

Taking Shape

Designing a tablet requires careful consideration to be given to its shape, as small adjustments to the size or profile can have a direct impact on both the production process and customer acceptance – resulting in success or failure

By Dale Natoli and
Bill Turner at Natoli
Engineering Company

Tablet shape affects many aspects of tablet production. We are often asked, “Why that tablet shape?” when submitting design suggestions after researching a solution to a tablet or tooling issue. An improper design can cost millions in lost production and potentially lead to disaster. While most companies complete their due diligence when selecting a tablet shape, some lack understanding of the extent to which shape can influence production – particularly the efficiency of the tableting operation.

Some companies design unique tablets hoping to reach an acceptable level of consumer recognition, with the objective to maintain customer loyalty; this effort is generally driven by marketing. Tablets are also designed to consider the end-user, such as a ‘break-easy’ bisect design or a three-dimensional animal-shaped multi-vitamin aimed at children. Tablets may be designed for a technical application like watch batteries, automotive airbags and pre-formed desiccants, while some companies desire a tablet shape engineered to provide easy and unobstructed production, such as a simple standard round.

Certain tablet shapes play havoc with tooling and press function – adding significant costs to the unit dose. The same can be said regarding packaging issues, as an incorrect tablet design can chip,



Figure 1: Tablet bisection

clog or produce an unacceptable level of dust at the bottom of the bottle. It is for these reasons, among others, that tablet shape should be carefully considered and engineered during the initial design phase. Even if the tablet is to be a particular shape, it is possible to add features into the design that will reduce production issues, and subsequently decrease the overall cost.

Tablet Scoring

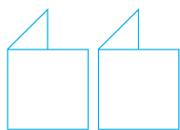
A recent hot button issue has been uniform tablet splitting as it applies to generic products relating to their reference product. When incorporating a bisect into a tablet design, proper tablet configuration, thickness, hardness, and bisect type, depth and placement can all affect achieving a uniform dose in a split tablet. If careful attention

is not paid to the score design, tablets can have edge attrition and chipping issues when breaking is attempted by the consumer (see Figure 1).

When deciding upon the type and depth of a score, the tablet diameter, width (if oblong in shape) and overall thickness must be taken into account. It is particularly important to know the thickness of the tablet to judge how deep the score should be to provide a complete and accurate break. If a tablet design results in an excessively thick tablet, it may be necessary to increase the size slightly to decrease the thickness. The ultimate goal is to receive accurate breaks and uniform doses after the split.

Keywords

Uniform tablet splitting
Score design
Edge attrition
Compression force



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Brand Duplication

There are many reasons to consider tablet shape during brand duplication. In addition to consumer acceptance, it is essential to look at the medication's physical characteristics so as to provide the best experience when swallowing the tablet. For example, it has been documented that patients find it difficult to swallow tablets more than 8mm in diameter. Certain shapes, such as ovals, are easier to swallow and have faster oesophageal transit times. The FDA has issued guidance recommending that drug applicants design and develop products with these points in mind.

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This increases patient compliance and acceptance of the medication, as well as reducing errors in dispensing. However, the FDA has recommended that when tablet shape can be improved from the branded product to make it easier to swallow, then changes to the design should be implemented in the generic.

All of these considerations aid in product success. Other factors, such as friability, tablet weight, transit time and dissolution time, also come into play when designing the tablet. Once these parameters are established for the medication, the production and packaging departments should be involved to ensure that the design can be produced without encountering issues such as chipping, picking or sticking. This will allow the design to be modified for success in production. When a tablet can be easily manufactured, it reduces tooling costs and eliminates wasted time that operators spend troubleshooting.

Design Configuration

Branded or generic, small design changes can yield notable results in improving the patient experience when swallowing tablets, as well as bringing cost savings to the manufacturer.

Bevel Edge

A common issue when designing tablets is attempting to duplicate an existing tablet that has an inherently weak or problematic design. This often happens when companies copy designs already in their portfolio. An example of an

often reproduced – but ill-advised – design is one of the oldest and most commonly used configurations: the flat face bevel edge (FFBE).

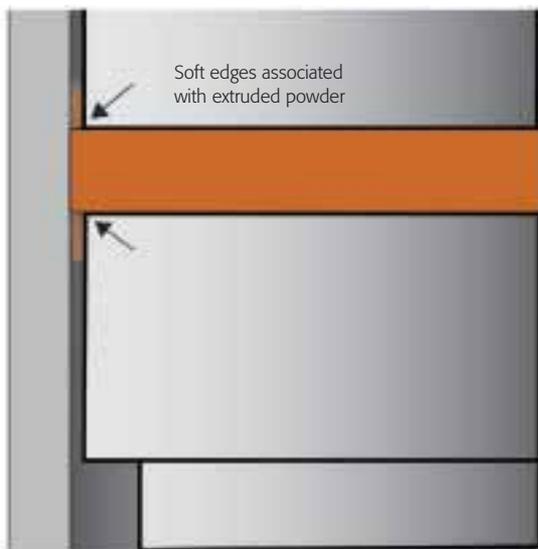
The FFBE was designed as an alternative to the more common flat face design. As commercial tablet manufacturing took off, the industry found it needed to rectify edge attrition in flat faced tablets. Edge attrition occurred as the flat face tool entered into the compression cycle and pushed powder to the outside perimeter of the punch tip and towards the die wall, which in turn extruded through the punch and die clearance (see Figure 2). In contrast, the FFBE design proved beneficial for reducing soft edges by guiding the powder back into the tablet. However, this design presented a new issue – punch weakness. A necessary lack of cup depth causes a limit on compression force in order to avoid tip bending and distortion.

Radius Edge

There is an alternative design to the FFBE: the flat face radius edge (FFRE). This allows for a significantly higher compression force to be applied without causing punch tip damage when producing flat faced tablets with a shallow cup depth. It should be considered when producing flat faced tablets as it provides better uniform tablet hardness; the powder has a natural flow across the radius, reducing hot spots and discolouration to the top of the tablet.

By eliminating the bevel edge and replacing it with a radius edge, the FFRE design allows maximum

Figure 2: Flat faced tablets can result in edge attrition, with powder being pushed to the outside perimeter of the punch before extruding through the punch clearance



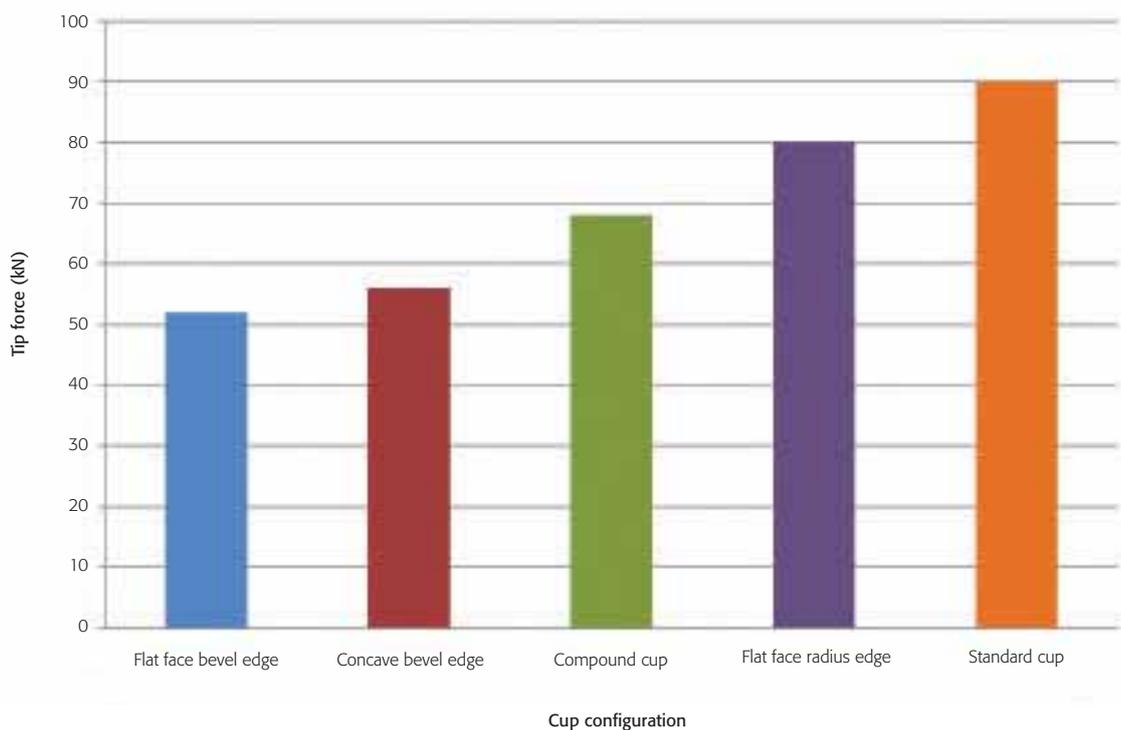


Figure 3: Maximum safe operating force (S7 steel), with a 7/16-inch diameter

compression forces – in a number of cases – to almost double, allowing additional pressure to alleviate conditions such as sticking in the corner junction of the bevel and the flat. Using this design clearly has advantages during tablet production and can eliminate many headaches when powder needs high compression force (see Figure 3).

The FFRE design can also improve product acceptance among consumers. Tablets produced on tooling with a radius edge design have a softer look and better mouth feel, which is highly desirable. Additionally, the difference between the FFBE and FFRE designs is often visually unnoticeable. As a result, FFRE presents enough advantages over FFBE for it to be considered for all new flat face designs applied to non-coated tablets – this may someday make the FFBE design obsolete.

Concave bevel edge tablets (CCBE) also benefit from the application of a radius edge. The CCBE is a design commonly used on both

round and shaped tablets to assist in reducing edge attrition during the coating process. Similar to issues experienced with FFBE, applying a radius edge to this tablet would make a better and more robust design, allowing an increase in maximum compression force. In effect, replacing the bevel with a radius creates a compound cup design, which is much more desirable than the original CCBE design.

Working Together

Many considerations should be taken into account when tablets are designed. Small adjustments to the tablet's shape can positively impact issues that arise from production, influencing customer acceptance. To design a tablet with a high degree of success, it is important to get all departments involved in the process.

From marketing through to production and packaging, everyone has a stake in the product's success and should be given the opportunity to comment. By involving a tooling

supplier as well, they should be able to provide the experience in tablet design and guidance that will help to head off possible problems before they occur. Keeping all responsible parties included in the design process will ensure a successful and timely launch.



Dale Natoli is President of Natoli Engineering Company Inc, and has over 35 years of global experience in the tablet compression industry. He has published articles for major pharmaceutical publications and authored chapters in three books, including the *Tablet Specification Manual* sponsored by the American Pharmaceutical Association. He presents lectures for universities, pharma associations and tablet manufacturers worldwide. Email: sales@natoli.com



Bill Turner is the Technical Service Manager of Tooling and Tablets at Natoli Engineering Company Inc, where he has also served as Engineering Manager and Tablet and Tool Designer for 25 years. He educates and trains Natoli sales and service staff and conducts training seminars to the industry in tablet design, tool design and troubleshooting, both in-house and on site. Email: eng@natoli.com