

## A new Product, BioCool®, Pested on Acne Vulgaris. Can it provide a Positive Clinical Effect?

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### Abstract

*The lack of effective treatment for acne vulgaris except for long periods of treatment with antibiotics, which increases the risk of developing resistance, is vulnerable. Bio Cool® which is a medical device that has been shown to kill microorganisms in topical treatment especially on the feet. In the present study evaluation was performed to find out whether the product BioCool® alleviates acne vulgaris. Number of acne papule decreased from  $25.4 \pm 12.4$  before the study was  $18.3 \pm 10.2$  after 30 days of treatment ( $p < 0.001$ ). Patients understated even minor symptoms with DLQ after treatment (from the media point 3, IQR 4 to 1.5, IQR 4,  $p < 0.002$ ). The study suggests that BioCool® can have a positive clinical effect of moderate acne vulgaris. Only mild side effects occurred*

**Keywords:** acne vulgaris, Propionibacterium acne, skin, treatment

### 1. Introduction

Acne vulgaris is a chronic inflammatory skin disease in thousands of skin pores. It is a complex reaction chain with increased sebum production and abnormal keratinization in the pore leading to the growth of *Propionibacterium acnes* triggering an immune reaction and inflammation in the skin pores and giving rise to lesions in the skin. (1,2)

*P. acne* an anaerobic gram-positive bacterium which prefer oxygen-poor environment, as is the case in skin pores. They are increasing in number and live on sebum produced by the sebaceous glands. *P. acne* itself is not harmful for the skin.

The diagnosis of acne vulgaris is often easy to put up with the right look with follicular lesions, the right age and the right localization (in the face and sometimes even on top of the chest, shoulders and back). For many of the vulnerable teenage period causes acne a severe psychosocial stress correlated to acne difficulty (3).

Treatment that works in the long term and provides good clinical effect is difficult to find on the market. Long courses of oral antibiotic treatment of acne have been used for over 50 years (5). The treatment is usually 3-6 months and repeated happily in periods when deterioration. It involves treatment with tetracycline is a broad-spectrum antibiotic that presents risks of resistance development in the use of oral therapy. Other local drugs for acne vulgaris often have side effects and skin irritation (1).

BioCool® is classified as a medical device Type 1. The product is CE marked and approved by the FDA. It has in previous study demonstrated that the product kills microorganisms in a release of oxygen molecules (9). The product has good clinical observed effect on nail fungus, athlete's foot and improves the symptoms of psoriasis. The theory is that the product is broken down to hydrogen peroxide and then free oxygen molecules. Hydrogen peroxide has an antibacterial effect and reduces the number of acne lesions (7).

The questions here raised is to evaluate whether the product BioCool® alleviates acne vulgaris and can daily topical application of the product BioCool® for a 30 day period relieve acne vulgaris?

### **Material and Method**

**Participant:** This pilot study consisted of a total of 16 patients, 2 males and 14 females. Mean age was 28.3 years. The study included men and women, previously healthy between 18-45 years not using contraception, is not breastfeeding or pregnant and have been diagnosed with moderate acne. Patients with ongoing treatment for acne vulgaris were excluded or treatment withdrawal one month before the start of the study. Also, patients who cannot follow instructions and who are assumed to have poor compliance were excluded.

**Statistical Methods:** Dropouts included in the result were 2 patients. These patients were followed up at the doctor's appointment number 2 and the results were included in the so-called "intention to treat" where the values produced two visits was the same for the coming weeks for follow-up visits. Here weret-test and Wilcoxon rank-sum testused.

**Treatment and follow-up:** On the first visit to a doctor, patients received the same information and instructions as given by the manufacturer BioCool®. Each patient received the product at home. The jars of powder were unmarked but if the patient wished to know the content they were informed. All processing is done at residences of the patient by the patient. The product was dissolved in water to form a solution to be used daily in the face. The product was applied to the face and washed away with tap water after 5 minutes. After about one hour the subjects could lubricate the skin with a moisturizing product, thus skin pores have time to close up for the additional product. Follow-up visits occurred weekly for four weeks. At each visit, the patient had completed the rating scale DLQ(Dermatology Life Quality Index) , they were photographed and put on an open interview.

**Photography:** Each patient was photographed prior to initiation of treatment and weekly for four weeks. Portrait photo is taken from the front and profile of each view of the face. Photos were taken with the same camera and the camera settings and the same person. The same light was used by 45-degree angle. However, technology is not validated and all the photos were not taken exactly the same. Each patient was encoded by the study manager with a number. After all the photos were taken counted outside observers (fellow doctor) number acnepapule for each patient for each visit without knowing the visit week it touched. Number of acne papules was summed frontal view, as well as the two side views. Results were calculated as an average of the number of acnepapule for each visit at the group level.DLQ survey summed with points for each patient for each visit. Even this was calculated with the average at group level.

DLQ (Dermatology Life Quality Index) is the first questionnaire designed specifically for skin diseases related to life and health. It is designed for people older than 18 years. It is validated. It can be used for 40 different skin diseases. The contents are 10 questions concerning symptoms and experience associated with skin disease. Acne disease affect quality of life and psychosocial well-being (3) It is possible answers for symptoms / feeling, "very much", "very", "little", "nothing at all". These questions concern the past week. (10). Patients filled in a questionnaire at each visit.

**Interview:** The patient's subjective experience was investigated with semi-structured interview based on the query field (11). The interview was conducted by research doctors. The text material was the question: How do you perceive the treatment? Follow-up question could be "Describe your feeling in the skin," "Can you give examples of the effect on the skin." After each follow-up visit the patient's response noted directly in the patient record. No recording method used. The texts were compiled and key words were taken out, for example, dryness, itching, burning, and the theme around the treatment procedure time-consuming and messy.

### **Results**

In the present study, 87.5% of subjects are women and the average age estimated to 28 years. Values for calculating acne papule was normally distributed and the average before starting treatment was 25.4 and after 4 weeks 18.3 i.e. a reduction and improvement in the number acnepapule. The result of the number of papulereduced over time was significant with p-value <0.001. (Table 1.). Table 1.Background data and results for DLQ symptom rating and papule counting for 4 weeks of treatment with Biocool®. Mean, median or percentage plus Standard Deviation or interquartile range p value are given.

Age 28 SD 7.4

Gender (% female) 87.5

**DLQ:**

Prior 3IQR4 .

After 4 weeks 1.5 IQR2 SD 0.002

**Papule estimation:**

Before 25.4 IQR 12.4

After 4 weeks 18.3 IQR 10.2 SD<0.001

DLQ values were not normally distributed and the median before the initiation of treatment was estimated at 3 and then after 4 weeks of treatment to 1.5. Interquartile range (IQR) 4 and 2 respectively with significant p-value of 0.002. (Table 1).

Number of acne papule declined over time and additionally estimated patient less points on the DLQ. (Table 1).

Dropouts: Two patients discontinued treatment after two weeks. One patient had more redness and itching on the skin which is why we stopped treatment. The second patient was traveling and could not complete the study. The loss was included in the result. These patients were followed up at the doctor's appointment number 2 and the results were included in the so-called "intention to treat".

During the patient interviews it was described the patients skin feeling cleaner, smoother, softer and firmer. Acne papule does not break out as often as before. They feel that they received less signs and symptoms of acne. Drawbacks are also mentioned by the subjects such as skin gets messy. The procedure is time-consuming and it is difficult to plan the time when the skin cannot moisturize until an hour afterwards. The skin feels very dry after application. The product cannot be applied directly to lesions due to risk of burning (Table 2).

Table 2. Interview. Summarizes patient's total experience for the four-week period of treatment with BioCool®.

Patients Keywords; experiencing treatment 1 Dry Consuming, 2 Smooth skin Good, 3 Burning Messy, 4 Dry Messy, 5 Smooth skin Good, 6 Smooth skin ( Good), 7 Smooth skin (Good), 8 Smooth skin (Good), 9 Dry (Messy), 10 Smooth skin (Messy), 11 Smooth skin (Messy), 12 Smooth skin (Messy), 13 Dry (Good), 14 Smooth skin (Good), 15 Dry (Messy), 16 Dry (Irritation).

**Discussion**

Number acne papule was clearly reduced and patients estimate fewer symptoms for each week under the DLQ. The most common side effect is dry skin according to the interview questions. In one study the effectiveness was analyzed and safety of different local agents (gel) for acne vulgaris and the number of acne papule was counted. The results showed that benzoyl peroxide 2.5% and clindamycin 1% was effective (number acne papule reduction) and the combination of benzoyl peroxide and nadifloxacin 1% showed better safety profile, statistically significant. In a third group tretinoin 0.025% and clindamycin 1% were analyzed. They found a statistically significant reduction in the number of acne papules in those treated with benzoyl peroxide and clindamycin. (12) In a randomized study the efficacy, safety and tolerability were analyzed of Adapalene and besoyl peroxide in patients with mild acne vulgaris. In both groups the number acne papules were significant reduced. Both treatments appear to be safe and effective in mild acne vulgaris. (13).

There are similarities in this pilot study and the aforementioned studies, which also have significant results in reducing the number of acne papules. BioCool® releases hydrogen peroxide which in turn decomposes to free oxygen molecules that kill anaerobic bacteria (7). In a randomized study it was looked at the difference in treatment between benzoyl peroxide and hydrogen peroxide cream to moderate acne vulgaris. The result showed that the hydrogen peroxide is at least as good and also better tolerance for skin (15). Perhaps BioCool® in formula cream gives similar results? It appears that patients think that the product is difficult to apply and powder is not as patient friendly as gel or cream which might be kinder to the skin. Additionally, one can consider adding the substance to increase effect of the treatment.

The product BioCool® has great development potential. Patients were very satisfied with the continuous medical attention and appreciate the expertise. They have better insight into their skin and have better hygiene routines. Using open questions patients have been telling about the experience, negative and positive effects. Some common keywords have been verified, which is strength. Dry skin was the most common effect of the treatment. However, it has the acne overproduction of sebum which is unfavorable for acne.

Dried out effect can be seen as a positive effect (8). One patient discontinued the study due to wrong diagnosis earlier. It is usual to be mistaken for acne rosacea (16). Photographing is performed with a non-standard approach, not validated, however, blinded which is a strength. DLQ survey has been used in previous research and validated (14).

### **Conclusion**

BioCool® can provide a clinical benefit over a four week period. The effect should be further evaluated in a randomized trial.

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