



DIGITAL LIVER PATHOLOGY AID (DLPA)

An advanced digital diagnostic tool for identifying Non Alcoholic Fatty Liver Disease (NAFLD).

Organic Research Corp. develops digital pathology solutions. The DLPA was developed to accurately and reproducibly quantify the histological lesions associated with Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic SteatoHepatitis (NASH).

BACKGROUND

Various research has demonstrated significant inter and intra-observer error by pathologists when reading liver tissue samples for the lesions associated with NAFLD. This has obvious implication when establishing patients disease stage and monitoring their response to therapeutics.

The Gold Standard for research is the NAFLD Activity Score (NAS) and was designed to drive consistency across NAFLD/NASH research. The NAS score is determined by assigning a numerical grade to a tissue sample for each of the three lesions associated with NASH diagnosis (steatosis, lobular inflammation, and hepatocyte ballooning) and summing those grades. While the NAS score has become the standard for monitoring NAFLD/NASH activity, the scale has two shortcomings. First, pathologists often time disagree on a lesion grade. Second, the scale in itself does not reflect the continuous nature of measuring disease lesions and rather forces similar levels of severity to be grouped together. For example, a patient with **6%** steatosis would receive the same steatosis Grade 1 as a patient with **32%**.

THE DIGITAL LIVER PATHOLOGY AID

Researchers, Hepatologists and Pathologists at the Medical College of Wisconsin (MCW), University of Wisconsin – Milwaukee (UWM) and the National Cancer Institute received funding via the National

Institutes of Health (NIH) and the UWM Research Foundation to develop computer algorithms that could take an image of liver tissue and automatically quantify the lesions used for the NAS score. The algorithms use supervised machine learning, a subset of artificial intelligence, designed to replicate the expertise of data provided by world-renowned NIH and MCW pathologists.

RESULTS & PUBLICATIONS

The algorithms powering the DLPA have been shown to perform with **95% plus accuracy**. The results have been peer reviewed and published in the medical journal Human Pathology and Gastroenterology, and presented at 2014 Digestive Disease Week national conference.

BENEFITS

If a patient had **32%** steatosis in the liver, and receives a therapeutic that reduces steatosis to **6%**, under today's Gold Standard NAS scoring system, the therapeutic would show no efficacy as it is a steatosis Grade 1 both pre and post therapeutic. Today's clinical studies may not accurately demonstrate efficacy. Additionally, study results are at risk due to the variability and subjectivity associated with pathologists' readings, and the underlying semi-quantitative nature of the NAS scoring system.

The DLPA provides objective and reliable measures of the lesions associated with NAFLD/NASH. Rather than semi-quantitative grades by human pathologists, lesions are measured on a continuum and receive a percentage score. For example, instead of knowing a patient is steatosis Grade 1, the DLPA reports the patient has **14.2%** steatosis. This provides the ability to accurately monitor a patient's response to a therapeutic and eliminates human subjectivity.

CONTACT INFO

If you would like to learn more about using the DLPA in a study contact Organic Research Corp. at:

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