ENHANCING ARTIFICIAL CORNEA WITH ARTIFICIAL INTELLIGENCE

Thomas Schmiedel
Theo Fleck

HealthInfo
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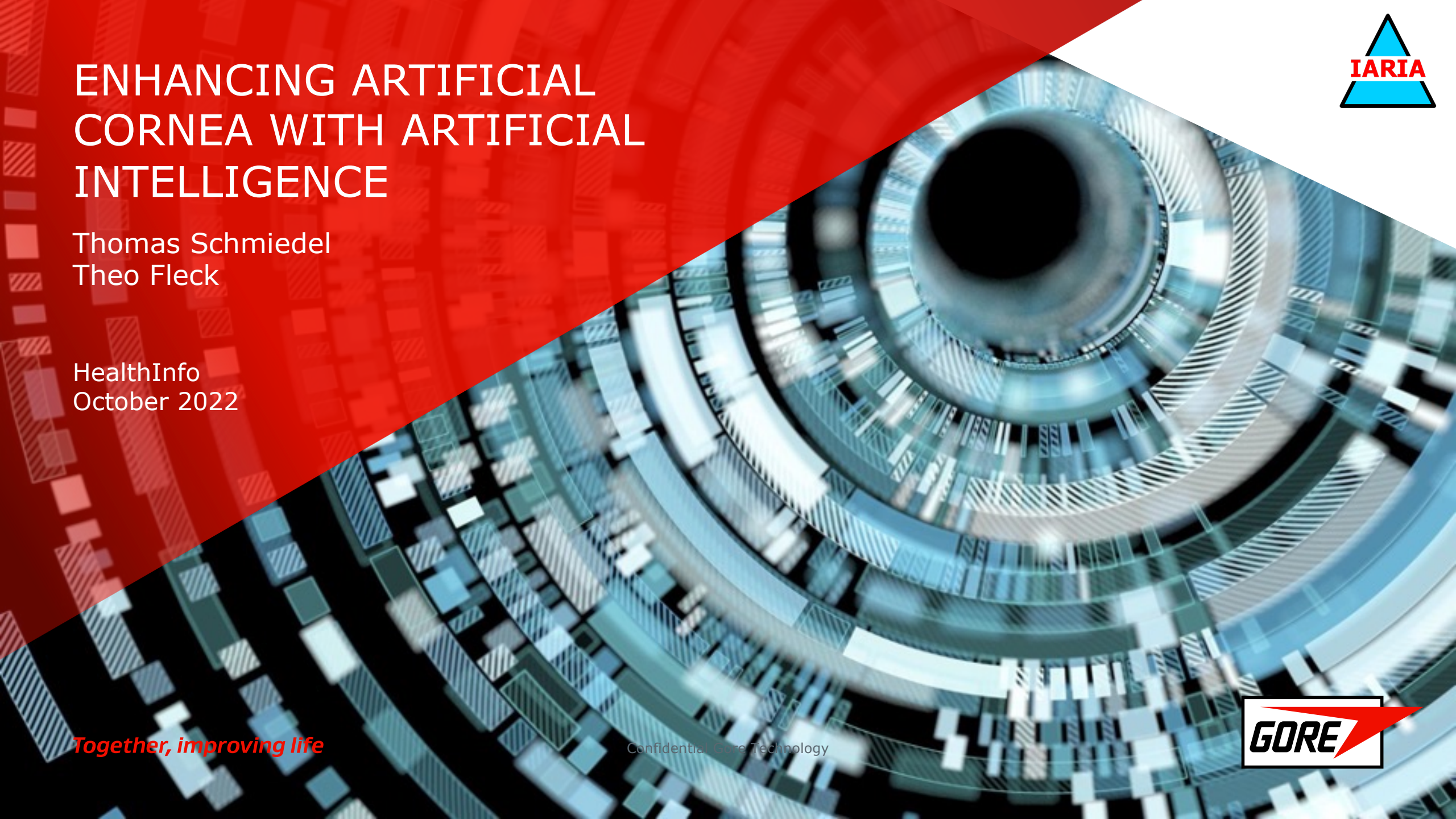


Together, improving life

Authors Bios

Thomas Schmiedel

Scientist

W.L. Gore & Associates

Thomas came from academia to join Gore about 25 years ago. With roots as a physicist, he has driven understanding in product function, development of novel measurement and analysis techniques and product innovation. The recent addition of AI/ML techniques to assess tissue health has been an exciting new opportunity and focus of study.

Theo Fleck

Innovation Architect

W.L. Gore & Associates

Theo is an Innovation Architect at W.L. Gore & Associates. At Gore, he works on cross-functional teams to bring emerging technologies such as AI, IoT, XR and Distributed Ledger to new and existing products. Theo’s most recent work at Gore uses Machine Learning algorithms to assess tissue health in one of our life sciences applications. The project began as an attempt to automate the analysis of one of our scientists and morphed into a commercial idea.

Agenda

Background

AI approach for Cornea

Summary

1. Background
   - Synthetic Cornea Mesoplant and risk for rejection
   - AI powered solution
   - Optical Coherence Tomography (OCT) Explainer
2. AI Approach
   - Defining the problem
   - Creating a dataset
   - Establishing success
   - Examples
3. Next Steps

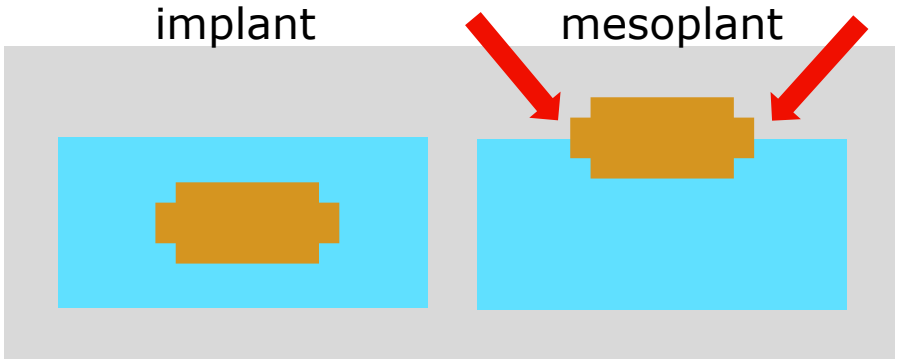
Artificial Cornea

Replaces a clouded natural Cornea (first surface of the eye)

Challenge is long term durability

Market is waiting for a solution

New approach is needed to ensure durability of mesoplant



Mesoplant:

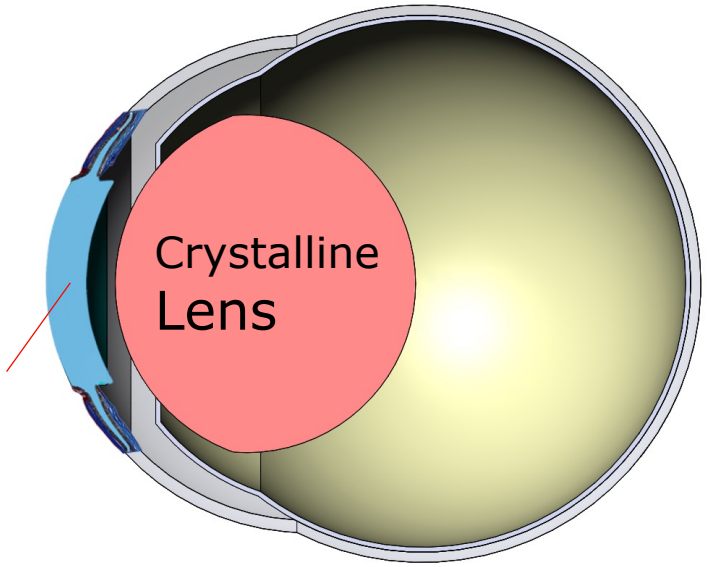
Interface between outside and inside the body

Strong barrier function is needed

Key is health of the interface

Gore Artificial Cornea Device*

* CAUTION Investigational Device. Limited by US law to investigational purposes.



Implanted in Rabbit eye

Optical Coherence Tomography (OCT)

Optical Coherence Tomography

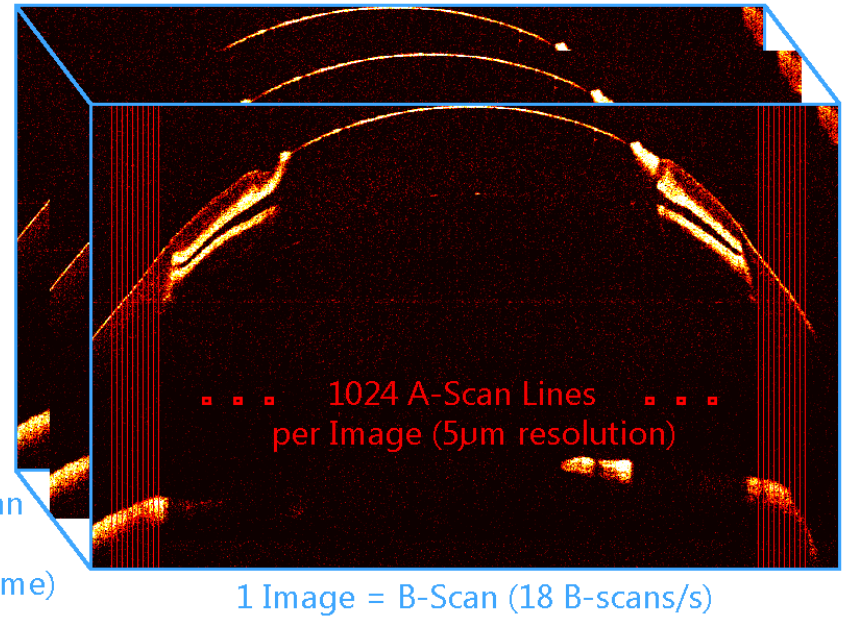
Cross-sectional Images of the eye

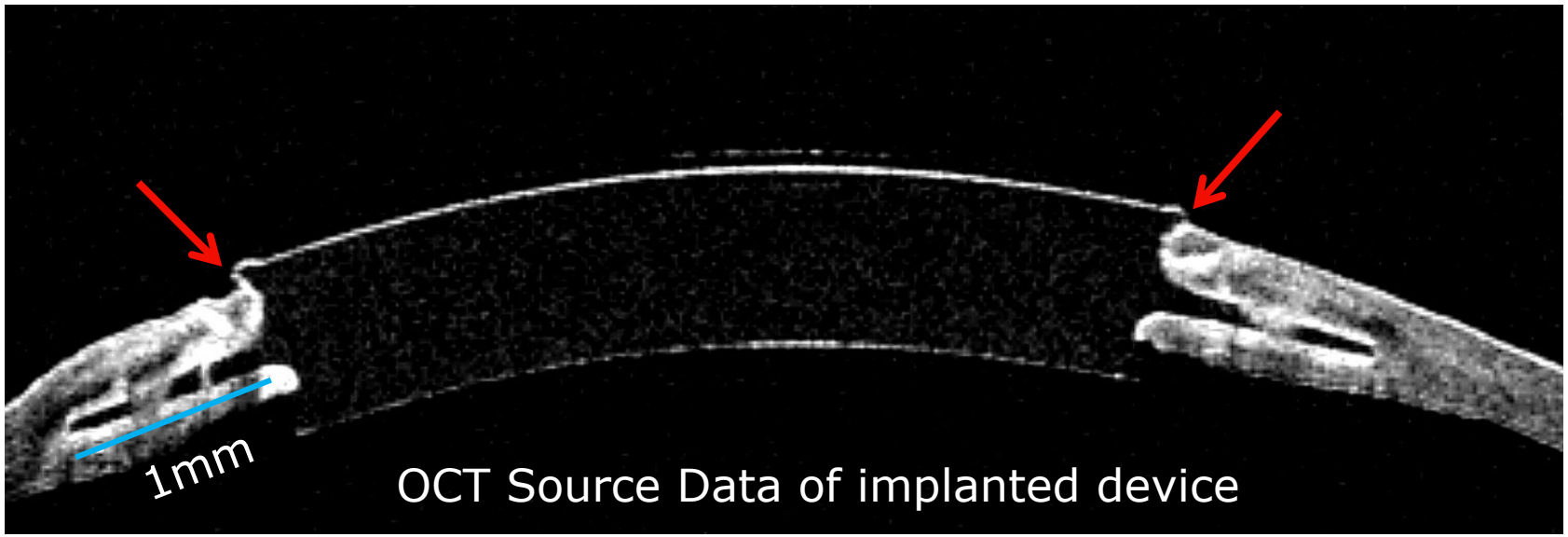
Detailed non-contact Anatomy

Large amounts of Data

6-month study (16 animals): 250 images in 112 exams

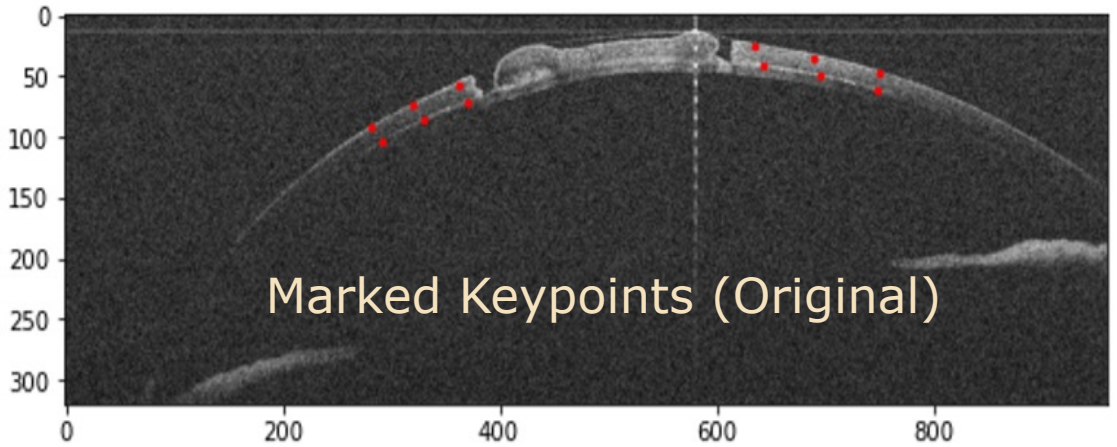
OCT Image Stack

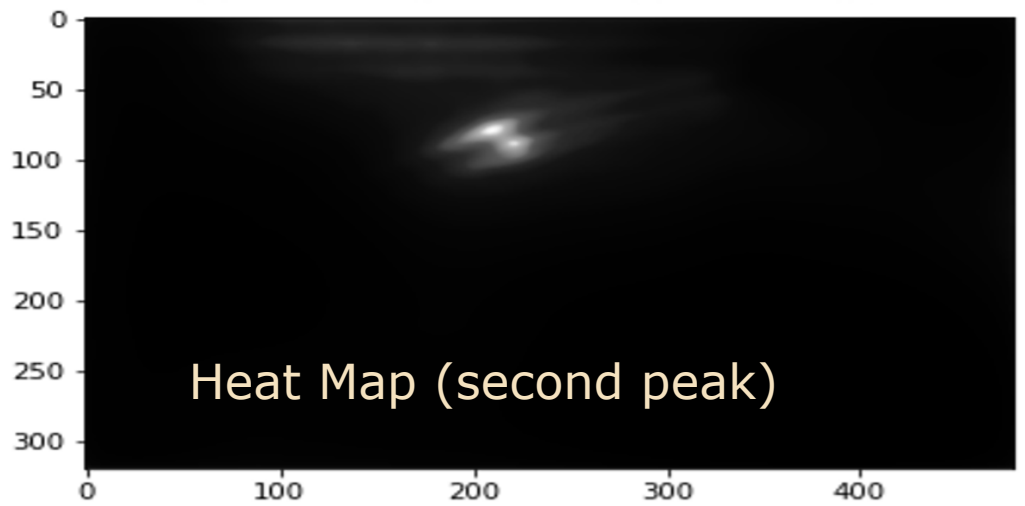




Starting Point – Key Point Detection

- Data volume made manual analysis prohibitive, requiring some form of automation
- Automation also takes out the human factor of variability
- Manual process automated with Artificial Intelligence / Machine Learning (AI/ML)
- Heat map yields good outcomes
- Stepping-stone from keypoint to tissue volume detection, requested by physicians





AI/ML and Artificial Cornea

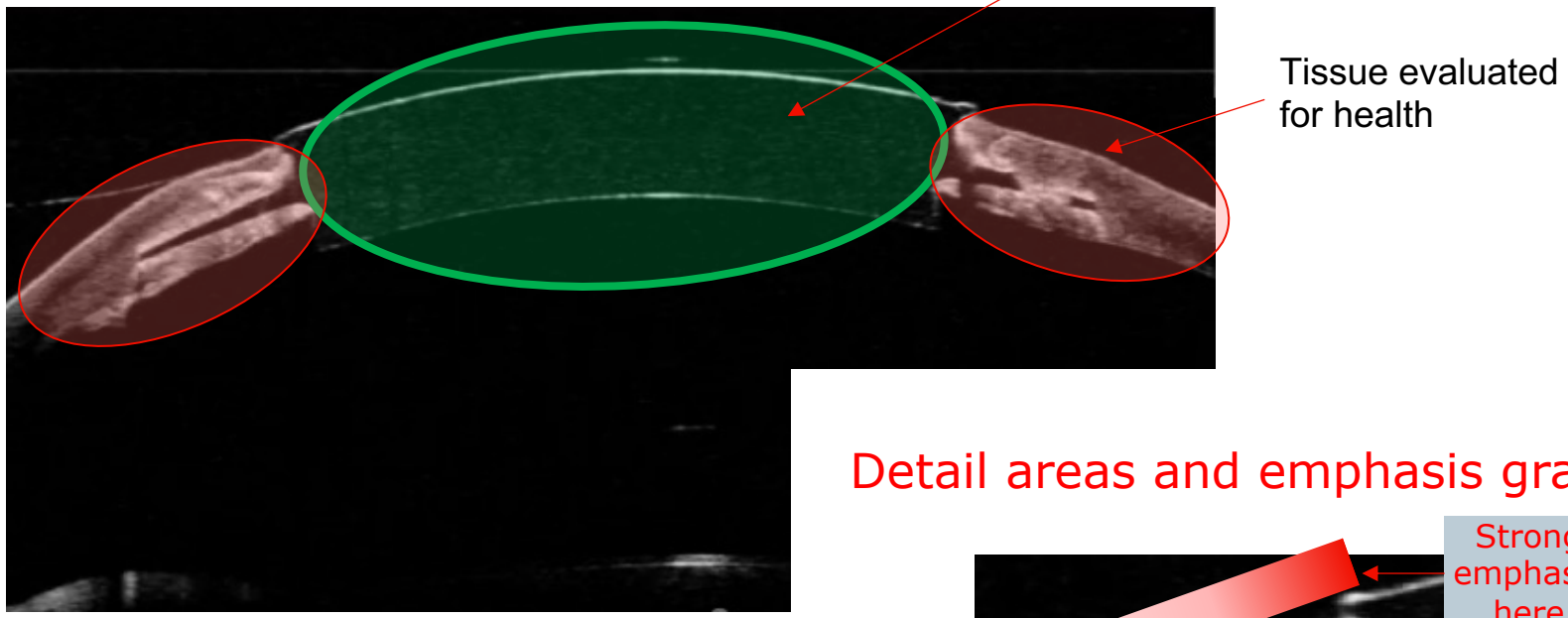
Let’s connect the two

Monitoring tissue health, measurement and root-cause analysis

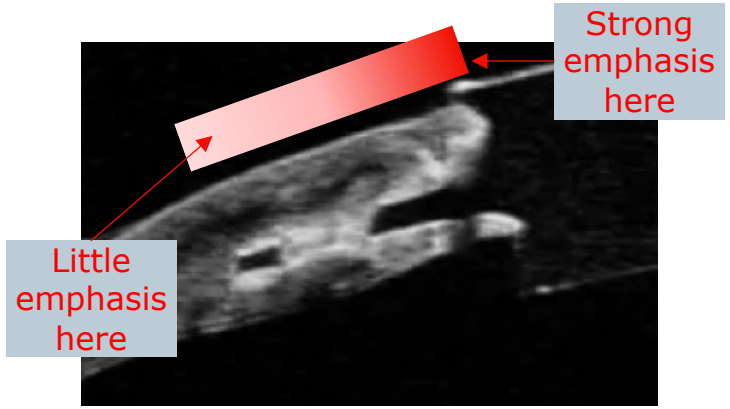
Image elements that capture tissue health

Quick analysis of data

Large amounts of data



Detail areas and emphasis gradient



How To of an AI/ML Project

Well defined task

Strong training sets

Well defined error function

Data post-processing

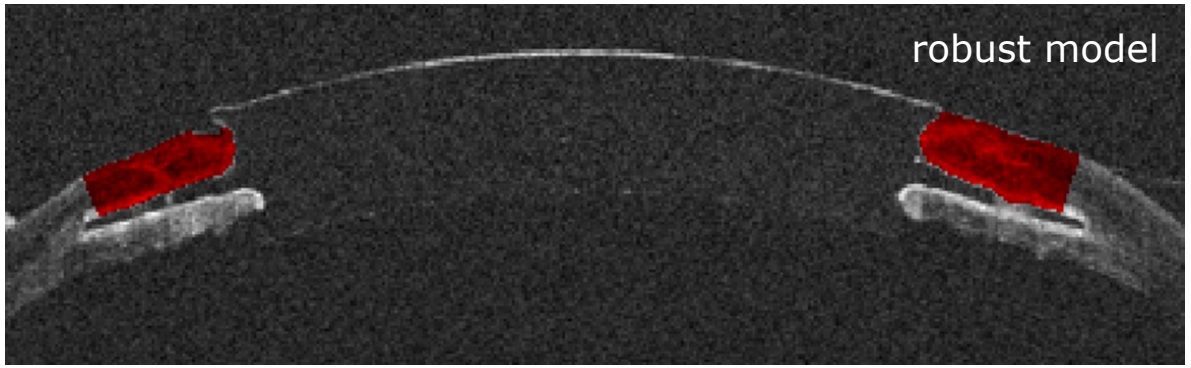
User-friendly output

Team feedback loop

- Define clear task for AI/ML to accomplish
- Create Training and Test Datasets using the input data
  - 80-90% Training | 10-20% Test
- Train a robust model (noise & distortions, to prevent false +/-)
- Verify output: Extremely important
  - Tolerance to Error, weighting functions)
- Work up Data: Corrections, Scaling, Metrics
- Present user-friendly output in a user interface (UI)
  - Consideration of vast amounts of data
- Team feedback loop

Tissue Volume Detection

Example Animal OCT Slice



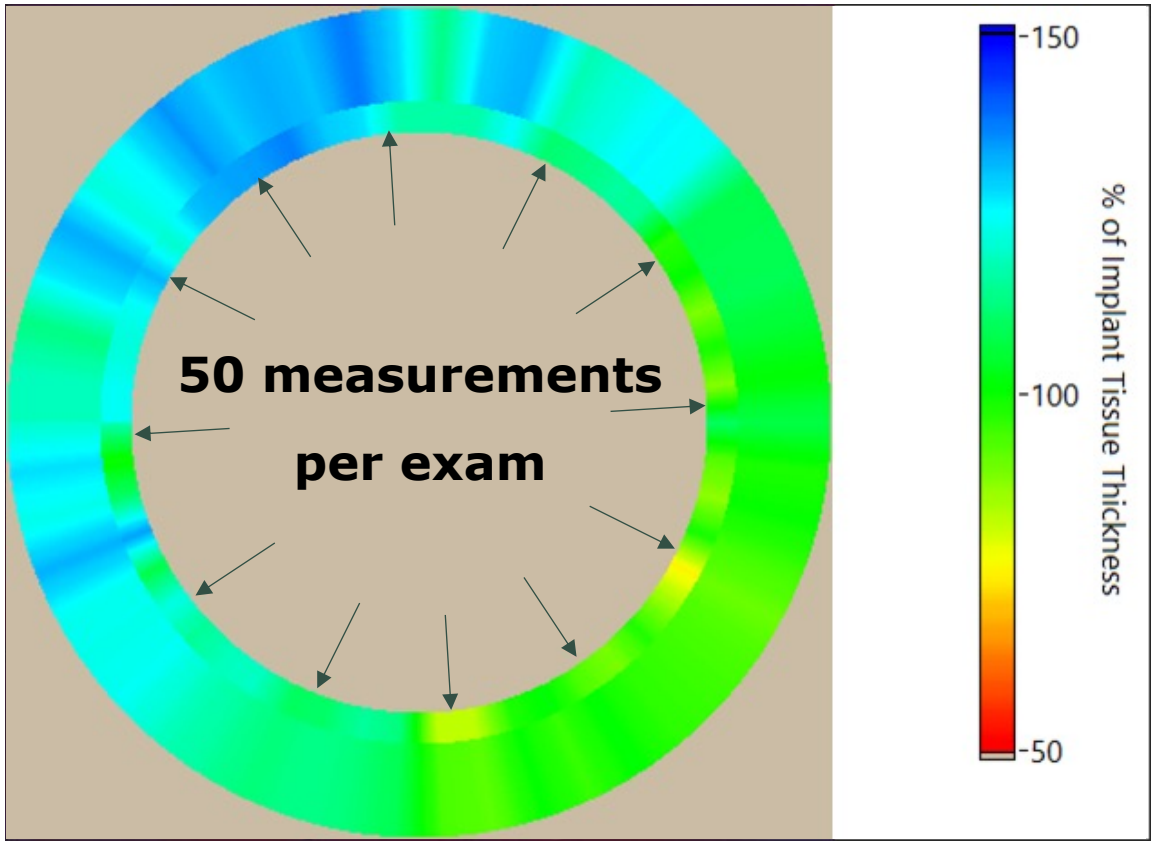
Convert to height
Error Correct
Scale and Collect

Reassociate data
Outcome scale
User-friendly plot

Work up Data

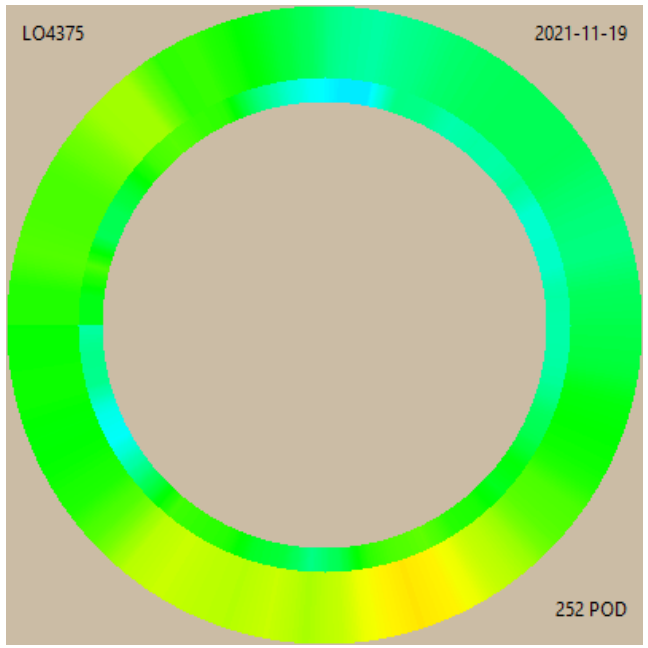
* Similar algorithm under development for quantifying percent exposed optic wall

Present user-friendly output (UI)

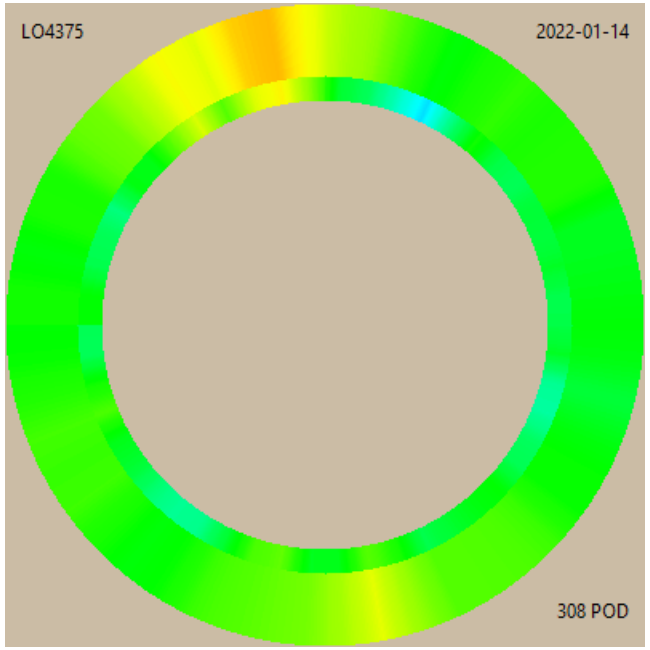


Early Intervention Opportunity

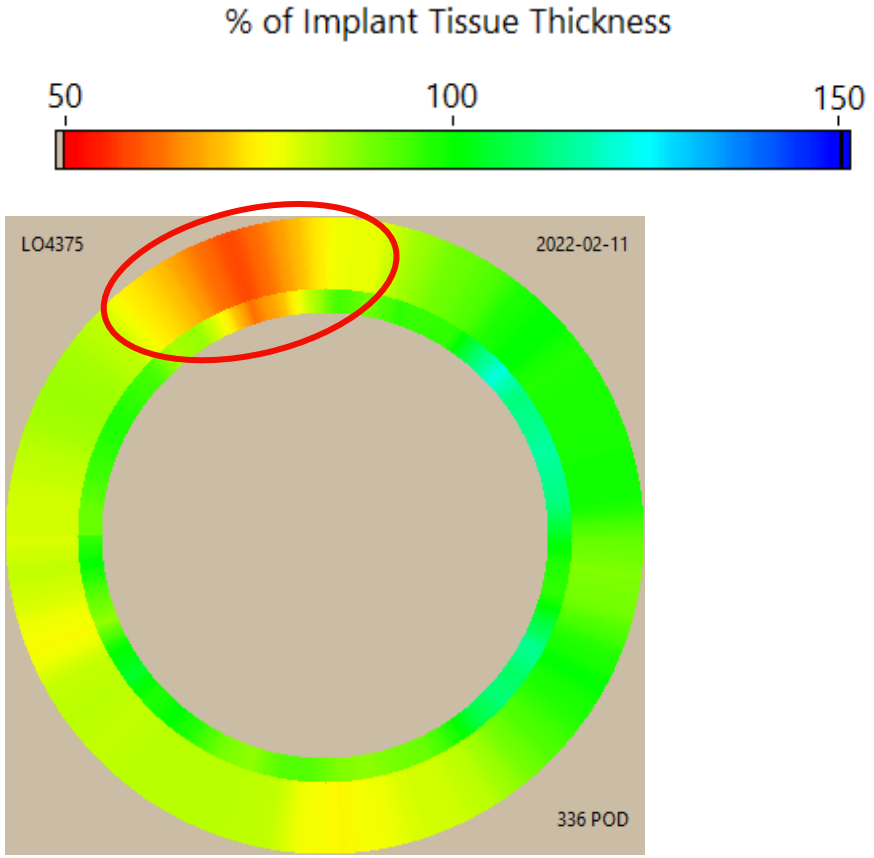
- Unremarkable Animal
- Healthy tissue, device stable



Month 8 post implant



Month 10 post implant



Month 11 post implant

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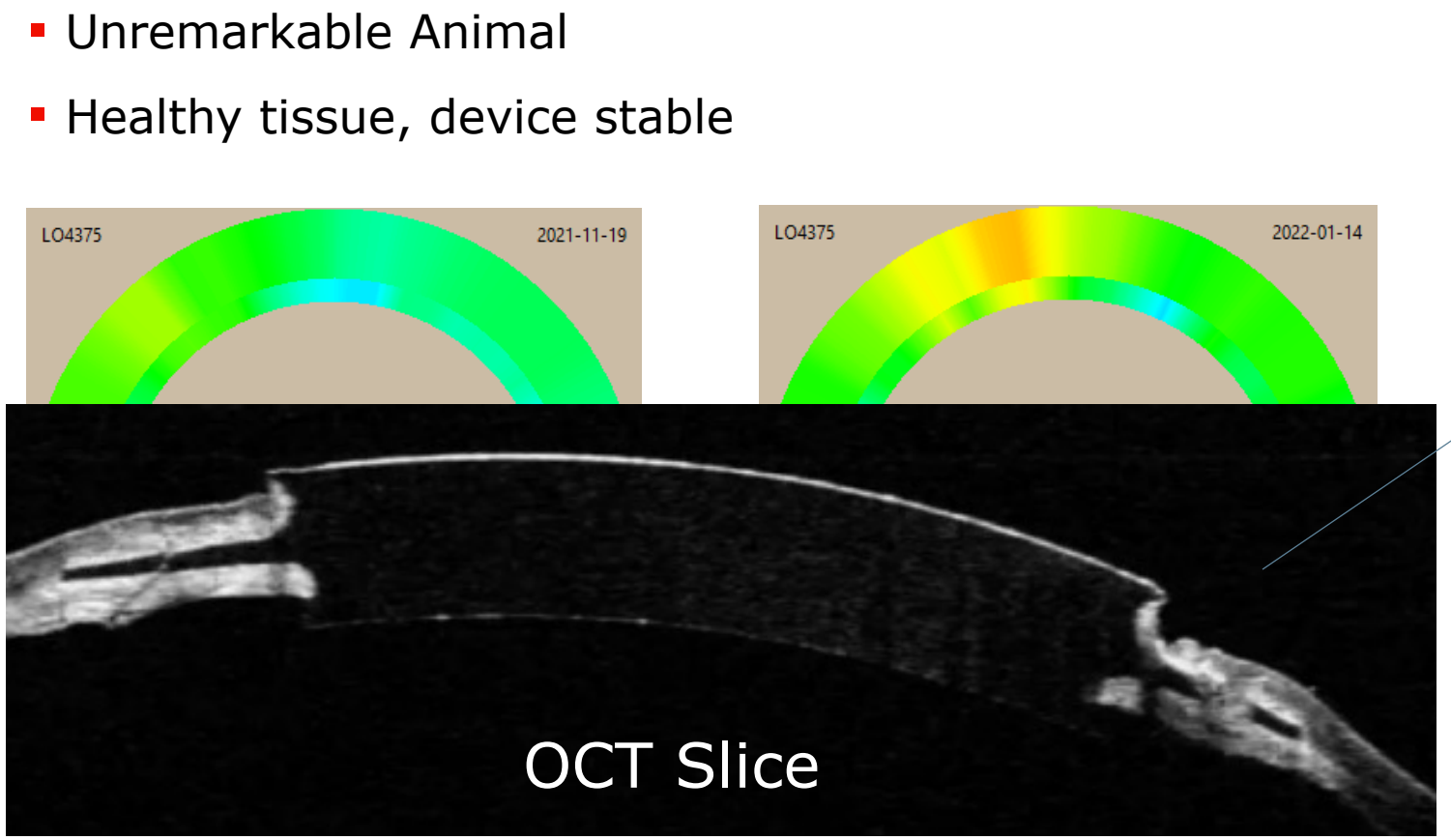
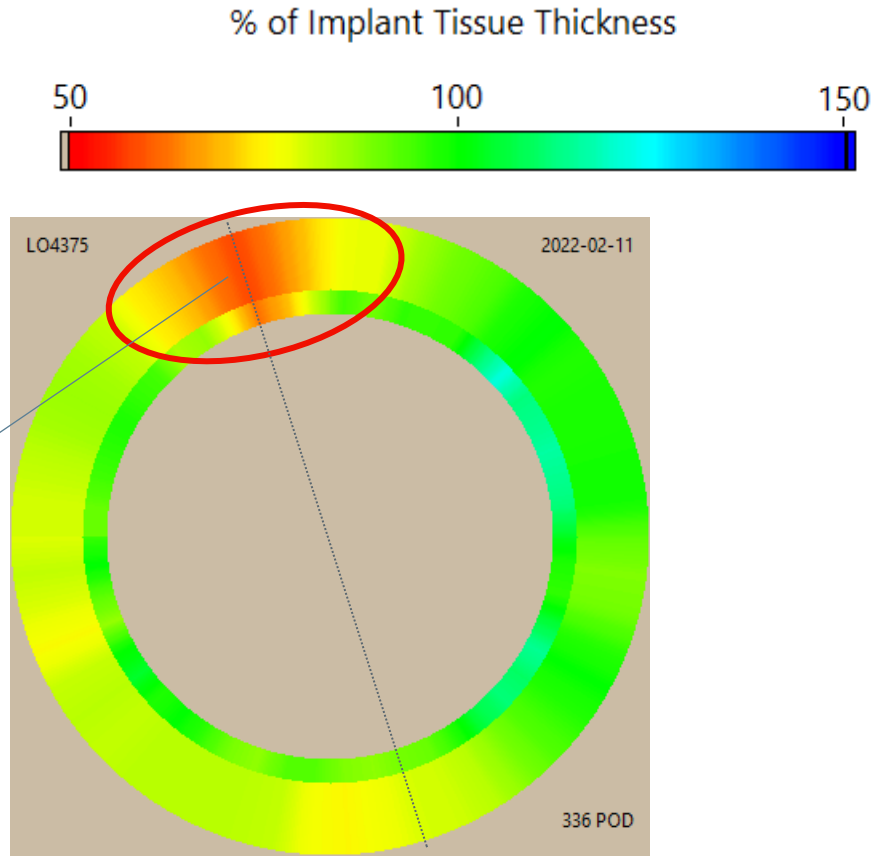


Month 8 post implant

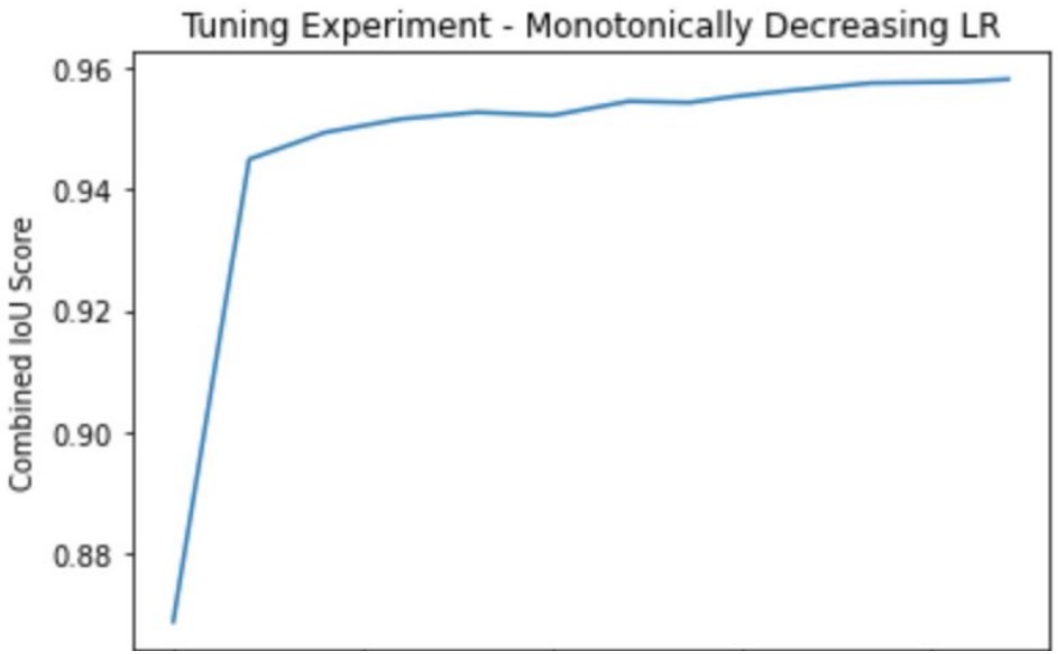
Month 10 post implant

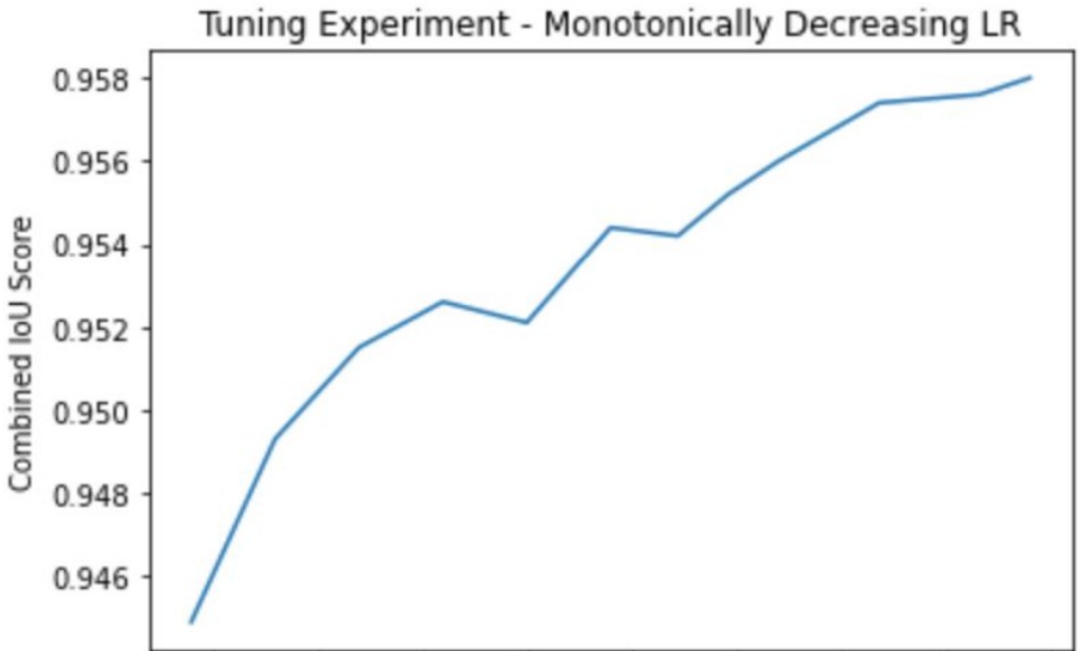


Month 11 post implant

"Big" Data isn't Required

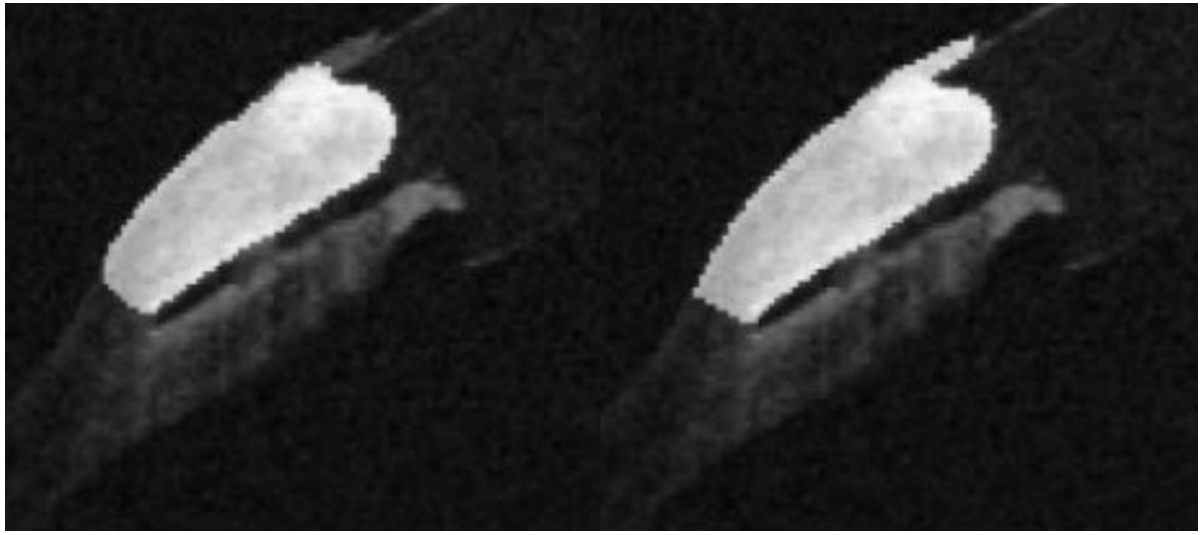
- The model becomes incredibly accurate very quickly at low data volumes
- Focus on set completeness & labeling consistency
- Quality > Quantity





How Success is Measured

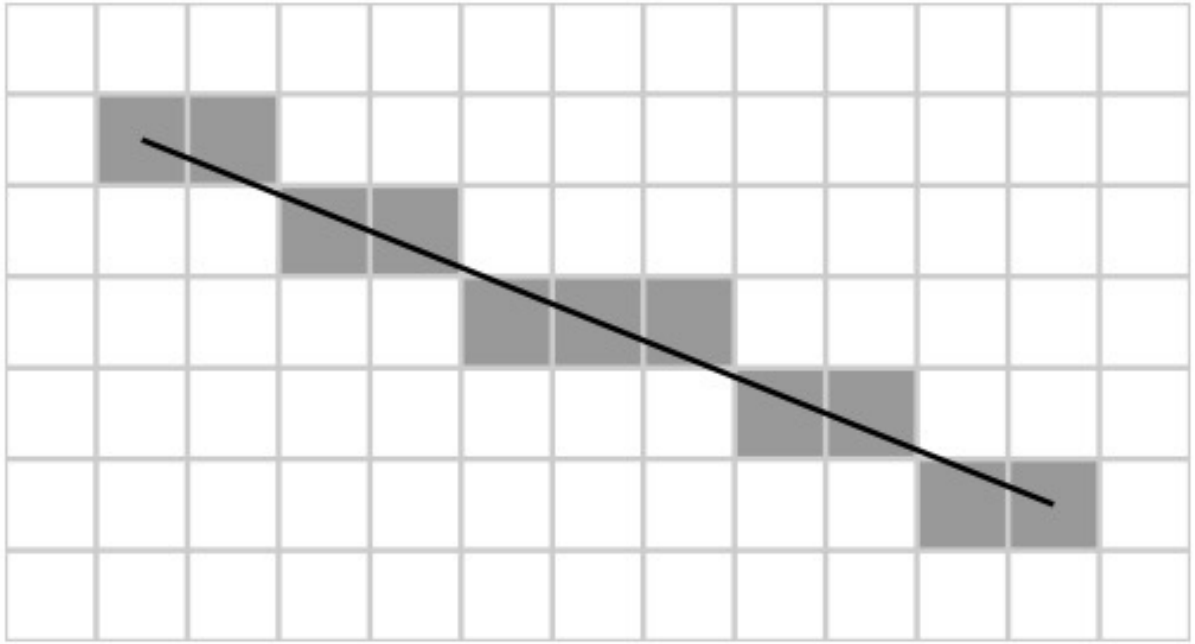
- How do we tell the AI what is valuable?
- Fine detail is very important to the downstream analysis
- Model gets a lot of credit for things that don't matter
  - A traditional Intersection over Union (IoU) metric would rate this prediction very highly because most of the mask area is interior pixels that don't give us much information
  - We can use weighting techniques to augment the IoU calculation to punish the model more for errors like this
- Fitness function quality drives to the business outcomes faster than data
  - It's very hard to get a model to learn what's important to you through a preponderance of the data



Ground Truth Prediction

Postprocessing

- Converting images into insights
  - Measuring tissue volume at ¼ & 1mm distances
  - Measuring the gap between tissue and device
- Aliasing problem
  - The images aren’t straight, so measurements must account for aliasing when doing anything since it does not align to the grid
  - The edge shape is very important, so any distortions must be mitigated as much as possible
- Cleanup
  - Remove additional artifacts



Next Steps

- Proven application in Rabbit eyes needs to meet the "real world" for a human eye application
- Application only targets the analysis, not a diagnosis (data gathering versus interpretation)
- Tackle robustness with respect to:
  - Device configuration changes (dimensional, etc.)
  - Variability in OCT instruments or general imaging modalities
  - Robust handling of over- and under-detection.
  - Standardized/intuitive data presentation
  - Physician interactions
- Physician feedback of data focus could change course of acquisition/analysis
- Expansion to other health metrics and acquisition techniques

Closing Remarks

- Indispensable need for AI/ML to process large amounts of data
- Keypoint detection and segmentation approaches presented
- Relationships between groups drive the analysis
- Learnings for future AI/ML projects:
  - Training and test data creation is an art-form
  - Fitness function critical to success
  - Large data sets not required though useful


IARIA
"All ventures start with a dream – and continue to grow and progress as long as the dream remains bright."
-Bill Gore
Thank you.
Together, improving life
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