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Bioscreen : An Innovative Approach to a Common Disease

Acne is ubiquitous and nondiscriminatory, affecting nearly all ages and races. Furthermore, it is by no means a harmless condition. It has the potential to leave permanent scars on the skin of those affected and is associated with increased psychological morbidity. The exact prevalence of acne is difficult to discern because statistical accuracy is compromised by a lack of criteria uniformity in describing the disease. Recent studies have estimated that 45 million people in the United States from the age of 12 to 44 have acne. Almost 90% of this number is composed of individuals aged 12 to 24. Studies which have employed the Leeds Acne Grading scale estimate that greater than 90% of males and 80% of females will be affected by acne by 21 years of age. The majority of adult acne is persistent from earlier years, but may present as late-onset acne. Also, up to 85% of women over the age of 25 report premenstrual increases in their acne severity. Interestingly, it has been shown that less than one third of those with acne will actually pursue professional medical treatment.

The key to the successful treatment of acne is a keen understanding of the pathogenesis that leads to clinically apparent lesions. Acne is a multifactorial disease of the pilosebaceous unit. This unit includes a hair follicle, hair shaft and sebaceous gland. Acne can be categorized as *non-inflammatory* lesions including opened/closed comedones or *inflammatory* lesions which include pustules, papules and cysts. There are four factors that have been identified as essential to the development of acne lesions in the pilosebaceous unit. These include follicular epidermal hyperproliferation, excess sebum production, presence and activity of Propionibacterium acnes and inflammation. Follicular epithelial hyperproliferation and alteration of keratinocyte desquamation is considered the first step in the pathogenesis of acne. This results in an accumulation of keratinocytes and an eventual follicular plugging.

The stimulus of this hyperproliferation has not been clearly established, but interleukins, changes in linoleic acid concentrations and androgens have all been implicated in this process. The onset of acne typically occurs during adrenarche at an average of eight years of age. During this time the body experiences a substantial increase in the production of androgenic hormones. Androgens in the circulation are taken up locally into the cells of the pilosebaceous unit where they are metabolized. This metabolism stimulates sebum production locally and also results in increases in the number of sebaceous lobules and the size of the follicle. This process creates the environment for a microcomedo. Sebum has both comedogenic and irritant qualities. Higher sebum secretion rates are associated with higher levels of P. acnes densities and a more severe clinical picture of acne. The clinically evident lesions of acne develop when the pilosebaceous unit filled with sebum and keratin becomes inhabited by P. acnes. P. acnes

is a gram positive, anaerobic commensal skin organism that is found in high numbers in sebaceous regions and is the most prevalent organism found in acne lesions. P. acnes creates by-products that are proinflammatory and act as chemotactic factors. These by-products include lipases, proteases, and hyaluronic acid. They work by surrounding the pilosebaceous unit, diffusing through the follicular wall and producing enzymes that are destructive to the natural follicle barrier. Various studies have shown that the severity of acne is related to the interactions between bacteria and the body's immune response. It also creates this immune response by recruiting CD4 lymphocytes and neutrophils. These neutrophils subsequently penetrate and weaken the wall of the follicle. The altered barrier eventually ruptures and allows more lipids, keratinocytes and bacteria to be released into the dermis. All of this results in an inflammatory foreign body reaction which clinically presents itself as acne.

Using the current understanding of acne pathogenesis, many different treatment modalities have been employed. The most common of which include antibiotics, retinoids and hormonal therapy. Topical antibiotics are both antimicrobial and weakly comedolytic. Systemic antibiotics decrease the inflammation and microorganisms that cause acne. While systemic antibiotics have proved to be important to acne treatment, long term antibiotic use has been documented to cause resistance in both the common microorganisms that contribute to acne and additional potentially harmful species. Specifically, concern over resistant species of Streptococcus pyogenes and Staphylococcus aureus makes using these antibiotics less ideal.

The treatment of acne has evolved in the last twenty-five years with the introduction of both topical and systemic retinoids. Although systemic retinoids target all four of the factors described above, they are well known for their long list of side effects including teratogenicity. In addition, various hormonal modalities including oral contraceptives have been employed in the treatment of acne. They work by decreasing circulating free testosterone. Spironolactone, which has anti-androgen effects, has also been effective in the treatment of acne. Spironolactone binds the androgen receptor which causes a reduction in androgen production. Both oral contraceptives and spironolactone may have stigmas that could prevent some patients from employing them in acne treatment.

The impetus for this clinical study arose from the problems with current popular treatments, creating a desire for new and potentially better tolerated treatment modalities. We introduce the agent Bioscreen to the world of acne treatment regimens. Bioscreen is an all natural antimicrobial and anti-inflammatory treatment that applies an innovative theory to acne eradication. The science behind bioscreen requires a different vocabulary from that which is commonly used when referring to antibiotics and microorganisms. Typical antimicrobial theory uses a language of proteins, enzymes, and DNA. However, Bioscreen operates at an electronic level and employs a language of protons, electrons, and water mediums. It works through a mechanism of bio-electric activities. Different microorganisms can be defined by their electronic and magnetic parameters. These parameters include protons, electrons, magnetic fields, coefficient of electrical resistance and the movement of microorganisms in association with all of these variables. The success of Bioscreen is a result of its ability to interfere with these specific parameters,

thus disrupting the electronic charge of the water environment of microorganisms. In part the Bioscreen strategy is based on the assumption that there is an intrinsic neutral property to water at the molecular level in the absence of microorganisms. Microorganisms alter this environment in a species and patient-specific manner, which increases the positive or negative charge of the water medium. In vivo studies have demonstrated that the antigenic ability of P. acnes is in part determined by its microenvironment. Bioscreen works through a mechanism of adjusting the water in the microenvironment to the opposite of that in which the organism flourishes, leaving the organism vulnerable.

Operating at a parallel level is the science employed in studying antimicrobials in the food industry. Technologies for inactivating microorganisms which colonize food consumed by the public use a process called pulsed electric fields (PEF). In this technology, which is currently being used to eradicate harmful organisms from consumer food products, the exact mechanism of antimicrobial inactivation is only minimally understood. The efficacy of PEF lies in the belief that when microorganisms are placed under substantial stresses, the energy the organism expends to overcome the hostile environment can lead to metabolic exhaustion and ultimately death. PEF consists of passing a short, high-voltage pulsed electric field through a liquid food which is held between two electrodes. PEF is hypothesized to cause irreversible electroporation of the cell membrane, causing intracellular components to leak from the cell. The outcome of the damage to the vital components of the cell is cell lysis and death. Although the antimicrobial mechanism differs from Bioscreen, the same theory of environmental manipulation is employed.

Clinical trials were performed with Bioscreen on 10 patients over the course of three months. All patients showed at least mild-moderate improvement, with no observed side effects or concerns from the study group. Each patient was treated by both topical and oral routes, with adjustments in the dosing regimen based on clinical results. We now describe three case reports, emphasizing the safety, efficacy, and tolerability of this new and exciting product, Bioscreen.

CASE 1:

A 21-year old Caucasian female presented with a 4-5 year history of acne. She had been an established patient of ours for over 2 years. Numerous acne regimens had been implemented, including topical benzoyl peroxide/clindamycin products, oral antibiotics, anti-bacterial cleansers, and chemical peels. She had noticed flares around her menstrual period, and was even counseled on potential Aldactone use. Similar to many acne patients, she has had periods of clearing, only followed up with bouts of flaring. She was placed on Bioscreen, with one pill by mouth daily and application of the topical product three times a day. The patient was given informed consent regarding this product, including education on the mechanism of action and expectations. A baseline picture was taken at this time (see Figure 1). Physical examination at baseline revealed many erythematous papules and pustules, with some cyst formation on her forehead and periorally. Scattered open and closed comedones were also present on exam. The patient was seen for follow-up weekly for the first month then biweekly for the next 2 months,

with pictures taken at each visit (see Figures 2-7). Even as early as one week (Figure 2) there was a dramatic decrease in both the number and size of inflammatory lesions. She continued to have improvement and clearing over time, mostly in regard to acne that was inflammatory in nature. At the end of the study (see Figures 6,7), she had minimal inflammatory lesions and only areas of post-inflammatory hyperpigmentation. Throughout the study, comedonal activity was decreased, although slight. She was very satisfied with the results and did not relate any side effects or complaints with use of the product. This patient continues to use Bioscreen both topically and orally as maintenance therapy to date.

FIGURE 1 - BASELINE

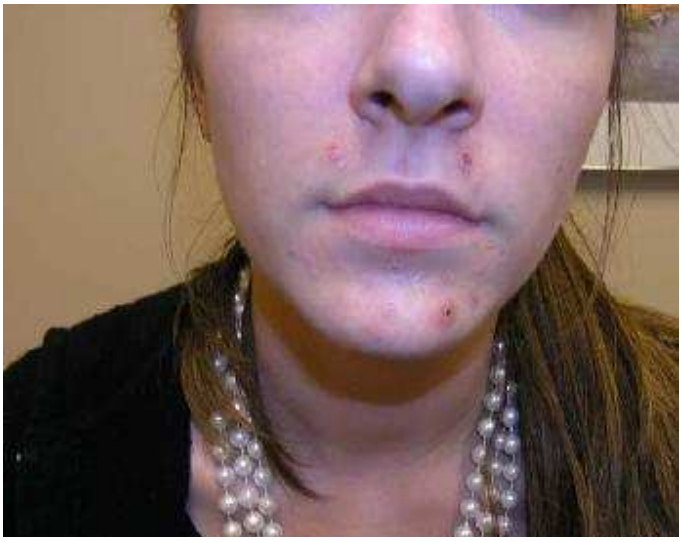


FIGURE 2 - BASELINE

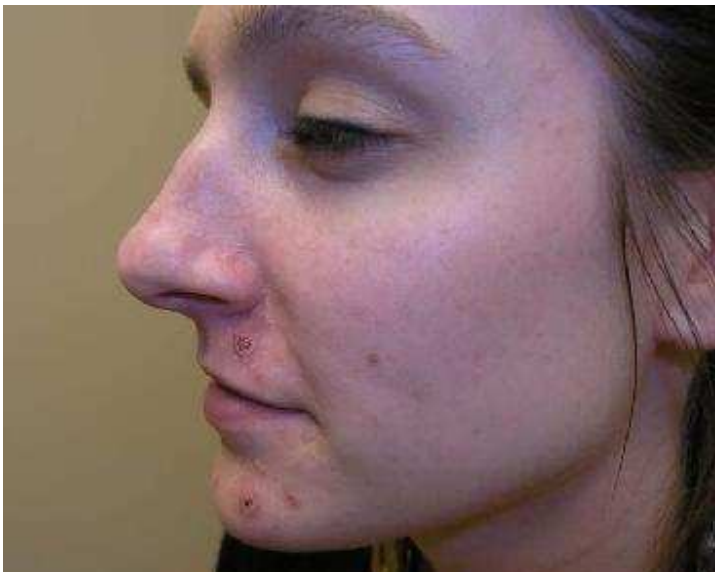


FIGURE 3 - ONE WEEK INTO TREATMENT

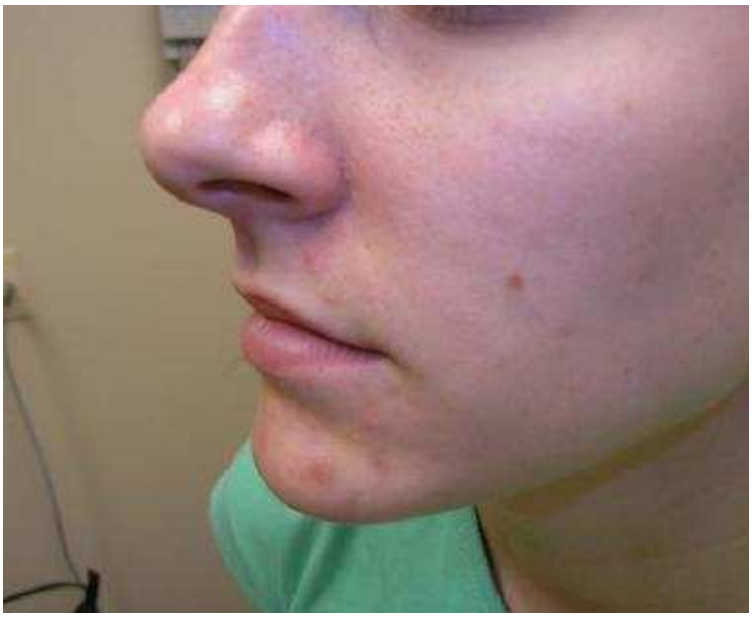


FIGURE 4 - TWO MONTHS INTO TREATMENT

FIGURE 5 - TWO MONTHS INTO TREATMENT

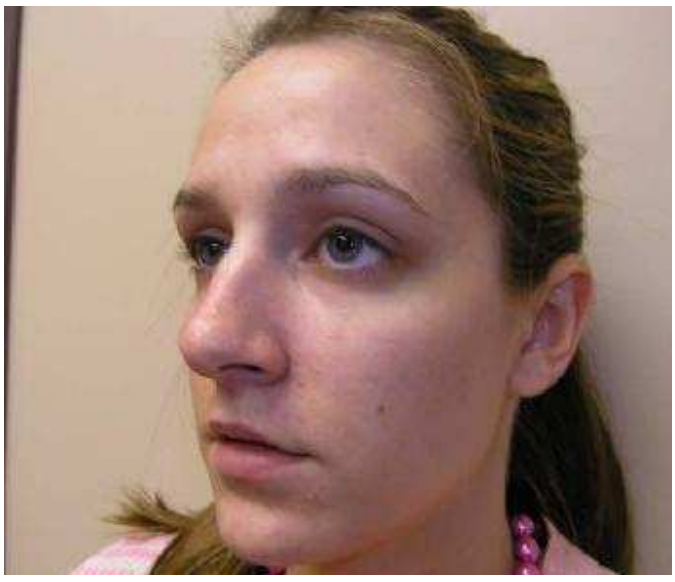


FIGURE 6 - THREE MONTHS INTO TREATMENT

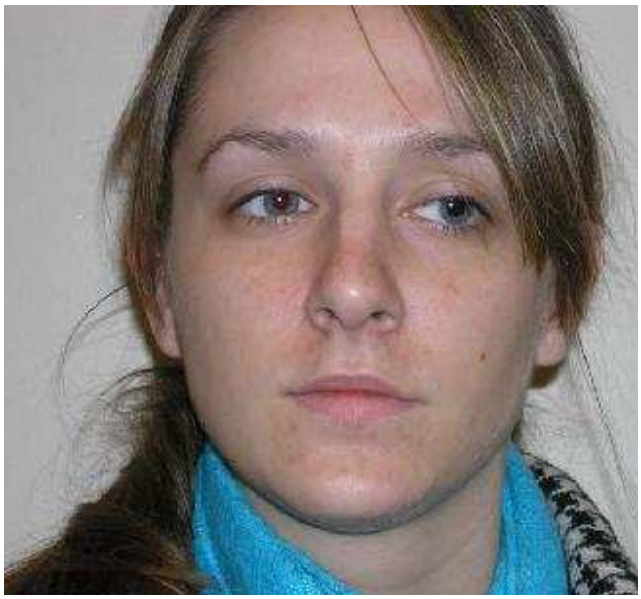
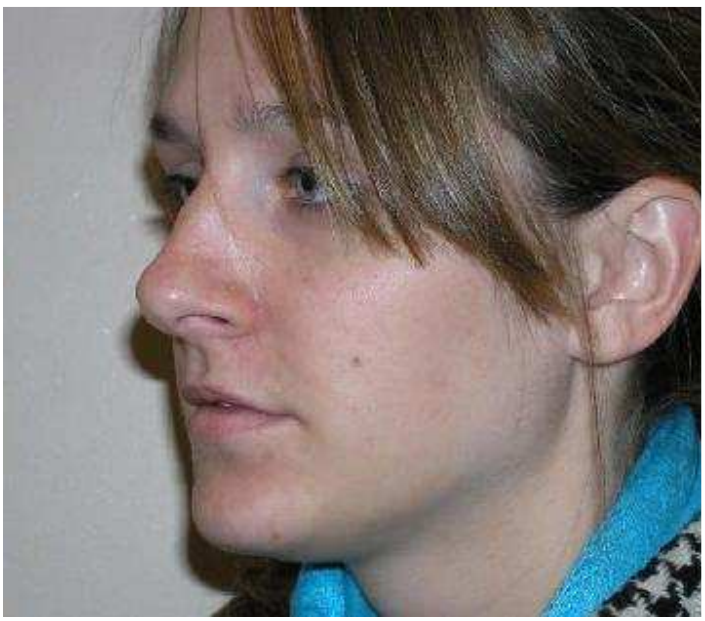


FIGURE 7 - THREE MONTHS INTO TREATMENT



CASE 2:

A 17 year-old Caucasian male presented with a one year history of acne. He had only tried OTC antibacterial washes and topical products without much benefit. The study parameters were discussed in detail with the patient, informed consent was provided, and he was started on Bioscreen. He was instructed to apply the topical solution three times daily and take the oral pill once a day. A baseline photograph was taken (see Figure 8). Physical examination showed multiple erythematous papules, pustules, and cysts with many open and closed comedones involving the cheeks, forehead, nose, chin and jawline. He was seen weekly for the first month and biweekly thereafter, and pictures were taken at each visit (see Figures 9-11). There was marked improvement in the inflammatory component of his acne, even after the first week (see Figure 10). Comedonal lesions were diminished in number, but not significantly. He continued to have marked reduction in inflammatory lesion count throughout the remainder of the study, particularly evident at the 2 month period (see Figure 11). There were no adverse effects reported. He too continues to use the product and is pleased with the success he is making.

FIGURE 8 - BASELINE

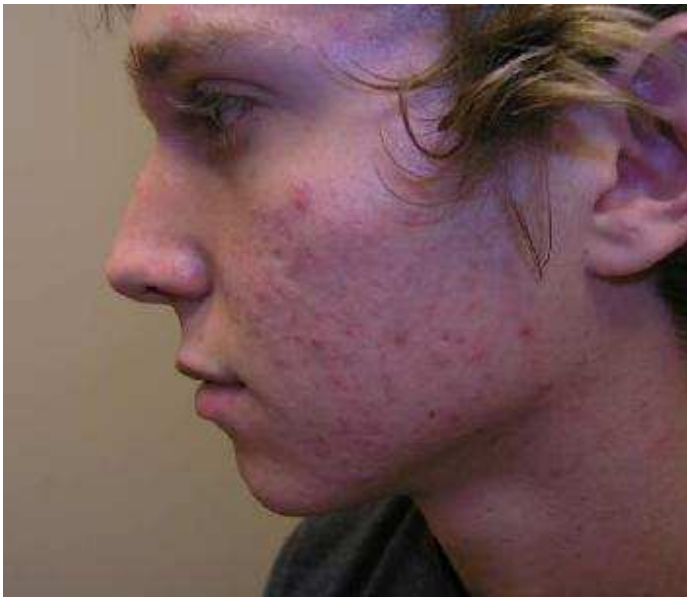


FIGURE 9 - BASELINE

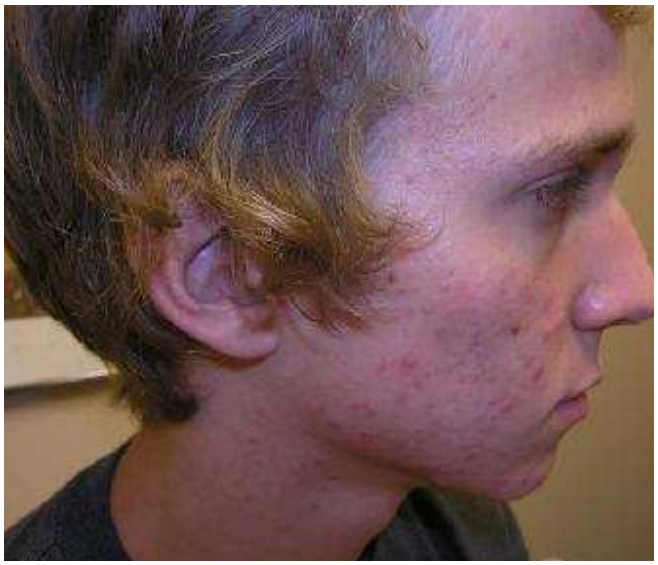


FIGURE 10 - ONE WEEK INTO TREATMENT

FIGURE 11 - TWO MONTHS INTO TREATMENT

CASE 3:

A 16 year-old Caucasian male presented with severe inflammatory acne for the past two years. He admits to using Proactive only, without much improvement. The study parameters were reviewed in detail with the patient and treatment was initiated with Bioscreen. Due to the severity at baseline, noting numerous erythematous papules, pustules and cysts (see Figure 12) covering most of the face, the patient was started on two pills daily and topical application 3 times daily. Progress was slow through 2 months, with some improvement noted in the overall inflammation, and oral therapy was increased to 3 pills twice a day. The response was dramatic over the next month (see Figure 13), with marked reduction in pustular and cystic acne lesion counts. The patient was extremely satisfied with the overall progress, denying any side effects, and continues Bioscreen to date.

FIGURE 12 - BASELINE

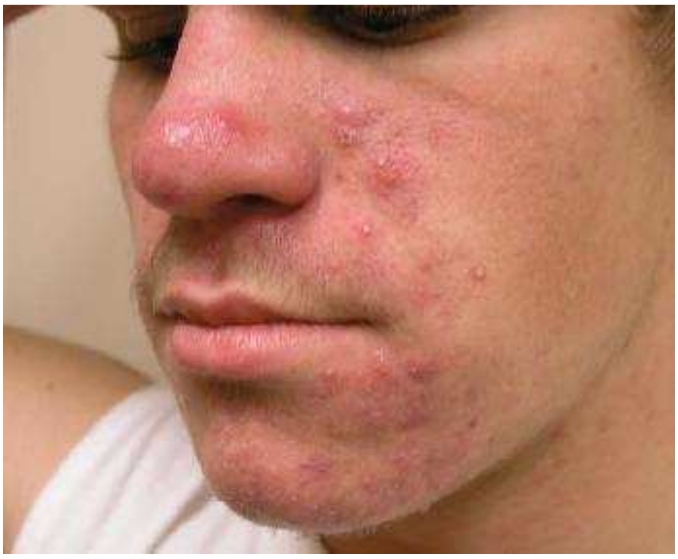


FIGURE 13 - THREE MONTHS INTO TREATMENT

Bioscreen is an appealing product on many levels. An understanding of the pathogenesis of acne, and the road blocks to effective treatment makes the use of Bioscreen a welcome innovation. The product is 100% natural, composed completely of non-toxic herbs and minerals, and has been determined "Generally Regarded as Safe" by the FDA. Bioscreen has no known side effects. Its mechanism of destruction has exhibited the ability to spare innate bacteria that normally live in the human body, such as Lactobacilli.

The product is 100% biodegradable and comes in a powder or liquid, and can be applied in various vehicles depending on the desired therapy. This versatility is ideal for dermatological applications. Our current clinical trials have shown positive outcomes, with a significant reduction in inflammatory acne. We believe that using this product in conjunction with a comedolytic agent will provide the best results for those patients with mixed inflammatory and comedogenic acne. Results to this date have been extremely promising and further study data will no doubt enhance the desirability of this treatment modality.

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