

Compression - Decompression Modulus (CDM) – An Alternative/Complementary Approach to Heckel Analysis

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PURPOSE

- Currently Heckel method has gained wider application to parameterize compression profiles to evaluate the macroscopic compression properties of the pharmaceutical materials.
- Heckel method is based on the measured powder particle density in addition to its sensitivity to the experimental conditions.
- A Heckel plot with high-pressure negative porosities is devoid of the entire decompression phase. The loss of the decompression phase in the Heckel plot is a possible squander of important information about the elastic behavior of the materials.
- It is vital information for understanding the potential tableting problems like capping and lamination.

OBJECTIVE

- To develop an alternative material modulus-based approach to characterize compression behaviors of model materials and propose a two-dimensional material classification system based on the compression and decompression modulus (CDM).

METHODS



Materials	
Microcrystalline Cellulose (Vivapur® 101)	(Plastic)
Pre-gelatinized Maize Starch (Starch 1500®)	(Elastic)
Dibasic Calcium Phosphate (Emcompress®)	(High Fragmenting)
Lactose Monohydrate (Tabletose® 100)	(Low Fragmenting)

RESULTS

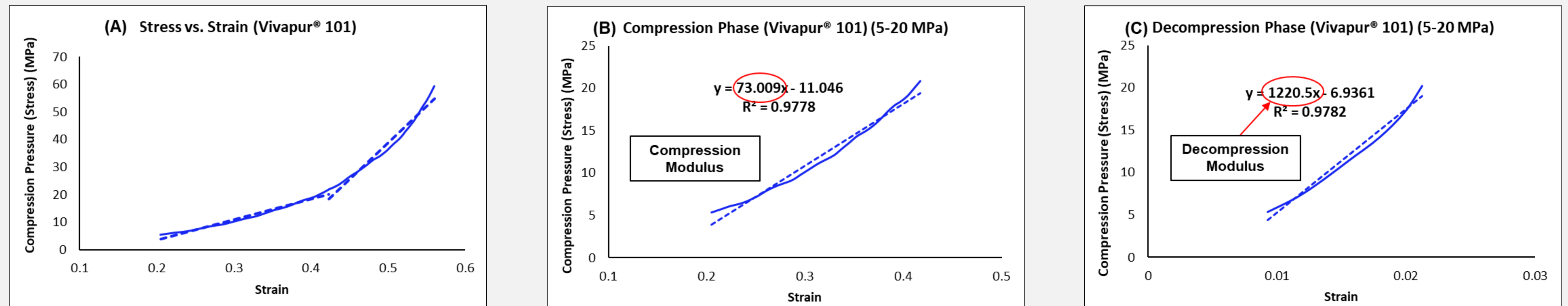


Fig. 1: (A) Stress vs. strain plot of Vivapur® 101 in the range of 5-60 MPa compression pressure representing 'bi-linear' regions between 5-20 MPa and 20-60 MPa compression pressure. (B) Compression modulus in compression phase of 5-20 MPa (C) Decompression modulus in the decompression phase of 5-20 MPa.

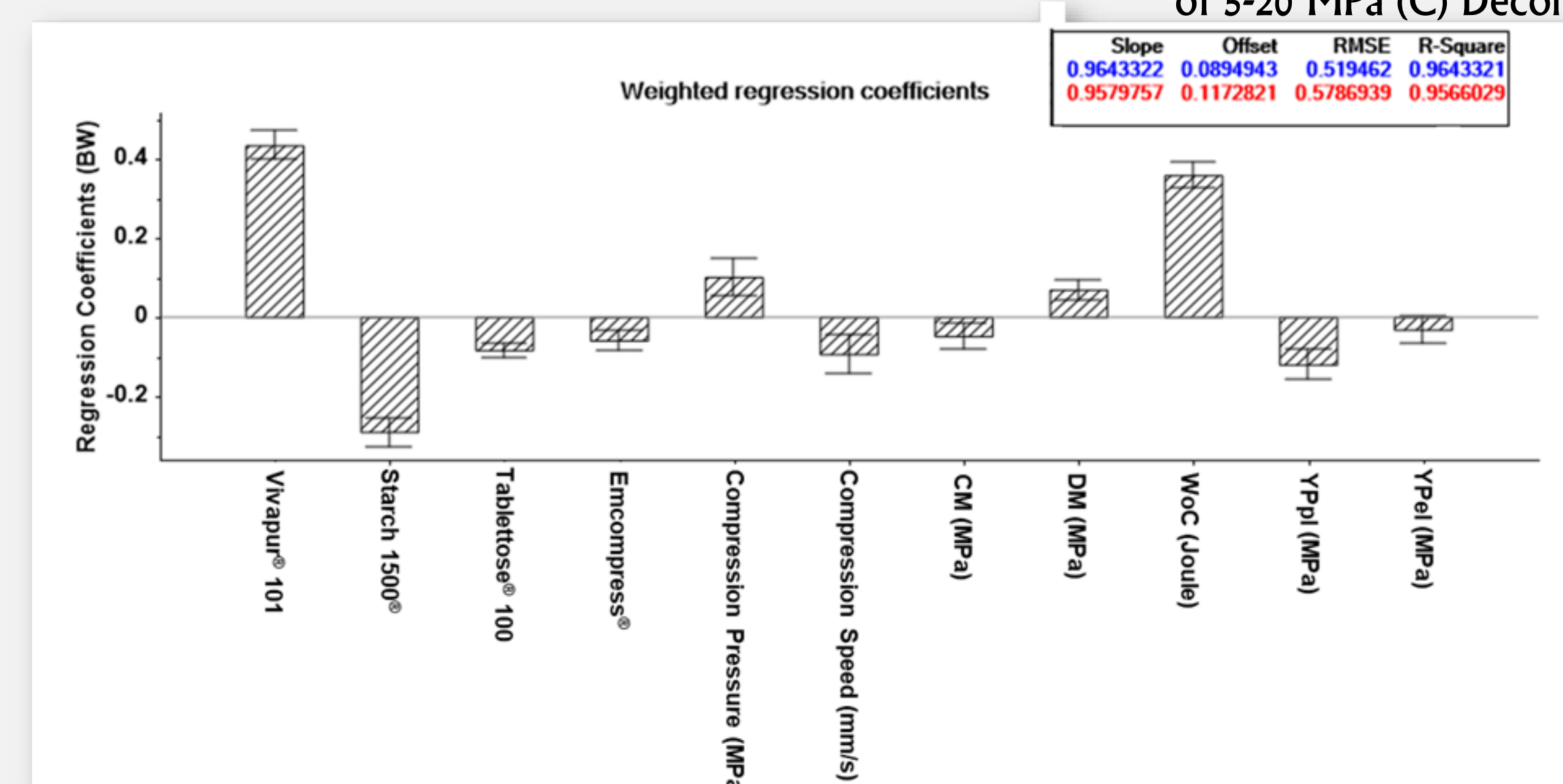


Fig. 2: The principal regression analysis plot indicating weighted regression coefficients of main effects of all X-variables (material type, compression pressure, compression speed, compression modulus, decompression modulus, work of compression, YPpl, and YPel) on the Y-variable (tablet mechanical strength).

Low Compression Pressure Range (5-20 MPa)

Mid Compression Pressure Range (20-60 MPa)

Low Compression Pressure Range (5-20 MPa)		Mid Compression Pressure Range (20-60 MPa)	
Class-I	Class-II	Class-I	Class-II
CM: Extremely Low DM: Low Stronger Tablet (Plastic Deformation)	CM: Low DM: Extremely High Strong Tablet (High Fragmenting)	CM: Extremely Low DM: Low Stronger Tablet (Plastic Deformation)	CM: Extremely High DM: Extremely High Strong Tablet (High Fragmenting)
Class-IV	Class-III	Class-IV	Class-III
CM: Extremely High DM: Extremely Low Weaker Tablet (Elastic Deformation)	CM: High DM: High Weak Tablet (Low Fragmenting)	CM: Low DM: Extremely Low Weaker Tablet (Elastic Deformation)	CM: High DM: High Weak Tablet (Low Fragmenting)

CM: Compression Modulus; DM: Decompression Modulus

Fig. 3: Compression-decompression modulus classification system (CDMCS) for Low (5-20 MPa) and Mid (20-60 MPa) compression pressure ranges.

CONCLUSIONS

- The present investigation demonstrated the application of compression and decompression modulus derived from the dynamic continuous compression profile in the characterization and classification of the deformation behavior of pharmaceutical materials.
- A two-dimensional pharmaceutical material classification system is established based on the compression and decompression modulus.
- The proposed compression behavior parameterization methodology and classification system could serve as a 'first-hand tool' in an early formulation development stage or as a 'tableting problem diagnostic tool' in the late development stage.

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