

Normal Reference Values in Han Adults of Skin Thickness
and Blood Flow by High-frequency Ultrasound:
a Multicenter Study in China (NOVAS-HFUS Study)

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Dear Madam / Sir:

We sincerely invite you to participate in the NOVAS-HFUS Study of Skin Thickness and Blood Flow Parameters in Chinese Han Adults. The study will be carried out in nine hospitals across the country, with an estimated 540 volunteers. This study has been approved by the Medical Science Research Ethics Committee of the First Affiliated Hospital of China Medical University. Before you decide whether to participate, please read the following carefully to help you understand the program. If you have any questions, please do not hesitate to ask and your doctor will answer them for you. If you wish, you can also discuss with your relatives and friends to help you make a decision. The following is the introduction of the research project:

[Research Background]

The skin is the body's largest organ and acts as a protective, permeable barrier against pathogen invasion and against chemical and physical attacks. Long-term exposure to solar ultraviolet radiation is a major factor in exogenous skin aging. With the gradual improvement of living standards and the development of medical cosmetology technology, Chinese consumers have gradually increased their acceptance of cosmetology consumption. Facial skin, as one of the important indicators of "beauty", has obviously received the attention of cosmetic surgeons and dermatologists. Skin thickness is one of the important indicators of facial aging. However, different gender, different parts of the skin thickness is very different, especially the facial skin, the thickness of the epidermis, dermis is different, and the facial plastic surgery, injection treatment, photoelectric treatment has a close relationship. In addition, the dermis is rich in blood vessels, especially in its deep layers, which play an important role in the nutritional support of tissues and homeostasis of the internal environment. With the increase of age, the degree of dermal vascularization decreases, which is also one of the factors affecting skin aging. Therefore, in aesthetic medicine, more accurate quantitative evaluation of skin thickness and blood flow rather than simple subjective evaluation is very important.

Ultrasound is a non-invasive imaging technique widely used in clinic. In recent years, with the development of ultrasound technology, the frequency of ultrasonic probes has been increasing. Because of its higher resolution, high-frequency ultrasound can clearly display the layer and structure of the skin, and achieve accurate measurement of skin thickness and evaluation of dermal blood flow. High-frequency ultrasound has become a new non-invasive tool for the diagnosis of skin diseases, aesthetic medicine and preoperative and postoperative evaluation. The purpose of this multi-center Study is to establish the normal reference values of skin thickness and blood flow parameters by high-frequency ultrasound in Chinese Han adults, and to explore the influencing factors, so as to provide quantitative reference for the evaluation of facial skin aging degree and cosmetic treatment.

[Research Objective]

1. To establish the normal values of skin thickness and blood flow parameters of Chinese Han adults by high-frequency ultrasound;
2. Determine the influencing factors of skin thickness and blood flow parameters.

[Inclusion and exclusion criteria]

1. Inclusion criteria:

Each volunteer must meet the following criteria to be included in the study:

- (1) Han nationality;
- (2) Ages 18-79;
- (3) Normal blood pressure (139-90/89-60mmHg);
- (4) Body mass index < 30 kg/m²;
- (5) Blood routine, fasting blood glucose, blood lipid, liver and kidney function, electrocardiogram were normal;
- (6) No history of skin disease, connective tissue disease, cardiovascular disease, diabetes, severe liver and kidney dysfunction.
- (7) No history of drug use affecting cardiovascular system.

2. Exclusion criteria:

- (1) Skin diseases (such as eczema, psoriasis, scleroderma, etc.);
- (2) Any skin disease at the test site (such as dermatitis, acne, breakages, previous skin lesions, etc.);
- (3) chronic systemic diseases;
- (4) Use corticosteroid drugs or immunosuppressants;
- (5) Pregnant or lactating women;
- (6) People who have been exposed to ultraviolet radiation for a long time or have a history of sun exposure within 3 months;
- (7) The examined skin area has previously received other treatments;
- (8) Unable to cooperate with the ultrasonic examination.

[Research content and procedure]

This is a prospective multicenter clinical study conducted in the People's Republic of China. The multi-center clinical study method was adopted.

The study will start in August 2023 and last for 18 months. Nine different medical institutions across the country participated in this study, a total of 540 people were included, 60 of whom will participate in this study in the cooperation center.

(1) Subject selection: Subjects are screened strictly according to clinical manifestations, blood pressure, blood biochemistry and electrocardiogram. Subjects are required to meet all criteria for inclusion and there are no exclusions.

(2) Sign informed consent.

(3) Fill in the questionnaire to measure height, weight, blood pressure and heart rate.

(4) To perform vascular ultrasound examination, the ultrasonic instrument used in the study is the ultrasonic diagnostic instrument currently used in hospitals, and no drugs or procedures are prohibited.

[What aspects of your cooperation are needed in the research]

To participate in this study, you will receive a skin ultrasound examination.

Your doctor will inform you of the examination time. No special preparation and precautions are required before and after participating in the study.

[Possible risks]

This study is a non-invasive ultrasound, and the placement of the probe during the examination may cause you slight discomfort, which will not be harmful to you.

[Study Fee]

You do not have to pay any fee to participate in this study. If you join the study, you will not receive any financial compensation.

[Rights and benefits]

If you meet the inclusion criteria and do not have the exclusion criteria and are willing to participate in the study, you may benefit from:

1. Free access to your current skin structure and blood flow parameters without financial compensation.
2. During the study period, a doctor will provide you with relevant knowledge.

[Voluntary study participation/withdrawal]

Participation in this study is voluntary. You may refuse to participate or withdraw from the study at any time, and you will not be subject to discrimination, unfair treatment or retaliation, and your medical treatment and rights will not be affected in any way.

[Privacy of Personal Information]

All information collected during the study will be confidential and kept by the investigator. Researchers, ethics committee members and relevant administrative authorities have the right to review your information records to the

extent permitted by law. In any research reports and publications related to this project, your personal information will not be independently disclosed.

[Contact information]

You can ask any questions about this study at any time. You can contact your doctor, contact: Ma Chunyan Tel: 024-83282129. If you have any complaints about participating in the program, please contact the Ethics Committee (tel: 024-83282837).

Declaration of consent

1. I have carefully read the above introduction to this study and have had the opportunity to discuss it with doctors and ask questions about it. All my questions were answered satisfactorily.

2. I know that participation in the study is voluntary, I confirm that I have had sufficient time to consider it, and I understand that:

1) I have understood the potential risks of participating in the trial and the treatment after the risk occurs;

2) I have understood the relevant alternative treatment plan of this trial;

3) I can always consult my doctor for more information;

4) I can withdraw from the study at any time without discrimination and retaliation, and my medical treatment and rights will not be affected;

Finally, I decided to agree to participate in this study, and I am willing to cooperate with the doctor to complete this study according to the requirements of the research program.

Subject signature:

date:

telephone:

(If there are minors or subjects with limited capacity to participate, they should also be signed by the guardian.)

Signature of guardian:

date:

telephone:

I have fully explained and explained to the subject the purpose of the study,

the operation process and the possible risks and benefits of the subject's participation in the project, and satisfactorily answered all relevant questions of the subject.

Investigator signature:

date:

telephone: