Relating flow properties to process behavior in tablet presses and capsule filling machines

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The standard methods used to model and predict flow behavior were developed years ago for large-scale bins, hoppers, and silos. When applied to the very small scale typical of tablet presses and capsule fillers, those methods frequently over-predict problems. This article offers an approach to help you better measure the flow properties of the small-scale operations common to the pharmaceutical industry.

Two key unit operations in the pharmaceutical industry—capsule filling and tableting—use machines that comprise many separate systems that must interact in order to introduce a bulk API-excipient mixture into a small-diameter, small volume space. And they must do so repeatedly and quickly while ensuring that each tablet or capsule weighs what it should and meets other well-defined, FDA-regulated quality attributes.

Consider the typical rotary tablet press. It comprises a surge hopper, a long feed chute, a feed frame, and a series of die filling and compaction stations. The behavior of a given mixture or granulation as it passes through each of these sections must be understood and optimized to generate a high-quality product. Keep in mind that tablets and capsules are very small compared with the size of the overall operation, including the bins and hoppers that hold powders until they reach the tablet press or capsule filler. In fact, even the hoppers that hold the materials during operation are small compared to the hoppers typi-
cal of other industries. Yet too often, engineers and formulators measure the basic flow properties of their materials and compute key behavioral parameters—such as arching and rathole tendencies—using standard methods.

Those standard methods, however, were developed years ago for large-scale bins, hoppers, and silos. When applied to the very small scale typical of pharmaceutical facilities, the methods frequently over-predict problems. That is, the methods indicate problems will arise when none in fact do. As a result, design engineers who use a traditional approach may find that in-process observations do not correspond to what was measured in the lab. This article addresses that problem and offers an approach to help you measure and use flow properties that are relevant to the small-scale operations typical of the pharmaceutical industry.

**Arch formation**

Solving this over-prediction problem boils down to understanding how an arch can form in process equipment. But we must also ask: Are the equations traditionally used to predict arching applicable to small hoppers or is there an error in the strength measurement technique?

It can be shown that if the bulk-strength value is known at or near the place that an arch will form, then Equation 1 can be used to relate the critical arching dimension (AI) to the strength of the material (fc) and to the bulk density of the material (g). Geometry also comes into play, as is reflected in the (Hg) term, which has a value of approximately 2.3 when the hopper is a cone and about 1.1 when it is shaped more like a wedge.

\[
AI = \frac{Hg \cdot fc}{g} \tag{1}
\]

Consider a typical scenario that often plays out between formulators and process engineers. The formulator’s job is to design a product that, among other properties, doesn’t hang up during processing, which usually means adding various excipients to the mixture/granulation to counter any cohesive flow problems. Upon obtaining a reasonable material, the formulators measure the strength of the bulk mixture and compute the critical arching dimension using the traditional Jenike method (presented in more detail below). They then look at the openings in the process equipment through which the powder must pass before becoming a tablet or filling a capsule shell. If the opening in the process is smaller than the good-flowing product likewise has an arching dimension greater than the orifices of the process. Then a debate between the formulators and process engineers ensues, as each team tries to determine what went wrong and why the material doesn’t follow typical design criteria.

**Limits of the Jenike method**

To shed some light on this scenario, let’s first understand the arching analysis that Jenike described and that engineers have used for four decades to design processes. The first step is to measure the bulk strength and bulk density of the material at various stress levels (Figure 1a). This is important because process equipment operates at various stress conditions and we need to know the strength values at the process stress level to predict arching. There is a line, the flow factor line, that approximates the stress levels typical of conical process equipment. This flow factor line represents the stresses that are available to break the arch. If a plot of the material’s strength falls below this line, then the arch will fail because the stresses in the process equipment are large enough to break it as it tries to form. Thus, the intersection of the flow factor line with the line denoting measured strength represents a critical strength level that we can use to compute the critical arching diameter for the process (Figure 1b).

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**Figure 1**

**Jenike arching analysis**

**a. Strength plotted as a function of various stress levels**

**b. Flow factor line plotted over strength plot to define critical strength level**
Indeed, the critical strength \( (fc) \) for arching is computed from the intersection of these two lines, and that strength is used—along with the bulk density \( (\rho) \) of the material—to compute the arching dimension as given by Equation 1. This seems like a straightforward method. So why does it over-arch in some cases?

One issue is the flow factor line. It approximates the expected stresses acting on material flowing in a conical hopper, but it only considers gravity as a force for breaking an arch, which is supported at its abutments. Thus, the flow factor line assumes a linear relationship between the span of the hopper and the stress. If this linear behavior does not exist, then the analysis is faulty. Also, because the flow factor analysis assumes that only gravity is acting to break the arch, it ignores air-pressure gradients, acceleration gradients, or vibrational gradients that would apply additional breaking force to the arch.

In many cases, such simplification is valid, but in other cases—such as during dynamic operation with gas flows—the assumption is wrong, and the arching analysis fails to predict reality. However, as long as a contact bed exists, the basic requirement—that the local stress must be larger than the local strength to break the arch—is valid. Thus, if we can compute local stress in the process equipment and include all the dynamic effects in calculating the stress, then we have a better indication of the stress needed to break an arch.

To that end, Equation 1 must be revised to include the effect of external forces. Thus, a more robust method of computing arching in process equipment would include the stress level in the equipment due to gravity flow, gas pressures, vibrations, etc. The strength at any point in the process equipment can also be determind, just as Equation 1 can be used to predict the arching tendency \( (AI) \) at any point in the process. This arching-tendency value could be divided by the local span \( (D) \) of the converging geometry to yield a dimensionless number (arching ratio \( (AR) \)). The arching ratio quantifies the potential of the material to arch in the process: If it’s greater than 1.0, arching occurs at that point in the process equipment. This method resolves the problems associated with using Jenike methods to compute critical arching dimensions in small process equipment.

Before presenting an example of the method, let’s examine yet another potential problem with using the typical Jenike method to describe arching in small hoppers. A close look at Figure 1b reveals that the lines intersect at a stress level that is almost an order of magnitude below the lowest measured strength value. That poses a problem because applying a text method limited to using high-stress strength values forces engineers to extrapolate a tremendous amount of strength data, increasing the risk of poor process prediction.

**Adapting the Jenike method**

However, recent developments in measurement techniques allow us to gauge the strength at much lower values than traditional testing methods. As a result, we can measure strength to stress levels as low as 100 pascals (Pa), which is much closer to the intersection point in Figure 1b. The exact methodology for these measurements is not discussed here, but it involves using an instrument, and the data it generates are presented to point how they affect process predictions.

Consider the case of a 50 percent ibuprofen mixture that also includes microcrystalline cellulose, lactose, magnesium stearate, and sodium starch glycolate and the results of measuring it at both high and low pressures (Figure 2).

![Figure 2](image)

If we concentrate on the low-pressure region and perform a Jenike arching analysis of these two curves, we get two very different arching values. Low-pressure strength data yields an arching dimension of 14.3 millimeters (mm) while using just high-pressure data coupled with extrapolation produces an arching dimension of 142 mm (Figure 3). The actual arching dimension was found by placing the ibuprofen mixture in a hopper and varying the size of its opening; it was found to be about 38 mm. It is obvious from this analysis that much of the arching prediction problem stems from a misunderstanding of or poor characterization of stress in the process equipment.

To clarify the source of off-target predictions, we computed the stress that would be expected in a typical feed hopper above a tablet press (Figure 4), which is a small conical hopper typically about 450 mm in diameter that necks down to a hopper outlet of 50 to 75 mm in diameter. From there, the material flows down a chute of 50 to 75 mm in diameter and empties into the feed frame on the die table. From there the material flows into the die cavities. But if the material doesn’t flow by gravity into the dies, the feed frame includes a rotating paddle that pushes the material into them. In addition, as the lower punch descends to accept the powder, it may create a gas pressure gradient, which helps suck material into the die.
To predict how well the powder will flow, we examined the typical stress levels in the feed hopper above the tablet press, which required measuring the bulk density of the ibuprofen mixture, as well as the wall friction angle of smooth Type 304-2B stainless steel (figures 5 and 6). This information was used to compute the stress level in the hopper before and during flow.

As shown in Figure 7, the stress increases and reaches its maximum at a point between one-third and one-half the way down the conical hopper. The stress level then decreases as the material approaches the outlet. The increase occurs as material converges in the flow channel, and the ratio of the stress against the wall to the stress in the vertical direction is about 2.2. This increases the stress in the hopper. However, as the stress against the wall increases, the wall’s friction tends to support more of the powder’s weight, and stress thus decreases as the powder approaches the outlet. The lowest pressure in the conical section is near the outlet and it can be an order of magnitude lower than the lowest strength measurement obtained when arching potential is tested using traditional methods.

We can use the data from the two strength curves to compute the expected unconfined yield strengths in the entire hopper (Figure 8). Using only the higher-stress measurements gives strength values close to 300 Pa. The data for the new strength measurements at lower stress values show more variability in the hopper, ranging from 26 to 39 Pa, depending on the location. We computed the arching tendency at each location in the conical hop-
per using these strength values and bulk density measurements. We also divided the arching dimension calculated in this manner by the span of the hopper (Figure 9). This gave a dimensionless number that describes the arching tendency based on how it relates to the hopper width. If this ratio becomes greater than 1.0, then the material will arch over the hopper span that corresponds to the point where the ratio grew past 1.0.

It is clear from Figure 9 that the data from the high-pressure strength measurements (traditional testing) predicts arching in the feed hopper. In fact, that method predicted a 139-mm arching span. However, the dimensionless arching ratio for the strength measurements—calculated using the new low-pressure strength measurement technique—never exceeded 1.0, suggesting that the material will flow from the hopper without hanging up. The highest arching ratio was at the 50.8-mm hopper outlet, which registered a dimensionless arching ratio of 0.564. That figure suggests that arching in the conical hopper may be near 28.6 mm when data from the low-pressure technique are used. This is more in line with reality (direct observation) of an arching dimension of 38 mm, ±9 mm.

Conclusion

The combination of acquiring strength measurements at low stress levels and calculating the stress values in actual hoppers helps give more accurate predictions of the arching dimension in process equipment. With better predictions, formulators and engineers can better adapt their materials and equipment. A similar analysis can be done for die filling, enabling engineers to determine if and when a force feed frame is required. Finally, this analysis suggests that Jenike’s old flow factor technique of estimating hangups in small process equipment may be in error. Further study should be done, however, before we dismiss the method.