Modeling Defects during Tableting: Formation of Bubbles Resulting from Entrapped Air

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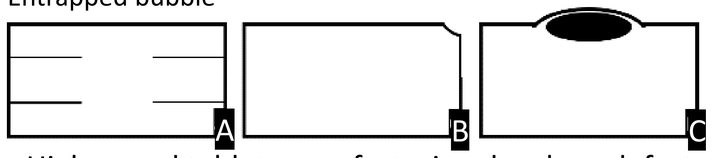
Defect Classification

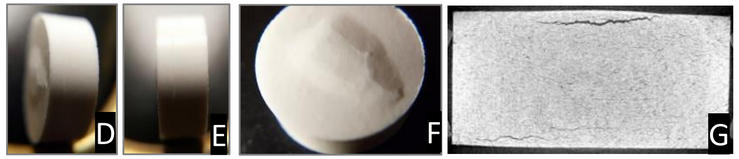
Various defects developed in oral dosage manufacture

A. Lamination (periodic horizontal cracks)
B. Chipping / Fragmenting
C. Entrapped bubble



High-speed tablet manufacturing develops defects

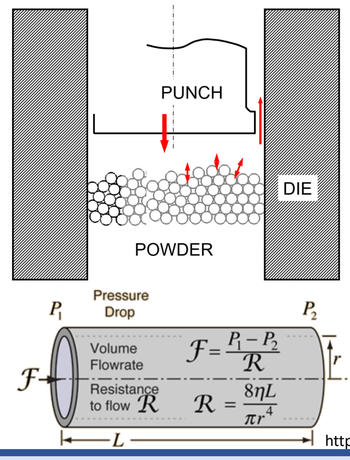
Visual defects observed (D, E, F): Bubble and side lamination
Interior defects observed via X-ray MicroCT: bubble, lamination



Air Presence and Impact

Multiple factors contribute to air entrapment

1. Tool clearances (punch/die separation)
2. High compaction speed



http://hyperphysics.phy-astr.gsu.edu/hbase/ppois.html

Air Sources

- Ambient air in die prior to fill
- Inside particles (for some materials)
- Pushed into die by punch

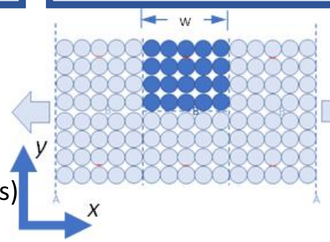
Air Escape

- Air needs to flow around upper punch to escape
- Pouisseille's Law: simple channel, fluid flow is pressure-driven:

$$q = \frac{\Delta P\, \pi (r)^4}{8 \mu L}$$

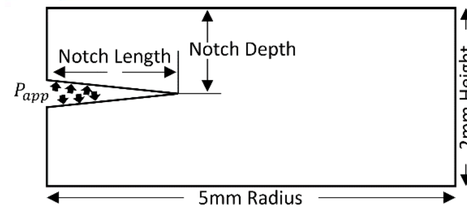
- Insufficient time to flow may result in entrapped air within tablet

Modeling Methods



Two methods of finite element models:

1. Particulate model
   - Individual particles inside tablet
   - Pressure applied to non-contact surfaces
   - Low number of particles
   - Boundary conditions imply infinite width system
2. Continuum model
   - Bulk model – tablet-scale dimensions
   - Pressure applied to large bulk region
   - Formation of observed defects, not local conditions
   - Axisymmetric boundary conditions

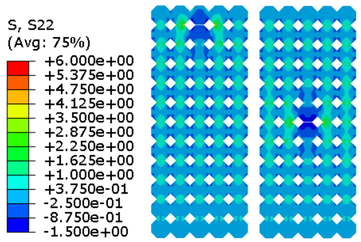


Both models developed in ABAQUS 2021.

Summary

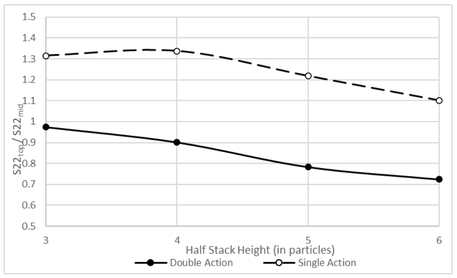
- Air presence within die develops defects observable post-compaction
  - Tool clearances and compaction speed keep air in-die
- Particulate and continuum models examine stress developments
  - Single Action pressure gradients develop higher surface S22
  - Entrapped air closer to surface develops higher SIF
  - Deep cracks still have difference in SIF due to pressurized surface

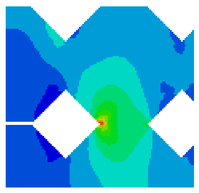
Particulate Results



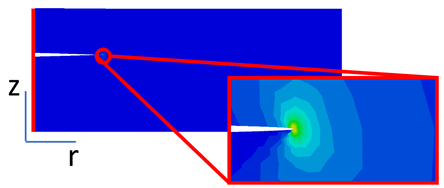
Direct Observation

- Single- and double-action pressure gradients applied to particles
- Single crack allowed to develop either at top or center of sample
- Compaction axis stress (S22) evaluated in





Continuum Results

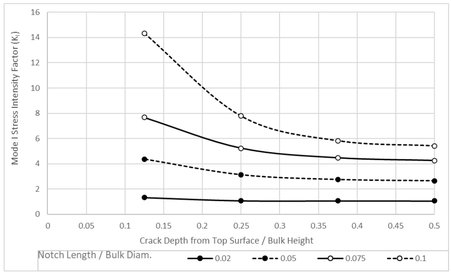


Direct Observation

- Large stress concentration near crack tip
- Stress Intensity Factor, K_I

$$K_I = Y\sigma\sqrt{\pi\alpha}$$

  - Y, system geometry factor
  - σ, applied load
  - α, crack length



Crack Length, Depth Studies

- Length varied, larger surface for pressure application
- Depth varied, surface interaction changes

- Larger cracks closer to surface develop greater SIF
- Difference exists for varied crack lengths sufficiently deep in compact

Future Work

Modeling Improvements

- Simulate larger number of particles with air effect
- Converge results for stress intensity evaluation

Tablet manufacture

- Obtain evaluation of in-tablet air volume
- Powder & tooling selection to eliminate entrapment

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