STU002089391

PROTOCOL TITLE: Diagnostic ultrasound for measuring fat of the body

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER:
1.1

PROTOCOL #:
MA07272018

VERSION DATE:
9-28-18

STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	LOGIQ P6 Diagnostic Ultrasound (GE Healthcare, Wauwatosa, WI)
IND / IDE / HDE #	Exempt/ no risk/ FDA cleared
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☐ Students/Employees
Sample Size	40
Funding Source	Investigator-initiated/ Department of Dermatology
Indicate the type of consent to be obtained	☒ Written ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☒ No

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OBJECTIVES:
To provide information about human subcutaneous fat thickness at different anatomic sites on the body by (1) measuring these thicknesses with a diagnostic ultrasound and also by (2) correlating patient perceptions of body image with measured fat distribution. The information obtained can useful in clarifying: (1) age, gender, and racial differences in subcutaneous fat accumulation that may inform patient education and (2) help us better understand which procedures may be better for particular patients.

BACKGROUND: (flesh out and refs)
High-frequency ultrasound allows for non-invasive assessment of physiological and pathological aspects of the integumentary system.[1] Although classical ultrasound (7.5-10 MHz) is not commonly used in dermatology, ultrasonography with frequencies of at least 20 MHz can provide information on tumoral extension, inflammatory infiltrate, and collagen content in various anatomical regions, with different intervals of age.[2,3] High-frequency ultrasound serves as an alternative to skin biopsy, the gold standard for investigation. [4,5] The use of high-frequency ultrasound also allows for a clear identification of skin layers and tissue assessment, allowing for the establishment of an imagistic aging model.[5,6,7] Microstructures have been characterized when ultrasound frequencies above 10 MHz have been used.[5] Additionally, high-frequency ultrasound helps identify variations in both skin thickness and echogenicity. Specifically, dermal density and echogenicity throughout the senescence process can be identified.[5]

To our knowledge, there have been no studies investigating relevant anatomy of the body using ultrasound technology for fat measurement and how this corresponds to patient perceptions of their body. This study seeks to remedy this deficiency.

STUDY ENDPOINTS:
The primary endpoints are the descriptive differences seen fat measurements taken with a diagnostic ultrasound, and the correlating the measurements with patient perceptions of body image with a questionnaire.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):

Drug/Device Handling: LOGIQ P6 Diagnostic Ultrasound (GE Healthcare, Wauwatosa, WI). Only trained and authorized personnel will operate the ultrasound. The microscope will be stored in a locked space in the Department of Dermatology at 676 N. St. Claire, Suite 1600, Chicago, IL 60611.

The ultrasound gel is the standard of care gel used when obtaining ultrasound images: AQUASONIC® 100 ULTRASOUND TRANSMISSION GEL (Parker Laboratories, Inc., Fairfield, NJ).

This gel and device is being used per the FDA approved use for imaging and there is no investigational use. This device is a non-significant risk device.

PROCEDURES INVOLVED:

Screening Visit (Day 0)

- Inclusion/exclusion criteria reviewed
- Written consent signed
- After the subject has provided signed and informed consent, he/she will be assigned a unique subject identification number.

Imaging Visit (Day 0)

- Participant demographics will be collected, including height and weight (Appendix II)
- Macroscopic photography will be obtained of the participant with a DSLR camera using ambient lighting and standardized positioning (front, 90 degrees, and back)
- Ultrasound gel will be applied to the ultrasound probe to be in contact with the skin areas.
- Ultrasound images will be obtained from various regions of the body, but not limited to:
    - Submental area
    - Upper inner arms
    - Upper back
    - Flanks
    - Abdomen
    - Inner thighs
    - Outer thighs
- Participants will fill out a questionnaire (Appendix I) about their perceptions of their body.

SHARING RESULTS WITH PARTICIPANTS

The Principal Investigator or sub-investigators may publish the results of this study in conjunction with appropriate scientific and medical personnel. The study results will not be shared directly with study participants, however, subjects interested in the study findings will be able to find them upon publication in a peer-reviewed journal.

STUDY TIMELINES

- The duration of each subject's participation in the study is 3 hours.
- Enrollment of all study participants is expected to take up to 7 months
- The estimated date for completion of the study's primary analysis is March 2019.

INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria

1. Males or females 18-85 years old.
2. Subjects are in good health as judged by the investigator.
3. Subjects with Body Mass Index (BMI) between 18-29.99.
4. Subjects who are willing and have the ability to understand and provide informed consent for participation in the study and are able to communicate with the investigator

Exclusion criteria

1. Evidence of another skin condition affecting the treatment area that would interfere with clinical assessments
2. Pregnant or breast feeding
3. Uncooperative patients or patients with neurological disorders who are incapable of following directions
4. Subjects who are unable to understand the protocol or give informed consent (including non-English speaking patients).

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PARTICIPANT POPULATION(S)

Accrual Number:	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented: Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled: Number to Complete the Study or Needed to Address the Research Question
Local	Adults	50	40
Study-wide	Adults	50	40
Total:	Adults	50	40

RECRUITMENT METHODS

- The investigator will passively inform subjects presenting to the Department of Dermatology Clinic at Northwestern University who meet the inclusion criteria. Those expressing an interest in study participation will be contacted by study personnel for a verbal explanation and discussion of the protocol.
- Printed and electronic advertisements will be posted on the Northwestern University Medical Campus and on the internet. Interested potential participants will contact study personnel for a verbal explanation and discussion of the protocol.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Participants will receive a $25 Visa debit card at the completion of the study.

WITHDRAWAL OF PARTICIPANTS

Criteria for terminating study participation

- Subject wishes to stop being in the study
- Subject no longer qualifies based on inclusion/exclusion criteria
- Adverse events occur that, in the opinion of the investigator, put the subject at increased risk and it is not in the best interest of the subject to continue the study

RISKS TO PARTICIPANTS

Photographs:

There is a possibility that subjects will be able to be identified from the photographs that will be taken for the study.

Ultrasound:

There is a possibility that subjects will be able to be identified from the ultrasound images that will be taken for the study.

Allowing the machine to transmit acoustic output with the probe not in use (or in its holder) can cause the transducer to build up heat. The probe therefore may be warm on the skin.
The use of damaged probes can result in injury or increased risk of infection. A damaged probe can also increase the risk of electric shock if conductive solutions come in contact with internal live parts.
Ultrasound can produce harmful effects in tissue and potentially result in patient injury. Exposure time will be minimized per area and ultrasound levels will be kept low when there is no medical benefit.

Ultrasound Gel:
There is a possibility that the ultrasound gel can cause skin irritation or skin allergic reactions.

POTENTIAL BENEFITS TO PARTICIPANTS
There is no direct benefit to the participant. The knowledge gained from this study could provide valuable information about anatomical fat measurements and how this corresponds to patient perceptions of their body..

DATA MANAGEMENT AND CONFIDENTIALITY
Statistical Analysis
Deidentified study data will be into a Microsoft Excel spreadsheet by authorized members of the research team. This is a descriptive study and no statistics will be performed other than any descriptive statistics. Power study and sample size were not performed since this is a descriptive study with descriptive analysis.

Data Storage

The study team will enter subject data into a spreadsheet and/or eCRFs that will be accessible to IRB authorized site personnel through a secure internet connection immediately after entry. Subject data will be de-identified; each subject will be given a unique identifier code and an additional spreadsheet with the unique identifier codes will be maintained on password protected computers, in password protected network folders. Data, photos, and ultrasound images will be stored in a secure drive (FSM Research Files drive) which is maintained by Northwestern University. Paper source documents will be kept in the department office in a locked file cabinet. Access to locked cabinets will be granted only to the PI and authorized study personnel. After study completion; all study documentation, including regulatory documents, copies of eCRFs, signed informed consent forms will be kept on-site in a secure locked cabinet for at least one month. Study documents may be shipped after one month to Iron Mountain, an off-site record storage/management facility. All study records are indefinitely stored per Iron Mountain's policies and procedure. Data generated as a result of this study are to be available for inspection on request by the Northwestern University Institutional Review Board (IRB).

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS
Participants have the right to be treated with respect, including respect for their decision whether or not they wish to continue or stop being in the study. They are free to choose to stop being in the study at any time.

Choosing not to be in the study or to stop being in this study will not result in any penalty to them or loss of benefit to which they are entitled. Specifically, their choice not to be in this study will not negatively affect their right to any present or future medical treatment or present or future employment to which they are otherwise entitled.

ECONOMIC BURDEN TO PARTICIPANTS
Subjects will be responsible for transportation costs, although they will be offered parking validation to partially cover parking expenses at the treatment site.

CONSENT PROCESS
Prior to performing any research procedures, consent for participation will be obtained in writing by signature on a consent form by the study staff at the in a quiet room (e.g. the exam room) at the study site. The consent form will be read by the subject and the subject will be encouraged to take all the time they need and to ask any clarifying questions they may have. Approximately 30 minutes will be devoted to the consent discussion. A copy of the subject's signed consent form will be retained in the study file.

Only authorized personnel that have been listed in the application as being involved in consent will have a role in consent.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)
We are committed to respect participant privacy and to keep their personal information confidential. Personal health information from their medical records and information that can identify them may be used. For example, personal health information may include name, address, phone number or e-mail address.

The health information we may collect and use for this research may include the following:

- all information in a medical record,
- results of physical examinations,
- medical history,
- lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires,
- records about study medication or drugs,
- records about study devices.

During this study, the participant may be coming to the Northwestern Memorial Healthcare Corporation (NMHC) clinical offices for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, they will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

Subject medical information obtained during this study is considered confidential and disclosure to their parties other than the principal investigator and the co-investigators is prohibited. All reports and communications relating to subjects in this study will identify each subject only by their initials and subject identification number. Medical information resulting from a subject's participation in this study may be given to the subject's personal physician or to the appropriate medical personnel responsible for the subject's welfare. Data generated as a result of this study

are to be available for inspection upon the Northwestern University Institutional Review Board (IRB).

NON-ENGLISH SPEAKING PARTICIPANTS
Only English-speaking patients will be enrolled in the study as inability to understand the protocol or give infomed consent (e.g., due to lack of English-speaking abilities) would fail to meet eligibility criteria (see **Exclusion Criteria**).

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE
All research related study visits will take place in the Department of Dermatology from presenting participant populations.

REFERENCES:

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6. Yoshimatsu T, Yoshida D, Shimada H, Komatsu T, Harada A, Suzuki T. Relationship between near-infrared spectroscopy, and subcutaneous fat and muscle thickness measured by ultrasonography in Japanese community-dwelling elderly. *Geriatr Gerontol Int*. 2012;13(2):351-357. doi:10.1111/j.1447-0594.2012.00906.x.

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