Development and Validation of a Breakthrough AI-Guided Echocardiography System

Ha Hong, Ph.D.
Founding Team Member
Prelude: understanding and emulating the brain

Image Encoding Neural Responses Decoding Behavioral Report

Airplane
Prelude: understanding and emulating the brain

Hierarchical Modulation of Convolutional Networks Achieves Representations Similar to Macaque IT and Human VTC Stream

Abstract

1. Introduction

Hierarchical Modulation of Convolutional Networks Achieves Representations Similar to Macaque IT and Human Ventral Stream

Yamins*, Hong*, Cadieu, et al.
Adv Neural Inf Process Syst, 2013

Cadieu, Hong, et al.,
PLOS Comput Biol, 2014

Deep Neural Networks Rival the Representation of Primate IT Cortex for Core Visual Object Recognition

Hong*, Yamins*, et al.,
Nature Neurosci, 2016
Too many people are dying from heart disease

- 600,000 deaths in the U.S.
- 17.9 million deaths globally.
- Many conditions are treatable or preventable: early and accurate detection and diagnosis are key.
- Medical imaging is the gateway to detection and diagnosis.
  - Ultrasound is effective with many advantages.

Images most organs
Low risk
Images in real-time
Small and low cost devices
"The stethoscope of the future"
Heart disease can be accurately diagnosed with echocardiography.
However, often this happens too late.
The problem: Ultrasound is hard to use

With AI, is it possible to make an ultrasound navigation system for everyone?
We developed AI-based heart ultrasound guidance technology that can empower healthcare providers to acquire high quality ultrasound exams.
Emulating the intuition of imaging experts

The guidance technology predicts the deviation of the current transducer positioning from the ideal positioning in real time.

The software then provides the user instructions to efficiently minimize the deviation.
Emulating the intuition of imaging experts

The guidance technology emulates imaging experts:

1. It recognizes the current transducer positioning from input image.
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2. It predicts the target ideal positioning and provides the user the instruction to reach the ideal.
3. It recognizes when the user reaches the target, getting diagnostic image.

The AI guidance software was accepted into FDA’s Breakthrough Devices Program in 2018

- Provides more effective diagnosis of a life-threatening or irreversibly debilitating disease or condition
- No approved or cleared alternatives
Initial verification and pilot study
Verification of the guidance technology

Is the quality of the clip suitable for diagnostic purposes?

2 level III cardiologists
3 imaging experts
The performance of the guidance technology in recognizing diagnostic quality images was evaluated by a panel of five experts.
Verification of the guidance technology

The performance of the guidance technology in recognizing diagnostic quality images was evaluated by a panel of five experts.

The performance (Area under the ROC curve) ranged from 0.8 to 1.0 across different imaging modalities.

The median performance for AI guidance and human experts is depicted on the graph. The 95% confidence intervals (CI) for each modality are also shown.
Testing with pilot study

Subjects
- **Range of BMI:**
  - Obese: 30+ BMI
  - Overweight: 25-30 BMI
  - Normal: 18.5-25 BMI
- **Presence of Pathology:**
  - Aortic valve replacement
  - Mitral valve repair
  - Atrial enlargement
  - Dilated cardiomyopathy
  - Conduction disease w/ pacemaker
- **Older Population, Gender Balanced:**
  - Median Age: 50
  - Male 56%, Female 44%

Imaging experts
- More than 5 years of professional experience
- Acquiring exams of 10 views without the AI-guidance

Performance assessment with a panel of Level III cardiologists
- Randy Martin, CMO, Caption Health
- Neil Weissman, MedStar Health
- Jim Thomas, Northwestern University
- Alan Pearlman, University of Washington
- Akhil Narang, Northwestern University

Can the exam be used to qualitatively assess the following clinical parameters?

Registered Nurses
- **2-day training:**
  - 1 hour didactic
  - 4 hours of practice
- Independently acquiring exams of 10 views with the AI-guidance
# Testing with pilot study

<table>
<thead>
<tr>
<th>Clinical Parameter</th>
<th>% Diagnostic RN exams</th>
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<tbody>
<tr>
<td>LV Size</td>
<td>98%</td>
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<tr>
<td>LV Function</td>
<td>98%</td>
</tr>
<tr>
<td>RV Size</td>
<td>92%</td>
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<td>Pericardial Effusion</td>
<td>98%</td>
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Validation with large-scale, prospective clinical trial
Validation with prospective clinical trial

Caption Guidance granted De Novo earlier this month

- Regulatory pathway for novel low-to-moderate risk devices
- First AI-guided image acquisition software cleared/approved

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<tr>
<th>Clinical Parameter</th>
<th>Performance Target</th>
<th>RN Achieved Performance (95% CI)</th>
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<tr>
<td>LV Size</td>
<td>80%</td>
<td>98.8% [97.6%, 100%]</td>
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Two-center clinical study

- 240 hospital patients
- 8 nurses
- Each nurse received minimal training, then independently scanned 30 patients with the AI-guidance
- Stratification on ranges of BMI
- Stratification on presence of cardiac pathology

Caption Health™ 2020

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Caption Health™ 2020
The AI-guided image acquisition technology emulates the skills of experts to empower front line healthcare providers.

The technology demonstrated safety and effectiveness with extensive tests.

We hope to see substantial increase in access to echo in clinical settings where it used to be impractical or impossible.