VASOMASK
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Pilot Study to Examine the Efficacy of using the Digital Heat Corporation Vaso Mask on Aging Skin

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Location: Arizona

Chapter 1: Rationale

1.1 Introduction

Aging skin is defined as “Skin aging is a superimposition of benign skin phenotypes indicative of histological and morphological changes which are both continuous and inevitable, caused by both intrinsic and extrinsic factors, wherein genetic and chronological influences constitute the former, and environmental influences constitute the latter.” (Wong & Chew, 2021)

Aging skin is encountered by all people, and studies examine a variety of phenotypes, the most frequent of which were pigmentation (n = 17), sagging (n = 12), telangiectasia (n = 11), and wrinkling (n = 35). Notably, the term pigmentation often referred to changes in pigmentation, dyspigmentation, or the formation of pigment spots; we henceforth refer to this phenotype as dyspigmentation. (Wong & Chew, 2021)

The goal of aging skin treatment is to achieve a healthy, smooth, blemish-free, translucent and resilient skin. Commonly used approaches and therapies are noted in table 1. (Ruta Ganceviciene, 2012)

Table 1. Skin antiaging approaches

Cosmetological care	Daily skin care Correct sun protection Aesthetic non-invasive procedures
Topical medical agents or topical agents	Antioxidants Cell regulators
Invasive procedures	Chemical peelings Visible light devices Intense pulsed light (IPL) Ablative and nonablative laser photo–rejuvenation Radiofrequency (RF) Injectable skin biostimulation and rejuvenation Prevention of dynamic wrinkles Correction of static, anatomical wrinkles Restoration (redistribution) of fat and volume loss, skin augmentation and contouring
Systemic agents	Hormone replacement therapy Antioxidants
Avoiding of exogenous factors of aging, correction of life style and habits	Smoking Pollution Solar UV irradiation Stress Nutrition, diet restriction and alimentary supplementation Physical activity Control of general health
Preventive medicine	

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An alternative way to treat aging skin is to use a warm compress or other skin heating device. The hypothesis of the Vaso Mask is to heat the facial tissue, triggering vasodilation and sweat. Ideally, the combination of vasodilation and sweat improve the blood flow of capillary and vascular system of the face, and subsequently increase the speed of metabolism to reduce the effect of aging.

1.2 Vaso Mask

The usages of various instruments to heat the dermis has been studied in the treatment of aging skin from the perspective of Invasive treatments identified in Table 1. Intense Pulse Light Therapy (IPL), laser treatments, and radio frequency treatments are well studied and thought to improve skin health by thermal means, and activating a thermal response in the dermis.

Considering thermocoagulation or photothermolysis as a mechanism for aged skin treatment they essentially work to “destruct” the dermis, which in turn causes an update of the skin layers (Anna Kołodziejczak, 2022; 37(2)). The Vaso Mask is not invasive, the heat from the mask will focus activating a thermal response in the dermis and on increased blood flow enabled by vasodilation resulting in the transport of more nutrients and oxygen to the cells, with quicker removal of metabolic waste (e.g. - increases the speed of metabolism.

Lasers and light devices produce a clinical effect when their light is absorbed by the skin, resulting in the emission of photons that carry thermal energy. Chromophores (e.g., hemoglobin, water, melanin) in the skin absorb the photons and are subsequently heated by thermal energy, causing their destruction through thermocoagulation. This phenomenon of selective photothermolysis is the underlying basis of IPL technology. (Anna Kołodziejczak, 2022; 37(2))

The Vaso masks mimics this phenomenon. The Vaso mask is designed to cover the facial regions, and to heat the facial skin tissue to approximately 40-44°C. Treatments times will include 10, 15, and 30 minute blocks, applied one time a day. It is an at home treatment that allows the patient to apply without the need for a visit to their practitioner.

1.3 Adverse Events

The adverse events that have been noted with the usage of heating compresses and devices have been the discoloration, blistering, or burning of skin. To date there have been no adverse events with the Vaso Mask.

1.4 Summary and Hypothesis

With previous research showing that many invasive treatments are well studied and thought to improve skin health by thermal means, and activating a thermal response in the dermis, Digital Heat Corporation proposes a prospective non-randomized interventional trial to study the efficacy of the Vaso Mask treatment on subjective and objective measures.

The study will enroll 60 patients who meet the participation criteria. These 60 patients will be broken up into 2 groupings of 30, where they will receive different treatments. All will start with a baseline cleaning routine.

1. Thirty patients will receive a Vaso Mask and will be requested to treat once every other day for 10 minutes, high heat, photograph before and after, for 30 days.
2. Thirty patients will receive a Vaso Mask and will be requested to treat every other day for 10 minutes, low heat, photograph before and after, for 30 days.

Both groups will be encouraged to use the mask as frequently as possible, but we want them to document the actual usage.

Subjectively, participants will be scored using a questionnaire, prior to treatment and post-treatment for their perception of their own skin. Objective measures at baseline and at the end of the study will include practical, and specific skin aging outcomes captured photographically as follows:

- Wrinkling
- Texture
- Telangiectasia
- Pigmentation
- Elasticity
- Pores
- Freckles

It is not anticipated that study participants will experience adverse effects with proper usage of the Vaso Mask for aging skin treatment.

Chapter 2: Study Overview and Design

2.1 Participant Inclusion Criteria

30-60 participants with evidence of skin aging will be recruited. Assessment of skin condition will be captured via survey and photograph. Daily skin care regimen will be documented. Participants must not be smokers. Participants must agree and have the ability to abstain from other skin treatments between the screening visit and the final study visit (normal cosmetics routine accepted). Participants must be of age 18 years and older of any gender or race with written informed consent to participate in the study and a willingness and ability to return for all study visits.

2.2 Participant Exclusion Criteria

Participants will be excluded if they are smokers. Individuals who are unable to complete the required patient questionnaires in English will be excluded. Additionally excluded are patients who, due to other diseases, dermatological or otherwise, would not be able to fulfill the follow-up appointments or give an informed consent to the study. Anyone allergic to thermoplastic polyurethane (TPU) will be excluded.

2.3 Participant Randomization

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This study will be a non-randomized, open label study of subjects with documented skin aging.

2.4 Data Collection and Analysis.

Data will be collected from 60 patients, 2 groupings of 30, with pre and post analysis of the ocular glands. Baseline data will be collected at the first visit and will include the following: demographic questionnaire, cosmetic routine questionnaire, perception of skin questionnaire, photograph results. Their data will be entered into an Excel Document ("data file") and which will be kept on a computer at Digital Heat Corporation.

Chapter 3: Procedures and Cost

3.1 Subjective Parameters

Perception of skin questionnaire. Patients will be shown medical artist illustrations of

- Wrinkling
- Texture
- Telangiectasia
- Pigmentation
- Elasticity
- Pores
- Freckles

3.2 Objective Parameters

Photograph of before and after. Prior to the start of treatment participants will have a photograph recorded and analyzed for the below aging characteristics. At the end of the 30 day period, another photograph will be taken and the patient will be reviewed for any visual changes by at least 3 reviewers.

- Wrinkling
- Texture
- Telangiectasia
- Pigmentation
- Elasticity
- Pores
- Freckles

3.3 Budget

Paid for by Digital Heat Corporation

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Chapter 4: Supplementary & Supporting Materials

4.1 Demographic Questionnaire-Each patient will be given a number as a proxy for name.

Confidential Name	
Confidential Contact inf.	
Patient ID #	
Age	
Sex	
Race	

4.2 Cosmetic Routine questionnaire

Face Care	Describe frequency, Brand, Product detail
Cleanser or soap	
Toner	
Serum	
Lotion	
Cream, Eye Cream	
Sunscreen	
Primer	
Foundation, Concealer	

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4.3 Perception of Skin questionnaire

The assessment of treatment efficacy by participants

Patient ID #					
BEFORE TREATMENT	Please indicate if you observe this condition-see medical artist illustrations. Make note or comment.				
Your main skin concern					
Wrinkling					
Texture					
Telangiectasia					
Pigmentation					
Elasticity					
Pores					
Freckles					
Acne					
	Please indicate if you observe this condition has changed after treatment with the Vaso Mask-see medical artist illustrations.				
AFTER TREATMENT	Definitely YES	I think so, not sure	No opinion	I think not, not sure	Definitely NO
Your main skin concern					
Wrinkling					
Texture					
Telangiectasia					
Pigmentation					
Elasticity					
Pores					
Freckles					
Acne					

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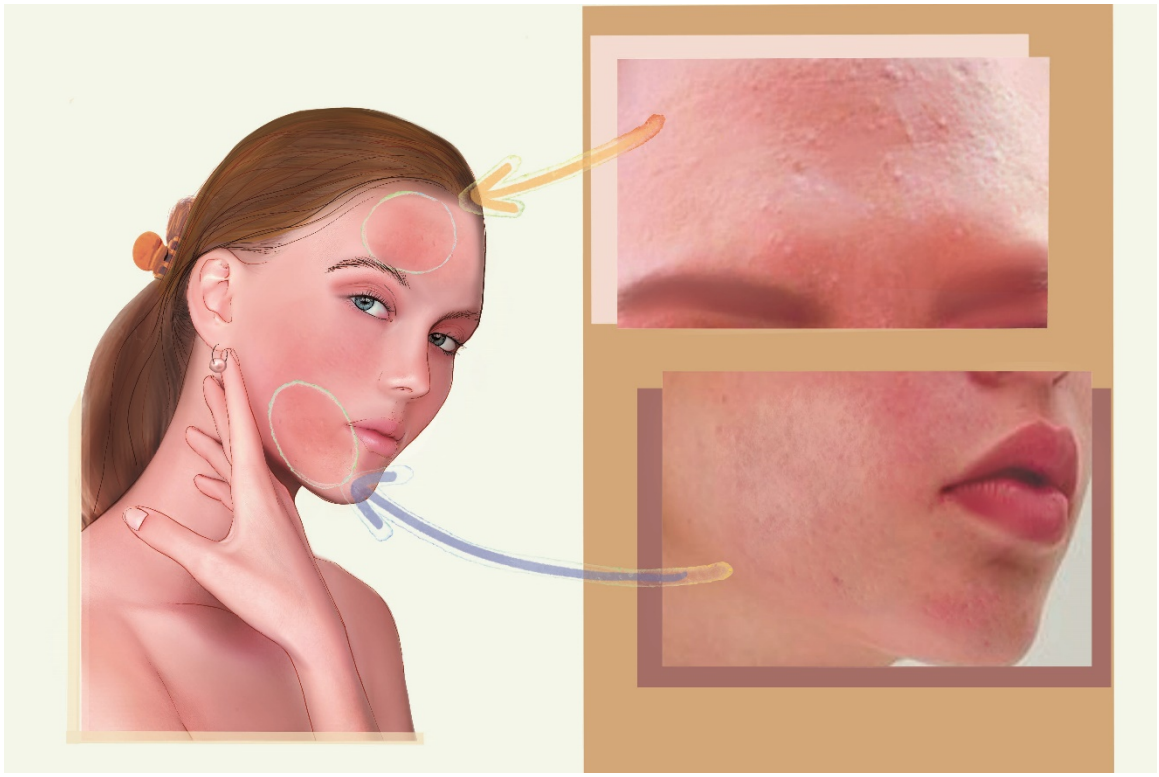
4.3 Medical Artist Illustrations of skin conditions

Wrinkling

Texture



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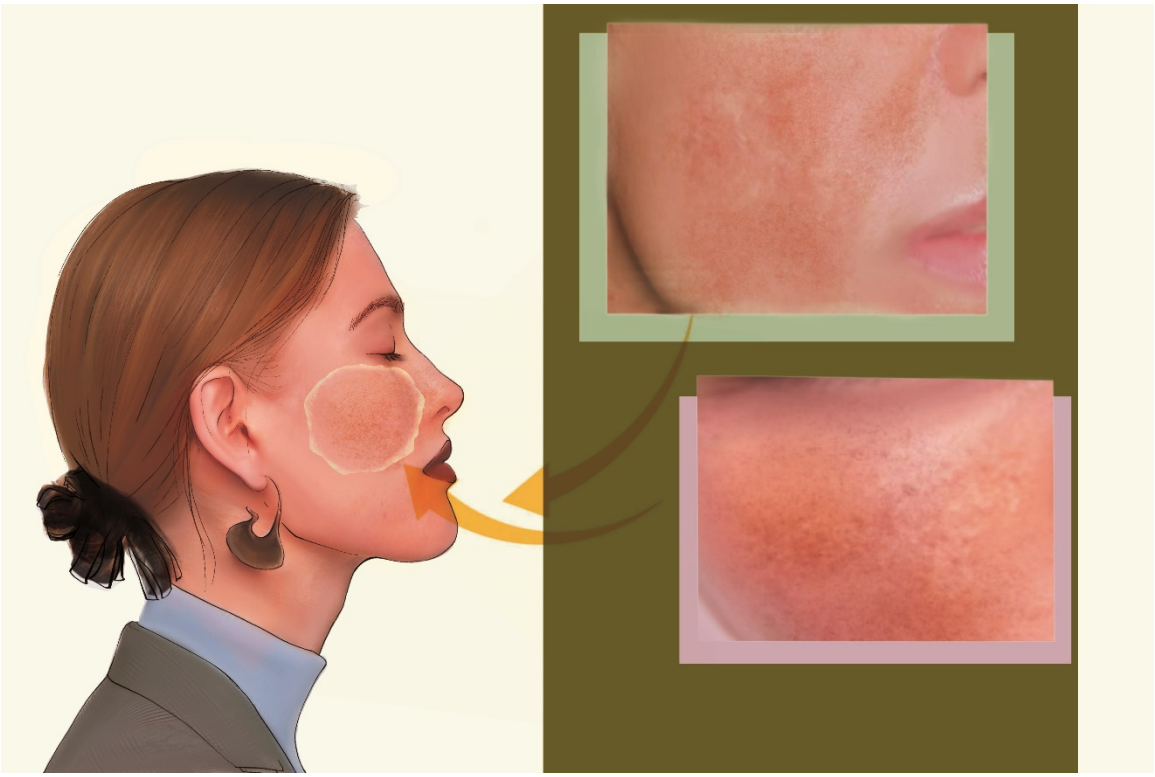
Telangiectasia

Pigmentation



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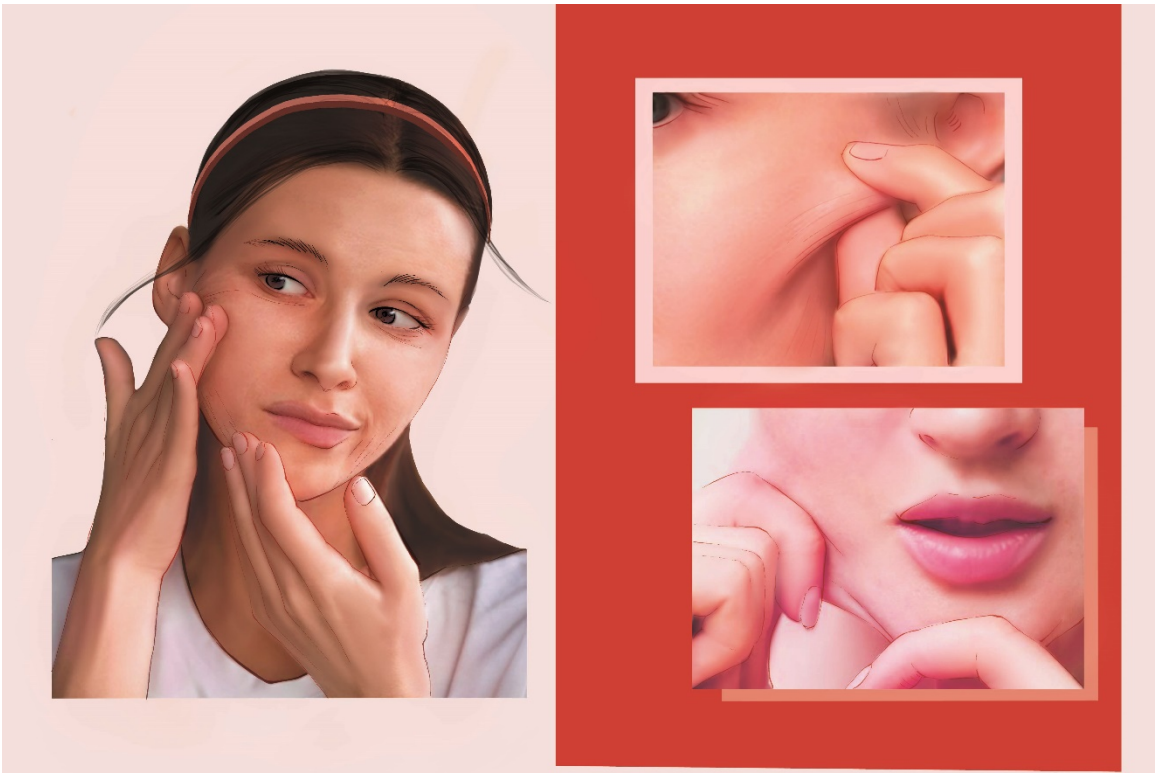
Elasticity



Pores

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Freckles

References

Bioscience, L. (2012). Skin anti-aging strategies. *Dermato-Endocrinology 4:3, July–December 2012;*, 308-319.

Wong, Q. Y., & Chew, F. T. (2021). Defining skin aging and its risk factors: a systematic review and meta-analysis. *Scientific Reports volume 11, Article number: 22075 (2021)* .