An Open-Label, Split-Face Trial Evaluating Efficacy and Safety of Photopneumatic Therapy for the Treatment of Acne

Eun Ju Lee, M.D., Hee Kyeong Lim, M.D., Min Kyung Shin, M.D., Dong-Hye Suh, M.D.,1 Sang-Jun Lee, M.D.1, Nack In Kim, M.D.

Department of Dermatology, Kyung Hee University School of Medicine, 1Arumdaun Nara Dermatologic Clinic, Seoul, Korea

Background: Acne vulgaris is the most common skin disease worldwide, with many available treatment modalities, including oral and topical medications and laser therapy. Recently, a novel device (Isolaz, Pleasanton, CA, USA) that combines vacuum pressure and a broadband light source (400 nm to 1,200 nm) was developed for the treatment of acne. Objective: To determine the clinical efficacy and safety of photopneumatic therapy for the treatment of acne vulgaris of the face. Methods: Twenty adults with mild to moderate facial acne vulgaris received 4 successive treatments on one side of the face with a combined photopneumatic device (intense pulsed light: fluence=5.8 J/cm²; negative pressure=iMP mode) at 2 week intervals. Acne lesions on the opposite side of the face were not treated. Lesion counts were performed at baseline, prior to each treatment session, and at 3 months after the final treatment session. Results: Significant lesion improvements and reduced numbers of acne lesions were observed on the treated side of the faces. Most patients experienced global clinical improvement. No severe side effects occurred during the study, with only a few patients experiencing transient erythema, purpura and/or exacerbation of pre-existing acne. Conclusion: Photopneumatic therapy is a safe and effective treatment for mild to moderate acne vulgaris. (Ann Dermatol 24(3) 280～286, 2012)

Keywords-
Acne vulgaris, Intense pulsed light

INTRODUCTION

Acne vulgaris is a common skin disease, affecting more than 85% of adolescents, often continuing into adulthood.1,2 Currently, while oral and topical antibiotics and retinoids represent the most conventional, widely-accepted pharmacologic therapies for acne, both have significant side effects: widespread use of antibiotics increases the risk of resistant bacterial strains, while oral isotretinoin has been linked to dry skin, headaches, fetal defects and depression. Alternatives to pharmacologic therapies include chemical and physical exfoliation techniques and light devices, most notably blue light, intense pulsed light (IPL), light-emitting diodes, various lasers (especially infrared) and photodynamic therapy (PDT). Interestingly, while IPL with or without PDT has proven effective for treating acne in patients of European descent, no significant improvements were observed in studies among Asians. Kawana et al.3 propose that this discrepancy results from the use of inappropriate wavelengths or inaccurate irradiating light source targeting. These authors also show that IPL using dominant wavelengths of 400 nm to 700 nm was effective in reducing acne vulgaris lesions among Asians. However, treatment with IPL is often poorly tolerated, with many subjects reporting pain (associated both with the IPL treatment and the topical anesthesia), immediate erythema, and sensations of burning and/or stinging. Additionally,
rare episodes of crusting, bulla formation and hyperpigmentation have been reported after IPL treatment. Recently, a novel device (Isolaz, Aesthera Co., Pleasanton, CA, USA) that combines vacuum pressure with a broadband light source (400 nm to 1,200 nm) was developed for the treatment of acne. Unlike other devices that are currently available, this device uses gentle pneumatic energy to draw the target tissue into the treatment tip, with negative pressure lifting the sebaceous gland and thus bringing it closer to the surface of the skin. The vacuum then elevates and everts the sebaceous gland, allowing it to open up and empty its contents, ejecting the acne-causing bacteria, sebum, dead skin cells, and other impurities onto the surface of the skin. Such photopneumatic devices are the only lasers approved by the United States Food and Drug Administration for the treatment of comedonal and pustular acne, as well as inflammatory acne. The purpose of this study was to determine the clinical efficacy and safety of photopneumatic therapy for the treatment of acne vulgaris of the face in an Asian sample.

**MATERIALS AND METHODS**

**Patients**

All components of this study were performed at the Kyung Hee University School of Medicine, Department of Dermatology, located in Seoul, Korea. The protocol adhered to the Helsinki guidelines, and the study underwent review and approval by the Kyung Hee University Institutional Review Board (KHUHMDIRB1105-01). Informed consent was obtained from all subjects prior to any study-related procedures. In total, 20 Korean patients with inflammatory acne vulgaris of the face were subjected to photopneumatic therapy between July 2010 and January 2011. For this study, exclusion criteria included concurrent pregnancy or lactation, the use of any photosensitizing drugs, a prior history of porphyria or photosensitivity, or oral antibiotic therapy at any point during the course of study. All topical and oral acne medications were discontinued 3 months prior to study enrollment, and no oral or topical acne medications were permitted during the study.

**Study design and laser treatment**

In this split-face controlled study, 10 patients received treatment on the right side of the face and 10 on the left side of the face, with the untreated side of each subject's face serving as a control. The subject's facial skin was first cleaned with a mild soap and water in order to remove any cosmetics or debris. A portable photopneumatic device (Isolaz) was used for all treatment sessions. No topical or systemic anesthetics were administered. For most treatments, the power was set at 6 (approximately equivalent to 5.2 J/cm²) and the vacuum at iMP (delivers multiple vacuum pulses in each cycle). A large tip (15×30 mm) was employed for treatments of the cheeks and a small tip (5×12 mm) for the nose. Typically, patients were treated with 1 pass during each of the four treatment sessions that occurred at 2 week intervals. Patients were assessed at three follow up visits 4, 8 and 12 weeks after the final treatment session.

**Evaluation**

Prior to each treatment session and during each follow-up visit, two different investigators manually counted the number of acne lesions for each patient on both the treatment and control sites. Clinical photographs were obtained at each of these time-points for evaluation purposes. Other clinical observations, including erythema, purpura, and treatment-associated pain level, were recorded by research staff. After each treatment session, all skin lesions were compared to pretreatment appearance and lesions on the contralateral side. Using these data, patients were then divided into three groups based on the clinical improvement seen in inflammatory acne lesions: responders, partial responders, and nonresponders. To quantify the actual degree of improvement, the ratio of remain acne lesions at each treatment to the initial acne lesion was calculated after the first, second, and third treatments. Responders were defined as showing a reduction in the ratio of inflammatory acne equal to or greater than 50%, partial responders as showing a reduction less than 50%, and nonresponders as showing a reduction less than 25%.

**Wood's light examination**

All patients were examined using a Wood's light both before and after treatment. Photos were also obtained under these conditions before each treatment session, so that the levels of porphyrin fluorescence could be compared to the subsequent set of photos by the clinic staff.

**Patient self assessment**

At 12 weeks after the final treatment session, patients assessed the improvement in their acne as one of the following: ‘marked improvement,’ ‘moderate improvement,’ ‘slight improvement,’ ‘no change,’ or ‘worse.’ Additionally, patients were asked whether they would recommend this particular treatment modality to others.