

Investigating the impact of risperidone CQAs on the *in vitro* release of *in situ* forming implants

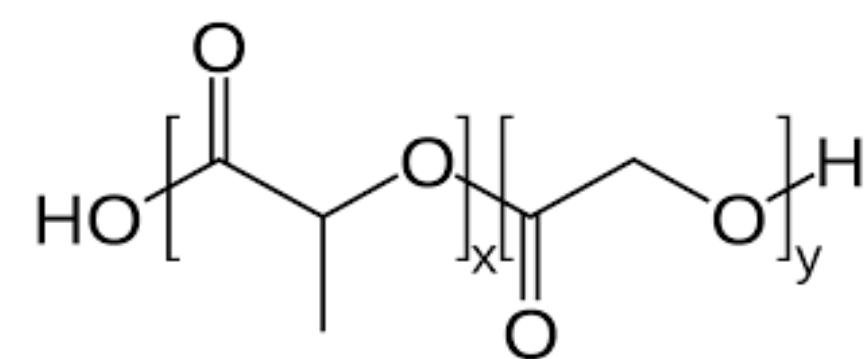
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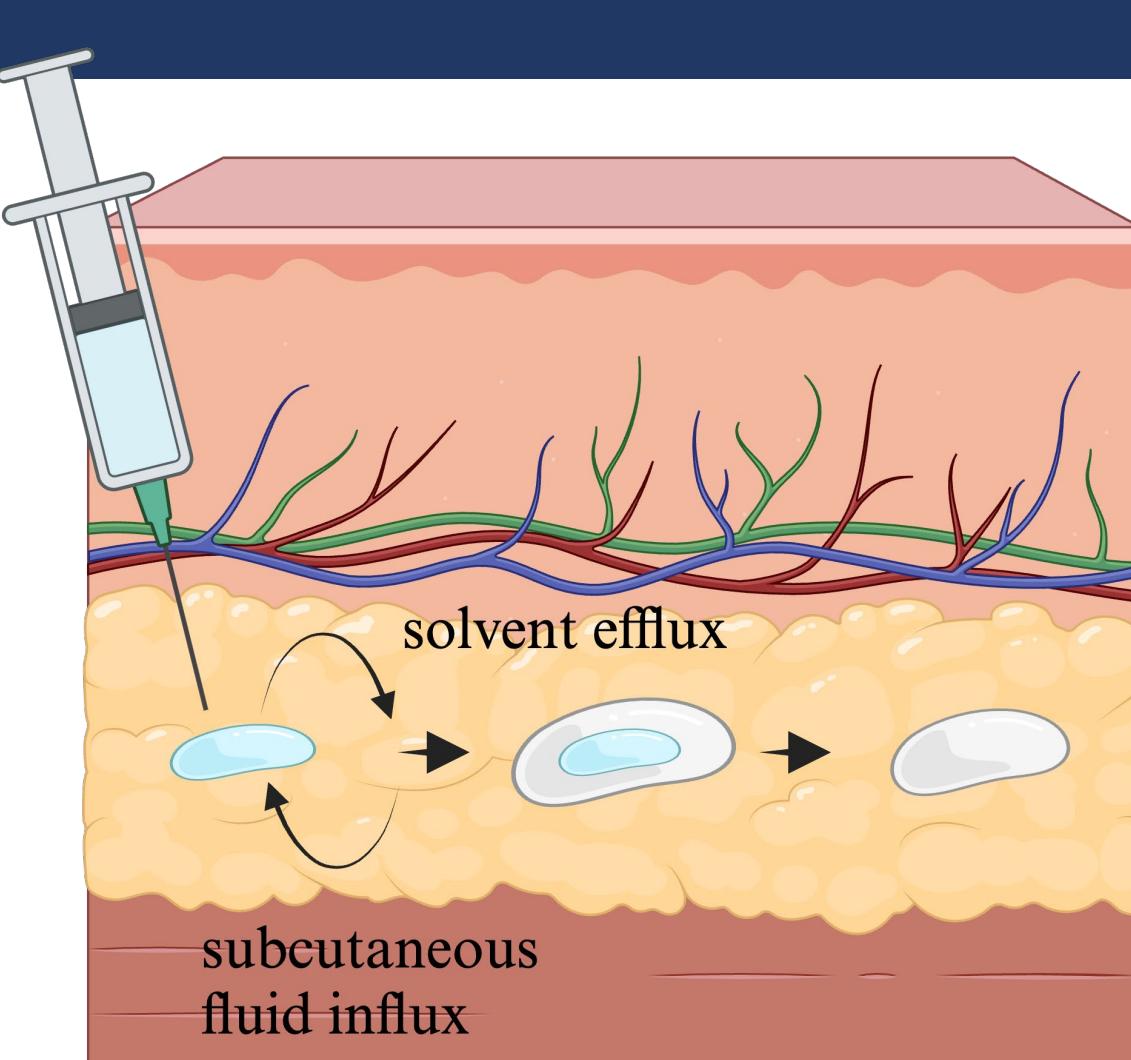
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Background

- ❖ *In situ* forming implant drug products utilize PLGA as their rate-controlling component.
- ❖ These complex products lack generic equivalents.



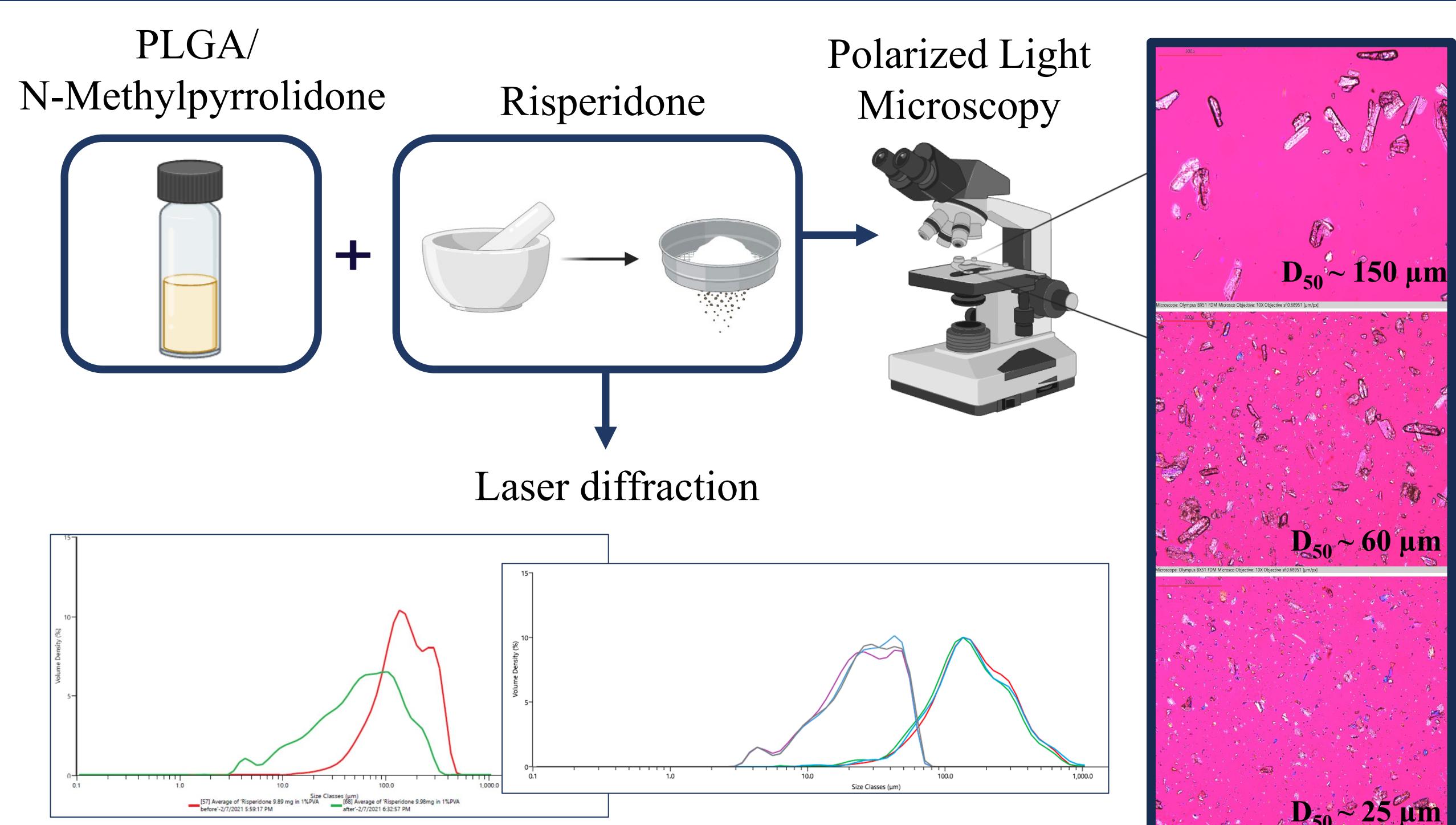
Poly (lactic-co-glycolic acid) (PLGA)



Objectives

- ❖ Investigate the impact of risperidone particle size on *in vitro* release behavior.
- ❖ Investigate the impact of risperidone physical state on *in vitro* release behavior.
- ❖ Understand how risperidone CQAs impact formulation viscosity, PLGA degradation, water uptake and implant microstructure.

Methods



1 Mixing cycle = push contents back and forth

	D ₅₀ (μm)	API physical state	Drug loading (% w/w)
F0	150	Suspension	15%
F1	60	Suspension	15%
F2	25	Suspension	15%
F3	150	Suspension	2.5%
F4	150	Solution	2.5%

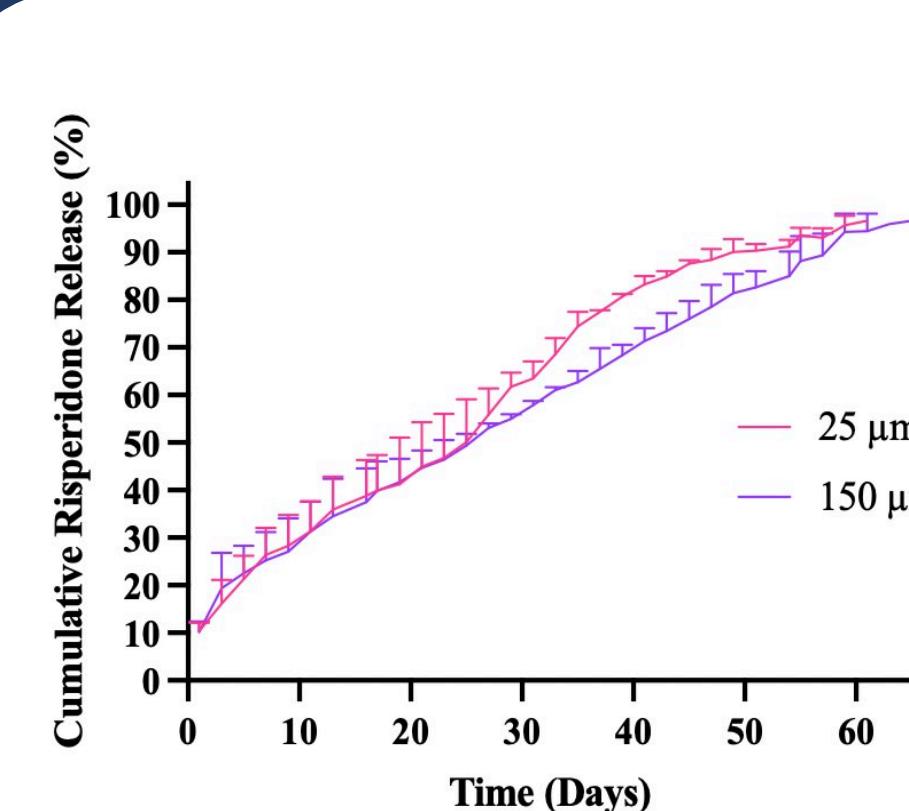
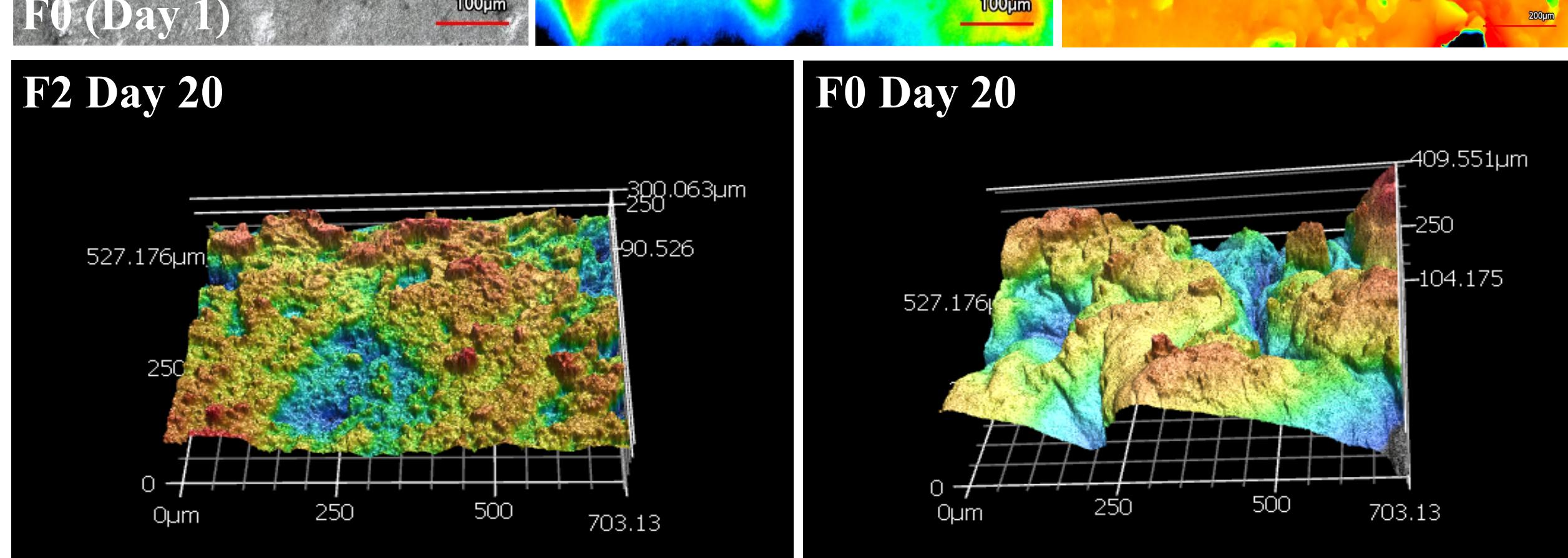
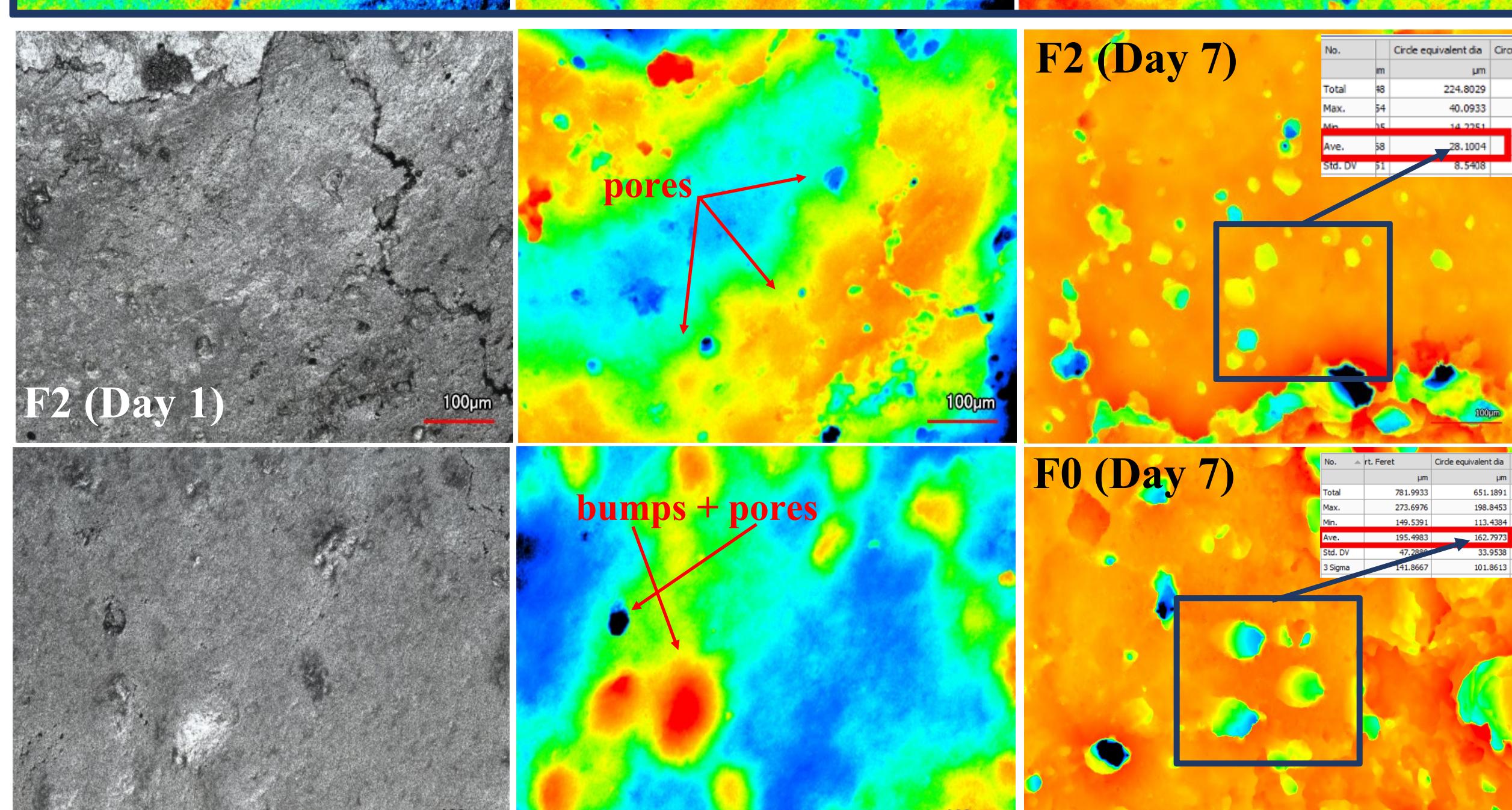
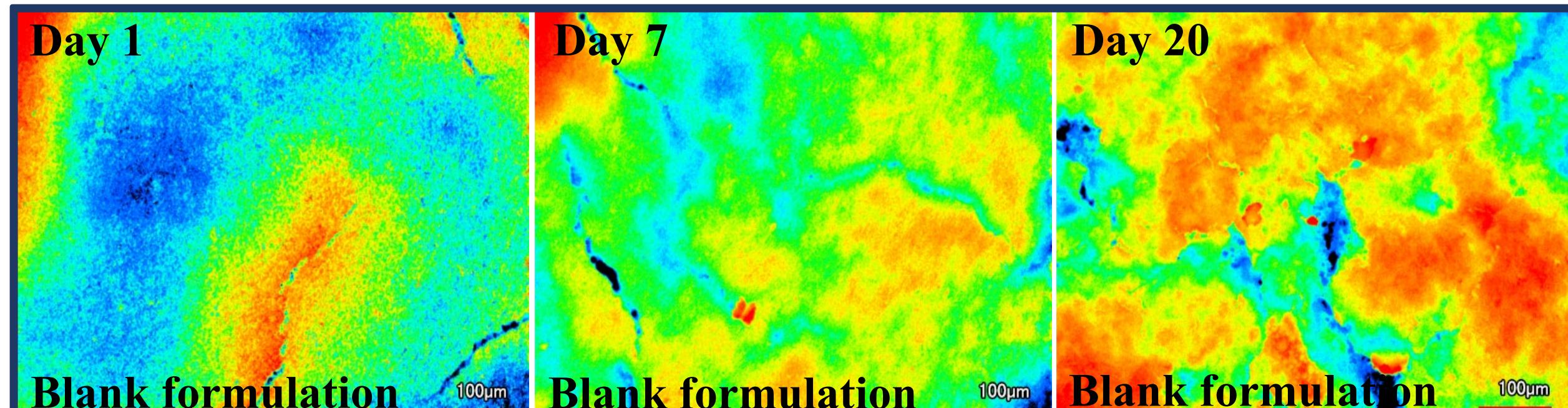
- ❖ *In vitro* release testing*
- ❖ Viscosity studies
- ❖ Gel permeation chromatography*
- ❖ Water uptake*
- ❖ Laser confocal microscopy*

- ❖ Water shaker bath
- ❖ PBS, pH 7.4
- ❖ 0.15% sodium azide
- ❖ 100 rpm
- ❖ 50 rpm
- ❖ 37 °C

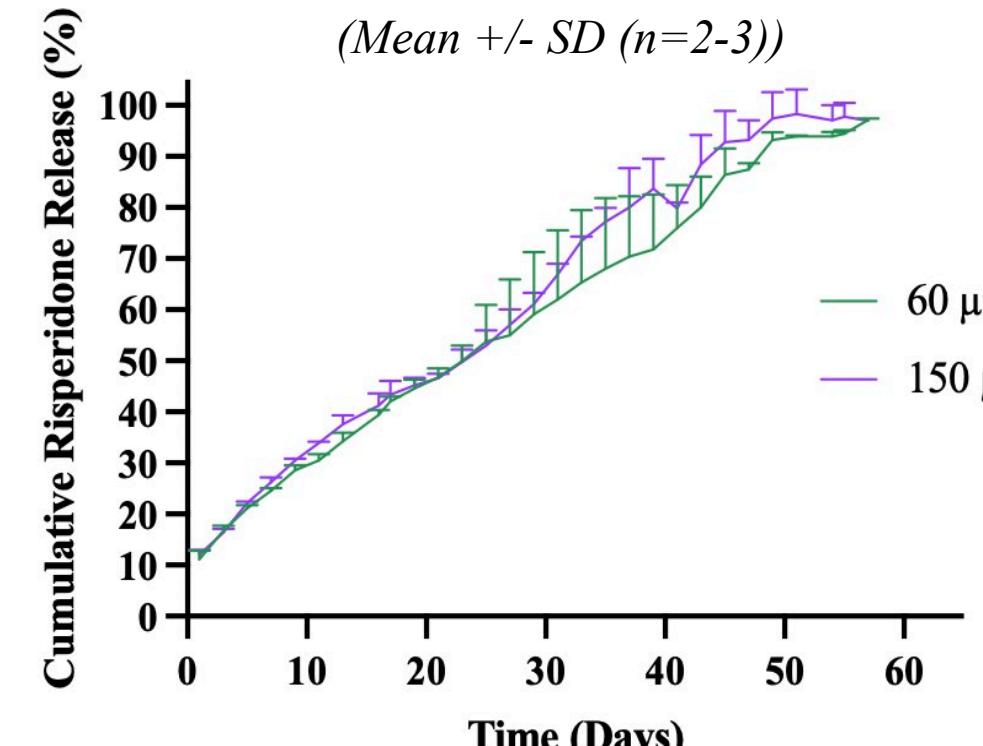
- ❖ PBS, pH 7.4
- ❖ 0.15% sodium azide
- ❖ 50 rpm
- ❖ 37 °C

Results

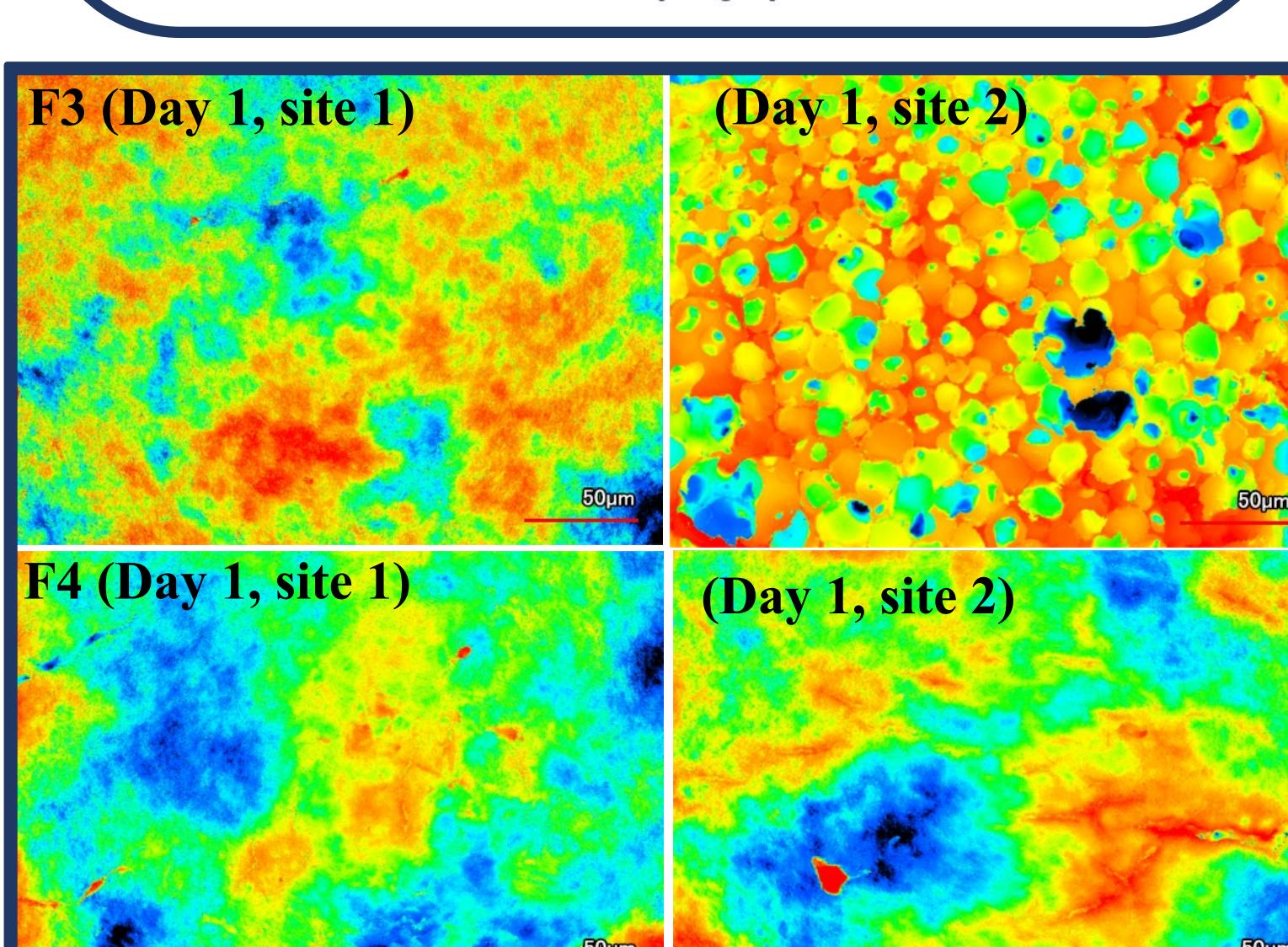
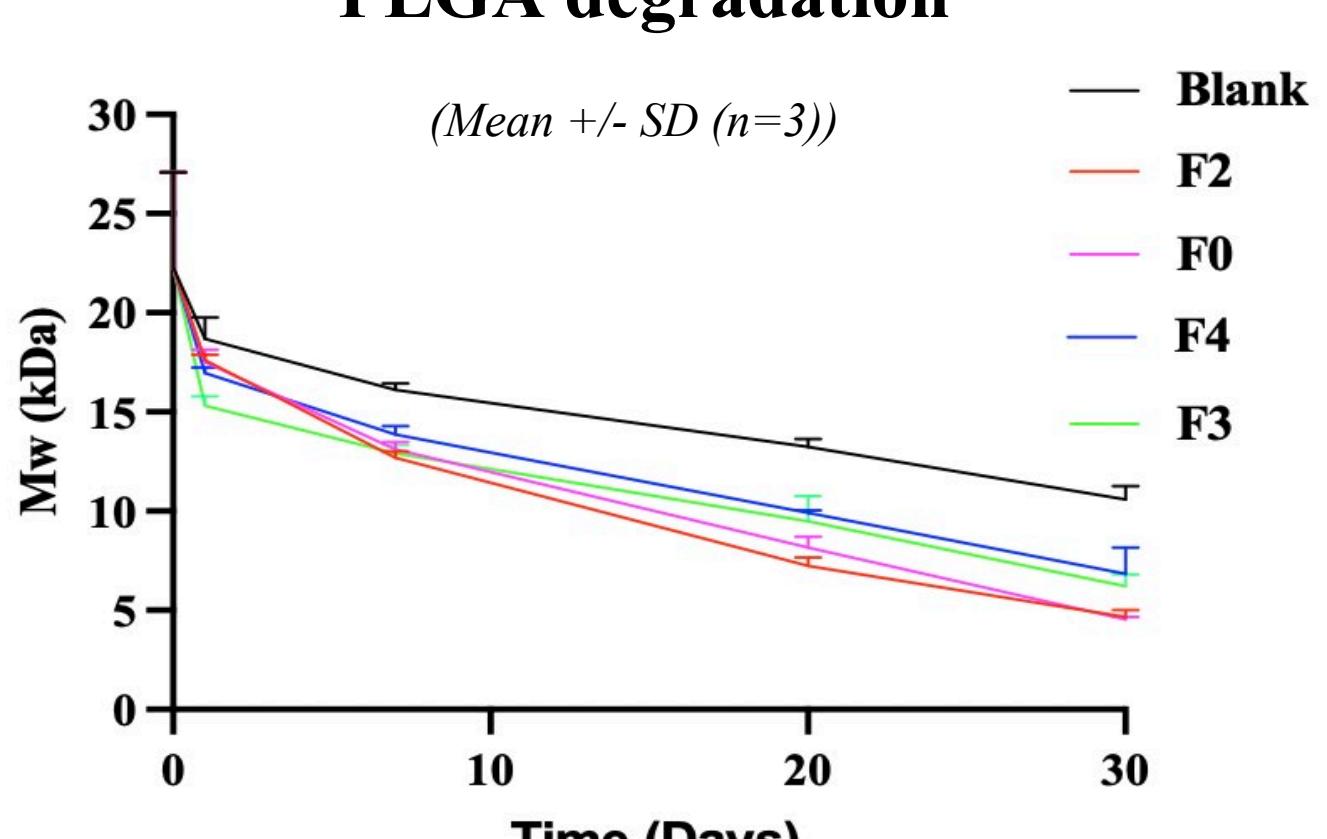
Laser confocal microscopy (implant surface microstructure)



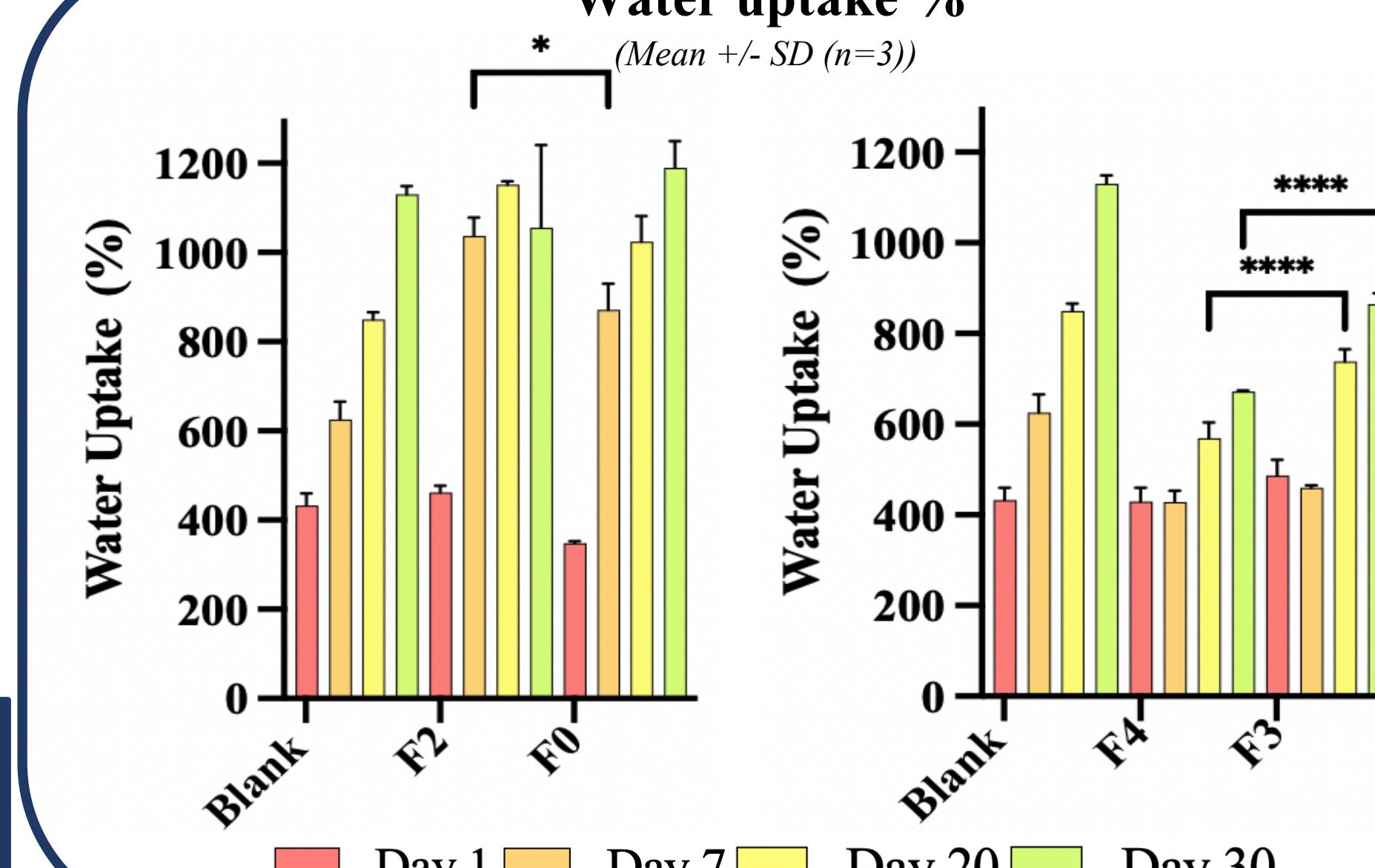
In vitro release



PLGA degradation



Water uptake %



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