

May 14, 2024

PDUS- Swelling_SOP_V3

This protocol is a draft, published without a DOI.

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Protocol Citation: Daniel Rohde 2024. PDUS- Swelling_SOP_V3. [protocols.io https://protocols.io/view/pdus-swelling-sop-v3-ddms246e](https://protocols.io/view/pdus-swelling-sop-v3-ddms246e)

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Protocol status: In development

We are still developing and
optimizing this protocol

Created: April 26, 2024

Last Modified: May 14, 2024

Protocol Integer ID: 99730

Abstract

This protocol details the study of standard operating procedures of swelling by Power Doppler ultrasonography (PDUS).

Guidelines

A	B	C
Revision History		
Version No.	Effective Date	Description
2	04-Jan-24	PDUS- Swelling SOP_V2
3	31-Mar-24	PDUS- Swelling SOP_V3

- **Template instructions (to be deleted upon use):**

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2. There are additional explanatory text and sample headings included for your convenience. Modify as appropriate during implementation.

Standard Operating Procedure

1. Background Information

1.1 Problem leading to the need for the study:

Current approaches to periarticular tibia fractures lack quantitative and objective measures to determine soft tissue readiness for definitive surgery resulting in a routine delay of about 10 to 20 days. This study proposes assessing power doppler ultrasound as a tool to quantify soft tissue perfusion in this context, exploring its sensitivity to changes in perfusion during staged management. Swelling in the tissue enhances skin perfusion, potentially causing complications in surgical healing.

1.2 Central Research Question:

- Is Power Doppler ultrasound effective in differentiating between normal and compromised skin perfusion states in patients with periarticular tibia fractures?
- Can Power Doppler ultrasound reliably track and quantify the improvement in skin perfusion in patients following surgery for periarticular tibia fractures?

1.3 Type of Data to Collect:

Data collection includes patient demographics and injury characteristics (AO-OTA classification, Wrinkle Test, Ultrasound, CT and Power Doppler measurements, clinical outcomes, and time-related variables will be tracked. The operative surgeon's Tscherne classification and longitudinal data for staged procedures will be documented. Imaging analysis will focus on vascularity index calculations.

1.4 What are potential outcomes for a given subject? For the study?

The study outcome involves a detailed comparison of vascularization in the injured limb both before and two weeks after the fixation procedure, in addition to comparing it with the uninjured limb.

1.5 What parameters can influence the primary outcome?

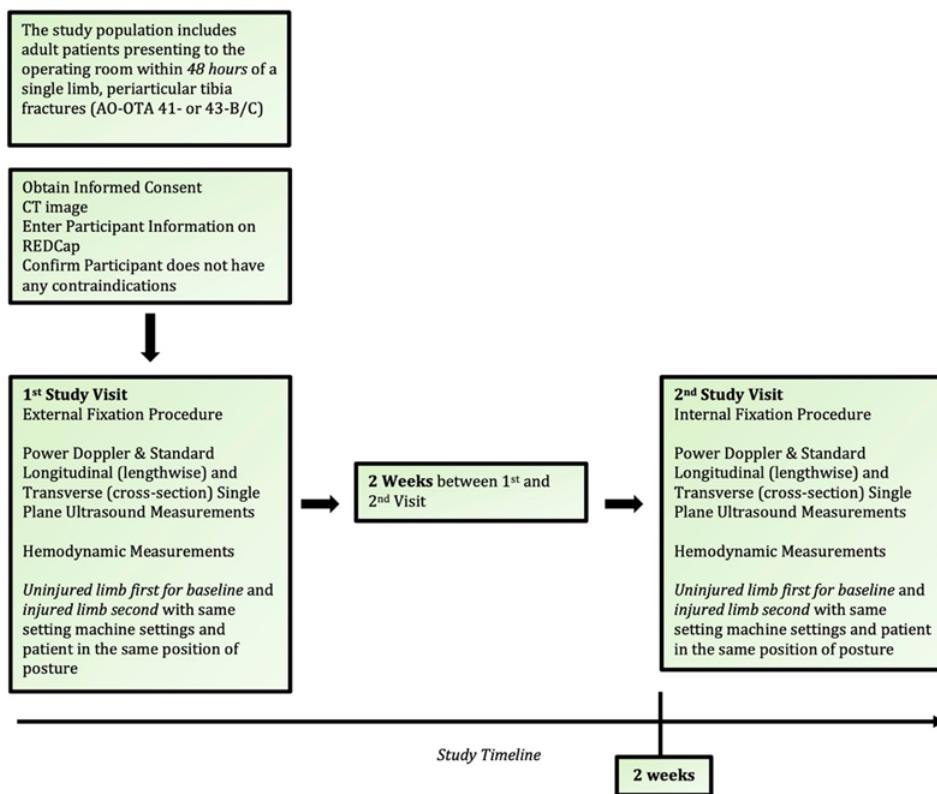
Soft tissue injury severity, time elapsed since injury, vascular disease/damage, BMI, and the sonographer (operator dependency).

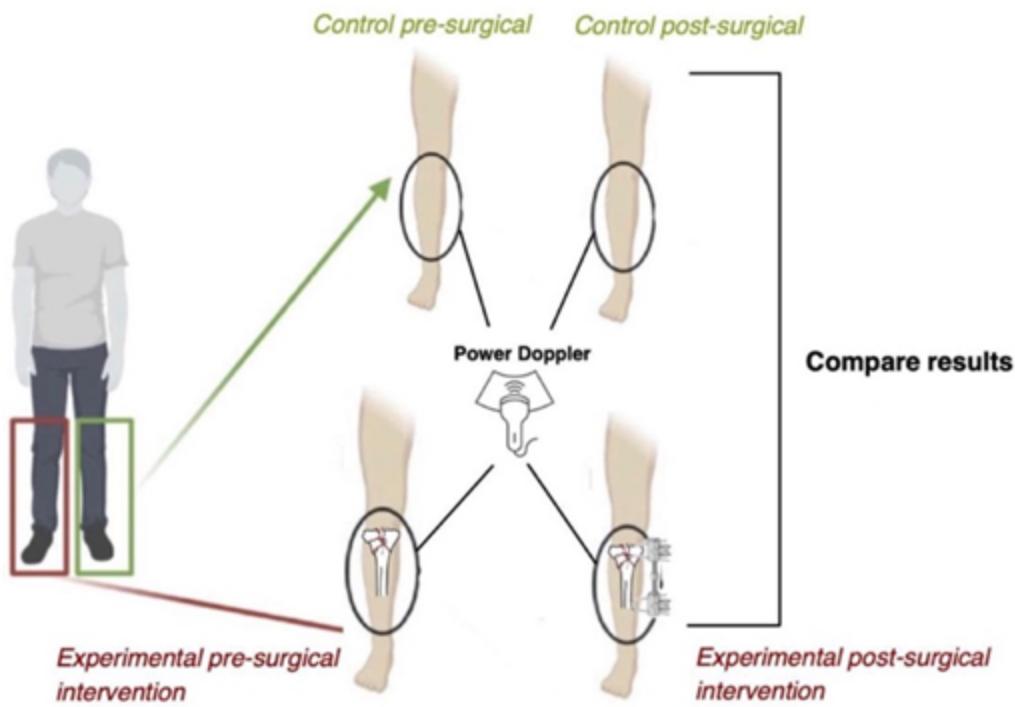
1.6 Overall Significance of the Study:

If successful, this study could provide an objective measurement of perfusion in the skin for periarticular tibia fractures allowing patients to undergo definitive surgery earlier with improved wound healing.

2. Study Methods and Equipment Inventory

2.1 Diagram of study with all procedures included





List of all necessary equipment / inventory to complete one iteration of study procedure:

A	B
Item	Quantity Needed
Sonosite LX Ultrasound System ("Power Doppler machine" with Ultrasound Gel) to Operating Room Designated Area	1
Paper Consent Form	1
OTI Laptop to enter data on REDCap	1
Obtain CT scan from Patient EMR	1
SOP Printed Checklist	1
Marking pen from Nurse's station	1
USB Drive	1
Backup USB Drive	1
\$20 Gift card for participation	1

Consent

- 1 Print a paper copy of the Informed Consent for the PDUS Swelling Study found on IRIS and hand it to the study participant. Go over the Informed Consent with the participant and have them and the study representative both sign and date the paper copy.
- 2 Ensure to explain the purpose, procedures, risks, benefits, and the right to withdraw from the study at any time. Emphasize the fact that we are only obtaining ultrasound images of their legs and not performing any intervention.
- 3 Store the signed Informed Consent in the participant file.

Entry of Participant Information into REDCap

- 4 Bring the designated laptop from OTI to the designated area in the Operating Room and enter the following data into REDCap:
 - Patient demographics
 - AO-OTA classification
 - Tscherne classification
 - CT Images (obtained from PACS – axial, coronal and sagittal cuts of maximal swelling zones).
- 5 Further data collection includes: Ultrasound images and Power Doppler measurements (image and vascularity index), time from injury.

Patient Preparation

- 6 **Option #1: Awake Patient**
 - 6.1 Pre-Procedure Instructions: Again, inform patients about the purpose and process of Power Doppler ultrasound imaging. Advise them on any clothing or accessory adjustments needed for easy access to the periarticular region of the tibia.
 - 6.2 Positioning: Position the patient supine, ensuring clear access to the affected periarticular tibia area. Special attention should be paid to minimizing movement during the imaging process, as movement can affect the quality of Power Doppler readings.
 - 6.3 Skin Preparation: Ensure the skin over the periarticular tibia area is clean and free of any substances that might interfere with ultrasound transmission. Use ultrasound gel to enhance contact between the transducer and the skin.

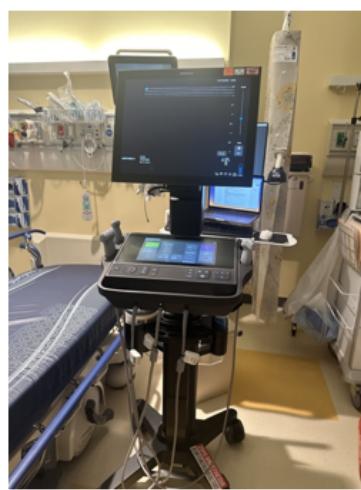
- 6.4 Pain Management: Consider the patient's comfort and pain levels.
- 6.5 Patient Education and Reassurance: Educate and discuss with the patient about what to expect during the Power Doppler ultrasound procedure. Address any concerns or questions they may have to alleviate anxiety and ensure cooperation during the imaging process.
- 6.6 Prepare site for Power Doppler measurement: Identify maximum point of swelling on injured side of patient and mark with marking pen (from Nurse's station). Repeat on the uninjured side.

7 **Option #2: Asleep Patient**

- 7.1 Wait for the patient to undergo anesthesia.
- 7.2 Wait for the patient to be positioned on the operating bed.
- 7.3 Image before the patient's uninjured leg is strapped down.
- 7.4 Mark point of maximal swelling and mark same point on uninjured.
- 7.5 Mark same point on uninjured side.
- 7.6 Record Wrinkle Test on both sides.
- 7.7 Save longitudinal US, Transverse US, PDUS images.
- 7.8 Repeat on the contralateral side .
- 7.9 Label every image with: image type, side, injured/uninjured

Ultrasound Machine Setup & Standard Images

8



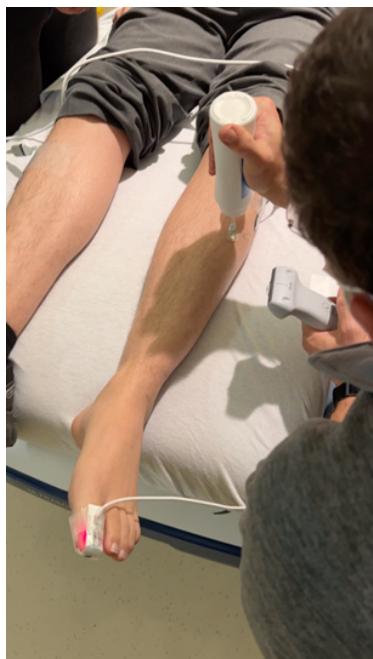
Transducer Selection: Choose the MSK transducer for Power Doppler imaging of the periarticular tibia area and is plugged into the machine properly. (Serial number: xxx)

- 9 Obtain standard longitudinal image (in-line with tibia) followed by standard transverse image (rotate probe 90°): Apply a sufficient amount of ultrasound gel on the linear probe to ensure good acoustic contact.
- 10 On the ultrasound machine, select the musculoskeletal (MSK) preset, which is optimized for viewing ligaments, tendons, and bones. Adjust the depth of the ultrasound to ensure the entire width and a substantial portion of the length of the tibia are visible.
- 11 Visualize the tibia from one end to the other, adjusting settings such as gain and depth as necessary to improve the image quality. Freeze the image when a clear, representative longitudinal section of the tibia is visible. Save the image.
- 12 Reposition the probe by 90 degrees and adjust settings to capture these images. Freeze and save.
- 13 Calibration and Settings Adjustment: Calibrate the machine settings specific to Power Doppler imaging. For this machine Color Doppler settings include Power/Velocity Doppler and is engaged with the "Color" setting on the control panel by pressing the "C" button and the "2D" button. Both lights should light up blue.



Power Doppler Measurements

- 14 Beginning with the uninured side point of maximum swelling (using the previously marking-pen marked point), apply ultrasound gel to the area to capture baseline measurements.



- 15 Then apply the MSK probe with an adequate amount of pressure to the uninured side point of maximum swelling to obtain an image on the monitor.

Note

Note that the yellow-outlined box is the area of focus for data analysis.



- 16 To optimize the Power Doppler image, adjust the following settings to optimize image quality: gain and depth. The **Gain** wheel is on the left-hand side of the device's control panel and is increased in a clockwise fashion and decreased in a counterclockwise fashion.



- 17 Specifically adjust the Gain setting until the yellow-outlined box (our area of focus for analysis) is red, indicating maximal blood vessel perfusion. This adjustment is crucial to stay consistent to ensure the accuracy of soft tissue perfusion measurements. The value of the Gain is indicated in the lower right-hand corner of the monitor.





Data collection

- 18 Image Freeze and Capture: When Gain and Depth setting are optimized at the point of maximal swelling, first hit the snowflake icon to freeze the image on the monitor and then the camera icon to save the image to the device.





- 19 After all images are captured, first tap Patient List on the control panel. Then insert the USB storage device into a USB port on the system. The USB storage device is ready when the USB icon appears on-screen.
- 20 Select all the images for the specific patient, tap “Send to”, then select “USB”.

- 21 The monitor will display “USB transfer complete” when complete. Then repeat these steps and export the images to the Backup USB Drive.
- 22 Adjusting the Depth: the Depth value appears in a rectangle in the lower right corner of the image area. To adjust, Press the ↑ upper depth control to decrease the displayed depth and view structures closer to the skinline.
- 23 Press the ↓ lower depth control to increase the displayed depth and view deeper structures.
- 24 Use the slider on the monitor touchscreen to increase or decrease the depth.



- 25 When the Gain and Depth settings are optimized for image capture, proceed to capture the images on the device for data collection.

Repeat Procedure on Injured Side

- 26 It is critical to keep the same Gain and Depth settings and repeat the Power Doppler Measurements and Data Collection procedures on the injured side point of maximal swelling for comparative purposes.

Schedule 2 Week Follow-Up

- 27 After the initial Power Doppler measurements and data collection, it is important to schedule a follow-up appointment two weeks post-procedure.
- 28 This follow-up is crucial to monitor any changes or developments in the patient's condition and to assess the progression of soft tissue perfusion.

- 29 Ensure that the appointment is recorded in the patient's file and communicated clearly to them, with appropriate phone calls and text messages to remind them about the appointment at designated intervals and emphasizing the importance of this subsequent assessment for the ongoing evaluation of their condition.

Return all equipment

- 30 Upon completion of the Power Doppler Measurements and data collection procedures, it is essential to promptly and efficiently return all equipment to its designated storage location. This includes the Sonosite LX Ultrasound System, transducers, blood pressure cuff, O₂ sensor, and any other auxiliary equipment used.
- 31 Ensure that each item is properly cleaned and disinfected according to the manufacturer's guidelines and checked for any signs of damage or malfunction.
- 32 The ultrasound system should be placed back on its charging station to ensure it is fully charged for future use. Additionally, all disposable items should be discarded appropriately.



Repeat all Power Doppler Measurements

- 33 During the two-week follow-up visit, repeat all Power Doppler measurements following the same procedure as the initial assessment.
- 34 This includes preparing the patient and the ultrasound equipment, applying the same settings for gain and depth, and following the same protocol for identifying and marking the point of maximum swelling on both the injured and uninjured sides.

- 35 Consistency in the procedure is key to obtaining comparable data, which is essential for assessing changes in soft tissue perfusion over time.

Repeat Data Collection

- 36 Along with repeating the Power Doppler measurements, it is essential to also repeat the data collection process. This involves capturing and storing ultrasound images and measurements in the same manner as during the initial visit.
- 37 Ensure that all images are accurately labeled with the patient's identification details and the date of the follow-up. After capturing the images, export them to a USB storage device and a backup drive for secure storage.
- 38 Maintaining a meticulous record of all data collected during the follow-up is vital for a comprehensive comparative analysis with the initial data set.

Coordination of Study Enrollment and Execution

- 39 Slack will be the main method of coordinating patient enrollment and study execution.
- 40 The execution plan for handling incoming cases will be to identify the patient either through Epic or the on-call physician.
- 41 Once the patient has been identified, the identifier will relay the information to the on-call member of the CRC SWAT team who will then be responsible for ensuring the patient is enrolled.

Procedure

- 42 Create detailed checklist of procedure that could be followed by anyone involved in the study. This checklist should encompass all activities that one subject would follow, from the pre-consent process to discharge for human studies, or the entirety of one data collection instance for other studies.
- 43 The table below is one example for how to report the procedure, but tailor it to best approach for each study. At a minimum, it should include the item, a field for details or the data to be collected, and whether or not the item was completed. If your study has completely independent procedures, create a checklist for each one.

PDUS - Swelling Checklist

- 44 At pressure set point and zone of interest, adjust the gain.

Note

Pressure setting: [____mBar]

Gain setting: [____]

*Gain adjusted so not washed out, 'red dots'

45 Uninjured Side

Obtain longitudinal image (in-line with tibia).

Note

2D [time stamp] PD [time stamp]

46 Obtain transverse image (rotate probe 90°).**Note**

2D [time stamp] PD [time stamp]

47 Injured side (do not adjust pressure or gain!)

Obtain longitudinal image (in-line with tibia).

Note

2D [time stamp] PD [time stamp]

48 Obtain transverse image (rotate probe 90°).**Note**

2D [time stamp] PD [time stamp]

Procedure- Participant Study Visit

49 Consent Form #1-3 Printed and Signed.

Note

Copies for research [] patient [] chart []

50 Ask the Block Team about using Ultrasound device for the study.

Note

Can be before or after surgery

51 Allow time for patient to be intubated.

Note

Bring ultrasound machine and communicate with surgical team.

52 Ensure pressure sensor charged and attach to the narrow probe.

Note

Requires elastic and backing, apply jelly to probe and pressure sensor, test on arm, zero pressure sensor.

53 Tscherne classification of fracture.

Note

Circle Below

- Tscherne classification: 0 1 2 3
- AO-OTA Classification: 41 or 43 B/C

- 54 Identify maximum point of swelling on injured side of patient and mark on both sides.

Note

Use marking pen from pre-op (**circle location:** anterolateral, posteromedial)

- 55 Perform Wrinkle Test (+ indicates wrinkling IS present)

A	B
Provider Name:	Injured Side Uninjured side
#1 _____	+ / - + / -
#2 _____	+ / - + / -

After Study Visit

- 56 Download all images to USB and Backup.

- 57 Schedule ~2-week follow-up with Participant (if 1st Study visit).

Note

Follow up Appointment:

Date_____

Time_____

- 58 Copy all data from this form to RedCap.

Note

Use computer to login to RedCAP and Epic **Record Name**, MRN, Age, Sex, Height, Weight, Injury Date, Collection Date, Mechanism of Injury (MOI), PMH/PSH, Injury Diagnoses, AO/OTA classification, Tscherne Classification, Wrinkle Test x 2, CT images x 6, PD/US images x 8