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ORIGINAL ARTICLE

Efficacy and tolerance of superoxidized solution in the treatment of mild to moderate inflammatory acne. A double-blinded, placebo-controlled, parallel-group, randomized, clinical trial

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Abstract

Introduction: Superoxidized solution (SOS) is an electrochemically processed aqueous solution manufactured from pure water and sodium chloride. Inflammatory skin disorders have all improved their outcomes with the use of SOS. These indications suggest that SOS could be useful in acne. *Methods*: A total of 89 patients were enrolled in this double blinded, clinical trial. Patients presented with 10–50 inflammatory lesions (papules and pustules) and an absence of nodulocystic lesions. *Results*: Improvement was excellent in nine patients (23%) using SOS, compared with five patients (21%) using benzoyl peroxide (BP) ($p = 0.378$); good in 21 patients (54%) using SOS and 12 patients (50%) using BP ($p = 0.794$), compared with four patients (18%) taking placebo ($p = 0.001$); and fair in six patients (15%) using SOS and five patients (21%) using BP ($p = 0.415$), compared with 12 patients taking placebo (55%) ($p = 0.014$). In three patients using SOS (8%) the response was poor, compared with two patients (8%) using BP ($p = 0.725$) and six patients (27%) taking placebo ($p = 0.075$). We did not need to change a dose during the study period and no systemic effect was observed. *Conclusions*: We found that SOS is an important choice to treat inflammatory acne, comparable with benzoyl peroxide; however, a larger sample is needed.

Key words: *Acne, benzoyl peroxide, superoxidized solution, treatment*

Introduction

Superoxidized solution (SOS) is an electrochemically processed aqueous solution manufactured from pure water and sodium chloride. During this electrolysis process, reactive species of oxygen and chlorine are formed. This reaction creates an unbalanced osmolarity that affects microbial homeostasis (1).

There are some reports showing the beneficial effects of SOS in other disorders besides infections. Skin ulcers, burns, peritonitis and inflammatory skin disorders (e.g. pemphigus, psoriasis) have all improved their outcomes with the use of SOS (2). Some of these indications imply that SOS could be useful in other inflammatory skin disorders such as eczema, acute contact dermatitis or even acne and rosacea.

Materials and methods

A total of 87 patients were enrolled in this randomized, double-blinded, placebo-controlled, clinical trial: 46 women and 41 men, aged 15–22 years. To be included, patients had to present with 10–50 inflammatory lesions (papules and pustules) with an absence of nodulocystic lesions. No other inflammatory cutaneous disease could be present on the face. Patients were not to have used any other topical treatment for 14 days, systemic antibiotics for 30 days, or systemic retinoid for at least 6 months prior to the start of treatment.

Patients were randomly assigned to treatment A, B or C using a balanced blocks method (columns of 10 patients), followed by random numbers generated by a computer and assigned to the patients by the

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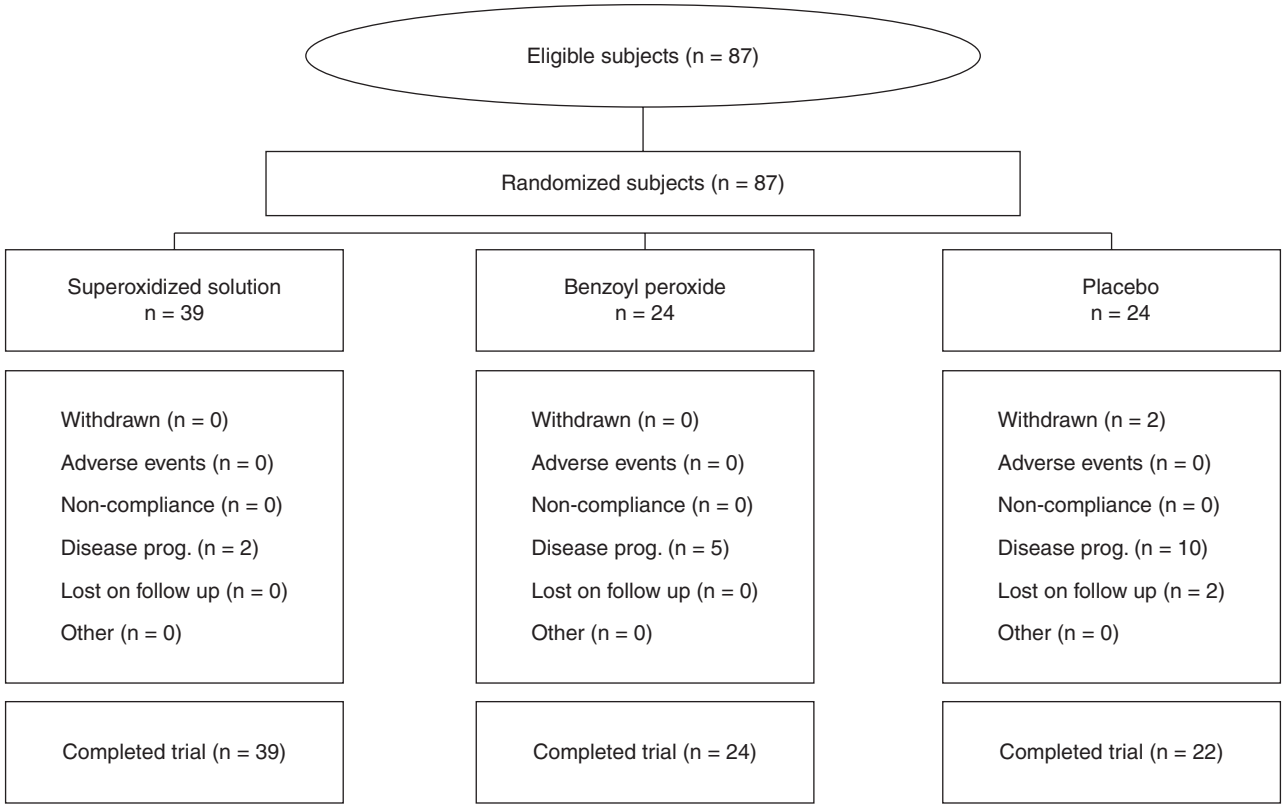


Figure 1. Flow chart of patients participating in the study.

Table I. Baseline characteristics of the sample.

Variable	SOS n = 39	BP n = 24	Placebo n = 22
Sex, n (%)			
Male	22 (56)	14 (58)	10 (45)
Female	17 (44)	10 (42)	12 (55)
Age, years			
Mean ± SD	19 ± 2.9	18 ± 3.3	19 ± 2.5
Lesions			
Inflammatory counts	34.5 ± 18.5	35.3 ± 19.82	33.5 ± 19.6

SOS = superoxidized solution; BP = benzoyl peroxide.

second investigator. The assessment of efficacy was performed by the first investigator.

Patients applied a thin amount of the study products to the entire face twice daily during the 12-week treatment period. Patients were evaluated at baseline, and weeks 4, 8 and 12. Efficacy was evaluated by counting the changes in the numbers of facial inflammatory lesions. Response was graded as excellent (≥ 75–100% reduction of lesions), good (≥ 50–74% reduction), fair (≥ 25–49%), or poor (< 25%). Tolerance was assessed by determining local and systemic adverse events on a scale of 0–3 points (0 = none to 3 = severe).

Statistical analysis was performed using the Friedman test to evaluate differences between the values of the four evaluation points. To compare efficacy between treatments at the different points, the Mann–Whitney test was used. Tolerance was evaluated with a chi-squared test (Fisher test for expected values < 5).

Results

Almost all patients included completed the study, 39 in the SOS group and 24 patients in the benzoyl peroxide (BP) and in the placebo group (two patients of the last group were lost on follow-up, the reasons were personal ones, not related to the study product) (Figure 1). Baseline characteristics of the sample are shown in Table I.

Improvement was excellent in nine patients (23%) using SOS compared with five patients using BP (21%) ($p = 0.378$); good in 21 patients (54%) using SOS and 12 patients (50%) using BP ($p = 0.794$), compared with four patients (18%) using placebo ($p = 0.001$); and fair in six patients (15%) using SOS and five patients (21%) using BP ($p = 0.415$), compared with 12 patients taking placebo (55%) ($p = 0.014$). In three patients

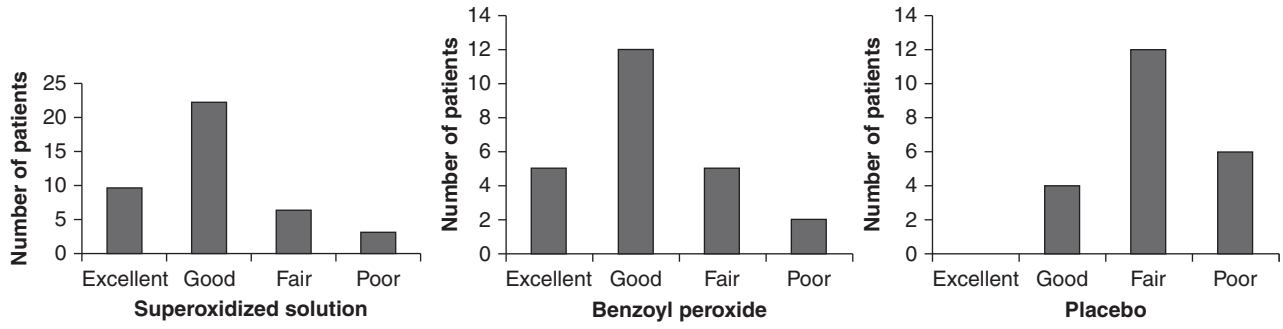
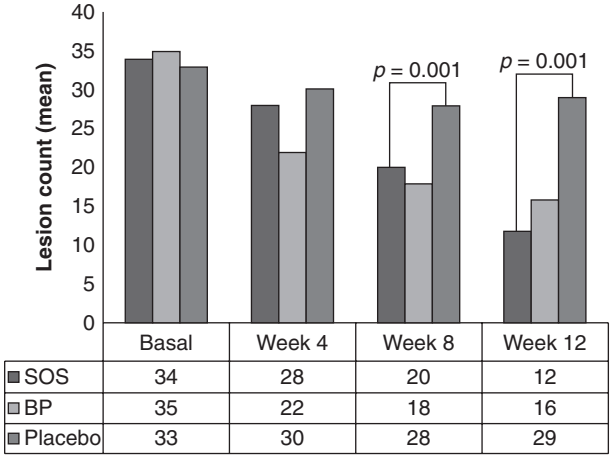


Figure 2. Improvement of lesions during a 12-week period.



	Basal	Week 4	Week 8	Week 12
SOS	34	28	20	12
BP	35	22	18	16
Placebo	33	30	28	29

Figure 3. Mean number of inflammatory lesions from 0 to 12 weeks following treatment with superoxidized solution (SOS), benzoyl peroxide (BP) and placebo.

using SOS (8%) the response was poor, compared with two patients (8%) using BP ($p = 0.725$) and six patients (27%) taking placebo ($p = 0.075$) (Figure 2).

There was a gradual, significant reduction in the counts of inflammatory lesions in the SOS group. The SOS group showed a greater reduction in inflammatory lesion counts than the placebo group in all follow-up visits and was comparable with the results of the BP group. These differences were pronounced following the second follow-up visit. The results of the clinical evaluation are shown in Figure 3. Figure 4 illustrates the effect of SOS on mild-to-moderate acne lesions over a 12-week treatment period.

In general, there were no local adverse events in any of the two groups. We did not need to change a dose during the study period and no systemic effect was observed.

Discussion

The results of this study indicate that SOS is a highly effective therapeutic option for inflammatory facial acne, comparable with BP. SOS showed a great improvement in inflammatory lesion counts, and was more effective than placebo. Tolerance was equal in SOS and BP treatments.

The efficacy of SOS is well known in skin infections and ulcers, but in the case of acne it is probably that the efficacy of SOS is related in part to the antiseptic effect of SOS (3) or to an anti-inflammatory effect (2). The precise mechanism by which SOS acts as an anti-inflammatory agent is unknown. Medina-Tamayo et al. (2) showed that SOS can inhibit mast cell degranulation. They explained that this effect is made by the SOS without altering the main signal transduction pathway, which may be useful to control localized allergic and inflammatory reactions. In acne, mast cells play an important role in inflammation with the production of IL-6 and TNF-α; moreover, there is an increased number of mast cells in adjacent areas to the sebaceous glands, suggesting that inflammation in acne is not only related to lipogenesis or *Propionibacterium acnes*, but is via mast cells (4).

In summary, our study is the first clinical trial to compare the effectiveness and tolerance of SOS in the treatment of acne. We found that SOS is an important choice to treat inflammatory acne; nevertheless, a larger sample is needed.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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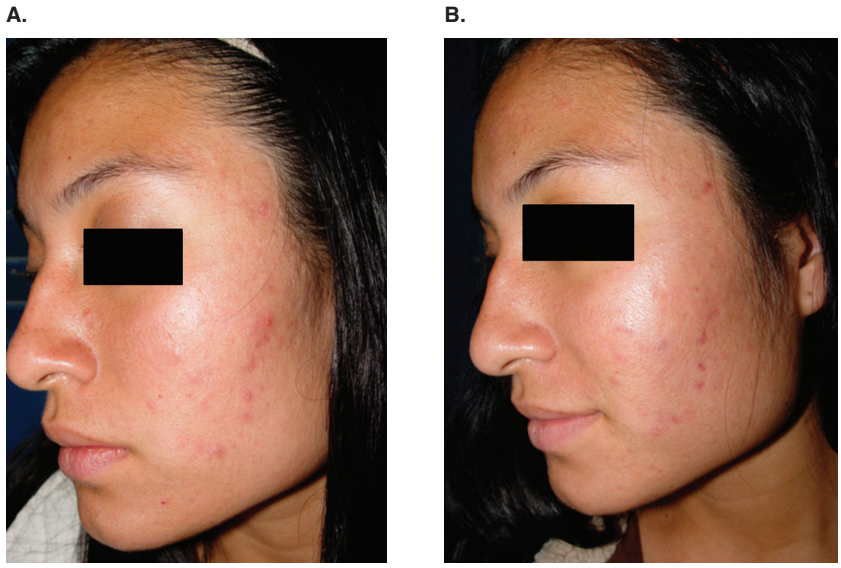

Figure 4. Effect of superoxidized solution on mild-to-moderate inflammatory acne lesions at baseline (A) and at 12 weeks (B).

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