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Proton Density Fat Fraction (PDFF) Measurement of Myelofibrosis in Mouse Tibia

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Protocol status: Working We use this protocol and it's working

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The claims hold when:

- Scanner hardware, proton density-weighted multi gradient-echo data acquisition method and parameters, image reconstruction, and data-reduction procedures are equivalent (or superior) to those detailed in section III.
- Use of the same animal model and interventions to induce myelofibrosis are performed as detailed in section V.
- PDFF change is assessed on an individual animal basis where each animal undergoes identical procedures on the same MRI system over longitudinal timepoints.

Keywords: preclinical imaging protocol, mouse tibia, proton density fat fraction MRI, bone marrow myelofibrosis, technical repeatability

ABSTRACT

This document details procedures for PDFF measurement in MF mouse tibia to achieve stated performance claims. In this profile PDFF values are expressed in "% units" on a 0 to 100% scale, such that bone marrow containing dominant red marrow and dominant yellow marrow have PDFF values of 0-few% and 80-100%, respectively. Tibia bone marrow composition in MF mouse models has gradation going from proximal to distil ends of the tibia, therefore separate claims are made for volume of interest (VOI) analysis of PDFF maps for each of three distinct sections along the length of the tibia (see Figure 1):

Section 1 (proximal)° VOI (~4-5mm³) within 9mm of proximal end of tibia Section 2 (transition)° VOI (~0.4-0.5mm³) from 10 to 12mm of proximal end of tibia Section 3 (distil)° VOI (~0.1-0.2mm³) from 13 to 14mm of proximal end of tibia

Claim 1:A measured change in the mean PDFF in Section 1 VOI of MF mouse model tibia that exceeds ±1.6% indicates a true biological change has occurred in the tibia bone marrow with 95% confidence.

Claim 2:A measured change in the mean PDFF in Section 2 VOI of MF mouse model tibia that exceeds ±15.5% indicates a true biological change has occurred in the tibia bone marrow with 95% confidence

Claim 3:A measured change in the mean PDFF in Section 3 VOI of MF mouse model tibia that exceeds ±25.5% indicates a true biological change has occurred in the tibia bone marrow with 95% confidence

ATTACHMENTS

UMich_PDFF_SOP-Profile_20230214.pdf