined oral contraceptive: ethinylestradiol 20 µg/dienogest 2 mg. Palacio-Cardona J, Caicedo Borrero DM. *Int J Womens Health*. 2017 Nov 16;9:835-842. doi: 10.2147/IJWH.S139289. eCollection 2017. <https://www.ncbi.nlm.nih.gov/pubmed/29180907>

Acne vulgaris is the most common skin disease. It affects the young adult female population and generates great impact on physical and mental health. One of the treatments with good results for affected women is combined oral contraceptive pills (COCPs). The aim of this study was to determine the clinical effect of facial acne management with ethinylestradiol 20 µg/dienogest 2 mg in a cohort of Colombian adult women. A cohort of 120 female university students was followed for 12 months. These participants were enrolled in the Sexual and Reproductive Health Program of the Santiago de Cali University. This cohort admitted women between 18 and 30 years old who had chosen to start birth control with ethinylestradiol 20 µg/dienogest 2 mg COCPs, did not have contraindications to the use of COCPs, and had been diagnosed with acne. Monthly monitoring of facial acne lesion count was performed. Relative changes in facial lesion count were identified. At the end of follow-up, the percentage of reduction of lesions was 94% and 23% of women had a 100% reduction in acne lesions. In conclusion, the continued use of the ethinylestradiol 20 µg/dienogest 2 mg COCPs reduced inflammatory and non-inflammatory acne lesions in reproductive-age women between 18 and 30 years of age with no severe acne.

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Diagnostic accuracy of pediatric teledermatology using parent-submitted photographs: A randomized clinical trial. O'Connor DM, Jew OS, Perman MJ, et al. JAMA Dermatol. 2017 Nov 15. doi: 10.1001/jamadermatol.2017.4280. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/?term=Diagnostic+Accuracy+of+Pediatric+Teledermatology+Using+Parent-Submitted+Photographs>

IMPORTANCE: Advances in smartphone photography (both quality and image transmission) may improve access to care via direct parent-to-clinician telemedicine. However, the accuracy of diagnoses that are reliant on parent-provided photographs has not been formally compared with diagnoses made in person. **OBJECTIVE:** To assess whether smartphone photographs of pediatric skin conditions taken by parents are of sufficient quality to permit accurate diagnosis. **DESIGN, SETTING, AND PARTICIPANTS:** A prospective study was conducted among 40 patient-parent dyads at a pediatric dermatology clinic at the Children's Hospital of Philadelphia from March 1 to September 30, 2016, to assess concordance between diagnoses made by an independent pediatric dermatologist based on in-person examination and those based on parental photographs. Half of the patient-parent dyads were randomized for a secondary analysis to receive instructions on how best to take photographs with smartphones. Clinicians were blinded to whether parents had received photography instructions. **EXPOSURES:** Half of the patient-parent dyads received a simple, 3-step instruction sheet on how best to take photographs using a smartphone (intervention group); the other half did not (control group). **MAIN OUTCOMES AND MEASURES:** Concordance between photograph-based vs. in-person diagnosis in the intervention vs. control groups, as quantified using Cohen κ , a measure of interrater agreement that takes into account the possibility of agreement occurring by chance. **RESULTS:** Among the 40 patient-parent dyads (22 female children and 18 male children; mean [SD] age, 6.96 [5.23] years), overall concordance between photograph-based vs. in-person diagnosis was 83% (95% CI, 71%-94%; $\kappa = 0.81$). Diagnostic concordance was 89% (95% CI, 75%-97%; $\kappa = 0.88$) in a subgroup of 37 participants with photographs considered of high enough quality to make a diagnosis. No statistically significant effect of photography instructions on concordance was detected (group that received instructions, 85%; group that did not receive instructions, 80%; $P = .68$). In cases of diagnostic disagreement, appropriate follow-up was suggested. **CONCLUSIONS AND RELEVANCE:** Parent-operated smartphone photography can accurately be used as a method to provide pediatric dermatologic care. **TRIAL REGISTRATION:** clinicaltrials.gov Identifier: NCT03246945.

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Using normal and high pulse coverage with picosecond laser treatment of wrinkles and acne scarring: Long term clinical observations. Dierickx C. Lasers Surg Med. 2017 Nov 15. doi: 10.1002/lsm.22763. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29140537>

OBJECTIVE: The picosecond 755 nm alexandrite laser using a diffractive lens array has demonstrated consistent clinical efficacy for improving the appearance of acne scarring and wrinkles amongst other benefits. This small pilot study is to assess the difference, if any, in clinical benefit if a higher than the standard protocol for number of pulses delivered to a tissue area is used compared to the standard protocol guidelines. **METHOD:** Seven subjects received treatment to one side of the face with a standard protocol number of laser pulses with the other side of the face receiving higher than standard number of pulses from the same 755 nm picosecond laser using an additional diffractive lens array. Photographs at final follow up were compared to baseline by two blinded Board Certified Dermatologists and assessed for improvements to acne scarring using a 6-point grading score, for wrinkles using the Fitzpatrick Wrinkle & Elastosis 3-point grading scale and a Global Aesthetic Improvement Scale assessment.

Subjects also completed a satisfaction questionnaire. RESULTS: For the acne scarring subjects, the average improvement from baseline to final follow up was 4.0 +/- 1.0 for the standard treated side and 4.5 +/- 0.5 for the high pulse side. There was no statistically significant difference between the two treated sides ($P > 0.05$, $n = 3$ paired t-test). For the wrinkle subjects, the average grading of the standard pulse side improved from 2.0 +/- 0.82 to 1.75 +/- 1.0 from baseline to final follow-up. The high pulse side improved from 1.5 +/- 1.0 to 1.125 +/- 0.25 from baseline to final follow-up. There was no statistically significant difference between the improvement of the standard and high pulse treatment sides ($P > 0.05$, $n = 4$ paired t-test). The comparison of baseline to final follow-up images of each subject found both sides to be Much or Very Much improved with no statistically significant difference between the standard and high pulse sides ($P > 0.05$, $n = 7$ paired t-test). Six of the seven subjects did not note any difference between the effect on different sides of the face and four of the seven rated their overall improvement after treatment as Good, three subjects as Reasonable and one subject with Slight Improvement. All subjects found the treatment comfortable and easy to tolerate and there was no increased incidence of side effects other than the mild occurrences typically observed for this type of treatment. CONCLUSION: This is a small pilot study with limited subject numbers and further data is needed to be able to make firm conclusions of observed trends, which suggest that the use of higher than standard suggested protocol number of pulses with the diffractive lens array and the 755 nm picosecond laser does not appear to offer any additional benefit over that that can already be achieved with the standard number of pulses, but also does not increase risk of detrimental post treatment effects either.

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Decrease in diversity of propionibacterium acnes phylotypes in patients with severe acne on the back.

Dagnelie MA, Corvec S, Saint-Jean M, et al. Acta Derm Venereol. 2017 Nov 14. doi: 10.2340/00015555-2847. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29136261>

Propionibacterium acnes, a major member of normal skin microbiota, is subdivided into 6 phylotypes: IA1, IA2, IB, IC, II and III. This study investigated P. acnes subgroups on the face and back in patients with severe acne and in healthy controls. In 71.4% of patients with severe acne, P. acnes phylotypes were identical on the face and back, whereas this was the case in only 45.5% of healthy controls. The healthy group carried phylotypes IA1 (39.1%) and II (43.4%), whereas the acne group carried a high predominance of IA1 (84.4%), especially on the back (95.6%). In addition, the single-locus sequence typing (SLST) method revealed A1 to be the predominant type on the back of patients with acne, compared with a wide diversity in the healthy group. We report here that severity of acne on the back is associated with loss of diversity of P. acnes phylotype, with a major predominance of phylotype IA1. The change in balance of cutaneous P. acnes subgroups might be an inducing factor in the activation of P. acnes, which could trigger inflammation.

Longitudinal observational study of hidradenitis suppurativa: impact of surgical intervention with adjunctive biologic therapy.

Shanmugam VK, Mulani S, McNish S, et al. Int J Dermatol. 2017 Nov 11. doi: 10.1111/ijd.13798. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29130482>

BACKGROUND: Hidradenitis suppurativa (HS) is a chronic inflammatory disease of the apocrine sweat glands affecting 1-4% of the population. While surgical excision is a mainstay of therapy, lesions often recur. Biologic therapies, including tumor necrosis factor- α and IL-12/23 inhibitors, are effective for mild to moderate HS. However, longitudinal studies investigating biologic therapy in conjunction with surgery are limited. The purpose of this analysis was to investigate impact of surgery and biologic therapy on HS disease activity. METHODS: Data from 68

HS patients were analyzed. Outcome measures included hidradenitis suppurativa Sartorius Score (HSS), active nodule (AN) count, Hurley stage, and probability of achieving 75% reduction in active nodule count (AN75). RESULTS: Mean age was 40 ± 14 years; 66% were female and 72% were African American. Mean disease duration was 10 years, and Hurley stage III disease was seen in 63% of patients. Patients who received biologics had a larger drop in HSS and AN count than those who never received biologics ($P = 0.002$). Biologic treatment was associated with average reduction in 22 (15-29) HSS points ($P < 0.0001$). The effect of biologics was greater in patients who also underwent surgery ($P = 0.013$). Timing of biologics relative to surgery did not impact efficacy. Patients who received HS surgery with biologic therapy were most likely to achieve the AN75 ($P = 0.017$). CONCLUSIONS: In this diverse cohort of patients with severe HS, biologic therapy was associated with a more rapid decline in disease activity, with the greatest effect in patients who also underwent HS surgery.

A cross-sectional epidemiological study of hidradenitis suppurativa in an Irish population. Delany E, Gormley G, Hughes R, et al. J Eur Acad Dermatol Venereol. 2017 Nov 10. doi: 10.1111/jdv.14686. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29125658>

BACKGROUND: Hidradenitis suppurativa (HS), a chronic inflammatory disease that affects apocrine gland-bearing skin, has a significant impact on patient quality of life. Estimates of the epidemiologic prevalence of HS are highly variable, and clinical data on disease characteristics and patient burden of disease remain limited. OBJECTIVE: The primary objective of this study was to determine the number of patients with HS attending dermatology clinics in a hospital setting in Ireland (within a 6-month time period). Secondary objectives included the assessment of disease characteristics and the collection of patient responses on disease burden and work productivity. METHODS: This was an epidemiologic, non-interventional, cross-sectional study across 4 dermatology clinics in Ireland over a 6-month time period. The disease prevalence was estimated by calculating the percentage of total patients with a diagnosis of HS (the primary population) across the selected sites. Secondary analyses were performed using the full analysis set, which consisted of eligible adults (≥ 18 years of age) from the primary population who provided informed consent. Data from these analyses are presented as descriptive summary statistics, with the use of an analysis of covariance for continuous endpoints. RESULTS: The prevalence of HS across the 4 selected sites was estimated at 1.4% (95% CI, 1.24-1.62). One hundred fifty eligible patients comprised the full analysis set. The majority of participants were white (95%), female (70%), cigarette smokers (56%), and overweight or obese (body mass index ≥ 25 kg/m², 82%). Most patients presented with Hurley stage II (45%), and more than a third had a relative with HS (35%). Questionnaire responses revealed a profound impact on quality of life, including diminished work productivity and various psychological comorbidities. CONCLUSION: This study offers insight into the clinical features and disease burden of hidradenitis suppurativa in an Irish population. This article is protected by copyright. All rights reserved.

Population-based clinical practice research Datalink study using algorithm modelling to identify the true burden of hidradenitis suppurativa. Ingram JR, Jenkins-Jones S, Knipe DW, et al. Br J Dermatol. 2017 Nov 1. doi: 10.1111/bjd.16101. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29094346>

BACKGROUND: Epidemiology data regarding hidradenitis suppurativa (HS) are conflicting and prevalence estimates vary 80-fold, from 0.05% in a population-based study, to 4%. OBJECTIVES: To assess the hypothesis that previous population-based studies under-estimated true HS prevalence by missing undiagnosed cases. METHODS: We performed a population-based observational and case-control study using the UK Clinical Practice

Research Datalink (CPRD) linked to Hospital Episode Statistics data. Physician-diagnosed cases in CPRD were identified from specific Read codes. Algorithms identified unrecognized 'proxy' cases, with at least five Read code records for boils in flexural skin sites. Validation of proxy cases was undertaken with General Practitioner questionnaires to confirm criteria-diagnosed cases. A case-control study assessed disease associations. RESULTS: On 30 June 2013, 23,353 physician-diagnosed HS cases were documented in 4,364,308 research-standard records. 68,890 proxy cases were identified, reduced to 10,146 criteria-diagnosed cases after validation, extrapolated from 107 completed questionnaires (61% return rate). Overall point prevalence was 0.77% (95% CI 0.76% to 0.78%). An additional 18,417 cases had a history of 1-4 flexural skin boils. In physician-diagnosed cases, ORs for current smoker and obesity (BMI>30) were 3.61 (95% CI 3.44 to 3.79) and 3.29 (95% CI 3.14 to 3.45). HS was associated with type 2 diabetes, Crohn's disease, hyperlipidaemia, acne and depression and not associated with ulcerative colitis or polycystic ovary syndrome. CONCLUSIONS: Contrary to results of previous population-based studies, HS is relatively common, with a UK prevalence of 0.77%, one-third being unrecognized, criteria-diagnosed cases using the most stringent disease definition. If probable cases are included, HS prevalence rises to 1.19%.

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Clinical Reviews

Skin barrier and microbiome in acne. Rocha MA, Bagatin E. Arch Dermatol Res. 2017 Nov 17. doi: 10.1007/s00403-017-1795-3. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29147769>

Acne is an immune-mediated chronic inflammatory disease. Although several factors are involved in its pathophysiology, this process is not completely understood. Androgen hormone activity increases sebum production inside the pilosebaceous follicle, adjusting the environment for the development of Propionibacterium acnes which triggers inflammation. Knowing how others factors such as the skin barrier and microbiome are involved in acne, can help in understanding more about the disease and may help to conduct a better treatment.

Cutibacterium (formerly propionibacterium) acnes infections associated with implantable devices.

Gharamti AA, Kanafani ZA. Expert Rev Anti Infect Ther. 2017 Nov 10. doi: 10.1080/14787210.2017.1404452. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29125405>

Cutibacterium acnes (*C. acnes*), a Gram-positive biofilm-forming rod implicated in acne vulgaris, is increasingly recognized for its role in implant-associated infections. The diagnosis of *C. acnes* implant-associated infections remains challenging. The optimal treatment is a combination of both surgical intervention and antibiotic therapy. Areas Covered: In this review, we discuss the different types of implant-associated infections caused by *C. acnes*. We also highlight the clinical manifestations pertaining to the various sites of infection, and identify several risk factors previously reported in the literature. We then cover the diagnostic laboratory markers, such as IL-6 and AD-1, optimizing *C. acnes* recovery in culture, and the specific molecular techniques. Finally, we examine the various effective antibiotic regimens and identify some preventive methods against *C. acnes* infections. Expert Commentary: Biomarkers such as IL-6 and AD-1 should be further investigated for the diagnosis of *C. acnes* implant-associated infections. The use of 16S rRNA gene sequencing and other molecular techniques should be

further explored in this setting. Longer incubation periods should be requested whenever *C. acnes* infection is suspected. If the clinical suspicion is high, sonication of the excised implant should be encouraged. Research should focus on developing effective anti-biofilm agents. Finally, preventive methods such as hair removal prior to surgery should be further explored.

PRACTICAL MANAGEMENT OF ACNE FOR CLINICIANS An International Consensus from the Global Alliance to Improve Outcomes in Acne. Thiboutot DM, Dréno B, Abanmi A, et al. *J Am Acad Dermatol*. 2017 Nov 7. pii: S0190-9622(17)32603-8. doi: 10.1016/j.jaad.2017.09.078. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29127053>

INTRODUCTION: Acne is a chronic inflammatory skin disease that is estimated to affect the approximately 85% of the population at some point in their lives.¹ Generally straightforward to recognize clinically, acne has a variable presentation with a constellation of lesion types including open and closed comedones, papules, pustules, nodules, and cysts.^{1, 2} The face is involved in the majority of cases, and the trunk may also be affected in up to 61% of patients.³⁻⁶ Acne lesions can progress to scars and/or post-inflammatory hyperpigmentation (PIH) both of which can be very bothersome to patients.^{3, 7, 8} The pathogenesis is multifactorial, involving the hormonal influence of androgens along with excess sebum production, disturbed keratinization, inflammation, and stimulation of the innate immune system by several pathways including hypercolonization by *Propionibacterium acnes*.⁹⁻¹¹ Although acne is a very common disease, little time is spent on it in medical curricula even within dermatology modules.¹² In fact, dermatology education as a whole is lacking in medicine in some countries: as an example, 33 United States medical schools have no undergraduate dermatology programs, and more than half of American medical schools teach <10 hours of dermatology.^{12, 13} In Europe, which is home to 25,000 dermatovenereologists, teaching hours vary between 18 to 60 during medical undergraduate training; however, all medical schools teach Dermato-Venereology. Scientific advances are continually improving knowledge of acne and contributing to the refinement of treatment options; it is important for clinicians to regularly update their practice patterns to reflect current standards. The Global Alliance to Improve Outcomes in Acne is an international group of dermatologists with an interest in acne research and education that has been meeting regularly since 2001. As a group, we have continuously evaluated the literature on acne. We created Consensus Recommendations about acne management based on our experience and available research, which were published in two previous supplements to the *Journal of the American Academy of Dermatology*.^{9, 10} Outside of the Global Alliance, we have also each been involved in creating evidence-based national and international guidelines for acne management, including those published by the European Dermatology Forum (EDF), the Colegio Ibero-Latinoamericano de Dermatología (CILAD), the Indian Society Dermatology, Venereology and Leprosy, the Australasian Dermatological Society and the American Academy of Dermatology (AAD).^{3, 14, 15} In our experience, evidence-based guidelines and clinical consensus recommendations can be quite different. Evidence-based guidelines rate the quality of evidence supporting available treatment options, but do not strongly advise the clinician about creating a practical treatment approach. Clinical consensus recommendations utilize expert opinion/experience and focus more on the philosophy of treatment, the individual patient as well as clinical experience of what options work well in particular situations. In this supplement, we aimed to identify the core principles of an effective acne management strategy using the Delphi method to reach consensus. The goal was to help guide clinicians to understand efficient acne therapeutic strategies that could be readily implemented in the office. We particularly focused on areas where the existing evidence base is less robust and expert opinion could have a role in refining practice patterns.

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Rosacea and alcohol intake. Drago F, Ciccarese G, Herzum A, et al. J Am Acad Dermatol. 2017 Nov 7. pii: S0190-9622(17)32432-5. doi: 10.1016/j.jaad.2017.08.063. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29126626>

To the Editor: The paper by Li¹ on alcohol intake and risk for rosacea prompted us to make some considerations and report our experience. We previously showed that rosacea patients have a significantly higher prevalence of small intestinal bacterial overgrowth (SIBO) than controls and that SIBO eradication significantly improved their lesions.^{2,3} Later, we investigated the role of various microorganisms in rosacea, with a 3-year follow-up of patients that had been treated.⁴ Demodex folliculorum, Helicobacter pylori, and SIBO were examined and all played a pathogenic role; SIBO prevailed in papulopustular rosacea, H. pylori in erythrotelangiectatic rosacea, and D. folliculorum did not prevail in any type of rosacea examined. Importantly, of patients treated for SIBO, 87.5% maintained clinical remission after 3 years of follow-up, even when >1 triggering agents were initially present.⁴

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Management of severe acne vulgaris with topical therapy. Stein Gold L, Baldwin HE, Lin T. J Drugs Dermatol. 2017 Nov 1;16(11):1134-1138. <https://www.ncbi.nlm.nih.gov/pubmed/29141062>

Acne vulgaris (acne) is the most common skin disease we see in dermatology practice. Although rare in childhood, severe acne can affect up to 12% of the adolescent population. A chronic disease, it requires both aggressive management and effective maintenance strategies. Oral antibiotics, in combination with topical agents are recommended for treatment, with topical agents being continued as maintenance therapy to minimize resistance and recurrence. However, concerns with systemic side effects have recently resulted in a greater focus on the potential of fixed combination topical therapies to treat severe acne. Here we review the available clinical evidence. There are no studies investigating the use of fixed combination topical therapy exclusively in severe acne. However, studies assessing the treatment of moderate-to-severe acne include subpopulation data in severe patients. Adapalene 0.3%-benzoyl peroxide (BP) 2.5% was found to be effective in patients with severe acne, whereas the fixed combination with a lower concentration of adapalene (0.1%) was no more effective than vehicle. Clindamycin-BP 1.2%/3.75% gel and clindamycin-BP 1.2%/2.5% gel were both found to be effective in severe acne with an apparent BP-dose response. Clindamycin phosphate 1.2%-tretinoin 0.025% demonstrated similar efficacy in severe acne, but with little benefit over individual monads. Realistic topical treatment options now exist for the management of severe acne where patient and physician preference can impact positive outcomes.

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Lasers, light, and the treatment of acne: A comprehensive review of the literature. Tong LX, Brauer JA. J Drugs Dermatol. 2017 Nov 1;16(11):1095-1102. <https://www.ncbi.nlm.nih.gov/pubmed/29141057>

INTRODUCTION: Acne vulgaris is common dermatologic condition with an estimated prevalence of 70 to 87%. Acne has been shown to have a significant impact on patient quality of life and mental health, especially as inflammatory lesions typically occur on cosmetically sensitive areas with the potential for permanent scarring. There have been numerous advances in the treatment of inflammatory acne with light-based and laser devices. OBJECTIVE: To review the current evidence for light-based and laser treatments in the management of inflammatory acne. METHODS: An analysis was conducted of PubMed indexed English language literature

regarding management of inflammatory acne using light-based and laser treatments. **RESULTS:** Evidence for the utilization of laser and light-based therapy for acne was summarized in a comprehensive review. Laser and light-based treatment holds the advantages of improved patient compliance and safety profiles in comparison to pharmacologic therapy. Efficacy of device based treatment varied in comparison to standard topical treatment regimens, often more effective when used in combination therapy. Adverse effects reported were generally self-limited. **DISCUSSION:** These treatments do and will continue to play an important and enlarging role in the management of acne. Larger scale studies with standardization of treatment protocols are warranted.

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Comorbidities in rosacea: A systematic review and update. Haber R1, El Gemayel M2. *J Am Acad Dermatol.* 2017 Oct 26. pii: S0190-9622(17)32342-3. doi: 10.1016/j.jaad.2017.09.016. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/29107339>

BACKGROUND: Rosacea is linked to abnormalities of cutaneous vasculature and dysregulation of the inflammatory response. Recent reports on rosacea have shown a significant association with cardiovascular, gastrointestinal, and psychiatric diseases, all of which may affect morbidity and mortality among these patients. **OBJECTIVE:** To review available data regarding comorbidities associated with rosacea, discuss their pathogenesis, and highlight the evaluation of affected patients. **METHODS:** We performed a complete and systematic literature review in PubMed/Medline, Embase, and the Cochrane Collaboration databases, searching for all articles on possible associated diseases that have been reported with rosacea, with no limits on publication date, participant age, sex, or nationality. **RESULTS:** A total of 29 studies were included in this systematic review, including 14 case-control, 8 cross-sectional, and 7 cohort studies. Statistically significant association with rosacea has been mostly demonstrated with depression (n = 117,848 patients), hypertension (n = 18,176), cardiovascular diseases (n = 9739), anxiety disorder (n = 9079), dyslipidemia (n = 7004), diabetes mellitus (n = 6306), migraine (n = 6136), rheumatoid arthritis (n = 4192), *Helicobacter pylori* infection (n = 1722), ulcerative colitis (n = 1424), and dementia (n = 1194). **LIMITATIONS:** Limitations included the accuracy of the published data, potential patient selection, and possible confounding factors. The true nature of the drawn correlations is uncertain, and causality cannot be established. **CONCLUSIONS:** Rosacea is associated with a number of systemic disorders. Recognition of these conditions is critical to providing appropriate screening and management of affected patients.

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An atypical localized form of hidradenitis suppurativa of the jawline and neck mimicking severe cystic acne on presentation. Castrillón Velásquez MA, Kim M, Tan MH, et al. *Skin Appendage Disord.* 2017 Oct;3(4):215-218. doi: 10.1159/000477412. Epub 2017 Jun 14. <https://www.ncbi.nlm.nih.gov/pubmed/29177152>

Hidradenitis suppurativa (HS) is a chronic and debilitating suppurative disease primarily affecting the axillae, perineum, and inframammary regions, where apocrine sweat glands are present. However, HS can occur in atypical locations. We present an interesting case of a 40-year-old man who developed chronic painful subcutaneous nodules, deep sinus tracts, and abscesses involving the jawline and the anterior aspect of the neck as the only parts of the body affected and who responded satisfactorily to adalimumab and laser hair removal treatment. This case is relevant because it helps clinicians to remember that HS may be isolated to atypical locations, such as the anterior aspect of the neck and chin. It also supports another possible HS pathogenesis which consists of the occlusion of terminal hair follicles rather than being essentially a disorder of the apocrine glands.

Algorithm for acne treatment: Ibero-Latin American consensus. Bagatin E, Florez-White M, Arias-Gomez MI, Kaminsky A. *An Bras Dermatol.* 2017 Sep-Oct;92(5):689-693. doi: 10.1590/abd1806-4841.20177003. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5674704/>

Acne is a chronic, immune-mediated, inflammatory disease with high prevalence among adolescents. By compromising face, thorax and back, with the risk of permanent scars, it has a negative impact on the quality of life. Effective, safe and early treatment is the key to remission, while decreasing the risk of physical and/or emotional sequelae. The Iberian-Latin American Group of Acne Studies joined professionals with expertise and developed a practical therapeutic algorithm, adapted to the reality of Latin American countries, Spain and Portugal. This article intends to disseminate it with an updated review on a rational, safe and effective acne treatment.

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Patient Counseling/Communication

Recommending efficacious cleansers for your patients. By Leslie S. Baumann, MD. November 14, 2017 http://www.mdedge.com/edermatologynews/article/151998/aesthetic-dermatology/recommending-efficacious-cleansers-your?oc_slh=40f65945dd3fe49f313534e23f36701bff77271d67beb261329378bb42086fd9&channel=177&utm_source=News_DERM_eNL_112817_F&utm_medium=email&utm_content=Stem%20cells%20spark%20successful%20skin%20regeneration

Cleansing is one of the most important steps in any skin care routine, but the surfeit of products on the market can lead to patients selecting an inappropriate cleanser for their skin type. This can engender various adverse cutaneous effects, including xerosis, flaking, acne, and flare-ups of chronic skin conditions such as eczema and rosacea. For example, acne medications are better tolerated when the proper cleanser is used. Cleanser choice is particularly important for individuals with dry skin who have an impaired barrier and those with sensitive skin who are susceptible to inflammation. The following discussion focuses on the factors that practitioners should address with patients when recommending cleansing products to help them maximize their outcomes and maintain clear, healthy-looking skin.

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Debunking acne myths: Does back acne need to be treated? November 1, 2017. *Cutis.* <http://www.mdedge.com/cutis/article/150864/acne/debunking-acne-myths-does-back-acne-need-be-treated?channel=171>

Myth: Back acne will clear on its own. Patients with back acne may not seek treatment options because they assume it will clear on its own; however, deep painful lesions typically require treatment by a dermatologist. Mild to moderate cases may respond to less aggressive over-the-counter treatments but also may benefit from a combination of topical and systemic antibiotic therapies. According to James Q. Del Rosso, MD, a dermatologist in Las Vegas, Nevada, "Many dermatologists believe that truncal acne vulgaris warrants use of systemic antibiotic therapy, which may not necessarily be the case, especially in patients presenting with mild to moderate acne

severity.” Cases of deep inflammatory acne on the back often warrant using systemic therapies such as oral isotretinoin. These severe cases may be less responsive to standard therapies and may require repeated treatment. Although back acne is not as cosmetically visible as facial acne, it has been associated with sexual and bodily self-consciousness in both males and females. Preliminary data from one study showed that 78% of patients with truncal acne (n=141) on the back and/or chest indicated they were definitely interested in treatment, but truncal acne was not mentioned by these patients without direct inquiry from a physician. As a result, it may be beneficial for dermatologists to ask acne patients about lesions presenting on the back and inform them that treatment options are available. Treatment application also is a consideration for back acne. Benzoyl peroxide cleanser/wash formulations are convenient, and the foam formulation of clindamycin phosphate allows for easy use due to its spreadability, rapid penetration, and lack of residue and fabric bleaching. It is important to inform patients that back acne can flare even during active treatment. Patients should be instructed to wear loose-fitting clothes made of cotton or other sweat-wicking fabrics when working out and to shower and change clothes immediately after. Sheets and pillowcases should be changed regularly to avoid exposure to dead skin cells and bacteria, which can exacerbate acne on the back. Backpacks and handbags also can rub against the skin on the back, causing acne to flare. As an alternative, patients should be encouraged to carry handheld bags or bags with shoulder straps to avoid irritation of the skin on the back.

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