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## Efficacy of adjunct (laser) therapy to topical agents among Southern Nigerian acne vulgaris patients



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#### ABSTRACT

This study evaluated the efficacy of Adjunct Laser therapy compared to self-management topical agents among acne vulgaris patients. A parallel randomized controlled trial involving 40 volunteer age ranged 17–28 years (22  $\pm$  4). 35 participants who completed the study were sampled from the stratified 6 faculties' population of the campus who were screened after meeting the selection criteria and giving the sorted individual consents. Both participants and assessors (physician) were parallel, block and blinded randomized. The outcome measures included distribution and severity of facial acne, counts of baseline lesion of comedones, papule, pustule and nodule, Estimate nos. of face acne eruptions; Mean density of acne calculated and recorded at base line prior each 8 RX sessions in 4 weeks [Density = n/25 cm² (Initial Density – Present Density = Level of Clearance)].  $2 \times 4 \times$  weeks  $R_x$  (laser group-invisible infrared nonablative laser therapy supine lying via 905 nm pulsed single probe [Operation frequency: 2000 Hz  $\pm$  10%; Pulse Width: 160 ns  $\pm$  10%; Dosage = 5 J/cm²  $\times$  12 min duration]. 10 min Post-RX monitor. Results showed significant improvement in clearance rate of acne (post-laser therapy) relative to their counterparts in control group (54.98% vs. 17.97%, t = 9.773, p = <0.0001, Cl = 95%). Conclusively, laser was observed significant adjunct therapy in improving acne clearance rate compared to self-administered topical agent approach only.

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#### 1. Introduction

Acne vulgaris is a common inflammatory disorder of the sebaceous gland involving the face, back and chest; characterized by the presence of comedones, papules, pustules, in severe cases, cysts and scares may be present [1] with potential significant psychosocial morbidity [2]. During middle to late teenage years, acne vulgaris affects male and females, but males tend to have more severe effects of the disease [3], accounting for at least 30% of all dermatology visits [4].

Estimate showed the prevalence of acne among young population as about 85% [5,6] and 92% of all cases were facial acne [7], which persists for an average of 8–12 years in most sufferers [8]. The main treatment of acne has been the use of topical and systemic

antibiotics, which became less effective in the advent of rapid bacterial mutation and increasing resistance of *Propionibacterium acnes* worldwide [9]; calling for non-antibiotic treatment arises [10].

However, most conventional forms of acne therapy have various drawbacks like low efficacy and potential adverse effects or inconveniences for patient [11,12]. In adverse effects, systemic use of drugs in acne management is indicated only in severe cases with cysts, pustules and formed scars; however, topical therapy seems safer, with no clear benefit in long-term prophylaxis [13].

Thus, the need for an adjunct therapy in the management of acne vulgaris is quite imperative. Infrared lasers are purported to provide benefits in acne management through transient thermal effects to damage the sebaceous glands [14].

Recently, pulsed dye laser therapy was reported to reduce acne lesion counts [15]. This postulated low morbidity and possible additional cosmetic benefit in simultaneous acne scarring therapy is encouraging [16]; including results range from 81% clearance of acne with light therapy [17] to limited or no benefit given by light therapies alone [18] is challenging too. Therefore, this work determined to evaluate the efficacy of laser when used as an adjunct therapy to self-management topical among male students with facial acne vulgaris in University of Nigeria, Nsukka, Southeast Nigeria.

Abbreviations: GAGS, Global Acne Grading System; LASER, Light Amplification by Stimulated Emission of Radiation; MAL, methyl aminolaevulinate; PDT, photodynamic therapy;  $R_x$ , treatment or therapy; UNEC, University of Nigeria Enugu Campus; UNTH, University of Nigeria Teaching Hospital Enugu.

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#### 2. Method and materials

#### 2.1. Participants

The study design was a parallel randomized, controlled, double-blinded clinical trial involving 40 patients drawn from an indefinite 6 stratified faculties population (equal numbers of patients were enrolled from each faculties of the campus (UNEC) and screened after meeting the eligibility criteria). But, 35 patients completed the study [control group = 20; laser (n = 15):: 1:1)] as 5 subjects withdrew from the trial group. All participants and the assessors (physicians) were blocked and blinded to the planned interventions during the randomization. Balloting by an independent physician after another independent clinician had generated the random allocation tags and numbers concealed in a uniform brown envelops. These were thoroughly mixed in an opaque container, and subjects picked numbers assigning them to their respective intervention groups.

#### 2.2. Selection inclusive and exclusive criteria

Subjects' selection was based on these criteria: Male student of UNEC, general good health, presence of clinically evident facial acne (GAGS severity level rating >19) [19], willingness and convenience to follow up treatment regime. Exclusion criteria were: Being under acne systemic therapy or other microbial for at least 1 month ago, presenting acne fulminans or follicular occlusion triad, female subjects and male subjects below 16 years under stress, severely photosensitivity or on steroid drugs for at least 6 month to the study.

#### 2.3. Standard operation procedures

Clinical Standard Operational Procedures as adopted from Electrotherapy Unit, Physiotherapy Department, UNTH, was demonstrated and rehearsed to ensure quality control and safety. Study was conducted in the multipurpose research gymnasium, Department of Medical Rehabilitation, UNEC. This followed ethical approval by the Health Research Ethical Committee, UNTH. Subjects' and any parental informed consent was sort and obtained with confidentiality of data maintained. Dignity and right of withdrawal from the study by subjects were maintained.

#### 2.4. Procedures of data collection

The face was arbitrarily divided into four  $(25\,\mathrm{cm}^2)$  quadrants (Global Acne Grading System – GAGS severity level rating >19) [19–21] to assess baseline distribution (number, type and the mean density of acne lesions of comedones, papule, pustule, nodules) face map pattern, also the frequency severity of facial acne. The clearance rate was calculated and recorded mean density of acne was calculated and recorded at base line after treatment for the four consecutive week treatment sessions. Density =  $n/25\,\mathrm{cm}^2$  (Initial Density – Present Density = Level of Clearance).

Earlier, subjects' Physical Activity Index was estimated using Kaiser Physical Activity Survey Standard Questionnaire based on its objectivity validity and reliability [22].

Subjects in the laser group were treated twice weekly (3 days interval) for four consecutive weeks, using invisible infrared non-ablative laser therapy device (Made in Brazil) by CARCI – Lasermed 4098; ANVISA (which has an inbuilt probe sensor for ascertaining the invisible beam before application). In supine lying, beam was delivered through 905 nm pulsed single probe; Operation frequency: 2000 Hz  $\pm$  10%; Pulse Width: 160 ns  $\pm$  10%; InGaAs MOCVD 905 nm 20 mW average 60 W peak {class 3b}. Both the subject and therapist wore protective goggle for safety. Duration of 12 min

**Table 1** Subject characteristics.

Parameters	Trial group $X \pm S.D.$	Control group $X \pm S.D.$	All $X \pm S.D.$
N	15	20	35
Age	$21\pm4$	$23\pm4$	$22\pm4$
PAI	$2.62 \pm 0.467$	$2.45 \pm 0.297$	$2.53 \pm 0.382$
Density <sup>a</sup>	$6 \pm 1.846$	$5\pm1.553$	$5 \pm 1.689$
Topical R <sub>x</sub>			
<ul> <li>Cream or lotion</li> </ul>	5	7	12
<ul> <li>Medicated soap</li> </ul>	4	5	9
<ul> <li>Talcum powder</li> </ul>	4	5	9
<ul> <li>Normal hygiene</li> </ul>	2	3	5

PAI: Physical Activity Index (1–5) using KPAS questionnaire; R<sub>x</sub>: treatment.

(dosage of  $5 \text{ J/cm}^2$ ) treatment was given using the grid method described by Singh [23]. Applicator was held 5-10 mm away from the skin, then 10 min observation on subjects for any possible adverse reaction post-treatment and control group patients were treated with a placebo-non radiating probe (Fig. 1. Trial profile). Recruitments and study got completed between May and July 2012. Data collected were descriptively analyzed (frequency, percentage and mean  $\pm$  standard deviation) SPSS 17 software (SPSS, Chicago). Inferences – test of hypotheses derived with Student t-test and regression equations (Fig. 2).

#### 3. Results

40 Southern Nigerian male subjects mean age  $(22\pm4~years)$  were recruited for the study (Table 1). Baseline clinical characteristics of subjects (Table 2) shows that at average, a subject presents with 60 lesions, 30 (50%) comedones, 15 (25%) papules, 11 (16.7%) pustule and 5 (8.3%) nodules. Right cheek had highest lesions 16 (26.7%), left check 15 (25%), fore head 14 (23.3%), jaw 8 (13.3%); the nose 7 (11.7%) recorded the least lesions.

Table 3 shows a significant increase of mean percentage clearance rate of facial acne was recorded among subjects post adjunct laser therapy treatment who used various topical approaches relative comparative to the control group subjects (t=9.773, p=<0.0001, CI=95%, Table 3). 1st week post-treatment week intervention, clearance rate of both groups remained at base line. After week 2, the mean percentage-clearance for control group was 4.90% and laser group 33.66% (t=10.235, p=0.002, CI=95%). Week 3; control = 10.92%, laser = 47.75% (t=5.372, t=0.01). Week 4; control 29.41%, laser = 69.71% (t=4.473, t=0.02, CI=95%).

Fig. 3 shows (regression) relationship between clearance rates in both groups (control group; y = 0.260x - 0.789 and laser group; y = 0.546x - 0.450, where x is number of trials [twice per week]).

However, three days follow-up post-fourth-week of intervention showed an apparent relapse in both groups; control = 26.64% (difference of 2.77%) and laser 68.78% (difference of 0.93%).

In all, a statistical significant difference occurred between the group that had sole topical approaches and the treatment group managed with laser as an adjunct (Table 4).

Antibiotic cream (30.65% vs. 57.41%, p = 0.007), medicated soaps (25.00% vs. 50.00%, p = 0.013), talcum powder (10.34% vs. 57.43%, p = 0.005) and normal hygiene (5.90% vs. 53.57%, p = 0.006).

The sole self-administered topical approach, antibiotic cream is more efficacious (30.65% clearance in 4 weeks), medicated soaps (25.00%), talcum powder (10.34%) and normal facial hygiene (5.90%) over a period of 4 weeks respectively.

When laser was used as an adjunct to self-administered tropical agents, talcum powder (57.43%) and antibiotic cream (57.41%) recorded appreciable clearance rate while normal facial hygiene (53.57%) and medicated soaps trialed in that order; meaning, that

a Density of acne = number of eruptions per 25 cm<sup>2</sup>.

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