Microstructure Imaging, INC

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General

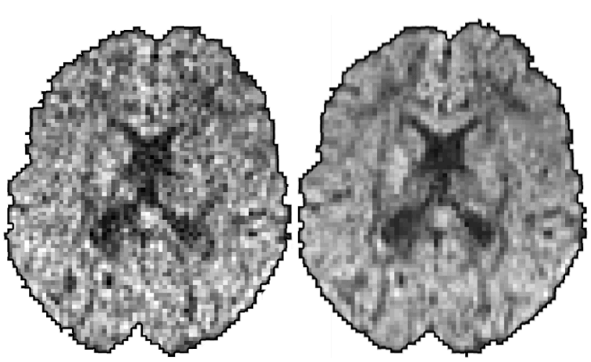
MICSI is a service company that (1) improves medical image quality using advanced post-processing and (2) provides quantitative imaging biomarkers specific to cellular-level pathology.

Resolution limitation in medical imaging

The advent of medical imaging has allowed radiologists to assess internal structures non-invasively. Various pathologies could be diagnosed prior to severe symptoms, where early diagnosis would mean adding decades onto the patient's life. The major limitation of medical imaging has always been its imaging resolution, which was roughly 1 mm for any voxel/pixel. In practice, pathologies originate at the cellular length scale, 1000 times smaller than the available imaging resolution. By the time that the pathologies, such as cancer, grow to be visible for medical imaging, the disease may have progressed to a point that is irreversible. A gut reaction to this resolution limit is to create a better imaging hardware; however, the current generation of hardware is near perfect, where the efficiency in signal to noise ratio (SNR) of commercial devices is approaching 90% of the theoretical "ultimate SNR" limit. Better hardware will not be enough to achieve cellular level resolution.

MP-PCA Denoising

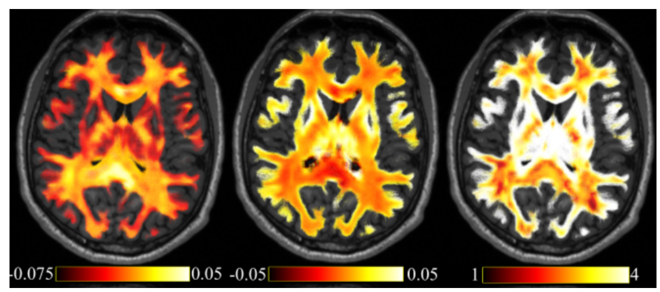
The ultimate-SNR limitation can be achieved and even surpassed by eliminating the noise-floor with mathematical modeling. In practice, our MP-PCA denoising application improves the SNR of MRI images by a factor of 2-3. We anticipate FDA-510k approval to be ready in early 2019.



Original **Denoised**

Cellular Imaging Biomarkers

Although MP-PCA is impressive, it is not sufficient to achieve cellular level resolution. To bridge the remaining gap, MICSI will offer a suite of biomarkers that are derived by using the MRI to study how water molecules interact with tissues. The trajectory of water molecules in the body can then be used to construct biomarkers that include: membrane permeability, cellular diameters, luminal diameters, structural orientation, tissue fractions, angular dispersion, and many more. Our biomarkers will assist radiologists and clinical practitioners to diagnose e.g. brain tumors and prostate cancer at an earlier stage. Full FDA premarket approval will be necessary for these biomarkers to be used in clinical practice.



Left to right: White matter fiber tracts color-coded by cellular permeability, diffusivity towards myelin walls, and axonal diameters. These tissue properties are among first indictors of neuronal degeneration.

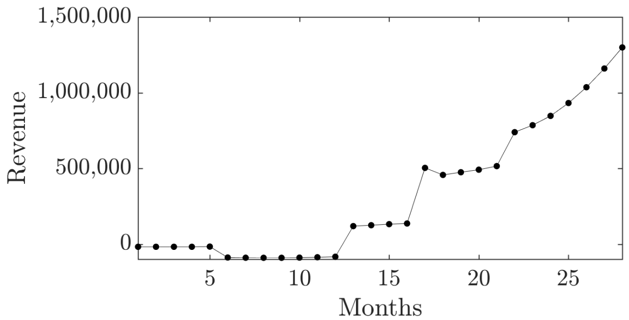
Revenue: Clinical Sales

MP-PCA (early stage) and various biomarkers (later stage) will be distributed on a cloud based system, where hospitals can sign up for annual prescriptions. The cloud based system will be connected to the picture archiving and communication system (PACS) and will therefore cause no disruption within the clinical workflow.

Revenue: Contract Research Sales

We intend to offer our biomarkers and image post-processing approaches to pharmaceutical and biotech companies. This may be particularly attractive since our biomarkers can capture changes originating at the cellular level, without the need for invasive procedures, such as biopsies. Non-invasive biomarkers hold the promise of smaller and more cost-effective clinical trials in Phase II and III.

Projected 3-year revenue:



Projections from sales and non-dilutive funding only.

Executive Board: Lieven Nuyttens (MBA), CEO
Lieven has an engineering background and an MBA from Wharton School of Business. He has 20 years of experience as an industry executive and has successfully brought FLUIDDA, a quantitative CT imaging company to the US market.

Executive Board: Gregory Lemberskiy (MS), CTO
Studied physics as an undergraduate at NYU and is in the process of completing his PhD in biomedical imaging at NYU School of Medicine. His PhD dissertation focuses on applying microstructural modeling to tissues outside of the brain.

Advisory Board: Dmitry S. Novikov (PhD)
Dmitry is a theoretical physicist with a PhD from MIT. His experience with hard condensed matter physics brought a technical rigor that has not been previously seen in the field of medical imaging. He has been recently elected to serve as president of the diffusion study group for the International Society of Magnetic Resonance.

Advisory Board: Els Fieremans (PhD)
Els is an experimental physicist with a PhD from Ghent University. She is credited with the first applications of diffusion kurtosis imaging and tissue exchange within the field. If a physical phenomenon exists, she can figure out how to image it.

Advisory Board: Timothy M. Shepherd (MD/PHD)
Tim is a world-renowned Neuroradiologist who has completed his residency and fellowship at UCSF. He is currently NYU's director of brain mapping and has an interest in guiding MICSI towards applications in pre-surgical planning.

Selected Patents and Publications

Image post-processing and MP-PCA Denoising

[1] Patent: System, method and computer accessible medium for noise estimation, noise removal and gibbs ringing removal. US Patent (pending, 2016)
1. Denoising of diffusion MRI using random matrix theory. Neuroimage 2016; 142:394-406.
2. Diffusion MRI noise mapping using random matrix theory. Magn Reson Med, 2016; 76:1582–1593

Quantifying cell membrane permeability and cell size, relevant for MRI in muscles and in prostate cancer assessment.

[2] Patent: System, method and computer-accessible medium for determining membrane properties relating to diffusion. US Patent US9295948 B2.
1. Random walk with barriers. Nature Physics 2011;7(6):508-514
2. Revealing mesoscopic structural universality with diffusion. PNAS USA 111(14), 5088–5093 (2014)
3. In vivo measurement of membrane permeability and myofiber size in human muscle using time-dependent diffusion tensor imaging and the random permeable barrier model. NMR Biomed. 2017 Mar;30(3). doi: 10.1002/nbm.3612. Epub 2016 Oct 7.

Brain microstructure biomarkers, relevant for early assessment of neurodegeneration, for fiber tracking and pre-surgical planning:

[3] Patent: System, method and computer-accessible medium for determining brain microstructure parameters from diffusion magnetic resonance imaging signal's rotational invariants. US patent (pending, 2016).

[4] Patent: System, method and computer accessible mediums or determining neurodegeneration. US Patent (pending, 2014, close to be finalized with USPTO).

[5] Patent: System, method and computer-accessible medium for obtaining and/or determining mesoscopic structure and orientation with fiber tracking. US Patent (pending, 2014).
1. MesoFT: Unifying diffusion modeling and fiber tracking. MICCAI, Part III, LNCS 8675, 201–208 (2014)
2. Rotationally-invariant mapping of scalar and orientational metrics of neuronal microstructure with diffusion MRI. Neuroimage. 2018 Mar; doi: 10.1016/j.neuroimage.2018.03.006