Weill Cornell Medicine

Integrated Framework for Human Embryo Ploidy Prediction Using Artificial Intelligence

Lead Inventors:

Iman Hajirasouliha, Ph.D.
Associate Professor of Physiology and Biophysics,
Weill Cornell Medical College

Nikica Zaninovic, Ph.D.
Associate Professor of Embryology in Clinical Obstetrics and Gynecology,
Weill Cornell Medical College

Olivier Elemento, Ph.D.
Director of the Englander Institute for Precision Medicine, Weill Cornell Medical College

Zev Rosenwaks, M.D.
Executive Director, Women's Service Center, Institute for Reproductive Medicine, Weill Cornell Medical College

Business Development Contact:
Donna J. Rounds
Associate Director, Business Development and Licensing
(646) 962-7044
djr296@cornell.edu

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Background & Unmet Need

- The success of in vitro fertilization (IVF) is limited by challenges in selecting the most viable embryos
- As women age, the incidence of euploid embryos (normal chromosome number) decreases while that of aneuploids (embryos with chromosomal abnormalities that may cause miscarriages or birth defects) increases
- The current standard methods for embryo selection, morphological quality and morphokinetic analyses, suffer from intra- and inter- observer variability
- A third method, pre-implantation genetic testing for aneuploidies (PGT-A), is less variable but has its own notable limitations, including invasiveness and cost
- Machine-learning approaches for assessment of embryo quality based on morphology have not demonstrated a clear benefit over current methods
- **Unmet Need:** A non-invasive, reliable, and high throughput method to predict ploidy of candidate embryos prior to implantation in order to increase the success of IVF

Technology Overview

- **The Technology:** A machine-learning based method, called STORK-A, to non-invasively predict embryo ploidy status
- Uses time-lapse microscopy images of embryos and clinical information (e.g., maternal age & morphological assessments) as inputs and outputs a probability of euploid vs aneuploid for each embryo
- **PoC Data:** The STORK-A algorithm was trained using a dataset of images and clinical information for >10k embryos with confirmed ploidy status and was then also tested on two independent external datasets
- STORK-A classified embryo ploidy status with accuracies of ~70% for both the training and independent datasets
- IVF transferred embryos that were predicted to be euploid by STORK-A exhibited a livebirth rate of 48%, which is very similar to that of the transferred embryos classified as euploid by PGT-A (49%)

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Patents:
PCT Application Filed

Publications:
Barnes et al. *Lancet Digital Health.* 2023.

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Technology Applications

- Supplement traditional methods of embryo selection and prioritization by assigning ploidy predictions to embryos in a high throughput and unbiased manner
- Assist embryologists in determining on which embryos the more invasive and costly PGT-A should be performed in IVF cases that are complex and/or unlikely to be successful (advanced maternal age, low embryo count, etc.)

Technology Advantages

- Not subject to observer variability
- Non-invasive and less expensive than PGT-A
- High-throughput and can easily be adopted by fertility clinics for use in the IVF process
- Machine-learning algorithm has ability to improve accuracy as more image data is accrued
- Accuracy can be further increased by integrating with spatiotemporal data (video)

Supporting Data / Figures

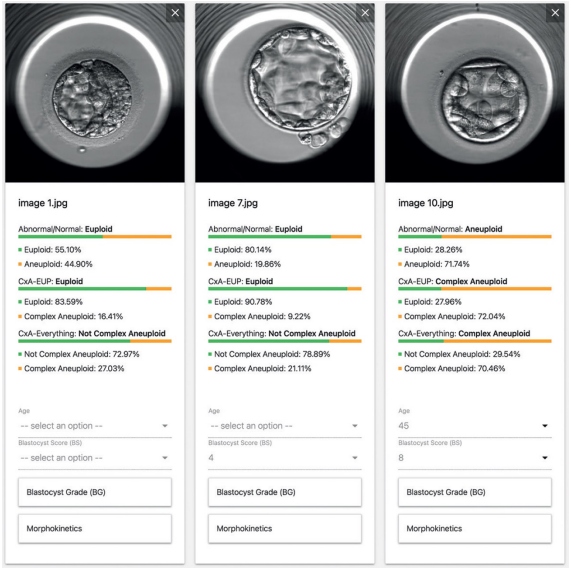

Figure 1: Example STORK-A interface and ploidy predictions for use in clinical settings as a support tool for embryologists.

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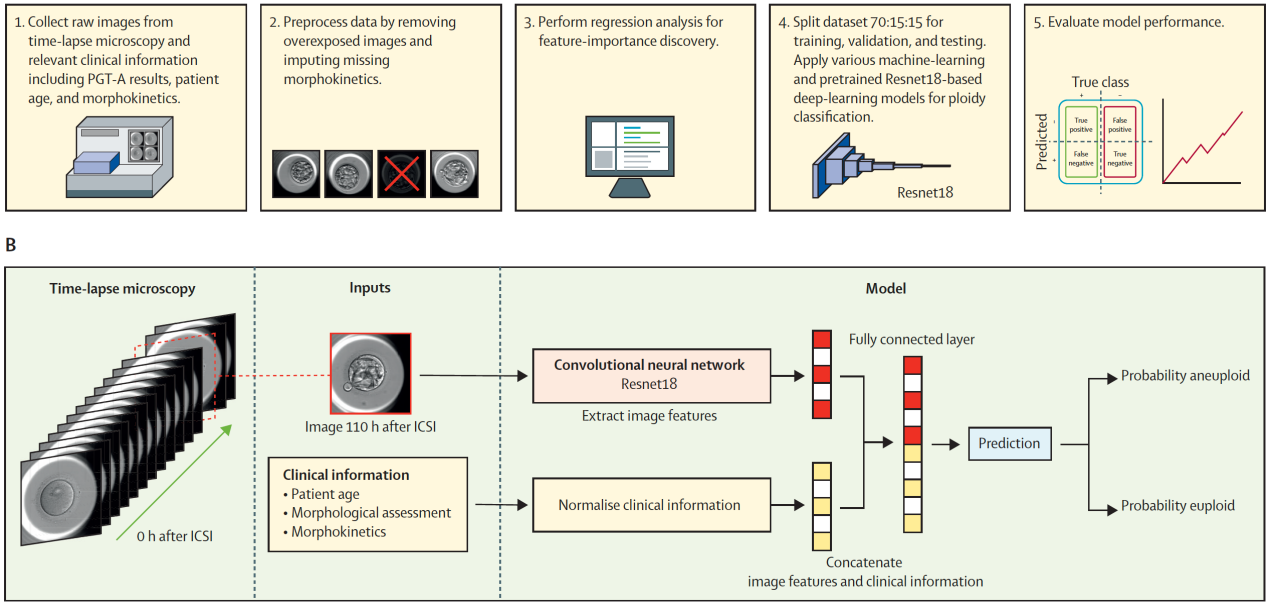

Figure 2: Top: Study Design for STORK-A development **Bottom:** STORK-A Schematic.

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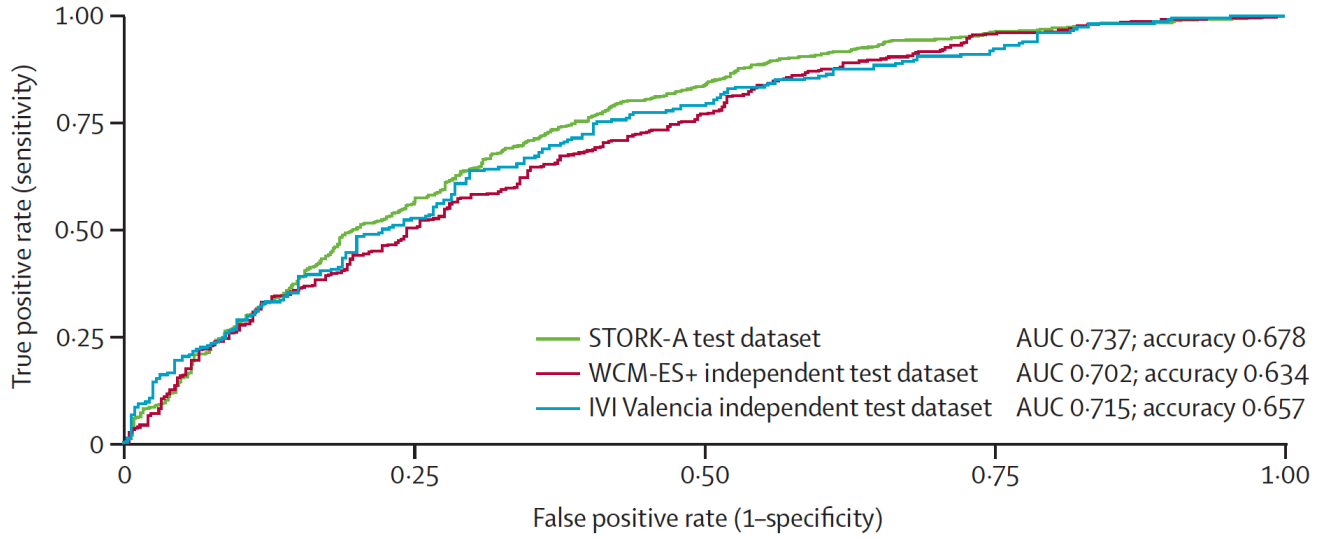

Figure 3: STORK-A classified aneuploids vs. euploids in two independent datasets with similar accuracies to that of its training test dataset.

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