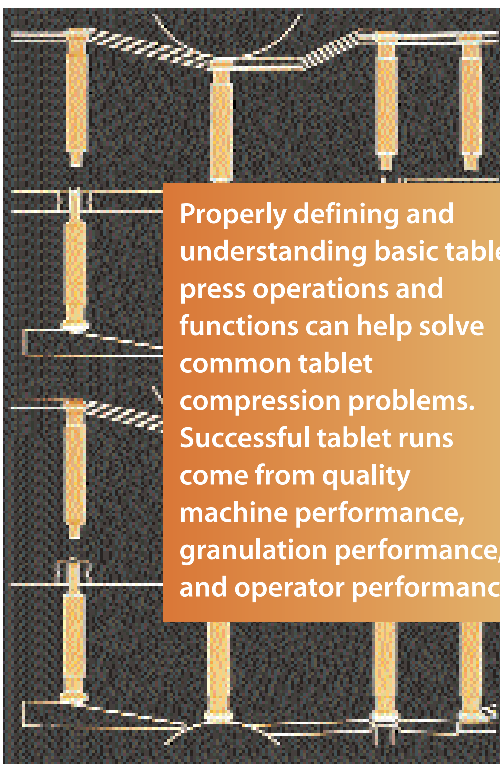
Optimal Tablet Press Operation

Machine versus Granulation

Michael D. Tousey



Properly defining and understanding basic tablet press operations and functions can help solve common tablet compression problems. Successful tablet runs come from quality machine performance, granulation performance, and operator performance.

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A tablet press is one of the most complex machines used in the manufacturing environment. Clearly defining the basic principles in tablet press operation is essential to having a successful run. Learning key factors can help to avoid the many obstacles that can interrupt a successful run.

Worldwide, more than 18 different companies make tablet presses. All tablet presses operate in the same basic way with only a few exceptions. This fact allowed the industry to define and create a standard for tablet press machines and tablet press tooling, which was published in the *Tablet Specification Manual* (*TSM*) by the American Pharmaceutical Association. The *TSM* can be acquired through any tooling or tablet press supplier. This article discusses how tablet press performance can be optimized by clearly distinguishing between granulation and machine issues; focusing on the importance of flow, compression, and ejection; and performing the necessary maintenance and quality control checks.

Tablet press and granulation

Clearly defining the role of the operator is important in any endeavor, but it is especially critical in the successful manufacture of a good tablet. An experienced tablet press operator can take a marginal granulation and make it work successfully and can differentiate between a machine-related issue and a granulation-related issue.

Many granulation problems can be solved on the press, but they can be created on the press as well. A successful run can be defined as an operation of the tablet press for a predetermined length of time without continued tablet problems such as picking, capping, weight variations, and hardness variation. In addition, the tablet press and tooling must complete the run without being damaged. A successful tablet press run can be defined as one that produces excellent tablets with minimum downtime and little to no wear to the mechanical components of the press and press tooling. Supervisors may wonder, Is this possible? Yes, it is very possible.

The first step in obtaining a successful run is performing proper cleaning and setup. If cleaning and setup are conducted completely and correctly, two-thirds of that successful run is accomplished. However, one must remember to differentiate between the granulation and the machine.

Machine function

Again, the purpose is to be fundamental. Taking into account the tablet press in sections of function, the three main issues of

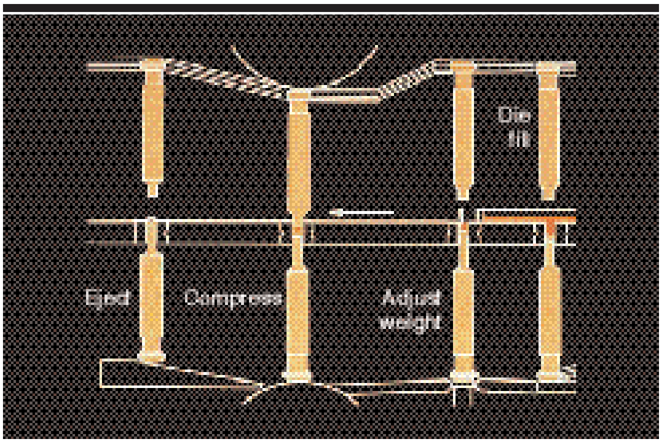

Figure 1: A depiction of a simple four-station rotary tablet press showing the basic key functions in the direction of rotation: (right to left) die fill, weight adjustment, compression, and ejection. (Figure provided by Thomas Engineering Inc.)

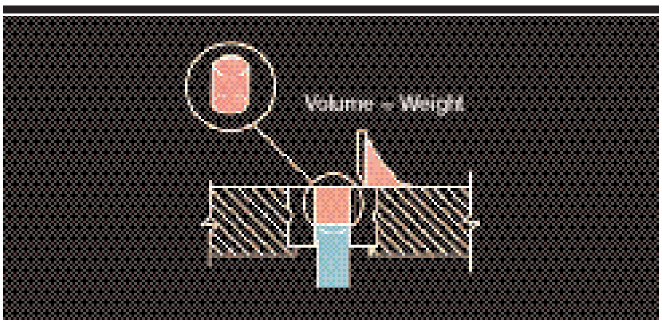

Figure 2: A tablet press does not weigh the granulation; weight is equal to the volume of fill within the die cavity. (Figure provided by Thomas Engineering Inc.)

the product–granulation process are flow, compression, and ejection. *Flow* is the ability of the granulation to flow like granulated sugar as opposed to flour, for example. *Compression* is the formation of a tablet within the die, and, simply put, *ejection* is getting the finished tablet out of the die (see Figure 1).

Solving a problem on the machine must start with the following thought process: flow, compress, and eject. The question then becomes whether the product issue is related to flow, compression, or ejection. The main sections of the press related to function are the press feed system, the compression station(s), and the ability to eject the tablet from the die and get the tablet safely off the tablet press.

The order of action is important to understand when defining problems. For example, the weight must be stable to compress a tablet to a consistent final tablet hardness. Optimizing granulation flow and consistency must begin by evaluating machine speed. The average press speed of 3000 tablets/min means that one is manufacturing 50 tablets/s. Granulations that are developed on a laboratory tablet press often will not work on a higher-speed machine without some change in the granulation's ability to flow, compress, and eject. Some tablet presses have features that will help with these problems but will not always solve them.

Flow

The press feed system. The main components of the press feed systems are the product hopper, the feeder, the fill cam, the weight cam, the scrapper blade assembly, and the recirculation channel. On a tablet press, a volume of granulation filled consistently into the die cavity determines tablet weight (see Figure 2). A tablet press does not preweigh the granulation. The weight is obtained by overfilling the die cavity and then pushing excess granulation out of the die and guiding it into a channel, thereby ensuring that the excess cannot spill back into the die cavity.

The paddle feeder. The hopper and feeder are designed to deliver product from a static position and get it moving with the rotational speed of the machine. The feeder does not push granulation into the die; it delivers granulation over the die cavity so that it can flow into the die cavity. The paddle speed can be adjusted to allow the granulation to accelerate until it matches the rotational speed of the turret.

Selecting the proper fill cam. The fill cam determines how much the die will overfill. Overfill is needed to get good, consistent tablet weight. Consistent flow of granulation into the die will provide the needed reproducibility and consistency, tablet to tablet. Too much overfill means that a high percentage of powder in the die gets pushed out of the die and must travel back into the feeder. The granulation travels repeatedly into and out of the feeder and the die, a process called *overworking the granulation.* The more often the granulation recirculates and travels through the feeder, the more likely the granulation will break down and cause increased weight fluctuation, particle-size reduction, density changes, and dust. To prevent this problem, select the proper fill cam to get a minimum overfill of no more than 20% by volume within the die cavity (see Figure 3).

Fines control. Dust on a press usually is defined as *fines.* Fines are fine particles of granulation that easily become airborne. The higher the percentage of fines, the more likely that common tablet defects such as weight variations, hardness variations, capping, picking, sticking, and content uniformity issues will occur. Fines can absorb the lubricating properties of oils and greases used to keep mechanical components moving freely on the press. The higher the percentage of fines, the more need to focus on dust collection, component lubrication, and final yields.

Weight control. The weight cam and scrapper assembly are the heart and soul of making a good tablet. Moving the adjustable weight cam during operation on a continual basis controls the final tablet weight. Moving the cam upward pushes excess granulation out of the die, resulting in a reduced final tablet weight. Increasing the fill into the die means moving the weight cam down to reduce the amount of granulation being pushed back up and out of the die. The scrapper assembly scrapes the excess granulation away from the die opening and directs it into the recirculation channel. The scrapper blade must be spring-loaded to follow the surface of the die table. The scrapper blade must have a straight and semisharp surface to ensure that the die surface is scraped cleanly. Particle-size variations are proportionate to proper die fill. A large particle scraped from the die will result in greater weight fluctuations.

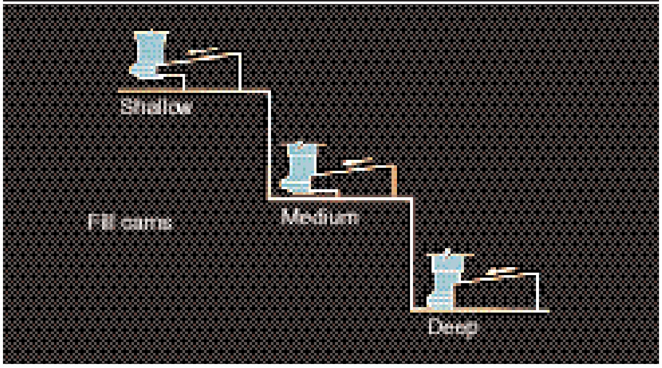

Figure 3: Selecting the proper fill cam provides the correct overfill within the die cavity. Proper overfill is essential to achieving good weight control. (Figure provided by Thomas Engineering Inc.)

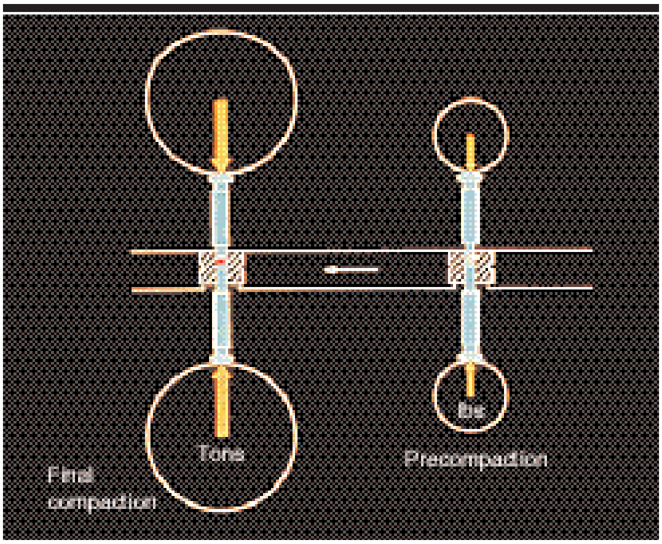

Figure 4: Precompression removes air from the granulation and extends the dwell time. (Figure provided by Thomas Engineering Inc.)

Granulation flow pattern. Recirculation of the granulation is part of the operation. When excess granulation is pushed out of the die cavity, that granulation must be fed back into the feeder. Controlling the amount of granulation that is recirculated is very important. Too much granulation in the recirculation channel may cause the granulation to compact and densify if the granulation is sensitive to compaction. Granulations that are friable can break up, thereby increasing the amount of fines. (A small percentage of fines is acceptable; they actually enhance the tablet appearance. Granulations that have a narrow particle-size profile tend to look granular. Granulations with a wider particle-size profile, including a small percentage of fines, have a much more compacted and shiny appearance, which is more desirable to consumers.)

Particle-size profiles. Generally speaking, the granulation particle-size profile increases as the size of the tablet increases. A very small tablet such as an oral contraceptive tends to have a very fine particle profile — from 240 to 100 mesh. A larger capsule-shaped tablet, such as a common 0.330 × 0.850 in. tablet, will have a larger particle-size target with a profile more in the 180–60 mesh range. The bigger the tablet, the better it is to have a larger particle-size profile. The particle-size profile must fall in line with the final tablet size.

Compression

The main components of compression consist of the precompression rolls, the main compression rolls, and the punch head configuration.

Compression cycle. Compression of the granulation is accomplished by pressing the punches together between pressure rolls. Most presses now have two compression stations: precompression and final compression.

Precompression can be used in two ways. The main purpose is to remove the air trapped within the granulation. Precompression also helps eliminate the air that is pushed into the granulation by the upper punch tip — the deeper the cup depth of the upper punch tip, the more air that gets pushed into the granulation. The other main purpose for precompression is to increase dwell time, which results in more consistent tablet-to-tablet hardness (see Figure 4). Again, most granulations must be pressed lightly or air will become trapped. Trapped air congregates along the top of the tablet band where the cup of the upper punch meets the band. This is called *capping*.

Capping. First, it is important to understand that the diameter of the upper punch tip is slightly smaller than the diameter of the lower punch tip. The lower punch tip stays in the die at all times — down for fill and up for weight control and through ejection. The lower punch tip stays in the die tightly to keep granulation from leaking between the tip and the die wall (see Figure 5).

The upper punch tip is smaller because this is where the air leaves the die during compression. If the upper punch tips were the same size as the lower punch tips, then the air would be entrapped. The tablet caps on the top of the tablet because that is where the air is pushed out. When the air is pushed out, it is also pushing the lighter, finer particles with it. Hence, if the tablet is not given time to compress fully, capping occurs. Also, these fines are pushed to the same location, and they have a tendency to not adhere to one another (see Figure 6).

Punch-head configuration. The punches are pressed together between pressure rolls to form the tablet. The length of time the punches are under pressure is called *dwell time*. There are three commonly used head profiles: US standard TSM, domed head TSM, and European head. The head flat on the domed head and the European head profiles is slightly larger than that of the US standard profile. This larger diameter provides for greater dwell time during compression. Many dwell-sensitive granulations will have increased hardness with longer dwell times. To determine whether a product is dwell sensitive, establish good weights and hardnesses, then increase press speed while maintaining good weight control. If tablet hardness drops off quickly with increased speed, then the product is dwell sensitive.

The other advantages of the domed head and the European head profiles allow for a smoother transition and less-abrupt transfer onto the pressure rolls because the head profile has a larger radius than that of the standard TSM angular head design. This smoother transition relates to improved tool life because wear is reduced with the domed design. The other critical issue to be aware of is that the European head profile is a narrower head profile with a 30° inside-head angle as opposed to the standard and domed inside-head angle of 37°. The sig-

Figure 5: The top of this tablet is coming off the rest of the tablet. This is called *capping*.

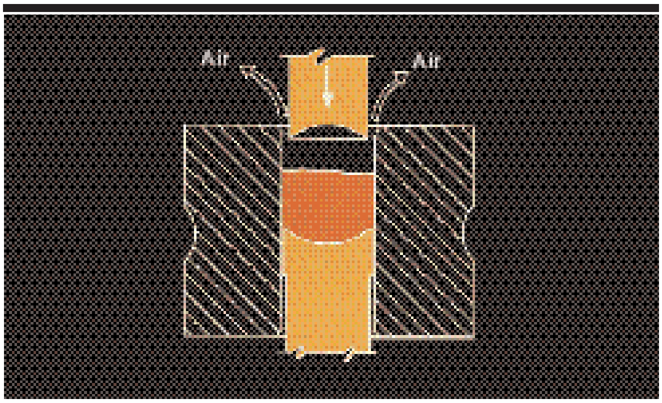

Figure 6: Air release on the press is controlled by the punch tip design and the point of compression within the die — the deeper the upper punch entry, the farther the air must travel to be released. (Figure provided by Thomas Engineering, Inc.)

nificant difference is that a machine configured with European cams must be used with a European head profile. They are not interchangeable with machines that use US and domed head profiles and matching cams. Machines used in North America typically are supplied with US cams.

A basic compression example. An example of a basic compression process is the making of a snowball. Kids (in cold climates — sorry to my friends in Puerto Rico) know that when snowflakes are large and wet, they can pick up a handful of snow, compact it quickly, and throw it at their buddy successfully. On days when the snow is very fine and light (low bulk density) and dry (low moisture content), if I compact it in the same way as the wet snow and throw it at my buddies, the snowball will never reach its intended target. When the snow is light and dry and fine it must be compressed for a longer period of time (dwell time).

Light, fine, and dry particles also are more sensitive to overcompression. Overcompressed particles laminate because they no longer lock together. The key is to understand the nature of a granulation. Operators who are lucky enough to produce one and only one product day after day know that the granulation does have variations like snow has. Some granulations can have overly wet areas and dry areas in the same batch. Recognizing this is important; otherwise, one may conclude that there is a machine problem. View the machine as a tool to make the granulation perform. Monitoring press speed and controlling dwell times are essential functions of operating the press to match the granulation. (By the way, be sure to feed this information to your buddies in granulation — they think you still don't know how to operate the press.)

Ejection

The main function of ejection is to get the tablet out of the die. The ejection cam, lower punch length, lower punch tip condition, take-off blade, machine speed, and proper mix of lubricant into the granulation all contribute to proper tablet ejection.

Ejection height should be set so that the lower punch tip is even with or slightly above the die. This ensures that the tablet is pushed completely out of the die. If the lower punches are worn and have different lengths, then the ejection height will not be consistent. Because punches tend to wear down, be sure the punch tip is kept smooth. A dented or rough punch tip often indicates poor handling. The punch cup also must be polished to keep the granules from sticking to the surface of the punch to eliminate the tendency of the granulation to pull away from the surface of the tablet. This is commonly referred to as *sticking* and *picking*. Sticking and picking also can be a result of granules that are not dry inside. When compressed, case-hardened granules will not be protected by the dry lubricant that is mixed in to help prevent sticking and picking. A wet granule will stick to the punch surfaces.

Once the tablet is pushed out of the die, it is guided off the machine by the take-off blade. The take-off blade guides the tablet off the surface of the lower punch and die table and directs it down the tablet ejection chute. The blade must be clean and level. If the take-off blade is set too high, the tablet might chip or even break, and densified tablet pieces will get into the flow of granulation causing weight, hardness, and most likely dissolution issues.

A good tablet

The main issues in making a tablet are tablet weight, hardness, thickness, friability, content uniformity, and appearance.

Weight control. Weight control was discussed previously. Tablet weight is determined by a volume of granulation filled consistently into the die cavity. A tablet press does not preweigh the granulation. The weight is a result of overfilling the die cavity, then pushing excess granulation out of the die and guiding the excess granulation into a channel, making certain that it cannot spill back into the die cavity. Good weight control is the essence of making a good tablet. Always check weights first, then thickness and hardness.

Tablet-hardness control. The main factors are weight, thickness, punch length, press speed, upper-punch penetration, and die condition. Don't try to solve hardness issues without having consistent weights first.

Thickness and punch length. Punches should be checked in-house regularly after each cleaning to ensure that they are maintained. New punches are made to be ±0.001 in. Worn dimensions depend completely on the end product. Some companies allow for a length variation of ±0.004 in., which is extreme.

Dwell time. As discussed previously, dwell time is time under pressure, which relates to punch-head flat and press speed.

Punch penetration. Upper-punch penetration is how far the upper punch enters the die. Old presses have a nonadjustable upper-punch penetration set at 6 mm. New and more modern machines have adjustable punch penetration. If the upper punch enters the die at 6 mm, then the air has a long way to travel to escape. Making the tablet higher in the die allows the air to evacuate sooner and allows for more consistent hardness control and higher press speed.

Die condition. Die condition can influence tablet hardness and appearance. As a tablet is compressed, radial forces will create compression rings within the die. Over time, these wear rings will become exaggerated. Compressing a tablet in a worn die can give the appearance that the tablet is capping. Hardness cannot be controlled, and the tablet band (sides) will not be hard, smooth, and shiny.

The role of supervisors and operators

Supervisors and operators should do the following:

- When the press is apart with no tooling, visually inspect all of the working areas of the machine (a flashlight is very helpful). Good or normal metal wear means that the metal is polished and shiny. Bad metal wear means that the metal has become dull, abraded, rough, and discolored.
- Visually inspect the punches and dies. Become familiar with the wear patterns and determine what is causing them. Look into the punch sockets and use a flashlight and a mirror if needed for the lower punches. As granulations cake in the socket they become shiny and look like steel. Buildup in the socket will cause the punches to run tight, resulting in shortened punch life. Inspect punch sockets closely.
- Never dry run a machine. Some machine manufacturers may claim that the machines have various safeties and that conducting a dry run is OK. It's not OK. Make sure that there is powder between the dies.
- Rotate the machines slowly and listen for metal-to-metal scraping sounds. The sounds will eventually go away but not before causing some damage. Don't run the machine until you solve this problem. One trick is to rotate the machine after each subassembly is complete (i.e., after installing the upper punches, the feeder, and the dust nozzles).
- Check weights often and routinely.
- Listen to the machine. Changes in the moisture content of the granulation will make the machine sound differently. A tough and abrasive granulation makes the press sound harder and rougher compared with the sounds produced when using a softer granulation.
- Inspect the tablets. Look for gray and black specks. These discolorations come from granulation packing in the feeder or on the die table, from a lack of lubrication in the upper punch sockets, misaligned punches and dies, and metal-to-metal contact.

Summary

Good operators are professionals. They can differentiate between the machine and granulation. They know how to adjust the machine within existing parameters to get the maximum performance from the machine and the granulation. Good operators know that the presence of fine airborne particles means that more frequent cleaning and higher frequency of punch lubrication are required. Granulations vary within each batch and from batch to batch. The operator must recognize this and adjust the machine accordingly. Don't leave the problem for the next shift. Proper monitoring and frequent checking will provide more-continuous operation. Sometimes a machine can run for days and other times, only for a few hours — it all depends on the initial cleaning, proper setup, and keeping the dust and fines to a minimum.

In the tablet press room, you know you're in trouble if you hear

- "The mechanics do that."
- "It's set at the factory."
- "We're not allowed to touch that."
- "We don't need to know what that does."
- "We don't use that feature."
- "Tablet presses are meant to run dirty."

Operators should know their tablet press because they are the experts. Under the umbrella of the SOP/batch record, they use all available press machinery options to optimize each batch. Mechanics assist operators with higher level problems. Machine setup, fundamental operation, tool–die installation, cam changes, and press cleanup are operator functions. Supervisors address productivity improvement and employee motivation. They drive positive change with a questioning attitude.

Constant feedback from the coating and packaging department should be viewed as a positive improvement strategy. The challenge of implementing positive changes in the tablet press room is important. It is one thing to learn the basics; it is quite another to effect positive change. Constant daily reinforcement of basic tablet manufacturing principles is absolutely required for ultimate success. Recognize that to effect true change, obtaining a broader agreement with support departments may require both education and diligence. We must understand, recognize, and track machine performance, granulation performance, and operator performance. All three are interrelated. **PT**

FYI

On-line toxicological database

Chemical Abstracts Service (CAS), a division of the American Chemical Society, has introduced its on-line toxicological database, Toxcenter, which is available now through the Scientific & Technical Information Network at www.fiz-karlsruhe.de/stn.html.

The database, updated weekly, includes more than 5 million records derived from pharmacological, biomedical, and chemical literature. The database also contains bibliographic information about methodology, industrial hygiene, legal issues and standards, and the toxicological, pharmacological, biomedical, and biochemical effects of drugs, chemicals, and food.

For more information, contact CAS, PO Box 3012, Columbus, OH 43210-0012, tel. 614.447.3600, fax 614.447.3713, www.cas.org.