

Tablet Punching: A Comprehensive Review of Mechanisms, Tooling, Defects, and Emerging Technologies

Jarhad Ashwini Nivrutti and Ms. Shraddha Madan Khaladkar

Student, Samarth Institute of pharmacy, Belhe, Pune, Maharashtra.

Associate Professor, Department of Quality Assurance Techniques

Samarth Institute of Pharmacy Belhe, Pune, Maharashtra.

ashwinjarhad2005@gmail.com and Khaladkar90@gmail.com

Abstract: *Tablet punching is a cornerstone process in solid dosage form manufacturing, responsible for the compaction of pharmaceutical powders and granules into mechanically robust, dose-accurate tablets. This review synthesizes knowledge across the fundamental mechanics of punch-and-die tooling, compaction physics, common punching defects, material science of tooling steels, lubrication strategies, and advancements driven by continuous manufacturing and digital process analytical technology (PAT). Special attention is given to the tribological behavior at punch-tip interfaces, fatigue failure mechanisms, and the growing role of finite element analysis (FEA) and machine learning in predictive maintenance. The review also critically examines regulatory considerations and future directions, including multi-tip tooling and additive manufacturing of punch sets. Understanding the full landscape of tablet punching is essential for pharmaceutical engineers seeking to optimize yield, reduce downtime, and ensure product quality.*

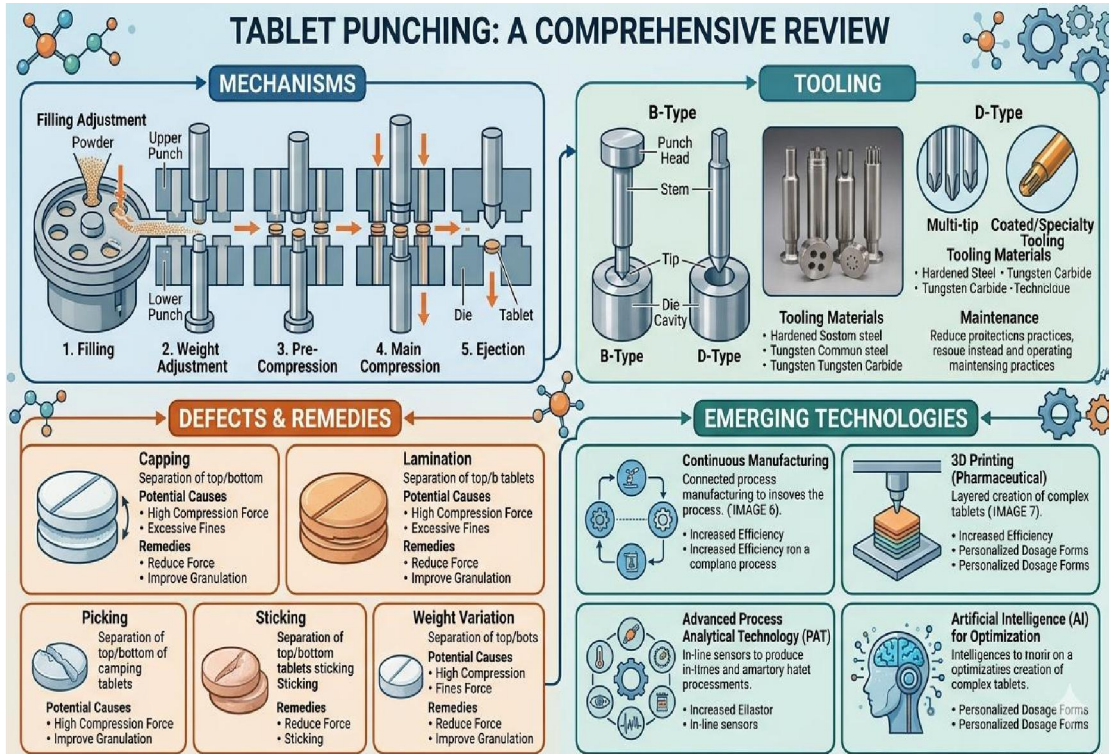
Keywords: tablet punching, rotary tablet press, punch tooling, compaction, tribology, capping, lamination, PAT, continuous manufacturing

I. INTRODUCTION

The oral solid dosage form remains the most preferred route of drug administration globally, owing to patient convenience, ease of manufacturing, and established regulatory frameworks. Among solid dosage manufacturing processes, tablet punching — the mechanical compaction of powdered or granulated material between an upper and lower punch within a die cavity — is the defining unit operation. Its origins trace to single-punch eccentric presses of the mid-nineteenth century, yet the modern rotary tablet press operating at thousands of tablets per minute represents one of the most mechanically sophisticated pieces of pharmaceutical machinery in existence.

Despite its maturity, tablet punching continues to yield challenges. Tooling wear, punch sticking, capping and lamination defects, weight variability, and hardness inconsistency remain persistent problems in both development and commercial manufacturing environments. The increasing complexity of drug molecules — including poorly compressible APIs, high-dose formulations, fixed-dose combinations, and moisture-sensitive compounds — has intensified demands on punch tooling design and process understanding.





This review aims to provide a unified, mechanistically grounded account of tablet punching by integrating classical tribology and materials science with contemporary pharmaceutical engineering and digital manufacturing concepts. The scope covers:

- Fundamental mechanics of compaction and punch kinematics
- Tooling design, materials, and surface engineering
- Compaction failure modes and their physicochemical origins
- Lubrication and anti-sticking strategies
- Continuous manufacturing integration
- Digital tools and emerging technologies

II. FUNDAMENTAL MECHANICS OF TABLET PUNCHING

2.1 The Compaction Cycle

The tablet punching process consists of four distinct phases within each compaction event:

Phase I — Filling: Powder or granules fill the die cavity as the lower punch descends to a preset fill depth. Gravity and, in forced-feeder systems, mechanical agitation drive die filling. Uniformity of fill is directly linked to weight variability of the finished tablet.

Phase II — Metering: The lower punch rises slightly to eject excess material from the die, fixing the tablet weight. This "weight" or "dosing" position is a critical control parameter.

Phase III — Compaction: The upper punch descends and contacts the powder bed. The compaction event itself is conventionally subdivided into:

Rearrangement: Initial particle repositioning under low stress, reducing interparticulate voids.

Elastic deformation: Reversible deformation of particles without permanent structural change.



Plastic deformation and/or brittle fracture: Permanent deformation (for ductile materials such as microcrystalline cellulose) or fragmentation (for brittle materials such as dicalcium phosphate), generating new surface area and bonding sites.

Consolidation: Formation of interparticulate bonds — primarily van der Waals forces, hydrogen bonds, and mechanical interlocking — yielding the compact.

Phase IV — Ejection: The upper punch withdraws; the lower punch rises to expel the tablet from the die. Ejection forces are a sensitive indicator of tooling lubrication status and formulation adhesion tendency.

2.2 Force-Displacement Relationships

The relationship between applied punch force and displacement yields the force-displacement (F-D) profile, which encodes mechanical information about the powder bed. The area enclosed by the loading and unloading curves — the compaction work — can be decomposed into:

Net work of compaction (W_{net}): Energy permanently absorbed by the tablet; associated with plastic deformation.

Elastic recovery (W_e): Energy returned during decompression; associated with elastic rebound, which may cause lamination if excessive.

Friction work (W_f): Energy dissipated at punch/die walls.

The ratio W_e / W_{net} is an important metric: high values signal formulations prone to capping or lamination. Heckel analysis ($\ln[1/(1-D)]$ vs. pressure, where D is relative density) provides the mean yield pressure (P_y), characterizing the plasticity of the formulation. Lower P_y indicates greater plastic flow and generally superior tablet-forming ability.

2.3 Punch Kinematics on Rotary Presses

On a rotary tablet press, punch displacement follows a sinusoidal cam profile. The key kinematic parameters are:

Turret speed (RPM): Determines production rate; increasing speed reduces dwell time.

Dwell time: The interval during which the punch head dwells under the compression roller at near-maximum force. Longer dwell times increase densification for time-dependent (viscoelastic) materials.

Pre-compression: A preliminary compaction stage preceding main compression, employed to expel entrapped air and reduce capping susceptibility.

The compaction rate — rate of punch displacement during loading — affects strain-rate-sensitive materials. Microcrystalline cellulose (MCC), a predominantly plastic material, is relatively rate-insensitive; highly viscoelastic excipients like hydroxypropyl methylcellulose (HPMC) show marked rate sensitivity.

III. PUNCH TOOLING: DESIGN, MATERIALS, AND SURFACE ENGINEERING

3.1 Tooling Standards and Geometry

Punch and die sets are manufactured to internationally recognized standards, principally:

TSM (Tablet Specification Manual): North American standard maintained by the American Pharmacists Association.

EU (European) Standard: Widely adopted in European press manufacturers; dimensional compatibility with TSM is partial.

A standard punch set comprises an upper punch, lower punch, and die. Key geometric parameters include:

Parameter

Description

Cup depth

Depth of the concave punch face; determines tablet thickness and crown profile

Land width

Flat annular margin at the punch tip; critical for edge integrity

Tip diameter

Determines tablet diameter; controlled to micron tolerances



Working length

Governs fill volume and weight reproducibility

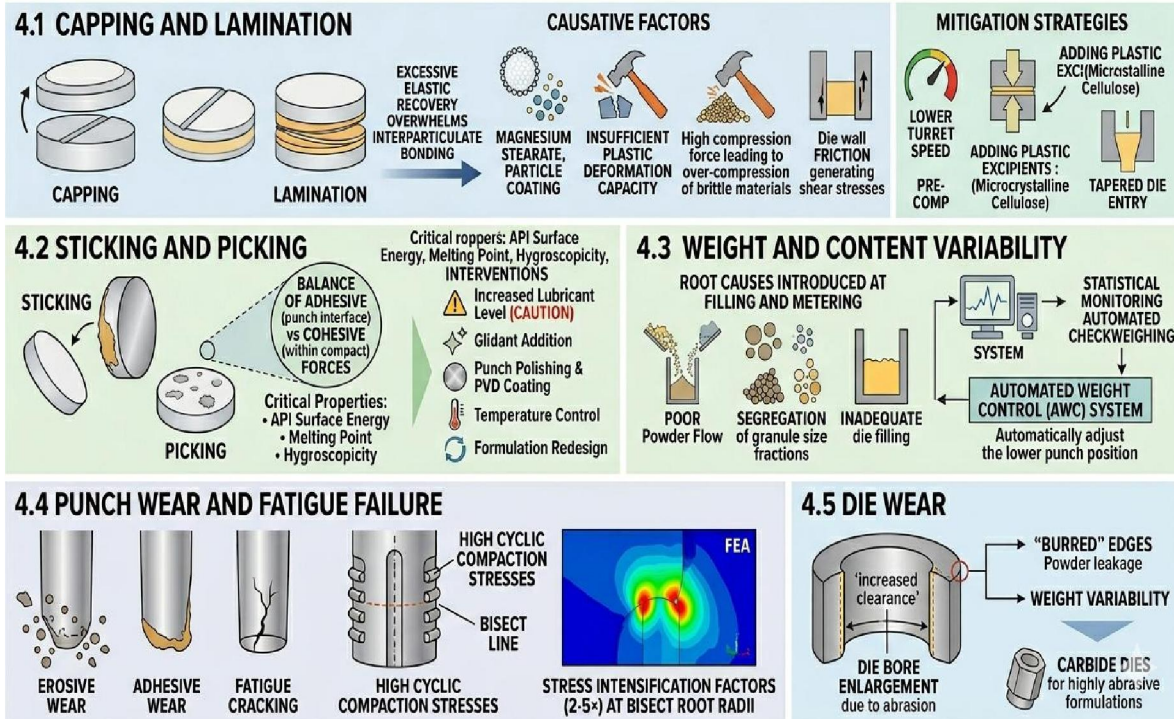
Barrel diameter

Interfaces with the punch guide; affects punch-to-guide clearance

Punch tip geometry is matched to the die bore with clearances typically in the range 2–8 μm per side, balancing the need to prevent powder leakage (which produces "picking" and die wear) with adequate punch movement freedom.

Tablet face design (embossing/debossing, bisect lines, bevels) is machined into the punch cup. Complex designs increase the risk of sticking, particularly for formulations containing adhesive APIs.

COMMON TABLET MANUFACTURING DEFECTS AND EQUIPMENT CHALLENGES



3.2 Tooling Materials

D2 Tool Steel (AISI D2): A high-carbon, high-chromium cold-work tool steel, representing the traditional benchmark for punch manufacture. Offers good wear resistance and hardness (typically HRC 58–62 after heat treatment), but moderate toughness.

S7 Tool Steel: A shock-resistant tool steel with higher toughness than D2, preferred for embossed punches or formulations generating high ejection forces. Slightly lower wear resistance.

M2 High-Speed Steel: Used where extreme hardness (up to HRC 64) and heat resistance are required. More brittle; employed for high-speed production environments.

Carbide-Tipped Punches: Tungsten carbide tip inserts pressed into a steel punch body. Offer exceptional wear resistance (3–10 \times steel) for highly abrasive formulations (e.g., calcium phosphate, certain mineral-laden vitamin tablets). Higher initial cost; susceptible to brittle chipping under impact.

Corrosion-Resistant Steels (440C, 17-4PH): Required for aqueous granulation environments or hygroscopic formulations where standard tool steels would corrode. Slightly lower hardness than D2.



Material selection must balance hardness (wear resistance), toughness (fracture resistance), and corrosion resistance — properties that are often mutually competing in steels.

3.3 Surface Coatings and Treatments

Surface engineering of punch tips has emerged as a primary strategy to address sticking and extend tooling life:

Hard Chrome Plating: Traditional coating; increases surface hardness and reduces friction. Environmental concerns (hexavalent chromium) have spurred alternative development.

Physical Vapor Deposition (PVD) Coatings:

Titanium Nitride (TiN): Gold-colored; widely used. Hardness ~2000 HV; reduces friction and abrasion.

Titanium Carbonitride (TiCN): Higher hardness (~3000 HV) than TiN; improved wear resistance.

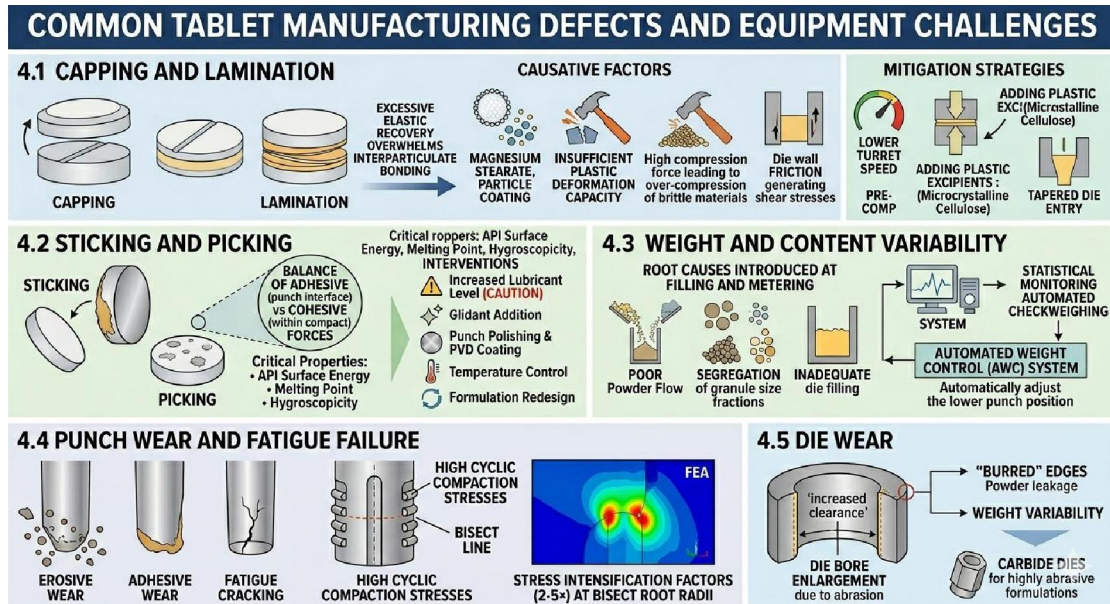
Chromium Nitride (CrN): Better corrosion resistance than TiN; preferred for moisture-sensitive formulations.

Diamond-Like Carbon (DLC): Extremely low coefficient of friction (~0.1); excellent anti-sticking properties. Can be brittle under high point loads.

Electroless Nickel Plating: Uniform deposition including complex geometries; moderate hardness (~500–700 HV post-heat treatment). Good corrosion resistance.

Polishing: Mirror-polished punch faces ($R_a < 0.05 \mu\text{m}$) reduce contact area with the powder compact, decreasing adhesion tendency. Regularly scheduled re-polishing is an integral part of punch maintenance protocols.

IV. COMMON TABLET PUNCHING DEFECTS



4.1 Capping and Lamination

Capping refers to the separation of a tablet's upper or lower crown, while lamination denotes horizontal layer separation through the tablet body. Both are manifestations of excessive elastic recovery overwhelming interparticulate bonding during decompression and ejection.

Causative factors:

Excessive lubricant concentration (particularly magnesium stearate), which disrupts bonding by coating particle surfaces with a hydrophobic film.

Insufficient plastic deformation capacity of the formulation.



Entrapped air — inadequate pre-compression, fast punch speed, fine poorly-flowing powders.

High compression force leading to over-compression of brittle materials.

Die wall friction generating shear stresses in the compact during ejection.

Mitigation strategies:

Optimization of lubricant concentration and blending time (over-lubrication is frequently the primary cause).

Reduction of turret speed to increase dwell time.

Activation of pre-compression stage.

Addition of plastic excipients (MCC, co-processed excipients).

Tapered die entry geometry to facilitate compact expansion.

4.2 Sticking and Picking

Sticking is the adhesion of tablet material to punch faces, producing surface defects on ejected tablets. Picking is a related phenomenon where small portions of the tablet are pulled away upon punch withdrawal, leaving pits on the tablet face.

Sticking is governed by the balance of cohesive forces within the compact vs. adhesive forces at the punch-compact interface. Critical material properties include API surface energy, melting point (low-melting APIs soften under compaction heat), and hygroscopicity.

Process and formulation interventions:

Increased lubricant levels (caution: over-lubrication).

Glidant addition (colloidal silicon dioxide).

Punch face polishing and PVD coating.

Temperature control of the tablet press environment.

Formulation redesign (granulation, amorphous-to-crystalline conversion of API).

4.3 Weight and Content Variability

Weight variability is introduced primarily at the filling and metering phases. Poor powder flowability, segregation of granule size fractions, and inadequate die filling are root causes. Statistical monitoring of tablet weight via in-process checkweighing or automated weight control systems (AWC) — which automatically adjust the lower punch position in response to weight feedback — is standard practice.

4.4 Punch Wear and Fatigue Failure

Punch tips are subject to cyclic compaction stresses, die wall friction, and abrasive powder contact. Wear manifests as:

Erosive wear: Abrasive API/excipient particles remove material from punch faces.

Adhesive wear: Transfer of formulation or punch material between surfaces.

Fatigue cracking: Cyclic stress concentrations at embossing features, bisect lines, or land edges initiate fatigue cracks that propagate to punch fracture.

Bisect lines are particularly high-stress regions; finite element analysis (FEA) of punch stress distributions has shown stress intensification factors of 2–5× at bisect root radii, underscoring the importance of generous fillet radii in punch design.

4.5 Die Wear

Die bore enlargement due to abrasion — most pronounced with mineral-containing formulations — leads to increased punch-to-die clearance, powder leakage (causing "burred" tablet edges), and weight variability. Carbide dies are the preferred remedy for highly abrasive formulations.



V. LUBRICATION IN TABLET PUNCHING

5.1 Role of Lubricants

Lubricants serve two functions in tablet punching:

Boundary lubrication: Reducing friction between the tablet compact and die wall during ejection (anti-friction function).

Anti-adherent function: Reducing adhesion between punch faces and tablet surfaces.

5.2 Magnesium Stearate: Benefits and Drawbacks

Magnesium stearate (MgSt) at 0.25–1.0% w/w is the dominant pharmaceutical tablet lubricant owing to its effectiveness at low concentrations and broad regulatory acceptance. Its mechanism involves orientation of the stearate chain along the compact/die interface, creating a low-shear monolayer.

However, MgSt is hydrophobic and coats particle surfaces during blending, impeding interparticulate bonding. The consequences are:

Reduced tablet tensile strength (hardness).

Decreased disintegration rate.

Retarded drug dissolution — a critical concern for BCS Class II and IV drugs.

The sensitivity of these properties to MgSt blending time and intensity (the "over-lubrication" phenomenon) demands strict control of final blend mixing conditions.

5.3 Alternative Lubricants

Growing interest in lubricant alternatives has driven investigation of:

Sodium stearyl fumarate (PRUV®): Less sensitive to over-lubrication; superior dissolution profile maintenance; increasingly preferred for extended-release formulations.

Glyceryl behenate (Compritol®): Lipid-based; suitable for melt granulation or direct compression.

Stearic acid: Weaker lubricant than MgSt; less detrimental to dissolution.

Leucine: Amino acid lubricant employed in dry powder inhalation (DPI) formulations; increasingly examined for tablets.

Magnesium lauryl sulfate: Good lubrication with improved wettability vs. MgSt.

5.4 External Lubrication Systems

External lubrication — applying lubricant directly to punch faces and die walls via a spray system, bypassing inclusion in the formulation — offers the potential to eliminate intra-formulation lubricant entirely, preserving tablet bonding and dissolution properties. The Fette and Korsch external lubrication systems are commercially available. Challenges include uniform coating of complex punch tip geometries and increased equipment complexity.

VI. PROCESS ANALYTICAL TECHNOLOGY (PAT) IN TABLET PUNCHING

6.1 In-Process Monitoring

The FDA's 2004 PAT Guidance catalyzed adoption of real-time monitoring in tablet compression. Key PAT tools applied to punching include:

Force Measurement:

Instrumented punches equipped with strain gauges or piezoelectric force transducers provide individual punch force profiles at production speed. Force data enables:

Real-time tablet hardness estimation (via calibration models).

Detection of weight variability (force correlates with fill weight for a given formulation).

Identification of faulty die positions (outlier force profiles).

Near-Infrared Spectroscopy (NIR):



NIR probes positioned at the tablet press outlet measure tablet content uniformity and blend homogeneity in real time, enabling detection of segregation or out-of-specification blends without destructive testing.

Acoustic Emission (AE):

AE sensors detect high-frequency stress waves generated during compaction and punch-die contact. AE signals have been correlated with tablet compaction events, punch wear progression, and sticking onset, offering a non-invasive monitoring modality.

Machine Vision:

High-speed cameras integrated at the tablet press outlet inspect tablet appearance — detecting capping, chipping, sticking artifacts, and embossing defects — at full production speed. Modern systems employ deep learning (convolutional neural networks) for defect classification.

6.2 Model-Based Control

Process data from instrumented presses feed real-time models for automatic press adjustment. Multivariate statistical process control (MSPC) monitors the trajectory of compaction data in principal component space, triggering alarms on deviation. Model predictive control (MPC) schemes adjust compression force, turret speed, and fill depth to maintain tablet quality attributes within specification.

VII. CONTINUOUS MANUFACTURING AND TABLET PUNCHING

7.1 Continuous Tablet Compression

Continuous manufacturing (CM) of tablets — replacing batch processes with uninterrupted material flow — has attracted intense pharmaceutical industry and regulatory attention since FDA's endorsement via PAT and Quality by Design frameworks. In continuous compression, powders or granules are fed to the tablet press via a loss-in-weight (LIW) feeder at a controlled rate synchronized with press turret speed.

The transition to CM introduces specific challenges for tablet punching:

Residence time distribution: Material of varying blend quality may reach the press during start-up, disturbances, or end-of-campaign. Real-time NIR monitoring and diversion systems are required.

Start-up and shut-down management: Transient states during press acceleration represent periods of potential quality risk.

Reduced in-process testing opportunity: Traditional off-line hardness and dissolution testing intervals are incompatible with continuous flow; PAT-based real-time release testing (RTRT) is required.

7.2 High-Throughput Development Presses

Miniaturized single-station compaction simulators (e.g., Presster®, Phoenix Simulator®) that mimic the kinematics of specific rotary presses enable formulation scientists to generate compaction data predictive of production-scale behavior using milligram-scale quantities of API. These instruments are essential for early-stage formulation development of scarce drug candidates.

VIII. FINITE ELEMENT ANALYSIS AND COMPUTATIONAL MODELING

8.1 FEA of Punch Tooling

Finite element analysis has been applied to tablet punch tooling design to:

Identify stress concentration regions in complex punch geometries (embossing, bisects, steep bevels).

Optimize fillet radii at critical junctions to mitigate fatigue initiation.

Predict fatigue life under defined cyclic loading spectra.

Guide material selection for specific formulation/production rate combinations.

Studies employing FEA have demonstrated that bisect root radius has the dominant influence on punch fatigue life; doubling the root radius from 0.1 mm to 0.2 mm may reduce maximum von Mises stress by 30–40%.



8.2 Discrete Element Method (DEM) and Compaction Modeling

DEM simulations model individual particle interactions during die filling and compaction, providing insight into:

Die filling uniformity as a function of particle size, shape, and flow properties.

Powder density distribution within the compact — directly relevant to tablet hardness uniformity.

Effect of punch speed on compaction mechanics of viscoelastic materials.

The integration of DEM with continuum-based FEA of the compact ("multi-scale modeling") represents the current frontier in tablet compaction simulation.

IX. MACHINE LEARNING APPLICATIONS

9.1 Punch Wear Prediction

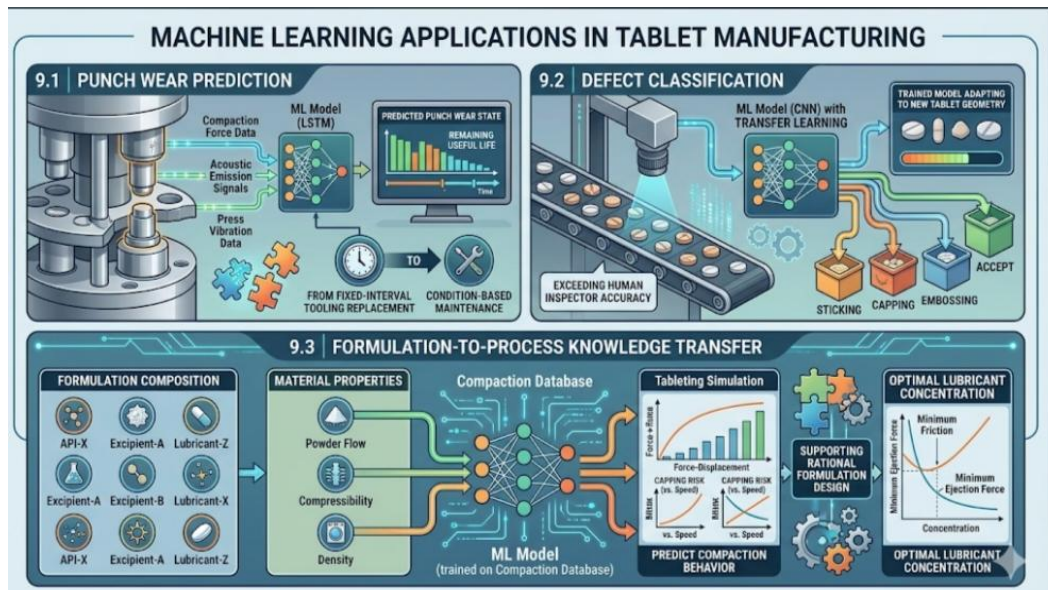
Machine learning (ML) models trained on compaction force data, acoustic emission signals, and press vibration data have demonstrated the ability to predict punch wear state and remaining useful life, enabling condition-based maintenance replacing fixed-interval tooling replacement schedules. LSTM (Long Short-Term Memory) recurrent neural networks have shown particular promise for time-series punch force data analysis.

9.2 Defect Classification

Convolutional neural networks (CNNs) applied to machine vision data classify tablet defects with accuracy exceeding trained human inspectors for sticking, capping, and embossing defects. Transfer learning approaches allow adaptation of pre-trained models to new tablet geometries with limited training data.

9.3 Formulation-to-Process Knowledge Transfer

ML models trained on large compaction databases (covering diverse APIs and excipients) are being developed to predict compaction behavior — including capping risk and optimal lubricant concentration — from formulation composition and material properties alone, supporting rational formulation design.



X. REGULATORY CONSIDERATIONS

10.1 GMP Requirements for Tooling

Current Good Manufacturing Practice (cGMP) regulations (21 CFR Part 211 for the US; EudraLex Vol. 4 for the EU) require that tablet punches and dies be qualified equipment, with documented specifications, cleaning procedures, and maintenance records. Punch identification (engravings or coding) must be maintained to ensure traceability. Tooling qualification includes dimensional inspection against drawing specifications, surface roughness measurement, and hardness verification. Change control applies to punch geometry modifications affecting tablet critical quality attributes (CQAs).

10.2 Elemental Impurity Considerations

ICH Q3D guidelines on elemental impurities are relevant to punch and die materials insofar as wear of metallic tooling may introduce trace metal contamination into tablets. Risk assessments for cobalt, chromium, nickel, and other components of specialty steels and coatings are increasingly required, particularly for high-abrasion formulations with long production campaigns.

10.3 Design Space and Quality by Design

ICH Q8(R2) encourages definition of a design space — the multidimensional combination of process parameters proven to deliver quality — for tablet compression. Compression force, turret speed, pre-compression force, and fill depth are typical design space variables. Real-time PAT monitoring enables operation across the design space with assurance of continuous quality.

XI. EMERGING TECHNOLOGIES

11.1 Multi-Tip Tooling

Multi-tip punches (2, 3, 4, or more tips per punch station) multiply output without increasing turret speed, reducing stress-per-tip while increasing tablets-per-revolution. Design challenges include equalization of force across all tips (requiring precise manufacturing tolerances) and increased complexity of cleaning and inspection.

11.2 Additive Manufacturing of Punch Tooling

Metal additive manufacturing (AM) — selective laser melting (SLM) and directed energy deposition (DED) — enables fabrication of punch geometries impossible with conventional machining, including internal cooling channels and complex embossing features. While the as-built surface roughness and residual stress state of AM parts require post-processing, AM offers a path toward on-demand manufacture of replacement tooling and novel punch tip designs. Current limitations include material qualification and validation for pharmaceutical GMP environments.

11.3 Electroactive and Shape-Memory Tooling Concepts

Research-stage concepts include piezoelectrically actuated punch tips capable of micro-vibration during compaction to improve die filling and reduce sticking, and shape-memory alloy (SMA) die elements enabling adaptive die wall geometry. These remain at early feasibility stages.

11.4 Digital Twins

The integration of physics-based compaction models, ML-based process models, and real-time press data into a digital twin of the tablet press enables simulation of the compaction process in parallel with physical production. Digital twins support operator decision-making, predictive maintenance, and virtual scale-up, and are an active area of pharmaceutical industry development.



XII. FUTURE PERSPECTIVES

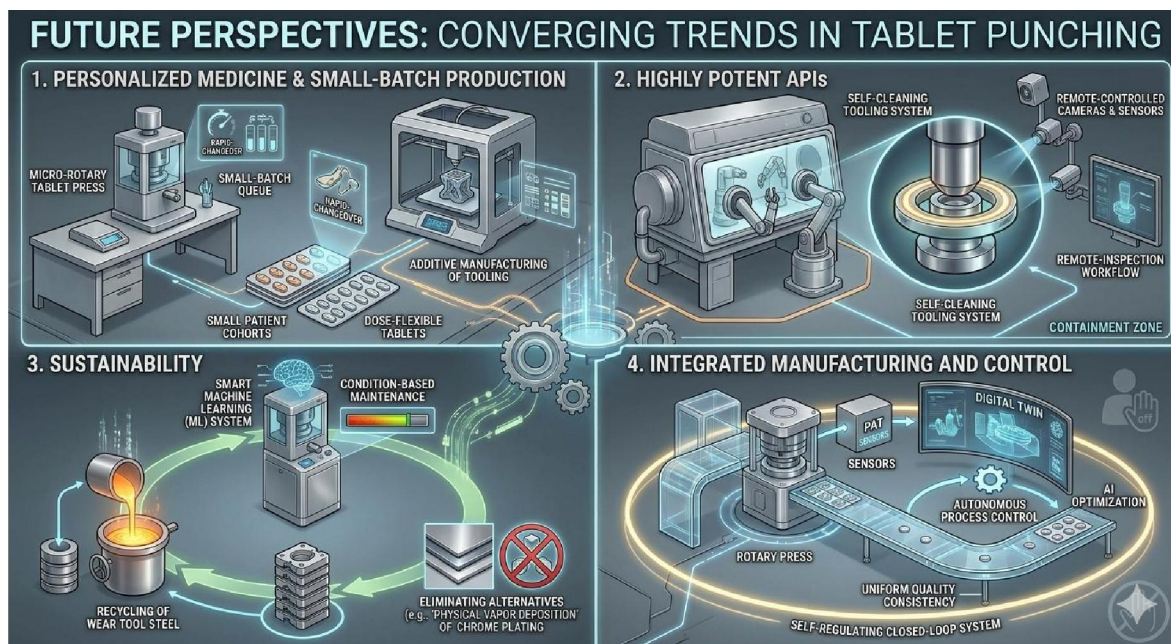
Several converging trends will shape the future of tablet punching technology:

Personalized medicine and small-batch production: Demand for small patient cohorts and dose-flexible tablets will increase the need for rapid tooling changeover, miniaturized presses, and additive manufacturing of tooling.

Highly potent APIs: Increasingly potent drugs impose containment requirements that complicate punch maintenance and inspection workflows; self-cleaning and remote-inspection tooling systems will grow in importance.

Sustainability: Reduction of tooling waste through condition-based maintenance (enabled by ML), recycling of wear tool steel, and elimination of hexavalent chrome plating are sustainability imperatives.

Integrated manufacturing and control: The fusion of PAT, digital twins, and autonomous process control promises a future where tablet punching operates continuously within self-regulating, self-optimizing closed-loop systems, reducing human intervention and improving product quality consistency.



XIII. CONCLUSION

Tablet punching, though mechanically simple in concept, encompasses a rich scientific domain spanning solid mechanics, tribology, materials science, pharmaceutical science, and digital engineering. This review has traced the process from fundamental compaction physics through tooling design, defect mechanisms, lubrication science, and computational modeling, arriving at the emerging landscape of continuous manufacturing, machine learning, and digital twins. The persistent challenges of sticking, capping, and punch wear remain active research frontiers, increasingly addressed through mechanistic modeling and intelligent monitoring rather than empirical trial-and-error. As pharmaceutical manufacturing evolves toward continuous, quality-by-design paradigms, a sophisticated, integrated understanding of tablet punching is indispensable to the pharmaceutical engineer and formulation scientist alike.

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