AI-Assisted Tool to Improve the Quality and Assessment of PLGA Formulations

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SUMMARY

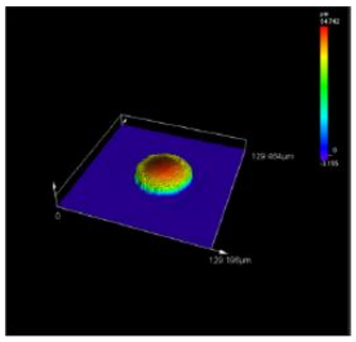
❖ The AI-based method provides high-throughput analysis of PLGA (poly (lactic-co-glycolic acid))-based long-acting injectable (LAI) formulations to establish a correlation between material attributes, processing conditions, and product quality/performance.

❖ This AI method may serve as a tool in the future to evaluate the sameness of proposed generic products to reference listed drugs (RLD) by analyzing feature similarity across different formulations.

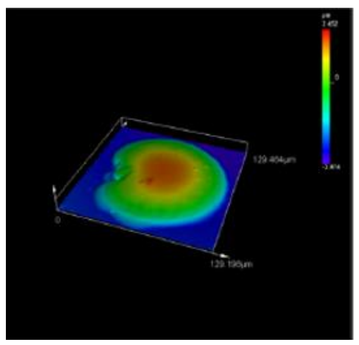
METHODS

❖ The study has compiled a comprehensive dataset of PLGA formulations from a previous FDA-funded research project [1].

❖ The dataset includes different formulation details, corresponding manufacturing data, detailed surface topographical characterization data due to solvent changes, and *in vitro* release testing data [1].



Formulation



After exposure to semi-solvent liquid to Formulation

QR Code of Previous Work

Fig 1: Microparticles of formulations in the dry state and after exposure to a semi-solvent liquid at 0°C for 1 min and details of previous work in the QR code [1]

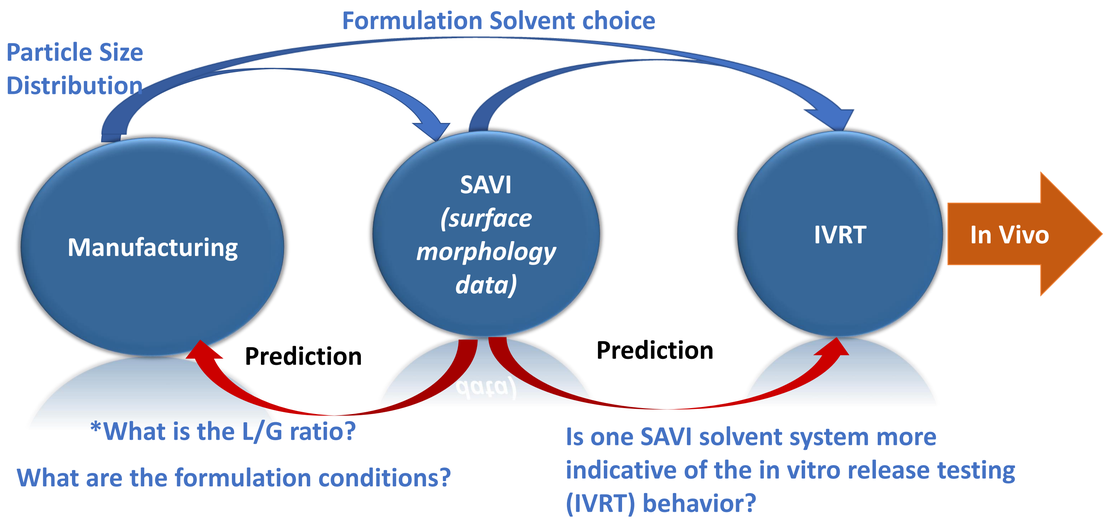


Fig 2: Functional flow of the work

RESULTS

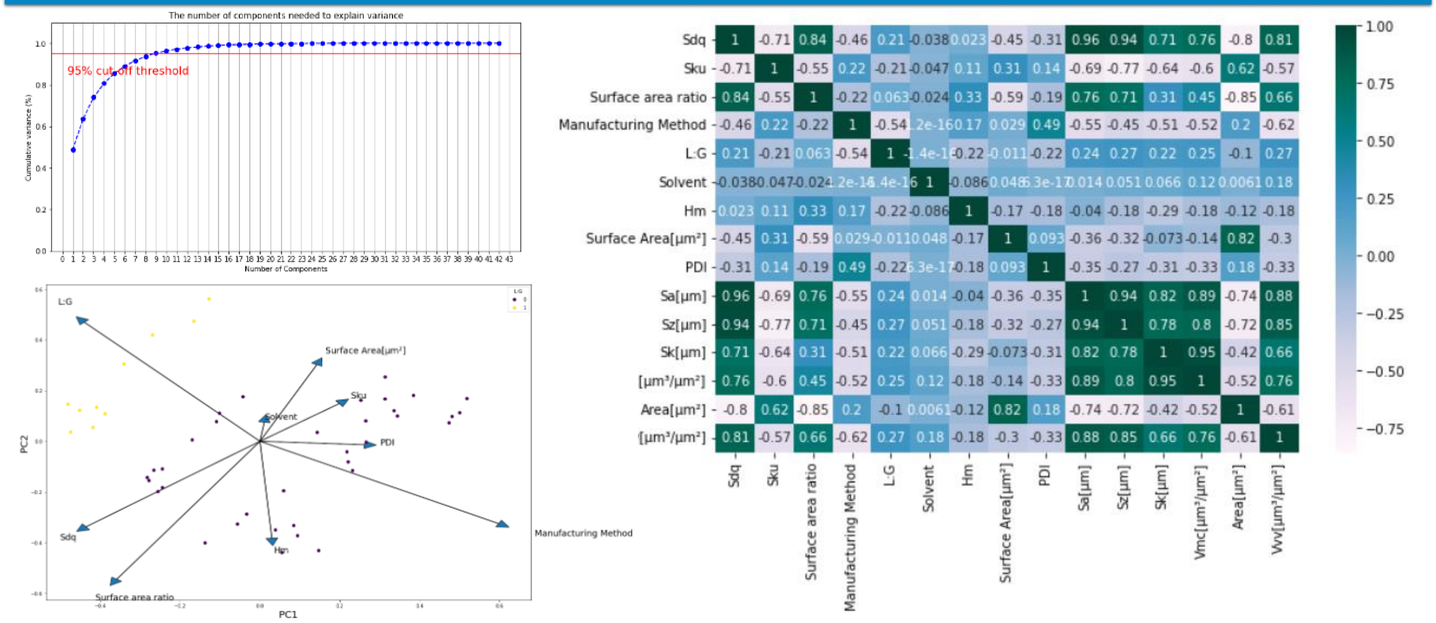


Fig 3: Principal component analysis (PCA) on the left and correlation matrix study on the right to find significant parameters

(A) Prediction of Formulation Conditions

Machine Learning Techniques	MSE	MAE	Accuracy (%)
Linear Regression	0.001	0.02	99.5002
Decision Tree	0	0	100
Random Forest	0.3439	0.4	90
Extra Trees Regressor	0.0042	0.0289	99.2778

(B) Prediction of L:G Ratios from PLGA Formulations

Machine Learning Techniques	MSE	MAE	Accuracy (%)
Logistic Regression	0	0	100
Decision Tree	0	0	100
Random Forest Regressor	0	0	100
Artificial neural network (ANN)	0.0021	0.0378	78

Table 1: Different machine learning (ML) algorithms were applied (A) to predict the formulation conditions and (B) to predict L:G ratios

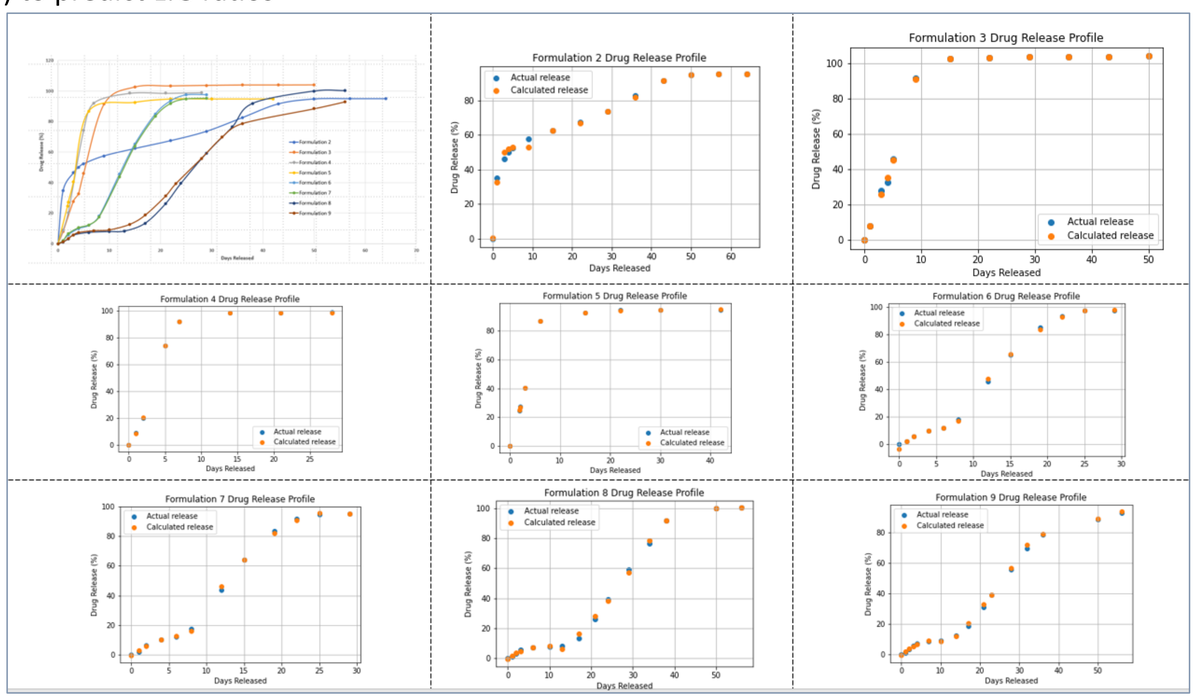


Fig 4: Prediction of IVRT profiles and compared with experimental release profiles

REFERENCE

1. Surface analysis of sequential semi-solvent vapor impact (SAVI) for studying microstructural arrangements of poly (lactide-co-glycolide) microparticles; John Garner, Sarah Skidmore, Justin Hadar, Haesum Park, Kinam Park, Bin Qin, Yan Wang; Journal of Controlled Release, 2022, 350, 600-612

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DISCLAIMER

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